Patient Safety Culture

Measurement - Leadership - Improvement

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MEASUREMENT - LEADERSHIP - IMPROVEMENT

BY
SOLVEJG KRISTENSEN

DISSERTATION SUBMITTED 2016

AALBORG UNIVERSITY
DENMARK

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by

Solvejg Kristensen

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DENMARK

Dissertation submitted

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CURRICULUM VITAE

Solvejg Kristensen is a Master of Health Science from Aarhus University, Denmark. In addition, Solvejg has completed a number of Graduate Diploma courses in Business Administration at the School of Business and Social Sciences, Aarhus University.

Since 2004 her field of work has been quality of care and patient safety within Danish and European health care systems, e.g. definitions and concepts, method development, indicator monitoring, improvement projects, network, sharing and learning activities and research.

Solvejg has worked as a quality and safety officer at Aarhus University Hospital Risskov, as a deputy manager and a regional risk manager at the Unit for Clinical Quality and Patient Safety, Central Denmark Region, and as a project manager for EU projects for the European Society for Quality in Healthcare, and the Danish Society for Patient Safety. She has taken part in several EU co-funded action and research projects.

Since 2007, Solvejg has been an external lecturer and supervisor at Danish universities within the fields of quality of care and patient safety.

Solvejg has extensive experience as a speaker at scientific conferences, and she has published research within child psychiatry and quality of care.

ENGLISH SUMMARY

BACKGROUND

Patient safety is a serious health concern in acute care hospitals, with one in ten patients exposed to adverse events during hospitalisation. Efforts to make patients safer have met with mixed success. Implementation of a safety culture has been suggested as a means of improving patient safety, but working systematically with assessment and development of patient safety culture is still in its infancy in Denmark.

OBJECTIVES

The main objectives of this dissertation were to:

I. Give a brief, easily accessible state-of-the-art overview of patient safety culture to professionals and leadership in the Danish health care system.
II. Adapt the Safety Attitudes Questionnaire for use in Danish hospitals, assess its construct validity and reliability, and present Danish benchmark data.
III. Investigate the patient safety culture before and after a leadership intervention.
IV. Investigate the patient safety culture of the National Hospital of the Faroe Islands prior to introducing hospital level quality management initiatives.

Objective I was investigated in Study I, objective II in Study II, and so on.

STUDY I

Study I was a literature study. It was found that patient safety culture represents the shared assumptions, values, attitudes and behaviours of professionals that characterise the safety of patients in a health care setting. Effective methods to create and develop the patient safety culture are characterised by strong leadership engagement, e.g. patient safety leadership walk rounds and multi-faceted unit-based programmes. The SAQ was identified as the questionnaire most often used to document a relationship between enhanced patient safety culture and enhanced patient safety, e.g. reduced mortality, community acquired pressure ulcers and readmissions, or promotion of family satisfaction.

STUDY II

Study II was a cross-sectional study; a Danish version of the SAQ (SAQ-DK) was distributed to 1,263 staff members of a mixed somatic psychiatric sample. SAQ covers six dimensions of patient safety culture, and results are calculated using two climate metrics. SAQ-DK showed acceptable Goodness-of-fit indices. Inter-scale correlations were moderate to high, and scale reliability acceptable. Proportions of

participants with a positive attitude to each of the six SAQ-DK scales did not differ between the somatic and psychiatric staff.

STUDY III

Study III was a repeated cross-sectional experimental study; across two assessments staff from a large psychiatric department answered SAQ-DK. A multi-component educational intervention was implemented in the management to strengthen leadership knowledge and skills. The perception among frontline staff of teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management improved over time. For safety climate, a perception gap between the frontline staff and the clinical leaders vanished over time. Staff leaving the department after the first assessment rated job satisfaction lower than staff staying on.

STUDY IV

Study IV was a cross-sectional study implemented at the National Hospital of the Faroe Islands. SAQ-DK was distributed electronically to 557 staff members from five clinical centres and one administrative unit. Safety climate was identified as the dimension with the greatest variability across clinical areas. The diagnostic centre had the most favourable culture of all centres. A perception gab between frontline staff and the clinical leaders was identified for teamwork climate, safety climate and working conditions. Among three management levels, the frontline staff perceived the unit management as most favourable and the top management as least favourable.

CONCLUSIONS

The current evidence supporting a positive relationship between safety culture and patient safety is still sparse, as is the literature documenting effective methods to create and develop the safety culture. It does, however, highlight strong leadership engagement as an important characteristic.

The Danish version of the SAQ is now available for use to evaluate hospital staff perceptions of patient safety culture.

Exceptional improvements in patient safety culture were found after addressing the clinical leaders' skills and knowledge with a multi-component educational intervention programme.

Results from the Faroe Islands give a seldom snapshot of the safety culture in a modern western hospital prior to implementation of hospital-wide quality management initiatives. A perception gap between the frontline staff and the clinical leaders was identified, and staff's perceptions of the leadership's support for patient safety varied by management level.

DANSK RESUME

BAGGRUND

Patientsikkerhed er et alvorligt problem i hospitalsvæsnet, hvor én ud af ti patienter udsættes for utilsigtede hændelser under indlæggelse. Forbedringsinitiativer rettet mod dette problem har haft blandet succes. Implementering af en patientsikkerhedskultur er blevet foreslået som en løsning, dog er arbejdet med at måle på og udvikle patientsikkerhedskulturen stadig på et tidligt stadie i Danmark.

FORMÅL

Hovedformålene med denne afhandling var at:

I. give et kort, lettilgængeligt opdateret overblik over patientsikkerhedskultur til professionelle og ledere i det danske sundhedsvæsen
II. tilpasse Safety Attitudes Questionnaire (SAQ) til brug på danske hospitaler og vurdere spørgeskemaets begrebsvaliditet og pålidelighed, samt præsentere danske benchmarking data
III. undersøge patientsikkerhedskulturen før og efter en ledelsesintervention
IV. undersøge patientsikkerhedskulturen på Landssygehuset på Færøerne før implementering af kvalitetsforbedringer på hospitalsniveau.

Formål I blev undersøgt i Studie I, Formål II i Studie II og således.

STUDIE I

Studie I var et litteraturstudie. Patientsikkerhedskultur blev præsenteret som sundhedspersonalets delte antagelser, værdier, attituder og adfærd relateret til patienternes sikkerhedstilstand i sundhedsvæsnet. Metoder, der er effektive til at skabe og udvikle en patientsikkerhedskultur, er karakteriseret ved et stærkt ledelsesengagement, fx patientsikkerhedsrunder eller multikomponente forbedringsprogrammer på afsnitsniveau. SAQ blev identificeret, som det spørgeskema, der oftest er brugt til at dokumentere en sammenhæng mellem forbedring af patientsikkerhedskulturen og en forbedring af patientsikkerheden, fx reduktion af dødelighed, liggesår, genindlæggelser eller en forbedring af pårørendetilfredshed.

STUDIE II

Studie II var et tværsnitsstudie, hvor en dansk version af SAQ (SAQ-DK) blev udsendt til 1.263 personalemedlemmer fra en blandet somatisk og psykiatrisk stikprøve. SAQ dækker seks dimensioner af patientsikkerhedskultur, og resultaterne beregnes ved brug af to resultatmål. SAQ-DK viste tilfredsstillende Goodness-of-fit værdier. Korrelationerne mellem skalaerne var moderate til høje, og skalaernes

pålidelighed tilfredsstillende. Der var ikke forskel på andelen af deltagere fra somatisk henholdsvis psykiatrisk regi med en positiv holdning til hver af de seks SAQ-DK dimensioner.

STUDIE III

Studie III var et gentaget tværsektorielt eksperimentelt studie; sundhedspersonale fra en stor psykiatrisk afdeling svarede på SAQ-DK to gange. Afsnitsledelserne deltog i et multikomponent uddannelsesprogram med henblik på at styrke kvalitetsledelse såvel som ledelse generelt. Over tid sås forbedring i frontlinepersonalets opfattelse af samarbejdsklimaet, sikkerhedsklimaet, jobtilfredsheden, arbejdsbetingelserne og opfattelsen af den daglige ledelse. Den forskel i opfattelsen af sikkerhedsklimaet, som var mellem frontlinepersonalet og ledelserne ved den første måling, forsvandt over tid. Personale, som rejste fra afdelingen i perioden mellem målingerne, havde en mindre positiv opfattelse af patientsikkerhedskulturen end personale, som blev.

STUDIE IV

Studie IV var en tværsnitsundersøgelse på Landssygehuset på Færøerne. SAQ-DK blev udsendt elektronisk til 557 personalemedlemmer fra fem kliniske centre og en administrativ enhed. Der var størst variation i opfattelsen af kulturen mellem afsnit og ambulatorier for sikkerhedsklimaet. Diagnostisk center havde den mest favorable kultur af de fem kliniske centre. Frontlinjepersonalet og de kliniske ledere opfattede samarbejdsklimaet, sikkerhedsklimaet og arbejdsbetingelserne forskelligt. Frontlinjepersonalet oplevede mest opbakning til patientsikkerhedsarbejdet fra afsnitsledelsen og mindst opbakning fra hospitalsledelsen.

KONKLUSION

Den evidens, der for nuværende dokumenterer et positivt forhold mellem patientsikkerhedskultur og patientsikkerhed, er sparsom. Det samme er den litteratur, som dokumenterer effektive metoder til forbedring af patientsikkerhedskulturen. Sidstnævnte fremhæver et stærkt ledelsesengagement som et vigtigt element.

Den danske version af SAQ kan nu anvendes til evaluering af opfattelse af patientsikkerhedskulturen på hospitaler.

Enestående forbedringer i patientsikkerhedskulturen blev fundet efter et multikomponent uddannelsesprogram, der adresserede ledelsernes færdigheder og viden.

Resultaterne fra Færøerne giver et billede af patientsikkerhedskulturen på et moderne vestligt hospital inden implementering af kvalitetsforbedringer på hospitalsniveau – dette er sjældent. Der var forskel på ledelsens og frontlinjepersonalets opfattelse af kulturen og frontlinjepersonalets opfattelse af ledelsens opbakning til patientsikkerhed varierede med ledelsesniveauet.

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"For the travellers the stars are guides.
For others they are nothing but tiny lights."

Antoine de Saint-Exupéry in The Little Prince

Undertaking this PhD has been a life-changing experience, and it would not have been possible without the support I received from many people.

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Solvejg Kristensen

Virum, June 23, 2016

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LIST OF PAPERS

The present thesis is based upon the following four papers:

I. Kristensen S, Bartels PD, Sabroe S, Mainz J. Patientsikkerhedskultur kan facilitere høj klinisk kvalitet. Ugeskr Laeger 2014;16(176):1483-6.

II. Kristensen S, Sabroe S, Bartels PD, Mainz J, Christensen KB. Adaption and Validation of the Safety Attitudes Questionnaire for the Danish hospital setting. Clinical Epidemiology 2015;17:149-60.

III. Kristensen S, Christensen KB, Jaquet A, Moeller-Beck C, Sabroe S, Bartels PD, Mainz J. Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study. BMJ Open 2016; 6010180. Dor:10.1136/bmjopen-2015-01080.

IV. Kristensen S, Túgvutein N, Zachariassen H, Sabroe S, Bartels P, Mainz J. The virgin land of quality management – a first measure of patient safety climate at the National Hospital of the Faroe Island. Drug Healthcare and Patient Safety 2016;8:49-57.

LIST OF ABREVIATIONS

AGFI	Adjusted goodness-of-fit index
AMSTAR	Assessment of multiple systematic reviews
CFA	Confirmatory factor analysis
CFI	Comparative fit index
CI	Confidence interval
CL	Clinical leaders
Clinical area	In and out patient units
CM	Composite measure
Cronbachs's α	Cronbach's alpha coefficient
CUSP	Comprehensive unit-based safety programme
DM	Perception of department/centre management
Doc	Doctor(s)
EFA	Exploratory factor analysis
EOS	Error Orientation Scale
Exp	Two or more years of work experience in the hospital
GFI	Goodness-to-fit index
HM	Perception of hospital/top management
HSPSC	Hospital Survey on Patient Safety
HUSCS	Hospital unit safety climate survey
ICU	Intensive care unit
InExp	Less than two years of work experience in the hospital
JS	Job satisfaction
Mgmt	Management/leadership
N	Number
N.A.	Not applicable
N.S.	Not significant
NDNQI RN survey	Database of Nursing Quality Indicators Registered Nurses Satisfaction Survey
NHFI	National Hospital of the Faroe Island
NHSNSS	National Health Service National Staff Survey
OR	Operating room
PE/DVT	Pulmonary embolism/deep vein thrombosis
PSC	Patient safety culture

To be continued

PSCHO	Patient Safety Cultures in Healthcare Organizations
PSO	Patient safety outcome
QM	Quality management
RMSEA	Root mean square error of approximation
RN	Nurse(s)
SAQ	Safety Attitudes Questionnaire
SC	Safety climate
SCS	Safety Climate Scale
SCSu	Safety Climate Survey
SD	Standard deviation
SOS	Safety organizing scale
SR	Stress recognition
SRMR	Standardized root mean square residual
TC	Teamwork climate
UM	Perception of unit management
VAPSCI	VA patient safety culture instrument
WC	Working conditions
ZSAEOS	Zohar safety climate and error orientation scale,
χ^2	Chi square
% positive	The proportion of staff with positive attitudes; defined as an individual scale score ≥75 on a SAQ scale
♀	Female
♂	Male

CHAPTER 1. INTRODUCTION AND OBJECTIVES

To do good, and to do no harm, has been a principle in medicine since the ancient times of Hippocrates (1). Nonetheless, the concept of patient safety was not established formally within health care until the 1990s. The Harvard Medical Practice Study I published in 1991 found that 3.7% of patients experienced an adverse event during hospitalisation, and 13.6% of these events caused death (2). In 1995 results from an Australian study reported that 16.6% of Australian hospital admissions were associated with an adverse event, and 4.9% of these events were fatal (3).

These two studies on adverse events put patient safety on the agenda, and the subsequent debate caught the attention of health care staff, politicians and the wider public. Attention was further enhanced when the Institute of Medicine released the report "To Err Is Human: Building a Safer Health System" in 1999. The report stated that every year over a million patients were injured, and between 44,000 and 98,000 patients died in American hospitals, due to medical errors. The goal of the report was to call for action to reduce the occurrence of adverse events by 50% (4). The year after, two pioneers in patient safety warned: *"The necessary changes are as much cultural as technical"*(5). Five years after the report, the most published topic within patient safety literature related to organisational culture (6).

A study from 2001 on adverse events in Danish hospitals showed a prevalence of adverse events of 9.0% (7). The results of the study were published in the Danish Medical Journal in a special issue on patient safety (8). The study results contribute to a decision to introduce mandatory reporting of adverse events. To support the reporting of adverse event and follow-up learning activities, the Danish Act on Patient Safety was introduced in 2004; the first of its kind worldwide. The Act requires reports on adverse events to be submitted electronically to a national reporting system, the Danish Patient Safety Database.

Already the year after, in 2002, the importance of a supportive culture for a high level of patient safety, and the active role of the line management in creating such a culture, was emphasised in the Danish National Strategy for Quality Improvement in Health Care 2002 - 2006 (9). In 2003 a group of pioneers in patient safety published a book on patient safety, stating: *"To enhance patient safety within Danish health care, it is necessary to identify any barriers that might hinder the development of a safety culture"* (10). When using the term safety culture in relation to patient safety, it reflects how risk management is conceived, structured and implemented (11).

The first Danish studies on patient safety culture formed part of the legislative preparation for the Act of 2004, and in 2006 the first Danish PhD thesis on patient safety culture was published (12). The thesis addressed topics such as experiences with reporting of adverse events, ethics in patient safety, apologising after adverse

events, and the relationship between safety culture, occupational health and patient safety (12). The conclusion of the thesis was that safety culture assessment tools are a promising approach to improving patient safety, and a Danish questionnaire for assessment of safety culture was developed, but not validated (12). Despite this early focus on patient safety culture, the topic has not managed to attract serious scientific, professional or political attention since. Therefore, the scientific results of the above PhD thesis have stood more or less alone for over a decade; supplemented mainly by results of quality improvement projects on patient safety culture (13;14).

At the practical level, a rich patient safety work is today anchored in the quality and safety organisation of Danish hospitals, and at regional and national levels through a number of networks, working groups, authorities, institutions and societies dealing with patient safety. The Danish patient safety work comprises a large number of diverse activities, from retrospective reporting of adverse events to prospective workflow analysis, including establishing and monitoring patient pathways, patient safety satisfaction surveys and patient involvement activities, clinical indicators monitoring, science of safety education, team training, auditing, and improvement programmes (15).

1.1. WHAT IS PATIENT SAFETY CULTURE?

1.1.1. THE CONCEPT OF CULTURE

Culture seems such a common sense concept, and we take for granted that others intuitively understand the concept and its predictors and ability to predict in the same way we do. As a result, the question *"what do you mean by the culture?"* is hardly ever asked, and the concept of culture might even be used to explain everything health care staff cannot explain otherwise (16). Therefore, clarification is needed.

The Latin word *"cultura"* is the etymological root of culture; it refers to the tilling of the land, tending, guarding and cultivating. Thus, culture is in opposition to nature - the uncivilized, and it can be regarded as both the ability to *"resist the norm and rise above the ordinary"*, and an expression of this achievement (17).

Culture was first defined in 1871 by the English anthropologist Sir Edward Burnett Tylor as: *"that complex whole which includes knowledge, belief, art, morals, law, custom and any other capabilities and habits acquired by man as a member of society"* (18). Tylor's idea was that human cultures invariably change over time to become more complex. Starting with Tylor, culture has become a central concept in anthropology, covering a range of phenomena that are transmitted through social

learning in human societies. Culture shapes how we interact within and across groups and hierarchies, and it permeates our interpersonal interactions (19).

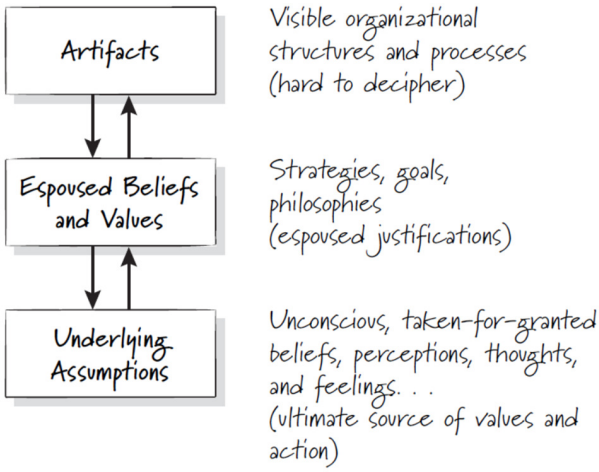
When used as a noun today, culture is defined in the Cambridge English Dictionary as *"the way of life, especially the general customs and beliefs, of a particular group of people at a particular time"*(20). Thus, culture is a multi-level concept comprised by e.g. national culture, organisational culture, group culture and individual culture; each of these levels are multi-dimensional, e.g. the national culture includes dimensions of art, law, food, bureaucracy and so on (18;21). Safety culture can be seen as part of the overall culture of an organisation (22).

Although the topic of organisational culture was first brought up in the literature in 1951 by E. Jaques (23), the theory of organisational culture did not emerge until the 1970s from a combination of organisational psychology, social psychology and social anthropology (24;25). Today over 150 definitions of organisational culture are provided in the literature (26), but there is no consensus on one specific definition, nor on the concept.

In 1993, E. Schein provided the following widely used characterisation of organisational culture *"a pattern of basic assumptions, invented, discovered, or developed by a given group, as it learns to cope with its problems of external adaptation and internal integration, that has worked well enough to be considered valid and, therefore is to be taught to new members as the correct way to perceive, think, and feel in relation to those problems"* (27). To accompany and operationalise the definition of organisational culture, E. Schein provided a model in which organisational culture is described at three levels according to its visibility to the observer: *artefacts*, *espoused values* and *basic underlying assumptions* (27). Schein's levels of cultural analysis are shown in Figure 1, with the permission of E. Schein (27). Safety culture as well as patient safety culture can be understood and analysed according to E. Schein's major levels of culture (27).

Artefacts are the surface manifestations of the organisational culture. They are the physical and verbal components of the organisation that can be seen, felt and heard by any observer. Artefacts include facilities, technologies, offices, furnishings, dress code, and how staff members visibly interact (behaviour, communication, rituals, ceremonies, contents of myths, stories and sagas). The declared and shared values of the organisation, include aspects of loyalty and service, strategies, goals, company slogans, mission statements and other operational creeds. The values are non-visual, but conscious. At the basic level of E. Schein's model, the organisation's implicit beliefs, thoughts, feelings and assumptions are found. They are unseen and not outspoken in everyday life; however, they are an underlying driving force (27).

Figure 1 The major levels of culture according to E. Schein (27)



Note; Figure 1 is presented with permission from E. Schein. The original source of the figure is (27).

The term *safety culture* gained its first official use in the aftermath of the Chernobyl accident in 1986. Safety culture weaknesses were identified as underlying causal factors explaining the organisational errors and operator violations that triggered the disaster (28). A widely used definition of safety culture characterises a positive safety culture as *"…the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterised by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventative measure"* (29).

1.1.2. DEFINITIONS OF PATIENT SAFETY CULTURE AND CLIMATE

There is an array of different definitions of patient safety culture applied in the literature (30). They have in common that patient safety culture can be seen as an aggregation of individuals' behaviour, habits, norms, values and basic assumptions related to patient care (31). The European Society for Quality in Healthcare has defined a culture of safety in the context of patient safety dynamically as presented in figure 2.

Figure 2 Definition of a culture of safety in the context of patient safety (32)

> **A culture of safety is** "*an integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery"*

Safety culture and safety climate are often used as interchangeable in the literature (33). However, safety climate is the *"surface features of the safety culture from attitudes and perceptions of individuals at a given point in time, or the measurable component of safety culture"* (34;35). That is, the "*Climate emerges through a social process, where staff attach meaning to the policy and practice they experience and the behaviours they observe"*, and the *"culture concerns the values, beliefs and assumptions that staff infer through story, myth and socialisation, and the behaviours they observe that promote success. In other words, culture is more interpretative"* (11).

It has been proposed to see culture as a metaphor for personality, and climate as one for mood (36;37); personality is relatively stable over time, while moods can change at short notice. In parallel, culture is regarded as a relatively stable concept which is not easily changed, while the climate is more fleeting and more easily changed (33).

In the context of patient safety, culture is often equated with the notions culture of safety and safety culture (30). In the following, the terms culture, safety culture, culture of safety and patient safety culture will be used interchangeably and all refer to the definition of a culture of safety in figure 2, whereas the terms climate and safety climate will refer to results from an assessment of the culture only.

1.1.3. CHARACTERISTICS OF PATIENT SAFETY CULTURE

Patient safety culture is specific to health care organisations; it is created by health care staff, and it concerns the safety of patients. The safety culture guides the motivation, commitment to and know-how of the safety management in a workplace (38;39), and how members of the workplace interact within and across organisational hierarchies (19). The safety culture is considered fundamental to the delivery of safe care (19;40;41).

As with culture in general, the safety culture is learned through the process of socialisation (observation, discussion and interaction), and transferred from one individual or sub-group to another, whereby the characteristics and traits of one safety

culture is replaced with those of another (42). Consequently, safety culture represents a wide range of social phenomena permeating the way of life in a workplace.

The concept of patient safety culture is multi-dimensional, just as its basis "culture". That is, patient safety culture comprises several different dimensions, such as leadership support for patient safety, teamwork, adverse event reporting, communication etc. There is a lack of agreement on the common dimensions of the concept safety culture (30), but some of the most commonly used dimensions of safety culture have been identified through two reviews (30;43) to be:

- leadership commitment to safety (30)
- open communication (30;43)
- organisational learning (30;43)
- just culture approach (30;43)
- teamwork (30;43)
- shared belief in the importance of safety (30)
- evidence-based patient care practices (43)
- patient-centred care approach (43).

Underlying assumptions, values, behaviour, habits and practices will vary over time as the culture develops; in other words, there will be drift and possibly variation across groups (44). Cultural sub-groups can be related to sex, profession, seniority and organisational role (45-47), and to the level of organisation, e.g. the clinical level where frontline staff operate, also called the sharp end of care, and the leadership levels, also called the blunt end of care (31). Leaders tend have more favourable perceptions of the culture than the frontline staff (46;48-53). Also, staff in non-clinical areas (in- and outpatient units) tend to have a more favourable view of the culture than staff in clinical areas (45).

A summary of characteristics of patient safety culture is given in Figure 3.

Figure 3 Characteristics of patient safety culture

Patient safety culture is:

- specific to health care organisations (32)
- learned through the process of socialisation (42)
- dynamic (42)
- exposed through artefacts and practices, and values and norms (27)
- a multi-level construct (43;54;55)
- multi-dimensional (56)
- a context-specific phenomenon related to demography (30)
- assessable and can be improved through targeted interventions (57;58).

1.2. CREATING AND IMPROVING PATIENT SAFETY CULTURE

The first steps when aiming to create a safe culture are to ensure consensus of the understanding of the concept (59); to legitimise working with the safety culture and to allocate resources; to assess the culture, reflect, share and learn from the cultural perceptions and link them to the day-to-day practices (60).

Monitoring the patient safety culture over time can give an insight into the culture as it is developing. To truly improve the culture, it is necessary to work from a common platform; specify the goals for the quality of the desired future culture (36), implement a well-defined intervention which is documented or assumed to have an impact on the culture (59), and define a valid and reliable method by which an improvement can be detected. Leadership support and commitment to the initiative seem a necessary perquisite for improvement (61;62).

1.2.1. LEADERSHIP ROLE

According to G. Yukl, leadership is *"the process of influencing others to understand and agree about what needs to be done and how to do it, and the process of facilitating individual and collective efforts to accomplish shared objectives"*(63). Therefore, leadership is a dynamic, interdependent relational process between the leader and the subordinates; at the clinical area level frontline staff.

In general, it is the leadership level that provides directions and standards for quality management (64). Hence, it is indirectly the leadership that drives the quality of the culture by outlining the framework conditions under which the frontline staff practise safety (65;66). In this sense, creating or improving a safety culture is a leadership task, regardless of where the leader is positioned within the organisation: top, department, or unit/ambulatory care level (or equivalent). The actual task involved in formulating the vision for the safety culture, monitoring the culture and implementing the vision is different depending on the leadership position and area of responsibility within the organisation. For the organisation as a whole, committed leaders who cooperate across the organisation are essential to the successful implementation of a coherent safety culture (67;68).

Currently the literature offers some answers as to how to develop leadership in order to promote a sound and positive patient safety culture. It is essential that the clinical leaders are educated in the science of safety, that they know their safety data, by having insight into the risks and safety problems at the sharp end of care, and that they are focused on patient safety (43). Accordingly, the leaders should ensure psychological safety; that is, create an environment where staff feel free to speak up about any risks or safety issues they are concerned about. Speaking up should be regarded positively, and it should not be associated with being incompetent, critical or misbehaving (69). A strong mean for creating psychological safety is the clinical leaders' ability to listen and relate to and communicate with frontline staff, and allowing upward communication in the organisation without classifying this as whistle blowing (44). However, it is a delicate balance for the leaders; they must ensure that staff members are not held accountable for system failures, but are held accountable for engaging in unsafe behaviour and know that gross negligence, wilful violations and destructive acts will not be accepted (69).

It has been shown that a transformational leadership style, as opposed to a laissez-faire leadership style, is a positive contributor to a safe culture (70). Transformational leadership is characterised by charismatic, inspiring leaders, who are able to develop a vision, motivate, encourage innovation and empower their staff to collaborate (51). However, a more recent type of leadership called complexity leadership has been predicted to hold great promise to improve cost and quality in health care (71). Leaders who exercise complex leadership emphasise interpersonal relationships by supporting and facilitating good collaboration and respect, which are predictors of a

strong patient safety culture (72). Practices of complexity leadership are characterised by an anti-hierarchical structure, e.g. the clinical area level leaders share clinical quality data, organisational, administrative and budgetary data with the frontline staff, and they work side by side with the frontline staff to apprehend the data and the day-to-day work in the frontline and come to a shared decision on improvement initiatives (71). So, complexity leadership style could be the key to bridge a cultural perception gap between clinical leaders and frontline staff.

1.2.2. METHODS FOR ENHANCING SAFETY CULTURE

Using the safety culture as a lever for high patient safety depends upon effective methods to enhance patient safety culture. The Keystone Intensive Care Unit (ICU) Project – a state-wide improvement project in Michigan, USA in 2008 – was the first to document noticeable improvements in teamwork climate and clinical outcomes after using an evidence-based intervention (64;73;74). Hence, the Keystone ICU Project has become a point of reference for later improvement projects aiming for a simultaneous improvement in safety culture and reduction in patient safety incidents (59;75-80). However, the most interesting aspect is *how* the improvements were achieved.

Work to create an effective method for promoting a safe culture started in 2001 at John Hopkins Hospital in Baltimore, USA (75) and resulted in the Comprehensive Unit-based Safety Programme (CUSP) in 2006 (57). CUSP is a multi-step patient safety framework which includes a number of initiatives, such as training the staff in the science of safety, motivating staff to identify safety hazards, establishing a partnership between the frontline staff and senior management, setting up possibilities for staff to learn from errors, facilitating and allowing focus on communication and teamwork. In essence, the programme creates a partnership between frontline staff and the management; frontline staff is empowered to take responsibility for safety in their work area while improving the safety culture. Patient safety culture is assessed before and after implementation of these initiatives (57).

In the Keystone ICU project, a total of 71 ICUs participated in assessment of the teamwork climate before and after the CUSP intervention, and patient outcome data was collected on central line-associated bloodstream infections. Changes in teamwork climate were measured using the 6-item teamwork climate scale of the SAQ. A 50% improvement in teamwork climate was achieved over 18 months between 2003 and 2005, ($P<0.05$). Furthermore, a median central line-associated bloodstream infections rate of zero was accomplished (64;73).

CUSP has been applied in other studies and has proved to be a successful framework for improvements in safety culture (59;75-80). This is supported by the findings of

two reviews investigating the impact of different kinds of interventions on patient safety culture (59;78). The reviews are from 2012 (59) and 2013 (78). Extensive descriptive information on the two reviews is listed in Appendix A. The review by R.T. Morello et al. from 2012 included 21 studies from the USA, the UK, Canada, the Netherlands and Australia. Both randomised controlled studies, controlled before and after the studies, and historically controlled studies were included. In the studies included, six different questionnaires for surveillance of patient safety culture had been used. The following types of interventions to enhance the culture were identified:

- patient safety leadership walk rounds; N=3
- multi-faceted unit-based programmes; N=7
- simulation-based training programmes; N=4
- team-based strategies; N=3
- structured educational programmes; N=2
- multi-component organisational interventions; N=1
- surgical safety checklist; N=1.

The review from 2013 by S.J. Weaver et al. included 35 studies from the USA, Canada and Australia (78). This review included the following types of studies: randomised controlled trials, before and after studies with and without control, and time-series studies. In the studies included, three different questionnaires had been used for surveillance of patient safety culture. The following interventions to enhance the culture were identified:

- patient safety leadership walk rounds or interdisciplinary rounds; N=8
- multi-faceted unit-based programmes; N=8
- team training or communication initiatives; N=20.

To assess the scientific methodological quality of the two reviews (59;78), the Assessment of Multiple Systematic Reviews (AMSTAR) checklist was applied. AMSTAR has been validated and has shown good face and content validity, reliability, construct validity and feasibility (81-83). The AMSTAR checklist consists of 11 items, which are to be answered: Yes, No, Cannot answer or Not applicable. Upon rating each of the 11 items, a total score is calculated based on the positive rating (Yes=1). A positive score indicates that the methodological issue addressed is fulfilled. The maximum score obtainable is 11 points (81-83). The AMSTAR ratings of the two reviews (59;78) are displayed in Appendix B, showing that 7/11 (64%)

(59) respectively 5/11 (51%) of the methodological issues were fulfilled (78). Thus, the reviews are of moderate quality.

An overview of results from the two reviews is presented in Table 1, showing effect of all included interventions on one or more dimensions of the climate; primarily safety climate and teamwork climate. It should be noted, however, that slightly different aspect of safety climate and teamwork climate might be covered, depending on the assessment instrument. Both reviews agreed that the evidence to support the impact of patient safety interventions is limited, but emerging. Moreover, the reviews agreed that the strongest evidence for improvement of the patient safety culture was found in studies applying patient safety leadership walk rounds or multi-faceted unit-based programmes, such as CUSP (59;78). Considering that the methodological quality of the two reviews included in this small review were of moderate character, and that the number of studies included for each intervention type was extremely small; the results should be interpreted with caution.

Table 1 Review results showing significant effect of eight types of interventions on different dimensions of patient safety culture (59;78)

Intervention	Effect on patient safety culture			
	Positive	No	Positive	No
	Review by R.T. Morello et al. (59)		Review by S.J. Weaver et al. (78)	
Patient safety leadership rounds or interdisciplinary rounds	SC #		SC	
Multi-faceted unit-based programmes	SC #		SC TC	
Simulation-based training programmes	SC	#		
Team-based strategies	TC #	#		
Team training or communication initiatives			SC	
Structured educational programmes	TC			
Multi-component organisational interventions	SC [a]			
Surgical safety checklist	#			

Notes: # Effect identified on one or more dimension(s) of the patient safety culture without specifying the dimension(s); [a] effect reported as negligible.
Abbreviations: SC, safety climate/safety culture; TC, teamwork/teamwork climate.

1.2.3. SAFETY CULTURE AND PATIENT SAFETY OUTCOMES

The ultimate aspect of interest is the association between patient safety culture and patient safety, and as mentioned above, this relationship was first established in the Keystone ICU Project. A reverse relationship was identified between teamwork climate and bloodstream infections (64;73;74).

A meta-analysis and a review have been performed with the purpose of investigating the relationship between safety culture and patient safety outcomes (84;85); both were published in 2014. Extensive descriptive information on the two papers is listed in Appendix C, and assessment of the methodological quality of the two papers using

the AMSTAR checklist is shown in Appendix D. The AMSTAR scores were 2/11 (18%) (84) and 7/11 (64%) (85) respectively, indicating low to moderate quality of the reviews.

The meta-analysis by P.S. Groves (85) included 10 studies (4 peer-reviewed articles and 6 dissertations). A total of 6 different questionnaires for surveillance of patient safety culture were used. Three meta-analyses were performed on single outcomes:

- pressure ulcers; N=4
- falls; N=4
- medication; N=5.

Two meta-analyses were performed on composite outcomes:

- non-surgical patient outcomes *(pressure ulcers, falls, medication errors, urinary tract infections, and nosocomial infections)*
- post-operative outcomes *(30-day risk-adjusted morbidity, infection, haemorrhage/hematoma, pulmonary embolism/deep vein thrombosis, a bleeding composite measure, and a general post-operative composite measure).*

Neither positive nor negative relationships were identified in the meta-analysis (85).

The review by M.H. Dicuccio (84) included 17 studies (10 peer-reviewed articles and 7 dissertations) involving registered nurses as participants in the patient safety culture assessment. In total, 16 of the studies included were cross-sectional and 1 was qualitative; 6 different questionnaires for surveillance of patient safety culture were used across the 17 studies. The following patient outcomes were investigated (84):

- patient satisfaction; N=1
- family satisfaction; N=1
- patient experience; N=2
- mortality; N=3
- readmission; N=1
- community acquired pneumonia; N=1
- hospital acquired pressure ulcers; N=1
- medication errors; N=2

- medication errors and urinary tract infections; N=1
- composite measure I *(catheter-associated urinary tract infections, central line-associated bloodstream infection, surgical site infections, hospital acquired pressure ulcers, falls and failure to rescue)*; N=1
- composite measure II *(hospital acquired pressure ulcers and falls)*; N=2
- composite measure III *(8 and14 patient safety indicators from the data base from the Agency for Healthcare Research and Quality, USA)*; N=2.

An overview of significant findings from the review (84) is presented in Table 2, stating the questionnaire used, the level of analysis and specialty area, the dimension of patient safety culture and the related outcome. The SAQ and the Hospital Survey on Patient Safety Culture (HSPSC) was used at the unit level, a positive relationship was found for family satisfaction, and a negative relationship for mortality.

In conclusion, this small review of the two papers investigating the relationship between patient safety culture and patient safety outcomes showed that the papers were of low to moderate methodological quality according to the AMSTAR assessment. Furthermore, the number of studies per patient safety outcome was small, and at the same time a variety of safety culture questionnaires were applied. The meta-analysis stated that there might be problems with both the validity and reliability of the patient safety culture questionnaires and the patient safety outcomes included in the analysis and unity in the use of the concept of patient safety culture across studies (85). Moreover, the review added that the level of analysis (e.g. unit versus hospital) must be considered when investigating this relationship (84). Hence, the conclusions must be interpreted with caution, and studies based upon sound methodological quality overcoming the issues mentioned above are needed.

Table 2 Significant relationships between dimensional climate and patient safety outcomes (84)

Questionnaire used ***Level of analysis and specialty area*** Dimension of patient safety climate	**Outcome and direction of relationship (▼ / ▲) [a]**
Safety Attitudes Questionnaire	
Unit level analysis in intensive care units	
Perception of management	Mortality ▼
Safety climate	Mortality ▼
Safety climate	Family satisfaction ▲
Hospital level analysis	
Perception of management	Community acquired pneumonia ▼
Safety climate	Community acquired pressure ulcers ▼
Hospital Survey on Patient Safety Culture	
Unit level analysis in medical and surgical units	
Several subscales [b]	Family satisfaction ▲
Hospital level analysis	
Several subscales [b]	Patient satisfaction ▲
Overall perception of patient safety	Mortality ▼
Safety climate [b]	Readmissions ▼
Patient Safety Cultures in Healthcare Organizations	
Hospital level analysis	
PSC composite score	AHRQ PSI composite ▼
Fear of blame	AHRQ PSI composite ▼
Fear of shame	AHRQ PSI composite ▼

Notes: [a] ▼= Negative relationship; ▲= positive relationship; [b] not otherwise specified.
Abbreviations: PSI, patient safety indicator.

1.3. ASSESSMENT OF SAFETY CULTURE

The main objective of assessing the patient safety culture is to get an insight into the quality of the culture. R. Westrum offers a basic, widely used and easily understandable framework for characterising safety cultures by five phases of cultural maturity, or stages of cultural development (86). The five phases have been adapted by M. Leonhard and A. Frankel; the phases are defined in regard to day-to-day safety practice and are illustrated in Figure 4 explaining the characteristics of the individual levels.

Figure 4 Five phases of safety culture maturity and their main characteristics

Maturity phase	Phase-specific characteristics of the system and staff attitudes
Generative	"Safety is an integrated part of how we do business" Staff philosophically embrace a mindful, forward-looking learning system Systematic process abounds
Proactive	"We try to anticipate safety problems before they arise" Systematic components fully implemented Actively seeks to learn from defects
Systematic	"We have systems in place to manage all hazards" Systematic components or attributes, with incomplete penetration
Reactive	"Safety is important; we do a lot every time we have an accident" Character is dependent on individual presence, with limited systematic components or attributes
Unmindful	"Who cares about safety as long as we don't get caught?" Limited or no awareness of safety culture Systematic processes are very limited with haphazard implementation

Note; Figure 4 is presented with permission from M. Leonhard and A. Frankel.

Cultural advancement or regress is possible e.g. from one phase of maturity to another (86). Given the multi-dimensional nature of the culture, cultural discordance might exist. Therefore, the different dimensions of the culture must be measured individually, allowing identification of strong and weak dimensions and prioritising dimensions that should advance to the next phase of maturity (86). To be truly useful the idea of cultural maturity phases should be exhaustively defined, and preferably coupled to specific standards for the phases. Such standards could be defined expectations, metrics tied to a patient safety culture instrument, or results from a previous assessment of the culture or a comparable group. When assessment of the

culture is repeated, it is possible to get an insight into how the culture evolves over time (56), and the results of the safety culture assessment can be used in the clinical setting for quality improvement, and or for research (87).

A quantitative assessment of the safety culture, e.g. using a questionnaire, gives an overview of *how* the culture is perceived at a particular point in time. The results represent a static snapshot of the climate, and unless appropriate in-depth follow-up methods are applied light is not shed upon *why* the culture is as it is. So, the quantitative assessment cannot capture the comprehensive picture of the patient safety culture on its own (56;88-90). To understand and improve day-to-day practice, it is necessary to understand *why* things are done in their distinctive ways (91).

Qualitative assessment information gathered through individual and/or group interviews can contribute to an understanding of the underlying causal factors of the culture e.g. artefacts, beliefs and values and underlying assumptions. Results from qualitative assessment of a safety culture can help identify the cultural drivers and barriers, and answer the question *why* the culture is as it is. However, results from qualitative methods mostly represent a subsample of the group in question, and the method is burdensome in terms of time and cost (92).

Thus, the ideal way to capture a comprehensive picture of the culture of safety is to conduct an assessment that combines the methods of *how* and *why* by applying 1) a questionnaire-based safety culture assessment, with 2) a dialogue-based assessment: leading to a plan for improvement initiatives. This approach is termed the mixed methods approach (92).

The results of a mixed method safety culture assessment can be used to:

- raise awareness about patient safety among staff (39;93)
- help to understand features of a workplace (94-96)
- identify cultural strengths and weaknesses (56;93;95)
- make judgements and set priorities for developing the safety culture (94)
- reinforce the cultural strengths and improve the weaknesses (97)
- link the culture to the safety practices and the safety of patients (39)
- tailor, support and direct interventions to improve the culture (75;94;95)
- track changes over time (56), and identify trends (93)
- evaluate the impact of improvement initiatives on the culture (56)
- benchmark results internally and externally (56;93)
- predict quality of care (98).

1.3.1. QUANTITATIVE ASSESSEMT

Quantitative measures of assessment of patient safety culture – questionnaires – consist of a series of questions or statements that measure perceptions of day-to-day practices, beliefs, values and attitudes related to the safety of patients. The questions or statements cluster along various dimensions of patient safety culture. Answers to the questions or statements are typically given on a multiple-point Likert scale (87).

A total of 33 different questionnaires for assessment of patient safety culture have been identified in the literature. They are listed in Appendix E.

The two best validated, frequently used and cited quantitative measures of patient safety culture applied internationally (99) are the SAQ (100-109) and the HSPSC (110-119). The reliability and predictive validity of these two questionnaires were compared in a study in which SAQ and HSPSC were administered to the same participants (120). It was found that all dimensions from both questionnaires – except the HSPSC's staffing dimension – had adequate levels of reliability. SAQ and HSPSC had comparable ability to predict the 1) frequency of event reporting, 2) overall perceptions of patient safety, and 3) overall patient safety grade. When choosing between the two questionnaires, the questionnaires' length, content, sensitivity to change and their ability to benchmark results should be considered (120), as well as any established link between questionnaire results and patient safety outcomes (34;121).

SAQ was developed from the Flight Management Attitudes Questionnaire, and an American version of the SAQ was introduced in 2004 by the University of Texas in the USA. Information on the validity of SAQ using data from the United Kingdom, New Zealand and the USA was published in 2006, and acceptable psychometric properties of SAQ were documented (58). Originally SAQ came in different versions for different specialties within hospital care, and in a generic short form applicable for use across specialties, but only the short form of SAQ has been recommended for use since 2015 (122). The SAQ Short Form includes 31 items, covering 6 dimensions for teamwork climate, safety climate, job satisfaction, stress recognition, perception of management and working conditions. Answers are given on a 5-point Likert scale (Disagree Strongly, Disagree Slightly, Neutral, Agree Slightly, Agree Strongly) (122). A link between dimensions of patient safety culture and patient outcomes has been established for use of the SAQ; favourable SAQ scores have been associated with fewer medication errors, lower ventilator associated pneumonia rates, lower bloodstream infection rates, lower risk-adjusted patient mortality rates, and shorter length of hospital stays (34). Improvements in SAQ results have been documented following multi-component interventions and patient safety leadership walk rounds (57;74;123-126).

Development of HSPSC was based on a review of the literature and other culture questionnaires, and in 2004 the HSPSC was launched by the Agency for Healthcare Research and Quality (AHRQ) in the USA (93). Investigation of the psychometric propertied of the HSPSC was carried out through three studies in 2009, 2010 and 2014, and acceptable psychometric properties were documented (127-129). HSPSC belongs to a series of questionnaires from AHRQ designed for application in different settings of health care (hospitals, nursing homes, general practitioners and pharmacies). AHRQ hosts a comparative database with voluntarily submitted data from hospitals (93). HSPSC includes 42 items covering 7 unit-level dimensions of safety culture (Supervisor/Manager Expectations & Actions Promoting Safety; Organizational Learning – Continuous Improvement; Teamwork Within Units; Communication Openness; Feedback and Communication About Errors; Nonpunitive Response to Error and Staffing); 3 hospital-level aspects of safety culture (Hospital Management Support for Patient Safety; Teamwork Across Hospital Units; Hospital Handoffs and Transitions), and 4 outcome variables (Overall Perceptions of Safety; Frequency of Event Reporting; Patient Safety Grade (of the Hospital Unit), and Number of Events Reported). Answers are given on different types of Likert scales with different numbers of answer categories and differently phrased answers. HSPSC results for 6 of the dimensions (Frequency of Event Reporting, Hospital Handoffs, Organizational Learning - Continuous Improvement, Staffing, Teamwork Within Units, and Teamwork Across Hospital Units) have been found reversely linked to a composite patient safety indicator. The composite indicator covered hospital adverse events such as iatrogenic pneumothorax, selected infections, post-operative haemorrhage or hematoma, post-operative physiologic and metabolic derangement, post-operative respiratory failure and post-operative sepsis (130).

1.3.2. VALIDITY AND RELIABILITY OF QUANTITATIVE METHODS

Measurement and improvement of patient safety culture is highly dependent on methods that are scientifically sound. The questionnaire must measure what it is intended to measure, the results must be trustworthy, and it should be possible to distinguish differences between individuals or groups (121). Thus, assessment of the questionnaire's validity, reliability and ability to discriminate is needed prior to releasing the questionnaire for general use (131). For this purpose, it is customary to test the questionnaire in a cross-sectional study in which the questionnaire is applied to a representative and sufficiently large sample, which allows various statistical analyses (131;132). The psychometric properties of the questionnaire must be evaluated according to standards set prior to the validity study (131).

Validity refers to the degree to which the questionnaire is measuring what it is intend to measure. Generally, a valid questionnaire should satisfy as many of the following validity criteria as possible (131):

- face validity; refers to how well the questionnaire – on the face – seems to measure the concept it is intended to measure
- content validity; states how appropriately the questionnaire represents all (or many) aspects of the concept
- construct validity; signifies the degree to which the questionnaire results relate to the underlying theoretical/hypothesised concept
- criterion-related validity; refers to how well the questionnaire results relate to a criterion measure; it can be divided into concurrent and predictive validity. Concurrent validity represents how well the questionnaire results correlate with the results of a validated measure of the same concept, measured simultaneously. Predictive validity represents how well the questionnaire results predict later outcome on a related criterion; that is, two different measures are used at two different points in time.

Reliability refers to the consistency of a measure. Reliability is sensitive to random variation as well as systematic errors (bias). Generally, a reliable questionnaire should satisfy as many of the following reliability criteria as possible (131):

- test-retest reliability; states the degree to which the same results are obtainable over time given the same method and a stable concept
- inter-observer reliability; signifies the degree to which different observers/raters responding to the questionnaire give the same answers
- inter-item reliability; indicate the degree to which a set of items designed to measure the same dimension of the concept are associated with each other
- internal consistency reliability; refers to the consistency of questionnaire results across items, which are intended to measure the same concept.

Validation of patient safety culture questionnaires has some inbuilt challenges due to the basic features of the concept of patient safety culture. Provided that the concept of patient safety culture is previously well-defined, then face, content and construct validity can be assessed. Criterion-related validity can be assessed; however, it might not always be desirable or even possible. Concurrent validity can be assessed if the same population has been surveyed using two different questionnaires and unique personal identifiers. Predictive validity is typically used to express how well safety

culture can predict a specific clinical outcome, e.g. patient fall, infections or medication. The study must be designed large enough to allow for analysis of the safety culture's predictive ability (group level of health care staff) of clinical outcomes (group level of patients); e.g. verifying if good management support can predict few medication errors.

Because patient safety culture is a dynamic concept, assessment of test-retest reliability is not suitable. Inter-observer reliability can be assessed; however, patient safety culture is as may other phenomena assessed with questionnaires experienced subjectively, so low inter-observer reliability must be expected, and the value of the assessment can be discussed. In opposition hereto, it seems crucial to assess the other two measures of consistency; inter-item reliability and internal consistency reliability.

In conclusion, face and content validity, construct validity, inter-item reliability and internal consistency reliability must be evaluated when testing the psychometric properties of a patient safety culture questionnaire. It is also necessary to know the questionnaires' ability to differentiate between groups (37), and to assess the usability of the questionnaire. Usability refers to the ease with which a questionnaire can be administered, understood and answered by the participants, and the data analysed and results interpreted by the clinicians. Assessment of the usability of the questionnaire can guide future users to an optimal survey process.

1.3.3. COMPLIANCE AND REPRESENTATIVENESS

It is critical to obtain high acceptability of among invitees of a questionnaire-based safety culture assessment. The literature states that when the response rate falls below 60%, the information obtained from the measurement represents opinions rather than the culture (121). To obtain an acceptable response rate, support of the kind described below is suggested:

- use e-mails, posters and informational presentations (37;56)
- highlight the importance of the assessment for patients' safety, the staff and the organisation (37;56)
- use best epidemiological practices for data collection (93)
- offer incentives for participation (93)
- create a competitive spirit (93)
- engage responsible leaders (37;56;93)
- distribute the questionnaires at a staff meeting or equivalent session (133)

- provide the opportunity to fill in the questionnaire during work hours (37)
- inform when results are available and to whom
- provide a contact for questions (133)
- ensure confidentiality (133)
- assure that results will not be reported for demographic groups with fewer responders than thought ethical correct e.g. five (133).

Furthermore, questionnaire length and complexity are likely to impact compliance (37). Feeding back results to the staff will enhance their participation in follow-up assessments (37).

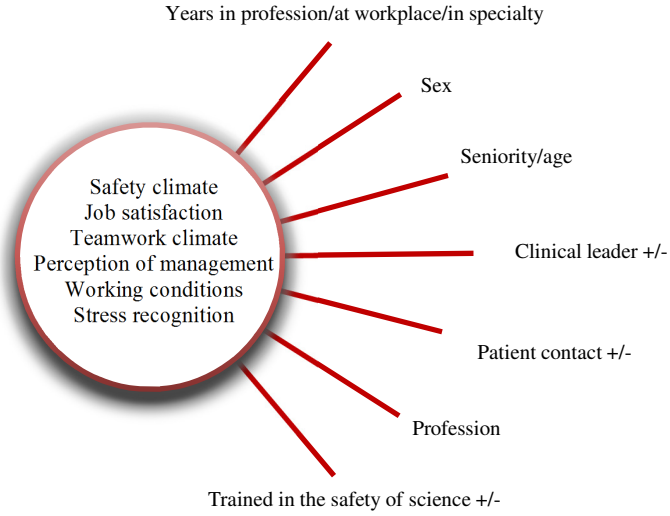
1.3.4. ANALYSIS OF RESULTS AND CLIMATE METRICS

Safety culture is a group-level characteristic; thus the scores of the individuals responding in a patient safety culture survey are aggregated to provide a snapshot of the safety climate (87). Because safety culture is a local, context-specific phenomenon and variation is evident between organisational levels and sub-groups (86;121), differentiated result feedback is recommended. This will allow improvement initiatives to be tailored specifically to meet the weaknesses of an organisational level and or sub-group.

The greatest variation in climate has been observed at the lowest leadership level (clinical area level), which consequently has been established as the most appropriate level of analysis, result feedback and implementation of improvement activities (40;49;134).

Moreover, results according to subgroup characteristics (e.g. profession, sex, seniority/age, organisational role, years in profession/workplace/specialty, +/- patient contact, +/- training in the science of patient safety) can serve to identify, discuss and suggest improvement plans for specific groups e.g. improving the introduction of new employees or educating secretaries in the science of safety. However, providing subgroup results should never violate anonymity or jeopardise psychological safety. Figure 5 provides an overview of possible multi-dimensional subgroup analysis.

Figure 5 Multi-dimensional sub-group analysis of safety climate



Result feedback must be both easily assessable to the health care staff and tailored according to the specific metrics of the questionnaire used. Dimensional scale mean scores can mask the extent to which a scale score has a large or small standard deviation (135); thus, they seem too complex to feed back to the clinical level if the aim is that all health care staff understand the results regardless of statistical proficiency. Scale means are suitable for research use. Proportions are deemed easy to understand for the staff (136), and therefore such results are particularly operable in day-to-day operations together with standards for the maturity phases of the culture. Proportions are suitable for both improvement activities and for research.

For SAQ and HSPSC, the following climate metrics apply:

- the mean scale scores equal to the level of climate, applicable for both SAQ and HSPSC (58;127)
- the *proportion of staff* with positive attitudes (%-positive); defined as an individual scale score ≥75 on a scale ranging from 0-100; only applicable for SAQ (58)
- the *proportion of positive answers*, e.g. aggregation of two or more answer categories on the Likert scale defined as a positive answer to the question/statement; only applicable for HSPSC (127).

For the SAQ, having less than 60% positive *responders* is regarded an immature cultural dimension, and improvement initiatives should be initiated (137). The aim is to exceed the threshold score of 60% positive responders with a goal zone of 80%-100% (56;75). A change or difference ≥10 percentage points is regarded clinically relevant (75;138). Furthermore, clinical areas with less than 60% positive responders are likely to benefit more from improvement initiatives than areas with higher scores (139).

For HSPSC, less than 50% of positive *responses* indicate a weak item/dimension in need of improvement. If more than 75% of the responses are positive, the item/dimension is regarded a strength (93).

1.3.5. QUALITATIVE FOLLOW-UP OF QUANTITATIVE ASSESSMENT

A vital contribution to the questionnaire-based climate results, is promoting an in-depth dialogue about the results (56). As working with safety culture is relatively new, and a complex and foreign concept in many clinical areas, sufficient support is needed to facilitate a fruitful and rewarding dialogue, which motivate staff to suggest and engage in improvements initiatives (138).

A semi-structured dialogue method for use with SAQ has been suggested by B. Sexton (138). A representative group of 5-7 staff members or all staff members of the clinical area convene for a 30 to 60-minute dialogue and discuss the quantitative results. Items with less than 60% positive responders are selected for in-depth investigation, using the four questions (138) below:

1. *"What does this statement mean to you?*
2. *How accurately does the unit score reflect your experience in this unit? Share examples.*
3. *How would it look (i.e., what behaviours would we see) in this unit if 100% of staff strongly agreed with this item?*
4. *Identify at least one actionable idea to improve unit results in this area".*

The purposes of this sort of in-depth dialogue are to let staff express their values, beliefs and observations in person (56), to enhance their ownership of the results, raise awareness of the quality of the culture, discuss the relation of the results to norms and behaviour, and recognise implications of the results in terms of safety. The method also allows the staff to express silent knowledge and can thus give early warning about weak signals of potential fatal safety issues, which clinical leaders as well as frontline staff must pay attention to (44). In essence, the dialogue will shed

light upon *why* the culture manifests itself as it does; what works well and which aspects of the culture should be strengthened (11).

1.4. MAIN OBJECTIVES

In conclusion, working strategically with patient safety culture is relatively new in Denmark. Evidence based knowledge of the concept, measurement of safety culture, and the leadership role in improvement of the culture is sparse. Consequently, the main objectives of this dissertation were to:

I. Give a brief, easily accessible state-of-the-art overview of patient safety culture to professionals and leadership in the Danish health care system. This objective was related to study I.

II. Adapt the Safety Attitudes Questionnaire for use in Danish hospitals, assess its construct validity and reliability, and present Danish benchmark data. This objective was related to study II.

III. Investigate the patient safety culture before and after a leadership intervention. This objective was related to study III.

IV. Investigate the patient safety culture of the National Hospital of the Faroe Islands prior to introducing hospital level quality management initiatives. This objective was related to study IV.

CHAPTER 2. STUDY I - STATE OF THE ART

Study I: Kristensen S, Bartels PD, Sabroe S, Mainz J. Patientsikkerhedskultur kan facilitere høj klinisk kvalitet. Ugeskr Laeger 2014;16(176):1483-6.

Study I is reported in Paper I, which is included in Appendix F. The main messages of Study I are summarised below.

2.1. SPECIFIC OBJECTIVES

The main objective of Study I was to give a brief, easily accessible state-of-the-art overview of patient safety culture to professionals and leadership in the Danish health care system. The study specifically focused on:

1. introducing the concept of patient safety culture
2. measuring and assessing patient safety culture
3. developing patient safety culture.

Moreover, Study I gave a brief overview of patient safety culture measurements in Denmark. It also established the association between patient safety culture and patient safety.

2.2. METHOD

The state-of-the-art overview was based upon a literature review.

The initial literature search for Study I was performed in PuBMed and Web of Science in January 2013. The following search terms were used on their own and in combinations: health care, patient safety culture, patient safety climate, adverse events, occurrence, incidence, assessment, questionnaire, improvement, effect, outcome, and Denmark. The search also included searching Google Scholar to capture literature originating from books, reports, white papers, dissertations etc.

Literature originating from studies in hospital settings or otherwise related to hospitals was selected. Furthermore, reviews and studies with a high evidence level according to the Oxford Centre for Evidence-based Medicine were given priority (140).

Titles and abstracts were screened and relevant literature identified. Further literature and information were identified via cascade search in the identified literature.

The initial search for Study I was supplemented by searches in Cochrane Library, CINAHL and Embase for the purpose of elaborating on the results as specified below. This search was mainly performed in January 2016.

2.3. RESULTS

The main findings of Study I are summarised below with reference to Paper I. Moreover, the content of Paper I was supplemented as described in Chapter 1, and specific reference to the relevant sections is given below. Last, Study 1 gave a short overview of Danish measurements of patient safety culture; the overview is supplemented in Chapter 1. Introduction and objectives.

2.3.1. CONCEPTALISING PATIENT SAFETY CULTURE

In Study I, patient safety culture was conceptualised as the health care staff's behaviour, values, attitudes and basic assumptions related of the safety of their patients. The culture was described as the social and normative glue that holds the members of the organisation together and defines the *"way we do things around here"*(11;121).

The seven most cited dimensions of the safety culture were given in Study I as: management, teamwork, evidence-based practice, communication, learning, patient-centred care, and a just culture. Just culture was emphasized and described as a culture in which staff are open, trusting and actively contributing towards developing the patient safety culture. And the opposite; that gross negligence, wilful violations and destructive acts are not accepted and will consequently be punished.

The findings presented in Study I are supplemented in section 1.1. What is patient safety culture? Definitions of culture, organisational culture and patient safety culture are offered, the link between the three concepts specified, and characteristics of patient safety culture elaborated. It is suggested to use the following definition of a culture of safety in regard to patient safety: a culture of safety is "*an integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery"* (32).

2.3.2. MEASURING AND ASSESSING SAFETY CULTURE

A qualitative and two quantitative methods for assessment of patient safety culture were introduced in Study I as the most frequently mentioned in the literature. The qualitative method was the Manchester Patient Safety Framework (MaPSaF), and the quantitative methods were the SAQ and the HSPSC. A list of 31 additional patient safety culture questionnaires is provided in Appendix E. Furthermore, assessment of patient safety culture was elaborated on in section 1.3. Assessment of safety culture, and specific features of SAQ and HSPSC described extensively in section 1.3.1 Quantitative assessment.

Also in section 1.3. Assessment of safety culture, it was emphasised that results from a culture questionnaire should be discussed in a dialogue-based qualitative process whose goal is to motive staff to engage in improvement initiatives.

2.3.3. DEVELOPING SAFETY CULTURE

In Study I, team training, patient safety leadership walk rounds and multi-faceted intervention programmes such as CUSP were identified as the most efficient for developing the safety culture. Patient safety leadership walk rounds and CUSP are both characterised by strong leadership support and engagement. Further, it was emphasised in Paper I that a reverse association between development of patient safety culture and e.g. infections or patient falls had been observed in studies in which CUSP was implemented. The basis for these results is presented in section 1.2.2. Methods for enhancing patient safety culture, Table 1. Also emphasised was team training as an effective intervention for promotion of patient safety culture (59;78).

2.3.4. PATIENT SAFETY CULTURE AND PATIENT OUTCOMES

Study I highlighted that experiences from other high-risk industries show that a successful gradual reduction of adverse events was typically initially related to enhancing technology; later on the focus shifted to work procedures, instructions, standards and education. Today, implementing and maintaining a culture of safety is regarded an underlying factor for safe performance.

Emerging evidence from health care suggests an association between enhancing patient safety culture and reduction of adverse events such as patient falls, infection and mortality (141).

In study I, it was highlighted that favourable SAQ scores have been associated with fewer medication errors, lower ventilator associated pneumonia rates, lower bloodstream infection rates, lower risk-adjusted patient mortality rates and shorter length of hospital stays (34).

The evidence-based link between safety culture and patient safety culture was elaborated on in section 1.2.3. Safety culture and patient safety outcomes. Significant relationships between dimensional patient safety culture and patient safety outcomes were identified and illustrated in Table 2 (84). Regardless of questionnaire used, the safety climate was the dimension most often related to clinical outcomes; it was negatively related to mortality, community acquired pressure ulcers and readmissions, and positively related to family satisfaction (84). It should be noted that the safety climate dimension differs in content across questionnaires. The review performed in section 1.2.3. Safety culture and patient safety outcomes also showed that the link between safety culture and aspects of patient safety has been established most extensively by the use of SAQ, as can be seen in Table 2.

Additionally, a scan of empirical evidence, exploring the nature of the relationship between safety culture and patient outcomes included 23 articles. The results of the scan add to the results in section 1.2.3. Safety culture and patient safety, finding that safety climate can predict urinary tract infections, and poorer safety climates have been found to be associated with longer length of hospital stay (142).

2.4. DISCUSSION

Patient safety culture was introduced as a multi-dimensional concept representing the shared assumptions, values, attitudes and behaviours of professionals that characterise the safety of patients in a health care setting. In short, patient safety culture was described as *"the way we do things around here"* in relation to patient safety.

The SAQ and the HSPSC were identified as quantitative methods for surveillance and monitoring of patient safety culture, and the MaPSaF was identified as a qualitative dialogue-based method for understanding the safety culture.

The dimension safety climate was most often positively associated with aspects of patient safety, e.g. reduced mortality, community acquired pressure ulcers, readmissions and enhanced family satisfaction. The link between safety culture and aspects of patient safety has been established most extensively by the use of SAQ.

Interventions characterised by a strong leadership engagement, e.g. patient safety leadership walk rounds and multifaceted interventions were most often associated with improvements in the patient safety culture.

2.4.1. METHODOLOGICAL CONSIDERATIONS

Study I was a literature study dealing with several aspects of patient safety culture simultaneously. Due to the editorial limitations of such an overview article, it was not possible to present, debate in depth or sufficiently support the contents of the article by the evidence. An alternative would have been a review article, which offers a more comprehensive approach; yet a review article was not deemed suitable to introduce a brief, easily accessible state-of-the-art overview of a new topic. To elaborate on and strengthen the messages of Paper I, the findings reported in Paper I are supplemented in this thesis with more information and underlying evidence in regard to the focus areas of Study I.

The initial literature search of Study I was limited to two scientific databases and searches on Google Scholar. The initial search was supplemented and strengthened by searches in Cochrane Library, CINAHL and Embase for the purpose of elaborating on the results and supporting the evidence.

Two small reviews of reviews were performed in section 1.2.2. Methods for enhancing the safety culture, and 1.2.3. Safety culture and patient safety. The first review included two reviews from 2012 (59) and 2013 respectively (78). Although these reviews are recent, they do not capture literature published after 2013. Likewise, the second review included two papers; they were published in 2014 and 2015 respectively; therefore literature published after that is not included.

2.5. RELATION OF THE FINDINGS TO OTHER STUDIES

A myriad of definitions of patient safety culture exists, and there is no consensus on one specific definition, nor on the concept (30). Hence, the connection between culture, organisational culture, safety culture and patient safety culture was established based upon acknowledged and well tested theories and definitions. The concept of patient safety culture was derived at and presented as a subset of organisational culture, with the same basic understanding of the patient safety culture as that of organisational culture (27). One simple widely used definition of patient safety culture was presented in Paper I as: *"the way things are done around here"*; it was first offered in the patient safety literature in 2005 by P. Pronovost (121) and

solidified in 2013 by the Health Foundation, United Kingdom, which added *"it's what you do when nobody's looking"* (11).

A more comprehensive definition developed by and used across the European Union (EU) (32) was introduced as *"an integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery"*. This definition defines patient safety culture as a dynamic concept integrated into the processes of care and directly linked to the safety of the patients. It also indicates that a culture of safety is also a culture of continuous improvement.

Three instruments for assessment of patient safety culture were identified as the most often used in the literature: the MaPSaF, the SAQ, and the HSPSC. They have all been recommended by the EU in 2010 (143), and evidence underlines that they are valid and used across the EU (113;114;116;117;119;139;144-152).

Interventions characterised by a strong leadership engagement were found to be most effective in promoting a culture of safety. Teamwork and safety climate on the SAQ were the two dimensions most often affected by interventions. These two dimensions mirror how staff experience the cooperation with their colleagues, general risk management and the patient safety in the clinical area where they work (153). Evidence to support the impact of the interventions to promote patient safety culture is currently limited, but seems to be emerging.

The same situation applies to evidence documenting the link between patient safety culture and patient safety. It is sparse, and the current literature indicates that there might be problems with both the definition of patient safety culture, the validity and reliability of the patient safety culture questionnaires, and the patient safety outcome measures used. Again, literature is emerging (85). The dimension safety climate on the SAQ was most often positively related to specific aspects of patient safety, e.g. reduction of mortality, community acquired pressure ulcers and readmissions and promotion of family satisfaction (84).

2.6. CONCLUSION

Although there is no consensus on a specific definition of patient safety culture, or on the concept, it is generally acknowledged that safety culture is comprised by assumptions, values, norms, practices and behaviour in regard to the safety of the patients. *"The way we do things around here"* can be used to define patient safety culture in day-to-day practice, whereas the definition provided by the European Society for Quality in Healthcare is suggested for use within clinical quality improvement and research.

MaPSaF, SAQ, and the HSPSC were identified as the most often used instruments to assess patient safety culture in the literature.

The literature documenting effective methods to create and develop the safety culture is sparse, but it highlights strong leadership engagement as an important characteristic. Likewise, the evidence supporting a positive relationship between dimensional safety culture and aspects of patient safety is still sparse. SAQ was most often used to document a positive relationship between the culture and specific aspects of patient safety, e.g. reduction of mortality, community acquired pressure ulcers and readmissions and promotion of family satisfaction.

CHAPTER 3. STUDY II - VALIDATION STUDY

Study II: Kristensen S, Sabroe S, Bartels P, Mainz J, Christensen KB. Adaption and Validation of the Safety Attitude Questionnaire for the Danish hospital setting. Clinical Epidemiology 2015;7:149-60.

Study II is reported in Paper II, which is included in Appendix G. The main messages of Study II are summarised below.

3.1. SPECIFIC OBJECTIVES

The objectives of Study II were to:

4. adapt the SAQ for use in Danish hospitals
5. assess construct validity of the Danish version of SAQ (SAQ-DK)
6. assess internal consistency reliability of SAQ-DK
7. present Danish benchmarking data.

Moreover, differences in perception of the culture related to gender and bedside staff; that is, doctors, nurses and nursing assistants, were explored and results displayed below.

3.2. METHODS AND MATERIALS

The study design and analysis plan for Study II were conceptualised partly based on the reasoning in section 1.3.2 Validity and reliability of quantitative methods, and upon findings of a review of the literature on validation of the SAQ. To identify relevant literature for the review, a literature search was performed in PubMed and Web of Science in the autumn of 2010. Combinations of the following search terms were used: Safety Attitudes Questionnaire, patient safety culture, hospital, psychometric properties, factor analysis, validity, and reliability. Titles and abstracts were screened to identify studies reporting psychometric properties of the SAQ or single scales of the SAQ, and the reference list of the studies screened to identify more possible studies.

A total of five studies were found reporting psychometric properties of different versions of the SAQ. That is, four studies in addition to the original SAQ validation study which was published by Sexton et al. in 2006 (58). The four additional studies were from Norway (154), Hungary (155), Taiwan (156) and Sweden (139). Review results of the studies are listed in Table 3; showing the year of the study, the SAQ version(s) used in the study, the number of study participants and the response rate, and the main psychometric properties found in the study. The different versions of SAQ were designed alike, only they addressed different specialties, e.g. stating "in this ICU…" or "in this OR…". The SAQ Short Form is generic and states "here…". All five studies applied a cross-sectional study design, testing the fit of a pre-hypothesised theoretical six-factor model. The size of the participating populations varied from 61 in Hungary (155) to 45,242 in Taiwan (156). The sample size of the Hungarian study was not large enough to comply with the recommendation of 10 health care staff per item, as desired for confirmatory factor analysis (CFA) (132). Moreover, the Hungarian study only included staff from a paediatric inpatient unit, and only the three scales for teamwork climate, safety climate and stress recognition were assessed. In the other four studies, CFA was applied, and internal consistency reliability of the questionnaire and/or the individual scales was established by Cronbach's alpha coefficient. These findings were taken into account in the design of Study II.

Study II was designed as a cross-sectional study and implemented in 2011. A Danish version of SAQ was adapted in a stepwise method modified from Beaton et al. (157).

The adaption of SAQ Short Form 2006 into Danish involved: a forward-backward translation technique, a consensus process in an expert panel, pilot testing of the first version of SAQ-DK, adjusting the questionnaire after pilot testing, and approval by the expert panel. The following professions were represented in the pilot test (N=15): doctors, nurses, physiotherapists, occupational therapists, secretaries/administrative staff and data managers. All had experience with clinical quality improvement. SAQ-DK is shown in Appendix J. Face as well as content validity was assessed by the expert panel during adaption of SAQ-DK into Danish. Information from pilot participants was taken into account in this assessment.

Upon adaption, the psychometric properties of SAQ-DK were tested.

Table 3 Main psychometric properties found in five SAQ validation studies, listed per year, ending in 2010

Year and country	SAQ version(s)	Number of participants (response rate)	Main psychometric results
2006			
United States (58) United Kingdom (58) New Zealand (58)	SAQ-ICU SAQ-Amb. care SAQ-Inpatient SAQ-ICU SAQ-OR SAQ-ICU	10,843 (67%)	Multilevel CFA showed: χ^2/df = 3.152, P<0.01; CFI = 0.90; RMSEA = 0.03; SRMR (between clinical areas) = 0.17; and SRMR (within clinical areas) = 0.04; Raykov's ρ coefficient = 0.90; Cronbach's α: 0.85
2008			
Norway (154)	SAQ Short Form	1,306 (68%)	CFA showed: χ^2/df = 2.583, P<0.01; RMSEA = 0.048; Probability RMSEA (p close) = 0.893; AGFI = 0.871; Hoelter 0.05 = 296; Cronbach's α: 0.68 - 0.85
Hungary (155)	SAQ-OR	61 (69%)	EFA revealed and CFA confirmed three factors for team climate, safety climate, and stress recognition. Cronbach's α: 0.72 - 0.89
2010			
Taiwan (156)	SAQ Short Form	45,242 (69%)	CFA showed: CFI = 0.99; RMSEA = 0.06; GFI= 0.98; TLI = 0.92; Cronbach's α: 0.79 - 0.85
Sweden (139)	SAQ-Pharmacy	7,244 (60%)	CFA showed: CFI = 0.90; RMSEA = 0.06; Cronbach's α: 0.72 - 0.89

Abbreviations: ICU, intensive care unit; Amb., ambulatory; OR, operating room; EFA, exploratory factor analysis; CFA, confirmatory factor analysis; χ^2, Chi square; df, degrees of freedom; CFI, comparative fit index; RMSEA, root mean square error of approximation; SRMR, standardized root mean square residual; clinical area, in- and outpatient units; Cronbach's α, Cronbach's alpha coefficient; AGFI, adjusted goodness-of-fit index; GFI, goodness-to-fit index; CFI, comparative fit index.

3.2.1. SAFETY ATTITUDES QUESTIONAIRE

The original American version of the SAQ (58) is developed from the Flight Management Attitudes Questionnaire (FMAQ), which was launched in 1996. FMAQ measures interpersonal aspects of crew performance, such as teamwork, communication, speaking up, collaborative decision-making and leadership. The FMAQ traces back to the Cockpit Management Attitudes Questionnaire, which was developed by R.L. Helmreich in 1984 (158).

R.L. Helmreich was a pioneer in cockpit research management and extended the principles from aviation into health care. He investigated the nature of personality or personality traits and attitudes among pilots. Personality or personality traits are relatively stable individual characteristics, resistant to change, whereas attitudes are less deeply internalised components of the being, and thus changeable through specific interventions. R.L. Helmreich documented that pilots' attitudes are independent of personality or personality traits, and that attitudes are major determinants of cockpit behaviour. He concluded that addressing the attitudes of the pilots by training in cockpit resource management may lead to changes in behaviour and consequently improvements in cockpit performance. He suggested evidence-based presentations, moderated group discussions and behavioural exercises (e.g. flight simulations) as successful interventions to address changes in attitudes, as opposed to lectures, media presentations and self-study programs (158). SAQ is founded upon the same logic chain of reasoning, starting with the assessment of attitudes to patient safety, and using the results to identify needs for improvements, then addressing attitudes to change behaviour, and ultimately expecting improvements in patient safety, e.g. the frequency of falls, infection rates, medication errors or suicides.

The current short-form version of SAQ applicable for use in hospitals has been presented in detail in section 1.2.2. Quantitative assessment. In brief, it is a one-page explorative questionnaire, with 31 items covering six dimensions for teamwork climate, safety climate, job satisfaction, stress recognition, perception of management and working conditions. The responders answer SAQ items on a 5-point Likert scale (1=Disagree Strongly, 2=Disagree Slightly, 3=Neutral, 4=Agree Slightly, and 5=Agree Strongly). Further, background information [e.g. date of answering the SAQ, SAQ completed before, profession, gender, years in specialty, and primary work area *(adult, children, both)*] is requested on the SAQ (58).

3.2.2. STUDY SETTING

Study II was integrated into two different large-scale national quality improvement projects: the Danish Safer Hospital Programme, and the Good Psychiatric Department (159;160)

Participants originated from 16 in and out patient units (clinical areas) from the same department in a psychiatric hospital, and from 15 inpatient units from five somatic hospitals.

The psychiatric clinical areas were: six outpatient clinical area and ten inpatient bed units. They were either disease-specific or generic, and either open or closed units.

The 15 somatic inpatient bed units were selected as follows: one operating room and one intensive care unit from each of the five hospitals. Further, across the five hospitals, a total of five bed units of internal medicine, oncology, neurology, surgery and cardiology were selected.

3.2.3. SAMPLE

In total, 1,263 staff members were invited: 362 staff members from the psychiatric department and 901 staff members from the five somatic hospitals. Study participants were identified based on human resources data provided by the hospitals.

All full- and part-time staff working in the clinical areas at least half of their working time were invited. In this way, staff (e.g. a therapist) spending most of his/her working hours in a specific clinical area (e.g. oncology) while being employed in another clinical area (e.g. the therapy department) were invited to participate.

3.2.4. DATA COLLECTION

At each hospital, a local project manager was appointed to cooperate with the main researcher in the data collection. Data collection guidelines were established and distributed to ensure uniformity in data collection. Qualitative information on the usability of the SAQ-DK was collected from the hospital coordinators.

Invitees from the psychiatric hospital received SAQ-DK via a secure link in a personal mail. Invitees were given four weeks to complete SAQ-DK. Reminders were

mailed to invitees who had not responded after two and three weeks respectively. The reminder contained information on the current participation rate.

In the somatic clinical areas, SAQ-DK was distributed via unit-specific kick-off meetings led by the main researcher accompanied by the local hospital project manager. Information about the questionnaire, patient safety culture and SAQ-DK was given at the kick-off meetings, and participants had the opportunity to ask questions, and complete the SAQ-DK. To ensure distribution of SAQ-DK to staff not participating in the kick-off meetings, the administration at the meeting was supplemented by hand delivery and in-house mailing. Invitees were given four weeks to complete the SAQ-DK. Reminders were posted in the units after two weeks; it stated the current unit-specific participation rate.

3.2.5. STATISTICAL ANALYSIS

Respondent demographics were expressed as frequencies.

For each scale, two climate metrics were calculated; 1) the percent of responders with a positive attitude (% positive), and 2) mean scale scores and standard deviations (SD).

To calculate these two scores, individual SAQ-DK item scores were converted to a 0-100 point scale, where 1=0, 2=25, 3=50, 4=75 and 5=100. Items 2 and 11 were reverse scored in order to match their valence with the positively worded items. Individual scale mean scores, which were calculated by the average score of the scaled items for each dimension (range 0-100), and the proportion of responders with a mean scale scores ≥75 were calculated (137). SAQ-DK mean scale scores were calculated for each dimension by the average score of the scaled items.

Chi-squared tests were used to compare dimensional % positive scores, and t-tests were used to compare mean scale scores.

Analyses of variance (ANOVAs) were performed to test for significant between-clinical area variability in mean scale scores.

To test construct validity of SAQ-DK, the underlying original six-factorial structure described by Sexton et al. (58) was hypothesised and tested. Goodness-of-fit indices were chosen as: chi-square statistics (χ^2, degrees of freedom [*df*], *P*-value), comparative fit index (CFI), and root mean square error of approximation (RMSEA) (131). Prior to performing the CFA, threshold values for an acceptable model fit were defined. Further, data on the construct validity of the SAQ were provided by the degree of linear association between pairs of two dimensions.

Internal scale consistency of the SAQ-DK was reported by Cronbach's coefficient alpha (161). If $\alpha > 0.70$ for items in a scale, then they were regarded closely as related (137).

Item discrimination was investigated to determine the degree to which differences between responders' ratings of a single item were consistent with differences in their ratings of the subscale as a whole. For this purpose, the item-subscale correlations were examined.

Only clinical areas/subgroups with more than five responders were included analysis (162). Differences in % positive ≥10 percentage point between groups were regarded clinically relevant (75;138).

Statistical significance was defined as $P<0.05$.

Results were generated by the use of IBM-SPSS version 21.0, SPSS AMOS version 22.0 (SPSS, Chicago, Illinois) and Windows Excel 2016.

3.2.6. ETHICS

The study was approved by the Danish Data Protection Agency. Invitees were informed that participation was voluntary, and that all answers were treated with confidentiality; it was emphasised that no individual answers would be available to the local clinical leaders.

3.3. RESULTS

The main findings of study II are summarised below. Results not reported in Paper II specific to gender and bedside staff are reported under section 3.3.5. Danish benchmarking data.

Clinical area level results and sub group results (gender, profession, work experience and organisational role) are displayed in Appendix K. Findings Studies II - IV.

3.3.1. THE DANISH VERSION OF THE SAQ

The adapted Danish hospital version of SAQ is an explorative questionnaire with 32 items, where the 31 items comprise six patient safety culture dimensions. The culture dimensions are:

- teamwork climate (items 1 - 6)
- safety climate (items 7 - 13)
- job satisfaction (items 15 - 19)
- stress recognition (items 20 - 23)
- perceptions of management (items 24 - 29)
- working conditions (item 30 - 32).

Item 14 is not part of any scale. SAQ-DK also include items on demographic information.

The management dimension can be applied at the different management levels according to the organisation of the hospital, e.g. top level, department level and clinical area level.

Description of the content of the SAQ-DK dimensions (153):

- *teamwork climate* embraces the perceptions of hospital staff about their collaboration within a specific clinical area to provide safe care for the patients
- *safety climate* reflects staff's attitudes towards the safety of patients and clinical risk management
- *job satisfaction* mirrors the attitudes of staff towards the job
- *stress recognition* captures staff's attitudes about recognition of stress which might affect patient safety. These items address self-behaviour versus the behaviour and attitudes of colleagues, as is the case in the other scales
- the *management dimensions* assess staff's perceptions about the leadership's dedication to patient safety, support of frontline staff and delivery of timely information on policies that influence their work
- *working conditions* reflect staff's perceptions of whether new employees are adequately trained, problem personnel are adequately dealt with and information vital to patient care is properly disseminated.

In comparison to the original American wording of the SAQ, the Danish version deviates in regard to items 1 and 6. Item 1 on SAQ-DK addresses health professionals as opposed to nurses in the American version; item 6 also addresses health professionals as opposed to physicians and nurses. Moreover, the original American SAQ addresses clinical area (e.g. …in this clinical area, it is…) in items 1, 2, 3, 8, 9, 11, 13, 18 and 29. A translation of clinical area into Danish in a word used in everyday language by health care staff was not suitable; hence, the word "here" was chosen, (e.g. …here, it is…), and it was explained in the introduction to SAQ-DK that responses should be based on experiences and perceptions in the in or out patient unit or the place where the responder works.

Responders answer the SAQ-DK on a 5-point Likert scale as: 1=Disagree Strongly, 2=Disagree Slightly, 3=Neutral, 4=Agree Slightly, and 5=Agree Strongly. Items are assumed to have interval properties. Further, SAQ-DK allows responders to select "not applicable" as a possible answer. As in the original American version, the "not applicable" answer is not part of the climate metric. Items 2 and 11 on SAQ-DK are negatively worded and so reverse scored.

Demographic information can be collected together with SAQ-DK on the following variables:

- profession (*doctors, nurses, nursing assistants, midwives, psychologists, physiotherapists, occupational therapists, speech or music therapists, pedagogues, radiographers, dieticians, pharmacists or pharmaconomists, service assistants and porters, social workers, administrative staff and secretaries, medical laboratory technicians, technical staff)*
- gender
- organisational role *(leader versus frontline staff)*
- age or age group
- work experience *(number of years in the specialty, and at the unit and hospital respectively)*
- organisational affiliation *(unit and department)*
- patient contact *(+/-)*
- special responsibility in regard to patient safety *(with a special training in safety of science)*
- primary work area *(adult, children, both).*

Face as well as content validity of SAQ-DK was verified by the expert panel during adaption process.

Usability of the SAQ-DK was found to be good. The electronic administration of the questionnaire was less burdensome than the paper administration in terms of workload related to data collection and analysis. As intended, participants at the kick-off meetings used the opportunity to clarify questions and complete the SAQ-DK. Responders filled in the questionnaire in three to twelve minutes.

3.3.2. PARTICIPATION

Of the 1,263 distributed questionnaires, 925 were returned (73.2%). The response rate in the psychiatric sample was 76.5%, and in the somatic sample it was 71.9%.

In the entire sample, 10.3% of responders were male: 10.1% doctors, 77.1% nurses and nursing assistants, 4.3% therapists, and 8.5% others/non-clinical staff (dieticians, social workers, administrative staff and hospital porters). One point four percent were clinical leaders, and 21.2% had been in their profession two years or less.

3.3.3. CONSTRUCT VALIDITY OF SAQ-DK

Construct validity of SAQ-DK was investigated by hypothesising and testing the six-factor structure present in the original American SAQ Short Form (58). Results of the CFA revealed the goodness-of-fit indices shown in Table 4.

Table 4 Goodness-of-fit results of the confirmatory factor analysis for SAQ-DK

Goodness-of-fit indices	**Entire model[a] (N=925)**
Chi-square test of the model fit (χ^2, df, *P*-value)	χ^2=1,496.760; df=419; P<0.001
Comparative fit index	0.901
Root mean square error of approximation (RMSEA)	0.053
90% CI for RMSEA	0.050 – 0.056
Probability RMSEA (p close)	0.057

Notes: [a] Handling of incomplete date by pair-wise present approach.
Abbreviations: χ^2, Chi-square; df, degrees of freedom; RMSEA, root mean square error of approximation.

All model-of-fit indices fulfilled the threshold criteria for a good model fit set prior to the analysis. The chi-square test of the model fit revealed a χ^2/df ratio of 3.572, which is below the acceptable threshold of 5.00, as desired. The CFI exceeded the threshold value of 0.90, as anticipated. The RMSEA was below the threshold value of 0.06, as anticipated. Lastly, the probability RMSEA (p close) was 0.057, which was above the threshold of 0.05, as wanted.

3.3.4. ITEM AND SCALE RELIABILITY AND SCALE CORRELATIONS

Item reliability was described by subscale-corrected item-total correlations, and item-factor loadings (N=925). Item-subscale correlations ranged from 0.23 to 0.77. Only item 2 in the teamwork climate scale had an item-subscale correlation below the anticipated threshold value of 0.30. Thus a weak relationship between item 2 and the other items in the teamwork climate scale was present. Item 2 also had an item-factor loading below the acceptable threshold of 0.30, which indicates that less than 8% of the variance between item scores is explained by the factor.

Total questionnaire reliability and scale reliability was investigated by Cronbach's alpha coefficient (α). The cut-off for acceptable reliability was: $\alpha > 0.70$. Cronbach's alpha coefficient for the total SAQ-DK was 0.89, which is high. It changed insignificantly (0.88 – 0.90) when items were removed. Cronbach's alpha exceeded 0.70 for all scales; it varied from 0.70 for the teamwork climate scale to 0.86 for the perception of unit management scale, indicating good scale reliability.

Scale-to-scale correlations were studied by Pearson's correlation coefficients. Pearson's correlations indicated significantly strong positive relationships between all scales ($P<0.01$) except the stress recognition scale, which correlated negatively with all other scales ($P<0.05$). Negative correlation coefficients ranged from -0.13 to -0.08. The positive correlation coefficients ranged from 0.47 for the correlation between teamwork climate and perception of unit management, to 0.67 for the correlation between the teamwork and the safety climate scale.

3.3.5. DANISH BENCHMARKING DATA

Benchmarking data for the entire sample and for the somatic and psychiatric samples were provided separately. Benchmarking data were reported as % positive and as mean scale statistics.

For the entire sample, % positive was lowest for perception of unit management (42.6%), and highest for teamwork climate (64.8%). In parallel, the degree to which

the culture was perceived as positive (mean scale score) varied from 66.8 for perception of unit management to 77.2 for teamwork climate. Safety climate was perceived as positive by less than half of the responders (% positive = 45.5%).

At the clinical area level, significant differences in the proportions of staff with a positive attitude were found for all cultural dimensions, $P<0.05$. Also the degree to which the culture was rated as positive differed across clinical areas for all dimensions of the culture, $P<0.05$.

Between the genders, it was generally found that more female (N=816) than male (N=95) perceived the culture as positive (% positive). This is evident from Figure 6; all red bars for females are higher than the blue bars for males. Also, females had more favourable perceptions (mean scale scores) of the culture than males, which can be seen in Figure 7. Again, red bars for females are higher than the blue for males. However, gender differences were only found simultaneously for both climate metrics for teamwork climate, $P<0.05$. Also, the difference in the proportions of female and male staff with positive attitudes towards teamwork climate was ≥10 percentage point.

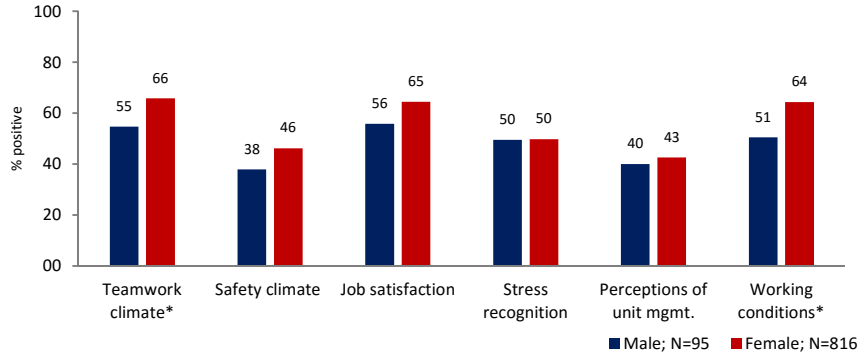
It has been documented that staff in non-clinical areas have a more favourable view of the culture than staff in clinical areas (45). Staff in clinical areas are primarily doctors, nurses and nursing assistants, or collectively known as bedside staff, and the staff closest to the patients. Variation in cultural perceptions among bedside staff might jeopardize patient safety; hence differences among the three types of bedside staff were investigated below.

Results for % positive for doctors, nurses and nursing assistants are shown in Figures 8a-c (showing 6a: teamwork climate; 6b: safety climate; and 6c: job satisfaction) and Figures 8d-f (showing 6d: stress recognition; 6e: perception of unit management; and 6f: working conditions) for the psychiatric and the somatic sample respectively.

The three bars at the right hand side of Figures 8a-c and Figures 8d-f respectively show results for the somatic sample. Across the two figures, it is evident that differences in % positive among somatic bedside staff were neither clinically relevant (≥10 percentage point) nor statistically significant.

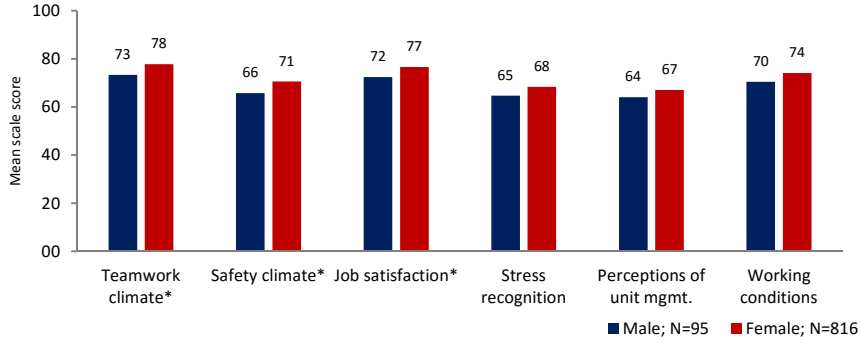
The three bars at the left hand side of Figures 8a-c and Figures 8d-f respectively show results from the psychiatric sample. Differences in % positive ≥10 percentage points were present among psychiatric bedside staff for all dimensions, except perception of unit management. Statistically significant differences in % positive among psychiatric bedside staff were present for safety climate, job satisfaction, stress recognition and working conditions, $P<0.05$. Moreover, it is noticeable that fewest nursing assistants and the like perceived the culture as positive for all dimensions except safety climate; this pattern was specific to the psychiatric sample.

Figure 6 Distribution of proportions of male and female staff with positive attitudes towards six dimensions of patient safety culture



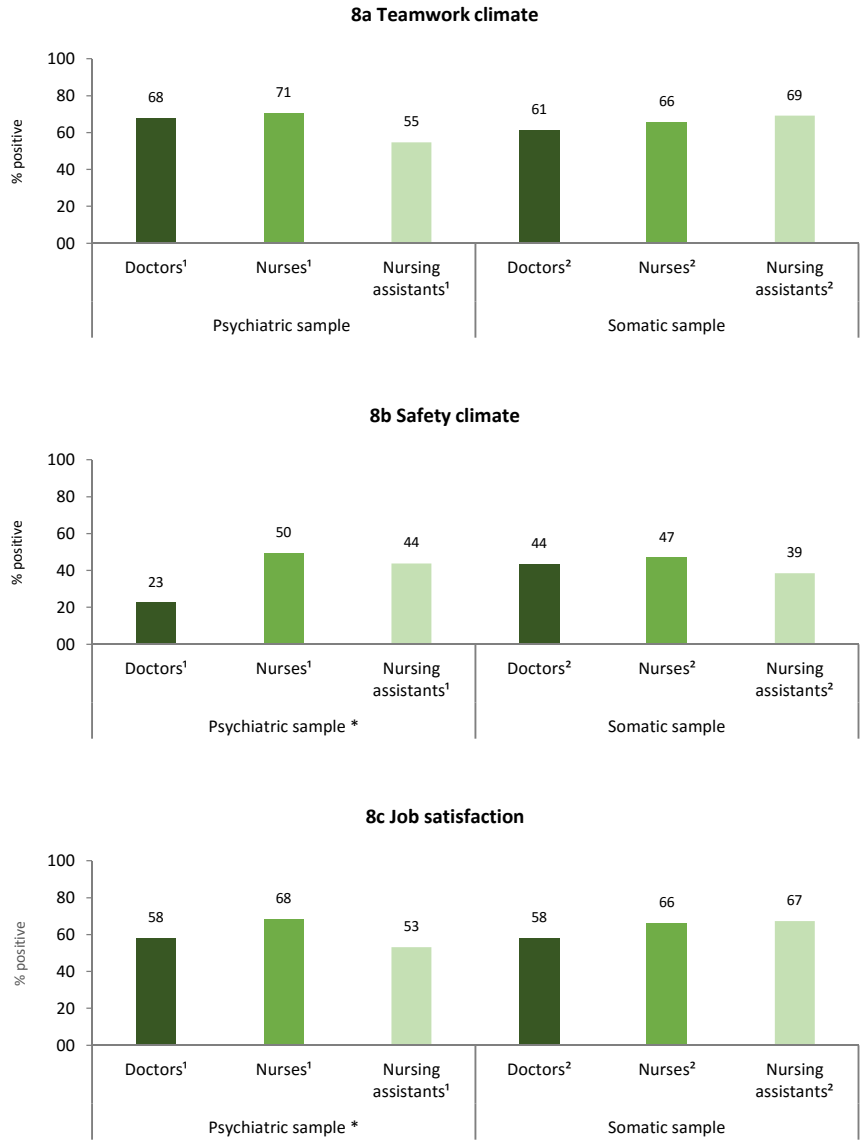
Notes: * Significant differences in % positive between male and female staff using Chi^2 test, P<0.05

Figure 7 The degree to which (mean scale score) male and female staff perceived six dimensions of patient safety culture as positive



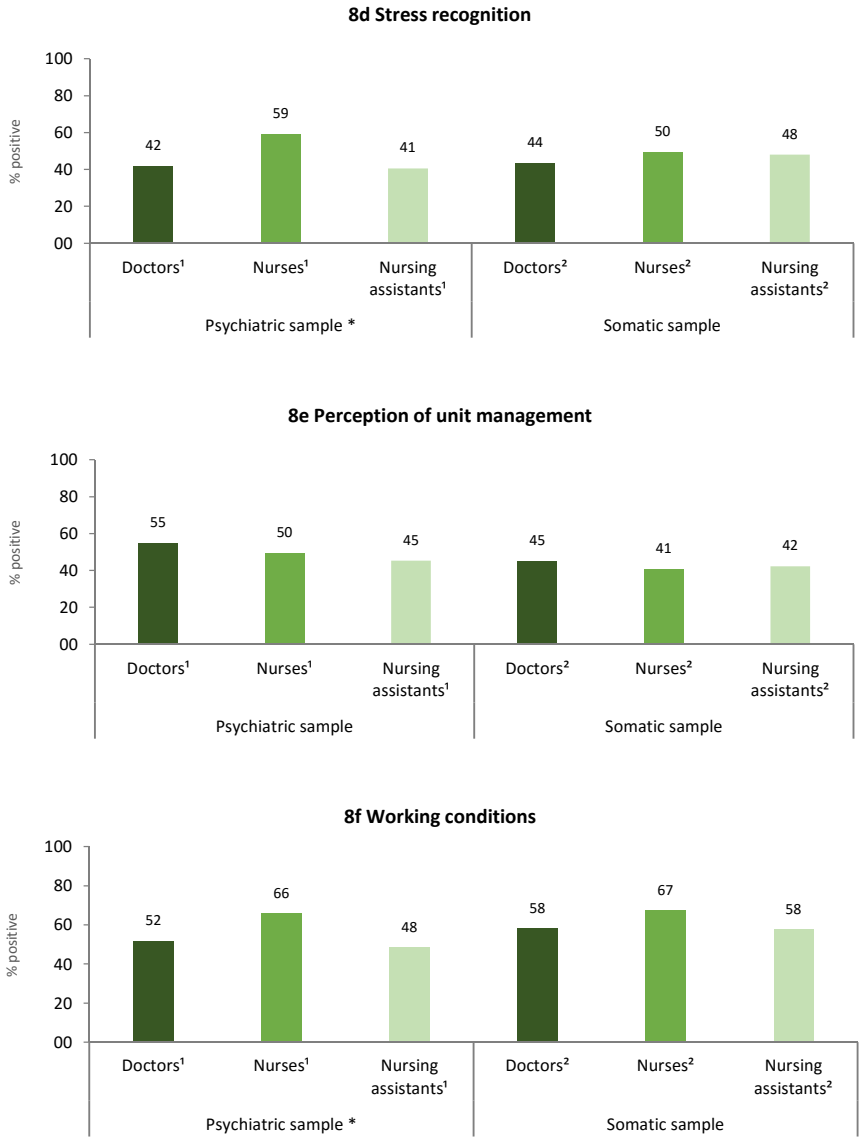
Notes: * Significant difference in scale means between male and female staff using independent t-test, P<0.05
Abbreviations: mgmt., management.

Figures 8a-c Proportions of three types of bedside staff with positive attitudes (% positive) towards three dimensions of safety culture in the psychiatric (N=218) and the somatic sample (N=588)



Notes: Doctors[1], N=31; nurses[1], N=123; nursing assistants and the like[1], N= 64; doctors[2], N=62; nurses[2], N=474; nursing assistants and the like[2], N= 52; * P<0.05, df=2 using Chi^2 test.

Figures 8d-f Proportions of three types of bedside staff with positive attitudes (% positive) towards three dimensions of safety culture in the psychiatric (N=218) and the somatic sample (N=588)



Notes: Doctors[1], N=31; nurses[1], N=123; nursing assistants and the like[1], N= 64; doctors[2], N=62; nurses[2], N=474; nursing assistants and the like[2], N= 52; * P<0.05, df=2 using Chi[2] test.

When comparing the attitudes of doctors (N=93) and nurses (N=597), no differences in means were found, P<0.05, for any dimensions. Higher proportions of nurses than doctors had positive attitudes (% positive) towards safety climate and working conditions, P<0.05.

Lastly, perceptions of safety culture were explored in regard to working experience in the hospital. It was found that staff with two or more years of experience in the hospital (experienced staff; N=849) perceived the working conditions more favourably (mean scale score) than staff with less than two years of working experience in the hospital (inexperienced staff; N=76), P<0.05. In parallel, more experienced staff than inexperienced staff had positive attitudes (% positive) towards the working conditions, P<0.05. Finally, the safety climate was perceived as positive (% positive) by more experienced than inexperienced staff, P<0.05.

3.4. DISCUSSION

The SAQ was adopted into Danish and tested; it showed good construct validity and good internal consistency reliability.

3.4.1. METHODOLOGICAL CONSIDERATIONS

Study II had participation rates above 70% in both samples, which is satisfactory and reflects a safety culture as opposed to mere opinions (121). The participation rate differed slightly between the somatic (72%) and the psychiatric sample (76%); this difference might be attributable to the different ways of distribution, the visibility of the assessment in the clinical setting, and local support from the clinical leaders.

Study II was integrated into two large- scale national quality improvement projects; the sampling accounted for inclusion of clinical areas across the somatic and the psychiatric hospital care, and for inclusion of multiple sub-specialised clinical areas. However, no university-based clinical areas were included in the somatic sample, and not all sub-specialties were represented, just as non-clinical areas were not included. So, it cannot be ruled out that sampling bias at the clinical area level was present and the sample was not representative for Danish hospital care in general.

Male staff in Danish hospitals account for 18% (163), but only 10% of the participants in Study II were males, hence males were underrepresented. Males perceived teamwork climate, safety climate and job satisfaction as less positive than their female colleagues, thus the benchmarking data for these SAQ-DK mean scales

scores might be overestimated. Likewise, fewer males than females were positive about teamwork climate and working conditions, hence the benchmarking data for % positive for these SAQ-DK scales might be overestimated.

The study was large enough to comply with 10 participants per item as anticipated for CFA (132), and the threshold of 13% missing and "not applicable" answers used in other studies for exclusion of items from the analysis was not enforced (108;164). Further, a full range of scores was obtained for all items. These findings compared well to previous international results (58;108;139;164;165) and add to the good internal reliability of Study II.

Per se, a cross-sectional study design only provides a snapshot of the phenomena studied at a specific point in time. Patient safety culture is a dynamic concept, sensitive to contextual influence. Therefore, different benchmarking results could possibly have been obtained at a different point in time.

Study II is based upon self-reported information, which might have created information and social desirability bias. Information bias is mostly suspected in regard to the two negatively worded items in the teamwork and safety climate scale, possibly leading to an underestimation of the cultural outcomes. Social desirability bias might have led participants to answer more favourably than the truth, leading to an overestimation of the cultural outcomes. Moreover, the attention of the research project might have created a Hawthorne effect; if so, the observed outcomes are also overestimated.

In conclusion, Study II might be prone to bias which could invalidate the external validity of the study, and the findings should be generalised with caution.

3.4.2. RELATION OF THE FINDINGS TO OTHER STUDIES

The goodness-of-fit indices of the SAQ-DK were all satisfactory according to the preselected cut-points. Also questionnaire as well as scale reliability was satisfactory. These findings compared well to findings from Norway, Sweden, Switzerland, Italy, Turkey, Taiwan and the USA (58;102-104;108;156;164;166).

Inter-scale correlations revealed negative correlations between the stress recognition scale and all other scales, indicating that this scale is distinct from the other scales and not part of the same underlying patient safety culture construct. Consistent results were obtained for inter-scale correlations in other international studies (167;168).

In regard to the Danish benchmarking data, some variation in dimensional climate across countries has been observed (169). In Australia, poorer climate was found in

psychiatric than in somatic hospitals (47); the Danish results for % positive are in opposition to this. However, the Danish mean scale score compares well to climate results from Switzerland and the USA (135).

3.5. CONCLUSION

The SAQ was adopted into Danish and tested. It showed good construct validity and good internal consistency reliability; SAQ-DK is now ready for implementation in the Danish hospital sector as a method for monitoring patient safety culture. Danish benchmarking data are available.

CHAPTER 4. STUDY III - INTERVENTION STUDY

Study III: Kristensen S, Christensen KB, Jaquet A, Moeller-Beck C, Sabroe S, Bartels PD, Mainz J. Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study. BMJ Open 2016; 6010180. Dor:10.1136/bmjopen-2015-01080

Study III is reported in Paper III, which is included in Appendix H. The main messages of Study III are summarised below.

4.1. SPECIFIC OBJECTIVES

The objectives of Study III were to investigate staff's perceptions of patient safety culture before and after a leadership intervention, and to describe differences in perceptions of safety culture according to status of employment and participation. The research questions were:

1. Do the proportions of staff with positive attitudes towards each of the seven patient safety dimensions improve by more than 5% from before to after the intervention?

2. Do the mean scale scores of each of the seven patient safety dimensions improve for responders participating both before and after the intervention?

3. Do the mean scale scores differ significantly between subgroups depending on status of employment and participation?

In addition, it was observed whether % positive for clinical areas with % positive <60% before the intervention changed more during the leadership intervention than clinical area exceeding the 60% threshold before the intervention (139). It was also investigated whether a cultural perception gap between clinical leaders and frontline staff was present before and after the intervention respectively.

4.2. METHODS AND MATERIALS

Study III was based on a repeated cross-sectional experimental study design implemented in 2013. Perceptions of patient safety culture were measured before and after a leadership intervention using the SAQ-DK.

4.2.1. STUDY SETTING

The study was situated in a psychiatric department of the Psychiatric Hospital of Aalborg University Hospital in the North Denmark Region. The department is one of the largest psychiatric departments in Denmark with approx. 460 employees. It comprises 10 outpatient and nine inpatient specialised clinical areas, which are either open or closed units. Nineteen clinical leaders (doctors, nurses and psychologists) served at the clinical area level, and two leaders served at the department level during the study period from April to November 2013.

4.2.2. VARIABLES OF INTEREST

The main measures of interest were the two SAQ-DK climate metrics: % positive and mean scale scores (170). The features of the SAQ-DK have been extensively described in section 1.3.1 Quantitative assessment, 3.2.1 Safety Attitudes Questionnaire, and 3.3.1 The Danish version of SAQ. In Study III, management support for patient safety was explored in relation to both the unit and the department management, therefore, seven SAQ dimensions were explored. The psychometric properties of SAQ-DK were tested in Study II, and SAQ-DK was found to be valid and reliable (170).

The secondary variables of interest were the responders' profession, gender, organisational role, age group, work experience and organisational affiliation.

4.2.3. SAMPLES

Two samples based on human resource data were used: a before-intervention sample (first survey) and an after-intervention sample (second survey).

For both samples, full- and part-time staff working at least half of their working time in the department qualified for inclusion; staff with no patient contact were excluded.

A total of 454 staff members were invited to participate in the first survey, and 470 staff members were invited for participation in the second survey. At both survey time points, the total staff included 19 clinical area level leaders, who were invited as well.

4.2.4. INTERVENTION

The clinical area level leaders were exposed to an intensive multi-component intervention consisting of academic input, exercises, reflections and discussions, networking, and action learning. It was anticipated that the intervention would enhance individual leadership, upgrade leadership and quality management knowledge and skills. The intervention was designed to match the needs of the department, and it was initiated by the department head.

The intervention was implemented from 3 May to 1 November 2013 in five off-site seminars of a total of nine days. The content of the intervention covered: a) leadership as profession and as subject, b) situational leadership and coaching, c) managing communication, conflicts and change, d) motivation, development and improvement, and e) leading groups and teams.

An external industrial-organisational psychologist designed and led the intervention programme.

4.2.5. DATA COLLECTION

SAQ-DK was administered electronically via a unique link in an e-mail. Before-intervention data were collected from 15 April to 3 May 2013; after-intervention data were collected from 23 October to 13 November 2013. Reminders were e-mailed to all staff who had not answered after one week, and after two weeks, and the survey was closed at the end of the third week.

A unique personal identifier was assigned to each participant and remained across the two surveys.

Clinical area specific SAQ-DK results for % positive were available to the clinical leaders approx. three weeks after closing the first survey.

4.2.6. STATISTICAL ANALYSIS

The sample data were described by numbers and proportions.

Internal scale consistency of SAQ-DK was reported by Cronbach's coefficient alpha (161). If $\alpha > 0.70$, then items were regarded as closely related (137). Pearson's correlation coefficients were reported to describe construct validity.

Dimensional SAQ-DK scores were presented, reporting 1) % positive, defined by an individual mean scale scores ≥75, and 2) scale mean scores and standard deviation (SD) (137). The two climate metrics were calculated as in Study II, section 3.2.5. Statistical analysis.

Chi-squared tests were used to compare dimensional % positive scores between survey times and subgroups. Paired-sample t-tests and independent t-tests were used to compare mean scale scores between survey times and across subgroups.

Analyses of variance (ANOVAs) were performed to test for significant between-clinical area variability in mean scale scores at the first and second survey time respectively.

For the purpose of subgroup analysis related to status of invitation and participation, the participants were classified into five groups:

1. **Leavers:** participating in the first survey, then leaving the department
2. **Dropouts:** invitees in both surveys, but only participating in the first survey
3. **Stable:** participants in both surveys
4. **Laggards:** invitees in both surveys, but only participating in the second survey
5. **Newcomers:** staff joining the department after the first survey, and participating in the second survey only.

Based upon standards set in and results from earlier studies (171;172), a change in % positive from the first to the second survey of >5% was deemed clinically relevant.

A perception gap was defined as a statistically significant difference in dimensional mean scale score between clinical leaders and frontline staff.

Only clinical areas/groups with more than five responders were included in group level analysis (162).

Statistical significance was defined as $P<0.05$.

All analyses were performed using IBM-SPSS version 21.0 (SPSS, Chicago, Illinois).

4.2.7. ETHICS

The study was not affected by the Danish Act on Processing of Personal Data, so only the works council of the department approved the study.

Invitees were informed that all answers would be treated with confidentiality, and that no individual responses would be available to any other employees in the department.

4.3. RESULTS

The main messages and findings of Study III are reported in Paper III, and summarised below. Results not communicated in Paper III but related to change in dimensional patient safety culture at the clinical area level are presented in section 4.3.3. Proportion of staff with positive attitudes. Moreover, results related to a possible perception gap between the clinical leaders and the frontline staff at the first and second survey respectively are presented in section 4.3.5. Results related to leadership.

Clinical area level results and sub group results (gender, profession, work experience and organisational role) are displayed in Appendix K. Findings Studies II - IV.

4.3.1. PARTICIPATION

Participation in both surveys was >75%; corresponding to 358 staff members in the first survey, and 325 staff members in the second survey. The total number of participants for the stable group was 223 frontline staff plus 15 clinical leaders. Responders of the first and the second survey and the stable group were comparable in terms of sociodemographic characteristics.

Participation according to the five groups mentioned above was: 47 leavers, 73 dropouts, 238 stable staff, 31 laggards and 56 newcomers.

4.3.2. SCALE CONSITENCY AND SCALE CORRELATIONS

Across the two surveys, the average rate of “not applicable” answers at the item level was <3%, and all answer categories (1 to 5) were used for all items.

Internal instrument reliability was ≥0.85 in both surveys.

At both survey times, the stress recognition scale correlated negatively with all other scales. Otherwise, moderately to strongly positive relationships were found between the scales. Person's correlation coefficients ranged from 0.25 to 0.63, P<0.01.

4.3.3. PROPORTION OF STAFF WITH POSITIVE ATTITUDES

Clinically relevant improvements in % positive (> 5 percentage point) were found for frontline staff (N=223) participating in both surveys for teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management. Furthermore, the improvements were statistically significant for teamwork climate, safety climate and job satisfaction, P<0.05. The largest improvement of 14.8 percentage point was observed for safety climate.

Chi-squared tests comparing % positive across clinical areas (N=19) showed differences at both times for all six dimensions, P<0.05.

It has been hypothesised that clinical areas in which less than 60% of the responders have a positive attitude to the culture (% positive <60%; low-scoring clinical area) have more to gain from improvement activities than clinical areas exceeding the 60% threshold before the intervention (% positive ≥60%; high-scoring clinical areas) (139). The change in % positive at the clinical area level is illustrated in Table 5 in bold, and in Figures 9a-d and Figures 9e-g. Despite the small number of clinical areas, a simple eye-ball test shows that the low-scoring clinical areas improve more than the high-scoring clinical areas over time. But, as illustrated in Figures 9a-d and 9e-g, there is a mixed picture at the clinical area level when it comes to the size and direction of changes in dimensional climate over time.

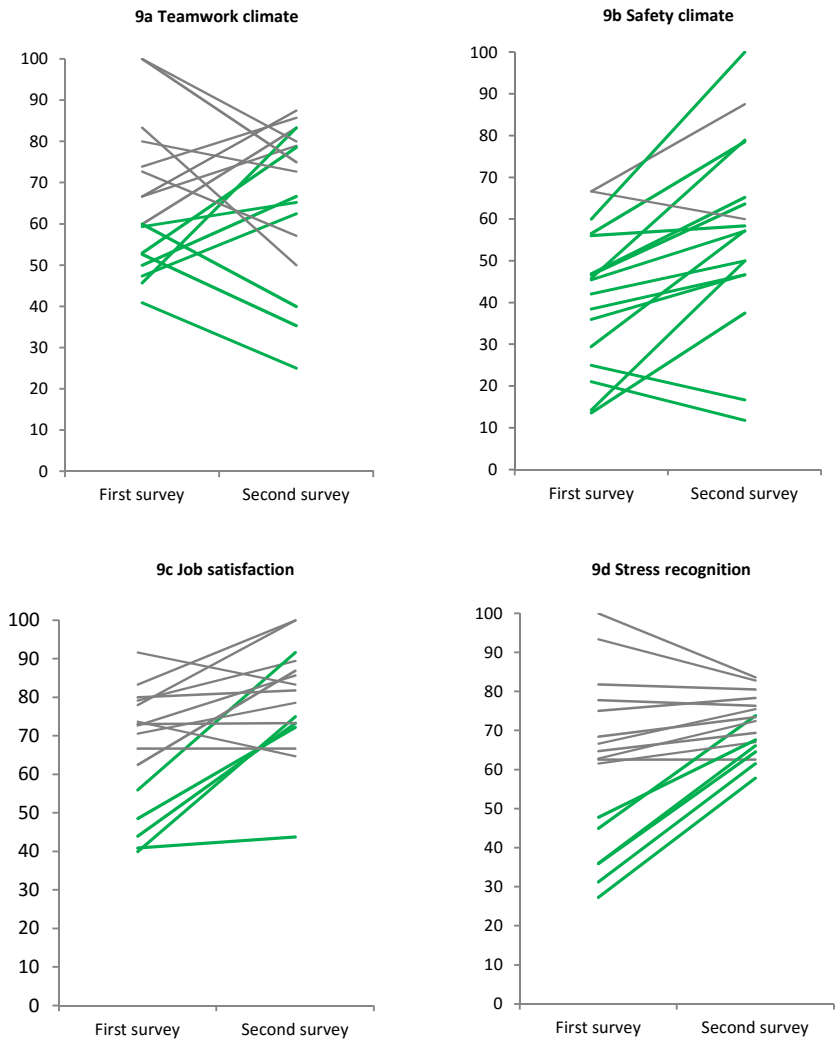
Table 5 At the clinical area level, average change in dimensional climate over time in the proportion of staff with positive attitudes[a] for low-and high-scoring clinical areas (N=17 clinical areas)

Dimension	**Change in % positive from before to after the intervention** *Number of clinical areas ; average change in % positive*	
	Low-scoring clinical areas[b]	**High-scoring clinical areas[c]**
Teamwork climate	8 ; **8**	9 ; **-3**
Safety climate	15; **13**	2 ; **7**
Job satisfaction	7 ; **22**	10 ; **8**
Stress recognition	6 ; **18**	11 ; **11**
Working conditions	16; **5**	1 ; **-7**
Perceptions of unit mgmt.	8 ; **7**	9 ; **2**
Perceptions of department mgmt.	7 ; **13**	10 ; **4**

Notes: [a] % positive, proportion of staff with positive attitudes (individual mean scale score >75); [b] Clinical areas with <60% % positive before the intervention; [c] clinical areas with ≥60% % positive before the intervention.
Abbreviations: mgmt., management.

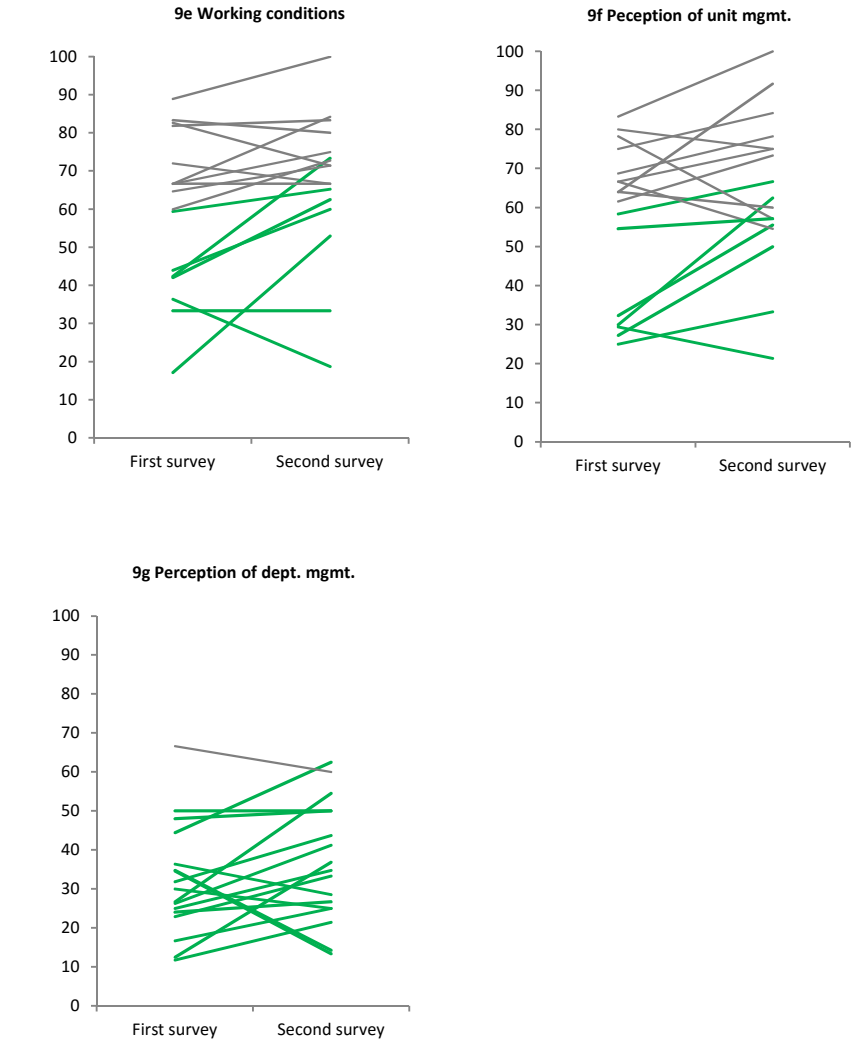
When using a simple eyeball test to Figure 9d, it is noticeable that % positive of all clinical areas in regard to stress recognition seems to draw nearer each other over time. All six clinical areas with low stress recognition score in the first survey had an increase in % positive >10 percentage points, but only for one clinical area did the increase reach above the threshold of 60%.

Figures 9a-d Changes over time in the proportion of staff with positive attitudes towards four dimensions of patient safety culture at the clinical area level (N=17)[a]



Notes: [a] Only displaying results for clinical areas with ≥5 responders. Clinical areas with <60 % positive at first survey show in green, and clinical areas with ≥60 % positive at first survey show in grey.

Figures 9e-g Changes over time in the proportion of staff with positive attitudes towards three dimensions of patient safety culture at the clinical area level (N=17)[a]



Notes; [a] Only displaying results for clinical areas with ≥5 responders. Clinical areas with <60 % positive at first survey show in green, and clinical areas with ≥60 % positive at first survey show in grey.
Abbreviations: mgmt., management; dept., department.

4.3.4. MEAN SCALE SCORES OVER TIME

For the frontline staff participating in both surveys (N=223), an increase in mean scales scores was observed for all dimensions, $P<0.05$, except stress recognition. The mean of the stress recognition scale was the only one increasing for the clinical leaders, $P<0.05$. Mean scale scores of the two survey times are illustrated in Figure 10, and differences across the two survey times within the group are marked with [4] by the second survey results.

Variability in scale means was tested separately at both survey times using ANOVA for each climate dimension. Nineteen clinical areas with more than five responders were included in the analysis. At the first survey time, all mean scale scores differed across the clinical areas, $P<0.01$. At the second survey time, five of seven mean scale scores differed across the clinical areas, $P<0.01$; for perception of department management, no difference was found, $P=0.06$.

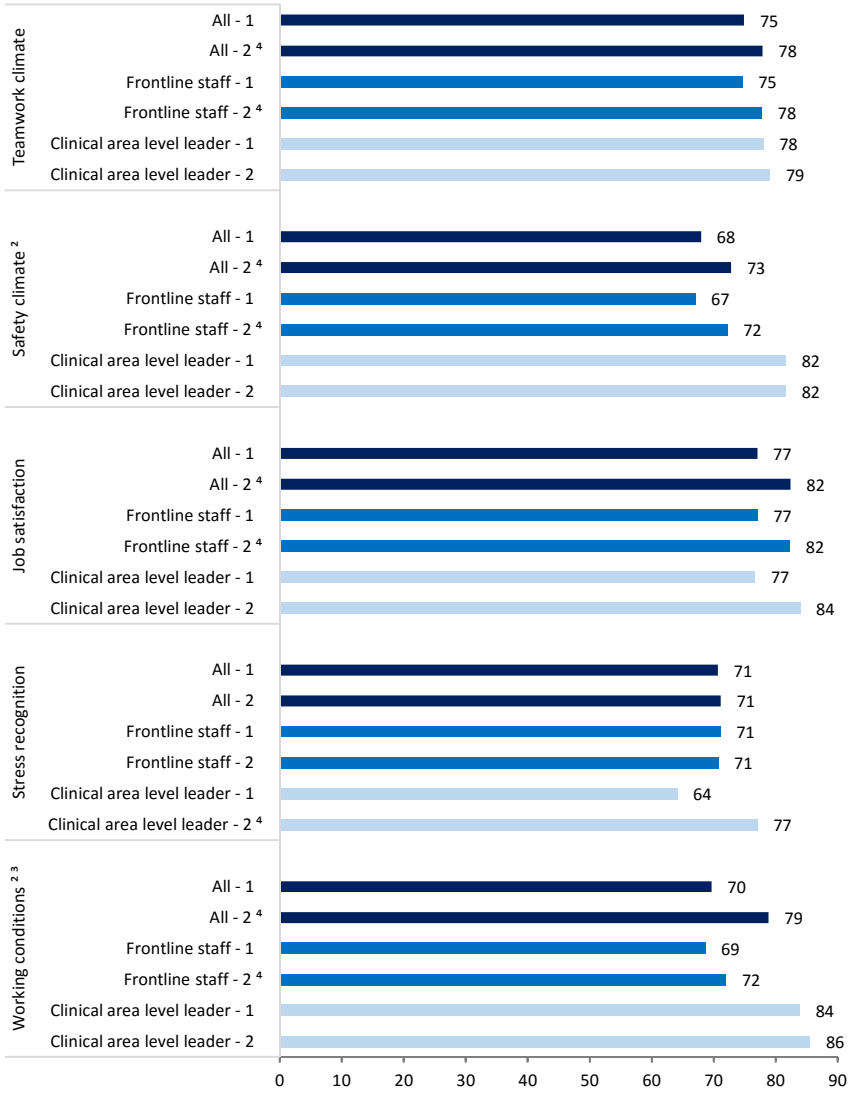
4.3.5. RESULTS REALTED TO STATUS OF EMPLOYMENT

At the first survey time, leavers, dropouts and stable staff participated. Across all seven dimensions, leavers were characterised by least % positive, but the difference between the three groups was only statistically significant for job satisfaction ($Chi=5.28$, $df=1$, $P=0.02$).

In parallel, the mean scale scores of the leavers were lowest for all dimensions; but again the difference in means was only significant for job satisfaction ($F=5.31$, $df=2$, $P<0.01$).

At the second survey time, stable staff, laggards and newcomers participated. No specific pattern was observed for either of the two climate metrics.

Figure 10 First (1) and second (2) survey: mean scale scores for five dimensions of the patient safety culture according to organisational roles (N=238)[1]



Note; [1] Frontline staff, N=223; clinical area level leader, N=15; [2] P<0.05 for comparison of means between frontline staff and clinical area level leaders in the first survey; [3] P<0.05 for comparison of means between frontline staff and clinical area level leaders in the second survey; [4] P<0.05 for comparison of means between the first and the second survey within the group (all, frontline staff or clinical area level leader).

4.3.6. RESULTS RELATED TO LEADERSHIP

It is well documented that a gap in perceptions between frontline staff and clinical leaders exists (46;48-52), and the larger the perception gap, the more errors are made among frontline staff operating at the sharp end of care (48). Knowing about a perception gap is essential for bridging it. Therefore, it was investigated whether a perception gap was present at the first and the second survey time respectively. For the purpose of these analyses, the management dimensions were excluded, and only the 238 stable responders were included (15 clinical leaders and 223 frontline staff).

In the first survey, there was a statistically significant difference in means between the leaders and the frontline staff for safety climate and working condition, $P<0.05$. Hence, there was a perception gap, which is marked in Figure 10 with [2] by the name of the dimension. At the second survey time, a difference in mean scale scores was only identified for working conditions, $P<0.05$; marked in Figure 10 with [3] by the name of the dimension. In summary, for safety climate the perception gap between the clinical leaders and the frontline staff was closed over time, but the perception gap for working conditions remained across the two survey times.

4.4. DISCUSSION

Following a leadership intervention, clinically relevant improvements (≥5 percentage points) in the proportion of stable frontline staff with positive attitudes (% positive) towards teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management were found, and for the first three dimensions the improvements were statistically significant.

Except for stress recognition, all dimensions of the culture were perceived to be more positive over time by the stable frontline staff.

Staff leaving the department during the study time had lower job satisfaction (mean scale score) than staff staying on.

The climate in the clinical areas in which less than 60% of the staff had positive attitudes at the first survey seemed to gain more from the intervention than the clinical areas where more than 60% had positive attitudes already.

For safety climate, the perception gap between the frontline staff and the clinical leaders vanished over time.

4.4.1. METHODOLOGICAL CONSIDERATIONS

Study III had participation rates in both surveys of above 75%, which is satisfactory and likely to reflect the safety culture, as opposed to mere opinions (121). Leaders had response rates above 80%, indicating good support for the patient safety culture survey. In addition, Study III was also strengthened by the high compliance rate in the leadership programme as 15 of 19 leaders participated in all seminars; again, it confirms engaged leaders, and supports the internal study validity.

Within Danish hospital care, approx. 14% of hospital staff are doctors, 43% nurses and nursing assistants, and 42% other staff such as allied health care professions, administrative and technical staff (173). Female employees in hospitals account for 82% (163). Consequently, the participants in Study III were underrepresented in regard to the category other staff, as only 26% belonged to the category other staff (therapists and others) in the first survey and 28% in the second survey. The group other staff is a mixed group of staff of which a substantial part work in non-clinical areas. According to the literature, such staff are expected to have more favourable attitudes towards the culture than staff from clinical areas (45). Therefore, the results for both climate metrics might be underestimated at both survey times.

The average range of "not applicable" answers was below 3% in both studies and thus did not give rise to exclusion of items from the analysis according to the threshold value of 13% used in earlier studies (108;164). Further, a full range of scores was obtained for all items. In this regard, Study III compares well to previous international results (58;108;139;164;165), which enhances the good internal reliability of Study III.

The intervention was comprehensive but designed and implemented dynamically to ensure that the needs of the clinical leaders and the department were met. In an attempt to eliminate influence from other factors which could possibly affect the safety culture at the same time as the intervention, the observation time was kept short. However, this excluded the possibility of surveillance of the sustainability of the improvements observed. However, on balance, this was considered the most optimal conditions to capture a possible improvement in the safety climate.

Study III was conducted in one department without a control group, which reduces the ability to attribute causality for the improvements observed in the climate. Furthermore, it is important to note that a repeated cross-sectional study design cannot infer causality.

The use of the personal identifier across survey times allowed transparency and paired-sample analyses over time. This approach has not been found in other patient safety culture studies, but it must be regarded as a strong approach which supports the positive findings.

As with Study II, Study III is based on self-reported information, which might have created information and social desirability bias, with a possible underestimation of both climate metrics for teamwork and safety climate in regard to information bias (due to reverse phrased items), and a general overestimation of both climate outcomes as a consequence of social desirability bias. A Hawthorne effect might also be present in Study III, leading to an overestimation of the results for both climate metrics.

It is also thinkable that the way the leaders chose to follow up on the first survey results could account for the differences between clinical areas gaining more or less respectively from the intervention – dialogue about the results and follow-up actions may have made a difference as results from Sweden with a method called the patient safety dialogue indicates (174). The possible impact of activities directed towards the climate results of the first survey are not known.

Consequently, bias might jeopardize the findings of Study III, invalidating its external validity. Thus the findings should be generalised with caution.

4.4.2. RELATION OF THE FINDINGS TO OTHER STUDIES

Clinically relevant improvements in % positive following the leadership intervention were observed among the frontline staff for teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management. In earlier intervention studies characterised by a strong leadership engagement - but without an educational approach - improvements were mainly found in teamwork and safety climate over time (59;78).

Except for stress recognition, all dimensions of the culture were perceived to be more positive (increase in mean scale scores) over time by the frontline staff. In the interpretation and follow-up activities of the first survey in Study III, a number of questions in regard to the stress recognition items were discussed to clarify the purpose of this dimension and the underlying evidence linking stress to performance. From Figure 9d, it is obvious that the spread in % positive at the clinical area level was reduced from the first to the second survey. This reduction could possibly be due to the educational dialogues in which the emphasis was on recognition of fatigue, stress and high workload as factors that could influence the safety performance negatively; a hypothesis which is supported in the literature (175). So, the validity issues with the stress recognition scale might originate from the fact that these items are not intuitively understandable in the same way as the other SAQ items. This is important to take this into account when using the SAQ, and it should be investigated further.

It was found that employees leaving the organisation had less favourable job satisfaction attitudes (mean scale scores) than staff staying on. This result stands alone in the patient safety culture literature; nevertheless, it speaks for itself.

The results of Study III support testing the hypothesis that clinical areas in which less than 60% of the responders have a positive attitude to the culture (% positive <60%) gain more from improvement activities than clinical areas exceeding the 60% threshold (139). However, the number of included clinical areas is small and larger variation in the size and direction of change in % positive at the clinical area level was also observed. At the same time, it was found that the proportion of staff with positive attitudes (% positive) as well as the quality of the culture (mean scale score) varied across clinical areas at the first survey time. This might indicate differing conditions for implementation and uptake of the intervention, which might influence the impact of the intervention. Such conditions could be related to leadership style (70).

A transformational leadership style has been documented to be a positive contributor to a safe culture (70). Support from the leader and a good relationship between the leader and the frontline staff characterised by mutual respect could possibly also act as a supportive accelerator for implementation of the intervention, and in the end for a positive culture (72;176). In opposition here to, innovation fatigue and accompanying collective burnout might have hindered the positive development of a safety culture (177). In this sense, the degree to which the individual leader managed to translate and share the knowledge and skills gained from the leadership intervention into everyday life in the clinical area could have been essential for development of the culture over time.

The literature suggests that managers tend have more positive perceptions of the safety culture than frontline staff (50;52;53). In the first survey of Study III, a perception gap (difference in mean scale score) between the clinical leaders and the frontline staff was only present for safety climate and working conditions. Over time, the perception gap for safety climate closed, whereas the one for working conditions remained. The dimension for safety climate comprises staff's perceptions and attitudes towards the safety of patients and clinical risk management (153). The closing of the perception gap between the clinical leader and the frontline staff for safety climate could indicate that both groups have achieved a more realistic picture of the safety values and practices, a situation which is fundamental to a better patient safety.

4.5. CONCLUSION

Updating quality management knowledge and leadership skills of the clinical area level leaders seems to be an anchor point for improvement in safety culture. Among the frontline staff participating in both surveys, clinically relevant improvements in % positive (improvements >5 percentage points) were found after the intervention for teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management. The improvements were statistically significant for teamwork climate, safety climate and job satisfaction.

Except for stress recognition, all scales were perceived to be more positive (mean scale score increased) over time by the frontline staff. The largest improvement in dimensional safety culture was observed for safety climate; here a perception gap between leaders and frontline staff was closed over time.

Staff leaving the organisation had less favourable job satisfaction attitudes (mean scale scores) than staff staying on.

It seemed that the low-scoring clinical areas had greater benefit from the leadership intervention than high-scoring clinical areas; this should be investigated further.

CHAPTER 5. STUDY IV - OBSERVATION STUDY

Study IV: Kristensen S, Túgvutein N, Zachariassen H, Sabroe S, Bartels P, Mainz J. The virgin land of quality management – a first measure of patient safety climate at the National Hospital of the Faroe Island. Drug Healthcare and Patient Safety 2016;8:49-57.

Study IV is reported in Paper IV, which is included in Appendix I. The main messages of Study IV are summarised below.

5.1. SPECIFIC OBJECTIVES

The objective of study IV was to investigate the patient safety culture in the National Hospital of the Faroe Islands (NHFI) prior to implementation of any organisational level quality management activity. More specifically, the study embarked on the following four research questions:

1. How do the staff of the NHFI perceive the patient safety culture?
2. Are there differences in staff's perceptions of the culture according to medical speciality?
3. Are there differences in perceptions between the frontline staff and the management?
4. Are there differences in the staff's perceptions of how the different management types support patient safety?

Results related to research questions 3 and 4 but not reported in Paper IV are reported in section 5.3.5 Results related to leadership.

5.2. METHODS AND MATERIALS

A cross-sectional study design was applied; the SAQ-DK was used to capture staff perceptions of the safety culture.

5.2.1. STUDY SETTING

The study was situated in the National Hospital of the Faroe Islands (NHFI), which is an acute care somatic and psychiatric teaching hospital located in Torshavn.

Although formally part of the Kingdom of Denmark, the Faroe Islands enjoy extensive autonomy. The Faroese Ministry of Health Affairs is in charge of the administrative functions in relation to the organisation and financing of the health care system, psychiatry and health insurance as well as the pharmacy sector. The Faroe Islands have approx. 48,100 (2013) citizens, and 40% of them live in the capital, Torshavn. The language spoken is Faroese; Danish is the first foreign language and taught in schools from the third grade upwards.

The 28 clinical areas of the NHFI are organized in the five clinical centres, a service centre and an administration unit directly under the top management. At the time of the survey in September 2013, the hospital had three levels of line management: top (hospital), centre (department) and clinical area level (unit and ambulatory) leaders (N=57).

Prior to the patient safety culture assessment, organisational level quality management initiatives had not been initiated at the NHFI.

5.2.2. VARIABLES OF INTEREST

The main measures of interest were the two climate metrics captured by SAQ-DK (170). The features of the SAQ-DK have been extensively described in section 1.3.1 Quantitative assessment, 3.2.1 Safety Attitudes Questionnaire, and 3.3.1 The Danish version of SAQ. In Study II, SAQ-DK was found valid and reliable (170).

The secondary variables of interest were gender, age group, profession, organisational role, work experience, and organisational affiliation.

5.2.3. SAMPLE

Full- and part-time staff of the NHFI, excluding staff employed at the service centre, qualified for inclusion in the safety culture survey (N=557).

The following professions were included: doctors, nurses, nursing assistants, midwives, medical laboratory technicians, dieticians, psychologists, speech and

music therapists, physiotherapists, occupational therapists, administrative staff and secretaries, service assistants and porters.

5.2.4. DATA COLLECTION

The SAQ-DK was administered electronically via an individual link in a personal e-mail on 21 September 2013. The questionnaire was open for invitees to complete until 23 October 2013. Weekly reminders were e-mailed to all staff who had not answered.

Since this was the first electronic staff questionnaire in NHFI, organisational support and information and communication about the survey were needed, e.g. regarding the purpose of the questionnaire, how it was distributed, how to access the questionnaire via the e-mail system, who would see the answers, and other practical as well as content and ethics-related issues. This kind of support was mainly given by a hospital-based administrator, who collaborated closely with the main researcher. The NHFI-based administrator used all kinds of means to support the data collection: meetings at the clinical area level, the intranet, posters throughout the hospital, e-mails, telephone and personal contact. Moreover, the hospital top management supported the survey through communication at leadership meetings. The introduction to the questionnaire stated that the survey was initiated by the hospital top management.

5.2.5. STATISTICAL ANALYSIS

The sample data were described by frequencies according to gender, age group, profession and organisational role.

The reliability of SAQ-DK was described by Cronbach's alpha (α). If $\alpha > 0.70$, items in a scale were regarded as closely related (137). Pearson's correlation coefficients were reported to describe construct validity.

SAQ-DK data were presented, reporting two climate metrics: 1) % positive, defined by an individual mean scale scores ≥ 75, and 2) scale mean scores and SD (137). The two climate metrics were calculated as in Study II, section 3.2.5. Statistical analysis.

For comparison of % positive across subgroups, Chi-square tests were used and for comparison of mean scale scores, independent t-tests were used. To test for variability in means across centres, ANOVA was used.

Based upon earlier research, a threshold value of 10 percentage points difference in % positive was regarded as clinically relevant (171;172).

Statistical significance was defined as $P<0.05$.

IBM-SPSS version 21.0 (SPSS, Chicago, Illinois) was used for the statistical analysis.

5.2.6. ETHICS

Formal ethical approval of the survey was not needed; therefore the management group of the hospital assessed SAQ-DK for its purpose and approved the study.

Invitees were informed that participation was voluntary and anonymous; that all answers would be treated with confidentiality, and that no individual answers would be available to the management.

5.3. RESULTS

The main messages and findings of Study IV are reported in Paper IV and summarised below. Results not included in Paper IV are presented in section 5.3.5 Results related to leadership.

Clinical area level results and sub group results (gender, profession, work experience and organisational role) are displayed in Appendix K. Findings Studies II - IV.

5.3.1. PARTICIPATION

The response rate was 65.8%, reflecting that 367 of 557 questionnaires were returned. The distribution of responders at the centre level was as follows:

- surgical centre; N=76
- psychiatric centre; N=93
- diagnostic centre; N=34
- medical centre; N=110

- acute care centre; N=40
- administrative units directly under the top management; N=40.

The number of participants varied from four in the smallest outpatient setting to 31 in the largest inpatient bed unit; six of the 28 clinical areas had five responders.

Leadership participation was 50 of 57 (87.7%). Participants were distributed according to their organisational role as follows:

- frontline staff; N=317
- clinical area level leaders; N=39
- centre level leaders; N=11.

Of the 367 participants, more than half were 46 years or older, approx. half of the participants were nurses, and 21.8% were nurses and 46 years or older.

5.3.2. SCALE RELIABILITY AND SCALE TO SCALE CORRELATIONS

Cronbach's alpha did not exceed the set cut-off point of 0.70 for teamwork climate (0.59) and safety climate (0.67). Cronbach's alpha indicates the degree to which a set of items measures a single one-dimensional latent construct; the closer α is to 1.0, the greater the internal consistency of the items in the scale. An α-value below the cut-off point indicates that items are not as closely related as desired.

Stress recognition correlated negatively with all scales, revealing Pearson's r between -0.15 and -0.06, $P<0.05$. For the remaining scales, inter-scale correlations indicated significantly strong positive relationships between the scales; Pearson's correlation coefficients ranged from 0.43 to 0.67, $P<0.01$.

5.3.3. PERCEPTION OF THE PATIENT SAFETY CULTURE

Across the entire sample, job satisfaction was the dimension with the most positive responders (71.1%) among all dimensions; it was also the dimension perceived as most positive [mean scale score (SD); 78.7 (20.6)]. In parallel, perception of the top management had the lowest proportion of responders with positive attitudes (12.8%), and of all dimensions, perception of the top management was perceived as least positive [mean scale score (SD); 47.6 (21.7)].

The % positive differed across the 28 clinical areas for all dimensions, P<0.05, except stress recognition, P>0.05. Noticeably, the variation in % positive across clinical areas ranged from 0.0 – 100.0 for safety climate, P<0.01; and only 28.9% of the responders had positive attitudes towards safety climate. The degree to which the staff perceived the culture as positive (mean scale score) varied significantly across the 28 clinical areas for all scales, P<0.01.

More males (N=42) than females (N=325) had positive attitudes (% positive) towards working conditions and perception of centre management (centre level leaders) respectively, P<0.05. Males had more favourable perceptions (means scale scores) of the centre management and the hospital management (top level leaders) than their female colleagues, P<0.05.

Staff with less than two years of work experience in the hospital (N=81) (inexperienced) perceived the working conditions as less favourable (mean scale score) than staff with two or more years of experience (N=286) (experienced), P<0.05. In parallel, fewer inexperienced than experienced staff had positive attitudes (% positive) towards the working conditions, P<0.05.

Doctors had more favourable perceptions of the working conditions (mean scale scores) than nurses, P<0.05, and more doctors than nurses had positive attitudes (% positive) towards the working conditions, P<0.05.

5.3.4. RESULTS ACCORDING TO MEDICAL SPECIALTY

The diagnostic centre had the highest % positive of all centres for all dimensions, and the highest mean scale scores. Both the mean scale scores and % positive differed simultaneously across clinical centres for each of the three management dimensions, P<0.05; indicating that both differences in the proportion of staff with positive attitudes towards the management (top, centre and clinical area level leaders) and the perception of the quality of the management support for patient safety differed across medical specialties.

Across dimensions, no specific pattern was found for the lowest scoring centre for any of the two climate metrics.

5.3.5. RESULTS RELATED TO LEADERSHIP

The three management dimensions were not included in the following analyses comparing perceptions of the frontline staff with those of the leaders. Across the five

dimensions investigated, job satisfaction was the dimension for which both most leaders (78.0%) and most frontline staff (70.0%) perceived the climate as positive. Job satisfaction was also perceived most positive by both clinical leaders [mean(SD); 83.5(14.7)] and by frontline staff [mean(SD); 78.8(21.3)].

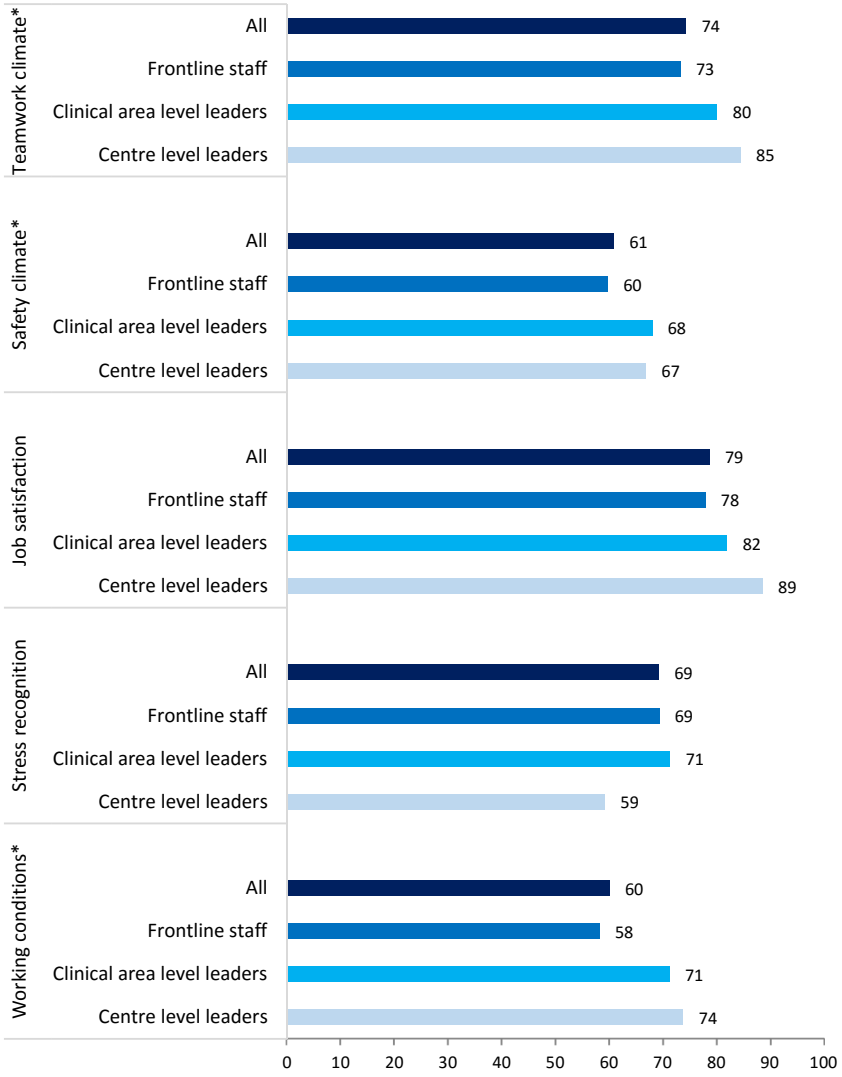
Safety climate was the dimension for which fewest clinical leaders (40.0%) and frontline staff (27.1%) respectively perceived the culture as positive. The difference in % positive between frontline staff and clinical leaders was ≥10 percentage points for safety climate and thus clinically relevant; it was also statistically significant, $P<0.05$.

Perceptions of dimensional safety culture are displayed according to organisational role in Figure 11. Organisational roles were as follows: frontline staff (N=317), clinical area level leaders (N=39), and centre level leaders (N=11). For teamwork climate, safety climate and working conditions, there was a significant difference in perceptions of the culture among frontline staff, clinical area level leaders and centre level leaders, $P<0.05$. The perception gaps between the frontline staff and the leaders of the NHFI are indicated with an * by the name of the dimension in Figure 11.

No differences in means or % positive were found for any dimensions across clinical area level leaders and centre level leaders, $P>0.05$.

Lastly, frontline staff's perceptions of the three management levels (top, centre and clinical area level) were investigated, and it was found that % positive was lowest for perception of the top management, and highest for perception of the unit management (clinical area level leaders), $P<0.01$. Likewise, the mean scale score for perception of the top management was lowest, and the perceptions of the unit management (clinical area level leaders), highest, $P<0.01$.

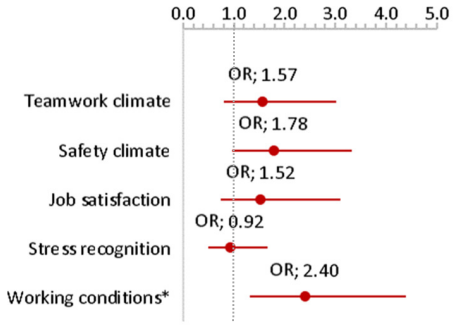
Figure 11 Mean scale scores for five dimensions of the patient safety culture according to three organisational roles (N=367)[a]



Note: [a] Frontline staff, N=317; clinical area level leaders, N=39; centre level leaders, N=11; *P<0.05 for comparison of means between frontline staff, clinical area level leaders and centre level leaders.

The probability of perceiving the culture as positive (individual mean scale score ≥75) was explored for clinical leaders (N=50; 39 clinical area level leaders and 11 centre level leaders) versus frontline staff (N=317). The results are shown as Odds Ratios (OR) including the 95% CI in Figure 12. As can be seen at the bottom part of Figure 12, the leaders were 2.4 (95% CI: 1.3 - 4.4) times more likely to perceive the working conditions as positive than the frontline staff, P<0.05. For teamwork climate, safety climate, job satisfaction and working conditions OR>1, but P>0.05.

Figure 12 Chance (Odds Ratio) of perceiving the culture as positive for clinical leaders[a] versus frontline staff[b]



Notes: [a] Clinical area level leaders and centre level leaders, N=50; [b] frontline staff, N=317; *P<0.05
Abbreviation: OR, odds ratio.

5.4. DISCUSSION

Safety climate was identified as the dimension with the greatest variability in % positive across clinical areas at the NHFI, and on average less than a third of the staff perceived the safety climate as positive.

The diagnostic centre had the most favourable management climate (mean scale score and % positive) of all centres.

A clinically relevant perception gap (difference in mean scale score) between the frontline staff and centre level leaders was found for teamwork climate, safety climate and working conditions. Moreover, the group of clinical leaders were 2.4 times more likely to perceive the working conditions as positive than the frontline staff.

Among the three management levels, the frontline staff perceived the support of the unit management (clinical area level leaders), most favourably (mean scale score) and the support for patient safety by the top management least favourably.

5.4.1. METHODOLOGICAL CONSIDERATIONS

With a non-response rate of 35% in Study IV, non-response bias cannot be ruled out. Given that the system approach to patient safety was in its infancy at the time of the patient safety culture assessment, it is to be expected that staff would be reluctant to expose negative perceptions of the culture, fearing the consequences. If non-participation is related to a less favourable perception of the safety culture, then the safety culture outcomes (both climate metrics) are overestimated. Non-participation could also be related to the fact that SAQ-DK was in Danish, which might have discouraged some invitees from participating. How this would have impacted the results is not known. Despite these problems, the participation was still above 60%, and thus the cultural results are expected to reflect the safety culture as opposed to mere opinions (121). Additionally, the response rate of the leaders was above 90%, which mirrors substantial support for the study, deemed important for the internal study validity.

Sampling bias might jeopardise the external validity of Study IV, as the service centre was excluded from participation. Because more favourable perceptions of the culture have been documented for non-clinical areas as opposed to clinical areas (45), the mean scale scores of study IV might be underestimated.

A full range of scores was obtained for all items in Study IV, likewise the proportion of "not applicable" answers did not give cause for concern, and no items were excluded from the analysis. These findings compared well with previous international results (58;108;139;164;165).

The internal reliability consistency of the two scales teamwork and safety climate was lower than anticipated. In Norway and Germany, Cronbach's alpha for teamwork climate was also less than the threshold value of 0.7 (108;164), and in the Danish validation study, α just exceed the threshold value for teamwork climate. At the scale level, Cronbach's alpha varied from 0.59 to 0.89 in other SAQ validation studies (58;102;103;108;156;164). Both the teamwork and the safety climate scale contain a negatively worded item, which might have caused problems to understand and answer as intended, especially among the Faroese staff whose mother tongue is not Danish. This might have influenced the internal reliability consistency of the two scales. It is an issue which should be investigated further.

As with Studies II and III, Study IV is also based on self-reported information, which might have created information and social desirability bias. Here, information bias might be present due to language issues with the Danish version of SAQ, which could lead to selecting the answer categories "not applicable" or neutral rather than one of the other answer categories. The proportion of "not applicable" answers was higher in Study IV than in Studies II and III, but "not applicable" answers did not give rise for concern in Study IV. The directional impact of possible information bias cannot be estimated. Social desirability bias might have led participants to answer more favourably than the truth, leading to an overestimation of both cultural outcomes. Moreover, the attention of the research project might have created a Hawthorne effect; if so, the observed outcomes are also overestimated.

Lastly, Study IV is also based on a cross-sectional study design, and it cannot be ruled out that different results for both climate metrics could have been obtained at a different point in time, as patient safety culture is a dynamic concept sensitive to contextual influence.

In conclusion, Study IV might be exposed to bias which could invalidate the external validity of the study, and the findings should be generalised with caution.

5.4.2. RELATION OF THE FINDINGS TO OTHER STUDIES

The patient safety culture survey of the NFFI was performed in a modern western hospital prior to implementation of organisational level quality improvement activities. This means that the questionnaire results are exceptional, as this is a situation which is extremely rare, given that quality management activities are commonly implemented in EU hospitals today and quality improvement has been on the agenda of the EU, the World Health Organization, the Organisation for Economic Cooperation and Development and scientific societies for decades. Interestingly therefore, the results from the Faroe Islands represent a health care organisation in which patient safety culture has not been consciously cultivated yet. Nevertheless, some of the Faroese results are in line with results in the literature, e.g. that the diagnostic centre had more favourable results (mean scale scores and % positive) than the other centres. There could be several reasons for this. The diagnostic centre consists of an X-ray unit and a laboratory; that is, both clinical areas without bedside activities. According to findings in the literature, the culture outcomes of non-clinical areas are expected to be more favourable than results for areas mainly characterised by bedside activities (45). Moreover, in the diagnostic centre, a certain amount of work procedures had already been subject to quality management procedures. Based on findings in an EU-wide study in which a positive association between a high degree of implementation of quality management systems and teamwork and safety climate was found (50), a more favourable culture would be expected in the

diagnostic centre than in other centres. Accordingly, the EU results support the management decision of the NHFI to implement organisation-wide quality management activities in order to support teamwork and safety climate.

It was found that frontline staff's attitudes towards the different levels of line management (top, centre and clinical area level leaders), varied by management level; the lower in the leadership hierarchy, the more positive the frontline staff. The management dimensions assess hospital staff's beliefs about the leadership's dedication to patient safety, support of frontline staff and delivery of timely information on patient safety policies that affect their work (153). It seems that the higher a leader is positioned in the line management, and consequently the further away from the sharp end of care, the more clearly and more visibly leaders need to show their support for and engagement in patient safety. Findings from an American study also documented that the highest of the organisational management levels was perceived as the least positive (53).

It was also found that the leaders of the NHFI were more than two times more likely than the frontline staff to perceive the working conditions as positive. In everyday work, this difference could reflect that the leaders are unaware of frontline staff's perception of inadequate training for the job and the need for more information at the sharp end of care. Moreover, frontline staff perceived the leaders' handling of problem staff as inadequate. These findings might be problematic for the delivery of safe care. (153).

Lastly, the attitudes of leaders at the different leadership levels of the NHFI were investigated, and no differences between the centre and clinical area level leaders were found. Thus the results of this study stand in contrast to findings from America where a variation in perceptions by management level was documented; leaders at higher levels were more positive than lower level leaders (53). The Faroese results might be attributable to influence from the underlying organisational or Nordic culture with its emphasis on a non-hierarchical approach characterised by team-oriented and value-based leadership (178).

5.5. CONCLUSION

The survey results from the NHFI represent a seldom snapshot of the patient safety culture in a modern western health care organisation in which patient safety culture has not been consciously cultivated at the organisational level. Not surprisingly for this situation, the safety climate, mirroring the staff's perception of patient safety and risk management, was identified as the dimension with the greatest variability across clinical areas. Tellingly, the diagnostic centre, in which external quality control had

been enforced for more than a decade, had the most favourable management climate of all centres.

A perception gap between the frontline staff and the clinical leaders was identified for teamwork climate, safety climate and working conditions.

Among the three management levels, the frontline staff perceived the unit management (clinical area level leaders) most favourably and the top management least favourably.

Introducing improvement initiatives rooted in the clinical leaders should be considered at the hospital as well as clinical area level.

CHAPTER 6. MAIN DISCUSSION

This thesis appears to be the first to validate a patient safety culture questionnaire for use in Denmark; confirm improvement in patient safety culture following an educational leadership intervention within psychiatry, and measure patient safety culture in the Faroe Islands, where attention to the importance of patient safety culture was new. The thesis presents the most comprehensive evidence-based up-to-date knowledge about patient safety culture in Denmark and the Faroe Islands.

Findings from Study I underline that safety culture is comprised by assumptions, values, norms, practices and behaviour in regard to patient safety. Study I also found that the evidence supporting a positive relationship between safety culture and patient safety is sparse; however, the current knowledge pins down safety climate as the dimension which is most often positively related to aspects of patient safety, e.g. mortality, readmissions, community acquired pressure ulcers and family satisfaction. This link has been established most extensively by the use of SAQ.

Based upon the findings in Study I, the SAQ was chosen, adapted and validated for use in the Danish hospital setting in Study II; the usability of SAQ-DK was good, and the psychometrical properties satisfactory.

Team training and interventions characterised by a high level of leadership engagement, such as patient safety leadership walk rounds and multi-faceted programmes, were identified as the most effective in improving the safety culture in Study I. These findings gave inspiration for the design of an educational leadership programme for Study III. The intervention was implemented in a large Danish psychiatric department. Clinically relevant improvements in the proportion of stable frontline staff with positive attitudes towards teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management were documented after the intervention.

Results from the Faroe Islands in Study IV indicated that frontline staff's perceptions of the leadership's support for patient safety varied by management level (both climate metrics), and a perception gap between the frontline staff and the clinical leaders was present for teamwork climate, safety climate and working conditions.

6.1. RELATION OF THE FINDINGS

The discussions provided on Studies II-IV above will be supplemented below, with reference to results displayed in Appendix K. Findings Studies II - IV.

The management dimensions were perceived as the least positive (mean scale score) of all dimensions in Study II, III and IV. Moreover, findings from Study III as well as Study IV, and of an American study, confirmed that the highest of the organisational management levels was perceived as the least positive (53). Teamwork climate was perceived to be most positive in Study II; in Study III as well as in Study IV job satisfaction was perceived most favourably. Across the international literature, variation in the least and the most favourably perceived dimensions is present (103;169;179), which indicates that safety culture is a local phenomena.

Both in Study II as well as in Study IV, less than half of the responders had positive attitudes towards safety climate. This means that the staff did not see a real commitment to patient safety in their clinical area. Although the results compare well with results from Australia where % positive was 39.0% (179), the goal must be to achieve above 60% of staff with positive attitudes. With the low proportion of staff with positive attitudes towards safety climate in mind, it is suggested to investigate the underlying cause of these results and initiate improvements. In the Faroe Islands, a reasonable explanation for the low proportion of staff perceiving the safety climate as positive could be that clinical risk management, including identification, reporting of, learning from and open communication about adverse events, had not been introduced at the organisational level of the NHFI at the time of the patient safety culture survey. Going forward, accentuating such issues might act as an important lever for a better safety climate, both in Denmark and in the Faroe Islands (50;180).

Variation in perceptions of dimensional safety culture (both climate metrics) at the clinical area level was documented in Studies II-IV, indicating that the clinical area level is the most suitable for assessment of safety culture and follow-up activities. This was also found for Norway (40), Australia (179), Switzerland (135), America (45;181;182) and Denmark (49).

In Study II, no differences between the somatic and the psychiatric sample in the proportion of responders with positive attitudes (% positive) were found for any of the six SAQ-DK dimensions measured; this indicates homogeneity in attitudes across the two specialties. In comparison, the centre-level analysis of variation in % positive in Study IV only showed the same kind of homogeneity across medical specialties in the Faroe Islands for teamwork climate, safety climate, job satisfaction and stress recognition. That is, there was a difference in the proportion of Faroese staff with positive attitudes towards working conditions and all three types of the management across clinical centres. In Study II differences in means between the somatic and the psychiatric sample were only found for stress recognition. In Study IV, differences in scale means were found for all scales except stress recognition and working conditions. Previous findings document more favourable cultures in paediatric,

psychiatry, and rehabilitation departments than in emergency departments and operating theatres (40;45;47;49;152).

In the results from Denmark and the Faroe Islands (Studies I-IV), there was no pattern in differences in attitudes across gender (both climate metrics). From findings in the international literature, female staff were expected to be more critical than their male counterparts (45;53); but another Danish study on patient safety culture did not find differences in attitudes across gender (49). It seems gender is not a characteristic which systematically distinguishes attitudes towards safety culture in the in a Danish or Faroese context.

Differences in attitudes among doctors and nurses were analysed, and again, no systematic pattern was identified in Studies II-IV (both climate metrics). According to the literature, differences were to be expected (45). Again, it seems that being a doctor or a nurse is not a characteristic which systematically distinguishes attitudes towards safety culture in a Danish or Faroese context.

Both in Denmark (Studies II-III) and in the Faroe Island (Study IV), inexperienced staff perceived the working conditions less favourably than experienced staff (mean scale scores). The SAQ dimension for working conditions measures whether new employees are adequately trained, problem personnel are adequately dealt with, and information vital to patient care is properly disseminated (153). Staff with less than two years of seniority at the hospital might be more critical of these issues as they are relatively new, still learning and dependent upon good introduction, helpful colleagues and availability of information. These findings are in accordance with findings in the literature (45;53).

CHAPTER 7. CONCLUSIONS

This thesis gives an introduction to patient safety culture, and presents methods for measuring and improving safety culture focusing on the role of the leadership. Based upon the findings in the four studies contained in this thesis, the following conclusions can be drawn:

I. It is generally acknowledged that safety culture is comprised of assumptions, values, norms, practices and behaviours in regard to the safety of patients. Evidence supporting a positive relationship between safety culture and patient safety is still sparse, just as the literature documenting effective methods to create and improve the safety culture is sparse. However, the existing evidence highlights strong leadership engagement as an important characteristic. The SAQ was found to be the instrument most often used to document a positive relationship between the culture and specific aspects of patient safety.

II. The Danish version of the SAQ was tested and showed acceptable psychometric properties and good usability. The SAQ-DK is now available for use to evaluate staff's perceptions of patient safety culture in Danish hospital care.

III. Exceptional improvements in five of seven dimensions of patient safety culture following a multi-component leadership intervention were documented. A perception gap found between the attitudes of the clinical leaders and the frontline staff towards the safety of patients and clinical risk management closed after the leadership intervention.

IV. The study from the Faroe Islands represents a seldom snapshot of the patient safety culture in a modern western hospital in which the patient safety culture had not yet been consciously cultivated at the organisational level. Staff's perceptions of the safety of patients and clinical risk management varied extremely across clinical areas. The role of leadership in patient safety was brought into focus due to perception gaps between frontline staff and the leaders, and differences in the frontline staff's perceived leadership support according to the management level.

In conclusion, the results show that leadership should be regarded an unambiguous anchor point for understanding and improving the patient safety culture. The clinical leaders are recommended to acknowledge their own role in regard to the safety culture, investigate how the culture is, and why so. The leadership should enable a culture of safety, which is at the same time a culture of continuous quality improvement.

CHAPTER 8. PERSPECTIVES

The Danish National Quality Programme for Healthcare 2015-2018 (183) highlights the importance of building a culture of continuously improvement in regard to the delivery of health care. It is emphasised that establishing such a culture needs a clear leadership focus; leaders need to enable the frontline staff to take ownership of and allow quality improvement activities in everyday clinical work (183). This thesis provides the leadership with evidence-based Danish methods and directions to support the implementation of the Danish National Quality Programme for Healthcare 2015-2018.

Although the findings of this thesis contribute positively towards closing the Danish knowledge gap in patient safety culture, a substantial amount of research will still be required to close this knowledge gap further.

Firstly, there are some specific issues in regard to measuring patient safety culture that need to be further investigated, e.g. the time between cycles of measuring, assessing and initiating change in safety culture. The most effective methods for health care staff to process and discuss the results and decide upon cultural improvement plans should also be investigated. More research on effective strategies to improve the safety culture, or specific dimensions of it, is suggested too. The need to research these issues in a Danish context is emphasised.

It is also proposed to investigate the effects of the leadership-frontline interaction mechanism on safety culture and ultimately on patient safety. As leadership style has been linked to burnout, it also seems reasonable to take an interest in the much under-researched link between work environment, safety culture and patient safety. Generally, assessing correlations between patient safety culture and other organisational measures might help shed light upon the preconditions for successful implementation of patient safety practices. Along this line, developing validated measures of cultural adaptability to change is proposed as well.

Involving patients in the surveillance of the patient safety culture is a new but promising area of patient safety culture (128). However, patient involvement and safety culture have yet to be documented as having a mutually additive effect on patient safety (184). Nevertheless, asking patients about their perceptions of the culture appears to offer perspectives for improving the safety culture and the interpersonal quality. In addition, integrating not only staff's perceptions of the patient safety culture, but also patients' perceptions of the culture and traditional outcomes reported by health care staff and patient reported outcomes into routine outcome measurement remains an opportunity for Danish hospitals. This would also enable the much needed Danish examination of the association between change in patient safety culture and change in patient outcomes.

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APPENDICES

Appendix A. Study characteristics A

Table A1 Descriptive information on two reviews investigating the effect of interventions to enhance patient safety culture (59;78)

Study characteristics	**R.T. Morello et al.** (59)	**S.J. Weaver et al.** (78)
Objective(s)	*"To critically assess the evidence for the effectiveness of patient safety culture strategies for improving patient safety climate in hospitals".*	To examine *"the evidence for interventions that articulate improvement in patient safety culture as a primary outcome and intervention goal".*
Setting and year of study	University, Australia, 2012	University, USA, 2013
Time period of included studies	January 1996 to April 2011	January 2000 to October 2012
Number of studies included	21	33
Studies originated from	USA; N=15 United Kingdom; N=3 Canada; N=1 The Netherlands; N=1 Australia; N=1	USA Canada Australia
Type and number of studies included	RCT; N=1 Controlled before and after studies; N=7 Historically controlled studies; N=13	RCT; N=3 Controlled and uncontrolled before and after studies; N=27 Time-series studies; N=3
Surveys used for assessment of PSC	SAQ; N=11 HSPSC; N=5 PSCHO; N=2 SCSu; N=1 NHSNSS; N=1 SCS; N=1	SAQ; N=21 HSPSC; N=10 PSCHO; N=2

To be continued

Study characteristics	**R.T. Morello et al.** (59)	**S.J. Weaver et al.** (78)
Specialty covered by the studies	Not specified	Intensive care Perioperative, labour and delivery Radiology General medical care Surgical care
The interventions concerned	Patient safety leadership walk rounds; N=3 Multi-faceted unit-based programmes; N=7 Simulation-based training programmes; N=4 Team-based strategies N=3 Structured educational programmes; N=2 Multi-component organisational interventions; N=1 Surgical safety checklist; N=1	Patient safety leadership walk rounds or interdisciplinary rounds; N=8 Multi-faceted unit-based programmes; N=8 Team training or communication initiatives; N=20

Abbreviations; PSC, patient safety culture; RCT; randomised controlled trial; SAQ, Safety Attitudes Questionnaire; HSPSC, Hospital Survey on Patient Safety; PSCHO, Patient Safety Cultures in Healthcare Organizations; SCSu, Safety Climate Survey; NHSNSS, National Health Service National Staff Survey; SCS, Safety Climate Survey.

Appendix B. AMSTAR ratings A

Table A2 AMSTAR assessment of "Strategies for improving patient safety culture in hospitals: a systematic review" by R.T. Morello et al. (59)

	Yes	No	Cannot answer	Not applicable
1. Was an 'a priori' design provided?	**x**			
2. Was there duplicate study selection and data extraction?	**x**			
3. Was a comprehensive literature search performed?	**x**			
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?		**x**		
5. Was a list of studies (included and excluded) provided?		**x**		
6. Were the characteristics of the included studies provided?	**x**			
7. Was the scientific quality of the included studies assessed and documented?	**x**			
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?	**x**			
9. Were the methods used to combine the findings of studies appropriate?	**x**			
10. Was the likelihood of publication bias assessed?		**x**		
11. Was the conflict of interest included?		**x**		
Total R.T. Morello et al.	**7**	**4**	**0**	**0**

Table A3 AMSTAR assessment of "Promoting a Culture of Safety as a Patient Safety Strategy - A Systematic Review" by S.J. Weaver et al. (78)

	Yes	No	Cannot answer	Not applicable
1. Was an 'a priori' design provided?	**x**			
2. Was there duplicate study selection and data extraction?	**x**			
3. Was a comprehensive literature search performed?	**x**			
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?		**x**		
5. Was a list of studies (included and excluded) provided?		**x**		
6. Were the characteristics of the included studies provided?	**x**			
7. Was the scientific quality of the included studies assessed and documented?		**x**		
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?		**x**		
9. Were the methods used to combine the findings of studies appropriate?	**x**			
10. Was the likelihood of publication bias assessed?		**x**		
11. Was the conflict of interest included?		**x**		
Total S.J. Weaver et al.	**5**	**6**	**0**	**0**

Appendix C. Study characteristics B

Table A3 Descriptive information on a review and a meta-analysis investigating the relationship between patient safety culture and patient safety outcomes (84;85)

Study characteristics	**M.H. Dicuccio** (84)	**P.S. Groves** (85)
Objective(s)	*"The purpose of this review is to evaluate the state of research connecting patient safety culture and nurse-sensitive patient outcomes".*	*"Is there a relationship between PSOs and safety culture in acute-care hospitals, and if so, what is its nature?"*
Type of study	Review	Meta-analysis
Setting and year of study	University, USA, 2015	University, USA, 2014
Time period of included studies	Not specified	No limitations mentioned
Number of studies included	Peer-reviewed articles; N=10 Dissertations; N=7	Peer-reviewed articles; N=4 Dissertations; N=6
Studies originated from	Not specified	Not specified
Type and number of studies included	Cross-sectional descriptive design; N=16 Qualitative design; N=1	Not specified
Surveys used for assessment of PSC	SAQ; N=4 ZSAEOS & EOS; N=2 EOS; N=2 PSCHO; N=2 HSPSC; N=6 NDNQI RN Survey; N=1	SAQ; N=4 ZSAEOS; N=2 PSCHO; N=1 HUSCS; N=1 VAPSCI; N=1 SOS; N=1

To be continued

Study characteristics	**M.H. Dicuccio** (84)	**P.S. Groves** (85)
Patient safety outcomes	Family satisfaction Patient experience Mortality	Different outcomes were used: 1. Pressure ulcers 2. Falls 3. Medication errors 4. Urinary tract infections 5. Nosocomial infections 6. 30-day risk-adjusted morbidity 7. Infection 8. Hemorrhage/hematoma 9. PE/DVT 10. A bleeding CM 11. A post-operative CM

Abbreviations: PSC, patient safety culture; PSO, patient safety outcome; SAQ, Safety Attitudes Questionnaire; ZSAEOS, Zohar safety climate and error orientation scale; EOS, Error Orientation Scale; PSCHO, Patient Safety Cultures in Healthcare Organizations; HSPSC, Hospital Survey on Patient Safety Culture; NDNQI RN, Database of Nursing Quality Indicators Registered Nurses Satisfaction Survey; HUSCS, Hospital unit safety climate survey; VAPSCI, VA patient safety culture instrument; SOS, Safety organizing scale; PE/DVT, Pulmonary embolism/deep vein thrombosis; CM, composite measure.

Appendix D. AMSTAR ratings B

Table A4AMSTAR assessment of "The Relationship Between Patient Safety Culture and Patient Outcomes: A Systematic Review" by M.H. Dicuccio (84)

	Yes	No	Cannot answer	Not applicable
1. Was an 'a priori' design provided?	**x**			
2. Was there duplicate study selection and data extraction?			**x**	
3. Was a comprehensive literature search performed?			**x**	
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?			**x**	
5. Was a list of studies (included and excluded) provided?		**x**		
6. Were the characteristics of the included studies provided?	**x**			
7. Was the scientific quality of the included studies assessed and documented?		**x**		
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?		**x**		
9. Were the methods used to combine the findings of studies appropriate?		**x**		
10. Was the likelihood of publication bias assessed?		**x**		
11. Was the conflict of interest included?		**x**		
Total M.H. Dicuccio	**2**	**5**	**3**	

Table A6 AMSTAR assessment of "The relationship between safety culture and patient outcomes: results from pilot meta-analyses" by P.S. Groves (85)

	Yes	No	Cannot answer	Not applicable
1. Was an 'a priori' design provided?	**x**			
2. Was there duplicate study selection and data extraction?		**x**		
3. Was a comprehensive literature search performed?	**x**			
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?	**x**			
5. Was a list of studies (included and excluded) provided?		**x**		
6. Were the characteristics of the included studies provided?	**x**			
7. Was the scientific quality of the included studies assessed and documented?	**x**			
8. Was the scientific quality of the included studies used appropriately in formulating conclusions?		**x**		
9. Were the methods used to combine the findings of studies appropriate?	**x**			
10. Was the likelihood of publication bias assessed?		**x**		
11. Was the conflict of interest included?		**x**		
Total P.S. Groves	**7**	**4**	**0**	**0**

Appendix E. Culture questionnaires

Table A5 List of 33 patient safety culture questionnaires

1.	Safety Attitude Questionnaire (34;185)
2.	Veteran Affairs Palo Alto/Stanford Patient Safety Center for Inquiry (185)
3.	Veterans Health Administration Patient Safety Culture Questionnaire (34;185)
4.	Hospital Safety Culture Questionnaire (185)
5.	Hospital Survey on Patient Safety Culture (34;185)
6.	Safety Climate Survey (185)
7.	Allina Hospitals and Clinics (185)
8.	Culture of Safety Survey (34;185)
9.	Teamwork and Patient Safety Attitudes Questionnaire (185)
10.	Modified Operating Room Management Attitudes Questionnaire (34;185)
11.	Patient Safety Climate in Anaesthesia (185)
12.	Trainee Supplemental Survey (185)
13.	Safety Climate Scale (34;132;185)
14.	Stanford Safety Culture Instrument (132)
15.	Hospital Survey on Patient Safety (132)
16.	Strategies for Leadership: An Organisational Approach to Patient Safety (34)
17.	Patient Safety Cultures in Healthcare Organisations (34)

To be continued

Table A7 Names of 33 patient safety culture surveys (cont.)

18. Medication Safety Self Assessment (34)
19. Hospital Transfusion Service Safety Culture Survey (34)
20. 46-item safety climate scale (part of longer questionnaire) (132)
21. Safety climate 11 items based on the 46-item safety climate scale (132)
22. 16 items about safety climate (part of longer questionnaire) (132)
23. 21-item safety climate scale based on studies by Murphy et al. (132)
24. 18-item scale based on Ostrom et al. (132)
25. 79-item questionnaire based on Offshore Safety Questionnaire (132)
26. Adapted Operating Team Resource Management Survey (132)
27. 10-item safety climate scale by Pronovost et al. (132)
28. Checklist for Assessing Institutional Resilience (143;186)
29. Error Orientation Questionnaire (143;186)
30. Hospital Culture Questionnaire (143;186)
31. Manchester Patient Safety Assessment Framework (143;186)
32. Nursing Unit Cultural Assessment Instrument (143;186)
33. Patient Safety Culture Questionnaire (143;186)

Appendix F. Paper I

Kristensen S, Bartels PD, Sabroe S, Mainz J. Patientsikkerhedskultur kan facilitere høj klinisk kvalitet. Ugeskr Laeger 2014;16(176):1483-6.

Patientsikkerhedskultur kan facilitere høj klinisk kvalitet

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Fokus på omkostningseffektive, patientsikre ydelser af høj kvalitet i det danske sundhedsvæsen øges. Flere og flere organisationer implementerer styringsgrundlag for at understøtte kvalitetsledelse til realisering af politiske mål og de ønskede resultater for borgerne. I kvalitetsledelse fokuserer man på at sikre og udvikle kvaliteten af sundhedsvæsnets ydelser ud fra evidensbaseret viden og organisationens kvalitetsdata. Gennem ledelsesinformationssystemer gøres kvalitetsdata om bl.a. patientskader, utilsigtede hændelser (UTH) og klinisk kvalitet let tilgængelige for at skabe en transparent datadrevet udviklingskultur, der er baseret på åben dialog, refleksion, videndeling og læring [1].

Patientsikkerhed handler om at opretholde et højt sikkerhedsniveau i sundhedsvæsenet. Ved systematisk risikostyring forebygges, at borgere, der er i kontakt med sundhedsvæsenet, udsættes for UTH. UTH er defineret ved både risiko for skade på patienten og egentlig skade. Skadesbegrebet strækker sig fra mild, forbigående skade over varig funktionsnedsættelse til død. Patientskade kan medføre øgede samfundsomkostninger gennem øget behandlingsintensitet, forlængelse af indlæggelse og erstatninger [2, 3].

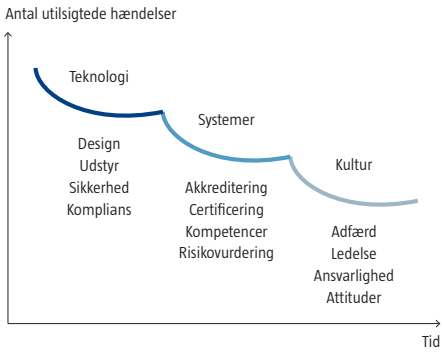
I 2001 blev der gennemført en dansk prævalensundersøgelse af forekomsten af UTH. Den omfattede 1.018 journaler fra somatiske patienter, der var blevet behandlet i hospitalsvæsenet, og viste, at cirka 9% af de udskrevne patienter havde været udsat for én eller flere UTH. Spændvidden var fra en til seks hændelser, og i gennemsnit var der 1,5 pr. indlæggelse. Hos 30 patienter forårsagede en UTH varige men eller død. Den gennemsnitlige forlængelse af indlæggelsen for patienter, der havde været udsat for en UTH, blev beregnet til syv sengedage. Der er fundet lignende resultater i andre lande [4-7].

Kvalitetsdata vedr. UTH rapporteres af sundhedspersonalet til et rapporteringssystem for UTH. Rapportering af UTH er sensitiv over for den lokale rapporteringskultur samt strategiske fokusområder, og data fra rapporteringssystemet er ikke egnede til brug i forbindelse med effektmonitorering af interventioner. Patientskade kan monitoreres ved hjælp af kliniske indikatorer, struktureret journalgennemgang eller Global Trigger Tool-metoden, hvor de seneste metoder dog udviser metodemæssige svagheder [8]. Tjernobylulykken i 1980'erne var årsag til, at man i industrien og blandt forskere blev mere opmærksomme på såvel teknologiske, organisatoriske som kulturelle faktorer som årsager til ulykker. I dag er det anerkendt, at hvor mennesker arbejder sammen om komplekse og risikofyldte opgaver, som kan have konsekvenser for andre mennesker, eksisterer der en sikkerhedskultur. I sundhedsvæsenet omfatter sikkerhedskulturen både arbejdsmiljøet og patientsikkerhedskulturen (PSK). Sidstnævnte skabes af personalet og angår patienterne [9].

Efter knap ti år med lovbundet patientsikkerhedsarbejde i det danske sygehusvæsen er der fortsat usikkerhed om, hvilke metoder der er mest effektive til kontrol af risiko og reduktion af antallet af patientskader. Erfaringer fra olieindustrien viser, at arbejdet med at nedbringe antallet af UTH har bevæget sig fra forbedring af teknologi og standarder via implementering af ledelsesstrategier til udvikling af sikkerhedskulturen (**Figur 1**). Samtidig har man i nyere internationale studier fra sundhedsvæsenet dokumenteret en sammenhæng mellem forbedring af PSK og samtidig reduktion af patientsikkerhedsproblemer som fald, infektioner og mortalitet [10-18].

Formålet med denne artikel er at skærpe det faglige og ledelsesmæssige fokus på forståelse, måling og udvikling af PSK.

FIGUR 1



Observationer fra olieindustrien. Forbedringsarbejdets fokus og antal utilsigtede hændelse ændres over tid [18].

HVAD ER PATIENTSIKKERHEDSKULTUR?

På trods af at begrebet PSK tiltrækker sig mere og mere opmærksomhed, er der i litteraturen ikke konsensus om, hvordan man definerer PSK, eller hvilke dimensioner der udgør begrebet. Fælles for de mange anvendte definitioner er, at PSK udgøres af sundhedspersonalets adfærd, værdier, holdninger og antagelser om patienternes sikkerhed. PSK er med andre ord den sociale og normative »lim«, der binder organisationens medlemmer sammen og stadfæster »måden vi typisk gør tingene på hos os«. PSK er således én egenskab til at undgåelse af patientskade [19, 20]. I et review af litteraturen blev de syv mest anvendte dimensioner af PSK identificeret ved en kvalitativ metaanalyse. De syv områder er ledelse, samarbejde, evidensbaseret praksis, kommunikation, læring, patienten i centrum og retfærdighedskultur [9].

Retfærdighedskultur betegner en balanceret situation i en organisation. Der eksisterer en atmosfære af tillid, og personalet bidrager aktivt til udvikling af patientsikkerheden, samtidig med at alle er bevidste om grænsen mellem acceptabel og uacceptabel adfærd i forhold til sikkerheden. Det er anerkendt, at uacceptabel adfærd er strafbar [21].

I en organisation, hvor personalet konstant håndterer risiko og tager ved lære af situationer, hvor man har succes med risikohåndtering, eksisterer der en moden, positiv eller veludviklet PSK. I en organisation, hvor UTH bortforklares, og ingen tager ansvar for patientsikkerheden og forbedring heraf, eksisterer der en umoden, negativ eller uudviklet PSK. De forskellige dimensioner af PSK vil sjældent være lige udviklede. Således kan en organisation have en moden samarbejdskultur, men en umoden læringskultur. Kulturens modenhedsgrad beskrives ved de metoder, som man anvender til at måle og vurdere kulturen med.

MÅLING OG VURDERING AF PATIENTSIKKERHEDSKULTUR

Der findes en række kvalitative og kvantitative instrumenter til måling af personalerapporteret PSK. Specielt to spørgeskemaserier og et dialogredskab er hyppigt omtalt i den internationale litteratur.

Manchester Patient Safety Framework (MaPSaF) er et dialogbaseret procesredskab. Det er udarbejdet til at bidrage til, at sundhedspersonalet kan reflektere over og vurdere deres egen PSK med henblik på at bedre praksis Kultur-Kompasset er en dansk bearbejdning af MaPSaF, med det er dog endnu ikke valideret [22].

De to PSK-spørgeskemaserier, som p.t. er mest anvendt, er skemaerne, som stammer fra henholdsvis University of Texas og benævnes Safety Attitudes

»Jeg ville føle mig tryg, hvis jeg var patient her« [24].

Questionnaire (SAQ) og fra Agency for Healthcare Research and Quality (AHRQ). Der er fire skemaer fra AHRQ udviklet til apoteker, plejehjem, hospitaler samt læge- og speciallægepraksis. De tre sidste er oversat til dansk, men er ikke dansk validerede. Skemaerne består af ca. 50 spørgsmål, der dækker 13 dimensioner af kulturen. Der er otte forskellige speciale- eller temaspecifikke SAQ-skemaer, som er målrettet til brug på hospitaler. Der findes en kort generisk version med 38 spørgsmål, som måler seks dimensioner af PSK f.eks. samarbejde og sikkerhedsbevidsthed. Det generiske SAQ-skema er under validering i Danmark [23, 24].

De respektive hospitalsversioner er vurderet op imod hinanden med den konklusion, at de begge har psykometriske og praktiske styrker og svagheder. Når man skal vælge målemetode, anbefales det, at man vurderer målingens formål op imod skemaets indhold, længde og personalets villighed til deltagelse [25].

Data fra PSK-undersøgelser opgøres på nederste ledelsesmæssige niveau, f.eks. på afsnitsniveau. Resultaterne formidles til og diskuteres med det sundhedsfaglige personale i en auditlignende proces, hvor målet er at forstå data, identificere styrker og svagheder ved kulturen samt planlægge forandringstiltag og effektmonitorering. Det er en ledelsesmæssig opgave at sætte resultater fra PSK-undersøgelser i sammenhæng med andre kvalitetsdata om f.eks. patientsikkerhed, faglig kvalitet, produktion og økonomi [9].

DANSKE MÅLINGER AF PATIENTSIKKERHEDSKULTUR

I forbindelse med forberedelse af lov om patientsikkerhed blev der i 2002 foretaget en tværsnitsmåling

FAKTABOKS

Nøglepunkter om patientsikkerhedskultur

Patientsikkerhedskulturen (PSK) er den måde, man tænker på patientsikkerhed og strukturerer og implementerer risikostyring i organisationen.

PSK udmøntes i personalets og ledernes værdier, normer og holdninger samt den faktuelle adfærd relateret til patienternes sikkerhed under komplekse og varierende omstændigheder.

PSK afspejler »måden vi typisk gør tingene på hos os«.

PSK kan f.eks. måles ved hjælp af et spørgeskema.

Der er dokumenteret en sammenhæng mellem en positiv udvikling af PSK og en reduktion af specifikke patientsikkerhedsproblemer.

Effektive interventioner til forbedring af PSK er karakteriseret ved stærkt ledelsesengagement.

UTH (N = 1.584). Deltagerne var ansat på sygehuse i fire af de daværende amter. I 2006 gennemførte det daværende H:S en spørgeskemaundersøgelse af PSK med inklusion af 21.388 medarbejdere. På trods af en svarprocent på 50, blev det konkluderet, at undersøgelsen »indikerer, at der generelt set er en åben, lærende og ikkesanktionerende kultur og en positiv vurdering af ledelsens involvering og engagement«. Man anvendte et danskudviklet spørgeskema til målingerne. Det var ikke valideret [26, 27].

For nuværende undersøges udviklingen i PSK over tre år i forbindelse med projektet Patientsikkert Sygehus, hvor der implementeres pakker med evidensbaseret praksis for at optimere patientsikkerheden. Ligeså pågår det p.t. en undersøgelse af udviklingen i PSK og et antal kliniske effektmål i Psykiatrien i Region Nordjylland. Undersøgelsen foregår over tid, og der interveneres over for ledelsesgruppen. De hidtidige erfaringer viser, at PSK-undersøgelserne giver de kliniske ledere en ny vinkel på ledelses- og patientsikkerhedsarbejdet.

EFFEKTIV FORBEDRING AF PATIENTSIKKERHEDSKULTUR

Effektive strategier til forbedring af PSK i hospitalsregi er klarlagt i to review af 21 henholdsvis 33 interventionsstudier. Der er dokumenteret en sammenhæng mellem forbedring af PSK – specielt samarbejdet og sikkerhedsbevidstheden - og en reduktion af specifikke kvalitetsproblemer f.eks. fald, infektioner, udskiftning af personale, indlæggelsestid og mortalitet. I studier, hvor man gennemførte teamtræning, implementerede patientsikkerhedsrunder eller multifacetterede forbedringsprogrammer, blev der fundet størst effekt. Fælles for disse interventioner

En patientsikkerhedsrunde er en kvalitativ interaktiv ledelsesmetode til identifikation af problemer med patientsikkerheden [11, 28, 29]. Comprehensive Unit-Based Safety Program (CUSP) er et multifacetteret interventionsprogram, der har sin oprindelse på Johns Hopkins Hospital i USA og er kendt fra Keystoneprojektet i Michigan. Det har vist sig at være specielt effektivt, når det benyttes i forbindelse med forbedring af samarbejde og sikkerhedsbevidsthed hos personalet, og desuden har det medført signifikant reduktion af f.eks. kateterrelaterede infektioner, fald og antal liggedage. Ved CUSP ændres PSK gennem et antal aktiviteter, som besluttes og implementeres trinvist ved et lokalt tværprofessionelt team, i programmet indgår bl.a. teamtræning og patientsikkerhedsrunder. Teamet identificerer patientsikkerhedsproblemer til forbedring via eget arbejde, fra patienterne, fra rapporteringer af UTH, patientklager, patientforsikringssager eller kliniske og administrative registre. Programmets succes tilskrives frontlinjepersonalets engagement og ansvar samt afdelingsledelsens direkte involvering i udviklingsarbejdet [11, 12].

KONKLUSION

PSK afspejler »måden vi typisk gør tingene på hos os« i relation til patienternes sikkerhed [19].

Der er ikke etableret en årsags-virknings-effekt mellem klinisk adfærd, PSK og kliniske effektmål, dette forhold synes at være komplekst og nonlineært, men der er dokumenteret en sammenhæng mellem forbedring af PSK – specielt samarbejdet og sikkerhedsbevidstheden - og en reduktion af specifikke kvalitetsproblemer.

For at kunne udstikke evidensbaserede styringsstrategier bliver afklaring af effektive metoder til forbedring af PSK og reduktion af patientskader en uundgåelig brændende platform i fremtidige danske forsknings- og udviklingsaktiviteter. Monitorering af PSK og udvikling i PSK over tid kræver valide undersøgelsesmetoder, og der pågår p.t. et dansk studie, som skal give ledere i sundhedsvæsenet en værktøjskasse med et dansk valideret PSK-spørgeskema og et evidensbaseret beslutningsstøtteredskab til brug i forbindelse med valg af effektive interventioner til forbedring af PSK og klinisk kvalitet.

SUMMARY

Solvejg Kristensen, Paul Bartels, Svend Sabroe & Jan Mainz: Patient safety culture can be a driver for high clinical quality Ugeskr Laeger 2013 Sep 2 [Epub ahead of print]

More and more health care organisations strive for a cost-effective, safe quality of care. Some studies have found

simultaneous improved safety culture and reduction of patient harm following improvement activities like patient safety walk around, team training or multifaceted intervention programmes. There is a lack of evidence concerning the relationship between improved patient safety culture and reduction of patient harm in a Danish health-care setting. Currently a Danish validation of the Safety Attitude Questionnaire and an intervention study to improve patient safety culture is ongoing.

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Appendix G. Paper II

Kristensen S, Sabroe S, Bartels P, Mainz J, Christensen KB. Adaption and Validation of the Safety Attitude Questionnaire for the Danish hospital setting. Clinical Epidemiology 2015;7:149-60.

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ORIGINAL RESEARCH

Adaption and validation of the Safety Attitudes Questionnaire for the Danish hospital setting

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Purpose: Measuring and developing a safe culture in health care is a focus point in creating highly reliable organizations being successful in avoiding patient safety incidents where these could normally be expected. Questionnaires can be used to capture a snapshot of an employee's perceptions of patient safety culture. A commonly used instrument to measure safety climate is the Safety Attitudes Questionnaire (SAQ). The purpose of this study was to adapt the SAQ for use in Danish hospitals, assess its construct validity and reliability, and present benchmark data.

Materials and methods: The SAQ was translated and adapted for the Danish setting (SAQ-DK). The SAQ-DK was distributed to 1,263 staff members from 31 in- and outpatient units (clinical areas) across five somatic and one psychiatric hospitals through meeting administration, hand delivery, and mailing. Construct validity and reliability were tested in a cross-sectional study. Goodness-of-fit indices from confirmatory factor analysis were reported along with inter-item correlations, Cronbach's alpha (α), and item and subscale scores.

Results: Participation was 73.2% (N=925) of invited health care workers. Goodness-of-fit indices from the confirmatory factor analysis showed: c^2=1496.76, $P<0.001$, CFI 0.901, RMSEA (90% CI) 0.053 (0.050–0056), Probability RMSEA (p close)=0.057. Inter-scale correlations between the factors showed moderate-to-high correlations. The scale stress recognition had significant negative correlations with each of the other scales. Questionnaire reliability was high, (α=0.89), and scale reliability ranged from α=0.70 to α=0.86 for the six scales. Proportions of participants with a positive attitude to each of the six SAQ scales did not differ between the somatic and psychiatric health care staff. Substantial variability at the unit level in all six scale mean scores was found within the somatic and the psychiatric samples.

Conclusion: SAQ-DK showed good construct validity and internal consistency reliability. SAQ-DK is potentially a useful tool for evaluating perceptions of patient safety culture in Danish hospitals.

Keywords: patient safety culture, questionnaire, validity, reliability, Denmark

Introduction

Billions of people use hospital services across the globe yearly, and the vast majority are treated without risk or harm. However, studies from the United States, Australia, and Europe suggest that one in ten hospital patients experience some sort of harm, and it has been shown that medical errors, low quality of patient care, and increased length of hospital stay can be caused by lack of attention to patient safety.[1,2] A culture of safety has been suggested to be a core mechanism of the organizational context underlying safe, effective, and timely patient care.[3] Patient safety culture (PSC) is a reflection of professionals' shared assumptions, values, beliefs, and practices.[4] Enhancing PSC has been associated with reductions in specific patient safety problems, such

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as ventilator-associated pneumonia, blood stream infections, patient falls, medication errors, and increased mortality.[5–7] Thus, clinical governance activities more and more often include measuring and improving PSC as a stepping stone to creating highly reliable organizations.[8]

Questionnaires can be used to capture a snapshot of an employee's perception of different dimensions of PSC. The results can help clinical leaders, frontline staff, quality and safety officers, etc, to identify cultural strengths and weaknesses, plan strategic improvement activities, and track changes over time, as well as provide benchmark data.[9]

A good questionnaire should be valid, reliable, and discriminating. The validity of a questionnaire is assessed by the degree to which the questionnaire measures what it is intended to measure, whereas reliability mirrors the degree of stability and repeatability of measures. Discrimination is the ability of the questionnaire to separate out important differences between the individuals or groups.[10]

There is a growing body of literature on the psychometric properties of PSC questionnaires.[11–15] Two of the most used PSC questionnaire were compared by Etchegaray and Thomas and considerable variation was found with regard to the number of items, topics of the cultural dimensions, feasibility, and usage. The Safety Attitudes Questionnaire (SAQ) was reported to be feasible in use and one of the most thoroughly validated and widely used instruments, with stable factors and good psychometric properties across different national settings.[16] Further, the SAQ has also been extensively used to explore the relationship between perceptions of PSC and clinical outcomes.[5–7]

The SAQ was originally developed for hospitals from the Flight Management Attitudes Questionnaire, an explorative human factor questionnaire used in commercial aviation.[17,18] The SAQ was developed via a multistep process, and it was validated using explorative and confirmatory factor analysis (CFA) on data from 10,843 respondents from 203 clinical areas in the United States, the United Kingdom, and New Zealand. Exploratory factor analysis was applied to explore the existence of a latent structure of the items, yielding six factors. Multilevel CFA was used to evaluate the factor structure underlying the six factors. The goodness-of-fit values indicated good internal construct validity of the model, confirming that the SAQ measures the aspects of the culture expressed in the hypothesized factors. Item-factor correlations within clinical areas indicated that the items can generally be regarded as important contributors to the hypothesized factor to which they belong. The scale reliability coefficients confirmed acceptable internal consistency reliability; items in the questionnaire are closely related as a group measuring the same underlying construct.[19]

The validity and reliability of translated versions of the SAQ has been documented in countries including Norway, Germany, Switzerland, Sweden, and the Netherlands. In these studies, the most frequently used method is to assess internal construct validity and reliability. Items indicated on the original factor structure are hypothesized as six factors.[20–28] They are preselected into the factors and confirmed using CFA.[20–28] Questionnaire and scale reliability are investigated by Cronbach's alpha (α).[20–24,28,29] When the items and the scales remain across cultural setting, one can benchmark data and cooperate in improvement and learning activities following a measurement.

A literature search on PubMed, PsycINFO, Embase, and MEDLINE, using the search terms "patient safety culture" or "patient safety climate" combined with "Denmark", did not reveal any validated instruments for measuring professionals' perceptions of PSC in Danish hospitals. A lack of evidence describing the quality of PSC in Danish hospitals was also identified, although one 12-year-old study described 1,584 doctors' and nurses' attitudes toward reporting of adverse events.[30]

The aim of this study was to adapt the SAQ for use in Danish hospitals, assess construct validity and internal consistency reliability, and present Danish benchmarking data.

Materials and methods

A cross-sectional study design was applied. A Danish version of SAQ (SAQ-DK) was distributed across five somatic and one psychiatric hospital.

The SAQ

The original SAQ short form is an explorative questionnaire with 31 items comprising six subscales, and additional items on demographic information. The subscales are: teamwork climate, safety climate, stress recognition, job satisfaction, working conditions, and perceptions of unit management. It can be used to assess safety attitudes across specialties in hospitals. Respondents answer on a 5-point Likert scale as 1= disagree strongly, 2= disagree slightly, 3= neutral, 4= agree slightly, and 5= agree strongly. Items are assumed to have interval properties. Items 2 and 11 are negatively worded.[18]

Adaption of the SAQ into Danish

The corresponding author obtained permission to translate and use the SAQ short form from 2007 into the Danish

language verbally from B Sexton, The University of Texas at Houston – Memorial Hermann Center for Healthcare Quality and Safety Houston, Texas, USA. The SAQ was adapted into Danish following modified principles adapted from Beaton et al, which involved a forward–backward translation technique, a pilot study, and a refinement process via an expert panel.[31] Jointly, panel members had linguistic skills, knowledge of terminology, and clinical and patient safety work experience in Denmark.

To establish face validity of SAQ-DK, the 15 respondents of the pilot study were asked to comment on any wording that could lead to doubt in understanding of the items or be misinterpreted, and suggest alternative wording. Most importantly, the adaption process resulted in addressing health care workers in general, not specifically doctors and nurses, and allowing respondents to select "not applicable" as a possible answer. This is consistent with recommendations from Norway.[20]

Study setting and sample

Denmark has a public health care system with free and equal access for citizens. The system is predominantly financed through general taxes, and operationalizing hospital care is the responsibility of the five Danish regions. Approximately 14% of hospital staff are doctors, 43% nurses and nursing assistants, and 42% other staff, such as allied health care profession, administrative, and technical staff.[32] Female hospital employees amount to 82%.[33] Denmark has a sophisticated array of initiatives for monitoring and developing the quality of care.[34] Analogs between Denmark and the other Scandinavian countries are present for hospital organization, education, and concepts of patient safety.

The study was integrated into two quality improvement projects: the Danish Safer Hospital Programme and the Good Psychiatric Department.[35,36] One acute care, regional, somatic, teaching hospital from each of the five regions and one psychiatric university hospital participated. Across the somatic hospitals, 15 inpatient bed units were selected as; one operating room and one intensive care unit in each hospital. Further, one unit of internal medicine, oncology, neurology, surgery, and cardiology participated across the five hospitals. In the psychiatric hospital, six outpatients units and ten inpatient bed units were included from the same ward. These were either disease-specific or generic and either open or closed units. In total, 31 in- and outpatient units (clinical areas) participated.

Based on human resource data provided by the hospitals, 1,263 respondents (doctors, nurses, nursing assistants and similar, psychologists, physiotherapists, occupational therapists, music therapists, logopedics staff, dietitians, social workers, administrative staff, and hospital porters) were eligible for participation. Full- and part-time staff working in the selected clinical areas at least half of their working time qualified for inclusion. This included staff with a significant work commitment to a clinical area, as they could influence or be influenced by the culture in that clinical area, but who were not based in that clinical area, eg, a physiotherapist spending most of her/his working hours in a specific bed unit while being employed in the physiotherapy department.

Data collection

Data were collected between April and August 2011.

A local project manager was appointed at each hospital to cooperate with the research team and ensure uniformity in the data collection by following the study guidelines.

Participants were given 4 weeks to answer the questionnaire. A reminder was posted in the units after 2 weeks; it also stated the current local participation rate.

In the 15 somatic clinical areas, the questionnaire was distributed through unit-specific staff meetings led by one of the researchers and/or the hospital project manager. Meeting administration was supplemented by hand delivery and in-house mailing to include staff not participating in the meetings. In the psychiatric clinical areas, the survey and study information were distributed electronically via emails to all included staff.

The participants were informed that participation was voluntary and anonymous, that all answers would be treated with confidentiality, and that no individual responses would be available to local management. The Danish Data Protection Agency approved the study.

Statistical analysis

Respondent demographics are expressed as frequencies.

To describe the construct validity of SAQ-DK, the underlying cross-national original factorial structure described by Sexton et al was tested.[19] The hypothesized six-factor model comprised teamwork climate (items 1–6), safety climate (items 7–13), job satisfaction (items 15–19), stress recognition (items 20–23), perceptions of unit management (items 24–29), and working conditions (items 30–32).[37] The hypothesized model was tested via CFA using the entire sample of 925 respondents from 31 clinical areas. The fit of the model was described by chi-square statistics (χ^2, degrees of freedom [*df*], *P*-value), comparative fit index (CFI), and root mean square error of approximation (RMSEA) in accordance with recommendations by Blunch[10] and previous SAQ validation studies.[19,20,22,23,29] The following threshold values were

used for an acceptable model fit: $\chi^2/df < 5.00$ as suggested by Wheaton et al;[38] CFI >0.90 as suggested by Bentler;[39] RMSEA <0.06 as suggested by Bentler;[39] and the probability RMSEA (probability RMSEA >0.05) as suggested by Browne and Cudeck.[40]

Item-factor loadings exceeding 0.30 were regarded as acceptable as per Hair et al.[41]

Further, construct validity was studied by the degree of linear association between pairs of two dimensions; Pearson's correlation coefficients (*r*) were described.

The reliability of SAQ-DK was described by measures of internal consistency. Items hypothesized as a factor were regarded as closely related if $\alpha > 0.70$.[42] The correlation between one item and the sum score of the other items in the hypothesized factor (item-subscale correlations) was examined to investigate item discrimination, which is the degree to which differences between respondents' ratings of a single item were consistent with differences in their ratings of the subscale as a whole. Item discrimination was regarded as acceptable if the correlation coefficients ≥0.30.[10]

SAQ-DK item scores were described as %-missing, mean item score, standard deviations (SDs), %-agree ("agree slightly" or "agree strongly") and %-disagree ("disagree slightly" or "disagree strongly"). Item mean scores were calculated based upon the 5-point Likert scale (range 1–5) as the total sum of scores from 1–5 from all respondents divided by the number of responses. Items with missing answers were eliminated from the item statistics.

Benchmarking data were presented for the entire sample and for the somatic and psychiatric samples respectively (subsamples), reporting the percent of respondents with a positive attitude (%-positive) and scale mean scores and SD. For this purpose, SAQ-DK item scores were converted to a 0- to 100-point scale, where 1=0, 2=25, 3=50, 4=75, and 5=100. Items 2 and 11 were reverse scored, so that their valence matched the positively worded items. Individual scale mean scores were calculated by the average score of the scaled items (range 0–100), and the %-positive was calculated as the proportion of respondents with an individual mean scale score of 75 or higher, according to recommendations in the literature.[43] SAQ-DK mean scale scores were calculated for each scale by the average score of the scaled items (range 0–100).

Subscale results of the somatic and the psychiatric samples were compared. For each scale, %-positive were compared using chi-square testing. Mean scale scores of the two subsamples were compared using independent *t*-testing.

Analyses of variance (ANOVAs) were performed to test for significant between-unit variability in mean scale scores within the psychiatric and the somatic samples respectively. Analysis of the somatic sample was controlled for the effect of hospital.

Statistical significance was defined as $P \leq 0.05$.

The CFA was performed using SPSS Amos version 22.0; all other analyses were performed using IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).

Results

In total, 925 of 1,263 questionnaires were returned (73.2%); 277 questionnaires originated from the psychiatric sample and 648 from the somatic sample. In the somatic subsample, the response rate was 71.9%, and, in the psychiatric subsample, it was 76.5%. The number of participants varied from six in small outpatient settings to 80 in large bed units. Respondent characteristics are shown in Table 1.

Item analysis

SAQ-DK item descriptions are shown in Table 2.

The average rate of incomplete (missing and not applicable) data at the item level was 2.3%, with a range of 0.3%

Table 1 Respondent characteristics

Characteristics	Entire sample N=925		Somatic hospital sample N=648		Psychiatric hospital sample N=277	
	N	%	N	%	N	%
Sex						
Male	95	10.3	63	9.7	32	11.6
Female	816	88.2	571	88.1	245	88.4
Missing	14	1.5	14	2.2	0	0
Age groups						
Under 26 years	33	3.6	22	3.4	11	4.0
26 to 35 years	195	21.1	118	18.2	77	27.8
36 to 45 years	263	28.4	194	29.9	69	24.9
46 to 55 years	288	31.1	206	31.8	82	29.6
56 years or older	131	14.2	93	14.4	38	13.7
Missing	15	1.6	15	2.3	0	0
Profession						
Doctors	93	10.1	62	9.6	31	11.2
Nurses and nursing assistants	713	77.1	526	81.2	187	67.5
Therapists[a]	40	4.3	7	1.1	33	11.9
Others[b]	79	8.5	53	8.2	26	9.4
Years in profession						
2 years or less	196	21.2	120	18.5	76	27.4
More than 2 years	729	78.8	528	81.5	201	72.6

Notes: [a]Psychologists, physiotherapists, occupational therapists, music therapists, logopedics staff; [b]dietitians, social workers, administrative staff, and hospital porters. Results in this table were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).

Table 2 SAQ-DK item descriptions, subscale-corrected item-total correlations, and item-factor loadings (N=925)

Dimension, item number, and text	%-missing	%-disagree	%-agree	Mean (SD)	Item-subscale correlations	Standardized item-factor loading
Teamwork climate						
1. Nurse input is well received in this clinical area	0.4	6.1	82.4	4.2 (0.9)	0.50	0.65
2. In this clinical area, it is difficult to speak up if I perceive a problem with patient care[a]	2.5	20.0	68.4	3.9 (1.2)	0.23	0.28
3. Disagreements in this clinical area are resolved appropriately (ie, not who is right, but what is best for the patient)	2.4	14.9	59.9	3.7 (1.2)	0.42	0.49
4. I have the support I need from other personnel to care for patients	2.3	3.7	87.1	4.3 (0.8)	0.53	0.65
5. It is easy for personnel in this clinical area to ask questions when there is something that they do not understand	0.4	3.0	92.4	4.5 (0.8)	0.48	0.60
6. Health care workers here work together as a well-coordinated team	1.1	10.9	77.2	3.9 (1.0)	0.57	0.72
Safety climate						
7. I would feel safe being treated here as a patient	1.3	9.0	74.4	4.0 (1.0)	0.50	0.68
8. Medical errors are handled appropriately in this clinical area	1.5	8.0	70.5	4.0 (1.0)	0.60	0.65
9. I know the proper channels to direct questions regarding patient safety in this clinical area	0.4	7.7	76.9	4.1 (1.0)	0.44	0.48
10. I receive appropriate feedback about my performance	0.9	21.8	55.0	3.4 (1.2)	0.50	0.62
11. In this clinical area, it is difficult to discuss errors[a]	1.6	11.7	69.3	4.0 (1.1)	0.35	0.41
12. I am encouraged by my colleagues to report any patient safety concerns I may have	2.3	13.5	50.3	3.6 (1.1)	0.41	0.45
13. The culture in this clinical area makes it easy to learn from the errors of others	1.6	14.4	58.2	3.6 (1.1)	0.57	0.64
Job satisfaction						
14. I like my job	0.3	2.7	92.5	4.5 (0.8)	0.58	0.67
15. Working in this hospital is like being part of a large family	3.6	17.6	50.6	3.4 (1.1)	0.60	0.64
16. This clinical area is a good place to work	0.4	5.4	82.1	4.1 (0.9)	0.77	0.87
17. I am proud to work in this clinical area	0.5	5.1	75.1	4.1 (0.9)	0.74	0.81
18. Morale in this clinical area is high	0.5	5.4	78.5	4.1 (0.9)	0.59	0.65
Stress recognition						
19. When my workload becomes excessive, my performance is impaired	0.4	14.1	79.0	4.1 (1.1)	0.52	0.63
20. I am less effective at work when fatigued	1.0	11.7	77.8	4.0 (1.0)	0.68	0.80
21. I am more likely to make errors in tense or hostile situations	1.3	21.3	59.8	3.6 (2.0)	0.64	0.71
22. Fatigue impairs my performance during emergency situations (eg, emergency resuscitation, seizure)	7.2	22.2	47.2	3.3 (1.3)	0.56	0.64
Perception of unit management						
23. Management supports my daily efforts	6.2	8.8	67.4	3.9 (1.0)	0.70	0.81
24. Management does not knowingly compromise the safety of patients	8.1	7.4	65.9	4.0 (1.1)	0.52	0.57
25. Management is doing a good job	6.5	7.7	68.0	4.0 (1.0)	0.75	0.88
26. Problem personnel in this clinical area are dealt with constructively by our management	7.1	15.1	58.7	3.7 (1.1)	0.69	0.81
27. I get adequate, timely information about events in the hospital that might affect my work from the unit management	8.0	12.0	49.1	3.6 (1.1)	0.69	0.81
28. The staffing levels in this clinical area are sufficient to handle the number of patients	1.8	41.5	41.7	3.0 (1.3)	0.30	0.33
Working conditions						
29. This hospital does a good job of training new personnel	1.1	15.1	71.5	3.9 (1.2)	0.63	0.77
30. All the necessary information for diagnostic and therapeutic decisions is routinely available to me	3.0	5.4	83.1	4.2 (0.9)	0.41	0.56
31. Trainees in my discipline are adequately supervised	2.6	16.6	64.6	3.7 (1.1)	0.65	0.78

Notes: [a]Negatively worded item, reverse scored so that its valence matches the positively worded items. Results in this table were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).

Abbreviations: %-agree, "agree slightly" or "agree strongly"; %-disagree, "disagree slightly" or "disagree strongly"; %-missing, missing answers and answers given as "not applicable"; SAQ-DK, Danish version of the Safety Attitudes Questionnaire; SD, standard deviation.

to 8.1%. Item 27, "I get adequate, timely information about events in the hospital that might affect my work from the unit management", provided the highest proportion (8.1%) of missing answers, and item 14, "I like my job", from the job satisfaction scale, provided the lowest proportion (0.3%). Items in the perception of unit management scale had the highest proportion of missing data together with item 22: "Fatigue impairs my performance during emergency situations (eg, emergency resuscitation, seizure)" (7.2%). No items were excluded in the further analysis because of the level of missing data.[20]

A full range of scores between 1 and 5 was observed for all items. Response patterns were observed according to the proportions of %-missing, %-agree, %-disagree, and %-neutral. Item responses were visibly skewed toward the positive, but showed considerable variation across all items. Item 14 had the highest proportion of %-agree (92.5%). Item 28, "The staffing levels in this clinical area are sufficient to handle the number of patients", provided the lowest level of %-agree (41.7%) and the highest level of %-disagree (41.5%) across all items.

The item mean of item 5, "It is easy for personnel in this clinical area to ask questions when there is something that they do not understand", and 14, "I like my job", was above 4.5, indicating little variability in the scores of these two items.

Item reliability characteristics are shown in Table 2. Item-subscale correlations, reflecting the correlation between the score on the item and the total scale score of the other items in the scale, ranged from 0.23 to 0.77. Item 2, "In this clinical area, it is difficult to speak up if I perceive a problem with patient care", had item-subscale correlations <0.30, indicating a weak relationship with the other items in the hypothesized factor. All other items correlated modestly to well with the sum of the other items in their scale; Pearson's $r>0.30$ confirmed good discriminative ability of the items.

The factor structure of the responses was analyzed, and fit indices regarding item-factor loadings are also shown in Table 2. Only item 2 had an item-factor loading below the acceptable threshold of 0.3. The item-factor loading was 0.28, meaning that less than 8% of variance is explained by the factor. Also, item 28 had a low item-factor loading of 0.33. All other items had item-factor loading between 0.41 and 0.88, explaining 16%–77% of the variance by the factor.

Factor structure of the SAQ

The factor structure of the responses was analyzed to provide formal testing of the goodness of fit of the pre-hypothesized six-factor model to the data. Goodness-of-fit indices following CFA are displayed in Table 3. The chi-square test of the model fit revealed a χ^2/df ratio of 3.572, which is below the acceptable threshold of 5.00.[38] The CFI was 0.901, exceeding the threshold value of 0.90.[39] The RMSEA was 0.053 (90% confidence interval: 0.050–0.056), which was below the anticipated threshold value of 0.06. Finally, the probability RMSEA (p close) was 0.057, which was above the threshold of 0.05, as desired.[39]

Scale reliability and correlations

The Cronbach's alpha coefficient for the total SAQ-DK was high (0.89), and it changed minimally when items were removed (0.88–0.90). Scale reliability is shown in Table 4. Cronbach's alpha exceeded the set cut off point of 0.70 for all scales (0.70–0.86), indicating good scale reliability.

Scale-to-scale correlations were studied by the degree of linear association between pairs of two scales: Pearson's correlation coefficients are shown in Table 4. All scales correlated negatively, with the stress recognition scale revealing Pearson's r between -0.13 and -0.08 ($P<0.05$). Pearson's correlations indicated significant strong positive relationships for all other scales; correlation coefficients ranged from 0.47 to 0.67 ($P<0.01$).

Benchmarking data

The entire sample

Subscale results for SAQ-DK (N=925) are shown in Table 5 for the entire sample, reporting %-positive and mean scale statistics.

Across the entire sample, %-positive ranged from 42.6% for perception of unit management to 64.8% for teamwork climate. Most variation in %-positive across the 31 clinical areas was found for working conditions, where the lowest %-positive was 5.0% and the highest %-positive was 91.7%.

Variations in %-positive across the clinical areas are shown as minimum–maximum in Table 5, and the distributions of %-positive for the 31 clinical areas are shown in Figure 1.

Table 3 Results of the confirmatory factor analysis

Goodness-of-fit indices	Entire model[a] N=925
Chi-square test of the model fit	χ^2=1,496.760, *df*=419, *P*<0.001
Comparative fit index	0.901
RMSEA	0.053
90% CI for RMSEA	0.050–0.056
Probability RMSEA (p close)	0.057

Notes: [a]Handling of incomplete data by pairwise deletion (cases containing some missing data are used in the statistical analysis). Results in this table were generated by the use of SPSS Amos version 22.0.
Abbreviations: CI, confidence interval; *df*, degrees of freedom; RMSEA, root mean square error of approximation.

Table 4 Scale reliability and inter-scale correlations of SAQ-DK (N=925)

Factor	Cronbach's α	Inter-scale correlations (Pearson's *r*)				
		1	2	3	4	5
1. Teamwork climate	0.70	1				
2. Safety climate	0.76	0.67**	1			
3. Job satisfaction	0.84	0.66**	0.61**	1		
4. Stress recognition	0.78	–0.08*	–0.13**	–0.09**	1	
5. Perceptions of unit management	0.86	0.47**	0.56**	0.52**	–0.10**	1
6. Working conditions	0.72	0.53**	0.56**	0.54**	–0.13**	0.48**

Notes: *Correlation is significant at the 0.05 level (two-tailed); **correlation is significant at the 0.01 level (two-tailed). Results in this table were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).
Abbreviation: SAQ-DK, Danish version of the Safety Attitudes Questionnaire.

Less than 60% of responders reporting positive attitudes would indicate a need for improvement, according to the literature.[27] The number of units with %-positive below 60% varied from ten units, (33%) for teamwork climate, to 24 units (77%), for safety climate. Differences in %-positive across the 31 clinical areas were analyzed by χ^2 statistics. Significant differences in the proportions of staff with a positive attitude per clinical area were found for all climate dimensions ($P<0.05$).

Higher proportions of positive responders were found among female staff than among male staff for all scales, but differences in %-positive between the sexes were only found for teamwork climate and working conditions ($P<0.05$). Differences in %-positive were found across doctors, nurses and nursing assistants, and others for perception of unit management only ($P<0.05$).

Mean scale scores (SD) are displayed in Table 5 and ranged from 66.8 (20.6) for perception of unit management to 77.2 (15.7) for teamwork climate. The scale means of the 31 clinical areas were significantly different for all six cultural dimensions ($P<0.001$).

Female staff had higher mean scale score than male staff on all scales; however, these were only statistically significant for teamwork climate, safety climate, and job satisfaction ($P<0.05$). Mean scales scores differed among doctors, nurses and nursing assistants, and others for teamwork climate, job satisfaction, and perception of unit management ($P<0.05$), but no consistent pattern was found.

The somatic and psychiatric clinical areas

Subscale results for the somatic and the psychiatric samples are shown in Table 6.

Comparing %-positive across the two subsamples revealed no differences in %-positive for any of the dimensions ($P>0.05$).

Comparing scale means across the two samples showed statistically significant differences for the stress recognition scale only, which was higher in the psychiatric than in the somatic sample ($t=-3.12$, $df=922$, and $P=0.002$).

Variability in scale means was tested in both samples separately using ANOVA for each climate dimension. In the somatic sample, testing was controlled for the effect of hospital. In both subsamples, all mean scale scores differed across the clinical areas ($P<0.001$) for all six dimensions.

Discussion

Based on data from a multisite, cross-sectional study involving 925 health care workers, construct validity and internal consistency reliability of SAQ-DK were investigated

Table 5 Subscale results for SAQ-DK (N=925)

Dimension	%-missing	%-positive	Min–max[a]	Sig[b]	Mean (SD)	Range[c]	Sig[d]
Teamwork climate	1.5	64.8	26.3–100.0	<0.01	77.2 (15.7)	59.6–94.4	<0.01
Safety climate	0.0	45.4	14.3–90.0	<0.01	70.3 (16.8)	48.9–88.2	<0.01
Job satisfaction	1.1	63.7	25.0–100.0	<0.01	76.2 (17.7)	59.0–91.0	<0.01
Stress recognition	2.5	49.6	35.0–91.7	<0.01	68.1 (22.7)	55.5–89.6	<0.01
Perception of unit management	6.3	42.6	3.3–80.0	<0.01	66.8 (20.6)	41.4–84.1	<0.01
Working conditions	2.2	62.6	5.0–91.7	<0.01	73.8 (22.0)	40.8–89.9	<0.01

Notes: [a]Variation in %-positive across the 31 clinical areas; [b]chi-square test comparing %-positive across clinical areas; [c]range in mean across clinical areas; [d]ANOVA for each culture dimension controlled for the effect of hospital with significance testing for unit variability in means. Results in this table were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).
Abbreviations: %-missing, missing answers and answers given as "not applicable"; %-positive, proportion of staff holding a positive attitude; ANOVA, analysis of variance; max, maximum; min, minimum; SAQ-DK, Danish version of the Safety Attitudes Questionnaire; SD, standard deviation; sig, significance.

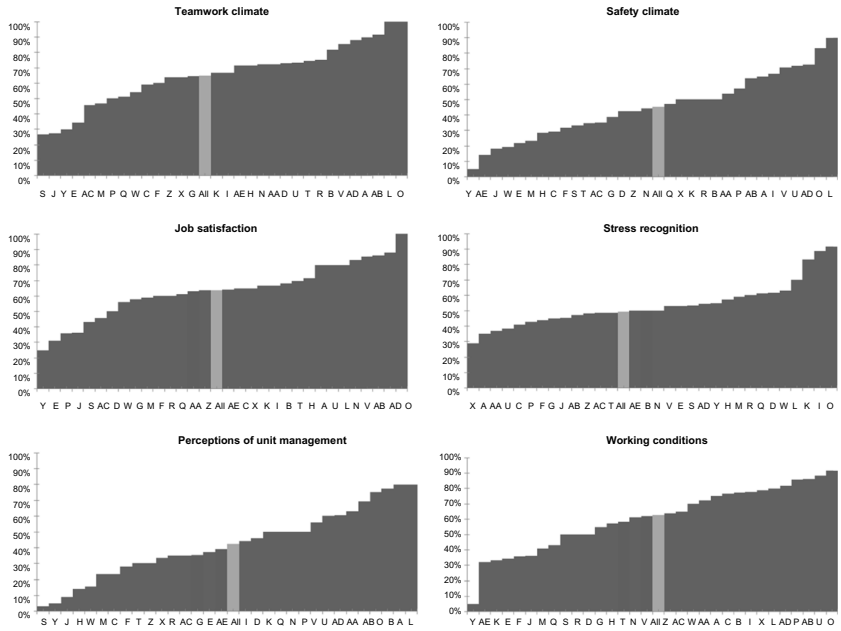

Figure 1 Distribution of percent of positive scores (%-positive) per dimension for the 31 clinical areas.[a]
Notes: [a]All clinical areas are ranked in ascending order according to %-positive for each dimension, and each clinical area was allocated a letter, and this letter was used in the graphical display for all dimensions, signalizing the position of each clinical areas with each dimension. The pale gray bar represents the average %-positive of all clinical areas. Results in this figure were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA) and graphically displayed by Microsoft Excel 2010.

and benchmarking data derived. To date, this study presents the most comprehensive evidence-based information on Danish hospital staff perceptions of PSC using a validated questionnaire.[30]

Construct validity and reliability

CFA was applied to the full dataset, and the fit of the hypothesized six-factor model was described. The χ^2/df ratio was below the acceptable threshold.[38] The Danish χ^2 ratio was higher than in Norway (2.583) and Switzerland (1.653), but well below that found by Sexton et al for the American-English language sample (13.152).[19,20,28] The CFI exceeded the threshold value.[39] The range for the CFI was 0.90 to 0.99 in other SAQ validation studies.[19,20,22–24,28] The RMSEA was below the anticipated threshold value.[39] In other SAQ validation studies, the RMSEA ranged from 0.03 to 0.07.[19,20,22–24,28]

Table 6 Subscale results within and between the somatic and psychiatric clinical areas

Dimension	15 somatic clinical areas (N=648)	16 psychiatric clinical areas (N=277)	Differences between the two subsamples	
			%-positive[a]	Means[b]
	%-positive; mean (SD)	%-positive; mean (SD)	χ^2; (*df*); sig	*t*-value; (*df*); sig
Teamwork climate	64.8; 77.3 (15.3)	64.6; 77.3 (16.7)	0.00; (1); 0.96	0.02; (923); 0.99
Safety climate	46.5; 70.2 (16.6)	43.0; 69.9 (17.3)	0.95; (1); 0.33	0.28; (923); 0.78
Job satisfaction	65.1; 76.8 (17.1)	60.3; 74.9 (19.0)	1.96; (1); 0.16	1.43; (923); 0.15
Stress recognition	48.0; 66.6 (23.5)	53.4; 71.6 (20.6)	2.29; (1); 0.13	–3.12; (922); <0.01
Perception of unit management	41.5; 66.7 (20.3)	45.1; 67.0 (21.1)	1.03; (1); 0.31	–0.09; (921); 0.93
Working conditions	64.5; 74.2 (21.5)	58.1; 71.8 (23.0)	3.38; (1); 0.07	1.03; (923); 0.31

Notes: [a]Chi-square test comparing %-positive of the two samples per dimension; [b]independent *t*-test comparing means of the two samples per dimension. Results in this table were generated by the use of IBM SPSS version 21.0 (IBM Corporation, Armonk, NY, USA).
Abbreviations: %-positive, proportion of staff holding a positive attitude; *df*, degrees of freedom; SD, standard deviation; sig, significance.

Finally, the probability RMSEA was above the threshold;[40] in Norway, it was 0.893.[20] Different SAQ validation studies use slightly different SAQ versions and different statistical approaches; this should be taken into account when comparing psychometric properties. For this reason, and because of analogs in education, and concepts and methods in patient safety, the Danish study compares best to the Norwegian.[20]

Inter-scale correlations revealed negative correlations between the stress recognition scale and all other scales, indicating that this scale is distinct from the other scales and not part of the same underlying construct. The intent of the stress recognition scale is to capture attitudes about stress in the delivery of patient care. Items in the stress recognition scale differ from all other items as they address self-behavior, eg, how stressors affect personal performance, but not to which degree. SAQ items from the other scales emphasize behavior and attitudes of colleagues and the effect on the safety climate. In-depth analysis of the psychometric properties of the stress recognition scale confirms that it is not reflective of PSC in the same way as the other scales, which should be accounted for when planning improvement activities.[44] Educating clinicians about how teamwork can effectively counteract, among other things, the impact of fatigue, stress, and high workload on human performance has proved effective.[45]

Significant strong positive relationships were found among all other scales, indicating that they belong to the same underlying construct. The same scale-to-scale correlation pattern has been found in other SAQ validation studies.[19,22,23,29]

The Cronbach's alpha coefficient for the total SAQ-DK was high and changed minimally when the different items were removed. Cronbach's alpha exceeded 0.70 for all scales. The closer Cronbach's alpha coefficient is to 1.0, the greater the internal consistency of the items in the instrument or the scale, indirectly indicating the degree to which a set of items measures a single one-dimensional latent construct. At the scale level, Cronbach's alpha ranged from 0.59–0.89 in other SAQ validation studies.[19,20,22–24,28] SAQ-DK showed good internal consistency at the scale and instrument level.

At the item level, item 2, "In this clinical area, it is difficult to speak up if I perceive a problem with patient care", raised validity concerns: the item-factor loading was below the acceptable threshold of 0.03, and the subscale-corrected item-total correlation indicated a weak relationship with the other items in the scale, thus impairing discriminative ability. A low item-factor loading for item 2 was also found in Turkey.[23] Further analysis of the discriminative ability of the items is suggested.

Benchmarking data

Benchmarking data for the full sample and the somatic and psychiatric samples were provided separately. Scale means can mask the extent to which a scale score has a large or small SD, while the proportion of respondents with positive attitudes (%-positive) gives a more explicit picture of the homogeneity of the attitudes of the staff within a specific SAQ dimension. Further, the %-positive is easy to both interpret and assess in terms of the need for improvement among managers and frontline staff; for example, 45% of staff reported positive attitudes, whereas the rule of thumb is that less than 60% of staff reporting positive attitudes in any SAQ dimension would indicate a need for improvement.[27]

Across the entire sample, %-positive ranged from 42.6%, for perception of unit management, to 64.8%, for teamwork climate. The proportion of staff with positive attitudes was lower for safety climate and perception of unit management in Denmark than in Switzerland and USA.[27] Further, the proportion of clinical areas with %-positive below 60% was 77% for safety climate. No differences were found for %-positive across the two subsamples for any of the dimensions, indicating homogeneity in the perceptions of the different dimensions of safety climate for the somatic and psychiatric staff. The Danish results differed from Australian results, wherein poorer PSCs were found in psychiatric than in somatic hospitals.[46] Differences in the proportions of staff holding positive attitudes across the 31 clinical areas were found for all dimensions, and the range of %-positive across the Danish clinical areas was larger than in USA and Switzerland.[27] Generally, the detected variation in %-positive across clinical areas may result from the local clinical managers demonstrating different levels of engagement in patient safety and support for provision of safe care; a large number of clinical areas might benefit from interventions targeting weak dimensions of the safety culture.[47]

The Danish scale means compare well with findings from USA and Switzerland.[27] Comparing scale means across the two subsamples showed statistically significant differences for the stress recognition scale only; this is consistent with previous research.[27] There was variability in all scale mean scores at the clinical area level within the somatic and psychiatric samples respectively. These findings underpin that Danish PSC results should be generated at the unit level to ensure a sense of relevance and ownership for both results and follow up activities based upon results; this is in line with findings from Norway.[48]

Methodological considerations

The overall response rate was 73%, which is better than in most other SAQ validation studies, with response rates of 52%–79%.[19–21,28,29] The response rate stresses the acceptability of measuring PSC and applying SAQ-DK in the Danish hospitals.

In the somatic sample, the response rate was 72%, versus 77% in the psychiatric sample. The different methods of questionnaire distribution (paper format at staff meetings, hand delivery, and internal mailing versus electronic delivery) might have impacted participation differently in the two samples. The extent of local support for the PSC survey and fundamental differences in customs and attitudes toward participation in surveys in the different settings could have influenced participation differently at the clinical area and hospital levels.

The somatic sample did not include university hospitals, and the psychiatric data only originated from one department in a university hospital. The somatic clinical areas represented only a subset of specialties, which should be taken into account when interpreting the results. The sample size was large enough to comply with ten health care staff members per item, as desired for CFA.[12]

Males were underrepresented in the sample (10%) in comparison with Danish hospital staff (18%) in general. Males generally scored lower than their female colleagues, thus the benchmarking data for the SAQ-DK scales might be overestimated. Further, no information on ethnicity was asked of the respondents, thus no conclusions can be drawn in regard to the influence of ethnicity in the benchmarking data. Although the study is strengthened by inclusion of multiple sites, selection bias cannot be ruled out, and generalization of the findings to other hospitals and health settings should be performed with caution.

The average rate of incomplete data was below 13% for all items; hence, no items were excluded from the analysis, in line with previous research.[28] Items in the perception of unit management had the highest proportion of missing answers. This might indicate respondents' reluctance to answer questions about the management because they regard these questions as sensitive, are not aware of the exact management involvement in patient safety issues, or are in doubt about whether the management could attain access to their answers. Further research could address the underlying causes and implications of high rates of incomplete data. These findings are in line with findings from the Netherlands.[21]

The phrasing and interpretation of items 2, 11, 22, and 23 was frequently discussed in staff meetings, where the survey was administered or results presented, indicating that information bias might be present. Items 2 and 11 were both negatively worded. Using negative or positive phrasing for these two items does not lead to differences in the fit of the model, based on data from Swedish pharmacies.[29] Adaptions of items 22 and 23 in the Swiss SAQ were recommended due to poor psychometric item properties.[28] Further studies at the item level are suggested to investigate phrasing, content, and interpretation, especially of items 2, 11, 22, and 23.

Conclusion

SAQ-DK showed acceptable psychometric properties, and seems to be an appropriate tool with which to evaluate health care staff perceptions of PSC in Danish hospitals. However, based upon results of testing, minor adjustments and further testing of a small number of items are suggested.

Studies to identify issues influencing perceptions of the different dimensions of PSC are essential to support decisions about ways to improve, and further studies to investigate the strength of the association between variations in perception of PSC and organizational and clinical variables are needed.

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Disclosure

The authors report no conflicts of interest in this work.

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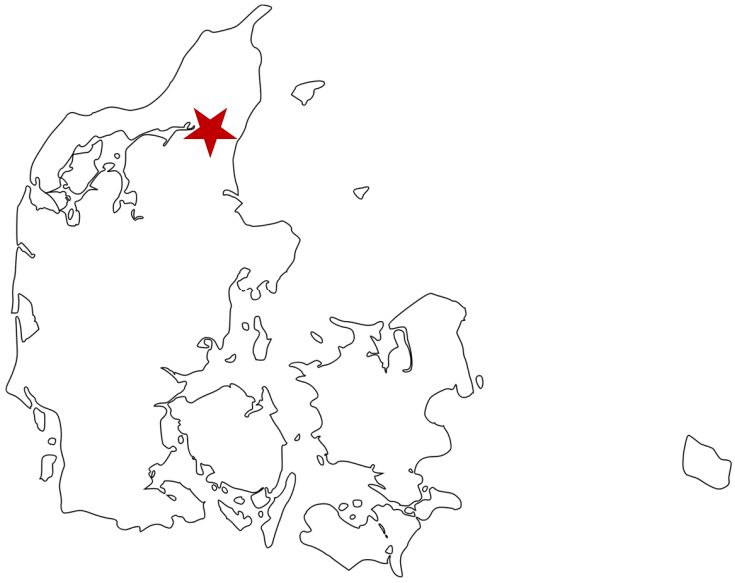
Appendix H. Paper III

Kristensen S, Christensen KB, Jaquet A, Moeller-Beck C, Sabroe S, Bartels PD, Mainz J. Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study. BMJ Open 2016; 6010180. Dor:10.1136/bmjopen-2015-01080.



BMJ Open

Strengthening leadership as a catalyst for enhanced patient safety culture: a repeated cross-sectional experimental study

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ABSTRACT

Objectives: Current literature emphasises that clinical leaders are in a position to enable a culture of safety, and that the safety culture is a performance mediator with the potential to influence patient outcomes. This paper aims to investigate staff's perceptions of patient safety culture in a Danish psychiatric department before and after a leadership intervention.

Methods: A repeated cross-sectional experimental study by design was applied. In 2 surveys, healthcare staff were asked about their perceptions of the patient safety culture using the 7 patient safety culture dimensions in the Safety Attitudes Questionnaire. To broaden knowledge and strengthen leadership skills, a multicomponent programme consisting of academic input, exercises, reflections and discussions, networking, and action learning was implemented among the clinical area level leaders.

Results: In total, 358 and 325 staff members participated before and after the intervention, respectively. 19 of the staff members were clinical area level leaders. In both surveys, the response rate was >75%. The proportion of frontline staff with positive attitudes improved by ≥5% for 5 of the 7 patient safety culture dimensions over time. 6 patient safety culture dimensions became more positive (increase in mean) ($p<0.05$). Frontline staff became more positive on all dimensions except stress recognition ($p<0.05$). For the leaders, the opposite was the case ($p<0.05$). Staff leaving the department after the first measurement had rated job satisfaction lower than the staff staying on ($p<0.05$).

Conclusions: The improvements documented in the patient safety culture are remarkable, and imply that strengthening the leadership can act as a significant catalyst for patient safety culture improvement. Further studies using a longitudinal study design are recommended to investigate the mechanism behind leadership's influence on patient safety culture, sustainability of improvements over time, and the association of change in the patient safety culture measures with change in psychiatric patient safety outcomes.

Strengths and limitations of this study

- Good acceptability of the study; response rate above 75% across survey times.
- The compliance rate of the leadership programme was high, confirming engaged leaders.
- Use of the personal identifier across survey times allowed for strong analysis; this practice is rather exceptional within patient safety culture research.
- The repeated cross-sectional study design cannot infer causality.
- The study was conducted in one department without a control group.

INTRODUCTION AND OBJECTIVE

Exposing hospital patients to risk is a universal unsolved problem; international studies have shown that ~9.2% of hospitalised patients experienced adverse events, and 7.4% of these adverse events were lethal, while 43.5% were considered as preventable.[1] Current literature emphasises patient safety culture (PSC) as a mediator with the potential to reduce the occurrence of adverse outcomes.[2–4] However, studies documenting effective methods to enhance PSC are sparse.[5 6]

A culture of safety can be defined as 'An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery'.[7] PSC is a deeper-rooted aspect of the safety climate, which can be measured and improved.[8] Safety climate survey outcomes constitute the sum of healthcare professionals' attitudes towards multi-dimensional aspects of patient safety, for example, teamwork, work conditions, and leadership support.[8]

In general, healthcare staff who spend more time at the bedside, and with more extensive knowledge about the safety of patients tend to be more critical of the PSC than professionals with less bedside time.[9 10] Consequently, leaders tend to have a more positive perception of the culture than frontline clinicians[9 11] and the larger this perception gap, the more errors are made at the sharp end of care.[12] Therefore, it is important to identify solutions to bridge such gaps in perception.

Clinical leaders enable a culture of safety; they address and prioritise safety, and create the organisational context in which safe care can be reliably delivered.[13 14] The enabling leadership activities set the frame for the clinical processes and shape frontline clinicians' attitudes towards a safety culture.[15] Viewed this way, PSC can be regarded as an outcome of leadership processes with the potential to impact healthcare practices and outcomes.[15] Hence, leadership is the anchor point for bridging any gaps in perceptions between the leaders and their frontline staff, thereby ensuring a safe culture at the sharp end of care.[16 17] To transform the services to achieve higher levels of excellence, the clinical leaders must be knowledgeable, skilled, and well trained in facilitating group communication, solving conflicts, creating motivation, development, and improvement.[16] The ideal leadership training is organised in such a way that academic input, and training of skills and behaviours are embedded through a sequence of reflection, application, and experience.[16] Additionally, leadership profiling and coaching can be effective means to help leaders build a safe and transparent environment for patients.[18]

Previous studies in which interventions characterised by strong leadership engagement have been implemented and PSC evaluated—preintervention and postintervention—have defined as their target an improvement of 10% in the proportion of staff with positive attitudes over a time period of minimum 18 months.[19 20]

The objectives of the present study were to investigate staff's perceptions of PSC before and after an intervention; these are intended to enhance knowledge and training skills among leaders, and to describe differences in perceptions of PSC according to status of employment and participation. The research questions were:

1. Do the proportions of frontline staff with positive attitudes towards seven PSC dimensions improve by more than 5% from before to after the intervention?
2. Do the mean scale scores of the seven PSC dimensions improve for responders participating both before and after the intervention?
3. Do the mean scale scores differ significantly between subgroups depending on status of employment and participation?

METHODS

Study design

A repeated cross-sectional experimental study design was applied; perceptions of PSC were measured before and after a leadership intervention.

Variables of interest: measures of PSC and participant demography

The Danish version of the Safety Attitudes Questionnaire (SAQ-DK) was used to survey perceptions of PSC.[21] SAQ-DK has been found to be psychometrically sound.[21] It is an explorative questionnaire with 31 items forming seven PSC dimensions for teamwork climate, safety climate, stress recognition, job satisfaction, perceptions of unit and department management, respectively, and working conditions. Answers are given on a 5-point Likert scale as: 1=disagree strongly, 2=disagree slightly, 3=neutral, 4=agree slightly, and 5=agree strongly.[22] Items 2 and 11 are negatively worded.

Demographic information on profession, gender, organisational role, age group, work experience, and organisational affiliation was also collected in the responders' completion of the SAQ-DK.

Setting

The study took place in a psychiatric department situated at the Psychiatric Hospital of Aalborg University Hospital in the North Denmark Region. The department is one of the largest psychiatric departments in Denmark with ~460 employees, and it serves the population of the southern part of Aalborg, Denmark's fourth largest city.

The department comprises 10 outpatient and 9 inpatient specialised units; these are either open or closed units. During the study period, there were 19 clinical leaders (doctors, nurses and psychologists) at the unit level, and 2 managers at the department level.

Material and data collection

Full-time and part time staff with patient contact and working for at least half of their working time in the department qualified for inclusion in the surveys of PSC. Based on human resource data, the number of invitees was identified as 454 before, and 470 after the intervention, respectively; 19 invitees were unit level leaders at both time points.

Each participant was assigned a unique personal identifier that remained the same across the two surveys.

Before-intervention data (1st survey) were collected from 15 April to 3 May 2013; after-intervention data (2nd survey) were collected from 23 October to 13 November 2013. SAQ-DK was distributed via a unique link of emails to all included staff. Reminders were mailed to staff who had not answered after 1 week, and after 2 weeks, and the survey was closed at the end of the third week. A department-based quality improvement officer collaborated with the research team in the data collection.

Leadership intervention

To strengthen knowledge and skills among the unit level clinical leaders, a multicomponent programme consisting of academic input, exercises, reflections and discussions, networking, and action learning was

implemented. The leadership programme intended to optimise individual leadership, upgrade leadership and quality management knowledge and skills, and ultimately bring the leaders and the department to a higher level of performance. The intervention was initiated and the overall content prespecified by the department head. However, it was designed and implemented in a dynamic way to best suit the needs of the department and the leaders, thus ensuring its relevance, motivation, and engagement. An external industrial organisational psychologist led the intervention programme.

The programme was implemented from 3 May to 1 November 2013 in five modules for a total of 9 days. The programme covered: (1) leadership as profession and as a subject, (2) situational leadership and coaching, (3) managing communication, conflicts and change, (4) motivation, development and improvement, and (5) leading groups and teams. Leader profile self-tests covering situational, change, and functional management were offered during the modules; also, a Jung-Based Type Analysis and individual supervision (up to 3 hours per leader) by the external psychologist were offered during the intervention time.

Uncommented unit-specific results from the first survey were fed back to the clinical leaders in mid-June 2013.

Ethics

As the PSC survey data were not considered as personal data, the study was neither subject to the Danish Act on Processing of Personal Data nor the Act on Research Ethics Review of Health Research Projects as the study did not involve human biological material. The department-based works council approved the study. Survey invitees were informed that: participation was voluntary; all answers would be treated with confidentiality; and no individual responses would be available to any other employee of the department. Outcomes of the leadership self-test profiles and supervision were private, and available only to the clinical leaders themselves.

Statistical analyses

The sample data were described by numbers and proportions for each of the two survey times, and for the responders participating in both surveys.

Internal scale consistency of SAQ-DK was reported by Cronbach's coefficient α,[23] and inter-scale correlations by Pearson's correlations coefficient.

SAQ-DK data were presented in accordance with the scoring guidelines of SAQ, reporting (1) the percentage of respondents with a positive attitude (% positive, defined by an individual mean scale score ≥75), and (2) scale mean scores (range 0–100) and SD.[24] Over time, improvements in % positive reflect an increase in the number of staff with positive attitudes, whereas improvements in the scale mean score reflect a more positive attitude among surveyed staff. Based on previous research,[19 20] a 5% improvement in staff with positive attitudes towards the PSC over the two survey time points was targeted and deemed clinically relevant. If <60% of staff report positive attitudes on any cultural dimension, improvement activities are suggested.[24]

Individual SAQ-DK item scores were converted to a 0–100 points scale, where 1=0, 2=25, 3=50, 4=75 and 5=100. Items 2 and 11 were reverse scored so that their valence matched the positively worded items.

Individual scale mean scores were calculated by the average score of the scaled items, and the % positive calculated (range 0–100).[24] For each scale, % positive were compared between survey times and subgroups, using χ^2 tests.

SAQ-DK mean scale scores were calculated for each dimension from the average score of the scaled items. Mean scale scores were compared using paired samples Student's t test for the responders participating in both surveys and independent Student's t test for subgroup analysis. All analyses were performed using IBM SPSS V.21.0 (SPSS, Chicago, Illinois, USA).

RESULTS

Invitees and participants

In total, 532 staff members were invited to participate in either of the two surveys or both; 62 were only invited for the before-intervention survey as they left the department during the study period; and 392 were invited before and after the intervention. In total, 78 joined the department after the first survey and were, therefore, only invited to participate in the second survey.

After the first survey, 358 of the 454 questionnaires were returned (78.8%), and 325 of the 470 invitees participated (76.2%) in the second survey. Participation in both surveys (stable group) was 238 of the 392 (60.7%); of the 238 in the stable group, 223 were frontline staff.

Sociodemographic respondent characteristics are shown in table 1, showing comparable characteristics across the stable group and participants in the first or second survey only, respectively.

Fifteen of the 19 leaders (78.9%) participated in the intervention and in both PSC surveys. Of these, four were male (26.7%); five were doctors (33.3%); two were psychologists (13.3%) and eight were nurses (53.3%). All had ≥3 years of experience in their profession.

The participants were classified into five groups according to their status of invitation and participation as follows:

1. *Leavers*: participating in the first survey, then leaving the department, N=47
2. *Dropouts*: invitees in both surveys, but only participating in the first survey, N=73
3. *Stable*: participants in both surveys, N=238
4. *Laggards*: invitees in both surveys, but only participating in the second survey, N=31
5. *Newcomers*: staff joining the department after the first survey, and participating in the second survey only, N=56

Table 1 Sociodemographic characteristics of responders of the Safety Attitudes Questionnaire

	Time of participation					
	First survey N=358		Second survey N=325		First and second survey N=238	
	N	Per cent	N	Per cent	N	Per cent
Characteristics						
Profession						
Doctors	43	12	36	11	23	10
Nurses	147	41	132	41	95	40
Nursing assistants*	74	21	67	21	49	21
Therapists†	56	16	51	16	41	17
Others‡	38	11	39	12	30	13
Gender						
Females	290	81	267	82	192	81
Males	68	19	58	18	46	19
Organisational role						
Clinical leaders	16	5	16	5	15	6
Frontline clinicians	342	95	309	95	223	94
Age groups (year)§						
<36	103	29	96	29		
≥36 to <56	203	57	181	56		
56 or older	52	15	48	15		
Work experience (year)§						
<3	91	25	86	26		
3 or more	267	75	239	74		
Organisational affiliation§						
Inpatient unit	239	67	203	63		
Outpatient unit	31	31	111	34		
No specific unit/other	8	2	11	3		

*Nurse assistants or the like, and pedagogues.
†Psychologists, physiotherapists, occupational therapists, music therapists.
‡Social workers and secretaries.
§Subject to change between the two surveys, thus not reported for the participants taking part at both survey times.

The aforementioned figures for invitees are shown in the bottom row of online supplementary annex table 1a, whereas the five groups are illustrated in the second to fourth columns of the table.

PSC scores over time

SAQ-DK scores between 1 and 5 were observed for all items across both surveys. The average rate of not applicable answers at the item level was 3.0% in the first survey, and 2.6% in the second survey. Internal instrument reliability of SAQ-DK was investigated, revealing Cronbach α=0.85 in both surveys.

At both survey times, all scales correlated negatively with the stress recognition scale, revealing weak Pearson's r correlation coefficients. For all other scales, Pearson's correlations indicated significantly moderate-to-strong positive relationships; correlation coefficients ranged from ∼0.25 to 0.63 ($p<0.01$).

According to the definition of PSC provided above, PSC is an inclusive group-level characteristic. For that reason, the proportions of responders with positive attitudes (% positive) are displayed graphically for all participants of the first (N=358) and the second survey (N=325). As can be seen in figure 1, job satisfaction was the dimension with most positive responders at both survey points and perception of department management, the dimension with least positive responders at both survey times. As such, figure 1 documents noteworthy variation in % positive across the seven dimensions at both survey times.

Figure 2 provides an overview of the proportions of stable frontline staff (N=223) with positive attitudes (% positive) for the two surveys. For teamwork climate, safety climate, job satisfaction, working conditions and perception of unit management, an improvement in % positive of ≥5% was observed over time. It was statistically significant for teamwork climate, safety climate and job satisfaction, $p<0.01$. For teamwork climate, stress recognition and perception of unit management, a rise in % positive from <60% in the first survey to ≥60% in the second survey was found. For stable frontline staff (N=223), the largest improvement in PSC was by 14.8% points; it was observed for safety climate, $p<0.01$. In comparison, % positive for the 15 stable unit-level clinical leaders improved by 6.7% points over time, $p>0.01$. In the first survey, the gap between clinical leaders and

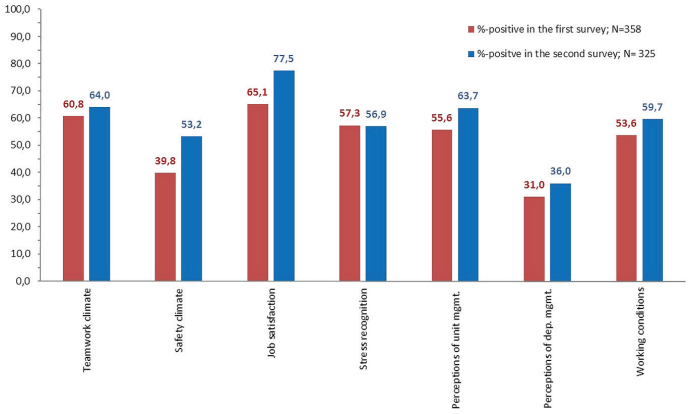

Figure 1 Proportions of participants with positive attitudes (% positive) per Danish version of the Safety Attitudes Questionnaire (SAQ-DK) dimension in the first and the second survey.

frontline staff in perception of the safety climate was 41.9% points; this gap decreased to 35.0% points in the second survey.

Mean scale results of the two surveys are shown in table 2 columns 2 and 3, respectively. Column 4 shows change in means for the stable group (N=238). The PSC became more positive (increase in mean) for all dimensions of the culture ($p<0.05$), except for stress recognition. These increases ranged from 2.7 (SD 17.6) for perception of unit management to 5.4 (SD 18.7) for job satisfaction. The improvements were attributable to frontline staff (N=223), who increased their mean scale scores significantly for all dimensions ($p<0.05$), except for stress recognition ($p>0.05$). In opposition to this, leaders only improved their mean scale score for stress recognition ($p<0.05$). Changes in SAQ-DK mean scale scores over time for leaders and frontline staff, respectively, are shown in the upper half of online supplementary material annex table 2a. Equivalent results for females and males are shown in the lower half of online supplementary material annex table 2a. The gap in perception between unit level clinical leaders and frontline staff decreased for teamwork climate, safety climate, and perception of department management over time.

In both surveys, no differences in mean scale scores were found between males and females or between staff with <3 and ≥3 years of work experience ($p>0.05$). Online supplementary material annex table 3a shows a mixed picture of statistically significant and non-significant improvements in dimensional PSC mean scores for five professional groups.

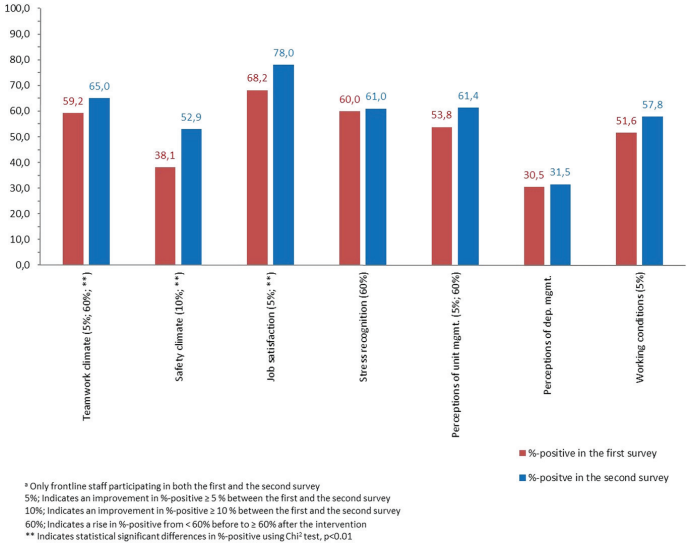

Figure 2 Proportion of stable frontline staff[a] with positive attitudes (% positive) per Danish version of the Safety Attitudes Questionnaire (SAQ-DK) dimension (N=223).

[a] Only frontline staff participating in both the first and the second survey
5%; Indicates an improvement in %-positive ≥ 5 % between the first and the second survey
10%; Indicates an improvement in %-positive ≥ 10 % between the first and the second survey
60%; Indicates a rise in %-positive from < 60% before to ≥ 60% after the intervention
** Indicates statistical significant differences in %-positive using Chi^2 test, $p<0.01$

Table 2 Mean scale results for Danish version of the Safety Attitudes Questionnaire (SAQ-DK) in the first and in the second survey, and the mean difference for the stable group

Dimension	First survey N=358 Mean (SD)	Second survey N=325 Mean (SD)	Mean difference over time N=238 Mean difference (SD); significance*
Teamwork climate	74.7 (17.9)	77.6 (17.0)	3.1 (17.4)†
Safety climate	68.0 (18.3)	72.1 (18.5)	4.8 (17.7)†
Job satisfaction	75.7 (19.3)	82.2 (17.9)	5.4 (18.7)†
Stress recognition	70.0 (22.9)	70.3 (22.9)	0.6 (19.6)
Perceptions of unit management	70.4 (22.3)	76.5 (18.1)	5.3 (20.2)†
Perceptions of department management	62.3 (19.7)	65.4 (18.6)	2.7 (17.6)‡
Working conditions	69.8 (23.6)	72.7 (23.7)	3.4 (22.5)‡

*Paired sample Student's t test comparing means across the two time points, N=238. Mean scale scores from the first and the second survey are shown in table 3 columns 4 and 5.
†Indicates a statistically significant difference over time, p<0.01.
‡Indicates a statistically significant difference over time, p<0.05.

For the stable group (N=238), both the proportion of responders with positive attitudes (% positive) and their perceptions of the PSC (mean scale score) improved significantly (p<0.05) for safety climate and job satisfaction. These results are shown in table 3 columns 4 and 5, rows 4 and 5.

Differences in perception of culture according to status of participation

PSC is a group level characteristic, and when conducting PSC before and after the measurements, it is customary to report and compare % positive and/or mean scales scores for the population taking part at each of the two assessment times. In practice, a group of staff is dynamic over time; staff are leaving and coming, and it cannot be ruled out that staff attitudes are related to the status of employment and choice of participation, for example, leavers and dropouts might be more negative in their perception than the stable group of staff. Likewise, laggards and newcomers might have safety culture perceptions different from the stable group. The unique personal identifier applied in this study allowed us to describe and compare SAQ-DK mean scores for the five subgroups aforementioned.

Three groups participated in the first survey: leavers (N=47), dropouts (N=73) and stable staff (N=238). Among the three groups and across all seven dimensions, leavers were characterised by least % positive. The difference was statistically significant for job satisfaction (χ^2=5.28, df=1, p=0.02) only. For all PSC dimensions, the mean scale score of the leavers was lowest, but again the difference in means was only significant for job satisfaction (F=5.31, df=2, p<0.01). No differences in means were found between the dropouts and staff in the stable group for any dimension, (p>0.05). All these results are shown in table 3 columns 2–4.

The three groups only participating in the second survey were: stable staff (N=238), laggards (N=31), and newcomers (N=56). No specific patterns were observed concerning the mean and the % positive among the three groups after the intervention; results are shown in table 3 columns 5–7.

DISCUSSION

This is the first intervention study within Danish psychiatry to report before-intervention and after-intervention measures of PSC, and the study adds to the sparse international literature on enhancing PSC.[5 6] The principal findings document improvements of ≥5% for frontline staff with positive attitudes towards teamwork climate, safety climate, job satisfaction, perception of unit management, and working conditions. For the first three of these dimensions, the improvements were significant. The largest improvement was found for stable frontline staff with regard to safety climate. Further, the PSC was rated more positively over time for all dimensions, except for stress recognition. For the stable group of clinical leaders and frontline staff participating in both surveys, the proportion of responders with positive attitudes as well as the degree of positive PSC perceptions improved significantly for safety climate and job satisfaction.

Strengths and weaknesses of the study

Both the high response rate (which was above 75% across survey times), the low average rate of not applicable answers at the item level, and the internal reliability of SAQ-DK were good, and comparable to previous Danish and international findings.[21 22 25] These issues underpin the acceptability of the study and support good internal validity of the study.

The use of the personal identifier across survey times enabled strong analysis of the before-data and after-data as well as subgroup analysis according to the organisational role, status of employment, and participation. This practice is rather exceptional within PSC research; it allows for a degree of transparency and subgroup analyses we have not found in other literature.

Table 3 Mean subscale results according to status of participation in five groups

Dimension	First survey % positive; mean (SD)			Second survey % positive; mean (SD)		
	Leavers*	Dropouts†	Stable‡	Stable‡	Laggards§	Newcomers¶
Teamwork climate	59.6%; 71.8 (20.8)	63.0%; 75.8 (15.5)	60.3%; 74.9 (18.0)**	65.1%; 77.9 (17.0)	64.5%; 76.6 (19.1)	58.9%; 76.6 (15.6)
Safety climate	36.2%; 64.3 (20.3)	38.4%; 70.3 (15.7)	40.9%††; 68.0 (18.6)**	55.0%; 72.8 (18.0)	48.4%; 69.6 (21.0)	48.2%; 70.3 (19.4)
Job satisfaction	51.1%††; 67.3 (24.8)**	63.0%; 76.8 (17.0)	68.5%††; 77.0 (18.4)**	78.2%; 82.4 (17.4)	74.2%; 77.4 (22.4)	76.8%; 83.9 (17.3)
Stress recognition	51.1%; 67.9 (25.4)	56.2%; 68.9 (20.0)	58.8%; 70.6 (23.2)	61.2%; 71.1 (23.4)	45.2%††; 69.3 (23.7)	46.4%; 67.4 (20.1)
Perceptions of unit management	55.3%; 68.5 (25.1)	58.3%; 70.9 (22.7)	55.3%; 70.6 (21.7)**	62.2%; 75.8 (18.9)	58.1%; 73.2 (20.6)	74.5%; 81.3 (11.4)**
Perceptions of department management	21.3%; 58.7 (18.9)	30.1%; 63.5 (19.3)	33.2%; 62.6 (20.0)**	34.5%; 65.4 (18.2)	22.6%; 58.7 (18.9)	50.5%; 69.4 (18.4)
Working conditions	46.8%; 68.5 (25.1)	58.9%; 70.9 (22.7)	53.6%; 69.6 (24.3)**	60.2%; 73.0 (23.3)	64.5%††; 77.2 (21.7)	57.1%; 69.7 (25.9)

*Leavers: participating in the first survey, then leaving the department, N=47.
†Dropouts: invitees in both surveys, but only participating in the first survey, N=73.
‡Stable: participants in both surveys, N=238.
§Laggards: invitees in both surveys, but only participating in the second survey, N=31.
¶Newcomers: staff joining the department after the first survey, and participating in the second survey only, N=56.
**Indicates a statistically significant difference in means when comparing with the stable participants (p<0.05).
††Indicates a statistically significant difference in % positive when comparing with the stable participants (p<0.05).

The leadership intervention was intensive, and dynamically designed and implemented specifically to match the needs of the individual leaders and the department. The rate of compliance with the leadership programme was high, confirming engaged leaders.

In terms of study weaknesses, the repeated cross-sectional study design cannot infer causality. Moreover, the study was conducted in one department only without a control group, which reduces the ability to attribute causality for the improvements observed in PSC dimensions. Further, the study design can only give an insight into the PSC at the time of the survey. Also, it should be taken into account that other simultaneous initiatives and context factors might have influenced the results besides the intervention. Such possible influences were sought to be minimised by the short observation period. However, the short observation period did not take into account the fact that the full effect of the intervention might not be immediate; achieving sustainable change in the PSC is a long-term process. Hence, it is possible that the ongoing long-term surveillance of the PSC in the department could reveal other results. In addition, the study was based on self-reported PSC, which might have created information, recall, and social desirability bias. Lastly, the Hawthorne effect cannot be ruled out; improvements in PSC might be attributable to staff's awareness of being observed.

Relation of the findings to other studies

A number of controlled before and after studies in which the intervention contained a substantial amount of leadership engagement have found varying levels of improvement in % positive, primarily in teamwork and safety climate.[5] These studies differ from ours in that they rely on patient safety intervention programmes primarily aiming to reduce adverse patient outcomes.[5 6 26 27] These use generic intervention methods such as executive walk rounds and the Comprehensive Unit-based Safety Programme.[5 6 26 27] The difference in findings between these studies and ours might be explained by multiple factors: our study addressed knowledge and training of the skills of leaders directly; the content of our intervention was specifically tailored to local needs, and it covered the generic aspects of leadership and quality management. The direct aim of our programme was to strengthen the individual leader, align skills and ways of doing things. The indirect aim was to bring the organisation to a higher level of performance. The aforementioned differences between our intervention and other standardised programmes must be considered when interpreting and generalising the findings of this study.

Most intervention studies have been carried out in a somatic setting,[5 6 26 27] and it seems fair to assume that PSC might differ across somatic and psychiatric hospitals as tasks and practices differ with different patient populations and needs. However, previous Danish research only found a difference in means for stress recognition.[21] So

the leadership approach in our intervention could also be effective in Danish somatic hospitals.

Our intervention worked well for improving the PSC in the setting it was designed for, but we did not collect clinical outcome data which could have shed some light on the ultimate question regarding the association between the PSC and the quality of the clinical performance. Other studies from somatic hospital care have shown simultaneous improvements in PSC and specific patient outcomes such as infections, mortality, and length of stay.[5 6 26 27]

Large variations in % positive were observed across dimensions at both survey times. This is consistent with findings in the literature[22 28–32] and underlines the importance of viewing PSC as a multidimensional concept. It also indicates that the dimensions differ in their sensitivity to influential factors over time.

Since we applied the unique personal identifier, we could perform analysis of subgroups related to organisational role, status of employment, and participation. We have not been able to find comparable analyses and results in the literature.

Our findings regarding leavers and stable staff imply that the PSC results obtained after an intervention, and described in the literature might be slightly overestimated if they rely on comparison of ratings of the before the intervention population with the rating of after the intervention without allowing for shift in staff. This problem seems most vital for job satisfaction. The findings regarding job satisfaction for staff leaving the department after the first survey imply that leaders should initiate indepth analysis of low ratings for job satisfaction to learn why these are low.

Clinical leadership is a complex and demanding task which requires leaders to act as role models for frontline staff, provide inspiring visions, foster behavioural change as well as manage implementation of change. Uptake and spread of change are facilitated through close cooperation between leaders and frontline staff.[33] Thus, clinical leaders are often the ones who opt for improvement, but it is the frontline staff who are expected to live out the changes. Consequently, change in behaviour and attitudes among leaders could be expected to be a lever for change among frontline clinicians. Frontline clinicians reported significant improvements (mean scores) in all dimensions of the culture, except stress recognition. By contrast, the leaders only significantly improved their attitudes towards stress recognition. The leaders were exposed to a substantial amount of new knowledge and exercises, which may have made them more realistic or critical in their assessment of the PSC, possibly affecting the leader-frontline gap in perception of safety climate—the dimension directly related to the clinical work and clinical risk management. Safety climate reflects the sum of healthcare staff's perceptions and attitudes towards the safety of patients.[34]

It has been suggested that units with <60% positive responders have the most to gain in PSC from quality improvement initiatives.[30] Our study only found a rise in % positive from <60% before the intervention to ≥60% after the intervention for teamwork climate, and the improvement was ≥5% and statistically significant. Teamwork climate embraces the perceptions of healthcare staff for working together collaboratively to provide safe care for the patients.[34] It seems likely that teamwork climate was directly influenced by the leadership intervention.

A cross-European study in air traffic management indicates that safety culture is more positive in Northern Europe in comparison to the rest of the EU.[35] Our findings in a psychiatric hospital context point in this direction too; mean scale scores as well as % positive were comparable to findings from Sweden, but somewhat higher than in the UK, Switzerland, Taiwan and Australia.[22 28–32] In addition, the subgroup analysis of differences in mean scale scores (from 1st to 2nd survey) revealed a pattern rather different to the findings in the literature,[36 37] as no statistical differences in the quality of the PSC were found between gender and the two groups of seniority. According to findings in the literature, bedside staff, females and inexperienced staff were expected to be more critical than their respective counterparts.[9 10] The study results can only point to *what* and not answer *why*; however, a possible explanation might have something to do with the underlying national cultural traits of the Danish society. Globally, the Nordic countries are the ones with most social trust.[38] Organisational culture develops from national cultural traits,[35] and PSC can be seen as a subset of organisational culture.[39] Thus, social trust might be an underlying factor that could explain why our findings differ from the ones reported in the international literature.

Study implications

Leadership knowledge and skills seem to be pivotal to improving the PSC. Consequently, leaders need to acknowledge their role in building a safe and caring culture, they need to understand the nature of the safety culture in their unit, and recognise when and how improvement is necessary. Exceptional improvements in PSC are possible when intervention programmes are tailored to the local needs in terms of content and ways of learning.

On the basis of the results of the subgroup analyses related to status of employment and participation, it is recommended that leaders direct their attention to low ratings of job satisfaction, uncover the reasons for it, and act accordingly.

CONCLUSIONS

The results imply that strengthening leadership can act as a significant catalyst for both improvements in the proportions of staff with positive attitudes and a more positive culture. Although the PSC improvements

observed are remarkable, a longitudinal study design is recommended to investigate the mechanism behind leadership's influence on PSC sustainability of improvements over time, and the association of change in the PSC measures with change in psychiatric patient safety outcomes.

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ANNEX

Table 1a Number of invitees versus number of participants across the two patient safety culture surveys

Status of participation	**Status of invitation** (Group of invitee) First survey only N (%)	Both surveys N (%)	Second survey only N (%)	Total N
No participation at all	15 (24.2%)	50 (12.8%)	22 (28.2%)	**87**
First survey only	47 (75.8%)[1]	73 (18.6%)[2]	-	**120**
Both surveys	-	238 (60.7%)[3]	-	**238**
Second survey only	-	31 (7.9%)[4]	56 (71.8%)[5]	**87**
Total (N)	**62 (100%)**	**392 (100%)**	**78 (100%)**	**532**

[1] Leavers; participating in the first survey, then leaving the department, N=47.

[2] Dropouts; invitees in both surveys, but only participating in the first survey, N=73.

[3] Stable; participants in both surveys, N=238.

[4] Laggards; invitees in both surveys, but only participating in the second survey, N=31.

[5] New comers; staff joining the department after the first survey, and participating in the second survey only, N=56.

Table 2a Difference in means across the two surveys according to organisational role and gender[1]

Population (size) Patient safety culture dimension	Mean difference[2]	SD	T-value[3]	Df[4]	P-value
Frontline clinicians (N=223)					
Teamwork climate	**3.2**	**17.1**	**2.8**	**221**	**0.01**
Safety climate	**5.1**	**17.1**	**4.4**	**221**	**0.00**
Job satisfaction	**5.2**	**17.8**	**4.4**	**222**	**0.00**
Stress recognition	0.2	19.2	0.2	221	0.85
Perceptions of unit mgmt.	**5.6**	**20.4**	**4.1**	**221**	**0.00**
Perceptions of department mgmt.	**2.8**	**17.9**	**2.3**	**222**	**0.02**
Working conditions	**3.5**	**22.6**	**2.3**	**219**	**0.02**
Leaders (N=15)					
Teamwork climate	1.1	22.5	0.2	14	0.86
Safety climate	0.0	25.7	0.0	14	1.00
Job satisfaction	7.3	29.4	1.0	14	0.35
Stress recognition	**12.9**	**21.7**	**2.3**	**14**	**0.04**
Perceptions of unit mgmt.	0.5	16.1	0.1	14	0.91
Perceptions of department mgmt.	2.0	13.6	0.6	14	0.58
Working conditions	1.7	21.2	0.3	14	0.76
Female (N=192)					
Teamwork climate	**2.8**	**17.9**	**2.2**	**190**	**0.03**
Safety climate	**4.7**	**17.8**	**3.7**	**190**	**0.00**
Job satisfaction	**4.8**	**19.5**	**3.4**	**191**	**0.00**
Stress recognition	0.5	19.0	0.3	191	0.74
Perceptions of unit mgmt.	**5.7**	**19.5**	**4.1**	**190**	**0.00**
Perceptions of department mgmt.	**2.5**	**16.9**	**2.0**	**191**	**0.05**
Working conditions	**3.1**	**22.2**	**1.9**	**189**	**0.06**
Male (N=46)					
Teamwork climate	4.0	15.7	1.7	45	0.09
Safety climate	4.9	17.6	1.9	45	0.07
Job satisfaction	**7.9**	**14.3**	**3.7**	**45**	**0.00**
Stress recognition	1.2	22.0	0.4	44	0.73
Perceptions of unit mgmt.	3.3	22.7	1.0	45	0.34
Perceptions of department mgmt.	3.9	20.4	1.3	45	0.20
Working conditions	4.7	23.7	1.3	44	0.19

[1] Results in bold are statistical significant at $p<0.05$; [2] A positive mean difference signifies that the mean of the second survey is higher than the one of the first; [3] Paired sample T-test; [4] Degrees of freedom.

Table 3a Difference in means across the two surveys for different professional groups[1]

Population (size) Patient safety culture dimension	Mean difference[2]	SD	T-value[3]	Df[4]	P-value
Doctors (N=23)					
Teamwork climate	1.2	15.9	0.4	22	0.71
Safety climate	5.6	16.1	1.7	22	0.11
Job satisfaction	**8.7**	**13.3**	**3.2**	**22**	**0.00**
Stress recognition	7.4	22.5	1.5	21	0.14
Perceptions of unit mgmt.	**13.4**	**24.0**	**2.7**	**22**	**0.01**
Perceptions of department mgmt.	4.8	17.6	1.3	22	0.20
Working conditions	2.7	19.3	0.6	21	0.53
Nurses (N=95)					
Teamwork climate	3.0	19.5	1.5	94	0.14
Safety climate	**4.6**	**18.8**	**2.4**	**94**	**0.02**
Job satisfaction	3.1	20.6	1.5	94.0	0.1
Stress recognition	1.9	17.9	1.0	94.0	0.3
Perceptions of unit mgmt.	3.3	18.8	1.7	94.0	0.1
Perceptions of department mgmt.	0.6	16.2	0.4	94.0	0.7
Working conditions	**4.5**	**20.3**	**2.1**	**94**	**0.03**
Nurse assistants or alike and pedagogues (N=49)					
Teamwork climate	4.2	16.1	1.8	48	0.08
Safety climate	**5.5**	**18.8**	**2.1**	**48**	**0.05**
Job satisfaction	**8.2**	**19.3**	**3.0**	**48**	**0.00**
Stress recognition	0.9	23.8	0.3	48	0.8
Perceptions of unit mgmt.	**5.1**	**18.0**	**2.0**	**48**	**0.05**
Perceptions of department mgmt.	1.4	20.6	0.5	48	0.64
Working conditions	5.7	24.7	1.6	48	0.11
Psychologists, physiotherapists, occupational therapists, music therapists (N=41)					
Teamwork climate	4.2	15.0	1.8	40	0.08
Safety climate	3.0	17.4	1.1	40	0.27
Job satisfaction	**6.6**	**13.3**	**3.2**	**40**	**0.00**
Stress recognition	0.9	15.7	0.4	40	0.73
Perceptions of unit mgmt.	2.1	23.4	0.6	40	0.57
Perceptions of department mgmt.	4.2	13.7	1.9	40	0.06
Working conditions	1.5	19.3	0.5	40	0.62
Social workers and secretaries (N=30)					
Teamwork climate	1.3	17.8	0.4	28	0.70
Safety climate	**5.9**	**14.8**	**2.1**	**28**	**0.04**
Job satisfaction	3.6	20.7	1.0	29	0.35
Stress recognition	4.4	19.0	1.3	29	0.22
Perceptions of unit mgmt.	**10.0**	**18.6**	**2.9**	**28**	**0.01**
Perceptions of department mgmt.	**8.0**	**20.8**	**2.1**	**29**	**0.04**
Working conditions	0.9	31.1	0.2	27	0.88

[1] Results in bold are statistical significant at $p<0.05$; [2] A positive mean difference signifies that the mean of the second survey is higher than the one of the first; [3] Paired sample T-test; [4] Degrees of freedom.

Appendix I. Paper IV

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ORIGINAL RESEARCH

The virgin land of quality management: a first measure of patient safety climate at the National Hospital of the Faroe Islands

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Purpose: The Faroe Islands are formally part of the Kingdom of Denmark, but the islands enjoy extensive autonomy as home ruled. In Denmark, extensive quality management initiatives have been implemented throughout hospitals, this was not the case in the Faroese Islands in 2013. The purpose of this study is to investigate the patient safety culture in the National Hospital of the Faroe Islands prior to implementation of quality management initiatives.

Methods: The Danish version of the Safety Attitudes Questionnaire (SAQ-DK) was distributed electronically to 557 staff members from five medical centers of the hospital, and one administrative unit. SAQ-DK has six cultural dimensions. The proportion of respondents with positive attitudes and mean scale scores were described, and comparison between medical specialties, and between clinical leaders and frontline staff was made using analysis of variance and chi-square test, respectively.

Results: The response rate was 65.8% (N=367). Job satisfaction was rated most favorable, and the perceived culture of the top management least favorable. Safety climate was the dimension with the greatest variability across the 28 units. The diagnostic center had the most favorable culture of all centers. More leaders than frontline staff had positive attitudes toward teamwork and safety climate, and working conditions, respectively. Also, the leaders perceived these dimensions more positive than the frontline staff, $P<0.05$. Among three management levels, the unit management was perceived most favorable and the top management least favorable.

Conclusion: The management group is recommended to raise awareness of their role in supporting a safe and caring environment for patients and staff, moreover the leaders should ensure that every day work achieves its objectives; keeping the patients safe. Furthermore, following the development in patient safety culture over time is recommended.

Keywords: safety attitudes questionnaire, medical specialties, frontline staff, clinical leaders, patient safety culture

Introduction

The quality of hospital care varies extensively across specialties, hospitals, and countries,[1–3] at its worst, the consequences are adverse patient outcomes and amplified costs.[4] Increasing awareness of such variations has emphasized the use of systematic quality management (QM) in health care. QM ensures that an organization, product, or service is consistent, accountable, and meeting the quality standards agreed upon.

Patient safety culture (PSC) has been proposed to be an underlying organizational context factor inducing safe, effective, and timely patient care.[5,6] Thus, many health care organizations are measuring and improving safety culture as an integrated part of their QM activities. Even at national level, countries like Sweden, Norway, and

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Belgium[7–9] have introduced PSC measures as part of government supported national level QM.

A culture of safety can be defined as "An integrated pattern of individual and organisational behaviour, based upon shared beliefs and values that continuously seeks to minimise patient harm, which may result from the processes of care delivery."[10] Safety culture is a multidimensional and multilevel construct.[6] Surveys can be used to capture a snapshot of the staff's perceptions of the different dimensions of the culture (eg, teamwork climate, safety climate, job satisfaction, stress recognition, perceptions of management, and working conditions).[11,12]

Perceptions of the different dimensions of the culture vary according to organizational role (eg, more leaders than frontline clinicians are positive), and there is variation by management level (eg, the higher in line management of the hospital the more positive attitudes).[13,14] Variation in the perceptions of the PSC is evident across units.[11,13,15] Also variation across medical specialties has been observed (eg, poorer culture has been found in emergency department and operating theater than in pediatric, psychiatry, and rehabilitation departments).[15–19] It has also been documented that staff in nonclinical areas have a more favorable view of the culture than staff closest to the patients.[18]

Although formally part of the Kingdom of Denmark, the Faroe Islands enjoy extensive autonomy as home ruled. The Faroese Ministry of Health Affairs is in charge of the administrative functions in relation to the organization and financing of the health care system, psychiatry and health insurance as well as the pharmacy sector. QM within hospital care of the Faroese Islands was at the very beginning in last quarter of 2013, meaning that QM initiatives such as national level clinical databases, clinical guidelines and standards, pathways, patient satisfaction surveys, accreditation, reporting of adverse events, and large-scale improvement programs[20,21] were not yet implemented in the Faroese Islands.

The objectives of this study are to investigate the PSC in the National Hospital of the Faroe Islands (NHFI) prior to implementation of any QM activity. More specifically, the study embarked on the following four research questions:

1. How do the staff of the NHFI perceive the PSC?
2. Are there differences in staff's perceptions of the PSC according to medical speciality?
3. Are there differences in perceptions of the PSC between the frontline staff and the management?
4. Are there differences in the staff's perceptions of how the different management types support patient safety?

Setting and context

The study took place in the NHFI, which is situated in the capital of the Faroe Islands, Torshavn. NHFI is an acute care somatic and psychiatric teaching hospital with ~160 hospital beds, 711 full- or part-time employees, 8,000 admissions, and 60,000 outpatients served per year. The hospital budget for 2013 was Euro 55 million, where 35% of the budget went to overseas treatment, mainly in Denmark and Iceland. The population of the 18 Faroe Islands amounts to ~48,100 (2013) citizens, where 40% live in Torshavn. The language spoken is Faroese, Danish is the first foreign language taught in the schools from the third grade upwards.

NHFI is organized in the six centers as follows: 1) medical center, 2) surgical center, 3) psychiatric center, 4) acute care center, 5) diagnostic center, and 6) service center. Further, an administration unit, an international patient service unit, a hygiene unit, and a human resource unit serve directly under the top management (collectively named administration unit hereafter). At the time of the survey, the NHFI had 28 clinical in- and outpatient units and one administrative unit, led by a total of 57 clinical leaders. The hospital has three layers of line management; top, center, and unit management.

The first official hospital wide QM initiative of the NHFI was to establish a QM board in the summer of 2013. In September 2013, the quality improvement program "Trygd and Dygd" (Patient Safety and Quality of Care) was launched with the kick off of the PSC survey. The "Trygd and Dygd" program entails initiatives such as reporting of adverse events, implementation of clinical indicator monitoring, executive leadership walk around, and implementation of the safe surgery checklist. The hospital enrolled in the Danish Patient Safety Program for Mental Health launched by the Danish Society for Patient Safety in the beginning of 2014.[22] In the summer of 2014, the Ministry of Health Affairs entered into a cooperation agreement with The Danish Healthcare Quality Programme; and preparation for accreditation of the NHFI began. The aforementioned initiatives are undergoing implementation.

Material

Full- and part-time staff of the NHFI qualified for inclusion in the PSC survey. Staff from the service center were excluded. Based on human resource data, the included number of participants was identified as 557. The following professions were included: doctors, nurses, nursing assistants, midwifes, medical laboratory technicians, dieticians, psychologists, speech or music therapists, physiotherapists,

occupational therapists, administrative staff and secretaries, service assistants, and porters.

Methods

A cross-sectional study design was applied; the Danish version of the Safety Attitudes Questionnaire (SAQ-DK) was used to capture staff perceptions of the PSC.[11]

Questionnaire used

SAQ-DK is an explorative questionnaire suitable for assessment of perceptions of PSC in hospitals. SAQ-DK has 31 items comprising six PSC composites and additional items on demography. The composites are: teamwork climate (six items), safety climate (seven items), job satisfaction (five items), stress recognition (four items), working conditions (four items), and perceptions of management (five items). The later composite was applied at the three management levels of NHFI. SAQ-DK has been found psychometrically sound, it can be used to assess safety attitudes across specialties in hospitals.[11]

Respondents answer the SAQ-DK on a five-point Likert scale as: 1, disagree strongly; 2, disagree slightly; 3, neutral; 4, agree slightly; and 5, agree strongly. Further, it is possible to rate the SAQ-DK items "not applicable". Items are assumed to have interval properties. Items 2 and 11 are negatively worded.[18]

Information on sex, age group, profession, organizational role, work experience, and organizational affiliation was collected electronically together with answers on SAQ-DK items.

All SAQ-DK items as well demography questions were mandatory, meaning that the electronic questionnaire would only allow participants to go to the next question once having answered the present.

Data collection

Data were collected between September 21 and October 23, 2013.

The questionnaire was administered electronically via an individual link in a personal email. Weekly reminders were mailed to all staff who had not answered. That is, a responder could receive a maximum of four reminders.

A hospital-based administrator collaborated with the research team in the data collection. She gave information about the survey to the leaders and in unit-based meetings, answered questions from leaders and staff per email, telephone and in person, gave information about the survey on the intranet, and posted information material throughout the hospital.

The management group of the hospital NHFI assessed SAQ-DK for its purpose and approved the study. The survey invitees were informed that participation was voluntary and anonymously, that all answers would be treated with confidentiality, and no individual answers would be available to the management.

Analysis

The sample data was described by frequencies according to demographic groups.

The reliability of SAQ-DK was described by measures of internal consistency. Items in a composite were regarded closely related if Cronbach's alpha (α) >0.70.[23] Construct validity was reported by the degree of linear association between pairs of two dimensions; Pearson's correlation coefficients were described.

SAQ-DK data were presented reporting two measures: 1) the percent of respondents with a positive attitude (%-positive, defined by an individual mean scale score ≥ 75), and 2) scale mean scores and standard deviation (SD); reflecting how positive the respondents perceived the culture.[24]

All composites were regarded continuous variables for the purpose of analysis.[24]

Individual SAQ-DK item scores were converted to a 0–100-point scale, where 1=0, 2=25, 3=50, 4=75, and 5=100. Item 2 and 11 were reverse scored so that their valence matched the positively worded items.

Individual scale mean scores were calculated by the average score of the scaled and scored items, and the %-positive calculated (range 0–100). SAQ-DK mean scale scores (range 0–100) were calculated for each dimension by the average score of the scaled and scored items.[25] Results of %-positive were compared across subgroups using chi-square test, and mean scale scores were compared using independent *t*-test. Analysis of variance was applied for each cultural dimension to test for variability in means across centers.

All statistical analyses were performed using IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA).

Results

Participation

In total, 357 of 557 questionnaires were returned (65.8%); 76 questionnaires originated from the surgical center, 93 from the psychiatric center, 34 from the diagnostic center, 110 from the medical center, 40 from the acute care center, and 14 from the administrative units directly under the top management.

Table 1 SAQ-DK respondent characteristics according to demography among health care staff of the National Hospitals of the Faroe Islands (N=367)

Demography	N	%
Sex		
Female	325	88.6
Male	42	11.4
Age (years)		
<36	61	16.6
36–45	112	30.5
46–55	95	25.9
≥56	99	27.0
Profession		
Nurses	178	48.5
Nursing assistants and similar	40	10.9
Doctors	32	8.7
Therapists[a]	28	7.6
Midwifes	4	1.1
Allied clinical support staff[b]	23	6.3
Administrative staff and social workers[c]	46	12.5
Service assistants, hospital porters, and technical staff[c]	9	2.5
Others	7	1.9
Organizational role		
Clinical leader	50	13.6
Frontline clinician	317	86.4

Notes: [a]Physiotherapists, occupational therapists, music therapists, psychologists; [b]medical laboratory technicians, pharmacologists, pharmacists, radiologists, dieticians; [c]nonclinical staff. Results in this table were generated by the use of IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA).
Abbreviation: SAQ-DK, Danish version of the Safety Attitudes Questionnaire.

The number of participants varied from four in the smallest outpatient setting to 31 in largest bed unit, six of the 28 units had five respondents. Respondent characteristics are shown in Table 1 for sex, age group, profession and organizational role, showing the number of participants in column 2, and the percentages in column 3. It is noticable that more than half of the participants are aged 46 years or older. This is evident from the figures in rows 8 and 9. Further as shown in row 11, the nurses amounts to approximately half of the sample. Last, the clinical leaders are well represented with 50 participants of 57 invitees, please see second row from the bottom of Table 1.

Scale reliability and scale to scale correlations

Cronbach's alpha ranged from 0.59 for teamwork climate to 0.86 for job satisfaction. The set cut point of 0.70 indicating good scale reliability was not exceeded for teamwork climate (0.59) and safety climate (0.67).

Scale to scale correlations were studied by the degree of linear association between pairs of two scales. All scales correlated negatively with the stress recognition scale revealing Pearson's r between –0.15 and –0.06, $P<0.05$. Pearson's correlations indicated significant strong positive relationships for all other scales; correlation coefficients ranged from 0.43 to 0.67, $P<0.01$.

Perception of the PSC among the Faroese staff

The average rate of not applicable answers at the item level was 6.4%. A full range of scores between 1 and 5 was observed for all items.

Dimensional results for SAQ-DK for the Faroese health care staff (N=367) are shown in Table 2, reporting %-positive and mean scale statistics in columns 3 and 6, respectively. Further, variation in %-positive and means are displayed in Table 2.

Across the entire sample, the proportion of staff with positive attitudes ranged from 12.8% for perception of top management to 71.1% for job satisfaction. In parallel, the top management was perceived least positive (mean scale score [SD]; 47.6 [21.7]), and job satisfaction most positive (mean scale score [SD]; 78.7 [20.6]).

Table 2 Dimensional patient safety culture results showing proportions of missing answers, proportions of staff with positive attitudes, mean scale statistics (N=367 responders), and variability across units in SAQ-DK dimensional scores (N=28 units)

Dimension	%-missing[a]	%-positive[b]	Min–max[c]	*P*-value[d]	Mean (SD)[e]	Range[f]	*P*-value[g]
Teamwork climate	4.0	63.5	20.0–100.0	<0.01	74.4 (19.5)	60.3–89.6	<0.01
Safety climate	3.3	28.9	0.0–100.0	<0.05	60.9 (20.2)	48.9–83.5	<0.01
Job satisfaction	0.3	71.1	16.7–100.0	<0.01	78.7 (20.6)	50.0–95.0	<0.01
Stress recognition	6.7	55.9	0.0–83.3	0.379	69.3 (23.4)	53.1–81.3	<0.01
Perceptions of unit mgmt	9.0	36.2	0.0–85.7	<0.01	62.3 (23.8)	30.6–85.1	<0.01
Perceptions of center mgmt	9.7	19.3	0.0–50.0	<0.05	51.5 (23.6)	20.1–71.7	<0.01
Perceptions of top mgmt	10.1	12.8	0.0–46.2	<0.05	47.6 (21.7)	18.8–65.3	<0.01
Working conditions	5.4	37.6	0.0–71.4	<0.01	60.1 (25.4)	40.4–87.5	<0.01

Notes: [a]Proportion of answers to all items in a scale given as "not applicable". [b]Proportion of responders with positive attitudes, N=367 responders. [c]Variation in %-positive across in- and outpatients units, N=28 units. [d]Chi-square test comparing %-positive across in- and outpatient units, N=28 units. [e]Mean scale scores, N=367 responders. [f]Range in mean across in- and outpatient units, N=28. [g]ANOVA testing for unit variability in means, N=28 units. Results in this table were generated by the use of IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA).
Abbreviations: ANOVA, analysis of variance; mgmt, management; %-positive, proportion of staff with a positive attitude; SAQ-DK, the Danish version of the Safety Attitudes Questionnaire; SD, standard deviation.

Variations in %-positive across all units (administrative, and clinical in- and outpatient units, N=28) are shown as minimum–maximum in Table 2 column 4, likewise the range of the means of the units are displayed in column 7. The %-positive differed across units (N=28) for all dimensions, $P<0.05$, except stress recognition, $P>0.05$. Noticeable, the variation in %-positive across units ranged from 0.0 to 100.0 for safety climate, $P<0.01$. The degree to which the staff perceived the culture positive (mean scale score) varied significantly across the 28 units for all scales, $P<0.01$.

No differences in means were found between staff under 36 years and staff aged 36 years or older, $P<0.05$. Differences in means between nonclinical staff (secretaries and social workers) and clinical staff was found for job satisfaction, working conditions, perception of center management and perception of top management, $P<0.05$.

PSC results according to medical specialty

Dimensional PSC results for the five specialized centers were described, compared, and illustrated in Table 3. The diagnostic center shown in column 4 had the highest %-positive and the highest mean scale scores of all centers for all dimensions. The diagnostic center represents the laboratory (N=24) and the X-ray unit (N=10). No such patterns were found for %-positive and the means identifying the lowest scoring center across all dimensions.

Differences in %-positive across the medial centers were identified for working conditions and all three management dimensions, $P<0.05$. The scale means differed statistically significant across centers for all scales, $P<0.05$; except for stress recognition and working conditions, $P>0.05$.

Clinical leaders' and frontline staffs' perceptions of the PSC

The NHFI is operated by three levels of line management; top, center, and unit management. According to Table 2, column 2, it is evident that the frequency of not applicable answers is highest for the three management dimensions, ranging from 9.0% for perception of unit management to 10.1% for perception of top management. If the leaders are excluded when calculating the frequency of not applicable answers for the three management dimensions, the percentage of not applicable answers amounted to 5.6% for perception of unit management, 9.7% for perception of center management, and 11.1% for perception of top management.

Table 3 Dimensional SAQ-DK result showing the proportions of staff with positive attitudes (%-positive) and means for each of the five specialized centers; and comparison of the scores across the centers for all eight dimensions

Dimension	Surgical center N=76	Psychiatric center N=93	Diagnostic center N=34	Medical center N=110	Acute care center N=39	Comparing the scores of the five medical centers	
	%-positive; mean (SD)	%-positive; mean (SD)	%-positive; mean (SD)	%-positive; mean (SD)	%-positive; mean (SD)	%-positive[a] χ^2; (df); *P*-value	Means[b] *F*-value; (df); *P*-value
Teamwork climate	69.7; 75.3 (17.1)	60.2; 73.2 (21.0)	79.4; 82.2 (16.4)	56.4; 70.7 (21.8)	65.0; 76.7 (13.9)	7.87; (4); 0.10	2.63; (4); 0.03
Safety climate	25.0; 60.9 (16.2)	22.6; 58.9 (20.4)	44.1; 70.9 (18.5)	30.9; 59.3 (22.1)	27.5; 59.8 (19.3)	6.48; (4); 0.17	2.61; (4); 0.04
Job satisfaction	73.7; 80.1 (18.6)	64.5; 73.2 (22.7)	82.4; 86.0 (20.9)	68.2; 77.6 (21.1)	77.5; 83.3 (15.2)	5.51; (4); 0.24	3.47; (4); <0.01
Stress recognition	57.9; 69.2 (24.3)	57.0; 68.5 (23.7)	61.8; 65.4 (30.3)	57.3; 72.6 (19.2)	42.5; 63.8 (26.3)	3.64; (4); 0.46	1.32; (4); 0.26
Perceptions of unit mgmt	26.3; 56.7 (24.8)	41.9; 64.5 (24.1)	55.9; 70.5 (25.0)	30.9; 56.4 (22.9)	32.5; 64.6 (20.9)	11.83; (4); 0.02	2.72; (4); 0.03
Perceptions of center mgmt	10.5; 47.6 (19.8)	25.8; 59.7 (22.1)	38.2; 60.8 (27.0)	11.8; 41.8 (23.7)	22.5; 56.2 (20.4)	18.54; (4); <0.01	10.63; (4); <0.01
Perceptions of top mgmt	6.6; 45.9 (17.6)	17.2; 54.5 (19.9)	26.5; 53.9 (24.9)	4.5; 37.7 (20.6)	12.5; 49.9 (21.4)	17.75; (4); <0.01	10.12; (4); <0.01
Working conditions	43.4; 59.7 (24.5)	28.0; 54.3 (27.1)	55.9; 66.7 (26.1)	35.5; 62.3 (22.9)	30.0; 56.7 (28.4)	10.78; (4); 0.03	2.11; (4); 0.08

Notes: [a]Chi-square test comparing %-positive across medical specialties', N=5 centers. [b]ANOVA for each culture dimension with significance testing for center variability in means. Results in this table were generated by the use of IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA).
Abbreviations: ANOVA, analysis of variance; mgmt, management; %-positive, proportion of staff holding a positive attitude; SAQ-DK, the Danish version of the Safety Attitudes Questionnaire; SD, standard deviation.

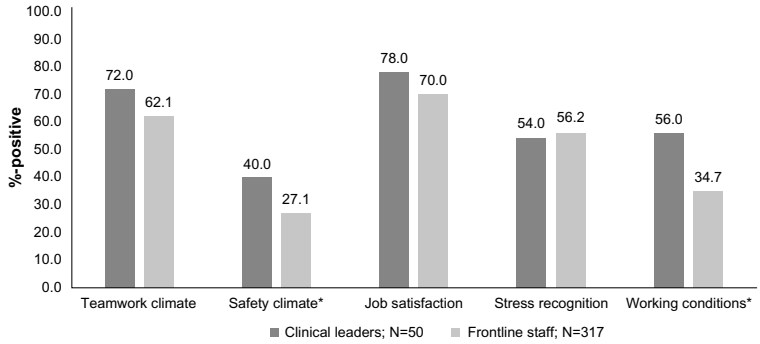

Figure 1 Distribution of proportions of clinical leaders and frontline staff with positive attitudes toward dimensional patient safety culture.
Notes: *Significant difference between the clinical leaders and the frontline staff using chi-square test, $P<0.05$. Results in this figure were generated by the use of IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA) and Windows Excel 2016.
Abbreviation: %-positive, proportion of staff with a positive attitude.

The three management dimensions were not included in the following analyses comparing perceptions of the frontline staff with those of the leaders.

Figure 1 shows %-positive for clinical leaders and frontline staff separately for teamwork and safety climate, job satisfaction, stress recognition, and working conditions. In parallel, Figure 2 shows the degree to which the leaders and frontline staff perceive the PSC positive. Across all dimensions, job satisfaction was the dimension where, both, most leaders (78.0%) and most frontline staff (70.0%) perceived the PSC positively, this is seen in the two middle bars of Figure 1. Among all five dimensions, job satisfaction was also perceived most positive by both clinical leaders (mean (SD); 83.5 [14.7]) and by frontline staff (mean [SD]; 78.0 [21.3]), this can be seen in Figure 2. Across dimensions, safety climate was the dimension, where least clinical leaders (40.0%), respectively, frontline staff (27.1%) perceived the culture positive, please see the two bars left of the middle in Figure 1. Safety climate was also perceived least positive by clinical leaders (mean [SD]; 67.8 [17.4]), but frontline staff perceived working conditions least positive (mean [SD]; 58.2 [25.6]), this is illustrated in Figure 2.

Figure 1 illustrates that more leaders than frontline staff had positive attitudes towards the safety climate and working conditions, $P<0.05$. Figure 2 illustrates, that the leaders perceived teamwork and safety climate, and working conditions more positively than the frontline staff, $P<0.05$.

When observing the three management dimensions displayed in Table 2 row 6-8; the least amount of staff had positive attitudes towards the top management, and most of

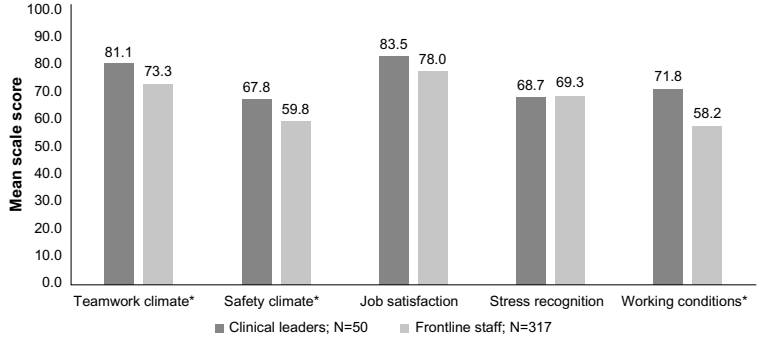

Figure 2 The degree to which (mean scale score) the clinical leaders and the frontline staff perceived dimensional patient safety culture positive.
Notes: *Significant difference in scale means between the clinical leaders and the frontline staff using independent *t*-test, $P<0.05$. Results in this figure were generated by the use of IBM-SPSS version 21.0 (SPSS, IBM Corporation, Armonk, NY, USA) and Windows Excel 2016.
Abbreviation: %-positive, proportion of staff with a positive attitude.

the staff had positive attitudes towards unit management, $P<0.01$. Likewise, the mean scale score for perception of the top management was lowest and the perceptions of the unit management highest, $P<0.01$.

Discussion

This study presents the first evidence-based information on PSC in the Faroe Islands. Based on data from 367 health care staff, job satisfaction was rated most favorable and perception of top management least. Unit level variation in the proportion of staff with positive attitudes toward the PSC was found for all dimensions, except stress recognitions. Moreover, unit level variability in how positive the dimensional PSC was perceived was found for all dimensions. Of the five medical specialties, the staff of the diagnostic center representing the laboratory and the X-ray unit perceived the culture most favorable for all cultural dimensions. The leaders perceived the culture more positive than the frontline staff for teamwork and safety climate, and working conditions. Across the three management layers, the unit management was perceived most positive and the top management least by the frontline staff. This also applied across medical specialties.

Methodological considerations

A good compliance representing all professions and a response rate above 65% was deemed highly acceptable given the challenges with this survey being the first staff survey in the NHFI, and the kick off of working with QM. Further, the average rate of not applicable answers at the item level compared well to international findings, not giving rise to any concern.[11,12,26,27] Additionally, the study was heavily supported by the top management of the NHFI, during planning, implementation, results feedback and interpretation. In conclusion, the study was strengthened by the very good support and acceptability of the SAQ-DK among Faroese hospital staff.

The study has a number of weaknesses. First, Cronbach's alpha was below the acceptable cut point for teamwork and safety climate, indicating that the items in those two scales are not related as closely as desired, and not as well, as found in other studies.[12,13,28] Second, the survey was carried out using SAQ-DK, which is in Danish. Although Danish is the second language in the Faroe Islands, this might have influenced participation and created biased answers due to misunderstandings. Moreover, selection bias cannot be ruled out as staff of the service center was not invited, such staff from nonclinical areas would be expected to have a more favorable perception of the culture than staff from clinical areas, thus the results for %-positive and the means might be underestimated. Finally, the results presented in this study are based upon self-reported PSC, which might have created information, recall and social desirability bias. Also, we did not check the accuracy of the findings against other assessments of PSC (eg, observations or interview). This might have consequences for the dimensional %-positive and the mean scale scores, but not for the comparative results as the same conditions apply across groups.

Relating the results to findings in the literature

We found that job satisfaction was rated most favorable in the Faroe Islands, and better than in Denmark, Australia, and the US,[11,29,30] but not as good as in Taiwan.[31] The quality of the top management was perceived least favorable, which is in line with some international findings,[11,29,30] but not with others.[31] Findings regarding the quality of the top management compared well to Danish and Australian findings.[11,30]

Previous studies have suggested a minimum threshold scale score of 60% for good PSC, and a goal zone of 80%–100%;[6,29,32,33] the 60% threshold was only exceeded for teamwork climate and job satisfaction in the NHFI, but the goal zone was not reached. This indicates that awareness of the concept of patient safety as defined by the dimensions of the SAQ is still in early days in the Faroe Islands, and improvement initiatives recommended. Executive walkarounds have proven effective in improving the safety culture,[32] and they are planned for implementation in the Trygd and Dygd program.

We found variability in the degree to which the staff perceived the culture positive (mean scale score) across units for all dimensions. This has also been found in other Nordic studies,[11,16] and emphasizes that PSC is a local phenomenon, which should be measured and acted upon locally.[34]

For safety climate, we found a large-scale variation in the proportions of staff with positive attitudes across the units of the NHFI, such great variation from 0 to 100 has, to our knowledge, not been identified in other studies. The safety climate of the NHFI was significantly poorer than in Denmark, where 45.4% perceived the safety climate positive.[11] We attribute the difference between the Faroese and the Danish safety climate to the fact that items in the safety climate dimension reflect: how adverse events are handled, openness about errors, concern about patient safety, and learning. In Denmark, reporting and analysis of adverse

events has been mandatory by law since 2004 in hospitals, and it is a leadership task to facilitate patient safety initiatives.[35] With the PSC survey in the NHFI, the Trygd and Dygd initiative was launched. The initiative aims to address patient safety actively by creating awareness of risk, harm, and ways to prevent adverse events and improve the safety for the patients. Working systematically with patient safety was put on the agenda of the clinical leaders of the NHFI for the first time after the PSC survey in 2013. Seen in this light, the quality of the safety climate is acceptable, and the variation in the quality of the safety climate across units might be attributable to different levels of awareness, knowledge, and skills among the clinical leaders and frontline staff at the unit level, also external influence through specific individual staff members from Denmark, Norway, and Iceland cannot be ruled out. Results from two cross-national studies of PSC data showed equivalent differences between countries with regard to the aspects covered by safety climate, emphasizing that this is a dimension sensitive to the local context factors.[36,37]

Working conditions was also rated significantly poorer in the NHFI than in Denmark, where 62% of the staff perceived working conditions in relation to patient safety.[11] The %-positive from the NHFI does not meet the suggested 60% threshold for good working conditions in relation to patient safety. Thus, adequacy of staff training, supervision, and access to information should be investigated further in the NHFI.

We found differences in the quality of the culture across the five medical centers. The diagnostic center had the highest %-positive and the highest mean scale scores of all centers for the three management dimensions. The management dimension reflects the clinical leader's support, communication, and actions in regard to the safety of the patients. The diagnostic center represents the X-ray unit and the laboratory, where certain work procedures are controlled by external bodies to ensure the quality of delivered services. Both units have strong leadership engagement in QM, and staff has worked systematically with quality and safety for more than 20 years. This might explain the findings. Our findings are supported by previous findings from the US indicating that nonclinical areas have a better safety culture than clinical areas with more intrinsically hazardous environment.[18]

In line with previous studies, the clinical leaders perceived the quality of the culture more positive than the frontline staff,[38] this was most evident for teamwork and safety climate, and working conditions. Across the three management levels we found the quality of the top management poorest and the quality of the unit level management most favorable. This pattern is in accordance with previous findings and deemed satisfactory.[11,29]

Conclusion

The survey results give a snapshot of PSC in a modern western hospital prior to implementation of any QM initiatives. Quality of the management climate was identified as the weakest area of the PSC, and safety climate was the dimension with the greatest variability across units. This gives an anchor point and a direction for improvement; the hospital leaders are recommended to raise awareness of their role in supporting a safe and caring environment for patients and staff, moreover the leaders should ensure that as much as possible goes right, in the sense that everyday work achieves its objectives: keeping the patients safe, and that effective QM methods for improving the safety culture are implemented.

Assessment of the PSC after the implementation of the Trygd and Dygd program and the accreditation process of the NHFI is planned and improvements anticipated, especially with regard to the safety climate.

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Disclosure

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Appendix J. SAQ-DK

	Udsagn om patientsikkerhedskulturen	Helt enig	Delvis enig	Neutral	Delvis uenig	Helt uenig	Ikke relevant
1	Her værdsættes det, at vi kommer med forslag og ideer						
2	Det er svært for mig at få det sagt, hvis jeg oplever problemer i forbindelse med pleje og behandling af patienterne						
3	Konfliktløsning blandt ansatte her hos os handler ikke om, hvem der har ret, men hvad der er bedst for patienten						
4	Jeg får den hjælp og støtte fra mine kollegaer, som jeg har brug for, for at kunne tage mig godt af patienterne						
5	Det er naturligt for personalet at stille spørgsmål, hvis der er noget, vi ikke forstår						
6	Her arbejder sundhedsfagligt personale sammen som et velfungerende team						
7	Jeg ville føle mig tryg, hvis jeg var patient her						
8	Vi håndterer utilsigtede hændelser på en hensigtsmæssig måde						
9	Jeg ved, hvor og hvordan jeg kan få svar på spørgsmål om patientsikkerhed						
10	Jeg får passende tilbagemeldinger på, hvordan jeg klarer mine arbejdsopgaver						
11	Det er svært at diskutere utilsigtede hændelser her hos os						
12	Kollegaer opfordrer mig til at sige til, hvis jeg er bekymret for patientsikkerheden						
13	Kulturen her hos os gør det nemt at lære af andres utilsigtede hændelser						
14	Hvis jeg kom med forslag til forbedring af patientsikkerheden, ville ledelsen følge op på dem						
15	Jeg kan godt lide mit arbejde						
16	At arbejde her er som at være medlem af en stor familie						

To be continued

Udsagn om patientsikkerhedskulturen		Helt enig	Delvis enig	Neutral	Delvis uenig	Helt uenig	Ikke relevant
17	Her er det godt at arbejde						
18	Jeg er stolt over at arbejde her hos os						
19	Vi er karakteriseret ved en høj arbejdsmoral						
20	Når arbejdsbyrden bliver for stor, går det ud over kvaliteten af mit arbejde						
21	Når jeg er træt, er jeg er mindre effektiv						
22	Jeg er mere tilbøjelig til at begå fejl i anspændte eller konfliktfyldte situationer						
23	Træthed forringer kvaliteten af mit arbejde i akutte situationer (fx ved hjertestopalarm, eller patientkramper)						
24	Ledelsen støtter mig i mit daglige arbejde						
25	Ledelsen beslutter og gør ikke bevidst noget, som kan forringe patientsikkerheden						
26	Ledelsen gør et godt arbejde						
27	Ledelsen tager hånd om personaleproblemer på en konstruktiv måde						
28	Jeg får tilstrækkelig information i rette tid om utilsigtede hændelser, der har relevans for mit arbejde fra						
29	Bemandingen er tilstrækkelig i forhold til antallet af patienter her hos os						
30	Nyt personale får en god introduktion						
31	Jeg har normalt adgang til alle de oplysninger, jeg har brug for, for at kunne træffe beslutninger om pleje og behandling						
32	Personale, der er under oplæring inden for mit fagområde, får den nødvendige supervision						

Appendix K. Findings Studies II - IV

Table A6 Patient safety culture outcomes of Studies II, III and IV

Study characteristics	Study II	Study III.1	Study III.2	Study IV
Country	Denmark	Denmark	Denmark	Faroe Islands
HC context	Mixed somatic and psychiatric	Psychiatric	Psychiatric	Mixed somatic and psychiatric
N (hospitals)	6	1	1	1
N (clinical areas)	31	19	19	28
N (participants)	925	358	325	367
Highest mgmt level reported	Clinical area	Department	Department	Hospital
Clinical area level scores				
% positive ▲	TC	**JS**	**JS**	**JS**
% positive ▼	UM	DM	DM	HM
Mean ▲	TC	**JS**	**JS**	**JS**
Mean ▼	UM	DM	DM	HM
Clinical area level variance				
% positive	All dimensions	All dimensions	All dimensions	All dimensions
Mean	All dimensions	All dimensions	All dimensions	All dimensions
Difference; gender				
% positive	TC; ♀ > ♂ **WC; ♀ > ♂**	**WC; ♀ > ♂**	N.S.	**WC; ♀ < ♂** DM; ♀ < ♂
Mean	TC; ♀ > ♂ SC; ♀ > ♂ JS; ♀ > ♂	N.S.	N.S.	WC; ♀ < ♂ HM; ♀ < ♂
Difference; doctors and nurses				
% positive	SC; Doc > RN	SC; Doc < RN WC; Doc < RN	WC; Doc < RN	WC; Doc > RN
Mean	WC; Doc > RN	JS; Doc < RN SR; Doc > RN	WC; Doc < RN	WC; Doc > RN

To be continued

Study characteristics	Study II	Study III.1	Study III.2	Study IV
Difference; experience				
% positive	SC; Exp > InExp WC; Exp > InExp	JS; Exp > InExp	N.S.	WC; Exp > InExp
Mean	WC; Exp > InExp	N.S.	SR; Exp < InExp	WC; Exp > InExp
Difference; Organisational role				
% positive	N.A.	SC; CL > FS	SC; CL > FS	WC; CL > FS
Mean	N.A.	SC; CL > FS **WC; CL > FS**	**WC; CL > FS**	TC; CL > FS SC; CL > FS **WC; CL > FS**

Notes: All reported differences are statistically significant.
Abbreviations: mgmt., management; % positive, proportion of staff with positive attitudes (individual mean scale score >75), TC, teamwork climate; SC, safety climate; JS, job satisfaction; SR, stress recognition; UM, perception of unit management; DM, perception of department/centre management; HM, perception of hospital/top management; WC, working conditions; ♀, female; ♂, male; Doc, doctor; RN, nurse; Exp, two or more years of work experience in the hospital; InExp, less than two years of work experience in the hospital; N.A., not applicable; N.S., not significant; CL, clinical leader; FL, frontline staff.

SUMMARY

Patient safety is highly prioritised in the Danish health care system, never the less, patients are still exposed to risk and harmed every day. Implementation of a patient safety culture has been suggested an effective mean to protect patients against adverse events. Working strategically with assessment and development of the patient safety culture is in early days in Denmark. It depends upon valid, reliable and effective methods.

The patient safety culture represents a wide range of social phenomena permeating the way of life in a health care. In essence, the safety culture is an aggregation of health care professional's behaviour, habits, norms, values, and basic assumptions related to patient care; it is the way things are done. The patient safety culture guides the motivation, commitment to and know-how of the safety management, and how all members of a work place interact.

This thesis presents a tested and valid questionnaire for measuring patients safety culture within hospital care, confirms the effectiveness of a leadership intervention to improve the safety culture, and highlights the boundary conditions and the role of leadership in creating a safety culture.

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