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DOCTORAL THESIS

Patient safety and safety culture in Belgian hospitals

Thesis submitted to obtain the degree of Doctor of Biomedical and Life Sciences by:

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Content

List of abbrevations

A	Anaesthetic
ACSNI	Advisory Committee on the Safety of Nuclear Installations
AE	Adverse Event
AGFI	Adjusted Goodness of Fit Index
AHRQ	Agency for Healthcare Research and Quality
APACHE	Acute Physiology and Chronic Health Evaluation
ABTBG	Antibiotherapy Policy Group
ANZCA	the Australian and New Zealand College of Anaesthetists
BAPCOC	Belgian Antibiotic Policy Coordination Committee
CI	Confidence Interval
CCU	Coronary Care Unit
CFA	Confirmatory Factor Analysis
CFI	Bentler Comparative Fit Index
CRM	Clinical Risk Management
EFA	Exploratory Factor Analysis
EUNetPaS	European Union Network for Patient safety
EWS	Early Warning (Score) System
FPS	Federal Public Service
GEE	Generalized Estimating Equations
GFI	Goodness of Fit Index
GW	General Ward
HACCP	Hazard Analysis and Critical Control Point tool
(H)FMEA	(Healthcare) Failure Mode and Effects Analysis
HRO	High Reliability Organization
HSPSC	Hospital Survey on Patient Safety Culture
ICPS	International Classification for Patient Safety
ICU	Intensive Care Unit
IOM	Institute of Medicine
JBI	the Joanna Briggs Institute
KCE	Belgian Health Care Knowledge Centre
LOS	Length Of Stay
LSM	Limburg Sterk Merk

M	Medical
MAR	Missing At Random
MCAR	Missing Completely At Random
MET	Medical Emergency Team
MFC	Medico-Pharmaceutical Committee
MFG	Minimal Financial Data
MICU	Medical Intensive Care Unit
MKG	Minimal Medical Data
NCC MERP	National Coordinating Council for Medication Error Reporting and Prevention
NNFI	Bentler-Bonett Non-normed Index
OR	Odds Ratio
OSA	Obstructive Sleep Apnea
P	Paediatric
PICU	Paediatric Intensive Care Unit
PPV	Positive Predictive Value
PRISMA	Preferred Reporting Items for Systematic reviews and Meta-Analyses
RCA	Root Cause Analysis
RMSR	Root Mean Square Residual
RPN	Risk Priority Number
S	Surgical
SAQ	Safety Attitude Questionnaire
SD	Standard Deviation
SICU	Surgical Intensive Care Unit
SRMSR	Standardized Root Mean Square Residual
TISS	Therapeutic Intervention Scoring System
UIA	Unplanned Intensive care admission after Anaesthesia
VA NCPS	the United States Department of Veterans Administration National Center for Patient Safety
WHO	World Health Organization

CHAPTER 1

General Introduction

Chapter 1

General Introduction

This chapter provides a general overview of the conceptual framework for measuring patient safety in healthcare organizations. In addition, the main objectives and research questions of this dissertation are outlined.

CONCEPTUAL FRAMEWORK FOR PATIENT SAFETY

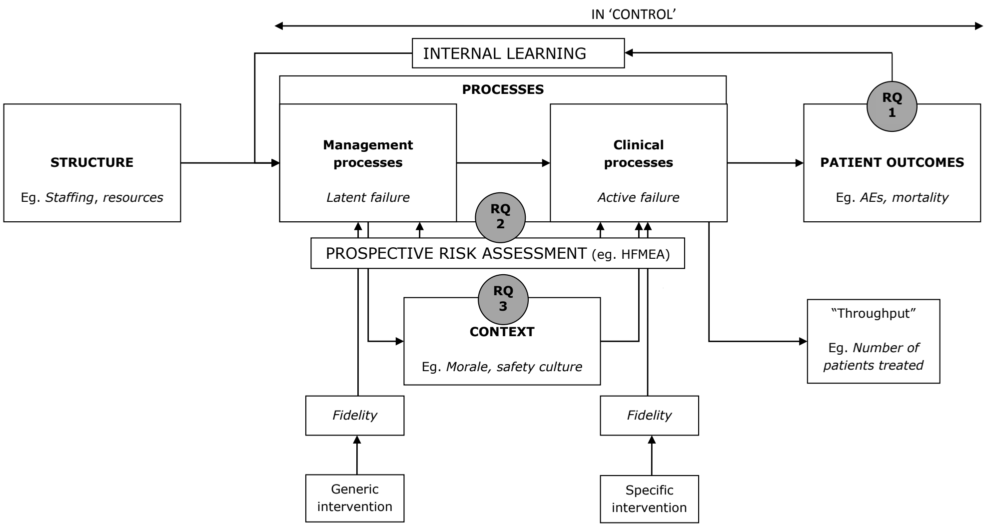
Since over a decade, there has been an increasing interest in patient safety research in divergent cognate disciplines, such as human factors, ergonomics, psychology and sociology. But also more attention is drawn from economical sciences, because of the social relevance of patient safety research. An overall shortcoming in the safety literature is the lack of clear and consistent definitions and conceptualizations.[1] Research results in this dissertation are interpreted in light of the following terminology.

In its simplest, *patient safety* can be defined as the way in which risks on unintentional and evitable harm to the patient are handled in the organization of care. This includes the avoidance, prevention and amelioration of adverse events stemming from the processes of health care.[2] This definition of Vincent differentiates patient safety from more general concerns about quality of care. In patient safety, the focus is laid on the 'dark side of quality' and the term refers to care that is actually harmful rather than just not of a good standard.[2] Elementary for the discussion on the differentiation between safety and quality of care is the measurement problem of immediacy and causality of errors. When errors have a high immediacy and causality (e.g. wrong site surgery), the term *safety* is applied. The concept of *quality of care* refers to outcomes that have a lower immediacy and causality, but which occur more frequently (e.g. failure to detect deteriorating patients).[3] From this perspective, patient safety cannot be strictly distinguished from quality and should be addressed by an integrated approach. The Institute of Medicine (IOM) suggests that safe care is one of the critical components of the delivery of quality of care.[4] Other elements of high-quality care defined by the IOM include effective, patient-centered, timely, efficient and equitable care.

From a more discernible perspective, patient safety includes topics such as medication safety, fall prevention or patient identification, and relatively new is the use of information technology, simulation and human factors engineering. For this recent area of research, the healthcare sector must rely on experience of other industries, such as the nuclear and petrochemical industry, aviation and the military industry.

Figure 1 presents a conceptual framework for patient safety based on the Donabedian's trilogy and Reason's causal chain, adapted from the four-part epistemiology of Brown et al.[3, 5-7] The Donabedian's trilogy represents the operation of healthcare organizations across a causal chain based on three pillars: 'structure' (*how care is organized*), 'processes' (*what is done by healthcare providers*) and 'outcome measurement' (*the healthcare results achieved)*.[3] A fourth key-element in the conceptual framework is the 'context' in which healthcare is delivered.

Figure 1 – Conceptual framework for patient safety based on Donabedian's triad showing how structure impacts on processes, which on their turn impact on patient outcomes. Points that can be measured are shown in italic. Research questions of this dissertation are numbered. (Adapted from Brown et al.[3])



1. Structure

'Structure' represents the exogenous factors or 'givens' that cannot be entirely determined by managers within a healthcare organization and are dependent on the national context. An example of structure is the provision of buildings, staff and equipment and the budgets that limit for example nurse staffing–patient ratios. Also, institutional characteristics such as qualifications of staff are accounted as structural measures. Basically, these structural measures can be changed, but are mainly depending on external factors and thus are difficult to be linked with quality and safety outcomes. However, considering a recent study of Needleman et al. which investigated the relationship between nurse staffing patterns and inpatient mortality analyzing 197 961 patient admissions, it was identified that there is a significant association between mortality and nurse staffing and in particular between mortality and a high patient turnover.[8] In a recent cross-sectional study by Aiken et al. it was found that specific structural factors, such as higher nursing staffing levels have an impact on patient safety, patient satisfaction and quality of care in European and American general hospital settings. The results of this study indicated that the associations between nurse staffing and the quality and safety of hospital care were remarkably similar across Europe and in the US. It was even concluded that improvement of hospital work environments can be a relatively low cost strategy to enhance safety and quality of care.[9] This area warrants further research, as it should be investigated in which way context variables, such as safety culture, intervene with structural measures.

2. Processes

Next in the causal chain are the processes, which are separated into management processes (e.g. human resource policy and training of staff) and clinical processes (e.g. the implementation of evidence-based interventions and protocols, and the communication of information during handoffs or transitions). Both managerial/ organizational and clinical processes are completely in control of the healthcare organization, but are in a substantive manner determined by the context in which healthcare is delivered. In Reason's model[10], processes are distinguished as the latent and active processes, which in case failure occur, are defined as system failure and active failure (human error). *Latent errors* (or latent conditions) refer to less apparent failures of the organization's structure or design that contribute to the occurrence of errors or even allow them to cause harm to patients. These latent work conditions include heavy workloads, inadequate knowledge or experience, inadequate supervision, a stressful environment, rapid change within an organization, incompatible goals (conflict between finance and clinical need), inadequate systems of communication and inadequate maintenance of equipment and buildings.[11] In contrast, *active errors* are the unsafe acts or inactions (omissions) committed by people who are in direct contact with the patient or the system. This term includes action slips or failures, cognitive failures (memory lapses and mistakes) and violations to procedures or standards.[11] Imagery conceptions also address the distinction between latent and active failure as respectively the 'blunt end' and the 'sharp end' of healthcare processes.

Rasmussen looked from a cognitive perspective at human failure and identified three types of errors: skill based, rule based, or knowledge based mistakes. Human error or why humans fail is exemplary described by Gawande as the 'necessary fallibility', as often, things people want to do, are simply beyond human capacity. Although modern healthcare is enhanced by technology, the human and physical powers are limited. Reasons for this failure are ignorance - partial knowledge of science- and ineptitude – failure to apply correctly-, for example by negligence.[12] Ineptitude includes failures in applying adequate standards or in executing a correct plan or ineptitude can stand for applying an incorrect plan. The latest decade, sufficient knowledge has been created within healthcare, however the balance of ignorance and ineptitude seems to be shifting.

When considering failures in the causation model presented in figure 1, errors are logically and chronologically the closest surrogate measure of adverse events.[6] *Risks* of creating errors in healthcare are the possibility or probability of the occurrence of an event multiplied by its severity.[13]

3. Patient outcomes

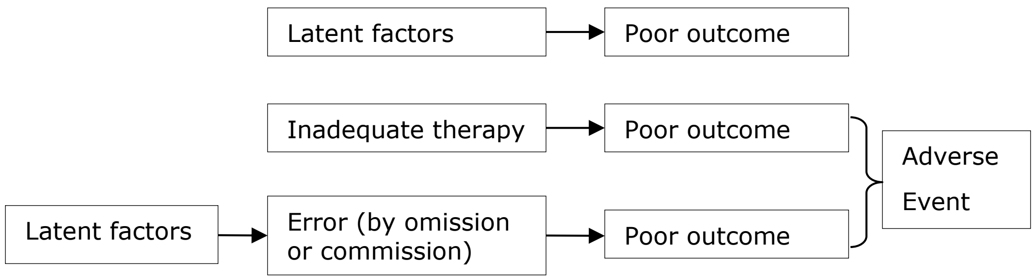
Finally in the causal chain, *patient outcomes* are the results that are achieved from the healthcare processes. Patient outcomes can be clinical (e.g. adverse event, mortality) or patient derived (e.g. patient satisfaction).[6]

Problematically, the term *safety performance* may be used interchangeably to refer to different concepts.[1] Sometimes, safety performance refers to an organizational metric for safety outcomes, such as for instance adverse events. Otherwise, safety performance may refer to a measure for individual safety related behavior. In line with Christian et al. we consider safety performance as safety behaviors and distinguish it from outcomes.[1]

An *Adverse event* is a 'negative' patient outcome and can be defined as 'an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient'.[14] A similar definition that is often used is: (1) an unintended injury or complication, (2) which results in disability at discharge, death or prolongation of hospital stay, and (3) is caused by healthcare management (including omissions) rather the patient's disease.[15-21] Patient harm that is resulting from the event is frequently denominated as *healthcare associated injuries* and are thus associated with the healthcare structure and processes, rather than the underlying disease.[13]

An adverse event is the result of (the combination of) an error (by omission or commission) and an inadequate treatment (figure 2). *Errors* are just one component in the causation of adverse events and are the closest surrogate measure of adverse events.[6] *Causation* refers to injury caused by health care management including acts of omission (inactions) e.g. failure to diagnose or treat, and acts. The latter could also be defined as 'association'. C*ausality*, however, can be defined as the confidence with which an adverse event, in case it occurs, can be attributed to the error. A *preventable adverse event* is an adverse event resulting from an error in management due to failure to follow accepted practice at an individual or system level. The accepted practice was taken to be the 'current' level of expected performance for the average practitioner or system that manages the condition in question.[20] Estimations of preventable adverse events are extreme difficult, since they are prone to subjective interpretation.

Figure 2: Relationship between errors and adverse events



4. Context

Organizational culture and organizational climate

The framework presented in figure 1 shows how 'context' is the chain between the managerial and clinical processes. Improving patient outcomes can directly be obtained by targeted or specific interventions aimed at clinical processes, but also by more general ('diffuse' or 'generic') interventions aimed at management/ organizational processes, which might affect patient outcomes through organizational culture and safety culture.

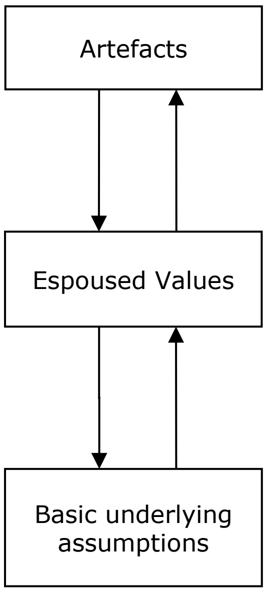
The theory of *organizational culture* emerges from a combination of organizational psychology, social psychology, and social anthropology.[22] In literature, the terms 'climate' and 'culture' are often confused and used interchangeably. However, it is important to remember that there are conceptually meaningful differences in their scope and depth. Climate is a meteorological metaphor, while culture originates from anthropology.

Organizational culture knows various definitions and refers to a wide range of social phenomena. In the research domain of organizational culture there are two divergent perspectives. In the first perspective culture is considered as something that an organization *is*, while the other approach considers the concept of *having* an organizational culture. In the first approach, the organization is a culture with symbols, a history and myths that give meaning to the people working in the organization. In the second approach, the organization has a culture as well as other organizational variables, such as structure, strategy or leadership.[23] James Reason defines organizational culture as *'the shared values and beliefs that interact with an organization's structures and control systems to produce behavioral norms'*.[24] From this perspective, organizational culture refers to a *shared* pattern of behavior by a group of members, rather than individual perceptions that compose climate.

In the organizational literature, the concept of culture is generally taken to mean something less tractable and more complex than climate. An important distinction comes from Schein (figure 3) who suggested that climate, as determined by attitudes and espoused values and beliefs, is only a reflection or a surface manifestation of culture and that culture manifests itself in deeper levels of unconscious assumptions.[25]

Schein addresses organizational culture by the metaphor of an onion as having several layers. His model distinguishes three levels of organizational culture.[25] The surface of the organizational culture includes the *artefacts* and refers to the more visible and observable elements (manifestations) such as language, technology, dress code, manners of address, etc. The *espoused values* refer to what is initially started by the leaders and then assimilated by all members. For example, these espoused values could be represented by the philosophies, strategies and goals of the organization. Leadership can influence organizational culture as areas that leaders pay attention to, measure and control can promote desired behaviors. Finally, the core or the essence of an organizational culture is represented by the *basic underlying assumptions and values*, which are more difficult to discern because they exist at a largely unconscious level. But yet, they provide the key to understanding why things happen the way they do. These basic assumptions form the deeper dimensions of human existence, such as the nature of humans, human relationships and activity, reality and truth (figure 3).

Figure 3: Edgar Schein's model of organizational culture



The most visible manifestations of culture, including dress codes, rituals, rewards and ceremonies; especially concerned with the observable patterns of behavior within organizations.

Espoused beliefs and values; may be used to justify particular behavior patterns, and for choosing between alternative courses of action; Strategies, goals, philosophies.

The unspoken, largely unconscious beliefs, values and expectations, perceptions, thoughts and feelings.

Thus, organizational climate exists at a concrete level and refers to behavior, attitudes and feelings which are easy to observe. In contrast, organizational culture, which is not a concrete phenomenon, refers to the underlying and deeper assumptions and values which exist at an unconscious level. In literature organizational culture is often addressed by an unlimited list of descriptors: *no blame, non-punitive, trusting, reporting, generative, resilient, mindful…*[2]

Safety culture: an aspect of organizational culture

Safety culture is one aspect of the wider culture of an organization. The concept of safety culture originated outside healthcare, in studies of High Reliability Organizations (HROs) that consistently aim to minimize adverse events despite carrying out intrinsically complex and hazardous work. HROs, such as commercial air travel, the chemical industry, the nuclear power industry and the military industry, handle extreme risks by maintaining continuous aware and observant workforces, while fostering cultures in which team members feel comfortable speaking up in risk full situations and applying disciplined safety solving approaches. Team members are thought to be on guard for the smallest indication that there is deviation of a standard process.[26] This is also addressed as a 'collective mindfulness'. In HROs, team members are accountable for their actions; however it is assured that they won't be blamed for system failures. Healthcare has some unique characteristics that differentiate this sector from other sectors. In healthcare the safety of the environment not only affects staff, but also the patient who might be injured by the actions of staff. In addition, this environment is very complex in terms of task characteristics, since every patient is unique. Consequently, creating a safe environment in healthcare requires more than adherence to policies and procedures. Finally, in healthcare organizations, healthcare professionals determine the guidelines for action, often leading to conflicting goals with management.[27]

The notion of the importance of safety culture can be traced back at April 26, 1986 when a major accident occurred at Unit 4 of the nuclear power station at Chernobyl, releasing molten core fragments into the immediate vicinity and fission products into the atmosphere. A poor safety culture was identified as a contributory factor in the Chernobyl disaster.[28] The recognition of the importance of safety culture in preventing accidents led to a number of studies attempting to define the concept. The importance of considering safety culture in patient safety improvement is widely accepted within the healthcare industry. The IOM report 'To err is human' highlighted the importance of safety culture as '*organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients*'.[29] In line with this core postulation of the IOM, safety culture is included in patient safety programs of several international healthcare organizations, such as the World Health Organization, the Organization for Economic Cooperation and Development and the European Union.[30]

The following definition on *safety culture* is widely accepted and originated in the nuclear power industry. This definition of the Advisory Committee on the Safety of Nuclear Installations (ACSNI) captures the essential elements: '*The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared* *perceptions of the importance of safety, and by confidence in the efficacy of preventative measures.'*[31] Guldenmund defines safety culture as '*those aspects of the organizational culture that will impact on attitudes and behavior related to increasing or decreasing risk'.*[32] Pronovost and Sexton suggest that having a culture that promotes safety within the organization is an important and necessary precursor to improve the insufficiencies in patient safety.[33] A safety culture demands a constant and active awareness of all members of the organization of the chance that things can go wrong and thus requires an organization-wide commitment. A safety culture should be open and fair and encourage people to speak up about mistakes.[2] Reason describes four components of organizational safety culture which interact to achieve learning and high reliability: a 'reporting' culture -an atmosphere where people have confidence to report safety concerns without fear of blame-, a 'just' culture –a context in which people are encouraged and supported to be fair-, 'flexible' culture -where the organization and the people in it are capable of adapting effectively to changing demands- and a 'learning' culture -organization is able to learn from its mistakes and make changes.[24]

Safety climate

The general consensus is that safety culture represents the more stable and enduring characteristics of the organization.[27] *Safety climate*, on the other hand, represents a more visible manifestation of the culture, which can be seen as its 'mood state' or surface manifestation, at a given point in time.[34] Zohar first defined safety climate as '*a summary of molar perceptions that employees share about their work environment.'*[35] More recently, Zohar stated that '*safety climate relates to shared perceptions with regard to safety policies, procedures, and practices.'*[36] From a functional perspective, safety climate relates to policies-in-use or enacted policies, rather than formally declared policies. This highlights a potential discrepancy between formal and executed policy, including a strategic discrepancy in which managers don't implement their own formal policies (e.g. declaring safety as the top priority of the organization). Zohar further states that '*the notions of climate as consensually agreed policies, and culture as meta-contingencies are functionally equivalent, except for their different levels of abstraction (climate is more concrete and easier to measure than culture)*.'[36]

A further distinction can be made between psychological and group safety climate. *Psychological safety climate* refers to the individual perceptions of safety-related policies, practices and procedures pertaining to safety matters that affect the personal well-being. *Group safety climate* emerges when these perceptions are shared among individuals in a particular work environment.[1, 37]

Measuring safety culture

Guldenmund describes three approaches in examining the concept of safety culture.[32] First, safety culture can be investigated by what is called the *academic approach*. In this approach, the research methodology is qualitative and culture is considered as something an organization *is*. The research method can be a narrative study and is usually based on grounded theory or case studies. Data collection techniques include interviews, observation techniques or focus groups. Second, the *analytic approach* of safety culture starts from the perspective of *having* a safety culture, which is considered as a multidimensional construct. The methodology of this approach is (semi)quantitative. What in fact is measured is a 'snapshot' of the current manifestations of an organization, by using for instance survey questionnaires. Currently, safety culture research is dominated by this approach. In addition, the analytical method provides the opportunity to comparing results, without a normative evaluation of organizations or groups. Conditional to this method is that groups are defined at meaningful organizational levels, such as the overall organization, the unit level or team level. Third, the *pragmatic approach* starts from the assumption that structure and processes of an organization are dynamically interrelated, and subsequently influence safety culture, behavior and performance. This approach introduces a normative aspect of safety culture as organizations should develop a desired maturity or generative level of safety culture. The main objective of the pragmatic approach is to enhance internal discussion and feedback of safety culture scores using expert opinions.[32] The levels of maturity of safety culture are also defined within the typology of Westrum, which is for instance applied within the Manchester Patient safety Framework.[38, 39]

Safety climate is typically measured by quantitative methods such as questionnaire surveys. However, the assessment of the underlying safety culture is normally conducted by measuring safety climate on aspects of management of safety and the prioritization of safety. These aspects are markers of the underlying safety culture in the organization.[34] Zohar and Flin even argument that management commitment to safety is the essential and fundamental dimension and that it should suffice as a measure of safety culture.[26, 35]

PATIENT SAFETY MANAGEMENT SYSTEM

Currently, there is an urgency in many countries to improve patient safety. International organizations, such as the World Health Organization, are encouraging healthcare organizations in using safety management methods from the more hazardous industries.[30] These industries take a strongly systematic approach to managing safety. As mentioned in the causation model of Reason, human factors play an important role in the contribution of adverse events, however also the role of the humans who are managing the organization is of importance.

In practice, a *patient safety management system* should be designed to reduce patient harm by utilizing a systematic, integrated, coordinated and continuous approach. From this perspective, a safety management system should be designed as an integrated part of the quality system of the hospital setting with attention to the organizational structure (including resources, competences), procedures and processes.[40] From the managerial perspective, *safety* can be defined as the 'control of accidental loss'.[41] In this definition the emphasis is laid on the control function of a safety management system as well as on the consequences or losses of adverse events. This means that adverse events are a suitable leading indicator for patient safety performance ('lagging' indicator). In the Loss Causation Model of Bird, the focus is led on 'lack of control'.[41] Possible reasons for a lack of control are for instance inadequate standards, procedures or protocols and inadequate compliance to these. From a *prospective* perspective, a *Safety Management System* refers to an organized and inter-related group of preventive safety measures that have the common purpose of preventing accidents, and improving and monitoring the safety performance of an organization. The advantage of using the term 'Safety Management System' is that it brings into focus the full set of measures and interventions that need to be done in improving patient safety performance. In contrast, the term 'lack of control' tends to highlight control measures like supervision and enforcement of rules.

There has been limited empirical evidence on the optimal approach and elements of a safety management system. Given the complexity of hospital settings it is recommended that a safety management system should be sufficiently flexible in order to respond to the specificity of different hospital units and services.[42] There are six interacting key elements of a safety management system[42]:

1. Measuring and improving *safety culture* is a condition for improving patient safety.

2. There is a need for continuously and prospectively measuring, evaluating and correcting the quantity and quality of organizational and clinical processes. *Prospective risk analysis*, such as Failure Mode and Effect Analysis (FMEA) which has so far been limited applied in healthcare, is aimed at assessing the occurrence, frequency and severity of possible risks within healthcare processes.[43] The prospective assessment of errors or failures is, as mentioned before, an important complementary and a chronologically surrogate measure for patient outcomes. As the single measurement of adverse events reflects an imprecise picture of the problem of patient safety, the assessment of processes provides more insight into the safety practices that precipitate adverse outcomes. Based on risk assessment, preventive barriers can be implemented to improve patient safety.

3. A patient safety management system must combine a prospective approach with *retrospective learning* from adverse events. A frequently used method for analyzing adverse events is Root Cause Analysis.[44] Adverse events may be detected by a variety of retrospective methods (medical record review, incident reporting, administrative data analysis). However, there has been much discussion on the robustness of these methods. Medical record review is the only method for which there are a substantial number of published estimates of reliability.[45-47]

4. A fourth element in the development of a safety management system is the creation and implementation of preventive barriers that should function as

layers of defense in the origination of errors. These barriers include the use of procedures, protocols and technical devices, and can relate to aspects of individual behavior and professionalism, interaction with other healthcare professionals, the work environment, equipment etc.[42] An example of a preventive barrier is the implementation of a safety surgery checklist, which requires teamwork and a multidisciplinary standardized approach.[48]

5. A fifth element is the role of the patient and the general practitioner, as they should be involved in the healthcare processes in order to improve patient safety. For instance, the correct, complete and timely transmission of patient information is not only in the patients right, but it also forms the individual relationship between the physician and the patient, which on its turn affects the safety policies at the level of the organization. Both the patient and the general practitioner should be involved as active participants in the healthcare processes and the management of patient safety.[42]

6. A particular element of a safety management system is the support of healthcare professionals who are confronted with an adverse event as a 'second victim'. Growing attention is being paid to making system improvements to create safer healthcare and to the appropriate handling of patients and families harmed during the provision of medical care. In contrast, there has been little attention to help healthcare professionals in coping with emotions of shame, guilt and depression.[49]

In conclusion, a safety management system which is also addressed in literature as clinical risk management (CRM) encompasses all structures, processes, instruments and activities enabling hospitals to identify, analyze, contain and manage risks while providing clinical treatment and the safest patient care.[50]

FACTS AND FIGURES OF PATIENT HARM

Adverse events in Belgian hospitals

Although, patient safety is receiving growing attention, there is scarce evidence on estimations of adverse events in Belgian hospitals. A retrospective analysis of the national hospital discharge dataset of all Belgian acute hospitals for the year 2000 estimated the incidence of adverse events to be 7.12% for medical and 6.32% for surgical hospital stays, with a high variability between hospitals, even after risk adjustment.[51] This first study on estimations of adverse events in Belgian hospitals already highlighted a number of potential safety problems and illustrated a high inter-hospital variation, which warrants further action.

In 2007, The Belgian Health Care Knowledge Centre (KCE) estimated the prevalence rate of healthcare associated infections in Belgian acute hospitals at 6.2%, which amounts to an estimation of 103 000 infected patients annually.[52] Between 2005 and 2011, the Belgian federal government promoted hand hygiene through several national campaigns to decrease healthcare associated infections. For the latest campaign in 2011, hand hygiene compliances increased from 62.3% to 72.9%, with the highest compliance rates within the pediatric units.[53] These figures show that sensibilization and creating awareness are important factors for improving patient safety.

Studying adverse events using medical record review

Patient safety has been high on the agenda for more than a decade. The catalyst for this was the Harvard Medical Practice Study which reviewed in 1984 a total of 30 121 patient records from 51 randomly chosen acute and non-psychiatric hospitals located in New York. This study, which was reported only a few years later in 1991, estimated that 3.7% of all hospitalized patients experiences an adverse event related to medical therapy and that 27.6% of the adverse events occurs due to negligence.[54] A number of similar reports were then published. It was only until the publication of the report 'To err is human' in 1999, that public attention was drawn to the importance and magnitude of the issue of patient harm from medical errors. The IOM report puts forward that between 44 000 and 98 000 patients hospitalized in the United States die each year as a result of medical errors.[29] Within other countries, similar rates of adverse events were reported (table 1).

The quality in Australian healthcare study identified adverse events in 16.6% of the hospital admissions.[19] In European countries incidence rates from medical record review were reported from Sweden (12.3%)[18], the United Kingdom (10.8%)[55], Denmark (9.0%)[17], and the Netherlands (5.7%)[21]. The variation in the incidence of adverse events among these studies in different countries may either be explained by true differences in patient safety of the different healthcare systems, or by methodological differences between studies.[56] For instance, the lower US rates might reflect the narrower focus on negligent injury rather than the focus on a broader quality improvement approach of most other studies. However, most of these studies reported that half of the adverse events are preventable. It is expected that the same number of preventable adverse events occur in Belgian hospitals. However, up till now, this has never been assessed using the method of medical record review.

Adverse events, preventability and mortality

Retrospective review of medical records has several methodological limitations, as this method will detect a lower estimate of actual patient harm. The often moderate inter-reliability agreement, particularly on judgments of preventability, raised the debate about the number of deaths due to adverse events. Using hospital mortality rates to judge hospital performance is yet being discussed.[57] Preventable mortality, or the degree to which problems in care contributed to death, has been found difficult to be estimated accurately. Potentially preventable deaths in Dutch hospitals were estimated based on a retrospective medical record review study in a random sample of 21 hospitals in the Netherlands. In total, 7 926 hospital admissions were reviewed, of which 3 983 admissions of deceased hospital patients and 3 943 admissions of discharged patients in 2004. One or more adverse events were found in 5.7% (95% CI 5.1% to 6.4%) of all admissions and preventable adverse events in 2.3% (95% CI 1.9% to 2.7%) of all admissions. Of all adverse events, 12.8% resulted in permanent disability or contributed to death. Preventable adverse events that contributed to death occurred in 4.1% (95% CI 3.5% to 4.8%) of all hospital deaths, which count for an extrapolation to the national Dutch level of between 1 482 and 2 032 potentially preventable deaths in 2004.[21] Further analysis of the medical records showed that the type of hospital explained 35% of the inter-hospital variance in adverse events and patient characteristics (age, sex, urgency of admission, length of stay, diagnostic groups and co-morbidity) and department characteristics (surgical or non-surgical department) explained 23% of the inter-department variance in preventable adverse events.[58] In a follow-up study in 2008, it was measured based on a representative sample of 20 Dutch hospitals if the number of potentially preventable adverse events had changed after a period of four years. In total, 4 023 records were reviewed including a random sample of 100 records of deceased hospital patients and 100 records of discharged patients in each hospital in 2008. Results of the study showed that a preventable adverse event occurred in 2.9% (95% CI 2.3% to 3.7%) of the hospital admissions and that preventable adverse events that contributed to death occurred in 5.5% (95% CI 4.5% to 6.6%) of all hospital deaths. However, when comparing both studies a small increase of (not preventable) adverse events was observed from 5.7% (95% CI 5.1% to 6.4%) in 2004 to 8.0% (95% BI 6.9 to 9.2) in 2008. These small changes in estimates demonstrate the difficulty of improving patient safety in hospitals.[59]

In a recent British medical record review study of 1 000 deceased patients in 2009, it was judged that 5.2% (95% CI 3.8% to 6.6%) of deaths has a 50% or greater chance of being preventable. The main problems associated with preventable mortality included poor clinical monitoring (31.3%; 95% CI 23.9 to 39.7), diagnostic errors (29.7%; 95% CI 22.5% to 38.1%), and inadequate drug or fluid management (21.1%; 95% CI 14.9 to 29.0). Extrapolating from these figures suggests there would have been 11 859 (95% CI 8712 to 14 983) adult preventable deaths in hospitals in England.[60] Although preventable hospital mortality is being discussed as a good indicator for quality of care, these examples of studies have implications for policy since there is need of understanding their causes.

The impact and costs of adverse events

The financial costs of adverse events, in terms of additional treatment and prolonged length of hospital stay, but also the wider costs of disability and lost working time, are substantial. It has been estimated in 1999 by Thomas et al. that in the United States the national costs of preventable adverse events are between $17 and $29 billion.[61] The consequences of patient harm has been estimated by Zahn et al. on an excess length of stay attributable to medical errors of 2.4 million hospital days, which account for $9.3 billion excess charges in the United States annually.[62] The IOM report 'To Err is Human' estimated the US costs associated with preventable adverse events to count for 2% of the national healthcare expenditure budget. The costs for all (preventable and non-preventable) adverse events were estimated about double.[29] Based on a study in Dutch hospitals in 2004, the annual direct medical costs were estimated at a total of 355 million Euros for all adverse events and 161 million Euros for preventable adverse events. This counts for 1% of the expenses of the Dutch national healthcare budget. The cost driver of the direct medical costs was the excess length of hospital stay (including readmissions).[63] It should be of note that the Netherlands, the highest spending European country in 2009, spends only 12.0% of their gross domestic product on health, compared with 17.4% spent in the US.[9]

Table 1 – Adverse events detected by medical record review in acute hospitals in different countries

Study	Publication year	Date of admission	Number of hospital admissions	Number of hospitals	Method of review	Adverse event rate (%admissions)
Harvard Medical Practice Study[54]	1991	1984	30 121	51	Two-stage record review: first, screening for one of 18 criteria by trained nurses; second,review by two physicians	3.7
Quality in Australian health Care Study[19]	1995	1992	14 179	28	Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by two medical officers	16.6
Utah Colorado Study[64]	2000	1992	14 052	28	Two-stage record review: first, screening for one of 15 criteria by trained nurses; second, review by physician	2.9
New Zeeland[15]	2002	1998	6 579	13	Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by medical officer	11.3
United Kingdom[55]	2001	1999	1 014	2	Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by clinician	10.8
Denmark[17]	2001	1998	1 097	17	Three-stage record review: first, nurse screening by 18 criteria identifying high-risk groups; second, independent reviews by pairs of physicians; third, in case of disagreement additional independent review by two physicians (internist and surgeon)	9
Canada[65]	2004	2000	3 745	20	Two-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by physician	7.5
Sweden[18]	2009	2004	1 967	28	Three-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by two independent physicians; third, in case of disagreement additional independent review by physician	12.3
The Netherlands[21, 59]	2007 2010	2004 2008	7 926 4 023	21 20	Three-stage record review: first, screening for one of 18 criteria by trained nurses; second, review by two independent physicians; third, in case of disagreement additional independent review by physician	5.7 8

FEDERAL PATIENT SAFETY PROGRAM IN BELGIAN HOSPITALS: FROM A FRAGMENTED TO AN INTEGRATED APPROACH

Language context and organization of hospital care in Belgium

Belgium is a federal state comprising three communities, three regions and four language areas: the Dutch, Bilingual (Brussels-Capital), French and German linguistic areas. Dutch is spoken by around 59% of the population, French by around 40% and German by less than 1%. The country is divided into Dutch-speaking Flanders in the north and French-speaking Wallonia in the south. Brussels is bilingual, but its dominant language is French. German is spoken in nine communities close to Germany.[66]

Numerous public authorities are responsible for the funding of healthcare and the oversight of its organization. The division of responsibilities mirrors the fragmented structure of the Belgian state. Since the early 1980s, elements of responsibility for healthcare have been devolved to the communities. However, devolution is limited, especially for curative medicine, for which the federal authorities remain responsible.[67]

Hospital care is provided by either private non-profit-making or public hospitals. There are two main categories of Belgian hospitals: the general and psychiatric hospitals. General hospitals are further divided into acute, long-term care (specialized care) and geriatric hospitals. According to the federal numbers of January 2012, there are currently 194 Belgian legitimatized hospitals, of which, 105 acute, 66 psychiatric and 23 long-term care or specialized hospitals located in the regions of Flandria (53%), Brussels (14%) and Wallonia (33%).[68] Acute hospitals consist of university hospitals, general hospitals ‘with university character’ and other non-university hospitals. Belgium has seven university hospitals, one for each medical school that offers the entire medical education. Psychiatric hospitals are exclusively designed for psychiatric care. Specialized or long-term care hospitals provide chronic treatment and/or revalidation of patients with e.g. cardiopulmonary diseases, locomotive diseases, neurological disorders, palliative care, NOS chronic diseases and psycho-geriatric care. They can be considered as mixed general hospitals. Most medical specialists work independently in hospitals or in private practices on an ambulatory basis.[67]

Legislative framework for Clinical Risk Management in Belgian hospitals

In Belgium, patient safety has been highly promoted within the hospitals by the federal government. In an early stage, the Belgian government focused the attention for clinical risk management in hospitals on specific domains with well-known risks. The government accomplished legislative work in these domains and created a framework for risk management, such as the establishment of a Committee for Hospital Hygiene (1987), a Medico-Pharmaceutical Committee and a Committee for Medical Materials in the context of the recognition of the hospital pharmacy (Order in Council. 04/03/1991). More recent was the establishment of a Blood Transfusion Committee (Order in Council. 16/04/2002). In 1999, the Coordinating Committee BAPCOC (Belgian Antibiotic Policy Coordination Committee) was founded. The Commission undertook numerous initiatives, such as the elaboration of guidelines for hospitals and ambulatory care and the drafting of a feedback from the antibiotic consumption data per pathology group, based on the link of the Minimal clinical data (MKG) and the minimum financial data (MFG). In order to guide initiatives within the hospitals, antibiotherapy policy groups (ABTBG) were founded (2002). The antibiotherapy policy group is a consulting and follow-up institution in the use of anti-infective drugs and the control of resistant micro-organisms. The ABTBG falls within the hospital organization chart under the medico-pharmaceutical committee. In October 2002, the Belgian government started a pilot project in which 37 hospitals established an ABTBG. In 2006, 24 hospitals were added. Since 2007, the project was extended to all acute and chronic hospitals with a minimum number of 150 Sp-and/or G-beds (Order in Council 19/06/2007). Furthermore, in 2002, the Federal Platform for Hospital Hygiene was founded under the jurisdiction of the BAPCOC-Commission.[69] This platform unites the local hospital committees within regional platforms which are funded by the government. The platform contributed to a structural reform by establishing teams for hospital hygiene and the optimization of the functions of physician and nursing hospital hygienists. At the end of 2004, the Federal Services of Public Health founded the Network of Medico-Pharmaceutical Committees.[70] This network provides a qualitative support for the Medico-Pharmaceutical Committees in all Belgian hospitals and is responsible for the collection, evaluation and dissemination of all initiatives.

Federal contracts on quality and safety in Belgian hospitals

More recently, the Belgian federal government shifted the fragmented attention for specific clinical risk domains to a more integrated approach for quality and patient safety within the Belgian hospitals. In 2006, the first pilot projects on patient safety were launched in 16 Belgian hospitals, with attention to safe medication practices.[71] Since July 2007, the Belgian government provides a yearly additional financing (within part B4 of the hospitals' financial budget) for the hospitals of 7.66 million Euros (in 2012) for the implementation of patient safety and quality initiatives in the acute, psychiatric and long-term care hospitals.[72] The federal program (2007-2012) aimed at promoting and supporting the coordination of initiatives based on Donabedian's triad: (1) development of a safety management system (structure), (2) analysis of intramural and transmural care processes (processes) and (3) development and use of indicators (results). The first pillar, the development of a safety management system, includes several elements of which five elements are considered essential: (1) implementation of a hospital wide notification and learning system for incidents and near-misses, (2) a safety culture measurement using the Hospital Survey on Patient Safety Culture (AHRQ), (3) analysis of (near-) incidents using Root Cause Analysis (RCA), (4) classification of incidents by using the International Classification for Patient Safety (ICPS) of the World Health Organization and (5) prospective risk assessment of healthcare processes using Healthcare Failure Mode and Effect Analysis (HFMEA).

MAIN OBJECTIVES AND RESEARCH QUESTIONS OF THIS DISSERTATION

In Belgium, patient safety research is more recent and in an early stage of development. As outlined in this dissertation, the organization of hospital care in Belgium is complex given the high diversity in settings, the multiple language context and the shared responsibilities for health policy between the federal level and the federated entities (regions and communities). In this dissertation, this complex context must be taken into account in the study design, data collection and interpretation of results.

The aim of this dissertation is to fulfill two parallel objectives: (1) to fill an important gap in the current research on patient safety and safety culture in the Belgian hospitals and (2) to create a solid basis for improving patient safety systematically in the Belgian hospitals. In fulfilling these aims, this research faces a major challenge of introducing and investigating safety culture in the healthcare environment, where the issue of patient safety is yet extremely difficult to discuss. In this dissertation, we decided to build on the Hospital Survey on Patient Safety Culture (HSPSC), originally developed by the Agency for Healthcare Research and Quality, for several reasons:[73]

1. We relied on the review which was conducted by Colla et al. and Flin et al. indicating that the HSPSC can be applied to both healthcare staff and non-clinicians.[26, 74, 75]
2. In addition, the HSPSC is one of the few surveys in which a comprehensive report of scale development was provided.[34] In contrast, many other safety culture and climate surveys have not succeeded to meet accepted psychometric standards, although there has been a considerable thematic overlap.
3. Our study aims to raise the awareness of hospital staff towards patient safety and to help hospitals to understand the nature of the safety culture within their organizations and implement strategies for improving patient safety.
4. Furthermore, a particular area of interest is to examine if there are divergences between organizational members, groups of members (e.g. professional groups) or organizational units. The HSPSC dimensions

differentiate hospital-level and unit-level perceptions and thus can be applied organization-wide.

5. The HSPSC lends itself well for internal and external benchmarking.
6. The HSPSC has been widely used in other countries, which allows future international comparisons.

This dissertation will explore and discuss these issues in the context of the Belgian hospitals. Regardless the outlined conceptual discussion of safety culture and safety climate, the term 'safety culture' is applied in this dissertation, as it is also suggested within the original conceptualization of the HSPSC. The basic idea of this research was to practically introduce the concept in the hospital environment, where the issue of safety is hard to discuss. The studies in this dissertation are conducted from several perspectives: the healthcare organization, the role of the government, the experiences and perceptions of the providers of care and most importantly the impact for the patient. The conceptual framework (figure 1) represents several measurement points and includes, what is proposed in a Safety Management System, a combined approach of retrospective methods (detection of adverse events), prospective risk analysis (estimation of risks) and a baseline and follow-up measurement of safety culture.

This dissertation starts with examining patient outcomes, then addresses an additional method for assessing risks in healthcare processes and ends with analyzing safety culture in Belgian hospitals.

Three main research questions are addressed (see also figure 1). Research question 1 is further addressed in two sub questions. Research question 3 is divided in four sub questions.

Overview of research questions and chapters in which they are addressed

Research question	**Corresponding chapter**
RQ1: What are the incidence rate, preventability and consequences of adverse events requiring a higher level of care?	
a) Based on the best available evidence?	Chapter 2
b) How can medical record review be applied within Flemish acute hospitals for the detection of this type of adverse events?	Chapter 3
RQ2: Which variants of Healthcare Failure Mode and Effects Analysis can be applied to prospectively measure risks in healthcare processes?	Chapter 4
RQ3: What is the current state of patient safety culture in the Belgian hospitals?	
a) What are the safety culture perceptions in Belgian hospitals using the HSPSC and what are opportunities for benchmarking safety culture data?	Chapter 5
b) Can the HSPSC be applied to measure variability in safety culture perceptions in the Belgian acute hospitals?	Chapter 6
c) Is the HSPSC suitable for use in the Belgian psychiatric hospitals and what are the psychometric properties of the questionnaire?	Chapter 7
d) Can we measure changes in safety culture after a period of three years?	Chapter 8

OUTLINE OF THE DISSERTATION

The chapters are written as separate articles and can be read independently of each other. As a consequence, the content of the chapters show some overlap, especially with respect to the description of the methods and instruments.

Chapter 1

Chapter 1 sets the scene for the doctoral thesis by providing an introduction and background of the research. First, a conceptual framework for patient safety is provided. This chapter also addresses the magnitude of patient harm and the importance of measuring and improving safety culture and patient safety in Belgian hospitals by using an integrated approach. Finally, the objectives and research questions of this dissertation are outlined.

Chapter 2

The second chapter addresses the first research question and presents a systematic review on the incidence and preventability of adverse events that necessitate intensive care admission.[76, 77] This type of adverse events is of importance, given their dramatically financial and social impact. Up till now, there is no substantial evidence on the occurrence of these events, or on their consequences. The PRISMA statement (Preferred Reporting Items for Systematic reviews and Meta-Analyses) was applied to report this systematic review. Systematic reviews and meta-analyses have become increasingly important in healthcare, as they are often used as a starting point for developing clinical guidelines. Also, granting agencies may require a systematic review to ensure there is justification for further research.[78] The protocol and the extended version of this systematic review are available from the Joanna Briggs Institute.[77]

Chapter 3

The third chapter builds further on the available evidence and describes the development of a medical record review tool to investigate adverse events that require a higher level of care in Flemish hospitals. In practice, these events relate to (1) (re)admission to the Intensive Care Unit from other care units in the hospital providing lower intensity care, (2) to an intervention by a Medical

Emergency Team due to an unanticipated change in the patient's clinical status or (3) to a redo procedure within 24 hours for ICU patients.[79]

Chapter 4

Chapter 4 addresses the second research question and presents a case study of prospective risk analysis in a radiotherapy setting. Prospective risk assessment can be seen as a complementary approach to retrospective adverse events detection. In this study, the method of Healthcare Failure Mode and Effects Analysis (HFMEA^{TM}) is evaluated in terms of time, costs and quality of outcomes.[80] HFMEA^{TM} is a systematic assessment of a healthcare process that enables organizations to determine the location and mechanisms of potential failures. In our design, we compare the risk assessment of Failure Mode and Effects Analysis (Risk Priority Numbers) with HFMEA^{TM} (Hazard Scoring Matrix^{TM} combined with HFMEA Decision Tree^{TM}) in terms of time investment and usefulness.

Chapter 5

In Chapter 5 the third research question is addressed by presenting the benchmark results of a nation-wide baseline safety culture measurement in 143 Belgian acute, psychiatric and long-term care hospitals using the Hospital Survey on Patient Safety Culture (HSPSC).[81] An exploratory hierarchical cluster analysis is conducted to examine the relationship of the underlying safety culture dimensions. The aim of this study is to investigate the opportunities for benchmarking results on the organizational level by providing each hospital with a baseline patient safety culture profile to direct an intervention plan.

Chapter 6

Chapter 6 builds further on Chapter 5 and analysis the baseline safety culture data of 89 acute hospitals. This study builds on the hypothesis that safety culture is a group characteristic and not a characteristic of the whole hospital as it is fragmented into multiple distinct subcultures (e.g. at the unit or professional group level). Generalized Estimating Equations (GEE) models are fitted to explore differences in perceptions based on language, work area, staff position and work experience.

Chapter 7

Chapter 7 chronologically follows Chapters 5 and 6 since this study is based on data of a follow-up safety culture measurement. In this chapter the psychometric properties of the Dutch and French translation of the Hospital Survey on Patient Safety Culture are presented for use within the Belgian psychiatric hospitals. The psychometric properties of the questionnaire are investigated by item analysis, exploratory factor analysis (EFA), confirmatory factor analysis (CFA), reliability analysis (Cronbach Alpha) and analysis of the composite scores and inter-correlations. Results are compared with findings of the acute Belgian and American hospitals.

Chapter 8

Chapter 8 examines the evolution of safety culture in 111 Belgian hospitals (acute, psychiatric and long-term care hospitals) which participated in a follow-up benchmarking after a period of three years. Besides possible time effects, it is examined in analogy with chapter 6 to what extent variations in safety culture are explained by hospital characteristics (including type, statute, language, number of beds) and demographic characteristics (work area, staff position and work experience e.g. numbers of hours worked per week). Results of these research questions could have implications for policy aimed applying interventions to improve safety culture.

Chapter 9

Chapter 9 contains the overall discussion and presents the main conclusions, methodological considerations of the applied study designs and recommendations for further research and for practice in the field of patient safety.

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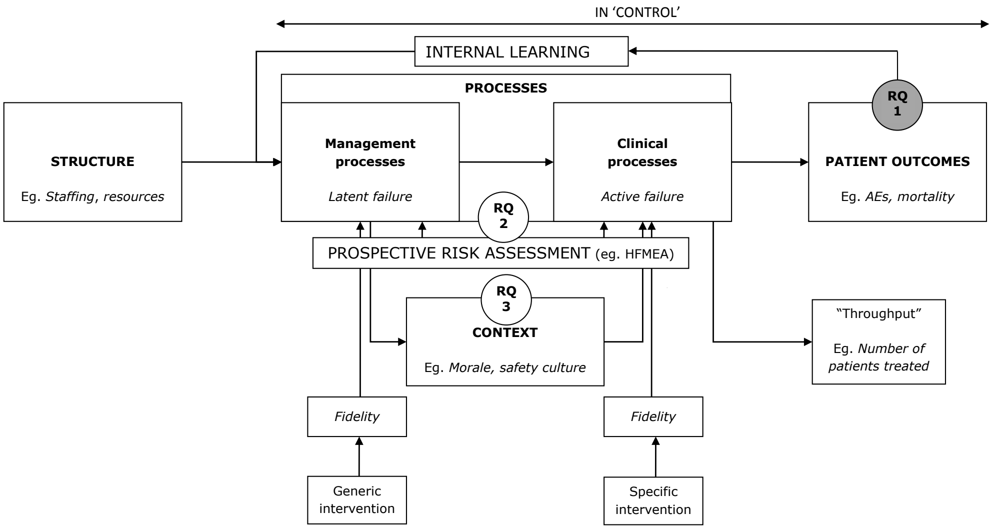
CHAPTER 2

Incidence and preventability of adverse events requiring intensive care admission: A systematic Review



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- Vlayen A, Verelst S, Bekkering GE*, et al.* Exploring unplanned ICU admissions: a systematic review. *JBI Library of Systematic Reviews*. 2011;9(25):925-59.
- The review protocol is available with the Joanna Briggs Institute.

SUMMARY

Rationale, aims and objectives: Adverse events are unintended patient injuries or complications that arise from healthcare management resulting in death, disability or prolonged hospital stay. Adverse events that require critical care are a considerable financial burden to the healthcare system, but also their global impact on patients and society is probably underestimated. The objectives of this systematic review were to synthesize the best available evidence regarding the estimates of the incidence and preventability of adverse events that necessitate intensive care admission; to determine the type and consequences (mortality, length of ICU stay and costs) of these adverse events.

Methods: MEDLINE (from 1966 to present), EMBASE (from 1974 to present) and CENTRAL (version 1-2010) were searched for studies reporting on unplanned admissions on intensive care units. Several other sources were searched for additional studies. Only quantitative studies that used chart review for the detection of adverse events requiring intensive care admission were considered for eligibility. For the purposes of this systematic review intensive care units (ICUs) were defined as specialized hospital facilities which provide continuous monitoring and intensive care for acutely ill patients. Studies that were published in the English, Dutch, German, French or Spanish language were eligible for inclusion. Two reviewers independently extracted data and assessed the methodological quality of the included studies.

Results: 27 studies were reviewed. Meta-analysis of the data was not appropriate due to methodological and statistical heterogeneity between studies; therefore, results are presented in a descriptive way. The percentage of surgical and medical adverse events that required ICU admission ranged from 1.1% to 37.2%. ICU readmissions varied from 0% to 18.3%. Preventability of the adverse events varied from 17% to 76.5%. Preventable adverse events are further synthesized by type of event. Consequences of the adverse events included a mean length of ICU stay that ranged from 1.5 days to 10.4 days for the patient's first stay in ICU and mortality percentages between 0% and 58%.

Conclusions: Adverse events are an important reason for (re-)admission to the ICU and a considerable proportion of these are preventable. It was not possible to estimate an overall incidence and preventability rate of these events as we

found considerable heterogeneity. To decrease adverse events that necessitate ICU admission, several systems are recommended such as early detection of patients with clinical instability on general wards and the implementation of rapid response teams. Step-down or intermediate care units could be a useful strategy for patients that require monitoring to avoid ICU readmissions. However, the effectiveness of such systems needs to be investigated.

INTRODUCTION

To date there is insufficient evidence on the causes of adverse events and to what extent patients are harmed. Several international organizations are putting efforts to create awareness to this issue and put forward recommendations and solutions in order to reducing patient harm.[1-3]

The consequences of patient harm has been estimated by Zahn et al. on an excess length of stay attributable to medical errors of 2.4 million hospital days, which account for $9.3 billion excess charges, and 32 591 attributable deaths in the United States annually.[4]

Several national studies describe the use of medical record review to measure the occurrence of adverse events in hospitals.[5-13] The large variation in the incidence of adverse events among these studies in different countries may either be explained by true differences in patient safety of the different health care systems, or by methodological differences between the studies.[14] Despite the awareness that a substantial number of adverse events are detected among unexpected ICU admissions, little is known about the epidemiology of these events. We conducted a systematic review to synthesize the best available evidence regarding the estimates of the incidence and preventability of adverse events requiring unplanned ICU (re-)admission. In addition, we synthesized the types and consequences of these events including mortality rates, length of ICU stay and direct medical costs.

METHODS

Review protocol

The review protocol is available from the authors and the Joanna Briggs Institute[15] and details the predefined criteria for this review.

Eligibility criteria

This review only considered quantitative studies on the incidence of adverse events requiring unplanned ICU (re)admissions in public or private general hospital settings. Only study designs which used chart review were included. An *adverse event* was defined as ‘an event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient'.[11, 16] *Unplanned ICU admissions* were defined as all patients unexpectedly admitted to the ICU from a lower level of care in the hospital. *Unplanned ICU readmissions* were all patients discharged from the ICU to a lower level of care in the hospital that had an unplanned return to the ICU. Studies that reported on patients admitted on Neonatal ICUs or transfers from outside hospitals were excluded.

Primary outcomes were the number of unplanned ICU (re)admissions (measured as a proportion, compared with number of ICU admissions), the number of adverse events requiring ICU admission (measured as a proportion, compared with the number of ICU admissions) and the number of preventable adverse events (measured as a proportion, compared with the incidence rate). Secondary outcomes were the type of event, contributory causes, location and subdivision by provider of care, consequences (mortality rates, harm, and length of ICU stay), direct medical costs of adverse events and kappa-coefficients (κ) of the chart review methods.

Search strategy

We completed searches in MEDLINE (from 1966 to present), EMBASE (from 1974 to present) and CENTRAL (version 1-2010) in January 2010. The search strategy combined selected MeSH terms and free text terms to identify quantitative studies on the incidence of adverse events requiring unplanned ICU (re)admissions in public or private general hospital settings (Appendix I). Only studies using chart review and published in the English, Dutch, German, French or Spanish language were included.
The journal of Intensive Care Medicine, Quality and Safety in Health Care, International Journal for Quality in Health Care, the proceedings of the International Symposium on Intensive Care and Emergency Medicine (Critical Care) were searched for relevant papers or conference abstracts. Reference lists of retrieved papers were screened for new studies. In addition, we focused on nationwide studies that used chart review for the detection of medical errors.[5-9, 11-13, 17] ISI Web of Knowledge, grey literature in OpenSIGLE, Google, AHRQ PSNet [18] and the Institute for Healthcare Improvement [19] were searched for relevant studies. Authors of relevant papers were contacted regarding any further published or unpublished work.

Study selection and appraisal

Two reviewers (AV, SV), using standardized screening forms, independently performed the initial scan of titles and abstracts of all retrieved citations, and applied the inclusion criteria. During the screening process, the reviewers decided to no longer apply the exclusion criterion on the definition of adverse events since few studies reported on the used definition. Both reviewers documented the reasons for study exclusion. Full text copies of all potentially relevant studies were obtained and further checked for inclusion (AV, SV). Two independent reviewers (AV, SV) assessed the included studies for methodological quality according to predetermined criteria (table 2). Any discrepancies between reviewers were resolved by discussion.

Data extraction

Data extraction was completed independently by two reviewers (AV, SV) using a standardized data collection form. Data on study design, chart review, incidence of adverse events requiring ICU admission, preventability, outcome, location, provider of care and type of event were extracted. Data to perform subgroup analysis were collected on the presence of a Medical Emergency Team, patient characteristics and characteristics of the ICUs. The data were checked for any discrepancies and were then collated. Any discrepancies identified were resolved through discussion until consensus was reached among the review authors.

Data synthesis

All primary outcomes were first presented descriptively, using data as reported in the paper (i.e. mean, SD, median, percentiles, range). Subsequently, appropriateness of meta-analyses on primary outcomes (proportions) was examined. To do so, for each study the proportion was expressed as a logit,[20] as the distribution of logits is more likely to be normal than the distribution of proportions. Heterogeneity was assessed by graphic inspection of forest plots and by measuring the degree of inconsistency in the studies' results (I^2)[21]. STATA statistical software was used for all analyses.

Secondary outcomes were reported in a descriptive way.

A subgroup analysis based on population, country of study, sample size, method of screening and the use of definitions on adverse events was performed to identify and assess the heterogeneity between the studies.
Subgroup analysis was pre-specified in the study protocol.

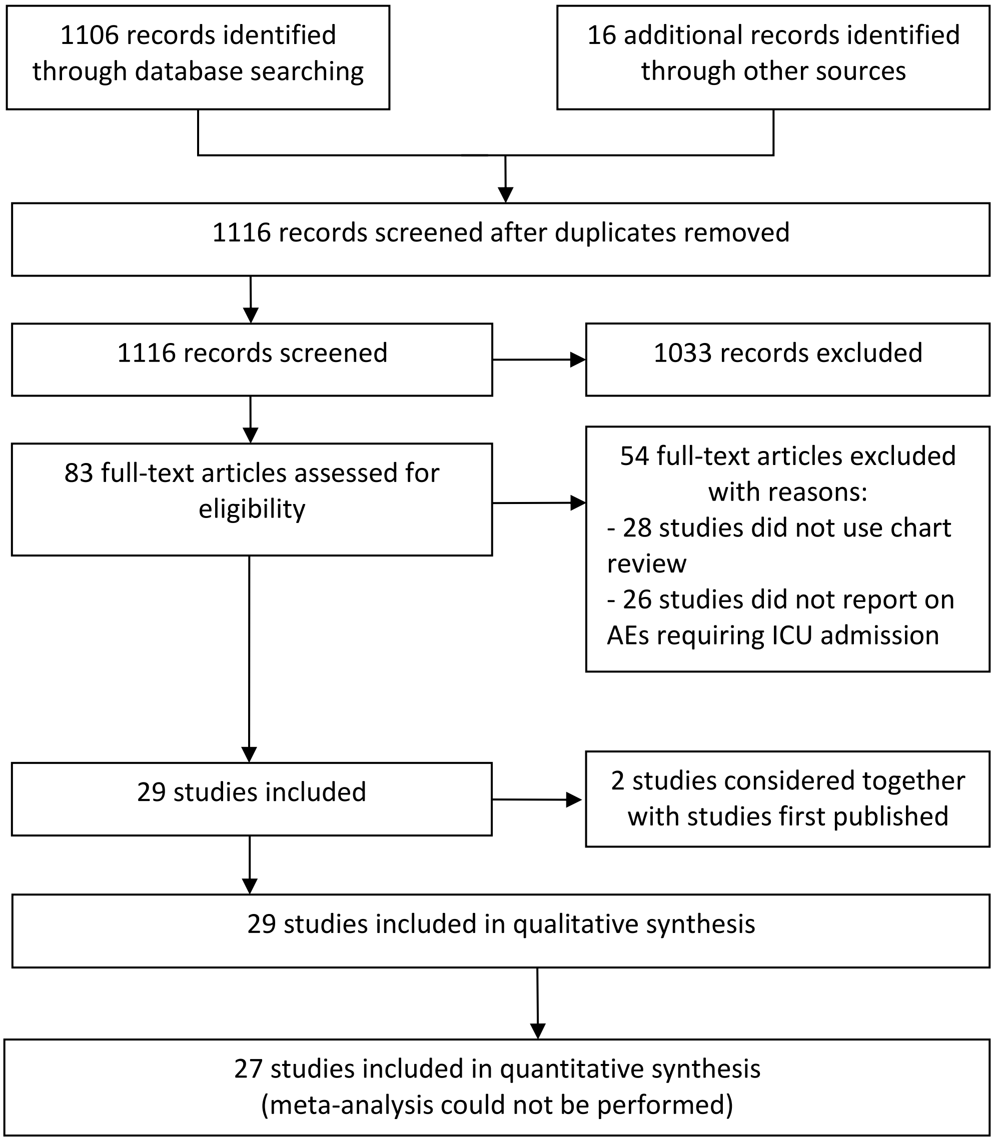
RESULTS

Results of the search

The initial database search identified 1100 unique citations (6 studies were duplicate) and 16 additional studies were identified through other sources, which were screened on title and abstract. 1033 studies were excluded. Full text copies of 83 potentially relevant studies were retrieved and reviewed and of these, 54 studies were excluded.

29 studies met the inclusion criteria for this review (figure 1). Two studies were considered duplicate studies [22, 23] as they reported on data already included in the review. These were reviewed together with the studies first published.[24, 25]

Figure 1 - Flow Diagram of study selection (based on PRISMA Statement, 2009)



Study characteristics and methodological quality

Characteristics of the included studies are presented in table 1. All studies used a retrospective study design with chart review in which the method of record selection was consecutive. A total of 10 391 patient records were derived from the included studies, with the median number of records reviewed per study of 385 (interquartile range 71-497). An overview of the methodological quality and the use of definitions for adverse events are presented in table 2.

Table 1 - Characteristics of included studies

Authors	Publication date	Country	Study period (months)	No/ type of hospitals	Method of chart review	No of records reviewed	Provider/ Population		Outcomes
Barnes[26]	1980	New Zealand	60	1 general hospital, 2 private hospitals	Not mentioned	110	A	Anesthetic	UIA=AE, mortality
Buist[27]	1999	Australia	12	1 teaching hospital (300 beds)	Multistage	112	GW	Cardiac arrest, unplanned ICU admission	AE, ICU readmissions, location, mortality, LOS, ICU LOS
Chaboyer[28]	2008	Australia	8	1 metropolitan hospital (580 beds)	Unistage	300	ICU	General ICU	ICU readmission=AE, κ
Cullen[29]	1992	USA	15	1 teaching hospital	Unistage	71	A, S	Anesthetic, surgical	UIA=AE, ICU readmission, location, type of event, harm, mortality, LOS, ICU LOS
Darchy[23, 24]	1998 1999	France	12	1 general hospital (500 beds)	Multistage	623	GW	All patients admitted to M, S ICU from GW	AE, preventable AE, location, type of event, mortality, ICU LOS, costs, workload
Downey[30]	1996	Australia	19	1 university-affiliated pediatric tertiary referral hospital (280 beds)	Not mentioned	35	P-A	Pediatric post-anesthetic	UIA=AE, preventable AE, location, type of event, mortality, TISS, ICU LOS
Dunn[31]	2006	Australia	72	1 pediatric referral hospital (250 beds)	Multistage	1612	P	Pediatric: deaths, clinical referrals, ICU admissions	AE, type of event, mortality
Durbin[32]	1993	USA	18	1 university teaching hospital (650 beds)	Not mentioned	82	MICU, SICU	Medical, surgical ICU readmissions	ICU readmissions=AE, type of event, mortality, LOS, ICU LOS
El SH[33]	2008	Canada	24	1	Not mentioned	250	S	Laparoscopic gastric bypass	AE, mortality
Endacott[34]	2009	Australia	12	1 regional hospital (220 beds)	Unistage	388	ICU	ICU readmissions	ICU readmission=AE
Franklin[35]	1983	USA	12	1 University hospital	Unistage	299	MICU	Medical ICU readmissions	ICU readmission=AE, preventable AE, type of event, mortality, ICU LOS
Gupta[36]	2001	USA	48	1 academic hospital	Not mentioned	202	S	Hip, knee replacement (OSA)	AE, type of event

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Authors (Continued)	Publication date	Country	Study period (months)	No/ type of hospitals	Method of chart review	No of records reviewed	Provider/ Population		Outcomes
Haller[22, 25]	2005 2008	Australia	63	1 university-affiliated hospital	Multistage	188	S	Surgical	UIA, AE, preventable AE, type of event, mortality, LOS, κ
Hayes[37]	1996	Australia	39	1	Multistage	23	S	Laparoscopic surgical	AE, location, type of event, mortality, LOS, ICU LOS
Heisler[38]	2009	USA	24	1 tertiary care hospital	Not mentioned	736	S-G	Hysterectomy + surgery	AE
Kafy[39]	2006	Canada	96	1 university teaching hospital	Not mentioned	1792	G	Hysterectomy	AE, ICU readmission, type of event
Kurowski[40]	2007	Australia	72	1 tertiary pediatric hospital	Not mentioned	358	P-A	Pediatric post-anesthetic	UIA=AE, type of event
Lehmann[41]	2005	USA	6	4 teaching hospitals	Multistage	64	S, M, P	Surgical, medical, pediatric	AE, preventable AE, type of event, mortality, ICU LOS
McGloin[42]	1999	UK	6	1 teaching hospital (702 beds)	Multistage	563	GW	Unexpected deaths and referrals from GW	AE, ICU readmission, preventable AE, type of event, mortality, ICU LOS
Okafor[43]	2009	Nigeria	48	1 university teaching hospital	Not mentioned	26	S, A	Postsurgical, anesthetic	UIA=AE, type of event, mortality, ICU LOS
Piercy[44]	2006	Australia	3	3 acute hospitals	Not mentioned	165	S, A	Postsurgical, anesthetic	UIA=AE, preventable AE, type of event, mortality,
Satyawan[45]	2006	Mumbai	6	1 general teaching hospital	Not mentioned	76	S, A	Postsurgical, anesthetic	UIA=AE, ICU discharges, mortality, ICU LOS
Stewart[46]	1997	Australia	16	1 teaching hospital	Multistage	44	CCU	ICU readmissions to a coronary care unit	ICU readmission=AE, preventable AE, type of event, mortality, ICU LOS
Swann[47]	1993	Canada	12	1	Multistage	265	S	Postsurgical	UIA=AE, preventable AE, type of event, mortality, ICU LOS
Wolff[48]	1995	Australia	12	1	Multistage	497	GW	All inpatients	AE
Wolff[49]	1996	Australia	38	1 rural base hospital	Multistage	1465	GW	All inpatients	AE
Yehia[50]	2002	New Zealand	72	1	Not mentioned	17	S	Haemodialysis	AE, type of event

ICU = intensive care; M = medical; CCU = coronary care unit; GW = general wards; A = anesthetic; S = surgical; P = pediatric; G = gynecological
UIA = unplanned intensive care admissions after anesthesia/surgery; AE = adverse event; LOS = length of hospital stay; κ = kappa value for interobserver reliability; TISS = Therapeutic Intervention Scoring System

Table 2 - Methodological quality and definitions for adverse events of included studies

Authors	Method of selecting medical records	Sample size	Method of screening	Kappa value for inter-observer agreement	Explicit definitions for adverse event
Barnes PJ[26]	A	B	C	C	N
Buist MD[27]	A	C	B	C	Y(2)
Chaboyer W[28]	A	B	B	C	Y(1)
Cullen DJ[29]	A	C	B	C	Y(2)
Darchy B[23, 24]	A	B	A	C	Y(1)
Downey GB[30]	A	C	C	C	Y(3)
Dunn KL[31]	A	A	A	C	Y(1)
Durbin CG[32]	A	C	C	C	N
El SH[33]	A	B	C	C	N
Endacott R[34]	A	B	B	C	Y(1)
Franklin C[35]	A	B	B	C	N
Gupta RM[36]	A	B	C	C	Y(2)
Haller G[22, 25]	A	B	A	A/B[a]	Y(1)
Hayes C[37]	A	C	A	C	Y(2)
Heisler CA[38]	A	B	C	C	Y(2)
Kafy S[39]	A	A	C	C	N
Kurowski I[40]	A	B	C	C	Y(3)
Lehmann LS[41]	A	C	A	A[b]	Y(1)
McGloin H[42]	A	B	B	C	Y(1)
Okafor UV[43]	A	C	C	C	N
Piercy M[44]	A	B	C	C	Y(3)
Satyawan A[45]	A	C	C	C	Y(2)
Stewart S[46]	A	C	A	C	N
Swann D[47]	A	B	A	C	Y(3)
Wolff AM[48]	A	B	A	C	Y(1)
Wolff AM[49]	A	A	A	C	Y(1)
Yehia M[50]	A	C	C	C	N

[a] Haller 2008: The kappa value for inter-observer agreement was 0.44 for incidence and 0.23 for preventability. The study in 2005 did not mention kappa values.

[b]Lehmann: Kappa value for preventability.

Methods of selecting medical records was A = adequate (selection method is correct and clearly described (ad random or consecutive)); B = inadequate (selection method is described, but no correct method is applied); C = Unclear (selection method is not mentioned) Sample size: The number of records reviewed was A = > 1000; B = > 100 and <1000; C = <100. Method of screening was A = adequate (the medical records were assessed using a multi-stage method: a primary assessment by trained clinician(s) using clear criteria. Each record that was positive for one or more criteria was then reviewed, independently, by (two) clinicians whether or not an adverse event occurred. The assessment of causation and preventability of adverse events was performed using a clear scale. When disagreement concerning the presence of adverse events and preventability prevailed, an independent assessment was performed; B = Less adequate (the medical records were assessed using a unistage or a multidisciplinary method: a primary assessment by trained clinician(s) using clear criteria. The records were reviewed by one or more clinician(s) whether or not an adverse event occurred); C = Unclear (there was insufficient information about the method of chart review). Kappa value for inter-observer agreement was A = adequate (κ > 0.40); B = Inadequate (κ < 0.40); C = unclear (kappa values were not mentioned).

Explicit definitions on unplanned ICU admissions, adverse/ critical events or serious complications were mentioned: yes (Y); no (N). Y(1) Studies that applied the following or a similar definition of adverse events as defined by the IOM or Wilson: 'an event that results in unintended harm to the patient by an act of commission or omission rather than by underlying disease or condition of the patient'. Y(2) studies that defined an adverse event, critical event or serious complication as an unplanned admission to an ICU. Y(3) Studies that suggest that an unplanned intensive care admissions may result from unexpected events.

Table 3 - Primary and secondary outcomes

	Participants		Sample size				Primary outcomes			Secondary outcomes	
Authors	Provider (population)	Surgical procedures/ hospital admissions (study period)	Records reviewed	ICU admissions (study period)	Unplanned ICU admissions	ICU discharges	AEs requiring ICU readmission	AEs requiring ICU admission	Preventable AEs	Mean length of ICU stay (days) for AEs	Mortality
Barnes[26]	A	83 173 procedures	110	1 929	110	-	-	110 (5.7)	-	-	12 (10.9)
Cullen[29]	A,S	17 093 procedures	71	-	71	63	0	71	-	1.5	8 (11.3)
Downey[30]	P-A	14 970 procedures	35	640 (P-A)[a]	35	-	-	35 (5.5)	7 (20)	4.2	1 (2.9)
El SH[33]	S	-	250	83	7	-	-	7 (8.4)	-	-	0 (0)
Gupta[36]	S	-	202	-	26	-	-	26	-	-	-
Haller[22]	S	44 130 procedures	188	5 552	201	-	-	183 (3.3)	140 (76.5)[b]	-	22 (10.9)
Hayes[37]	S	2 444 procedures	23	-	23	-	-	23	-	10.4	3
Heisler[38]	S-G	903 procedures	736	-	7	-	-	7	-	-	0 (0)
Kurowski[40]	P-A	55 196 procedures	358	420	76	-	-	76 (18.1)	-	-	-
Okafor[43]	S, A	6 581 procedures	26	497	26	-	-	26 (5.2)	-	3.2	8 (30.8)
Piercy[44]	A	-	165	-	165	-	-	165	28 (17)	-	24 (14.6)
Satyawan[45]	S	13 170 procedures	76	204	76	48	-	76 (37.3)	-	-	28 (36.8)
Swann[47]	S	18 555 procedures	265	679	34	-	-	34 (5)	7 (20.6)	1.5	0 (0)
Yehia[50]	S	-	17		-	-	-	2	-	-	-

(Continued)	Participants		Sample size				Primary outcomes			Secondary outcomes	
Authors	**Provider (population)**	**Surgical procedures/ hospital admissions (study period)**	**Records reviewed**	**ICU admissions (study period)**	**Unplanned ICU admissions**	**ICU discharges**	**AEs requiring ICU readmission**	**AEs requiring ICU admission**	**Preventable AEs**	**Mean length of ICU stay (days) for AEs**	**Mortality**
Buist[27]	GW	19 853 admissions	112	515	75	40	4	7((14.6)	-	5 ±6.9	35 (46.7)
Darchy[23]	GW	24 555 admissions	623	623	68	521	-	68 (10.9)	35 (51.5)	6.9± 9.3	9 (13.2)
Dunn[31]	P	103 255 admissions	1612	-	1 066	-	-	207	-	-	48 (23.2)
Kafy[39]	G	-	1 792	-	6	-	0	6	-	-	-
Lehmann[41]	S, M, P	-	64	5 727	64	-	-	64 (1.1)	22 (34.4)	3	8 (12.5)
McGloin[42]	GW	15 635 admissions	563	-	98[c]	-	11	98[c]	31 (31.6)	3.5[c]	43 (50)
Wolff[48]	GW	5 115 admissions	497	-	-	-	-	14	-	-	-
Wolff[49]	GW	-	1 465		24	-	-	24	-	-	-
Chaboyer[28]	ICU	-	300	507	-	-	8	-	-	-	-
Durbin [32]	ICU (M,S)	-	82	-	-	1 803	83	-	-	8.3±16.1 (first stay)	34 (41)
Endacott[34]	ICU	-	388	-	-	388	71	-	-	-	-
Franklin[35]	MICU	-	299	512	-	365	36[d]	-	15 (41.6)	11[d]	18 (58)[d]
Stewart[46]	CCU	-	44	1 776	-	-	44	-	15 (34.1)	13.3[e]	4 (9.1)

A = anesthetic; S = surgical; GW = general wards; P = pediatric; G = gynecological; ICU = intensive care unit; M = medical; CCU = coronary care unit.

Numbers (percentages). Percentages of unplanned ICU admissions and AEs are calculated against the number of ICU admissions. Percentages of preventable adverse events (AEs) and mortality are calculated compared with the number of adverse events requiring ICU (re)admission.

[a]Downey investigated only post-anesthetic errors. There were 1175 PICU admissions of which 640 post-anesthesia admissions. [b]Haller: reported in 2005 on 183 AEs. The study in 2008 reported an AE rate of reviewer A of 174/188 and reviewer B of 164/188 (κ=0.44). The preventability rates were 129/188 and 151/188 (κ=0.23). [c]McGloin: 86 patients ward patients were unexpectedly admitted to the ICU on a total of 98 occasions. 11 patients were readmitted, one being readmitted twice. Survivors had a similar ICU stay (3 days) versus non-survivors (4 days). [d]Franklin: 31 patients were readmitted with 5 patients readmitted twice. The average length of initial admission was 5 days (range 1-10 days) and the average of subsequent admission (readmission) was 6 days (range 1-41 days). [e]Stewart: Average length of ICU stay of the initial (5.9 days) and second (unplanned) admission to the coronary care unit (CCU) (7.4 days), experienced by 39 patients with unstable angina pectoris or acute myocardial infarction.

Primary outcomes

Data on primary outcomes are presented in table 3. They were sorted by the providers of care and population that were studied: anesthetic/surgical care, general wards and intensive care units.
Primary outcome data were divided into three categories: incidence of adverse events requiring unplanned ICU admission, ICU readmissions and preventability of adverse events.

20 studies reported on unplanned ICU admissions due to adverse events. In almost every study, an unplanned ICU admission was counted as an adverse event. Nine studies reported on adverse events on ICU resulting in ICU readmission. Most of these studies made a comparison with ICU discharges. Only nine studies investigated the preventability of the adverse events.

Due to considerable heterogeneity, we refrained from pooling the results. For all primary outcomes, the degree of inconsistency I^2 was 99.9%. It may be misleading to quote an average value for the primary outcomes. As an illustration of the heterogeneity in results, table 4 provides the ranges of the primary outcomes (proportions). A subgroup analysis based on the population (i.e. surgical, general wards and intensive care units) and study characteristics (i.e. country, sample size and outcome definitions) could not clarify the causes of heterogeneity.

Table 4 - Ranges of the primary outcomes (proportions)

Primary outcome	Number of studies that reported outcome	Range	
		Lower value	Upper value
Proportion adverse events (compared with ICU admission)	11	0.11	0.37
Proportion ICU readmissions (compared with ICU discharges)	5	0	0.18
Proportion preventable adverse events (compared with adverse events)	9	0.17	0.77

Types of preventable event

In this review, it was not possible to classify the adverse events into categories of attributable causes, since there was not enough information provided in the studies on the circumstances or contributory factors leading to adverse events.

Types of events were further specified for those studies that reported on preventability of adverse events (n=9, table 5). The types of events were mutually exclusive and could be divided into ten groups: premature discharge on ICU, diagnostic errors, inappropriate or inadequate treatment, technical error, adverse drug event, inappropriate intravenous fluid therapy, problems with medical procedures, problems with anesthetic or surgical procedures, reason not apparent and other. Numbers could not directly be compared between studies because different populations (inclusions and exclusions) were studied.

Preventable adverse events due to anesthetic-surgical care

Piercy investigated unplanned ICU admissions after anesthesia (UIA), as this is a recommended measure by the Australian Council on Healthcare Standards.[51] Only 19.3% of the unplanned admissions contained an anesthetic contribution to the admission of which only 5.4% within this group were deemed possibly preventable. The majority of these events were drug related and occurred more commonly in elective surgical patients.[44] In contrast, Haller found that 52.2% of UIA patients had an incident or near miss during their procedure of which most were preventable (74% to 92%).[22] Downey identified 20% UIA patients in a pediatric cohort whose ICU admission could have been prevented by a change in anesthesia management. 74.3% of those admissions emerged after elective surgery. No pattern of preventability could be deduced due to the range in preventable problems.[30] Finally, Swann identified 12.8% UIAs of which 20.6% were deemed preventable. The majority of events were related to inappropriate fluid.[47]

Preventable adverse events on general wards

Darchy found 68 adverse events, accounting for 10.9% of unexpected ICU admissions of which 51% was deemed preventable. The majority of preventable adverse events was drug related.[23] In a multicenter study by Lehmann, 66 (1.2%) patients were identified as having an iatrogenic medical event that was the primary reason for ICU admission. Twenty-two (34%) cases were thought to be preventable. The majority of events were secondary to technical error (45%) or were drug related (33%).[41] Finally, McGloin reviewed 563 ICU admissions of which 98 (17.4%) were unexpected admissions. 31 cases were deemed to be preventable and were due to incorrect or delayed diagnosis or therapy.[42]

Preventable adverse events on intensive care units

Two studies reported on the reasons for readmissions on ICU. Franklin identified 36 (12.0%) unexpected ICU readmissions of which nineteen (53%) were readmitted because of a recurrence of their original problem. Detailed analysis revealed that the majority of patients might have benefited from a longer ICU stay.[35] Finally, Stewart found 44 (2.5% of ICU admissions) unexpected readmissions to a coronary care unit and concluded that fifteen (34.1%) cases were related to incorrect or delayed therapy and thus could have been prevented.

Length of ICU stay, mortality and costs

Data reported on length of ICU stay and mortality are presented in table 3. The mean length of ICU stay reflected the average days that patients who experienced an adverse event spent in the intensive care unit. The results varied from 1.5 days to 10.4 days for the patient's first stay in ICU. For the patients that were readmitted on ICU the ICU length of stay, including the second stay, varied between 8.3 days and 13.3 days.

The percentage mortality was calculated as the number of deaths compared with the number of adverse events requiring ICU admission. Mortality percentages varied between 0% and 58%.

Only one study reported on the financial costs of adverse events. In the cohort of 68 unexpected ICU admissions by Darchy, these patients accounted for a total of 472 days in ICU, with a mean length of stay of 6.9 ± 9.3 days (range, 1-52 days) and a 13% (9/68 patients) fatality rate. Costs of medical care in the ICU for these patients were estimated at US $ 688 470.[23]

Table 5 - Preventable adverse events classified by type of event

Authors	Franklin[35]	Swann[47]	Downey[30]	Stewart[46]	McGloin[42]	Darchy[23]	Lehmann[41]	Piercy[44]	Haller[22]
Population	MICU	S	P-A	CCU	GW	M/ S	M/ S/ P	A	S
No. of AEs	36	34	35	44	98	68	64 [b]	165	183[d]
No. of preventable AEs	15	7	7	15	31[a]	35	22	28[c]	129 to 151
Categories of types									
Premature discharge on ICU	15								
Diagnostic error					12		6		
Inappropriate/ inadequate treating					19				
Technical error							29		
Averse drug event									
Dosing error			1			8	9	5	
Idiosyncratic reaction							7		
Frequency error							2		
Unable to classify							2		
Inappropriate drug						6	1	1	
Inadequate follow-up of drug therapy						14			12%
Inappropriate antiplatelet or anticoagulant therapy				15					
Failure to use prophylactic treatment						2			
Inappropriate intravenous fluid therapy		6	1				2		
Problems with medical procedures									
Radiocontrast infusion						2			
Hemorrhoid sclerotherapy						1			
Problems with anesthetic-surgical procedures									
Suprapubic cystotomy tube						1			
Epistaxis tamponade						1			
Choice/application anesthetic/surgical technique									39 to 52%
Equipment/ monitoring failures									1% to 6%
Problems with preoperative assessment								1	24 to 27%

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Authors (continued)	Franklin[35]	Swann[47]	Downey[30]	Stewart[46]	McGloin[42]	Darchy[23]	Lehmann[41]	Piercy[44]	Haller[22]
Traumatic intubation with airway bleeding		1							
Reluctance to commence inotrope infusion intraoperatively			1						
Reluctance to administer CPAP immediately postoperatively			1						
Intubation of the right main bronchus			1						
Delay in drainage of bilateral pneumothoraces			1						
Inadequate preoperative respiratory operation			1						
Aspiration								1	
Pulmonary oedema								1	
Reason not apparent							4		
Other							2		

ICU = intensive care unit; M = Medical; S = Surgical; P = Pediatric; A = Anesthetic; CCU = coronary care unit; GW = General Ward. Numbers or percentages were given. [a]McGloin defined suboptimal care as either non recognition of (the severity of) an abnormality clearly apparent from physiological recordings or laboratory data (diagnostic error) or inappropriate/ inadequate treatment. [b]Lehmann: Categories for adverse events are presented. Categories for preventable adverse events are not available. Technical error was defined as a medical procedure event such as an injury occurring during an operation or bleeding. Adverse drug event was defined as an injury resulting from complications of noninvasive therapy. Diagnostic error was defined as a delayed or incorrect diagnosis or therapy. [c]Piercy: only types of anesthetic-related problems were given. [d]Haller: numbers or percentages were given for two independent reviewers. 105 patients with UIA had an incident or near miss during their procedure. In nearly half of the cases, there was more than one event reported.

DISCUSSION

We conducted a systematic review to investigate the incidence, preventability and consequences of adverse events that necessitate intensive care admission. It was not possible to estimate the incidence based on multiple studies due to considerable heterogeneity. The percentage of surgical and medical adverse events that required ICU admission ranged from 1.1% to 37.2%. ICU readmissions varied from 0% to 18.3%. Furthermore, the preventability of the adverse events varied from 17% to 76.5%. Consequences of the adverse events included a mean length of ICU stay that ranged from 1.5 days to 10.4 days for the patient's first stay in ICU and mortality percentages between 0% and 58%. Authors suggested several systems to reduce adverse events that necessitate intensive care admission but the effectiveness of such systems still needs to be researched.

We performed a comprehensive search strategy. We searched several electronic sources and put considerable effort in identifying studies using alternative sources such as reference lists, patient safety journals and websites. We also contacted the authors of relevant papers. The additional sources yielded nine additional studies. The rigorous search strategy strengthens the methodological quality of our review.

We found considerable heterogeneity between the studies, which precluded pooling of study results. For all outcomes, the I^2 was close to 100%. As I^2 describes the percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error [21], this means high diversity between the studies. Subgroup analyses based on population, country and methodological quality of the studies could not clarify heterogeneity. However, care must be taken in the interpretation of these analyses, since the included studies have small sample sizes and few studies report on the same outcomes.

Clinical diversity may be due to population mix (variability in type of participants e.g. surgical, pediatric, gynecological, and inclusions and exclusions of participants) and the use of different definitions on outcomes. Institutional factors like bed size (e.g. high dependency beds outside ICU), teaching status or staffing may also play an important role. These clinical characteristics could not be investigated due to the poor reporting of study results. Differences in study design and methods of medical record review may explain methodological diversity. Only three studies were multi-center studies.[26, 41, 44] All other studies were case studies investigating unplanned admissions on one ICU.

The limitations of this review mainly concern the scope of the review. This review only includes studies that used the investigation of adverse events through chart review. Our strict inclusion criteria potentially may have caused us to exclude interesting studies with prospective study designs or studies addressing incident reporting.

The use of the method of medical record review itself might lead to an underestimation of adverse events. The quality of the medical records is often poor as too much information is missing or incomplete. Because many errors are not (well) documented in the medical records, study results may be an underestimation of the true incidence rate of adverse events leading to unanticipated intensive care admission. In addition, estimates on preventability are prone to subjective judgments of the authors. Darchy mentions the difficulty in distinguishing between an adverse event and a preventable adverse event after surgery because the surgeon is both judge and judged. Haller made in his study a classification of preventable complications with a rather moderate level of exact agreement between reviewers of 79.7%, with a kappa=0.23 (95% CI: 0.16 to 0.29).[22] In the multi-center study of Lehmann the preventability of the events could not be evaluated with certainty in 52% of the cases.[41] Several studies warn that the review of each case via the medical records is hampered by the retrospective nature of the analysis, and by the dependence on the quality of note taking by anesthetics, intensivists and nursing staff.[30, 33] One particular difficulty that was mentioned was the lack of recording in the notes of the actual reason for admission to ICU. This may arise from the reluctance of house staff, perhaps from medico legal reasons, to record the nature of misadventures under anesthesia.[41] These measurement errors in the measurement of error, as Lilford describes,[52] can degrade the ability to measure the impact of interventions or to provide evidence of association or causality between processes of care and outcome.

Despite the limitations of the available literature, several key findings suggest the need for further high quality research in the detection and classification of adverse events requiring ICU admission. The following suggestions can be made for future research.

Consecutive selection of ICU admissions allows that any information missing in the medical charts can be collected prospectively. Patient demographic data, the reason for ICU admission, severity of illness score e.g. APACHE II score (Acute Physiology and Chronic Health Evaluation), hospital outcome (mortality, discharge, transfer), and length of ICU stay could be better documented in a follow-up study. In addition, this study design allows a better comparison between patients with planned and unplanned ICU admissions.[27, 29, 38]

A multidisciplinary approach with professional involvement is a main condition in conducting medical chart review. In addition, a physician led program in contrast to nursing led initiatives might affect the acceptance of such a program in other settings.[31]

Several studies have shown some strengths of the method as an auditing tool.[31, 39, 40, 42, 43, 45, 47-50]. Continuous medical record review can be a useful strategy in quality improvement,[31] as the detection of adverse events, followed by an in-depth analysis of the underlying causes and specific prevention strategies can reduce the occurrence of adverse in hospitalized patients. However, in this review only one study predominated this approach.[23] It is a challenge to better understand the failures in the organization of care and an important source of information lies with the health care providers and with the patient. Within this issue, an important question arises whether it is appropriate to measure actual harm (adverse events) or the causes that lead to adverse events (errors). In this context Brown et al. propose an excellent framework for study design and measurement of errors.[53]

Although higher heterogeneity must be dealt with, multi-center studies also allow the possibility to aggregate data and analyze patterns of factors leading to adverse events across different hospital settings. This approach demands an appropriate design as there is an important loss of power that results from greater similarity across individuals within a cluster than across individuals between clusters.[53] The study of Hillman et al., which investigates the impact of a medical emergency team on the incidence of unplanned ICU admissions in 23 Australian hospitals, applied an illustrative evaluation framework.[54]

There is a need for a better standardization and validation of recommended improvements aimed at reducing morbidity and mortality arising from unplanned ICU admissions. In this regard, McGloin favors the early recognition and correction of abnormalities by introducing a rapid response team or medical emergency team.[42] Other authors support these findings.[27, 28] However, a recent systematic review on this issue showed that there is minimal evidence on the effectiveness of these systems.[55] Swann recommends grand rounds (educational training) on the management of perioperative fluid administration.[47] In order to reduce ICU readmissions, Stewart suggests the implementation of formal mechanisms to ensure appropriate pharmacotherapy when patients are transferred to lower levels of care.[46] Several authors suggest from their experience that a progressive care ("step-down") unit may be an effective alternative to early ICU discharge by reducing the likelihood of 'premature' ICU discharge and, hence, reducing readmissions to the ICU.[28, 35, 47] However, the effectiveness of any of these systems still needs to be confirmed.[55]

CONCLUSIONS

Implications for practice

The currently available evidence is relatively weak and it is not possible to estimate the overall incidence and preventability rate of adverse events that necessitate ICU admission. Variability in methodology and definitions, and poor reporting in studies may be the main reasons, so this can be researched in order to improve quality of care. Hospitals should better document the reasons for admission on intensive care units. Several authors recommend early detection of patients with clinical instability on general wards and the implementation of rapid response teams. Step-down or intermediate care units can be a useful strategy for patients that require monitoring to avoid ICU readmissions. However, the effectiveness of any of these systems still needs to be confirmed.

Implications for future research

There is a need for further studies on the detection of adverse events. Planning of future studies should aim to standardize terminology and measures of outcomes (standard taxonomy) and to apply more explicit study designs in order to allow for comparisons across studies. This area of research is important in order to identify and explain failure of healthcare systems leading to patient harm, with the ultimate aim to improve the quality and safety of care.

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Contribution of authors

AV conceived the study, carried out the literature searches and is guarantor. AV and GEB designed the protocol, analyzed and interpreted the data. GEB supported with methodological advice. AV and SV selected the studies, assessed the included studies and collected the data. AV draughted the manuscript. SV contributed to the writing of the paper. GEB, WS, NC and JH critically revised the manuscript for important intellectual content. All authors approved the final version to be published.

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53. Brown C, Hofer T, Johal A, Thomson R, Nicholl J, Franklin BD, Lilford RJ: An epistemology of patient safety research: a framework for study design and interpretation. Part 3. End points and measurement. *Qual Saf Health Care* 2008, 17:170-177.

54. Hillman K, Chen J, Cretikos M, Bellomo R, Brown D, Doig G, Finfer S, Flabouris A: Introduction of the medical emergency team (MET) system: a cluster-randomised controlled trial. *Lancet* 2005, 365:2091-2097.

55. McGaughey J, Alderdice F, Fowler R, Kapila A, Mayhew A, Moutray M: Outreach and Early Warning Systems (EWS) for the prevention of intensive care admission and death of critically ill adult patients on general hospital wards. *Cochrane Database Syst Rev* 2007:CD005529.

APPENDIX I – SEARCH TERMS

A. MEDLINE

The following terms were used in the MEDLINE search strategy. This search strategy was translated into the other databases using the appropriate controlled vocabulary as applicable.

Search terms	
Studies on Adverse Events	
1	ADVERSE EVENT
2	PREVENTABLE ADVERSE EVENT
3	INCIDENT
4	CRITICAL EVENT
5	ADVERSE OUTCOME
6	ADVERSE EFFECTS (Mesh)
7	ADVERSE DRUG EVENT
8	MEDICAL ERRORS (Mesh)
9	MEDICATION ERRORS (Mesh)
10	DIAGNOSTIC ERRORS (Mesh)
11	OR/1-10
Studies on Intensive Care	
12	INTENSIVE CARE (Mesh)
13	INTENSIVE CARE UNITS (Mesh)
14	CRITICAL CARE (Mesh)
15	CRITICAL ILLNESS (Mesh)
16	ICU
17	OR/12-16
Studies on medical record review	
18	MEDICAL RECORDS (Mesh)
19	MEDICAL AUDIT (Mesh)
20	MEDICAL RECORD REVIEW
21	CHART REVIEW
22	TRIGGER TOOL
23	OR/18-22
24	11 AND 17 AND 23
Studies on unplanned ICU admissions	
25	UNPLANNED
26	UNEXPECTED
27	UNANTICIPATED
28	OR/25-27
29	28 AND 17
30	24 OR 29

B. EMBASE

Search terms
Studies on Adverse Events
1. ‘ADVERSE EVENT’
2. ‘PREVENTABLE ADVERSE EVENT’
3. INCIDENT
4. ‘CRITICAL EVENT’
5. ‘ADVERSE OUTCOME’/exp OR ‘ADVERSE OUTCOME’
6. ‘ADVERSE DRUG EVENT’/exp OR ‘ADVERSE DRUG EVENT’
7. ‘MEDICAL ERROR’/exp OR ‘MEDICAL ERROR’
8. ‘MEDICATION ERROR’/exp OR ‘MEDICATION ERROR’
9. ‘DIAGNOSTIC ERROR’/exp OR ‘DIAGNOSTIC ERROR’
10. OR/1-9
Studies on Intensive Care
11. ‘INTENSIVE CARE’/exp OR ‘INTENSIVE CARE’
12. ‘INTENSIVE CARE UNIT’/exp OR ‘INTENSIVE CARE UNIT’
13. ‘CRITICAL CARE’/exp OR ‘CRITCAL CARE’
14. ‘CRITICAL ILLNESS’/exp OR ‘CRITICAL ILLNESS’
15. ICU
16. OR/11-15
Studies on medical record review
17. ‘MEDICAL RECORD’/exp OR ‘MEDICAL RECORD’
18. ‘MEDICAL AUDIT’/exp OR ‘MEDICAL AUDIT’
19. ‘MEDICAL RECORD REVIEW’/exp OR ‘MEDICAL RECORD REVIEW’
20. ‘CHART REVIEW’/exp OR ‘CHART REVIEW’
21. ‘TRIGGER TOOL’
22. OR/17-21
23. 10 AND 16 AND 22
Studies on unplanned ICU admissions
24. UNPLANNED
25. UNEXPECTED
26. UNANTICIPATED
27. OR/24-26
28. 27 AND 16
29. 23 AND 28

C. CENTRAL

'adverse events' *or* 'medical errors' *or* 'adverse outcomes' [All text]

‘adverse events’ and ICU [All text]

APPENDIX II - SREENING FORM

Studies will be included if they:

1. were published in the English, Dutch, German, French or Spanish language (from 1966 to present);
2. used chart review. This retrospective method consists of a multidisciplinary assessment of the patient records by trained clinicians. Each record that is positive for one or more criteria is then reviewed whether or not an adverse event occurred;
3. reported on adverse events requiring unplanned, unexpected or unanticipated admissions on readmissions to ICUs in public or private general hospital settings; and
4. used the following or similar definition of an adverse event: 'an event that results in unintended harm to the patient by an act of commission or omission rather than by underlying disease or condition of the patient' (IOM, 2004).

APPENDIX III – CRITICAL APPRAISAL TOOLS

Methods of selecting medical records

Was the method of selecting medical records adequately generated?

A. Adequate: selection method is clearly described (ad random or consecutive);
B. Inadequate: selection method is described, but no correct method is applied;
C. Unclear: selection method is not mentioned.

Sample size

The number of records reviewed is:

A. 1000;
B. 100 and <1000;
C. <100.

Method of screening

Were the medical records adequately and multidisciplinary assessed?

A. Adequate: The medical records were assessed using a multi-stage method: a primary assessment by trained clinician(s) using clear criteria. Each record that was positive for one or more criteria was then reviewed, independently, by (two) clinicians whether or not an adverse event occurred. The assessment of causation and preventability of adverse events was performed using a clear scale. When disagreement concerning the presence of adverse events and preventability prevailed, an independent assessment was performed.
B. Less adequate: The medical records were assessed using a (multidisciplinary) method: a primary assessment by trained clinician(s) using clear criteria. The records were reviewed by one or more clinician(s) whether or not an adverse event occurred.
C. Unclear: There is insufficient information about the method of chart review.

Kappa value for inter-observer agreement

How was the inter-observer variability assessed (for incidence or preventability)?

A. Adequate ($\kappa > 0.40$);
B. Inadequate ($\kappa < 0.40$);
C. Unclear: kappa values are not mentioned.

APPENDIX IV – DATA COLLECTION TOOL

<table>
<tr>
<td>
Source

Study ID
Authors
Country
Publication date
Title

Eligibility

Confirm eligibility
Reason for exclusion

Methods

Study design
Inclusion period (study duration)
Method of medical record review
Method of record selection

Participants

Number of hospitals
Types of hospitals
Number of medical records reviewed
Number of ICUs
Types of ICUs
Population
>1 adverse event per patient? (yes, no, not specified)

</td>
<td>
Outcomes
Primary outcomes

Definition of adverse events
Number of ICU admissions
Number of unexpected ICU admissions
Number of ICU readmissions
Number of adverse events requiring unplanned ICU admission
Number of preventable adverse events requiring ICU admission

Secondary outcomes

Time frame
Type of event
Location/ provider
Attributable causes
Mortality rates
Degree of harm
Prolonged length of stay
Direct medical costs
Other consequences
Kappa values (incidence, preventability)

Subgroup analysis

Type of ICU
Presence of Medical Emergency Teams (yes or no)
Patient characteristics (age, gender and comorbidities)
Type of adverse event
Study quality

Suggested improvements
</td>
</tr>
</table>

APPENDIX V - LIST OF EXCLUDED STUDIES

The ‘x’ marks which criteria were not fulfilled:

1. were published in the English, Dutch, German, French or Spanish language (from 1966 to present)

2. used a multi-stage method for medical record review. This multi-stage method consists of a multidisciplinary assessment of the patient records by trained clinicians. Each record that is positive for one or more criteria is then reviewed whether or not an adverse event occurred

3. used the following or similar definition of an adverse event: ‘an event that results in unintended harm to the patient by an act of commission or omission rather than by underlying disease or condition of the patient’ (IOM, 2004)

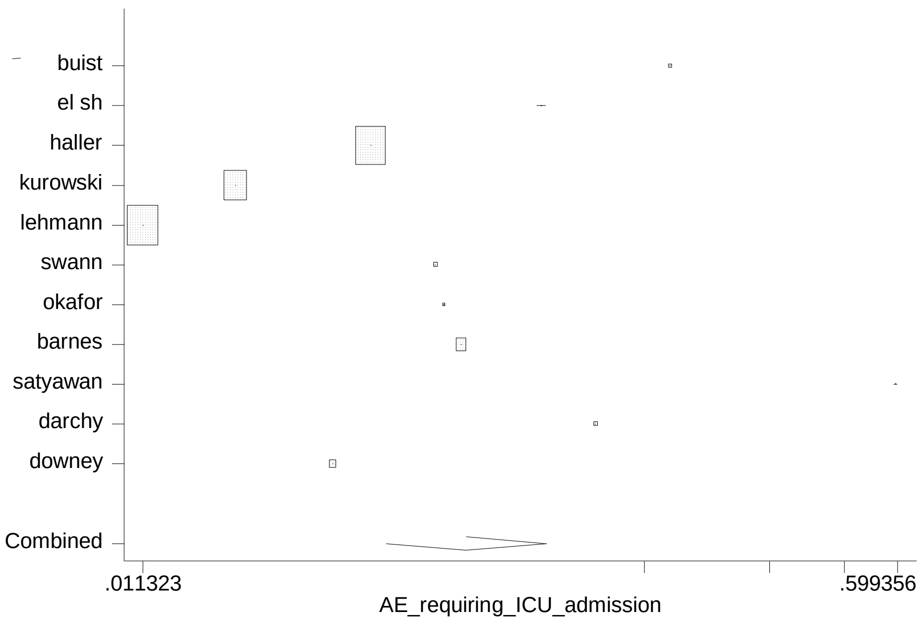
4. reported on adverse events requiring unplanned, unexpected or unanticipated admissions or readmissions to ICUs in public or private general hospital settings

Reference	1	2	3	4
1. Alderman C. Critical alert. Nurs Stand 2006 Apr 5;20(30):24-5.		x	x	x
2. Ambrosio IU, Woo MS, Jansen MT, Keens TG. Safety of hospitalized ventilator-dependent children outside of the intensive care unit. Pediatrics 1998 Feb;101(2):257-9.		x	x	x
3. Aneman A, Parr M. Medical emergency teams: a role for expanding intensive care? Acta Anaesthesiol Scand 2006 Nov;50(10):1255-65.		x		
4. Bader MK, Neal B, Johnson L, Pyle K, Brewer J, Luna M, et al. Rescue me: saving the vulnerable non-ICU patient population. Jt Comm J Qual Patient Saf 2009 Apr;35(4):199-205.		x		
5. Baker DR, Pronovost PJ, Morlock LL, Geocadin RG, Holzmueller CG. Patient flow variability and unplanned readmissions to an intensive care unit. Crit Care Med 2009 Nov;37(11):2882-7.		x	x	
6. Berenholtz SM, Dorman T, Ngo K, Pronovost PJ. Qualitative review of intensive care unit quality indicators. J Crit Care 2002 Mar;17(1):1-12.		x	x	x
7. Blecher GE, Mitra B, Cameron PA, Fitzgerald M. Failed Emergency Department disposition to the ward of patients with thoracic injury. Injury 2008 May;39(5):586-91.		x		
8. Boulanger BR, Stephen D, Brenneman FD. Thoracic trauma and early intramedullary nailing of femur fractures: are we doing harm? J Trauma 1997 Jul;43(1):24-8.		x		x
9. Bowman L, Carlstedt BC, Hancock EF, Black CD. Adverse drug reaction (ADR) occurrence and evaluation in elderly inpatients. Pharmacoepidemiol Drug Saf 1996 Jan;5(1):9-18.				x
10. Burrington-Brown J. Leaping ahead with patient safety. J AHIMA 2002 Apr;73(4):59-60.		x		
11. Byth PL, Mullens AJ. Peri-operative care for oesophagectomy patients. Aust Clin Rev 1991;11(1-2):45-50.		x	x	x
12. Chawla S, Pastores SM, Hassan K, Raoof ND, Voigt LP, Alicea M, et al. ICU admissions after actual or planned hospital discharge: incidence, clinical characteristics, and outcomes in patients with cancer. Chest 2009 Nov;136(5):1257-62.				x
13. Cohen MR. Five flaws in drug delivery. Nursing 2007 Sep;37(9):10.		x	x	x
14. Cooper AL, Leigh JM, Tring IC. Admissions to the intensive care unit after complications of anaesthetic techniques over 10 years. 1. The first 5 years. Anaesthesia 1989 Dec;44(12):953-8.		x		
15. Curtis K, Zou Y, Morris R, Black D. Trauma case management: improving patient outcomes. Injury 2006 Jul;37(7):626-32.		x	x	x
16. Davis JW, Hoyt DB, McArdle MS, Mackersie RC, Eastman AB, Virgilio RW, et al. An analysis of errors causing morbidity and mortality in a trauma system: a guide for quality improvement. J Trauma 1992 May;32(5):660-5.			x	x
17. de Rooij SE, Govers A, Korevaar JC, bu-Hanna A, Levi M, de JE. Short-term and long-term mortality in very elderly patients admitted to an intensive care unit. Intensive Care Med 2006 Jul;32(7):1039-44.		x		x
18. Dial S, Silver P, Bock K, Sagy M. Pediatric sedation for procedures titrated to a desired degree of immobility results in unpredictable depth of sedation. Pediatr Emerg Care 2001 Dec;17(6):414-20.			x	x
19. Duke BJ, Modin GW, Schecter WP, Horn JK. Transfusion significantly increases the risk for infection after splenic injury. Arch Surg 1993 Oct;128(10):1125-30.			x	
20. Duke GJ, Morley PT, Cooper DJ, McDermott FT, Cordner SM, Tremayne AB. Management of severe trauma in intensive care units and surgical wards. Med J Aust 1999 May 3;170(9):416-9.				x
21. Ehrlich R, Emmett SM, Rodriguez-Torres R. Pediatric cardiac resuscitation team: a 6 year study. J Pediatr 1974 Jan;84(1):152-5.		x	x	x
22. Ezri T, Muzikant G, Medalion B, Szmuk P, Charuzi I, Susmallian S. Anesthesia for restrictive bariatric surgery (gastric bypass not included): laparoscopic vs open procedures. Int J Obes Relat Metab Disord 2004 Sep;28(9):1157-62.			x	x
23. Fairfax LM, Christmas AB, Deaugustinis M, Gordon L, Head K, Jacobs DG, et al. Has the pendulum swung too far? The impact of missed abdominal injuries in the era of nonoperative management. Am Surg 2009 Jul;75(7):558-63.			x	x

24. Fan JS, Kao WF, Yen DH, Wang LM, Huang CI, Lee CH. Risk factors and prognostic predictors of unexpected intensive care unit admission within 3 days after ED discharge. Am J Emerg Med 2007 Nov;25(9):1009-14.			x	x
25. Frost SA, Alexandrou E, Bogdanovski T, Salamonson Y, Parr MJ, Hillman KM. Unplanned admission to intensive care after emergency hospitalisation: risk factors and development of a nomogram for individualising risk. Resuscitation 2009 Feb;80(2):224-30.		x		x
26. Green AL, Williams A. An evaluation of an early warning clinical marker referral tool. Intensive Crit Care Nurs 2006 Oct;22(5):274-82.		x		x
27. Jacobs B. Electronic medical record, error detection, and error reduction: a pediatric critical care perspective. Pediatr Crit Care Med 2007 Mar;8(2 Suppl):S17-S20.		x		
28. Katz RI, Cimino L, Vitkun SA. Preoperative medical consultations: impact on perioperative management and surgical outcome. Can J Anaesth 2005 Aug;52(7):697-702.			x	x
29. Kloppenborg E, Wheeler TA, Luria J. ADEs and automation. Nurs Manage 2009 Jan;40(1):43-7.				x
30. Knudson MM, Shagoury C, Lewis FR. Can adult trauma surgeons care for injured children? J Trauma 1992 Jun;32(6):729-37.			x	x
31. Kunac DL, Reith DM. Preventable medication-related events in hospitalised children in New Zealand. N Z Med J 2008 Apr 18;121(1272):17-32.		x		
32. Latronico N, Guarneri B, Alongi S, Bussi G, Candiani A. Acute neuromuscular respiratory failure after ICU discharge. Report of five patients. Intensive Care Med 1999 Nov;25(11):1302-6.		x		
33. Lawrence A, Havill JH. An audit of deaths occurring in hospital after discharge from the intensive care unit. Anaesth Intensive Care 1999 Apr;27(2):185-9.				x
34. Lee JY, Park SK, Kim HJ, Hong SB, Lim CM, Koh Y. Outcome of early intensive care unit patients readmitted in the same hospitalization. J Crit Care 2009 Jun;24(2):267-72.		x		
35. Lim PC, Macintyre PE. An audit of intrathecal morphine analgesia for non-obstetric postsurgical patients in an adult tertiary hospital. Anaesth Intensive Care 2006 Dec;34(6):776-81.		x		x
36. McFarlan SJ, Hensley S. Implementation and outcomes of a rapid response team. J Nurs Care Qual 2007 Oct;22(4):307-13, quiz.		x		
37. McGaughey J, Alderdice F, Fowler R, Kapila A, Mayhew A, Moutray M. Outreach and Early Warning Systems (EWS) for the prevention of intensive care admission and death of critically ill adult patients on general hospital wards. Cochrane Database Syst Rev 2007;(3):CD005529.		x		
38. McGrath MA, Peet GI, Franke JG, Mildenberger RR, Morch JE, Mackenzie GW. PTCA in elderly patients: hospital events. Am J Crit Care 1993 Mar;2(2):171-6.				x
39. Posa PJ, Yonkee DE, Fields WL. Development and implications of an interdisciplinary quality assurance monitor on unplanned transfers into the intensive care units. J Nurs Care Qual 1992 Jan;6(2):51-5.			x	x
40. Prado R, Albert RK, Mehler PS, Chu ES. Rapid response: a quality improvement conundrum. J Hosp Med 2009 Apr;4(4):255-7.		x		
41. Raymer K, Yang H. Patients with aortic stenosis: cardiac complications in non-cardiac surgery. Can J Anaesth 1998 Sep;45(9):855-9.			x	x
42. Rosenberg AL, Watts C. Patients readmitted to ICUs* : a systematic review of risk factors and outcomes. Chest 2000 Aug;118(2):492-502.			x	x
43. Russo SG, Eich C, Roessler M, Graf BM, Quintel M, Timmermann A. [Medical emergency teams: current situation and perspectives of preventive in-hospital intensive care medicine]. Anaesthesist 2008 Jan;57(1):70-80.		x		x
44. Slonim AD, Ognibene FP. Sedation for pediatric procedures, using ketamine and midazolam, in a primarily adult intensive care unit: a retrospective evaluation. Crit Care Med 1998 Nov;26(11):1900-4.			x	x
45. Bristow PJ, Hillman KM, Chey T, Daffurn K, Jacques TC, Norman SL, et al. Rates of in-hospital arrests, deaths and intensive care admissions: the effect of a medical emergency team. Med J Aust 2000 Sep;173(5):236-40.			x	
46. Flack S, Ojemann J, Haberkern C. Cerebral hemispherectomy in infants and young children. Paediatr Anaesth 2008 Oct;18(10):967-73.			x	x

47. Lee KL, Freiha F, Presti JC, Jr., Gill HS. Gender differences in radical cystectomy: complications and blood loss. Urology 2004 Jun;63(6):1095-9.			x	x
48. Moller AM, Maaloe R, Pedersen T. Postoperative intensive care admittance: the role of tobacco smoking. Acta Anaesthesiol Scand 2001 Mar;45(3):345-8.			x	x
49. To EW, Tsang WM, Lai EC, Chu MC. Retrospective study on the need of intensive care unit admission after major head and neck surgery. ANZ J Surg 2002 Jan;72(1):11-4.		x	x	x
50. Gordon W, Perrott J, Dahri K. Accuracy of medication histories: the first step of medication reconciliation. Ann Pharmacother 2008 Jan;42(1):144.			x	x
51. Singer DE, Mulley AG, Thibault GE, Barnett GO. Unexpected readmissions to the coronary-care unit during recovery from acute myocardial infarction. N Engl J Med 1981 Mar 12;304(11):625-9.			x	x
52. Harrison-Woolrych M. Garcia-Quiroga J. Ashton J. Herbison. Safety and usage of atypical antipsychotic medicines in children: A nationwide prospective cohort study. Drug Safety (2007) 30:7 (569-579). Date of Publication: 2007.		x		x
53. Smith W.D. Winterstein A.G. Johns T. Rosenberg E. Sauer B.C. Causes of hyperglycemia and hypoglycemia in adult inpatients. American Journal of Health System Pharmacy (2005) 62:7 (714-719). Date of Publication: 1 Apr 2005				x
54.Bitar G. Mullis W. Jacobs W. Matthews D. Beasley M. Smith K. Watterson P. Getz S. Capizzi P. Eaves III F. Safety and efficacy of office-based surgery with monitored anesthesia care/sedation in 4778 consecutive plastic surgery procedures. Plastic and Reconstructive Surgery (2003) 111:1 (150-156)				x

APPENDIX VI – Forest plot of studies reporting on adverse events requiring ICU admission. Dots represent weighted proportions and larger dots represent larger studies



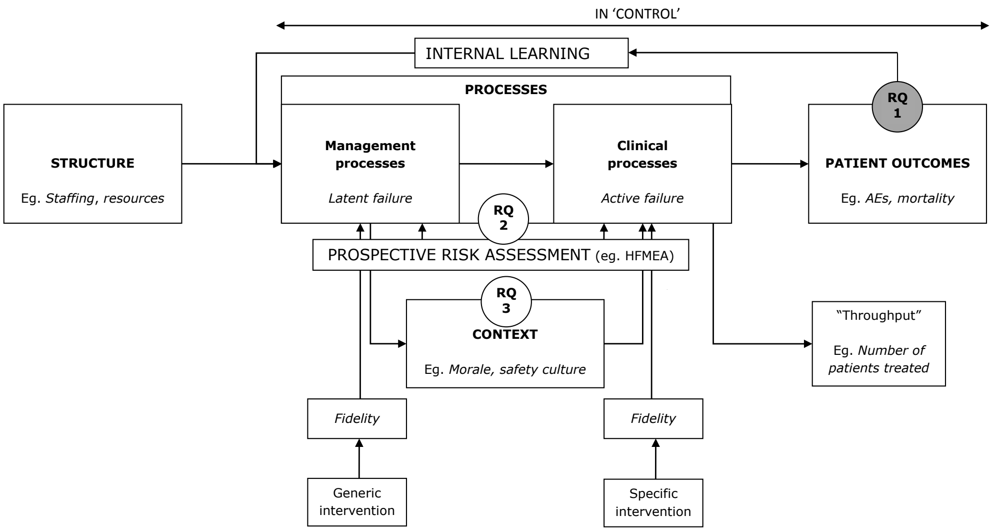
APPENDIX VII – : Results of subgroup analyses for studies reporting on adverse events requiring ICU admission

Subgroup	Number of studies	Range proportion	I^2 (%)
Country			
Australia	4	0.03-0.18	99.9
Canada	2	0.05-0.08	99.9
New Zealand	1	0.06	-
Nigeria	1	0.05	-
Mumbai	1	0.37	-
USA	1	0.01	-
France	1	0.11	-
Study size			
>1000	3	0.01-0.06	99.9
100-1000	7	0.03-0.37	99.9
<100	1	0.08	-
Method of screening			
adequate (multidisciplinary)	4	0.01-0.05	99.9
no clear method/ inadequate	7	0.03-0.37	99.9
Use of definitions on adverse events			
explicit definitions	8	0.01-0.37	99.9
no definition	3	0.05-0.08	99.9

A subgroup analysis based on country of study (Australia, USA, Canada, New Zealand, UK, France, Mumbai and Nigeria), sample size (number of records reviewed: > 1000 records, between 100 and 1000 records and < 100 records reviewed), method of screening (multidisciplinary versus no clear method) and the use of definitions on adverse events (explicit versus no definition).could not clarify the causes of heterogeneity.

CHAPTER 3

Design of a medical record review study on the incidence and preventability of adverse events requiring a higher level of care in Belgian hospitals



This chapter is published as:

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ABSTRACT

Background

Adverse events are unintended patient injuries that arise from healthcare management resulting in disability, prolonged hospital stay or death. Adverse events that require intensive care admission imply a considerable financial burden to the healthcare system. The epidemiology of adverse events in Belgian hospitals has never been assessed systematically.

Findings

A multistage retrospective review study of patients requiring a transfer to a higher level of care will be conducted in six hospitals in the province of Limburg. Patient records are reviewed starting from January 2012 by a clinical team consisting of a research nurse, a physician and a clinical pharmacist. Besides the incidence and the level of causation and preventability, also the type of adverse events and their consequences (patient harm, mortality and length of stay) will be assessed. Moreover, the adequacy of the patient records and quality/usefulness of the method of medical record review will be evaluated.

Discussion

This paper describes the rationale for a retrospective review study of adverse events that necessitate a higher level of care. More specifically, we are particularly interested in increasing our understanding in the preventability and root causes of these events in order to implement improvement strategies. Attention is paid to the strengths and limitations of the study design.

BACKGROUND

An important indicator of patient safety is the rate of adverse events in hospitals. An *Adverse event* can be defined as (1) an unintended injury or complication, (2) which results in disability at discharge, death or prolongation of hospital stay, and (3) is caused by healthcare management (including omissions) rather the patient's disease.[1-5] Although all medical errors should be a concern, errors that either result in serious consequences for patients or that are preventable are of particular concern. A substantial number of adverse events are detected among unintended Intensive Care Unit (ICU) admissions and readmissions. Unplanned Intensive Care Admission (UIA) is an existing clinical indicator, used in several countries on a regular basis. It was developed and implemented in Australia, in a close collaboration between the Australian and New Zealand College of Anaesthetists (ANZCA) and the Australian Council on Healthcare Standards (ACHS) and recommended as a measure of patient safety ("avoidable incidents in anaesthesia") and the effectiveness of care ("lack of planning").[6]

To estimate the incidence and preventability of adverse events requiring ICU (re)admission, we conducted a systematic review including medical record review studies.[7] A total of 27 studies were included, of which 14 studies addressed unplanned ICU admissions due to anaesthetic or surgical adverse events, eight studies investigated adverse events on general wards and five studies focused on ICU readmissions. Due to study heterogeneity, meta-analysis of the data was not appropriate. Results showed that the percentage of surgical and medical adverse events requiring ICU admission ranged from 1.1% to 37.2%. ICU readmissions varied from 0% to 18.3%. Preventability of the adverse events varied from 17% to 76.5%. Consequences of the adverse events included a mean length of ICU stay that ranged from 1.5 days to 10.4 days for the patient's first stay in ICU and mortality percentages between 0% and 58%.The large variation in study outcomes can be explained by methodological diversity. The included studies varied in sample size, applied different methods of screening and only three out of 27 studies used a multi-center design. On the other hand, clinical diversity was high because of population mix and variation (or absence) of definitions on adverse outcomes. As a conclusion, we suggest that planning of future studies should aim to standardize terminology and measures of outcomes (standard taxonomy) and to apply more explicit study designs in order to allow for comparisons across studies.

Several nationwide studies describe the use of medical record review to measure the occurrence of adverse events in hospitals.[1-4, 8-11] 'Unplanned transfer from general to intensive care' is often used as a criterion ('trigger' or clue) to uncover adverse events and medical errors.[2, 4, 8, 10, 12] The positive predictive value (PPV) reflecting the reliability of this screening criterion varies from 1.9%[10]- 3.1%[4] to 6.5 %[2]. Basically, the process of medical record review involves a multi-stage record review in which in the first stage the records are assessed by trained nurses for the presence of a predefined set of explicit criteria, indicating a potential adverse event. Each record that is positive for one or more criteria is forwarded to the next stage and reviewed by physicians for confirmation. The assessment of causation and preventability is performed using classification scales. Modifications in methodology among these studies involve different screening criteria, the reviewers' education, definitions, timeframe of included events or the assessment of causation and preventability.[1, 2, 4, 9, 11]

In Belgium, the occurrence of adverse events has never been assessed through medical record review. Retrospective analysis of the national hospital discharge dataset of all Belgian acute hospitals for the year 2000 estimated the incidence of adverse outcomes to be 7.12% for medical and 6.32% for surgical hospital stays, with a high variability between hospitals.[13]

Currently, there are 194 Belgian hospitals, of which 105 acute, 66 psychiatric and 23 long-term care hospitals. Acute hospitals consist of university hospitals, general hospitals 'with university character' and other non-university hospitals. Belgium has seven university hospitals, one for each medical school that offers the entire medical education. The Flemish region of Belgium has 55 acute hospitals. The province of Limburg, which is a part of the Flemish region, has seven acute hospitals, of which two hospitals with a university character.[14] This multicenter study is initialized in the province of Limburg and aims at identifying preventable adverse events that contributed to the transfer of patients to a higher level of care using the method of chart review. This study is funded by 'Limburg Sterk Merk', a foundation of public use that supports healthcare and economic development projects.

It is not in the purpose of this study to detect all the adverse events in the inpatient records. An important goal is to make a clear distinction between the causality (errors) and the consequences (patient harm) of the adverse events. Rating preventability is important in understanding the system specific aspects of health care processes in order to design preventive or mitigating barriers.

The objectives of this multicenter study are to:

1. Determine the incidence of adverse events requiring a transfer to a higher level of care;
2. Assess the preventability of these adverse events;
3. Assess the clinical impact of these events;
4. Evaluate the adequacy and completeness of the patient charts;
5. Evaluate the use of medical record review as an auditing tool.

Spin-off studies will be undertaken to:

6. Explore the clinical and system specific causes of these adverse events and gain insight into potential preventive strategies (Root Cause Analysis); and
7. Assess the costs of the adverse events (separate cost study).

METHODS/ DESIGN

Design and setting

A retrospective cohort study will be undertaken in six acute hospitals in the province of Limburg. All acute hospitals from the province of Limburg were invited to participate in this study. Six out of seven hospitals confirmed their participation and gave permission to access their patient charts.

Type of participants and record selection

To minimize selection bias, all records of the patients being transferred to a higher level of care and being discharged from or deceased in the hospital during the inclusion period (November 2011 - May 2012), irrespective the hospital admission date of the patient, will be screened for the occurrence of adverse events. In practice, record selection is based on (1) (re)admission to the Intensive Care Unit from other care units in the hospital providing lower intensity care, (2) an intervention by a Medical Emergency Team (MET) due to an unanticipated change in the patient's clinical status or (3) a redo procedure within 24 hours for ICU patients. Considering that record selection is not based on routine hospital registration, hospitals were instructed to select the cases using a uniform selection form.

Because of their specific nature, patients admitted on neonatal or maternal ICUs will be excluded. Also planned admissions to the ICU from the operation room (major elective surgery) and ICU admissions directly from the emergency department will be excluded. As the included hospitals have no pediatric ICUs, only patients from the age of 16 or over will be included.

Starting from January 2012, patient records will be reviewed in a multistage review process by a research nurse (holder of a specialization degree in Intensive Care/ Emergency care), a physician (holder of a specialization degree in Anesthesiology/ Urgent and Emergency Medicine) and a clinical pharmacist. Chart review will be performed once the entire -closed and complete- record is available to the reviewers. A complete record consists of a medical (including laboratory and radiology results), nursing and pharmaceutical record. However, medical reports that are found to be incomplete or ambiguous are also included in the review process, as exactly in these cases the possibility of containing adverse events might be higher [15]. The review period is accomplished when all the included records are reviewed. It is expected that the period between record selection and review is relatively short and is largely dependent on (1) the length of stay from the time of transfer to a higher level of care and (2) the date of availability of the medical records. It is also expected that the structure of the records will not be uniform in all participating hospitals.

Power calculation

The main (numerical) objective of this study is to estimate an overall incidence rate of adverse events (number of adverse events/patient days at risk). It is not in the aim to compare the results of the participating hospitals.

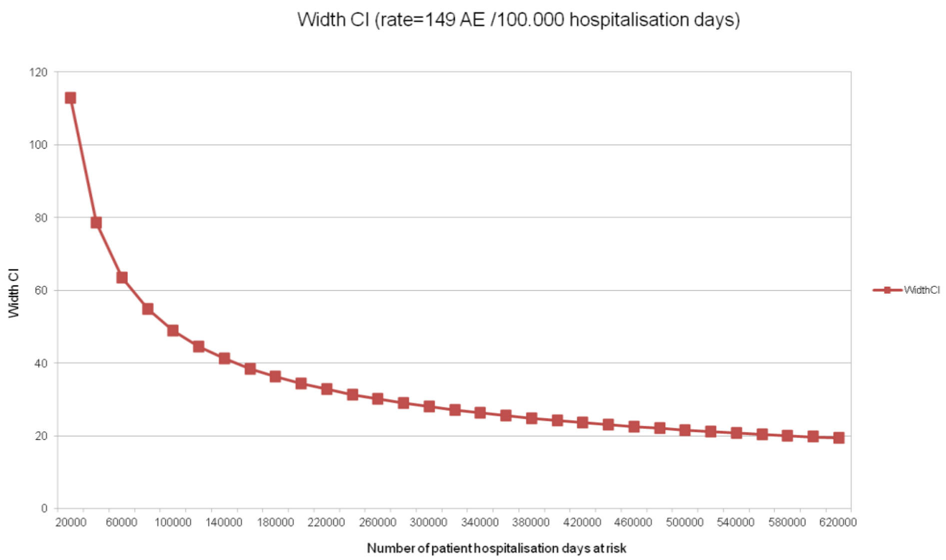
The precision of this estimate will be provided by a 95% confidence interval. The sample size of this study is determined in order to guarantee a sufficiently narrow confidence interval for the estimate.

From a pilot study of two months, 66 patients with one or more adverse events leading to a higher level of care were detected for 44 165 days at risk (149 per 100 000 patient days at risk). (figure 1) At this rate, a sample size of 100 000 patient days at risk would provide a confidence interval of approximately 20% (+/- 10% around the estimate). As the total yearly number of in- patient days (excluding palliative, neonatal, pediatric and one day-stay admissions) for the six participating hospitals is 76 0057 (year 2010), this sample size corresponds to an inclusion period of six to seven months.

Different levels of clustering can be considered in this study: hospital level, ward level, pathology level, and individual patient level. Since little is known about the impact of these different levels of clustering, clustering is not considered in calculating the sample size.

Figure 1 – Sample size calculation

Abrreviations: *CI*, Confidence Interval; *AE*, Adverse Event



Outcome measures

Primary outcome measures are the number of patients transferred to a higher level of care because of an adverse event -or a combination of adverse events- per 100 000 patient days at risk, and the number of preventable adverse events in comparison with the number of adverse events. The number of patient days at risk is calculated as the total number of hospitalization days in the participating hospitals during the study period (excluding palliative, neonatal, pediatric and day-stay admissions).

Secondary outcomes are the type of event (operative, procedural, diagnostic, therapeutic, drug/ intravenous fluid or system issue), attributable causes and consequences of the events (level of patient harm, mortality and length of stay in hospital and ICU).

Independent variables are presented in a non-exhaustive list in table 1.

Table 1 – Independent variables

- Primary diagnosis for admission to the hospital
- Patient history
- Patient age (in years); year of birth
- Gender
- Number of prescribed drugs before hospital admission
- Admission day and time to ICU
- ICU admission source (location/ providers of care)
- Length of total hospital stay (prior to ICU admission) (LOS) (in days)
- Length of ICU stay (in days)
- Outcome in the ICU (discharge, mortality)
- Acute Physiology and Chronic Health Evaluation (APACHE) II
Patient complexity and mortality risk are defined according to the All Patient Refined Diagnosis Related Groups, which is calculated based on patient diagnosis, procedure, and age using a scale of 1 (least complex/lowest risk) to 4 (most complex/highest risk).
- Quality and completeness of the medical records
- Time measures screening process

Definitions

The definitions are adopted from previous adverse events studies. They are described in table 2.

Table 2 – Definitions

Adverse event	(1) An unintended injury or complication, which results in (2) disability at discharge, death or prolongation of hospital stay, and (3) is caused by healthcare management (including omissions) rather than the patient's disease.[4]
Unintended injury	Refers to any disadvantage for the patient that leads to prolonged or strengthened treatment, temporary or permanent (physical or mental) impairment or death.[11]
Disability	Refers to temporary or permanent impairment of physical or mental function attributable to the adverse event (including prolonged or strengthened treatment, prolonged hospital stay, readmission, subsequent hospitalization, extra outpatient department consultations or death).[11]
Causation	Refers to injury caused by health care management including acts of omission (inactions) i.e. failure to diagnose or treat, and acts of commission (affirmative actions) i.e. incorrect diagnosis or treatment, or poor performance.[11]
Health Care Management	Includes the actions of individual hospital staff as well as the broader systems and care processes and includes both acts of omission (failure to diagnose or treat) and acts of commission (incorrect diagnosis or treatment, or poor performance).[10]
Preventable Adverse Event	An injury that is caused by medical intervention or management (rather than the disease process) and either prolonged hospital stay or caused disability at discharge, where there was enough information currently available to have avoided the event using currently accepted practices.[16]
Higher Level of Care	A higher level of care may include: 1. An unplanned transfer to an Intensive Care Unit, 2. An intervention of a Medical Emergency Team or 3. A redo procedure within 24 hours of ICU patients.
Intensive Care Units (ICUs)	Hospital units providing continuous surveillance and care to actually ill patients (Mesh definition). E.g. medical and surgical ICUs, for example Medium Care,

	Coronary Care Units, Pediatric ICUs and Respiratory Care Units.
Planned ICU admissions	Admissions of patients expected to arrive on the ICU. E.g. routinely scheduled post-surgery admissions or transfers directly to the ICU from outside hospitals.
Unplanned ICU admissions	All patients unexpectedly admitted to the intensive care unit from a lower level of care in the hospital during the study period. If a patient experienced more than one unplanned ICU admission during his/her hospital stay, each unplanned admission is included in the analysis (adapted from Baker, 2009).[17]
Patient harm	Unintended physical injury resulting from or contributed to by medical care that requires additional monitoring, treatment or hospitalization, or that results in death (IHI).[18]

Data collection and review process

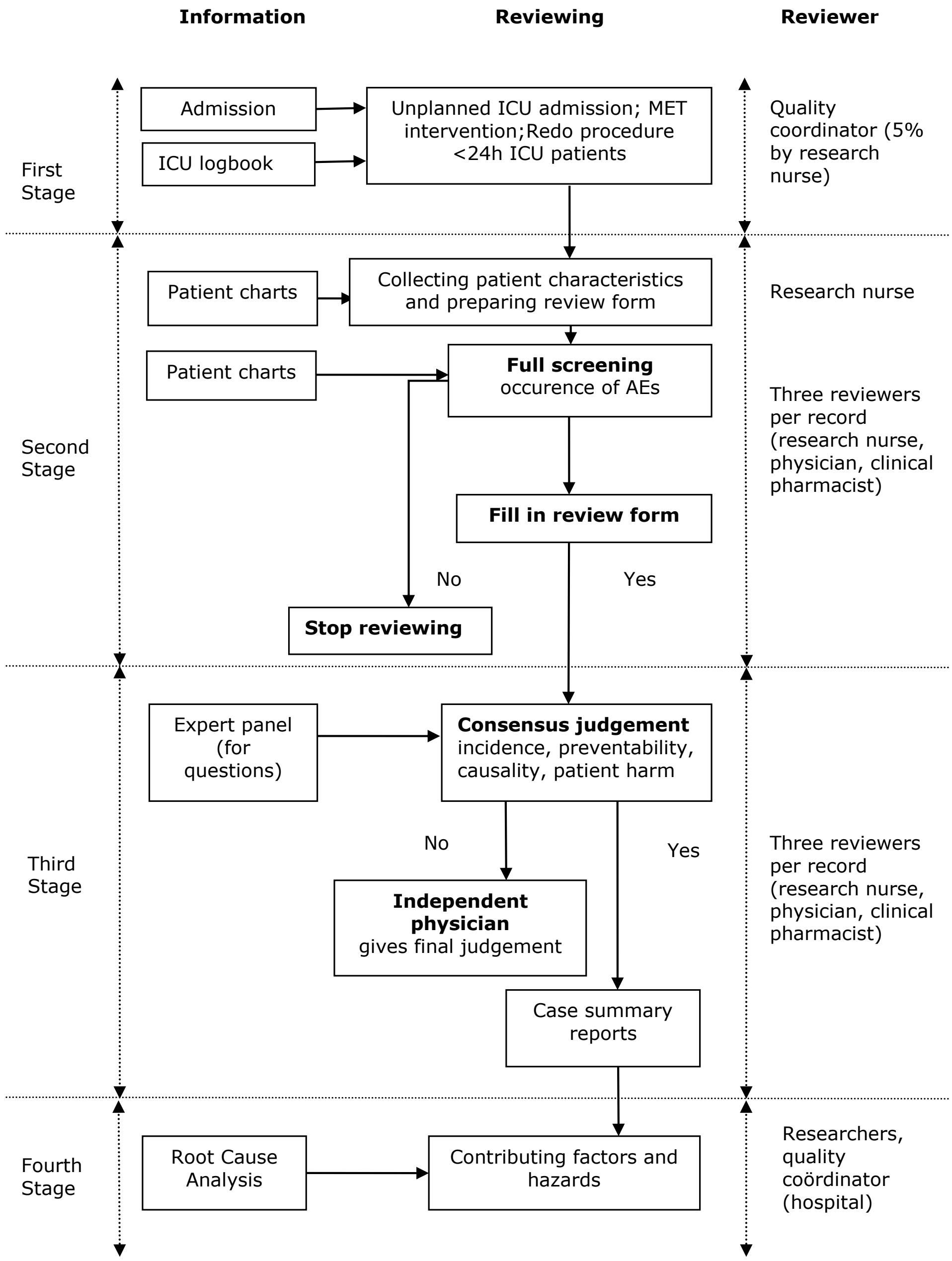
In each hospital, the patient records will be reviewed in a multistage review process (figure 2, based on Zegers, 2007).

Stage 1: Selection of charts

A master list of eligible patients is generated at each hospital from the hospital administrative database by the quality coordinator using a uniform selection form across hospitals. Patient records selection is based on (1) an unplanned ICU admission, (2) a MET intervention or (3) a redo procedure within 24 hours for ICU patients. ICU admissions are registered on the ICUs, while MET interventions are registered on the emergency departments. Only closed patient records (after discharge from the hospital or decease of the patient) are forwarded to the next stage.

Figure 2 – Review process

Abbreviations: *ICU*, Intensive Care Unit; *MET*, Medical Emergency Team; *AE*, Adverse Event



Stage 2: Chart review for adverse events

First, the research nurse collects from the patient records data on basic patient characteristics (gender, year of birth, reason for hospital intake, reason for transfer to ICU, number of days in the hospital prior to ICU transfer, admission day and time to ICU, number of prescribed drugs before hospital admission, ICU admission source (location/ providers of care) and outcome in ICU. The research nurse notes the data in a structured abstraction instrument, which was developed for this study.

Subsequently, each record will be reviewed by the clinical team to determine if an adverse event occurred according to the definition of Wilson (table 2). Although each of the persons of the clinical team has a specific focus during the chart review, respectively the medical record (physician), the nurse record (research nurse) and the pharmacologic record (clinical pharmacist), assessments are made collectively. The medical records are reviewed using the structured abstraction instrument to standardize the judgments of the reviewers.

In order to evaluate the process of medical record review, data on the quality and completeness of the medical records, missing records and time measures of the screening processes are recorded. An important criterion is the recording of the actual reason for the transfer to a higher level of care.

Stage 3: Consensus judgment on occurrence, preventability and harm

The members of the clinical team compare their findings and come to consensus on the occurrence of an adverse event. Once the team concludes on the occurrence of the event, the assessment on preventability and severity ratings is performed by consensus judgment.

The assessment of causation is performed using a scale from 1 to 6 (table 3). Upon ratings of at least 4 (i.e. more than 50% likelihood), unintended injuries or complications are classified as adverse events. If the clinicians identify an adverse event, the review is continued with an assessment of its preventability using a similar six-point scale grouped into categories: no preventability, low and high evidence of preventability (table 3). Further classification is done by type of adverse event and patient harm (severity categories) (table 3). The severity categories of the adverse events identified are based on the classification of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). The classification only includes categories E, F, G, H and I because these categories describe errors that resulted in patient harm.

An expert panel of physicians is available for second advice when needed. In case of continued disagreement, an independent physician, who does not review the patient records, but only the review forms, gives the final judgment.

Case summary reports of patients that experienced an adverse event (brief narratives of the key points of each patient's hospital stay) are written in order to facilitate an overview of the cases.[19]

Table 3 – Outcome measures

Determination of the presence of an **adverse event** is based on three criteria[4, 5, 10]: 1. An unintended (physical and/or mental) **injury** which 2. results in temporary or permanent **disability**, death or prolongation of hospital stay, and is 3. **caused** by health care management rather than the patient's disease
To determine whether the injury is **caused by health care management** or the disease process a 6-point scale will be used[4, 5, 10]: 1. (Virtually) no evidence for management causation 2. Slight to modest evidence of management causation 3. Management causation not likely (less than 50/50, but 'close call') 4. Management causation more likely (more than 50/50, but 'close call') 5. Moderate to strong evidence of management causation 6. (Virtually) certain evidence of management causation
The **degree of preventability** of the adverse events is measured on a 6-point scale, grouped into three categories[4, 5, 10]: *No Preventability* 1. (Virtually) no evidence for management causation *Low Preventability* 2. Slight to modest evidence of management causation 3. Management causation not likely (less than 50/50, but 'close call')

High preventability 4. Management causation more likely (more than 50/50, but 'close call') 5. Moderate to strong evidence of management causation 6. (Virtually) certain evidence of management causation
Severity categories of AE's based on the classification of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).[20] An error occurred that: - *Category E*: contributed to or resulted in temporary harm to the patient and required intervention - *Category F*: contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization - *Category G*: Contributed to or resulted in permanent harm - *Category H*: Required intervention to sustain life - *Category I*: Contributed to or resulted in the patient's death (mortality rate) The classification only includes categories E, F, G, H and I because these categories describe events that resulted in patient harm.
Classification of the type of AE's[4, 21]
- *Operative*: an adverse event in relation to a surgical procedure or anesthesia.
- *Procedural*: an adverse event in relation to a non-surgical procedure such as insertion of a central venous line, nasogastric tube, cardiac catheterization, etc.
- *Anesthesia*: an adverse event in relation to anesthesia.
- *Diagnostic*: an adverse event arising from a delayed or wrong diagnosis.
- *Therapeutic*: an adverse event arising when a correct diagnosis was made but there was incorrect therapy or a delay in treatment.
- *Drug/intravenous fluid*: an adverse event arising from the incorrect administration of a drug or intravenous fluid.
- *System issue*: an adverse event in relation to problems with hospital processes such as nosocomial infection or equipment malfunction.

Stage 4: Analysis of causes

The further analysis of the adverse events fits within a broader study that aims to explore the underlying mechanisms related to the existing safety and quality frameworks used within the hospital settings. This includes insights from the organizational-wide safety culture measurement.[22] As there is usually no single root cause, the underlying causes and contributing factors of the adverse events will be further explored using the London Protocol of Root Cause Analysis.[23, 24]

For each participating hospital, all the cases that were assessed by the clinical team as high preventable events are selected for further analysis. In order to conduct the analyses, additional information is collected from a variety of sources, such as for instance the availability and quality of protocols, the accessibility of information, patient identification, training of healthcare professionals, work patterns…The purpose of these analyses is to facilitate the identification of systems issues, which often relate to structure and process (both management and clinical processes).[25] The strength of deconstructing adverse events into component elements of defaults (e.g. communication on patient information, staffing, drugs, equipment,…) lies in the fact that, once identified or characterized, potential preventive or corrective strategies can be formulate.

Confidentiality

In this study anonymity of hospitals, health care providers and patients is of great importance. Several measures are taken to ensure confidentiality of the data.

During data collection, records are never left unattended and they are stored in a locked room or closet. Each participating hospital and each hospital admission receives a unique study number. Patient identifiers are kept in a dataset separately from the primary database. During the review process in the hospitals, the data are directly entered into a protected electronic database. The reviewers have a personal password for the electronic database. The web-based database complies with the safety and privacy requirements. Patients' names are not included in the database and after completion of the data collection and analysis, patient record identifiers are destroyed. The identity of patients or healthcare professionals will not be revealed in research reports.[5]

If a reviewer has during the review process any concern about unrecognized potential deliberate harmful acts, illegal acts, or repetitive negligent behavior, these concerns will be discussed with the ethics committee of Hasselt University.

The confidentiality agreement, in which the confidentiality and the rules for disseminations of results are specified, was established between the researchers, Hasselt University and the participating hospitals. Therefore, informed consent from the patients was not necessary.

Ethical approval

Approval was obtained from the ethics committee of Hasselt University and from the ethics committee of the participant hospitals.

Statistical analysis

The incidence of unplanned ICU (re)admissions and (preventable) adverse events requiring ICU admission will be calculated.

Primary outcomes will be measured as a rate (number of adverse events per 1000 in-hospital patient years at risk). The number of preventable adverse events (preventability rate) will be calculated as a proportion, compared with the incidence rate.
Secondary outcomes (causality, severity) are presented as incidence rates for each category.

A subgroup analysis will be performed on patient characteristics and comorbidities, type of event, location and provider of care and type of ICU.

Testing reliability and validity

On a regular basis, the hospitals are followed up by the researchers to discuss their problems concerning the selection process of patient charts.

To test the validity of the process of screening by medical records analysts, 5% of all records are reviewed a second time by the research nurse.

DISCUSSION

This paper describes the rationale for a retrospective review study of adverse events that necessitate a transfer to a higher level of care. More specifically, we are particularly interested in increasing our understanding in the preventability and the root causes of these events.

There are several methodological limitations inherent to medical record review, which we are addressing within our study design.

The most important limitation is that the use of the method of medical record review itself might lead to an underestimation of adverse events. The quality of the medical records is often poor as information is missing or incomplete. Therefore, a multidisciplinary approach, in which the team is composed of a research nurse, physician, and clinical pharmacist which have experience in this area, is a key condition and adds value to conducting this chart review. A strength of our study design is the efficiency in which the members of the clinical team can focus on their own expertise. The nurse can concentrate on the nursing records, while the physician is focusing on the medical records and the clinical pharmacist is examining the medication processes. Assessments on adverse outcomes are always made collectively. In case of doubt or disagreement, a panel of physicians with different specialties is available for consultation. In addition, the clinical team assesses the completeness and usefulness of the patient charts. Incomplete records are included in the review process, as there is a higher possibility that these cases contain adverse events.[15]

Second, there is the lack of an actual gold standard for adverse event detection.[26] Inevitably, the clinical team must deal with differences of medical record keeping within the participating hospitals. We therefore attempted to standardize our study protocol by conducting a pilot test in one hospital over a period of two months, in which the definitions, causality and severity ratings, abstraction instrument and the review processes were evaluated.

Third, success of this type of research is dependent on the acceptance and participation of organizations, professional groups, and individuals who may be at varying stages of readiness for investigation in this area. More specifically, the perceived threat to physician reputation or from medico-legal action should not be underestimated.[21] Therefore, the involvement of a physician might promote the acceptance of the method. Since the clinical team is composed of external researchers, almost no workload is imposed on the hospital staff and health care processes are not interrupted. Moreover, ethical approval was obtained by the ethical committees of the participating hospitals and the academic institute. An agreement was signed between the researchers, participating hospitals and the academic institute in which the privacy of the

participants and the confidentiality of the data is guaranteed. It is not in the purpose of this study to compare hospitals.
Finally, although descriptive studies such as root cause analysis have limitations, they raise important challenges that will need to be overcome for future research to succeed.[21] From this perspective, we plan to obtain additional information, such as for instance the presence of protocols and accessibility to information, in order to gain additional insight in the circumstances and contributing factors leading to adverse events. Our multicenter study design allows us to aggregate data and analyze patterns of these contributing factors. Results are always interpreted within the context of the current safety management systems in the participating hospitals and recommendations will be formulated for the hospital management.

Based on this study of adverse event detection, several additional studies can be launched. It would be interesting to link the results of this study to the hospitals administrative databases to trace whether adverse events can be properly flagged. In a later time period, a cost study can be undertaken to assess the costs of care for patients with an adverse event. Insights from this study can provide information for the hospital management and policy makers to implement cost reducing interventions.

In conclusion, review of the records and further analysis of the adverse events may trigger important system changes within the hospitals.

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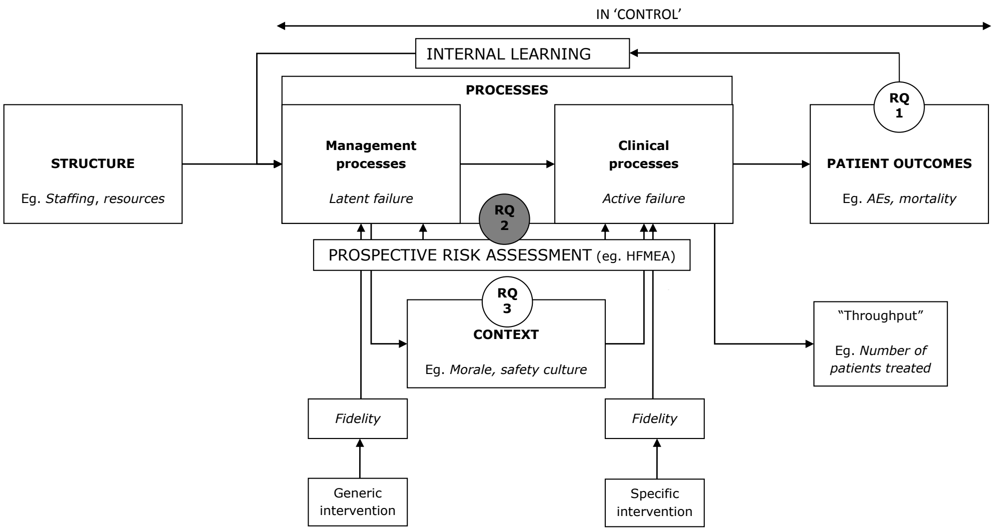
CHAPTER 4

Evaluation of time and cost saving modifications of HFMEA: An experimental approach in radiotherapy



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ABSTRACT

Objective: To evaluate different 'short-cuts' of Healthcare Failure Mode and Effects Analysis (HFMEA) in a radiotherapy setting.

Design: A two by two study design was set up in which four similar groups analyzed separately the possible risks of the same process by using different versions of HFMEA.

Setting: In Maastricht Radiation Oncology (MAASTRO) clinic, a radiotherapy institute in the Netherlands, the treatment of cancer patients is organized within three different units, each focusing on a specific area (thorax, abdomen, and neck- head). The institute plans to treat all radiation areas in one generalized unit (Linac-pool).

Participants: All four teams were composed of three Radiation Technologists (one from each working unit), one Manager Radiation Technologist and a facilitator.

Intervention(s): The prospective risk analyses were completed in parallel within one month.

Main Outcome Measure(s): Time investment and cost data on the different steps of the HFMEAs were registered from the organization perspective. Each team suggested a number of corrective actions for the Linac-pool. The quality and feasibility of the proposed actions were assessed by an expert panel (managers and safety staff).

Results: The HFMEA analyses resulted in direct costs varying from 1028.6 to 1701.6 Euros. In total the expert panel assessed 86 corrective actions of which 43 (50%) were relevant to implement before the start of the Linac-pool. Many of these actions related to the compliance, control and education of standard operating procedures in daily practice of radiotherapy.

Conclusions: Based on the results of this case study, it seems feasible to develop less time and cost consuming versions of HFMEA, which would increase even more the added value of prospective risk analysis tools for healthcare organizations.

INTRODUCTION

Patient safety can be defined as the way in which risks on unintentional and evitable harm to the patient are handled in the organization of care. This includes the avoidance, prevention and amelioration of adverse outcomes stemming from the processes of healthcare.[1] As Vincent mentions, this definition doesn't capture the conceptual context of patient safety, but it clearly underlines that harm reduction should be the primary focus of patient safety. From this perspective, when implementing safety management systems the main objective should be to prevent and reduce patient harm by installing effective barriers. Such barriers, often concretized as procedures, protocols or technical appliances, can be related to human behaviour, communication, working circumstances or equipment.

A widely applied method in preventing errors is Failure Mode and Effects Analysis (FMEA). FMEA is an industrial tool to evaluate potential failures of the system, processes, or technology design, and to identify the possible causes and prioritize corrective actions.[2, 3] FMEA even dates back to the United States military procedure MIL-P-1629 (dated November 09, 1949) where it was used as a reliability technique to determine the effect of system and equipment failures. The procedures called out in MIL-STD-1629A are the most widely accepted methods throughout the military and commercial industry.[4]

In 2002, the method of FMEA was adapted by the United States Department of Veterans Administration National Center for Patient Safety (VA NCPS) into the Healthcare Failure Mode and Effects Analysis (HFMEA™), by combining ideas from Root Causes Analysis (RCA)[5] and the US Food and Drug Administration's Hazard Analysis and Critical Control Point tool (HACCP).[6] Because terms and concepts were adjusted, this method is more applicable in healthcare settings.[7] Since 2001, the Joint Commission requires that U.S. accredited institutions incorporate the use of proactive risk assessment as a part of the hospitals patient safety program.[8, 9]

FMEA, traditionally used in industry looks at a device or component and uses the calculation of risk priority numbers (RPN) to assess the importance of remedial measures. RPN scores are typically expressed as the product of the severity, likelihood of occurrence and detectability (RPN = S x O x D).[2, 10-12]

HFMEA^{TM} evaluates (the organization of) healthcare processes by using multidisciplinary teams,[13-15] process diagramming,[13-15] failure modes (ways in which something could go wrong),[14] failure mode cause identification, a hazard scoring matrix and a decision tree algorithm to identify vulnerabilities in the system.[16] As part of the method, corrective actions are suggested, developed and implemented to tackle the failure mode causes.[7, 14] (Appendix I – HFMEA Worksheet ^{TM}). In HFMEA^{TM} the decision tree - which is a triage concept from the HACCP - and the Hazard Scoring Matrix^{TM} - which is based on the SAC Matrix of Root Cause Analysis - are both used in combination for prioritizing risks.[7]

Recent studies have described the use of a single FMEA analysis in healthcare[10, 11, 17, 18] and HFMEA analysis.[13-16, 19-21] Despite the strengths of the method, there are some limitations of FMEA related to its use in healthcare. Firstly, FMEA is generally used on a local level with often a limited focus on safety issues. In addition, FMEA does not allow to analyze the effect of combinations of multiple risk points that could lead to errors and as a qualitative tool does not assist health organizations in prioritizing corrective actions based upon quantitative risk.[3] There are few published applications of HFMEA^{TM} that provide guidance for its use in healthcare.[22, 23] Recently, a multicenter study of HFMEA analyses has been conducted in Dutch healthcare settings.[24] In qualitative terms HFMEA is considered as a useful method for risk identification. However, HFMEA - in particular the steps of process mapping and risk assessment - is a very time time-consuming and complex method.[13] The Dutch HFMEA study puts forward the suggestion to shortcut these steps to reduce the amount of time necessary to conduct the analysis.[24] Still, there is no insight in their impact on the costs or on the quality of outcomes.

The purpose of this study was to evaluate different short-cuts of HFMEA in terms of time investment and costs and to make an assessment on the quality of the results.

METHODS

Setting

Maastricht Radiation Oncology (MAASTRO) clinic, a radiotherapy institute in the South of the Netherlands, was invited to participate in the study. Patient Safety is one of the overriding concerns of MAASTRO. Hospital and radiation treatment involve certain high risks. MAASTRO wishes to reduce such risks, and has used a model taken from the aviation and petrochemicals industry to develop its own risk and safety system that is unique in the Dutch healthcare system. The institute is the first healthcare organization in The Netherlands that acquired a certification of their safety management system according to the national Dutch NTA 8009:2007 standards. Before setting up new processes or techniques MAASTRO clinic routinely uses the HFMEA method.

In MAASTRO the treatment of cancer patients is organized within three different units each focusing on a specific area (thorax, abdomen, and neck-head). This approach causes certain capacity constraints concerning the use of equipment (linear accelerators), individual patient materials and the assignment of specialized Radiation Technologists. Often, a unit has a planning of treatments that exceeds the capacity, while another working unit is functioning below the available capacity. In the future, the institute plans to treat all radiation areas in one generalized unit (Linac-pool). A prospective risk analysis could give more insight into the potential risks that go paired with the restructuration of the treatment units.

Study design

A two by two study design was set up in which four similar groups analyzed separately the possible risks of the Linac-pool by using different versions of HFMEA (Figure 1).

The process mapping was either conducted by the full team (groups 1 and 2) or by a subgroup of the team (groups 3 and 4). The risk assessment was carried out using the Decision Tree™ displayed in Appendix II (groups 1 and 3) or using Risk Priority Numbers based on the likelihood of occurrence (O), the severity if it occurred (S), and the likelihood of detection (D) with RPN = O x S x DT. (groups 2 and 4).

Consequently, group 1 used the full version of HFMEA™. Group 4 applied the version with both variations in the process description and risk assessment.

Figure 1 - 2x2 study design resulting in 4 versions of HFMEA

		Process description	
		Full group	*Subgroup*
Risk assessment	*Decision tree*	Group 1	Group 3
	Risk priority numbers	Group 2	Group 4

All teams were composed of three Radiation Technologists (one from each working unit), one Manager Radiation Technologist and a facilitator (researcher/author).
The HFMEA analyses were completed in parallel, within one month. Each session had a postulated duration of 1, 5 hours.

Cost analysis

Throughout the study, the cost perspective was that of the organization. All costs to conduct the HFMEA analyses were progressively registered. The cost data included fixed or overhead costs and variable costs.

Overhead costs are costs for resources that are shared by different departments (e.g. power, heating and cleaning). The price, accounting for the meeting rooms, projector, insurance, cleaning, power and heating, for a total of € 80.53 per half day was assumed to cover for the overhead costs. These are fixed costs because they don't vary with the level of activity (HFMEA).

Variable costs are those that change as the level of activity changes and include personnel costs for each HFMEA session. The duration of the sessions in person hours was used as a quantity for the calculation of the costs for personnel input. Using the opportunity concept, these quantities were multiplied with the unit costs (i.e. wages per hour) (Table 1).

The sessions were facilitated by the author for research purposes only. Nevertheless, the costs of the facilitator were included in the cost analysis, because the facilitator is a constant factor in HFMEA^{TM} analysis. The costs of the facilitator were estimated on the average wage of a patient safety manager.

Table 1 - Overhead costs and unit costs for personnel and material input

Overhead costs (€/half day)	
Light, heat, electricity, rent	80.53
Personnel input (€/hour)	
Radiation Technologist	33*
Manager Radiation Technologist	44*
Patient Safety Manager	45*

* Local Hospital Records

Quality assessment of HFMEA results

The HFMEA analyses were conducted separately resulting in a number of process steps, failure modes, failure mode causes and proposed corrective actions for each group.

An expert opinion was consulted to make a judgment on the quality of outcomes. The corrective actions that were formulated by the four groups were assessed on their feasibility through consensus of an expert panel (consisting of managers and safety staff). A distinction was made between: (1) actions that could not be implemented and that were rejected (not feasible), (2) actions that needed immediately implementation and (3) actions that needed a more general approach on a longer time scale.

RESULTS

Costs analysis

Group 1, 2 and 3 conducted the HFMEA in five sessions, while group 4 completed the analysis needing only four sessions. The results of the costs analysis of the four HFMEA analyses are presented in Table 2.

The HFMEA analyses resulted in direct costs varying from € 1028.6 to 1701.6. The overhead costs were calculated by multiplying the rent of the meeting rooms per half day (€ 80.53) with the number of sessions that were needed to complete the analyses. The variable costs per HFMEA were calculated by multiplying the duration of the sessions with the mean salaries per hour (Table 1) of the attendant team members (Radiation Technologists, Manager Radiation Technologist and facilitator).

Table 2 - Results of cost analysis

	Group 1	Group 2	Group 3	Group 4
Number of sessions	5	5	5	4
Total duration HFMEA analysis (hours)	7.6	7.3	7.1	4.9
Attendance rate of team members (%)	88	96	86	85
Total time investment (person hours)	33.1	34.7	29	18.7
Overhead costs (€)	**402.7**	**402.7**	**402.7**	**322.1**
Personnel input (€)	**1265.6**	**1298.9**	**1076.1**	**706.5**
Facilitator (Patient Safety Manager) (€)	341.1	326.7	318.6	221.4
Staff expenses (€)	924.5	972.2	757.5	485.1
Total costs HFMEA analysis (€)	**1668.3**	**1701.6**	**1478.8**	**1028.6**

Overview of team activities and numbers

Table 3 provides an overview of the results of the HFMEA analyses. For each group the numbers are presented for the sub processes, process steps (within each sub process), failure modes, failure mode causes and corrective actions suggested by the team members.

Table3 - Overview of team activities: numbers of sub processes, process steps, failure modes, failure mode causes and corrective actions identified by each group

	Group 1	Group 2	Group 3	Group 4
Sub processes	5	5	5	3
Process steps	14	34	30	25
Failure modes	26	57	77	44
Failure mode causes	28	99	55	80
Corrective actions	14	22	32	18

Quality assessment of HFMEA results

In total, 86 corrective actions were formulated. Many of these related to the compliance, control and education of standard operating procedures and protocols in daily practice. The expert panel made a judgment on the relevance and applicability of the actions by assigning scores in four categories. The scores are presented in Table 4.

In total, 43 (50%) actions were estimated relevant or essential to implement before the start of the reorganization process (Linac-pool). Thirty-one (36.05%) actions were assessed being relevant to implement on a longer time scale and 12 (13.95%) actions were not feasible.

Table 4 - Expert opinion scores on the relevance of the proposed corrective actions

	Group 1	**Group 2**	**Group 3**	**Group 4**
Score 1	3 (3.49%)	6 (6.98%)	18 (20.93%)	3 (3.49%)
Score 2	5 (5.81%)	3 (3.49%)	3 (3.49%)	2 (2.33%)
Score 3	6 (6.98%)	12 (13.95%)	7 (8.14%)	6 (6.98%)
Score 4	0 (0%)	1 (1.16%)	4 (4.65%)	7 (8.17%)

Score 1 = action is essential to the Linac-pool; Score 2 = action is relevant for the Linac-pool; Score 3 = action is relevant for on a longer time scale; Score 4 = action is irrelevant, not applicable

DISCUSSION

Cost analysis is an essential tool for visualizing actual activity conditions in a quantitative context and can help hospital managers (administrators) make decisions in implementing patient safety systems. Cost information can also help in the budgeting of patient safety activities.[25]

In this cost analysis different 'short-cuts' of HFMEA^{TM} were evaluated in a radiotherapy setting. The attendance rate of the team members explains for a great part the differences in time investment of the HFMEA analyses. In the assumption of an attendance rate of 100%, the total costs of a HFMEA conducted by group 1, 2 and 3 wouldn't differ much, because the total duration of the analyses is similar for these groups. Only group 4 consumed less time in conducting the HFMEA. The study pointed out that it is possible to save time and costs by conducting the step of process mapping by a subgroup of the team, without diminishing the quality of outcomes. When comparing the risk assessment of FMEA (RPN scores) and HFMEA^{TM} (Hazard Scoring Matrix^{TM}

combined with HFMEA Decision Tree™) there were no clear differences in time investment nor in usefulness.

Our results, as in other studies,[12, 22] highlight the qualitative and subjective nature of HFMEA, since the formulation of failure modes, failure modes causes and relevant corrective actions differed between the four groups while analyzing the same process.

The RPN assessment is considered as a more objective method[11] and requires an explicit cutoff score in which all parties agree.[7, 11] However, different teams tend to score common failure modes with different RPN scores.[12] In addition, the highest RPN scores are typically assessed far below the maximum possible score.[11] This is a reflection of the fact that severe events rarely occur and their detectability is considered high given the controls and checks that already are in place. A disadvantage of the Hazard Scoring Matrix is that scale descriptors always need to be adjusted in function of the selected process and the aim of the analysis.[16] Furthermore, a recent study found considerable variability in hazard scoring results when comparing individual scoring with a team consensus procedure, which rather confirms the subjectivity of this method[22].

There are several limitations to this study. This study was carried out in a radiotherapy setting and the results may not be generalizable to other institutions. Secondly, the teams were not fully multidisciplinary composed as there was no representation of radiation oncologists or clinical physicists. This might lead to an incomplete picture of the problem. Though, the HFMEAs were facilitated by an outsider (author) who was unfamiliar with the process, which is considered as an advantage for an unbiased approach.[22] Thirdly, because a narrow process was selected and the teams were small, the amount of personnel resources was lower than reported in several other studies.[15, 16, 20, 21, 24] A fourth limitation is the lack of quantitative outcome data which is inherent to the method and increases the difficulty of comparing the benefits of the different HFMEA variants.[3]

Because HFMEA does not take into account the financial consequences of the recommended actions, the role of the management is crucial in evaluating the outcomes of an HFMEA and prioritizing actions. HFMEA™ includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.[7] A follow-up study using HFMEA once the reorganization of the radiation therapy processes is completed, could give more insight in the controlled risks or new potential vulnerabilities of the treatment processes.

Without examining the validity or reliability of the HFMEA instruments or taking into account the discrepancies between the different groups, all HFMEA analyses contributed to a concrete corrective plan for the reorganization of the radiotherapy units. The corrective actions mainly concerned the compliance and education of protocols and procedures. Encouraging individuals to participate in HFMEA and discussing the processes already raised awareness about the risks.

CONCLUSIONS

This case study demonstrates the usefulness of cost assessment of safety tools as HFMEA can be conducted at an acceptable cost. The study provides more insight into the amount of financial resources needed to conduct a prospective risk analysis while taking into account the quality of the method.

Based on the results of this case study, it seems feasible to develop less time and cost consuming versions of HFMEA, which would increase even more the added value of prospective risk analysis tools for healthcare organizations.

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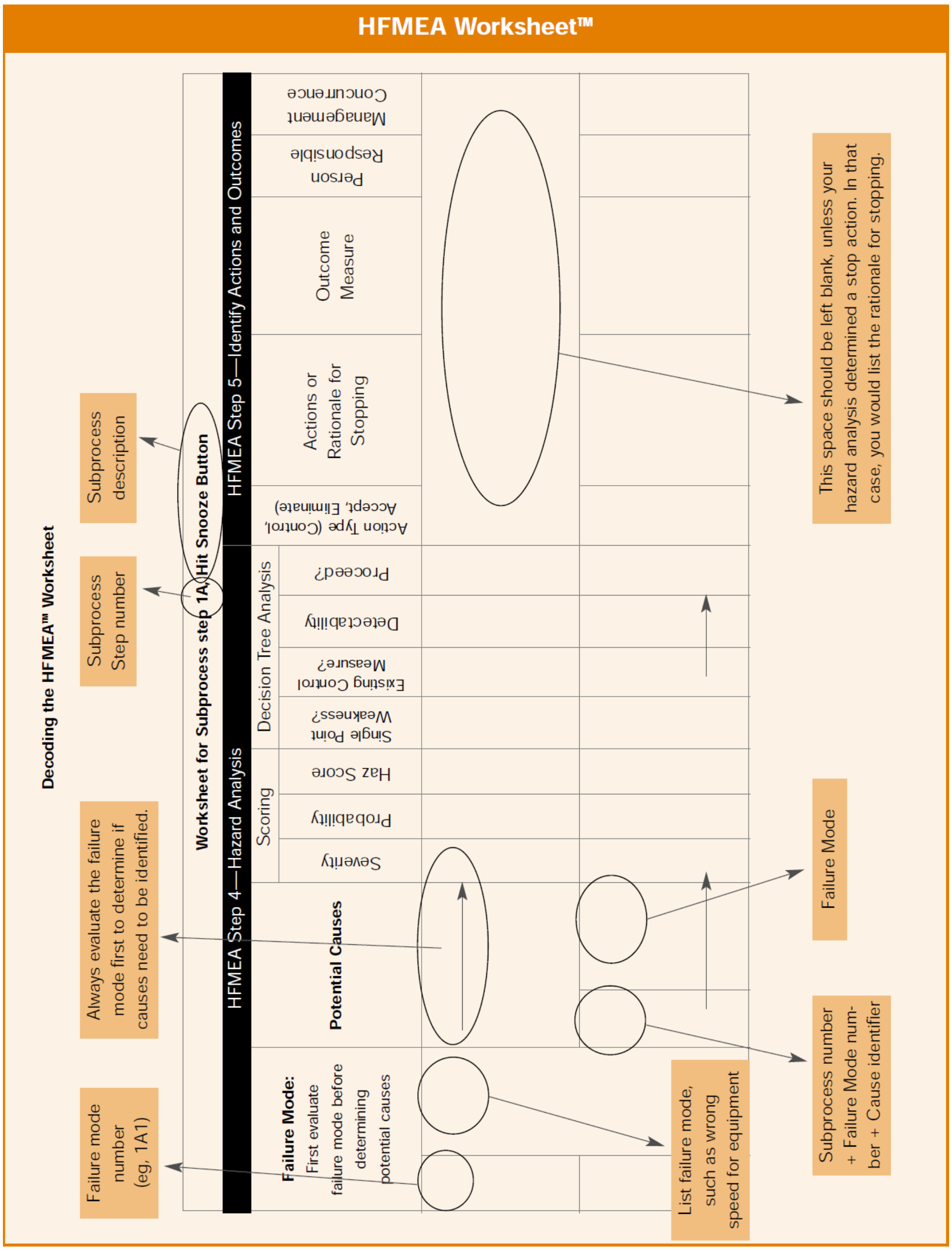
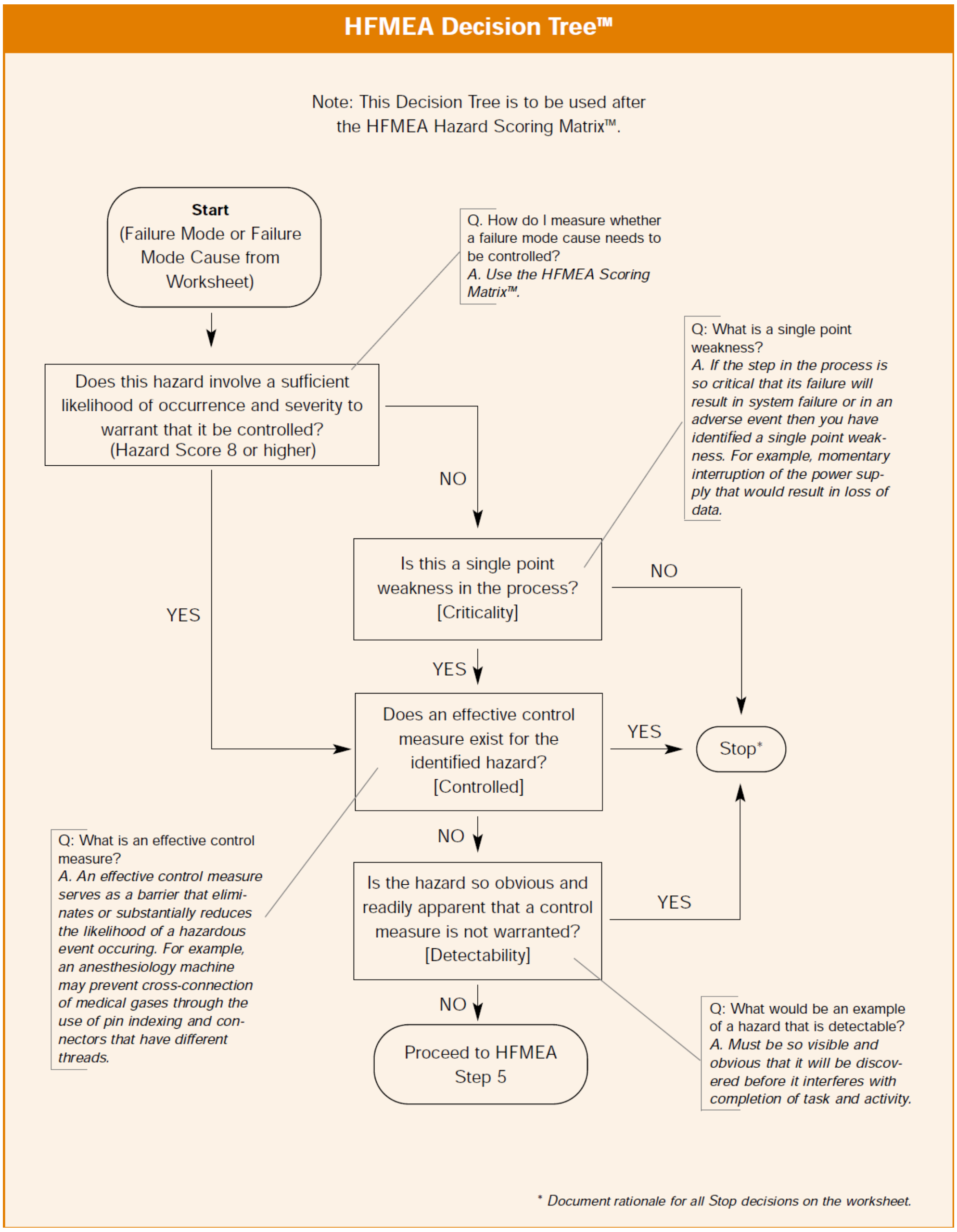
APPENDIX I: The HFMEA™ Worksheet was used to record the team's assessment, proposed actions, and outcome measures (DeRosier et al.[7])

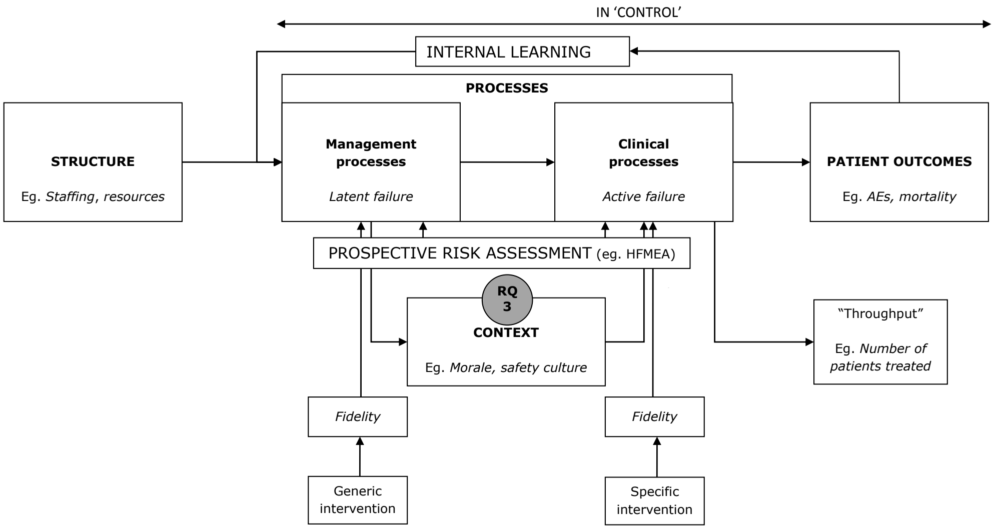


APPENDIX II: The HFMEA Decision Tree™ was used to determine whether the failure mode warrants further action on the basis of a lack of detection, criticality, and absence of effective control measures (DeRosier et al.[7])



CHAPTER 5

A nationwide Hospital Survey on Patient Safety Culture in Belgian hospitals: Setting priorities at the launch of a five year patient safety plan



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- This chapter will contribute to the book 'Patient Safety Culture: Theory, Methods and Application' to be published by *Ashgate* (2013) (Dr. Patrick Waterson, Editor)

ABSTRACT

Objective: To measure patient safety culture in Belgian hospitals and examine the homogeneous grouping of underlying safety culture dimensions.

Methods: The Hospital Survey on Patient Safety Culture was distributed organization-wide in 180 Belgian hospitals participating in the federal program on quality and safety between 2007 and 2009. Participating hospitals were invited to submit their data to a comparative database. Homogeneous groups of underlying safety culture dimensions were sought by hierarchical cluster analysis.

Results: 90 acute, 42 psychiatric and 11 long-term care hospitals submitted their data for comparison to other hospitals. The benchmark database included 55238 completed questionnaires (53.7% response rate). Overall dimensional scores were low, although scores were found to be higher for psychiatric and long-term care hospitals than for acute hospitals. The overall perception of patient safety was lower in French speaking hospitals. Hierarchical clustering of dimensions resulted in two distinct clusters. Cluster I grouped Supervisor/manager expectations and actions promoting safety, Organizational learning–continuous improvement, Teamwork within units and Communication openness, while Cluster II included Feedback and communication about error, Overall perceptions of patient safety, Non-punitive response to error, Frequency of events reported, Teamwork across units, Handoffs and transitions, Staffing and Management support for patient safety.

Conclusion: The nationwide safety culture assessment confirms the need for a long-term national initiative to improve patient safety culture, and provides each hospital with a baseline patient safety culture profile to direct an intervention plan. The identification of clusters of safety culture dimensions indicates the need for a different approach and context towards the implementation of interventions aimed at improving the safety culture. Certain clusters require unit level improvements, whereas others demand a hospital wide policy.

INTRODUCTION

Patient Safety is receiving growing attention in Belgium. A five year program (2007-2012) was launched to implement quality and patient safety initiatives in the acute, psychiatric and long term care hospitals, with a yearly additional financing (annual budget of € 6.8 million in 2007). In 2007, the federal contract was signed by 80 % (n=164) of the hospitals, including 97 acute hospitals, 52 psychiatric hospitals and 15 long term care hospitals. The Belgian government provides a framework for implementing quality and safety strategies with attention to structure (*how care is organized*), processes (*what is done by healthcare providers*) and outcome measurement (*the healthcare results achieved*), according to Donabedian's trilogy.[1]

One of the main priorities in the federal program is developing a culture of safety. "Safety culture refers to the beliefs, values and attitudes of patient safety shared by all members of the organization. These shared values are reflected in the day to day operations of the organization".[2] Understanding safety culture is seen as a key component in improving patient safety in Belgian hospital settings. During the first program year (2007-2008), 158 hospitals completed a hospital-wide measurement of the safety culture using the Hospital Survey on Patient Safety Culture (HSPSC). During the second program year (2008-2009), 22 other hospitals entering the federal patient safety program assessed the safety culture. In total, 88% of the Belgian hospitals (180 out of 205 hospitals) applied the HSPSC to measure the hospital wide safety culture. The federal government is planning to organize a second measurement in 2011 in order to track changes in patient safety culture over time and evaluate the impact of specific safety interventions.[1]

The Belgian versions, manual, psychometric validation reports and instruments of the HSPSC are available in Dutch, French and German.[3] Yet, the instrument is also highly recommended by the European Union Network for Patient safety (EUNetPaS) for internal use, though not for benchmarking.[4]

In many other countries the HSPSC is used to measure safety culture and previous research has shown that the instrument is psychometrically sound.[5-8] The instrument has also been tested to determine the most appropriate level - individual, unit and hospital level- for interventions aimed at improving the culture of patient safety. The unit level appears to be the dominating level for the clustering of responses to the dimensions, which would confirm that the HSPSC measures group values of culture and not just individual attitudes.[9] Previous Belgian research suggested differences between professional subgroups, although no representative conclusions could be made for the Belgian hospital sector.[10]

This study reports on a national aggregation of the data of the HSPSC within the Belgian hospitals and aims at providing each hospital a baseline score on 12 dimensions in order to set priorities and follow-up on the evolution of safety culture. In this way, the measurement of safety culture reflects a 'snapshot' of the current state of safety culture within the hospitals.[11]

OBJECTIVES

The primary aim of the study was to measure patient safety culture in Belgian hospitals. In order to formulate actions for improvement, it is important for hospitals to assess their baseline scores for the existing safety culture and determine areas of priority.

This study describes the survey results of the acute, psychiatric and long term care hospitals which voluntarily submitted their data for comparison to other hospitals. In addition, this study aims at examining (clustering) the underlying dimensions of patient safety culture. Results of these analyses can provide additional information on the common strengths or areas that need improvement.

A second nationwide survey and benchmarking are planned three years after the initial measurement to track changes in patient safety culture over time.[1] The nationwide safety culture measurement already raised high awareness about the role of culture in Belgian hospitals and may in itself be regarded as a patient safety initiative.

METHODS

Instrument

The HSPSC measures safety culture on 12 dimensions, including ten safety dimensions and two outcome dimensions, and is designed to measure staff perceptions on patient safety issues, medical errors and event reporting (table 1).[12]

Table 1 - Safety and outcome dimensions

	Safety dimensions
D1	Supervisor/manager expectations and actions promoting safety
D2	Organizational learning–continuous improvement
D3	Teamwork within units
D4	Communication openness
D5	Feedback and communication about error
D6	Nonpunitive response to error
D7	Staffing
D8	Management support for patient safety
D9	Teamwork across units
D10	Handoffs and transitions
	Outcome dimensions
O1	Overall perceptions of patient safety
O2	Frequency of events reported

The validation of the translation into Dutch and French was performed using the original validation strategy and included item analysis, exploratory factor analysis, confirmatory factor analysis, reliability analysis and analysis of the composite scores and inter-correlations.[13] The reliability coefficients (Cronbach's alpha) of the 12 safety culture dimensions ranged from 0.57 to 0.85 for the Dutch version and between 0.52 and 0.87 for the French version, which is comparable to the original questionnaire. Frequency of events reported and Staffing showed respectively the highest and lowest internal consistency (Appendix I).

Data collection

The HSPSC was distributed organization-wide in 180 (88%) Belgian hospitals participating in the federal program on quality and safety in 2007-2009. A first group of 158 hospitals initiated the safety culture assessment in 2007-2008, while 22 other hospitals started up one year later. Through a contract with the federal authorities, participating hospitals (in their first contract year) committed to measure safety culture within the entire organization. A workshop was organized for the participating hospitals in which the objectives and the tools for conducting the safety culture measurement were explained. The measurement toolkit contained the validated version of the HSPSC (in Dutch and French) and a manual (protocol). The protocol was comparable to the original version and imposed a time plan of 13 weeks with the encouragement to send two reminders to non-responders. Though, not all hospitals sent reminders. An MS Access based instrument was designed to standardize data-entry and automate the application of the exclusion criteria and analyses. Throughout the measurement period, technical assistance was available. Hospitals were free to distribute the survey electronically or paper based. The questionnaire was distributed anonymously to all individuals working in direct or indirect interaction with patients. Participating hospitals were invited to submit their data to a research database created by Hasselt University, a neutral academic institute. The database is not accessible for the governmental authorities and was developed to allow hospitals to compare their data to other hospitals and to provide data to hospitals to facilitate internal assessment and learning in the patient safety improvement process.

Statistical analysis

Questionnaires were excluded in case an entire section was incomplete, fewer than half of the items throughout the survey were answered, and all items were scored identically (as defined in the manual of the HSPSC questionnaire).

First, a mean dimensional score (range 1-5) was calculated on the individual level. Answers to negatively worded questions were reversed. Dimensional scores higher than 3 were considered as positive values towards patient safety. Based on these values, the dimensional scores were calculated on the hospital level (percentage positive values of all individuals). A percentage on an item was given on the total number of respondents for this specific item.

Based on the positive dimensional hospital scores, an explorative hierarchical cluster analysis was conducted using a squared Euclidean distance measure to assess similarity/dissimilarity across variables. Ward's algorithm for hierarchical cluster analysis was selected, because it minimizes the heterogeneity of the clusters. Ward’s method builds the hierarchy from the individual elements by progressively merging clusters, in order to minimize the internal variance. In short, this method attempts to minimize the Sum of Squares of any two (hypothetical) clusters that can be formed at each step.

In addition, three other cluster algorithms- between-groups linkage, centroid clustering, and median clustering- resulted in the same clusters confirming the robustness of the result found by Ward's method. Based on the cluster algorithm, a dendogram was generated for visual classification of similarity for grouping the underlying dimensions. In the dendogram, the dimensions were represented as nodes and the branches illustrated when the cluster method joined groups of dimensions. The length of the branch indicated the distance between groups of dimensions when they were joined.

All data were analyzed confidentially. SPPS 17 was used for all analyses.

RESULTS

Characteristics of participating hospitals

90 acute, 42 psychiatric and 11 long term care hospitals were interested in comparing their results to other hospitals. A comparative report was provided to each hospital, including its position on each dimension among other hospitals according to the type of hospital (acute, psychiatric and long term care), to facilitate internal assessment and learning in the patient safety improvement process.
Characteristics of the participating hospitals are presented in table 2.

Table 2 - Hospital characteristics

Hospital characteristics	**Numbers submitted for benchmark database**		
	Acute	***Psychiatric***	***Long term care***
Number of hospitals	90	42	11
Language			
Dutch speaking	58	31	9
French speaking	31	11	2
Both Dutch and French speaking	1	0	0
Survey administration			
Paper	68	38	11
Electronic	15	4	0
Mixed-mode	7	0	0

Characteristics of respondents

Respondents' characteristics are set out in table 3, based on the respondents' answers to survey questions about their hospital work area, staff position, direct interaction with patients, professional experience, and working time in the hospital. Generally, respondents working in psychiatric and long term care hospitals indicated for work area respectively "psychiatry" and "revalidation".

The benchmark database consists of data of 55238 respondents (53.7% response rate) who completed the survey. Dutch speaking hospitals had a higher overall response rate (59.6%) than French speaking hospitals (43.1%), given a high variability between hospitals. A similar response rate was observed among questionnaires distributed on paper (53.8%) in comparison with the questionnaires that were distributed electronically (53.2%). In total, 49925 employees (56.7% response rate) and 5313 physicians (35.6% response rate) completed the survey.

Table 3 - Respondent characteristics

Respondent characteristics	**Numbers submitted for benchmark database (%)**		
	Acute (n=90)	***Psychiatric (n=42)***	***Long term care (n=11)***
Total number of respondents	**47635 (100%)**	**6341 (100%)**	**1249 (100%)**
Work area/ Unit*	**38852 (81.6%)**	**4259 (67.2%)**	**1117 (89.4%)**
Many different hospital units/No specific unit	3147 (6.6%)	187 (2.9%)	88 (7.0%)
Internal Medicine (including day-stay admissions)	5201 (10.9%)	77 (1.2%)	182 (14.6%)
Surgery (including day-stay admissions)	4923 (10.3%)	1 (0%)	1 (0.1%)
Operating theatre	2588 (5.4%)	1 (0%)	-
Gynecology/ obstetrics	1918 (4%)	90 (1.4%)	1 (0.1%)
Pediatrics	1653 (3.5%)	73 (1.2%)	1 (0.1%)
Intensive care unit	2349 (4.9%)	-	-
Emergency	1701 (3.6%)	-	-
Revalidation	1710 (3.6%)	38 (0.6%)	764 (61.2%)
Geriatrics	2563 (5.4%)	188 (3%)	1 (0.1%)
Psychiatry	1367 (2.9%)	3 309 (52.2%)	-
Medical-technical services (diagnostics)	4680 (9.8%)	95 (1.5%)	8 (0.6%)

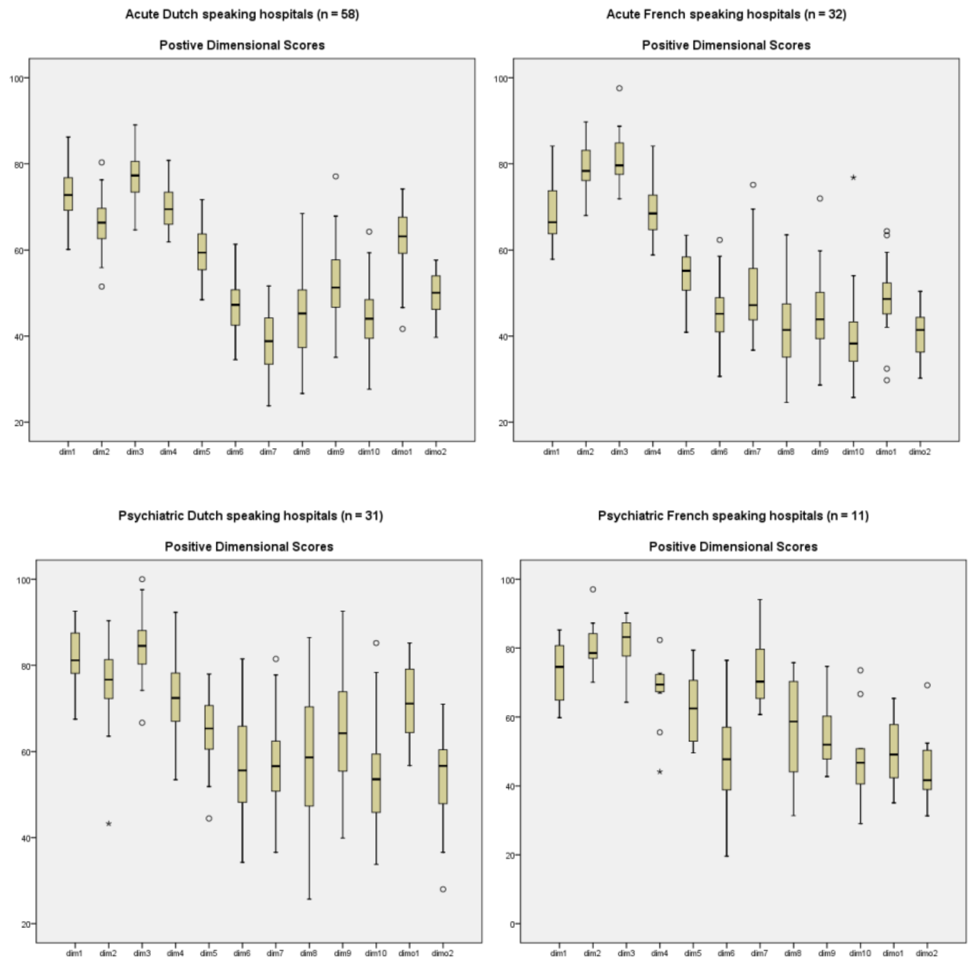
Pharmacy	824 (1.7%)	55 (0.9%)	14 (1.1%)
Other	4228 (8.9%)	145 (2.3%)	57 (4.6%)
Missing	8783 (18.4%)	2 082 (32.8%)	132 (10.6%)
Staff position	**42851 (90%)**	**4746 (74.8%)**	**1187 (95%)**
Nurse	22910 (48.1%)	1882 (29.7%)	389 (31.1%)
Head nurse	2038 (4.3%)	251 (4%)	40 (3.2%)
Nursing aid	3437 (7.2%)	693 (10.9%)	254 (20.3%)
Physician/ Physician – head of department/ Physician assistant/ physician in training	4665 (9.8%)	178 (2.8%)	49 (3.9%)
Pharmacist	304 (0.6%)	23 (0.4%)	10 (0.8%)
Assistant pharmacy	453 (1.0%)	30 (0.5%)	12 (1.0%)
Middle management	1517 (3.2%)	130 (2.1%)	21 (1.7%)
Technician (EKG, Lab, Radiology)	2063 (4.3%)	26 (0.4%)	6 (0.5%)
Therapist (dietitian, physical, psychologist)	2697 (5.7%)	1 024 (16.1%)	299 (23.9%)
Other	2776 (5.8%)	509 (8%)	107 (8.6%)
Missing	4784 (10%)	1595 (25.2%)	62 (5.0%)
Interaction with patients	44669 (93.8%)	6201 (97.8%)	1223 (97.9%)
YES, have direct patient interaction	40247 (84.5%)	5956 (93.9%)	1133 (90.7%)
NO, do NOT have direct patient interaction	4422 (9.3%)	245 (3.9%)	90 (7.2%)
Missing	2966 (6.2%)	140 (2.2%)	26 (2.1%)
Professional experience	**44758 (94%)**	**6191 (97.6%)**	**1223 (97.9%)**
Less than 1 year	1902 (4.0%)	299 (4.7%)	44 (3.5%)
1 to 5 years	8423 (17.7%)	1 177 (18.6%)	193 (15.5%)
6 to 10 years	8035 (16.9 %)	1 159 (18.3%)	240 (19.2%)
11 to 15 years	5880 (12.3%)	745 (11.7%)	173 (13.9%)
16 to 20 years	6582 (13.8%)	809 (12.8%)	165 (13.2%)
21 years or more	13936 (29.3%)	2002 (31.6%)	408 (32.7%)
Missing	2877 (6%)	150 (2.4%)	26 (2.1%)
Working time in hospital	**45030 (94.5%)**	**6231 (98.3%)**	**1238 (99.1%)**
Less than 20 hours per week	4885 (10.3%)	629 (9.9%)	178 (14.3%)
20 to 39 hours per week	28532 (59.5%)	4 356 (68.7%)	869 (69.6%)
40 to 59 hours per week	9638 (20.2%)	1127 (17.8%)	172 (13.8%)
60 to 79 hours per week	1553 (3.3%)	97 (1.5%)	16 (1.3%)
80 hours per week or more	422 (0.9%)	22 (0.3%)	3 (0.2%)
Missing	2605 (5.5%)	110 (1.7%)	11 (0.9%)

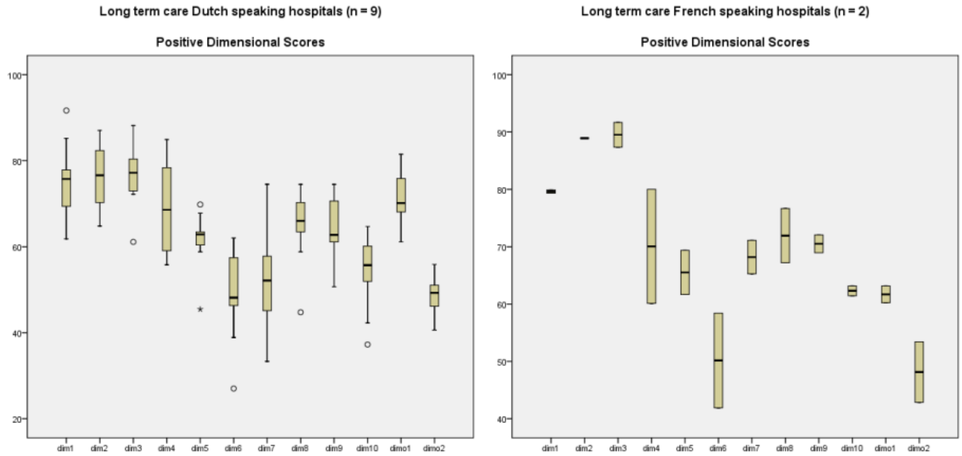
*Section less relevant for psychiatric and long term care hospitals.

Positive dimensional scores

Figure 1 provides the dimensional scores expressed in terms of percent of positive response. Percent positive reflects the percentage of positive responses (e.g., Agree, Strongly agree) to positively worded items or negative response to negatively worded items.

Figure 1 - Boxplots for Positive Dimensional Scores (one Acute hospital was both Dutch and French speaking and was calculated as a French speaking hospital)





Cluster analysis

The clustering of the positive dimensional scores for the acute and psychiatric hospitals is shown in figure 2 (using Ward's method with the Squared Euclidean Distance measure). We refrained from clustering the dimensional scores of the long term care hospitals because of the low number of participating hospitals (n=11).

For acute hospitals, clustering identified two distinct groups:

- *Cluster I*: including the dimensions Communication openness (dim 4), Supervisor/manager expectations and actions promoting safety (dim 1), Organizational learning–continuous improvement (dim 2) and Teamwork within units (dim 3). Within this cluster, the distance between these 4 dimensions was small, with the smallest distance between dimension 1 and 4.
- *Cluster II*: including the dimensions Feedback and communication about error (dim 5), Overall perceptions of patient safety (dim 11), Non-punitive response to error (dim 6), Frequency of events reported (dim 12), Teamwork across units (dim 9), Handoffs and transitions (dim 10), Staffing (dim 7) and Management support for patient safety (dim 8).

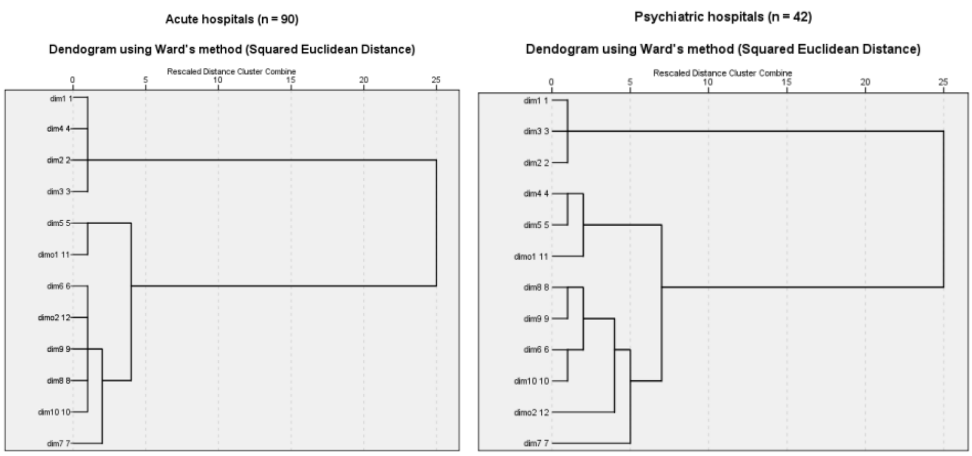
  Within this cluster, two sub-clusters can be distinguished:

- Dimensions Feedback and communication about error and Overall perceptions of patient safety;
- Dimensions Non-punitive response to error, Frequency of events reported, Teamwork across units, Handoffs and transitions and Management support for patient safety and at a slightly larger distance the dimension Staffing.

For psychiatric hospitals a similar structure was found (figure 2), except Communication openness (dim 4) clustered within cluster II.

An additional test with small sample sizes of variables (10%) yielded the same results. Other clustering methods as between-groups linkage, centroid clustering, and median clustering confirmed the robustness of the results (Appendix II).

Figure - Dendogram from the hierarchical cluster analysis of dimensions (acute and psychiatric hospitals)



DISCUSSION

This report presents the results of a national patient safety culture assessment, including results from 55238 respondents (53.7% response rate) working in 143 Belgian hospitals.

Generally, areas Teamwork within units, Supervisor/manager expectations and actions promoting safety, Organizational learning – continuous improvement and Communication openness were dimensions that emerged as areas of strength.

Handoffs and transitions, Staffing, Management support for patient safety, Non-punitive response to error and Teamwork across units, showed potential for improvement.

Positive dimensional scores were higher for psychiatric and long term care hospitals than for acute hospitals, suggesting that patient safety is more encouraged within these settings. Another explanation could be that patient safety is more often at danger in acute hospitals –inherent to the more complex tasks that are performed in this setting- resulting in more frequent witnessing of unsafe patient care and a more negative evaluation of safety by the healthcare professionals working in acute hospitals.

We found that perspectives involving organizational learning and continuous improvement, staffing and teamwork within units were more positive in French than in Dutch speaking hospitals. However, on all other dimensions we found in the French speaking part a lower percentage of positive answers, with the lowest values on both outcome dimensions. Caution must be taken in the interpretation of these results, since the number of participating French speaking hospitals was lower (less than half of the Flemish hospitals) and so were the response rates of the employees and physicians. Moreover, the response rate in the Dutch speaking hospitals might be higher because of the earlier local patient safety initiatives, which might have raised the experience and awareness of patient safety in these settings.

Hierarchical clustering of patient safety dimensions suggested within acute hospitals clear clustering schemes of the dimensions related to teamwork within units, communication openness and learning. Results show an important role of the supervisor of the unit when working on these dimensions. Initiatives to improve these dimensions should be focused at the level of the individual unit.

In our study, Staffing clustered at greater distance from the other dimensions. Our findings are in line with the results of studies investigating the multilevel psychometric properties of the survey, which suggest that staffing falls slightly below cutoffs in a number of areas.[5, 8] Also, staffing seems to be more related to teamwork between different units and handoffs, rather than teamwork within units, meaning that staffing cannot be allocated to differences in perceptions between units. Earlier research found a significant clustering at the hospital level of the dimensions Feedback about and learning from error, Teamwork across hospital units and Non-punitive response to error.[9] We found that these dimensions were related to Frequency of events reported, Handoffs and transitions and Management support for patient safety. These dimensions are of importance at the hospital level, for instance when setting up a centralized incident reporting system.

One of the strengths in our study was that hospitals were asked to organize a hospital-wide safety culture assessment. We succeeded to collect responses of 5313 medical staff members and 49925 employees. Yet, the nationwide safety culture measurement raised high awareness about the role of culture in Belgian hospitals and may in itself be regarded as a patient safety initiative.
Comparisons between our results and the AHRQ 2011 User Comparative Database Report[14], providing results from 472397 hospital staff in 1032 American hospitals, show that in our study the overall response rate was higher, with a remarkable higher response from the medical staff. Reminders were an important driver in the survey to get a satisfactory response rate. We refrained from comparing dimensional scores to other countries, since there are too many national or health care specific differences that limit any useful comparison. In addition, there are too many differences in respondents' characteristics between studies, as our study mainly focused on health care providers who work in direct interaction with patients (85.7%). What's more, we applied a different method in calculating positive dimensional scores. In our study, data were first used to calculate a mean dimensional score (range 1-5) on the individual level. Based on these individual scores, the percentage of positive response was calculated on the hospital level. In the original method, the average percent positive scores were calculated by averaging composite-level percent positive scores across all hospitals in the database, as well as averaging item-level percent positive scores across hospitals. A disadvantage of this method, since the percent positive is displayed as an overall average, is that scores from each hospital are weighted equally in their contribution to the calculation of the average.[14]

There are several limitations to our study.
First, hospitals were not randomly selected. The database only included data of hospitals that voluntarily submitted their data for comparison and did not represent a randomly selected sample of all 205 Belgian hospitals. However, 79.6% of the acute, 61.8% of the psychiatric and 55% of the long term care

hospitals were included in the analysis. Overall, the characteristics of the included hospitals are fairly consistent with the distribution of all Belgian hospitals.[15]

Second, hospitals used a different survey method (paper, electronic or mixed-mode) and not all of the hospitals sent reminders, which could have led to differences in response rate. Though, hospitals were instructed to conduct the survey through several workshops. Technical assistance was available if necessary.

Thirdly, the data hospitals submitted were cleaned for out-of-range values (e.g., invalid response values due to data entry errors) and blank records (where responses to all survey items were missing). In addition, some logic checks were made. Otherwise, data were presented as submitted. No additional attempts were made to verify the accuracy of the data submitted.[14]

Fourthly, an important disadvantage of cluster analysis is that once a score is assigned to a cluster, it cannot be assigned to another one. Some scores may have more than one significant property or fall on the edge of two clusters.

Finally, we recognize the limitations of this quantitative approach of safety culture, measuring group values, perceptions and attitudes on predefined dimensions, which might underexpose other important layers of safety culture.[16]

Alongside repeated measurement of patient safety culture, additional qualitative research, such as focus groups, staff interviews or observations might highlight important dimensions that are more related with cultural dynamics and cultural change.[10, 12] An interesting area warranting further research lies in understanding the perception of healthcare leaders towards patient safety.[17-19] Yet, a great polarization is found in the management views on patient safety [17], but it’s not clear how leadership influences organizational culture.

At the other hand, there is still limited evidence on a quantitative relationship between safety culture and outcomes measures of safety that apply to the entire hospital.[20, 21] Therefore, future research is needed to understand how improvement strategies influence patient safety culture and how safety culture assessment can be related to outcome measurement.

CONCLUSION

Clearly, healthcare organizations are interested in the potential for evaluating, benchmarking and improving safety culture perceptions. In this study, we presented aggregated results of a nationwide survey on patient safety culture. In addition, we investigated clustering of the underlying dimensions of the HSPSC. Our results suggest a different approach towards certain clusters of dimensions, and on the other hand confirm the robust composition of the survey towards the different dimensions.

Our recommendations for health care managers concern that interventions aimed at communication openness and teamwork within units should be handled decentralized at the unit level. Error management, transitions and staffing require a more centralized approach at the hospital level. Repeated measurement after several years can track evolution in these dimensions.

Further research should be based on the combination of both quantitative and qualitative approaches in the assessment of safety culture. Greater attention must be paid at the hospital management view of patient safety in order to evaluate the organizational readiness towards patient safety strategies. An important shortcoming in the HSPSC lies in the fact that some sections, such as work area and staff position, are not fully applicable in psychiatric and long term care facilities. We recommend refinement of these categories in order to compare and understand possible differences in dimensional scores.

Acknowledgements

We are grateful to all the Belgian hospitals who took the time and effort to participate in this study.

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Conflict of interests

There were no conflicts of interests.

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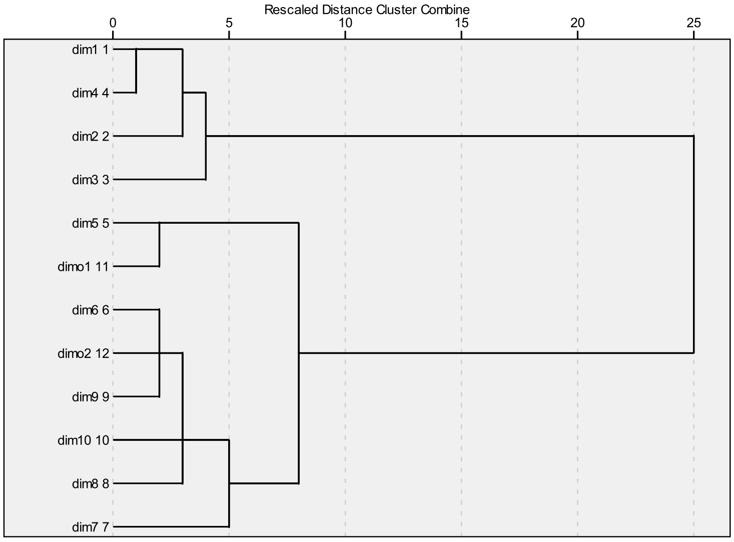
APPENDIX I – Reliability coefficients (Cronbach's alpha) of the 12 safety culture dimensions

Dimensions	**Items**	**Alpha (Dutch version)**	**Alpha (French version)**
Frequency of events reported	D1, D2, D3	0.85	0.87
Overall perceptions of patient safety	A10, A15, A17, A18	0.58	0.63
Supervisor/manager expectations and actions promoting safety	B1, B2, B3, B4	0.77	0.75
Organizational learning—continuous improvement	A6, A9, A13	0.59	0.59
Teamwork within units	A1, A3, A4, A11	0.66	0.82
Communication openness	C2, C4, C6	0.65	0.72
Feedback and communication about error	C1, C3, C5	0.78	0.76
Non-punitive response to error	A8, A12, A16	0.68	0.64
Staffing	A2, A5, A7, A14	0.57	0.52
Management support for patient safety	F1, F8, F9	0.72	0.77
Teamwork across units	F2, F4, F6, F10	0.66	0.68
Handoffs and transitions	F3, F5, F7, F11	0.71	0.72

APPENDIX II - Dendograms from the hierarchical cluster analysis of dimensions (acute and psychiatric hospitals)

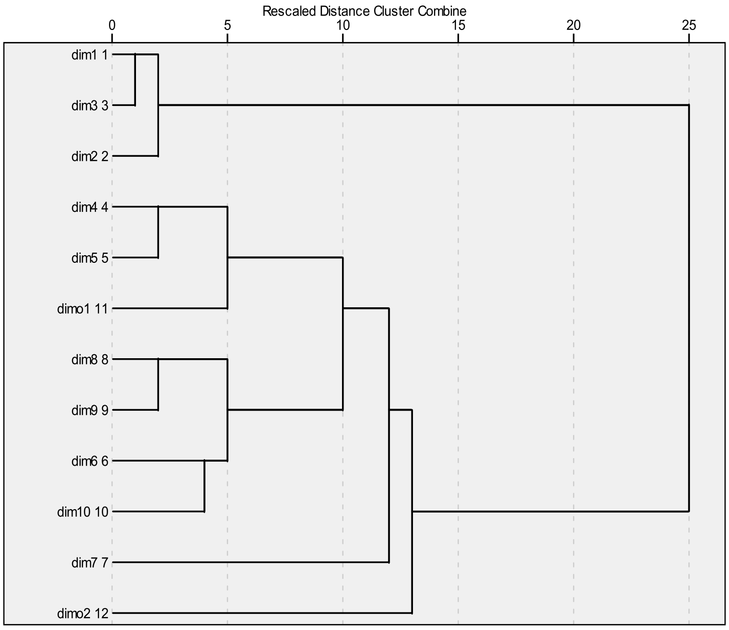
Acute hospitals (n = 90)

Dendrogram using Average Linkage (Between Groups)



Psychiatric hospitals (n = 42)

Dendrogram using Average Linkage (Between Groups)



APPENDIX III – Hospital Survey on Patient Safety Culture (Flemish)

Onderzoek naar de cultuur van patiëntveiligheid in het ziekenhuis met betrekking tot de veiligheid van de patiënt

Dit onderzoek peilt naar uw mening over de organisatiecultuur in het ziekenhuis met betrekking tot de veiligheid van de patiënt. Organisatiecultuur kan worden gezien als datgene wat de leden van een organisatie met elkaar delen, wat zij gezamenlijk van belang vinden of waar zij waarde aan hechten. Inzicht in de organisatiecultuur van het ziekenhuis is belangrijk om gerichte acties ter verbetering van de patiëntveiligheid te kunnen kaderen en uitwerken. Hiervoor is er een belangrijke consensus in de literatuur, maar zijn er ook recente aanbevelingen vanuit de Europese Unie en de Wereldgezondheidsorganisatie.

De voorliggende vragenlijst is een vertaling van de "Hospital Survey on Patient Safety" die ontwikkeld werd door J. Sorra en V. Nieva in opdracht van het Agency for Healthcare Research and Quality in de Verenigde Staten. Het instrument in de originele versie is vrij beschikbaar, met een uitvoerige handleiding en een aparte statistische verantwoording op www.ahrq.gov/qual/hospculture. Deze vragenlijst werd vertaald door de werkgroep patiëntveiligheid van het Ziekenhuis Oost Limburg en er werd door Li Wenqi een validatieonderzoek uitgevoerd. Deze vragenlijst werd, met een aanpassing op basis van dit validatieonderzoek, gebruikt door Johan Hellings in het kader van een breder doctoraatsonderzoek inzake patiëntveiligheid, in vier Vlaamse ziekenhuizen, onder leiding van Prof. Dr. A. Vleugels van de KUL en Prof. Dr. N. Klazinga van de Universiteit van Amsterdam, tevens met een positief advies vanuit twee ethische commissies.

Enkele verduidelijkende begrippen die vaak voorkomen in de vragenlijst:

- Met **"fout"** wordt hier gelijk welk type van fout, vergissing, accident of afwijking bedoeld, los van het feit of dit geleid heeft tot schade voor de patiënt.
- **"Patiëntveiligheid"** wordt hier gedefinieerd als het vermijden of voorkomen van schade voor de patiënt als gevolg van het proces van hulp- of zorgverlening.
- Met **"medewerkers"** worden de personen bedoeld die in dienstverband werken in het ziekenhuis: verpleegkundigen, paramedici, apothekers,….
- Met **"collega's"** worden de artsen bedoeld die in het ziekenhuis aangesteld zijn.

Om een goed beeld te bekomen van de cultuur in het ziekenhuis met betrekking tot patiëntveiligheid, is uw medewerking van groot belang. De betrouwbaarheid van dit onderzoek wordt immers mede bepaald door de mate van participatie in het ziekenhuis.

De vragenlijst die voor u ligt bestaat uit een aantal uitspraken. Per uitspraak zijn er vijf mogelijke antwoorden. Gelieve het bolletje dat overeenstemt met uw antwoord, per uitspraak, duidelijk zwart te maken.

Het duurt een 15 à 20-tal minuten om deze vragenlijst in te vullen. Voor het invullen van deze vragenlijst is het belangrijk dat de focus gericht wordt op de globale ziekenhuiswerking met betrekking tot patiëntveiligheid, zoals die door u ervaren wordt, vanuit uw perspectief.

Er wordt een volledige anonimiteit gewaarborgd. Het nummer dat u desgevallend op de eerste pagina vindt is enkel dienstig om te kunnen opvolgen wie nog niet geantwoord heeft. Deze personen krijgen dan een herinneringsbrief met een nieuwe enquête toegestuurd. Noch de directie van het ziekenhuis, noch de personen die de gegevens van deze vragenlijst verwerken kunnen de herkomst van deelnemers achterhalen en de gegevens worden enkel globaal verwerkt.

Hartelijk dank voor uw medewerking

A. UW WERKOMGEVING/ AFDELING

Met werkomgeving wordt bedoeld de klinische omgeving (dienst, afdeling, …) waarin u het grootste stuk van uw tijd werkt.

Wat is uw primaire werkomgeving (u kan slechts één antwoord geven):

① Verschillende afdelingen / geen specifieke afdeling

② Internistische afdelingen/diensten (dagkliniek inbegrepen)	⑦ Intensieve zorgen	⑫ Medisch-technische dienst (radiologie, labo,bloedafname, …)
③ Chirurgische afdelingen/diensten (dagkliniek inbegrepen)	⑧ Spoedgevallen	⑬ Apotheek
④ Operatiekwartier	⑨ Revalidatie	⑭ Andere, gelieve te specifiëren:
⑤ Gynaecologie / verloskunde	⑩ Geriatrie	
⑥ Pediatrie	⑪ Psychiatrie	

Duid aan in welke mate u akkoord gaat met volgende uitspraken over uw werkomgeving / afdeling.

Binnen uw werkomgeving…	Helemaal niet akkoord ▼	Niet akkoord ▼	Neutraal ▼	Akkoord ▼	Helemaal akkoord ▼
1. Medewerkers en collega's steunen elkaar in mijn werkomgeving.	①	②	③	④	⑤
2. We hebben voldoende bestaffing om de werkbelasting aan te kunnen.	①	②	③	④	⑤
3. Wanneer er veel werk op korte tijd gedaan moet worden, werken we samen als een team.	①	②	③	④	⑤
4. In mijn werkomgeving behandelen medewerkers/collega's elkaar met respect.	①	②	③	④	⑤
5. In mijn werkomgeving werken medewerkers/collega's meer uren dan goed is voor de zorgverlening aan de patiënt.	①	②	③	④	⑤
6. We ondernemen acties om de patiëntveiligheid te verbeteren.	①	②	③	④	⑤
7. Er worden te veel tijdelijke medewerkers ingeschakeld dan goed is voor de zorgverlening aan de patiënt.	①	②	③	④	⑤
8. Medewerkers/collega's hebben het gevoel dat fouten tegen hen gebruikt worden.	①	②	③	④	⑤
9. Fouten hebben hier al geleid tot positieve veranderingen.	①	②	③	④	⑤
10. Het is eerder toevallig dat er hier geen ernstigere fouten gebeuren.	①	②	③	④	⑤
11. Wanneer het zeer druk wordt, komen andere medewerkers/collega's ons helpen.	①	②	③	④	⑤
12. Wanneer een fout gerapporteerd wordt, hebben we het gevoel dat men zich vooral op de persoon richt en niet op het probleem.	①	②	③	④	⑤
13. Als we veranderingen doorvoeren ter verbetering van patiëntveiligheid, evalueren we achteraf steeds de effectiviteit.	①	②	③	④	⑤

Binnen uw werkomgeving… (vervolg)	Helemaal niet akkoord ▼	Niet akkoord ▼	Neutraal ▼	Akkoord ▼	Helemaal akkoord ▼
14. We werken vaak in een “crisis - toestand” : we proberen te veel te doen, te snel.	①	②	③	④	⑤
15. Patiëntveiligheid wordt nooit opgeofferd om meer werk gedaan te krijgen.	①	②	③	④	⑤
16. Medewerkers/collega’s vrezen dat fouten die gemaakt worden in hun persoonlijk dossier bewaard blijven.	①	②	③	④	⑤
17. We hebben problemen in verband met patiëntveiligheid in mijn werkomgeving.	①	②	③	④	⑤
18. Onze procedures en systemen zijn geschikt om fouten te vermijden.	①	②	③	④	⑤

B. UW “SUPERVISOR”

Voor de artsen wordt met “supervisor” de collega/het medisch diensthoofd bedoeld. Voor verpleegkundigen en paramedici is dit de hoofdverpleegkundige/hoofdparamedicus, maar kan dit ook betrekking hebben op de arts wanneer het betrekking heeft op opdrachten die onder rechtstreeks toezicht van de arts uitgevoerd worden. Voor de hoofdverpleegkundige is de verpleegkundige directie (middenkaderdirectie) “supervisor”. Voor de apothekers wordt de hoofdapotheker als “supervisor” beschouwd.

Duid aan in welke mate u akkoord gaat met volgende uitspraken over uw “supervisor”.

	Helemaal niet akkoord ▼	Niet akkoord ▼	Neutraal ▼	Akkoord ▼	Helemaal akkoord ▼
1. Mijn “supervisor” toont waardering wanneer er gewerkt wordt met de uitgewerkte procedures in verband met patiëntveiligheid.	①	②	③	④	⑤
2. Mijn “supervisor” houdt ernstig rekening met suggesties van medewerkers/collega’s die de patiëntveiligheid trachten te verbeteren.	①	②	③	④	⑤
3. Wanneer de werkdruk toeneemt verwacht mijn “supervisor” dat we sneller werken zelfs als we daarvoor stappen in de procedures moeten overslaan.	①	②	③	④	⑤

4. Mijn “supervisor” ziet steeds terugkerende problemen op vlak van patiëntveiligheid over het hoofd.	①	②	③	④	⑤

C. COMMUNICATIE

Duid voor volgende uitspraken aan hoe dikwijls ze van toepassing zijn voor uw werkomgeving.

Binnen uw werkomgeving…	Nooit ▼	Zelden ▼	Soms ▼	Meestal ▼	Altijd ▼
1. We krijgen feedback over veranderingen die gebeuren op basis van foutrapporteringen.	①	②	③	④	⑤
2. Medewerkers/collega’s kunnen vrijuit spreken wanneer ze iets zien dat de zorg voor de patiënt negatief beïnvloedt.	①	②	③	④	⑤
3. Wij worden geïnformeerd over fouten die gebeuren binnen onze werkomgeving.	①	②	③	④	⑤
4. Medewerkers/collega’s kunnen beslissingen of acties van personen met een hogere hiërarchische positie kritisch, maar constructief, bespreekbaar maken.	①	②	③	④	⑤
5. In onze werkomgeving worden fouten besproken om te voorkomen dat ze opnieuw gebeuren.	①	②	③	④	⑤
6. Medewerkers/collega’s zijn bang om vragen te stellen wanneer er iets niet in orde lijkt.	①	②	③	④	⑤

D. FREQUENTIE VAN FOUTMELDINGEN

Duid aan hoe vaak volgende fouten gemeld worden wanneer ze gebeuren binnen uw werkomgeving.

	Nooit ▼	Zelden ▼	Soms ▼	Meestal ▼	Altijd ▼
1. Er wordt een fout gemaakt, maar deze fout wordt opgemerkt en gecorrigeerd voor de patiënt er schade van ondervindt. Hoe vaak wordt dit gemeld?	①	②	③	④	⑤
2. Er wordt een fout gemaakt waarvan we weten dat deze fout de patiënt niet kan schaden. Hoe vaak wordt dit gemeld?	①	②	③	④	⑤
3. Er wordt een fout gemaakt die de patiënt schade had kunnen berokkenen, maar hem uiteindelijk ongedeerd liet. Hoe vaak wordt dit gemeld?	①	②	③	④	⑤

E. BEOORDELING VAN PATIENTVEILIGHEID

Geef een beoordeling van de globale patiëntveiligheid in uw werkomgeving. Duid slechts één antwoord aan.

①	②	③	④	⑤
Excellent	Zeer goed	Aanvaardbaar	Zwak	Zeer zwak

F. HET EIGEN ZIEKENHUIS

Duid aan in welke mate u akkoord gaat met volgende uitspraken over uw ziekenhuis

Denk aan uw ziekenhuis	Helemaal niet akkoord ▼	Niet akkoord ▼	Neutraal ▼	Akkoord ▼	Helemaal akkoord ▼
1. Het ziekenhuismanagement* zorgt voor een werkklimaat dat patiëntveiligheid bevordert.	①	②	③	④	⑤
2. Ziekenhuisafdelingen werken niet zo goed gecoördineerd samen.	①	②	③	④	⑤
3. Bij het transferen van patiënten naar andere afdelingen worden zaken over het hoofd gezien.	①	②	③	④	⑤
4. Er is een goede samenwerking tussen afdelingen/diensten die vaak samenwerken.	①	②	③	④	⑤
5. Er gaat vaak belangrijke informatie over de patiënt verloren bij het wisselen van werkposten.	①	②	③	④	⑤
6. Het is vaak onaangenaam om samen te werken met medewerkers/collega's van andere afdelingen/diensten.	①	②	③	④	⑤
7. Er treden vaak problemen op bij het uitwisselen van informatie tussen afdelingen/diensten.	①	②	③	④	⑤
8. De acties van het ziekenhuismanagement geven aan dat patiëntveiligheid een topprioriteit is.	①	②	③	④	⑤
9. Het ziekenhuismanagement lijkt enkel geïnteresseerd in patiëntveiligheid als er iets is misgelopen.	①	②	③	④	⑤
10. Afdelingen/diensten werken goed samen om de best mogelijke zorgen aan de patiënten te kunnen	①	②	③	④	⑤

* Het ziekenhuismanagement: alle medewerkers en collega's die lid zijn van het hoger leidinggevend kader en die effectief sturende bevoegdheden hebben: middenkaders, directieleden, medische directie, hoofdapotheker,…

bieden.

11. Het wisselen van werkposten is problematisch voor de patiënten in het ziekenhuis.	①	②	③	④	⑤

G. AANTAL MELDINGEN VAN FOUTEN

Hoeveel fouten* heeft u gemeld gedurende de afgelopen 12 maanden? Gelieve slechts één antwoord aan te duiden.

① Geen enkel voorval
③ 3 tot 5 voorvallen
⑤ 11 tot 20 voorvallen
② 1 of 2 voorvallen
④ 6 tot 10 voorvallen
⑥ 21 of meer voorvallen

H. ACHTERGRONDINFORMATIE

Deze informatie is belangrijk voor de interpretatie van de resultaten van deze vragenlijst. Gelieve telkens één antwoord aan te duiden.

1. Hoelang werkt u al in het ziekenhuis?

① Minder dan 1 jaar
③ 6 tot 10 jaar
⑤ 16 tot 20 jaar
② 1 tot 5 jaar
④ 11 tot 15 jaar
⑥ 21 jaar of langer

2. Hoelang werkt u in uw huidige werkomgeving/afdeling?

① Minder dan 1 jaar
③ 6 tot 10 jaar
⑤ 16 tot 20 jaar
② 1 tot 5 jaar
④ 11 tot 15 jaar
⑥ 21 jaar of langer

3. Hoeveel uur per week werkt u gemiddeld gezien in het ziekenhuis?

① Minder dan 20 uur / week
③ 40 tot 59 uur / week
⑤ 80 uur / week of meer
② 20 tot 39 uur / week
④ 60 tot 79 uur / week

* Met **“fout”** wordt hier gelijk welk type van fout, vergissing, accident of afwijking bedoeld, los van het feit of dit in schade voor de patiënt heeft geresulteerd.

4. Wat is uw functie in het ziekenhuis? Gelieve het antwoord aan te kruisen dat het best uw functie omschrijft.

① Verpleegkundige (master, bachelor, 4de graad)

② Hoofdverpleegkundige

③ Verpleeghulpen (kinderverzorgster, logistiek assistenten, …)

④ Geneesheer

⑤ Geneesheer-diensthoofd

⑥ Geneesheer-assistent

⑦ Ziekenhuisapotheker

⑧ Medewerker ziekenhuisapotheek

⑨ Middenkader, stafmedewerker

⑩ Medewerker technische onderzoeken (labo, RX, …)

⑪ Paramedicus (kinesist, dietist, psycholoog)

⑫ Andere, gelieve te specifiëren:

5. Heeft u binnen uw huidige functie directe interactie en/of contact met patiënten?

① Ja, ik heb directe interactie en/of contact met patiënten.

② Nee, ik heb geen directe interactie en/of contact met patiënten.

6. Hoelang werkt u reeds in uw huidig beroep of specialisme?

① Minder dan 1 jaar

② 1 tot 5 jaar

③ 6 tot 10 jaar

④ 11 tot 15 jaar

⑤ 16 tot 20 jaar

⑥ 21 jaar of langer

I. UW OPMERKINGEN

Hieronder kan u vrij eventuele opmerkingen of suggesties schrijven over patiëntveiligheid, fouten en foutrapporteringen in het ziekenhuis.

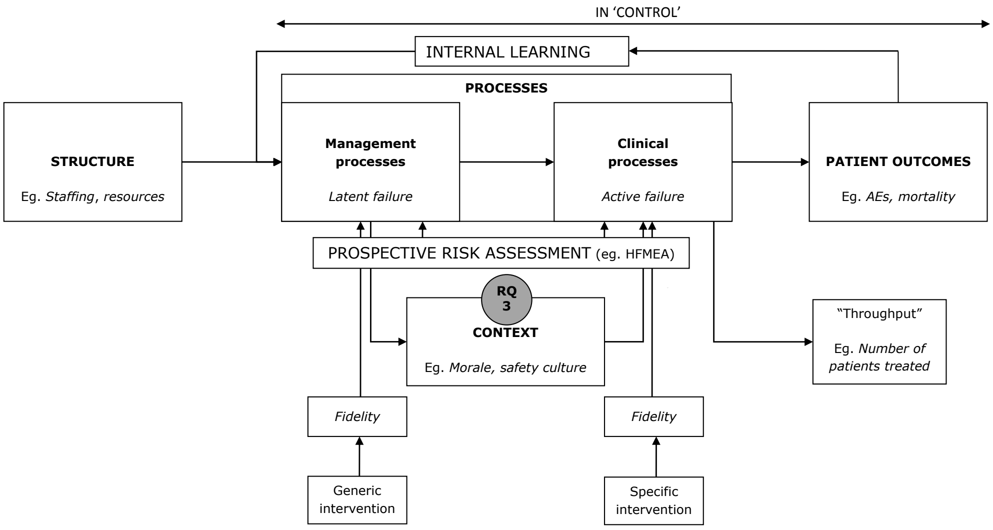
Gelieve de ingevulde vragenlijst via bijgevoegde omslag terug te bezorgen.

HARTELIJK DANK VOOR UW MEDEWERKING!

CHAPTER 6

Variability of patient safety culture

in Belgian acute hospitals



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This chapter will contribute to the book 'Patient Safety Culture: Theory, Methods and Application' to be published by *Ashgate* (2013) (Dr. Patrick Waterson, Editor)

ABSTRACT

Objectives: The aim of this study was to measure differences in safety culture perceptions within Belgian acute hospitals and to examine variability based on language, work area, staff position and work experience.

Methods: The Hospital Survey on Patient Safety Culture was distributed to hospitals participating in the national quality and safety program (2007-2009). Hospitals were invited to participate in a comparative study. Data of 47 136 respondents from 89 acute hospitals were used for quantitative analysis. Percentages of positive response were calculated on 12 dimensions. Generalized Estimating Equations models were fitted to explore differences in safety culture.

Results: Handoffs and transitions, Staffing and Management support for patient safety were considered as major problem areas. Dutch speaking hospitals had higher odds of positive perceptions for most dimensions in comparison with French speaking hospitals. Safety culture scores were more positive for respondents working in pediatrics, psychiatry and rehabilitation compared with the emergency department, operating theatre and multiple hospital units. We found an important gap in safety culture perceptions between leaders and assistants within disciplines. Administration and middle management had lower perceptions towards patient safety. Respondents working less than one year in the current hospital had more positive safety culture perceptions in comparison with all other respondents.

Conclusions: Large comparative databases provide the opportunity to identify distinct high and low scoring groups. In our study, language, work area and profession were identified as important safety culture predictors. Years of experience in the hospital had only a small effect on safety culture perceptions.

INTRODUCTION

Patient safety is high on the agenda in quality improvement strategies and accreditation programs of healthcare organizations in many countries. Important principles underlying accreditation standards include leadership, the creation of safe work environments and continuous quality improvement. Developing a culture of safety is a key element in the improvement of patient safety and quality of care within healthcare organizations. The milestone report of the Institute of Medicine (IOM) highlighted the importance of a safety culture as '*healthcare organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients*'.[1] More specifically, a culture of safety can be personified by the shared values, beliefs, norms, and procedures related to patient safety among members of an organization, work unit, or team. Safety culture forms the staff perceptions on 'normal' behavior related to patient safety in their work area.[2]

Measuring safety culture is considered as a key condition to improve patient safety in Belgian hospitals.[3] In 2007, the Belgian government launched a five-year quality and safety program with a yearly additional financing (annual budget of 7.66 million Euros in 2012) for the acute, psychiatric and long-term care hospitals. The Hospital Survey on Patient Safety Culture (HSPSC), originally developed by the Agency for Healthcare Research and Quality (AHRQ), was selected since it covers a broad range of patient safety aspects and previous research demonstrated good psychometric properties of the survey.[3-8] For the Belgian translations, the reliability coefficients (Cronbach's Alpha) of the 12 safety culture dimensions ranged from 0.57 to 0.85 for the Dutch translation and between 0.52 and 0.87 for the French translation, which is comparable to the original questionnaire. Frequency of events reported and Staffing showed, respectively, the highest and lowest internal consistency.[9, 10] In addition, the HSPSC lends itself well for internal and external benchmarking purposes.[10, 11] Thus far, 143 Belgian hospitals participated in a comparative study managed by a neutral academic institution, in which a patient safety profile was provided for each participating hospital.[10] In the future, safety culture measurements and benchmarking of results will be repeated on a regular basis to track safety culture changes over time.

So far, safety culture measurements have been limited to the diagnosing of problem areas and raising awareness towards patient safety. The implementation of improvement strategies that are tailor-made for target groups is still often deficient. Gallego et al. found that safety culture varies in a limited extent according to the type of service within the South Australian public health system, i.e. community care and smaller hospitals showed a more positive patient safety scoring profile in comparison with larger hospitals (e.g. teaching hospitals) and psychiatric hospitals.[12] It was also demonstrated in previous research that within larger and more complex healthcare organizations, such as hospitals, safety culture varies across units.[13-17] Therefore, it was recommended by Smits et al. that patient safety interventions should be aimed at the level of the hospital unit.[16] Also, Deilkas et al. concluded that safety interventions should not be limited to the hospital level, but should include involvement at the ward level, aimed at low scoring wards.[15] However, there is conflicting evidence to which extent demographic characteristics of healthcare professionals influence safety culture perceptions. Gallego et al. concluded that differences in safety culture were not attributable to staff demographics.[12] In contrast, other studies were able to show differences in attitudes towards patient safety associated with particular groups of healthcare staff.[17]

Clearly, there is a need to measure sources of variation in safety culture perceptions within hospitals, relating to individual and hospital characteristics in order to implement targeted interventions.[18] It is hypothesized that members with the same educational background seem to share a common set of cultural features. Furthermore, hospitals comprise many different types of wards and units, with a high diversity in offered services, patient populations, organizational structure and protocols, which might explain variability in patient safety culture. For instance, it can be assumed that safety culture is associated with the level of complexity and intrinsic hazard associated with healthcare delivered in different work areas.[17] Also the years of experience of hospital staff might influence their perceptions towards patient safety. As staff become more experienced, they might develop a more critical attitude towards patient safety within their work environment. A specific research question for the Belgian hospitals is whether the language context is an influencing factor in safety culture perceptions of hospital staff. Although the federal program on quality and safety was launched in 2007 for all Belgian hospitals, Flemish (Dutch speaking) hospitals have more experience in quality improvement. In an earlier stage, quality management in hospitals was organized at the regional level and was only regulated within the region of Flanders by the Flemish Decree on Quality of Care (1997).

This study was based on the hypothesis that complex healthcare organizations like acute hospitals are likely to comprise a number of coexisting subcultures.[19] The aim of this study was to measure differences in safety culture within Belgian acute hospitals based on language, work area, staff position and years of work experience in the hospital by conducting a multiple regression analysis. Analysis of the individual responses within work unit or staff position can be helpful in targeting efforts to improve patient safety within these levels.

METHODS

Instrument and data collection

The HSPSC includes 42 items that assess safety culture on 12 dimensions, including aspects of patient safety such as, work setting, supervisor support, communication about errors and frequency of events reported. Each item is measured on a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree' (with a midway point of 'neither') or from 'never' to 'always' (with a midway point of 'sometimes').[3] The Belgian versions of HSPSC are validated instruments[3, 9] and are recognized by the Agency for Healthcare Research and Quality (AHRQ) on their list of international survey users.[20] A nationwide baseline patient safety culture measurement was organized by the federal government between 2007 and 2009 for hospitals participating in the federal program on quality and safety. For research purposes, participating hospitals were invited to submit their data to a comparative database. The database is not accessible for the governmental authorities and only includes data of hospitals which voluntarily submitted their data for comparison. In total, 143 hospitals submitted their data for comparison to other hospitals, of which 90 acute, 42 psychiatric and 11 long-term care hospitals.[10] The baseline results from 89 acute Dutch and French speaking hospitals were used in this analysis.

Statistical analysis

An average dimensional score (range 1-5) for each of the 12 dimensions was calculated on the level of the individual respondent. Answers to negatively worded questions were reversed. Dimensional scores higher than 3 were considered as positive values towards patient safety. For exploratory data analysis purposes, the dimensional scores were expressed as the percentage of positive answers towards patient safety for language, work area and staff position.

Multiple regression was performed using the method of Generalized Estimating Equations (GEE)[21] to examine any existing relationships between safety culture predictor variables and each of the 12 safety culture dimensions. The GEE method is applied to estimate the parameters of a generalized linear model accounting for a possible correlation between outcomes.[22] It is assumed that observations from respondents within the same hospital are more alike than observations from different hospitals, inducing within-hospital correlation. The method of GEE estimates 'marginal' effects, which have a population averaged interpretation. This method is also applicable to situations with missing data. A complete case GEE analysis (including only the fully observed cases) is valid under the assumption of Missing Completely At Random (MCAR)[23], but would imply loss of data of incomplete cases and hence would lead to less efficient estimates. Here, missingness was addressed using the method of multiple imputation (number of imputations, m=5)[24], which is a more efficient approach and also valid under the less strict Missing At Random (MAR) assumption. Multiple imputation for missingness was performed in two stages using all available information from the predictor and response variables. First, the missing observations on the hospital level were imputed 5 times. For each of these imputed datasets another 5 imputations were performed for the remaining missingness on the level of the observations. Each of the 25 imputed data sets were fitted using a Generalized Estimating Equations Model.

Binary scores of the safety culture dimensions (score=1 if answer >3 or positive towards patient safety; score=0 if answer ≤3 or negative towards patient safety) were modeled as the response variables. Language, work area, profession, work experience (including items of period working in the current hospital, staff position and work area, and hours worked per week) and direct interaction with patients were considered as predictor variables. For all categorical covariates a reference level for comparison was chosen.

Considering the number of predictor variables and the number of levels for each predictor variable, the initial saturated (or full) model for each of the 12 dimensions was found to be complicated. Therefore, as an initial step in the model building, univariate analysis of all predictor variables was used to investigate the influence on the response variables. The findings did not reveal any justification for dropping any of the predictor variables at this stage. Hence, all predictor variables were treated as equally important. The initial model contained the main effects of all predictor variables. No interaction effects were considered. A step-down hierarchical model building approach was applied to each of the 12 safety culture dimensions. As a result of the analysis, the odds ratios of the response variables were calculated adjusting for all the predictor variables included in the model. In this way, it was possible to investigate the effect of a specific predictor variable (adjusting for all others) on the response variables of the 12 safety culture dimensions.

All data were analyzed using IBM SPSS 20® and SAS 9.2®. The level of significance was chosen to be 5% (i.e. $\alpha=0.05$) throughout the analysis.

RESULTS

Respondent characteristics

The benchmark database includes data of 47 136 respondents (response rate of 51.7%) working in 89 acute hospitals, of which 58 hospitals were Dutch speaking and 31 hospitals were French speaking. Dutch speaking hospitals had a higher overall response rate (58%) in comparison with French speaking hospitals (41.3%), although with a high variability between hospitals. Response rates of physicians (34.3%) were lower compared with response rates of the other hospital staff (54.9%).

Respondents’ characteristics are set out for the Dutch and French speaking hospitals in table 1, based on the respondents’ answers to survey questions.

Table 1: Respondent characteristics

	Total number of respondents 47 136 (100%)			
	French speaking 14 232 (30.2%)		Dutch speaking 32 904 (69.8%)	
Work area	**10 431**	**73.3%**	**27 938**	**84.9%**
Multiple hospital units/No specific unit	1 043	7.3%	2 068	6.3%
Internal Medicine	1 343	9.4%	3 855	11.7%
Surgery	1 169	8.2%	3 719	11.3%
Operating theatre	549	3.9%	2 012	6.1%
Gynecology/ obstetrics	522	3.7%	1 396	4.2%
Pediatrics	528	3.7%	973	3.0%
Intensive care unit	670	4.7%	1 643	5.0%
Emergency	506	3.6%	1 172	3.6%
Rehabilitation	471	3.3%	1 239	3.8%
Geriatrics	444	3.1%	2 119	6.4%
Psychiatry	355	2.5%	981	3.0%
Medical-technical services (diagnostics)	1 067	7.5%	3 580	10.9%
Pharmacy	211	1.5%	613	1.9%
Other*	1 553	10.9%	2 568	7.8%
Missing	*3 801*	*26.7%*	*4 966*	*15.1%*
Staff position	**12 955**	**91%**	**29 403**	**89.4%**
Nurse	6 083	42.7%	16 621	50.5%
Head nurse	655	4.6%	1 366	4.2%
Nursing aid	1 039	7.3%	2 387	7.3%
Physician	953	6.7%	2 184	6.6%
Physician – head of department	479	3.4%	653	2.0%
Physician assistant/ physician in training	66	0.5%	187	0.6%
Pharmacist	110	0.8%	194	0.6%
Assistant pharmacy	100	0.7%	353	1.1%
Administration/ Middle management**	1 195	8.4%	291	0.9%
Technician (EKG, Lab, Radiology)	543	3.8%	1 513	4.6%
Therapist (dietitian, physical, psychologist)	797	5.6%	1 853	5.6%
Other*	935	6.6%	1 801	5.5%
Missing	*1 277*	*9%*	*3 501*	*10.6%*

Respondent characteristics continued	**French speaking 14 232 (30.2%)**		**Dutch speaking 32 904 (69.8%)**	
Period working in current hospital	**14 043**	**98.7%**	**30 753**	**93.5%**
Less than 1 year	849	6.0%	1 786	5.4%
1 to 5 years	2 810	19.7%	6 501	19.8%
6 to 10 years	2 490	17.5%	5 380	16.4%
11 to 15 years	1 643	11.5%	3 731	11.3%
16 to 20 years	2 156	15.1%	4 296	13.1%
21 years or more	4 095	28.8%	9 059	27.5%
Missing	*189*	*1.3%*	*2 151*	*6.5%*
Direct interaction with patients	**13 811**	**97%**	**30 369**	**92.3%**
YES, have direct patient interaction	12 435	87.4%	27 358	90.1%
NO, do NOT have direct patient interaction	1 376	9.7%	3 011	9.9%
Missing	*421*	*3%*	*2 535*	*7.7%*

*****Many respondents chose the 'Other' response option, which allowed them to note their specific work area or staff position, but no data are available to further describe the respondents in the 'Other' categories.

**Administration/ middle management includes all hospital staff working in administration or holding a managerial function.

Missingness

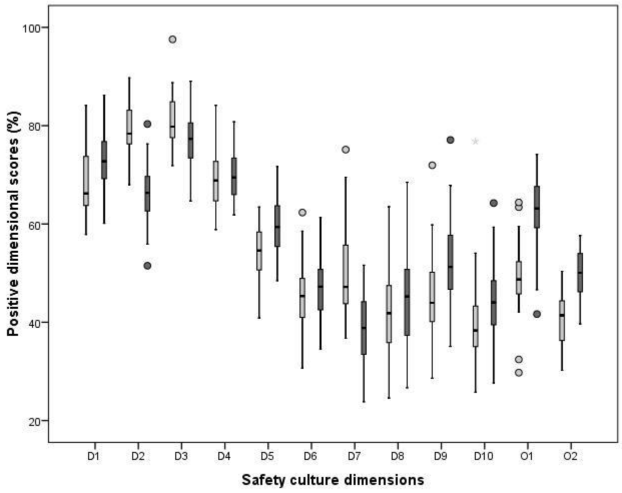
For most dimensional variables, missing data rates were low (<2 %) except for the dimension Frequency of events reported (O2), which had a missing rate of 6.4%. Missingness was more frequent in the predictor variables (5% or more), such as 18.4% for work area and 10% for staff function, as compared with missingness in the dimensional variables (response variables).

Positive dimensional scores

Exploratory data analysis indicated that overall safety culture scores were low to moderate and varied widely across Dutch and French speaking hospitals, work units and disciplines.

In figure 1 and Appendix I positive dimensional scores are presented by language. Generally, the lowest positive dimensional scores were found for the dimensions Handoffs and transitions (D10), Staffing (D7) and Management support for patient safety (D8). Dimensional scores were more positive for Dutch speaking hospitals in comparison with French speaking hospitals, except for the dimensions of Organizational learning and continuous improvement (D2), Teamwork within units (D3) and Staffing (D7). Positive dimensional scores for Overall perceptions of patient safety (O1) were 14.5% lower for French speaking hospitals.

Figure 1: Positive dimensional scores for language

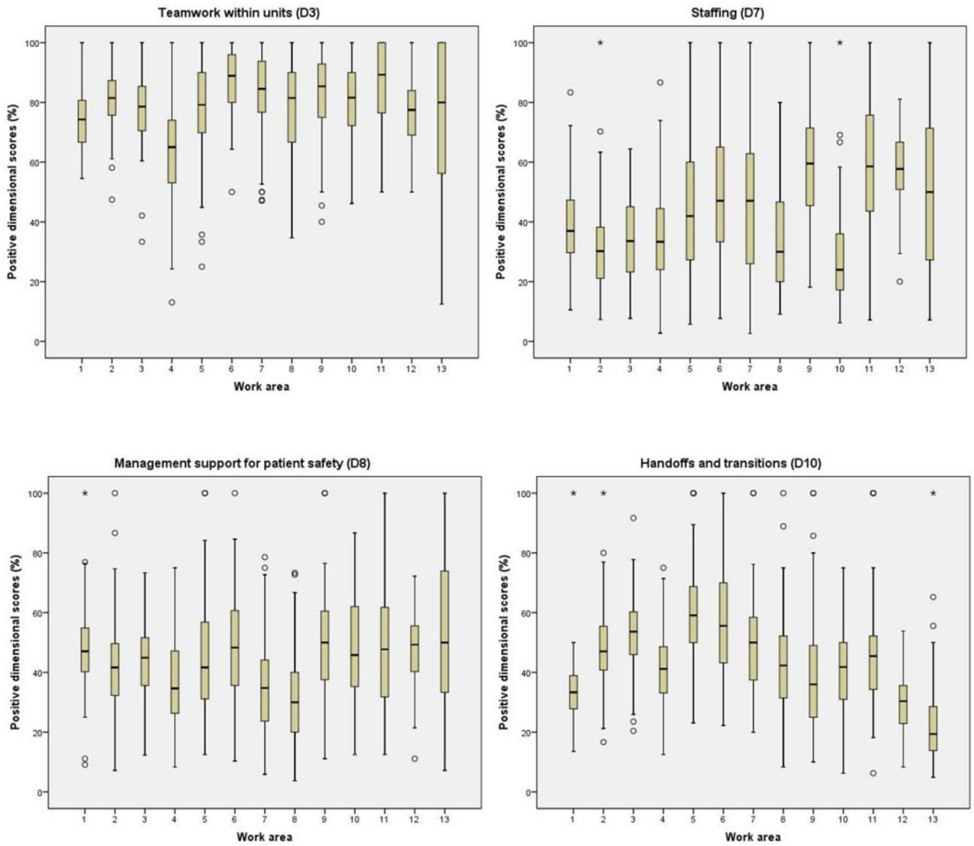


Light grey box plots present the positive dimensional scores of the French speaking hospitals (n=31). Dark grey box plots present the positive dimensional scores of the Dutch speaking hospitals (n=58).

Safety culture dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

In figure 2 and Appendix II positive dimensional scores are displayed by work area. Perceptions on Teamwork within units (D3) were lower for staff working in the operating theatre (65%) than staff working in psychiatry (89.3%) and pediatrics (88.9%). Geriatrics had the lowest scores on Staffing (D7; 24%), while rehabilitation had the highest perceptions on this dimension (59.5%). The lowest scores for Handoffs and transitions (D10) were found for respondents working in multiple units (33.3%), medical-technical services (30.3%) and pharmacy (19.4%). Overall perceptions of patient safety (O1) were found to be low for respondents working in the emergency department (40.5%) compared to medical-technical services (71.3%) and pediatrics (69.6%).

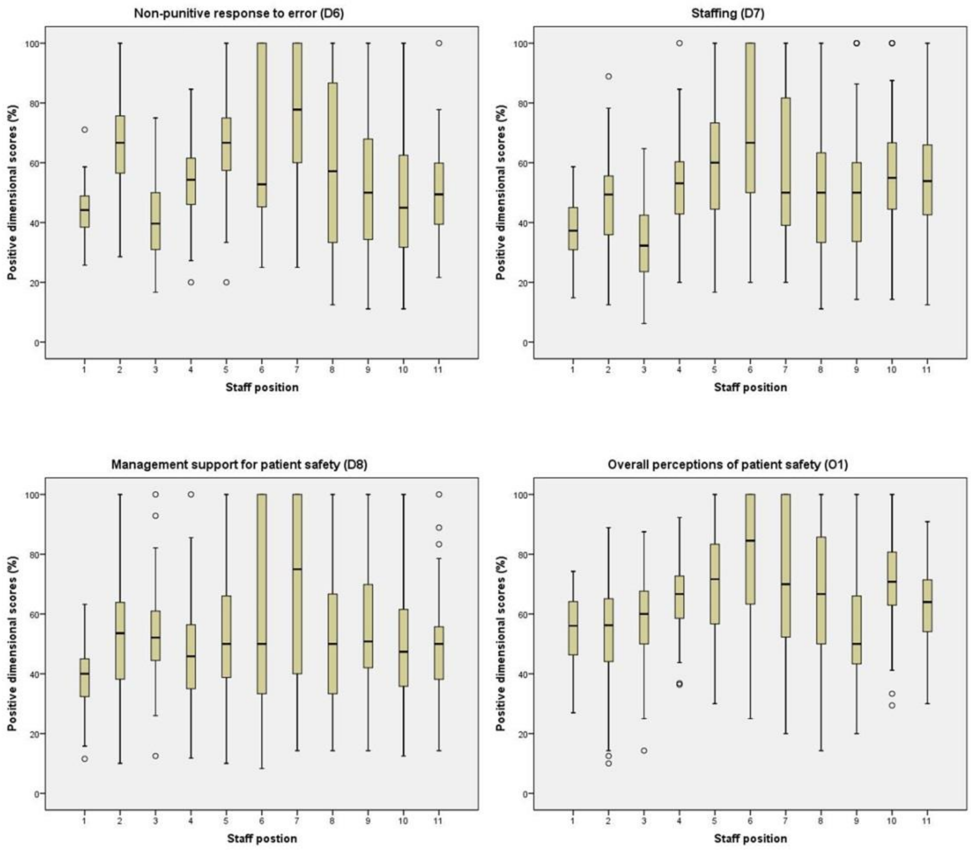
Figure 2: Positive dimensional scores for work area (selected dimensions)



Work area: 1=Multiple hospital units/No specific unit, 2=Internal Medicine, 3=Surgery, 4=Operating theatre, 5=Gynecology/ obstetrics, 6=Pediatrics, 7=Intensive care unit, 8=Emergency, 9=Rehabilitation, 10=Geriatrics, 11=Psychiatry, 12=Medical-technical services (diagnositics), 13=Pharmacy

Figure 3 and Appendix III present the positive dimensional scores for staff position. Results show a gap in safety culture perceptions within disciplines since clinicians with a higher hierarchical position including head nurses, head physicians and pharmacists had better perceptions in comparison to clinicians with a lower hierarchical position, such as nurses, nursing aids, physician assistants and pharmacist assistants. Nurses and nursing aids had lower scores for Non-punitive response to error (D6; respectively 44.2% and 39.6%) in comparison to physicians (54.3%). Pharmacists had more positive but divergent scores on the dimension of Non-Punitive response to error (D6; 77.8%) and Management support for patient safety (D8; 75%). Nurses and physician assistants had low scores on Management support for patient safety (D8; respectively 40% and 50%). Staffing (D7) was found to be problematic for the nursing profession and in particular for the nursing aids (33.3%). Overall perceptions of patient safety (O1) were more favorable for head physicians (71.7%) as compared to all other groups.

Figure 3: Positive dimensional scores for staff position (selected dimensions)



Staff position: 1=Nurse, 2=Head Nurse, 3=Nursing Aid, 4=Physician, 5=Physician, Head of Department, 6=Physician Assistant/ in Training, 7=Pharmacist, 8=Assistant Pharmacy, 9=Administration/Middle Management, 10=Technician, 11=Therapist

Regression Analysis Models

Results of the GEE model fit (Odds ratios) are displayed in Table 2 for variables with a significant impact on safety culture scores. Years of experience in the current work area and profession, numbers of hours worked per week and direct interaction were found to have only a small significant effect on safety culture perceptions.

The odds of having positive values towards patient safety were found to be significantly lower for French speaking in comparison with Dutch speaking respondents for all dimensions, except for Organizational learning–continuous improvement (D2; OR 1.92), Teamwork within units (D3; OR 1.48) and Staffing (D7; OR 1.48). Furthermore, results for patient safety perceptions between hospital units (with the reference category of internal medicine) were less straightforward over the different dimensions. Respondents working in low hazard units, e.g. rehabilitation and psychiatric units, had higher odds of having positive perceptions towards patient safety with significant OR for Organizational learning and continuous improvement (D2), Non-punitive response to error (D6) and Staffing (D7). Geriatrics had significantly higher OR for Organizational learning and continuous improvement (D2; OR 1.38), Feedback and error communication (D5; OR 1.17), Management support for patient safety (D8; OR 1.14) and Frequency of error reporting (O2; OR 1.19). In contrast, respondents working in multiple units or higher hazardous units, such as the operating theatre and emergency care had significantly lower OR for most dimensions. The OR for Handoffs and transitions (D10) were the lowest for the medical-technical services (OR 0.68) and pharmacy (OR 0.55). Analysis of staff position showed that head nurses, head physicians and pharmacists had higher odds of positive perceptions in comparison with respectively the nurses and nursing aids, physicians and assistants, and pharmacy assistants. The odds of better safety culture perceptions were higher for respondents working less than one year in comparison with respondents working over 21 years in the current hospital.

Table 2: Odds Ratios for safety dimensions (General Estimating Equations)

Variables	Odds Ratios											
Language (reference = Dutch speaking)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
French speaking	**0.79***	**1.92***	**1.20***	**0.92***	**0.82***	**0.90***	**1.48***	**0.83***	**0.71***	**0.85***	**0.56***	**0.64***
Work Area (reference = Internal Medicine)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Multiple Units	**0.70***	**0.82***	**0.76***	**0.78***	**0.76***	**0.80***	**1.24***	1.10	1.01	**0.73***	**0.85***	**0.64***
Surgery	**0.90***	0.98	**0.87***	0.97	1.04	0.96	**1.19***	1.06	1.06	**1.24***	**1.10***	**0.88***
Operating theatre	**0.66***	**0.84***	**0.48***	**0.79***	**0.75***	0.86	1.06	0.90	1.06	**0.84***	**0.84***	**0.77***
Gynecology	**0.71***	**0.80***	0.91	**0.85***	**0.88***	**0.88***	**1.65***	1.00	**1.13***	**1.38***	1.11	**0.69***
Pediatrics	1.06	1.07	1.14	**1.24***	1.07	**1.19***	**1.85***	1.07	1.00	**1.15***	**1.28***	0.96
Intensive Care Unit	**0.82***	**0.84***	0.95	0.93	**0.85***	1.01	**1.92***	**0.82***	0.95	0.97	**1.10***	**0.76***
Emergency	**0.79***	**0.65***	**0.81***	**0.87***	**0.77***	**0.73***	**1.39***	**0.78***	**0.69***	**0.82***	**0.68***	**0.67***
Rehabilitation	0.98	**1.23***	1.01	1.14	1.11	**1.26***	**2.21***	**1.21***	0.98	**0.84***	**1.30***	0.96
Geriatrics	0.99	**1.38***	0.96	1.06	**1.17***	1.05	1.12	**1.14***	0.98	**0.85***	0.99	**1.19***
Psychiatry	1.04	**1.31***	1.08	1.03	**1.17***	**1.31***	**2.72***	1.00	1.01	**0.88***	1.11	1.07
Medical-technical services	**0.80***	0.96	**0.79***	1.01	**1.27***	1.09	**2.58***	1.09	0.97	**0.68***	**1.62***	**0.91***
Pharmacy	0.85	1.13	**0.75***	**1.23***	1.12	**1.29***	**1.84***	0.99	0.94	**0.55***	**1.33***	1.14
Period in current hospital (reference = 21 years or more)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Less than 1 year	**1.33***	0.99	**1.40***	**1.29***	**1.27***	1.14	1.13	**1.35***	**1.17***	**1.39***	**1.46***	1.10
1 to 5 years	0.95	**0.78***	1.02	0.93	0.96	0.98	1.04	0.97	**0.87***	**1.12***	1.10	0.96
6 to 10 years	0.88	**0.78***	1.06	**0.86***	**0.86***	0.92	0.94	0.92	**0.84***	1.00	0.98	**0.88***
11 to 15 years	0.99	0.95	1.03	0.93	0.94	0.96	1.01	0.93	**0.89***	1.00	1.01	0.94

16 to 20 years	0.91	0.89	1.02	0.91	0.92	**0.91***	1.00	**0.89***	**0.90***	0.98	0.97	1.01
Profession (reference = nurse)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Head Nurse	**1.39***	**1.57***	**1.59***	**2.19***	**1.42***	**1.92***	**1.38***	**1.49***	**1.33***	**1.16***	1.04	**1.12***
Nursing Aid	**1.12***	0.93	**0.86***	1.02	**1.28***	**0.92***	**0.91***	**1.45***	1.00	0.93	**1.13***	**1.15***
Physician	1.00	1.00	**1.39***	1.12	1.01	1.03	**1.36***	**1.45***	0.98	**0.88***	**1.68***	1.01
Physician, Head of Department	0.96	0.96	**1.48***	1.01	**1.40***	1.01	**1.30***	**1.43***	1.02	0.96	**1.71***	0.97
Physician Assistant/ in Training	0.93	1.02	0.98	0.98	0.92	1.03	1.27	**1.47***	0.98	**0.75***	1.18	0.85
Pharmacist	1.05	1.15	1.21	**1.27***	1.10	**1.36***	**1.35***	**1.63***	1.27	**0.58***	1.21	1.00
Assistant Pharmacy	**0.75***	**0.67***	0.82	**0.79***	0.87	0.92	1.14	**1.42***	0.88	**0.58***	1.13	0.93
Administration/ Middle Management	**0.75***	**0.63***	**0.83***	**0.75***	**0.78***	**0.83***	**1.14***	**1.57***	0.90	**0.60***	1.01	**0.60***
Technician	**0.76***	**0.77***	0.96	**0.84***	0.92	0.90	**1.48***	**1.21***	0.91	**0.63***	**1.28***	**1.14***
Therapist	**0.69***	**0.65***	1.09	**0.87***	**0.75***	**1.13***	**1.60***	**1.19***	**1.13***	**0.58***	**1.36***	**0.63***

***Indicates statistically significant at 5% level of significance.** Light grey areas show significant higher odds; Dark grey areas show significant lower odds than the reference group.

Safety culture dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

DISCUSSION

Our multicenter study aimed at examining differences in safety culture perceptions within Belgian acute hospitals based on language, work area, staff position and work experience.

We succeeded to gather questionnaires from 47 136 respondents working in 89 acute hospitals. Similar to international studies, we found differences in response rates between medical staff (34.3%) and employees (54.9%). Although hospitals made efforts to encourage physicians to participate in the survey by sending reminders or assuring confidentiality, the medical staff seemed more difficult to be involved. Response rates were higher for Dutch speaking hospitals (58% response rate) in comparison with French speaking hospitals (41.3% response rate). In addition, we found that safety culture perceptions were overall more positive within Dutch speaking hospitals. The higher response rate and more positive safety cultures scores in the Dutch speaking hospitals could be explained by the fact that local patient safety initiatives were undertaken at an earlier stage within the Flemish (Dutch speaking) hospitals. This might have raised the experience and overall awareness of patient safety of the Flemish healthcare professionals.

Our data add to the suggestion, as concluded in prior research, that patient safety interventions should not solely be addressed at the hospital level, but should be tailored for professional groups and work units, without stigmatizing groups as 'low-scoring'.[15, 17] What's more, lessons could be learned from better scoring groups. Our results pointed out that Handoffs and transitions (D10), Staffing (D7) and Management support for patient safety (D8) are major problem areas in the Belgian hospitals and obviously require being an organization-wide priority. In particular, Handoffs and transitions (D10), referring to aspects such as the loss of information when transferring patients from one unit to another or during shift changes, was identified as a significant problem for the pharmacy, medical-technical services and staff working in multiple units. Healthcare professionals that provide services to other work units, or that shift frequently, have a clearer view on the transitional care processes and the flow of patient information, which could explain a higher awareness and the lower scores within this dimension. Although Staffing (D7) has low reliability scores (Chronbach's alpha of 0.57 for the Dutch translation and 0.52 for the French translation), as also reported in American[7, 20, 25] and European studies,[4-6, 8-10] this dimension provides important information on the workload for hospital staff. In our study, Staffing (D7) was identified as a major problem within geriatrics, the operation room, and the internal and surgical units and particularly for the nursing professions. Scores on this dimension reflect the current norms on staffing within the Belgian hospital financing and thus should be a signal for the federal authorities to invest into higher (nurse) staffing levels.

Furthermore, we found that the emergency care, intensive care units, the operating theatre, gynecology and staff working in multiple units had lower scores on Overall perceptions of patient safety (O2) in comparison with geriatrics, rehabilitation, pediatric and psychiatric units. Prominent low scores were found in the operating theatre for Teamwork within units (D3; 65% positive scores), derived from survey items such as '*People support one another in this unit*' and '*When a lot of work needs to be done quickly, we work together as a team to get the work done'*. Lessons on teamwork within units (D3) could be learned from psychiatry (89.3% positive scores) and pediatrics (88.9% positive scores). It is remarkable that intensive care and emergency care units, which provide more complex and hazardous care, had significant lower OR of positive perceptions on Management support for patient safety (D8). In our survey, this dimension measures the extent in which hospital management provides a work climate that promotes patient safety and show that patient safety is a top priority. Our findings may reflect actual poor hospital management in these work units. In a multicenter study of Huang et al. in 30 intensive care units (ICUs), safety climate scores were linked with clinical outcomes.[26] In their study, perceptions of management were measured by the Safety Attitudes Questionnaire and referred to approval of hospital managerial actions, derived from survey items such as '*Hospital administration supports my daily efforts*' and '*Hospital management does not knowingly compromise the safety of patients*'. They found that lower perceptions of management were significantly associated with higher hospital mortality in ICUs. Results of Kaafarani et al. point in the same direction, as they show that patient safety culture in post-anesthesia care units and the operating room was less favorable in comparison with other hospital units on the particular aspect of a 'lack of understanding of the senior management' [13]. Also Singer et al. reported that emergency department personnel had lower perceptions of safety climate in comparison with workers in other areas.[17] A possible explanation for the low safety culture perceptions in high intrinsic hazard units, such as operating theatres, intensive care units and emergency departments is that these units usually have a high turnover of patients and are dealing with more complex tasks and thus could be more frequently witnessing of unsafe patient care.[13] Since these units experience a high work pressure and healthcare professionals are operating under less comfortable conditions, they might set lower priorities for safety versus priorities for speed or productivity.

Besides variation in safety culture between hospital units, there seems to be a considerable disparity among safety culture perceptions between and within disciplines. Our findings are in line with results of prior studies investigating the perceptions of professional groups towards patient safety.[27, 28] Our results point out that clinicians with a higher hierarchical position have more positive safety culture perceptions in comparison with staff holding a lower hierarchical position. In our study, head nurses had more positive perceptions compared with nurses and nursing aids. The gap in safety culture perceptions between pharmacists and pharmacy assistants was found to be peculiar. In the same respect, physician heads had higher safety culture scores in comparison with physicians and physicians in training for most dimensions. A possible explanation is that clinical department heads tend to overestimate their units' safety performance.[29] In addition, ranges for positive dimensional scores were larger for staff position than for work area, suggesting higher culture differences based on professional or educational background than work area.

Finally, in our GEE model we included variables of period working in the current hospital unit or profession, working hours per week and direct interaction with patients in order to provide accurate estimations of odds ratios. However, we only found minor significant effects of these variables on patient safety culture perceptions. Period working in the current hospital had a significant impact, since staff working less than one year had higher odds of positive perceptions on most aspects in comparison to their more experienced colleagues. This group seems to be less aware of patient safety and requires a higher attention, for instance in educational and training programs on patient safety.

There are some limitations to this study. First, although overall response rates were favorable in comparison with other international studies, there was a lower response from the medical staff (34.9%) in comparison with other employees (55%). This could result in overestimation of safety culture scores, as non-responders could be more dissatisfied in their work environment or function.[14] Although differences in response rates cannot be ruled out entirely, we addressed missingness in our analysis by multiple imputation, taking into account the differences in response rates of all hospital staff.

A second limitation in our study is that we limited our analysis to variables that were included in the survey questionnaire (e.g. work area, staff position, period working in the hospital) and that we did not dispose of control variables for drawing alternative conclusions. For instance, the inclusion of the average bed occupancy for each hospital unit or the nursing staffing ratio could have been applied as control variables for the workload in each unit. Hence, our conclusions are based on a limited number of independent variables, which cannot possibly fully explain the mechanisms underlying the variability in safety culture perceptions.

Another limitation concerns data collection at a lower micro-level. In our study, we addressed variation in safety culture by examining perceptions at the level of the hospital units and professional groups. Based on the structure of the HSPSC, respondents are categorized by work area and profession. Given our approach of guaranteeing the anonymity of individual respondents, it was not possible to measure variation at the team level, as for instance the lower perceptions of Teamwork within units (D3) within the operating theatres. It would be interesting for future research to focus on (operating) teams, since their structure, functioning and autonomy differ across hospitals.

Up till now, only few studies investigated the relationship between safety culture perceptions and outcomes of care.[26, 30] For instance, earlier research demonstrated that most adverse events occur in surgical care and that the use of surgical briefings or checklists is related with a better safety climate within the operating theatre.[28] Data collection at the team level might help explaining variability of safety culture.

An interesting area warranting further research is the predictive validity of safety culture instruments, which is whether safety culture scores can be related to safety performance (safe behavior, such as better adherence to procedures e.g. safe surgery checklist) and outcomes of care (e.g. less adverse events, lower mortality). [31-33] For instance, future research should address the research hypothesis that hospital management support for patient safety or the safety priority moderates safety performance. In our study, we found that the perceptions of management support varied between different hospital units, as a result of their diverse activities. In high hazardous units (e.g. operating theatre, emergency care), work speed and productivity might have a higher priority than safety. A higher priority of safety in these units can potentially motivate staff to take greater ownership of, and responsibility for safety. This, in turn, is likely to influence the tendency of staff to behave safely.[34]

CONCLUSION

In this multicenter study of Belgian acute hospitals we found that language (in the Belgian federal context), work area and staff position had a significant influence on patient safety culture perceptions. A polarization of safety perceptions was observed between staff with a higher hierarchical position and staff with a lower hierarchical position. In addition, variations in perceptions were measured between high and low intrinsic hazardous units. Years of experience in the hospital had only a small effect on safety culture perceptions.

Hospital management should be aware that there is a high variability in safety culture between different units and professional groups. Our approach of comparing safety culture perceptions based on a large dataset indicates that improvement strategies should be tailored for a local level within the hospital. Future research should address the relationship between safety culture and outcomes of care at all levels of the organization. In particular, the level of priority that management gives to safety within hospital units might influence safety performance and outcomes.

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Appendix I - Positive dimensional scores for language (median, percentile 25 and percentile 75)

Safety culture dimensions		Language		Safety culture dimensions		Language	
		French	**Dutch**			**French**	**Dutch**
D1	Median	66.2	72.8	**D7**	Median	47.2	38.8
	P25	63.8	69.2		P25	43.7	33.5
	P25	74.1	76.8		P25	56.2	44.2
D2	Median	78.4	66.3	**D8**	Median	41.8	45.3
	P25	76.2	62.6		P25	35.8	37.3
	P25	84.1	69.7		P25	47.6	50.7
D3	Median	79.8	77.3	**D9**	Median	44.0	51.3
	P25	77.2	73.4		P25	40.0	46.7
	P25	85.8	80.6		P25	50.7	57.7
D4	Median	68.9	69.5	**D10**	Median	38.3	44.0
	P25	64.6	66.0		P25	34.3	39.5
	P25	73.5	73.4		P25	44.3	48.5
D5	Median	54.6	59.4	**O1**	Median	48.7	63.2
	P25	50.6	55.4		P25	45.6	59.2
	P25	58.6	63.7		P25	52.5	67.6
D6	Median	45.3	47.2	**O2**	Median	41.4	50.1
	P25	40.9	42.5		P25	36.2	46.2
	P25	49.1	50.8		P25	44.6	54.0

Safety culture dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

Appendix II - Positive dimensional scores for work area (median, percentile 25 and percentile 75)

		D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	O1	O2
Multiple hospital units/ no specific unit	Median	66.7	64.9	74.3	62.7	50.0	41.7	37.0	47.1	48.1	33.3	51.5	36.0
	P 25	56.4	54.5	66.7	52.9	36.8	32.6	29.4	40.0	42.9	27.8	43.2	27.8
	P 75	71.0	73.1	80.7	69.8	56.6	46.2	47.4	55.6	57.9	39.0	59.7	42.1
Internal Medicine	Median	73.5	72.1	81.5	70.2	57.5	44.2	30.2	41.7	52.1	47.0	56.1	50.0
	P 25	68.2	62.9	75.7	63.8	48.0	38.1	21.1	32.3	42.6	40.8	47.0	43.8
	P 75	80.0	81.1	87.3	76.0	657	53.6	38.4	49.6	60.0	55.4	65.7	59.0
Surgery	Median	70.5	73.1	78.6	69.8	59.1	42.5	33.6	44.9	51.5	53.7	58.7	47.6
	P 25	65.3	62.7	70.5	62.9	51.3	37.4	22.4	35.3	44.6	45.8	46.5	39.2
	P 75	80.3	79.6	85.4	75.4	66.6	52.3	45.5	52.2	62.4	60.5	66.7	53.2
Operating theatre	Median	66.7	66.7	65.0	63.6	47.1	41.0	33.3	34.6	50.7	41.2	49.7	40.6
	P 25	55.6	54.8	52.8	55.9	39.7	33.3	24.1	26.3	39.4	32.9	40.0	33.3
	P 75	80.0	78.9	74.7	70.8	60.0	51.5	44.4	47.2	63.4	48.8	64.3	50.0
Gynecology/ obstetrics	Median	71.8	66.7	79.2	67.5	54.5	43.2	41.9	41.7	55.4	59.1	61.1	40.0
	P 25	60.7	53.6	69.2	56.3	46.2	32.5	27.3	31.0	43.2	50.0	50.0	33.3
	P 75	79.3	80.8	90.0	78.9	64.3	54.3	60.0	57.1	65.4	68.8	72.7	50.0
Pediatrics	Median	82.9	78.6	88.9	80.0	65.7	53.8	47.1	48.3	50.0	55.6	69.6	57.1
	P 25	73.1	65.0	80.0	70.6	54.5	40.0	33.3	35.5	36.8	42.9	53.8	40.0
	P 75	91.7	90.0	96.9	88.5	78.6	68.0	65.0	60.9	62.5	70.0	82.4	66.7
Intensive care unit	Median	75.0	71.0	84.5	72.4	54.4	50.0	47.0	34.8	47.6	50.0	61.3	44.4
	P 25	63.1	57.1	76.7	63.6	41.6	35.7	26.0	23.7	36.2	37.0	47.6	33.3
	P 75	90.9	81.9	93.8	79.7	66.7	62.2	62.8	44.1	58.7	58.5	72.5	57.1

Appendix II continued		D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	O1	O2
Emergency	Median	73.1	60.0	81.5	68.2	46.7	33.3	30.0	30.0	37.1	42.3	40.5	35.7
	P 25	58.3	46.7	66.7	57.1	39.3	25.0	20.0	20.0	27.3	31.4	29.8	26.7
	P 75	81.3	70.0	90.0	78.6	60.0	45.8	46.7	40.0	50.0	52.2	52.6	45.5
Rehabilitation	Median	76.5	78.6	85.4	74.3	60.4	56.4	59.5	50.0	50.0	36.0	66.7	47.0
	P 25	63.1	66.7	75.0	62.0	50.0	42.9	45.5	36.7	38.5	25.0	57.1	36.4
	P 75	85.4	88.5	92.9	81.4	66.7	70.3	71.4	61.0	65.9	50.0	75.7	57.5
Geriatrics	Median	77.8	80.0	81.6	70.6	63.2	48.1	24.0	45.8	46.8	41.8	55.0	55.9
	P 25	66.7	70.6	72.2	64.0	52.6	38.5	17.2	35.3	33.8	31.0	42.1	48.1
	P 75	84.6	86.2	90.0	79.3	73.5	55.6	36.0	62.0	59.7	50.0	62.9	63.5
Psychiatry	Median	79.4	78.6	89.3	72.2	58.1	56.8	58.6	47.7	50.0	45.5	54.2	55.6
	P 25	70.0	68.6	76.5	62.5	50.0	46.2	43.6	31.8	36.4	34.3	45.8	44.4
	P 75	90.9	88.6	100	86.1	75.8	66.7	75.7	61.8	66.7	52.2	70.5	66.7
Medical-technical services	Median	71.4	70.6	77.5	69.7	63.8	51.1	57.7	49.3	48.2	30.3	71.3	52.2
	P 25	65.5	61.5	68.4	63.6	55.2	42.2	50.8	40.0	39.6	22.9	62.5	45.0
	P 75	76.2	80.6	84.2	75.6	69.4	58.9	66.7	55.6	55.1	35.7	75.6	60.0
Pharmacy	Median	75.6	75.0	80.0	75.0	66.7	59.2	50.0	50.0	50.0	19.4	65.9	57.1
	P 25	54.5	56.0	56.3	63.6	50.0	42.9	27.3	33.3	31.8	13.8	50.0	42.9
	P 75	100.	87.5	100.	100.	77.8	75.0	71.4	73.9	66.7	28.6	76.5	77.3

Safety culture dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

Appendix III: Positive dimensional scores for staff position (median, percentile 25 and percentile 75)

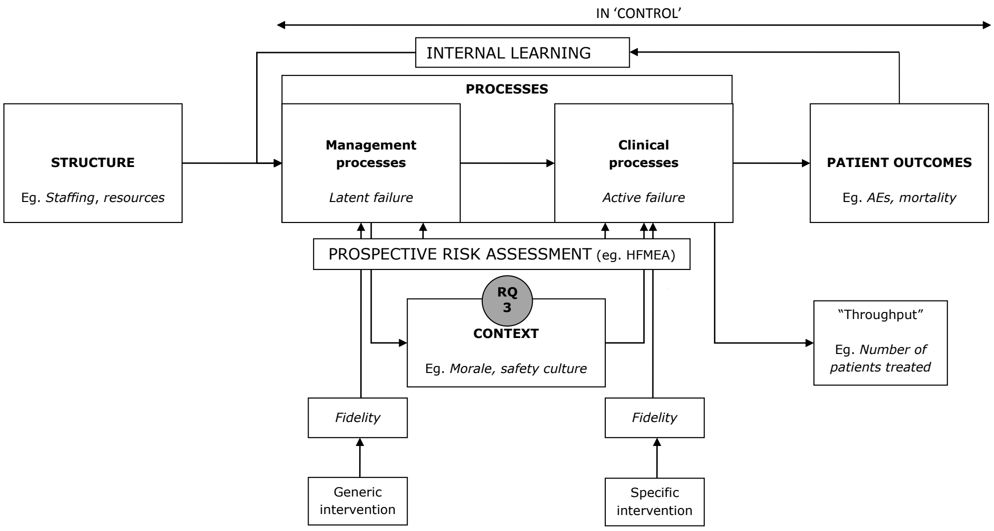
		D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	O1	O2
Nurse	Median	72.0	70.8	78.1	68.1	56.9	44.2	37.3	40.0	47.4	46.8	56.0	47.4
	P 25	68.9	64.1	74.1	64.1	53.2	38.4	30.9	32.4	41.4	42.0	46.3	41.0
	P 75	78.2	79.2	82.2	71.6	61.4	48.9	45.0	45.0	53.1	51.2	64.2	52.4
Head nurse	Median	83.2	82.0	88.7	87.6	66.7	66.7	49.4	53.6	58.3	50.0	56.3	51.0
	P 25	73.9	75.0	81.2	83.0	59.2	56.5	36.0	38.2	46.7	39.6	43.8	41.3
	P 75	88.2	88.9	93.8	93.0	76.7	75.7	55.6	63.9	66.7	60.4	65.2	60.4
Nursing aid	Median	75.2	70.8	78.6	69.7	66.2	39.6	32.3	52.1	47.8	45.5	60.0	52.3
	P 25	67.9	62.2	70.0	62.7	56.8	31.0	23.3	44.4	38.6	37.5	50.0	43.0
	P 75	81.9	81.3	84.3	76.9	74.7	50.0	42.9	61.0	59.0	55.9	67.6	62.8
Physician	Median	69.2	70.4	82.9	75.6	56.1	54.3	53.1	45.8	58.4	40.0	66.7	46.2
	P 25	60.5	59.4	76.3	68.6	44.9	46.0	42.9	35.0	48.8	34.1	58.6	39.7
	P 75	78.0	80.0	88.2	82.4	63.4	61.5	60.3	56.4	66.7	45.8	72.7	53.8
Physician, Head of Department	Median	75.6	80.4	87.5	84.0	71.0	66.7	60.0	50.0	62.0	43.4	71.7	50.0
	P 25	61.5	66.7	79.3	77.8	56.7	57.1	44.4	37.5	50.0	35.3	56.7	40.0
	P 75	87.5	90.1	93.5	93.3	81.5	75.0	73.3	66.7	73.3	55.6	83.3	64.0
Physician Assistant/ in Training	Median	83.3	90.0	100	100	75.0	52.8	66.7	50.0	66.7	43.7	84.5	50.0
	P 25	66.7	55.6	75.0	75.0	50.0	45.2	50.0	33.3	50.0	33.3	63.3	38.8
	P 75	100	100	100	100	100	100	100	100	100	66.7	100	100

Appendix III continued		D1	D2	D3	D4	D5	D6	D7	D8	D9	D10	O1	O2
Pharmacist	Median	100	100	100	100	75.0	77.8	50.0	75.0	60.0	33.3	70.0	66.7
	P 25	75.0	80.0	75.0	80.0	60.0	60.0	39.0	40.0	44.4	20.0	50.0	41.7
	P 75	100	100	100	100	100	100	81.7	100	83.3	50.0	100	100
Assistant Pharmacy	Median	70.0	67.7	68.2	71.4	66.7	57.1	50.0	50.0	50.0	33.3	66.7	64.1
	P 25	50.0	50.0	50.0	50.0	50.0	33.3	33.3	33.3	30.8	18.7	50.0	47.1
	P 75	100	88.9	100	100	83.3	90.0	63.3	66.7	64.7	50.0	85.7	83.3
Admini-stration/ Middle Management	Median	75.7	75.0	80.0	73.2	53.8	50.0	50.0	50.8	50.0	33.3	50.0	33.3
	P 25	55.0	64.0	71.4	50.9	41.7	33.3	33.7	42.0	33.3	23.2	42.9	25.0
	P 75	100	100	100	100	72.7	69.2	60.0	69.9	66.7	50.0	66.7	43.2
Technician	Median	66.1	64.5	75.9	64.6	61.0	44.9	54.9	47.4	46.9	28.6	70.8	55.0
	P 25	57.1	52.9	66.7	51.7	50.0	31.7	44.4	35.8	30.0	17.9	63.0	42.3
	P 75	75.0	78.3	83.9	75.0	75.4	62.5	66.7	61.5	57.5	35.4	80.7	65.8
Therapist	Median	63.8	66.7	83.3	66.7	47.0	49.4	53.9	50.0	52.8	29.4	64.0	36.4
	P 25	54.4	55.1	75.9	57.8	38.0	39.4	42.6	38.1	40.0	20.3	54.1	28.6
	P 75	73.9	74.3	87.5	72.9	58.3	59.9	65.9	55.9	58.8	38.7	71.4	48.0

Safety culture dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported

CHAPTER 7

Measuring safety culture in Belgian psychiatric hospitals: Validation of the Dutch and French translation of the Hospital Survey on Patient Safety Culture



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ABSTRACT

Objective: To measure safety culture on 12 dimensions within Belgian psychiatric hospitals. To examine the psychometric properties of the Dutch and French translation of the Hospital Survey on Patient Safety Culture (HSPSC) for use within psychiatric hospitals.

Methods: 6 658 completed questionnaires (70.5% response rate) from a baseline measurement (2007-2009) in 44 psychiatric hospitals and 8 290 questionnaires (71.5% response rate) from a follow-up measurement (2011) in 46 psychiatric hospitals were used for analysis. Psychometric properties of the questionnaire were investigated by item analysis, exploratory factor analysis (EFA), confirmatory factor analysis (CFA), reliability analysis (Cronbach Alpha) and analysis of the composite scores and inter-correlations.

Results: For both translations, CFA showed an acceptable fit with the original 12-dimensional model. EFA showed a 10-factor and a 9-factor optimal measurement model for respectively the Dutch and French translation. Cronbach's alpha indicated for most dimensions an acceptable level of reliability (≥0.70). Most pair-wise correlations were significant and less than 0.5 implying a good construct validity.

Conclusion: The Dutch and French translations of the HSPSC were found to be valid and reliable for measuring patient safety culture in psychiatric hospitals. Nevertheless, our results suggest combinations of specific dimensions as also recommended in previous research.

INTRODUCTION

Since the publication of the report 'To err is human' by the Institute of Medicine (IOM) in 1999, public attention was drawn to the importance and magnitude of the issue of patient harm from medical errors.[1] Patient safety is defined by the IOM as a subset of quality of care and focuses on the way in which risks on unintentional and evitable harm to the patient are handled in the organization of care. Patient safety should be the top priority in every healthcare organization. Still often, it is not enough in the attention of healthcare professionals and organizations. Lack of awareness of the severity of the problem and the difficulty in dealing with human error[2], as well as the complexity of healthcare organizations, the current reimbursement structure, medicine's tenacious commitment to individual professional autonomy and the lack of data as a result of the paucity of measures are important barriers for improving safe care.[3] Improving patient safety needs a system approach, integrating different initiatives, such as blame-free reporting of incidents and near-misses, analysis of the root causes and contributory factors of adverse events, pro-active risk assessment, education and training of healthcare staff. Although many of those issues apply for psychiatric care, there are unique safety issues for these settings.

Within psychiatric settings, the focus of patient safety is often laid on the safe physical environment in which the chances for patients to hurt themselves are reduced. A safe physical environment enhances for instance fall prevention and medication safety. But at the other hand, a safe psychological environment for the patient as well as for the healthcare professional, which helps patients to form a therapeutic alliance with staff and the care to be effective[4], can reduce aggressive and violent behavior.[5] Furthermore, issues related to seclusion and restraint[5], self-harm, substance-use related harm, suicide and absconding are unique concerns to mental health.[6] The difficulty within psychiatric care is that patient safety cannot be considered on its own, given the thin line between the healthcare professionals' safety and patient safety. In psychiatry, patient safety is balanced against the patient's rights and autonomy.[6] Finally, patient safety in mental health is context dependent and differs from the type of psychiatric setting (e.g. emergency department, neuropsychiatry, forensic setting) and the specific therapeutic approach.[6]

It is recognized by several international organizations that cultural change is the necessary first step to improve patient safety.[7] Leadership and structural involvement of management and staff is considered as a key component in developing a safety culture. Currently, there is a trend of measuring and benchmarking safety culture in healthcare organizations using administering surveys, in order to diagnose areas for improvement. Safety culture, as an element of organizational culture, can be defined as the product of individual and group values, attitudes, perceptions, competencies and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management.[8] There are limited studies which describe the role of safety culture in improving patient safety within psychiatric settings. A recent literature review of Kanerva et al. describes the diversity and relevance of the concept of patient safety in psychiatric inpatient care.[4] The authors address the importance of a safety culture and conclude that organizational management has a main role in creating a safety culture by leadership and creating a safety environment. A recent study of De Benedictis et al. measured team climate using the Group Environment Scale to investigate a possible relationship with the use of seclusion and restraint on psychiatric wards.[9] Certain aspects of the team climate, staff perceptions of aggression, and organizational factors were associated with greater use of seclusion and restraint on psychiatric wards. Factors as type of unit (intensive care unit and emergency department), perception of the frequency of incidents of physical aggression against patients and perception of insufficient safety measures in the work environment were found to have a significant influence on safety climate. Gallego et al. used the Safety Attitudes Questionnaire for measuring safety climate across all service types of the public health workforce in the state of South Australia, such as rehabilitation hospitals, country hospitals, dental services, pediatric hospitals, and drug and alcohol services, and found that psychiatric hospitals and mental health services were among those with more negative safety culture.[10]

In Belgium, the federal government is putting much effort in implementing patient safety strategies within the acute, psychiatric and long-term care hospitals. As outlined before in this dissertation, the federal government launched a five-year quality and safety program (2007-2012) with a yearly additional financing (annual budget of 7.66 million Euros in 2012) for the participating hospitals. One of the main requirements within this program is that hospitals should measure safety culture at a regular basis using the Hospital Survey on Patient Safety Culture (HSPSC).[11] The HSPSC was originally developed for use within acute hospital settings and covers a broad range of general patient safety aspects, including aspects which are related to the unit level, such as, manager expectations, organizational learning, teamwork within units and communication openness. Other aspects relate to hospital wide issues, such as non-punitive response to error, staffing, management support for patient safety, teamwork across units and handoffs and transitions. Finally, two aspects of the survey are related to outcomes of care: overall perceptions of patient safety and frequency of events reported.[12, 13] Between 2007 and 2009, the Belgian government organized a nationwide baseline safety culture measurement. For research purposes, hospitals were invited to participate in a benchmarking database, developed by Hasselt University, a neutral academic institute.[14] Hospitals received feedback on their patient safety profile. Overall perceptions of patient safety were found to be higher for the psychiatric hospitals in comparison with the acute and long-term care hospitals.[14] After a period of three years (in 2011), it was measured to what extent safety culture evolved on 12 dimensions. Also for this follow-up measurement hospitals were invited to participate in a comparative study organized by Hasselt University. Yet, the Belgian HSPSC benchmark database, consisting of 115 827 records drawn from 176 hospitals, is to our knowledge the largest set available within European countries.

Despite the importance of safety culture assessment in healthcare, the psychometric properties of existing surveys have seldom been tested. Up till now, the Belgian translations of the HSPSC were only validated for use within the acute hospitals.[11] This study aimed at investigating the factor structure of the Dutch and French translations of the HSPSC and the applicability of the survey in Belgian psychiatric hospitals. In addition, we aimed at comparing our results with the prior results of the Belgian and American acute hospitals. To our knowledge, this is the first study investigating such a large sample of patient safety perceptions of healthcare professionals working in psychiatric hospitals.

METHODS

Hospital Survey on Patient Safety Culture (HSPSC)

The HSPSC measures safety culture by means of a 5 point Likert scale on 12 dimensions (42 items), including ten safety dimensions and two outcome dimensions and is designed to measure staff perceptions on patient safety issues, medical errors and event reporting.[15] The HSPSC was translated in Dutch and French and validated for use within the acute hospitals.[11-13] The reliability coefficients (Cronbach's alpha) of the 12 safety culture dimensions ranged from 0.50 to 0.85 for the Dutch version and between 0.52 and 0.87 for the French version, which is comparable to the original American questionnaire. Frequency of events reported and staffing showed respectively the highest and lowest internal consistency.

Adjustment of demographic survey items to the context of psychiatric hospitals

The HSPSC as originally developed for acute hospitals showed limitations when benchmarking the results for psychiatric hospitals.[14] Therefore, the demographic categories of work area and profession were adapted to the context of the psychiatric hospitals in consensus through several meetings between the researchers, delegates of the psychiatric hospitals and the quality and safety commission of the federal government. In the survey section relating to work area, new categories were created in order to address the variety of psychiatric care and specific populations within the psychiatric settings: mobile team, admission/observation or crisis unit, day- or night hospitalization, supporting services (pharmacy, medical-technical services, technical services, administration), and specialized units including addiction therapy, psychosis care, mood disorders, behaviour disorders, pediatric psychiatry, elder psychiatry, neurology and rehabilitation. The category of 'other' was maintained in case a respondent was unable to indicate his work area. For staff position, several categories of the acute hospitals were merged, for example given the lower number of physicians within the psychiatric hospitals. The adjustment for the categories of staff position included merging of: (1) nurses and nursing aids, (2) head nurse, middle management and executive staff, (3) physicians, physicians head and physician assistants and (4) pharmacists, pharmacist assistants, technicians and logistics (as 'supporting services'). The categories of therapists included psychologists, social workers, criminologists, educators, mentors, physiotherapists, ergo therapists, dietitians, music therapists, speech therapists… The category 'others' was provided in case no straightforward assignment was possible.

Data collection

The HSPSC was distributed to all hospitals participating in the federal patient safety program (2007-2012).[16] The distribution and data collection for the second nationwide safety culture measurement in 2011 was identical to the method of the first initiative in the period of 2007 and 2009[14] and was based on the original American survey of the Agency for Healthcare Research and Quality (AHRQ).[17] A measurement toolkit was available containing the questionnaire (in Dutch and French) and a manual (protocol) for data collection and internal feedback. Workshops were organized for the participating hospitals in which the objectives and tools for conducting the safety culture measurement were explained. The protocol imposed the hospitals with a 13 weeks' timetable and encouraged the use of reminders. Hospitals were stimulated to obtain a response rate above 60%. Hospitals were free to use paper-based or electronic survey forms.

For analysis and benchmarking purposes, an MS Access-based instrument was designed to standardize data entry and automate the application of the exclusion criteria of respondents and analysis of the results. The Access tool automatically filtered questionnaires in case an entire section was incomplete, fewer than half of the items throughout the survey were answered and all items were scored identically. Moreover, the Access tool provided the possibility to instantly create a hospital report with an overview of the respondent characteristics and the hospital scores on the different items and 12 composite dimensions.

Hospitals that participated in the federal program were invited to join in a benchmark initiative on a voluntary, confidential and free of charge basis in order to provide a patient safety profile for internal learning. The comparative database is owned by Hasselt University, a neutral academic institution, and is not accessible by the governmental authorities. Technical assistance was available during the period of data collection (January 2012 – March 2012) and after feedback of the results (June 2012).

Calculation of positive dimensional scores

First, positive dimensional scores were calculated on the level of the individual respondent. Scores of negatively worded questions (18 items) were reversed. Answers above 3 were considered as positive towards patient safety. Based on the individual scores, positive dimensional scores (percentage of positive response) were calculated on the hospital level and for groups of respondents, such as work area and profession.

Assessment of psychometric properties of HSPSC

Item analysis was performed in order to identify problematic items with a high missingness (35% or more) or with a highly skewed distribution (85% or more of the respondents answered on the same side of the response scale).

Exploratory factor analysis (EFA) was used to investigate the number of latent constructs underlying the set of 42 items by examining the pattern of observed correlations between these items. EFA has three basic decision points: decide the number of factors, choosing an extraction method, and choosing a rotation method. The Kaiser-Guttmann rule or "eigenvalues greater than one" was applied to decide the number of factor to retain. Maximum likelihood extraction method (followed by a principal component method to check the stability of the results) was used for factor extraction and orthogonal rotation method (Varimax) for factor rotation, as the a priori hypothesis assumes that factors are independent.

The Kaiser-Meier-Olkin (KMO) measure of sampling adequacy (MSA), a summary of how small partial correlations are relative to ordinary correlations, was used to assess the appropriateness of factor analysis. High values (between 0.5 and 1.0) indicate that factor analysis is appropriate. Values below 0.5 imply that factor analysis may not be appropriate. KMO measures higher than 0.80 are considered as excellent.

The Bartlett's test of sphericity was used to examine the hypothesis that the variables are uncorrelated in the population. It tests the hypothesis that the population correlation matrix is an identity matrix, each variable correlates perfectly with itself (r=1) but has no correlation with the other variables (r=0). Rejection of this hypothesis indicates the appropriateness of the factor analysis.

Confirmatory factor analysis (CFA) was used to test whether the observed dataset fitted to the predefined 12-factor model. Several measures of Goodness of fit were used to assess the fit of the data to the model. The Comparative Fit Index (CFI) is equal to the discrepancy function adjusted for sample size. CFI ranges from 0 to 1 with a higher value indicating a better model fit. Acceptable model fit is indicated by a CFI value of 0.90 or higher.[18] Root Mean Square Error of Approximation (RMSEA) is related to residual in the model. RMSEA values range from 0 to 1 with a smaller RMSEA value indicating better model fit. Acceptable model fit is indicated by an RMSEA value of 0.06 or less.[18] Finally, the ratio of the Chi-square statistic and its corresponding degree of freedom close to 1 is an indication of an acceptable fit. The CALIS (covariance analysis of linear structural equations) procedure in SAS 9.2 was used to fit the model.

Reliability analysis was done to verify the internal consistency of each dimension using Cronbach's alpha (α). Values equal to or greater than 0.7 indicate acceptable reliability of the underlying construct.[19] The values were compared to the results of the acute Belgian and American hospitals.

Composite scores and inter-correlations were examined to assess the validity. A composite score for a dimension was calculated by averaging the responses of all the items within a dimension. Extreme absolute values for inter-correlations between 2 dimensions may be an indication that these dimensions need to be combined as they seem to provide similar information. These correlations may also be used to investigate the a priori hypothesis that the dimensions are independent.

Data of the follow-up safety culture measurement were used for EFA in order to construct a measurement model for the items. Data of the baseline measurement were used to test the model by CFA.

All statistical analyses were done using IBM SPSS Statistics 20 and SAS 9.2.

RESULTS

Hospital characteristics

Table 1 presents the characteristics and response rates of the participating hospitals for the first and second safety culture measurement.

Table 1: Characteristics and response rates for psychiatric hospitals participating in first and second nationwide measurement

		First measurement (n=44)		Second measurement (n=46)	
Characteristics		French speaking (n=12)	Dutch speaking (n=32)	French speaking (n=11)	Dutch speaking (n=35)
Method of survey	Missing	0	0	0	2
	Electronic	2	2	0	12
	Paper-based	10	30	11	21
Number of beds	Missing	4	18	0	2
	<250	5	8	3	19
	250-499	2	4	6	10
	500-1000	1	2	2	4
Statute	Missing	9	18	0	3
	Public	0	2	3	4
	Private	3	12	8	28
Response rates	physicians	53.3%	67%	44.6%	41.8%
	Employees	62.1%	74.1%	62.6%	77.2%
	Total	61.6%	73.8%	61.8%	76.7%
		70.5%		71.5%	

Respondent characteristics

A total of 5 969 respondents from 35 Dutch speaking hospitals and 2 384 respondents from 11 French speaking hospitals were collected in 2011. The data of 5 096 (Dutch language) and 1 562 respondents (French language) from the baseline measurement were used for confirmatory factor analysis. Respondent characteristics are displayed in table 2.

Table 2: Respondent characteristics

MEASUREMENT 1 (6 658 respondents)			MEASUREMENT 2 (8 290 respondents)		
	Dutch speaking n=5 096 (100%)	**French speaking n=1 562 (100%)**		**Dutch speaking n=5 969 (100%)**	**French speaking n=2 384 (100%)**
Work area/ Unit*	**3 031 (59.5%)**	**1 531 (98%)**	**Work area/ Unit**	**5 732 (96.0%)**	**2 234 (93.7%)**
Many different hospital units/No specific unit	139 (2.7%)	77 (4.9%)	Different hospital units/ mobile team	594 (10%)	350 (14.7%)
Internal Medicine (including day-stay admissions)	43 (0.8%)	117 (7.5%)	Admission/ observation or crisis unit	739 (12.4%)	367 (15.4%)
Surgery (including day-stay admissions)	20 (0.4%)	-	Specialized unit	3 318 (55.7%)	1 126 (47.2%)
Operating theatre	2 (0%)	1 (0.1%)	Addiction therapy	284 (4.8%)	-
Gynecology/ obstetrics	17 (0.3%)	90 (5.8%)	Psychosis care	433 (7.3%)	-
Pediatrics	23 (0.5%)	-	Mood disorders	266 (4.5%)	-
Intensive care unit	6 (0.1%)	-	Behaviour disorders	144 (2.4%)	2 (0.1%)
Emergency	9 (0.2%)	72 (4.6%)	Pediatric psychiatry	218 (3.7%)	305 (12.8%)
Rehabilitation	9 (0.2%)	33 (2.1%)	Eldern psychiatry	390 (6.5%)	5 (0.2%)
Geriatrics	34 (0.7%)	170 (10.9%)	Neurology	35 (0.6%)	34 (1.4%)
Psychiatry	2 528 (49.6%)	811 (51.9%)	Rehabilitation	146 (2.4%)	32 (1.3%)
Medical-technical services	65 (1.3%)	88 (5.6%)	Specialized unit - Other	1402(23.5%)	748 (31.4%)
Pharmacy	15 (0.3%)	40 (2.6%)	Day or night hospital	337 (5.6%)	57 (2.4%)
Other	121 (2.4%)	32 (2.0%)	Supporting services (pharmacy, medical-technical services)	222 (3.7%)	196 (8.2%)
Missing	*2 065 (40.5%)*	*31 (2.0%)*	Other	522 (8.7%)	138 (5.8%)
			Missing	*237 (4.0%)*	*150 (6.3%)*
Staff position	**3 522 (69.1%)**	**1 540 (98.6%)**	**Staff position**	**5 909 (98.9%)**	**2 333 (97.9%)**
Nurse	1 557 (30.6%)	503 (32.2%)	Nurse	3 391 (56.8%)	1 066 (44.7%)
Head nurse	173 (3.4%)	89 (5.7%)	Pysician/ physician head of departement/ physician assistent	175 (2.9%)	88 (3.7%)

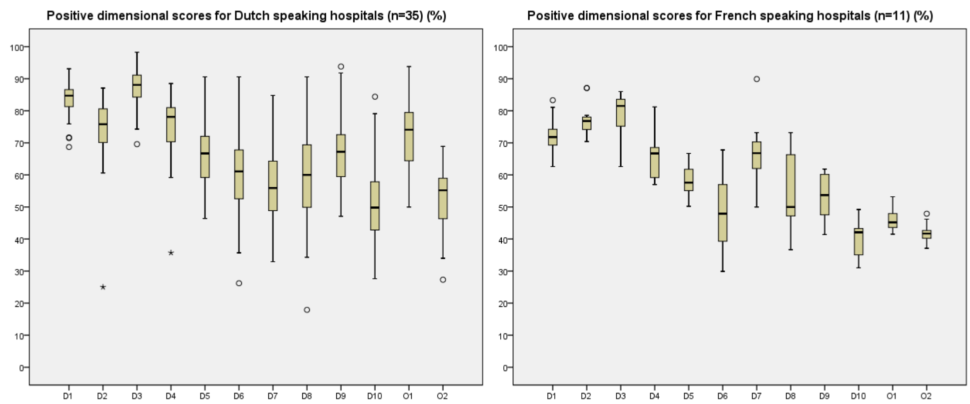
Staff position (continued)	3 522 (69.1%)	1 540 (98.6%)	Staff position	5 909 (98.9%)	2 333 (97.9%)
Nursing aid	448 (8.8%)	258 (16.5%)	Supporting services (e.g. medical –technical services)	289 (4.8%)	259 (10.9%)
Physician	83 (1.6%)	37 (2.4%)	Middle management/ executive staff/ head nurse	425 (7.2%)	110 (4.6%)
Physician – head of department	96 (1.9%)	35 (2.2%)	Therapist	1 490 (25.0%)	569 (23.9%)
Physician assistant	11 (0.2%)	3 (0.2%)	Other	132 (2.2%)	241 (10.1%)
Pharmacist	8 (0.2%)	15 (1.0%)	*Missing*	*61 (1.1%)*	*51 (2.1%)*
Assistant pharmacy	13 (0.3%)	17 (1.1%)			
Middle management	66 (1.3%)	73 (4.7%)			
Technician (EKG. Lab. Radiology)	5 (0.1%)	22 (1.4%)			
Therapist (dietitian. physical. psychologist)	688 (13.5%)	344 (22.0%)			
Other	374 (7.3%)	144 (9.2%)			
Missing	*1 574 (30.9%)*	*22 (1.4%)*			
Interaction with patients	**4 981 (97.7%)**	**1 533 (98.1%)**	**Interaction with patients**	**5 888 (98.6%)**	**2 327 (97.6%)**
Direct patient interaction	4 827 (94.7%)	1 434 (91.8%)	Direct patient interaction	5 685 (95.2%)	2 154 (90.4%)
No direct patient interaction	154 (3.0%)	99 (6.3%)	No direct patient interaction	203 (3.4%)	173 (7.3%)
Missing	*115 (2.3%)*	*29 (1.9%)*	*Missing*	*81 (1.4%)*	*57 (2.4%)*
Professional experience	4 977 (97.7%)	1 528 (97.8%)	Professional experience	5 791 (98.1%)	2 320 (97.3%)
Less than 1 year	254 (5.0%)	60 (3.8%)	Less than 1 year	285 (4.8%)	72 (3.0%)
1 to 5 years	987 (19.4%)	283 (18.1%)	1 to 5 years	1271(21.3%)	434 (18.2%)
6 to 10 years	907 (17.8%)	289 (18.5%)	6 to 10 years	912 (15.3%)	401 (16.8%)
11 to 15 years	578 (11.3%)	210 (13.4%)	11 to 15 years	862 (14.4%)	434 (18.2%)
16 to 20 years	610 (12.0%)	231 (14.8%)	16 to 20 years	596 (10.0%)	292 (12.2%)
21 years or more	1641(32.2%)	455 (29.1%)	21 years or more	1924(32.2%)	687 (28.8%)
Missing	*119 (2.3%)*	*34 (2.2%)*	*Missing*	*119 (2.0%)*	*64 (2.7%)*
Working time (hours) in hospital	**5 012 (98.4%)**	**1 532 (98.1%)**	**Working time (hours) in hospital**	**5 887 (98.6%)**	**2 348 (98.5%)**
Less than 20 hours per week	501 (9.8%)	150 (9.6%)	Less than 20 hours per week	659 (11.0%)	191 (8.0%)
20 to 39 hours per week	3 426 (67.2%)	1 122 (71.8%)	20 to 39 hours per week	4 043 (67.7%)	1 637 (68.7%)
40 to 59 hours per week	993 (19.5%)	222 (14.2%)	40 to 59 hours per week	1 111 (18.6%)	450 (18.9%)
60 to 79 hours per week	69 (1.4%)	35 (2.2%)	60 to 79 hours per week	53 (0.9%)	61 (2.6%)
80 hours per week or more	23 (0.5%)	3 (0.2%)	80 hours per week or more	21 (0.4%)	9 (0.4%)
Missing	*84 (1.6%)*	*30 (1.9%)*	*Missing*	*82 (1.4%)*	*36 (1.5%)*

* Categories for work area from the original questionnaire were not suitable for psychiatric hospitals

Positive dimensional scores

Figure 1 provides the dimensional scores of the second measurement expressed in terms of percent positive response. Percent positive reflects the percentage of positive responses (e.g. Agree, Strongly agree) to positively worded items or negative response to negatively worded items.

Figure1: Positive dimensional scores (%) of second safety culture measurement for Dutch and French speaking psychiatric hospitals



Dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

Psychometric properties

Item analysis

Overall, missingness was low, with the highest proportion of 4.3% for item d3 (*When a mistake is made that could harm the patient, but does not, how often is this reported?,* from dimension Frequency of events reported*)* for Dutch speaking hospitals and 17.2% for item a7 (*We use more agency/temporary staff than is best for patient care,* from dimension Staffing) within the French speaking hospitals. In addition, there were no items with extreme skewness.

Exploratory Factor Analysis (EFA)

Eigenvalue criteria (Kaiser-Guttmann rule or "eigenvalues greater than one") selected 9 factors for the Dutch translation and 10 factors for the French translation. The average prior communality (the variance in each item explained by the extracted factors) of 0.40 selected 12 factors. These dimensions only explained about 59.37% (Dutch translation) and 61.57% (French translation) of the original variance but account for 43.90% (Dutch translation) and 46.66% (French translation) of the common variance. The null hypothesis of 'No Common Factors' was rejected (p-value < 0.0001), supporting that there is at least one common factor. Moreover, the null hypothesis of '12 Factors are sufficient' was rejected (p-value < 0.0001), meaning that there is eventually room for selection of more factors. The Bartlett's Test of Sphericity was significant (p-value<0.0001) and the Kaiser-Meyer-Olkin (KMO) measure of Sampling Adequacy was 0.921 (Dutch translation) and 0.915 (French translation) which strongly support the adequacy of the sample for factor analysis.

For the Dutch and French translation, respectively 33 and 35 out of 42 items loaded high (>0.40) on only one factor. No item loaded high on two or more factors (Appendices I and II: Rotated factor matrix-ML extraction method). For both translations, the dimensions 'Teamwork across hospital units' and 'Hospital handoffs and transitions' were treated as one dimension. Also dimensions 'Feedback and communication about error' and 'Communication openness' were considered as one dimension. For the French translation, there was an additional combination of 'Staffing' and 'Overall perception of safety'.

Table 3 shows the 12 extracted factors, the eigenvalues and the explained variance.

Table 3: The extracted 12 factors based on Maximum Likelihood method

Factor	Initial Eigenvalues					
	Dutch translation			French translation		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	9.06	21.58	21.58	9.63	22.94	22.94
2	2.53	6.03	27.61	2.36	5.62	28.56
3	2.14	5.11	32.71	2.14	5.11	33.68
4	1.71	4.08	36.79	1.96	4.66	38.35
5	1.62	3.85	40.64	1.69	4.02	42.38
6	1.40	3.34	43.98	1.55	3.71	46.09
7	1.34	3.20	47.18	1.26	3.00	49.09
8	1.21	2.87	50.05	1.17	2.78	51.88
9	1.08	2.58	52.63	1.09	2.61	54.50
10	0.99	2.35	54.98	1.04	2.49	56.99
11	0.94	2.24	57.22	0.98	2.34	59.33
12	0.90	2.15	59.37	0.941	2.24	61.57

Factor	Extraction Sums of Squared Loadings					
	Dutch translation			French translation		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	8.35	19.87	19.87	9.07	21.60	21.60
2	1.99	4.75	24.62	1.85	4.41	26.02
3	1.80	4.28	28.90	1.73	4.11	30.14
4	1.18	2.82	31.72	1.51	3.60	33.74
5	1.22	2.92	34.63	1.11	2.65	36.40
6	0.97	2.30	36.93	1.16	2.78	39.13
7	0.77	1.82	38.75	0.73	1.74	40.97
8	0.63	1.51	40.26	0.64	1.53	42.43
9	0.43	1.02	41.29	0.50	1.20	43.65
10	0.42	1.00	42.29	0.43	1.03	44.67
11	0.40	0.95	43.24	0.47	1.11	45.83
12	0.28	0.66	43.90	0.33	0.80	46.66

Factor	Rotation Sums of Squared Loadings					
	Dutch translation			French translation		
	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	2.79	6.64	6.64	2.64	6.22	6.22
2	2.26	5.39	12.03	2.43	5.81	12.13
3	2.10	4.99	17.03	2.05	4.98	17.11
4	1.94	4.62	21.65	2.01	4.86	21.91
5	1.85	4.41	26.06	1.86	4.45	26.36
6	1.55	3.69	29.75	1.81	4.46	30.83
7	1.53	3.63	33.38	1.76	4.19	34.92
8	1.45	3.45	36.83	1.64	3.86	38.88
9	1.19	2.83	39.66	1.23	2.93	41.81
10	0.75	1.80	41.46	0.94	2.24	44.05
11	0.68	1.63	43.09	0.72	1.76	45.81
12	0.34	0.81	43.90	0.33	0.75	46.66

Confirmatory factor analysis (CFA)

CFA was performed to test the original American 12 factor model for respectively the Dutch and French translations. SAS 9.2 was used with procedure Proc CALIS (Covariance Analysis of Linear Structural Equations). On the one hand, the Chi-square test indicated that the data did not fit the proposed dimensional structure of 12 dimensions. It has been reported that Chi-Square statistic is in essence a statistical significance test as it is sensitive to sample size.[20] Chi-Square statistic nearly always rejects the model when large samples are used.[21] On the other hand, the RMSR and the SRMSR were found to be less than 0.05 for both translations suggesting an acceptable fit of the 12 factor model. Moreover, GFI, AFGI, CFI, and NNFI were close to 1, which also suggested an acceptable model. Therefore, there is some evidence that the data fit the a priori hypothesized 12-dimensional structure in an acceptable way.

Table 4: Confirmatory factor analysis model fits of the 12 dimensions of HSPSC

Goodness of fit indices	Dutch translation	French translation
Chi-Square	49248.7017	1648.2444
Chi-Square DF	496	505
Pr > Chi-Square	<.0001	<.0001
Chi-Square/ Chi-Square DF	99.2	3.26
Root Mean Square Residual (RMSR)	0.0251	0.0381
Standardized RMSR (SRMSR)	0.0346	0.0387
Goodness of Fit Index (GFI)	0.9489	0.9257
Adjusted GFI (AGFI)	0.9356	0.9073
Bentler Comparative Fit Index (CFI)	0.9366	0.9241
Bentler-Bonett Non-normed Index (NNFI)	0.9288	0.9105

Reliability analysis

Estimates for Cronbach's alpha, used to examine internal consistency reliability for the 12 dimensions, are presented in Table 5. Reliability estimates for the 12 dimensions ranged between 0.50 (Organizational learning and continuous improvement) and 0.85 (Frequency of events reported) for the Dutch speaking and between 0.50 (Staffing) and 0.84 (Frequency of events reported) for the French speaking hospitals. The results were comparable with those of the questionnaires for Belgian acute hospitals, but were generally found to be lower in comparison with the results of the American acute hospitals. About half of the dimensions received reliability coefficients below 0.7. Removing items from the dimensions Staffing and Organizational learning and continuous improvement did not improve the Chronbach's alpha.

Table 5: Reliability of the 12 safety culture dimensions of the psychiatric hospitals compared with the Belgian (Dutch and French speaking) and American acute hospitals

		Belgian psychiatric hospitals		Belgian acute hospitals		American acute hospitals
Dimensions	**Items**	**Alpha PH (Dutch)**	**Alpha PH (French)**	**Alpha AH (Dutch)**	**Alpha AH (French)**	**Alpha AHRQ***
D1: Supervisor/manager expectations and actions promoting safety	b1-b2-b3-b4	0.77	0.74	0.77	0.75	0.75
D2: Organizational learning and continuous improvement	a6-a9-a13	0.50	0.58	0.59	0.59	0.76
D3: Teamwork within units	a1-a3-a4-a11	0.65	0.84	0.66	0.82	0.83
D4: Communication Openness	c2-c4c-c6	0.66	0.71	0.65	0.72	0.72
D5: Feedback and Communication about error	c1-c3-c5	0.76	0.70	0.78	0.76	0.78
D6: Non-punitive response to error	a8-a12-a16	0.70	0.68	0.68	0.64	0.79
D7: Staffing	a2-a5-a7-a14	0.55	0.50	0.57	0.52	0.63
D8: Management support for patient safety	f1-f8-f9	0.72	0.79	0.72	0.77	0.83
D9: Team work across units	f2-f4-f6-f10	0.69	0.66	0.66	0.68	0.80
D10 Handoffs and transitions	f3-f5-f7-f11	0.70	0.70	0.71	0.72	0.80
O1: Overall Perceptions of Safety *(Outcome dimension)*	a10-a15-a17-a18	0.54	0.58	0.58	0.63	0.74
O2: Frequency of events reported *(Outcome dimension)*	d1-d2-d3	0.85	0.84	0.85	0.87	0.84

*Results of the American pilot study

PH=psychiatric hospitals; AH=acute hospitals; AHRQ=Agency for Healthcare Research and Quality

Validity assessment

Pair-wise correlations for the composite scores of the dimensions are shown in Table 6. There was one correlation with magnitude less than 0.1 obtained in both translations between 'Staffing' and 'Frequency of events reported'. The highest correlation coefficients were observed between dimension 'Communication Openness' and dimension 'Feedback and communication about errors' on the hand, and dimension 'Team work across units' and dimension 'Handoffs and transitions' on the other hand, with both correlation values of 0.57 for the Dutch translation and 0.56 for the French translation. This is not surprising since the methods we used in exploratory factor analyses combined these dimensions into one dimension, probably due to their strongly related content. However, none of the correlations were extremely high to indicate the need to combine some dimensions. Also, most of the correlations are less than 0.5 implying that the a priori hypothesized independence between the dimensions may be plausible.

Table 6: Pair-wise correlations between the 12 safety culture dimensions

	Dutch translation												French translation											
Dimensions	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
D1:Supervisor/manager expectations and actions promoting safety	1												1											
D2: Organizational learning and continuous improvement	0.38	1											0.44	1										
D3: Teamwork within units	0.35	0.34	1										0.36	0.35	1									
D4: Communication Openness	0.46	0.36	0.42	1									0.52	0.32	0.38	1								
D5: Feedback and Communication about error	0.45	0.43	0.35	**0.57**	1								0.48	0.43	0.34	**0.56**	1							
D6: Non-punitive response to error	0.34	0.26	0.31	0.47	0.30	1							0.36	0.26	0.35	0.48	0.30	1						
D7: Staffing	0.23	0.12	0.19	0.25	0.17	0.32	1						0.29	0.16	0.22	0.32	0.26	0.36	1					
D8: Management support for patient safety	0.33	0.35	0.24	0.35	0.36	0.33	0.27	1					0.38	0.37	0.23	0.35	0.36	0.35	0.27	1				
D9: Team work across units	0.31	0.31	0.33	0.34	0.32	0.28	0.25	0.43	1				0.31	0.26	0.28	0.34	0.31	0.32	0.26	0.45	1			
D10: Handoffs and transitions	0.27	0.23	0.27	0.30	0.27	0.29	0.27	0.36	0.56	1			0.30	0.18	0.27	0.35	0.32	0.29	0.25	0.32	**0.56**	1		
O1: Overall Perceptions of Safety	0.38	0.36	0.31	0.38	0.32	0.38	0.37	0.41	0.34	0.36	1		0.37	0.35	0.30	0.38	0.35	0.41	0.39	0.48	0.34	0.33	1	
O2: Frequency of events reported	0.24	0.26	0.18	0.28	0.39	0.16	0.**04**	0.18	0.20	0.18	0.20	1	0.21	0.22	0.16	0.22	0.33	0.12	**0.08**	0.15	0.17	0.15	0.17	1

DISCUSSION

The HSPSC is one of the most applied instruments of measuring safety culture in healthcare settings and there is extensive evidence that the psychometric properties of the HSPSC are good.[12, 22-25] Until now, this instrument has been limited used within psychiatric settings. Therefore, the purpose of our study was to assess the psychometric properties of the Dutch and French translations adapted to the context for psychiatric hospitals.

Response rates for the Belgian psychiatric hospitals were 70.5% for the baseline measurement and 71.5% for the follow-up measurement, which is an encouraging achievement in comparison with other international research. Of course, psychiatric settings are generally smaller which enables a larger involvement of all members of the organization. Similar to international findings, response rates were found to be lower for physicians in comparison with other professional groups. The fewer missing answers on the demographical categories of work area and staff position for the second measurement in comparison with the first measurement showed that the construction of the new categories for the psychiatric hospitals was useful.

In order to identify areas of weaknesses and strengths in safety culture, positive dimensional scores were first calculated based on the individual level (percentage of positive response) and then calculated on the hospital level. Previous research demonstrated scores to be higher for psychiatric hospitals in comparison with acute hospitals.[14] In our study within psychiatric hospitals, scores were higher for dimension ‘Teamwork within units’, indicating positive perceptions regarding items of teamwork, support and respect. Results showed that ‘Handoffs and transitions’ was inadequate for patient safety, meaning that important patient care information is lost during shift changes and transferring of patients.

No problematic items were found since the thresholds of 30% and 85% for percentage of missingness and skewed responses were not exceeded. A total of 5 969 respondents from 35 Dutch speaking and 2 384 respondents from 11 French speaking psychiatric hospitals, collected from the follow-up measurement in 2011, were used for EFA. EFA yielded for both translations the combination of dimensions ‘Communication openness’ and ‘Feedback and communication about error' and dimensions 'Teamwork across units' and 'Handoffs and transitions'. This suggestion of combinations has also been reported in the Scottish study.[23] For the French translation in our study, EFA indicated an additional grouping of the items that previously formed 'Staffing' and 'Overall perceptions of safety'. This finding was also reported within the English, Scottish and Swiss study within acute hospital settings.[23, 26, 27]

A sample of 5 096 (Dutch language) and 1 562 respondents (French language) from the baseline safety culture measurement was used for CFA. The adequacy of the sample we used in this study for factor analysis was strongly supported by the Bartlett's Test of Sphericity (p-value<0.0001) and the Kaiser-Meyer-Olkin (KMO) measure of Sampling Adequacy (>0.915).

CFA indicated that the original 12-factor structure fits the data of both Dutch and French speaking psychiatric hospitals. The Comparative Fit Index (CFI), equal to the discrepancy function adjusted for sample size and which ranges from 0 to 1 with a larger value indicating better model fit, was 0.9366 for the Dutch and 0.9241 for the French HSPSC indicating an acceptable model fit.[18] Caution must be taken when comparing CFA results across studies, since a different use of samples is reported. Within our study the baseline measurement was used for CFA, while the American study for instance tested the model using the same sample. In a British study CFA indicated a low fit applying a split-half validation technique.[26]

Items a11 (Teamwork within units), a10 (Overall Perceptions of Safety) and a9 (Organizational learning-and continuous improvement) loaded relatively low on the factors and could be reconsidered in both Dutch and French models. In addition, for the French questionnaire, also items f11 (Handoffs and Transitions) and a7 (Staffing) loaded relatively low on the factors.

For both translations, there was an acceptable level of internal consistency. However, half of the dimensions had Chronbach's Alpha lower than 0.7 showing a lower level of reliability. The lowest internal consistency was found for 'Organizational learning and continuous improvement' (0.50 for Dutch questionnaire) and for 'Staffing' (0.50 for French questionnaire) and the highest Alpha values were found for 'Frequency of events reported' (0.85 for Dutch and 0.84 for French questionnaire). All coefficients for the psychiatric hospitals were similar to those of the acute settings, but were lower than the coefficients reported by the AHRQ[15], with only half reaching the minimal recommended Chronbach alpha level of 0.70. The lower reliability of 'Staffing' was also reported in American[22, 28] and European studies[23, 24, 26, 29] within acute hospital settings.

Finally, the inter-correlations between the 12 dimensions ranged between 0.04 and 0.57 for the Dutch questionnaire and between 0.08 and 0.56 for the French translation, with the lowest inter-correlations between 'Staffing' and 'Overall perceptions of patient safety' and the highest correlations between dimensions 'Communication Openness' and 'Feedback and Communication about error' and dimensions 'Teamwork across units' and 'Handoffs and transitions', which supports that these dimensions are not independent of each other.

The following limitations should be taken into account. A first limitation concerns the construction of the HSPSC. One likely explanation for the differences in scores that were found between dimensions is that the more positive scoring dimensions contain only positive worded items in contrast with lower scoring dimensions, such as 'Staffing', 'Non-punitive response to errors' and 'Handoffs and transitions', which contain the highest number of negatively worded items. This finding on its own, which is explained by Blegen et. al.[28], makes that the meaning of identifying high and low scoring dimensions could be questionable. In this way, it is possible that low scoring dimensions might be a reflection of the negatively worded items rather than the weaknesses of these areas of safety culture.[28] Second, caution must be taken when comparing psychometric properties of the HSPSC with other health care settings or other countries, since other data collection methods and analysis techniques could have been applied. Therefore, comparisons of national safety culture results should be based on matched samples, which take into account the hospital types, structure and respondent characteristics. Future research can then try to explain whether differences can be explained by cultural differences.[27] Furthermore, besides exploring the dimensionality of safety culture instruments, it is important to investigate the meaningfulness of the data in terms of predictive validity. Although psychometric properties of the HSPSC have been investigated, there is still limited evidence on the relationship between safety culture and actual patient safety outcomes in order to assess the predictive validity of the questionnaire.

CONCLUSION

The validation of the Dutch and French translations was performed using the same strategy as the original American HSPSC. The HSPSC was found to be reliable and valid for use within the Belgian psychiatric hospitals. Although EFA resulted in a 10-dimensional and a 9-dimensional structure for respectively the Dutch and French questionnaire, it is suggested that no modifications are required to the original 12-factor model in order to allow internal and external benchmarking. Still, caution must be taken when generalizing safety culture perceptions between or even within different types of healthcare settings, given their context-specific nature. It is recommended that safety culture survey instruments are validated before their use within a specific healthcare context. However, it is not only important to confirm stable dimensionality of the HSPSC. The questionnaire offers important information on a broad range of aspects for both the hospital management and healthcare professionals.

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APPENDIX I – Rotated factor matrix - ML extraction method (Dutch translation)

	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8	Factor9	Factor10	Factor11	Factor12
Handoffs and transitions (f7)	0.66140	0.03464	0.05366	0.03400	0.12336	0.03532	0.09441	0.09121	0.03188	0.03018	0.24408	-0.18117
Handoffs and transitions (f3)	0.59680	0.07726	0.06268	0.02159	0.08908	0.06363	0.07535	0.11391	0.05872	0.00304	0.08723	-0.22601
Teamwork across units (f10)	0.58866	0.09262	0.07553	0.11245	0.04412	0.06564	0.18304	0.06792	0.15758	0.02554	-0.01353	0.21278
Teamwork across units (f4)	0.57677	0.09726	0.03270	0.11421	0.05046	0.04497	0.07480	0.03059	0.16318	0.02380	-0.02739	0.23711
Teamwork across units (f2)	0.57135	0.12947	0.07068	0.02489	0.09061	0.03070	0.18082	0.13085	0.06857	0.01805	-0.05829	-0.02424
Hospital Handoffs and transitions (f5)	0.44832	0.10432	0.07627	0.10325	0.06814	0.03926	0.02279	0.11074	0.09248	0.05289	0.40862	-0.21558
Teamwork across units (f6)	0.41890	0.04957	0.03482	0.10633	0.13791	0.07720	0.07755	0.07445	0.01131	0.08654	0.17711	0.12649
Teamwork within units (a11)	0.22143	0.10366	0.04208	0.16997	-0.00696	0.06597	0.08811	0.08642	0.04713	0.00984	-0.13647	0.00297
Feedback and communication about error (c3)	0.11412	0.69803	0.18432	0.09926	0.07193	0.09059	0.10061	0.01970	0.10904	0.04396	0.01321	-0.05129
Feedback and communication about error (c1)	0.13959	0.58315	0.17518	0.02561	0.05711	0.13483	0.14084	0.04575	0.17041	0.03532	-0.06001	-0.11385
Feedback and communication about error (c5)	0.12195	0.57660	0.18471	0.22265	0.14776	0.17381	0.09042	0.05452	0.24354	0.06758	0.10450	0.06325
Communication openness (c4)	0.11838	0.49097	0.07557	0.15673	0.25277	0.14595	0.16453	0.09941	0.01302	0.03404	0.06180	0.08796
Communication openness (c2)	0.08964	0.47623	0.09576	0.25868	0.28293	0.18290	0.05734	0.09760	0.09724	0.05609	0.12075	0.13174
Frequency of events reported (d2)	0.08549	0.12025	0.89765	0.04851	0.06001	0.05185	0.03852	-0.00075	0.06530	0.00880	0.01670	-0.00190
Frequency of events reported (d1)	0.06631	0.16623	0.73490	0.03029	0.06022	0.04554	0.05874	-0.01661	0.10094	0.02694	-0.02420	-0.02084
Frequency of events reported (d3)	0.09958	0.17184	0.71173	0.07196	0.03817	0.06707	0.03093	-0.00328	0.10509	0.07079	0.06794	0.02699
Teamwork within units (a1)	0.09144	0.14111	0.03976	0.76113	0.13424	0.08715	0.04449	0.04043	0.08837	0.01987	0.07619	-0.00453
Teamwork within units (a4)	0.10410	0.09880	0.03204	0.71494	0.19297	0.08775	0.04306	0.01554	0.08170	0.02650	0.08661	0.03144
Teamwork within units (a3)	0.12401	0.15281	0.07069	0.58215	0.07767	0.10100	0.01765	0.10732	0.18416	0.03044	0.01188	-0.01844
Nonpunitive response to error (a8r)	0.10203	0.09741	0.05309	0.17019	0.65955	0.05814	0.09591	0.17960	0.09481	0.04335	0.01792	-0.04302

Nonpunitive response to error (a12r)	0.12560	0.15511	0.06101	0.12541	0.58829	0.10783	0.08924	0.13153	0.11911	0.05657	0.06384	0.04523
Nonpunitive response to error (a16r)	0.09648	0.10068	0.02505	0.04968	0.55750	0.03222	0.09460	0.13970	-0.02383	0.04908	0.03152	-0.02735
Communication openness (c6r)	0.12046	0.26090	0.09438	0.19732	0.30365	0.09066	0.03644	0.12372	0.06896	0.10877	0.13685	0.08790
Supervisor/manager expectations (b2)	0.08421	0.22028	0.06897	0.14371	0.13347	0.77120	0.08980	0.06641	0.14104	0.12139	0.02853	0.05458
Supervisor/manager expectations (b1)	0.12636	0.23692	0.08783	0.13929	0.06396	0.64411	0.09637	0.02033	0.16321	0.11034	-0.00201	-0.04819
Supervisor/manager expectations (b4r)	0.10834	0.16389	0.08952	0.12668	0.16899	0.44807	0.10670	0.12473	0.16106	0.40151	0.09686	-0.00455
Management support for patient safety (f8)	0.18061	0.13689	0.06558	0.02404	0.05491	0.06558	0.65808	0.05044	0.19804	0.04057	-0.02380	-0.01473
Management support for patient safety (f1)	0.22143	0.15593	0.03380	0.08302	0.12591	0.11748	0.61105	0.20881	0.15902	0.00562	0.07054	0.05483
Management support for patient safety (f9r)	0.24103	0.11787	0.03759	0.02094	0.21922	0.04663	0.52731	0.09760	0.06674	0.06566	0.09990	-0.01291
Staffing (a14)	0.11176	0.03835	0.02669	0.03698	0.12866	0.01540	0.01891	0.60054	0.08564	0.10358	0.03545	-0.01856
Staffing (a2)	0.12265	0.05885	-0.01222	0.12330	-0.00918	0.02041	0.17157	0.55687	-0.00287	-0.01790	-0.09447	-0.02940
Staffing (a5r)	0.05212	0.00022	-0.02831	-0.04312	0.10060	0.01310	0.00232	0.35887	-0.00678	0.04403	0.05752	0.04708
Overall perceptions of patient safety (a17r)	0.09418	0.04191	0.03383	0.10249	0.20631	0.06276	0.18244	0.33959	0.24444	0.05305	0.22317	-0.01045
Staffing a7r	0.05936	0.06684	-0.00734	0.05472	0.20408	0.04650	0.04597	0.33609	0.03353	0.02542	0.12473	-0.03818
Organizational learning-improvement (a13)	0.14407	0.23395	0.14670	0.09992	0.04539	0.13334	0.07106	0.02659	0.47485	0.03449	0.00210	-0.04587
Organizational learning-improvement (a6)	0.11121	0.11723	0.08753	0.15003	0.04845	0.11523	0.18357	-0.02277	0.43620	0.02551	0.00630	0.02315
Overall Perceptions of Safety (a18)	0.19450	0.14923	0.07845	0.08502	0.12755	0.12576	0.25879	0.17335	0.32429	-0.03745	0.12189	-0.00894
Overall Perceptions of Safety (a15)	0.06754	0.05356	0.08292	0.09008	0.03905	0.04779	0.10014	0.17766	0.29111	0.15944	0.06973	0.00640
Organizational learning-improvement (a9)	0.08886	0.16970	0.02344	0.13824	0.16329	0.14159	0.10497	0.00868	0.21427	-0.00053	0.00812	0.11078
Supervisor/manager expectations (b3r)	0.08131	0.08923	0.07152	0.02505	0.13128	0.21707	0.04080	0.17493	0.07610	0.67425	0.06069	0.00304
Handoffs and transitions (f11r)	0.26256	0.05770	0.01388	0.10600	0.09870	0.01837	0.08637	0.13917	0.02534	0.06404	0.37036	0.03506
Overall perceptions of patient safety (a10r)	0.06460	0.04781	0.04531	0.10286	0.24635	0.05763	0.06873	0.19745	0.18982	0.07163	0.25648	0.06140

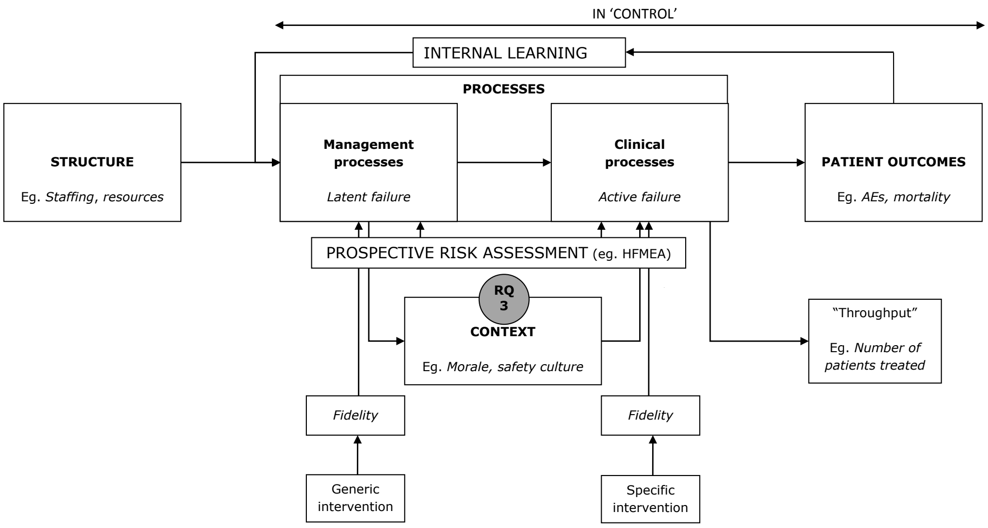
APPENDIX II – Rotated factor matrix - ML extraction method (French translation)

	Factor1	Factor2	Factor3	Factor4	Factor5	Factor6	Factor7	Factor8	Factor9	Factor10	Factor11	Factor12
Handoffs and transitions (f7)	0.67967	0.03856	0.09270	0.04815	0.06948	0.06686	0.00566	0.12480	0.04102	0.11372	0.18901	-0.01436
Teamwork across units (f4)	0.66522	0.14741	0.07654	0.04927	0.06219	0.13520	0.11138	0.03201	0.07293	-0.04324	-0.01282	0.02949
Handoffs and transitions (f3)	0.53933	0.02831	0.11343	0.01284	0.00493	0.05152	0.05435	0.04938	-0.00729	0.04585	0.25779	0.08254
Teamwork across units (f2)	0.52335	-0.00631	0.04084	0.05478	0.12695	0.14078	0.03186	0.16605	-0.00090	0.04277	-0.02134	-0.00877
Teamwork across units (f10)	0.48565	0.13652	0.07419	0.04684	0.04449	0.26247	0.18061	0.05292	0.07289	0.02052	-0.00671	-0.00502
Teamwork across units (f6)	0.39698	0.12208	0.06225	0.06300	0.13672	0.03405	0.03112	0.08991	0.12021	0.08332	0.00959	-0.06061
Teamwork within units (a4)	0.10601	0.74547	0.05072	0.07400	0.13828	0.04520	0.13328	0.06686	0.02455	0.03959	0.03182	-0.23624
Teamwork within units (a1)	0.09898	0.73883	0.12331	0.06196	0.16874	0.08104	0.10717	0.03549	0.02072	0.08627	0.02049	-0.12331
Teamwork within units (a3)	0.12015	0.70764	0.11530	0.04673	0.07874	0.04902	0.12027	0.09860	0.09633	0.02934	0.10261	0.20214
Teamwork within units (a11)	0.13638	0.63558	0.10104	0.03023	0.11436	0.01518	0.22526	0.14965	0.07216	0.08199	0.01679	0.33646
Feedback and communication about error (c3)	0.13527	0.07133	0.62851	0.13941	0.06135	0.09838	0.14985	0.15366	0.04587	0.11200	0.07521	0.01399
Feedback and communication about error (c1)	0.13384	0.05449	0.60050	0.18943	-0.01527	0.10280	0.19019	0.20496	-0.03262	0.12979	0.07645	-0.01026
Communication openness (c2)	0.09852	0.16043	0.57183	0.07019	0.33364	0.08719	0.13893	0.02843	0.30991	0.05287	0.05832	0.01049
Communication openness (c4)	0.14941	0.15466	0.50423	0.08039	0.39227	0.14286	0.08507	0.05383	0.15452	0.10299	-0.03772	0.00556
Feedback and communication about error (c5)	0.12116	0.22016	0.40366	0.13286	0.15148	0.10201	0.35350	-0.00079	0.16464	0.11559	0.03811	0.01139
Frequency of events reported (d2)	0.06684	0.04659	0.08906	0.86175	0.03879	0.00570	0.03294	0.03045	-0.05119	0.05445	0.01694	0.04607
Frequency of events reported (d1)	0.07807	0.05648	0.10617	0.75804	0.01827	0.03834	0.14775	0.03446	0.06197	0.03554	0.00222	0.01285
Frequency of events reported (d3)	0.06822	0.06097	0.12770	0.72716	0.03923	0.06460	0.09731	0.03836	0.07231	0.01149	0.06544	-0.05655
Nonpunitive response to error (a8)	0.12614	0.14678	0.07208	0.01771	0.64346	0.10330	0.10187	0.22850	0.06580	0.09226	0.04667	-0.00483
Nonpunitive response to error (a12)	0.15109	0.12906	0.11978	0.02214	0.53793	0.10775	0.18200	0.23674	0.07781	0.08191	0.05394	-0.02002

Nonpunitive response to error (a16)	0.05195	0.08047	0.05280	0.01847	0.50892	0.07666	0.00027	0.18363	0.08474	-0.01182	-0.00202	0.02568
Communication openness (c6)	0.17332	0.16415	0.21118	0.05502	0.37636	0.08212	0.11758	0.05627	0.23451	0.04818	0.09541	-0.01282
Management support for patient safety(f8)	0.18824	0.04245	0.10665	0.05204	0.07670	0.77321	0.21291	0.06565	0.02629	0.06187	-0.00302	0.08536
Management support for patient safety(f9)	0.22467	0.03804	0.08818	0.03363	0.17619	0.61250	0.11193	0.21912	0.10629	0.07988	0.10681	-0.04121
Management support for patient safety(f1)	0.23457	0.07741	0.15669	0.05165	0.15522	0.57177	0.13700	0.24528	0.10918	0.03299	-0.00048	-0.04126
Organizational learning-improvement (a13)	0.06057	0.06798	0.14150	0.11897	0.08930	0.03971	0.63338	0.11474	0.04807	0.10960	0.06024	0.01961
Organizational learning-improvement (a6)	0.06530	0.20942	0.13294	0.10111	0.02388	0.18947	0.54168	0.07775	0.08273	0.02157	0.00187	-0.03278
Overall perceptions of patient safety (a15)	0.09189	0.11371	0.04183	0.11076	0.07956	0.17086	*0.36561*	0.20220	0.15500	-0.01261	0.13209	0.01801
Organizational learning-improvement (a9)	0.09524	0.11676	0.13424	0.02098	0.11234	0.12457	*0.36347*	0.02876	0.03753	0.13955	-0.03303	0.02564
Overall perceptions of patient safety (a17)	0.07255	0.03748	0.00032	0.03545	0.13512	0.17672	0.09169	0.45937	0.04632	0.11637	0.07528	-0.03807
Staffing (a14)	0.11982	0.00175	0.07483	0.04907	0.20927	0.01529	0.11827	0.45173	0.19274	0.00002	0.07527	0.15997
Staffing (a2)	0.13208	0.10630	0.17117	-0.02461	0.03221	0.15332	-0.02654	0.42276	0.07453	0.00927	-0.02575	0.10219
Overall perceptions of patient safety (a10)	0.09908	0.03352	0.03347	0.06269	0.22898	0.08584	0.09955	0.39599	0.02927	0.07453	0.09520	-0.02675
Staffing (a5)	0.06896	0.07276	0.05688	0.01148	0.13930	0.01390	0.06639	*0.37143*	0.17746	-0.08139	-0.02468	-0.08984
Overall perceptions of patient safety (a18)	0.15621	0.13976	0.20858	0.03151	0.07840	0.32000	0.27199	*0.33405*	0.00532	0.00825	0.03796	-0.13436
Supervisor/manager expectations (b3)	0.10079	0.03839	0.05051	0.03828	0.16872	0.06784	0.09837	0.21936	0.61061	0.12050	0.04875	0.05088
Supervisor/manager expectations (b4)	0.11362	0.10470	0.15855	0.04341	0.10367	0.20344	0.22387	0.19178	0.56442	0.27718	0.08299	-0.06457
Staffing (a7)	*0.03749*	*0.02631*	*0.08156*	*0.00847*	*0.07570*	*-0.00400*	*0.00718*	*0.15013*	*0.18633*	*-0.10842*	*-0.00234*	*0.00160*
Supervisor/manager expectations (b1)	0.16858	0.15031	0.28103	0.10537	0.12305	0.06507	0.18767	0.04443	0.05944	0.56990	0.03012	0.00301
Supervisor/manager expectations (b2)	0.13805	0.14592	0.31297	0.05705	0.12434	0.14884	0.24995	0.06217	0.29726	0.55977	-0.00864	0.02149
Handoffs and transitions (f5)	0.38560	0.14228	0.09987	0.09150	0.04823	0.07002	0.09169	0.11342	0.04913	0.04053	0.65446	-0.01757
Handoffs and transitions (f11)	*0.29116*	*0.04891*	*0.09025*	*0.03389*	*0.20818*	*0.01799*	*0.03229*	*0.10147*	*0.14143*	*-0.03592*	*0.30697*	*0.02201*

CHAPTER 8

Evolution of patient safety culture in Belgian hospitals after implementing a national patient safety plan



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ABSTRACT

Introduction: Within the federal program on quality and safety (2007-2012), the Belgian government provided a framework for implementing improvement strategies in the acute, psychiatric and long-term care hospitals.

Objectives: To examine whether safety culture evolved in Belgian hospitals after a period of three years and to explore predictor variables of safety culture.

Methods: Patient safety culture was measured on 12 dimensions using validated translations of the Hospital Survey on Patient Safety Culture (Flemish, French and German). Hospitals were invited to participate in a second nationwide benchmark initiative. Generalized Estimating Equations models were fitted to explore differences in safety culture.

Results: The Belgian safety culture database contains 115 827 records drawn from 176 hospitals. For 111 hospitals it was possible to calculate changes in safety culture. Improvements were observed for most dimensions with a major improvement for 'Management support for patient safety'. Although encouraged within the federal program, a decline was observed for 'Handoffs and transitions' and 'Frequency of events reported'. Hospitals had difficulties with indicating which targeted interventions were implemented to improve safety culture. Work area, staff position, language, hospital type and statute were found to have important effects on safety culture perceptions. Hospital size and experience, such as period working in the hospital, unit or profession showed to have less effect on safety culture scores.

Conclusions: Large comparative patient safety databases allow identifying patterns and trends. Future research should focus on enriching the evidence of the effectiveness of strategies aimed at improving patient safety culture. In addition, future work should aim to explore the relationship between safety culture, safety behavior and outcomes of care.

INTRODUCTION

Since the publication of the report 'To err is human' by the Institute of Medicine (IOM) in 1999, public attention was drawn to the importance and magnitude of the issue of patient harm from medical errors.[1] Still, patient safety remains an important global challenge. Yet, the importance of a safety culture in patient safety improvement is widely accepted within healthcare organizations. The milestone report of the IOM highlighted the importance of a safety culture as '*health care organizations must develop a culture of safety such that an organization's care processes and workforce are focused on improving the reliability and safety of care for patients*'.[1]

In Belgium, within a 5-year federal program on quality and safety (2007-2012), the government provided a framework for implementing quality and safety strategies in the acute, psychiatric and long-term care hospitals with attention to three pillars according to Donabedian's trilogy: structure (*how care is organized*), processes (*what is done by healthcare providers*) and outcome measurement (*the healthcare results achieved*). Based on a contract with the government, participating hospitals received an additional annual funding (7.66 million Euros for 178 hospitals in 2012) for implementing quality and safety improvements.[2] One of the main objectives in the federal program was the development of a safety culture as a key condition to implement a hospital-wide safety management system. In order to measure safety culture within the Belgian hospitals, the Hospital Survey on Patient Safety Culture (HSPSC) was selected since it covers a broad range of patient safety aspects and previous research demonstrated good psychometric properties of the instrument.[3-5] Also, previous research confirmed the robustness of the HSPSC, showing that the survey's constructs are useful for measuring patient safety at different levels.[4, 6] In addition, the HSPSC lends itself well for internal and external benchmarking purposes. A collective approach enables hospitals to learn from each other and helps identifying patterns in safety culture scores.[4]

Between 2007 and 2009, 88% of all Belgian hospitals (180 out of 205) entered the quality and safety program and conducted a baseline measurement of the safety culture in their organization, using a validated version of the HSPSC in Dutch (Flemish)[3], French and German.[5] Within the federal contract of the year

2011, 91% of the hospitals (179 out of 197) committed to conduct a second organization-wide safety culture assessment in order to track changes in safety culture.

The aim of this study was to investigate to what extent safety culture evolved within the Belgian hospitals after a period of three years. Although it was not feasible within this study to prospectively measure the effectiveness of improvement strategies, we sought to explain the evolution of safety culture based on additional information obtained from the hospitals. Finally, this study aimed at examining to what extent variations in safety culture could be explained by hospital characteristics (including type of hospital, statute, language and number of beds) and respondent characteristics (including work area, staff position, work experience and numbers of hours worked per week). Answers to these research questions could have implications for policies aiming at implementing interventions to improve safety culture.

METHODS

Implementing a Federal Program on Quality and Safety in Belgian hospitals

The federal program on quality and safety (2007-2012) was built of three main pillars. The first pillar aimed at developing a hospital-wide safety management system, including the establishment of a strategic plan and committee for patient safety, the implementation of a reporting system for (near) incidents, a classification system for adverse events (ICPS, International Classification for Patient Safety of the WHO), retrospective analysis, prospective risk assessment (Healthcare Failure Mode and Effects Analysis), a safety culture assessment (Hospital Survey on Patient Safety Culture) and the implementation of targeted safety culture interventions based on the hospitals' results of the baseline safety culture measurement. Furthermore, the program aimed at analyzing and improving multidisciplinary intramural and transmural care processes, for instance by conducting a SWOT - Strengths, Weaknesses, Opportunities and Threats – analysis and by implementing PDCA – Plan, Do, Study, Act - cycles. Finally, the third pillar aimed at developing an indicator set for measuring the quality and safety of care within the hospitals. Hospitals were free to address the content of interventions within the three pillars and instructions were guided by the type of hospital (acute, psychiatric and long-term care hospitals). Throughout the federal program, support was offered to the hospitals by organizing workshops and providing tools and information on relevant topics (e.g. Root Cause Analysis, Healthcare Failure Mode and effects Analysis). The federal website provides all the necessary information for the participating hospitals regarding the quality and patient safety contracts. Yearly, the federal government collects information on the adherence to the contracts and provides feedback by publishing a national report of the results.[2]

Data collection of second nationwide safety culture measurement

The HSPSC includes 42 items that assess safety culture on 12 dimensions. Each item is measured on a 5-point Likert scale ranging from 'strongly disagree' to 'strongly agree' (with a midway point of 'neither') or from 'never' to 'always' (with a midway point of 'sometimes'). The survey distribution and data collection for the second nationwide safety culture measurement were identical to the method of the first initiative[4] and were based on the original survey of the Agency for Healthcare Research and Quality (AHRQ).[7] To enhance the suitability of the HSPSC for its use within the psychiatric hospitals, the demographic categories of work area and profession were adapted to the context of psychiatric care. A measurement toolkit was available containing the validated version of the HSPSC (in Dutch, French and German) and a protocol for data collection and internal feedback. Workshops were organized for the participating hospitals, in which the objectives and tools for conducting the safety culture measurement were explained. The protocol suggested to conduct the survey within a 13 weeks' timetable and encouraged hospitals to use reminders. Hospitals were free to use paper-based or electronic survey forms. Questionnaires were distributed anonymously to all individuals working in direct or indirect interaction with patients.

For analysis and benchmarking purposes, an MS Access-based instrument was designed to standardize data entry and automate the application of the exclusion criteria of respondents and analysis of the results. The Access tool automatically filtered out questionnaires with unanswered sections, fewer than half of the items throughout the survey were answered or all items were scored identically. Additionally, the Access tool provided the possibility to instantly create a hospital report with an overview of the respondent characteristics and the hospital scores on the different items and 12 composite dimensions.

Hospitals participating in the federal program were invited to join in a benchmark initiative on a voluntary, confidential and free of charge basis. The comparative database is managed by Hasselt University, a neutral academic institution, and is not accessible by the governmental authorities. Technical assistance was available during the period of data collection (January 2012 – March 2012) and after feedback of the results (June 2012).

A short questionnaire was sent to the contact persons of the participating hospitals (in most cases the quality or safety coordinator) in order to obtain additional information on the adequacy of the safety culture measurement and on interventions that were implemented after the first measurement. More specifically, the questionnaire asked information about (1) the adequate application of the measurement protocol (e.g. target group and use of reminders), (2) whether the measurement was conducted organization-wide, (3) the method of survey administration (electronically, paper-based, or both), (4) the number of distributed and retrieved questionnaires from the physicians and other employees, (5) the number of full-time equivalent (FTE) nurses, (6) the number of hospital beds, (7) the statute of the hospital (private or public), (8) which dimensions were addressed after the baseline safety culture measurement and (9) which interventions were implemented to improve these dimensions. The latter included any intervention that could improve safety culture. The data were linked with the safety culture database (at the hospital level) and the safety culture interventions were sorted for each dimension.

Statistical analysis

Based on the responses to the survey, a mean dimensional score (range 1-5) was calculated at the respondent level. Answers to negatively worded questions were reversed. Mean dimensional scores higher than three were considered as positive values towards patient safety (binary score=1= if mean answer >3; binary score=0 if mean answer ≤3). Based on these values, positive dimensional scores were computed at the hospital level (percentage positive answers of all individuals).

The baseline and follow-up dimensional scores were compared for hospitals that completed both surveys. The relative change in each of the 12 dimensional scores was calculated by deducting the dimensional scores of the two measurements. Statistical significance of improvement is greatly influenced by sample size. So as the number of observations gets larger, small differences in scores will be statistically significant. While a 1 percent difference between percent positive scores might be 'statistically' significant (that is, not due to chance), the difference is not likely to be meaningful or 'practically' significant. Therefore, we followed the recommendation of the AHRQ to use a 5-percentage point as a meaningful difference to consider.[8] In the assumption that the population was not normally distributed, the Related Samples Wilcoxon Signed Rank test was used to compare the distribution of the two repeated measurements.

Multiple regression was performed on all safety culture data (first and second measurement) of the 111 trending hospitals using the method of Generalized Estimating Equations (GEE) to examine any possible relationship between safety culture predictor variables and the 12 safety culture dimensions, as well as to determine the effect size.[9-11] It is assumed that observations from respondents within the same hospital are more alike than observations from different hospitals, inducing within-hospital correlation. The method of GEE estimates 'marginal' effects, which have a population averaged interpretation. This method is also applicable to situations with missing data. A complete case GEE analysis (including only the fully observed cases) is valid under the assumption of Missing Completely At Random (MCAR),[12] but would imply loss of data of incomplete cases and hence would lead to less efficient estimates. Here, missingness was addressed using the method of multiple imputation, which is a more efficient approach and also valid under the less strict Missing At Random (MAR) assumption. This multiple imputation technique replaces each missing value with *m* acceptable values representing a distribution of possibilities. Given the fact that 3 to 10 imputations are sufficient to obtain stable results, the number of imputations in our study was $m=5$.[13]

Binary scores of the 12 safety culture dimensions were modeled as the response variables: Supervisor/manager expectations and actions promoting safety (D1), Organizational learning–continuous improvement (D2), Teamwork within units

(D3), Communication openness (D4), Feedback and error communication (D5), Non-punitive response to error (D6), Staffing (D7), Management support for patient safety (D8), Teamwork across units (D9), Handoffs and transitions (D10), Overall perceptions of patient safety (O1) and Frequency of events reported (O2). The predictor variables included measurement occasion (first or second measurement), type of hospital, number of beds, language, work area, profession, period working in the current hospital, period working in the current area, period working in the current profession and hours worked per week (Appendix I).

A step-down hierarchical model building approach was applied to each of the 12 safety culture dimensions. The initial model contained the main effects of all predictor variables. No interaction effects were considered. In a sequential order, the least significant effects were removed from the model leading to a model with only significant covariates for each dimension. As a result, the 'best' end models are presented for each dimension (Appendix II).

The odds ratios (ORs) of the response variables were calculated adjusting for all the predictor variables included in the model. A reference level for comparison was chosen for all categorical covariates. For number of beds, which was considered as a continuous variable, the OR indicates the increase or decrease in the odds of being positive towards patient safety per increase of 10 beds.

All data were analyzed confidential using R 2.15.1, SAS 9.2® and IBM SPSS 20®. The level of significance was chosen to be 5% (i.e. $\alpha=0.05$) throughout the analysis.

RESULTS

Hospital and respondent characteristics

In total, the Belgian safety culture benchmark database includes 115 827 records drawn from 176 hospitals. Of those, 147 hospitals conducted a first measurement (53.6% response rate) and 140 hospitals repeated the measurement after three years (50.6% response rate). Several hospitals participated once only in the comparative research. In addition, seven hospitals underwent a hospital fusion in the period between the two measurements, which reduced the number of participants in the second measurement.

Trending of data was possible for 111 hospitals, which participated twice in the benchmark initiative, of which 69 acute, 34 psychiatric and 8 long-term care hospitals. The hospitals' characteristics are presented in table 1. For the second measurement, a higher number of hospitals applied a mixed method using both paper-based and electronic questionnaires for administering the survey in comparison with the first measurement. In most of these cases, the questionnaires were distributed on paper, while reminders were sent electronically. The overall response rate was higher for the second measurement (52.2%) in comparison with the first measurement (51.0%). The trending database consists of 86 262 respondents. Respondents' characteristics are presented in table 2, based on the respondents' answers on the demographical items of the survey.

Table 1: Hospital characteristics and response rates

Type of hospital	AH (n = 69)		PH (n = 34)		LTCH (n = 8)	
Language						
Dutch	48 (69.6%)		28 (82.4%)		7 (87.5%)	
French	19 (27.5%)		6 (17.6%)		1 (12.5%)	
Both Dutch and French	2 (2.9%)		0 (0%)		0	
Statute						
Public	49 (71%)		29 (85.3%)		1 (12.5%)	
Private	19 (27.5%)		3 (8.8%)		7 (87.5%)	
Missing	*1 (1.4%)*		*2 (5.9%)*		*0 (0%)*	
Number FTE (nurse)						
< 100	35 (50.7%)		19 (55.9%)		8 (100%)	
100 - 499	0 (0%)		11 (32.4%)		0 (0%)	
500 - 999	17 (24.6%)		1 (2.9%)		0 (0%)	
1000 - 1499	6 (8.7%)		0 (0%)		0 (0%)	
≥ 1500	4 (5.8%)		0 (0%)		0 (0%)	
Missing	*7 (10.1%)*		*3 (8.8%)*		*0 (0%)*	
Number of beds						
< 250	15 (21.7%)		17 (50%)		6 (75%)	
250 - 499	26 (37.7%)		11 (32.4%)		2 (25%)	
500 - 999	16 (23.2%)		4 (11.8%)		0 (0%)	
≥ 1000	5 (7.2%)		0 (0%)		0 (0%)	
Missing	*7 (10.1%)*		*2 (5.9%)*		*0 (0%)*	
	Measurement 1	**Measurement 2**	**Measurement 1**	**Measurement 2**	**Measurement 1**	**Measurement 2**
Survey administration						
Paper	52 (75.4%)	41 (59.4%)	30 (88.2%)	25 (73.5%)	8 (100%)	6 (75%)
Electronic	13 (18.8%)	14 (20.3%)	4 (11.8%)	7 (20.6%)	0 (0%)	2 (25%)
Mixed-mode	4 (5.8%)	13 (18.8%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Missing	*0 (0%)*	*1 (1.4%)*	*0 (0%)*	*2 (5.9%)*	*0 (0%)*	*0 (0%)*
Total response rate	**49.0%**	**49.4%**	**68.7%**	**74.4%**	**59.5%**	**65.5%**
Physicians	32.9%	33.5%	61.1%	61.3%	39.1%	61%
Employees	52.1%	52.5%	69.0%	75.0%	60.6%	65.7%

AH=Acute Hospitals, PH=Psychiatric Hospitals, LTCH=Long Term Care Hospitals.

Table 2: Respondent characteristics for 111 trending hospitals for 2 measurements

Respondent characteristics	Numbers submitted for benchmark database: 86 262 respondents (100%)					
	MEASUREMENT 1 (43 732 respondents)			MEASUREMENT 2 (42 524 respondents)		
	69 acute hospitals	34 psychiatric hospitals	8 long-term care hospitals	69 acute hospitals	34 psychiatric hospitals	8 long-term care hospitals
Total number of respondents	**37 451**	**5 329**	**952**	**35 495**	**5 985**	**1 044**
Work area/ Unit*	**30 946 (82.6%)**	**3 250 (61.0%)***	**877 (92.1%)***	**34 864 (98.2%)**	**5 673 (94.8%)**	**1 019 (97.6%)***
Many different hospital units/No specific unit	2 502 (6.7%)	124 (2.3%)	76 (8.0%)	2 887 (8.1%)	-	98 (9.4%)
Internal Medicine (including day-stay admissions)	4 229 (11.3%)	42 (0.8%)	4 (0.4%)	4 414 (12.4%)	-	5 (0.5%)
Surgery (including day-stay admissions)	3 989 (10.7%)	1 (0.0%)	-	4 469 (12.6%)	-	2 (0.2%)
Operating theatre	2 089 (5.6%)	1 (0.0%)	-	2 548 (7.2%)	-	2 (0.2%)
Gynecology/ obstetrics	1 551 (4.1%)	90 (1.7%)	1 (0.1%)	1 862 (5.2%)	-	1 (0.1%)
Pediatrics	1 272 (3.4%)	73 (1.4%)	1 (0.1%)	1 716 (4.8%)	-	1 (0.1%)
Intensive care unit	1 870 (5.0%)	-	-	2 070 (5.8%)	-	-
Emergency	1 397 (3.7%)	-	-	1 514 (4.3%)	-	-
Revalidation	1 354 (3.6%)	10 (2.0%)	720 (75.6%)	1 345 (3.8%)	-	793 (76.0%)
Geriatrics	2 091 (5.6%)	127 (2.4%)	1 (0.1%)	2 213 (6.2 %)	-	2 (0.2%)
Psychiatry	1 033 (2.8%)	2 607 (48.9%)	-	941 (2.7%)	-	-
Medical-technical services (diagnostics)	3 710 (9.9%)	18 (0.3%)	8 (0.8%)	4 086 (11.5%)	-	8 (0.8%)
Pharmacy	685 (1.8%)	44 (0.8%)	11 (1.2%)	684 (1.9%)		11 (1.1%)
Categories psychiatric hospitals (measurement 2)	-	-	-	-	**5 673 (94.8%)**	-
Different hospital units/ mobile team				-	662 (11.1%)	
Admission/ observation or crisis unit	-	-	-	-	866 (14.5%)	-
Specialized unit (e.g. mood or behavior disorders, psychosis care, addiction therapy)	-	-	-	-	3 038 (50.6%)	-
Day or night hospital	-	-	-	-	280 (4.7%)	-
Supporting services (pharmacy, medical-technical services, technical services, administration)	-	-	-	-	343 (5.7%)	-
Other	3 173 (8.5%)	113 (2.1%)	55 (5.8%°	4 115 (11.6%)	484 (8.1%)	96 (9.2%)
*Missing**	*6 506 (17.4%)*	*2 079 (39.0%)*	*75 (7.9%)**	*631 (1.8%)*	*312 (5.2%)*	*25 (2.4%)*

Respondent characteristics (continued)	MEASUREMENT 1 (43 732 respondents)			MEASUREMENT 2 (42 524 respondents)		
	69 acute hospitals	**34 psychiatric hospitals**	**8 long-term care hospitals**	**69 acute hospitals**	**34 psychiatric hospitals**	**8 long-term care hospitals**
Staff position*	**33 629 (89.8%)**	**3 748 (70.3%)***	**894 (93.9%)**	**33 719 (95.0%)**	**5 901 (98.6%)**	**1 023 (98.0%)**
Nurse	18455(49.3%)	1 523 (28.6%)	284 (29.8%)	18518(52.2%)	3 254 (54.4%)	375 (35.9%)
Nursing aid	2 623 (7.0%)	491 (9.2%)	171 (18.0%)	2 259 (6.4%)		176 (16.9%)
Head nurse	1 497 (4.0%)	187 (3.5%)	30 (3.2%)	1 638 (4.6%)	396 (6.6%)	35 (3.4%)
Middle management	1 031 (2.8%)	107 (2.0%)	19 (2.0%)	941 (2.7%)		26 (2.5%)
Physician	2 659 (7.1%)	83 (1.6%)	30 (3.2%)	2 739 (7.7%)	189 (3.2%)	33 (3.2%)
Physician – head of department	793 (2.1%)	30 (0.6%)	4 (0.4%)	874 (2.5%)		7 (0.7%)
Physician assistant/ physician in training	185 (0.5%)	12 (0.2%)	-	208 (0.6%)		1 (0.1%)
Pharmacist	244 (0.7%)	17 (0.3%)	6 (0.6%)	252 (0.7%)	449 (7.5%)	6 (0.6%)
Assistant pharmacy	354 (0.9%)	25 (0.5%)	8 (0.8%)	349 (1.0%)		7 (0.7%)
Technician (ECG. Lab. Radiology)	1 631 (4.4%)	16 (0.3%)	3 (0.3%)	1 635 (4.6%)		2 (0.2%)
Therapist (dietitian. physical. psychologist)	2 161 (5.8%)	807 (15.1%)	251 (26.4%)	2 196 (6.2%)	1 484 (24.8%)	280 (26.8%)
Other	1 996 (5.3%)	450 (8.4%)	88 (9.2%)	2 110 (5.9%)	128 (2.1%)	75 (7.2%)
Missing	*3 822 (10.2%)*	*1581(29.7%)**	*58 (6.1%)*	*1 776 (5.0%)*	*84 (1.4%)*	*21 (2.0%)*
Interaction with patients	**34 975 (93.4%)**	**5 211 (97.8%)**	**929 (97.6%)**	**33 903 (95.5%)**	**5 835 (98.5%)**	**1 036 (99.2%)**
YES, have direct patient interaction	31718(84.7%)	5 018 (94.2%)	854 (89.7%)	30797(86.8%)	5 606 (93.7%)	981 (94%)
NO, do NOT have direct patient interaction	3 257 (8.7%)	193 (3.6%)	75 (7.9%)	3 106 (8.8%)	287 (4.8%)	55 (5.3%)
Missing	*2 476 (6.6%)*	*118 (2.2%)*	*23 (2.4%)*	*1 592 (4.5%)*	*92 (1.5%)*	*8 (0.8%)*
Professional experience	**35 059 (93.6%)**	**5 203 (97.6%)**	**928 (97.5%)**	**33 890 (95.5%)**	**5 873 (98.1%)**	**1 029 (98.6%)**
Less than 1 year	1 402 (3.7%)	25 (4.8%)	37 (3.9%)	1 199 (3.4%)	257 (4.3%)	43(4.1%)
1 to 5 years	6 516 (17.4%)	1 001 (18.8%)	159 (16.7%)	6 822 (19.2%)	1 201 (20.1%)	178 (17.0%)
6 to 10 years	6 304 (16.8%)	957 (18.0%)	195 (20.5%)	5 465 (15.4%)	889 (14.9%)	165 (15.8%)
11 to 15 years	4 675 (12.5%)	618 (11.6%)	132 (13.9%)	5 050 (14.2%)	882 (14.7%)	169 (16.2%)
16 to 20 years	5 328 (14.2%)	683 (12.8%)	121 (12.7%)	4 141 (11.7%)	649 (10.8%)	119 (11.4%)
21 years or more	10834(28.9%)	1 687 (31.7%)	284 (29.8%)	11213(31.6%)	1 995 (33.3%)	355 (34.0%)
Missing	*2 392 (6.4%)*	*126 (2.4%)*	*24 (2.5%)*	*1 605 (4.5%)*	*112 (1.9%)*	*15 (1.4%)*

Respondent characteristics (continued)	MEASUREMENT 1 (43 732 respondents)			MEASUREMENT 2 (42 524 respondents)		
	69 acute hospitals	34 psychiatric hospitals	8 long-term care hospitals	69 acute hospitals	34 psychiatric hospitals	8 long-term care hospitals
Working time in hospital	**35 282 (94.2%)**	**5 237 (98.3%)**	**941 (98.8%)**	**35002 (98.6%)**	**5 829 (98.4%)**	**1 029 (28.6%)**
Less than 20 hours per week	3 766 (10.1%)	548 (10.3%)	129 (13.6%)	4 192 (11.8%)	637 (10.6%)	164 (15.7%)
20 to 39 hours per week	22402(59.8%)	3622 (68.0%)	666 (70.0%)	22015(62.0%)	4 045 (67.6%)	708 (67.8%)
40 to 59 hours per week	7 589 (20.3%)	967 (18.1%)	134 (14.1%)	7 217 (20.3%)	1 123 (18.8%)	142 (13.6%)
60 to 79 hours per week	1 186 (3.2%)	79 (1.5%)	9 (0.9%)	1 239 (3.5%)	63 (1.0%)	14 (1.3%)
80 hours per week or more	339 (0.9%)	21 (0.4%)	3 (0.3%)	339 (1.0%)	24 (0.4%)	1 (0.1%)
Missing	*2 169 (5.8%)*	*92 (1.7%)*	*11 (1.2%)*	*493 (1.4%)*	*93 (1.6%)*	*15 (1.4%)*

*For the psychiatric hospitals categories of work area and staff position were adapted for the follow-up measurement. For work area new categories were defined. For staff position, the groups of nurses and nursing aids were merged; the groups of head nurse, middle management and executive staff were merged; the groups of physicians were merged; the groups of pharmacists, technicians and logistics were merged as 'supporting services'.

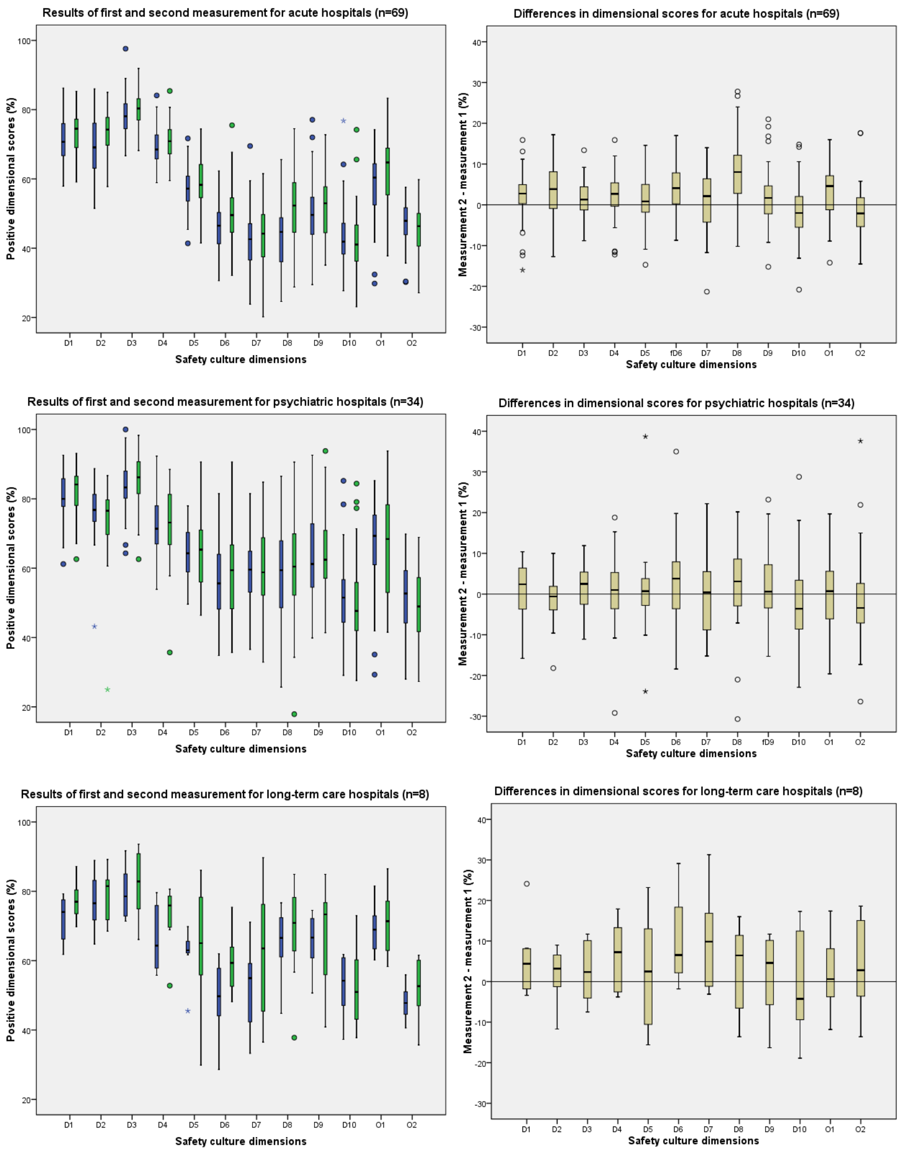
Evolution of safety culture dimensions

The evolution of safety culture on 12 dimensions is presented by type of hospital in figure 1 and Appendix III. Positive dimensional scores are displayed using box plots, which provide an indication of the dispersion between hospitals, possible skewness of data and outliers (hospital level). The left boxes present the positive scores of the first and second measurement per type of hospital. The right boxes display the evolution of safety culture per type of hospital calculated by the differences of scores.

Regression analysis models

Regression analysis was performed to examine the effect of the predictor variables on the 12 safety culture dimensions. Results from General Estimations Equations are presented by means of Odds Ratios (OR) for each dimension in table 3. Odds ratios of the categorical variables indicate the increase (if OR > 1) or decrease (if OR < 1) in the odds of positive perceptions towards patient safety in comparison with the reference category. For the continuous variable number of beds, the OR indicates the increase or decrease in odds for each increase of 10 beds. Covariates which had no significant effect on the response variables were removed from the GEE model (Appendix II).

Figure 1: Evolution of safety culture on 12 dimensions (acute, psychiatric and long-term care hospitals)



Blue boxplots represent the first measurement; green boxplots represent the second measurement. **Dimensions:** D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

Table3: Odds Ratios for 12 safety culture dimensions

Variable		Odds Ratio											
Measurement occasion (Reference = First)		**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Second measurement		1.16*	1.21*	1.12*	1.16*	1.08*	1.17*	1.07*	1.34*	1.06*	0.94*	1.12*	/
	Work area (Reference = Internal Medicine)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Acute and long-term care hospitals	Surgery	1.02	0.99	0.89*	0.97	1.04	0.90*	1.14*	1	1.08*	1.23*	1.08*	0.88*
	Operating theatre	0.75*	0.82*	0.44*	0.77*	0.72*	0.81*	1.08*	0.83*	1.01	0.83*	0.78*	0.72*
	Gynecology	0.90*	0.83*	1.09	0.90*	0.99	0.86	1.68*	0.91*	1.19*	1.57*	1.17*	0.73*
	Pediatrics	1.34*	1.26*	1.48*	1.45*	1.23*	1.28*	1.76*	1.12*	1.07	1.31*	1.41*	1.08
	Intensive Care Unit	0.96	0.96	1.14*	1.02	0.85*	1.03	1.94*	0.78*	0.92*	1.05	1.18*	0.77*
	Emergency	0.77*	0.62*	0.80*	0.80*	0.73*	0.64*	1.09*	0.70*	0.61*	0.86*	0.58*	0.60*
	Geriatrics	1.09*	1.46*	0.99	1.03	1.11*	0.98	0.88*	1.18*	1	0.93*	0.95	1.17*
	Psychiatry	1.14*	1.15*	1.07	0.99	1.04	1.14*	1.82*	0.99	0.99	1	1.07	1.01
	Medical-technical services	0.94	1.04	0.72*	1.09*	1.24*	1.08*	2.56*	1.09*	0.94	0.67*	1.61*	1.08*
	Pharmacy	0.84	0.88	0.64*	0.97	0.98	1.16	1.55	0.95	0.97	0.46*	1.22	0.93
Psychiatric hospitals	Admission/observation/crisis	0.99	0.85	1.06	0.89	1.01	0.94	1.08	0.76*	0.93	1	0.83*	0.90
	Specialized unit	0.76*	0.82*	0.70*	0.81*	0.93	0.83*	1.17*	0.61*	0.78*	0.71*	0.71*	0.87*
	Day/night hospital	1.77*	1.08	1.35	1.50*	1.30	2.17*	2.92*	1.21	1.37*	1.29	1.64*	0.93
	Psychiatric supporting services	0.93	0.99	0.76	0.88	0.93	0.96	2.01*	1.08	0.88	0.62*	1.14	0.76*
	Addiction therapy	1.35	1.08	1.35	1.31	1.24	1.24	1.64*	0.92	1.05	1.17	1.41*	0.83
	Psychosis care	1.37	1.16	1.38	1.36	1.55*	1.33*	1.30*	1.01	1.61*	1.11	1.23	1.12
	Mood disorder care	1.02	0.90	0.93	0.77	0.91	1.06	1.57*	0.96	1.33	1.22	1.15	0.88
	Behavioral disorder care	1.79*	1.85*	1.45	1.96*	2.91*	1.32	1.24	1.10	1.38	1.41	0.80	1.17
	Child psychiatric department	1.10	1.01	1.07	0.67*	0.82	1.23	0.87	0.94	0.92	1.38*	0.84	1.13

	Elderly psychiatric department	1.20	2.26*	0.77	0.97	1.37*	1.25	1.03	1.24	1.13	0.95	1.07	1.16
	Neurology	0.87	0.64	0.49*	0.85	1.04	0.83	1.81*	1.07	1.14	0.63	0.67	0.93
All hospitals	Many units	0.78*	0.83*	0.82*	0.80*	0.75*	0.79*	1.15*	1.01	0.99	0.72*	0.82*	0.69*
	Rehabilitation	1.10	1.20*	1.11	1.07	1.09	1.23*	1.90*	1.19*	1.01	0.84*	1.36*	0.96
	Other	1	1.02	0.99	1.16*	1.13*	1.13*	1.95*	1.22*	1.06	0.85*	1.35*	0.97
	Profession (Reference = Nurse)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Acute and long-term care hospitals	Head nurse	1.63*	1.88*	2.07*	2.96*	1.67*	2.68*	1.80*	1.95*	1.61*	1.24*	1.29*	1.08*
	Nursing aid	1.17*	0.98	0.81*	1.10*	1.42*	0.88*	0.88*	1.37*	1.04	1.05	1.06	1.37*
	Physician	0.96	0.94	1.51*	1.53*	0.96*	1.69*	1.99*	1.35*	1.47*	0.89*	1.71*	0.97
	Physician, Head of department	1.19*	1.32*	1.85*	2.13*	1.47*	2.08*	2.08*	1.62*	1.59*	1.06	1.99*	1.10
	Physician assistant/ in training	0.86	0.65*	0.99	1	0.76*	1.16	1.26*	0.94	1.01	0.74*	1.10	0.77*
	Pharmacist	1.64*	2.13*	1.80*	2.20*	1.43*	2.11*	1.40*	1.77*	1.27	0.59*	1.29	1.12
	Assistant pharmacy	0.70*	0.77*	0.75*	0.77*	0.86	0.86	1.13	1.27*	0.76*	0.59*	1.09	1.09
	Middle management	0.90*	0.79*	0.89*	0.84*	0.87*	1	1.11*	1.53*	0.99	0.72*	1.05	0.69*
	Technician	0.74*	0.75*	1.06	0.83*	0.98	0.94	1.31*	1.12*	0.91*	0.73*	1.27*	1.09
Psychiatric hospitals	Nurse/nursing aid	0.83*	0.81*	1.07	1.01	1.12*	0.96	1.47*	1.13*	1.22*	0.85*	1.06	1.08
	Physician/Physician head of department/Physician assistant	0.72*	0.97	1.77*	1.72*	1.25	1.72*	1.50*	1.62*	1.56*	0.89	1.70*	1.22
	Supporting services (pharmacy/assistant pharmacy/technician)	0.56*	0.66*	1.02	0.84	1.02	0.90	1.33*	1.39*	0.99	0.60*	1.24	1.10
	Head nurse/middle management	0.97	1.23	1.71*	2.13*	1.24*	1.65*	1.84*	1.66*	1.43*	1.12	1.50*	0.89
All hospitals	Therapist	0.73*	0.67*	1.10*	0.90*	0.75*	1.16*	1.50*	1.13*	1.05	0.60*	1.23*	0.68*
	Other	0.78*	0.74*	0.85*	0.93	1.06	0.94	1.11*	1.29*	0.95	0.73*	1	0.91*

Errors reported in last 12 months (Reference = None)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
1 or 2 incidents	1.20*	1.29*	1.077*	1.13*	1.26*	1.09*	0.93*	1.03	1.01	0.9957	0.91*	1.46*
3 to 5 incidents	1.12*	1.31*	0.94*	1.09*	1.29*	1.06*	0.84*	0.92*	0.90*	0.86*	0.73*	1.61*
6 to 10 incidents	1.02	1.27*	0.85*	1.03	1.27*	1.02	0.75*	0.81*	0.80*	0.77*	0.61*	1.63*
11 to 20 incidents	1.01	1.14*	0.78*	0.99	1.21*	1.13*	0.72*	0.74*	0.77*	0.67*	0.53*	1.76*
21 or more incidents	0.88*	1.07	0.67*	1	1.17*	0.98	0.65*	0.61*	0.63*	0.57*	0.45*	1.98*
Period in current hospital (Reference = 21 years or more)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Less than 1 year	1.25*	0.94	1.29*	1.38*	1.39*	1.24*	1.34*	1.45*	1.38*	1.34*	1.35*	1.14*
1 to 5 years	0.94	0.78*	0.99	1	0.95	1.07*	1.01	1.03	1	1.05	1.05	0.93
6 to 10 years	0.85*	0.76*	0.98	0.89*	0.85*	0.934*	0.96	0.90*	0.89*	0.974	0.95	0.88*
11 to 15 years	0.96	0.91*	0.98	0.96	0.88*	0.97	1.03	0.94	0.95	1	1.01	0.92*
16 to 20 years	0.96	0.90*	0.97	0.91*	0.88*	0.91*	1.05	0.92*	0.95	0.964	0.95	0.96
Period worked in unit (Reference = 21 years or more)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Less than 1 year	1.16*	1.15*	1.29*	/	1.11*	0.90*	1.23*	/	/	/	/	1.07
1 to 5 years	1.18*	1.11*	1.10*	/	1.07*	0.98	1.21*	/	/	/	/	1.09*
6 to 10 years	1.09*	1.09*	1.00	/	0.99	1.02	1.13*	/	/	/	/	1.10*
11 to 15 years	1.02	1.04	1.04	/	1.02	1.01	1.13*	/	/	/	/	1.08*
16 to 20 years	1	1.06	0.99	/	0.99	1.02	1.04	/	/	/	/	1.01
Hours worked per week (Reference =80 hours or more)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Less than 20 hours	1.20*	1.19*	1.31*	1.41*	/	1.24*	1.74*	1.48*	1.31*	1.36*	1.31*	/
20 to 39 hours	1.31*	1.22*	1.31*	1.43*	/	1.35*	1.72*	1.38*	1.22*	1.31*	1.33*	/
40 to 59 hours	1.29*	1.34*	1.30*	1.48*	/	1.36*	1.37*	1.34*	1.19*	1.20*	1.23*	/
60 to 79 hours	1.13	1.37*	1.11	1.30*	/	1.19*	1.23*	1.27*	1.17	1.05	1.11	/
Contact with patients (Reference = No)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Yes	/	/	/	0.92*	1.27*	/	0.91*	1.10*	/	0.83*	0.91*	1.11*

Period in this profession (Reference = 21 years or more)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Less than 1 year	1.18*	1.14*	1.40*	1.26*	/	/	/	0.91	1.04	0.92	1.31*	0.93
1 to 5 years	1.06	1.07	1.17*	1.09*	/	/	/	0.87*	0.97	0.85*	1.17*	0.93*
6 to 10 years	0.96	0.97	1.04	1.04	/	/	/	0.81*	0.95	0.85*	1.08*	0.90*
11 to 15 years	0.97	0.93	0.97	1	/	/	/	0.87*	0.94*	0.88*	0.98	0.89*
16 to 20 years	0.97	0.95	0.94	1.01	/	/	/	0.91*	0.98	0.95	1.03	0.97
Statute (Reference = Private)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Public	0.93*	0.91*	0.92*	0.92*	0.94*	0.85*	1.11*	0.82*	0.82*	0.91*	/	/
Type of Hospital (Reference =Acute hospital)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
Long-term care hospital	1.08	1.46*	1.12	0.97	1.08	1.15*	1.49*	1.42*	1.81*	1.83*	1.28*	1.06
Psychiatric hospital	1.82*	1.53*	1.22*	1.22*	1.20*	1.41*	1.52*	1.32*	1.37*	1.41*	1.32*	1.19*
Language (Reference = Dutch)	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
French	0.75*	1.73*	1.16*	0.91*	0.88*	0.89*	1.31*	0.82*	0.73*	0.84*	0.47*	0.78*
Both (French and Dutch)	0.73*	1.59*	1.18*	1.04	0.92	0.88*	1.12*	0.70*	0.68*	0.79*	0.59*	0.92
Number of Beds [Continuous variable]	1*	/	1*	1*	1*	1*	/	1*	/	1*	1*	1*

P-values ≤ 0.05 indicated by (*); Significant higher odds ratios are marked gray, significant lower odds ratios are marked dark grey. / indicates that the covariate was removed from the GEE model, because of no significant effect on the safety culture dimension under consideration.

Dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported.

Overall, ORs were higher for the second measurement, except for *Handoffs and transitions* (D10). The lowest ORs for this dimension were found for the pharmacy and medical-technical services (supporting services in psychiatric hospitals) and also for the professions of pharmacists and technicians. Hospital staff working in many different units, the operating theatre, the emergency department and specialized units in psychiatric hospitals were less likely to have positive perceptions for most dimensions and particularly for *Overall perceptions of patient safety* (O1). In contrary, ORs were found to be higher for staff working in pediatrics. Perceptions on *Staffing* (D7) were found to be the lowest for geriatrics. However, geriatrics, elderly psychiatric departments and behavioral disorder care showed the highest odds for *Organizational learning–continuous improvement* (D2). The ORs for work area in the psychiatric hospitals were often insignificant or inconsistent across the safety culture dimensions.

Besides variations in safety culture perceptions between hospital units, a considerable disparity in perceptions was found between professional groups and within disciplines. For instance, results indicated an important gap of perceptions between clinical leaders (head nurses, head physicians, head pharmacists) and assistants (nurses, nursing aids, physicians assistants/ in training, assistants pharmacy).

'Errors reported in the last 12 months' was significantly related to higher odds of positive perceptions on dimensions *Organizational learning–continuous improvement* (D2), *Feedback and error communication* (D5) and *Frequency of events reported* (O2) and to lower odds for dimensions *Teamwork within units* (D3), *Staffing* (D7), *Hospital management support* (D8), *Teamwork across units* (D9), *Handoffs and transitions* (D10) and *Overall perceptions of patient safety* (O1). ORs were higher for respondents working less than one year in the hospital. Covariates of period working in the unit and profession, hours worked per week and contact with patients were removed for several dimensions during model building because of no significant effect.

Overall, ORs for public hospitals were lower in comparison with private hospitals. Also, respondents working in psychiatric and long-term care hospitals had higher odds of positive perceptions in comparison with respondents working in acute hospitals. Furthermore, language was found to be significantly associated with safety culture perceptions, since ORs of Dutch speaking hospitals were higher in comparison with ORs of French and bilingual hospitals, except for dimensions *Organizational learning–continuous improvement* (D2), *Teamwork within units* (D3) and *Staffing* (D7).

Finally, 'number of beds' was found to have only a small effect on safety culture perceptions.

Strategies for improving safety culture

The evolution of 12 safety culture dimensions is presented by type of hospital in table 4. Following the rule of thumb suggested by the AHRQ[8], it was indicated for each dimension how many hospitals had improved with 5% or more. For these hospitals, it was listed for each dimension how many hospitals implemented strategies for improving safety culture. The information on improvement strategies was obtained from the hospitals using an additional questionnaire. However, this information was not verified and thus could have been incomplete. Therefore, we provide exemplary interventions in table 4 (last column).

Table 4: Strategies for improving safety culture

Dimensions	% of improvement or decline (p-values)			N hospitals with ≥ 5% improvement** (of which N hospitals with targeted actions)	Examples of improvement strategies (indicated by hospitals)
	AH (n=69)	PH (n=34)	LTCH (n=8)		
D1: Supervisor/manager expectations and actions promoting safety	*+2.8** *(0.000)*	+2.6 (0.245)	+4.4 (0.093)	32 (2)	Improvement of communication between management and units
D2: Organizational learning–continuous improvement	*+3.9** *(0.000)*	-1.0 (0.293)	+3.2 (0.484)	41 (6)	In-hospital patient safety campaign; registration of incidents; sensibilization (posters, dashboard); organizational structural change by implementation of care teams which are accountable for quality and safety; medical record review by quality team; constitution of a patient safety committee; multidisciplinary analysis of events; audits of hospitals units and feedback; encouraging incident reporting
D3: Teamwork within units	*+1.3** *(0.002)*	+2.6 (0.084)	+2.3 (0.327)	29 (5)	Designation of unit team leaders; triage on emergency care; optimization of hospital unit briefings; implementation of a safe surgery checklist
D4: Communication openness	*+2.7** *(0.000)*	+1.0 (0.281)	+7.2 (0.093)	33 (4)	Communication plan on quality and safety issues; alignment of communication between hospital management and units; presence of hospital management during team meetings
D5: Feedback and error communication	*+0.9** *(0.045)*	+0.8 (0.422)	+2.5 (0.674)	28 (9)	Feedback of incident reporting; communication of specific patient safety issues (e.g. hemovigilance); mandatory education of new staff on patient safety; discussion of feedback incident reports with units on regular basis in order to implement improvements; patient safety column in hospital magazine; patient safety dashboard via intranet; designation of incident administrator
D6: Non-punitive response to error	*+4.1** *(0.000)*	+4.1 (0.150)	*+6.6** *(0.025)*	49 (14)	Involvement of head nurses in feedback and discussion of events; patient safety committee is responsible for communication of patient safety issues to hospital management and hospital staff; education on incident reporting; stimulating a culture of openness and reporting; ending blame and shame culture; drafting a patient safety organogram to enlarge involvement of all hospital committees; sensibilization of head nurses in non-blaming job evaluations; assignment of external company as responsible for incident registration and data processing

Dimensions (continued)	AH (n=69)	PH (n=34)	LTCH (n=8)	N hospitals with ≥ 5% improvement**	Examples of improvement strategies (indicated by hospitals)
D7: Staffing	+2.2 (0.066)	+0.5 (0.966)	+9.9 (0.069)	41 (4)	Support of mobile teams to reduce high workloads; international recruitment of nurses; enhancement of medical staff; clinical receptionists; coaching of new staff; implementation of two night shifts on geriatric, oncology on respiratory units; additional administrative support for nursing care
D8: Management support for patient safety	*+8.5* (0.000)*	*+3.6* (0.041)*	+6.5 (0.401)	66 (15)	Communication of safety culture data; elaboration of a hospital-wide safety plan with SMART objectives for each hospital unit; patient safety on agenda of board meetings; development of patient safety charter; establishment of a patient safety committee; reorganization of quality and safety policy; head physician in lead of root cause analysis of incidents; discussion of patient safety indicators on board meeting; patient safety committee is accountable for incident reporting system; organization of patient safety symposium; organization-wide patient safety campaign
D9: Teamwork across units	*+1.7* (0.039)*	+0.6 (0.231)	+4.6 (0.484)	34 (5)	Mapping and improving transfer processes; examining for all hospital units which information is needed; implementation and evaluation of electronic medical record; exchanging hospital staff across units if necessary
D10: Handoffs and transitions	*-2.0* (0.018)*	-4.5 (0.064)	-4.3 (1.000)	15 (5)	Mapping and improving transfer processes; implementation and evaluation of electronic medical record; implementation and evaluation of protocols for patient identification wrist bands; implementation of nursing transfer checklist
O1: Overall perceptions of patient safety	*+4.6* (0.000)*	+0.5 (0.898)	+0.6 (0.726)	43 (4)	Hospital-wide patient safety campaign; elaboration of hospital-wide procedure book; implementation of targeted actions based on incident reporting; safety walk rounds; elaboration of accreditation processes; patient safety alert weeks; assigning quality labels to hospital units
O2: Frequency of events reported	*-2.0* (0.000)*	-3.7 (0.110)	+2.8 (0.271)	18 (3)	Designation of responsible persons for analyzing incidents; raising awareness on reporting specific types of adverse events; sensibilization campaigns for incident reporting on each unit

AH: acute hospitals; PH: psychiatric hospitals; LTCH: long-term care hospitals

**Statistical significant* based on Related Samples Wilcoxon Signed Rank test ($p<0.05$)

**Of 8 out of 111 hospitals information on actions was missing; The AHRQ's guideline was followed of considering an absolute difference of ≥ 5% in the proportion of positive ratings as potentially indicating a meaningful difference.

DISCUSSION

Within a 5-year quality and safety program (2007-2012), the Belgian federal government encouraged all hospitals to conduct a baseline and follow-up safety culture measurement using the HSPSC. For research purposes, hospitals were invited to participate on a voluntary basis in a benchmark database managed by a neutral academic institute. This study presents the largest multicenter safety culture database available within European countries. In our study, the evolution of safety culture was assessed based on 86 262 respondent records from 111 trending hospitals. Our approach of benchmarking safety culture perceptions was similar to the US comparative database, which included a total of 650 trending hospitals in 2012.[8] Response rates were similar to the American survey and increased from 51.0% for the first to 52.2% for the second measurement. Reminders were an important driver in the survey to get a satisfactory response rate. Similar to other studies,[14, 15] lower response rates were observed for physicians (33.5% for acute hospitals) in comparison with other professional groups (52.5% for acute hospitals), which might be an important indication for a lower involvement of medical staff in patient safety initiatives. To enhance the usefulness of the HSPSC in psychiatric hospitals, demographic categories of work area and staff position were redefined to the context of psychiatric care. This refinement resulted in lower missing rates for the respondent characteristics scales.

Improvements were identified for most safety culture dimensions, with a remarkable significant improvement for *Management support for patient safety* (D8) within the acute (+8.5%) and psychiatric hospitals (+3.6%). We found that 66 of the 111 hospitals improved with 5% or more on this dimension. Of these, only 15 hospitals indicated that they implemented targeted actions for improving *Management support for patient safety*, such as the establishment of a patient safety committee. The overall improvement on this dimension demonstrates the growing involvement of the hospital management in Belgian hospitals, which is an essential precondition in achieving safe care.

However, perceptions of *Handoffs and transitions* (D10) and *Frequency of events reported* (O2), which were already found to be low for the baseline measurement, showed to have significantly declined. The decline for these dimensions could be explained by the fact that the higher attention paid to these areas within the federal program might have raised the awareness of hospital staff. This could explain the more critical evaluation of these dimensions. However, these areas warrant a continuous attention. Especially the pharmacists, technicians and therapists had low ratings for *Handoffs and transitions* (D10). These groups of healthcare professionals often provide services to other work units and shift frequently, which could explain the more frequently witnessing of unsafe transmission of patient care information.

Although *Staffing* (D7) has low reliability scores (Chronbach's alpha) as reported in American[16-18] and European studies,[14, 19-21] this dimension provides important information on the workload for hospital staff. In our study *Staffing* was identified as a major problem within geriatrics, the operation room, internal and surgical units and particularly for the nursing professions. Analysis of demographic items confirmed the problem of staffing, since more than a quarter of the Belgian hospital staff indicates to work over 40 hours a week. This area might be less susceptible for progression given the current norms on staffing within the Belgian hospital financing and thus should be a signal for the federal authorities to invest into higher (nurse) staffing levels. Indeed, the impact of staffing adequacy in hospitals has been the subject of prior research, demonstrating a clear relationship between nurse staffing levels and the incidence of adverse events.[22-24]

There is conflicting evidence to which extent demographic characteristics of healthcare professionals influence safety culture perceptions. Gallego et al. could not explain differences in safety culture scores by demographic characteristics of staff, such as profession or organizational role.[25] In contrary, other studies were able to show differences in attitudes towards patient safety associated with particular groups of healthcare staff[15, 26] and across hospital units.[6, 15, 26-29] In our study, we found an important gap of safety culture perceptions between and within professional groups. For instance, head nurses showed to have more positive perceptions towards patient safety compared with nurses and nursing aids. Equally, physicians head of department showed to have more favorable safety culture perceptions in comparison with physicians and physicians in training. The gap in safety culture perceptions was most distinct between pharmacists and pharmacy assistants. Possibly, clinical department heads tend to overestimate their units' safety performance.

Also work area was found to be highly associated with safety culture perceptions. As reported in other studies, respondents working in many hospital units or units delivering more complex and hazardous care, such as the operation theatre and emergency care had less positive safety culture perceptions in comparison with internal medicine units.[15] Pediatrics showed to have a more positive safety culture profile and thus could offer lessons that could be used by other units as recourse to facilitate internal learning.

Besides demographical differences in safety perceptions, also language, hospital type and statute were observed to account for differences in safety culture profiles. Although small but significant effects were observed for each increase of 10 beds, hospital size could not explain differences in safety culture scores.

We found that 'errors reported in the last 12 months', which was modeled as a predictor variable, was significantly associated with higher odds of positive perceptions on *Frequency of errors reported*. The increasing OR for this dimension per increasing unit of errors reported indicates the adequacy of this predictor variable. In addition, it was found that 'errors reported in the last 12 months' was strongly related to higher odds of positive perceptions on *Organizational learning – continuous improvement* (D2), *Feedback and error communication* (D5), *Non-punitive response to error* (D6) and to a lower extent to *Supervisor/manager expectations and actions promoting safety* (D1) and *Communication openness* (D4). These findings might suggest that higher levels of reporting (compared to no errors reported) are positively associated with a culture of learning.

Our study has some limitations. First, although our study presents a representative sample of Belgian hospitals and acceptable response rates, the evolution of safety culture could only be measured at the hospital level. The anonymous nature of the survey inhibited us to track individual respondents. Perceptions of non-respondents might differ from those of respondents, which could lead to bias in our findings.[15]

Another note to this study concerns the construction of the instrument itself. One likely explanation for the variation in dimensional scores is that more positive scoring dimensions contain more positive worded items in contrast with lower scoring dimensions, such as *Staffing* (D7), *Non-punitive response to errors* (D6) and *Handoffs and transitions* (D10), which contain more negatively worded items. This finding on its own, which is also explained by Blegen et. al.,[17] makes that the meaning of identifying high and low scoring dimensions could be questionable. In this way, it is possible that low scoring dimensions might be a reflection of the negatively worded items rather than the weaknesses of these areas of safety culture.[17]

Third, in this study it was not feasible to prospectively measure the effectiveness of single safety culture interventions. Hospitals were not instructed to implement targeted actions and were free to address the content of interventions based on their individual safety culture profile of the baseline measurement. We collected additional information from the participating hospitals on these safety culture improvement strategies. This information was not verified and thus could have been incomplete and inconsistent. In addition, there is no information on how these interventions were implemented and intervene in practice with other quality improvement strategies, existing policies and procedures within the hospitals. This fact makes it unlikely that improved safety culture scores can directly be attributed to specific actions. Therefore, we provided an exemplary inventory of actions from hospitals with improved scores that could had a possible effect on the safety culture dimensions.

Nevertheless, our results showed a slight positive evolution of the safety culture in Belgian hospitals after the implementation of a national program on quality and safety. From this perspective, both nationwide safety culture measurements can be seen as interventions as such, which might have raised the awareness towards patient safety within the Belgian hospitals. This could explain that the wide range of interventions that were implemented in the hospitals within the federal program had the effect that all dimensions improved a little bit, rather than one dimension that improved a lot.

Caution must be taken when comparing safety culture scores with other countries, since other data collection methods and analysis techniques could have been applied. For instance, an advantage in our study was that the number of respondents per hospital was taken into account when calculating positive dimensional scores. In the US study, the percent positive scores were calculated by averaging composite-level percent positive scores across all hospitals, leading to an incorrect equal weight of hospital scores.[8] In addition, in our study there was a higher participation of staff working in direct interaction with patients (86.8% for acute hospitals) in comparison with the US sample (76%), which might explain the overall lower safety culture perceptions within Belgian hospitals.

Although the psychometric properties and application of the HSPSC have been investigated widely, there is still limited evidence on the relationship between safety culture, safety behavior and outcomes of care in order to assess the predictive validity of this instrument. In addition, future research should focus on enriching the evidence of the effectiveness of strategies aimed at improving patient safety culture. Also, a better understanding of the role of safety culture as a contextual factor that can moderate the effectiveness of other patient safety practices is required. Currently, many Flemish hospitals are elaborating a hospital-wide accreditation program and with the aid of hospital associations, a basic set of quality and safety indicators is being developed. A second federal program for quality and patient safety is being developed for the next stage of 5 years (2013-2017). This new program will focus on specific domains, such as high risk medication, safe surgery, identity-vigilance and transmural care. More generic aspects, such as patient safety management, leadership, communication and patient and family empowerment will also be addressed within the program. This provides several research opportunities since the future challenge will be to systematically measure and improve patient safety with safety culture as an important breeding ground.

CONCLUSION

The Belgian safety culture research proves that even in a small country large comparative patient safety databases allow to identifying patterns and trends and to offer high key areas for improvement. Within the Belgian hospitals, a higher attention should be paid to the transmission of patient care information and reporting of (near) incidents. Also, staffing showed to be an area that requires the attention of the federal authorities. The positive evolution on the dimension of Management support for patient safety shows the increasing attention of the hospital management towards patient safety and this is considered as an important precondition for improving safety culture in the Belgian hospitals. Our findings on variations in safety culture perceptions between types of hospitals, hospital units and professional groups implicate the need for a tailor-made approach.

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APPENDIX I: Generalized Estimating Equations (GEE) Model

Covariates included in the fitted models accompanied by their representing indicator variables included as effects.

Covariate	Indicator variable (effects in model)
	<u>Individual Level Covariates</u>
Measurement occasion (Reference=First)	
	Second measurement
Work Area (Reference= Internal Medicine)	
	Many Units
	Surgery
	Operating theatre
	Gynecology
	Pediatrics
	Intensive Care Unit
	Emergency
	Rehabilitation
	Geriatrics
	Psychiatry
	Medical-technical services
	Pharmacy
	Other
	Admission/observation/crisis
	Specialized unit
	Day/night hospital
	Psychiatric supporting services
	Addiction therapy
	Psychosis care
	Mood disorder care
	Behavioral disorder care
	Child psychiatric department
	Elderly psychiatric department
	Neurology
Errors reported in last 12 months (Reference=None)	
	1 or 2 incidents
	3 to 5 incidents
	6 to 10 incidents
	11 to 20 incidents
	21 or more incidents

Period in this Hospital (Reference=21 years or more)	
	Less than 1 year
	1 to 5 years
	6 to 10 years
	11 to 15 years
	16 to 20 years
Period Worked in Unit (Reference=21 years or more)	
	Less than 1 year
	1 to 5 years
	6 to 10 years
	11 to 15 years
	16 to 20 years
Hours worked per week (Reference=80 hours or more)	
	Less than 20 hours
	20 to 39 hours
	40 to 59 hours
	60 to 79 hours
Profession (Reference=Nurse)	
	Head Nurse
	Nursing Aid
	Physician
	Physician, Head of Department
	Physician Assistant/ in Training
	Pharmacist
	Assistant Pharmacy
	Middle Management
	Technician
	Therapist
	Other
	Psychiatric nurse/nursing aid
	Psychiatric Physician/Physician head of depart./Physician assist.
	Psychiatric supporting services pharmacy/assistant pharmacy/technician
	Psychiatric Head nurse/middle management
Contact with patients (Reference= No)	
	Yes

Period in this Profession ***(Reference= 21 years or more)***	
	Less than 1 year
	1 to 5 years
	6 to 10 years
	11 to 15 years
	16 to 20 years
<u>Hospital Level Covariates</u>	
Statute (Reference= Private (P))	
	Public (O)
Type of Hospital ***(Reference=Acute Hospital))***	
	Long-term care hospital
	Psychiatric Hospital
Language(Ref=Dutch)	
	French
	Both (French and Dutch)
Number of Beds [Continuous variable]	Observed number of beds x 0.1

APPENDIX II: Model building approach

Sequential model building results: least significant covariate which is removed from the model in subsequent model fits, accompanied by estimated p-value.

Model fits	**D1**	**D2**	**D3**	**D4**	**D5**	**D6**	**D7**	**D8**	**D9**	**D10**	**O1**	**O2**
1	H5: 0.3222	Beds: 0.7171	H5: 0.389	H2: 0.2124	H3: 0.1633	H5: 0.2541	Beds: 0.5397	H2: 0.0996	Beds: 0.802	H2: 0.6489	O: 0.7289	H3: 0.2247
2	Final	H5: 0.1054	Final	Final	H6: 0.0556	H6: 0.0521	H6: 0.0975	Final	H5: 0.0607	Final	H2: 0.2864	O: 0.153
3		Final			Final	Final	Final		H2: 0.0571		Final	Meas.Occ: 0.1367
4									Final			Final

APPENDIX III: Evolution of safety culture on 12 dimensions for type of hospital (Median, Percentile 25, Percentile 75)

Dimensions	Acute hospitals								
	Measurement 1			Measurement 2			Measurement 2-1		
	Median	P 25	P 75	Median	P 25	P 75	Median	P 25	P 75
D1	70.7	66.7	76.0	74.6	69.1	77.3	2.8	0.3	5.0
D2	69.1	63.1	76.1	73.9	70.1	77.7	3.9	-0.9	8.3
D3	78.1	74.5	81.7	80.4	77.0	83.2	1.3	-0.7	4.4
D4	68.5	65.8	72.7	71.0	67.4	74.2	2.7	-0.3	5.4
D5	57.2	53.6	60.8	58.5	55.0	64.6	0.9	-1.8	5.3
D6	46.5	41.3	50.3	49.6	44.6	54.6	4.1	0.3	7.9
D7	42.6	36.6	47.1	43.9	37.8	49.7	2.2	-4.1	6.3
D8	44.7	36.1	48.8	51.9	44.9	58.6	8.5	2.9	12.0
D9	49.6	44.0	54.7	52.9	45.1	57.4	1.7	-2.4	4.3
D10	41.9	38.3	47.2	41.0	36.3	46.3	-2.0	-5.8	1.9
O1	60.4	52.5	64.4	64.8	55.4	68.9	4.6	-1.2	7.2
O2	47.9	43.9	51.7	46.5	40.7	50.5	-2.0	-5.3	2.1

Dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported

Dimensions	Psychiatric hospitals								
	Measurement 1			Measurement 2			Measurement 2-1		
	Median	P 25	P 75	Median	P 25	P 75	Median	P 25	P 75
D1	79.9	76.2	85.8	84.2	78.1	86.5	2.6	-3.7	6.4
D2	76.8	72.3	81.3	76.6	69.7	79.7	-1.0	-4.8	1.9
D3	83.3	77.7	88.0	86.2	81.5	90.7	2.6	-2.5	5.4
D4	71.4	67.0	78.0	73.2	66.8	81.3	1.1	-3.6	5.7
D5	63.6	57.7	70.3	65.4	56.0	71.0	0.8	-2.8	3.9
D6	55.6	48.2	64.0	59.4	48.3	66.7	4.1	-3.6	7.9
D7	60.0	53.1	65.0	58.8	52.2	68.8	0.5	-8.8	6.3
D8	58.7	47.3	67.9	60.5	52.2	69.9	3.6	-2.9	8.6
D9	61.2	54.5	72.8	62.5	57.1	70.9	0.6	-3.4	7.2
D10	52.2	44.4	56.7	47.7	42.0	55.9	-4.5	-8.6	3.4
O1	69.1	61.0	75.3	68.4	53.0	78.3	0.5	-6.1	5.6
O2	52.6	43.2	59.3	49.0	41.7	57.3	-3.8	-7.2	2.6

Dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported

Dimensions	Long-term care hospitals								
	Measurement 1			Measurement 2			Measurement 2-1		
	Median	P 25	P 75	Median	P 25	P 75	Median	P 25	P 75
D1	74.1	66.3	77.6	77.0	73.6	80.4	4.4	-1.8	8.1
D2	76.6	71.8	83.2	81.5	71.8	83.3	3.2	-1.3	6.6
D3	78.6	72.9	85.0	82.9	75.0	90.9	2.3	-4.1	10.1
D4	64.4	57.9	75.9	75.9	69.7	78.6	7.3	-2.6	13.3
D5	63.0	62.3	65.6	65.1	55.9	78.3	2.5	-10.6	13.0
D6	49.8	44.1	57.8	59.4	52.6	63.9	6.6	2.2	18.4
D7	55.0	42.4	59.2	63.6	45.5	76.3	9.9	-1.2	16.9
D8	66.6	61.1	72.4	70.9	62.8	78.3	6.5	-6.6	11.4
D9	66.7	60.8	72.2	73.4	56.0	76.8	4.6	-5.7	10.2
D10	54.2	47.1	60.9	51.0	43.1	60.3	-4.3	-9.4	12.5
O1	69.0	63.4	73.0	71.4	63.0	77.2	0.6	-3.8	8.1
O2	47.8	44.6	51.1	52.7	47.0	60.1	2.8	-3.6	15.1

Dimensions: D1: Supervisor/manager expectations and actions promoting safety. D2: Organizational learning–continuous improvement. D3: Teamwork within units. D4: Communication openness. D5: Feedback and error communication. D6: Non-punitive response to error. D7: Staffing. D8: Management support for patient safety. D9: Teamwork across units. D10: Handoffs and transitions. O1: Overall perceptions of patient safety. O2: Frequency of events reported

CHAPTER 9

Overall Discussion

Chapter 9

Overall Discussion

INTRODUCTION

In the first chapter it was outlined that patient safety should be measured at different points from the organization of care, including the managerial and clinical processes and the outcomes of care. Also, understanding the organizational context (culture) is a condition for improving patient safety.

In this chapter, the most relevant findings are outlined with respect to each research question. Furthermore, this chapter addresses the methodological implications of measuring patient safety outcomes (chapter 2 and 3), processes (chapter 4) and safety culture (chapter 5, 6, 7 and 8). Finally, based on our findings, recommendations for practice and further research are formulated to fulfill the main objective of this research: How to measure and improve patient safety and safety culture in Belgian hospitals.

Table 1 highlights the main findings of each chapter.

Table 1 - Overview of the main findings

Chapters **Research questions**	**Study design -** ***Applied methods***	**Measurement points within framework**	**Main findings**
Chapter 1 Is there a conceptual framework available for patient safety?	**Literature review**	Structure, management and clinical processes, patient outcomes, organizational context (chapter 1, figure 1)	A conceptual framework is presented based on Donabedian's triad and Reasons' causation model (adapted from Brown et al.)[1].
Chapter 2 **<u>RQ1:</u> What are the incidence rate, preventability and consequences of adverse events requiring a higher level of care?** **<u>Sub question 1:</u>** Based on the best available evidence?	**Systematic review** *Independent assessment (by 2 reviewers)* - *Study protocol* - *Selection of studies* - *Critical appraisal* - *Data extraction* - *Data synthesis* - *Subgroup analysis* - *Reporting results* - *Dissemination*	**Estimation of patient outcomes**: adverse events, preventable adverse events, length of hospital stay, mortality and direct medical costs	Due to study heterogeneity, meta-analysis was not appropriate. Therefore, results are presented in a descriptive way. - The percentage of surgical and medical adverse events that required ICU admission ranged from 1.1% to 37.2%; - ICU readmissions varied from 0% to 18.3%; - Preventability of the adverse events varied from 17% to 76.5%; - Consequences of the adverse events included a mean length of ICU stay that ranged from 1.5 days to 10.4 days for the patient's first stay in ICU and mortality percentages between 0% and 58%. Planning of future studies should aim to standardize terminology and measures of outcomes (standard taxonomy) and to apply more explicit medical record review designs in order to allow for comparisons across studies.

Chapter 3 **<u>RQ1:</u> What are the incidence rate, preventability and consequences of adverse events requiring a higher level of care?** **<u>Sub question 2:</u>** How can medical record review be applied within Flemish acute hospitals for the detection of this type of adverse events?	**Study protocol for retrospective medical record review** - *Selection of population* - *Selection of hospitals* - *Selection of medical records* - *Assessment of causation and preventability of adverse events* - *Power calculation* - *Ethical approval*	**Measurement of patient outcomes**: adverse events, preventable adverse events, length of hospital stay and mortality	A multistage retrospective review study of patients requiring a transfer to a higher level of care is launched in six acute hospitals in the province of Limburg. Record selection is based on (1) (re)admission to the Intensive Care Unit from other care units in the hospital providing lower intensity care, (2) an intervention by a Medical Emergency Team (MET) due to an unanticipated change in the patient's clinical status or (3) a redo procedure within 24 hours for ICU patients. Patient records are reviewed starting from January 2012 by a clinical team consisting of a research nurse, a physician and a clinical pharmacist. Besides the incidence and the level of causation and preventability, also the type of adverse events and their consequences (patient harm, mortality and length of hospital stay) will be assessed. Moreover, the adequacy of the patient records and quality/usefulness of the method of medical record review will be evaluated.
Chapter 4 **<u>RQ2:</u> Which variants of Healthcare Failure Mode and Effects Analysis can be applied to prospectively measure risks in healthcare processes?**	**Prospective risk assessment** - *Defining HFMEA variants* - *Time/ cost analysis* - *Expert opinion*	**Process (risk) assessment**	Variants of HFMEA, using a hazard scoring matrix or a decision tree algorithm, were tested in terms of time investment and usefulness. The HFMEA time investment for the different HFMEA variants ranged from 18.7 to 34.7 person hours, which accounted for direct costs varying from 1 028.6 to 1 701.6 Euros.

Chapter 5 **<u>RQ3:</u> What is the current state of patient safety culture in the Belgian hospitals?** **<u>Sub question 1</u>**: What are the safety culture perceptions in Belgian hospitals using a validated questionnaire (HSPSC) and what are opportunities for benchmarking safety culture data?	**Baseline survey** - *Baseline measurement using the Hospital Survey on Patient Safety Culture (HSPSC) in French, Dutch and German* - *Benchmarking of hospitals* - *Hierarchical clustering of responses*	**Measurement of context** or intervening variable (safety culture)	90 acute, 42 psychiatric and 11 long-term care hospitals participated in a baseline benchmarking of safety culture perceptions. The overall response rate of hospital staff was 53.7%. Overall patient safety culture perceptions were low, with a high variability between the types of hospitals. Aspects of culture related to the hospital-wide approach of patient safety, such as *Handoffs and transitions*, *Staffing*, *Non-punitive response to errors* and *Management support for patient safety* were concluded to be major areas for improvement. The identification of clusters of safety culture dimensions indicated the need for a different approach and context towards the implementation of interventions aimed at improving the safety culture. Repeated measurement after several years can track the evolution of safety culture within hospitals.
Chapter 6 **<u>RQ3:</u> What is the current state of patient safety culture in the Belgian hospitals?** **<u>Sub question 2:</u>** Can the HSPSC be applied to measure variability in safety culture perceptions in the Belgian acute hospitals?	**Baseline survey** - *HSPSC* - *Benchmarking of hospitals* - *Multiple regression (GEE)*	**Measurement of context** or intervening variable (safety culture)	Language, work area and profession were identified as important safety culture predictors. Safety culture scores were found to be more positive for respondents working in pediatrics, psychiatry and rehabilitation in comparison with the emergency department, operating theatre and multiple hospital units. We found an important gap in perceptions of patient safety between leaders (head nurses, head physicians, head pharmacists) and assistants within disciplines. Administration and middle management had lower perceptions towards patient safety. Work experience, including variables as period working in the current hospital and hospital unit, working hours per week and professional experience, showed to have less influence on patient safety culture perceptions.

Chapter 7 **<u>RQ3:</u> What is the current state of patient safety culture in the Belgian hospitals?** **<u>Sub question 3:</u>** Is the HSPSC suitable for use in the Belgian psychiatric hospitals and what are the psychometric properties of the questionnaire?	**Follow-up survey** *Testing of psychometric properties of HSPSC in Belgian psychiatric hospitals: CFA, EFA, reliability analysis, analysis of composite scores and inter-correlations*	**Validity and reliability measurement** of safety culture survey (HSPSC)	For both translations, CFA showed an acceptable fit with the original (American) model. EFA results showed a 10-factor optimal measurement model for the Dutch translation and a 9-factor optimal model for the French translation. For half of the dimensions Chronbach's alpha scores were ≥0.70. Most of the pair-wise correlations were less than 0.5 implying a good construct validity of the questionnaire. The Dutch and French translations of the HSPSC were found to be valid and reliable for measuring patient safety culture in psychiatric hospitals.
Chapter 8 **<u>RQ3:</u> What is the current state of patient safety culture in the Belgian hospitals?** **<u>Sub question 4:</u>** Can we measure changes in safety culture after a period of three years?	**Follow-up survey** - *Follow-up measurement (HSPSC)* - *Benchmarking of hospitals* - *Multiple regression (GEE)* - *Survey on safety culture improvement strategies*	**Measurement of context** or intervening variable (safety culture)	For 111 hospitals it was possible to calculate changes in safety culture. Improvement was observed for most dimensions with a meaningful improvement for *Management support for patient safety*. Although encouraged within the federal program on quality and safety, a decline was observed for *Handoffs and transitions* and *Frequency of events reported*. Work area, profession, language, hospital type and statute had important effects on safety culture perceptions. Hospital size, period working in the hospital, unit or profession showed to have less effect on safety culture scores.
Chapter 9 Overall discussion	**Literature review and discussion of findings**	**Evaluation of framework**	- Findings with respect to the formulated research questions - Methodological implications of studies: strengths and limitations - Implications for practice - Implications for health policy - Recommendations for future research - Conclusion

FINDINGS WITH RESPECT TO THE FORMULATED RESEARCH QUESTIONS

RQ1: ***What are the incidence rate, preventability and consequences of adverse events requiring a higher level of care?***

a) Based on the best available evidence?

In a first phase we conducted a systematic review in order (1) to make an estimation of (preventable) adverse events that lead to serious harm to patients and (2) to identify relevant studies, which could be exemplary for our own medical record review design, and (3) to identify strategies that can reduce these adverse events. We focused on a particular group of preventable adverse events that anticipate to the admission of the patient on an intensive care unit. The selection of this particular population is founded on an economical perspective, since these patients are a major financial burden to the health care system. We included 27 studies in this review. However, meta-analysis was not possible due to study heterogeneity and so results were presented in a descriptive way. The overall incidence of surgical and medical adverse events compared with ICU admissions ranged from 1.1% to 37.2%. ICU readmission rates varied from 0% to 18.3%. The preventability rates of the adverse events varied from 17% to 76.5%. Consequences of the adverse events included a mean length of ICU stay that ranged from 1.5 days to 10.4 days for the patient's first stay in ICU. Mortality rates varied between 0% and 58%. Several authors recommend early detection of patients with clinical instability on general wards and the implementation of rapid response teams. Step-down or intermediate care units could be a useful strategy for patients that require monitoring to avoid ICU readmissions. However, the evidence surrounding these strategies is rather limited. The poor quality of current research evidence and the heterogeneity across studies requires that planning of future studies should aim to standardize measures of outcomes to allow for comparisons across studies. A multidisciplinary approach, in which the team is composed of independent physicians, nurses and pharmacists, is a key condition in conducting chart review. Physician led initiatives might promote the acceptance of the method. There is a need of multicenter studies in this area to allow to aggregate data and analyze patterns of the contributing factors of the detected adverse events.

b) *How can medical record review be applied within Flemish acute hospitals for the detection of this type of adverse events?*

Based on findings of the systematic review, a study protocol for retrospective analysis of medical records was designed. The study protocol focused on patients requiring a transfer to a higher level of care in six acute hospitals located in the province of Limburg. A 'higher level of care' was defined as: (1) a (re)admission to the Intensive Care Unit from other care units in the hospital providing lower intensity care, (2) an intervention by a Medical Emergency Team (MET) due to an unanticipated change in the patient's clinical status or (3) a redo procedure within 24 hours for ICU patients. Based on this protocol, patient records were reviewed starting from January 2012 by a clinical team consisting of a research nurse, a physician and a clinical pharmacist. Besides the incidence and the level of causation and preventability, also the type of adverse events and their consequences (patient harm, mortality and length of stay) were to be assessed. Moreover, the adequacy of the patient records and quality/usefulness of the method of medical record review was to be evaluated. In addition, the study protocol described the rationale for a further root cause analysis of the detected adverse events, in order to systematically explore the primary systemic causes of the adverse events and identify actions to prevent recurrences.

***RQ2:* Which variants of Healthcare Failure Mode and Effects Analysis can be applied to prospectively measure risks in healthcare processes?**

Besides a retrospective approach of measuring adverse events (negative patient outcomes), an exemplary case report was presented on the additional value of prospective assessment of risks (antecedents of adverse events). The case report addressed possible risks of (the organization of) radiotherapy processes by using variants of Failure Mode and Effects Analysis (FMEA) and Healthcare Failure Mode and Effects Analysis™ (HFMEA). When comparing the risk assessment of FMEA (Risk Priority Numbers) and HFMEA™ (Hazard Scoring Matrix™ combined with HFMEA Decision Tree™), there were no clear differences in time investment or in usefulness. As in other studies[2, 3], our results highlight the qualitative and subjective nature of HFMEA. However, we showed that prospective risks analysis can be conducted as an additional method and at an acceptable cost for healthcare organizations, since it resulted in a concrete corrective plan to be implemented within the organization on a short time scale. The corrective actions that were suggested by the multidisciplinary teams mainly concerned the compliance and education of protocols and procedures.

<u>RQ3:</u> What is the current state of patient safety culture in the Belgian hospitals?

This research question was addressed in four sub questions:

a) *<u>What are the safety culture perceptions in Belgian hospitals using a validated questionnaire (HSPSC) and what are opportunities for benchmarking safety culture data?</u>*

As outlined and motivated in the first chapter of this dissertation, safety culture was measured organization-wide using the Hospital Survey on Patient Safety Culture (HSPSC). The HSPSC was selected since it covers a broad spectrum of relevant aspects related to the hospital-level and unit-level and prior research indicated that the psychometric results are good.[4] In total, 143 Belgian hospitals participated in our comparative study. The overall response rate was 53.7%, which is high in comparison with international studies. The high participation in the survey proves that there is a high willingness of both the hospital management and staff to improve patient safety. Generally, safety culture scores were low, with the lowest scores for *Staffing*, *Handoffs and Transitions* and *Management support for patient safety*. The highest scores were found for *Teamwork within units*, *Supervisor/ manager expectations and actions promoting safety* and *Organizational learning – continuous improvement*.

A hierarchical clustering of the safety culture responses was conducted in order to explore the underlying structure of dimensions and the forming of clusters/ groups of dimensions. This method generates a possible hypothesis for addressing the different dimensions in practice. It was found that several dimensions clustered at a small distance, including *Supervisor/manager expectations and actions promoting safety*, *Organizational learning and continuous improvement*, *Teamwork within units* and *Communication openness*. These dimensions were concluded to be addressed at the local level of the hospital unit. The dimensions *Feedback and communication about error*, *Non-punitive response to error*, *Management support for patient safety, Teamwork across units* and *Handoffs and transitions* were suggested to be improved at the organization wide level. However, *Staffing*, which clustered at greater distance, should be considered as a separate dimension relating to the structure of the organization and is an aspect that is of limited control to the hospitals. Although the internal consistency of the dimension *Staffing* is low (Chronbach's Alpha of 0.57 and 0.52 for respectively the Dutch and French translations), this dimension provides important information on the workload of hospital staff. This supports our argument that this dimension should be included in the survey.

b) *Can the HSPSC be applied to measure variability in safety culture perceptions in the Belgian acute hospitals?*

Further analysis of the baseline safety culture data of 89 acute hospitals (47 136 respondents) proved that language, work area and profession are important safety culture predictors. Significant disparities in patient safety perceptions were identified between work units and between and within disciplines. For instance, safety culture scores were more positive for respondents working in pediatrics, psychiatry and revalidation in comparison with the emergency department, operating theatre and multiple hospital units. Positive values towards patient safety were found to be lower for French speaking in comparison with the Dutch speaking respondents for almost all dimensional scores, except for *Organizational learning–continuous improvement*, *Teamwork within units* and *Staffing*. Head nurses, physicians and pharmacists had better perceptions of safety, when compared to assistants. Building on our previous findings, which suggest a hospital unit versus a hospital wide approach, additional recommendations were made for targeting specific interventions for professional groups and work areas, without stigmatizing groups as 'low-scoring'.

c) *Is the HSPSC suitable for use in the Belgian psychiatric hospitals and what are the psychometric properties of the questionnaire?*

Up till now, the HSPSC has been limited used within psychiatric settings. To enhance the usefulness of the instrument for the psychiatric hospitals, the demographic categories of work area and profession were adapted to the context of psychiatric care. Furthermore, the psychometric properties of the HSPSC were assessed for use within the psychiatric Belgian hospitals based on 8 290 questionnaires of a follow-up measurement in 46 psychiatric hospitals (71.5% response rate). Confirmatory factor analysis (CFA) was based on 6 658 completed questionnaires of the baseline measurement in 44 hospitals (70.5% response rate). As a result of the analysis, dimension *Frequency of event reported* showed the highest internal consistency, while *Staffing* and *Organizational learning* showed the lowest reliability scores. These findings are supported by several international studies.[5-10] For both translations, CFA showed an acceptable fit with the original 12-dimensional model. Exploratory Factor Analysis resulted in a 10-dimensional and a 9-dimensional structure for respectively the Dutch and French questionnaire. Nevertheless, we suggest that no modifications are required to the original 12-factor model in order to allow internal and external benchmarking.

d) <u>*Can we measure changes in safety culture after a period of three years?*</u>

Based on 86 262 respondent records of 111 hospitals, which participated twice in the benchmark initiative, it was possible to measure changes in safety culture. The follow-up measurement, which accounted for a 52.2% response rate, showed consistent results with the baseline benchmarking in 2008. For instance, the unit level dimensions (e.g. *Supervisor/manager expectations and actions promoting safety, Organizational learning–continuous improvement, Teamwork within units* and *Communication openness*) were found to receive more favorable responses compared to hospital level safety culture dimensions (e.g. *Teamwork between units, Handoffs and transitions*).

It was found that there was a general slight positive evolution of most safety culture dimensions with significant improvements for the acute hospitals. However, *Handoffs and transitions* and *Frequency of events of reported* were noticed to have declined, even though improvement efforts were coordinated at the national level. There were no significant changes in perceptions of *Staffing*. Only 30% of the respondents indicated that there is enough hospital staff to handle the workload. Analysis of the demographic data of the respondents confirms this finding. In total, 63.2% of hospital staff works between 20 and 39 hours per week, 21.1% works between 40 and 59 hours and 4.4% works over 60 hours per week (11.3% missing records). This proves that more than a quarter of hospital staff works long hour days, which as such might have important implications on safe care.

Despite the overall positive tendency, improving safety culture in the hospitals seems to be difficult and involves several tensions. One tension is balancing the urgency to improve safety culture and the lack of evidence on the effectiveness of improvement strategies. Another tension concerns the necessity of individual behavioral change of healthcare professionals and their professional autonomy. Interventions aimed at cultural change need to include the cooperation and involvement of all healthcare professionals, who exercise a large degree of control in the hospital environment. In this aspect, the hospital management has a central role and the responsibility in improving safety culture. Management support for patient safety, measuring the priority of safety which is paid by the hospital management, is a crucial and essential factor in improving safety culture and was found to be largely improved in the hospitals (+8.5% for acute hospitals).

OVERALL METHODOLOGICAL CONSIDERATIONS AND DISCUSSION

Study designs for patient safety research: strengths and limitations

One of the strengths of this dissertation is that we used *a combination of study designs*, including a systematic review, a large-scale (repeated) safety culture survey, prospective risk assessment and a retrospective medical record review design for the detection of adverse events. The use of multi-level or mixed study designs allows circumventing the fragmented and incommensurate findings that are generated from small-scale projects. A second strength is that we applied a *multidisciplinary approach* in our medical record review study (chapter 3), since this approach of a combined expertise increases the objectivity of the results. In addition, the involvement of a physician in this research might also promote the acceptance of patient safety strategies in the participating hospitals. A third strength is the use of *multicenter study design*s (chapters 3, 5, 6, 7 and 8). A fourth strength includes the application of a *cross-sectional design* for measuring safety culture in Belgian hospitals. The nationwide baseline and follow-up measurements of patient safety culture allowed us to aggregate data, analyze patterns and trends, and benchmarking of results. Our dataset included sufficient participants to average out random influences guaranteeing reliability of our results. A theoretically strength of our study is that we took a multidimensional approach of safety culture. Our study brings some evidence regarding the differences between dimensions. We believe that our practical approach of providing feedback to the hospitals increases the motivation for participating in future safety culture research.

A limitation of our study is that our results are insufficiently supported by qualitative research, since this was not feasible within this dissertation. Therefore, we suggest using medical record review for detection of adverse events (quantitative approach) in combination with a qualitative analysis, such as *root cause analysis* of the adverse events. As often, the quality of the medical records is poor and information is missing or incomplete, additional qualitative information, e.g. experiences from the healthcare providers who were involved in the event, can provide additional insight in the circumstances and contributing factors leading to adverse events.

In this dissertation we quantitatively measured safety culture within the Belgian hospitals. Safety culture data were collected using the same questionnaire and therefore, were susceptible to same-method bias. Although we gathered data from a considerable sample of hospital staff, there could be non-random measurement errors in the survey responses. For instance, several dimensions mainly include negatively formulated questions (*Staffing*, *Non-punitive response to errors* and *Handoffs and transitions*), which could have led to confusion on the part of the respondents.[11] It is possible that this fact is partially an explanation for the lower scores on these dimensions, rather than it is a reflection of real dissatisfaction.[7] In addition, there could be a higher tendency of modal responses to items, when the survey had to be completed quickly.[11] This could be the case in the specific context of hospitals, where valuable time should be spent on the patient. This tendency of giving modal responses could even increase over time (after surveying several years). Also, given the use of different surveys within the hospitals (e.g. employee satisfaction), it is possible that there could originate 'survey fatigue'.

Therefore, future research should develop additional sources of data for safety culture assessment. For fully assessing safety culture, it is recommended to apply a *triangulation* of quantitative and qualitative techniques.[11] More specifically, perceptions of safety culture can be measured by using quantitative questionnaires. Individual behavior can be assessed by observation. The underlying assumptions of safety culture can be investigated by qualitative research (e.g. in-depth interviews).

Measurement of adverse events: methodological considerations

Sample size

The sample size of the medical record study (chapter 3) was determined in order to guarantee a sufficiently narrow confidence interval for the estimate (95%). From a pilot study of two months, 66 patients with one or more adverse events leading to a higher level of care were detected for 44 165 days at risk (149 per 100 000 patient days at risk). At this rate, a sample size of 100 000 patient days at risk would provide a confidence interval of approximately 20% (+/- 10% around the estimate). As the total yearly number of in- patient days (excluding palliative, neonatal, pediatric and one day-stay admissions) for the six participating hospitals was 76 0057 (in year 2010), this sample size corresponds to an inclusion period of six to seven months.[12]

Hindsight bias

Besides the practical implications of medical record review, such as the time-consuming character by a paper-based detection, this method also has several methodological limitations. Adverse events, when used as a single measure for patient safety, reflect an imprecise picture of the problem, since no attention is paid to practices that precede the events. Therefore, the assessment of (the risks of) errors, which anticipate adverse events often in a more common way, is recommended as an additional method. An example of such an additional method is proactive risk assessment. An important step after identification of the adverse event is to analyze deficiencies, which might contribute to the occurrence of the adverse event. Both the prediction and analysis of adverse events provide more insight into barriers that should be implemented to reduce patient harm.

Subjectivity

Furthermore, the judgment of the presence of an adverse event is always prone to subjectivity of the reviewers. The fallibility of judgment was demonstrated earlier in several medical record review studies. In the Harvard Medical Practice Study, kappa values (κ) were found to be 0.61 for judgment on the presence of an adverse event and only 0.24 for the judgment on negligence, meaning that the inter-rater reliability for negligence was only 24%.[13] Judgments on preventability are even more prone to subjectivity.[14, 15] An important reason for this is that the review of each case is hampered by the retrospective nature of the method of medical record review and by the dependence on the quality of note taking, which also are addressed as 'hindsight bias'. Therefore, in our design of the medical record review study, hindsight bias was attempted to be minimized by using the same independent observers across the participating hospitals. Hindsight bias which is expected to be equal across the hospitals was investigated by an additional comparison of the quality and completeness of the medical records.

Case-mix

Furthermore, in the multi-center design of the medical record review study, it was important to avoid case-mix bias. Case-mix or clinical diversity of the antecedent conditions of the patient can lead to internal heterogeneity, which affects the accurate estimation for a particular population. Case-mix-bias in multi-center (comparative) study designs must be adjusted for confounders, such as comorbidities and age. The selection of a particular population -patients requiring a higher level of care- and the exclusion of pediatric patients reduced this limitation. 'Unplanned transfer from general to intensive care' is often used as a criterion ('trigger' or clue) to uncover adverse events and medical errors. Its positive predictive value, reflecting the reliability of this screening criterion, is relative high varying from 1.9% to 14% in other studies.[16-18] In order to avoid bias of systematic differences in case-mix in our study, when drawing conclusions from adverse events across organizations, the quality and completeness of the patient records was assessed. In this way, differences in 'opportunities' for errors were equally addressed. The selected records were reviewed in an implicit manner, meaning that no explicit screening criteria were applied. This approach has the advantage that every event is assessed in detail on several criteria, which produces a global measure of patient safety.[19]

Measurement of processes (risk assessment): methodological considerations

Methods of proactive risk assessment have been widely applied in healthcare. In this dissertation a case sample was described, which examined the usefulness of Healthcare Failure mode and Effects Analysis (HFMEA) in terms of time investment and usefulness. As in other studies[20-22], we found that HFMEA is a very time-consuming method, but can be applied at an acceptable cost when applying shortened variations. Optimizing the part of process mapping could reduce the healthcare professionals' time investment. However, there is still a methodological challenge of calculating Risk Priority Number scores, since this method has not yet been proven to be objective. In addition, the validity and reliability of the outputs of HFMEA needs further examination. In the case study reported in this dissertation, HFMEA was useful as it led to the identification of several failure modes within radiotherapy processes and a corrective action plan which contributed to the reorganization of the radiotherapy units in MAASTRO clinic.

Measurement of safety culture: methodological considerations

Psychometric properties and clustering of responses of the HSPSC

As outlined in chapters 5 and 7, we assessed the psychometric properties of the Dutch and French translations of the HSPSC and compared results between the acute and psychiatric hospitals. Overall, the reliability coefficients (Cronbach’s alpha) of the 12 safety culture dimensions were found to be acceptable to moderate and similar for both translations and types of hospitals. However, low reliability scores were found for *Staffing* and *Organizational learning and continuous improvement*. Exploratory factor analysis of the data of the psychiatric hospitals resulted in a 10-dimensional and a 9-dimensional optimal structure for respectively the Dutch and French speaking psychiatric hospitals. Confirmatory factor analysis of the original 12-dimensional structure resulted in an acceptable fit.

Hierarchical cluster analysis of the safety culture data confirmed the robustness of HSPSC as the instrument measures what it is intended to measure. On the one hand, we found clustering of dimensions measuring unit level aspects (e.g. *Supervisor expectations* and *Teamwork within units*) and on the other hand, we found clustering of dimensions related to organization wide safety aspects (e.g. *Management support* and *Teamwork between units*). At the conceptual level, the clustering of responses confirms that the HSPSC does not just measures individual attitudes, but that the survey's constructs are useful for measuring patient safety both at the hospital and unit level.

Data collection and benchmarking of safety culture data

Within this study, a large sample of safety culture perceptions was collected from a baseline and a follow-up measurement using the HSPSC within the Belgian acute, psychiatric and long-term care hospitals participating in the federal program on quality and safety (2007-2012). Results of the second measurement were found to be consistent with the baseline measurement, which adds to the generalizability of the results to a wider population of interest. Both for research and internal learning purposes, benchmarking of patient safety culture data was performed at the level of the hospital, hospital units and professional groups. Yet, the Belgian HSPSC database, consisting of 115 827 records drawn from 176 hospitals, is the largest set of safety culture data available within European countries. The large sample size of respondents assured that confident generalizations were made and provided the opportunity to analyze patterns (differences between groups) and trends (evolution over time).

Response bias and missingness

Response bias was addressed at the level of the hospital and at the level of the individual respondent. It is assumed that response bias was relatively low at the hospital level given the high number of participating hospitals in the benchmark initiative (69.8% of all Belgian hospitals for the first benchmark and 72.7% for the second benchmark). This high participation rate was obtained given the fact that the Belgian government encourages through the federal contracts that hospitals should measure safety culture on a regular basis.

In addition, it was encouraged that the highest possible response rate should be obtained within the hospitals. Surveys were completed anonymously, since respondents might be anxious to reveal their identity. Consequently, it was not possible within this research to track individual respondents. As a result of this fact, safety culture perceptions were analyzed at the level of the hospital,

hospital unit and professional level. On the one hand, it is possible that the comparative database includes perceptions of respondents that completed both baseline and follow-up surveys. On the other hand, it is likely that respondents only answered to the first or second survey. Conclusively, respondents might have entered the research during the second measurement, while other respondents might have dropped out. Perceptions of non-respondents could have differed from perceptions of respondents producing bias in our findings. Although not ideal, we assume that this is not a major limitation to our study, since our dataset was large enough and respondents are unlikely to recall the responses of the first measurement.[11]

Missingness, although considered to be low in our research, was addressed using the method of multiple imputation, which is an efficient approach and also valid under the less strict Missing At Random (MAR) assumption. The number of imputations, $m=5$, was chosen as a compromise between amount of missingness and desired level of efficiency. Imputations were done for both missing response variables and missing predictor variables. First, the missing observations on the hospital level were imputed 5 times. For each of these imputed datasets another 5 imputations were performed for the remaining missingness on the level of the observations. Each of the 25 imputed data sets were fitted using a Generalized Estimating Equations Model.

Variability of patient safety culture

At the hospital level

In our study we examined differences in safety culture within types of Belgian hospitals (acute, psychiatric and long-term care). We found more positive safety culture profiles for psychiatric hospitals in comparison with acute hospital settings. In addition, we found that language and statute were observed to account for differences in safety culture profiles. Public hospitals showed more negative safety culture profiles in comparison with private hospitals. However, hospital size could not explain differences in safety culture scores.

At the subgroup level

As in other studies[23-26], we found that safety culture varies across hospital units (high vs. low hazardous units) and professional groups. Our findings imply that patient safety interventions should be tailor-made at these levels. On the contrary, demographic characteristics related to staff experience, such as number of years working in the hospital, unit and profession seemed to have smaller effects on individual safety culture perceptions.

Evolution of safety culture

In our study, we addressed changes in safety culture at the national level (per type of hospital), by calculating the percentage of positive responses at the hospital level. Our approach allowed us to make straightforward conclusions on changes in safety culture perceptions, while other approaches e.g. using continuous data might reveal less nuancing results. We found that most safety culture dimensions improved slightly after a period of three years with a statistical significance (α=0.05) for the type of acute hospitals (except for dimension *Staffing*: +2.2%; p=0.066). An important improvement was found for *Management support for patient safety* (+8.5%; p=0.000), measuring the priority which is paid by the hospital management to patient safety. At the other hand, exploration of positive dimensional scores indicated a decline of safety culture perceptions for *Handoffs and transitions* (-2.0%; p=0.018) and *Frequency of events reported* (-2.0%; p=0.000).

While for instance a 1 percent difference between percent positive scores might be ‘statistically’ significant (that is, not due to chance), the difference is not likely to be meaningful or ‘practically’ significant. Besides statistical significance, also effect size was considered in our approach. Multiple regression was performed on all safety culture data (first and second measurement) of the 111 trending hospitals using the method of Generalized Estimating Equations (GEE) to examine any possible relationship between safety culture predictor variables and the 12 safety culture dimensions, as well as to determine the effect size. We modeled measurement occasion (first or second measurement) as a predictor variable to explore the effect of this variable on each of the 12 safety culture dimensions (modeled as the response variables), while controlling for all other predictor variables (e.g. statute, work area, profession…). *Frequency of errors reported* was removed during model building, since measurement occasion had no significant effect on this dimension. All other dimensions, except *Handoffs and transitions*, had higher odds ratios for the second measurement (OR>1) in comparison with the first measurement, indicating clear improvements in safety culture.

IMPLICATIONS FOR PRACTICE

Patient safety interventions are often called 'complex' interventions that require a properly planned evaluation and adjustments in sample size.[27] Still often, there is limited evidence on the effectiveness of specific patient safety interventions, such as for instance the implementation of outreach and Early Warning Systems.[28] On the other hand, evidence-based guidelines on safety practices are extensively available, such as measures to reduce central line-associated bloodstream infections[29], but are found difficult to be implemented in day to day practice. This gap between the availability of evidence-based guidelines and their translation and application into practice proves that improving patient safety is not just a methodological issue, but also an implementation problem.

Based on our extensive systematic review regarding unplanned intensive care admissions, several prevention strategies can be recommended for in-hospital practice in order to reduce intensive care (re)admissions, including rapid response systems and step-down units for patients requiring monitoring. However, based on this systematic review, we also raise concerns about the limited evidence surrounding these strategies.[30]

Based on our findings of the nation-wide safety culture measurements, several recommendations can be formulated for practice:

1. *Management support for patient safety* is considered as a key-element in improving safety culture within the Belgian hospitals. Yet, this aspect was found to be significantly improved for the acute and psychiatric hospitals. The commitment of the hospital management is an important structural and preconditioned aspect for improving safety culture and is characterized by good leadership. Available evidence supports for instance the rationale for applying safety (leadership) walk rounds to improve safety culture.[31] Most likely, direct contact between frontline staff and hospital management opens lines of communication and provides leaders with an opportunity to demonstrate their commitment to creating a culture of safety.

2. Our results suggest that improvement strategies should be tailored for types of hospitals, professional groups and hospital units, since these groups might be at different levels of readiness or maturity to improve safety culture. As a practical guide, our comparative safety culture report provides a 'patient safety profile' at the hospital level, professional level and hospital unit level in order to improve specific areas of weakness.[32] Without stigmatizing low scoring groups, lessons can be learned from high scoring groups.

   For instance, our results indicated that *Teamwork within units* should be improved in the operating theatres. Although their structure, functioning and autonomy differ across hospitals, operating teams would benefit from team training. Team training refers to a set of structured methods for optimizing teamwork processes, such as communication, cooperation, collaboration, and leadership. Also, the use of a standardized safe surgery checklist would expect to have a positive effect on safety culture in these units.[33] Our results indicated that psychiatric and pediatric units had very positive perceptions on teamwork within the unit and these units could offer lessons on this aspect.

3. Despite the slight positive evolution of safety culture, there is still an emergent necessity for the Belgian hospitals to improve transitional care processes. Important patient care information is often lost during shift changes and when transferring patients from one hospital unit to another. This seems to be a particular problem area within the pharmacy and medical-technical services, suggesting that the transmission of patient information related to medication and lab tests could be an important problem. Solutions to improve transition care processes include for instance the use of structured handoff and sign-out protocols, standardized patient admission and discharges processes (e.g. standardized medication reconciliation processes) and IT solutions.
4. There should be a higher awareness towards the importance of incident reporting within the Belgian hospitals. Our results demonstrate that events, although they don't always have the potential to harm patients, are seldom or not reported. Also, the punitive response towards errors

seems to be problematic. These areas warrant a continuous attention by the hospital management which is accountable for these processes. Although incident reporting has been advocated by the federal government for several years, there seem to be important (legal and organizational) barriers to confidential reporting within the hospitals. This brings up the discussion whether it would be sensible to place emphasis and resources on a national level reporting system and the creation of a legal and regulatory framework.

5. The dimension of *Staffing* seems to be less susceptible for progression and was identified as a major problem within geriatrics, the operation room, internal and surgical units and in particular for the nursing professions. For this aspect, hospital staff indicated that they must work too often in a crisis mode, meaning that too many things must be done too quickly. Obviously, this situation might create risks for a safe healthcare delivery and requires structural solutions. This finding might be an important signal to the federal authorities to increase the current norms on staffing within the Belgian hospital financing.

As outlined in chapter 1, a patient safety management system provides an integrated approach in which hospitals can monitor risks and adverse events, formalize safety policies and improve and evaluate safety interventions. A safety management system is the ‘anchoring’ of patient safety into practice. It requires the involvement of different stakeholders of patient safety: the providers of care (hospitals and healthcare professionals), the legislative and financing authorities (federal government) and most importantly, the patient.

IMPLICATIONS FOR HEALTH POLIY

Yet, there is an increasing attention and support for the improvement of quality and safety of care within the Belgian hospitals both on the federal and local level. The federal government makes an explicit commitment with the hospitals based on the quality and safety program. Participating hospitals receive an additional funding of 7.66 Euros on a yearly basis (to be divided by the distribution code of number of hospital beds). At the regional level, patient safety is part of the Flemish agreement on improving quality and safety within the Flemish hospitals. The Flemish Care Inspectorate aims to promote the quality of care provided by the Flemish welfare and healthcare sectors. For this reason the Flemish Care Inspectorate monitors compliance with regulations and ensures that public resources are used both rightfully and transparently. To that end, the inspectorate carries out inspections and draws up reports, on which the future license, recognition and allocation of grants will be decided.[34] In addition, a systematic approach towards quality and patient safety is met within the international accreditation programs, which require an explicit commitment of healthcare organizations towards improving patient safety.[35, 36] Currently, several Flemish hospitals are elaborating a hospital-wide accreditation program with the aid of the hospital federations.[37] These recent developments provide a range of new improvement and research opportunities.

RECOMMENDATIONS FOR FUTURE RESEARCH

Future research is needed to further the understanding of safety culture, particularly with an emphasis on theory-driven longitudinal research designs. Future research should address mixed methods designs, as qualitative data can support quantitative findings. The debate in literature on conceptual differences between safety climate and safety culture arouses the discussion on the assessment of both concepts. Besides a quantitative assessment of safety culture using survey questionnaires, qualitative methods (e.g. interviews, observation, focus groups) are required.[11]

Our safety culture dataset provides an enhanced opportunity for future research in the field of patient safety. In this discussion section, we make several recommendations for future research and formulate research hypotheses related to: (1) the influence of situation- and person-related factors on safety performance, (2) patient involvement in patient safety, (3) the relationship between safety culture and outcomes of care, and (4) the effectiveness of safety culture strategies.

1. **Examine the influence of situation- and person-related factors on safety performance (behavior)**

There are many theoretical frameworks of safety climate and safety culture available in safety science.[38-41] There is overall agreement that safety climate provides a framework for the interpretation of organizational events and processes in relation to personnel and organizational values and reflects the appropriateness of safety-related behavior.[40] However, in healthcare there has been limited attention paid to test the psychological mechanisms that could mediate the relationship between safety culture or climate and individual safety related behavior.

Future research should examine how person and situation factors interact in influencing safety performance behaviors. A meta-analysis of Christian et al. suggested that both the person and the situation are important factors related to safety performance.[38] In their meta-analysis, they define safety performance as safety related behavior (and not the 'tangible' safety outcomes). There are two types of safety behavior: compliance and participation. Safety compliance refers to the core activities that individuals need to carry out to maintain safety (e.g. adherence to standard procedures and wearing protective clothing). Safety participation describes behaviors that do not directly contribute to an individual's personal safety, but that help to create a safe environment.[42] Safety participation thus reflects workers' active involvement and commitment to safety. Person related factors can mediate the relationship between safety climate and safety behavior. Person related factors include safety knowledge and the individual safety motivation to enact safety behaviors. Person related factors also include personality characteristics (e.g. conscientiousness, neuroticism, extraversion, locus of control, propensity for risk taking) and job (safety) attitudes.[38]

It can be assumed that individual healthcare professionals are motivated to comply with safe working practices and to participate in safety activities, if they perceive that there is an overall positive safety culture within the hospital. Healthcare professionals can be trained and supported through positive safety culture to maximize safety motivation and safety knowledge, which in turn leads to safe behaviors (e.g. compliance to a safe surgery checklist, hand washing, reporting incidents, etc.). In contrast, for instance, respondents who are experiencing staff shortages and a higher workload might comply less with safety protocols. However, they may engage in more voluntary safety activities in order to compensate for the negative effects of staff shortages. Teamwork for instance might help to mitigate the negative consequences of the perceptions of inadequate staffing.[43]

Future research should also examine the effect of situation related factors (e.g. leadership styles) on personnel related factors and safety behavior. A meta-analysis of Clarke showed that both transformational (proactive) and transactional (responsive) leadership were positively associated with safety climate and safety participation in managing workplace safety. Transformational leadership behaviors (acts within the existing organizational culture) were most effective in encouraging safety participation, while transactional leadership (works to change the organizational culture by implementing new ideas) was most effective in promoting safety compliance.[44]

In short, we can formulate these examples as an overall research hypothesis:

> *H1: Safety culture is positively correlated with safe behavior (safety compliance and participation).*

Ideally, data on safety behavior should be collected through observational techniques. However, since observations can be difficult to gather in hospitals (see also recommendation 3), self-reported measures are frequently used to assess safety behaviors.[43] Since the HSPSC does not contain items on safety behavior, self-reported items on safety compliance and safety participation could be added to the questionnaire.

2. Examine patient involvement in safety behavior

Internationally, patient involvement is a key priority within the World Health Organization's World Alliance for Patient Safety in its program 'Patients for Patient Safety'.[45] Despite international emphasis on patient involvement in safety, there is a lack of research evidence on (1) the acceptability to patients (acceptance of the patient role) and (2) that such involvement leads to improvements in patient safety. There is a need to further the understanding how patients can best be involved and how they can act to improve safety of care.[46] Contributions that can be made by patients include for instance the reminding of healthcare staff to wash their hands and notifying staff if their patient identification bracelet is missing or incorrect. The approach of engaging patients makes part of an open culture, in which communication is important and patients can be more assertive.[47] A better understanding of the factors that influence patient participation in safety is critical to facilitating 'active'

involvement and to enabling effective interventions to be designed.[48] Future research should address the potential value of patient engagement, such as for instance in patient education, adverse events reporting, information technology and patient advocacy.
An overall research hypothesis can be formulated:

> *H2: Patient education is an important means to alter patient behavior and reduce the risk of adverse events.*

3. Linking safety culture and patient outcomes

We already outlined the lack of testing of the psychological mechanisms that could mediate the relationship between safety culture and safety related behavior. One step further is determining the relationship between safety culture and outcomes of care. Evidence from healthcare as well as other industries demonstrates that improved safety culture is associated with improved staff outcomes.[38, 40] The meta-analysis of Christian et al. demonstrated a link between better safety climate scores and lower worker accident rates and self-reported injuries.[38] Several studies reviewed evidence on the influence of organizational and safety culture on healthcare outcomes.[49-51] Only few studies found a clear relationship between safety culture and outcomes of care.[52-54] For instance, Huang et al. found that lower perceptions of management were independently associated with increased hospital mortality and that lower safety climate, expressed as perceptions of organizational commitment to safety, was independently associated with increased hospital length of stay.[52] Also, Hansen et al. found that hospitals and units with higher levels of patient safety climate had lower patient readmission rates.[53] Unfortunately, many other studies failed in finding any clear relationship.[50, 55, 56] Of these, only one study has adjusted for organizational factors, such as staffing and educational levels.[55] Articulating the nature of that relationship proves to be very difficult. The wide range of varieties for measuring healthcare outcomes makes it even harder to examine a possible relationship.

Future research should examine the extent to which safety culture perceptions are related to specific outcome measures. When safety culture is associated with safer patient care, it may also be associated with better safety for healthcare professionals. The following general research hypothesis can be formulated:

> *H3: Higher levels of hospital safety culture are associated with lower adverse event rates and lower work injuries.*

Ideally, the latter should be based on objective and reliable data that are measured from a different source than for instance the use of a safety culture questionnaire. In the HSPSC for instance, healthcare professionals are asked how often they report adverse events and how they score their unit on patient safety. The relationship between safety culture and the self-reported safety outcomes has been investigated in prior research.[43, 57] However, these outcome measures are behavior related perceptions and thus subjective outcome measures. For assessing a relationship with safety culture, more objective outcome measures are desirable.

In terms of patient safety, possible objective independent outcome data could include adverse events (from incident reporting, chart review or hospital administrative data), worker injuries or other organizational outcomes (e.g. litigation costs). However, it should be taken into account that this type of data is very expensive to collect by observation studies and reliable objective measures are often not easily available.

Current developments in the field of patient safety provide several opportunities for examining the relationship between safety culture and outcomes of care in the Belgian hospitals:

1. Recently, a basic set of quality and safety indicators was developed by a collaboration of the Flemish hospital associations, scientific institutions and patient- and healthcare societies. This set of indicators is available for use in the hospitals and includes compliance measures (e.g. hand hygiene, patient identification, use of a safe surgery checklist), the registration of adverse outcomes (e.g. hospital readmission rates) and patient experiences.

   Based on the HSPSC dataset, a possible relationship can be explored between safety culture perceptions and specific safety outcomes. It will be necessary to control for any confounding organizational factors (e.g. hospital type, size, statute, staffing ratios, and regional and language context) and patient related factors (e.g. case mix, comorbidities, age, and multiple medication).

2. A particular area of interest is linking safety culture perceptions with findings from the medical record review study that is being conducted in six Flemish acute hospitals (chapter 3). It can be hypothesized that higher levels of safety culture are associated with lower incidence rates of (preventable) adverse events requiring a higher level of care (e.g. unplanned ICU admissions, MET interventions, redo procedures). Without the aim of comparing hospitals, this hypothesis can be addressed at the organizational level, but also at the local level, since we found (in chapter 6) different safety culture perceptions among professional groups (head clinicians vs. assistants, physicians, nurses, pharmacists…) and hospital units (high vs. low hazardous units).

It could be investigated whether inter-unit variance in adverse events (*dependent variables*), considering the organizational and patient characteristics (*control variables*), can be explained by safety culture (*independent variables*).

From this perspective, several sub hypotheses could be formulated. For instance, the risk of a post-surgical complication and specific aspects of safety culture that might protect against such complications (e.g. teamwork, communication) may be most accurately perceived by a surgeon. Pharmacists and medical technicians might experience significant exposure to transition care processes within the hospital. It should thus be expected that safety culture perceptions related to handoffs and transitions of this particular group of healthcare professionals will be closely associated with adverse events of this type (e.g. ICU readmissions, medication errors). A particular hypothesis concerns the role of the hospital management in prioritizing patient safety. For instance, it can be assumed that hospital units which experience a low support by the management (low safety priority), as for instance high hazardous units such as the operating theatre, emergency care and intensive care units (chapters 6 and 8), have a higher incidence rate of adverse events.

4. Examine the effectiveness of safety culture strategies

Theoretically, strategies for improving patient safety culture should be aimed at reducing latent failures by applying 'generic' or 'diffuse' interventions (chapter 1, figure 1).[19] In practice, these interventions should be targeted at improving preconditioned factors including the management and organizational processes, such as adequate staffing, education and training. Also leadership and management commitment to safety have been considered the most central component in improving safety culture. However, the effectiveness of strategies aimed at improving patient safety culture is hard to prove.[27] Often, a combination of strategies is observed as having a positive impact without a clear relationship between the single strategy and safety culture improvement. A recent systematic review by Morello et al. only revealed limited evidence to support the effectiveness of patient safety culture strategies including incident reporting, leadership, human factors, accountability, communication, safety walk rounds, educational programs, simulation training and teamwork.[58] The strongest evidence to have a positive impact on safety culture was found for leadership walk rounds conducted by nursing staff[59] and the use of multi-faceted unit-based programs. 'Leadership walk rounds' is an interventional strategy that engages organizational leadership directly with frontline healthcare providers. Executives or senior leaders visit frontline patient care areas with the goal of observing and discussing current or potential threats to patient safety. Walk rounds aim to show leadership commitment to safety, foster trust and psychological safety, and provide support for healthcare professionals to proactively address threats to patient safety.[31]

Exemplary is the study of Pronovost et al. which introduced a multi-faceted unit-based program within two intensive care units (ICUs; intervention and subsequent control group) including a safety culture measurement, the education of staff, identification of safety concerns, the adoption of the unit by senior executives (by committing to patient safety), implementing improvements for the identified safety concerns, sharing results and a reassessment of the safety culture. After the period of one year, the program resulted in an improved safety culture, the introduction of patient transport teams, the presence of a pharmacist within the ICUs, a decrease in length of ICU stay and a reduction of medication errors in transfer orders. This study is exemplary since the improvement program was founded on unit team efforts and showed to be a basic replicable approach.[51]

Furthermore, a recent study of Jones et al. evaluated the impact of a team training intervention in 24 hospitals, using Team Strategies and Tools to enhance Performance and Patient Safety (TeamSTEPPS) and communication techniques, on safety culture using the HSPSC. Positive dimensional safety culture scores of the intervention group were significantly higher than the control group scores on three dimensions (Organisational learning— continuous improvement (76% vs 71%), Teamwork within departments (82% vs 80%) and Teamwork across units (67% vs 62%) assessing the flexible and learning components of safety culture.[60]

However, the generalizability of such safety culture strategies is strongly dependent on intrinsic organizational factors, such as the level of management support, the extent of the strategy, the size of the organization and the involvement of healthcare professionals facilitating change.[58]

Future research should focus on enriching the evidence of the effectiveness of strategies aimed at improving patient safety culture. Improvement strategies should be more selective and flexible and should be adapted to the specific context of the hospital or hospital unit. Since hospitals are organizations with an inherent hierarchical structure and also seem to be built upon subcultures, strategies should be aimed at target groups. Future research is also needed to better understand the role of safety culture as a contextual factor that can moderate the effectiveness of other patient safety practices, such as for instance the implementation of Early Warning Score Systems (EWS). An overall research hypothesis is:

> *H4: A positive safety culture moderates the effectiveness of patient safety practices.*

Organizations considering the implementation of potentially costly and resource-intensive strategies, should evaluate programs within a robust study design.[58] For instance, the implementation of strategies for improving patient safety (e.g. implementation of EWS) can be evaluated by using a stepped-wedge design. In a stepped-wedge design (controlled comparative study design), an intervention is rolled out sequentially to the trial participants (either individuals or clusters) over a number of time periods. From an ethical perspective, all individuals or groups might gain from the patient safety strategy and no unit is excluded from the opportunity to improve patient safety. Second, this design provides the possibility of measuring effects compared with a control group and compared over time.[27]

CONCLUSION

The *Hospital Survey on Patient Safety Culture* produced a considerable and informative dataset. Our approach demonstrated that examining safety culture can help explaining variability at the hospital and unit level. The resulting safety profiles of the participating hospitals revealed areas of strength but also of concern, in relation to (nurse) staffing levels, transition of patient care information and the hospital management's support for patient safety. Based on our findings, we suggest that hospitals need to ensure a strong management commitment to safety and that both the federal authorities and hospitals need to address staffing deficits in order to achieve the desired level of safety.

Future safety culture research in healthcare should profit from developing and testing behavioral models that attempt to explicate the mechanisms that influence both patient safety and worker safety. An interesting area warranting future research is to what extent safety culture can be linked with safety behaviors (e.g. compliance to a safe surgery checklist, hand hygiene, reporting of incidents, etc.) and outcomes of care. A combination of a patient safety management system and robust research designs should be coherently applied to identify risks, errors and adverse outcomes. An important challenge remains to systematically improve patient safety supported by the reinforcement of a safety culture.

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General summary

Since the publication of the report 'To err is human' by the Institute of Medicine (IOM) in 1999, public attention was drawn to the importance and magnitude of the issue of patient harm from medical errors. Patient safety is defined by the IOM as a subset of quality of care and focuses on the way in which risks on unintentional and evitable harm to the patient are handled in the organization of care. Patient safety should be the top priority in every healthcare organization. Still often, it is not enough in the attention of healthcare professionals and organizations. Lack of awareness of the severity of the problem, the complexity of healthcare organizations and the lack of data as a result of the paucity of measures are important barriers for improving safe care. Improving patient safety in healthcare organizations needs a system approach integrating different methods, such as the assessment and improvement of the safety culture, adverse events detection, analysis of the root causes and contributory factors of adverse events, prospective risk assessment, the implementation of improvement strategies and the education and training of healthcare staff.

Although, patient safety is receiving growing attention, there is scarce evidence on estimations of adverse events in Belgian hospitals. In addition, safety culture has not been measured on a broad scale in order to provide a basis for improving patient safety systematically in Belgian hospitals. Therefore, the primary objective of this dissertation was to fill an important gap in the current research on patient safety and safety culture in the Belgian hospitals. A secondary objective was to help hospitals to understand the nature of the safety culture within their organizations in order to implement strategies for improving patient safety.

First, a systematic review was conducted to estimate the incidence and preventability of adverse events that have a high impact for the patient, the hospital and society. The next phase built further on the available evidence and describes the development of a medical record review tool to investigate adverse events that require a higher level of care in Flemish hospitals. A case study was performed to evaluate the usefulness and time-investment of the

method of Healthcare Failure Mode and Effects Analysis for the assessment of risks in healthcare processes.

Within the federal program on quality and patient safety (2007-2012) two nationwide safety culture measurements were organized in the Belgian acute, psychiatric and long-term care hospitals. The Hospital Survey on Patient Safety Culture (AHRQ) was used to measure perceptions of hospital staff on a broad range of patient safety aspects. Hospitals were invited to participate in a comparative research to provide each hospital a patient safety profile for internal learning. A follow-up study after a period of three years aimed at tracking changes in safety culture after the implementation of a national patient safety plan. Furthermore, it was measured to what extent safety culture differed across hospital units and professional groups. Finally, it was assessed how well the Hospital Survey on Patient Safety Culture applies to the specific context of psychiatric care.

As a conclusion, Belgian hospitals are interested in the potential for evaluating, benchmarking and improving safety culture perceptions. Our research approach proves that large comparative databases allow to identifying safety culture patterns, trends and areas for improvement. Our results highlight that a continuous attention is required for the transmission of patient information and the reporting of (near) incidents in the Belgian hospitals. Also, staffing is an area which is less susceptible for improvement and thus should be a signal for the federal authorities to invest into higher (nurse) staffing. The overall positive evolution of safety culture and the important improvement for 'Management support for patient safety' show that there is a high potential within the Belgian hospitals for structurally improving patient safety.

Curriculum Vitae Annemie Vlayen

Annemie Vlayen was born on June 19, 1974 in Leuven, Belgium. She obtained a Master degree in Rehabilitation Sciences and Physiotherapy in 1996 at the KU Leuven. Between 1997 and 2005 she worked as a physiotherapist in the Hospital Heilig-Hart Tienen and the University hospitals Leuven. In 2005 she obtained the degree of Healthcare Management and Policies at the Centre of Health Services and Nursing Research, Department of Public Health at the KU Leuven. She followed different courses on quality improvement, Evidence Based Healthcare and the registration of hospital (administrative) data. From 2005 until 2008 she worked as a scientific researcher at the Centre of Health Services and Nursing Research, Department of Public Health at the KU Leuven on several projects of patient safety. She coordinated the federal pilot projects on patient safety (2006-2007) in 16 Belgian hospitals focusing on safe medication practices, safety culture, the implementation of a patient safety committee and the reporting of incidents. She participated in the Federal Patient Safety Committee and collaborated in the elaboration of the federal program on quality and patient safety (2007-2008). Since December 2008, she is preparing a PhD on 'Patient safety and safety culture in Belgian hospitals' at Hasselt University, Faculty of Medicine and Life Sciences.

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