General introduction

A patient, let's call him Mr Jansen, is admitted to the emergency department (ED) on clinical suspicion of stroke. To confirm the diagnosis and to distinguish between a cerebrovascular infarction and a haemorrhage, neurologist Marieke immediately requests a CT scan. Mr Jansen is brought to the CT by ED nurse Janine, who takes a quick look at the CT images before she returns to the ED. On the images, Janine sees a cerebral bleeding. After she had taken care of her next patient, Janine calls the stroke unit to inform how Mr Jansen is doing. Her colleague tells her that Marieke just started the thrombolytic therapy. Janine is puzzled by this; in the case of an infarction immediate thrombolysis is of vital importance, but in the case of a haemorrhage the therapy could worsen the bleeding rather than control it, and she had seen a bleeding on Mr Jansen's CT images. Janine does, however, not share her concerns. After all, Marieke is a highly experienced and knowledgeable physician who always takes good care of her patients. 'She will know best', Janine thinks.

In her endeavour to deliver the best possible care to her patient, Marieke wanted to start a treatment as soon as possible – after all, 'time is brain' – and, therefore, she checked the CT scan herself rather than waiting for the results of the radiologist. The scan she saw revealed no bleeding, thus Marieke started thrombolytic therapy. However, at the time Marieke checked the CT images, the scan that was made during the admission was not yet uploaded in the patient's record; instead she checked a previously made cerebral scan. As a result, Marieke erroneously excluded haemorrhage as a diagnosis and she prescribed thrombolysis; a treatment which most likely worsened the bleeding rather than being beneficial for Mr Jansen's health. In the end, Mr Jansen died.

(Case description based on an interview with a member of the board of directors of one of the hospitals that participated in this study; all names are fictitious)

Healthcare professionals, like doctor Marieke and nurse Janine, bear a great responsibility for delivering high-quality, safe care to all of their patients. However, as illustrated by the case of Mr Jansen, safety incidents may easily occur. Since healthcare professionals work at the centre of care delivery, they are often directly involved in safety incidents, but they are also in the position to early detect errors and to take preventive actions in order to avoid iatrogenic injuries. However, care providers are not the only ones who have an important role in ensuring patient safety, so do healthcare managers. Managers may, for example, contribute to patient safety by creating a climate in which patient safety is highly valued and employees feel safe to express themselves, by encouraging or enforcing appropriate safety behaviours, and by providing the necessary resources to deliver safe care. When confronted with safety incidents like the one that happened to

Mr Jansen, managers could increase managerial control by checking the (stroke-related) protocols and procedures, tightening them if necessary and more strictly enforcing compliance. In contrast, managers could also focus on increasing awareness of safety risks and professionals' responsibilities (e.g., in terms of speaking up) by organising a debriefing and discussing the incident within the healthcare team. Despite growing recognition that managers have a leading role in ensuring safe care delivery, *"little is known about what healthcare managers are doing in practice to ensure and improve quality of care and patient safety"* (Parand, Dopson, Renz, & Vincent, 2014, p. 1); especially when it comes to middle and frontline managers. The current study aims to gain insight into the management approaches that managers use while managing patient safety and to explore the effect of different safety management approaches on the attitudes and behaviour of healthcare professionals as well as patient safety performance.

In 1863, Florence Nightingale stated already that *"the very first requirement in a Hospital [is] that it should do the sick no harm"* (Nightingale, 1863). As a nurse, she observed that the care, that was supposed to cure patients, involved various safety risks that could cause harm or even lead to patients' deaths. In other words, patient safety – defined as the *"freedom from accidental or preventable injuries produced by medical care"* (AHRQ, no date) – was not guaranteed and a hospital treatment could be more hazardous than beneficial for patients. Even though hospital care has significantly improved over the past 150 years, it is still not self-evident that patients are safeguarded from (preventable) adverse events that cause temporary or permanent harm to them. Over the last decades, various studies have shown that incidence rates of adverse events range from 3.3% to 12.3% of hospitalised patients of which 30% to 70% are judged preventable (Aranaz-Andres et al., 2008; Baker et al., 2004; Brennan et al., 1991; Kohn, Corrigan, & Donaldson, 2000; Rafter et al., 2017; Sommella et al., 2014; Soop, Fryksmark, Köster, & Haglund, 2009; Sousa, Uva, Serranheira, Nunes, & Leite, 2014; Vincent, Neale, & Woloshynowych, 2001; Zegers et al., 2009). The occurrence of adverse events is frequently associated with additional treatments or prolonged hospital stay, and studies demonstrated that almost 5% of adverse events result in permanent disability and around 10% contribute to the patient's death. In the Netherlands, up to 5.7% of all of the patients admitted to a hospital suffer from an adverse events, such as an hospital-acquired infection or medication-related event (Baines, Langelaan, de Bruijne, Spreeuwenberg, & Wagner, 2015), leading to around 1,000 preventable deaths annually (Langelaan et al., 2013; Langelaan et al., 2017). Direct medical costs of these adverse events are estimated to be 523 million euros per year. In recent years, public awareness of safety risks in care delivery created a sense of urgency and focused hospitals' attention and action towards minimising patient harm. Experts in the field of patient safety generally agree that, as a result of these efforts, healthcare is safer now than it was 15 years ago, when the Institute of Medicine published its landmark report *'To err is human'* (Kohn et al., 2000; National Patient Safety Foundation, 2015), but

longitudinal studies show that incidence rates of adverse events remain fairly consistent (e.g., Baines et al., 2015; Landrigan et al., 2010). As a result, healthcare organisations face great pressure to improve patient safety.

Notwithstanding the widely agreed necessity to improve safety in care delivery, no clear consensus exists on how to effectively manage patient safety. In the literature, a wide array of leadership behaviours and management practices has been described with regard to patient safety management (e.g., Parand et al., 2014; Verschueren, Kips, & Euwema, 2013). Managers show, for example, role modelling behaviour (e.g., Leroy et al., 2012), implement evidence-based safety protocols and checklists (e.g., Pronovost et al., 2006; de Vries et al., 2010), organise team trainings (e.g., Weaver, Dy, & Rosen, 2014), participate in safety walk rounds (e.g., Frankel et al., 2008) and provide employees with performance feedback to make them aware of the safety risks that care delivery entails (e.g., Giesbers, Schouteten, Poutsma, van der Heijden, & van Achterberg, 2015). Some of these interventions demonstrated reductions in adverse events or preventable mortality, but evidence on their effectiveness is often inconclusive (Shekelle et al., 2013). Moreover, safety interventions are never implemented in isolation and their chances of success seem to depend largely on the implementation process and their embedding within the organisation (Singer & Vogus, 2013). Prior research did also focus on hospital managers' leadership style in relation to patient safety management. Particular interest was shown in transformational leadership (Verschueren et al., 2013), characterised by leaders who show commitment, inspire followers and engage their employees in patient safety (Northouse, 2013). It is, however, questionable whether such charismatic and inspirational leadership styles best characterise the role of hospital managers in patient safety management, especially at an operational level. Moreover these leadership styles exclusively focus on the traits and behaviour of the leader, overlooking the broader spectrum of management practices used to ensure safe care delivery. Therefore, it may be relevant to shift the focus to the combination of leader behaviours and management practices that are used to optimise patient safety; also referred to as a safety management approach.

A management approach differs from a leadership style in that it encompasses both the personality and behaviour of the leader as well as the broader spectrum of management practices and devices used to ensure that employees show appropriate safety behaviours. Human resource management (HRM) broadly distinguishes two management approaches that guide employee behaviour: control- and commitment-based management (Arthur, 1994; Walton, 1985). These management approaches have been described as two extremes in a management spectrum, in which the former is a formalised, top-down approach that focuses on regulating, monitoring and controlling employee behaviours; whereas commitment-based management is characterised by creating awareness and facilitating an internalisation of the organisation's mission, vision and goals to ensure that employees demonstrate appropriate behaviour (Boselie, 2002; Walton, 1985). Both man-

agement approaches may be applicable to and relevant for patient safety management (Khatri, Baveja, Boren, & Mammo, 2006); although good insight into the management approaches and clear consensus on the use of both approaches to minimise patient harm is lacking. This lack of consensus is, for example, illustrated by recommendations on how to improve poor standards of care and high rates of preventable mortality in the Mid-Staffordshire hospital in the United Kingdom. While Francis (2013) recommended numerous types of new regulations and highlighted, among other things, the importance of compliance with standard procedures and taking action when expectations are not met. Berwick and colleagues placed greater emphasis on prioritising patient safety within the organisation, embracing transparency, engaging and empowering healthcare professionals, and creating a learning environment (National Advisory Group on the Safety of Patients in England, 2013). So, elements of both extremes of the management spectrum were suggested as a means to improve patient safety in this specific case, raising questions about the use and effectiveness of both management approaches with regard to patient safety management.

RESEARCH QUESTIONS

This dissertation aims to provide insight into how hospital managers manage patient safety, why they choose a specific safety management approach and how different management approaches affect healthcare professionals' safety-related attitudes and behaviour as well as patient safety performance. Therefore, the main research question is:

How do hospital managers manage patient safety, and what are the effects of different safety management approaches on healthcare professionals' safety attitudes, behaviour and patient safety performance?

The main research question is subdivided in five sub-questions, the first of which addresses the conceptualisation of different safety management approaches in hospital care.

1. **How can safety management approaches in hospital care be conceptualised, using the concepts of control- and commitment-based management?**

Walton (1985) originally developed the concepts of control- and commitment-based management to describe two different approaches to workforce management in a factory. The former (implicitly or explicitly) assumes that employees are incapable of self-regulation and, therefore, their behaviour constantly needs to be regulated and controlled. The latter emphasises the creation of an environment in which employees

gain commitment to organisational objectives, which gives them cues about appropriate behaviours and stimulates them to take initiative (Khatri et al., 2006; Walton, 1985). At first sight, a commitment-based management approach seems better suited while dealing with complex safety issues in a context of highly-skilled and autonomous working professionals (Khatri et al., 2006). Standardisation of work processes and managerial control have, however, proven to be effective as well (e.g., de Vries et al., 2010) and are considered important factors in ensuring safety in high-reliability organisations (e.g. aviation) which are – despite criticism against the parallel – often seen as an example for managing safety in healthcare (Katz-Navon, Naveh, & Stern, 2007; Rogers & Gaba, 2011). So, both management approaches might be relevant for managing patient safety. However, to be able to apply the concepts of control- and commitment-based management in this study, they first need to be adapted specifically to the realm of patient safety management in hospitals; after all, every situation and task to be accomplished requires specific leadership behaviours and management practices. Moreover, the current conceptualisations of the management approaches (Arthur, 1994; Khatri et al., 2006; Walton, 1985) are rather abstract and do not give detailed insight into the concrete actions that managers take to ensure desired behaviours of their employees. Therefore, the concepts of control- and commitment-based management first need to be reconceptualised to gain insight into what it exactly is that hospital managers do to manage patient safety.

Secondly, we were interested in why hospitals choose a specific safety management approach. Therefore, the second sub-question is:

2. **How do internal organisational characteristics and external environmental conditions influence the shaping of safety management approaches in hospital care?**

Awareness of adverse events in hospitals placed patient safety in the centre of attention of healthcare professionals, managers, governmental organisations, health insurance companies and patient associations. External stakeholders increasingly put pressure on hospitals to improve patient safety. On the one hand by providing directions for safety behaviours as well as improvements, on the other hand by enforcing transparency on safety performances. In 2008, the Dutch national safety programme 'Prevent Harm, Work Safely' introduced, for example, concrete interventions targeted at high-risk safety themes, initiated improvement in safety leadership and risk assessments, and guided the implementation of a safety management system in Dutch hospitals (Baines et al., 2015). Furthermore, medical professional associations do increasingly provide directions for safe care delivery by establishing evidence-based protocols and guidelines (Noordegraaf & Steijn, 2013). Moreover, hospitals are required to report safety performance indicators to governmental organisations as well as health insurers (Van de Bovenkamp, de Mul, Quartz, Weggelaar-Jansen, & Bal, 2014) and to participate in accreditation systems in order to ensure high-quality and safe care delivery. While shaping their safety management

approaches, hospitals will have to balance these external demands from institutional and competitive stakeholders with the internal needs and possibilities of the organisation. Hospitals employ, for example, a highly professionalised and autonomous working workforce which is originally characterised by self-regulation inside the professional domain and which generally mounts considerable resistance to managerial interference (Freidson, 2001). This raises the question how hospitals deal with the wide variety of possibly conflicting safety demands while shaping their safety management approach, and how they balance the external demands with their internal needs and organisational characteristics.

3. How can safety management approaches in hospital care be measured?

Gaining insight into the effect of different safety management approaches first requires the ability to measure a management approach. Various assessment tools already exist for managerial actions and leader behaviours in relation to patient safety management, but none of them directly corresponds with the conceptualisation of the management approaches used in this study. Khatri and colleagues (2007) previously investigated the concepts of control- and commitment-based safety management, but their measurement scale remains rather abstract and does not focus on concrete management practices and leader behaviours. Avolio & Bass's (2004) conceptualisations of transactional and transformational leadership resemble our management approaches, but it is questionable whether these charismatic and inspirational leadership styles best characterise the role of hospital managers in patient safety management, especially at the operational level. Furthermore, according to some scholars *"there is a pressing need for much stronger conceptualizations of leadership that clearly define leadership practices"* (Wong, Cummings, & Ducharme, 2013, p. 719). Safety management is also incorporated as a theme in frequently cited safety culture assessment tools (Halligan & Zecevic, 2011). These tools do, for example, include items on safety commitment of senior management, managerial support for patient safety, communication openness, leaders' awareness of safety problems and their reactions to reported safety concerns (e.g., Blegen, Gearhart, O'Brien, Sehgal, & Alldredge, 2009; Ginsburg et al., 2009; Sexton et al., 2006; Singer et al., 2007). Hence, attention is predominantly given to managerial practices and leader behaviours in line with a commitment-based management approach. This is also the case for other measurement scales which focus on specific safety leadership behaviours, such as behavioural integrity (Leroy et al., 2012). Far less attention has been devoted to objectifying hospital managers' role in regulating, monitoring and controlling employee behaviour. Therefore, we aim to develop a measurement instrument which highlights both control- and commitment-based safety management.

4. **What is the effect of different safety management approaches on healthcare professionals' safety attitudes and behaviour?**

In HRM literature it is increasingly recognised that leader behaviour and management practices do not directly influence organisational performance but that *"improved performance is [instead] achieved through the people in the organization"* (Guest, 1997, p. 269). The same applies to patient safety management. Therefore, *"in order to clearly understand the relationship between [management practices] and performance, one must attempt to understand how practices impact individuals, who may then collectively impact performance"* (Paauwe, Wright, & Guest, 2013, p. 11). A safety management approach can be considered an organisational communication device that sends a certain message to employees (Bowen & Ostroff, 2004). It may, for example, signal whether delivering safe care is considered important within the organisation (i.e., climate for safety) or whether the organisation is safe to take interpersonal risks like asking for help or speaking up about patient safety concerns (i.e., psychological safety) (Edmondson, 1999; Zohar, Livne, Tenne-Gazit, Admi, & Donchin, 2007). Employees' interpretation of the message communicated by managers may also guide their behaviour. A wide range of behavioural processes is considered relevant for delivery safe care, including compliance which safety protocols or checklists (e.g., de Vries et al., 2010), (interdisciplinary) teamwork and effective communication (Flin, O'Connor, & Crichton, 2008). In our research we will specifically focus on employee voice. By discretionary raising concerns, asking questions and coming up with suggestions, healthcare professionals can prevent the occurrence of adverse events and contribute to improving patient safety (Okuyama, Wagner, & Bijnen, 2014). This is, for example, illustrated by the case described at the start of this chapter: when nurse Janine would have expressed her concerns about the treatment given to Mr Jansen, she might have prevented the fatal adverse event. Whether healthcare professionals engage in voice behaviour is, among other things, influenced by the behaviour of their direct supervisor (Ashford, Sutcliffe, Christianson, 2009). Deeper understanding of the effect of different leadership behaviours and management practices is, however, needed to be able to shape effective management approaches to optimise healthcare professionals' safety-related attitudes and voice behaviour.

5. **What is the effect of different safety management approaches on patient safety performance?**

All efforts put into safety management are aimed at ensuring patient safety and reducing the incidence of iatrogenic injuries or preventable mortality. Using preventable harm as a measure of the effectiveness of safety management is, however, challenging because safety incidents are rare and it can be difficult to separate harm due to safety incidents from harm due to illness or being inherent to a patient's treatment (Vincent, 2010). Alternative patient safety assessment tools are, among other things, found in structural measures or

process indicators (Vincent, 2010), self-reported safety incidents (e.g., Leroy et al., 2012), and patient- or staff-reported perceptions of the level of patient safety (e.g., Lawton et al., 2015). The latter is considered a useful indicator for patient safety performance as staff perceptions are found to align with more objective safety measures such as the proportion of patients who received harm-free care (Lawton et al., 2015; Smeds-Alenius, Tishelman, Lindqvist, Runesdotter, & McHugh, 2016; Stalpers, Kieft, van der Linden, Kaljouw, & Schuurmans, 2016). In contrast, studies demonstrated that incident reporting provides a gross underestimate of the true incidence of adverse events and near misses (e.g., Vincent, 2010; Westbrook et al., 2015). Therefore, we will operationalise patient safety performance as staff perceptions of the level of patient safety in a department.

RESEARCH DESIGN

To answer the research questions, both qualitative and quantitative research methods were used. First, a qualitative study was conducted to gain insight into *how* hospitals manage patient safety and *why* they choose a specific safety management approach. From September 2013 to April 2014, five Dutch hospitals participated in the qualitative phase of our research. Within each hospital, semi-structured interviews were conducted with respondents who occupy a central role in safety management and who work at different hierarchical levels within the organisation. We conducted a total of 45 interviews with 50 respondents (some interviews were duo-interviews), including (chief) patient safety officers, members of the board of directors, members of the medical advisory board, medical managers, business unit managers and nurse managers. The variety of positions held by the respondents included in this study provided us with the opportunity to obtain a broad overview of the safety management approaches used within the hospitals. Results of the qualitative research are presented in chapters 2 and 3 of this dissertation.

The second part of this dissertation is based on a cross-sectional survey study conducted among healthcare professionals and direct supervisors working in clinical hospital departments. The quantitative phase of our research focused on how different safety management approaches affect healthcare professionals' safety-related attitudes, behaviours and patient safety performances. Via hospital associations, all of the Dutch hospitals were invited to participate, resulting in a sample of 7 general hospitals, 8 top-clinical teaching hospitals and 2 university medical centres (respectively 15%, 29% and 25% of all of the hospitals in the Netherlands) (Dutch Hospitals Association, 2015). From September 2014 to May 2015, all of the 11,809 nurses working in the clinical departments of these hospitals as well as their 712 direct supervisors (i.e., nurse managers) were invited to complete a questionnaire. We specifically focused on nurses because of their central role in care delivery and ensuring patient safety (Institute of Medicine, 2004), since they

form the largest occupational group employed in hospitals and because they have a clear 'chain of command' with a nurse manager as their direct supervisor. The nurses answered questions about the perceived safety management approaches, their attitudes towards a climate for safety and psychological safety, safety-related behaviours and the perceived level of patient safety within the department. Data gathered from nurse managers consisted of their perceptions of the safety management approaches they put into practice and ratings of their nurses' safety-related behaviours. The survey data that we collected were used for multiple purposes. First, part of the data was used to develop and test a measurement instrument for control- and commitment-based safety management. Subsequently, we used the dataset to explore the relationships between both safety management approaches and nurses' safety-related attitudes, behaviours and patient safety performances. Because of the complexity of these relationships two conceptual models were developed which were analysed separately. Results of the quantitative research are presented in chapters 4, 5 and 6 of this dissertation.

OUTLINE OF THE DISSERTATION

Chapter 2 presents a reconceptualisation of the concepts of control- and commitment-based management that specifically fits patient safety management in hospital care. Based on findings from the semi-structured interviews, we adapted and refined the concepts as described in HRM literature (Arthur, 1994; Walton, 1985). Furthermore, differences in safety management approaches between and within hospitals are discussed, as well as some first insights into the reasons that underlie the variation.

In ***chapter 3***, we focus in more detail on why hospitals choose a specific safety management approach. Using a heuristic framework based on the contextually-based HR theory (Paauwe, 2004), we analysed how institutional, competitive and configurational factors as well as internal issues of strategic choice affect the safety management approach that is used by hospital managers.

Building on the conceptualisation that is presented in chapter 2, ***chapter 4*** describes the development of a measurement instrument for control- and commitment-based safety management. A set of survey items was formulated which address nurses' perceptions of the leadership behaviours and management practices that their direct supervisors put into practice. Psychometric properties of the new measurement instrument were tested in a sample of nurses working in clinical hospital departments.

Chapters 5 and 6 do, subsequently, aim to gain insight into the influence of control- and commitment-based safety management on healthcare professionals' safety-related attitudes, behaviour and patient safety performances. In ***chapter 5***, we explore the relationship between both management approaches and nurses' willingness to engage in

problem-focused voice – defined as raising *"concerns […] for the benefit of patient safety and care quality upon recognising or becoming aware of the risky or deficient actions of others within healthcare teams"* (Okuyama et al., 2014, p. 1). Furthermore, we investigated whether the relationship between control- and commitment-based safety management and problem-focused voice is mediated by nurses' perceptions of the climate for safety and team psychological safety within their department.

Chapter 6 focuses on the combined influence of control- or commitment-based safety management and climate for safety on nurses' suggestion-focused voice and their perceptions of the level of patient safety within the department. Constructive suggestions of nurses may contribute to improving patient safety performances. We were interested in whether the perceived safety management approach is associated with nurses' expression of suggestion-focused voice and whether this relationship varies for different levels of climate for safety.

Finally, *chapter 7* provides a summary of and reflection on the main findings from the studies reported in this dissertation. Furthermore, methodological issues are discussed as well as suggestions for future research and recommendations for practice.

Table 1 Overview of dissertation chapters, research design and research sub-questions

Chapter	Title	Research design	Sub-questions
2	Commitment or control: Patient safety management in Dutch hospitals	Semi-structured interviews	1, 2
3	The influence of environmental conditions on safety management in hospitals: A qualitative study	Semi-structured interviews	2
4	The ConCom Safety Management Scale: Developing and testing a measurement instrument for control- and commitment-based safety management approaches in hospitals	Quantitative survey	3
5	Speaking up about patient safety concerns: The influence of safety management approaches and climate on nurses' willingness to speak up	Quantitative survey	4
6	Nurse managers' role in stimulating suggestion-focused voice: A moderated-mediation model of safety management, climate and patient safety	Quantitative survey	4, 5