TAKING CARE OF THE CAREGIVERS

How characteristics of work environment affect patient safety

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Table of contents

ACKNOWLEDGEMENTS 9

LIST OF ABBREVIATIONS 11

LIST OF STUDIES 12

SUMMARY 13

SAMMENDRAG 16

1 INTRODUCTION 19

1.1 Structure of the thesis 21

1.2 The rationale for this thesis 22

2 BACKGROUND 24

2.1 Patient safety 24

2.2 Medical errors 25

2.3 Patient safety initiatives 27

2.3.1 Legal and punitive incentives 28

2.3.2 Pay for performance 29

2.3.3 Incident reporting 29

2.3.4 Public safety campaigns 30

2.3.5 Patient safety initiatives in Norway 31

2.4 Healthcare accreditation 32

2.5 Patient safety culture 33

2.6 Work environment 34

2.7 Workarounds 35

2.8 Burnout 36

2.9 Moving forward 37

Safety-I model 37

Safety-II model 38

3 AIMS 41

4 THEORIES 42

4.1 Systems thinking 42

4.2 Systems theory 42

4.2.1 Human Factors Engineering (HFE) 43
4.2.2 Structure-Process-Outcome framework (SPO) 43
4.2.3 Systems Engineering Initiative for Patient Safety (SEIPS) 44
4.3 Resilience theory 45
5 MATERIALS AND METHODS 48
5.1 Philosophical underpinnings of research 48
5.2 Defining my research paradigm 49
5.3 Defining this thesis's research paradigm 49
5.4 Study designs 50
5.4.1 Systematic literature review 51
5.4.2 Cross-sectional study design 51
5.4.3 Longitudinal study design 52
5.5 Study population 52
5.5.1 Systematic review, paper I 52
5.5.2 Nurses, middle managers, and physicians, paper II 53
5.5.3 Hospital unit safety climate, paper III 55
5.6 Data collection 55
5.6.1 Literature search 55
5.6.2 Papers II and III 56
5.6.3 Safety climate data 58
5.7 Outcome measures 58
5.7.1 Effects of hospital accreditation, paper I 58
5.7.2 Patient survival probability, paper II 59
5.7.3 Safety climate maturity, paper III 59
5.8 Quality of data 60
5.9 Data analysis 60
5.9.1 Paper I 60
5.9.2 Paper II 61
5.9.3 Paper III 62
5.10 Ethics approval 63
6 KEY FINDINGS 64
6.1 Paper I 65
6.2 Paper II 66
6.3 Paper III 67
6.4 Summary of results 67

7 DISCUSSION ... 69

7.1 The effects of accreditation on patient safety and quality of care ... 69

7.2 Work environment and seven-day patient survival probability ... 73

7.2.1 The power of teamwork ... 74

7.2.2 Nurse workload ... 76

7.2.3 Middle manager engagement ... 81

7.2.4 Physician work environment ... 82

7.2.5 Working systems ... 83

7.3 Work environment and patient safety culture ... 84

7.3.1 Improvement ... 85

7.3.2 Quality ... 85

7.3.3 Patient-Centered ... 86

7.3.4 Commitment ... 87

7.3.5 Culture within the SEIPS framework ... 87

7.4 Methodological considerations ... 89

7.4.1 Paper I ... 89

7.4.2 Paper II ... 91

7.4.3 Paper III ... 95

7.4.4 What might it all mean? ... 97

7.4.5 The impact of the COVID-19 pandemic on patient care ... 99

8 IMPLICATIONS ON PRACTICE AND FURTHER STUDIES ... 101

9 CONCLUSIONS ... 103

REFERENCES ... 104

APPENDICES ... 125

ERRATA LIST ... 140

PAPERS I - III ... 149

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Kirsten Brubakk

LIST OF ABBREVIATIONS

AMI	Acute Myocardial infarction
AMSTAR	A MeaSurement Tool to assess systematic Reviews
HCW	Healthcare worker
HFE	Human Factor Engineering
HMPS	Harvard Medical Practice Study
HRO	High Reliable Organization
HSØ	Helse Sør-Øst Regionale Helseforetak (The South-Eastern Norway Regional Health Authority)
IHI	Institute of Healthcare Improvement
IOM	Institute of Medicine (now called National Academy of Medicine, NAM)
JCAHO	Joint Commission on Accreditation of Healthcare Organizations (now called The Joint Commission)
MeSH	Medical Subject Headings
OECD	Organisation for Economic Co-operation and Development
PDSA	The Deming cycle; plan-do-act-study
PICO	Population, Intervention, Comparison, Outcome
PSM	Patient Safety Movement
RCT	Randomized Controlled Trial
SAQ	Safety Attitude Questionnaire
SEIPS	System Engineering Initiative for Patient Safety
SPO	Donabedian Structure-Process-Outcome
TEH	Institute of Medicine report: To Err is Human
WAD	Work-as-done
WAI	Work-as-imagine
WES	Work Environment Survey
WHO	World Health Organization

LIST OF STUDIES

This thesis is based on the following published papers:

I. Brubakk K, Vist GE, Bukholm G, Barach P, Tjomsland O
A systematic review of hospital accreditation: the challenges of measuring complex intervention effects. BMC Health Services Research 2015. (https://doi.org/10.1186/s12913-015-0933-x)

II. Brubakk K, Svendsen MV, Hofoss D, Hansen TM, Barach P, Tjomsland O
Associations between work satisfaction, engagement, and 7-day patient mortality: a cross-sectional Survey. BMJ Open 2019.
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III. Brubakk K, Svendsen MV, Deilkås E, Barach P, Hofoss D, Tjomsland O
Hospital work environments affect the patient safety climate: A longitudinal follow-up using a logistic regression analysis model. Plos One 2021.
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SUMMARY

Background. Patient safety was brought into the forefront of public debate with the groundbreaking report "To Err is Human" (Kohn Lt 1999) calling for quality to be a critical component of high-performing health systems. The patient safety focus shifted from the understanding of patient safety as a product of individual skills and mindset to a new form of quality, which is a byproduct of the complex system interrelationships in healthcare. Yet despite decades of attention, activity and investment, patients continue to suffer preventable harm and improvement has been dismally slow.

Dr. Peter. F. Hjort (2007) translated the global patient safety challenge to a Norwegian context and began raising awareness among Norwegian politicians, policy makers and healthcare providers. In response, several system improvement strategies were introduced. This thesis was initiated as a response to the suggested mandatory accreditation requirements for Norwegian hospitals. Accreditation may be associated with high costs and extra workload; thus, a systematic evaluation of the value of accreditation is needed. Regulatory standardization and employee autonomy are often seen as opposing goals. However, reducing the gaps between managers struggling to balance resource constraints and staff at the sharp end of clinical operations might facilitate a work environment supportive of performing safely and with joy under varying environmental conditions.

Aims. The overall aim of this thesis is to investigate how health work environments affect patient safety in hospitals. To answer the research question, two perspectives were chosen: a) assessing the effects of accreditation on patient safety and quality of care; and b) assessing the work environment characteristics' impact on patient survival and safety climate.

Methods. This thesis is based on a multifaceted approach including a systematic literature review supported by two studies: a cross-sectional study, and a longitudinal study. i) The systematic review, conducted according to the PRISMA guidelines, evaluated the effects of hospital

accreditation on the quality of care and patient safety. ii) The cross-sectional study is based on 8,800 responses from nurses, middle managers, and physicians who participated in a validated work environment survey. The primary end point was the seven-day survival rate. The responses were linked to patient administrative data from 46,000 patients admitted to the hospital and treated with acute myocardial infarct (AMI), stroke, or hip fracture. iii) The longitudinal study's aim was to investigate the relationships between the perceptions of 25,220 staff in 970 clinical units at 21 Norwegian hospitals about their work environment and the safety climate in their clinical units. The associations between work environment characteristics (exposure) and patient survival probability and the organizational safety climate (outcome) were analyzed using multivariable linear regression models.

Results. i) The systematic review revealed a lack of studies with a controlled design. We found only weak conclusions could be reached to support the effectiveness of hospital accreditation on patient safety and the quality of care due to scant and heterogeneous evidence. ii) For the cross-sectional study, the factors Workload of nurses Beta 0.0019 (0.009 to 0.028) and Engagement of middle managers Beta 0.024 (0.010 to 0.037) were positively and significantly associated with patient survival but no association was found related to physicians' actions. iii) The longitudinal study confirmed an association between work environment characteristics and raising a unit's safety climate to a mature level, and, when present, maintaining a mature safety climate over time.

Conclusions. A variety of safety measures to improve patient safety have been suggested and implemented to support safer healthcare. The empirical evidence for the effects of external accreditation on patient safety were inconclusive. Hospital accreditation may be important for ensuring a basic level of quality; however, to be relevant accreditation standards need to support staffs' work processes in providing safe quality care. Policy makers and management need to carefully consider this when allocating resources to the accreditation processes. The COVID-19 pandemic demonstrated a need for standardization and regulation, and calls on policymakers to involve healthcare professionals and patients more fully to close the gaps between work-as-imagined and work-as-done. A work environment that inspires trust, authentic management

commitment to improvement, staff commitment, and patient-centeredness might enhance patient safety. This thesis confirms the importance and value of bringing patient safety to the forefront of health policy and care, which can help fulfill the promise to do no harm to patients.

SAMMENDRAG

Bakgrunn. Rapporten "To Err is Human" (Kohn Lt 1999) som ble publisert i 1999 bidro til å sette fokus på pasientskader som følge av uønskede hendelser samtidig som den fremhevet kvalitet som en viktig del av det som blir ansett som gode helsetjenester. Rapporten var et viktig bidrag til at pasientsikkerhet ikke lenger blir oppfattet som et resultat av den enkelte ansattes ferdigheter og tankesett, men som et produkt av samspillet mellom alle komponenter i komplekse helsetjenester. Selv om rapporten fikk stor oppmerksomhet og førte til betydelige investeringer i kvalitetsforbedrende arbeid, påføres over 10% av pasientene som behandles i spesialisthelsetjenesten fremdeles skader som kunne vært forebygget og forbedringsarbeidet har ikke gitt de resultatene man hadde ønsket.

Dr. Peter. F. Hjort (2007) bidro til å sette den globale pasientsikkerhetsutfordringen i en norsk kontekst noe som medførte økt bevissthet blant norske politikere, beslutningstakere og helsepersonell. Ulike strategier for forbedring og implementering av disse ble lansert. Et av tiltakene som ble vurdert var forslag om obligatorisk akkreditering av norske sykehus. Akkreditering er blitt forbundet med høye kostnader og ekstra arbeidsbelastning for sykehusansatte, samtidig som det ikke forelå gode kost-nytte vurderinger. Det var bakgrunnen for starten av dette Ph.d. arbeidet hvor første artikkel er en sammenstilling av publiserte systematiske evalueringer som vurderte effekten av sertifisering og akkreditering på kvalitet og pasientsikkerhet i spesialisthelsetjenesten. Standardisering av helsetjenesten og ansattes autonomi blir ofte sett på som motstridende mål. Imidlertid kan involvering av ansatte og pasienter i utforming av tjenesten redusere gapet som oppstår mellom ledere som ønsker regulatoriske grep for å balansere begrensede ressurser og klinisk ansatte sitt ønske om å yte best mulige helsetjenester til den enkelte. En slik tilnærming kan legge til rette for et arbeidsmiljø som understøtter ansatte i å utføre sitt arbeid trygt og med glede under varierende forhold.

Mål. Det overordnede målet er å undersøke hvordan ansattes arbeidsmiljø påvirker pasientsikkerheten i sykehus. For å besvare forskningsspørsmålet ble det valgt to perspektiver: a)

vurdere effekten av akkreditering på pasientsikkerhet og kvalitet, b) vurdere hvordan arbeidsmiljø virker på pasientoverlevelse og sikkerhetsklima i sykehus.

Metoder. Avhandlingen inkluderer en systematisk litteraturgjennomgang samt en tverrsnitts- og en longitudinell studie. i) Den systematiske litteraturgjennomgangen, utført i henhold til PRISMAs retningslinjer, evaluerte effekten av akkreditering på kvalitet og pasientsikkerhet i sykehus. ii) Tverrsnittstudien er basert på 8 800 svar fra sykepleiere, mellomledere og leger som deltok i en validert arbeidsmiljøundersøkelse. Det primære utfallsmålet var syv dagers overlevelse for pasienter innlagt med hjerteinfarkt, hjerneslag eller hoftebrudd. Svarene fra ansatte ble koblet til pasientadministrative data fra 46 000 sykehuspasienter innlagt med de aktuelle diagnosene. iii) Den longitudinelle studiens mål var å undersøke sammenhengen mellom 25 220 ansattes vurdering av eget arbeidsmiljø i 970 kliniske enheter ved 21 norske sykehus og sikkerhetsklimaet i disse enhetene. Ved hjelp av multivariat lineær regresjonsanalyse ble sammenhengen mellom arbeidsmiljø (eksponering) og pasientens overlevelsessannsynlighet og enhetens sikkerhetsklimaet (utfall) analysert.

Resultater. Litteraturstudien avdekket mangel på studier med kontroller som vurderte effekt av sertifisering og akkreditering. Vi fant kun begrensede data som ikke var nok til å kunne vurdere eventuell effekt av akkreditering på pasientsikkerhet og kvalitet. I tverrsnittstudien fant vi at arbeidsbelastning for sykepleiere (Beta 0,0019 (0,009 til 0,028)) og lederengasjement (Beta 0,024 (0,010 til 0,037)) var signifikant positiv assosiert med pasientoverlevelse. Vi fant ingen tilsvarende assosiasjon relatert til legers arbeidsmiljø. Den longitudinelle studien viste en signifikant sammenheng mellom arbeidsmiljø og evne til å bedre sikkerhetsklima til et modent nivå eller opprettholde et modent sikkerhetsklima der dette var tilstede ved målingstidspunktet.

Konklusjoner. En rekke tiltak er foreslått og implementert for å forbedre pasientsikkerheten i helsetjenesten. Resultater fra studier som vurderer effektene av akkreditering og sertifisering på pasientsikkerheten var ikke entydig. Akkreditering kan være viktig for å sikre et grunnleggende kvalitetsnivå, imidlertid bør akkreditering også fokusere på det som er viktig for ansatte og

pasienter. Erfaringer fra COVID-19-pandemien viste at standarder er etterspurt av ansatte. Myndigheter og ledelse bør imidlertid nøye vurdere effekten av akkreditering før de allokerer ressurser til akkrediteringsprosesser. Basert på funnene i Ph.d. arbeidet vil det være av stor betydning at beslutningstakere involverer ansatte og pasienter for å lukke gapet mellom forestilling om det som skjer i virksomheten og det arbeidet som faktisk utføres. Et arbeidsmiljø som inspirerer til tillit, autentisk ledelsesforpliktelse til forbedring, mobilisering av ansatte og pasientfokus vil kunne bidra til å bedre pasientsikkerheten. Ph.d. arbeidet bekrefter viktigheten og verdien av å se pasientsikkerhet i sammenheng med beslutninger som påvirker arbeidsmiljøet.

"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm."

Florence Nightingale (1863)

1 INTRODUCTION

An international sense of urgency to reduce patient harm was created over 20 years ago when the Institute of Medicine (IOM) published their landmark report "*To Err is Human. Building a safer Health System*" (Mitchell, Schuster et al. 2016). According to Kohn et al. (1999), each year between 44,000 and 98,000 patients die due to medical errors in US hospitals. The report was a clarion call for political action for change as the consequences for patients and healthcare systems were devastating. The core message was that good people are working in inadequate systems and that a system view was needed to reduce the number and the significance of medical errors and patient harm (Bates and Singh 2018).

However, the extensive efforts for safer healthcare have not led to measurable improvements in the overall high rates of preventable harm (Braithwaite and Donaldson 2016, Wears and Sutcliffe 2019). Remarkably, as many as 8-12% of patients hospitalized in European hospitals experience adverse events while receiving healthcare (WHO 2019). A 2013 study in Norwegian hospitals found that 13% of in-house patients were injured as a consequence of their treatment (Deilkås 2014). In Norway, there have been extensive efforts to work systematically on improving patient safety, with aims to build public trust, by reducing patient harm, building sustainable structures for patient safety, and improving the reliability of public healthcare services.

This thesis was initiated in response to the suggested value of implementing mandatory hospital accreditation in Norway. As a senior union representative for 23,000 hospital nurses and a long-time board member of the South-Eastern Regional Health Authority, I observed the gaps between the good intentions of stakeholders and management to provide efficient, effective, and safe care, and the employees who felt stretched in a stressful, resource constrained, and complex systems.

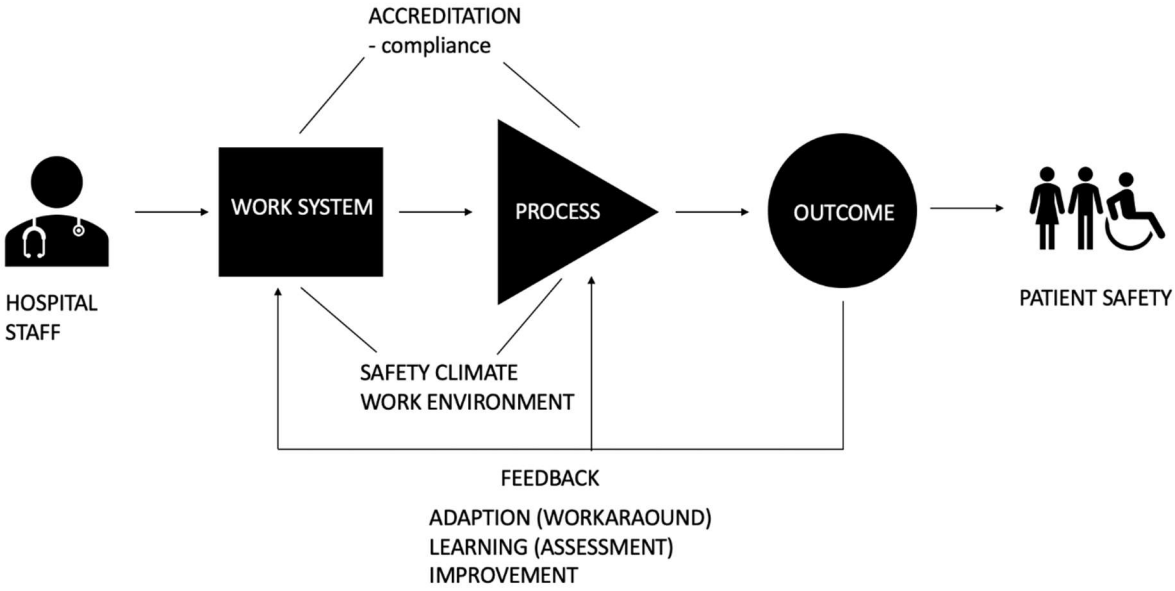
Questions were raised about the effects of accreditation on patient safety while not involving frontline staff working with management to improve the work environment conditions that underpin safe patient care.

Industrial safety is often conceived as the absence of accidents and incidents. Safety-I is defined as a state where as few things as possible go wrong and is concerned with a linear cause-effect chain (Hollnagel, Wears et al. 2015). The key concept is that factors which contribute to adverse outcomes can be identified by tools such as incident reporting and root cause analysis and prevented by regulation and standardization (Reason 1990, Mannion, Davies et al. 2005). Notably, the Safety-I perspective does not consider how healthcare professionals are able to get things right even in flawed systems (Hollnagel, Wears et al. 2015). Safety-II however, "*assumes that everyday performance variability provides the adaptations that are needed to respond to varying conditions, and hence is the reason why things go right"* (Hollnagel, Wears et al. 2015)p4. Consequently, the staff are the essential resource for system flexibility and resilience and attention must be directed to the conditions under which employees work (Hollnagel, Wears et al. 2015, Mannion and Braithwaite 2017).

The overall perspective of this thesis is to explore how healthcare work environment can affect the safe conduct by staff and lead to improved and safe patient outcomes. A raft of systems thinking theories to underpin the key thrust of the work was used (De Savigny and Adam 2009). According to Donabedian (1988), the performance of an organization is linked to the systems in which care is provided and supported. Figure 1 depicts how work environment is seen as the system in the System-Process-Outcome model on which this research is grounded. Accreditation and safety climate could be seen as system components affecting process and outcome. Study I searched publications that analyzed the effects of accreditation on patient safety and quality of care. In study II, the association between work environment and patient survival probability was explored and study III analyzed the relationship between work environment characteristics and a mature safety climate. However, this thesis only studied effect in one direction, from system to outcome, but describes the resilient and adaptive behavior that is performed to attain a different outcome than the one produced by the system. The feedback loop illustrates how outcome data could

adjust process and systems to achieve improved patient safety and might close the gap between work-as-imagined and work-as-done.

Figure 1. The model for the thesis and supporting articles



1.1 Structure of the thesis

Three interlinked studies address the overall aims of the thesis. The studies applied different methods and data sources, though the second and third study applied data from the South-Eastern Regional Health Authority (HSØ), the largest health region in Norway and the system that provides hospital services for nearly 3 million inhabitants.

Chapter 1 consists of the introduction. In chapter 2, a detailed background is provided that includes definitions of the key concepts of patient safety, medical errors, safety culture, and work environment. Furthermore, a description of various patient safety initiatives is given. Finally, a discussion of the Safety-I and Safety-II perspectives is presented. Chapter 3 introduces the main

research questions, while chapter 4 provides the analytical framework for the thesis. In chapter 5, the materials and methods used in the studies are detailed, while chapter 6 summarizes the three studies that make up the thesis. The results are discussed in detail in chapter 7 and combined with a review of the methodological strengths and limitations. Finally, chapter 8 provides thoughts on further needed research on this seminal topic. Chapter 9 concludes with the major findings of the thesis.

1.2 The rationale for this thesis

Historically, improvements in medicine and nursing were aimed at providing more advanced treatment and better care. The Hippocratic Oath guided healthcare professionals to do no harm, and harm was mainly seen as a side effect of illness and treatment. 'To Err is Human' marked a new era. The good intentions of individuals were no longer enough for safe patient care and a new requirement to hold healthcare accountable for the quality of care was needed, as control shifted from the professions to others to reduce variance and increase quality. The tools of accreditation and external inspections were chosen to monitor hospital staffs' adherence to the new requirements. However, the well-intended efforts of policymakers and managers have had many unintended side effects; healthcare professionals increasingly report loss of autonomy, burnout, and the desire to leave healthcare. Understanding how the system in which care is provided affects employees' performance and commitment is increasingly seen as key to improvement. In the South-Eastern Regional Health Authority (HSØ), the staffs' perceptions of their work environment are surveyed annually. Combining these data with data on patient survival probabilities and safety climate might explain which factors can describe what is important to staff and supportive of their safety efforts.

This thesis is underpinned by systems thinking and resilience theory, and understands the shift from Safety-I to Safety-II as a paradigm shift according to the thinking of Thomas Kuhn (1962) as scientists have taken a different attitude towards the existing and evolving worldview of safety thinking and practice. The linear thinking about why errors occur cannot fully explain safety, nor can true safety be fully explained within this concept; thus, the need for Safety-II is proposed to

better explain the observations and offers performance models closer to real world challenges. Safety-II is not new, but new to healthcare and potentially may have a major impact on management practices as the shift in perspective offers a fundamental new way to talk about safety when moving from merely counting to meaningful and continuous learning.

"Patient safety is about the patient but requires that healthcare professionals have the right tools and environment to perform their tasks and coordinate their efforts."

Carayon and Wood (2009)p8.

2 BACKGROUND

The origin of the term 'patient safety' is unknown, but the term is widely used in clinical settings, academic research and various reports concerned with healthcare quality. Although the term is not universally defined, there have been several efforts to establish a commonly accepted definition (Runciman, Hibbert et al. 2009). According to the Institute of Medicine (IOM), patient safety is freedom from accidental injury (Kohn Lt 1999). Emanuel et al. (2008)p6 on the other hand, propose the following definition; "*Patient safety is a discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of and maximizes recovery from adverse events."* This definition provides a scope for the conceptual model for patient safety by dividing the healthcare system into four domains: healthcare employees, patients, the environment, and methods for improvement- a division that is well suited for the scope of this thesis.

2.1 Patient safety

Patient safety is often perceived as a subgroup of healthcare quality, although boundaries remain poorly defined (Pronovost, Goeschel et al. 2009). The need to distinguish patient safety from quality in healthcare is still questioned and remains essential to some scholars while being dismissed by others as a semantic exercise (Emanuel, Berwick et al. 2008). According to Weinger and Gaba (2014), quality and patient safety are complementary but not the same. Quality is focused on improving reliability and efficiency, whereas patient safety focuses on understanding avoidable risks of harm to patients due to individual or systems failure. Nevertheless, safety cannot be seen as separate from the broader perspective of quality. Safety is one consideration in the overall aim of providing healthcare that must be safe, effective, person-centered, timely, efficient, and equitable (Corrigan 2005). One interpretation could be that quality addresses the

intended result of healthcare services. On the other hand, patient safety is concerned with the many ways a system can fail (Vincent 2013). A new understanding is emerging as the focus has shifted from failure-based model that counts errors (Safety-I) towards one that focuses on what goes right (Safety-II). This new approach focuses on the readiness of the healthcare teams to deliver safe care every day in a pressurized and fast-moving environment (Braithwaite, Wears et al. 2015).

2.2 Medical errors

People make mistakes, and healthcare workers are not immune against making errors. To prevent errors, some argue it is necessary to understand such errors and why they occur (Reason 1995). According to Reason (2017), errors occur when a planned action fails to achieve its desired goal. Rasmussen (1983) argues that errors happen due to a combination of expectable and inevitable human failure combined with the design of the system at hand. Humans might trigger the event but are themselves part of the enabling conditions embedded deep in the organization, such as understaffing, high workload, insufficient training, and unworkable procedures (Rivera and Karsh 2008). These latent conditions result from decisions made by policymakers, system designers, and management upstream from the sharp end where care is delivered (Vincent 2013). On the other hand, things go right more often than wrong; thus, we can learn more about the organizational characteristics and culture underpinning safe attitudes from routine, everyday processes, rather than by focusing on snapshots of dysfunctional states (Hollnagel 2017).

The TEH report estimated that more Americans die in hospitals every year due to preventable medical errors than from motor vehicle accidents, breast cancer, or AIDS (Kohn Lt 1999). These numbers were extrapolated from two large medical record review studies, one from New York state in 1984 (The Harvard Medical Practice Study), and one from the states of Colorado and Utah in 1992 (The Utah Colorado study). When extrapolating the estimates of these studies to the US population, deaths due to medical errors were found to be the 8th-leading cause of death (Hoyert, Kochanek et al. 1999). More recently, James (2013) estimated that the US hospital deaths due to medical errors are in the range of 210,000 – 400,000 annually. Makary and Daniels (2016)

calculated a mean annual rate of 250,000 deaths in 2015, making medical error the third leading cause of death in the US. While these estimates have been questioned and the data challenged, scholars agree about the magnitude of medical errors in healthcare. The OECD (Organisation for Economic Co-operation and Development) estimated that one in ten hospital patients experience adverse events, and patient harm is the 14th leading cause of the global disease burden (Slawomirski, Auraaen et al. 2017). Recent estimates show that one incident of patient harm is reported every 35 seconds in the United Kingdom (WHO 2017). In Norway, the Global Trigger Tool was introduced to monitor adverse events in 2010. In 2018, 11.9 % of the hospital stays resulted in at least one adverse event, with approximately 1,100 patients reported to have died due to iatrogenic events (Guldvog 2019).[1]

The consequences of patient harm can affect patients in terms of time lost to injury, reduced quality of life, increased morbidity, and the risk of premature death (Small and Barach 2002). Besides the personal costs due to suffering, the true societal cost of harm should also include the impact on healthcare resources that could be used in alternative ways, productivity losses, and forgone income taxes. In addition, the direct and indirect costs associated with patient harm might also affect the political economy regarding loss of public trust in healthcare systems and the undermining of public health and preventive interventions (Slawomirski, Auraaen et al. 2017).

Healthcare workers (HCW) are often anguished—the second victims, alongside their patients when harm occurs (Wu 2000). Seys et al. (2013) found that almost 50% of HCW experience negative emotions after their patients were harmed. Wu and Steckelberg (2012) argue that insufficient attention is devoted to prepare and assist healthcare professionals in coping with such a response. The consequences of limited support include burnout, leaving the profession,

[1]The Global Trigger Tool was developed by the Institute for Healthcare Improvement and uses specific methods for reviewing medical charts to identify adverse events. The tool was translated and adapted for the Norwegian context.

functional impairment, and serious mental health challenges including depression and even suicide (Ibid).

The financial burden on healthcare systems from adverse events is enormous. The OECD found that 15% of all hospital costs can be attributed to patient harm that arises from adverse events, and the aggregated cost is estimated to be trillions of dollars annually (Slawomirski, Auraaen et al. 2017).[2] These costs include additional treatment costs for more diagnostic procedures, prolonged stay, and hospital readmissions. The resource constraints in healthcare systems, including the Norwegian, calls for more accountable and efficient usage of the resources made available, which might be stated as 'doing the right thing every time'.

2.3 Patient safety initiatives

Preventable harm has been a topic in the history of medicine and is reflected in the guiding principle 'first do no harm' (Sokol 2013). Hammurabi 1700 BC was the first to propose laws to control healthcare and protect the vulnerable: "*If a physician performs major surgery with a bronze lancet upon an awīlu and thus causes the awīlu's death, or opens an awīlu's temple with a bronze lancet and thus blinds the awīlu's eye, they shall cut off his hand",*[3] Law 218 (Hays 2014). In the mid-1800, Dr. Ignaz Semmelweis standardized procedures on handwashing, and Florence Nightingale collected data and measured outcomes to promote improvement in care and advocate change. In 1913, the American College of Surgeons implemented minimum standards for hospitals (Neuhauser 2003, Best and Neuhauser 2004, Pearn 2016). However, the many efforts of individuals and organizations were not enough to hold healthcare accountable for uneven quality of care. In the 1990's public attention was increasingly drawn to the amount of preventable adverse events in healthcare, ultimately leading to the emergence of a patient safety movement (Emanuel, Berwick et al. 2008). A brief presentation of key patient safety initiatives follows to

[2] One trillion dollars equal the Norwegian oil fund. US healthcare expenditures exceeded 3.5 trillion dollars in 2019.

[3] The awīlu class referred to free citizens.

illustrate the transition from poor performance of individuals to a system-based focus on health systems thinking and strengthening.

2.3.1 Legal and punitive incentives

Failures in healthcare have traditionally been managed by blaming individuals, for example, by assigning the responsibility for adverse events to the last person in the production chain (Berwick 1989). The prevailing culture has been that punitive actions send a clear message of errors and harm being unacceptable. Malpractice law is concerned with adverse events, and such events are pinned to the negligence of individuals leading to patient damage and compensation (Grepperud 2005). Developing a safety management system has been the counterargument to tort reform, claiming that without legal accountability, 'bad apples' will continue to harm patients (Sage and Underhill 2020).

Legislation has evolved over time to support safer healthcare. In fact, the data retrieved for the Harvard Medical Practice Study (HMPS) originated from the need to study malpractice claims against healthcare providers (Brennan, Leape et al. 1991). However, there is scarce evidence that tort litigation and criminalization of healthcare professionals promotes safer behavior (Dekker 2011). The medical malpractice system may potentially increase the risk of errors as the fear of sanctions greatly contributes to healthcare professionals not reporting adverse events (Liang 2001). Dekker (2011) found that penalties, rather than offering learning opportunities, drove staff to conceal their mistakes and contributed to remarkably low adverse event reporting by HCW. Mello et al. (2020) in their systematic review suggest that malpractice liability in its current form is not associated with improved quality of care.

Nearly all adverse events involve a complex interaction between active failures and latent conditions (Reason, Hollnagel et al. 2006). Active failures are errors, mistakes, and violations committed by humans at the sharp end, whereas the latent conditions are built into the system. To punish individuals for mistakes caused by system breakdown would not make sense, as errors will continue until the latent conditions are identified (Reason 2017). Thus, individual blame is

seen as the wrong solution and possibly counterproductive to creating highly reliable and safe healthcare delivery systems.

2.3.2 Pay for performance

The pay for performance reimbursement scheme was meant to establish incentives for healthcare providers to meet specific quality performance standards and align HCW payments with value and quality metrics. This type of incentive system rewarded care performance above certain observable standards (Kazel 2004). There are two basic types of pay for performance models for hospitals; withholding funds later used to reward good performance, and penalize sub-par performance. Such public disclosures have been associated with improvement (Marshall, Shekelle et al. 2000). However, the pay for performance schemes have led to gaming and manipulation of data that might have perverse incentives that undermine the intended effects and help create unintended consequences in other areas (Leape and Berwick 2005, Heath, Hippisley-Cox et al. 2007). On a positive note, pay for performance policies focus on data transparency as the metrics are publicly reported, providing incentives for improvement. Critics note that pay for performance might reduce access for disadvantaged populations and greatly reduce job satisfaction and staff motivation (Catalyst 2018).

2.3.3 Incident reporting

Incident reporting has been a cornerstone in patient safety. According to Barach (2003)p19 "*reporting systems are only a part of a 'culture of safety' that sees adverse events as opportunities for learning and improvement"*. Reason (2016) identifies four critical elements of an effective safety culture: a reporting, just, flexible, and learning culture. According to Wears (2017), the patient safety movement has been obsessed with reporting systems, and roughly 20% of TEH deals with aspects concerning incident reporting. Adapted from other high-risk industries, much effort has been invested in incident reporting systems. However, the uneven translation to healthcare settings and building sound structures for investigation and change have prevented sustainable improvement from the incidents reported (Stavropoulou, Doherty et al. 2015, Macrae and Stewart 2019). In healthcare, voluntary reporting systems should complement the mandatory

reporting systems that focus on serious injury and preventable death, as voluntary systems also focus on errors that result in no harm or little harm; thus providing additional information relative to mandatory reporting (Kohn Lt 1999).

While there are benefits gained from the establishment of large reporting systems, there are challenges that accompany their development and successful implementation (Hutchinson, Young et al. 2009). Barach and Small (2000) found an estimated underreporting in the range of 50% - 96%, indicating that much information is missed, and they identified a punitive blaming culture as an essential reporting barrier. Other barriers identified were; i) the cost and time associated with reporting (Renshaw, Vaughan et al. 2008), ii) reporting systems being too bureaucratic (Travaglia, Westbrook et al. 2009), iii) the lack of effective feedback systems (Benn, Koutantji et al. 2009), and iv) the lack of a shared understanding about what to report (Dixon-Woods 2010). A key to overcome the barriers and disincentives to incident reporting is the introduction of a non-punitive learning culture. However, collecting data with the absence of specific goals and direct feedback to providers usually means that meaningful learning is unlikely and, staff will become more cynical and even less likely in the future to take the time to report incidents (Barach 2003, Shojania 2008).

2.3.4 Public safety campaigns

Public campaigns have been launched at the global, national, and institutional levels to create awareness and mobilize all stakeholders to improve patient safety. Campaigns such as the IHI campaigns '100 000 lives' and the '5 million lives' are intended to act as major drivers of national improvement by proposing large-scale, multi-institutional efforts (Berwick, Calkins et al. 2006, McCannon, Hackbarth et al. 2007). The WHO launched the World Alliance for Patient Safety for global attention (World Health Organization 2008). Campaigns attempt to achieve planned effects with an organized communication within a set time (Ozieranski, Robins et al. 2014). The lasting effects of campaigns remain hard to measure; however, campaigns create important awareness about patient safety issues that may yield change (Benn, Burnett et al. 2009, Ross 2009).

2.3.5 Patient safety initiatives in Norway

In Norway, many patient safety initiatives have been influenced by the TEH report. A national body of supervision was established to provide oversight of the quality and accountability in healthcare. The main task of the Norwegian Board of Health Supervision (NBHS) is to ensure that health services are provided according to statutory requirements. Regular audits are based on site visits and mandatory incident reports of serious events. The NBHS board has the authority to sanction both healthcare institutions and healthcare professionals. Additionally, the Norwegian government has encouraged voluntary incident reporting and analysis of adverse events to help ongoing learning and harm prevention. For this purpose, the National Unit for Patient Safety was established in 2004. In 2010, the Global Trigger Tool was implemented in Norwegian hospitals and a National Patient Safety Campaign 'In Safe Hands 24-7' was launched in 2011.

In 2014, a Norwegian version (KBF) of the US pay for performance scheme (see page 22) was added to the national hospital reimbursement scheme[4] and a percentage of the hospital budget was directly tied to quality indicators. A quality and safety regulatory framework was introduced to the Norwegian healthcare systems in 2017.[5] Lastly, The National Accident Investigation Board (UKOM) was established in 2017 to improve patient safety through independent investigation of serious adverse events and circumstances leading to harmful events.[6] To further increase public accountability and quality of care, the 30-day survival probability[7] after hospital admission and the Health Atlas [8] of unwarranted variation in care are published regularly to identify hospitals with potential for improvement based on Deming's Plan, Do, Study, Act Cycle (PDSA) for continuous improvement, (Kristoffersen, Helgeland et al. 2015).

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[4] More on KBF: Oddvar Kaarbøe, Norwegian Medical Journal nr. 19/2017.

[5] Forskrift om ledelse og kvalitetsforbedring i helse- og omsorgstjenesten.

[6] Lov om Statens undersøkelseskommisjon for helse- og omsorgstjenesten. 1.juni 2017.

[7] https://www.helsedirektoratet.no Overlevelse 30 dager etter innleggelse på sykehus.

[8]https://helseatlas.no

A wide range of patient safety initiatives addressing all organizational levels have been implemented in Norway. The knowledge and attention related to patient safety issues have undoubtedly increased due to the combination of national efforts and local engagement, and many successes can be noted.[9] Nevertheless, the rate of patients experiencing adverse events remain the same, and the urgency to move forward is commonly shared. Furthermore, to our knowledge, no systematic or robust evaluation of the impacts of these interventions on patient safety and quality of care have been performed in Norway.

2.4 Healthcare accreditation

The history of accreditation dates back to 1787, when the University of the State of New York became the first accrediting agency to visit and review the work of other academic institutions. In 1847, the American Medical Association was voluntarily associated with the program, but more than 60 years elapsed before medical education improvement took place (Harcleroad 1980). The American surgeon Dr. Ernest Amory Codman launched 'The End Result System' in 1910 (Donabedian 1989, Warshaw 2014), which later developed into a program of standards for surgeons leading to the foundation of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).[10]

Accreditation in healthcare began as an assessment and monitoring of process through measuring compliance against standards (Mumford, Forde et al. 2013). The WHO formally defines standardization as *"the process of developing, agreeing upon and implementing uniform technical specifications, criteria, methods, processes, designs or practice that can increase compatibility, interoperability, safety, repeatability and quality"* (Leotsakos, Zheng et al. 2014)p111. An independent accreditation body may be responsible for developing standards essential to hospitals. Common themes in accreditation programs include management, documentation, data

[9] https://pasientsikkerhetsprogrammet.no

[10] JCAHO – Joint Commission on Accreditation of Healthcare Organizations was renamed to Joint Commission in 2007.

management, quality management, patient safety, and staff education and training (Bogh 2017). However, accreditation is not standardized because different countries and accreditation agencies apply different standards and requirements for becoming accredited (Alkhenizan and Shaw 2011). Over the past decades, accreditation has been gaining support around the world. The widespread use of accreditation and the vast resources allocated to accreditation agencies indicates that accreditation is seen as a fundamental strategy to assure healthcare quality (Lam, Figueroa et al. 2018). However, several countries perceived as leaders of external independent accreditation, such as Denmark, Singapore, Australia, have decided to abandon mandatory accreditation or search for more effective self-assessment and monitoring programs (Bogh 2017).

2.5 Patient safety culture

A safety culture is increasingly seen as an important strategy to improve the reliability of healthcare services and the widespread deficits of patient safety (Pronovost and Sexton 2005). Safety culture is part of the wider concept of organizational culture. It refers to individual and group values, attitudes, perceptions, competencies, and patterns of behavior that specifically affect the management of safety (Nieva and Sorra 2003). In healthcare, culture is considered to be the softer aspect of healthcare organizations and is manifested in patterns of care (Mannion and Davies 2018).

Culture can be defined in numerous ways. Kroeber and Kluckhohn, in a paper from 1952, identified 164 different definitions (Kroeber and Kluckhohn 1952, Braithwaite, Herkes et al. 2017). A synthesis of these definitions is not easy, but there seems to be an agreement in the literature that culture can be defined as *"the social-organizational phenomena in terms of attitudes or behavior, that emerge from a common way of sense-making, based on shared values, beliefs, assumptions, and norms"* (Hesselink 2013)p9. This normative belief perspective focuses on the way people think and behave about safety (Cooper 2000). Culture represents the common agreement on the way things are 'done here' and what new team members are socialized into (Hollnagel 2017). A positive culture within workplaces and across the wider organization is essential for positive patient outcomes (Braithwaite, Herkes et al. 2017). In addition, a positive

safety culture can induce staff engagement supporting safe behavior and is related to error reporting, reduction in adverse events, and reduced patient mortality (Weaver, Lubomksi et al. 2013). There appears to be some distinction in the literature between safety culture and safety climate, but the relationship between these constructs remains unclear (McFadden, Stock et al. 2015). However, for our purposes, the term culture is viewed as a more all-embracing concept than climate. A safety climate has been described as the surface features of the underlying safety culture (Flin, Burns et al. 2006). Safety climate reflects the employee's perceptions about the conditions, policies, and practices in the work environment (Blegen, Pepper et al. 2005).[11] Safety attitude is influenced by the individual's beliefs about safety and a positive attitude develops into a strong safety culture (Han, Kim et al. 2020).

2.6 Work environment

The work environment is conceived as a multi-dimensional concept that, while immensely important, remains ill defined. Nitisemito's definition; "*work environment is anything that is around the workers who can influence themselves in carrying out the tasks entrusted*" cited in a paper by Nguyen et al. (2020), might not provide clarity; however, it aligns with the notion that human performance is affected by their work systems. The definition appears to be an implicit characterization of the context in which work is done. In fact, social and structural characteristics will strongly influence employee behavior (Pronovost, Goeschel et al. 2009). In this thesis, work environment factors are understood as interdependent elements of a system, and safety emerges from the interactions between these elements.

[11] Climate will be used when referring to the Safety Attitude Questionnaire (SAQ) in this thesis.

2.7 Workarounds

A workaround is the deliberate deviation from standards and can be seen as a safety precaution where staff bypass system barriers to provide efficient care adaptive to changing circumstances. Workarounds may be understood as the behaviors that differ from intended procedures and the temporarily 'fix' of workflow hindrance (Morath and Turnbull 2005). Such hindrances may be any rule, regulation, standard, safety precaution, technology, or system design perceived as inadequate for the assigned task. Workarounds might occur when employees perceive a gap between the ways management perceives the frontline work versus the work that is actually done at the sharp end. As a result, the employees may shape strategies to 'get the job done'. Such bridging behaviors are known as workarounds, shortcuts, non-compliance, or violations (Morath and Turnbull 2005, Runciman, Merry et al. 2007).

A scoping review by Debono et al. (2013) found that a typical precursor for workaround behaviors are complex tasks not compatible with predefined structures. Furthermore, organizational factors (e.g., culture, work process factors, and mismatch between policy and current workflow), patient-related factors (e.g., securing timely care), and individual, social and professional factors can actively contribute to the proliferation of workarounds. In addition, Wheeler et al. (2012) suggest that inadequate resources might contribute to workaround behaviors. Finally, Mansour and Tremblay (2019) found that the psychosocial safety climate concerning employees' psychosocial health and safety can affect workarounds and burnout and that staff burnout can further trigger workaround behaviors.

The consequences of workarounds have been widely debated. While some interpret such behavior as violation and resistance, others point out that workaround actions provide important information and improvement opportunities (Mansour and Tremblay 2019). Learning from aviation and other highly reliable organizations, strategies such as simplification, standardization, and the use of protocols can control complicated tasks (Barach, Hamman et al. 2004). However, such measures need to be adapted to the complex environments of healthcare. If not, employees will be engaged in workarounds, described as non-compliance, which may reduce patient safety

and, if discovered, put employees in harm's way (Debono, Clay-Williams et al. 2018). Furthermore, the local 'firefighting' prevents systematic improvement and systemic learning, as problems are not escalated upwards for definitive systems solutions by management in charge (Shand, Allwood et al. 2021). Reason (2008) introduced the phrase: 'lethal convergence of benevolence,' to describe healthcare professionals' well-intended actions to smooth out the wrinkles of the working days by overcoming and working around defenses. According to Reason (2016), workarounds conceal systematic problems from those who can implement improvements but who might lack access to staff's 'ground-level' insight. Management responses to workarounds might be more top-down firm measures that reduce the freedom of front-line staff, trapping patient safety in an ever-more constricting regulatory regime (Braithwaite, Wears et al. 2015). Staff responses might be the reinforcement of workaround behavior. In sum, this may mean that workarounds can create an underground economy of unsafe practices, jeopardizing future care provided to patients (Debono, Clay-Williams et al. 2018).

2.8 Burnout

Burnout can be understood as the process of 'wearing out and wearing down' an individual's energetic resources (Mansour and Tremblay 2019). IHI presented the Triple Aim as a framework for optimizing health system performance to improve the population's health, enhance patient experiences, and reduce treatment costs (Berwick, Nolan et al. 2008). Based on a general notion about too much waste in healthcare (Berwick and Hackbarth 2012), requirements of efficiency, standardization, and cost reduction were enforced on the workforce, reducing complex caregiving relationships to a series of demanding tasks performed under resource constraints (Sikka, Morath et al. 2015). According to Hobfoll (2001), the combination of fewer resources and increasing workloads are additive stressors for burnout.

Understanding the factors that affect burnout is essential from a patient safety perspective, since burnout among healthcare professionals can affect patient outcomes and drive healthcare organizations away from their goal to deliver safe, high-quality care (Dyrbye, Shanafelt et al. 2017). Previous studies have identified job requirements as an important predictor of burnout.

The most significant causal factors were role conflict, workload, and work pressure (Lee and Ashforth 1996, Alarcon 2011, Mansour and Tremblay 2019). Maslach et al. (2001) noted that the significance of burnout lies in its link to crucial outcomes. In healthcare, burnout has a dual pathway. First, it affects the health of healthcare professionals (Peterson, Demerouti et al. 2008), their job performance (Bakker and Heuven 2006), and increases their absenteeism (Schaufeli, Bakker et al. 2009). Second, patients are affected by lower service quality (Shanafelt, Bradley et al. 2002) and more mistakes and harm (West, Dyrbye et al. 2018). Recognizing this, the IHI added a fourth aim to their framework the Triple Aim, the 'Joy in Work' initiative—now called the Quadruple aim, as a measure for fighting burnout by increasing workforce well-being and staff motivation (Sikka, Morath et al. 2015). Burnout also has a considerable financial effect, Han et al. (2019) estimated the costs related to physician burnout in the US at approximately $4.6 billion in 2019, and burnt out physicians report higher rates of medical errors and self-harm (Panagioti, Geraghty et al. 2018). For nurses, 31.5% of those leaving their current employment reported burnout as their main reason for resignation (Shah, Gandrakota et al. 2021).

2.9 Moving forward

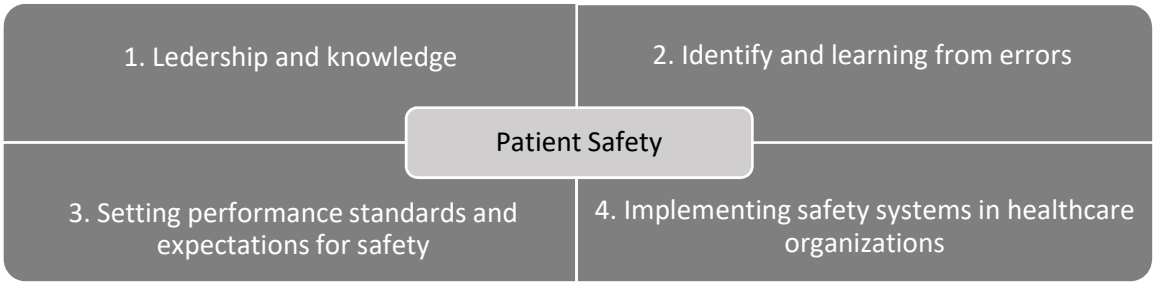
Safety-I model

Healthcare contains multiple moving parts, changes over time, and does not react predictably or timely to external inputs (Braithwaite 2018). This complexity obstructs the best intentions of policymakers and managers to build a safer healthcare, as the safety strategies offered often are based on how top managements perceive the work done and not on how the actual work processes are performed nor reported on at the sharp ends of the organization (Braithwaite, Churruca et al. 2017). The recommendations of TEH are perceived as representing a linear cause-effect perspective of safety, derived from their definition of safety as *"freedom from accidental injury"* (Braithwaite, Runciman et al. 2009). It follows from the definition that the purpose of safety management is to achieve and maintain low numbers of adverse events by identifying causal factors for each incident to prevent the problem from reappearing. This perspective, often called Safety-I, reflects recommendations such as the need for standardization, incident reporting, root-cause analysis and external oversight. The Safety-I philosophy is designed to prevent and

eliminate what can go wrong, improve the system's defenses, and cope with complexity by simplification (Hollnagel 2017).

According to TEH, building a safer health system by understanding why errors occur, often means designing care processes to ensure that patients receive high quality care and are safe from accidental injury (Kohn Lt 1999). Figure 2 depicts the four-tiered approach recommended by the Institute of Medicine (IOM).

Figure 2. The four-tiered initiative for patient safety suggested by IOM



Based on the recommended improvement initiatives from IOM, the paper *"Free from harm: Accelerating patient safety improvement fifteen years after To Err Is Human"* found that specific improvements had occurred but the broad aim to make healthcare safer has not been achieved (Berwick, Shojania et al. 2015). Although increased awareness of patient safety issues was a definite success after the launching of TEH, the combined safety efforts have yielded mixed results in patient safety, and still, one in ten patients admitted to the hospital experience adverse events (Lark, Kirkpatrick et al. 2018, Mannion and Davies 2018). As a response to these disappointing results, an increasing number of researchers have questioned whether the patient safety community should aim broader than the Safety-I approach (Hollnagel 2014, Mitchell, Schuster et al. 2016, Mannion and Smith 2017, Sujan, Huang et al. 2017, Braithwaite 2018).

Safety-II model

The Safety-II approach was proposed to complement the Safety-I initiatives (Hollnagel, Wears et al. 2015). Safety-II defines safety as the ability to make things go right. It recognizes that patient

safety cannot be improved by more regulation, increased bureaucracy, and more use of standardization alone but by paying attention to how work is performed and by working with the informal characteristics of systems in order to achieve intended outcomes (Braithwaite, Wears et al. 2015, Braithwaite, Churruca et al. 2017). The Safety-II initiative has been described as paying attention to the successes of healthcare and systematic discovery of everything that supports a system and to what gives life to people and their organizations (appreciative inquiry) (Cooperrider and Fry 2020). Despite the variation, complexities, and local adjustments in care things go right more often than things go wrong (Hollnagel, Wears et al. 2015, Mannion and Braithwaite 2017). A key activity is to understand how staff facilitate and manage their work flexibly and safely under varying and often adverse conditions (Braithwaite, Wears et al. 2015).

The Safety-II initiative does not abandon Safety-I initiatives such as incident reporting, standardization, and external oversight of healthcare organizations but argues that such policies cannot by themselves accurately capture a complete picture of the factors affecting safe care. Rather it offers an alternative perspective: *"If something that goes wrong has a cause, then something that goes well must have one too"* (Hollnagel 2017)p62. Thus, understanding what goes right in healthcare is a significant contribution to understanding patient safety (Braithwaite, Wears et al. 2015). Lawton (2018) suggests that the main difference between Safety-I and Safety-II might be the language that is underpinned by different mental models. Systems thinking is no 'quick fix' but it recognizes the complexity in healthcare and the many interacting factors that contribute to its outcome in both Safety-I and II models. However, by turning the perspective on its head, Safety-II asks new questions within the systems-thinking regime, and new interventions based on the work-as-done concept emerge. Work-as-done (WAD) refers to how something is performed, with a difference between how work is 'imagined' or thought of and how work is actually done.

The concept of workarounds might be perceived both as a consequence and a critique of the Safety-I perception. However, the objectives of Safety-I and Safety-II are to reduce the adverse events but the way this is achieved differs across the two perspectives. Whereas Safety-I strives to eliminate what can go wrong, Safety-II underpins resilience in every-day work to ensure acceptable outcomes under changing and complex conditions (Braithwaite, Wears et al. 2015). Safety-II provides a way out from the top-down paradigm by working closely with staff in

redesigning systems. The goal is to accept full transparency of the risks inherent in the system, building on the natural resilience in healthcare organizations, still under the guidance of standards, but by engaging staff more fully through deep consultation about what works well for them rather than telling them what to do (Braithwaite, Churruca et al. 2017). Leveson (2021) has further proposed a Safety-III perspective, a modified system's approach to safety and resilience. Leveson, expanding on Safety-II, argues that safety is attained when hazards and losses are prevented leading to organizational learning from incidents, and system performance is audited. For this thesis, Safety-I and Safety-II provide hallmarks for the changes needed to reliably improve healthcare. As noted above, there cannot be one without the other. When combining Safety-I and Safety-II efforts, the result might be Safety-III, recognized as a *system* that allows staff to be resilient and flexible with a 'just culture' for reporting and improving. Table 1 provides a summary of the safety I-III perspectives.

Table 1. Characteristics and comparison of the Safety-I, Safety-II and Safety-III model.

	Safety-I	**Safety-II**	**Safety-III**
Definition	As few things as possible go wrong.	As many things as possible go right.	Freedom from unacceptable losses.
Safety management principle	Reactive. Responds when something goes wrong.	Proactive, continuously trying to anticipate developments and events.	Concentrates on preventing hazards and losses and learns from accidents and audits on how system is performing.
Explanation of accident	Caused by failure and malfunction. Errors are investigated to identify contributory factors.	Outcome results in the same system. Investigation to understand how things usually go right.	Inadequate control over hazard. Linear causality is not assumed. There is no one root cause.
Attitude to human factors	Humans are predominantly seen as a risk or a hazard.	Humans are seen as a resource necessary for flexibility and resilience.	Systems must be designed to allow humans to be flexible and resilient and handle variation.
Role of performance variability	Should be prevented.	Should be monitored and managed.	Performance variability is safe within the system boundaries and conflicts should be eliminated.

Adapted from a more extensive version by Leveson (2021).

3 AIMS

The aim of this thesis is to investigate how systems factors affect patient safety in hospitals. To explore the aim, two perspectives were chosen by assessing: i) the effects of hospital accreditation on patient safety and quality of care, and. ii) the association between work environment characteristics and both patient outcomes and safety climate. More specifically, the thesis explores the empirical evidence for accreditation and its effects on patient safety and quality of care. Furthermore, it aims at identifying the meaningful work environment factors that are significantly associated with patient survival and the development and maintenance of a mature safety climate in hospital units.

The specific aims were to:

1. Systematically assess the effects of accreditation and/or certification of hospitals on organizational processes and patient safety outcomes by exploring peer-reviewed research.

2. Examine the associations between profession-specific work environment characteristics for nurses, middle managers, and physicians, and seven-day patient survival probability.

3. Explore the association between work environment characteristics and the changes in patient safety climate, and the factors significant for developing and maintaining a mature patient safety climate.

4 THEORIES

Exploring how accreditation and work environment factors are associated with patient safety and quality of care requires an understanding of the underlying mechanisms. This thesis applied theories of systems thinking and resilience theory to gain such knowledge. According to Haraldsson (2004)p13, "*the principle in systems thinking is that all behavior in a system is a consequence of its structure*" and systems theory is a general approach for understanding system behavior (Adams, Hester et al. 2014). In health services research, systems thinking analyses the parts of a defined system and their connections with the whole (Schneider, Sturmberg et al. 2016). However, capturing all parts within a system is too complex. We aim then to map accreditation and work environments as parts of the reality in such a way that it allows a better understanding of complex safety problem. Resilience theory helps explain the organizational readiness and potential to respond to variation and disruption and to understand how the system functions within the multiple constraints of a system (Hollnagel, Woods et al. 2007).

4.1 Systems thinking

Systems thinking is based on the understanding that errors can best be prevented by considering the relationships between system components and the overall system (Trbovich 2014). Braithwaite (2018)p1 argued that no system is more complex than healthcare where *"performance and behavior changes over time and cannot be completely understood by simply knowing about the individual components."* By simplification, systems thinking could be understood as system safety by acknowledging that safety is the result of multiple factors and the interaction between them within a system (Vincent, Burnett et al. 2013).

4.2 Systems theory

From an analytical view, systems theory is the understanding of a phenomenon by examining its constituent parts (Rapoport 1986). The phenomenon we choose to focus on in this thesis is patient safety, and the constituent parts are the work systems and processes leading to the outcome. This thesis limits a working system to the work environment where the factors studied are the

interacting parts of the system. To explore how work systems affect outcomes, this thesis draws on several theoretical models.

4.2.1 Human Factors Engineering (HFE)

HFE was developed after World War II when psychologists were called on to understand why pilots crashed perfectly good aircrafts (Wickens, Hollands et al. 2015). HFE designs systems to better fit people to the system, meaning that systems are designed to perform with a high probability of safety, quality, and job satisfaction (Rivera and Karsh 2008). The Human Factors approach looks at sources for safety and risk everywhere in a system, including economic and human resources offered, the technology available, and the underlying organizational culture (Dekker 2016). For example, technologies are increasingly seen as an important solution for quality improvement; however, a systems approach is needed to understand the interaction between technology and humans, the potentially unintended consequences caused by introducing new technologies, and the actual work processes. From a Human Factors perspective, de Vries et al. (2010) showed that HFE-designed checklists could improve compliance and reduce in-hospital mortality. According to HFE, medical errors and preventable harm can be avoided by focusing on the design of systems and processes (Carayon and Wood 2010). The design of efficient systems and processes might reduce the workload of staff and produce better outcomes for patients. Several levels are defined at which interventions are needed to improve patient safety, including the clinical microsystem defined as small organized groups of providers and staff caring for a defined population, which is the focus of this thesis (Mohr, Batalden et al. 2004).

4.2.2 Structure-Process-Outcome framework (SPO)

Avedis Donabedian understood healthcare as a system and provided a conceptual SPO model for examining health services. He conceptualized a chain linking structure, process, and outcome. The structure is the context in which care is delivered; this includes material resources, human resources, and organizational structure. Process denotes the transactions between patient and provider as the methods by which healthcare is provided, while outcome refers to healthcare's effects on patients (Donabedian 1966). Donabedian notes the necessity to draw connections

between the categories to create a chain of causation (Donabedian 1988). The original SPO model by Donabedian focused on the causal chain of optimal performance by healthcare professionals rather than merely on the work system in which healthcare is performed (Carayon, Hundt et al. 2006).

While the SPO model can be seen to fall short in understanding the full impact of systems thinking, technology, continual process redesign, and patient-centeredness (Berwick and Fox 2016), it offers great insights into causality of systems' outcomes. Patient safety researchers have developed the SPO model further by expanding the description of the structure, adding human factors engineering and organizational resilience to the model (Vincent, Taylor-Adams et al. 1998, Carayon, Hundt et al. 2006, Emanuel, Berwick et al. 2008, Hollnagel, Wears et al. 2015). Extending the SPO model allows the effects of many cost effective policy and service interventions to be measured and could help improve the design and interpretation of evaluative studies (Lilford, Chilton et al. 2010).

4.2.3 Systems Engineering Initiative for Patient Safety (SEIPS)

The SEIPS paradigm is a human factors system model developed as a framework for understanding structures, processes, and outcomes in healthcare (figure 3). The SEIPS model is anchored within HFE and integrates Donabedian's SPO model (Xie and Carayon 2015) but "*goes further by clearly specifying the system components that can contribute to causes and control of medical errors and adverse events"* (Carayon, Hundt et al. 2006)p2. By adding the external environment to the model, factors outside the organization can be understood. These might be macro-level factors such as legislation, policies, and reimbursement. From an employee perspective, regulatory issues such as workforce regulation, work hour restrictions, welfare policies, and governance might affect their ability to provide safe care (Holden, Carayon et al. 2013). According to SEIPS thinking, the work system contains six components: Person, Organization, Technologies and Tools, Task, Internal and External environment. The interacting components envelop persons and emphasize how systems should support people in doing their work. The external environment includes the decisions made at the macro-level and the multi-level interaction between work systems that might affect the micro-levels' ability to deliver outcomes (Holden, Carayon et al. 2013). The process depicts

performance processes that accomplish an outcome, and in contrast to SPO, patients are part of the process as co-producers of outcomes. The outcome is defined as the conditions resulting from the work process and can be desirable and undesirable. Where gaps are identified, the feedback loop allows for adaption in the work system for different outcomes (Hollnagel, Woods et al. 2007). Adaption also depicts ad-hoc adaption or workarounds where one or more work system components are relatively fixed, and staff develops strategies to get the work done in spite of obtuse systems (Carayon, Karsh et al. 2013). The feedback loop is crucial to support organizational learning and improvement (Holden, Carayon et al. 2013).

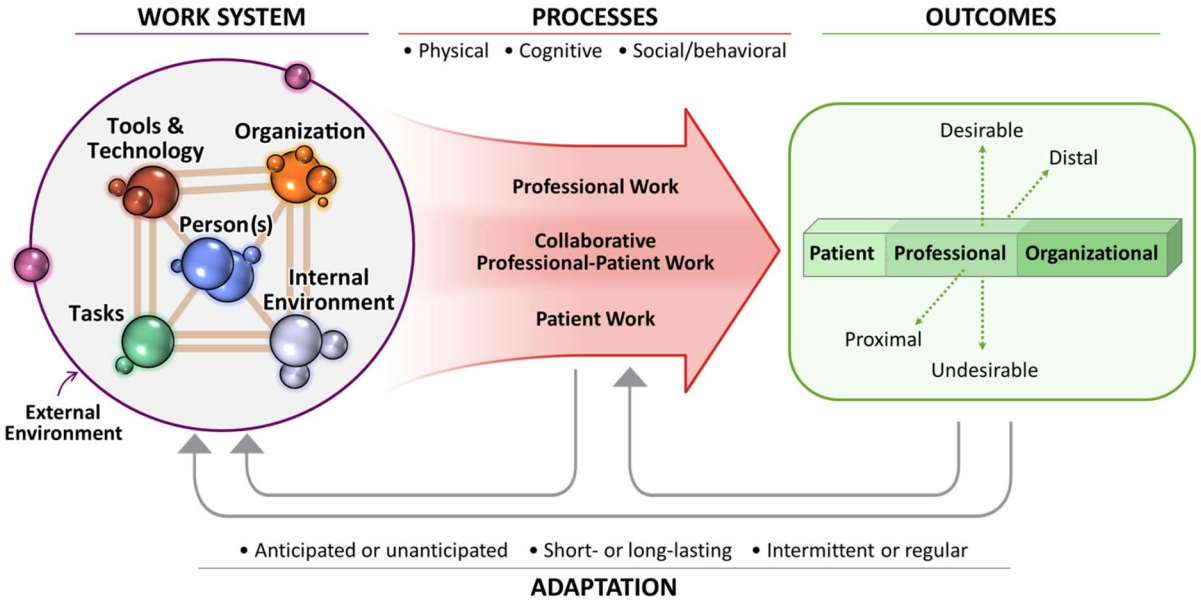


Figure 3. SEIPS 2.0 model by Holden, Carayon et.al (2013). Reprinted with permission.

4.3 Resilience theory

Resilience is defined as *"… an expression of how people, alone or together, cope with everyday situations – large and small – by adjusting their performance to the conditions. An organization's performance is resilient if it can function as required under expected and unexpected conditions alike (changes/disturbance/opportunities)"* (Hollnagel 2017)p14. The definition includes how staff successfully adjust to match the changing conditions under which they work and can perform under changing conditions. The hallmark is not meant to be error-free but to have the capacity

and ability to detect and prevent errors from resulting in harm (Sutcliffe, Paine et al. 2017). Sujan (2018)p 663 captured this well, saying that *"Studies undertaken under the umbrella of resilient healthcare demonstrated that healthcare workers and clinical systems can adapt and to make dynamic trade-offs, which enables them to provide safe care in the face of disturbance, ambiguities, tensions and contradictions, and competing for organizational priorities."*

Resilience theory has evolved over the past 70-80 years and is experiencing a recent renaissance (Van Breda 2001). In a resilience framework, the focus is shifted from deficits to strengths; thus, promoting an environment conducive to individuals and organizations (Chapin 1995). The Salutogenic perspective[12] of Antonovsky (1979) originated as a stress and coping model for survivors of the Holocaust and offered a paradigm for thinking about resilience (Van Breda 2001). *"Antonovsky turned the traditional question on causes of disease upside down and asked what factors could make people maintain and develop health, even under difficult external circumstances"* (Suominen and Lindstrom 2008) p337. This perspective may be transmissible to patient safety and in thinking about the impacts of the environment including the physical built environment. Healthcare produces safe and unsafe outcomes in the same environment; the question of interest is which attitudes and factors contribute most to mitigating unsafe conditions to produce safe outcomes (Mannion and Braithwaite 2017). From a Salutogenic perspective, resilience could be seen as the ability to maintain safety under various conditions.

Hollnagel (2016) argues that an organization's resilience potential to respond, monitor, learn, and anticipate should be explored. For this thesis, the choice was made to see resilience as a process as part of an SPO perspective. Resilience is a characteristic of a certain kind of performance, and human performance depends on the influences from its surroundings (Hollnagel 2017). According to SEIPS (Holden, Carayon et al. 2013), performance processes can be broken down into specific activities, including the workaround, adaption, and adjustment to keep patients safe. Berg et al.

[12] For more on Salutogenic theory, please see: Mittelmark et al., Handbook of Salutogenesis. ISBN 978-3-319-04600-6. Barach P, Parker D, Designing Salutogenic Health Care Facilities for Safety and Quality, Ed. Alan Dilani, Cambridge Press, in press, 2022.

(2018) warn that focusing on the perspective of healthcare professionals alone might yield incomplete knowledge on resilience. Nevertheless, in this thesis system boundaries were drawn at the micro-level to explore how the staff‘s perceptions of their work environment is associated with best patient outcomes and if work environment factors might underpin the adaptive efforts of staff in response to the misalignment between work-as-imagine (WAI) and work-as-done (WAD).

The main premise of this thesis is predicated on the concept of systems thinking. The chain of causation describes how the resources available affect healthcare outcomes and staffs’ ability to best utilize resources. Furthermore, the empirical evidence for the effects of accreditation on patient safety and quality of care were studied. Accreditation fits well within the context of systems thinking. For example, standards could be seen as part of the work system, whereas the audit is part of the process. Previous research has indicated that systems thinking could improve the accreditation process as standard compliance is interconnected with other parts of the system (Taylor 2003). This thesis explored how the work environment might affect the actions and culture of healthcare professionals; in this light, the choice of applying systems thinking seemed sensible and compelling.

5 MATERIALS AND METHODS

5.1 Philosophical underpinnings of research

Research has been described as a systematic investigation whereby data are collected, analyzed, and interpreted (Burns 1997). All research has a philosophical foundation that influences its conduct, and researchers must be aware of the assumptions made about gaining knowledge ethically and be explicit about them (Creswell and Clark 2017). These philosophical assumptions inform the choice of theories that guide research (Ibid). As distinct from a theory, the theoretical framework is referred to as a paradigm (Mackenzie and Knipe 2006). The choice of a paradigm sets down the intent, motivation, and expectations for the research (Ibid). A paradigm consists of certain basic theories, values, and beliefs about the world and how it is constituted and the criteria for what constitutes 'good science' (Guba and Lincoln 1994). According to Denzin and Lincoln (2011), a paradigm is a net that contains the researcher's theoretical orientation or paradigm based on ontological, epistemological, and methodological premises.

The differences between research paradigms are philosophical and have implications for the conduct of research (Barrow 2018). Ontology can be defined as the nature of the world and what can be known about it (or issues related to the nature of reality and its characteristics). In the positivist paradigm, the ontological position assumes reality to exist independently of beliefs or understanding; it can be observed, and knowledge can be gained applying quantitative methods. Epistemology poses the question about the relationships between the known, the inquirer, and what can be known. In the positivistic paradigm, the world is independent of the researcher, facts and values are distinct, and knowledge is seen as hard, tangible, and objective. Knowledge is acquired by hypothesis testing and deductive research. The interpretive paradigm, in contrast, seeks to understand values and beliefs. The ontological position called constructionism sees reality as subjective, and from an epistemological point of view, the world is seen as constructed and interpreted. The interpretive perspective is the theoretical framework for qualitative research, and the logic followed is inductive, where theory is generated from the data collected (Guba and Lincoln 1994, Tuli 2010, Al-Saadi 2014, Creswell and Poth 2016, Cohen, Manion et al. 2018).

5.2 Defining my research paradigm

As a nurse, I was trained within the positivist and the interpretive paradigms. Part of the education lies within the so-called 'hard science' applicable to the realist perspective and quantitative methodology. Whereas nursing also entails the 'softer' aspect of science, seeking to understand the meaning individuals ascribe to their actions and the reactions of others (Weaver and Olson 2006). In healthcare, adherence to one paradigm is common and often split between the positivism and the interpretive paradigm (Broom and Willis 2002). From epistemological and ontological points of view, paradigmatic plurality is problematic. In my research approach, I cannot both be objective and subjective; furthermore, it is not easy to hold several realities simultaneously. Nevertheless, it is argued that the combination of paradigms provides more complete and accurate knowledge as the different perspectives complement each other (Leddy 2000), and there seems to be a trend towards using multiple paradigms for research (Weaver and Olson 2006). Therefore, reflecting upon my research questions and the available datasets, choosing both paradigms might offer a broader perspective and help develop deeper insights into the unique individual responses to accreditation and the work environment. However, the systematically gathered data in this thesis from large representative population-wide samples and well-defined variables solidly orientates this research within the positivist paradigm.

5.3 Defining this thesis's research paradigm

For this thesis, I chose the philosophical assumption of the positivist paradigm. Survey data was collected and statistically analyzed to identify and predict possible interconnections between variables. In this worldview, causes determine the effects or outcomes, and an objective theory is sought via stringent control of contextual variables (Mackenzie and Knipe 2006, Weaver and Olson 2006). The assumption made is that an association between variables can be determined by scientific methods within the frame of a realist ontology of a single truth (e.g., a proper way to manage patient safety), and an objectivist epistemology, meaning that the truth is apprehended through objective measurements (Barrow 2018). Rather than searching for one truth, this thesis maintains a dependence on robust measurement tools to develop a causal understanding of the world *"within the limitations of our times, techniques, and currently available knowledge"* (Young

and Ryan 2020)p695. This post-positivist paradigm emerged in response to realizing that reality can never be completely known and that measuring it is limited by human comprehension (Weaver and Olson 2006). Table 2 illustrates how the positivist paradigm lays out the ontology, epistemology, and methodology for this research.

Table 2. Overview of positivist and post positivism paradigm

Paradigm	**Positivist**	**Post positivism**
Ontology	Realist	Critical realist
Epistemology	Objective Empirical/Evidence	Modified dualist Objective
Methodology	Quantitative	Modified experimental
Methods	Questionnaire Tests Statistical analysis	Questionnaire Tests Statistical analysis
Theory	Deductive	Deductive

5.4 Study designs

This thesis is based on several years of work, a number of international presentations[13] and three published papers (I-III). Different research designs were used to address the aims of each study. The aim of study I was assessed by performing a systematic literature review. To address the aim of study II, a cross-sectional study design was employed, and for study III, a longitudinal study design was used. For papers II and III, a set of hypotheses was formulated based on systems theory, and the hypotheses were tested.

[13] ISQUA conference (International Society for Quality in Health Care), 21-24. Oct. 2012, Geneva, ICN conference (International Council of Nurses), 30. June 2019, Singapore

5.4.1 Systematic literature review

A systematic review is considered a strong and robust form of knowledge synthesis and a reliable source of evidence to guide clinical practice (Clarke 2011). According to the Cochrane Collaboration, a systematic review *"uses explicit, systematic methods that are selected to minimize bias, thus providing more reliable findings from which conclusions can be drawn and decisions made"* (Higgins and Green 2011). Furthermore, a systematic review is an excellent method for gaining an in-depth understanding of a research field (Sykes 2004). The design was therefore considered appropriate to meet the first aim of this thesis. The systematic review process allowed for a rigorous assessment of the literature on the effects of accreditation, which provided insights on the methodological challenges of measuring complex interventions. The Cochrane handbook was used to guide the systematic review and reported using the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Moher, Liberati et al. 2009).

5.4.2 Cross-sectional study design

Cross-sectional studies are carried out at one point and provide a snapshot of the outcome and the characteristics associated with it (Levin 2006). Cross-sectional design is used for a number of purposes as the design allows for collecting data over a short time without requiring long periods of follow-up, measuring prevalence for all factors under investigation; the amount of data makes it possible to make statistically robust generalizations and claims, and replicability (Hua and David 2009).

For study II, the mean work environment unit score and patient administrative data was collected and analyzed for the same three-year period. As suggested by Wilson (2003) a deductive descriptive study was performed to test the associations between work environment characteristics and patient survival probability. According to the design, a causal relationship could not be established in a cross-sectional study; the design explored the interrelationship between variables (Setia 2016). Nevertheless, based on the data available, the design was seen as relevant for generating hypotheses for further studies.

5.4.3 Longitudinal study design

The longitudinal study design goes one step further than the cross-sectional design and can examine a possible causal relationship between variables (Caruana, Roman et al. 2015). The longitudinal design allows researchers to trace changes in variables over time by comparing data collected at different times, and provide a more comprehensive and representative picture of the variables under investigation (Hua and David 2009). For study III, the same hospital units were studies at different points in time, and changes in safety climate scores were identified. Levin (2006) argues that data collection following the same procedure and a large sample reduces the risk of selection bias, as was the case for this study.

5.5 Study population

5.5.1 Systematic review, paper I

In the systematic review (the one primary study and the 83 studies included in the three reviewed systematic reviews), a large number of healthcare settings and patients were included. Most studies were performed in a hospital (>45).[14] The studies were conducted on all 5 continents, but nearly 50% (n=41) were conducted in the US. The primary study specifically included nurse perceptions on accreditation and patient satisfaction (Salmon, Heavens et al. 2003). The matrix review studied the impact of accreditation on management and staff, professional practice, and patient outcomes (de Santè 2010). The systematic review by Flodgren et al. (2011) evaluated the effects of external inspection of compliance with standards in improving healthcare organization behavior, healthcare professional behavior, and patient outcomes. Whereas the review by Alkhenizan and Shaw (2011) evaluated the impact of accreditation programs on the quality of healthcare services. Combined, the studies targeted a broad spectrum of stakeholders when evaluating the effects of accreditation, e.g., healthcare professionals, managers, and patients.

[14] In the systematic review, only hospitals were included. This was not the case in the systematic reviews included. Not all studied clearly stated which healthcare organization was studied.

5.5.2 Nurses, middle managers, and physicians, paper II

For paper II, we included healthcare professionals with more than three months of employment working on the 56 wards treating patients with the included diagnoses (in 20 hospitals in HSØ)[15] and who stated their profession voluntarily in the work environment survey. This included nurses (n=5,602), physicians (n=2,195), and middle managers (n=1,036). The mean age range was 40-49 years. 90.9% of the nurses, 44.3% of the physicians, and 68.1% of the middle managers were female. Table 3 provides a detailed description of survey participants. The 20 hospitals were organized in eight hospital trusts with each trust ranging from 1-6 hospital sites. Two trusts were teaching hospitals. The number of hospital beds ranged from 51 – 656 (SSB 2012).[16]

Table 3. Description of survey respondents by age and profession

	N			**Age**			**Permanent employment**	**Female**
	8833	**<30**	**30-39**	**40-49**	**50-59**	**60+**		
Physician	2195	5.5%	40.7%	25.7%	17.9%	10.3%	68.9%	44.3%
Nurses	5602	15.3%	27.4%	26.2%	25.0%	6.1%	92.2%	90.9%
Managers	1036	0.7%	13.0%	33.7%	41.0%	11.6%	96.9%	68.1%

The survival data was extracted from administrative data of 46,026 patients with first time acute myocardial infarctions (AMI) (n=17,734), strokes (n=14,442) and hip fractures (n=13,850). Patients with AMI and stroke >18 years and patients with hip fracture >65 years were included. A detailed description of the patient characteristics is presented in Table 4.

[15] One hospital trust in HSØ was excluded, as this hospital was a specialized rehabilitation hospital.

[16] Official data from Statistics Norway. www.ssb.no

Table 4. Description of patients and clinical outcomes

	Acute Myocardial Infarction (First time)	**Stroke**	**Hip Fracture (>65 years)**
Number of Patients	17,734	14,442	13,850
Number of admissions	17,734	15,235	14,427
Death within 7 days, unadjusted	1234 (7.0%)	1180 (7.7%)	399 (2.8%)
Death within 30 days, unadjusted	2030 (11.4%)	2167 (14.2%)	1314 (9.1%)
Mean length of stay (days)	7.0	10.2	7.2
Treated in two or more hospitals	10,412 (58.7%)	1915 (12.6%)	1252 (8.7%)
Gender, female	6785 (38.3%)	7297 (47.9%)	10,297 (71.4%)
Age, mean	71.0	74.6	83.4
0-17 years	0 (0.0%)	0 (0.0%)	0 (0.0%)
18-49 years	1411 (8.0%)	777 (5.1%)	0 (0.0%)
50-75 years	8854 (49.9%)	6234 (40.9%)	2549 (17.7%)
>75 years	7469 (42.1%)	8224 (54.0%)	11,878 (82.3%)
Number of previous hospitalization during last two years, mean	5.8	5.8	5.9
0	3786 (21.3%)	2432 (16.0%)	1652 (11.5%)
1	2799 (15.8%)	2181 (14.3%)	2069 (14.3%)
2	2189 (12.3%)	1914 (12.6%)	2008 (13.9%)
3-5	4130 (23.3%)	3922 (25.7%)	4142 (28.7%)
6+	4830 (27.2%)	4786 (31.4%)	4556 (31.6%)
Carlson comorbidity index*, mean	1.5	1.3	1.8
0 points	8827 (49.8%)	8131 (53.4%)	5914 (41.0%)
1 points	1646 (9.3%)	1658 (10.9%)	1404 (9.7%)

2 points	3096 (17.5%)	2638 (17.3%)	3493 (24.2%)
3+ points	4165 (23.5%)	2808 (18.4%)	3616 (25.1%)

**Carlson Comorbidity Index* predicts the ten-year mortality for a patient who may have a range of comorbid conditions.

5.5.3 Hospital unit safety climate, paper III

For paper III, the studied population was 970 clinical units in the 21 hospitals in HSØ. Two of the hospitals are teaching hospitals with more than 600 beds. Six hospitals have less than 100 beds and one hospital is a rehabilitation hospital. Clinical units were defined as units with direct patient contact. We included responses from 25,220 employees with more than three-month employment or more than 30% employment in the hospital prior to the survey. The same clinical units were studied in years 2011, 2012, and 2014. Important to note, due to the responder's anonymity, we do not know whether the same person responded to all surveys. However, it was not the individual staff who was of interest but the unit's work environment score.

5.6 Data collection

5.6.1 Literature search

The systematic review's objective was to identify empirical evidence on the effects of hospital accreditation on patient safety and quality of care. A review team was established with methodological expertise in performing systematic reviews. A search strategy for the systematic review was designed and the search conducted by an information specialist librarian at the Norwegian Knowledge Centre of the Health Services (FHI). As suggested by O'Connor et al. (2008) keywords and Medical Subject Heading terms (MeSH) were combined to identify relevant literature and the PICO framework (population, intervention, control or comparison, and outcome) was used to formulate the search strategy (Richardson, Wilson et al. 1995).

MEDLINE, EMBASE, CRD, and the Cochrane Library databases were searched, including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effect

(DARE), and Health Technology Assessment Database (HTA) from the first record up to 2014. The search was conducted in 2009 and repeated in years 2013 and 2014 due to the elapsed time between the first search and data publication. No additional studies were identified in the repeated searches. The search strategy used in all three searches is provided in Appendix 1. We also searched papers' reference lists, grey literature, and a google search was conducted to identify studies not identified through the MeSH search.

All studies assessing the effects of accreditation or certification of hospitals in any language with a control design were included. Studies without controls, studies conducted outside hospitals, studies not reporting on effect, and studies lacking baseline measurements were excluded. Two researchers independently reviewed all titles and abstracts. The selection process included removing duplicates and papers that were not within the scope. Studies selected by one or both reviewers were read in full-text and assessed in a standardized form for internal validity. Each assessment was performed independently by the two reviewers, and the results were compared. Differences were reconciled by consensus. A synthesis of the included studies was made. For studies with several outcomes, all outcomes were reported.

5.6.2 Papers II and III

For these studies, secondary data from the annual work environment survey in HSØ, the national quality indicator on 30-days survival probability, and safety culture data from the national patient safety campaign were used.

5.6.2.1 Work environment survey data (WES)

The WES is a validated work environment questionnaire. The questionnaire is adapted to the Nordic context to provide a comprehensive picture of workers' perceptions of their work environment (Wännström, Peterson et al. 2009). The instrument includes 19 factors; each factor consists of 1 to 6 items. The response alternatives are presented on a 5-point Likert scale. Every item was converted onto a 0-100 scale according to the following formula (Tam, Kwai et al. 2011):

Scale score for a respondent = (((mean of scale items)-1)*25)

A score of zero represents the most undesirable result, and 100 represents the most desirable. For paper III, the dataset consisted of 18 WES factors due to an incomplete dataset for the factor Goal. It was assumed that the lack of this factor would not affect the results of the study. For analyses, the WES factor Patient Safety Culture was excluded in paper III as this was the outcome variable (Safety Climate).

Participating in the survey was voluntary for the hospital trust and employees. However, there was a clear expectation from the South-Eastern Norway Regional Health Authority (HSØ) for annual participation. The web questionnaire was distributed to all hospital staff. A board of survey coordinators representing each trust oversaw the survey process and follow up. The surveys were sent to employees' work mail with email reminders of participation. Completion of the survey was made possible during work hours. Disruption is common in hospitals; thus, the survey could be completed over time. This particular strategy was employed with success to increase the response rate to >70%.

For paper II, the responder's background data included profession, age, type of employment, and gender. For the profession specific analysis, only responders voluntarily providing background data were included. For paper III, there was no profession-specific inclusion criterion.

5.6.2.2 Patient administrative data

The Norwegian Knowledge Center for Health Services (NOKC) provides mortality data for all Norwegian hospitals. The 30-days survival probabilities after hospital admission are annually reported as a quality indicator.[17] NOKC collected data from Norwegian hospitals and the Norwegian Patient Registry (NPR) for analysis. According to a method developed by Hassani et al.

[17] Mortality is seen as a negative framing; thus, survival probabilities are presented in Norway.

(2015) the outcome (dead/alive within 30 days) was attributed to the hospital where the patient received treatment allowing hospital-wide and diagnose-specific survival rates to be presented (Helgeland, Damgaard et al. 2011). For this study, data on seven-day survival probabilities were used due to the average length of stay for the included diagnosis.

5.6.3 Safety climate data

For paper III, data from the National Patient Safety Campaign was used to assess patient safety climate in Norwegian hospitals. The Safety Campaign collected data from all Norwegian somatic and psychiatric hospitals and all staff associated with a clinical unit were included. The improvement of patient safety culture in hospitals was the main aim of the campaign, and the staff's perceptions of the safety climate in their unit were collected in the years 2012 and 2014 to identify change. More than 2,300 units responded to the survey. Data was collected by the same method as for WES. For the study in this thesis, the data was extracted from all staff in 970 clinical units in HSØ that had not undergone major reorganization and participated in the WES in year 2011 and the SAQ in years 2012 and 2014.

5.7 Outcome measures

5.7.1 Effects of hospital accreditation, paper I

The effects of accreditation or certification on patient safety and quality of care was the primary interest of the systematic review. Any process or patient outcome was seen as relevant. This included:

- The effects of accreditation or certification in all types of hospitals;
- Description of any hospital accreditation or certification;
- Comparison of any hospital that was not accredited or certified; and
- Description of process measures or clinical outcomes

Accreditation was defined as the systematic assessment of hospitals against accepted standards. Certification is a confirmation of characteristics of an object, person, or organization against published standards.

5.7.2 Patient survival probability, paper II

Paper II's primary outcome measure was the seven-day survival probability for patients admitted with AMI, stroke, and hip fracture in hospital. The average length of stay for hospital patients in Norway was 4.3 days (2010-2012).[18] For the patients included in this study, the average length of stay was 8.1 days. Therefore, a seven-day survival rate was chosen, as an extended observation period might confound the findings and include mortality unrelated to the underlying hospitals' characteristics.

A relative mortality rate was defined to compare mortality across all three diagnosis groups and allow for pooling of all hospital unit data. The deviation of the units' mortality rate from the mean mortality rate for the specific diagnosis group was divided by the mean mortality rate for the specific diagnosis group. Thus, the formula could be presented as follows:

$$Relative\ mortality\ rate_{unit} = \frac{\text{Mean mortality rate}_{patient\ group} - Mortality\ rate_{unit}}{\text{Mean mortality rate}_{patient\ group}}$$

5.7.3 Safety climate maturity, paper III

For paper III, the outcome of interest was the propensity for hospital units to be classified as having a mature patient safety climate. Three outcome measures were included:

- The change in safety climate score (2012-2014).
- Rising safety climate to a mature level (>60% of staff scores 75 or higher).

[18] Tabell 134, døgnopphold. www.ssb.no. Norwegian Statistics

- Maintaining a mature safety climate level over time.

  In order to identify a mature safety climate (>60% of staff agree or strongly agree to the statements) the percent of responders who received a scale score of 75 or higher were calculated (Sexton, Helmreich et al. 2006).

5.8 Quality of data

The studies included in the systematic literature review were quality assessed with the recommended instrument for primary studies and systematic reviews (AMSTAR and Cochrane risk of bias tool for RCT) (please see Tables 2 and 3 in paper I). Validated survey instruments were used to collect work environment and safety climate data (Deilkas and Hofoss 2008, Wännström, Peterson et al. 2009). The adjusted work environment survey (WES) for the hospitals in HSØ was continuously improved, tested, and validated.[19] According to Pronovost et al. (2008), the analyses at the unit-level and our acceptable response rates adds credibility to our results. Furthermore, a response rate >60% is required for accurate interpretation (Pronovost, Goeschel et al. 2009). For this thesis, the WES response rate was 77%. The response rate for the SAQ was 57% and 61% (years 2012 and 2014, respectively). The surveys were distributed electronically. Data from the two different sets of surveys were collected and handled using the same technological solution, securing efficient data administration and anonymous data handling. The patient administrative data set was assumed to be complete due to the unique personal identity number held by all Norwegian citizens and the mandatory reporting system for hospital admissions.

5.9 Data analysis

5.9.1 Paper I

As only one primary study was eligible for inclusion in the systematic review, the meta-analysis was not possible. Furthermore, no meta-analysis was performed in the included systematic

[19] Flemmen HØ, Svendsen MV. Validering av medarbeiderundersøkelsen (MBU). Intern rapport Sykehuset Telemark 2007.

reviews due to the studies' heterogeneity and variation in methods; thus, it was impossible to form a pooled estimate from the different studies. Therefore, data was synthesized narratively.

The risk of bias in the included studies in the systematic review was evaluated according to the appropriate risk of bias tools. The primary study was evaluated by applying the Cochrane Collaboration's tool for assessing the risk of bias (Higgins and Green 2011). The assessment was done for the domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other potential threats to validity (Ibid). According to the Cochrane risk of bias tool, each of the domains was rated as high/low risk or unclear. For example, insufficient information on the randomization process and no mention of allocation concealment or detection bias made the risk of bias unclear. In contrast, incomplete outcome data and selective reporting increased the risk of bias in the study.

The AMSTAR checklist framework for the included systematic reviews assessed bias (Shea, Hamel et al. 2009). This validated tool consists of eleven domains: establishing research question and inclusion criteria before review, comprehensive literature review, list of included/excluded studies, and publication bias. Two of the included systematic reviews held a moderate quality (6/11 and 7/11). The third review was scored as high quality (9/11).

5.9.2 Paper II

The diagnosis-specific outcome was aggregated over three years (2010-2012) to ensure adequate statistical power. In addition, patient data was adjusted for age, gender, Carlson Comorbidity Index based on patient hospital admission three years before the admission studied, type of stroke, and the total number of hospitalizations during the previous two years.

Descriptive data of survey responses were given as median and range due to the non-normal distribution. Normality was tested by the Kolmogorov–Smirnov test (Berger and Zhou 2014). The frequencies presented patient data and comorbidity. Univariate logistic regression was performed

to examine the associations between the independent variables (work environment factors) and patient survival probability. The effects of the different work environment factors were analyzed and reported separately due to the limited number of units available for analysis. All units in HSØ treating patients with AMI, stroke, and hip fracture (n=56) were included, but the limited number prohibited including all explanatory variables in one multi-variable predictive model.

A stepwise backward conditional regression analysis included all the significant environmental factors from the separate initial analysis: nurses 12/19, middle managers 9/19, and physicians 0/0. The level for the removal of variables was set at $p > 0.05$. The variables available for the backward regression and the final models were evaluated against our hypothesis and prior research and they were plausible. Furthermore, alternative approaches as manually built models and other settings for the stepwise regression did not identify better performing models. Finally, the work environment effects for nurses, middle managers, and physicians were analyzed separately to assess how patient mortality was associated with the work environments of the three studied professions.

5.9.3 Paper III

Frequencies were used to describe the change in safety climate maturity level. Bivariate regression analyses were performed to identify which of the 17 hypothesized explanatory work environment factors were significantly associated with a change in safety climate score and the odds of achieving and maintaining a mature safety climate. Factors with *p*-values not exceeding 0.05 were included in the stepwise regression models.

A stepwise linear regression was used to assess the work environment characteristics most significant for predicting the maturity of the safety climate. A forward logistic regression was used to calculate Odds Ratio (OR) of raising a unit safety climate to a mature level (yes/no) and in maintaining a mature safety climate level over time (yes/no). The models' fit to the data was assessed by the adjusted r^2 (r^2_{adj}) and the Nagelkerke R-squared (Nagelkerke 1991). To adjust for

the potential for improvement at baseline, unit SAQ_{2012} scores were included in all models, as was unit size.

For papers II and III, the statistical analyses were performed using the IBM SPSS statistical software package version 21 and 25 (IBM Corp, Armonk, NY, USA) respectively. All reported *p* values are two-sided. *P* values equal/lower than 0.05 were considered statistically significant. For paper III, 95% confidence intervals are presented for B and ORs. The statistical analyses were performed under guidance and in collaboration with a senior statistician.[20]

5.10 Ethics approval

The research project protocol for the three studies was submitted for approval to the Regional Committees for Medical and Health Research Ethics (REC). Due to the use of anonymous data with no direct or indirect possibility for the patient or staff identification or harm, the study was exempted from ethical approval (Case number 2011/2345 D). Data from the work environment survey were the judicial property of each hospital trust. Written consent was given by each trust for the use of data for this project and in support of this thesis. The staff were informed that data from the survey could be used for research on the front page of the questionnaire. Agreeing to participate in the survey was seen as giving full consent.

The beneficence principle obligates to maximize the benefits to the study participants (Polit and Beck 2012). In this project, no participants were approached directly, as secondary data was used. However, the results from this thesis have been presented to stakeholders, survey responders, the Regional Patient Council in HSØ, national media and international conferences.

[20] Martin Veel Svendsen, Sykehuset Telemark

6 KEY FINDINGS

For study I, the finding was inconclusive about the effects of accreditation on patient safety and quality in hospitals. In study II, an association between work environment characteristics and patient outcome was found. The key finding of study III was the association between work environment scores and the development of a mature safety climate in hospital units. An overview of the research designs, samples and conclusions of the three papers constituting this thesis is provided in Figure 4.

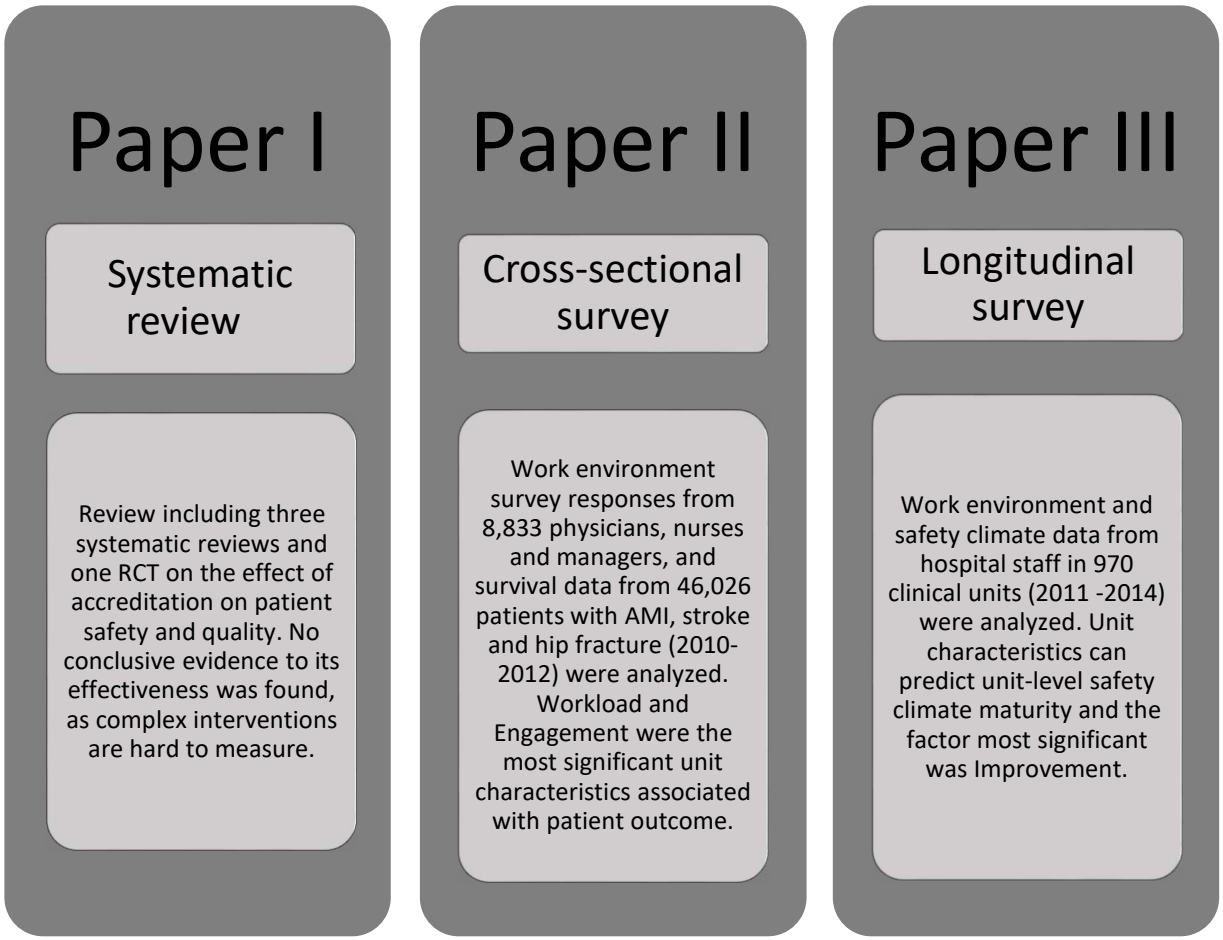


Figure 4. Summary of the three published papers supporting this thesis.

6.1 Paper I

A systematic review of hospital accreditation: the challenges of measuring complex intervention effects.

The systematic review was performed to gain access to empirical evidence answering the research question: Does accreditation and certification affect hospitals' patient safety and quality of care?

The systematic search of the literature identified four studies for inclusion, one original study, and three systematic reviews. The original study, an RCT from South Africa, studied the effect of accreditation in ten hospitals, whereas ten other hospitals served as controls. Researchers found a significant increase in one of the eight measured quality indicators, with little to no effect in the others. The included systematic reviews aimed at evaluating the effectiveness of the external inspection, assessing the impact of accreditation, and evaluating accreditation programs' impact on the quality of healthcare services. Rated by AMSTAR, the quality of the reviews varied. The primary study from South Africa was also identified in the included systematic reviews; apart from the RCT, the studies in the included reviews did not have a control study design and hence were not eligible for inclusion in this systematic review. The overall conclusion of the included reviews was that the impact of accreditation was inconclusive.

The systematic review was conducted according to the PRISMA statement. In addition, a narrative review of excluded studies was performed, as the information in these studies was deemed as relevant for the discussion on assessing the full measure of complex interventions. A conclusion of the effectiveness of accreditation and certification in hospitals could not be drawn. Nor did the study find empirical evidence for linking accreditation or certification to measurable changes in quality of care. As a result, the strategies hospitals should implement to improve patient safety related to accreditation and certification remain unclear. The study added to an emerging body of literature questioning accreditation bodies' claims that the seal of approval assures high-quality performance. However, it is essential to note that the systematic review could not conclude a lack of effect merely that measuring the effect is a challenge.

6.2 Paper II

Association between work satisfaction, engagement, and seven-day patient mortality: A cross-sectional survey.

The associations between work environment characteristics and patient survival probability were explored. The research questions investigated were: 1. Are work environment factors associated with patient survival probabilities? 2. Do the factors associated with patient survival probability differ between healthcare professionals?

The analysis identified that staff, in general, rated their work environment positively, with managers giving the highest mean score (76.3) and physicians the lowest (67.2) on a 0-100 scale. The seven-day patient mortality rate varied from 2.8% - 7.7%. Differences were identified between physicians, nurses, and middle managers. Nurse workload (Beta 0.019 (CI95 0.009-0.028)) and middle manager engagement (Beta 0.024 (CI95 0.010-0.037)) were significantly associated with a seven-day patient survival probability. In contrast, no association was found between physician-reported work environment and patient survival. The lack of association between physician work environment and patient survival may be a methodological issue as they serve several units; thus, their perception of the work environment is more challenging to capture at the unit level used in the study. For nurses, they generally serve one unit only, which is reflected in their evaluation of their work environment.

The study concluded that work environment characteristics were associated with patient outcomes and that the factors deemed significant, varied among health professionals when analyzing the WES factors in the 56 units studied with survival data for the patients most likely treated in these units. In addition, the 8,800 responses, an average survey response rate of 75%, and 100% inclusion of patients with the studied diagnosis strengthens the association and the hypothesis.

6.3 Paper III

Hospital work environments affect patient safety climate: A Longitudinal follow-up using a logistic regression analysis model.

The main objective was to study how work environment factors are associated with the development of a mature patient safety climate at the hospital unit level. The aim was to answer three research questions: 1. Can work environment factors be predictive of the unit's patient safety climate? 2. Which work environment factors are predictive of a mature safety climate? 3. Which work environment factors are predictive of maintaining a mature safety climate over time?

The analysis identified 14 of the 17 work environment factors significantly associated with change in the safety climate score. The Improvement, Quality, and Patient-Centered factors, when adjusted for SAQ_{2012} and unit size, explained nearly 30% of the variation found in the unit safety climate score. For raising to a mature safety climate level, 12/17 factors were significant, and all 17 factors were significantly associated with maintaining a mature level. When calculating the OR for the two binary outcomes: gaining a mature safety climate level (yes/no) and maintaining a mature safety climate level (yes/no), the factor Improvement was significant. The factors Patient-Centered and Commitment were also significant for maintaining the mature safety climate level. Of the 970 clinical units studied, 18% gained a mature safety climate level, and 41% maintained their mature safety climate level during the studied period (2012-2014). Furthermore, the analyses identified that the factors predictive of gaining a mature safety level slightly differentiate from those predictive of maintaining a mature safety climate level.

6.4 Summary of results

The three papers in this thesis report on different aspects of efforts to advance patient safety in hospitals. Accreditation and optimizing work environment factors are central to systems thinking as interdependent parts. However, their contribution to patient safety is explored differently.

Accreditation has increasingly been utilized as a critical driver to reduce patient harm, but the effects on patient safety have been hard to measure and are thus anecdotal. Therefore, a rigorous systematic review with controls was called for. Due to the methodological challenges of measuring complex interventions, and the lack of studies with a control, the evidence for accreditations' effect remains inconclusive. The accreditation process has been described as 'top-down' driven initiatives, time-consuming and costly, and draws attention of staff from their clinical work. The findings in paper I highlight the importance of exploring other factors, closer to the sharp end of organizations, which might affect patient safety. Papers II and III targeted the microsystems by exploring the associations between work environment characteristics and patient outcomes (paper II), and safety climate levels (paper III).

The common denominator of the three studies is patient safety. The systematic review targeted the macrosystem, where the choice to seek accreditation is often made. An interpretation of the inconclusive effects could be seen in the light of the work-as-imagine perspective. Standards imposed on health professionals do not necessarily align with the actual work processes and varying conditions, and staff might deem other factors than standardization more important for providing safe care. The work environment factors associated with better patient outcomes were explored in paper II. Paper III aimed at understanding which work environment factors can predict a change in safety climate. Patient outcome results may be caused by many factors, including compliance to standards (Shafi, Barnes et al. 2014); however, results are inconclusive where standards do not support the actual work process (Rhee, Filbin et al. 2018). Compliance might also be seen from a cultural perspective. Two recent studies verify that compliance varies with the level of patient safety culture (Asefzadeh, Rafiei et al. 2020, Kim and Moon 2021). Finally, several studies confirm the link between patient safety culture and patient outcomes (Groves 2014, DiCuccio 2015, Lee, Scott et al. 2019) addressing the 'missing link' of this thesis. The three papers cover key aspects of patient safety, and the results in each study are interconnected.

7 DISCUSSION

Ensuring quality is a critical component of high-performing health systems. We have known for decades that hospitals differ in their ability to provide high-quality care for patients—and one strategy for ensuring and improving care has been accreditation. Although the logic may be sound, it has not been clear whether this approach works. We found that the effect of accreditation was inconclusive, whereas work environment characteristics affect patient outcome and the development of a mature patient safety climate. For paper II, the factor Workload of nurses and the factor Engagement of middle managers were significantly associated with patient survival, but no association was identified for physicians. In paper III, an association was found between the work environment factors and changes in safety climate levels. Based on the findings in the included papers, this thesis further explores how the results could guide hospitals to improve their patient safety efforts.

7.1 The effects of accreditation on patient safety and quality of care

The all-encompassing strategy of accreditation has been used as a tool for reduced variability in care. TEH recommended incentives for fundamental changes through performance standards, and accreditors should hold healthcare organizations accountable for ensuring a safe environment for patients. While there is little disagreement about using standards to guide work processes, implementing standards and compliance has been slow (Leotsakos, Zheng et al. 2014). Thus, paper I examines the effects of accreditation on patient safety and quality of care.

The methodological challenges of measuring complex interventions make it hard to isolate the 'accreditation factor' as these interventions comprise many separate, multi-level, and concurrent elements. The review further exposed a low level of methodological rigor in most of the included studies and outcome measures were ambiguous, leaving the question in respect to how accreditation may affect patient safety unanswered. Nevertheless, the studies identified in the systematic review provided important information about changes observed. However, the study design prevented us from inferring an association with accreditation (Pasquale, Peitzman et al.

2001, Chen, Rathore et al. 2003, Juul, Gluud et al. 2005, Greenfield and Braithwaite 2008). According to one group of authors, the use of standards incorporated into the accreditation process will improve quality care outcomes (Bogh, Falstie-Jensen et al. 2016, Marković-Petrović, Vuković et al. 2018, Jarrah 2019, Batomen, Moore et al. 2020, Ko, Yang et al. 2020, Sun, Li et al. 2020, Lee, Chun et al. 2021). In contrast, other studies conclude that accreditation is not linked to better quality of care (Sack, Scherag et al. 2011, Bogh, Falstie-Jensen et al. 2015, Lam, Figueroa et al. 2018, Wardhani, van Dijk et al. 2019). Interestingly, the findings of the systematic review are supported by findings from recent research; there may be an effect for accreditation, but a positive interpretation is cautioned due to the methodological shortcomings (Araujo, Siqueira et al. 2020, Mosadeghrad 2020, Swathi, Barkur et al. 2020).

According to the systems theory framework of this thesis, accreditation can be understood within the SPO model and was seen as part of both structure and process components (Donabedian 1988). The standards set by the accreditation agency can be seen as tools in the work system, whereas assessment and monitoring compliance against standards is the process (Holden, Carayon et al. 2013, Mumford, Forde et al. 2013). Given that accreditation is not inspection but offers opportunities for quality improvement, an association with outcome could be expected (Duckett and Jorm 2019). Seen from the SEIPS perspective, the feedback from the accreditors offers valuable insights on how to incorporate the standards into care processes whose application could reduce the probability of an adverse event (Thornlow and Merwin 2009). However, accreditation organizations have mainly focused on improving structure factors and clinical process measures rather than improving patient outcomes. (Griffith, Knutzen et al. 2002, Lam, Figueroa et al. 2018).

The systematic review did not find empirical evidence to sustain the widely touted claims about the benefits of accreditation on patient safety, and several factors might limit a meaningful association. Hospitals with better and more resources might seek voluntary accreditation to confirm their excellence, which may bias finding the benefits of accreditation. Where accreditation is mandatory, paradoxes occur when accreditation reports are used for resource allocation or as a ‘seal of approval,’ creating gaps between hospitals at different stages in the accreditation process.

Furthermore, comparisons between accredited and non-accredited hospitals may not consider preexisting differences between hospitals. Pre- and post-accreditation studies report positive outcomes that could be attributed to other factors implemented simultaneously with accreditation. Hospitals might seek accreditation because of moral hazard or consumer misperception, but do not necessarily believe that quality improvement will flow from accreditation. Finally, facilities choosing accreditation might be more committed to improvement and willing to invest in improving quality (Pomey, Francois et al. 2005, Grepperud 2014, Nomura, Silva et al. 2016, Lam, Figueroa et al. 2018, Araujo, Siqueira et al. 2020, Bracewell and Winchester 2021). On the other hand, the benefits of accreditation are likely to be modest where improvement initiatives are implemented independently of accreditation status or where the measures are close to 100% (ceiling effect); any subsequent improvement benefit will only be minor (Devkaran, O'Farrell et al. 2019, Bracewell and Winchester 2021). The lack of consensus regarding the effects of accreditation on patient safety can be explained in part by the difficulty in comparing complex interventions. Heterogeneous accreditation programs, where surprisingly few accreditation processes begin with a clear view of what accreditation is intended to achieve, makes the measurement of effect even more challenging (Ng, Leung et al. 2013, Shaw 2015, Araujo, Siqueira et al. 2020).

Despite the lack of evidence, the literature we reviewed identified three main dimensions claimed to be affected by accreditation. The impact of accreditation programs was found on evidence-based practices such as in preventing central line infections or preventing surgical site infection. These studies are essential as they contribute to awareness of quality and patient safety issues and drive risk management and compliance attention. The second dimension was the context in which accreditation was implemented. Studies reporting effects were to a larger extent identified in developing healthcare systems where accreditation could provide an essential 'floor' framework for accountable systems (Bukonda, Tavrow et al. 2003, Chen, Rathore et al. 2003, Salmon, Heavens et al. 2003, Al Tehewy, Salem et al. 2009, Braithwaite, Greenfield et al. 2010, Pomey, Lemieux-Charles et al. 2010, Al Awa, de Wever et al. 2011, Alkhenizan and Shaw 2011). The distinction between developing and developed healthcare systems were not found in a recent systematic review (Hussein, Pavlova et al. 2021). Finally, some studies addressed experiences with accreditation. Whereas multiple studies describe staff attitude towards accreditation, only a few

studies described accreditations' impact on patient satisfaction (de Santè 2010, Alkhenizan and Shaw 2012). The findings in these studies were not further explored, as they did not meet the inclusion criteria of the systematic review.

This thesis focuses on the **gaps described as work-as-imagined (WAI) versus work-as-done (WAD)**. In this perspective, accreditation could be seen as the macro-level response to increase healthcare accountability but not sensitive enough to the work processes at the micro-level. The gap becomes evident as accreditation relies on the documentation of processes but does not guarantee compliance with standards (Bracewell and Winchester 2021). Standards are typically something to aspire to since "*divergent patterns of care result in worse clinical outcomes*" and the removal of variance can reduce risks to patients (Leotsakos, Zheng et al. 2014)p111. However, accreditation itself might be a barrier to compliance. There is inherent complexity in implementing system-level reforms; the accreditation processes were perceived as bureaucratic control instruments affecting compliance when staff is not involved. This especially applies where standards lack consideration of diversity when formulated, as forced conformity challenges the professional autonomy and patients' right (and need) to individualized care. Furthermore, staff compliance might be driven by the expectation of the external surveyors when present at the clinical level rather than agreement with standards, and the impact ends following the completion of the survey (Paccioni, Sicotte et al. 2008, Benn, Burnett et al. 2009, Barnett, Olenski et al. 2017, Mosadeghrad, Akbari-sari et al. 2017, Ansmann and Pfaff 2018). These challenges need to be addressed as the primary benefit of accreditation is the integration of standards into routine workflows (Devkaran, O'Farrell et al. 2019). If not, a workaround is a potential unintended consequence of standardization (Debono, Greenfield et al. 2010). Paradoxically, when the accreditation process is done well, it might build a bottom-up system as it helps nurture and mobilize the whole organization to reflect and self-evaluate their performance and risk assess their work (Jovanovic 2005).

Accreditation can be seen from a Safety-I perspective as simplistic systems thinking. In this perspective, regulations and standardized work practice are implemented to prevent harm from occurring. Standardization has been defined as the process of agreeing and implementing uniform

methods and processes (Leotsakos, Zheng et al. 2014). Safety and quality are the results of adherence and compliance to standards, but standards are followed to varying degrees. For example, managers believe that standardized solutions have positive effects on patient safety, whereas healthcare professionals view standards to undermine autonomy and expertise (McDonald, Waring et al. 2006). A Safety-II approach recognizes accreditation as an input into the system, influencing the ability to navigate successfully the varying conditions in complex systems (Schneider, Sturmberg et al. 2016, Mannion and Braithwaite 2017). However, the effectiveness of accreditation depends on the capacity of organizations and individuals to change attitudes and behavior (Shaw 2015). Accreditation is theoretically attractive as standards are ubiquitous within healthcare and considered an essential means for improving quality of care and patient safety (Greenfield, Pawsey et al. 2012). The guidance of standards is beneficial, but the evidence about whether accreditation standards sustainably change staff behavior is at best uncertain (Ibid). The inconsistent adoption of standards could indicate the necessity for creating a receptive culture and a broader staff and patient involvement to make standards (accreditation) more relevant to the actual work processes (Greenfield, Pawsey et al. 2012).

The systematic literature review did not find evidence to support accreditation as being strongly linked to measurable quality and patient safety improvement. Nevertheless, there is no reason to believe that the more than 120 accreditation programs in over 80 countries will be abandoned due to scarce evidence of its effect. Accreditation is a thriving industry and stakeholders may profit by promoting these services despite the lack of robust evidence of their effectiveness (Braithwaite, Westbrook et al. 2006, Hinchcliff, Greenfield et al. 2012). However, given the limited evidence seen in empirical studies, it raises intriguing questions about the emphasis on accreditation to improve patient safety and quality of care.

7.2 Work environment and seven-day patient survival probability

An association between profession-specific work environment and patient survival probability was found. Patients treated in hospital units where staff rated their work environments favorably had

a higher survival probability. However, a causal relationship could not be established due to the cross-sectional design.

Mortality (lack of patient survival) is an important indicator of quality and patient safety because when risk-adjusted for patient characteristics, some hospitals have structures and processes that minimize the risk better than others (Krumholz, Wang et al. 2006, Tourangeau, Cranley et al. 2006, Cecil, Wilkinson et al. 2018). In Norwegian hospitals, mortality is generally low, but variations between hospitals exist and some perform significantly below the national average. This study found that work environment characteristics could explain part of this variation. Discussing these characteristics may highlight the opportunities deemed as most important by staff to improve patient outcomes.

7.2.1 The power of teamwork

Inter-professional teamwork is seen as a prominent factor in improvement programs as the complexity in healthcare requires a collaborative interaction of healthcare professionals to share tasks and common goals (Baker, Salas et al. 2005). Furthermore, explicit links are established between teamwork and patient outcome (Sorbero, Farley et al. 2008, Manser 2009, Ezziane, Maruthappu et al. 2012, Dinius, Philipp et al. 2020). However, the culture, work processes, and interrelated relationships among nurses differ from physicians and middle managers. In general, hospital staff rated their work environment positively on the 0-100 scale (100 is the most favorable) presented in Table 5. Nevertheless, there are differences between professions where middle managers are the most positive and physicians the least positive. Therefore, asking what is deemed essential to physicians, nurses, and middle managers seems rational, as one-size-fits-all initiatives' successes have been scarce (Sheps and Cardiff 2014).

Table 5. Work environment factor scale scored by profession

	Nurses			Physician			Managers		
Measures	**Mean**	**SD**	**% ≥75**	**Mean**	**SD**	**% ≥75**	**Mean**	**SD**	**% ≥75**
Improvement	68.1	17.8	42.6	69.8	19.1	49.8	76.6	18.2	66.6
Quality	75.9	17.4	69.5	75.8	17.7	68.3	76.9	17.8	70.2
Patient centered	77.4	15.5	72.8	75.2	16.3	68.3	76.8	17.2	70.7
Respect	74.6	14.9	64.8	73.7	15.7	63.5	77.0	16.5	69.2
Motivation	77.6	17.4	71.7	80.0	17.4	78.2	81.8	17.4	79.7
Engagement	77.4	19.6	65.0	74.1	21.7	61.9	80.7	19.0	73.1
Commitment	76.8	20.9	68.9	68.1	24.4	52.8	79.2	20.2	72.9
Personal development	63.6	20.8	37.0	65.1	22.0	42.3	72.0	20.5	55.7
Empowerment	56.1	24.4	33.8	60.9	26.6	45.0	77.2	22.6	72.3
Role expectations	89.2	13.9	94.7	84.6	16.7	88.8	88.9	14.6	92.6
Social climate	82.9	16.5	81.8	79.8	19.1	76.0	79.5	19.7	74.2
Conflicts and bullying	74.8	18.5	62.8	72.1	20.6	59.8	81.1	16.6	77.1
Workload	59.9	21.5	29.5	55.4	20.4	22.0	60.5	20.6	30.2
Autonomy	40.0	24.7	13.7	39.5	25.1	14.7	47.5	24.1	20.4
Role conflicts	69.6	18.7	48.6	65.4	19.8	41.4	63.2	20.6	36.6
Sick leave	87.3	24.5	85.7	92.0	20.5	91.4	93.5	19.3	93.1
Leadership	74.9	19.8	57.9	73.8	21.0	57.2	79.8	18.9	69.9
Patient safety culture	82.3	22.4	77.5	82.9	22.5	79.3	87.8	19.4	86.1

The factors in the WES measure a broad spectrum of work environment items, and cover dimensions found significant to patient safety and quality of care in other studies (e.g., workload, empowerment, engagement, patient safety culture) (Brannon, Zinn et al. 2002, Aiken, Sloane et al. 2011, Kirwan, Matthews et al. 2013, Angerer and Weigl 2015, Copanitsanou, Fotos et al. 2017). However, the list is not complete as to which factors contribute to high-quality care. Research on the associations between work environment and patient safety is imperative now more than ever due to growing pressures on healthcare service budgets leading to concerns about the working

conditions and the well-being of healthcare staff (Hall, Johnson et al. 2016). The external environment affects hospital units from outside, such as legal, regulatory, economic, political or cultural contexts (Waring, Allen et al. 2016, Holden and Carayon 2021). For the purpose of this study, the effects of external environmental factors and patient demographics were not considered. The study was conducted within the same system and it was assumed that the external environment was consistent for all work environments in HSØ.

7.2.2 Nurse workload

Nurse workload was the single most significant factor associated with patient survival probability. Workload might be measured by objective administrative data such as staffing, nurse-patient ratio, and patient turnover rates. In this study, workload was measured by the perceptions of the workload on staff as being *too heavy*, the work pace challenging, and having to perform tasks without sufficient training. Nurse workload is affected by several factors. Aside from the external environment and the clinical conditions of the patient, changes within the unit may contribute to the excessive workload. Norway's relatively high nurse-patient ratio does not tell the whole story as ancillary personnel are lacking from hospital units. Therefore, nurses are expected to perform nonprofessional tasks such as delivering food, transporting patients, ordering supplies, and coordinating services. This may add to the workload or leaving good nursing care undone (Aiken, Clarke et al. 2001). Other factors contributing to nurse workload are performance obstacles such as poor physical work environments, supplies not well stocked, and ineffective communication among multidisciplinary team members (Carayon and Gurses 2008).

According to the SEIPS model, workload may affect outcomes. Nurse workload definitely affects the time that nurses can spend on each task assigned (Carayon and Gurses 2008). Medication errors are most notably associated with patient safety; the wrong medication is delivered, lack of double-check, distractions, delay in delivering medication to patient, and duplication of dose leading to patient harm (Amato, Salazar et al. 2017). While nurses prioritize the tasks most directly connected to patient care, other tasks such as collecting patient information, observation, deliberation with colleagues, communication, and collaboration with others are under pressure

due to an increased workload. Furthermore, the time pressure experienced with high workload may reduce the attention devoted to safety; thus, creating conditions for unsafe practices (Carayon and Gurses 2008). The RN4CAST research program demonstrated that an increase in nurse workload in hospital units by one additional patient was associated with a seven percent increase in 30-day patient mortality (Aiken, Sloane et al. 2014). If causality could be assumed in paper II, the result would indicate that a shift of one standard deviation in the workload for nurses or engagement for middle managers corresponds to a one percent shift in the patient mortality. This could mean approximately 150 lives annually saved in the studied population.

7.2.2.1 Motivation

Workload has significant implications for nurses. One impact is the effect of increased workload has on motivation and burnout. In this study, motivation was found as a factor associated with patient survival. The items denoting motivation, such as perceiving work as positively challenging or the work being so interesting that it is strongly motivating, are not necessarily negatively affected by workload. Being busy at work could indicate that there is a lot going on, but resources are available for getting the job done. Motivating staff requires policies that are responsive to the complex interplay of needs, values, and environment (Buetow 2007). Motivational factors could be defined as those contributing to achievement and recognition, whereas factors such as salary and work conditions can lead to dissatisfaction when not fulfilled (Ong, Tan et al. 2019). Nevertheless, in the original Norwegian version of WES, the staff responded that their workload was *too heavy*. Because the need for acceptable working conditions was not met, high workload may create dissatisfaction and decreased motivation, and contribute to worse patient outcomes.

7.2.2.2 Burnout

In light of the increased number of healthcare professionals reporting burnout during the COVID-19 pandemic, the finding of workload and motivation as factors affecting patient survival probability could be disturbing (Galanis, Vraka et al. 2021). Burnout is a stress-related outcome conceptualized as emotional exhaustion, depersonalization, and reduced personal accomplishment (Patrick and Lavery 2007). As noted elsewhere in this thesis, burnout is a major

threat to healthcare systems and their patients. Burnout affects the staff's ability to provide safe care and is associated with medical error, healthcare-associated infections, patient mortality, job dissatisfaction, loss of productivity, and the intent to leave (Dyrbye, Shanafelt et al. 2017). According to Bodenheimer (2014), 46% of US physicians and 34% of hospital nurses experience burnout. In a recent US study, nurses reported burnout as the key reason for leaving their jobs (Shah, Gandrakota et al. 2021). In Norway, 15% of nurses want to leave the healthcare sector due to excessive workload.[21] According to the WHO, an additional 9 million nurses are needed by the year 2030, and 28,000 nurses will be lacking in Norwegian healthcare by 2035.[22] With this perspective in mind, any nurse lost due to working conditions is a waste, as nurse shortage will increase the negative effects of heavy workload on remaining staff.

7.2.2.3 Autonomy

Autonomy, described as the ability to influence the amount of work assigned and adjust the pace, was significantly associated with patient survival in this study. Autonomy is perceived as empowerment and understood as a process where people gain mastery over their lives. Generally, scholars acknowledge employee empowerment as a factor contributing to job satisfaction, a healthy work environment, quality improvement, and sustaining a patient safety culture (McDonald, Tullai-McGuinness et al. 2010, Choi, Goh et al. 2016, Metcalf, Habermann et al. 2018). In contrast, Argyris (1998) warns that empowerment has its limits where the working conditions do not underpin the internal commitment to the organization and the patients but rather focus on external commitment or contractual compliance. In this setting, empowerment might be understood as 'doing your own thing – the way we tell you'. The workaround performed by staff may describe reclaim of autonomy where staff themselves adjust practices to fit the local context and demands (Mannion and Braithwaite 2017, Debono, Clay-Williams et al. 2018).

[21] NSF medlemsundersøkelse 2018, Sykepleien 18.02.2019

[22] WHO.int/newsroom/nursing and midwifery and Norwegian Statistics (SSB)

Workarounds might also be a response to compensate a *too heavy* workload, since healthcare leaders too often address errors and burnout without a systems approach. Consequently, instead of lessening the workload, new training, routines or assessments are introduced, adding to the stress (Cohen 2020). On the positive side, autonomy could be seen as part of the resilience concept. From a Safety-II perspective, resilience is the ability to perform as needed under various conditions (Hollnagel 2017). However, in this study, the average score on autonomy was low < 40 on a 0-100 scale, indicating that nurses seldom perceive autonomy in handling their workload. As autonomy was associated with increased patient survival probability, more efforts should be put into understanding how performance pressure increase workload on frontline staff and thus the ability to tailor the work to the actual work processes and the individual patient.

7.2.2.4 Nursing

Nursing is a significant workforce in healthcare and a key contributor to quality of care and patient safety (Sim, Joyce-McCoach et al. 2019). The IHI recognized nurses' role in their report *"Keeping patients safe: Transforming the work environment of nurses"* (Page 2004). Paper II found that 12 of the 19 work environment factors studied for nurses were significantly associated with seven-day patient survival rates. The result may indicate that most factors measured in the WES have to be favorably rated to support efficient nursing care. This is in line with the objective of systems thinking (Holden and Carayon 2021). Work systems are comprised of several elements that are interrelated and interacting; together, they produce great performance. As opposed to the role of physicians and managers, nurses have the most direct contact with hospitalized patients, and thus the organization of work influences nurses' ability to mitigate threats (Malinowska-Lipień, Brzyski et al. 2021). The thesis aimed not to describe each factor associated favorably with patient survival in detail but point out the fact that the most significant factor identified, Workload, has implications for the remaining factors analyzed in the study. This finding was supported by a critical mass of research associating nurse workload with patient care quality, risk of adverse events, and mortality (Estabrooks, Midodzi et al. 2005, Lake, Hallowell et al. 2016, McHugh, Rochman et al. 2016, Carthon, Davis et al. 2019, Needleman, Liu et al. 2020). The implications of this research seem straightforward. Hospitals seeking to improve quality of care and patient safety should attend to the nurse work environment since high-performing hospitals are better at

retaining staff, encouraging patient-centeredness and developing a strong patient safety culture (Clarke and Aiken 2006). Furthermore, a work environment rated as favorable by nurses have consistently demonstrated links between better care environments and superior nurse and patient outcomes (Armstrong and Laschinger 2006, Aiken, Cimiotti et al. 2011, Kelly, McHugh et al. 2012, McHugh, Kelly et al. 2013, Weigl, Hornung et al. 2013, Taylor, Clay-Williams et al. 2015, Olds, Aiken et al. 2017, Lee and Scott 2018, Needleman, Liu et al. 2020).

7.2.2.5 The Norwegian nurse work environment

Of interest is the context in which the result of this study was attained. Nurses scored their work environment positively (over 70) on a 0-100 scale. This is consistent with the general satisfaction reported by Norwegian employees compared to employees in other countries (Hanglberger 2011). All Norwegian nurses hold a bachelor's degree in nursing and more than 40% of hospital nurses are nurse specialists.[23] In 2021, the nurse-patient ratio in Norway was 17.9 per 1000 population, the second highest in OECD (OECD 2021). Based on these facts, it has been argued that the results from international studies on the effect of nurse workload are not applicable to the Norwegian healthcare system. However, the results in paper II indicate that excessive workloads may affect patient outcomes in any systems. Important to note is that nearly 50% of all staff in HSØ reported that their workload was *too heavy* in 2018,[24] and pressure on hospital staff continues to rise with resource constraints and demographical changes in the patient population (Malinowska-Lipien, Micek et al. 2021). Seen from a work system perspective, several elements of the work system can affect nurse performance. Therefore, using a human factors engineering approach to assess the factors that contribute to nurse workload, is a first step for redesign of work processes and improvement (Carayon and Gurses 2008). Reason suggests that errors are the result of both active and latent conditions (Reason 2017). For nurses, a poor practice environment, high workload, and

[23] The monthly HR reporting in South-Eastern Norway Regional Health Authority. Data on all hospital staff, including skill mix, level of education, and turnover. Available on request.

[24] Nasjonal rapport ForBedring, accessible at www.helse-sorost.no

poor staffing levels could be seen as latent errors that predispose individuals to make mistakes and contribute to patient harm (Clarke and Aiken 2006).

7.2.3 Middle manager engagement

Middle managers' engagement was a factor notably associated with patient survival. Middle managers can be defined as employees supervised by the organizations' senior management and those tasked to supervise frontline staff (Gutberg and Berta 2017). The position is important as middle managers are situated between senior leaders and frontline staff and may disseminate information top-down and bottom-up, bridging the gap of WAI and WAD (Engle, Lopez et al. 2017). While some see managers as a bureaucratic burden to healthcare organizations (Veronesi, Kirkpatrick et al. 2018), there is sufficient evidence to support the positive impact of management on patient outcomes (West 2001, Wong and Cummings 2007, Cummings, Midodzi et al. 2010, Künzle, Kolbe et al. 2010, McFadden, Stock et al. 2015, Sexton, Adair et al. 2018). Middle managers' proximity to both the strategic decisions of top management and the everyday activities of frontline employees have the potential to bridge the information and trust gaps that can impede implementation of healthcare innovations (Birken, Clary et al. 2018). Managers influence patient safety through the systems and processes they implement and oversee. Largely, these systems are based on a safety-I approach using standardization, compliance, and internal inspection as main safety strategies. However, when asked, the managers respond that they trust their staff to safeguard patients as they recognize their limited ability to control or influence the actual work done at the sharp end of care (Leggat, Balding et al. 2021). This evidence suggests that managers need to build upon the trust in their staff, and engage in creating a shared understanding of work-as-done to support the everyday work processes (Hollnagel, Wears et al. 2015). Furthermore, middle managers are well positioned to create an environment perceived as a 'good place to work'. The annual WES is conducted to provide middle managers with their subordinates' perceptions of the work environment and prepare the ground for staff involvement and improvement. A psychologically safe culture is the key for speaking up, and managers play a critical role in developing and nurturing a supportive culture that promotes shared meanings and practices (Edmondson and Moingeon 1999, West, Borrill et al. 2002, Rosenbaum 2019). Organizational change is predicated on management and leadership (Glickman, Baggett et al.

2007) and managers' time spent, their engagement and work can influence quality and safety performance, processes and outcome (Parand, Dopson et al. 2014).

We found that middle manager engagement levels were significant on a personal level. The items used in the survey were related to their overall satisfaction with the work and looking forward to coming to work. Middle managers work in hierarchical structures facing contextual constraints, and the position has often been described as 'stuck in the middle', reducing their level of autonomy. The bureaucratic and time-consuming systems of Safety-I, may stifle manager engagement as their energy is demanded by the mandated systems and processes (Leggat, Balding et al. 2021). The single factor that needs to be further explored regarding manager engagement is the manager-staff ratio (span of management) (Van Fleet and Bedeian 1977, Veronesi, Kirkpatrick et al. 2018). In HSØ nearly one in four units have more than 40 employees. In intensive care >100 staff might report to one single manager. According to Cathcart et al. (2004), managers with large spans of control manage at arm's length and are more likely to enforce rules and standards than managers with smaller spans of control. For staff the larger span deprives them of the personal support needed to develop and improve, and internalize the workplace culture. Furthermore, "*large spans of control pull the manager away from their most important role, being the vital link that can build trust and better communication between the administrative strategic plan and the point of care"* (Kendall 2018)p13.

7.2.4 Physician work environment

A counterintuitive finding in this study was the lack of association found between physician work environments and patient survival. The result does not assume that physicians would produce the same result under any condition. Earlier research identified high-demand hospital work environment to affect the physician-perceived quality of care and lower mortality rates were found in hospitals with a higher percentage of board-certified physicians (Hartz, Krakauer et al. 1989, Krämer, Schneider et al. 2016). The work of Spurgeon et al. (2011) advocates that medical engagement is crucial for organizational performance. Physicians need to engage in planning and decision-making to ensure effective implementation of improvement initiatives. However,

engagement is the willingness to 'go the extra mile', and organizational factors might affect the motivation to provide more than the minimum required. Physician workhours, production pressure, and working conditions have all been suggested to affect performance and outcomes (Gaba, Howard et al. 1994, Fletcher, Davis et al. 2004, Weigl, Hornung et al. 2013). Even more so, the emphasis on Safety-I initiatives such as rules and standardization might counteract engagement as this can undermine physician expertise and autonomy (Exworthy, Wilkinson et al. 2003). In Norway, 21% of physicians intend to leave their current job in hospitals due to the organizational context and lack of professional-supportive leadership (Martinussen, Magnussen et al. 2020). As a remedy, creating a good work environment and an organizational culture built on trust was suggested. Furthermore, improvement in physicians' working conditions is needed to reduce the influence of organizational factors on task demand and physician burnout (Tawfik, Profit et al. 2019). Comprehensive studies suggest an association between physician work environment and patient outcome (Scheurer, McKean et al. 2009, Wallace, Lemaire et al. 2009), even though the association was not established in this study. The methodological challenge underpinning this result will be discussed later.

7.2.5 Working systems

This study examined the staffs' perceptions of their work environment and its association with diagnosis-specific patient survival. The factors assessed in the survey could be described as physical, cognitive, and social/behavioral performance processes (Karsh, Holden et al. 2006). Staff score their work environment's ability to support the work processes assigned. The patient survival probability was defined as the outcome resulting from the work process. In Norway, survival rates are reported as quality indicators (Helgeland, Damgaard et al. 2011). Within the SEIPS model, the feedback from outcome indicators may support improvement initiatives when used to adjust the system to produce other outcomes. However, healthcare is never so straightforward, and Vincent at al. (2013) propose that a combination of measurements are needed to drive change, including the perceptions of patients and staff.

This study found that the work environment was important for patient survival, and the finding is supported by a large community of systems thinking research (Karsh, Holden et al. 2006, Hollnagel, Woods et al. 2007, Carayon 2010, Holden, Scanlon et al. 2011, Lawton, McEachan et al. 2012, Carayon, Wetterneck et al. 2014, Clarkson, Dean et al. 2018). The outcome measure in this study was patient survival. However, the findings in this study might indicate an effect on staff wellness as well. The results can be extrapolated to support an overarching model, proposing that a supportive work environment creates joy in work and helps to retain healthcare professionals eager to provide safe and high-quality care for their patients.

7.3 Work environment and patient safety culture

Paper III found that staff's perceptions of their work environment was predictive of patient safety culture. Cultural improvement is difficult as it affects the organization's values and beliefs within healthcare professions and individuals. However, the system might support specific actions, denoted 'the way things are done here', and these actions are affected by culture. Safety culture is a complex phenomenon that is not clearly understood (Sammer, Lykens et al. 2010). According to Hollnagel (2017), measuring safety culture or levels of it does not necessarily make it more real or prove its existence, and the thorny question is whether a culture change will lead to change in people's performance or the other way around. Culture could be seen as a synthesis of performance rather than the independent variable where culture is the determinant of human actions. The premise underpinning this study was based on the safety literature claiming that culture affects patient outcomes (Ausserhofer, Schubert et al. 2013, Groves 2014, DiCuccio 2015, Berry, Davis et al. 2016, Braithwaite, Herkes et al. 2017). Studies on the relationships between safety climate and lower accident rates demonstrate that employees with a 'positive safety attitude' were less likely to be involved in adverse events (Vincent, Burnett et al. 2013) and a positive safety climate improves adherence to safety standards (Asefzadeh, Rafiei et al. 2020). Safety climate was measured according to the degree to which staff share the perception of safety climate, and units where more than 60% of staff rate the safety climate factor above 75 on a 0-100 scale were less likely to experience adverse events (Edmondson and Moingeon 1999, Zohar, Livne et al. 2007).

7.3.1 Improvement

The factor Improvement was significantly associated with a change in climate score. In the work environment survey, improvement was related to incident reporting and follow-up on adverse events and to the culture to openly discuss adverse events and encourage each other to think of ways to do things better. It could be argued that the Improvement factor is just one reflection of safety climate. A study by McFadden et al. (2015) found the need for both patient safety climate and improvement initiatives, as these are not interchangeable and target process and outcome differently. Hospital units where staff perceived that it was safe to report adverse events and openly discuss what goes wrong are more likely to develop and persist a mature safety climate. However, we do not know whether a high score on the improvement factor reflects high numbers of incidents being reported, or if it reflects the unit's climate perceived as being safe to speak up about worries. What is known is that management attitudes and institutional climate can significantly influence the success or failure of reporting efforts (Barach and Small 2000). On the other hand, Macrae (2016) points to some potential pitfalls when the assumption is made that higher levels of overall reporting reflect a better safety culture. For example, the lack of a clear definition of what should be reported and repeated reports on the same incident might produce a high number of reports but reflect a weak learning culture. Organizational learning is described as a process from which cultural change ensues (Rashman, Withers et al. 2009). Cultural change or change in mindset occurs when error reporting and correction truly involves employees (Stavropoulou, Doherty et al. 2015). Several items in the Improvement factor align with the Safety-I perspective as reporting adverse events has been seen as identifying and counting mistakes; on the other hand, the factor has a proactive side where staff improvement is encouraged and aligned with the Safety-II perspective. The psychological safety to 'speak up' is clearly a significant driver for safety culture and overall safer outcomes.

7.3.2 Quality

A change in safety climate was seen where the factor Quality was rated positively. The factor captures staff's perceptions of teamwork, efficiency, and the ability to maintain high quality. For example, collaboration and communication between all those involved might indicate a climate of

safety as every team member has the information needed to provide high-quality care (Blegen, Sehgal et al. 2010). The National Academy of Medicine (NAM, before called the IOM) has defined healthcare quality according to six aims: Safe, effective, patient-centered, timely, efficient, and equitable.[25] The survey does not reveal what staff have in mind when they respond to the item 'in my unit high quality is maintained', but it could be assumed that the NAM aims depict quality for most healthcare professionals.

7.3.3 Patient-Centered

The Patient-Centered factor includes respect for patients' views and empowering patients to participate in their care decisions. Patient preferences and views could very well be an essential source for keeping patients safe (Epstein, Fiscella et al. 2010, Longtin, Sax et al. 2010, Flink, Öhlén et al. 2012). Creating a patient-centered environment is a management responsibility and calls for a leadership style that values patient contribution (Manser 2009, Sammer, Lykens et al. 2010, Subbe C 2020). However, patients as co-producers might challenge the standardization of healthcare since patients have their own rational for the choices they make, and these cannot be completely controlled by standards (Ansmann and Pfaff 2018). Co-producing health outcomes with patients is now mandatory in Norwegian hospitals[26] but not fully implemented at the patient level. There are several barriers to patient involvement, such as patient characteristics, lack of information, and appropriate co-production tools (Lopez, Hanson et al. 2017). One crucial barrier could be the lack of empowerment of patients and healthcare professionals. Spence Laschinger et al. (2010) proposed a nurse/patient empowerment model that suggests that empowering working conditions could result in greater patient empowerment and better health outcomes.

[25] https://www.ncbi.nlm.nih.gov/books/NBK2677/table/ch4.t2/

[26] New regulations for healthcare require co-production with patients when making treatment decisions.

7.3.4 Commitment

Finally, Commitment was associated with maintaining a mature safety climate over time. Sustaining change over time is a challenge but this study does not reveal whether maintaining a mature safety climate over time is possible because staff is committed, or that the commitment is a result of a culture, which resonates well with the values and beliefs of staff. However, this 'chicken and egg' discussion might not be relevant. The factor has been defined as a psychological attitude that attaches employees to an organization and reduces the intention to leave (Allen and Meyer 1990). Kaplan and colleagues (2012)p1 state that commitment "*is crucial to hospitals due to the critical role employees' play in the provision of healthcare services*". Job satisfaction and employee engagement are significantly associated with organizational commitment (Kaplan, Ogut et al. 2012, Hanaysha 2016). Furthermore, hospital staff who perceive their work environment as supportive of their clinical practice are more likely to recommend their workplace to colleagues and patients (Laschinger 2008), putting these units in a better position to retain and attract staff socialized into a culture being attentive to safety and patient needs.

7.3.5 Culture within the SEIPS framework

In the SEIPS model, culture is seen as a key element in the work system's unpinning work processes (Carayon, Hundt et al. 2006) as safety culture is associated with safety attitudes and behavior (Griffin and Neal 2000, Yule, Flin et al. 2007). Others argue that a patient safety culture is the overarching perception about 'how things are done here', steering the organization's actions, and thus crucial as an outcome on its own (Donaldson, Corrigan et al. 2000, Curry, Brault et al. 2018). Keeping within the SEIPS framework, culture applies to all components of the model: system, process, and outcome (Holden, Carayon et al. 2013). Understanding the finding of this study within the framework is not straightforward, as the hypothesis assumed that the work environment is predictive of safety climate as an outcome. A causal association was indicated, but the data does not reveal if the safety climate at baseline might drive the work environment scores.

This study identified key factors associated with a safety climate for improvement, but the model only explains 5.3% of the variation in raising safety climate to a mature level and 15.8% of the variation in maintaining a mature safety climate level. These findings may indicate that the factors studied are only part of the complete picture. Nevertheless, the term 'organizational culture' is one determent of performance, and periodic staff surveys have been proposed as a means to capture this phenomenon (Nieva and Sorra 2003, Colla, Bracken et al. 2005, Pronovost and Sexton 2005). Figure 5 depicts the safety climate maturity levels in the studied units. The majority of units kept their status as having a mature safety climate where more than 60% of the staff agreed with the safety climate statements. Whereas, more than one fourth did not meet the threshold. However, there is an increase in the units gaining mature safety climate by 4 percentage points versus those losing their mature status. Compared to the national patient safety campaign in this period, the change might seem modest. However, healthcare is complex and culture change is related to many factors; thus, the positive trend is noteworthy.

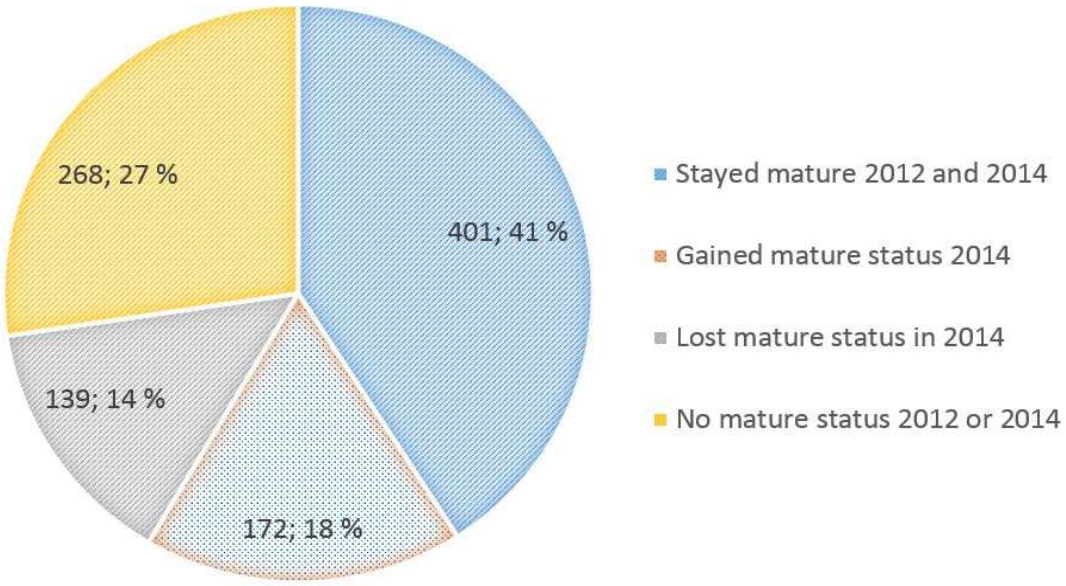


Figure 5. Change in mature safety climate in the 970 hospital units studied between years 2012 and 2014.

Where a change was observed, different work environment factors were significant. A cautious interpretation could be that patient safety is enabled when management focuses on quality and

patient needs and is maintained in a nurturing and entrusting setting that supports the staff to speak up and feels committed to their unit's improvement efforts. The interpretation concurs with the results in this study, as changes in patient safety climate were multifaceted and embedded in the work environment.

7.4 Methodological considerations

7.4.1 Paper I

The systematic literature review's trustworthiness was strengthened by collaborating with an information specialist librarian who designed and conducted the search. One of the unavoidable limitations of systematic reviews is that results may appear outdated as new studies are published (Gough, Oliver et al. 2017). A thorough literature search was conducted in accordance with the Cochrane guidelines for systematic reviews (Higgins and Green 2011). There was a considerable time gap between the first search and the publication of the paper. The search was repeated upon publication with the same search strategy to ensure up-to-date data. No additional studies matching the pre-defined inclusion criteria were identified. The PRISMA (Preferred Reporting Items for Systematic Reviews) statement was used to ensure transparent and complete reporting (Liberati, Altman et al. 2009). In addition, reference lists and Google search engines were studied for potentially relevant studies (snowballing). However, it cannot be ruled out that there may be other studies that the review missed as studies of accreditation or certification impact might have been described in other words than the ones in the search strategy. There is a perceivable risk of bias in the literature published. Positive results are more likely to be reported than negative or no results (Dwan, Gamble et al. 2013). Potentially missing these studies might affect the conclusion. There was no language limitation in the search, but the search provided only studies published in English. However, the studies reported from a wide range of settings and geographical locations.

To address the known subjective elements of systematic reviews, such as reviewers' perspectives, we performed independent assessments by at least two review team members, and an agreement was obtained. The selection process of studies has been described as a sieve where evidence is

elected or rejected and it seeks positive support when ambiguity occurs (Sykes 2004). A selection strategy with predetermined inclusion criteria was developed to minimize this potential bias. The Overview of Cochrane reviews supported the decision to include systematic reviews in the review (Becker, Oxman et al. 2008). Initiatives have been taken to review systematic reviews to summarize knowledge where there is more than one review (Smith, Devane et al. 2011). However, the choice to mix a primary study and systematic reviews could be questioned. The PRISMA statement does not mention the mix of these study designs but it opens to the possibility that more studies than papers are reported because papers may report on multiple studies (Moher, Liberati et al. 2009). The Cochrane handbook (Higgins, Thomas et al. 2019) states that including an individual study is beyond the scope of a Cochrane Overview. An overview (umbrella review) addresses research questions broader in scope than a systematic review and is conducted to answer questions related to healthcare interventions (Ibid). For example, with three systematic reviews on hospital accreditation eligible for inclusion, an overview could be performed but was not discussed. The main purpose of the systematic review was to conduct a study-level search for primary studies not included in any systematic review. Retrospectively, an overview would produce the same result as the systematic review but might present a clearer picture of the findings without the separate assessment of the primary study.

The lone RCT from South Africa was the only primary study eligible for inclusion in the systematic review; this study was also present in the three systematic reviews included. The challenge of overlapping reviews was considered (Pollock, Fernandes et al. 2019). According to the Cochrane Handbook, chapter V (Higgins, Thomas et al. 2019), topic overlap could create bias, and overlapping reviews are complex to report transparently. However, as the purpose was to describe the current body of evidence, it may be appropriate to include all the results included in the systematic reviews, regardless of topic overlap.

The primary methodological consideration for this systematic review was the choice of inclusion criteria. The accreditation covers a cluster of activities (e.g., management systems and checklist compliance) at several organizational levels, making it difficult to link the accreditation activity with the outcome. Further, most accreditation programs do not hold an endpoint; thus, measuring

the effect is challenging (Bogh 2017). Controlled study design can be challenging to perform on complex interventions such as accreditation, and it is hard to identify a linear cause-and-effect relationship. Therefore, our inclusion criteria could be debated. The chosen criteria significantly reduced the number of eligible studies; nevertheless, the research group upheld the importance of controls to evaluate the effect. However, the choice of inclusion criteria presumably did not prevent a sound conclusion, as the included systematic reviews with a broader inclusion of studies did not present more clarity on the effects of accreditation on patient safety (de Santè 2010, Alkhenizan and Shaw 2011, Flodgren, Pomey et al. 2011).

7.4.2 Paper II

Health service researchers often rely on data from secondary sources (Huston and Naylor 1996). This thesis's datasets were collected for improvement and administrative purposes and made available for the studies in this thesis. Survey data was used to assess staff perceptions about their work environments. The Likert scale was used to capture the respondent's level of agreement on a series of statements.[27] A 5-point scale was chosen as it carefully balances positive and negative agreement options and provides a 'neutral' position, providing fewer opportunities for responders to choose their agreement with statements. Equidistance between the points on the scale was assumed, but the individual responder might rank them differently (Brown 2011, Joshi, Kale et al. 2015). However, the items were combined for this study, and a score was presented for all items constituting a factor; thus, an interval scale can be assumed (Carifio and Perla 2008).

Surveys about certain aspects may not always result in accurate reporting (Glasow 2005). First, the single-scale format in the Likert scale might reduce the cognitive process and encourage straight-line responses that are not connected to the actual item content (Rindfleisch, Malter et al. 2008).

[27] Two schools of thought debate whether the Likert scale is ordinal or an interval scale. The ordinal scale ranks the items, showing the order but not the distance between rankings. The interval scale shows the order but with equal intervals between the points of the scale.

Second, the response could be motivated by other factors than an honest description of the work environment (Boynton 2004). Third, misreporting of behavior could be done to confound survey results (Glasow 2005). Fourth, non-response can result in bias of the measured outcome if those participating in the study differ from those who do not (Sedgwick 2014). Finally, there was no information about the effect of mood, leadership style, and other features might have on the responses. As suggested by Glasow (2005) we aggregated the individual questionnaire responses across a unit to lessen the effects of idiosyncratic or individual attitudes.

According to Pronovost and Sexton (2005), the high response rate (>75%) in the WES survey may contribute to the representativeness of the data. Surveys can fail because participants do not feel comfortable with the questionnaire (Boynton and Greenhalgh 2004). Thus, a survey pilot was performed and adjusted before being submitted to staff to reduce the risk of non-responders due to misunderstanding, dislike of the lay-out, or non-relevant items. A limitation in the survey design was the fixed structure. Factors and items were set and validated according to reliability and validity, but there was limited validation about the statements' ability to identify what is deemed important to staff.

A profession-specific association between work environment characteristics and patient survival was made. A methodological challenge was the way a profession-specific work environment is defined. In this study, the work environment of physicians, middle managers and nurses were studied separately. The patient's unit was not studied exclusively, but the clinical unit for nurses, the unit organizing the manager responsible for the clinical unit, and the physician unit serving the clinical unit. The hypothesis was that every profession contributes to patient treatment, and their work environment is associated with patient survival probability. A limitation in defining the work environment separately for professions is that physicians often take care of patients on several clinical units. Even if they were asked to evaluate their physician work environment, it could not be ruled out that they had several clinical units in mind when responding. This could create more 'noise' in their response as it could be a mean of multiple clinical units that was assessed. No significant association between physician work environment and patient outcome was found. A possible explanation might be the challenge of contributing their 'average' perceptions of the work

environment to the outcome in a single unit. Further studies should deliberate if physicians should respond to one survey for each unit they serve or if a 'physician' culture affected their overall work environment perceptions.

The study follows the organizational hospital structure and assesses the unit level, defined as the level where patients are treated. However, this way of organization may not reflect the staff actually treating the patient. Patients with AMI, stroke and hip-fracture will most likely be treated by the microsystem in charge of their 'patient group'. However, the unit assessed also provides care to patients with other diagnoses. The choice to explore the unit level is explained below, but the choice has some implications. We did not study the work environment of the staff giving care to the individual patient but the aggregated work environment of all staff in the unit. The use of data from all employees includes data from staff never in contact with the patient (diagnosis). On the other hand, the effect identified at the unit level might underestimate the effect at the individual level, leading to the assumption that work environment factors matter for patient outcome more likely. This is a potential explanation of why no association was found between physicians' work environment and patient outcome. It might indicate that the study captures the work environment for physicians less accurately than for nurses. The same argument could be made for middle managers, however for managers an association was found. A possible explanation might be that managers have more power to affect culture and WE factors, and that management actually works.

Mizushima et al. (2018) suggest that mortality rates could be seen as an objective quality indicator. However, the suitability of mortality as a metric for hospital performance has been debated as the lack of standardized mortality calculation might provide considerable variation between the hospitals (Crede and Hierholzer 1988, Thomas and Hofer 1999). This study uses standardized data recommended as indicators for performance (Kristoffersen, Helgeland et al. 2012). Most commonly, the 30-day mortality rate is used (Clench-Aas, Helgeland et al. 2005). However, we chose a seven-day mortality rate as the 30-day mortality rate might confound findings by including mortality not related to the hospital characteristics studied due to low average length of stay (e.g. post-discharge care in local nursing homes or home healthcare

services). One implication of the shorter observation time chosen could be that the deaths observed were those that died of their illness's severity, regardless of staff's work environment and care provided.

Furthermore, it could be argued whether the diagnosis-specific outcome results from the quality of care or patient safety. Mortality may have some limitations in understanding how the organization and management of hospitals affect the patient outcome as death rates heavily depend on patient characteristics, and there is limited information on the severity of patient illness (West 2001). The variation in the patient's risk profile, when risk-adjusted, does not take the severity of illness into account (Jencks, Brook et al. 1987). The diagnosis-specific dataset used in this study was case-mix adjusted for age, gender, number of hospital episodes during the previous two years, The Carlson Comorbidity Index, and type of stroke, but not for disease severity as this information is currently not available (Hassani, Lindman et al. 2015). Still, the study revealed a relationship between work environment and mortality (Bettencourt, McHugh et al. 2020). However, the cross-sectional study design does not support causality but identified a strong association that should be explored further (Levin 2006).

As mentioned above, a methodological challenge in the study design could be the choice to use hospital unit data rather than individual data. The diagnosis-specific survival rate was attributed to 56 units in 20 hospitals. All acute hospitals and all units treating this patient population in HSØ were included, but Norway's size restricts the number of variables to conduct a multivariate analysis. Thus, a selection of inclusion variables in the final model based on significance in the univariate models was made, but this approach could be challenged. Selecting single variables for inclusion in the model to identify a significant association with the dependent variable might only identify a spurious correlation, as the bivariate association is uncontrolled. An alternative approach could be to study the work environment of the individual healthcare professionals treating the actual patient. This was debated, but several issues restricted this approach. First, patients are exposed to several work environments, collecting these data at an individual level is challenging; Second, the mortality rate is generally low and collecting data for each unit would be time consuming and costly. Finally, matching the individual patient with the responding staff might

not be possible due to data de-identification. The unit levels seemed appropriate as Pronovost, Sexton, and Deilkås, Hofoss (2005, 2010) found that more safety climate variation was seen at the unit level than at the department level and between hospitals.

The use of statistical analysis to establish a relationship between work environment characteristics and patient outcomes was useful, but we encountered a limitation as the indicators selected might fail to capture the broader underlying factors for high performance (Taylor, Clay-Williams et al. 2015). Alternative explanations about factors that could be associated with the findings, such as patient characteristics, have been discussed. A cross-sectional design was used in this study. Other methods might provide different results. Qualitative research designs, such as in-depth interviews, focus groups, or participant observation, could be used. However, participating in the work environment as an observer might affect those observed (Carlson and Morrison 2009). Structured interviews with focus groups or individual staff might give a more nuanced picture of the environment but could be prone to selection bias and affect the results (Levin 2005). The choice to use survey data providing a large number of variables from a representative sample was supported by Hox and Boeije (2005).

The data in this study are from the years 2010-2012 but remain the only comprehensive study based on the data from the annual validated staff survey in Norwegian hospitals. Moreover, the study's interest were the associations between the work environment and patient survival. There is no reason to expect the relationship to have changed since then. The current context of efficiency, resource constraint, and complexity is still as challenging as when the data were collected.

7.4.3 Paper III

We chose a longitudinal study design and used retrospective secondary data, which may provide a more comprehensive set of results (Hox and Boeije 2005, Caruana, Roman et al. 2015). One advantage of using secondary data was accessing the work environment and safety climate

without imposing the researcher's hypothesis on the survey participants. In addition, the anonymity and primary purpose of the surveys may safeguard the staff's true perspective and encourage results that are more truthful. Finally, as suggested by Cheng and Philips (2014), the data collected for another purpose was evaluated for its quality before being deemed relevant for this study.

In longitudinal research a temporal gap between the initial and a follow-up survey may allow intervening events to arise (Caruana, Roman et al. 2015). Therefore, only units where no major reorganization had occurred were included in this retrospective study. According to Sedgwick (2014), caution is needed if the participants differ at each time point. For example, manager and staff turnover is anticipated but may alter the relationships between the work environment and patient safety climate. However, it was not the individual employee that was studied but the unit characteristics. Another major consideration was the patient safety campaign launched in 2012 and from which the SAQ data was collected. All staff were exposed to the campaign and adjusting for this exposure was not possible. Consequently, we cannot rule out that the change in safety climate scores identified was due to the campaign and the increased awareness about patient safety. Flipping the coin, the changes observed might be the result of work environment factors making some units more susceptible to the campaign message than others. The national patient safety campaign generated increased awareness about patient safety, but its effect to penetrate the organizational layers and change safety attitude at the sharp end remains unclear.

Staff in the same units were responders in the work environment survey and the safety attitudes questionnaire. Thus, the independent and dependent variables were measured in the same population. A potential drawback of longitudinal surveys is response attrition, which might introduce a risk of non-respondent bias (www.verywellmind.com). The WES has been performed annually in hospitals for more than a decade and a structure for including responders and follow-up on the survey results has been well established, as well as a defined practice for participation among staff and managers. As part of the National Patient Safety Campaign, hospital staff received the SAQ in 2012 and 2014. In contrast to the WES, the SAQ was imposed on hospitals and local ownership was lacking. The differences in engagement and involvement might explain some of the

differences in response rates between the surveys. Whereas the WES generally held a response rate >75%, the responses to the SAQ were significantly lower (61% and 57%). The variation in survey response rates might also be attributed to attrition: some of the SAQ items resemble WES questions (some even copy them), and non-responders may have decided that they already addressed this matter. A potential bias is the lower response rate in the SAQ study, since there is no knowledge about the non-responders and the responders might not be random and representative of the population studied. However, the outcomes in this study are changes in safety climate levels and the potential effects of the lower response rates was seen as minor. Furthermore, as the response results (61% and 57%) are quite similar, it is likely that the responders in the two surveys are rather homogenous. The factors Teamwork Climate and Safety Climate from the Norwegian SAQ were chosen for full assessment in the Patient Safety Campaign survey (Skjellanger, Deilkås et al. 2014). For this study, the factor Safety Climate was assessed as the outcome variable. The exclusion of the factor Teamwork Climate was done to minimize the overlap of items between the WES and SAQ.

In the regression analysis, the data was adjusted for SAQ_{2012}. This was done to adjust for the potential for improvement and prevent a regression to the mean effect. The units scoring high on safety climate in 2012 had less potential for improvement than those scoring lower on safety climate. Adjustment for SAQ_{2012} was done to prevent masking the real effect of improvement. As previous analysis of the data indicated size as a confounder, the model was also adjusted for unit size. Generally, larger units scored lower than smaller units. A limitation in the study is the potential for unknown confounding factors affecting the independent and dependent variables. However, as the WES data was used to predict the longitudinal development of safety climate, confounding factors affecting the result were less likely than in a cross-sectional study. Despite this, we cannot rule out potential confounders that might affect the results.

7.4.4 What might it all mean?

The healthcare work environment lies at the core of this thesis. Reason argues that *"we cannot change the human conditions, we can change the conditions under which humans work"* (Reason

2000)p768. Designing systems resilient to unanticipated events and supporting human performance by understanding how humans interact with the work environment is essential (Russ, Fairbanks et al. 2013). The work environment is the physical, social, psychological, and organizational environment under which tasks are performed, including the organizational culture. Scrutinizing the work environment to identify why things more often go right than wrong might provide managers with the information needed to support staff more effectively to perform safely, but even more, it may sustain staff engagement and motivation and make staff want to stay. Improving safety in healthcare is not only about new equipment, rules and regulations but a fundamental rethinking about the relationships between management and staff and the environment that management creates in which care is delivered (Clarke and Aiken 2006).

Accreditation is viewed as a reputable tool to evaluate and enhance the quality of healthcare, and a recent systematic review found reasonable evidence to support the notion that compliance with accreditation standards improves hospital performance (Hussein, Pavlova et al. 2021). According to the systematic review (Ibid) hospital accreditation has a positive effect on safety culture. In paper III, the factor Improvement was the most significant driver for change in patient safety culture. The items reflect the willingness and psychological safety to report adverse patient events. Managers investing in accreditation may be perceived by staff as being genuinely engaged in safety efforts, and thus create the culture for reporting adverse events. Risk management is essential for accreditation and managers who use incident reports for organizational learning could support a culture of safety as a non-punitive managerial attitude can motivate staff to report. The accreditation cycle might enhance culture further when incident reports are used to adjust standards that adhere and support the everyday work processes. On the other hand, the Improvement factor was not significantly associated with nurse, middle manager or physician perceptions of their work environments and patient survival probability in paper II. According to the systematic review by Hussein et al. (2021), the evidence for accreditation effects on patient mortality was inconclusive; however, accreditation was found to negatively affect job stress. Accreditation has been described as time consuming and drawing attention away from essential patient care. While the decision to implement accreditation may have administrative benefits, it could increase clinical workload, and workload was significantly negatively associated with patient survival in paper II. The steady increase in standards might trigger workarounds and other

adaptive strategies where the standards are seen as disruptive to the actual working processes. These behaviors could further add to the workload and increase job stress levels. For middle managers, accreditation processes might affect engagement if the accreditation process is seen as being primarily about compliance and the resources needed to adhere are not made available.

In this thesis, the assumption is made that regulatory efforts and standardization of work processes alone will not make healthcare safer, but the interventions are vital for accountable and safe care. Based on the perspective of work-as-imagined (WAI) and work-as-done (WAD), there is a gap between the regulatory efforts of stakeholders and policymakers viewing the actual work processes from a distance and how healthcare professionals cope with constant changes and unexpected situations in the actual workplace (Iflaifel, Lim et al. 2020). Therefore, the perspective of this thesis is to deepen the understanding of how the system might affect patient safety as patient outcomes or safety culture underpinning the attitudes of health professionals. This goes to the core of healthcare by exploring the factors deemed important to frontline by asking staff what works, rather than telling them what to do (Braithwaite, Churruca et al. 2017). This insight might help to bridge the gap between the WAI and WAD and contribute to safer and reliable healthcare.

7.4.5 The impact of the COVID-19 pandemic on patient care

The COVID-19 pandemic has challenged healthcare organizations and healthcare workers all over the world. The pandemic was an ultimate stress test for systems, managers, and frontline workers. Work had to be done in unfamiliar environments, with new colleagues, new equipment, and patients were taken care of outside existing pathways and without guidelines and standards to guide (Van Zundert, Barach et al. 2020). Together this affected healthcare professionals' well-being and their ability to provide safe and high-quality care (Lai, Ma et al. 2020). Despite the feeling that the pandemic challenged healthcare in new ways, many of the strategies applied in everyday work also proved relevant when everything seemed unpredictable. Staff impressively adapted their care processes to the new situation and managers responded to their needs by listening to the local expertise. As suggested by Carayon and Perry (2021), the SEIPS framework could be used to identify the various barriers and facilitators in the work system experienced during COVID-19 for organizational learning and improvement. The speed of learning was seen in

the production of guidelines and procedures, and opposed to the general notion that compliance is challenged, standards were welcomed to minimize variation in the treatment of COVID-19 patients (Berwick 2020). The pandemic truly reinforced the tenet that health professionals and their well-being (safety) are key to excellent and safe care. Much of the success could be ascribed to organizational resilience, staff engagement, and managers bridging the gap between WAI and WAD (Wong, Ahmed et al. 2021). The challenge remains how to sustain the cultural changes seen during the pandemic to ongoing patient safety efforts. However, COVID-19 is a long-term and complex occupational trauma. The pre pandemic resource shortage has been exacerbated by the impact of the pandemic. Staff who 'held on' are now exhausted and report increased propensity to leave their job and require respite and support (EFN 2020). The pandemic demonstrated how poor work environments and heavy workload could be related to stress, burnout and high levels of staff absence. In contrast, improved work environments and staffing can reduce stress, improve healthcare professionals' ability to provide quality care, and encourage staff to be 'retained'.

8 IMPLICATIONS ON PRACTICE AND FURTHER STUDIES

This thesis could spur a host of new ideas for future research. An important step forward would be to include the patient perspective alongside with the perceptions of staff. Combining patient experience and clinical expertise may reveal more risks and opportunities to prevent harm. The research was intentionally developed to gain a deeper understanding of culture and safety from an operational perspective. Few studies provide insight into the patients' perspective on accreditation and culture, and this should be part of future research.

Our findings imply that involvement and engagement of staff and managers are needed to succeed in implementing significant interventions. This applies to systemic interventions such as accreditation as well as micro-level initiatives around safety and culture change. Identifying what matters to those at the sharp end, carefully appreciating the lived experience of front-line staff can help tailor interventions for improving the workflow and will likely increase compliance. Further research should aim to capture the role of middle managers in filling the gap between work-as-imagine and work-as-done.

The work environment survey provides managers with large amounts of data regarding staff perception of their work environment. The rationale behind the survey is an invitation to open a respectful dialogue between unit staff and managers to further develop an environment supportive of the unit goals. We found that different factors were deemed important by different professions. An implication might be that future survey responses are presented according to profession in order to tailor improvement initiatives. Furthermore, future research should explore to which extent the data from the survey are used to systematically drive change. In addition, the effects of the external environment and the decisions made by politicians and stakeholders on patient safety need to be further explored.

For nurses, the workload was the most significant factor for patient outcomes. An implication of this result might be that managers need to monitor and evaluate the effect of workload. Different

strategies need to be implemented to reduce the workload, including redesigning pathways of care and employing a new cadre of care workers to support professionals. In Norway, more than 90% of the hospital unit caregivers are nurses. Further studies are suggested to explore the effect of the homogeneity in care competency on patient safety.

The data was obtained before the COVID-19 pandemic. The unprecedented pressure due to the pandemic has augmented the risk and frequency of burnout and stress-related disorders and could lead to an increase in employees leaving their profession.[28] Based on the findings in this thesis, further research is needed on the effect of work environment on staff retention. To attain an even deeper understanding on the effect of work environment on staffs' practices, attitudes and culture, our research should be supplemented with qualitative studies.

[28] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7812159/

9 CONCLUSIONS

Based on the results in the three studies constituting this thesis, the work environment could be seen as the 'magic bullet' for enhancing patient safety. A large number of patient safety initiatives are targeting the micro-level for change and improvement; this thesis found that some factors are more important than others for success. Exploring the effects of several initiatives recommended by the Institute of Medicine, the thesis informs policymakers and healthcare providers on what to consider when introducing patient safety initiatives. This thesis aimed to describe in a concrete manner what good conditions for providing high-quality care are and makes robust suggestions about where hospital management should focus their efforts for success.

For policymakers and leaders, understanding the linkages between the organizational decisions and how the various components of the external environment can affect the work system is crucial. This can help frontline workers to have adequate control and resources to react to changing circumstances, including the extraordinary conditions created by a long-lasting pandemic.

This research provides action-able data for hospital managers to inform decisions about patient safety initiatives that are influenced by systems thinking and work environment factors. In essence, the message of this thesis is that patients fare better in hospitals in which employees declare a supportive and nurturing place to work.

Taking care of the caregivers is patient safety.

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APPENDICES

Appendix 1.

Search Strategy

Contact person: Gunn Elisabeth Vist

Information specialist librarian: Gyri Hval Straumann

January 18, 2013: search strategy in the Cochrane Library

Database: The Cochrane Library:

Cochrane Database of Systematic Reviews, Issue 12 of 12, December 2012

DARE, Cochrane Central Register of Controlled Trials of Technology Assessments, Issue 4 of 4 October 2012

#1 MeSH descriptor Hospitals explode all trees 2423

#2 MeSH descriptor Hospital Departments explode all trees 2516

#3 MeSH descriptor Hospital Units explode all trees 2562

#4 MeSH descriptor Rehabilitation Centers, this term only 203

#5 (hospital or hospitals or ward or wards or (medical next clinic*) or (private next clinic*) or ((academic or university) next medical next (center* or centre*)) or (university next health next facilit*) or (health next facilit* next (department* or unit*)) or (cancer next care next (facilit* or unit*)) or (cancer near/2 (center* or centre*)) or (cancer next (clinic* or institute*)) or (oncology next service*) or ((oncology or oncologic) next care next unit*) or (cardiac next care next (facilit* or unit*)) or (cardiology next service*) or ((coronary or stroke) near/2 unit*) or ccu or ccus or ((cardiologic or cva) next unit*) or (heart next (center* or centre*))):ti,ab,kw 45147

#6 (hospice* or (pain next (clinic* or center* or centre*)) or (acute next pain next service*) or (pain next relief next unit*) or (rehabilitation next (center* or centre* or clinic* or department* or service* or unit*)) or (rehab next (center* or centre*)) or (psychiatric next (clinic* or department* or unit* or (health next facilit*))) or (mental next (institution* or (health next facilit*))) or (psychiatry next unit*) or (day next clinic*) or surgicenter* or surgicentre* or

((surgery or surgical) next (center* or centre* or department*)) or (surgical next service*) or ((ambulatory or outpatient) next (surgery or surgical) next facilit*) or (geriatric next (center* or centre* or clinic* or institute*))):ti,ab,kw 2543

#7 (child near/2 clinic*) or (children next institution*) or (child next health next (center* or centre*)) or ((pediatric or paediatric) near/2 (center* or centre*)) or ((pediatric or paediatric) next (clinic* or unit*)) or ((delivery or delivering or labo*r) next room*) or (delivery next unit*) or (maternity next (clinic* or home* or unit*)) or (midwifery next service*) or ((birth or birthing) next (center* or centre*)) or ((gynecology or obstetrics) next department*) or (obstetric* next service*) or ((operation or operating) next room*) or ((operation or operating or surgical) next (theater* or theatre*)):ti,ab,kw 4407

#8 (outpatient next (department* or clinic* or unit* or service*)) or (ambulatory next care next facilit*) or (outdoor next clinic*) or pol*clinic or pol*clinics or ((radiology or x-ray or radiodiagnosis or radiography or radiological or radiotherapy or roentgen) next department*) or (roentgen next facilit*) or (radiology next service*) or (recovery next room*) or (((post next anesthesia) or postanesthesia) next care next unit*) or pacu or pacus or ((emergency or "a & e" or "a&e" or "a and e" or casualty) next department*) or (("a & e" or "a&e" or "a and e") next service*) or (emergency next (room* or unit*)):ti,ab,kw 8149

#9 (trauma next (center* or centre* or unit*)) or (intensive next (care or therapy) next unit*) or icu or icus or itu or itus or picu or picus or pitu or pitus or nicu or nicus or nitu or nitus or itun or ituns or ((burn or burns) next (unit* or center* or centre*)) or (admitting next department*) or (medical next (record or records) next (department* or service*)) or (health next information next management next service*) or (nuclear next medicine next department*) or ((hemodialysis or (renal next dialysis)) next unit*) or ((self or minimal or cooperative) next care next unit*) or (observation next unit*) or (pre next (admission or admitting) next unit*) or (step next down next unit*):ti,ab,kw 7192

#10 (medical next assessment next unit*) or (anesthesia near/2 department*) or (anesthesiology next service*) or (occupational next therap* next (department* or service*)) or (pathology next department*) or (physical next therap* next (department* or service*)) or (respiratory next therap* next (department* or service*)) or (respiratory next care next unit*) or (social next work next department*) or (urology next department*) or (venereal next disease next department*) or (endoscopy next department*) or ((clinical or nuclear) next pharmacy next service*) or (inpatient next pharmac*) or (((intravenous next therap*) or (iv next therapy)) next department*) or (nursing next unit*):ti,ab,kw 285

#11 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10) 57741

#12 MeSH descriptor Accreditation explode all trees 11

#13 MeSH descriptor Certification, this term only 35

#14 (accr* or "jcaho" or "jcia" or "urac" or "equip" or "carf" or "evaluation and quality improvement program" or ((international next organi*ation) near/2 standard*) or (international next standard* next organi*ation) or (iso near/10 (certif* or "9001" or standard* or system* or qualified or quality or based or assessment*))):ti,ab,kw 3413

#15 “Joint Commission on Accreditation of Healthcare Organizations":ti,ab,kw 5

#16 (#12 OR #13 OR #14 OR #15) 3446

#17 (#11 AND #16) 73

#18 (#17), from 2011 to 2013, in Cochrane Reviews (Reviews and Protocols), Other Reviews, Trials and Technology Assessments 65

January 18, 2013: search strategy in Ovid Embase

Database: Embase 1980 to 2013 Week 02,

1. cancer center/ or hospice/ or pain clinic/ or rehabilitation center/ or exp hospital/

2. hospital$1.tw.

3. ward$1.tw.

4. medical clinic$.tw.

5. private clinic$.tw.

6. ((academic or university) adj medical adj (center$ or centre$)).tw.

7. university health facilit$.tw.

8. (health facilit$ adj (department$ or unit$)).tw.

9. (cancer care adj (facilit$ or unit$)).tw.

10. (cancer adj2 (center$ or centre$)).tw.

11. (cancer adj (clinic$ or institute$)).tw.

12. oncology service$.tw.

13. ((oncology or oncologic) adj care unit$).tw.

14. (cardiac care adj (facilit$ or unit$)).tw.

15. cardiology service$.tw.

16. ((coronary or stroke) adj2 unit$).tw.

17. ccu$1.tw.

18. ((cardiologic or cva) adj unit$).tw.

19. (heart adj (center$ or centre$)).tw.

20. hospice$.tw.

21. (pain adj (clinic$ or center$ or centre$)).tw.

22. acute pain service$.tw.

23. pain relief unit$.tw.

24. (rehabilitation adj (center$ or centre$ or clinic$ or department$ or service$ or unit$)).tw.

25. (rehab adj (center$ or centre$)).tw.

26. (psychiatric adj (clinic$ or department$ or unit$ or health facilit$)).tw.

27. (mental adj (institution$ or health facilit$)).tw.

28. psychiatry unit$.tw.

29. day clinic$.tw.

30. (surgicenter$ or surgicentre$).tw.

31. ((surgery or surgical) adj (center$ or centre$ or department$)).tw.

32. surgical service$.tw.

33. ((ambulatory or outpatient) adj (surgery or surgical) adj facilit$).tw.

34. (geriatric adj (center$ or centre$ or clinic$ or institute$)).tw.

35. (child adj2 clinic$).tw.

36. children institution$.tw.

37. (child health adj (center$ or centre$)).tw.

38. ((pediatric or paediatric) adj2 (center$ or centre$)).tw.

39. ((pediatric or paediatric) adj (clinic$ or unit$)).tw.

40. ((delivery or delivering or labo?r) adj room$).tw.

41. delivery unit$.tw.

42. (maternity adj (clinic$ or home$ or unit$)).tw.

43. midwifery service$.tw.

44. ((birth or birthing) adj (center$ or centre$)).tw.

45. ((gynecology or obstetrics) adj department$).tw.

46. (obstetric$ adj service$).tw.

47. ((operation or operating) adj room$).tw.

48. ((operation or operating or surgical) adj (theater$ or theatre$)).tw.

49. (outpatient adj (department$ or clinic$ or unit$ or service$)).tw.

50. ambulatory care facilit$.tw.

51. outdoor clinic$.tw.

52. pol#clinic$1.tw.

53. ((radiology or x-ray or radiodiagnosis or radiography or radiological or radiotherapy or roentgen) adj department$).tw.

54. roentgen facilit$.tw.

55. radiology service$.tw.

56. recovery room$.tw.

57. ((post anesthesia or postanesthesia) adj care unit$).tw.

58. pacu$1.tw.

59. ((emergency or "a & e" or "a&e" or "a and e" or casualty) adj (department$ or ward$)).tw.

60. (("a & e" or "a&e" or "a and e") adj service$).tw.

61. (emergency adj (room$ or unit$)).tw.

62. (trauma adj (center$ or centre$ or unit$)).tw.

63. (intensive adj (care or therapy) adj unit$).tw.

64. (icu$1 or itu$1 or picu$1 or pitu$1 or nicu$1 or nitu$1 or itun$1).tw.

65. (burn$1 adj (unit$ or center$ or centre$)).tw.

66. admitting department$.tw.

67. (medical record$1 adj (department$ or service$)).tw.

68. health information management service$.tw.

69. nuclear medicine department$.tw.

70. ((hemodialysis or renal dialysis) adj unit$).tw.

71. ((self or minimal or cooperative) adj care unit$).tw.

72. observation unit$.tw.

73. (pre adj (admission or admitting) adj unit$).tw.

74. step down unit$.tw.

75. medical assessment unit$.tw.

76. (anesthesia adj2 department$).tw.

77. anesthesiology service$.tw.

78. (occupational therap$ adj (department$ or service$)).tw.

79. pathology department$.tw.

80. (physical therap$ adj (department$ or service$)).tw.

81. (respiratory therap$ adj (department$ or service$)).tw.

82. respiratory care unit$.tw.

83. social work department$.tw.

84. urology department$.tw.

85. venereal disease department$.tw.

86. endoscopy department$.tw.

87. ((clinical or nuclear) adj pharmacy service$).tw.

88. inpatient pharmac$.tw.

89. ((intravenous therap$ or iv therapy) adj department$).tw.

90. nursing unit$.tw.

91. or/1-90
92. accreditation/ or certification/ 93. accredit$.tw. 94. (jcaho or jcia or urac or equip or carf).tw. 95. "Joint Commission on Accreditation of Healthcare Organizations".tw. 96. "evaluation and quality improvement program".tw. 97. (international organi#ation adj2 standard$).tw. 98. (international standard$ adj organi#ation).tw. 99. (iso adj10 (certif$ or "9001" or standard$ or system$ or qualified or quality or based or assessment$)).tw. 100. or/92-99
101. 91 and 100
102. limit 101 to "reviews (best balance of sensitivity and specificity)"
103. 2011$.em,dp,dd,yr. 104. 2012$.em,dp,dd,yr. 105. 2013$.em,dp,dd,yr. 106. or/103-105 107. 102 and 106
108. clinical trial/ 109. randomized controlled trial/ 110. randomization/ 111. double blind procedure/ 112. single blind procedure/ 113. crossover procedure/ 114. placebo/ 115. placebo$.tw.

116. randomi?ed controlled trial$.tw.

117. rct.tw.

118. random allocation.tw.

119. randomly allocated.tw.

120. allocated randomly.tw.

121. (allocated adj2 random).tw.

122. single blind$.tw.

123. double blind$.tw.

124. ((treble or triple) adj blind$).tw.

125. prospective study/

126. or/108-125

127. case study/

128. case report.tw.

129. abstract report/

130. letter/

131. human/

132. nonhuman/

133. animal/

134. animal experiment/

135. 132 or 133 or 134

136. 135 not (131 and 135)

137. or/127-130,136

138. 126 not 137

139. 101 and 138

140. 106 and 139

141. evaluation.sh.

142. evaluation stud$.tw. 143. "types of study".sh. 144. intervention study.sh. 145. (intervention$ adj (stud$ or trial$)).tw. 146. comparative study.sh. 147. comparative stud$.tw. 148. experimental study.sh. 149. experimental stud$.tw. 150. (time adj series).tw. 151. (pre test or pretest or post test or posttest).tw. 152. or/141-151
153. 101 and 152 154. 106 and 153
155. 107 or 140 or 154

Database: Ovid MEDLINE(R) 1948 to Present

Dato: 18.1.2013.

Search terms
1. exp hospital departments/ or exp hospital units/ or exp hospitals/ or rehabilitation centers/
2. hospital$1.tw.
3. ward$1.tw.
4. medical clinic$.tw.
5. private clinic$.tw.
6. ((academic or university) adj medical adj (center$ or centre$)).tw.
7. university health facilit$.tw.
8. (health facilit$ adj (department$ or unit$)).tw.
9. (cancer care adj (facilit$ or unit$)).tw.
10. (cancer adj2 (center$ or centre$)).tw.
11. (cancer adj (clinic$ or institute$)).tw.
12. oncology service$.tw.
13. ((oncology or oncologic) adj care unit$).tw.
14. (cardiac care adj (facilit$ or unit$)).tw.
15. cardiology service$.tw.
16. ((coronary or stroke) adj2 unit$).tw.
17. ccu$1.tw.
18. ((cardiologic or cva) adj unit$).tw.
19. (heart adj (center$ or centre$)).tw.
20. hospice$.tw.
21. (pain adj (clinic$ or center$ or centre$)).tw.
22. acute pain service$.tw.

23. pain relief unit$.tw.

24. (rehabilitation adj (center$ or centre$ or clinic$ or department$ or service$ or unit$)).tw.

25. (rehab adj (center$ or centre$)).tw.

26. (psychiatric adj (clinic$ or department$ or unit$ or health facilit$)).tw.

27. (mental adj (institution$ or health facilit$)).tw.

28. psychiatry unit$.tw.

29. day clinic$.tw.

30. (surgicenter$ or surgicentre$).tw.

31. ((surgery or surgical) adj (center$ or centre$ or department$)).tw.

32. surgical service$.tw.

33. ((ambulatory or outpatient) adj (surgery or surgical) adj facilit$).tw.

34. (geriatric adj (center$ or centre$ or clinic$ or institute$)).tw.

35. (child adj2 clinic$).tw.

36. children institution$.tw.

37. (child health adj (center$ or centre$)).tw.

38. ((pediatric or paediatric) adj2 (center$ or centre$)).tw.

39. ((pediatric or paediatric) adj (clinic$ or unit$)).tw.

40. ((delivery or delivering or labo?r) adj room$).tw.

41. delivery unit$.tw.

42. (maternity adj (clinic$ or home$ or unit$)).tw.

43. midwifery service$.tw.

44. ((birth or birthing) adj (center$ or centre$)).tw.

45. ((gynecology or obstetrics) adj department$).tw.

46. (obstetric$ adj service$).tw.

47. ((operation or operating) adj room$).tw.

48. ((operation or operating or surgical) adj (theater$ or theatre$)).tw.

49. (outpatient adj (department$ or clinic$ or unit$ or service$)).tw.

50. ambulatory care facilit$.tw.

51. outdoor clinic$.tw.

52. pol#clinic$1.tw.

53. ((radiology or x-ray or radiodiagnosis or radiography or radiological or radiotherapy or roentgen) adj department$).tw.

54. roentgen facilit$.tw.

55. radiology service$.tw.

56. recovery room$.tw.

57. ((post anesthesia or postanesthesia) adj care unit$).tw.

58. pacu$1.tw.

59. ((emergency or "a & e" or "a&e" or "a and e" or casualty) adj department$).tw.

60. (("a & e" or "a&e" or "a and e") adj service$).tw.

61. (emergency adj (room$ or unit$)).tw.

62. (trauma adj (center$ or centre$ or unit$)).tw.

63. (intensive adj (care or therapy) adj unit$).tw.

64. (icu$1 or itu$1 or picu$1 or pitu$1 or nicu$1 or nitu$1 or itun$1).tw.

65. (burn$1 adj (unit$ or center$ or centre$)).tw.

66. admitting department$.tw.

67. (medical record$1 adj (department$ or service$)).tw.

68. health information management service$.tw.

69. nuclear medicine department$.tw.

70. ((hemodialysis or renal dialysis) adj unit$).tw.

71. ((self or minimal or cooperative) adj care unit$).tw.

72. observation unit$.tw.

73. (pre adj (admission or admitting) adj unit$).tw.

74. step down unit$.tw.

75. medical assessment unit$.tw.

76. (anesthesia adj2 department$).tw.

77. anesthesiology service$.tw.

78. (occupational therap$ adj (department$ or service$)).tw.

79. pathology department$.tw.

80. (physical therap$ adj (department$ or service$)).tw.

81. (respiratory therap$ adj (department$ or service$)).tw.

82. respiratory care unit$.tw.

83. social work department$.tw.

84. urology department$.tw.

85. venereal disease department$.tw.

86. endoscopy department$.tw.

87. ((clinical or nuclear) adj pharmacy service$).tw.

88. inpatient pharmac$.tw.

89. ((intravenous therap$ or iv therapy) adj department$).tw.

90. nursing unit$.tw.

91. or/1-90

92. exp accreditation/ or certification/

93. accredit$.tw.

94. (jcaho or jcia or urac or equip or carf).tw.

95. "Joint Commission on Accreditation of Healthcare Organizations".tw.

96. "evaluation and quality improvement program".tw.

97. (international organi#ation adj2 standard$).tw.

98. (international standard$ adj organi#ation).tw.

99. (iso adj10 (certif$ or "9001" or standard$ or system$ or qualified or quality or based or assessment$)).tw. 100. or/92-99
101. 91 and 100
102. limit 101 to "reviews (best balance of sensitivity and specificity)"
103. 2011$.ed,ep,yr,dp. 104. 2012$.ed,ep,yr,dp. 105. 2013$.ed,ep,yr,dp. 106. or/103-105 107. 102 and 106
108. randomized controlled trial.pt. 109. controlled clinical trial.pt. 110. randomi#ed.ab,ti. 111. placebo.ab,ti. 112. clinical trials as topic.sh. 113. randomly.ab,ti. 114. trial.ti,ab. 115. or/108-114 116. exp animals/ not humans.sh. 117. 115 not 116
118. 101 and 117 119. 106 and 118
120. evaluation studies.pt,sh. 121. evaluation stud$.tw. 122. intervention studies.sh. 123. intervention stud$.tw.

124. comparative study.pt,sh. 125. comparative stud$.tw. 126. experimental stud$.tw. 127. (time adj series).tw. 128. (pre test or pretest or post test or posttest).tw. 129. or/120-128
130. 101 and 129 131. 106 and 130
132. 107 or 119 or 131

ERRATA LIST

Side	Linje	Fotnote	Originaltekst	Type rettelse	Korrigert tekst
10	31		…and physicians that…	Cor	…and physicians who…
12	4		..som blir ansett gode helsetjenester…	Cor	…som blir ansett som gode helsetjenester…
12	13		…økt bevisstheten blant…	Cor	…økt bevissthet blant…
12	15		…forslag om obligatoriske…	Cor	…forslag om obligatorisk…
12	24		…klinisk ansatte om å yte…	Cor	...klinisk ansatte sitt ønske om å yte…
13	11		…av mulitivaritabel lineære regresjonsmodeller…	Cor	…av multivariat lineær regresjonsanalyse…
13	12		…og pasients…	Cor	…og pasientens…
15	31		The accreditation process was perceived as rigid, bureaucratic, time-consuming and drawing vital attention of front-line clinicians away from patient care.		Delete. This sentence is stated elsewhere in the thesis and its appearance on page 15 was not intended.
16	6		..that factors that…	Cor	..,that factors which…
17	9		…and third studies both applied…	Cor	…and third study applied…
17	13		Chapter 1 is…	Cor	Chapter 1 consists of…
17	18-19		Chapter 5 details the materials and methods used in the studies,	Cor	In chapter 5 the material and methods used in the studies are detailed,
18	17		…the staff's perception…	Cor	…the staffs' perception…

18	26		, and true safety cannot be fully…	Cor	, nor can true safety be fully…
20	8		…not immune from making errors…	Cor	…not immune against making errors…
21	19		…(HCW) often are anguished…	Cor	…(HCW) are often anguished…
21	21		…patients are harmed.	Cor	…patients were harmed.
22	19		…1990's the public attention…	Cor	…1990's public attention…
22		[2]	…dollars equal…expenditure exceed…	Cor	…dollars equals…expenditure exceeded…
25	4		…less likely in future…	Cor	---less likely in the future…
26	16		…experience adverse…	Cor	…experiencing adverse…
26	19-20		…care in Norway have been performed.	Cor	…care have been performed in Norway.
26	23		…dates to 1787…	Cor	…dates back to 1787…
27	10		...essential for hospitals…	Cor	…essential to hospitals…
27	29		…is considered the softer…	Cor	…is considered to be the softer…
29	10		…the temporality…	Cor	…the temporarily…
29	20		…behaviors is complex…	Cor	…behaviors are complex…
30	4		…and if discovered put…	Cor	…and, if discovered, put…
30	20		…'wearing out and wearing' down…	Cor	…'wearing out and wearing down'…
30	26		…relationship with a series…	Cor	…relationship to a series…
31	5		…burnout lies with its link…	Cor	…burnout lies in its link…

31	15		, and burned-out physicians…	Cor	, and burnt out physicians…
32	8		Table 1 depicts…	Cor	Figure 2 depicts…
32	11		Table 1.	Cor	Figure 2.
32	15		…found specific improvements…	Cor	…found that specific improvements…
32	22		…questioned if the patient…	Cor	…questioned whether the patient…
33	28		…is actually done,…	Cor	…is performed,...
34	18		Table 2	Cor	Table 1
34	21		Table 2	Cor	Table 1
35	7		….and patient outcome and…	Cor	…and both patient outcome and..
37	4		…better fit the people in the system,	Cor	…better fit people to the system,
37	10		…potential unintended…	Cor	…potentially unintended…
37	30		…merely the work system…	Cor	…merely on the work system…
37	31		…(Carayon, Hundt et al. 2006)..	Cor	…(Carayon, Hundt et al. 2006).
38	13		…(figure 2).	Cor	…(figure 3).
39	7		Figure 2.	Cor	Figure 3.
40	11		…is what attitudes…	Cor	…is which attitudes…
42	15		…education is within…	Cor	…education lies within…
43	15		Table 3…	Cor	Table 2…
43	18		Table 3.	Cor	Table 2.
44	7		..considered the strong and…	Cor	…considered a strong…
45	22		…all five continents…	Cor	…all 5 continents…
46	10		Table 4…	Cor	Table 3…

46	15		Table 4.	Cor	Table 3.
46	20		Table 5.	Cor	Table 4.
46	22		Table 5.	Cor	Table 4.
47	12		…not know if the same…	Cor	…not know whether the same…
47	13		…staff that was of…	Cor	…staff who was of…
50	1		…background data was included…	Cor	…background data were included…
50	19-20		…unit was collected in years…	Cor	…unit were collected in the years…
54	5		…and were plausible.	Cor	…and they were plausible.
55	27		Table 6.	Cor	Figure 4.
56	2		Table 6.	Cor	Figure 4.
56	12		…ten hospitals served as controls…	Cor	…ten other hospitals serve as controls…
57	2		…hence not eligible…	Cor	…hence were not eligible…
59	13		…and thus anecdotal…	Cor	…and are thus anecdotal…
60	12		...-and the strategy…	Cor	…-and one strategy…
61	4		…the question with…	Cor	…the question in…
62	9		However, pre- and post…	Cor	Pre- and post…
63	1		…an essential «floor»…	Cor	…an essential ‘floor’…
63	25		…expectation by the…	Cor	…expectation of the…
64	24		…accreditation being strongly linked…	Cor	…accreditation as being strongly linked…
64	28		…may profit on promoting…	Cor	…may profit by promoting…
65	24		…in Table 7.	Cor	…in Table 5.

65	30		Table 7.	Cor	Table 5.
67	22		…time pressures…	Cor	…time pressure…
68	5		...the work is so interesting…	Cor	…the work being so interesting…
69	13		…and patients…	Cor	…and the patient…
69	28		…performance pressures increase…	Cor	…performance pressure increase…
70	11		…point to the fact…	Cor	…point out the fact…
70	28		…environment positive…	Cor	…environment positively…
71	1		…nurse specialist[24].	Cor	…nurse specialist.[24]
71	11		...nurse workload is a first step…	Cor	…nurse workload, is a first step…
72	3		…, and accreditation…	Cor	…, and internal inspection…
72	5		…patients as managers recognize…	Cor	…patients as they recognize…
72	13		…safety culture is key for…	Cor	---safety culture is the key…
72	17		, engagement, and…	Cor	, their engagement and…
72	21		...to overall satisfaction…	Cor	…to their overall satisfaction…
72	26		…the need…	Cor	…the needs…
72	29		…report to a single manager…	Cor	…report to one single manager…
72	31		…likely to enforced rules…	Cor	…likely to enforce rules…
73	7		...lack of an association…	Cor	…lack of association…
73	29		,even if the…	Cor	,even though the…
74	10		…never that straightforward…	Cor	…never so straightforward…

74	22		…care for patients.	Cor	…care for their patients.
75	17		…events and the culture…	Cor	…events and to the culture…
75	23		…know if a high score…	Cor	…know whether a high score…
76	17		…the NAS…	Cor	…the NAM…
76	27		…and these cannot by completely…	Cor	…and these cannot be completely…
77	8		…not reveal if…	Cor	…not reveal whether…
77	10		…a culture that resonates…	Cor	…a culture, which resonates well…
77	20		...into a culture attentive…	Cor	…into a culture being attentive…
78	8		Figure 3…	Cor	Figure 5…
78	17		Fig 3.	Cor	Figure 5.
79	31		…and seeks positive…	Cor	…and it seeks positive…
80	6		…but is opens to…	Cor	…but it opens to…
81	1		Thus, our inclusion…	Cor	…therefore, our inclusion…
81	14-15		We choose a 5-point…	Cor	A 5-point scale was chosen…
81	17		Equidistant…	Cor	Equidistance…
84	1		…it could be argued if the diagnose-specific…	Cor	…it could be argued whether the diagnosis-specific…
84	6		The diagnose-specific…	Cor	The diagnosis-specific…
84	18		…Norway’s small size…	Cor	…Norway’s size…
84	29-30		Pronovost and Sexton and Deilkås and Hofoss…	Cor	Pronovost, Sexton and Deilkås, Hofoss…

85	13-14		…provided a large number of variables from a large and representative sample available for analysis was supported…	Cor	…providing a large number of variables from a representative sample was supported…
85	16-21		The data in this study are from years 2010-2012 but remain the only comprehensive study based on the data from the annual validated staff survey in Norwegian hospitals. Moreover, the study's interest was the associations between the work environment and patient survival. There is no reason to expect that the relationship has changed since then. The current context of efficiency, resource constraint, and complexity is still as challenging as when the data was collected.	Cor	The data in this study are from the years 2010-2012 but remain the only comprehensive study based on the data from the annual validated staff survey in Norwegian hospitals. Moreover, the study's interest were the associations between the work environment and patient survival. There is no reason to expect the relationship to have changed since then. The current context of efficiency, resource constraint, and complexity is still as challenging as when the data were collected.
85	28		Furthermore,…	Cor	Also,…
86	23		…as well as a well defined…	Cor	…as well as a defined…
87	1		(61% and 57%) is quite similar…	Cor	(61%and 57%) are quite similar…
87	23		…environment is at the core…	Cor	…environment are at the core…
88	1		…equipment and rules and regulations…	Cor	…equipment, rules and regulations…

88	12		..being genuine engaged…	Cor	…being genuinely engaged…
88	29		…is seen…	Cor	…is seen as…
89	21 and 31		…wellbeing…	Cor	…well-being…
90	8		…related to stress and burnout, and…	Cor	…related to stress, burnout and…
90	14		…alongside the perceptions…	Cor	…alongside with the perceptions…
90	16		…to gain a deep understanding…	Cor	…to gain a deeper understanding…
91	11		…including in redesigning…	Cor	…including redesigning…
91	18		…has been seen to increase the risk…	Cor	…has augmented the risk…
92			…the thesis inform policymakers and healthcare providers on what to consider when initiating patient safety initiatives. This thesis aimed to describe in a concrete manner what are good conditions for providing high-quality care and makes robust suggestions about where hospital management should focus their efforts for success.	Cor	…the thesis informs policymakers and healthcare providers on what to consider when introducing patient safety initiatives. This thesis aimed to describe in a concrete manner what good conditions for providing high-quality care are and makes robust suggestions about where hospital management should focus their efforts for success.
92	14		This research provides action-able data for hospital managers to inform decisions about ongoing and future patient safety…	Cor	This research provides action-able data for hospital managers to informed decisions about patient safety…

93 - 112			No numbering of references	Cor	Numbering of references

PAPERS I - III

I

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RESEARCH ARTICLE Open Access

A systematic review of hospital accreditation: the challenges of measuring complex intervention effects

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Abstract

Background: The increased international focus on improving patient outcomes, safety and quality of care has led stakeholders, policy makers and healthcare provider organizations to adopt standardized processes for evaluating healthcare organizations. Accreditation and certification have been proposed as interventions to support patient safety and high quality healthcare. Guidelines recommend accreditation but are cautious about the evidence, judged as inconclusive. The push for accreditation continues despite sparse evidence to support its efficiency or effectiveness.

Methods: We searched MEDLINE, EMBASE and The Cochrane Library using Medical Subject Headings (MeSH) indexes and keyword searches in any language. Studies were assessed using the Cochrane Risk of Bias Tool and AMSTAR framework. 915 abstracts were screened and 20 papers were reviewed in full in January 2013. Inclusion criteria included studies addressing the effect of hospital accreditation and certification using systematic reviews, randomized controlled trials, observational studies with a control group, or interrupted time series. Outcomes included both clinical outcomes and process measures. An updated literature search in July 2014 identified no new studies.

Results: The literature review uncovered three systematic reviews and one randomized controlled trial. The lone study assessed the effects of accreditation on hospital outcomes and reported inconsistent results. Excluded studies were reviewed and their findings summarized.

Conclusion: Accreditation continues to grow internationally but due to scant evidence, no conclusions could be reached to support its effectiveness. Our review did not find evidence to support accreditation and certification of hospitals being linked to measurable changes in quality of care as measured by quality metrics and standards. Most studies did not report intervention context, implementation, or cost. This might reflect the challenges in assessing complex, heterogeneous interventions such as accreditation and certification. It is also may be magnified by the impact of how accreditation is managed and executed, and the varied financial and organizational healthcare constraints. The strategies hospitals should impelment to improve patient safety and organizational outcomes related to accreditation and certification components remains unclear.

Keywords: Accreditation, Certification, Hospital, Patient Safety, Evaluation

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Background

Patient safety and patient centered care are emerging as key drivers in healthcare reform.

Accreditation is the most frequently external quality assessment of healthcare organizations' strategic goals [1]. We defined hospital accreditation programs as the systematic assessment of hospitals against accepted standards [2] and certification is a confirmation of characteristics of an object, person, or organization against published standards [3]. Little information is available on effective accreditation and certification strategies. Prominent national organizations have recommended accreditation which is being implemented widely. However, little evidence supports their effect on patient outcomes or other important markers such as core measures, organizational culture nor reliability.

Hospital accreditation was started by The American College of Surgeons 100 years ago, and since then the number of hospital accreditation programs has expanded rapidly. The World Health Organization identified 36 nationwide healthcare accreditation programs in 2000 [4]. Accreditation is an essential part of healthcare systems in more than 70 countries and is often provided by external and independent review, assessment or audit [5]. The systematic evaluation of healthcare services is a way to obtain regulatory peer review on the organizational maturity and reliability [6]. Literature reviews on the effects of accreditation on the quality of care do not provide strong evidence due to limitations of the studies [7–12].

Greenfield and Braithwaite [7] identified the effects of accreditation on promoting change and professional development, indicating that the effects were probably due to accreditation and certification, but lacking firm evidence. A systematic review by Nicklin *et al.* [8] found several positive benefits of accreditation, however, the study lacked rigor to support their conclusions. Shaw *et al.* [13] found evidence for positive effects between accreditation, certification and clinical leadership, systems for patient safety and clinical review, but was fell short of endorsing accreditation, and concluded with recommending further analysis to explore the association of accreditation and certification with clinical outcomes. Furthermore, Ho *et al.* have demonstrated an unintended negative impact on the learning environment of medical students and trainees, including decreased clinical learning opportunities, increased non-clinical workload, and violation of professional integrity in preparation and during accreditation and certification [14].

The aim of this study is to systematically assess the effects of accreditation and/or certification of hospitals on both organizational processes and outcomes.

Methods

We searched for published articles that assessed the effects of accreditation and/or certification of hospitals. The studies were reviewed for their research design and internal validity. We assessed each study's findings in regard to their effects on patient mortality, morbidity, patient safety, as well as process outcomes.

Data sources and search strategy

We searched MEDLINE, EMBASE, CRD, and the Cochrane Library, including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) for all studies on accreditation/certification in 2006 [11], and this was repeated in 2009 [12], 2013 and 2014. The same search criteria were used to monitor the studies addressing effect of accreditation/certification in hospitals.

The search was designed and conducted by an information specialist librarian who updated the search strategies from 2006 to 2009 and used the combinations of key words and Medical Subject Heading terms (MeSH) related to accreditation, certification and hospitals. The reference lists of selected articles were searched for potentially relevant studies meeting the inclusion criteria (snowballing). In addition, we used Google search engine using the search words accreditation, certification and patient safety. We updated our literature search in July 2014, searching the same databases with the same inclusion criteria. We found no relevant additional studies to include in our analysis.

Study selection

We included studies identified in any language using the search strategy with the following study design: systematic reviews, randomized controlled trials (RCT), non-randomized controlled trials, controlled before and after studies (CBAs), and interrupted time series (ITS) (defined as at least three measurements before and three after the introduction of accreditation and/or certification).

The inclusion criteria used were:

Population: all types of hospitals were included.
Intervention: all types of accreditation and/or certification of hospitals.
Comparison: any hospital that was not accredited or certified, either by not seeking or not receiving accreditation and/or certification.
Outcomes: both clinical outcomes and process measures.

Two of the authors (GEV, KB) independently reviewed all titles, references and abstracts generated by the original search in order to identify articles for potential

inclusion. All reports, independent of language, were evaluated for the inclusion criteria.

Each article considered potentially eligible according to the chosen criteria was independently read in full text and then assessed using a standardized form for internal validity by two authors (GEV, KB,). If several estimates for one study outcome were reported, the most fully adjusted estimate was abstracted. Each assessment was conducted independently by two reviewers, the results were compared, and the differences were all reconciled by consensus.

This study did not involve human material or human data, so an ethic approval was not needed. No written consent was obtained from participants for this literature study. Additional file 1 provides a complete description of the search strategies; and Additional file 2 provides a detailed overview of the updated search results. The PRISMA checklist (Preferred Items for Systematic Reviews and Meta-Analyses) was used for this systematic review. Please see Additional file 3.

Results

Search results

Our search of electronic databases identified a considerable increase in studies addressing the effect of accreditation and/or certification. In 2006, 672 studies were identified [11]. Over the next 3 years 522 new studies were published. In 2013 we identified another 910 relevant studies. Of the identified studies in 2013 fifteen citations were considered potentially eligible based on the inclusion criteria. Two additional articles were identified, and an additional three references were identified by manually searching the articles' reference lists. Twenty references were considered potentially eligible and were retrieved for a full text assessment. Of these, 16 articles were excluded because they did not fulfil the inclusion criteria; Table 4 presents the excluded studies and the detailed reasons for their exclusion.

The agreement between reviewers for study eligibility was complete. As only one original study was included a meta-analysis was not possible (Fig. 1).

Characteristics of included studies

We included systematic reviews as well as controlled studies. A total of four references, three systematic reviews and one primary study met the inclusion [15–18]. The aims and the inclusion criteria of the three reviews were slightly different. However, their inclusion criteria overlapped with the inclusion criteria for this review. Please see Table 1 for included systematic reviews in this review.

The qualities of the systematic reviews were assessed using the AMSTAR quality checklist framework, the standard for assessing methodological quality of systematic reviews [19]. The results of the assessment are shown in Table 2. Two of the reviews were of moderate quality scoring 6/11 [17], and 7/11 [16], respectively, whereas the third review was scored as high quality with a score of 9/11 [15]. Our review scored 9/11 in the AMSTAR assessment. The primary study [18] was assessed as having a high risk of bias after using the risk of bias assessment as described in the Cochrane Handbook for randomized controlled trails [20]. The assessment is shown in Table 3.

Included systematic reviews

The Cochrane review by Flodgren *et al.* has the best quality AMSTAR score [15]. The authors identified two studies which met their inclusion criteria that focused on the effect of external inspection on: a) compliance with standards improving healthcare organizations; b) healthcare professional behavior; and, c) patient outcomes.

The first study was a cluster-randomized controlled trial by Salmon *et al.* [18] that involved 20 South African public hospitals. The other study was an interrupted time- series conducted to identify the effects of the NHS Healthcare Commissions Infection Inspection program on the MRSA rates in UK trusts hospitals, but did not meet our inclusion criteria. Flodgren *et al.* concluded that the results could not be used to draw firm conclusions on the effectiveness of external inspection.

The Matrix Knowledge group searched the literature in 2010 and found 56 articles that addressed the impact of hospital accreditation [16]. The vast majority of these studies used surveys with standardized questionnaires, and reported staff, patient and stakeholders' perceptions of impact. Overall they reported a positive impact of accreditation on hospital and professional practice. Only the South African cluster-randomized controlled trial was consistent with the inclusion criteria of our study.

Alkhenizan and Shaw searched the literature in 2009 and included 26 studies that assessed either the general impact of accreditation on hospitals or impact on a single aspect of performance of healthcare services, and on subspecialty accreditation programs. The authors found a positive effect of accreditation on improving the process of care and clinical outcomes [17]. Sixteen (62 %) of the 26 included studies reported significant positive results attributed to accreditation, mainly related to better compliance with guidelines. Ten studies (38 %) reported weak or no improvement after accreditation. Alkhenizan and Shaw included the one RCT by Salmon *et al.* [18].

Included primary study

There was one primary study identified that met all of our criteria, the randomized controlled trial from South Africa by Salmon *et al.* [18]. This study was not identified through the database search, but by searching reference lists (snowballing); it was missed by our literature review in 2009. The authors included 20 hospitals in their study. The hospitals were randomly selected and

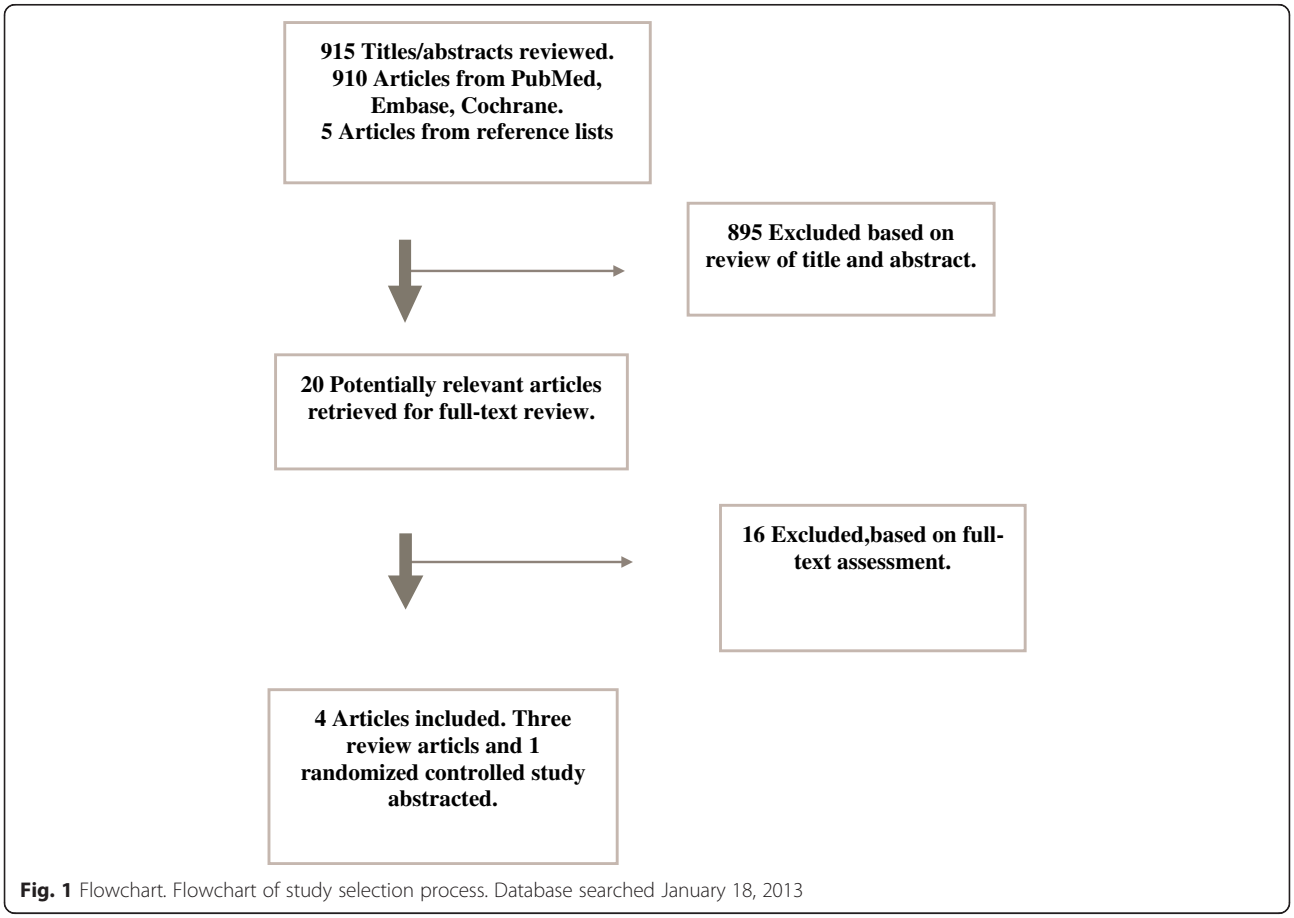

Fig. 1 Flowchart. Flowchart of study selection process. Database searched January 18, 2013

stratified into groups according to hospital size (number of beds). Ten hospitals were randomized to start an accreditation program, while the other 10 served as controls. Two sets of data, before and after measures, were collected by the Council for Health Services Accreditation of Southern Africa (COHSASA), and by independent research teams. Initially, 12 indicators of hospital care quality were identified and used for the first data collection – this number was reduced to eight in the second data collection. Of these indicators, surgical wound infection, time to surgery, neonatal mortality rate and financial solvency were left out due to challenges in data collection. It is unclear whether the four indicators that were abandoned would have influenced the overall magnitude, range of results or conclusions of the study.

The compliance with the COHSASA accreditation standard was found to have increased substantially in the accredited hospitals ($p < 0.001$), whereas the control hospitals maintained their score throughout the study. Eight hospital quality indicators were reported. The nurses' perceptions of clinical quality was increased in the accredited hospitals ($p = 0.031$); however, the other seven indicators showed little or no effect on the quality indicators; patient satisfaction with care ($p = 0.484$); patient medication education ($p = 0.395$); accessibility of medical records ($p = 0.492$); completeness of medical records ($p = 0.114$); completeness of peri-operative notes ($p = 0.489$); labelling of ward stock ($p = 0.112$); and, composite assessment of hospital sanitation ($p = 0.641$).

Excluded studies

Sixteen of the 20 studies were excluded after they were independently evaluated by two researchers (GVE, KB). The reasons for exclusion were as follows: four studies had no control groups [21–24]; two performed the study outside hospitals [25, 26]; four studies did not report on the effects of accreditation [27–30]; two studies lacked baseline measurements [31, 32]; one study lacked description of the accreditation intervention [33]; two studies did a comparison of the clinical outcome in accredited hospitals with outcome in non-accredited hospitals, but did not assess the effect of the intervention *per se.* [34, 35]; and, one systematic review conducted a qualitative assessment of healthcare professionals' attitude toward accreditation, but the effect of the intervention was not assessed [36]. A complete list of the excluded studies and the reasons for their exclusion is presented in Table 4.

Table 1 Included systematic reviews

Reference	Search date	Aim of review	Study design included	Number of included studies	Main conclusion stated by authors	Studies that match our inclusion criteria
Flodgren *et al.* 2011 [15]	May 2011	Evaluate the effectiveness of external inspection of compliance with standards in improving healthcare organizations behavior, healthcare professionals behavior and patient outcomes	RCT, CCT, ITS, CBA	Two in total, 1 RCT, 1 ITS	No firm conclusion were drawn due to paucity of high-quality controlled evaluations	Salmon *et al.* [18]
Matrix Knowledge group 2010 [16]	August 2010	Produce a general overview of results obtained and methodologies used to assess impact of accreditation	Studies containing an element of comparison	56 in total, 40 studies with quantitative design of which 1 study presented empirical data	Most studies suggest that accreditation/certification has an impact on the organization or on the professional practice. The impact on health outcomes or improvement in these outcomes was not demonstrated.	Salmon *et al.* [18]
Alkhenizan & Shaw 2011 [17]	June 2009	Evaluate the impact of accreditation programs on the quality of healthcare services	Clinical trials, observational studies and qualitative studies	26 in total, 10 studied accreditation of hospitals of which 1 had a hospital control group	Accreditation improves the process of care provided by healthcare services	Salmon *et al.* [18]

A synthesis of the three included systematic reviews

Table 2 AMSTAR, assessing methodological quality of systematic reviews

Study	Alkhenzian *et al.* 2011	Matrix group 2010	Flodgren *et al.* 2011	Brubakk *et al.*
AMSTAR question	Yes, No, Can't answer, Not applicable			
1. Was an 'a priori' design provided?	Yes	Yes	Yes	Yes
2. Was there duplicate study selection and data extraction?	No	No	Yes	Yes
3. Was a comprehensive literature search performed?	Yes	Yes	Yes	Yes
4. Was the status of publication (i.e. grey literature) used in the inclusion criterion?	No	Yes	No	No
5. Was a list of studies (included and excluded) provided?	Yes, although only for the included	Yes, although only for the included	Yes, both included and excluded studies	Yes, both included and excluded studies
6. Were the characteristics of the included studies provided?	Yes	Yes	Yes	Yes
7. Was the scientific quality of the included studies assessed and documented?	Yes	Yes, No	Yes	Yes
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	No	Can't answer	Yes	Yes
9. Were the methods used to combine the findings of studies appropriate?	Not applicable (N/A)	Yes	Not applicable (N/A)	Not applicable (N/A)
10. Was the likelihood of publication bias assessed?	No	No	Yes	Yes
11. Was the conflict of interest stated?	No	No	Yes	Yes

AMSTAR. Assessing Methodological Quality of Systematic Review, quality assessment of included systematic reviews categorized by yes, no, cannot answer, not applicable

Narrative review of excluded studies

We identified one primary study and three systematic reviews. Notably, we had strict inclusion criteria and found few studies that met these strict criteria. A summary of the methods used in the excluded studies is relevant to the discussion on assessing the full measure of complex interventions. Accreditation was addressed in several ways in the publications that failed to fulfil the criteria for inclusion in the present review. Seven of the 16 excluded studies conducted cross-sectional studies

Table 3 Risk of bias assessment of study by Salmon et al. [18][a]

Domain	Support for judgement	Review author's judgement
Selection bias		
Random sequence generation	They state stratified randomisation, but give no information about the procedure	Unclear
Allocation concealment	Not mentioned	Unclear
Performance bias		
Blinding of participants and personnel	Not mentioned and appears impossible/not possible to blind hospitals	Unclear
Detection bias		
Blinding of outcome assessor	Not mentioned	Unclear
Attrition bias		
Incomplete outcome date	The largest hospital did not complete the study. Follow- up time was shortened because controls wanted to receive the intervention	High risk
Reporting bias		
Selective reporting	Outcome selection conducted by participants and accreditor. Many outcomes/ indicators were dropped from the follow- up measurement	High risk
Other bias		
Other sources of bias	This was a cluster randomized trial, adjustment for clustering in analysis of results were not mentioned	Unclear

[a]The risk of bias assessment as described in the Cochrane Handbook for randomized controlled trails [20]
Risk of bias assessment of the included primary study by Salmon el at [18]
SOURCE: Higgins J, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011

Table 4 Excluded studies

Reference (country)	Reason cited for exclusion	Aim of study
Al Awa *et al.* 2011 [22], Saudi Arabia	No control group	Determine if patient safety and quality care indicators improve post accreditation
Al Awa *et al.* 2011 [23], Saudi Arabia	No control group	Evaluate nursing perception of care/safety after accreditation
Al Tehewy *et al.* 2009 [26], Egypt	Not in hospital (health units)	Determine the effects of accreditation of non-governmental organizations
Chen *et al.* 2003 [31], USA	Measured outcome at only one point	Identify association between JCAHO accreditation and quality of care for acute myocardial infection
Chuang *et al.* 2009 [27], Australia	Did not measure effect	Propose an integrated research model
du Bois *et al.* 2009 [33], Germany	Review not linked to accreditation	Evaluate the impact of different physician and hospital characteristics on outcome in ovarian cancer patients
Gokenbach *et al.* 2011, USA [24]	No control group	Identify the effects of Magnet accreditation on one hospital
Lichtman *et al.* 2009 [28], USA	Did not measure effects of accreditation	Determine whether hospitals certified had better outcome within the first year of accreditation than non accredited hospitals
Lichtman *et al.* 2011 [32], USA	Measured outcome at only one point	Identify outcomes after ischemic stroke for hospitals with and without TJC certification
Menachemi *et al.* 2008 [25], USA	Not in hospital	Identify quality outcome in accredited and non-accredited ambulatory surgical centers
V Phua *et al.* 2011 [29], Singapore/Asia	Did not evaluate effects of accreditation	Assess compliance to sepsis bundles in intensive care units in Asia
Al-Awa *et al.* 2012 [30], Saudi Arabia	Compares survey results in accredited hospital to international results	Perform an unbiased assessment of the impact of accreditation on patient safety culture
Alkenizan & Shaw 2012 [36], UK,	Review, Qualitative assessment of attitude, did not measure effect	Review the literature of the attitude of healthcare professionals towards accreditation
Bohmer *et al.* 2012 [21], Germany	No controls	Identify to which extent pain management standards was implemented in hospitals after accreditation
Schmaltz *et al.* 2011 [34], USA	Compared the difference in development of accredited vs. non accredited hospitals, not the effects of accreditation	Examine the association between Joint Commission accreditation status and both absolute measures and trends in hospital performance
Nguyen *et al.* 2012 [35], USA	Compared the difference in development of accredited vs. non accredited hospitals, not the effects of accreditation	Analyze the peri-operative outcomes of bariatric surgery performed at accredited vs. non accredited centres

Excluded studies after full text assessment presenting aim of study and reason for exclusion

comparing patient outcome in accredited and non-accredited hospitals [23, 25, 31, 32, 34, 35]. In general, performance in accredited hospitals was higher than in non-accredited hospitals and showing higher compliance to standards also affecting outcome positively [29]. The study by Lichtman *et al.* identified the risk of selection bias as certified hospitals had better outcome than non-certified hospitals even before the program began [28]. Four studies used survey to assess the staff and patient' perception of patient safety culture, quality and patient satisfaction pre- and post accreditation [21, 22, 26, 30]. Nurses and patients reported that positive changes in their organization were a result of accreditation, while physicians in general were more sceptical. This is consistent with the findings in Alkhenizan and Shaw's systematic review studying healthcare professionals' attitude toward accreditation. Nurses in general were more favourably inclined than physicians indicating the necessity of special education schemes to involve staff in the accreditation process [36]. Another systematic review did not address accreditation directly, but found that physician specialization had effect on outcome of ovarian cancer patients [34]. A study on implementing nurse accreditation in one hospital reports increased staff and

patient satisfaction, improved nurse-physician relationship, improved nursing quality and reduced turnover and vacancy rates [24]. The last study aims at proposing an integrated research model of the accreditation and quality measurement/reporting systems, providing more supportive information on the system weakness [27].

Discussion

In this systematic review, we examined 20 studies involving accreditation and certification aimed at improving patient and organizational outcomes. Because few studies specifically addressed the correlation between accreditation and certification of hospitals and patient outcomes, we could not reach firm conclusions regarding effective strategies in this area.

This is no surprise as accreditation is anticipated as a prototypical example of a complex intervention. Within our classification of interventions, the manner in which the studies carried out specific interventions varied widely. There is complexity in the intervention components as well as in the theoretical background of the intervention, the implementation context, and the targeted outcomes [37]. The literature is dominated by descriptive studies attributing changes in the organization to the accreditation process. The research has ranged from identifying the change in compliance to standards, patient satisfaction, performance indicators, health professionals' satisfaction and an overall review of the perceptions of accreditation and/or certification among patients, professionals and other stakeholders. Many of the studies we reviewed were heterogeneous, uncontrolled and fraught with confounding variables, adding little clarity or guidance. Despite the lack of convincing evidence there is no reason to believe that accreditation and certification will be abandoned. The lack of documented effect may simply mean that due to the heterogeneity of study design and methods much uncertainty remains regarding its putative effects.

The paucity of evidence is highlighted by our systematic search that revealed variable degrees of rigor. The search identified only one controlled study, the randomized trial from South Africa from 2003. The study, however, is weak scientifically, and does not address morbidity or patient safety measures well enough to support any conclusions across a wide range of safety systems examined.

The methodological challenges of measuring the effects of accreditation/certification are increased by the complexity of the hospital organizations and their heterogeneous components. It is unclear what elements are being subjected to assessment [38, 39]. The UK Medical Research Council points out that it is hard to identify the "active ingredient" of complex interventions such as falls prevention or hand washing campaigns, as these interventions comprise many separate, multi-level and concurrent elements [40]. Furthermore, the interventions are interpreted in many ways and are used in different settings which strongly complicate the evaluation of the effects [41, 42]. Lessons can be learned from non-controlled studies such as cross-sectional studies. Comparison between accredited and non-accredited hospitals yields important information about potential differences between these hospitals, but cannot provide information about the observed variations, and whether the results are transferable to other settings.

It is noteworthy that there was a low level of methodological rigor in most of the studies included in this review, as outcome measures were ambiguous and only limited operational details were reported. Significant methodological challenges such as self-selection and lack of robust controls undermine the ability to extrapolate or infer from the published literature if these effects were caused by accreditation and/or certification [43]. Even though our systematic review was conducted carefully adhering to the Cochrane guidelines, we were unable to find conclusive evidence on accreditation and certification. Some studies surveyed staff, stakeholders or other hospital representatives before, during and after a certification and/or accreditation process. Some studies show higher quality in accredited hospitals when compared to non-accredited hospitals, but it is uncertain if this is the result of accreditation, self-selection or is due to other extraneous factors.

Working with predetermined inclusion criteria allowed a specialized literature search which generally increases the chances of finding all relevant studies although it only identifies the published literature. Reports of studies that are only posted on the web pages of organizations or stakeholders (grey literature) are more difficult to find. Notably, the randomized controlled trial from South Africa was only available as grey literature and was not identified through a systematic literature search of electronic databases. Although unlikely, it is possible that there may be other studies that the present or other reviews have missed.

Our study has several limitations. An unavoidable limitation of systematic reviews is that they may appear out-dated rapidly as new studies are published; hence, our review only included recently published systematic reviews. Notably, we repeated the search in July 2014 to ensure that we captured any new studies. Future investigations might control for case mix and time trends, employ suitable comparison groups, and consider other analytic approaches for analyzing time series data such as interrupted time series data, or ARIMA methods [44]. Interrupted time series analyses, Bayesian analysis and ARIMA may be suited for adjusting for clustering of effects within sites, while accounting for patient-level

effects, and site-level structural measures. Studies addressing how and why the interventions might work, rather than just the effects of the intervention, might provide valuable information on complex interventions [39].

Conclusions

Hospitals are now faced with the challenge of improving their patient outcomes and reliability. Our study provides a comprehensive overview of the effects of accreditation and/or certification of hospitals on quality and patient safety outcomes and concludes that due to scant evidence, no conclusions could be reached to support its effectiveness. The accreditation programs require substantial financial and labor investments, and distract healthcare teams from their primary clinical goals. Accordingly further research on the clinical impact of these programs is needed, and it is important to weigh the transactional opportunity and financial costs of accreditation against other financial investments in quality improvement interventions [45–48]. Furthermore, we found little guidance demonstrating the cost effectiveness of accreditation and/or certification.

In summary, we found that the proven role of accreditation and certification in improving patient and organizational outcomes remain largely undefined. Accreditation and certification is a thriving industry and there are many interested stakeholders who may profit on promoting these services despite the lack of robust evidence of their effectiveness [49, 50]. Finally, because hospitals are expending resources on accreditation and/or certification they may not be able to address other, more pressing patient safety issues [51]. There is little reason to believe however that accreditation or certification will be abandoned because of the lack of empirical evidence of its effects, so future contributions should probably focus on what aspects of accreditation serve a useful purpose, rather than focusing on "does it work".

Before planning further studies to evaluate impact of accreditation and certification efforts, a more thorough and nuanced analysis of the available evidence about which components of accreditation/certification seem to be most effective in enabling patient centered, high quality and safer outcomes should be performed [37].

Additional files

Additional file 1: Complete search strategy January 2013. Complete search strategy performed in PubMed (from 1948), EMBASE (from 1980), CRD, and the Cochrane Library, including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) January 2013.

Additional file 2: Complete search strategy July 2014. Complete search strategy performed in PubMed (from 1948), EMBASE (from 1980), CRD, and the Cochrane Library, including the Cochrane Database of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE) and Health Technology Assessment Database (HTA) July 2014.

Additional file 3: PRISMA 2009 Checklist. PRISMA 2009 Checklist. Transparent reporting of systematic reviews and meta-analyses. Prisma-statement.org.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

GEV and KB designed and managed the study. GEV and KB reviewed title, references and abstracts. All authors (GEV, KB, GB, PB, and OT) were involved in the interpretation of the data. KB, PB and OT drafted the manuscript. All authors read and approved the final version.

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II

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Associations between work satisfaction, engagement and 7-day patient mortality: a cross-sectional survey

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ABSTRACT

Objective This study examines the association between profession-specific work environments and the 7-day mortality of patients admitted to these units with acute myocardial infarction (AMI), stroke and hip fracture.

Design A cross-sectional study combining patient mortality data extracted from the South-Eastern Norway Health Region, and the work environment scores at the hospital ward levels. A case-mix adjustment model was developed for the comparison between hospital wards.

Setting Fifty-six patient wards in 20 hospitals administered by the South-Eastern Norway Regional Health Authority.

Participants In total, 46 026 patients admitted to hospitals with AMI, stroke and hip fracture, and supported by 8800 survey responses from physicians, nurses and managers over a 3-year period (2010–2012).

Primary and secondary outcome measures The primary outcome measures were the associations between the relative mortality rate for patients admitted with AMI, stroke and hip fractures and the profession-specific (ie, nurses, physicians, middle managers) mean scores on the 19 organisational factors in a validated cross sectional, staff survey conducted annually in Norway. The secondary outcome measures were the mean scores with SD on the organisational factors in the staff survey reported by each profession.

Results The Nurse workload (beta 0.019 (95% CI0.009–0.028)) and middle manager engagement (beta 0.024 (95% CI0.010–0.037)) levels were associated with a case-mix adjusted 7-day patient mortality rates. There was no significant association between physician work environment scores and patient mortality rates.

Conclusion 7-day mortality rates in hospital wards were negatively correlated with the nurse workload and manager engagement levels. A deeper understanding of the relationships between patient outcomes, organisational structure and their underlying cultural barriers is needed because they may provide a better understanding of the harm and death risks for patients due to organisational characteristics.

Strengths and limitations of this study

- ► This is the first study, to our knowledge, combining profession-specific work place survey data with patient mortality data correlated with the hospital ward levels.
- ► This study is strengthened by the use of ward-specific level data as hospital data can mask inter-ward differences.
- ► A case-mix adjustment model was developed for the comparison between hospital wards but not for the disease severity, thus it is hard to distinguish between patients who might die from the severity of their illness and less severe cases, for whom the lack of high-quality care ultimately may have reduced their chances of survival.
- ► Although the study included hospitals providing healthcare services to more than half of the Norwegian population, the number of wards is too small to allow the use of complex multivariate analyses.

INTRODUCTION

Hospitals are complex social–cultural organisations defined by their complexity of operations, uncertainty and interdependency.[1] A strong linkage between the organisation of care and patient outcomes has been found in several studies.[2 3] Complex organisations rely on authentic inputs and interactions while they deliver an array of clinical services. In these settings, it can be hard to determine the proximal causes of an adverse patient event such as a cardiac arrest or a medication error.[4 5] Numerous initiatives have been promoted to enhance the quality of the patient's journey when in hospital, and yet at least one in ten patients still experiences adverse events.[6] High-reliability organisational theory posits that organisational features including psychological safety,[7] leadership involvement,[8] team based care,[9] trusting support[10] and a relentless culture of quality measurement are needed to sustain reliable improvements in care.[11]

The impact of organisational culture on quality, reporting of data and safety in non-medical organisations is well documented.[12–15] Monitoring staff perceptions of their work environment and their organisational culture

is used by managers to discover what is deemed meaningful and makes organisational sense to employees.[16 17] Leggat *et al*[18] have consistently demonstrated that a reported positive relationship between high-performance workplaces and organisational outcome also applies to patient outcomes in healthcare organisations.[19]

Systems science and human factors engineering posit that focusing on the workflow and environment, and the organisational culture can reduce work hazards and enable safer outcomes.[20 21]

Our hypothesis was that there is an association between the work environment and patient mortality, and that this association is profession-specific for nurses, physicians and middle managers. The secondary objective of this study was to examine the associations between profession-specific work environments and the 7-day mortality of patients admitted with one of three diagnoses: acute myocardial infarction (AMI), stroke and hip fracture.

METHODS

The survey population was drawn from one healthcare service provider, the South-Eastern Regional Health Authority (HSO), which is responsible for delivering healthcare services to approximately 3 million people—more than half of the population in Norway. The patient outcome data were derived from a national database (Norwegian Patient Register) for all patients admitted with AMI, stroke and hip fracture in 20 hospitals in Norway.

The Work Environment Survey

Staff in all hospitals administered by the HSO in Norway were invited to participate in a web-based work environment questionnaire based on the General Nordic Questionnaire for Psychological and Social Factors at Work (QPSnordic), that was adapted for healthcare.[22] More than 75 000 are employed in HSO, and all staff employed for more than 3 months in the hospital were eligible for participation. Nearly 50 000 questionnaires were distributed in each of the studied years (2010, 2011, 2012). The data was collected electronically. To secure anonymity of the participants, only data from wards with more than five responders were processed.

The survey was designed to assess the local hospital work environment and distinguish the differences between hospital wards. The questionnaire has 57 items, measuring the work environment along 19 dimensions (table 1). The survey was supplemented with questions addressing the factor patient safety culture as an important aspect of the healthcare work environment. The safety culture questions were adapted from the Norwegian validated version of the Safety Attitude Questionnaire.[23] The response alternatives are presented on a 5-point Likert scale (for some items 'Strongly disagree', 'Disagree', 'Neither disagree nor agree', 'Agree', 'Strongly agree' or, where appropriate, 'Never/very seldom', 'Seldom', 'Sometimes', 'Quite often', 'Very often/always'). The categories were assigned the values 0-25-50-75-100, assuming an equal distance between scores.[24] The value zero reflects the highest burden/least favourable conditions and the score 100 means the most positive rating (ie, is coping/satisfied). The coding of negatively worded items was reversed to ensure that the higher code values always indicate a more positive response. The score on each dimension was calculated as the mean of the score on each item included in the dimension. For each of the 56 wards in the study, the mean work environment scores were calculated. The individual responses with missing data were excluded from the analysis. A report with the mean average scores on each item and factor in the survey for each ward was produced and made public. Nurses in HSO are assigned to work on one designated hospital ward and the nurse responses were attributed to the specific ward; however, physicians and middle managers cover several wards or units. We measured the perceptions about the work environments where the physicians and middle managers work (entire clinical departments).

We defined the work system to include the persons, organisation, tools and technologies, tasks and their work environment.[25] Work environment is the *physical and organisational culture under which healthcare professionals perform their tasks*. Patient safety culture is a component of organisational culture and has been shown to be associated with patient outcomes.[26]

The definitions and measurements of culture vary. For this study, we defined organisational culture as *the behaviours that emerge based on shared values, beliefs, assumptions and norms*.[12 13 27] Previous research has demonstrated more variation in culture assessments between different clinical wards within the same hospital than between the hospitals.[28] We used the ward level as our level of outcomes, as previous studies have shown that data aggregated at the hospital level may mask the hospital unit's differences.[29]

Patient Outcome Data

The Norwegian Institute of Public Health (FHI) reports annually hospital survival probabilities for patients diagnosed with AMI, stroke, hip fracture and hospital-wide survival rate quality indicators for Norwegian hospitals.[30] The mortality rates are estimated based on all-cause deaths, tracking patients with their unique Norwegian Personal Identification Number. The mortality rates were risk-adjusted for age, gender and the Charlson Comorbidity Index scores based on the patients' hospital admissions during the 3 years prior to their hospital admission, type of stroke (cerebral haemorrhage/cerebral infarction) and the total number of hospitalisations during the previous 2 years. In the event where a patient admission involved more than one hospital, the patient mortality probability was split between the two hospitals according to the time the patient spent at each hospital in order to reduce potential bias. The management and analysis methods of the Norwegian survival data are described in great detail by Hassani *et al*.[31 32] This study

Table 1 Work environment factors and survey items

Domain scale	Items
Goals	The unit goals are well known to all employees. I know how I can contribute to the unit to reach its goals. We regularly evaluate our achievements according to our goals.
Improvement	In my unit, we do well in reporting and follow-up on adverse events. It is safe to report adverse events in my/this unit. We openly discuss adverse events and learn from them. In this unit, we encourage each other to think of ways to do things better.
Quality	In my unit different professions collaborate well. We work efficiently in my unit. In my unit high quality is maintained.
Patient centred	In my unit, we listen to the views of patients/clients. In my unit, we are available to patients/clients. In my unit, sufficient information is given to patients/clients.
Respect	In my unit, we respect patients/clients cultural background and religion. In my unit, we comply to keep appointments made. In my unit, we communicate clearly and in an understandable way.
Motivation	Is your work challenging in a positive way. My work tasks engage me. The work is so interesting in itself that it is strongly motivating.
Engagement	Do you look forward going to work. How often does dissatisfaction with your work make you want to change employer. Overall, how satisfied are you with the work you do now.
Commitment	To my friends, I praise this organisation as a great place to work. This organisation inspires me to give my very best job performance. I am proud of my workplace.
Personal development	I can develop professionally through my work. I get sufficient training and advice to do a good job. Is your work organised in a way that lets you improve your abilities? Do you get feedback about the quality of the work you do?
Empowerment	Are you encouraged to participate in decision making? Are you encouraged to speak up when you have a different opinion?
Role expectations	Do you know what your responsibilities are? Do you know what is expected of you at work?
Social climate	Is the social climate in your unit characterised by a team spirit? If needed, can you get support and help from your coworkers? Do you perceive good collaboration in your unit? Have you observed anyone being harassed or bullied at your workplace during the last 6 months? Have you noticed disruptive conflicts in your unit? When conflicts occur, are they handled in a professional manner?
Workload	Is the physical load of your work too burdensome? Is your work pace challenging? Is your workload challenging? Do you perform work tasks for which you need more training?
Autonomy	Can you influence the amount of work assigned to you? Can you set your own work pace?
Role conflicts	Do you have to perform procedures which you feel should be done differently? Are you given assignments without adequate resources to complete them? Do you receive incompatible requests?
Sick leave	Issues at work have contributed to my sick leaves during the last 12 months.

Continued

Table 1 Continued

Domain scale	Items
Leadership	My immediate superior is available to me when I need it. My immediate superior does an excellent job of giving us information about what goes on in our organisation. My immediate superior makes clear performance demands. My immediate superior adheres to what we have agreed on. If I were subjected to violence or threats, I could count on the support of my immediate superior. If I were sick for a more extended period, I could count on the support of my immediate superior.
Patient safety culture	I would feel safe if I was a patient here. Adverse medical events are appropriately handled here.

used risk-adjusted patient data from the FHI for patients admitted to hospitals with AMI, stroke and hip fracture.

The 7-day mortality rate was chosen to study the possible associations between the work environment and mortality for high-risk patients in hospital. A more extended observation period (such as 30 days), might confound the findings and include mortality unrelated to hospital characteristics, such as variations in post discharge care at local nursing homes and home healthcare services. Importantly, the ward mortality rates were calculated for the patients with the included diagnosis only, and not combined with the mortality of patients with other diagnoses, even if they were cared for on the same wards.

The relative mortality rates were defined as the deviation of the hospital unit's mortality rates from the mean mortality rates for the specific diagnosis groups, and then they were divided by the mean mortality rates for the specific diagnosis group. This relative mortality rate can be compared across all three diagnostic groups and allows for pooling of all hospital ward data. The formula we used is as follows:

$$Relative\ morality\ rate_{unit} = \frac{\text{Mean morality rate}_{patient\ group} - Morality\ rate_{unit}}{\text{Mean morality rate}_{patient\ group}}$$

The diagnosis-specific outcomes were aggregated over a 3-year period (2010, 2011, 2012) to ensure adequate statistical power.

Selection of hospitals

All 20 public hospitals in HSO providing acute care were included, with 17 hospitals that treated all three patient diagnoses included in this study, while three hospitals treated only one or two of the three included patient subgroups, for a total of 56 wards. The hospitals varied in size and geographical catchment areas, but had comparable organisational structures and policies, with specially designated patient wards caring for the three subgroups of patients. Patients admitted with a cerebral stroke were treated in stroke units according to national guidelines,[33] whereas patients with a hip fracture were postoperatively cared for on orthopaedic wards. Patients with AMI were subjected to a prehospital triage such that patients with suspected ST-elevation myocardial (STEMI) infarction were transported directly to PCI centres, whereas, patients with non-STEMI infarction were admitted to cardiac units at each of the respective HSO hospitals.

The ward level data on the work environment scores was made available from HSO and the patient mortality rates were made available from the FHI for the 3-year period (2010, 2011, 2012) and were combined using ward names as an identifier.

Statistical analyses

The descriptive data on number of patients treated and survey responses were given as medians and the range due to the non-normal distribution. Normality was tested by the non-parametric Kolmogorov-Smirnov test.[34] The associations between the profession-specific work environments and adjusted patient mortality rates at a specific ward level were analysed using a linear regression model that was adjusted for diagnosis and the annual number of treatments.

The effects of the different work environmental factors were analysed and reported separately, as the limited number of wards studied (n=56) prohibited including all explanatory variables in one single multivariable predictive model. A backward conditional regression analysis was performed by including all the significant work environmental factors from the initial separate analysis (Nurses: patient centred, respect, motivation, engagement, commitment, role expectations, workload, autonomy, role conflicts, sick leave, leadership, patient safety climate; Physicians: none; Managers: quality, motivation, engagement, commitment, personal development, empowerment, social climate, workload, role conflicts). The level for the removal of variables was set to p>0.05. Both the variables available for the backward regression and the final models were evaluated against our hypothesis and prior research and was found to be plausible. In addition alternative approaches as manually built models did not identify better performing models. The work environment effects for physicians, nurses and middle managers were analysed separately to assess how patient mortality was associated with the work environment for the three professions. The statistical significance level was set at 0.05, and the 95% CIs are presented below.

Table 2 Description of survey Respondents by age and profession

	N	Age					Permanent employment	Female
		<30	30–39	40–49	50–59	60+		
Physician	2195	5.50%	40.70%	25.70%	17.90%	10.30%	68.90%	44.30%
Nurses	5602	15.30%	27.40%	26.20%	25.00%	6.10%	92.20%	90.90%
Managers	1036	0.70%	13.00%	33.70%	41.00%	11.60%	96.90%	68.10%

All outcomes and statistical analyses were carried out using the IBM SPSS statistical package V.21.

Patient and public involvement

The study protocol and results of this study have been presented to the regional patient representative committee who supported the study design and its relevance.

RESULTS

The web-based work environment and safety culture data were collected from 2010 to 2012. Nearly 50 000 questionnaires were distributed annually. The response rates for 2010, 2011 and 2012, were 72%, 77% and 75%, respectively. The background information such as gender, age and profession was stated voluntarily. Seventy-eight percent of the respondents defined their occupation. In total, 5602 responses from nurses, 2195 from physicians and 1036 from middle managers were included in the analysis (table 2).

All emergency patients admitted with AMI, stroke and hip fracture were included. Diagnosis-specific mortality rates were calculated for all adult patients (age >18) with the corresponding diagnoses as follows: 17 734 patients admitted with first time AMI (ICD-10 I21.x), 14 442 cerebral stroke patients (ICD-10 I61.63.64), and 13 850 patients admitted over the age of 65 with a hip fracture (ICD-10 S72.0–2). The average length of hospital stay for the patients included in the study was 8.1 days. The 7-day mortality rates varied from 2.8%–7.7%. The mean Charlson Comorbidity Index score was 1.5 (table 3).

The median number of treatments for the 56 wards that participated in this study, (patients within the diagnosis codes included) were 214, with a range varying from 36 to 1242. The median number of work environment survey responses per ward included in the analysis was 87 (range 26–296) for nurses, 32 (range 5–157) for physicians and 15 (range 5–47) for managers.

Hospital staff rated their work environment positively on the 0–100 scale (100 indicating the most favourable condition): the mean scores for nurses, physicians and middle managers were 70.5, 67.2 and 76.3, respectively. The middle managers reported higher scores than physicians and nurses on all but three of the 19 organisational factors, while the nurses scored lower than managers and physicians on nine of the 19 factors. The mean scores and SD for each factor are presented by profession in table 4.

Table 5 shows that several organisational factors were significantly associated with increased patient mortality probability. The backward regression model demonstrated that a higher perceived workload by nurses was significantly associated with increased patient mortality: beta=0.019 (95% CI0.009, 0.028). Nurses: workload p<0.001, respect p=0.002, patient safety culture p=0.003, role conflicts p=0.004, patient centred p=0.005, engagement p=0.005, autonomy p=0.007, sick leave p=0.007, commitment p=0.009, motivation p=0.022, role expectation p=0.031, leadership p=0.045. For middle managers, engagement was significantly associated with 7-day mortality: beta=0.024 (95% CI 0.010, 0.037). Middle managers: engagement p=0.001, personal development p=0.001, motivation p=0.002, social climate p=0.005, workload p=0.006, commitment p=0.010, role conflict p=0.010. No significant association was found between the physician reported work environment scores and patient mortality.

DISCUSSION

We found a strong correlation between organisational work environment and 7-day patient mortality. This study extends findings in the literature demonstrating that the work environment at the 20 South-Eastern Norway Health Region Hospitals were significantly related to their reported 7-day mortality for patients admitted with AMI, stroke and hip fractures. We observed a significant increase in patient mortality in hospital units where nurses reported excessive workload and middle managers reported a lack of professional and organisational engagement. No such associations were found between physician reported work environment and patient mortality.

Hospital staff scored their work environment positive (over 70) on a 0–100 scale (100 being the most favourable), consistent with the general satisfaction reported by Norwegian employees who report higher job satisfaction than employees in other countries.[35] However, there were profession-specific differences that may have contributed to the observed variation in the patient outcomes across the 56 hospital wards. Overall, the middle managers scored higher than physicians and nurses, and nurses scored lowest on more organisational factors than managers and physicians.

Whereas nurses typically worked on one hospital ward, physicians and middle managers usually worked and saw patients on several clinical units, and the assessment of

Table 3 Description of patients and clinical outcomes

	Acute myocardial infarction (first time)	Stroke	Hip fracture (>65 years)
Number of patients	17734	14442	13850
Number of admissions	17734	15235	14427
Death within 7 days, unadjusted	1234 (7.0%)	1180 (7.7%)	399 (2.8%)
Death within 30 days, unadjusted	2030 (11.4%)	2167 (14.2%)	1314 (9.1%)
Mean length of stay (days)	7.0	10.2	7.2
Treated in two or more hospitals	10412 (58.7%)	1915 (12.6%)	1252 (8.7%)
Gender, female	6785 (38.3%)	7297 (47.9%)	10297 (71.4%)
Age, mean	71.0	74.6	83.4
0–17 years	0 (0.0%)	0 (0.0%)	0 (0.0%)
18–49 years	1411 (8.0%)	777 (5.1%)	0 (0.0%)
50–75 years	8854 (49.9%)	6234 (40.9%)	2549 (17.7%)
>75 years	7469 (42.1%)	8224 (54.0%)	11878 (82.3%)
Number of previous hospitalisation during last 2 years, mean	5.8	5.8	5.9
0	3786 (21.3%)	2432 (16.0%)	1652 (11.5%)
1	2799 (15.8%)	2181 (14.3%)	2069 (14.3%)
2	2189 (12.3%)	1914 (12.6%)	2008 (13.9%)
3–5	4130 (23.3%)	3922 (25.7%)	4142 (28.7%)
6+	4830 (27.2%)	4786 (31.4%)	4556 (31.6%)
Charlson Comorbidity Index, mean	1.5	1.3	1.8
0 points	8827 (49.8%)	8131 (53.4%)	5914 (41.0%)
1 points	1646 (9.3%)	1658 (10.9%)	1404 (9.7%)
2 points	3096 (17.5%)	2638 (17.3%)	3493 (24.2%)
3+ points	4165 (23.5%)	2808 (18.4%)	3616 (25.1%)

their work environment should be interpreted accordingly. We stress that it is not the physician or manager perceptions of the patient ward that are being measured, but the explicit perceptions about their work environments where physicians and middle managers work (entire clinical departments) supporting these patient wards.

Twelve of the 19 organisational environmental factors scored by nurses were significantly associated with 7-day patient mortality suggesting that the reported nursing workload may be underappreciated as an important driver for nurse satisfaction.[36] The workload was the most prominent and derived from survey items such as: 'Is the physical load of your work too heavy?', 'Is your workload challenging?' and 'Do you perform work tasks for which you need more training?' These survey items describe the nurses' perceptions about their degree of control over the daily assigned tasks. Our findings reinforce previous studies suggesting that reducing the nurse workload may increase nurse satisfaction and decrease patient mortality.[37–43]

Managers play a critical role, as frontline leaders, in nurturing a psychologically safe culture by setting the norms for speaking up, and promoting shared *meanings* and *practices*.[44–46] The middle managerial roles, situated between the senior hospital management and frontline workers, offers a unique vantage point to assess the maturity of the culture as they implement and oversee strategies and work policies. At the same time, middle managers are responsible for bringing staff concerns and needs back to senior management for consideration and action. Managers can contribute to organisational change by capitalising on this position,[47] as management involvement and engagement have been documented as a positive influence on care delivery systems.[8 48 49] At the same time, top-management and hospital boards engagement in patient safety initiatives can enhance the middle managers' support for a safety culture that can affect patient mortality.[50]

As noted above, we did not find a correlation between patient mortality and physicians' perception of their work environment. The interpretation may not necessarily mean that physician work environment is unrelated to patient outcomes. We think this may be the result of physicians' sense of autonomy,[51] and their responsibility covering patients on multiple departments and service lines simultaneously, and this might affect their responses. Nurses define their work environment in more

Table 4 Organisationalfactor score averages by professions in 56 hospital units

	Nurse		Physician		Manager	
Measures	Mean	SD	Mean	SD	Mean	SD
Goals	62	7	63	9	72	8
Improvement	65	6	69	7	76	6
Quality and efficiency	77	6	77	8	78	8
Patient-centred	76	6	76	6	77	6
Respect for patients	74	4	74	6	76	6
Motivation	75	5	78	7	82	5
Engagement	76	7	75	8	81	7
Commitment	75	9	71	10	81	7
Personal development	62	7	63	8	70	9
Empowerment	55	6	60	9	74	9
Role expectations	89	3	85	6	88	5
Social interactions	83	6	79	8	81	7
Conflicts and bullying	75	5	73	9	81	7
Workload	52	9	54	7	62	7
Autonomy	39	7	38	7	46	9
Role conflicts	68	5	66	7	64	9
Sick leave	86	6	93	8	94	8
Leadership	74	9	75	9	77	12
Patient safety culture	78	8	85	7	90	7

straightforward terms. Their work is generally restricted to one patient ward, and they will have this ward in mind when responding to work surveys. Nurses report to, and are assigned tasks by, a supervisor on a daily basis; the same cannot be said for physicians who have much autonomy about when and where their care activities take place. This structural difference can lead to a physician-as-manager philosophy and a nurse-as-employee philosophy in many healthcare organisations and contribute to variation seen when assessing the impact of clinical interventions on different providers. Previous research has identified differences in culture and work styles within hospitals, and much of this variance was found to be located at the ward and microsystem levels.[29] The responses from physicians working on several hospital wards may attenuate these interward differences, as their answers are based on their 'average experiences' from several clinical environments. This might explain the physician lack of significant association by hospital ward.

We focused on mortality rates as our dependent variable as mortality is well-defined, easily measured, considered useful for estimating the effect of hospital care[32 52] and 'it matters a lot to patients'.[53] Patient mortality rates in Norwegian hospitals and the variation between hospitals is lower than in other OECD (Organisation for Economic Co-operation and developement) countries.[54]However, some Norwegian hospitals have mortality rates significantly higher than the national average. Although a significant part of the variation observed in hospital mortality can be explained by differences in the case-mix and to random variation, it has been suggested that as much as 30%–60% of this variation can be attributed to differences in the practices and quality of patient care.[55] Some hospitals have structures and processes that minimise avoidable patient deaths better than others.[56] Studying these high-performing hospitals can be valuable as they provide deeper insights about which factors are most important for organisational success and reliability.[57]

Our study have several limitations. First, the lack of available, detailed data on the severity of the patient's illnesses at the time of their hospital admission. Our data was case-mix adjusted for age, gender, comorbidity and the number of previous hospitalisations 2 years before the present admission, but not, for the disease severity of each diagnosis. Accordingly, it is challenging to distinguish between patients who may have died from the severity of their illness and less severe cases, for whom the lack of high-quality care ultimately may have reduced their chances of survival.

Second, the study design did not allow the linking of nurse, physician and middle manager' care culture evaluation to the survival of the individual patients under their care. That is, we were only able to relate the average staff evaluations to the average patient mortality for each hospital unit. However, we addressed this by using a diagnosis-specific mortality rate that allowed us to link the work environmental perceptions to the hospital wards where the patients were treated for their primary diagnosis. This afforded us the opportunity to dig deeper into our study dataset to examine the robust links between the work environment and patient outcomes.

Third, the previous safety culture literature may also be subject to publication bias.[58] Few randomised controlled studies exist to demonstrate the causal relationships between organisational culture and clinical outcomes. Thus, our findings are important and have practical implications. Also, the culture evaluation surveys are susceptible to response bias at both the individual and ward respondent levels, but our response rate of 70%–75% compares favourably with those of similar studies.[59] We believe that one should consider other methodologies (qualitative/ethnographic) as useful tools for a deeper exploration of the informal work cultures of the high and low performing wards in our study and how they might affect the success of these hospital wards.[60 61]

Because all the analyses are conducted at the hospital ward level, our sample of 56 wards is relatively small to detect statistical significance, making the size and direction of the correlation coefficients more informative in this context. Although the included hospitals represent nearly half of all Norwegian hospital beds, Norway is a small country and the limited number of units prevents complex multivariate analyses. This could mean that the variables that could have explained the mortality variation could not be controlled

Table 5 Association between organisational factors and 7-day mortality

Relative 7-day mortality (2010–2012) Diagnosis-specific*	Nurse		Physician		Managers	
	Beta (95% CI)	P value	Beta (95% CI)	P value	Beta (95% CI)	P value
Goals	0.008 (–0.006 to 0.022)	0.245	0.007 (–0.003 to 0.019)	0.204	0.009 (–0.003 to 0.021)	0.139
Improvement	0.011 (–0.005 to 0.027)	0.189	0.008 (–0.007 t 0.023)	0.305	0.012 (–0.004 to 0.027)	0.130
Quality	0.017 (–0.001 to 0.034)	0.057	0.004 (–0.008 to 0.016)	0.481	0.014 (0.001 to 0.027)	0.032
Patient centred	0.023 (0.007 to 0.039)	0.005	0.001 (–0.015 to 0.017)	0.882	0.014 (–0.001 to 0.030)	0.075
Respect	0.035 (0.013 to 0.057)	0.002	0.005 (–0.013 to 0.023)	0.577	0.015 (–0.002 to 0.031)	0.077
Motivation	0.024 (0.004 to 0.044)	0.022	–0.004 (–0.019 to 0.010)	0.53	0.028 (0.010 to 0.045)	0.002
Engagement	0.021 (0.007 to 0.036)	0.005	–0.006 (–0.019 to 0.008)	0.407	0.024 (0.010 to 0.037)	0.001
Commitment	0.015 (0.004 to 0.026)	0.009	–0.004 (–0.017 to 0.009)	0.537	0.018 (0.004 to 0.031)	0.010
Personal development	0.012 (–0.002 to 0.025)	0.094	–0.002 (–0.017 to 0.014)	0.826	0.018 (0.007 to 0.029)	0.001
Empowerment	0.010 (–0.006 to 0.025)	0.231	0.000 (–0.012 to 0.011)	0.948	0.011 (0.001 to 0.022)	0.037
Role expectations	0.039 (0.004 to 0.074)	0.031	0.003 (–0.014 to 0.019)	0.750	0.011(–0.008 to 0.031)	0.236
Social climate	0.012 (–0.006 to 0.030)	0.194	–0.008 (–0.020 to 0.004)	0.211	0.019(0.006 to 0.031)	0.005
Conflicts and bullying	0.003 (–0.017 to 0.023)	0.765	–0.009 (–0.021 to 0.002)	0.111	0.010 (–0.005 to 0.026)	0.180
Workload	0.019 (0.009 to 0.028)	<0.001	–0.002 (–0.016 to 0.012)	0.742	0.018 (0.005 to 0.031)	0.006
Autonomy	0.021 (0.006 to 0.035)	0.007	–0.005 (–0.019 to 0.009)	0.496	0.009 (–0.002 to 0.021)	0.106
Role conflicts	0.027 (0.009 to 0.046)	0.004	0.002(–0.012 to 0.016)	0.786	0.015 (0.004 to 0.026)	0.010
Sick leave	0.021 (0.006 to 0.036)	0.007	–0.003 (–0.017 to 0.010)	0.656	0.009 (–0.003 to 0.021)	0.125
Leadership	0.011 (0.000 to 0.022)	0.045	0.002(–0.010 to 0.014)	0.726	0.008 (–0.001 to 0.017)	0.067
Patient safety climate	0.017 (0.006 to 0.029)	0.003	0.005(–0.009 to 0.020)	0.449	0.003 (–0.013 to 0.018)	0.717

Results in red indicate statistical significance.
*The relative 7-day survival rates (2010–2012) were adjusted for age, gender, number of hospitalisations during the previous 2 years and a Charlson Comorbidity Index score.
†All analyses were adjusted for diagnoses and the annual number of treatments on each hospital ward.
‡Statistical significance at the p<0.05 level.

for. We cannot rule out the possibility that the associations we observed may therefore be non-causal.

Finally, our study reflects the context and distinct constraints of the Norwegian healthcare delivery systems, which may be different from other healthcare systems. Norwegian employees generally perceive their work environment as more positive than staff in other countries,[35] and patient survival is relatively high.[54] The study, however, probably carries relevance for the population as a whole, and has strong external generalisability to other countries, because it stems from a large and diverse sample of hospitals.

CONCLUSIONS

Patients fare better in hospitals in which employees declare a supportive and nurturing place to work. Our data suggest that if nurses feel supported, and managers feel engaged in their work, these organisational features of care delivery systems can affect patient hospital mortality. A deeper understanding of these cultural and organisational influences, and how they can increase the performance toward achieving the overall organisation goals, is critical to developing meaningful interventions to improve patient outcomes. Assessment of these organisational and cultural metrics might be quite useful in monitoring the safety of hospitals and supporting hospital quality improvement efforts.

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III

PLOS ONE

RESEARCH ARTICLE

Hospital work environments affect the patient safety climate: A longitudinal follow-up using a logistic regression analysis model

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Abstract

Background

Occupational worker wellness and safety climate are key determinants of healthcare organizations' ability to reduce medical harm to patients while supporting their employees. We designed a longitudinal study to evaluate the association between work environment characteristics and the patient safety climate in hospital units.

Methods

Primary data were collected from Norwegian hospital staff from 970 clinical units in all 21 hospitals of the South-Eastern Norway Health Region using the validated Norwegian Work Environment Survey and the Norwegian version of the Safety Attitudes Questionnaire. Responses from 91,225 surveys were collected over a three year period. We calculated the factor mean score and a binary outcome to measure study outcomes. The relationship between the hospital unit characteristics and the observed changes in the safety climate was analyzed by linear and logistic regression models.

Results

A work environment conducive to safe incident reporting, innovation, and teamwork was found to be significant for positive changes in the safety climate. In addition, a work environment supportive of patient needs and staff commitment to their workplace was significant for maintaining a mature safety climate over time.

Conclusions

A supportive work environment is essential for patient safety. The characteristics of the hospital units were significantly associated with the unit's safety climate scores, hence improvements in working conditions are needed for enhancing patient safety.

Introduction

Providing high value, patient-centered, and quality care while preventing patient harm remains a worldwide challenge [1]. During the past two decades, acute-care hospitals have been challenged as never before to develop and sustain operating systems to ensure patient safety. Many factors, latent and active, interact to cause adverse events [2] and Vincent and colleagues describe safety climate and work environment as important factors influencing clinical practice [3]. Healthcare organizations must consider issues across whole systems, including organizational and cultural factors affecting the system in which care is provided if they are to improve their patient outcomes [4,5].

Patient safety culture, a specific aspect of organizational culture, is increasingly recognized as a critical determinant in reducing patient risk due to adverse medical care [1,4,6,7]. Patient safety culture refers to the collection of individual and group values, attitudes, and practices that guide hospital staff behavior [8]. Addressing organizational culture is viewed as essential to health system transformation [9,10] and remains an important factor in the successful implementation and sustainability of quality improvement initiatives on the front lines of care [11]. The organization's culture also shapes staff perceptions of "normal" behavior. In essence, the culture on the front line of care is "the way things are done here" and is highly influenced by the organization-wide culture and norms [12]. Zhou et al. captured this well, saying that *"the safety culture of an organization can motivate workers to engage in safe behaviors and facilitate the translation of these behaviors into daily practice, and can also influence the ability of staff to raise concerns regarding safety and the ability of managers to respond to those concerns"* [13].

According to most up to date safety science, the analysis of working processes and organizational conditions are necessary to understand how adverse events can be prevented [14,15]. There is significant potential to enhance patient safety performance and eliminate hazards in work environments with a mature patient safety culture [16,17]. The staff perceptions of their work environment can vary over time with changes in work and the psycho-social working conditions including leadership, patient safety climate, competence, training, ability to safety speak up, and organizational design characteristics [18–21]. These factors may influence safety precautions, routines, and ultimately patient safety and quality of care. Organizations with diverging cultural perceptions and low social trust among staff are regarded as having weak and immature cultures, with a limited ability to nurture and support staff best practices, and often leading to unpredictable and harmful outcomes [22]. A consistent association between a positive (mature) patient safety culture and beneficial clinical outcomes is demonstrated in previous studies [20,23–27]. Safety culture is necessary to shape front-line staff behaviors and encourage safe-conduct [28]. Reliably measuring patient safety culture is challenging [29]. A promising approach to assess the safety culture in caregiving units is to use validated questionnaires [30]. According to Sexton et al., when using questionnaires to study group-level perceptions, the most appropriate term to use is climate [31]. Climate refers to the shared perceptions

about norms, processes, and policies related to patient safety and provides a snapshot of how staff perceive aspects of their culture [30].

We do not fully understand what factors explain the wide variation in culture despite the emphasis on safety culture as an important strategy to patient safety [4,12,32,33]. We hypothesize that the work environment is related to how patient safety is handled on care giving unit. This study aims to explore the association between work environment characteristics and the development in safety climate.

Materials and methods

Design and data sources

This study was conducted using a longitudinal prospective design, combining data from the validated annual Work Environment Survey (WES) and the safety climate data from the Norwegian Safety Attitude Questionnaire (SAQ), both country-wide, large multisite organizational surveys.

Setting and sample

Hospital staff with more than three months, or 30% employment before the survey administration at 21 hospitals in nine hospital trusts in South-Eastern Norway were eligible for inclusion. Two of the hospitals were teaching hospitals with $>$ 600 beds, 6 hospitals had $<$ 100 beds, and one hospital was a rehabilitation hospital. The sample for this study was retrieved from the 970 clinical units participating in all three surveys (WES 2011, SAQ 2012 and SAQ 2014) with more than five responders from each unit and where no major reorganization had taken place between 2011 and 2014. Clinical units were defined as units where employees have direct patient contact.

Questionnaire

Two survey instruments provided data for this study. The Norwegian SAQ, adapted from the Safety Attitude Questionnaire, generic version (SAQ) [34,35] and validated in Norwegian settings [36] was used to evaluate the safety climate among staff. The Work Environment Survey (WES), based on the General Nordic Questionnaire for Psychological and Social Factors at Work (QPSnordic) [37] was used to evaluate staff perceptions about their work environment characteristics.

Safety Attitude Questionnaire (SAQ) (Table 1). The Norwegian SAQ used for the National Patient Safety Campaign consists of the factors Teamwork Climate and Safety Climate [38]. However, for this study only data retrieved from the safety climate factor were included. The exclusion of a factor was done to minimize the overlap of items between the WES and SAQ surveys. The subset of safety climate from the larger SAQ has previously been validated and the psychometrics are sound [12]. The safety climate factor consists of seven

Table 1. Safety Attitudes Questionnaire (SAQ) factors and items.

FACTOR	Items
Safety Climate	I would feel safe being treated here as a patient Medical errors are handled appropriately in this unit I know the proper channels to direct questions regarding patient safety in this unit I receive appropriate feedback about my performance In this unit, it is difficult to discuss errors I am encouraged by my colleagues to report any patient safety concerns I may have The culture in this unit makes it easy to learn from the errors of others

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unit level items presented in Table 1, addressing staff perspectives concerning patient safety, support and feedback, and incident reporting. All items were scored on a five-point Likert scale (i.e., from "1 = strongly disagree", "2 = disagree", "3 = neutral", "4 = agree" and "5 = strongly agree") and were converted to a 0–100 scale [39] and given the values 0, 25, 50, 75, 100. A score of zero represents the most undesirable result, and 100 represents the most desirable. Negatively worded items were reversely scored to match positively worded items.

We ascribed a mature safety climate to units where more than 60% of the staff responded positively to the safety climate items (scores above 75 on a 0–100 point scale). The Norwegian Directorate of Health used this definition in its national report on patient safety culture measurements in 2012 and 2014 [40]. The definition is based partly on Pronovost et al. in their assessment of progress toward improving safety culture by achieving at least 60% agreement at the unit-level and in line with Zohar et al. who defined climate strength by the degree of staff consensus about the importance of patient safety [22,41].

The Work Environment Survey (WES) (Table 2). The Work Environment Survey (WES) instrument is a validated work environment questionnaire based on QPSnordic. The questionnaire is adapted to the Nordic context to provide a comprehensive picture of workers' perceptions about their work environment [37]. The instrument includes 18 factors, with each factor consisting of 1 to 6 items, please see Table 2. The response to each item is rated using a 5-point Likert scale (for some items "1 = Strongly disagree", "2 = Disagree", "3 = Neither disagree nor agree", "4 = Agree", "5 = Strongly agree" or, where appropriate, "1 = Never/very seldom", "2 = Seldom", "3 = Sometimes", "4 = Quite often", "5 = Very often/always") and each item is converted to a 0–100 scale. The Patient Safety Culture factor was excluded from the analysis as safety climate was the outcome variable in this study.

Data collection

The web surveys were distributed by email to eligible staff. Responding to the survey was encouraged by management and time to complete the survey was made available during work hours. Management reminded staff to respond to the survey. WES data was collected in 2011 and SAQ data were collected in years 2012 and 2014. The surveys were anonymous, and identified only with unit affiliation.

Ethics approval

The Medical and Health Research Ethics Committee (REC) in the South-Eastern Norway Region approved the study with a waiver of informed consent since all data retrieved from the surveys were anonymous.

Study outcomes

The primary outcome in the study was patient safety climate. We studied three specific outcomes associated with the development of a safety climate:

1. Change in safety climate score over two years (2012–2014).
2. Raising safety climate to a mature level (>60% of staff scores 75 or higher).
3. Maintaining a mature safety climate over time.

Table 2. Work Environment Survey (WES) factors and items.

Factors	Items
Improvement	In my unit, we do well in reporting and follow up on adverse events It is safe to report adverse events in my/this unit We openly discuss adverse events and learn from them In this unit, we encourage each other to think of ways to do things better
Quality	In my unit different professions collaborate well We work efficiently in my unit In my unit high quality is maintained
Patient-Centered	In my unit, we listen to the views of patients/clients In my unit, we are available to patients/clients In my unit, sufficient information is given to patients/clients
Respect	In my unit, we respect patients'/clients' cultural background and religion In my unit, we ensure that we keep made appointments In my unit, we communicate clearly and in an understandable way
Motivation	Is your work challenging in a positive way My work tasks motivate me The work is so interesting in itself that it is strongly motivating
Engagement	Do you look forward to go to work How often does dissatisfaction with your work make you want to change employer Overall, how satisfied are you with the work you do now
Commitment	To my friends, I praise this organization as a great place to work This organization inspires me to give my very best job performance I am proud of my workplace
Personal Development	I can develop professionally through my work I get sufficient training and advice to do a good job Is your work organized in a way that lets you improve your capacities Do you get feedback about the quality of the work you do
Empowerment	Are you encouraged to participate in decision making Are you encouraged to speak up when you have a different opinion
Role Expectations	Do you know what your responsibilities are Do you know what is expected of you at work
Social Climate	Is the social climate in your unit characterized by a team spirit If needed, can you get support and help from your coworkers Do you perceive good collaboration in your unit
Conflict	Have you observed anyone being harassed or bullied at your workplace during the last six months Have you noticed disruptive conflicts in your unit When conflicts occur, are they handled in a professional manner
Workload	Is the physical load of your work too heavy Is your work pace challenging Is your workload challenging Do you perform work tasks for which you need more training
Autonomy	Can you influence the amount of work assigned to you Can you set your own work pace
Role conflicts	Do you have to perform procedures which you feel should be done differently Are you given assignments without adequate resources to complete them Do you receive incompatible requests
Sick leave	Issues at work have contributed to my sick leaves during the last 12 months
Leadership	My immediate superior is available to me when I need it My immediate superior does an excellent job of giving us information about what goes on in our organization My immediate superior makes clear performance demands My immediate superior adheres to what we have agreed upon If I were subjected to violence or threats, I could count on the support of my immediate superior If I were sick for a more extended period, I could count on the support of my immediate superior
Patient Safety Culture	I would feel safe if I was a patient here Adverse medical events are appropriately handled here

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Statistical analysis

Bivariate regression analyses were performed to identify which of the 17 hypothesized explanatory factors listed in Table 2 were significantly associated with improvements in the safety climate scores and with the odds of achieving and maintaining a mature safety climate. Factors with p-values not exceeding 0.05 were included in the multivariate explanatory model.

A stepwise linear regression model was used to assess the work environment characteristics most significant for predicting a change in safety climate score. A backward regression was performed to identify the most significant factors predicting a change in the unit's safety climate. A forward logistic regression model was used to calculate the predictor odds ratio (OR) of raising a unit's safety climate to a mature level (yes/no) and in maintaining a mature safety climate level over time (yes/no).

The models' fit to the data was assessed by the r^2_{adj} and the Nagelkerke R-squared [42]. To adjust for the potential for improvement at baseline, the unit SAQ_{2012} score was included in all models, as was the hospital unit size. All reported P values are two-sided. P values equal/lower than 0.05 were considered statistically significant. The 95% confidence intervals are presented for B and ORs. The data were analyzed using SPSS statistical software package for Windows (version 25; IBM Corp, Armonk, NY, USA).

Results

A total of 91,225 surveys were completed over a three year period. Table 3 shows the response rates ranging from 57% to 77%. The mean size of the included clinical units was 26 employees, ranging from five to 110. Individual perceptions were aggregated by clinical unit, providing a means score (snapshot) of work environment characteristics and safety climate on a given unit [31]. At baseline 2012, 440 units did not have a mature safety climate and were well positioned to improve their safety climate. Five hundred and thirty units had the potential to maintain their mature climate. Fig 1 shows that during the two-year interval studied, 2012–2014, 172 units (18%) raised their safety climate levels to a mature level and 401 units (41%) maintained a level of a mature safety climate.

Table 4 shows the 14 factors identified by the initial univariate analyses that were included in a multivariate backward regression model adjusted for the SAQ_{2012} and unit size. The data were adjusted for unit size as larger units significantly reported lower WES scores than smaller units and was corroborated by previous research [43]. The variables were eliminated from the regression analysis to identify the model that best explains the data and to reduce the multicollinearity problems between the factors. Table 5 presents the three factors which significantly predicted a change in the safety climate levels: *Improvement*, *Quality*, *and Patient-Centered*. Together, the three factors explain nearly 30% of the variation found in the hospital unit's safety climate scores. Change in score is depicted as Δ in the table.

The logistic regression model analyzed each of the 17 factors adjusted for the SAQ_{2012} and unit size to identify the unit characteristics most significantly associated with development of a unit-level maturity. To raise the safety climate from a non-mature level to a mature level, 12 of

Table 3. Response rate for each survey year.

YEAR	2011 WES	2012 SAQ	2014 SAQ
No. surveys distributed	55 815	40 737	41 052
No. surveys returned	42 977	24 849	23 399
Response rate	77%	61%	57%

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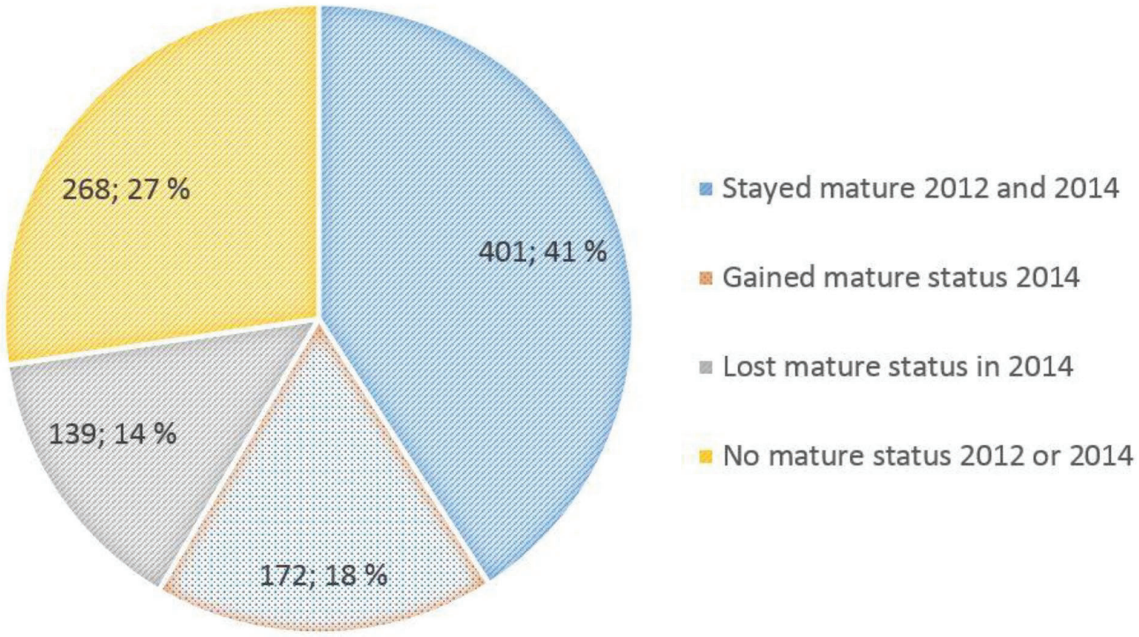

Fig 1. Units that changed their level of mature safety climate between 2012 and 2014, by number of units and percentage.

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Table 4. Each WES factors univariate association with the change in climate score.

Factors	Δ Safety climate score* (n = 970), B(95% CI)
Improvement	**0.15 (0.10, 0.21)**
Quality	**0.18 (0.12, 0.24)**
Patient-Centered	**0.16 (0.10, 0.23)**
Respect	**0.21 (0.14, 0.28)**
Motivation	**0.11 (0.05, 0.16)**
Engagement	**0.09 (0.04, 0.14)**
Commitment	**0.11 (0.06, 0.15)**
Personal Development	**0.08 (0.03, 0.12)**
Empowerment	**0.07 (0.03, 0.11)**
Role Expectation	**0.17 (0.10, 0.24)**
Social Climate	**0.13 (0.07, 0.18)**
Conflict	**0.05 (0.01, 0.09)**
Workload	0.03 (-0.01, 0.07)
Autonomy	0.01 (-0.02, 0.03)
Role Conflict	**0.11 (0.05, 0.17)**
Sick Leave	0.04 (-0.1, 0.09)
Leadership	**0.04 (0.002, 0.09)**

* Adjusted for score SAQ_{2012}.

Statistical significance at the $P < 0.05$ level in bold.

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Table 5. Work environment factors most significantly associated with a change in climate score.

Factors	Δ Safety climate score* (n = 970), B(95% CI)
R^2_{adj}	0.284
Improvement	0.092 (0.030, 0.154)
Quality	0.084 (0.008, 0.161)
Patient-Centered	0.084 (0.009, 0.158)

Only factors significant in at least one of the models are presented.

* Adjusted for unit size and score SAQ_{2012}.

Statistical significance at the $P < 0.05$ level.

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Table 6. Hospital unit work environment factors associated with the unit-level mature safety climate score.

Factor	Raising safety climate to a mature level (n = 440)* OR(95% CI)	Maintaining mature safety climate level (n = 530)* OR(95% CI)
Nagelkerke R^2 (variance explained)	0.053	0.158
Improvement	1.043 (1.019, 1.068)	1.041 (1.007, 1.077)
Patient-Centered		1.062 (1.021, 1.105)
Commitment		1.037 (1.009, 1.066)

Factors significant in at least one of the models are presented.

* Adjusted for unit size.

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the 17 factors needed to be significant at a $P<0.05$ level (six at the $P<0.01$). To maintain a mature level, all 17 factors needed to be significant at a $P<0.01$ level.

The odds ratio (OR) was calculated for the two binary outcome variables: raising safety climate to a mature level (yes/no) and maintaining a mature safety climate level over time (yes/no). Three of the factors were retained in the model: Improvement, Patient-Centeredness, and Commitment (Table 6). Scoring one point higher on the Improvement factors was associated with an increase of 4.3 percent in the odds of raising to a mature safety climate level. For maintaining a mature safety level, one additional point on Improvement, Patient-Centered and Commitment factors, was associated with an increase of 4.1, 6.2 and 3.7 percent, respectively. An explained variance (Nagelkerke R^2) of 5.3 percent and 15.8 percent indicates that developments in safety climate might be explained by explanatory variables not included in our logistic model.

Discussion

The major findings of this study are the significant associations of organizational factors measured in the work environment survey and a change in the unit's safety climate scores. The most prominent change factors associated with higher and mature safety climates were Improvement, Patient-Centered, Quality, and Commitment. These factors highlight the key organizational activities that ensure patient safety. The Improvement factor was significantly associated with all three study outcomes and displayed both the culture of reporting adverse events and the emotional characteristics of the unit environment where staff feel safe to speak up and "stop-the-line" if hazards are identified without fear of negative sanctions against them [44–46]. It could be argued that the Improvement factor is just one reflection of a safety

climate: that is, perceived physiological safety and incident reporting is as likely to shape the safety climate as the safety climate supports staff attitudes [47]. However, McFadden et al. found that the patient safety climate and quality improvement were not interchangeable, but act in concert, and together can produce greater combined benefits [48]. We define quality in our survey based on the items teamwork and efficiency. It is widely recognized in the patient safety literature that teamwork and team performance are important in providing safe patient care [4,49]. A review by Manser [50] found that teamwork including coordination, communication, and leadership, are crucial to assuring patient safety. This finding suggests that strong unit networks and management resources for change are needed to create the important conditions for developing and nurturing a positive safety climate.

Patient preferences and views are essential sources for system co-design by making patient participation and agency a significant driver to attain better patient outcomes [51–54]. Patient-centered care calls for leadership styles that value patient contributions and encourage co-participation in decision-making [50,55]. There are multiple barriers to patient involvement, but engaged and involved employees are more likely to involve patients in a meaningful manner [56]. Organizational commitment may indicate a willingness to engage and make extra efforts to keep a work environment safe. Staff that perceive their work environment as supportive of their clinical practice, in which their views were valued, and the care improvement is the norm, are more likely to recommend their workplace to colleagues and patients [57]. The loyalty commitment that encourages staff to stay in their roles, and do their best may also affect patient safety outcomes.

Our analyses suggests that organizational targeted strategies to raise the safety climate to a mature safety level should be slightly differentiated from strategies aimed at maintaining a mature climate. We found that leadership efforts related to the Improvement factor are a key initiative for lifting a hospital unit to a mature climate level where more than 60% of the staff respond positively to the survey items. To maintain an established mature safety climate over time, the factors of Patient-Centered and Commitment are significant. A cautious interpretation could be that a safety climate is enabled when management is demonstrably focusing on quality and patient needs. However, to maintain a mature safety climate, the hospital management must go further, and create a nurturing and entrusting organizational setting that supports the staff to speak up when care is unsafe, and the staff feel committed, loyal, and actively involved in their unit's improvement efforts.

This study has several limitations and must be interpreted in the context of its design. First, the staff survey measures the staff perception of their work environment and safety climate. We did not observe the actual unit work environment or culture, nor did we have objective clinical quality measures. Based on previous research we studied the safety climate at the hospital unit level as the variation in safety climate is more likely masked when aggregated to a hospital level [58,59]. We are aware, however, that not only the characteristics of each unit, but the overall organizational culture also influences the unit culture [60]. Moreover, hospitals represent a cultural mosaic consisting of several subcultures with varying values and attitudes not captured in this study [61]. Second, we did not include all the factors that could affect our results. Success and failures in developing an optimal patient safety climate in hospital units may depend on effectiveness of local leadership efforts to customize strategize at each hospital unit. Third, the study measured change in safety climate over time. We cannot rule out that the observed changes in the climate scores were due to unforeseen factors other than the ones measured. These limitations invite a more detailed analysis of factors affecting hospitals' safety climate and unique unit characteristics over time and under variable environmental factors.

The study is susceptible to response bias. We used the longitudinal study design to assess staff perception of their work environment and safety climate in the same 970 hospital units

over time. Our response rate compares favorably to response rates in other studies [62]. We are well aware that hospital staff might answer the survey questions untruthfully or misleadingly, for example, if they feel pressure to give socially acceptable answers or due to their fears of speaking up. These influences might include insecurity about the survey response anonymity, and the responders' mood or cultural features. However, aggregating individual questionnaire responses across a unit lessens the effect of idiosyncratic or individual attitudes [63]. Finally, our study reflects the context and distinct constraints of the Norwegian healthcare system, which might differ from other healthcare systems and limit its generalizability. Norwegian employees generally perceive their work environment as more positive than staff in other countries [64]. Norwegian work life is highly regulated to secure staff's physical and psychological wellbeing and national efforts such as monitoring staff perception on their work environment and safety climate are implemented in all Norwegian hospitals. Still variation was identified between the clinical units in our study, indicating the potential to improve the culture even where staff perceive their general work conditions as positive. We believe that our study's results have relevance for the population as a whole and have external generalizability to other countries as the study dataset stems from a large and diverse representative sample of hospital units across South Eastern Norway.

Conclusions

Our findings have important implications for hospital management practices. We demonstrated that the work environment characteristics were associated with significant changes in raising and maintaining a safety climate—essential for delivering safe and reliable care. Creating a hospital work environment where staff physical and psychological safety are a priority is key to an effective patient safety improvement strategy.

We believe that safety culture efforts should not be restricted to inspiring staff to reduce risks to their patients but should also include genuine staff buy-in and support of improvement efforts by hospital management to improve the usability and support for robust occupational environments.

Supporting information

S1 STROBE checklist. STROBE statement—Checklist of items that should be included in reports of observational studies.
(DOCX)

S1 File.
(XLSX)

S2 File.
(DOCX)

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