Hospital Quality Systems

unraveling working mechanisms

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"Care and Quality are internal and external aspects of the same thing. A person who sees Quality and feels it as he works is a person who cares. A person who cares about what he sees and does is a person who's bound to have some characteristic of Quality."

Robert M. Pirsig

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1

General introduction

Introduction

In November 2012, the Healthcare Inspectorate of the Netherlands closed down the cardiology department of a general hospital. The high mortality rate of the cardiology department in particular led to this decision. The mortality rate for 2010 was calculated at the end of 2011 and turned out to be the highest of all Dutch hospitals. It indicated that the hospital had more deaths than could be expected based on its patient population. In response, the hospital started an independent investigation into possible explanations by means of record review. An interim report became available in June 2012 and highlighted severe shortcomings in the organization of the hospital. Despite these shortcomings, no improvement measures were undertaken in reaction to the interim report. The final report was completed in October 2012. Serious and persistent shortcomings were noted in the cardiology department, especially in the diagnosis and treatment of patients, resulting in a multitude of avoidable incidents. Furthermore, researchers found carelessness in the prognoses of disease progression and procedures at end-of-life decisions. When the Healthcare Inspectorate received the final report, it immediately closed down the cardiology department. Several days later, all four cardiologists were suspended and prohibited from working in the hospital until further notice. More in-depth investigations into the problems at the hospital revealed that: (1) there were long-lasting conflicts between the Hospital Board and Medical Staff Association, up to the point that both parties were unwilling to communicate with each other for months; (2) there was a high turnover of members of the Hospital Board, Board of Trustees and Medical Staff Association; (3) a greater emphasis was placed on financial challenges than on quality and safety issues; (4) there was poor collaboration between the different medical disciplines and the culture encouraging healthcare professionals to speak out was inadequate.[1,2]

The case described above is an example of a hospital that 'on paper' had quality and safety under control. The hospital had met all requirements set by law, inspection and accreditation bodies. The Dutch hospital accreditation body NIAZ granted the hospital accreditation in 2008.[3] Nonetheless the hospital experienced a dramatic system failure leading to potentially avoidable deaths of patients. Unfortunately, similar examples surface every now and then in hospitals in the Netherlands, but also in other countries. Although the aforementioned Dutch hospital in fact had implemented a quality system and received accreditation status, which is generally seen as a guarantee for quality and safety, incidents happened nonetheless. The question arises of whether something structural was underlying these incidents and how it can be explained.

This research is set out to gain thorough insights into the working mechanisms underlying the structure-process-outcome relationships of quality improvement within hospital quality systems. These insights can lead to a better understanding of the conditions under which a quality system can result in higher quality of care. Furthermore, this research aims to gain insights into the determinants of effective quality systems and the long-term added value of quality systems for hospitals. The main research questions of this thesis are:

(1) Does having a hospital quality system lead to higher quality of care?
(2) What are the working mechanisms of hospital quality systems that lead to higher quality of care?

Quality of care

The Institute of Medicine (IOM) has defined quality of healthcare as: *'The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'*.[4] In addition, the WHO describes quality of healthcare as follows: *'quality of care means that a health system should seek to make improvements in six areas or dimensions of quality'*.[5] These quality dimensions are (1) *effective care*, (2) *efficient care*, (3) *accessible care*, (4) *acceptable care*, (5) *equitable care*, (6) *safe care*.[5] Effective care means that healthcare should be delivered in a way that is evidence-based that it improves health outcomes for individuals and communities and that this care is based on need. Efficient healthcare means that care is delivered in a way that maximizes efficient use of resources (avoidance of waste). Accessible healthcare means that the delivery of care should be on time, geographically reasonable, and provided in a setting where skills and resources are appropriate to medical needs. Acceptable healthcare means that the design and delivery of healthcare should respond to and meet the needs, preferences and aspirations of individual service users and the cultures of their communities, encompassing the concept of patient involvement and promoting a culture of kindness, consideration and respect for those using the service. Equitable healthcare implies delivering healthcare that does not vary in quality because of personal characteristics of patients such as gender, race, ethnicity, geographical location, or socioeconomic status. And lastly, safe healthcare refers to delivery of healthcare that minimizes risks and harm to service users.[5]

Quality systems in healthcare

The implementation of quality systems in healthcare organizations is a strategy for quality assurance and quality improvement. The underlying assumption is that a quality system will improve the performance of an organization by facilitating and improving the processes within the organization. There are many different definitions for quality systems. Some are more general, such as the definition from ISO : *"A quality system is defined as the organizational structure, responsibilities, procedures, processes and resources needed to assure and improve the quality of care"*.[6] Others are more specifically applicable to the healthcare setting. In this thesis, we have adopted one such more specific definition of healthcare from the European research project 'Deepening our understanding of quality improvement in Europe (DUQuE)'[7]:*"A quality system is a set of interacting activities, methods and procedures used to direct, control and improve the quality of care"*.[7] There are various types of quality systems, each with their own interpretation, but one feature that quality systems have in common is that they almost always cover the following five domains in some form: policy and strategy, personnel, protocols and procedures, cyclical quality activity, and clients (i.e. patients, in the case of a hospital).[8] The key aspects of a quality system are therefore: (1) addressing the responsibilities of stakeholders; (2) procedures for process management; (3) human resource management; (4) continuous education, training and development of professionals targeted at both technical and non-technical skills; (5) leadership commitment; (6) analysis and monitoring of performance and continuous improvement and patients involvement.[8]

The effectiveness of quality systems in healthcare

Various studies have examined the relationship between quality systems or derivatives (such as hospital-level accreditation) and outcomes in terms of quality of care. See also Chapter 4 of this thesis. Shaw *et al.* studied the effectiveness of different forms of external quality assessment of hospitals and found that accredited hospitals performed better on patient safety outcomes.[9,10] Weiner *et al.* linked quality improvement with a set of patient safety indicators at the organizational level and found that higher percentages of physicians participating in quality improvement teams led to fewer postoperative complications and lower rates of technical difficulties with procedures.[11,12] Kunkel *et al.* found higher scores for structure and outcomes when the implementation of a quality system was initiated by managers and when staff provided input to the quality system design.

Subsequently, this was found to result in more advanced quality systems.[13,14] Groene *et al.* found that better-developed quality systems were associated with lower rates of hospital complications and to some extent with fewer hospital readmissions in Spanish hospitals.[15] However, the same study found no association between the maturity of the quality system and hospital mortality and length of admission.[15] The European research project DUQuE assessed the association between quality management and patient outcomes in a wider setting: the European Union.[7,16] Results from this project showed some associations between quality management measures at the hospital level and quality measures at the department level.[17] However, these associations were weak and the variability between countries was high.[17] Despite these examples from the literature, research into the relationship between quality systems and measures of quality and safety is limited and often restricted by small sample sizes and lack of availability of sufficient outcome measures.[12,14] Although implementing quality systems in healthcare aims to improve the quality of care and patient safety by improving the processes, no clear evidence can be found in the literature that this is actually the case. Furthermore, little is known about the mechanisms through which a quality system can lead to high quality of care.

Social context of the Dutch healthcare system

This thesis is based on research that was carried out in the Dutch hospital sector. In 2012, the hospital sector in the Netherlands consisted of 8 academic medical centres, 75 general hospitals and 23 teaching hospitals. Academic medical centres conduct scientific research and education for medical faculties and develop new medical technologies. General hospitals concentrate on treatment, nursing and the education of doctors and nurses. In the Netherlands, teaching hospitals provide specialized medical care and are committed to training and education. The level of care is generally complex and lies between that of general hospitals and academic centres. The number of hospitals has decreased over the years due to mergers. In 2012, 132,000 full time equivalents and 188,000 people worked at general hospitals. The number of medical specialists is 20,863.[18] In the Netherlands, most medical specialists are self-employed and work in just one hospital. These self-employed medical specialists work together with other medical specialists of the same specialty in so-called partnerships.

Various Dutch policies and national quality improvement activities that were aimed at improving the quality of healthcare shaped the way quality

and safety are embedded to date in healthcare organizations in the Netherlands. The three most important ones are:

1996: Quality Act
The Care Institutions Quality Act came into effect in the Netherlands in 1996. This act requires all care institutions to monitor, control and improve their own quality. The act imposes four requirements on care institutions: they must be responsible in their provision of care, their policy must be oriented towards quality, they must implement a quality system and must draw up an annual quality report. In response to these requirements, care institutions started setting up and implementing quality systems. These quality systems focused on monitoring care processes and preventing unintentional harm as the result of medical actions by putting the right preconditions in place for improving the quality of care.[8,19-21]

2003- 2005: Sneller Beter (Better Faster)
The national action programme *Sneller Beter* (Better Faster) was launched on 20 November 2003 as an initiative by the Ministry of Public Health, the Order of Medical Specialists, NVZ (Dutch Hospitals' Association) and V&VN (Dutch Nurses' Association). The programme was initiated since the improvement of quality in healthcare institutions was seen as unsatisfactory. The aim of *Sneller Beter* was to use three pillars to further encourage improvements in transparency, efficiency and quality: (1) creating quality awareness; (2) developing a national set of indicators for safer and better care, and (3) setting up a Quality, Innovation and Efficiency programme. A total of 24 hospitals took part in this third pillar of *Sneller Beter*. They were split up into three groups of 8 hospitals. Each group received support in implementing the programme for two years from a consortium.[22-25]

2008- 2013: Dutch Hospital Patient Safety Programme (Safety Programme)
The Safety Programme was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2013. The Safety Programme consisted of a safety management system and ten evidence-based patient safety themes; clinical guidelines were developed for each theme. Hospitals were given five years to implement these guidelines. In the spring of 2013, the final report was issued on the evaluation of the Safety Programme. The report showed that hospitals had improved in some of the patient safety themes, however for most of the themes there was no visible improvement.[26]

The development of quality systems in Dutch hospitals

The literature distinguishes several development phases in the implementation of a hospital quality system. These phases are described in Table 1. The higher the development stage, the further the quality system is implemented.

Table 1 Development stages of hospital quality systems.

Stage 0	Orientation and awareness	Little with respect to quality has yet been arranged in concrete terms, but people are starting to realize more and more that quality and quality assurance are important.
Stage 1	Preparation	The first steps towards setting up a quality system have been taken. A number of quality improvement activities may already be cautiously initiated.
Stage 2	Experimentation and implementation	The organization has already progressed quite some way in setting up policy, procedures and guidelines relating to quality for all parts of the quality system. However, these elements are not yet integrated into the operational processes.
Stage 3	Integration	All the elements of the quality system are integrated into the operational processes. This final stage is the ultimate aim of any organization, because it reflects the highest level of development of the quality system and a process of continuous quality improvement is in effect.

Adapted from: Wagner *et al.*, 1999.[8]

Since the Care Institutions Quality Act came into effect in the Netherlands in 1996, hospitals have started to implement quality systems within their organizations. Several studies have shown that quality systems of Dutch hospitals became more developed over the years.[19-22,27] However, the implementation took quite some time and at the last measurement in 2007, 35 per cent of hospitals had reached the highest stage of development ('Integration').[22] Attention to quality in the form of national quality improvement programmes and national quality policy such as *Sneller Beter* and the Dutch Patient Safety Programme stimulate structural quality and safety activities in healthcare organizations. These activities contribute to the

implementation of quality systems in healthcare organizations by providing a solid and structural basis for quality improvement at the system level. It is therefore expected that hospitals will have continued their efforts from 2007 onwards to develop their quality systems further. This is expected to result in a higher percentage of hospitals that have reached the 'Integration' stage of development compared to the last measurement in 2007.

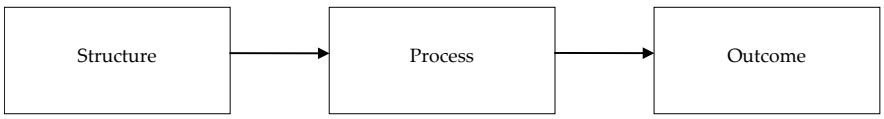
Chapter 2 describes the development (sometimes also referred to in the literature as the 'maturity') of quality systems in the Netherlands and the current state of implementation of hospital quality systems in Dutch hospital organizations. This chapter can be seen as defining the baseline to make it possible to answer the research questions in this thesis.

Theory and hypotheses

This section describes the main theory and hypotheses underlying this thesis. Five hypotheses were derived from the literature in order to answer the main research questions and the sub-questions of this thesis.

According to Donabedian's model of quality improvement (see Figure 1), quality can be achieved by means of a structure-process-outcome relationship in which the quality system –the structure– is thought of as improving the organizational processes that in their turn should positively influence quality of care –the outcomes.[28-30] The quality system is the structure within which quality improvement policies and quality improvement activities can be embedded and this quality system is hypothesized to have an influence on quality improvement activities at the process level. The improved processes in their turn influence the outcomes of the organization.[5,28-30]

Figure 1 Donabedian's model of quality improvement



Based on Donabedian's model, it can be assumed that the implementation of a quality system is positively related to outcomes of the organization. In organizations with a fully implemented quality system, the outcomes of the organization will be better than in organizations where the quality system is

less than optimally implemented. In a well-developed quality system the quality activities are integrated into the daily working processes throughout the healthcare organization. This leads to broad and systematic quality improvement. This is visible through a reduction of variation in results of the healthcare organization and improvement of these results over time.

Hypothesis 1: A higher degree of implementation of the hospital quality system leads to improved outcomes of the organization.

Furthermore, it can be assumed that this positive relationship between the quality system and outcomes of the organization results from a positive relationship between the implementation of the quality system and the improvement of organizational processes. In organizations with a fully implemented quality system, the processes will be better designed compared to organizations where the quality system is implemented to a lesser extent. In a developed quality system the quality activities are integrated into daily working processes throughout the healthcare organization. The policies and management of the healthcare organization ensure that this is done at the process level of organizations as well and this becomes visible in a reduction of variation in processes of the healthcare organization and improvement of these processes over time.

Hypothesis 2: A higher degree of implementation of the hospital quality system leads to improved processes in the organization.

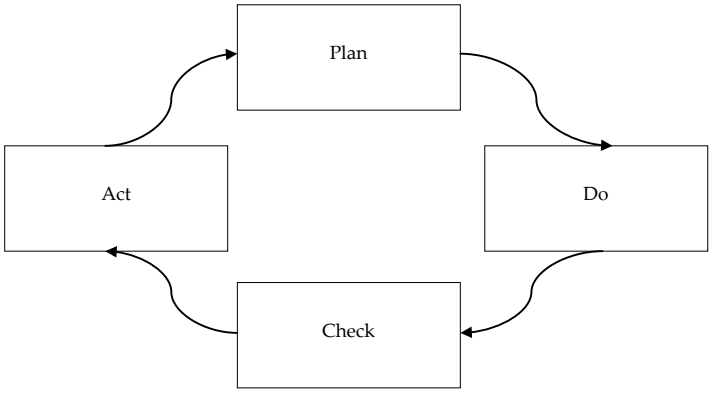
In turn, these improved processes in the organization are thought to have a positive effect on the outcomes of the organization. Well-designed processes standardize working methods and the behaviour of healthcare professionals working according these methods and this leads to a reduction of the variation in outcomes of the organization.

Hypothesis 3: Improved processes of the organization lead to improved outcomes of the organization.

One important aspect of quality improvement is the continuous nature of the improvements, which can lead to improvement of results over time: hospitals use the results of their organization to learn from, and adjust the structure of their organization. According to Deming, all improvement activities should follow four steps (see Figure 2). First, an organization plans which organizational areas they would like to improve and *how* they want to improve these areas: 'Plan'. Second, this plan is carried out in practice: 'Do'.

Third, the results of the improvement effort are checked. It is important to evaluate whether the activities have led to the desired outcomes: 'Check'. And last, this information is used to take action and adjust the original plan where necessary: 'Act'. These four steps are necessary to achieve a cycle of continuous improvement in the outcomes of an organization.[31,32]

Figure 2 The Deming cycle of Plan-Do-Check-Act



In hospitals with more developed quality systems, it can be assumed that the four steps of the plan-do-check-act model are being followed in quality improvement efforts and a cycle of continuous quality improvement is visible in these organizations. In other words, the hospital is systematically using the results of the organization to adjust its quality policy and strategy at the system level. This creates a cycle of continuous improvement which becomes visible not only in an improvement of results but also in improvement of the system itself over time.

Hypothesis 4: In a more developed quality system, the outcomes of an organization feed back into the structure of the organization and this forms a cycle of continuous quality improvement.

Surrounding the structure-process-outcome relationship is another key aspect of a quality system: the people who have to work in this system and have to interact with the system. In hospitals, the main actors in the system are management (top management and middle management), healthcare professionals and patients. Patients have to interact with the quality system but are also part of the outcome of the system. The degree to which a quality

system can attain its desired effects (higher quality of care) is modified by the attitudes and behaviour of these actors. In this thesis, we focus mainly on healthcare professionals as actors affecting the quality system. In hospitals where the awareness of the importance of quality improvement is high amongst healthcare professionals, it is more likely that healthcare professionals act according to the standards and rules set by the quality system. Compliance with these standards and procedures is thought to be positively related to positive organizational outcomes at the process and patient levels. Non-compliance by healthcare professionals could hamper the degree to which the mechanism of a quality system can function optimally. One important precondition for a quality system is therefore awareness among healthcare professionals of the importance of quality of care (attitudes of healthcare professionals) and their compliance with standards and procedures aimed to improve the quality of care (behaviour of healthcare professionals). Awareness of the importance of quality and safety creates an environment where it becomes natural to act according to standards and procedures set by the quality system. This is a prerequisite for quality policy and strategy at the system level to seep through to the organizational results, thereby optimizing the functioning of the quality system.

Hypothesis 5: The relationship between the level of development of a quality system and the processes, and the relationship between the processes and outcomes of a hospital are modified by the degree to which healthcare professionals are aware of the importance of standards and procedures set by the quality system and act accordingly.

Research questions in this thesis

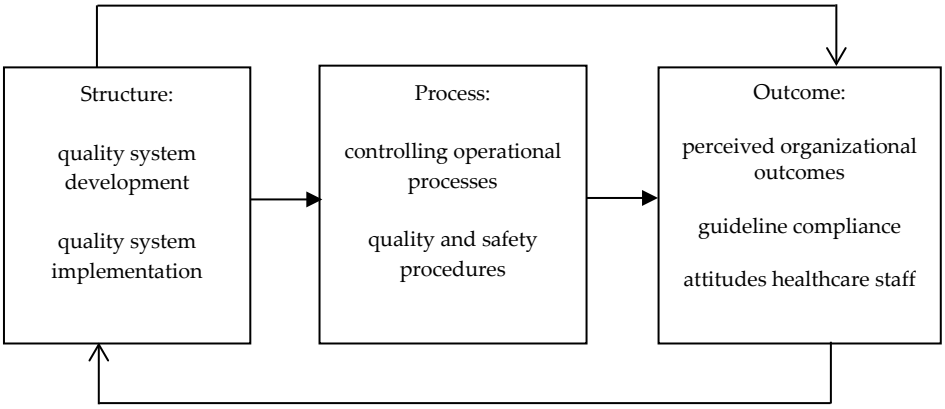
In order to answer the main research questions, the sub-questions and to test the hypotheses, the following research questions were addressed in the following six chapters of this thesis.

1. *How did quality systems in Dutch hospitals develop between 1995 and 2011? (Chapter 2)*
2. *What is the relationship between the implementation of a hospital quality system and perceived outcomes of the hospital? (Chapter 3)*
3. *What is the relationship between the implementation of a hospital quality system and measures at process level? (Chapter 4)*
4. *What are the ecometric properties of a measurement instrument for controlling operational processes in hospital departments? (Chapter 5)*

5. *To what extent do healthcare professionals comply with a procedure intended to prevent wrong surgery in hospitals and what factors are associated with compliance? (Chapter 6)*
6. *How do healthcare professionals assess risks in operational processes related to procedures in their daily work and how do hospital departments differ in their risk assessments? (Chapter 7)*

The various elements from the research questions can be translated into Donabedian's model of quality improvement. Figure 3 shows the place of the different elements of this thesis in the model of quality improvement.

Figure 3 This thesis in terms of Donabedian's model of quality improvement



Methods

This results of this thesis are based on a combination of several research methods. Quantitative as well as qualitative data were used to address the main research questions and sub-questions. To answer the research questions, we have used triangulation of data sources. Each of the different methods will be described briefly in the following section; a more detailed description of the methods that were used in this thesis can be found in chapters 2 to 7.

Chapter 2 relies on longitudinal questionnaire survey data about quality systems in hospitals, with measurements made in 1995, 2000, 2005, 2007 and 2011. The chief executive officers of all Dutch hospitals were approached

with a request to complete a written questionnaire about the quality management and safety management in the hospital in which they worked. Questions were asked within five different domains about quality improvement activities that the hospital had undertaken. The results of the questionnaires were used to describe how the development of hospital quality systems has progressed in the period between 1995 and 2011 in the Netherlands.

In Chapter 3, the same longitudinal questionnaire survey data was used in a different manner. The questions from the questionnaire were regrouped in order to reflect the five enabler and the four results criteria of the European Foundation for Quality Management model (EFQM Excellence Model). This data was then used to measure the performance of hospitals on enabler and results criteria over time (1995-2011), to see whether high scores on enabler criteria would lead to higher scores on results criteria, and to test a feedback loop of the results criteria into the enabler criteria.

Chapter 4 uses the data from the final measurement of the questionnaire on quality systems, the measurement in 2011. This data is linked to five process indicators that were measured in the Safety Programme. The Safety Programme was a national programme aimed at improving ten patient safety themes in hospitals. The Safety Programme was carried out between November 2011 and December 2012 in 20% of all Dutch hospitals (18 hospitals participated). Two academic hospitals, four teaching hospitals and twelve general hospitals were included in this evaluation study, which assessed the implementation of patient safety themes. The process indicators from the Safety Programme that were used in Chapter 4 were: (1) wrong surgery, which reflected the percentage of operations in which all the three steps of a Time-Out Procedure (TOP) were performed correctly before the start of an operation; (2) early recognition and treatment of pain, which reflected the percentage of postoperative patients who were in pain as measured in a standardized way three times a day during the first three days after surgery; (3) contrast-induced nephropathy, this was an indicator for the percentage of high-risk patients who received an intervention (hydration) to prevent contrast-induced renal failure as a result of contrast administration; (4) medication reconciliation, which is the percentage of patients for whom the bundle of medication reconciliation on admission and discharge had been implemented completely; (5) high-risk medication, reflects the percentage of administration processes in which all recommended steps have been followed by the person administering the drug. The data for 'Early recognition and treatment of pain', 'Contrast-

induced nephropathy' and 'Medication reconciliation' was extracted from patients' records. The data for 'Wrong surgery' and 'High-risk medication' was obtained through observations.[26]
Chapter 5 describes the development and validation of an instrument for prospective risk analysis at the department level in hospitals. The questionnaire that was used is called Tripod Delta and was originally developed for the petrochemical industry. The questionnaire asks the healthcare professional questions about perceived risks in five organizational domains: (1) Procedures, (2) Training, (3) Communication, (4) Incompatible Goals and (5) Organization. In our study we modified the questions slightly so that they were applicable in the healthcare sector. This altered version was named Tripod Delta Health Care and was administered in thirteen departments of two Dutch hospitals. A multilevel method called ecometrics was used to evaluate the validity and reliability of the questionnaire. An ecometrics approach allows differences between departments and individual perceptions to be distinguished so as to ensure that differences in risk analysis between departments are really reflecting differences between departments and not between individuals.

Chapter 6 uses data from a larger evaluation study of the Safety Programme, focusing on one of these patient safety themes: the prevention of wrong surgery. The goal was to have ten observation days per hospital at intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably involving different surgeons and different surgical procedures. One observer per surgical procedure evaluated whether the TOP was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure and side/site, attention of the team (focus), completeness of the team and interruptions, plus several background variables such as the type of surgical procedure, the patient's age and sex.

Chapter 7 uses a mixed method approach: the validated Tripod Delta Health Care was measured in ten departments of one general Dutch hospital and this was complemented by interviews about the attitudes of healthcare professionals towards the use of procedures in their work. These two data sources were combined to give a broad overview of risk perceptions and attitudes concerning procedures in the daily work of healthcare professionals.

Outline of this thesis

This thesis comprises eight chapters, including this introductory chapter. Chapter 2 describes the development of hospital quality systems in Dutch hospitals between 1995 and 2011. Chapter 3 describes the degree to which the EFQM Excellence Model in hospitals can be used as a framework for Total Quality Management within organizations. Chapter 4 takes a closer look at the association between quality system development in hospitals and quality indicators at the process level. In Chapter 5, a measurement instrument for prospective risk analysis at the department (process) level was validated by describing the ecometric properties of a questionnaire that was originally developed for the petrochemical industry and modified for a healthcare setting for the purposes of this thesis. In Chapter 6, the compliance of healthcare professionals with a safety procedure to prevent wrong surgery in hospitals is described and possible explanations for low compliance are discussed. Chapter 7 describes the attitudes of healthcare professionals towards the use of procedures in their daily work and highlights barriers and facilitators in the use of procedures. Chapter 8 provides a summary and general discussion of the results that were presented in this thesis. Furthermore, the methodological considerations, implications for practice and future research are formulated.

This thesis is based on six papers, each written to be read as a stand-alone paper in its own right. Some degree of overlap across chapters is therefore inevitable.

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The development of quality systems in Dutch hospitals between 1995 and 2011

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Abstract

This chapter describes the development of quality systems in Dutch hospitals between 1995 and 2011. Research using longitudinal questionnaire surveys among all Dutch hospitals in 1995, 2000, 2005, 2007 and 2011 measured how the quality systems have progressed. In 1995, 52% of the hospitals taking part were still in the preparation stage of their quality system development, whereas 53% of participating hospitals had all the requisite components of a quality system by 2011. By 2011, 45% of the hospitals had also succeeded in integrating these elements into a system for continuous quality improvement, meaning that the highest level of quality system development had been achieved. If the development of quality systems is examined in terms of the separate quality system components, it can be seen that this development did not progress in the same way for all elements. It is also possible to see that quality systems at larger hospitals have developed further. Future research should focus on additional explanations of differences between hospitals in the development stages of their quality systems and the effects that these systems have on the quality of care.

Introduction

This chapter describes the development of quality systems in Dutch hospitals between 1995 and 2011.

The Care Institutions Quality Act came into effect in the Netherlands in 1996.[1] This act requires all care institutions to monitor, control and improve their own quality. The act imposes four requirements on care institutions: they must be responsible in their provision of care, their policy must be oriented towards quality, they must implement a quality system and must draw up an annual quality report.[2] In response to these requirements, care institutions started setting up and implementing quality systems. These quality systems focused on monitoring care processes and preventing unintentional harm as the result of medical actions by putting the right preconditions in place for improving the quality of care.[3,4]

The implementation of quality systems in all care sectors was first mapped out in 1995, followed by another measurement in 2000.[3-6] Comparison of the results from these two measurements showed that development was not progressing as had been hoped. One of the measures that was taken at that point to speed up development was a nationwide action programme for hospitals under the name *Sneller Beter (Better Faster).* This action programme was launched on 20 November 2003 as an initiative by the Ministry of Public Health, the Order of Medical Specialists, NVZ (Dutch Hospitals' Association) and V&VN (Dutch Nurses' Association).[7] The aim of *Sneller Beter* was to use three pillars to encourage improvements in transparency, efficiency and quality: (1) creating quality awareness; (2) developing a national set of indicators for safer and better care, and (3) setting up a Quality, Innovation and Efficiency programme. A total of 24 hospitals took part in this third pillar of *Sneller Beter*. They were split into three groups of 8 hospitals. Each group received support in implementing the programme for two years from a consortium.[7-9]

During the time the *Sneller Beter* implementation programme was running, several interim evaluations were carried out.[10,11] The final evaluation followed in 2008. One part of it involved obtaining insights into the effect of the implementation programme on the development of quality systems.[9,12] To that end, the development of the quality systems was measured in 2005 and 2007 according to the same method that had been used in previous measurements.[13] This showed that quality systems had continued to develop and that this development was stronger in hospitals where *Sneller Beter* had

been introduced than in hospitals where it had not. However, the development stage of the quality systems of *Sneller Beter* hospitals was not significantly higher than in the other (non-participating) hospitals.[9,12,14]

The Dutch Hospital Patient Safety Programme was then set up in 2008. This programme was a combination of the implementation of a safety management system and ten evidence-based substantive safety themes.[15] There were two goals to this programme. Firstly, all hospitals had to have an accredited safety management system by the end of 2012. Secondly, all the defined objectives for the ten safety themes had to have been achieved. A safety management system would let hospitals continuously signal risks and carry out improvements; this is seen as embedding patient safety in the organization.[15] There is an ongoing discussion as to whether the effects of safety interventions can in fact be demonstrated in the first place.[16] In the spring of 2013, the final report was issued about the evaluation of the Safety Programme and this was supposed to show whether hospitals had achieved the intended safety objectives.

In this chapter we examine whether the development of quality systems was continued during the timeframe of the Safety Programme. The objective of this study is to determine how far quality systems in Dutch hospitals have developed since the previous measurement in 2007 and how that development relates to earlier measurements from 1995 onwards. The question being studied is:

- *How has the development of quality systems in Dutch hospitals progressed between 1995 and 2011?*

Quality systems

There are various types of quality systems, each with their own interpretation, but one common feature is that they almost always cover the following five domains in some form: policy and strategy, personnel, protocols and procedures, cyclical quality activity, and clients (i.e. patients, in the case of a hospital).[4,17] Each of these domains covers a number of activities. The level of development or 'maturity' of the quality system can be derived from the extent to which these activities are carried out systematically.

The literature distinguishes four development stages of quality systems.[4,17-22] First comes Stage 0, 'orientation and awareness'. In this stage of the quality system, little has yet been arranged in concrete terms, but people are starting

to realize more and more that quality and quality assurance are important. The next stage is the 'preparation' phase (Stage 1), in which the first steps towards setting up a quality system are taken. A number of quality improvement activities may already have been cautiously initiated. In Stage 2 ('experimentation and implementation'), the organization has already progressed quite some way in setting up policy, procedures and guidelines relating to quality for all parts of the quality system. However, these elements are not yet integrated into the operational processes. This is the case in the final stage, 'integration' (Stage 3). Here, not only are the quality improvement activities integrated into the working processes and the daily practice, but policy is also systematically adjusted as a result of quality information (a so-called feedback loop). In this stage, there is a cyclical process of continuous quality improvement. This final stage is the ultimate aim of any organization, because it reflects the highest level of development of the quality system and a process of continuous quality improvement is in effect.[4]

Method

To determine the development of quality systems in Dutch hospitals, longitudinal questionnaire-based research was done in the period from 1995 to 2011 among all Dutch hospitals. Measurements were made in 1995, 2000, 2005, 2007 and 2011.

Respondents

Chief executive officers of all Dutch hospitals were approached with a request to complete a written questionnaire about the quality management and safety management of the hospitals at which they worked. If appropriate, the questionnaire could also be completed by the hospital's quality officer or with his/her assistance. There was a space on the questionnaire to indicate who had filled it in. The average response over the years combined is 73%. One explanation for the high response rate is that feedback reports were offered, in which the hospital's own responses were compared with the answers of the overall group of participating hospitals. As a result of several hospitals having merged during the observational period, the number of hospitals that were approached was not the same in all years; the number of hospitals in the Netherlands has decreased over time.

The questionnaire

The questionnaire that was used in this study was developed and validated in 1995.[4] It contains questions about quality management and safety management in hospitals. Questions were asked within five different domains about quality improvement activities that the hospital had undertaken (see Table 1). The five domains used for this are features that virtually all quality systems have in common: policy and strategy, human resource management protocols and procedures, systematic quality improvement, and patient involvement. The questionnaire was used in the same format at each of the recurring measurement moments. In the policy and strategy domain, the questions asked were about whether the hospital had certain quality documents, such as *a written description of the mission, a written description of the quality policy, or a quality manual.* Respondents could choose to answer the question with 'yes, we have it', 'under development' or 'no'. In the human resource management domain, respondents could say how much their personnel policy was focused on quality policy. An example statement could be *new staff get quality assurance training*. Respondents could place a cross on a five-point agreement scale running from 'None' to 'Extremely', with the last of these representing the desired situation. In the protocols and procedures domain, the questions were about whether particular protocols were present in the organization, for example for *preoperative screening* or *infection prevention*. In the systematic quality improvement domain, respondents could indicate whether particular activities took place in their hospital and whether the results of those activities were demonstrably used (cyclical) to adjust policy. Examples of systematic quality activities are *incident analysis* and *internal inspections.* Finally, there was the patients domain. Here, respondents were asked to what extent patients and/or their interest groups were involved in certain quality activities such as *developing quality criteria or patient satisfaction surveys*.[4,17,23] The division into stages is cumulative, i.e. hospitals enter a given phase when they are carrying out at least one of the activities from that stage and are carrying out virtually all the activities of the underlying stages. In addition, this subdivision assumes that any hospital is in principle capable of reaching the highest level.

Table 1 Quality improvement activities broken down into five categories and four development stages

	Policy and strategy *Does your hospital have the following documents?*	**Human resource management** *How much does your personnel policy focus on quality policy?*	**Protocols and procedures** *What protocols are used?*	**Systematic quality improvement** *Do the following activities take place in your hospital? If so, are the results demonstrably used for adjusting the policy?*	**Patient participation** *Which quality activities involve patients and/or organizations representing their interests?*
Stage 0: Orientation and awareness	- mission - product description	- encouraging professional development	protocols for: - specific treatment	- peer review - care plans	- patients are not involved
Stage 1: Preparation	- quality policy - institutional quality working plan - annual quality report	- training for the managers - training for the staff - involvement in quality activities during working hours - indicated by the board	- patient information - diagnostic related groups - reserved treatments - medical aids	- committees - complaints registration - clients' council - job assessment interviews	- patients are involved in: - discussing results - evaluating whether goals have been achieved

Table 1 Quality improvement activities broken down into five categories and four development stages (*Continued*)

	Policy and strategy *Does your hospital have the following documents?*	**Human resource management** *How much does your personnel policy focus on quality policy?*	**Protocols and procedures** *What protocols are used?*	**Systematic quality improvement** *Do the following activities take place in your hospital? If so, are the results demonstrably used for adjusting the policy?*	**Patient participation** *Which quality activities involve patients and/or organizations representing their interests?*
Stage 2: Experimentation and implementation	- quality working plan for some departments - quality working plan for all departments	- management controls - monitored by the board - new staff selected on quality attitude	- cooperation with other providers	- satisfaction surveys - research into needs - management information system - accreditation	- development of quality protocols or guidelines - development of criteria
Stage 3: Integration	- quality manual - institutional quality working plan	- systematic selection and training depending on the priorities in the quality policy	- patient routing - critical incidents	- internal auditing - systematic satisfaction surveys among patients	- participation in committees or improvement projects

(modified version, Sluijs & Wagner, 2000)

Data collection
Respondents were approached in writing with a request to complete the questionnaire about quality management and safety management. The study was explained in an accompanying letter. Reminder letters were sent after two and four weeks. In exchange for their participation, the hospital received a feedback report in which the results of their own hospital were compared against the (anonymised) results of the overall group of hospitals taking part.

Data analysis
The answers to the questionnaire were used for obtaining a picture of quality improvement activities at the hospitals. This was used as the basis for determining the development stage of hospital quality systems. The degree of development represented by each item on the questionnaire was determined and used as the basis for assigning a score that could be used for categorizing the development stage (see Table 1). Descriptive statistics were used to determine how the development of quality systems in hospitals progressed between 1995 and 2011.

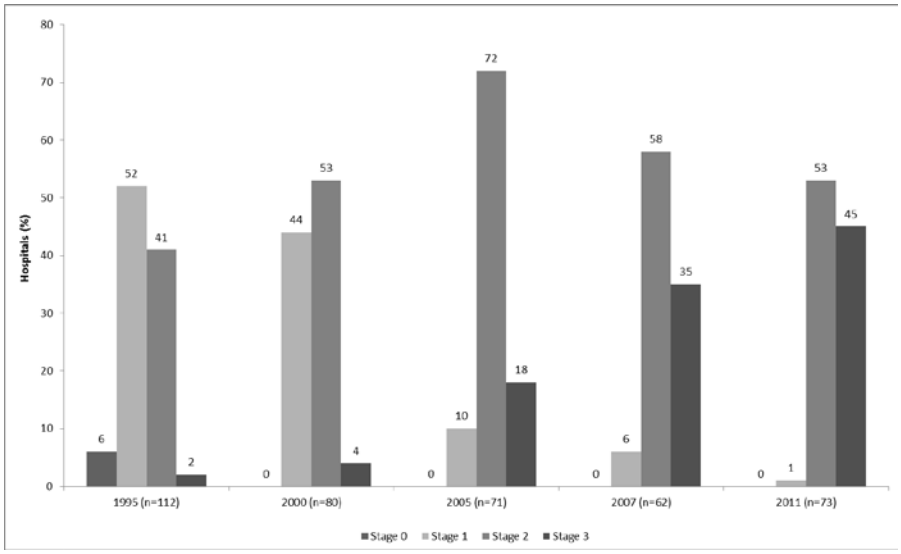
Multi-level analyses were performed in order to determine whether the levels of quality systems had progressed over time. Multi-level analysis was needed because of the hierarchical data structure, which meant that the various measurements from the same hospital were not independent of each other. In addition, another important reason for choosing multi-level analysis was that this technique is able to handle incomplete datasets. The dataset in this study is incomplete because not each hospital participated in the study every year that measurements were made. A multi-level model is able to make allowances for this. Hospitals that merged were handled as follows in the analysis. During the study period, two possible situations could arise: (1) two or more hospitals merged, and in doing so formed one new hospital organization, or (2) a hospital ceased to exist. In the first case, this could result in two hospitals in the dataset with identical numbers, for instance when both hospitals completed the questionnaire for the measurement separately after they had merged. In that case, a new identification number was created for one of the two hospitals. In the second case, the hospital disappears as a unit in the analysis and its identification number will have missing values for the remainder of the study period.

The multi-level analyses also examined whether the development of quality systems varied between larger and smaller hospitals. To do so, the number of reported FTEs (full-time equivalents) for the hospitals was included in the

model as a variable. Because only 54 of the 112 hospitals (48%) from 1995 could be identified, it was decided that the data from 1995 should not be included in the multi-level analyses. These analyses therefore only cover the period from 2000 to 2011 (in the descriptive analyses all measurement years were included). The descriptive analyses were carried out using STATA version 11.0. The multi-level analyses were carried out with MlwiN version 2.24.

Results

Figure 1 The development of quality systems in Dutch hospitals between 1995 and 2011.



Stage 0 = Orientation and awareness; Stage 1 = Preparation; Stage 2 = Experimentation and implementation; Stage 3 = Integration.

Figure 1 shows the development of quality systems between 1995 and 2011, showing that quality systems have kept developing further over the years. By 2011, there were virtually no hospitals any more that were in the lowest two stages of development (Stage 0 and Stage 1). By 2011, 45% of all hospitals had reached the highest stage of development and a further 53% of hospitals were in the penultimate development stage. Those figures were 35% for Stage 3 and 58% for Stage 2 in 2007. The development of quality systems seems at first glance to have slackened off somewhat between 2007 and 2011, but statistical checks showed that this was not statistically significant (the results of this analysis have not been included in the tables).

Table 2 Average score for the development stage of the quality system and average scores for domains of the quality system between 1995 and 2011

	1995 (n=112)			2000 (n=80)			2005 (n=71)			2007 (n=62)			2011 (n=73)		
Domain	Avg	SD	Range	Avg	SD	Range	Avg	SD	Range	Avg	SD	Range	Avg	SD	Range
Policy and strategy	1.53	0.64	0.00-2.00	1.73	0.64	0.00-3.00	2.15	0.47	0.00-3.00	2.40	0.49	2.00-3.00	2.48	0.53	1.00-3.00
Human resource management	1.72	0.84	0.00-3.00	1.30	0.58	1.00-3.00	2.56	0.58	1.00-3.00	2.53	0.53	1.00-3.00	2.67	0.55	1.00-3.00
Protocols and procedures	1.81	0.84	0.00-3.00	2.10	0.67	1.00-3.00	2.30	0.68	1.00-3.00	2.53	0.65	1.00-3.00	2.62	0.59	1.00-3.00
Systematic quality improvement	1.00 [a]	0.00	1.00-1.00	2.05	00.00	0.00-3.00	1.72	0.86	1.00-3.00	00.00	0.97	0.00-3.00	2.39	0.88	1.00-3.00
Patient participation	1.53	1.06	0.00-3.00	1.28	1.23	0.00-3.00	1.62	1.10	0.00-3.00	1.94	1.05	2.00-3.00	1.68	1.03	0.00-3.00
Stage [b]	1.39	0.62	0.00-3.00	1.60	0.56	1.00-3.00	2.08	0.53	1.00-3.00	2.29	0.58	1.00-3.00	2.44	0.53	1.00-3.00

a missing b stage 0 = Orientation and awareness; Stage 1 = Preparation; Stage 2 = Experimentation and implementation; Stage 3 = Integration.

Table 2 shows the average scores of all hospitals for all five quality system domains over the course of the years. This shows again that quality systems kept developing further during the period from 1995 to 2011. In 1995, the average development stage was 1.39 (SD 0.62) and in 2011 it was 2.44 (SD 0.53). If the development for each domain of the quality systems is examined separately, it is noticeable that the progression is not the same in all domains. In particular, the pattern for the patient participation domain is variable. At the last measurement, the average score went down from 1.94 (SD 1.05) in 2007 to 1.68 (SD 1.03) in 2011.

Table 3 Multi-level analysis of the effect of time and type of hospital on the development stage of quality systems between 2000 and 2011

	Model 0 (empty model) n=284	**Model 1 (model 0 + time) n=284**	**Model 2 (model 1 + FTE) n=270**
Fixed effects	B coefficient (SE)	B coefficient (SE)	B coefficient (SE)
Development stage of the quality system intercept (constant)	2.084 (0.033)***	1.728 (0.045)***	1.657 (0.051)***
Time (2000-2011)	-	0.064 (0.006)***	0.062 (0.006)***
FTE (FTE x 1000)	-	-	0.052 (0.017)**
Random effects			
Variance components:			
- hospital (level 2)	0.023 (0.017)	0.039 (0.014)**	0.029 (0.013)*
- moment of measurement (level 1)	0.241 (0.025)***	0.154 (0.016)***	0.158 (0.017)***
-2 log likelihood (IGLS)	425.534 (ref)	328.086	306.727
Deviance test	Reference	P<0.001	P<0.001

* p<0.05, ** p<0.01, *** p<0.001

Table 3 shows the results of the multi-level analyses. The first column contains the baseline model and shows the average development stage. The random effects show significant differences between the measurement moments. In model 1, time has been included and reduces the variance between the measurement moments and the variance between hospitals has become statistically significant. The deviance test shows that model 1 fits the

data significantly better than model 0 ($p<0.001$). This means that the differences in development stages over time are not caused by differences in the composition of the group of hospitals taking part over the years. Instead, over time the development stage advanced. The third column shows the results of model 2, in which the number of FTEs has been added as a variable. This variable shows the effect of hospital size (expressed in FTEs). The deviance test shows that model 2 fits the data significantly better than model 1 ($p<0.001$). This means that larger hospitals are at a more advanced stage of development.

Discussion

The aim of this study was to obtain insight in how the development of quality systems in Dutch hospitals progressed between 1995 and 2011. The results of this study show that there has been growth in the development stages of quality systems at hospitals from the initial measurement in 1995 onwards, and that this growth continued until to the last measurement in 2011. If this development is split up into the various quality system domains, it becomes clear that the development did not progress in the same way in all domains. One striking finding in this respect is the recurrent drop in the patient participation domain. Patient participation has developed strongly over recent decades; it is seen as a way of improving the quality of care.[24] A wide range of methods are used for patient participation, such as focus groups, mirror interviews, participation in patients' councils and working groups. The high level of institutionalization of participation, plus proto-professionalization of patients, presents problems that make it difficult to convert patient participation into a genuine contribution to the quality of care.[25] The effects of participation are therefore also insufficiently proven, so there is some reluctance on the part of hospitals and authorities to encourage participation.[25] In addition, there is another issue in the specific case of participation in the development of guidelines. Guidelines in the care sector are largely derived from evidence-based medicine (EBM) and there is a gap between EBM and patients' experiences.[25] There is a risk that experiences may not be included in the final guideline at all because it can be difficult to integrate patients' experiences with EBM.[25] The above could be a possible explanation for the scores observed in the patients domain.

The analyses have also shown that the quality systems of larger hospitals are further developed. This is consistent with research that makes the case for increased scale in the care sector in order to improve quality.[26-29] It is however

unclear what the effects of hospital mergers are and it has not yet been demonstrated convincingly enough that mergers do lead to improved quality of care.[26-29] The number of hospitals in the Netherlands went down from 143 in 1995 to 92 in 2012. This drop is primarily the consequence of mergers that have resulted in larger hospital organizations. The results of this study contribute to the discussion about the effects of increasing scale; they seem to suggest the increasing scale does indeed have a positive effect on quality as systems or continuous quality improvement are then better developed.

In general, the results of this study suggest that hospitals should continue to invest in all the individual domains of the quality system, even if a high level has already been attained. If this is not done, parts of the quality system may then regress to lower development stages. In addition, it transpires that it is difficult to reach the highest level of quality system development, in which quality improvement is integrated into the day-to-day working processes and policy is systematically adjusted. That can be concluded from the fact that more than half (53%) of the hospitals taking part have not yet reached the highest stage of development. These hospitals do have all the requisite elements of a quality system, but the various parts are not yet integrated to create a system of continuous quality improvement.

The results of the present study can be compared against European research into the implementation of quality systems. One of the first large-scale European projects was ExPeRT, in which the strengths of ISO, EFQM, peer review and accreditation were examined.[30] The ENQual network was then set up as a European cooperative project that emphasized exchange of knowledge relating to quality management. A questionnaire was developed in ENQual that can be used for quantifying quality management at hospitals.[31] The MARQuiS project was the first to investigate the added value of various quality improvement strategies used in European hospitals.[31] The results showed that there were hospitals in all the participating countries that did have quality systems that were well advanced, but that there were large differences both within countries and between countries. The variation within countries was actually almost as large as the variation between countries.[31,32]

Limitations of the study

One of the possible limitations of this study is the self-reporting by chief executive officers and quality officers. It is in the hospitals' own interest to present themselves favorably, particularly in times such as these when increasingly stringent requirements are being imposed and more and more data is being made public because of transparency obligations. On top of that, there may have been changes at any given hospital within the Board of Directors or of quality officials, meaning that the answers from any one hospital over the years may not always have been provided by the same person. However, the wide range of scores, the general tendency of a shift to higher stages, the anonymity of the respondent and the provision of feedback reports for benchmarking do seem to suggest that the questionnaires were filled in honestly. A second limitation is that the questionnaire gives a picture of the hospital as a whole, without providing any insights into differences between and/or within departments or parts of the hospital. The possibility of such differences should be taken into account when interpreting the results.

Future research

Future research should focus on an explanation of differences between hospitals in the development stage of their quality systems. What factors or conditions contribute to an advanced stage, and can hospitals exert any influence on this themselves? Possible explanations can be sought in organizational characteristics such as the complexity (e.g. differences between general, academic, clinical and specialist hospitals) or whether they have recently been through a merger. As discussed earlier, it has not been demonstrated that scale increases will achieve the intended effects. The relatively limited statistical power of the current study meant that it was not possible to include further variables in the analyses.

In addition to investigations into possible causes of differences between hospitals in the structure of their quality systems, it is also important to pay attention to the effects that these systems have on the quality of care. A quality system is after all intended to guarantee and improve the quality of care: it is seen as a precondition for guaranteeing and improving patient outcomes. However, little or no research has been done into the effects of quality systems. Research that has been carried out is often based on small samples, or focuses on a single measure of outcome or a single organization.[33] Weiner et al.[33] were one of the first to find a relationship between the number of physicians participating in quality improvement teams and two measures of patient safety: the number of post-operative

complications and the number of technical problems with procedures. Groene et al.[32] found a relationship between the 'maturity' of a quality system and a lower number of hospital complications. The European DUQuE (Deepening our Understanding of Quality Improvement in Europe) research project is currently looking at the relationship between quality systems and the quality of care in European hospitals.[34] The results of that project are expected. Future research must fit in with this and should focus on the relationship between quality systems and care outcomes.

Conclusion

The development of quality systems in Dutch hospitals between 1995 and 2011 shows that they are progressing: almost half of the hospitals had reached the cyclical stage of quality improvement by 2011. However, attaining this highest stage in which the quality system is integrated into the day-to-day working processes and in which quality is embedded in the organization seems to be a difficult final step for the remaining half of hospitals. These hospitals do have all the components of the quality system, but have not yet managed to integrate them into a system in which quality information is used in a systematic feedback loop to adjust policy.

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3

The EFQM Excellence Model as a framework for Total Quality Management in healthcare: results of a longitudinal quantitative study

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Abstract

Purpose

To guide organizations towards Total Quality Management (TQM), various models have been developed such as the European Foundation for Quality Management Excellence Model (EFQM Excellence Model). This paper is a longitudinal investigation of whether the EFQM Excellence Model can serve as a framework for TQM in healthcare.

Methodology

Data on a national representative survey about quality management in the hospital population in the Netherlands were used to conduct this study. The survey had five measurement points between 1995 and 2011.

Findings

The results of our study show that applying the EFQM Excellence Model in hospitals is related to improvement in organizational performance over time, a feedback loop in which hospitals use their results to further improve their organizational processes is established, and improvement is stronger when all the model's elements are considered simultaneously.

Practical implications

The results of our study can be applied by quality managers of healthcare institutions to achieve higher quality of care.

Value

Previous research on the relationship between the EFQM Excellence Model and TQM neglects two essential characteristics of the TQM philosophy, namely the holistic perspective on quality management and the presumed feedback loop of organizational performance that feeds a cycle of continuous quality improvement. Our study provides new insights into the long term benefits of applying the EFQM Excellence model as a framework for TQM in healthcare.

Introduction

The last decades, the standards and expectations of customers have risen and as a result there has been a growing concern about quality of goods and services. In response, many quality improvement methods have been developed. One of these methods is called Total Quality Management (TQM). TQM is defined as an integrative management philosophy that aims for continuous improvement in the quality of products and services within an organization.[1-5] Various models have been developed to guide organizations towards TQM such as the Malcolm Bridge Quality Award and the European Foundation for Quality Management Excellence Model (EFQM Excellence Model).[2,6]

Previous research into the relation between the EFQM Excellence Model and TQM neglects two essential characteristics of the TQM philosophy, namely: (1) the holistic perspective on quality management and (2) a continuous cycle of quality improvement that is presumed to be established through a feedback loop of organizational performance.[2,7] Previous research was mostly based on testing isolated relations of the EFQM Excellence Model within cross-sectional study designs.[2,7,8] However, a holistic approach that takes account of all organizational aspects and organizational performance over a longer period of time is required. The aim of this paper is to investigate whether the EFQM Excellence Model can serve as a framework for TQM and takes a longitudinal approach. Our study contributes to a deeper understanding of the value of applying the EFQM Excellence Model. The following research question is empirically tested in this paper by means of longitudinal survey research: *'Can the European Foundation for Quality Management Excellence Model serve as a framework for Total Quality Management?'.*

We chose to conduct this research in a particular sector with a high societal relevance, namely the healthcare sector. More specifically, this research was carried out in hospitals. Even though the EFQM Excellence Model was originally developed for the for-profit sector, to date the model has also been applied in not-for-profit sectors such as healthcare and education.[9-17] In healthcare, quality improvement has become increasingly important over recent years, as it is supposed to have a direct effect on patient outcomes, both clinical outcomes and patient satisfaction. The improvement of quality in this sector has the potential to improve the quality of lives or even save lives.

This paper has the following structure: in the next two sections we give a more detailed overview of existing literature on TQM and the EFQM Excellence Model. Based on that overview, the specific research questions and hypotheses are presented. The fourth section describes the methodology: the longitudinal design, the questionnaire, the data collection in a national representative sample of hospitals and the statistical analyses. Section five presents the results and shows the long-term effects of applying the EFQM Excellence Model in terms of TQM. In the last section, the conclusions stemming from this research and its implications and limitations are discussed, as well as directions for future research.

Overview of the literature

The concept of TQM

Several definitions for TQM have been developed, all slightly different but these definitions share the general idea that TQM is an integrative management philosophy that aims at continuous quality improvement to meet the expectations of customers.[2,3,18,19] According to TQM, this can only be attained when the individual parts of an organization are managed in an interrelated (holistic) way.[18,20,21] In the literature on TQM, three main principles that underlie this concept are distinguished. Firstly, the core concepts of TQM fall into *two dimensions* that are named the 'social-soft' dimension and the 'technical-hard' dimension.[2,18,22] The 'social-soft' dimension encapsulates the human resource management aspects of an organization, whereas the 'technical-hard' dimension considers continuous improvement of goods and services by improving production processes. Secondly, the two dimensions and their underlying aspects need to be *managed simultaneously* because they are interrelated. If the aspects are dealt with separately, this will not lead to the desired improvement.[2-5,23] As pointed out by Hietschold:*'The main focus of TQM is on the organization as a whole'*.[24] Thirdly, the management of both dimensions will lead to *improved organizational performance*. Several studies have confirmed a causal relationship between dimensions of TQM and performance of organizations.[8,18,20,21] However, about seventy percent of organizations fail to put TQM in practice.[25] Therefore it is important to know the mechanisms through which TQM leads to continuous quality improvement. As TQM is a long-term approach, the improvement achieved in performance is expected to persist and accumulate over time leading to a cycle of continuous improvement. However, as yet there is no evidence for a cycle of continuous improvement in the literature since most studies had a cross-sectional design.[7,8,26]

TQM in healthcare

As a result of quality methods being applied in the industrial sector as a part of daily business processes, healthcare became interested in such methods as well. TQM initiatives were implemented in healthcare to ensure and improve the quality of care and reduce costs.[27-30] From the early 1990s these TQM initiatives were applied in healthcare organizations throughout the world. The application of TQM spread rapidly,[27] partly due to the fact that it is an appealing approach for customer-oriented sectors.[31] This follows from the definition of TQM in healthcare: *'the systematic involvement of healthcare teams in identifying the underlying causes of unnecessary variation in processes and outcomes of care, and taking corrective and preventive action with the goal of continuous quality improvement in patient care delivery'*.[32] As such, TQM in healthcare has the potential to reduce variation in outcomes and aims to detect opportunities for improvement both in terms of clinical outcomes and cost-effectiveness.[30,33]

Despite this, questions are raised about the universal applicability of TQM[34] because there is growing awareness that successful implementation of TQM highly depends on contextual variables.[24,35] Previous studies identified industry type as an important context factor.[34] In relation to this, some studies have been conducted to identify the various practices underlying the success of TQM implementation in healthcare settings.[36] In addition, a review by Nicolay et al.[33] identifies the performance effects of TQM implementation for various medical disciplines and patient groups. However, more research is needed that concerns the detailed impact of dimensions of TQM on performance, taking into account the entire organization as well as (longitudinal) performance measures that are relevant to both healthcare organizations and patients.[33,36]

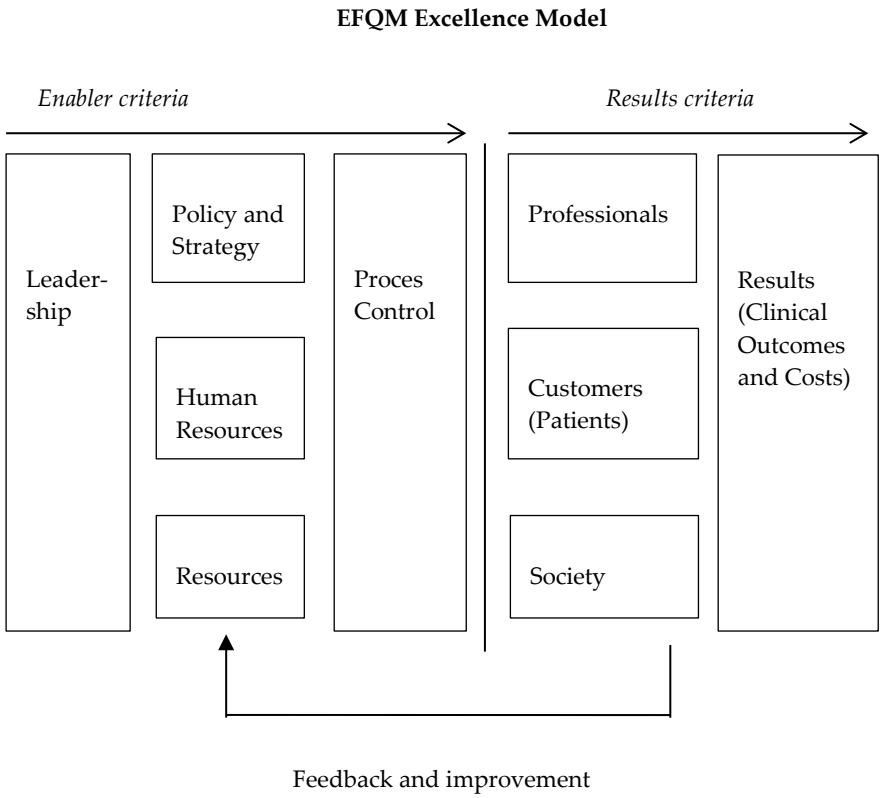
Several models have been designed to guide organizations towards TQM, such as the EFQM Excellence Model and the Malcolm Bridge Quality Award. Multiple studies consider such quality models as operational frameworks for TQM.[2,37-41] In this paper we will focus on the EFQM Excellence Model as a framework for organizations to reach TQM since this model has been widely used throughout Europe. In the following section, the EFQM Excellence Model is described and an overview of studies on the results of applying the model to organizational performance is given.

The EFQM Excellence Model as a framework for TQM

The EFQM Excellence Model

Since the early 1990s, the EFQM Excellence Model has been used to shape organizations' quality policy and detect areas for improvement. The model is a broad, generic and non-directive framework[42] that is applied in three ways. Firstly, it is used as a frame of reference for an organization's quality policy. Secondly, the model can serve as a self-assessment instrument to identify the strengths and weaknesses of the quality management of an organization. And lastly, organizations use it to apply for the European Quality Awards.[2,43] The EFQM Excellence Model consists of five organizational areas and four outcome areas, see Figure 1.

Figure 1 The EFQM Excellence Model



The organizational areas are often referred to as 'enabler criteria', whereas the outcome areas represent the 'result criteria' of an organization or in other words the performance of an organization. In this paper we adopt this terminology and will refer to the areas of the model as enabler criteria and result criteria. The enabler criteria are Leadership, Policy & Strategy, Human Resources, Resources, and Process Control. The result criteria are: Professionals (in healthcare: healthcare professionals such as physicians and nurses); Customers (in healthcare: Patients); Society, and Results (in healthcare: Clinical Outcomes and Costs). Table 1 describes the enabler and result criteria.

The model is based on the assumption that improving operational processes will lead to improvement and superiority of performance.[7,14,26,42,44] The EFQM Excellence Model proposes a pattern of relationships within[23,45,46] and between[12,26] the enabler criteria and result criteria. These propositions follow the same logic as the main ideas behind TQM. The model assumes that an organization should focus on all its activities and levels to establish a continuous pathway towards improvement.[43] In addition, the various elements should be balanced: all criteria need to be managed at the same time. According to TQM, in other words, combining the management of all the enabler criteria will have a larger effect on result criteria compared to focusing on individual enabler criteria.[42]

Table 1 Description of the EFQM Excellence Model enabler criteria and result criteria

Enabler criteria	**Description**
Leadership	Leaders need to demonstrate their commitment to excellence and continuous improvement and support improvement and involvement by providing adequate resources and support.
Policy & Strategy	Policy and Strategy includes the organization's mission, vision, values and strategy, how these reflect a total quality orientation and how these are developed, communicated, implemented, regularly updated, and improved.
Human Resources	Human Resources concerns the management of the people in the organization, how their full potential is released, their resources improved, capabilities sustained and developed; how performance is continuously assessed; how people are involved, empowered, and recognized.
Resources	Resources refer to how the resources of an organization are effectively deployed in support of policy and strategy.
Process Control	Process Control addresses how processes are identified, reviewed, and revised in order to sustain continuous improvement of the organization's service.
Result criteria	**Description**
Professionals	Comprehensively measure and achieve excellent results with respect to their professionals.
Customers (Patients)	Comprehensively measure and achieve excellent results with respect to their customers (patients).
Society	Comprehensively measure and achieve excellent results with respect to society.
Results (Clinical Outcomes and Costs)	Comprehensively measure and achieve excellent results with respect to results (clinical outcomes and costs).

(EFQM, 2013, Shergold and Reed, 1996)

Literature on the results of applying the EFQM Excellence model

In practice the use of the EFQM Excellence Model is accepted and widespread. Empirical research on the causal relationships within the EFQM

Excellence Model is extensive, however, the evidence suggesting that applying the EFQM Excellence Model leads to improvement of performance is limited.[2,7] Existing research is mostly based on descriptive studies that use single cases or lack control groups.[2,7] Furthermore, previous research focused on partial or isolated relationships. In the following paragraph we will briefly describe the important contributions to the literature on the empirical evidence of applying the EFQM Excellence Model in terms of improved performance. For a more detailed and in-depth description of this literature, we refer to the papers by Bou-Llusar *et al.* and Doeleman *et al.* which contain detailed literature reviews on the topic.[2,7]

Oakland & Oakland showed a significant relationship within the result criteria of the EFQM Excellence Model where achievements in one of the result criteria are associated with improved outcomes in other result criteria.[47] Eskildsen & Kanji conducted a study that found that poor management of people and processes is reflected in two of the results criteria.[48] Prahbu *et al.* demonstrated strong associations between the enabler criterion Human Resources and the result criterion Professionals; between the enabler criterion Leadership and the result criterion Customers through the assurance of good training for employees; and between people-related issues and operational outcomes measures.[49] Eskildsen & Dahlgaard showed that the enabler criteria Human Resources and Process Control are positively associated with the result criterion Professionals.[50] Bou-Llusar *et al.* were the first to take into account all of the elements of the model by testing the relationships between the various enabler criteria and the result criteria and thereby made an important contribution to the understanding of the complete set of relationships in the model. They found evidence that the enabler criteria and result criteria are strongly associated. Furthermore, they concluded that a positive enabler-result criteria correlation exists when all the criteria in the model are considered simultaneously and a balanced approach in the development of the enabler criteria allows the correlation between enabler criteria and result criteria to be maximized.[26] Despite the fact that this study took an integrative approach, the study was cross-sectional and did not consider the long-term relationship between the enabler criteria and result criteria.[26] In the light of continuous improvement, analyzing the long-term effects of enabler criteria is a prerequisite if premises are to be stated about the contribution of the EFQM Excellence Model to organizational performance.[2,7,26] Furthermore, as it can be assumed that the implementation of quality management aspects does not have an instant effect but instead requires time before any effect becomes manifest, it seems reasonable to suppose that the results of this implementation will not

be visible if measured at the moment of implementation, but only at a later point in time.[7,51]

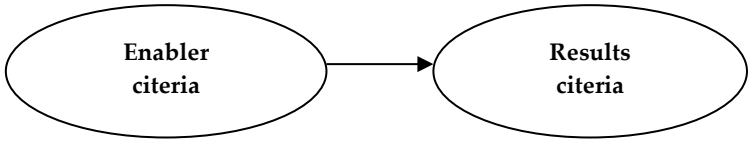
Expanding on the existing literature on the relationships of the EFQM Excellence Model and whether the model can serve as a framework for TQM, the current study takes a longitudinal perspective on this relationship. In addition, this study takes a holistic perspective to investigate the effect of managing all the enabler criteria simultaneously instead of testing the effects of individual enabler criteria.

Hypotheses

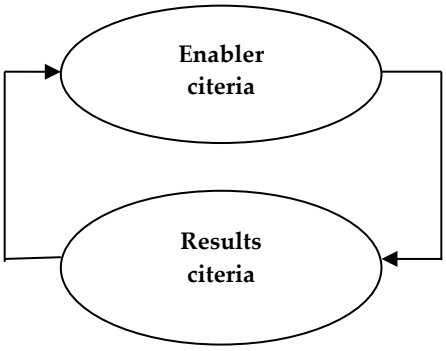
The hypotheses that will be tested in this study are derived from the main ideas of TQM, which were described in the previous section: (1) The management of enabler criteria of the EFQM Excellence Model lead to improved organizational performance,[18,20,21] (2) The management of enabler criteria of the EFQM Excellence Model lead to improved organizational performance that will persist and accumulate over time resulting in a feedback loop of continuous improvement, [7,26] (3) The relationships between the enabler criteria and the result criteria of the EFQM Excellence Model are stronger when all the enabler criteria are managed in parallel, because they are interrelated.[3-5,23,26] This leads to the following hypotheses that will be tested in this study (see Figure 2):

Figure 2 Hypotheses

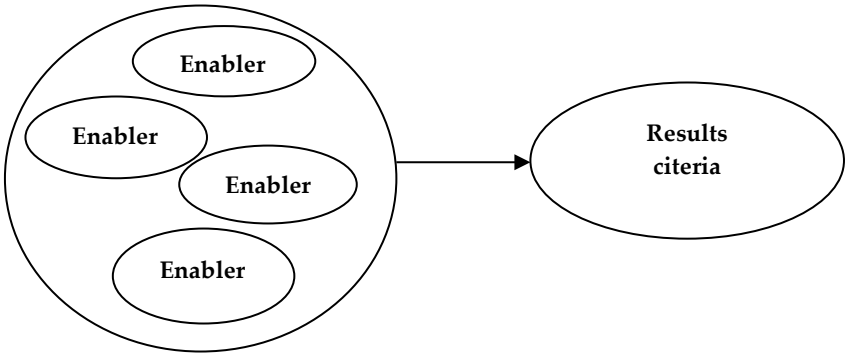
[H1]



[H2]



[H3]



[H1] There is a positive causal relationship between the enabler criteria and the result criteria of the EFQM Excellence Model. High scores for the enabler criteria will lead to high scores for the result criteria.

[H2] The enabler criteria and the result criteria of the EFQM Excellence Model continuously improve over time, resulting in a feedback loop of continuous improvement of both the enabler criteria and the result criteria.

[H3] The relationships between the enabler criteria and the results criteria of the EFQM Excellence Model will be stronger when all of the enabler criteria are developed.

Methodology

EFQM enabler and result criteria were measured using data from a national representative survey among the hospital population in the Netherlands. The survey had multiple measurement points and was carried out in 1995, 2000, 2005, 2007 and 2011 by NIVEL (Netherlands Institute for Health Services Research).[52-57] The questionnaire was originally developed and validated in the Netherlands in 1995 and was used to measure quality management activities and quality system development in hospitals through self-assessment.[52-57] For the fifth measurement in 2011 the questionnaire was slightly adjusted to correspond to current issues and definitions within the hospital sector.[57] For the purpose of the current research, items were regrouped according to the various enabler and result criteria of the EFQM Excellence Model using the definitions of the enabler and result criteria in Table 1. For example, the item *'Management indicate what is expected from staff regarding the quality policy of the hospital'* was grouped under the enabler criterion Leadership and the item *'Staff can participate in quality improvement activities during working hours'* was grouped under the enabler criterion Human Resources. This regrouping was undertaken by the author in consultation with the co-authors, who all had significant experience in research in the field of quality improvement and quality models. The number of items varies within different enabler and results criteria. The final set of items, their answer categories and year of measurement are shown in Appendix A.

Study design, sample and questionnaire

All Dutch hospitals were approached and asked to participate in the study. A total of 548 questionnaires were sent to the total population of Dutch hospitals over the years 1995, 2000, 2005, 2007, and 2011. The number of hospitals in the Netherlands decreased over that timeframe due to mergers. The average response over the years was 73%, the average number of completed questionnaires per measurement point was 80, and in total 398 questionnaires were completed during the length of the study. Response rates per measurement year are shown in Table 2. The questionnaire was completed by either a member of the management team or the quality coordinator of the hospital. The views of nurses, medical specialists, and other professionals as well as those of patients or other stakeholders were not included in this survey.

Table 2 Response per measurement year

	1995	2000	2005	2007	2011	Total
N	143	117	96	97	95	548
completed questionnaires	112	80	71	62	73	398
response percentages	78%	68%	74%	65%	77%	73%

Data preparation

The questionnaire contained both positively and negatively worded items. The negatively worded items were recoded to ensure that a high score reflects a more positive response. Hospitals were allowed to have missing data on items for the various criteria; however, at least one of the items for each of the criteria needed to be answered in order to include that criterion in the analyses. If this was not the case, the hospital was excluded from the analyses for this criterion. Mergers of hospitals were dealt with in the analyses as follows. Hospitals were assigned a unique identifier at the first year of measurement that was used as a unit of analysis. This unique identifier remained the same during the entire study period unless one of the following two situations occurred: (1) A larger or more (financially) dominant hospital took over a smaller or less dominant hospital, (2) Two hospitals started working together as a new organization. In the first case, the two hospitals had a unique identifier up to the point of the merger. After the merger, the identifier of the smaller hospital disappeared as a unit of analysis and the identifier of the larger hospital remained in the study. This assumes that the policy of the larger, more dominant hospital was 'forced upon' the smaller hospital that was taken over. In the second case, the two hospitals started jointly working together as a new organization, with neither of the two being more dominant. Each hospital had its own unique identifier before the merger, but a new unique identifier was created thereafter for the new joint organization. The two original individual identifiers were excluded from the analyses for the remaining period of the study after the merger.

Ecometrics model

Ecometrics is a statistical multilevel method to evaluate the validity and reliability of imperfect measures of contextual properties.[58,59] The aim of this method is to measure latent characteristics of 'ecological units' (in this study the ecological unit is the hospital). Furthermore, the method aims to combine multiple observations into one scale to analyze reliability and validity of the scale. With an ecometrics approach, all available data can be used in a multiple response model.[58,59] An ecometrics approach was needed in the current study for two reasons. First, to handle the fact that not every hospital participated in every year of measurement and not all items were measured in every year of measurement, and second, because the data are hierarchical, since the different measurements are clustered within hospitals. The data structure is as follows: the items are at the lowest level (level 1) and these are nested in hospitals at the highest level (level 2).

A weighted average scale value is calculated by the model (intercept fixed part) over all items using equal weights for the items. Each item had its own level 1 error variance, which captures the measurement error. At the hospital level for every year of measurement (five measurements in total) a separate between hospital variance is estimated. From this for every hospital a residual (deviation from the average scale value) is estimated for every measurement year. The sum of the average scale score and the residuals give for every hospital a scale score in that year of measurement (if the hospital has data in that year). The remaining analyses were based on these yearly hospital scale scores.

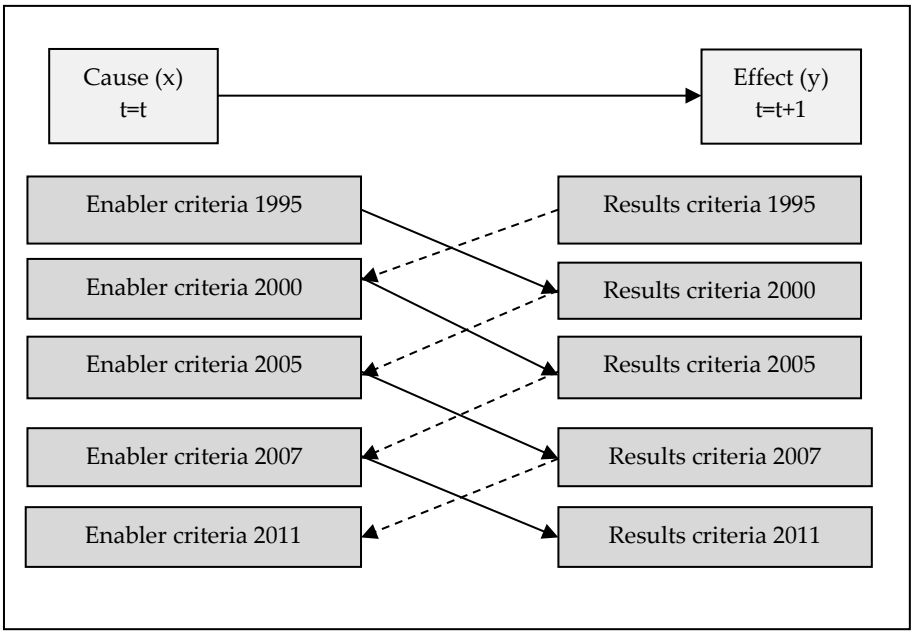
The internal consistency of the various enabler and result criteria was calculated to ensure that our measurement instrument was reliable and that hospitals were responding consistently to the items within any one criterion. The reliability coefficient was calculated in a multilevel multiple response model. The interpretation of this value is comparable to Cronbach's alpha in psychometric studies.[58,59] When the items within a certain criterion are measuring the same construct, the coefficient should be at least 0.6.[60]

Multilevel linear regression analyses within a time lag model

To test the hypotheses in a multilevel linear regression model, a time lag data model was built beforehand. A time lag model takes account of the temporal sequence of a possible causal effect. An observed relationship might be causal when the cause (x) precedes the effect (y).[60] As we assume that the implementation of quality management aspects does not have an instant effect but instead requires time to become manifest, a time lag model

is the appropriate approach.[7,51] The time sequence between our predictor variables (the enabler criteria) and the outcome variables (the result criteria) was modeled in this time lag model. Furthermore, to test the presumed feedback loop in the model, whereby the results of the quality management system feed back into the organization (in other words, improved result criteria lead to improved enabler criteria) leading to improved policy and processes, the same procedure was followed the other way around. We hypothesized that organizations with improved result criteria are likely to adjust their enabler criteria to further improve, therefore we performed the same principles to the effect of result criteria on enabler criteria. This way we were able to analyze the possibility of a continuous cycle of quality improvement. The resulting data structure, which was used to test the causal relationships in this study, is illustrated in Figure 3.

Figure 3 Time lag model for the relationship between enabler criteria and feedback loop



Given that the time lag in the dataset took account of the year of measurement, there was no need to perform separate analyses for the different years of measurement and all data stemming from one year of measurement could be combined in the analyses. This was the starting point for the multilevel linear regression analyses.

The multilevel linear regression analyses were done in several steps. Firstly, separate analyses were performed for every enabler-results relationship in the model, both with and without controlling for year of measurement. Secondly, separate analyses were performed for every results-enabler relationship in the model to test the feedback loop, again with and without controlling for year of measurement. And thirdly, the relationship between the combined enabler scores and the results was analyzed, with and without controlling for year of measurement. For this last analysis, a new variable was constructed to reflect the total development of all the enabler criteria combined. This variable was construed according to a procedure called summated rating scale construction.[61] Each hospital was assigned a score of 0 or 1 for each of the enabler criteria. A hospital that had performed better than average on an enabler criterion was assigned a score of 1 and hospitals performing at or below average on an enabler criterion were assigned a score of zero. The sum of these five scores became a hospital's score for the overall development of the enabler criteria. The range of this new variable was between 0 and 5, as there are five enabler criteria. The score was used in the last multilevel linear regression analysis to test whether hospitals that had developed all enabler criteria simultaneously were performing better in terms of results compared to hospitals that developed fewer enabler criteria. The descriptive analyses were performed using STATA 13.0. Multilevel analyses were performed using MLwiN 2.24. Coefficients in the multilevel regression analyses were considered statistically significant at $p<0.10$, because of the relatively small number of hospitals and because hypothesis testing was one-sided.

Findings

Reliability of the measurement scales

The reliability of the measurement scales is shown in Table 3. Reliability coefficients of the scales in the enabler criteria ranged from 0.82 to 0.96 with an average of 0.88. Reliability coefficients for the scales in the result criteria ranged from 0.30 to 0.81 with an average of 0.65. All the scales had acceptable to good internal consistency except for the scale that measures the result criterion Professionals, which had a reliability coefficient of 0.30. Deleting items in this scale did not contribute to the internal consistency. It seems that it was not possible to capture the intended underlying construct of this results criterion with the items used in this study.

Table 3 Internal consistency coefficients of measurement scales

Enabler criteria	Internal consistency	Result criteria	Internal consistency
Leadership	0.85	Professionals	0.30
Policy and Strategy	0.82	Customers	0.69
Human Resources	0.96	Society	0.78
Resources	0.85	Results	0.81
Process Control	0.94		

Descriptive statistics of the scales

Table 4a gives an overview of the averages scores of all participating hospitals for the various enabler criteria for the different years of measurement. The mean score for all enabler criteria increased over time. Standard deviations decreased over time, indicating that the spread in scores between hospital on the enabler criteria decreased over time.

Table 4b shows averages scores of all participating hospitals for the various result criteria, for the different years of measurement. The mean score for most of the result criteria increased over time. In one of the result criteria (Professionals), there was an increase up until the final measurement in 2011, when the average score decreased slightly. The standard deviations in the results criteria increased over time, which indicates that there is a larger spread in scores between hospitals in the final measurement than in earlier measurements.

Table 5a gives the between hospital variance in scores for the enabler criteria for every measurement year. The variance decreased over time for each enabler criterion. Hospitals' scores for the enabler criteria became more similar over time which is another indication for the fact that the organizational input of hospitals became more similar between hospitals over time.

Table 5b gives the between hospital variance in scores for the result criteria for every measurement year. For the result criterion Professionals, variance was relatively consistent over time. For the criterion Results, variance decreased first, but increased again in the last two measurements. For the criteria Customers and Society, variance increased over time, indicating that there were larger differences in scores for these criteria during the final measurements than for the earlier measurements.

Table 6a shows the correlations between the enabler criteria of the EFQM Excellence Model and Table 6b shows the correlation between the result criteria. Correlations between the enabler criteria ranged between 0.30 and 0.62. Correlations between results criteria ranged from 0.27 and 0.56. All correlations were positive, and significantly different from zero.

Table 4a Mean enabler criteria scores between 1995 and 2011: means, standard deviations and ranges

Enabler criteria	**Leadership**			**Policy and Strategy**			**Human Resources**			**Resources**			**Process Control**		
	Mean	SD	Range (0-1)	Mean	SD	Range (1-3)	Mean	SD	Range (0-1)	Mean	SD	Range (0-1)	Mean	SD	Range (0-1)
1995	0.55	0.23	0.19-0.94	1.82	0.38	1.10-2.62	0.53	0.30	0.06-0.98	0.36	0.29	0.05-0.96	0.73	0.21	0.12-0.97
2000	0.56	0.23	0.20-0.94	2.43	0.19	1.71-2.77	0.66	0.18	0.26-0.96	0.63	0.23	0.14-0.95	0.82	0.12	0.51-0.97
2005	0.82	0.11	0.42-0.88	2.53	0.02	2.47-2.57	0.88	0.10	0.40-0.96	0.65	0.08	0.41-0.77	0.86	0.11	0.39-0.96
2007	0.80	0.13	0.41-0.91	2.55	0.11	2.22-2.71	0.87	0.08	0.71-0.97	[a]	[a]	[a]	0.91	0.08	0.63-0.98
2011	0.83	0.11	0.41-0.91	2.56	0.06	2.38-2.65	0.87	0.16	0.22-0.98	0.64	0	0.64-0.64	0.91	0.06	0.73-0.96

a There are no observations for Resources in 2007.

Table 4b Mean result criteria scores between 1995 and 2011: means, standard deviations and ranges

	Professionals			**Customers**			**Society**			**Results**		
Results criteria	Mean	SD	Range (1-3)	Mean	SD	Range (1-3)	Mean	SD	Range (1-3)	Mean	SD	Range (1-3)
1995	2.26	0.08	1.94-2.37	2.23	0.05	2.21-2.35	2.13	0.21	1.74-2.65	1.96	0.21	1.57-2.56
2000	2.27	0.01	2.24-2.30	2.21	0.28	1.39-2.76	2.13	0.24	1.42-2.68	1.99	0.22	1.45-2.68
2005	2.29	0.05	2.15-2.41	2.29	0.28	2.08-2.77	2.24	0.32	1.72-2.84	2.10	0.25	1.64-2.68
2007	2.28	0.08	2.09-2.47	2.30	0.30	2.07-2.87	2.26	0.32	1.72-2.84	2.17	0.34	1.64-2.80
2011	2.26	0.12	1.96-2.53	2.34	0.39	1.65-2.84	2.23	0.36	1.21-2.86	2.14	0.28	1.77-2.78

Table 5a Between hospital variance in scores for enabler criteria for every measurement year

	Leadership		**Policy & Strategy**		**Human Resources**		**Resources**		**Process Control**	
	var	S.E.	var	S.E.	var	S.E.	var	S.E.	Var	S.E.
1995	3.87	1.13	0.69	0.14	7.02	1.62	6.22	1.63	3.24	0.84
2000	3.71	0.91	0.07	0.02	2.75	0.59	2.42	0.68	1.58	0.40
2005	1.31	0.65	0.00	0.01	1.37	0.39	0.51	0.37	1.51	0.33
2007	1.39	0.68	0.03	0.01	0.96	0.32	[a]	[a]	1.26	0.41
2011	1.35	0.66	0.01	0.01	2.77	0.67	0	0	0.91	0.28

a There are no observations for Resources in 2007.

Table 5b Between hospital variance in scores for result criteria for every measurement year

	Professionals		**Customers**		**Society**		**Results**	
	var	S.E.	var	S.E.	var	S.E.	var	S.E.
1995	0.02	0.01	0.02	0.03	0.08	0.03	0.11	0.05
2000	0.00	0.01	0.11	0.03	0.10	0.03	0.08	0.02
2005	0.01	0.01	0.12	0.03	0.13	0.03	0.08	0.02
2007	0.02	0.01	0.13	0.03	0.13	0.03	0.14	0.03
2011	0.03	0.01	0.20	0.04	0.16	0.03	0.10	0.02

Table 6a Correlations between enabler criteria

	Leader-ship	Policy & Strategy	Human Resources	Resources	Process Control
Leadership	1.00				
Policy & Strategy	0.52*	1.00			
Human Resources	0.62*	0.60*	1.00		
Resources	0.30*	0.60*	0.37*	1.00	
Process Control	0.45*	0.44*	0.50*	0.32*	1.00

*significant p<0.001

Table 6b Correlations between results criteria

	Professionals	Customers	Society	Results
Professionals	1.00			
Customers	0.27*	1.00		
Society	0.34*	0.56*	1.00	
Results	0.32*	0.54*	0.56*	1.00

*significant p<0.001

Multilevel linear regression analyses

Table 7a shows the results of the separate multilevel linear regression analyses of the enabler criteria against the result criteria. All the coefficients are positive which indicates that a higher score on enabler criteria results in a higher score on result criteria in the next measurement year. The results are statistically significant ($p<0.10$) for the relationships between all the enabler criteria and the result criteria Customers, Society and Results, but not for the result criterion Professionals.

Table 7b shows the results of the separate multilevel linear regression analyses of the enabler criteria against the result criteria, controlled for measurement year. A similar pattern emerges when the same analyses are performed with the measurement year as a control variable: the relationships between enabler and result criteria are again positive and some, but not all, remain statistically significant ($p<0.10$).

Table 8a shows the results of the separate multilevel linear regression analyses of the result criteria against the enabler criteria, the feedback loop.

Almost every coefficient is positive, which indicates that a higher score on result criteria leads to higher scores on enabler criteria. However, only a few relationships proved to be statistically significant at $p<0.10$. Statistically significant relationships were found between the result criterion Professionals and the enabler criterion Leadership. Furthermore, statistically significant relationships were found between the result criterion Society and the enabler criteria Leadership, Policy and Strategy, Human Resource Management and Process Control. And last, statistically significant relationships were found between the result criterion Results and the enabler criteria Leadership, Policy and Strategy, Human Resource Management and Process Control.

Table 8b shows the results of the separate multilevel linear regression analyses of the results criteria against the enabler criteria (feedback loop), controlled for measurement year. When the same analyses are performed controlling for measurement year, none of the relationships are statistically significant which indicates that measurement year has an effect on the enabler criteria.

Table 9a shows the results of the multilevel linear regression analysis of the total development against the enabler criteria. The results show that developing all enabler criteria has a positive effect on results criteria. The effect of the total development is positive and significant for all result criteria except the result criterion Professionals.

Table 9b shows the results of the multilevel linear regression analysis of the total development against the enabler criteria, controlled for the measurement year. The results of this analysis are similar; the positive relationship between the total development score and result criteria is still present. However, only the relationship between the total development score and the results criterion Results is not statistically significant at $p<0.10$. This indicates that, for three out of four result criteria and controlled for the moment of measurement, developing all enabler criteria has a positive effect on results.

Table 7a Separate multilevel linear regression analyses of the enabler criteria against the result criteria

Results criteria	**Professionals**		**Customers**		**Society**		**Results**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
Enabler criteria								
Leadership	0.019	0.024	0.154	0.101	0.193*	0.102	0.202*	0.084
Policy & Strategy	0.009	0.015	0.188*	0.061	0.230*	0.061	0.202*	0.050
Human Resources	0.019	0.024	0.294*	0.099	0.288*	0.101	0.289*	0.082
Resources	-0.001	0.018	0.278*	0.094	0.241*	0.098	0.280*	0.089
Process Control	0.005	0.040	0.327*	0.168	0.257	0.170	0.313*	0.140

*p<0.10

Table 7b Separate multilevel linear regression analyses of the enabler criteria against the result criteria, controlled for measurement year

Results criteria	**Professionals**		**Customers**		**Society**		**Results**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
Enabler criteria								
Leadership	0.042	0.029	0.014	0.120	0.126	0.122	0.089	0.099
Measurement year	-0.008	0.006	0.052*	0.025	0.025	0.025	0.042*	0.020
Policy & Strategy	0.030	0.020	0.145	0.085	0.290*	0.085	0.186*	0.070
Measurement year	-0.010	0.007	0.021	0.029	-0.030	0.028	0.008	0.023
Human Resources	0.045	0.030	0.214*	0.124	0.272*	0.125	0.215*	0.102
Measurement year	-0.009	0.006	0.027	0.026	0.005	0.026	0.025	0.021
Resources	-0.010	0.020	0.233*	0.106	0.158	0.109	0.165*	0.099
Measurement year	0.007	0.006	0.030	0.033	0.056	0.034	0.075*	0.030
Process Control	0.021	0.044	0.169	0.184	0.150	0.187	0.155	0.154
Measurement year	-0.005	0.005	0.045*	0.023	0.031	0.023	0.044*	0.019

*$p<0.10$

Table 8a Separate multilevel linear regression analyses of the result criteria against the enabler criteria (feedback loop)

Enabler criteria	**Leadership**		**Policy and Strategy**		**Human Resources Management**		**Resources**		**Process Control**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
					Results criteria					
Professionals	0.358*	0.214	0.214	0.142	0.270	0.185	0.064	0.147	0.066	0.118
Customers	0.041	0.056	0.058	0.037	0.066	0.047	0.018	0.040	0.046	0.030
Society	0.111*	0.049	0.054*	0.033	0.090*	0.041	-0.005	0.036	0.045*	0.027
Results	0.092*	0.053	0.065*	0.035	0.121*	0.044	0.004	0.034	0.052*	0.029

*p<0.10

Table 8b Separate multilevel linear regression analyses of the result criteria against the enabler criteria (feedback loop), controlled for measurement year

Enabler criteria	**Leadership**		**Policy and Strategy**		**Human Resources Management**		**Resources**		**Process Control**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
Results criteria										
Professionals	0.234	0.188	0.156	0.134	0.185	0.171	0.083	0.147	0.011	0.109
Measurement year	0.082*	0.011	0.038*	0.008	0.056*	0.010	-0.009	0.008	0.035*	0.006
Customers	-0.013	0.049	0.033	0.035	0.030	0.044	0.027	0.040	0.021	0.028
Measurement year	0.082*	0.011	0.038*	0.008	0.053*	0.010	-.012	0.008	0.035*	0.006
Society	0.044	0.044	0.023	0.032	0.046	0.039	0.006	0.037	0.014	0.025
Measurement year	0.080*	0.011	0.038*	0.008	0.052*	0.010	-0.011	0.008	0.035*	0.006
Results	-0.018	0.049	0.014	0.035	0.054	0.043	0.021	0.036	-0.002	0.028
Measurement year	0.084*	0.011	0.039*	0.008	0.050*	0.086	-0.012	0.008	0.036*	0.007

*p<0.10

Table 9a. Multilevel linear regression analysis of the total development** against the result criteria

Result criteria	**Professionals**		**Customers**		**Society**		**Results**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
Total development	0.003	0.002	0.026*	0.008	0.029*	0.009	0.027*	0.008

*p<0.10

**the total development is the sum of the development of all the different enabler criteria.

Table 9b. Multilevel linear regression analysis of the total development ** against the result criteria, controlled for measurement year

Result criteria	**Professionals**		**Customers**		**Society**		**Results**	
	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.	Coef.	S.E.
Total development	0.004*	0.003	0.019*	0.010	0.022*	0.010	0.009	0.009
Measurement year	-0.005	0.003	0.020	0.133	0.017	0.014	0.048*	0.012

*p<0.10

**the total development is the sum of the development of all the different enabler criteria.

Discussion

This study examined whether the EFQM Excellence Model can serve as a framework for TQM in healthcare. Consistent with previous research, we found positive correlations between the various enabler criteria and between the various result criteria.[26] This is according to expectations since the individual enabler criteria are all supposed to measure different aspects of enablers, and the individual result criteria all measure different aspects of organizational outcomes. Coherence is therefore a necessity. Our findings also showed that variance of scores between hospitals on enabler criteria and result criteria decreased over time. This indicates that hospitals became more similar over time, both in terms of their organizational structure and input as in terms of their organizational outcomes. This might be due to increased sector-wide standardization through the use of standards and protocols, which might have caused less variance. Another possible explanation could be the plentitude of laws, national action programs and nation-wide improvement projects enrolled in Dutch hospitals in the last decade.[62,63] Consistently with the idea of TQM, the results obtained show that applying the EFQM Excellence Model is related with better organizational

performance. We found a positive causal relationship between the various enabler criteria and the various result criteria. These findings confirm hypothesis 1 of our study. Secondly, we also found a positive causal relationship between the various result criteria and the various enabler criteria over time. Although this effect was weaker than the relationship between enabler criteria and result criteria, it remains an indication for a cycle of continuous quality improvement. Hypothesis 2 of our study can thus be confirmed. In this study, we hypothesized that higher scores in result criteria lead to improved enabler criteria in the next time period. However, it could also be argued that low scores in results criteria at one point in time lead to improved enabler criteria in the next time period. The idea behind this is that low scores in result criteria urge organizations to improve their enabler criteria more than high scores in result criteria would. However, it is likely to expect that these improved enabler criteria should in the next time period lead to improved result criteria and the end result will be the same: both enabler criteria and result criteria improve over time. Furthermore, the results of our study show that the positive relationship between the enabler criteria and the result criteria of the EFQM Excellence Model is stronger when all of the enabler criteria are developed. This is in line with hypothesis 3 of our study, which states that managing all the aspects of the EFQM Excellence Model in an integrative manner has a stronger impact on organizational outcomes in comparison to focusing on parts of the model. Overall, our study suggests that the EFQM Excellence Model could serve as a framework for TQM. However, stronger evidence for the feedback loop of continuous quality improvement is desirable and needs to be obtained in future research.

Implications

Our study replicates the findings of earlier studies on the internal structure of the EFQM Excellence Model in a different setting: healthcare. The results of our study indicate that hospitals became not only more quality oriented, but also more similar over time. Most quality approaches, including more recent ones such as Six Sigma and Lean that have also been applied to health care settings,[64] aim to reduce variation by standardizing processes. The results of this study could be seen as evidence in favor of standardization. However, it is very important to note that standardization is only desirable when it is thoroughly substantiated, and hospital managers as well as health care professionals should look into their processes in order to see where standardization can be applied and unnecessary and undesirable variation can be reduced in a way that processes are still being sensitive to individual patient needs and requirements.

This study established a positive causal relationship between the enabler criteria and the result criteria of the EFQM Excellence Model. This is consistent with findings of other studies in different sectors on the empirical evidence when applying the EFQM Excellence Model.[2,7,26] However, as mentioned before, these studies were mostly cross-sectional and focused on single organizations and were not carried out in the healthcare sector.[2,7,26] The results of the current study can therefore be seen as a major contribution to both theory and practice and in favor of using the EFQM Excellence Model as a framework for TQM in the healthcare sector. In addition, the longitudinal design reveals that it requires time before the results of quality activities become clearly visible in organizational outcomes. This implicates that managers and professionals should be urged to be patient and not to expect quality changes instantly.

Consistently with the holistic TQM approach to quality management, we found that the relationship between enabler criteria and result criteria is stronger when all of the enabler criteria are managed simultaneously. This is important, but perhaps also complex, for the management of organizations: no organizational aspects should be neglected and the development of all aspects should be interrelated in order to give the greatest effect on organizational performance.

Strengths and limitations of the study

This study is the first to consider the long-term contribution of applying the EFQM Excellence Model as a framework for TQM in healthcare. To our knowledge there were only a few studies with a longitudinal design but these were based on single cases.[65,66] A longitudinal design is required in order to identify any causal relationships between variables. Secondly, this study is the first that examines continuous quality improvement through a feedback loop of organizational performance, an essential part of the philosophy behind TQM. Thirdly, this study takes account of all the relationships in the model and not single isolated relationships. This is important because the management of all organizational input is assumed to have an accelerating effect on organizational performance.

Despite these strengths, we acknowledge several limitations to this study as well. Firstly, organizational performance was measured by taking the respondents' perceptions of the various result criteria and not the actual objective performance. This means that quality improvement activities may have been overestimated in the current study. However, the range of scores and persistent improvements in scores over time suggests that respondents

filled out the questionnaire honestly. In the time lag model, the scores on the result criteria were linked to the scores on the enabler criteria of the previous measurement which meant that in many cases this was a different respondent and thereby eliminating possible socially desirable reporting. Ideally, more objective measurements of outcomes would be taken into account (such as standardized patient mortality rates), but these were not available for the total duration of the study. Secondly, the statistical power to generalize findings is limited. Sampling in this study was restricted by the number of hospitals in the Netherlands. Due to hospital mergers, the total number of hospitals decreased. For the most part, this problem was overcome by the longitudinal design of the study and the multilevel analyses resulting in a greater total study sample and hence more power. However, generalizations to wider healthcare settings, other countries, or even other sectors need to be drawn with a certain amount of caution. Thirdly, the reliability of the measurement scale for the result criteria Professionals was inadequate. This might be due to the fact that the items that were used capture on the one hand values of healthcare professionals (such as satisfaction) and on the other hand the way in which healthcare professionals are being evaluated (for example motivation and flexibility). Furthermore, the result criteria Professionals as measured in this research does not refer to all employees, but specifically to healthcare professionals such as physicians and nurses. The items used in this study did not seem to capture the underlying intended construct and therefore the findings related to this measurement scale should be interpreted with caution.

Directions for future research

Future research should try to replicate the findings of our study to strengthen the evidence that the EFQM Excellence Model can be used by hospitals and other healthcare institutions to guide TQM activities. Related to this, future research should base its studies on longitudinal data with multiple measurements. As Doeleman pointed out, a longitudinal design with a control group is preferable.[7] However, in practice a controlled setting in which it is possible to account for moderating influences is difficult to achieve.[7] Furthermore, the majority of research to date on the relationship between applying the EFQM Excellence Model and TQM was carried out in educational settings and results of these studies showed similar patterns of results.[9,10,67,68] Our research was carried out in a specific subsector of healthcare, namely hospitals and future research could expand to other fields in healthcare such as long-term care. In long-term care there is a specific focus on customer needs, which would make an interesting setting to research a customer driven model such as TQM.

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Appendix A

This appendix contains the items that were used to measure the various enabler criteria and result criteria of the EFQM Excellence Model and years of measurement.

Enabler criteria					
LEADERSHIP	Year of measurement				
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Management indicate what is expected from staff with regard to quality policy of the hospital.	x	x	x	x	x
Management assess whether staff adhere to agreements made with regard to the quality policy of the hospital.	x	x	x	x	x
Management monitor the execution of unit working plans.	x	x	x	x	x
POLICY AND STRATEGY					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Quality policy document: a description of the aims of quality assurance, the desired level of care delivery and the ways of the organization for achieving these goals.	x	x	x	x	x
Quality action plan for the entire organization: written document with measures for implementation and planning of action to realize quality goals.	x	x	x	x	x
Annual quality report, or quality section in the annual general report: a justification and the results of all activities that have been carried out within the framework of quality policy.	x	x	x	x	x

Written description of the mission: the basic principles and vision of the organization.	x	x	x	x	x
Quality manual: a description of all quality management procedures and of the people responsible for maintaining them.	x	x	x	x	x
Product descriptions: detailed description of the care for various patient populations.	x	x	x	x	x
Quality action plan for some departments.	x	x	x	x	x
Quality action plan for every department.	x	x	x	x	x
Written Safety Management Plan.					x
HUMAN RESOURCES					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Professionals are encouraged to develop in their profession.	x	x	x	x	x
Staff receive systematic feedback on the results of the treatment of patients.	x	x	x	x	x
Professionals are encouraged to report incidents and adverse events.			x	x	x
New staff are trained in quality improvement methods.	x	x	x	x	x
New staff are trained in adherence to guidelines/protocols.			x	x	x
Training /education of staff.	x	x	x	x	x
Training / education of management.	x	x	x	x	x
Staff can participate in quality improvement activities during working hours.	x	x	x	x	x
Staff receive systematic feedback on adherence to guidelines/protocols.			x	x	x

Staff receive systematic feedback on incident reports.			x	x	x
Selection of new staff with a positive attitude to quality improvement.	x	x	x	x	x
RESOURCES					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
A specific internal budget is reserved for quality improvement.	x	x	x		x
One or more steering groups or quality committees have been established.	x	x	x		x
One or more quality and safety officers / coordinators have been appointed.	x	x	x		x
Support by (external) consultants.	x	x	x		x
PROCESS CONTROL					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Prophylactic use of antibiotics.		x	x	x	x
Preoperative screening.			x	x	x
Blood transfusion policy.			x	x	x
Prevention of central line infection.			x	x	x
Prevention of pressure ulcers.			x	x	x
Prevention of falls.					x
Prevention of medication errors.					x
Standards for specific treatments/interventions.	x	x	x	x	x
Standards for patient education.	x	x	x	x	x
Standards for the use of medical aids (e.g. crutches, bandages, etc.).	x	x	x	x	x

Standards for critical moments in service provision.	x	x	x	x	x
Standards for specific target groups and diagnoses.	x	x	x	x	x
Standards for patient routing from intake to discharge.	x	x	x	x	x
Standards for cooperation with other organizations.	x	x	x	x	x
Results criteria (perceived)					
PROFESSIONALS					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Increased staff satisfaction.	x	x	x	x	x
More motivation among staff.	x	x	x	x	x
Staff have opportunities to develop further.			x	x	x
A culture of continuous learning has emerged.			x	x	x
More flexibility among staff.	x	x	x	x	x
CUSTOMERS (PATIENTS)					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Increased patient satisfaction.		x	x	x	x
Improved patient orientation.	x	x	x	x	x
SOCIETY					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Improved public relations of the unit / hospital.	x	x	x	x	x

Increased satisfaction of referring professionals.	x	x	x	x	x
Improved competitive position.			x	x	x
RESULTS (CLINICAL OUTCOMES AND COSTS)					
Item	*1995*	*2000*	*2005*	*2007*	*2011*
Cost savings in own hospital.	x	x	x	x	x
Cost savings not in own hospital.		x	x	x	x
Increasing productivity.		x	x	x	x
Better risk management.					x
Improved care processes.		x	x	x	x
Improvements in patient safety.			x	x	x
Improved clinical outcomes.		x	x	x	x
Hospital more manageable.	x	x	x	x	x

4

The association between quality system development stage and the implementation of process-level patient safety themes in Dutch hospitals: an observational study

Under review
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Abstract

Background
Quality systems are believed to be positively related to quality and safety in healthcare. However, there is no convincing evidence for this relationship in the literature. This study aims to examine the association between the development stage of hospital quality systems and the implementation of patient safety themes at the process level.

Methods
This study combines data from a national survey on the development stage of quality systems in Dutch hospitals with results from an evaluation study of the Dutch Hospital Patient Safety Programme. Data on the development stage of quality systems were collected in Dutch hospitals in 2011. A total of 73 quality coordinators completed a questionnaire (response rate 77%) covering five quality system domains: policy and strategy, human resource management, patient involvement, practice guidelines, and systematic quality improvement. Data were included on the implementation of five patient safety themes from the Dutch Hospital Safety Programme. Process indicators for each theme were measured every four to six weeks, resulting in ten measurements in each hospital. Data were analyzed using multilevel analysis.

Results
The mean score for hospital quality system development was 2.30 (range 1 to 3). The mean scores for the various quality system domains ranged from 1.56 (Patient Involvement) to 2.66 (Human Resources Management). The mean percentages for the implementation of the patient safety themes ranged from 12% for the 'Pain' process indicator to 73% for execution of the 'Time-Out Procedure'. The intraclass correlation coefficients of the intercept-only model ranged between 11.6 and 51.6, which indicates large differences between hospitals in the implementation of the patient safety themes. Positive associations between quality system development stage and implementation of patient safety themes were found for four of the five patient safety themes, although they were not statistically significant.

Conclusions
This study found no association between the development stage of a hospital quality system and the implementation of patient level safety themes at the process level. This contradicts the hypothesis that quality improvement is caused by a positive relationship between structure (the quality system) and processes (the safety programme implementation), which in their turn mold the quality of care at the patient level.

Background

Growing concern about quality and safety within healthcare organizations made quality improvement an important topic in healthcare. According to Donabedian's well-known model of quality improvement, quality can be achieved through a continuous cycle in which the organizational structure enhances organizational processes, which in turn leads to improved outcomes at the patient level.[1-3] In this model, the organizational structure is the quality system, and it is a prerequisite for continuous improvement.[1-3] A quality system is defined as a set of interacting activities, methods, and procedures aimed at directing, controlling, and improving the quality of care.[4] Quality systems contain quality improvement strategies in different areas such as policy, healthcare staff, patient involvement, and systematic measurement of outcomes.[4-8] Most healthcare organizations have now implemented quality systems. However, there is large variation between countries and between individual healthcare organizations in terms of how well developed their quality system is.[5,7,9,10] Insight into the development stage of a quality system is important, because it is assumed that this shapes the organizational processes, in turn leading to higher quality of care at the patient level.[9,11]

Several studies examined the relationship between quality systems or derivatives (such as hospital-level accreditation) and outcomes in terms of quality of care. Shaw *et al.* studied the effectiveness of different forms of external quality assessment of hospitals and found that accredited hospitals performed better on patient safety outcomes.[11,12] Weiner *et al.* linked quality improvement with a set of patient safety indicators at the organizational level and found that higher percentages of physicians participating in quality improvement teams led to fewer postoperative complications and lower rates of technical difficulties with procedures.[13,14] Kunkel *et al.* found higher scores for structure and outcomes when the implementation of a quality system was initiated by managers and when staff provided input to the quality system design. Subsequently, this was found to result in more advanced quality systems.[15,16] Groene *et al.* found that better-developed quality systems were associated with lower rates of hospital complications and to some extent with fewer hospital readmissions in Spanish hospitals.[9] However, the same study found no association between the maturity of the quality system and hospital mortality and length of admission.[9] The European research project DUQuE assessed the association between quality management and patient outcomes in a wider setting: the

European Union.[17,18] Results from this project showed some associations between quality management measures at the hospital level and quality measures at the department level.[19] However, these associations were weak and the variability between countries was high.[19]

Despite these examples from the literature, research into the relationship between quality systems and measures of quality and safety is limited and often restricted by small sample sizes and lack of availability of sufficient outcome measures.[13,14] Although implementing quality systems in healthcare aims to improve the quality of care and patient safety by improving the processes, no clear evidence can be found in the literature that this is actually the case. This study aims to provide more insights into the association between the development stage of a hospital quality system (structure) and the quality of care at the process level. It should thereby be able to shed light on how quality systems work and provide more insights into the relationship between structure and processes in quality improvement. In this study, processes are quantified by the degree of implementation of patient safety themes within a national patient safety programme. The degree of implementation of the patient safety themes is reflected in the scores for process indicators. The programme will be described in more detail in the methods section. The research question addressed in this study is:

- *Is there a positive association between hospital quality system development stage and the implementation of patient safety themes on process level?*

In line with Donabedian's principles of quality improvement outlined above, we expect a positive association between the development stage of hospital quality systems and the implementation of patient safety themes. In other words, the patient safety themes measured in this study are expected to be more thoroughly implemented in hospitals with better-developed quality systems and this should be reflected in higher scores for the process indicators.

Methods

Study design

This study combines data from a national survey on the development stage of quality systems in hospitals (Study 1) with the results of an evaluation

study of the Dutch Hospital Patient Safety Programme (Study 2). The methods for each of the two studies are described below.

Study 1. Structural level: hospital quality system development

Since 1996, all Dutch healthcare institutions are obligated to have a quality system implemented in their organization. Therefore we chose to conduct this study with a more sophisticated measure namely the development stage of the quality system. Data on quality system development were collected during a large national survey on quality management in Dutch hospitals in 2011. All Dutch hospitals (N=95) were approached and asked to participate in the study. The questionnaire was filled out by the quality coordinator of the hospital or a member of the management team. A total of 73 questionnaires were returned (response rate 77%). The questionnaire covered five domains of the hospital quality system: policy and strategy, human resource management, patient involvement, practice guidelines, and systematic quality improvement (see Wagner, 1999 for the items and psychometric properties of the questionnaire[4]). Data from this survey were used to assign each hospital to a development stage on a continuous scale from 0 to 3 for each of the five quality system domains, as well as the quality system overall. The development stage score reflects the level of implementation of the quality system in the organization. Stage 0 is 'orientation and awareness'. In this stage, the organization has a notion that 'something needs to be done' about quality, but there are no systematic activities for quality assurance and improvement. In Stage 1 'preparation', organizations create the necessary conditions for quality insurance and improvement. Stage 2 is 'experimentation' and involves developing quality improvement projects. Stage 3 is the highest stage of development and involves continuous improvement of quality of processes and outcomes, referred to as 'integration'.[4-8,18]

Study 2. Process level: patient safety themes

The Dutch Hospital Patient Safety Programme (hereinafter referred to as the Safety Programme) was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012. The Safety Programme consisted of ten patient safety themes to be implemented in the hospitals.[20] Clinical guidelines were developed by an expert group for each theme and presented in practical modules. Hospitals were given five years to implement these guidelines. Training and several practical recommendations for successful implementation of the protocol were offered to the hospitals. An evaluation study was performed between November 2011 and December 2012 to assess the extent to which six of the

ten themes had been implemented. The study protocol was granted approval by the VU University Medical Center ethical review board in Amsterdam. This evaluation study took a representative sample of 38 hospitals (22 general, 12 tertiary teaching and 4 academic hospitals) from the total sample of Dutch hospitals, stratified by area and type of hospital. The participating hospitals were assigned to three of the themes in two groups, resulting in a sample of 19 hospitals for every theme. In the present study, data has been included for five themes, as data was collected for process indicators that are the main outcome measure of this research. The patient safety themes are: (1) Wrong surgery, (2) Contrast- induced nephropathy, (3) Early recognition and treatment of pain, (4) Medication reconciliation at admission and discharge, and (5) High-risk medication. Table 1 gives an overview of the aims of the five different patient safety themes, the data collection, and the process indicators that were used as outcome measures in this study. Process indicators were measured every four to six weeks during a one-year follow-up for each of these five themes by a trained research assistant, resulting in a total of ten observation days for every theme in each hospital. The multiple measurements reduce the chance of a Type I error (false positive). A percentage was calculated for each process indicator, with higher percentages reflecting better implementation of the corresponding patient safety theme.

Only hospitals that participated in both Study 1 and Study 2 were included in our study sample. This study therefore includes different numbers of hospitals and patients than the Safety Programme. The data flow diagram for hospitals and patients included in the present study is shown in Figure 1.

Table 1 Content and data collection of the five patient safety themes to evaluate implementation of the Safety Programme.

Patient Safety Theme	**Aim within the Safety Programme**	**Interventions in modules of the Safety Programme**	**Design evaluation study**	**Process indicator evaluation study**
Theme 1. Wrong surgery	Reducing the amount of wrong patient, wrong site, wrong procedure events. The aim is 0 events.	Time-out verification before surgery during which the total OR team is present and checks patient name, procedure to be performed and where to perform procedure (site and side).	Observational research with 6-10 observations of operations during 10 measurements in 18 hospitals.	Percentage of operations in which all 3 steps of the Time Out Procedure were performed correctly.
Theme 2. Contrast-induced nephropathy	Prevention of contrast-induced nephropathy by identifying all high-risk patients and taking suitable preventive measures.	1. Identifying high risk patients (eGFR and medication review). 2. General prevention measures. 3. Specific prevention measures.	Patient record review with 20 - 25 randomly selected records during 10 measurements in 19 hospitals.	Percentage of high-risk patients who were hydrated before undergoing contrast administration.
Theme 3. Early recognition and treatment of pain	Reduce avoidable suffering by early recognition and treatment of pain.	1. Three times a day: a standardized pain measurement. 2. Register the pain scores 3. Take action at a pain score of 4 and higher.	Patient record review with 20-25 randomly selected records during 10 measurements in 19 hospitals.	Percentage of postoperative patients who were in pain was measured in a standardized way three times a day in the first three days after surgery.

-.Table 1continued -

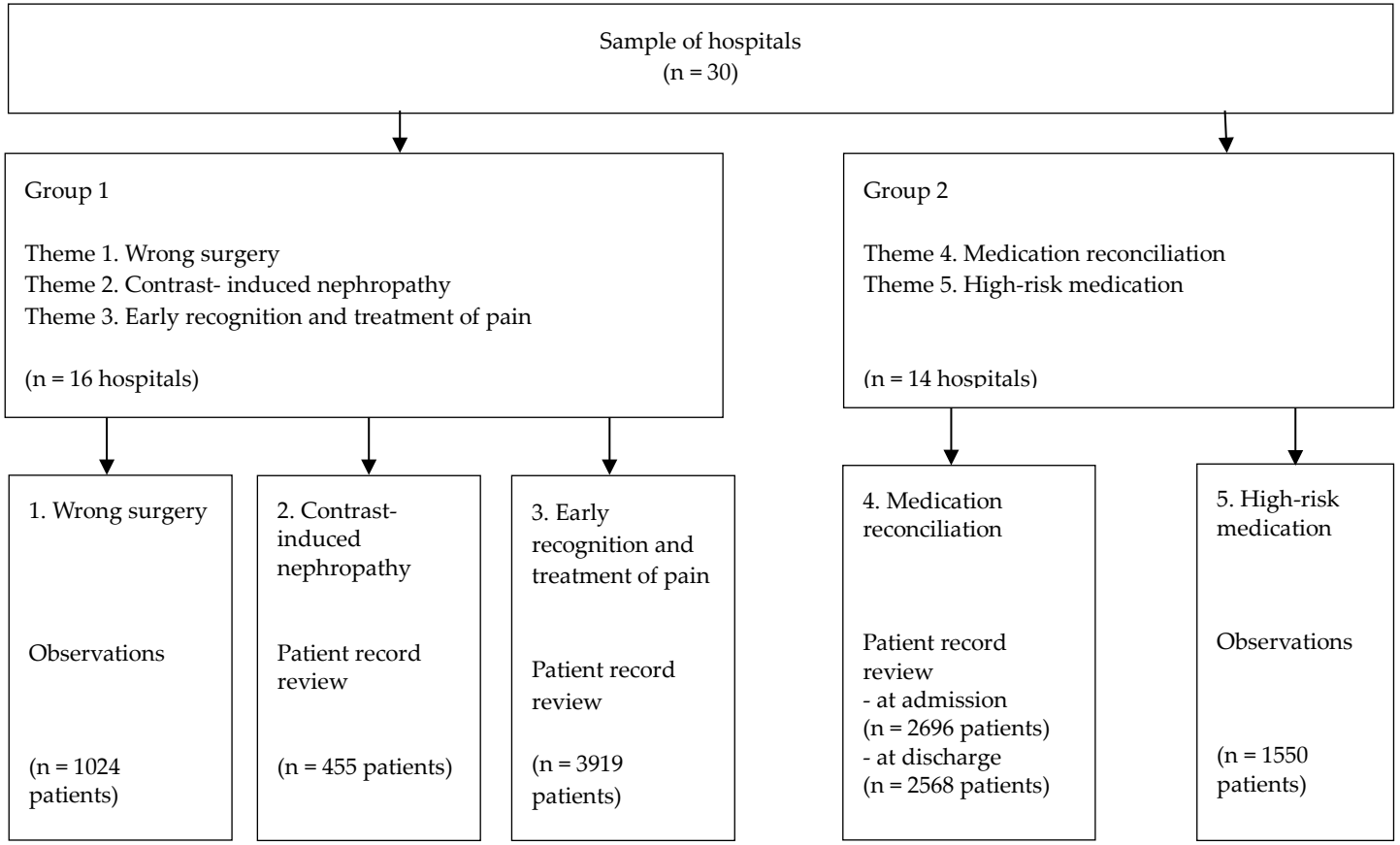
Patient Safety Theme	**Aim within the Safety Programme**	**Interventions in modules of the Safety Programme**	**Design evaluation study**	**Process indicator evaluation study**
Theme 4. Medication reconciliation	Medication reconciliation on admission and discharge.	Bundle 1. Medication reconciliation on admission. 1. Obtain the primary medication history from the central pharmacy. 2. Interview by a trained practitioner. 3. Develop a current and accurate medication review. Bundle 2. Medication reconciliation at discharge. 1. Develop a current and accurate medication review. 2. Make an overview of discharge description authorized by the main specialist. 3. At discharge review with the patient and/or responsible family member of previous medication lists alongside the list of medication prescribed at discharge and reconcile the differences. 4. Communicate changes to a patients' medication regimen to the pharmacist, general practitioner en other caregivers.	Patient record review with 20 - 25 randomly selected records during 10 measurements in 19 hospitals.	Percentage of patients for whom the bundle of medication reconciliation on admission and discharge had been implemented completely.

-.Table 1 continued -

Patient Safety Theme	**Aim within the Safety Programme**	**Interventions in modules of the Safety Programme**	**Design evaluation study**	**Process indicator evaluation study**
Theme 5. High-risk medication	Implementing the described process for preparing and administering parenteral medication.	1. Process of preparing parenteral medication in non-acute situations. 2. Process of admission of parenteral medication in non-acute situations (only this one was focus of the evaluation). 3. Process of preparing and admission in acute situations.	Observational research with 20 - 25 observations of administration processes of parenteral medication at the intensive care unit, internal medicine and general surgery departments. 10 measurements in 19 hospitals.	Percentage of administration processes in which all recommended steps have been followed by the person administering the drug.

Adopted from De Blok et al. 2013.[20]

Figure 1 Data flow diagram for observations included in the present study.



Data analyses

The mean scores for the development stage of the quality system were computed using descriptive analyses, as were the process indicators per patient safety theme. Separate multilevel logistic regression analyses were used to assess the associations between hospital quality system development stage and scores for the process indicators of the different patient safety themes. The data had a two-level structure, as the measurements at the patient level were clustered within hospitals. Intraclass correlation coefficients (ICC) were calculated to assess the degree to which variance in outcomes could be attributed to differences between hospitals. Patient characteristics were not included in the analyses. An ICC of >20% is seen as substantial.[21] Descriptive analyses were performed using Stata version 11.1 and the multivariate analyses were performed using MLwiN version 2.24. Hypothesis testing was one-sided and p-values of <0.10 were therefore considered to be statistically significant.

Results

In total, data from 30 hospitals and 12485 observations were included in this study. Table 2 shows the results of the quality system development stage variables and the results of the process indicators of the patient safety themes. The mean score for hospital quality system development stage was 2.30 (range 1 to 3). This indicates that all hospitals have implemented a quality system into their organization and that most hospitals have designed quality improvement projects but do not systematically use performance measures to adjust quality policy. The mean scores of the development stage of the different quality system domains ranged from 1.56 for Patient Involvement to 2.66 for Human Resources Management (range 1 to 3). This indicates that most hospitals have in fact developed activities to train and educate healthcare staff in quality methods, but patient involvement to quality activities lags behind. The mean percentage of process indicators for the patient safety themes ranged from 12% (Pain indicator: standardized pain measurements, three times a day in the first three days after surgery; Medication Reconciliation at Discharge) to 73% (Time Out Procedure Execution). This indicates large differences between hospitals in the degree to which they have implemented the patient safety themes.

Table 2 Mean scores of descriptors of hospital quality system development and patient safety themes.

Hospital Quality System development	**n**	**Mean**	**SD**	**Range**
Overall	30	2.30	0.41	1-3
Policy and strategy	30	2.50	0.53	1-3
Human resource management	30	2.66	0.52	1-3
Patient involvement	30	1.56	0.92	0-3
Practice guidelines	30	2.54	0.60	1-3
Systematic quality improvement	30	2.22	0.93	1-3
Patient Safety themes		**Mean %**	**SD**	**Range**
Time out procedure	1024	73	44	0-100
- Check patient		- 96	- 21	- 0-100
- Check procedure		- 83	- 40	- 0-100
- Check side/site		- 92	- 27	- 0-100
- Focus during Time-out Procedure		- 55	- 50	- 0-100
Contrast- induced nephropathy	455	67	47	0-100
Pain process indicator 100%	3919	12	33	0-100
Medication reconciliation on admission	2696	35	48	0-100
Medication reconciliation at discharge	2568	12	33	0-100
High-Risk Medication	1550	18	38	0-100

Table 3 Variation between hospitals in the association between hospital quality system development and outcomes for patient safety themes.

	Intercept-only model		**Quality system (overall)**		**1: Policy and strategy**		**2: Human resource management**		**3: Patient involvement**		**4: Practice guidelines**		**5: Systematic quality improvement**	
Patient Safety themes	Hospital range	ICC	Hospital range	ICC	Hospital range	ICC	Hospital range	ICC	Hospital range	ICC	Hospital range	ICC	Hospital range	ICC
Time-out procedure	16-98	35.9	24-96	27.5	22-97	29.4	19-97	33.2	17-98	35.7	20-97	32.6	20-97	32.3
Check patient	74-100	38.3	85-100	26.0	83-100	28.4	*	*	83-100	28.4	*	*	76-100	36.8
Check procedure	16-100	51.6	23-100	46.5	20-100	49.0	18-100	50.2	17-100	51.9	18-100	50.7	22-100	47.0
Check side/site	79-98	11.6	83-97	7.2	80-98	10.6	80-98	10.6	89-96	1.9	79-98	11.6	79-98	11.4
Focus during TOP	18-88	19.8	19-87	18.4	18-88	19.0	18-88	19.8	20-87	17.2	18-89	20.1	18-88	20.1
Contrast- induced nephropathy	22-93	23.1	24-93	21.1	33-90	45.7	22-94	23.3	29-91	17.2	22-94	23.4	22-93	22.7
Pain process indicator 100%	0.4-56	38.9	0.4-55	39.1	0.4-54	38.4	0.4-54	38.9	0.4-52	37.1	0.4-53	37.5	0.4-55	39.0
Medication reconciliation on admission	0.6-96	58.1	0.6-0.96	58.4	0.6-96	58.3	0.5-97	59.4	0.7-95.7	55.9	0.5-97	59.0	0.5-96.8	59.9
Medication reconciliation at discharge	0.1-61	50.7	0.1-56.9	49.1	0.2-47	43.2	0.1-57	49.4	0.1-59	50.9	0.1-52	46.2	0.1-58	49.9
High-Risk Medication	0.8-69	38.9	0.8-68	38.3	0.7-69	39.2	0.9-65	35.9	1.2-60	31.3	0.7-68	38.8	0.7-69	38.9

* there were not enough observations to calculate the associations between Human Resource Management & Practice Guidelines and Check Patient.

Table 3 shows the variation between hospitals in the association between hospital quality system development stage and scores for process indicators for the patient safety themes. The wide range in scores for the various process indicators indicates large differences between hospitals in the implementation of the patient safety themes. For example, there was one hospital in our sample performing Medication Reconciliation on Admission only in 0.6% of admissions, whereas another hospital performed Medication Reconciliation in 96% of admissions. And for Contrast- Induced Nephropathy, the percentage of high-risk patients who were hydrated before undergoing contrast administration varied from 22% to 93%. The ICCs of the intercept-only model ranged between 23.1% for Contrast-Induced Nephropathy and 58.1% for Medication Reconciliation on Admission. The ICC indicates the percentage of the total variance in scores for the process indicators that came from the hospital level. For example, an ICC of 58.1 means that 58% of the total variance was related to differences between hospitals. As an ICC of >20% is considered to be substantial,[21] the differences between hospitals were relatively large in our sample. The ICC decreased when the hospital quality system development stage variable was added to the model. In this model, the ICC ranged from 21.1 for Contrast-Induced Nephropathy to 58.1 for Medication Reconciliation on Admission. The decrease in ICC indicates that the differences between individual hospitals on the process indicator scores can be partly explained by differences in the development stage of the hospitals' quality systems. The remaining variance can be explained by other differences between hospitals that were not measured in this study.

Table 4 Separate associations between hospital quality system development and outcomes for patient safety themes.

	Model 1 Quality system (overall)		1: Policy and strategy		2: Human resource management		3: Patient involvement		4: Practice guidelines		5: Systematic quality improvement	
Outcome	**Estimate (SE)**	**R^2**	**Estimate (SE)**	**R^2**	**Estimate (SE)**	**R^2**	**Estimate (SE)**	**R^2**	**Estimate (SE)**	**R^2**	**Estimate (SE)**	**R^2**
Time-out procedure	-1.89 (0.82)	32.3	-1.33 (0.66)	25.4	-1.25 (0.89)	11.4	-0.16 (0.38)	0.9	-1.08 (0.74)	13.7	-0.57 (0.37)	14.7
- Check patient	-2.49 (1.13)	43.5	-1.65 (0.88)	36.2	-	-	-0.73 (0.40)	36.0	-	-	0.19 (0.51)	6.1
- Check procedure	-2.61 (1.37)	18.3	-1.46 (1.06)	9.6	-1.78 (1.48)	5.2	-0.18 (0.58)	-1.2	-1.02 (1.13)	3.3	-1.02 (0.55)	16.8
- Check side/site	-0.96 (0.49)	40.8	-0.32 (0.44)	8.8	-0.40 (0.54)	8.8	-0.59 (0.14)	8.5	0.09 (0.46)	-0.5	-0.02 (0.23)	1.0
- Focus during TOP	-0.75 (0.62)	8.8	-0.45 (0.50)	4.8	-0.28 (0.61)	-0.1	-0.39 (0.24)	15.8	-0.08 (0.53)	-1.9	-0.02 (0.27)	-1.7
Contrast- induced nephropathy	0.86 (0.68)	0.11	0.29 (0.44)**	14.0	-0.08 (0.63)	-0.9	0.55 (0.25)*	30.8	-0.11 (0.45)	-1.7	-0.17 (0.29)	2.2
Pain process indicator 100%	0.09 (0.98)	-0.5	-0.55 (0.75)	2.3	0.41 (0.89)	0.1	0.28 (0.37)	7.3	-0.66 (0.62)	5.8	0.12 (0.40)	-0.2
Medication reconciliation on admission	0.64 (1.40)	-1.3	0.53 (0.99)	-0.9	0.42 (1.06)	-5.5	0.97 (0.76)	8.4	-0.41 (1.00)	-3.8	-0.13 (0.67)	-7.5
Medication reconciliation at discharge	1.01 (1.30)	6.3	1.73 (0.87)*	26.0	-0.64 (0.87)	5.0	-0.002 (0.74)	-0.8	1.33 (0.92)	16.6	0.21 (0.59)	3.1
High-Risk Medication	0.51 (0.91)	2.4	-0.04 (0.68)	-1.2	-0.81 (0.61)	12.0	0.89 (0.42)*	28.4	0.20 (0.66)	0.1	0.20 (0.45)	-0.1

* $p<0.10$, ** $p<0.05$

Table 4 shows the association between hospital quality system development stage and scores for the process indicators for the patient safety themes. For four of the five safety themes, positive associations were found between the development stage and the process indicators. However, none of these associations were statistically significant. Inconsistent results were found when examining the associations between the different dimensions of the quality system development stage. Some of the associations were positive and some were negative, but only a few were statistically significant. Statistically significant positive associations were found between the Policy and Strategy dimension and the patient safety themes Medication Reconciliation at Discharge and Contrast- Induced Nephropathy. Statistically significant positive associations were found between Patient Involvement and the patient safety themes Contrast-Induced Renal Failure and High-Risk Medication. One additional analysis was performed, as the association between the hospital quality system development stage and the process indicators for the patient safety theme Wrong Surgery was in the opposite direction to what had been expected. This association was investigated in more detail by examining the association between the hospital quality system development stage and the three individual checks of the TOP. Negative associations were found between the development stage of the quality system and the checks on the patient identity and the check on the side/site.

Discussion

Quality systems are hypothesized to have an influence on quality improvement activities at the process level, which in turn influence hospital outcomes at the patient level. This study linked the development stage of a hospital quality system (structure) to the implementation of patient safety themes at the process level (processes) in Dutch hospitals. This was measured by means of process indicators. We found no statistically significant associations between the development stage of a quality system and the implementation of patient safety themes. Some statistically significant associations were found between dimensions of the quality system development stage and process indicators for the implementation of patient safety themes. However, given the large number of associations that were tested compared to the limited number of statistically significant associations found, it is possible that these findings can be attributed to chance. We therefore conclude that this study found no conclusive evidence for a positive association between the development stage of a hospital

quality system and the implementation of patient safety themes at the process level. An interesting finding is the large variation in scores of hospitals on the implementation of the patient safety themes.

The results of this study could indicate that no association exists between structure and processes in the cycle of quality improvement. However, other explanations seem more likely. These might be associated with the translation of the quality systems into quality improvement activities at the process level on the one hand, or with the complexity of implementation itself on the other. Firstly, several factors could hinder the translation of structural factors into more practical activities that can be applied on the work floor. For example, the extent to which hospital management uses a top-down approach to make a connection between the quality system and processes in their hospital could influence the extent to which quality system components are adequately translated into quality activities at the hospital department level. Alternatively, the attitudes of healthcare staff to quality improvement might play a role in the extent to which parts of the quality system are adopted and adhered to at the clinical level. These factors might mediate the relationship between quality systems and processes, making it complex to measure and attribute to the variation of scores on process indicators that we found in this study.

Secondly, the structure of quality management is unlikely to be the only explanatory factor in the degree of implementation of patient safety themes. Implementation is seen as highly complex, as the extensive body of literature on barriers and facilitators for implementation illustrates.[22-25] Besides organizational aspects that can facilitate implementation of interventions into healthcare practice, individual factors play an important part as well. More specifically, implementation is assumed to require behavioral changes by individual healthcare staff and numerous theories on behavioral change have been developed to guide interventions. Recently, the theoretical domains framework has captured the key concepts of all these different theories in a comprehensive framework of 14 domains that can help to explain implementation problems and provide input for the design of interventions.[26,27] The theoretical domains framework highlights not only the importance of a theoretical grounding in the design of interventions but also the broad spectrum of concepts that are associated with healthcare staff behavior.[26,27] These behavioral components were not measured in the present study but might have been important in the level of implementation of the patient safety themes en might explain the large differences that between hospitals.

Strengths and limitations

This study expands upon existing literature on the effectiveness of quality systems by studying the association between organizational structure and organizational processes. This corresponds to current views that quality systems do not directly influence outcomes at the patient level, but that this is achieved through the improvement of processes.[9,11,19,28] Taking all the different dimensions of a quality system into account lets our study offer a broad picture of the associations between structure and processes within the theory of quality improvement. The multilevel approach that was used in the present study accounted for the clustering of observations at the patient level within hospitals, allowing data at the hospital level to be linked to data at the patient level.

We acknowledge several limitations to our study. Firstly, the independent variable in our study (quality system development) relied on self-reported data and this might have led to socially desirable responses. The measurement instrument used for determining the development stage of hospital quality systems has been widely used and validated.[4-8] We are therefore confident that we have captured the key aspects of the development of hospitals' quality systems. Secondly, this study combined data from two different studies. Only the hospitals that participated in both data collections could therefore be included in the present study, which limited the number of hospitals. Thirdly, the variation of scores for our independent variable (the quality system development stage) was small. This may have limited the possibilities for finding significant associations. Future research should explore or develop new and more sensitive possibilities for measuring (aspects of) quality systems.

Conclusions

This study found no association between the development stage of a hospital quality system and the degree of implementation of patient level safety themes at the process level. This contradicts the hypothesis that quality improvement is caused by a positive association between structure and processes, which in turn contribute to outcomes at the patient level. Several factors may have contributed to the results of this study. Future research should try to resolve methodological constraints associated with the measurement of quality systems as well as quantifying more factors associated with the implementation of quality improvement interventions.

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5

The ecometric properties of a measurement instrument for prospective risk analysis in hospital departments

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Abstract

Background
Safety management systems have been set up in healthcare institutions to reduce the number of adverse events. Safety management systems use a combination of activities, such as identifying and assessing safety risks in the organizational processes through retrospective and prospective risk assessments. A complementary method to already existing prospective risk analysis methods is Tripod, which measures latent risk factors in organizations through staff questionnaires. The purpose of this study is to investigate whether Tripod can be used as a method for prospective risk analysis in hospitals and whether it can assess differences in risk factors between hospital departments.

Methods
Tripod measures risk factors in five organizational domains: (1) Procedures, (2) Training, (3) Communication, (4) Incompatible Goals and (5) Organization. Each domain is covered by 15 items in the questionnaire. A total of thirteen departments from two hospitals participated in this study. All healthcare staff working in the participating departments were approached. The multilevel method ecometrics was used to evaluate the validity and reliability of Tripod. Ecometrics was needed to ensure that the differences between departments were attributable to differences in risk at the departmental level and not to differences between individual perceptions of the healthcare staff.

Results
A total of 626 healthcare staff completed the questionnaire, resulting in a response rate of 61.7%. Reliability coefficients were calculated for the individual level and department level. At the individual level, reliability coefficients ranged from 0.78 to 0.87, at the departmental level they ranged from 0.55 to 0.73. Intraclass correlations at the departmental level ranged from 3.7% to 8.5%, which indicate sufficient clustering of answers within departments. At both levels the domains from the questionnaire were positively interrelated and all significant.

Conclusions
The results of this study show that Tripod can be used as a method for prospective risk analysis in hospitals. Results of the questionnaire provide information about latent risk factors in hospital departments. However, this study also shows that there are indications that the method is not sensitive enough to detect differences between hospital departments. Therefore, it is important to be careful when interpreting *differences* in potential risks between departments when using Tripod.

Background

Patient safety is an important aspect of the quality of care in hospitals. Patient safety can be defined as the reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum.[1] Previous studies have shown that between 2.9% and 16.6% of hospital admissions lead to adverse events[2], of which approximately 50% are potentially preventable.[3] Adverse events can be defined as harm to patients that was not caused by the underlying disease but by medical management, leading to prolonged hospitalization, re-hospitalization, disability or death.[1] In order to reduce the number of adverse events, safety management systems have been set up in healthcare institutions.[4-6] Safety management systems aim to prevent undesired outcomes in healthcare by a combination of activities, such as improvement projects, incident reporting and analyses, and risk assessments to identify and assess safety risks in the organizational processes.[6]

Risk assessments can be performed retrospectively or prospectively. To date, retrospective risk management has been most common in healthcare.[7] Several methods for retrospective risk assessments in healthcare are currently used; the key element in all these methods is the analysis of the *causes* of incidents, near-misses and unsafe situations in order to prevent them from happening again in the future. Examples of these methods are the Prevention and Recovery Information System for Monitoring and Analysis (PRISMA) and Root Cause Analysis (RCA).[7,8] These methods have two disadvantages. First, they require an open incident reporting culture since they rely on reporting by healthcare staff. Second, the analysis can only take

place *after* an unsafe situation has been revealed, with or without consequences.[7] It therefore makes sense to analyze risks in a prospective manner, complementary to retrospective methods, to prevent unsafe environments that could potentially lead to adverse events.[7]

In prospective risk analysis, processes are analyzed for potential risks in order to prevent errors from happening in the first place. Some well-known methods are the Healthcare Failure Mode and Effect Analysis (HFMEA) and Bow-Tie.[9-13] Both methods focus on analysis of care processes, and are often organized around a specific disease and therefore bound to one particular medical specialty. In these methods, a group of professionals meets several times to systematically map out the care process that was chosen for the risk analysis. The potential risks and their consequences are determined, and ways of preventing these situations are considered. Although these methods can create awareness about potential risks, they are time- consuming and only focus on one care process at a time.

A complementary method to existing prospective risk analysis methods is Tripod, which takes account of the key organizational processes. Tripod measures latent risk factors categorized into what are termed Basic Risk Factors (BRFs) at the departmental level by means of staff questionnaires. Latent risk factors are risk factors that are present within departments but are not always clearly visible. Tripod uses the individual risk perception of staff to determine the BRFs for an individual department. BRFs are used to determine potential risks in five general organizational domains: Procedures, Training, Communication, Incompatible Goals, and Organization. The method has its origins in the petrochemical sector[14-16] but could also be applied in the healthcare setting.[17] Tripod has the potential to be broader and less time-consuming than existing methods. The method can be used as a starting point to obtain a broad picture of the level of control over the organizational processes at the departmental level, and the results allow prioritization of further in-depth prospective risk analyses. The purpose of this study is to investigate whether Tripod is appropriate as a method for prospective risk analysis within hospital departments. This study is based on the adjusted Tripod for prospective risk analysis in healthcare, known as Tripod Delta HC. We will discuss the changes to Tripod to create Tripod Delta HC in more detail in the Methods section.

The research questions addressed in this study are:

- *Can Tripod Delta HC be used as a measurement instrument for prospective risk analysis in hospitals?*
- *Can Tripod Delta HC be used to assess differences in latent risk factors between hospital departments?*

Methods

Measurement instrument: theory and development

Tripod is founded on the idea that human error can be prevented or mitigated by controlling the environment people work in.[14,16,18-20] According to Tripod, there are latent failures in every work environment and these can be categorized into BRFs. Each of the BRFs may contribute to adverse events in different ways, and when a combination of different undesirable situations emerge at the same time, this will lead to disturbances in the operational process, with or without consequences.[21,22] BRFs are controllable in the sense that they can be influenced by changing the organization and management of processes.

Tripod was originally developed for use in the petrochemical industry but is also seen as a promising option for patient safety.[5,20] However, the original questionnaire could not be applied in healthcare without some modifications to create ownership of the users in a healthcare setting.[23] In this study, we took the shortened Tripod questionnaire, known as Tripod Delta Lite, as a starting point for the development of Tripod Delta HC. This shortened questionnaire, which contained five general BRFs and consisted of 75 items, was extracted from the full version that contained ten further specific risk factors and a total of 150 items.

Modifications to Tripod Delta Lite were made by the authors, who consulted a group of 14 experts. The group consisted of registered nurses and researchers with experience in healthcare who assessed the content validity of the questionnaire by reviewing the modified questionnaire. Experts were asked to evaluate the importance and content of each item in the questionnaire and state whether they thought any important aspects were

missing. Comments and suggestions were summarized. Nurses generally suggested changes to improve the applicability of the item in a healthcare setting. Researchers commented on the structure of the questionnaire and response categories. This led to the use of five-point scales rather than dichotomous (yes/no) response categories that were used in Tripod Delta Lite. The modifications did not alter the underlying assumptions of the items or the underlying constructs of the questionnaire and led to a revised questionnaire that was used in this study and is called Tripod Delta HC. In the remainder of this article we will only refer to this modified healthcare version.

Measurement instrument: structure

Tripod Delta HC measures BRFs in five organizational domains: (1) Procedures, (2) Training, (3) Communication, (4) Incompatible Goals and (5) Organization. Each BRF is covered by 15 items that form a scale. Table 1 gives the definitions of the different BRFs and some example items.

In total the questionnaire contains 75 items that are measured on a five-point Likert scale ranging from 'totally disagree' to 'totally agree'. Respondents were also offered the response option of 'not applicable': this box could be checked if the participant was unfamiliar with the content of the item or had no opinion. Respondents were asked to answer the questions with the last six months in mind. In addition, some background characteristics were measured (i.e. age, gender, years working in hospital). See Additional file 1 for the items used.

Sampling

This study was carried out at one academic hospital and one general hospital, based on a convenience sample. Three departments in the academic hospital took part and ten departments in the general hospital, making thirteen departments in total. There was a wide variety of departments. All healthcare staff working in the participating departments at the time of the study were approached, regardless of whether they had daily patient interaction. The Dutch Medical Research Involving Human Subjects Act does not apply to this research. Therefore, no approval was needed from the Medical Ethics Committee.

Table 1 Definitions of the five basic risk factors of Tripod Delta HC

Basic Risk Factors	Definition	Example item
BRF Procedures	Insufficient quality or availability of procedures, guidelines, instructions, and manuals (specifications, administration, use in practice).	"Because procedures are insufficiently clear, I sometimes have to act according to my own discretion".
BRF Training	No or insufficient competence or experience among healthcare staff (not sufficiently suited to their tasks, inadequately trained).	"There are always sufficiently experienced healthcare staff present in the department".
BRF Communication	No or ineffective communication between the various sites, departments or healthcare staff of an organization or with the official bodies.	"Important information is often sent to the wrong department in the hospital".
BRF Incompatible Goals	The situation in which healthcare staff must choose between optimal working methods according to the established rules on one hand, and the pursuit of production, financial, political, social or individual goals on the other.	"Necessary maintenance work has been postponed due to high costs".
BRF Organization	Shortcomings in the organization's structure, organization's philosophy, organizational processes or management strategies, resulting in inadequate or ineffective management of the organization.	"The tasks are not properly coordinated between departments so that work is carried out twice".

(Controlling the controllable, Jop Groeneweg 2002).

Procedure

Data was collected between December 2011 and March 2012. Each hospital appointed one contact, who was the quality coordinator in both cases. The contact invited all the hospital's departments to participate in our study. In both hospitals, all departments were approached and asked to participate.

However, in the academic hospital, the participation of departments was voluntary and the decision of a department to participate lay with the head of that department. In the general hospital, the director made the decision that all departments needed to participate in the study. The e-mail addresses of all healthcare staff currently working in the participating departments were collected. To guarantee privacy, the researcher did not receive the personalized e-mail addresses. The two hospitals followed different procedures to ensure this. In the academic hospital, invitation e-mails were sent to the secretaries of the departments, who forwarded invitation e-mails to the individual e-mail addresses. In the general hospital, the e-mail addresses were encrypted by personnel number. The invitation e-mail contained the purpose of the study and information about the procedure and guaranteed anonymity of the respondent. As participation was voluntary, no written informed consent needed to be obtained from the participants. The e-mail contained a link that led to the questionnaire simply by clicking on it. Reminder e-mails were sent to non-respondents after two and four weeks. The questionnaire took approximately 15–20 minutes to complete. In total, 1015 persons were invited and 626 healthcare staff completed the questionnaire, resulting in a response rate of 61.7%. Table 2 gives an overview of the response rates per hospital. Table 3 gives an overview of characteristics of the study population and shows that the largest group of respondents consists of registered nurses (47.4%).

Table 2 Response rates

	Invited (n)	**Completed (n)**	**Response (%)**
Hospital A- academic	332	195	58.7
Hospital B- general	683	431	63.1
Total	1015	626	61.7

Table 3 Overview of the study population

		N	%
Gender	Male	120	19.2
	Female	505	80.8
Age	<30	110	17.7
	30-50	350	56.2
	>50	163	26.2
Department	Children's department	48	7.7
	Emergency room	33	5.3
	Gynecology	69	11.0
	Intensive care department	48	7.7
	Internal department	29	4.6
	Lung diseases & cardio department	35	5.6
	Neurology	92	14.7
	Operating rooms	57	9.1
	Orthopedic department	16	2.6
	Short-stay nursing department	42	6.7
	Surgical department	26	4.2
	Thorax center	131	20.9
Experience	0-5 years	230	36.7
	6-20 years	266	42.1
	>20 years	130	20.8
Profession	Nurse	297	47.4
	Physician	43	6.9
	Other (interns, operation assistants etc.)	286	45.7
Patient contact	Yes	549	87.7
	No	77	12.3

Note: Neurology was included in both hospitals.

Data preparation

First, negatively worded items were recoded so that a lower score reflected a lower potential risk for all items. In general, respondents were more likely to agree that a positive situation applied than a negative situation. Data was checked for completeness. All items in the questionnaire were mandatory and respondents were not able to skip questions, although they could exit the questionnaire before the end. A total of 32 respondents (5.1% of the total

sample) did not answer at least 50% of the questions, meaning that they had stopped partway through the questionnaire; these respondents were excluded from further analyses. The remaining dataset did not contain any missing data. When respondents checked the category 'not applicable', the score was replaced by a missing value. The analyses were performed on the remaining 594 respondents.

Ecometrics approach

Ecometrics is a multilevel method to evaluate the validity and reliability of imperfect measures of contextual properties.[24] An ecometrics approach was used to ensure that the differences between departments are attributable to differences in potential risks at the departmental level and not to differences between the individual perceptions of the healthcare staff who responded to the questionnaire. The aim of this method is to measure the latent characteristics of ecological units (in this research, the ecological unit is the hospital department). Furthermore, the method aims to combine multiple observations into one scale to analyze the reliability and validity of the scale. The data structure is as follows: the items are at the lowest level, nested within the healthcare staff member, and healthcare staff are nested within the departments, which are at the highest level. There were 13 departments in our sample, which were treated as separate units in the analyses. A weighted item average for all healthcare staff was calculated for each item to calculate an average scale value. This was done by using the item weights for the fixed effects. The item variance, which is an indication of the measurement error, was taken into account in this analysis.

Statistical procedure

Aspects of the reliability of the scales were assessed in terms of internal consistency using a reliability coefficient. Reliability indicates how well the individual items of a scale measure the underlying concept of the scale. The interpretation is the same at the individual level as at the departmental level, and comparable to Cronbach's alpha coefficient[24,25]: values range between 0 and 1, with a higher score representing a more reliable scale. If the reliability coefficient for a scale is at least 0.70, this suggests that the items in a scale are measuring the same concept. Values above 0.80 indicate high internal consistency. Descriptive analyses were used to calculate means, standard deviations and the range of scores for the different scales in the

questionnaire at the individual and departmental levels. Variance and intraclass correlations were calculated to assess the clustering of answers at the individual and departmental levels.[24] An intraclass correlation of 20% is seen as moderate.[26] Correlations between scales were calculated at the individual and departmental levels to check that the scales were measuring different concepts. High correlations between scales indicate that the scales are measuring similar concepts. The minimum required sample size to assure adequate reliability for comparing results between departments was estimated for each of the scales, based on the number of healthcare staff in each department and reliability coefficients in the current study. This gives the minimum number of respondents per BRF that is needed to make reliable inferences about differences between departments. The descriptive analyses were conducted using STATA version 11.0 and the multi- level analyses were performed using MlwiN version 2.24.

Results

Reliability analyses

Table 4 gives the reliability coefficients for the different scales. At the individual level, the reliability coefficients ranged from 0.78 to 0.87. This indicates good to excellent internal consistency at the individual level. The internal consistency at the departmental level ranged from 0.55 to 0.73. For the BRF Procedures and the BRF Incompatible Goals the internal consistency of the scales at the departmental level was less than 0.70, which is below the minimum preferred value.

Table 4 Reliability of scales at the individual and departmental level

BRF	Reliability Individual level	Reliability Departmental level
BRF Procedures	0.87	0.68
BRF Training	0.83	0.70
BRF Communication	0.79	0.71
BRF Incompatible Goals	0.80	0.55
BRF Organization	0.78	0.73

Note: 0.70 or higher can be assumed sufficient.

Variance and intraclass correlations

The clustering of responses at the individual and departmental levels for each of the BRFs is shown in Table 6. The intraclass correlations (ICCs) at the departmental level ranged from 3.7% for the BRF Incompatible Goals to 8.5% for the BRF Organization. The ICC of 8.5% for the BRF Organization means that 8.5% of the variance in the responses to the various items in the BRF Organization can be attributed to differences between departments. In this study, clustering effects are relatively small. In the case of all the dimensions (BRFs) of Tripod Delta HC, most of the variance was at the individual level.

Descriptives of the scales

Table 5 gives the descriptive statistics for the scale scores at the individual and departmental levels, calculated using the multilevel model. On a scale from 1 to 5 (a lower score reflects a lower potential risk), the mean scale scores at the individual level ranged from 2.12 for the BRF Training to 2.89 for the BRF Procedures. At the departmental level, the mean scale scores ranged from 2.12 for the BRF Training to 2.92 for the BRF Procedures.

Table 5 Descriptive statistics of the basic risk factors at the individual and departmental levels on a scale from 1 to 5

BRF	Individual level (N = 588)		Departmental level (N = 13)	
	Mean (SD)	**Range**	**Mean (SD)**	**Range**
BRF Procedures	2.89 (0.47)	1.42 - 4.11	2.92 (0.11)	2.68 - 3.09
BRF Training	2.12 (0.41)	1.14 - 4.05	2.12 (0.10)	1.92 - 2.28
BRF Communication	2.49 (0.33)	1.51 - 4.01	2.49 (0.09)	2.29 - 2.59
BRF Incompatible Goals	2.16 (0.36)	0.99 - 3.42	2.17 (0.06)	2.01 - 2.24
BRF Organization	2.64 (0.36)	1.49 - 3.83	2.63 (0.11)	2.38 - 2.82

Table 6 Variance at the individual and departmental levels and intraclass correlation coefficients (ICCs)

	Individual level	**Departmental level**	
	Variance (SE)	**Variance (SE)**	**ICC%**
BRF Procedures	0.241***	0.016	6.36%
	(0.017)	(0.009)	
BRF Training	0.184***	0.014	6.85%
	(0.013)	(0.008)	
BRF Communication	0.121***	0.010*	7.57%
	(0.009)	(0.005)	
BRF Incompatible Goals	0.158***	0.006	3.70%
	(0.012)	(0.004)	
BRF Organization	0.150***	0.014*	8.53%
	(0.011)	(0.007)	

*p < 0.05. ** p < 0.01. ***p < .0.001 (significance was tested using the Wald statistic).

Correlations between scales

The correlations between BRFs were examined in order to test the interdependency of the five different scales of Tripod Delta HC. The results are shown in Table 7. At both the individual and departmental levels, BRFs were positively correlated and all correlations were significant (P < 0.05). At the individual level, the correlations between BRFs ranged between 0.40 and 0.75. At the departmental level, the correlations ranged between 0.29 and 0.83. At both levels there was heterogeneity in the size of the correlations. Most correlations were stronger at the departmental level than the individual level. This indicates that the average responses at the departmental level are strongly correlated. For example, a department that scores highly for the BRF Organization is likely to have a high score for the BRF Communication as well.

Table 7 Correlations at the individual level (left of the diagonal) and departmental level (right of the diagonal)

	BRF Procedures	**BRF Training**	**BRF Communi-cation**	**BRF Incompatible Goals**	**BRF Organization**
BRF Procedures	-	0.29	0.62	0.80	0.60
BRF Training	0.40	-	0.70	0.61	0.71
BRF Communication	0.56	0.53	-	0.81	0.83
BRF Incompatible	0.64	0.59	0.62	-	0.81
BRF Organization	0.56	0.61	0.65	0.75	-

All correlations were significant at $p < 0.05$.

Minimum required sample size for acceptable reliability at the departmental level

Table 8 gives the minimum required sample size for acceptable reliability at the departmental level. For each of the BRFs, the reliability coefficient is calculated for any given sample size. This makes it possible to determine how many healthcare staff per department need to be included in the study in order to make reliable interferences about differences between departments. For example, including 75 healthcare staff in a study results in a reliability coefficient of 0.82 for the BRF Procedures but the reliability for the BRF Incompatible Goals is 0.70 with 75 healthcare staff.

Table 8 Minimum required sample size for acceptable reliability at the departmental level*

Number of respondents	BRF Procedures	BRF Training	BRF Communication	BRF Incompatible Goals	BRF Organization
	Reliability coefficient				
20	0.54	0.55	0.57	0.38	0.59
25	0.60	0.60	0.62	0.43	0.64
30	0.64	0.65	0.66	0.48	0.69
40	0.70	0.71	0.72	0.55	0.74
50	0.75	0.75	0.76	0.60	0.78
75	0.82	0.82	0.83	0.70	0.84
100	0.86	0.86	0.87	0.75	0.88
125	0.88	0.88	0.89	0.79	0.90
150	0.90	0.90	0.91	0.82	0.92
200	0.92	0.92	0.93	0.86	0.94
250	0.94	0.94	0.94	0.88	0.95

*A reliability coefficient of less than 0.70 is considered below the minimum value for acceptable reliability.

Discussion

This study assessed whether Tripod Delta HC can be used as a measurement instrument for prospective risk analysis in healthcare, and whether it can detect differences in risk factors between hospital departments. Most studies in healthcare use classical psychometric methods originating from psychology for assessing the reliability and validity of questionnaires, for example research into patient safety climate.[27,28] However, in healthcare these methods are only suitable for assessing differences in individual perceptions or attitudes. This study is mainly interested in the characteristics of the ecological construct (the department), and less in individual attitudes. Using individuals to assess the characteristics of departments results in imperfect measures because it is an indirect way to assess a department characteristic.[24] Therefore, this study used ecometrics to filter out this individual component. The individual variance is split from the variance at the departmental level and the remaining variance at the departmental level can be used as an indication for differences between departments. The results of this study show that the variance at the departmental level is small, although significant for some BRFs. This could have several causes. First, there might actually be only small differences between departments in the study population. Our study population consisted of only two hospitals; it could be that the departments within the hospitals were made very similar by organization-wide policies. In terms of patient safety, this is positive as it indicates that departments are similar and obtain low scores for the different BRFs. Second, there could be a large spread in the individual scores which would increase the variance at the individual level. However, we found no indication for this in our data. And lastly, Tripod Delta HC might not be sensitive enough to detect differences between departments. Given the small number of hospitals in this study, we are unable to determine the precise cause. However, this study does point out that it is important to take account of the variance at the higher level when measuring ecological units. Good psychometric properties are needed to describe differences in individual scores (healthcare staff), but when the intention of a measurement instrument is to describe differences in compositional scores (departments), good ecometric properties are needed.

Practical implications

The results of this study show that the reliability of Tripod Delta HC is acceptable and that the questionnaire can be used to assess potential risks in hospitals. However, some of the BRFs exhibit lower reliability and little variance at the departmental level. For these BRFs it is important to be careful when drawing conclusions about differences between departments in potential risks. The minimum required sample size for acceptable reliability should be considered when using Tripod Delta HC in healthcare. This can be used as a tool to improve the reliability of the scales but also to prevent the unnecessary inclusion of healthcare staff in a study. As can be seen from Table 8, a larger number of respondents is needed for the BRF Incompatible Goals to assure good reliability than for the other BRFs. In practice, hospital departments are generally not large enough to deliver these numbers of healthcare staff. In these cases, the scores should not be used to compare departments with respect to this BRF. Furthermore, when developing interventions to improve patient safety, it is important to consider whether they need to be implemented at the individual level or the departmental level. As all BRFs show low variance at the departmental level, it would be more effective to implement interventions at the individual level throughout the hospitals.

Limitations

We acknowledge several limitations to this study. First, only two hospitals were included in this study. The results cannot be generalized to the wider hospital population without caution. Future research, for instance in a larger group of hospitals, is needed to validate the findings of the current study. Second, the recruitment of departments was different in the two participating hospitals. However, the questionnaires were filled out by the healthcare staff and the decision to participate in both hospitals was individual and voluntary. Furthermore, the aim of this study was not to compare the two hospitals, but to validate the questionnaire that was used. Therefore, we are confident that the difference in numbers of participating departments between the hospitals did not affect the results of this study. Third, the largest group of respondents was registered nurses (47.4%; see Table 3). The group of physicians in our study was too small for separate statistical analyses. Fourth, questions in the questionnaire were grouped per BRF. This was meant to make it more convenient for the respondent to fill in

the questionnaire, not having to switch mentally between concepts. It would be interesting to test whether a mix of questions from different concepts can improve the sensitivity of reliability measures. Although improving Tripod Delta HC was not the purpose of this study, future research could study the practical usage, for example by excluding items with low sensitivity or study the meaning of differences in correlations between departments with similar specialties from different hospitals.

Conclusions

This research assessed whether Tripod Delta HC can be used as a method for prospective risk analysis in hospitals and whether it can measure differences between departments in their assessed risks, using a multilevel ecometric approach. Tripod Delta HC measures five BRFs at the hospital departmental level. In general, the ecometric properties of the modified healthcare version of Tripod Delta HC are satisfactory. The results show that the reliability of the instrument, as measured by the internal consistency of the items, is good at both the individual and departmental levels for most of the BRFs. This indicates that Tripod Delta HC can be used as a measurement instrument for prospective risk analysis in hospitals. However, two BRFs did not show much clustering at the departmental level or acceptable internal consistency at the departmental level. It was not possible to detect differences between departments for these BRFs. Overall, the results show that Tripod Delta HC is a useful instrument for assessing latent risks at the individual level, and for some BRFs at the departmental level as well. It might not be possible to measure differences between departments with Tripod Delta HC but further research in larger settings is needed to confirm these findings.

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Appendix A
Tripod Delta Health Care: questionnaire

Welcome to the risk assessment Tripod Delta HC
In this questionnaire we will inquire about your experiences with regard to a number of possible risk factors in your department. The questionnaire contains 75 statements and can be answered in about 15 minutes. Before starting with filling in the questionnaire we would like to first request some background information from you.

The questions below will assist us with the analysis and interpretation of the questionnaire.		
A1.	What is the year of your birth?	
A2.	What sex are you?	o female o male
A3.	How long have you been working at this hospital?	o less than 3 months o 3 months to 1 year o 1 to 5 years o 6 to 10 years o 11 to 15 years o 16 to 20 years o 21 years or more
A4.	How long have you been working in your current department?	o less than 3 months o 3 months to 1 year o 1 to 5 years o 6 to 10 years o 11 to 15 years o 16 to 20 years o 21 years or more
A5.	In which department in this hospital do you mainly work?	o Internal medicine o Cardiology o Neurology o Surgery o Orthopaedics o Intensive care o Accident and emergency o Other, namely:

A6.	What is your position in this hospital? Give 1 answer which describes your position best.	o Nursing assistant/ auxiliary nurse o Trainee nurse o Qualified nurse o Physician's Assistant / Nurse Practitioner o Physician o Physician in training for specialist (fellow) o Medical specialist o Pharmacist o Administrative employee / Secretary o Physiotherapist / Occupational therapist /Speech therapist o Medical analyst / laboratory technician o Radiotherapy technician o Function department employee (for example heart function, lung function, EEG) o Management o Other, namely:
A7.	How long have you been working within your current specialism or this position?	o less than 3 months o 3 months to 1 year o 1 to 5 years o 6 to 10 years o 11 to 15 years o 16 to 20 years o 21 years or more
A8.	How many hours per week do you usually work in this hospital?	o less than 20 hours per week o 20 to 39 hours per week o 40 to 59 hours per week o 60 or more hours per week
A9.	Based on your position within this hospital, do you usually have direct interaction or contact with patients?	o YES, I usually DO have direct interaction or contact with patients o NO, I usually DO NOT have direct interaction or contact with patients

Completion instructions Tripod Delta HC

Please carefully read the instructions below before starting to fill in the questionnaire.

Whilst deciding on your answer **ONLY** think about the situation at your department during the **LAST HALF YEAR** (anything that happened longer ago is no longer relevant to this research).

Please indicate for each statement the extent to which this statement applies to your department.
For this you can chose from the answer possibilities below:

1 *Strongly disagree*
2 *Disagree*
3 *Neutral*
4 *Agree*
5 *Strongly agree*
NA *Not applicable or no opinion*

We use the term 'healthcare staff' in this questionnaire. We mean all care providers and disciplines which are involved in direct patient care.

1. Less experienced healthcare staff is given work without clear working instructions.
2. Tasks are inadequately carried out, or not carried out at all, because the knowledge and skills of the healthcare staff is insufficient.
3. New healthcare staff is sufficiently monitored during their work.
4. The executing staff have sufficient qualifications to carry out their work.
5. Inexperienced healthcare staff is given sufficient time to gain practical experience.
6. Superiors have the competence to carry out their work.
7. The management provides sufficient opportunities to attend courses.
8. There is an instruction programme for new healthcare staff which covers all important aspects of their work.
9. My application for a course or training programme is often rejected without clear reasons.

10. It happens often that I apply for a course or training programme, but cannot attend due to capacity problems at the department.
11. Thanks to the training policy it is clear which training programmes I can attend and when.
12. I sometimes have doubts about the professional competence of a colleague.
13. There is always sufficiently experienced healthcare staff present at the department.
14. I regularly have to redo the work of an inexperienced colleague because it was not carried out correctly.
15. All important positions at my department are filled by qualified healthcare staff.
16. I often received conflicting information from different sources without knowing which source is correct.
17. When I am searching for specific information (for example a procedure) I often don't know where to find this.
18. My questions are always answered within a reasonable period of time (from, for example, supporting departments or specialists).
19. I often receive important information about changes in working methods and arrangements through the grapevine instead of through the official route.
20. I have sometimes made a mistake because the necessary information had not been correctly conveyed.
21. Important information is often sent to the wrong department in the hospital.
22. I often receive so much information that I have to ignore (part of) this information.
23. I am often confronted with a code or abbreviation the meaning of which I don't know and cannot easily find out.
24. In my work area there is often so much noise that I cannot understand important information.
25. Generally I can reach other departments easily by telephone.
26. I sometimes do not receive a letter or email with important information because I was omitted from the mailing list by mistake.
27. I often receive outdated information.
28. When I ask something from different colleagues I get a different answer from each of them.

29. I am aware of departments within my hospital that do not give me information when I ask for this, without good grounds.
30. Patient information is often sent too late to a department.
31. The tasks are not properly coordinated between departments so that work is carried out twice.
32. Relatively unimportant matters take up too much of my time.
33. I have sometimes been held wrongly responsible for something.
34. I sometimes have to take decisions although I know that they are not part of my responsibilities.
35. Management sometimes give me orders which in my opinion are unnecessary.
36. My superior has sometimes reversed a decision I made without consulting with me.
37. The management has persevered with an unusual policy.
38. I often have to work outside my normal working hours due to poor cooperation.
39. I have the sufficient competence to carry out my work properly.
40. It has happened before that I did not know to whom I could delegate tasks.
41. It has happened before that I disagreed with a specific approach but did not dare speak about this with my superior.
42. It is always clear in my work situation who is responsible for what.
43. There are sometimes complaints made against me although I was not responsible for what had happened.
44. I sometimes have carried out the same work twice due to miscommunication between departments.
45. There is sufficiently qualified healthcare staff present to carry our all necessary work in my department.

46. I sometimes carry out work against my will, under pressure from my superior.
47. I have to deal with unworkable procedures in my work.
48. A discussion has arisen before about a decision to be taken as a result of unclear procedures.
49. Necessary maintenance work has been postponed due to high costs.
50. I always have a sufficient budget available to carry out my work properly.
51. At busy times I have to carry out more work than my actual task requires of me.
52. There are procedures in force that are too cumbersome to work with.
53. I work together with people who have been employed on the basis of financial considerations and not on the basis of their qualities.
54. Management has failed before to resolve a clear risk situation because it is economically cheaper (for example a defect of equipment, colleagues who do not want to communicate with each other etc.)
55. I report all incidents in accordance with the usual procedure at my department.
56. Problems have arisen regarding adherence to procedures that have been implemented too quickly.
57. There is always sufficiently qualified healthcare staff at the department to carry out the work properly.
58. I have had to sacrifice my lunch break before because there is a shortage of staff.
59. Sometimes I dare not discuss a complaint with my superior because I am afraid of his/her reaction.
60. Certain informal rules within the hospital are in conflict with formal rules.

Explanation: The following questions are about working procedures. Procedure means a description of a working method, working process, guideline or system. This research is in particular about working procedures, which describe how a task must be carried out by healthcare staff. For example, think of a working procedure about the double-checking of medication, calculation of doses, putting in a drip, standards of competence for the use of equipment, requests for laboratory tests etcetera.
61. Because procedures are insufficiently clear, I sometimes have to act according to my own discretion.
62. There are rules in the hospital which can be interpreted in different ways.

63. I have sometimes been confronted with a procedure, the meaning of which was completely unclear to me.
64. I sometimes have had extra work for a relatively simple task because I had to follow a cumbersome procedure.
65. I have sometimes searched for information which I subsequently found spread over different places.
66. I have sometimes been confronted with a procedure which was formulated in a such a complex way that I could not oversee what would happen if I would follow the procedure.
67. The procedures which I need for my work link up with practice.
68. I sometimes work with instruments or equipment for which a clear manual is lacking.
69. I have sometimes ended up in a situation whereby it was unclear if a procedure existed about how to act in such a situation.
70. I have sometimes been confronted with new procedures which were not workable.
71. I have sometimes not been able to find a procedure which I needed at that time.
72. I have sometimes had to use a procedure which was so unclear that I had to determine myself how I had to act.
73. There have sometimes been procedures concerning my work which had been changed without me being informed about this.
74. I sometimes have had to deal with procedures the authors of which clearly had no understanding of how it would function in practice.
75. It has happened that I did not understand a procedure due to the unclear lay-out.

Thank you for filling in the questionnaire!

If you have any comments about the questionnaire then you can note these down below.

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Compliance with a time-out procedure intended to prevent wrong surgery in hospitals: results of a national patient safety programme in the Netherlands

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Abstract

Objective
To prevent wrong surgery, the WHO 'Safe Surgery Checklist' was introduced in 2008. The checklist comprises a time-out procedure (TOP): the final step before the start of the surgical procedure where the patient, surgical procedure and side/site are reviewed by the surgical team. The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the operating room, whether compliance has changed over time, and to determine factors that are associated with compliance.

Design
Evaluation study involving observations.

Setting
Operating rooms of 2 academic, 4 teaching and 12 general Dutch hospitals.

Participants
A random selection was made from all adult patients scheduled for elective surgery on the day of the observation, preferably involving different surgeons and different procedures.

Results
Mean compliance with the TOP was 71.3%. Large differences between hospitals were observed. No linear trend was found in compliance during the study period. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.

Conclusions
Large differences in compliance with the TOP were observed between participating hospitals which can be attributed at least in part to the type of hospital, surgical specialty and patient characteristics. Hospitals do not comply consistently with national guidelines to prevent wrong surgery and further implementation as well as further research into noncompliance is needed.

Introduction

Ideally, hospitals should be safe environments for their patients. However, making errors is inherent in all humans.[1] The report 'To Err is Human' showed that errors cause 44 000–98 000 deaths and over one million injuries each year in American hospitals.[1] As a result, patient safety became a major topic on the healthcare agenda.[2–4] Patient safety covers the prevention of errors and adverse events associated with healthcare that affect patients.[5] An adverse event is unintentional harm caused by healthcare management rather than by the patient's underlying disease that results in a prolonged hospital stay, temporary or permanent disability or death.[6] In 2004, adverse events occurred in approximately 5.7% of hospital admissions in the Netherlands: approximately 2.3% of the adverse events were potentially preventable.[6] More than 54% of the unintentional adverse events were associated with the surgical procedure, of which 34% were reviewed as being preventable.[6] It is therefore important to ensure and improve patient safety during surgery.

Patient safety in surgery has several aspects. One of these aspects is wrong surgery, which can be classified into three groups: surgery at the wrong site, surgery on the wrong patient and carrying out the wrong procedure.[7] Wrong site surgery occurs whenever a planned surgical procedure is performed at or on the wrong place, part and side or site. Wrong patient surgery refers to a different procedure performed on the wrong patient. Wrong procedure surgery refers to a different procedure being performed than the one planned for the patient. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sentinel event database ranked wrong site surgery as the second most frequently reported adverse event between 1995 and 2005.[8] In the USA, for instance, the estimated rate of wrong site surgery ranges from 0.09 to 4.5/10.000 operations.[3 8–13]

To prevent wrong surgery, the JCAHO guideline 'Universal protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery' was adopted in 2003 by the Joint Commission in the USA.[14] Consequently, the WHO introduced a checklist in 2008 for worldwide use, called the 'Safe Surgery Checklist'. In 2009, the WHO concluded that the use of a checklist in the operating room (OR) is associated with a significant decrease in

postoperative complication (30%) and mortality rates (50%).[15] Based on these results, the WHO estimated that implementing the checklist could save 500.000 lives every year worldwide.[15] Other studies provided evidence supporting the use of surgical checklists as well.[16–19] In the Netherlands, the SURgical PAtient Safety System (SURPASS) was developed with the same intention. It is based on safety checks used in the aviation industry to reduce human error.[20] Research on the external validation of the SURPASS shows a reduction in unintentional harm.[21–23]

Each of the checklists aforementioned comprises a time-out procedure (TOP). Errors can be avoided by including a preoperative discussion just before the start of the surgical procedure. This takes place during a time-out involving a review of the names and roles of all team members, characteristics of the patient, the operation plan, familiarity with the procedure, the presence of the correct materials/equipment and potential issues for the patient.[24 25] Although evidence is scarce, it is likely that these TOPs reduce uncertainties in the OR among the surgical team and reduce the risk of wrong surgery. The TOP is the final step before the start of the surgical procedure and is therefore crucial in preventing wrong surgery. A TOP is carried out just before anaesthesia,[26] and consists of three checks (the patient, the procedure and the side/site), all of equal importance in preventing wrong surgery.

The aim of this study is to evaluate the extent to which hospitals carry out the TOP before anesthesia in the OR, whether compliance has changed over time, and to determine factors that are associated with the TOP compliance. Insights into compliance with the TOP and the factors associated with compliance are important because they have the potential to improve the TOP and reduce adverse events in surgical processes throughout the world. This study was carried out in the Netherlands and was part of a larger evaluation study of the Dutch Hospital Patient Safety Program (hereinafter 'Safety Program') that was carried out during the final year of the programme (box 1).

Box 1 The Dutch Hospital Patient Safety Program

The Dutch Hospital Patient Safety Program (Safety Program) was set up in 2008 to reduce preventable unintentional adverse events in Dutch hospitals by 50% by the end of 2012.[26] The Safety Program consisted of 10 patient safety themes and clinical guidelines were developed for each theme. Hospitals were given 5 years to implement these guidelines. One of the themes was prevention of wrong surgery. There are several risk factors for wrong surgery, for example, insufficient compliance, inadequate identification and verification and bad preoperative planning.[27 28]

The Safety Program therefore instructed the participating Dutch hospitals to implement several steps to decrease wrong surgery, based on the SURPASS checklist. One of the steps is identification and verification by means of a TOP consisting of checks on the correct patient, correct side, and correct intervention.29

On the basis of the goals of the Safety Program, it was expected that the compliance with the TOP would increase over time and would become more visible during the final year of the programme when hospitals approached the public deadline at the end of 2012.
The research questions are:

- *To what extent do Dutch hospitals comply with the TOP before anesthesia in the OR?*
- *How has the compliance with the TOP changed during the final year of the Safety Program?*
- *What factors are associated with compliance with the TOP?*

Methods

Study design

This study was part of a larger evaluation study of the Safety Program that was carried out between November 2011 and December 2012 in 18 Dutch hospitals (about 20% of all Dutch hospitals). Hospitals were randomly selected using a stratified sample based on geographical regions and hospital type. Two academic hospitals, four teaching hospitals and 12 general hospitals were included in this study. All hospitals consented to the study and were informed about further practical issues. Twelve observers

participated in this study. Inter-observer variability was not measured, but limited by training of observers prior to the start of the observations. Moreover, regular feedback meetings were held where observers exchanged experiences and discussed how to deal with certain situations and observations at the OR. A random selection was made from all adult patients scheduled for elective surgery on the day of the observation. This selection was made by the observers who were instructed to attend as many different surgeries as possible while ensuring they were present in the OR before the start of each surgery, which was essential in order to be able to observe the TOP procedure. The goal was to have 10 observation days per hospital at intervals of 4–6 weeks, and to observe 6–10 surgical procedures per day, preferably involving different surgeons and different procedures. One observer per surgical procedure evaluated whether the TOP was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure, and side/site, attention of the team (focus), completeness of the team, interruptions, and several background variables such as the type of surgical procedure, the patient's age and sex. The OR team was not aware of the exact subject matter of the observation; the observer was instructed to introduce the study in abstract terms, referring to it as a study about the surgical process in general.

TOP compliance

The outcome measure was whether the TOP was done correctly and was dichotomous (yes/no). This variable was used to examine mean TOP compliance and the changes in compliance during the study period. A correct TOP consists of three checks: patient, procedure and side/site. Since all three checks are equally important for preventing wrong surgery, the TOP was only deemed correct when all three checks were performed. Furthermore, during a TOP the entire OR team gathers around the patient and the surgeon asks the patient his/her name, the type of procedure and the side/site of the procedure.

Four independent variables were included so that any association with compliance could be determined. The type of hospital was categorized into academic, teaching, and general. In the Netherlands, teaching hospitals provide specialized medical care and are committed to training and

education. The level of care can be characterized as complex and lies between that of general hospitals and academic centers. Hospital size was operationalized as the number of beds in the hospital (a continuous variable). Surgical specialty was added as a categorical variable with general surgery as the reference category. Focus (yes/no) was included to measure the degree to which the OR team was paying full attention to the TOP and was not performing any other activities during the TOP. In addition, the patient characteristics 'age' and 'sex' were included as covariates. Completeness of the team (yes/no) was added as an explorative analysis. The complete team in this study was seen as the group of persons that performed the surgery on the patient. To be able to perform a TOP correctly, the complete team was present during the TOP. When this was not the case, meaning that one or more persons joint the team after the TOP had been completed, team completeness was scores as 'no'.

Statistical analyses

Descriptive analyses were performed to obtain a picture of the study population, mean TOP compliance, changes in compliance over time, mean compliance for the different hospital types, mean compliance for the different surgical specialties, and the focus and completeness of the team during the TOP.

A multilevel logistic regression analysis with two levels was used to determine whether TOP compliance changed between the 10 measuring moments. Multilevel analysis was chosen to correct for the fact that the surgical procedures are not independent from each other, but clustered within hospitals. Time was modelled by adding 10 indicator variables for the measurement moments (removing the intercept from the model); trends were tested using polynomial contrasts (to the fourth order) to study changes over time. Variance and intraclass correlations (ICCs) were calculated to assess the clustering of TOP compliance at the hospital and surgical procedure level. An ICC of 20% was seen as moderate.[30] The changes over time were also analyzed for the different hospital types to determine the relationship between hospital type and the changes in TOP compliance. Separate logistic multilevel analyses were performed for each independent variable to analyze the effects of the independent variables 'hospital size' and 'surgical specialty'; this was necessary because not

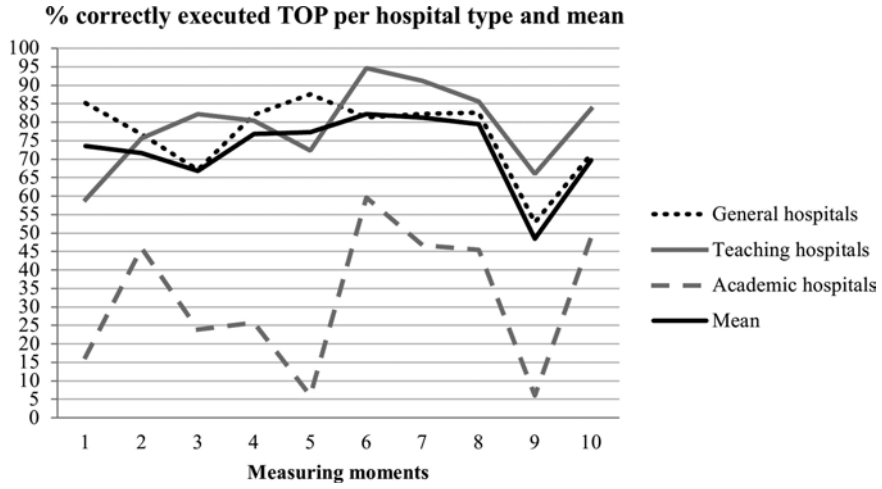
enough units at the highest level (hospitals) were available to have more than one independent variable in a model.[30] There were not enough units at the highest level (hospitals) to model the effect of hospital type on the TOP score in the pooled analyses. Age and sex of the patient were added as covariates in all analyses. All descriptive analyses were performed using SPSS version PASW Statistics V.18. The multilevel analyses were performed using MlwiN V.2.24 (using PQL, second order, unconstrained level 1 variance, and options).

Results

Descriptive analyses

A total of 1281 surgical procedures were observed at the participating hospitals. After patients younger than 18 were excluded, 1232 observations remained for analysis. Ages ranged from 18 to 96. The gender distribution was 41.4% male, 53.8% female, and 4.8% not registered. The range in types of surgical procedures was broad; observers had been instructed to observe different procedures and observed surgical procedures of in total 13 different specialties. Mean compliance with the TOP during the total study period was 71.3%. Descriptive analyses showed that TOP compliance did not improve during the study period. There was a large spread between hospitals: one of the hospitals never performed the TOP correctly and two had mean compliance rates higher than 90%. A low mean TOP compliance (48%) was found at the ninth measuring moment for all the participating hospitals. The academic hospitals had a mean compliance rate of 42.1%, teaching hospitals 76.2% and general hospitals 73.9%. Differences between specialties were shown to exist: trauma, gastroenterology and hepatology and ear, nose and throat medicine (ENT) had the highest compliance rates. Anesthesiology, cardiothoracic surgery and cosmetic surgery had the lowest compliance rates. In 44% of the observations the team was not focused on the TOP and in 56%, the team was incomplete.

Figure 1 Trend in the time-out procedure compliance per hospital type, and overall mean (n=1232).



Multilevel regression analyses

In the first multilevel regression analysis, the changes in TOP compliance were tested. The effect was statistically significant for the fourth-order polynomial ($p<0.01$), meaning that TOP compliance was not linear but fluctuated over time and no clear trend was observed. Furthermore, there were large differences between the measuring moments and between individual hospitals (see figure 1). The multilevel analysis shows that 44% (ICC=44.01) of the total variance in TOP compliance can be attributed to the differences between the individual hospitals. Adding hospital type to the analysis caused the ICC to drop to 40.11 (40%; see table 1).

Table 1 Trend in the time out procedure per hospital type (n=1232; 18 hospitals)

	Trend overall			**Trend per hospital type**								
				General hospitals			**Teaching hospitals**			**Academic hospitals**		
	N	**Mean %**	**95% CI**	**N**	**Mean %**	**95% CI**	**N**	**Mean %**	**95% CI**	**N**	**Mean %**	**95% CI**
Fixed effects TOP (constant)												
MM 1	121	73.52	53.20 to 87.14	85	85.18	2.00 to 94.35	25	59.00	21.26 to 88.46	11	16.48	0.91 to 80.91
MM 2	137	71.64	51.26 to 85.85	91	76.73	54.48 to 90.09	33	75.65	36.60 to 94.36	13	45.91	2.90 to 96.02
MM 3	134	66.79	45.78 to 82.73	87	67.09	42.94 to 84.66	33	82.19	44.85 to 96.32	14	23.86	1.55 to 86.19
MM 4	118	76.77	57.01 to 89.17	75	82.01	60.92 to 93.02	27	80.40	41.08 to 96.02	16	25.73	1.76 to 87.03
MM 5	125	77.26	57.99 to 89.32	85	87.56	70.27 to 95.44	30	72.30	32.65 to 93.36	10	5.97	0.29 to 57.90
MM 6	127	82.18	64.73 to 92.05	85	81.27	60.55 to 92.46	27	94.63	65.68 to 99.39	15	59.61	5.32 to 97.48
MM 7	114	81.20	62.89 to 91.67	78	82.23	61.44 to 93.07	26	91.13	57.87 to 98.72	10	46.67	2.40 to 96.89
MM 8	112	79.41	60.46 to 90.68	82	82.59	62.33 to 93.16	22	85.56	46.93 to 97.54	8	45.42	1.80 to 97.43

Table 1 Trend in the time out procedure per hospital type (n=1232; 18 hospitals) (*Continued)*

	Trend overall			Trend per hospital type								
				General hospitals			Teaching hospitals			Academic hospitals		
	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI	N	Mean %	95% CI
Fixed effects												
TOP (constant)												
MM 9	129	48.44	28.65 to 68.74	89	52.86	29.81 to 74.75	25	66.00	26.36 to 91.33	15	6.00	0.40 to 50.29
MM 10	115	69.68	48.46 to 84.88	85	71.32	47.57 to 87.20	21	83.56	43.24 to 97.13	9	48.84	2.39 to 97.38
Random effects												
Variance components:												
ICC	44.056			40.106								
Hospital (level 2)	2.591 (0.916)*			2.203 (0.798)*								
Surgical procedure (level 1)	0.988 (0.040)			0.984 (0.040)								

*p < 0.05 Raw data for the remaining variables (specialty, focus and individual checks) is available with the author on request. ICC, intraclass correlation coefficient; MM, measurement moment; TOP, time-out procedure

When correcting for age and sex of the patient, the ICC dropped to 26% (ICC=26.58). The relationship between the age of the patient and the TOP was found to be significant ($p<0.05$). This relationship was tested and found to be linear. Based on the results described above, there was no rationale to correct for time (measurement moments) in further analyses. Observations from the different measurement moments were pooled in the remaining analyses. Separate analyses were performed for the independent variables 'hospital size', 'surgical specialty', and 'focus'. No statistically significant relationship was found between hospital size and TOP compliance (data not shown in tables). A positive relationship was found between patients undergoing ENT surgery and the TOP (reference=general surgery; $p<0.01$). Another positive relationship was found between patients undergoing ophthalmic surgery and the TOP (reference=general surgery; $p<0.05$; see table 2).

Table 2 Relationship between surgical specialties (n=1130; 18 hospitals) and compliance with the time-out procedure

	Model 0 (time-out procedure+age+sex)	**Model 1 (model 0+specialties)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time out procedure (constant)	1.173 (0.268)	1.196 (0.269)
Specialties—general surgery	–	*Reference*
Specialties—gynecology	–	0.050 (0.264)
Specialties—ENT	–	0.905 (0.316)*
Specialties—ophthalmology	–	0.616 (0.302)*
Specialties—orthopedic surgery	–	0.163 (0.241)
Specialties—urology	–	0.084 (0.287)
Specialties—other	–	0.046 (0.279)
Patient age	−0.011 (0.004)*	−0.011 (0.004)*
Patient sex	0.064 (0.153)	0.074 (0.155)
Random effects		
Variance components:		
Intraclass correlation	25.331	25.499
Hospital (level 2)	1.116 (0.422)*	1.126 (0.426)*
Surgical procedure (level 1)	0.996 (0.042)	1.006 (0.043)

*$p<0.05$. ENT, ear, nose and throat medicine.

This indicates that TOP compliance is significantly higher in patients undergoing ENT surgery or ophthalmic surgery compared with patients undergoing general surgery. The relationship between the age of the patient and TOP compliance was found to be significant ($p<0.05$) in all analyses. This indicates that TOP compliance decreases with the patient age. The TOP is performed correctly less often for older patients. An additional analysis was performed based on these results to determine which of the three individual checks of the TOP attributed most to the negative relationship between the age of the patient and TOP compliance. Table 3 shows the results of the additional analysis. The check procedure contributes most to the negative relationship between age of the patient and TOP compliance, this check is more often skipped when an older patient is involved.

Table 3 Age effects for the three different checks in the time-out procedure: checking the patient (n=1074), the procedure (n=1074), and the side/site (n=1074)

	Model 0 (check patient+age+sex)	**Model 1 (check procedure+age+sex)**	**Model 2 (check side/site+age+sex)**
Fixed effects	Estimate (SE)	Estimate (SE)	Estimate (SE)
Check patient (constant)	3.499 (0.334)	–	–
Check procedure (constant)	–	2.276 (0.282)	–
Check side/site (constant)	–	–	2.739 (0.204)
Patient's age	0.008 (0.008)	−0.021 (0.006)*	0.012 (0.007)*
Patient's sex	−0.185 (0.288)	0.124 (0.198)	0.160 (0.246)
Random effects			
Variance components:			
Intraclass correlation	27.172	24.990	10.854
Hospital (level 2)	1.228 (0.623)*	1.096 (0.464)*	0.401 (0.236)*
Surgical procedure (level 1)	0.834 (0.036)	0.922 (0.040)	0.950 (0.041)

*$p<0.05$.

The relationship between the focus of the team during the TOP and the correct execution of the TOP is shown in table 4. There is a positive significant relationship between focus and TOP compliance, which indicates that the TOP is more often correctly executed when the entire team is focused on the TOP and not performing any other activities at the same time.

Table 4 Relationship between focus (n=1074; 18 hospitals) during the time-out procedure and compliance with the time-out procedure

	Model 0 (time-out procedure+age+sex)	**Model 1 (model 0+focus)**
Fixed effects	Estimate (SE)	Estimate (SE)
Time-out procedure (constant)	1.540 (0.163)	1.471 (0.156)
Focus	–	0.567 (0.171)*
Patient's age	−0.006 (0.005)	−0.005 (0.005)
Patient's sex	−0.012 (0.162)	−0.016 (0.163)
Random effects		
Variance components:		
Intraclass correlation	8.971	7.991
Hospital (level 2)	0.324 (0.154)*	0.286 (0.140)*
Surgical procedure (level 1)	0.968 (0.042)	0.966 (0.042)

*p<0.05.

Discussion

The objective of this study was to investigate the compliance at Dutch hospitals with the national guidelines of a TOP set by the Safety Program and how this changed over the final year of the programme. Furthermore, we studied variables that might be associated with compliance. This study found a mean TOP compliance of 71.3%. There was no linear trend in the TOP compliance during the study period. Large differences were found between and within individual hospitals, which were partly influenced by

age of the patient. The type of hospital was associated with the TOP compliance: academic hospitals had lower compliance rates than general and teaching hospitals. Given the low number of academic hospitals in this study (N=2), these findings cannot be generalized to academic hospitals as a whole. ENT medicine and ophthalmological surgery had higher TOP compliance than the reference group (general surgery). No statistically significant relationship between TOP compliance and hospital size was found. The TOP was correctly performed more often when the OR team was focused on it. The negative relationship between age of the patient and the TOP indicates that higher patient age is associated with lower TOP compliance. Of all the observed TOPs, 44% were performed without the focus of the entire team, and the team was not complete in 56% of the TOPs.

A wide range in compliance rates for surgical checklists can be found in previous studies, ranging from 12% to 99% with a mean of 75%.[31–33] The compliance rate (71.3%) found in our study is slightly lower than the mean rate found in other studies.

We found a difference in TOP compliance between the different types of hospitals. The general and teaching hospitals hardly differed from each other, which is interesting because a previous study[34] found teaching hospitals to be better at implementing checklists than general hospitals. According to the organizational learning theory, the availability of knowledge in an organization contributes to the adoption of innovations.[34 35] Teaching hospitals are learning environments, aimed at spreading and developing knowledge; better compliance can therefore be expected in teaching hospitals. We found that academic hospitals showed lower TOP compliance.

The literature is inconsistent about the influence of hospital size on the use of checklists. Some argue that larger hospitals are better developed and use standardized processes, which increases the quality of the hospital more often,[36–38] whereas others conclude that smaller hospitals implement checklists better.[39] We found no relationship between TOP compliance and hospital size. The high ICC rates found in this study suggest that the differences between individual hospitals are high, and differences in

compliance cannot be explained by general hospital characteristics such as hospital size. The differences between individual hospitals need to be examined in further research, but possible explanations might be found in different organizational structures, the creation of awareness among healthcare staff and differences in speaking-up cultures between hospitals.

The relationship found between surgical specialties and the TOP is different from the results of previous studies. One study showed a difference between surgeons and anesthesiologists[40] and another study showed no difference between surgical specialties at all.[41] The TOP is a standardized procedure, and the way in which it should be carried out does not depend on the surgical specialty performing the procedure or the patient characteristics. Compliance with the TOP varied between different specialties and was lowest among general surgery teams. One explanation for these differences could be that not all medical disciplines and their scientific communities have placed the same amount of weight on a thorough implementation of the Safety Program. If so, this could have had an influence on the sense of urgency experienced by different specialties to comply with TOP in their daily functioning. Further research that includes specialty-specific factors is needed to verify and deepen our findings. The negative relationship between TOP compliance and the age of the patient was an unexpected result, since the TOP should be executed in the same way for all patients. In particular, the exact surgical procedure that would be carried out was less often verified with elderly patients. Explanations might be found in factors inherently associated with the elderly patient themselves. For example, elderly patients might be less able to verbally express themselves to healthcare staff. On the other hand, explanations might be found in factors that are associated with the medical procedure itself. For example, the level of standardization of procedures that are commonly performed in the elderly population (such as hip-replacement surgery or cataract surgery) is relatively high and it is unclear what effect this has on compliance with TOP. Elderly people are a vulnerable group with a higher risk of complications after surgery, therefore further in-depth research is important to explain the differences in compliance for different age groups.

Completeness and focus are important factors in the TOP and performing it when team members are busy with other activities creates a risk. Our study

showed that focus in the team contributes to the TOP being performed correctly. However, there was poor focus on the TOP in almost half of the surgical procedures observed. Several possible causes could be underlying to poor focus during the TOP, which was observed frequently in our study. First, there could have been a lack of awareness of the importance of the TOP among healthcare staff. Regular emphasis on the importance of the TOP during team meetings or during the joint briefing at the start of a new working day could help raise awareness. Second, when surgery schedules are tight, healthcare staff might experience time pressure. In trying to keep up with the schedule and being efficient, healthcare staff might be tempted to perform multiple tasks simultaneously which in turn could negatively affect compliance with TOP.

On the basis of these results, it seems that hospitals still have a lot to gain by carrying out the TOP properly. Qualitative research methods could provide insight into the underlying reasons and incentives of why healthcare staff perform the TOP in the way they currently do. This type of research could complement and deepen the findings that were presented in the current study.

Strengths and limitations

Our study was the first to evaluate TOP compliance over time through observations in the OR and look into the factors associated with compliance. Our dependent variable was a process indicator, because the incidence of wrong surgery is too low to be observed with our study design. Based on the literature, it seems fair to assume that higher TOP compliance can contribute to a decrease in the incidence of wrong surgery,[15] although this study gives no information about the actual number of wrong surgeries and TOP compliance might not be the only factor in the reduction of wrong surgery.

This study has several limitations. First, the presence of the observer might have influenced the behaviour of the OR staff and indirectly our dependent variable TOP. However, the design of our study aimed to prevent this potential observer bias, because the precise goal of the observations was not known to the OR team. Second, a potential selection bias can be found in the selection of surgical procedures on the observation days. Surgical

procedures were selected based on practical considerations: the day of the week, the duration of the procedure and the OR schedule. The relationships found between different specialisms might be partially overestimated, because the same surgical teams were sometimes observed on the same day or on different observation days. However, the overall goal was to observe as may different surgical procedures with different teams as possible, in order to limit potential selection bias. Third, there is no information available about the changes in compliance during the first period of the Safety Program, and hospitals may have made progress during this period.

Conclusions

The mean TOP compliance was 71.3% during the final year of the Safety Program and no improvement in compliance over time was found. Large differences were found between hospitals, and these differences were influenced by age of the patient. Compliance was influenced by several factors: hospital type, surgical specialty, age of the patient and focus of the team during the TOP. Furthermore, in almost half the TOPs, the team was not focused on the TOP or the team was incomplete. Despite the fact that almost three quarter of operations are preceded by a TOP, hospitals need to make an effort to improve TOP compliance and the way in which the TOP is carried out in order to prevent wrong surgery from happening in the future.

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7

Risk evaluation and attitudes of healthcare professionals towards procedures in their daily work: a mixed methods approach

Submitted for publication.
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Abstract

Objective
Procedures are a cornerstone of a hospital quality system as they include all the relevant (clinical) guidelines, protocols and procedures that a hospital has in place to guide the organization and its healthcare professionals towards good quality of care. Based on the assumption that implementing and working according to procedures reduces risks for patients, it is expected that healthcare professionals working in hospitals with a more developed quality system will experience lower risk at operational failures in processes and therefore less risk at patient harm. The aim of this study was to describe how healthcare professionals evaluate risks of operational disruptions related to procedures and to describe their attitudes towards the use of procedures in their daily work.

Design
Mixed methods approach combining results from a risk assessment questionnaire and interview data. Healthcare professionals, mainly nurses, of ten departments of one general hospital in the Netherlands participated in this study. 413 prospective risk analysis questionnaires were returned by healthcare professionals and 34 interviews with nurses from the different departments were conducted.

Results
Healthcare professionals report a considerable amount of perceived risk in the procedural domain and there are large differences between hospital departments. Variation between departments can be understood by differences in the extent to which preconditions for working with procedures are met in different departments, differences in how healthcare professionals perceive the added value of a procedure, and differences in compliance with procedures.

Conclusion
Differences in preconditions, perceived added value and compliance with procedures contribute to our understanding why hospitals are not always optimally effective in translating the requirements of a quality system into effective implementation of, and compliance with procedures.

Introduction

Healthcare institutions implement quality systems in order to assure and improve healthcare delivery to patients.[1-4] A quality system is defined as *'a set of interacting activities, methods and procedures aimed at directing, controlling, and improving the quality of care'*.[1-4] Different types of quality systems exist, but most include at least the following five domains: (1) policy and strategy, (2) human resources management, (3) procedures, (4) cyclical quality improvement activities at the department level and (5) patient involvement.[2] Hospital quality systems structure the organizational processes of a hospital and aim to create a cycle of continuous quality improvement. Continuous improvement can thereby lead to a reduction in variation in processes, which in turn should lead to more predictable outcomes of treatment for patients.

During the development and implementation of quality systems in hospitals, a great deal of emphasis is often placed on effectively implementing procedures and assuring compliance with these procedures.[2-5] Procedures are a cornerstone of the quality system as they include all the relevant (clinical) guidelines, protocols and procedures that a hospital has in place to guide the organization and its healthcare professionals towards good quality of care.[3,4] Working according to procedures is assumed to standardize the behavior of healthcare professionals and this leads to a reduction in the variation of outcomes of this behavior.[3,4] As such, procedures are considered to be an instrument to reduce the risks of adverse events and unintended events for patients.

Based on the assumption that implementing and working according to procedures reduces risks for patients, it would be expected that healthcare professionals working in hospitals with better developed quality systems will have a lower risk of operational failures in the processes and therefore a lower risk of patient harm. Operational failures are disruptions in the operational process that are a combination of different undesirable situations that occur at the same time and that can have consequences in terms of patient safety and quality of care.[6,7] As procedures are part of the quality system, they are expected to reduce the risk of such operational disruptions when they are available and when there is little variation in the way healthcare professionals work and comply with them. However, it is known from the literature that compliance with procedures is often low and large differences exist between departments in their compliance with (and organization of) procedures.[8-19] So far, little is known about reasons

underlying these differences. The aim of this study is to describe how healthcare professionals evaluate risks of operational disruptions to procedures and to explore their attitudes towards the use of procedures in their daily work in order to better understand differences in risk evaluation. The research questions of this study are: *(1) How do healthcare professionals assess risks in operational processes related to procedures in their daily work? (2) How do hospital departments differ in their risk assessments? (3) What are the attitudes of healthcare professionals towards the use of procedures in their daily work?*

Methods

In this study, a mixed methods approach was used. Combining quantitative and qualitative methodologies increases the depth of understanding of the risk evaluations and attitudes of healthcare professionals towards procedures in their daily work.[20-22] We conducted this study in a general hospital in the Netherlands. The hospital's participation was based on a convenience sample. The hospital's quality system was accredited by the Dutch healthcare accreditation body NIAZ. All procedures and protocols in this hospital are entered into a digital system and could be found by all healthcare professionals on the intranet using a digital search engine. The procedures and protocols in this database were indexed according to title. The Tripod Delta HC questionnaire was administered to assess risks in operational processes in the procedural domain and differences in this risk evaluation between departments. Semi-structured, face-to-face interviews were conducted to explore attitudes to the use of procedures in daily work in order to better understand differences in risk evaluation. The Dutch Medical Research Involving Human Subjects Act does not apply to this research. Approval was therefore not needed from the Medical Ethics Committee.

Questionnaire: Tripod Delta HC

Tripod Delta HC is a generic prospective risk management instrument that measures Basic Risk Factors (BRFs) in five organizational domains. According to Tripod, there are latent failures in every work environment and these can be categorized into BRFs. Each of the BRFs may contribute to adverse events in different ways, and when a combination of different undesirable situations emerge at the same time, this will lead to disruptions in the operational process, which may or may not have consequences.[6,7,23] The five BRFs are (1) Procedures, (2) Training, (3) Communication, (4)

Incompatible Goals and (5) Organization. Each BRF is covered by 15 items that form a scale. The definitions of the various BRFs and some example items are described in Table 1. Items are measured on a five-point Likert scale ranging from 'totally disagree' to 'totally agree'. Respondents were asked to answer the questions with the last six months in mind. The reliability, validity and the items of the questionnaire are described elsewhere.[23] At the individual level, the reliability coefficients ranged from 0.78 to 0.87. This indicates good to excellent internal consistency at the individual level.[23] The internal consistency at the departmental level ranged from 0.55 to 0.73. For the BRFs Procedures and Incompatible Goals, the internal consistency of the scales at the departmental level was less than 0.70, which is below the minimum preferred value.[23]

Table 1 Definitions of the five Basic Risk Factors of Tripod Delta HC.

Basic Risk Factors	***Definition***	***Example item***
BRF Procedures	Insufficient quality or availability of procedures, guidelines, instructions, and manuals (specifications, administration, use in practice).	*"Because procedures are insufficiently clear, I sometimes have to act according to my own discretion."*
BRF Training	No or insufficient competence or experience among healthcare professionals (not sufficiently suited to their tasks, inadequately trained).	*"There are always sufficiently experienced healthcare professionals present in the department."*
BRF Communication	No or ineffective communication between the various sites, departments or healthcare professionals of an organization or with the official bodies.	*"Important information is often sent to the wrong department in the hospital."*

Table 1 Definitions of the five Basic Risk Factors of Tripod Delta HC. (*Continued*)

BRF Incompatible Goals	The situation in which healthcare professionals must choose between optimal working methods according to the established rules on one hand , and the pursuit of production, financial, political, social or individual goals on the other.	*"Necessary maintenance work has been postponed due to high costs."*
BRF Organization	Shortcomings in the organization's structure, organization's philosophy, organizational processes or management strategies, resulting in inadequate or ineffective management of the organization.	*"The tasks are not properly coordinated between departments so that work is carried out twice."*

From: *Controlling the controllable*[28]

Data collection and analysis

The Tripod Delta HC questionnaire was administered at all ten departments of one general hospital in the Netherlands. The data were collected in March and April 2012. All healthcare professionals working in the departments were approached to fill out the online questionnaire. The healthcare professionals were invited by e-mail and informed about the purpose of the study, the procedure and privacy protection. As participation was voluntary and anonymous, no written informed consent was obtained. The e-mail contained a link that led to the questionnaire. Reminder e-mails were sent to non-respondents after two and four weeks. The questionnaire took approximately 15-20 minutes to complete. Negatively worded items were recoded in the analyses so that a higher score reflected a higher potential risk for all items.

Interviews

The topic list for the additional, in-depth and semi-structured, face-to-face interviews was designed on the basis of the Tripod Delta HC results and structured around several themes: hospital-wide and department-specific changes in the past 12 months, communication and procedures. The themes communication and procedures were chosen because the hospital scored

lowest on the BRF Communication (lowest potential risk) and highest on the BRF Procedures (highest potential risk) in the Tripod Delta HC measurement and requested more information about these two topics. The current study focuses on the interview fragments from the questions about procedures, as hospitals reported significantly higher risks in this domain. This was also the case in the other hospital that participated in the pilot study[23], and three other hospitals in a pre-pilot study (data not published). The interview questions concerned: procedures in daily work, the characteristics of an understandable and workable procedure, areas for improvement in procedures, non-compliance with procedures and communication about non-compliance, procedures and the relationship with quality of care.

Data collection and analysis

The semi-structured interviews were conducted in April and May 2013 which was about one year after administration of the Tripod Delta HC. To capture the diversity of attitudes and perceptions within the hospitals, the goal was to interview three participants from each department with a balance between junior and senior healthcare professionals. Every head of department was interviewed and selected at least two other healthcare professionals from their department. In addition, the quality coordinator of the hospital was interviewed. In total, 34 healthcare staff participated in the interviews. Participants received information about the study prior to the interview, an outline of the topic list, estimated duration of the interview (one hour) and privacy issues. Two researchers conducted the interviews (SVS = 5, MG = 29) using the same topic list. During the first two interviews, both researchers were present in order to discuss and verify the topic list to make sure that there was a shared understanding of the purpose of the questions. The interviews were conducted in a private room in a quiet part of the hospital. Interviews were audiotaped with consent of the participants. The researchers gave an assurance that no reported information could be traced to the respondent. All interviews were recorded and transcribed by the researchers. Participants were sent a transcript of their interview to validate the content. Two participants requested minor changes, which were made accordingly. The researcher sent the participants confirmation of the requested amendments. Thematic content analyses were performed by two researchers independently (SVS and JT). Both researchers analyzed all interviews. The extracted themes were discussed until consensus was reached.

Results

Tripod Delta HC: BRF Procedures

In total 683 healthcare professionals were invited to participate. Of these, 413 returned the questionnaire (60.5% response rate). The characteristics of the sample who filled out the Tripod Delta HC questionnaire are described in Table 2. The Tripod Delta HC results show that the hospital scored significantly higher on the BRF Procedures, compared to the mean of the other BRFs, indicating a higher potential risk in this domain (see Table 3). The scores for the individual items of the BRF Procedures are also shown in Table 3. Table 4 also shows the percentage of healthcare professionals who indicated a high risk for the individual items. A high risk means that the healthcare professional chose 4 or 5 on the answer scale. The hospital obtained the highest score (highest potential risk) on the items related to the availability and interpretation of procedures. This indicates that about one third of healthcare professionals perceive risks for the hospital because procedures are not available when they need them or procedures are so ambiguous that they cannot be applied in the real working situation. Furthermore, differences were found between hospital departments on the perceived risk for the individual items of the BRF Procedures. For example: *'There are rules in the hospital which can be interpreted in different ways'* in one department had 50% of the healthcare staff indicating a high risk, whereas the figure in another department was 2.3%. Overall, healthcare professionals working in the internal medicine department indicated the highest risks and professionals working in the pediatric department indicated the lowest risk.

Table 2 Characteristics of the Tripod Delta HC sample and the sample of interviewees.

		Tripod Delta HC	*Interviews*
		n=413	***n=34***
Gender	Female	384	34
	Male	29	0
Age	<30	81	unknown
	30-50	228	
	>50	101	
	Unknown	3	
Department	Pediatric department	47	4
	Emergency room	31	3
	Gynecology	64	3
	Intensive care department	47	2
	Internal department	28	3
	Lung diseases & cardio department	34	5
	Neurology	43	3
	Operating rooms	55	3
	Short-stay nursing department	40	4
	Surgical department	24	3
	Quality and safety department		1
Experience	0-5 years	131	16
	6-20 years	181	16
	>20 years	101	2
Profession	Nurse	271	29
	Physician	5	2
	Other (intern, theater assistant etc.)	137	3

Table 3 Descriptive statistics of the Basic Risk Factors of Tripod Delta HC and descriptive statistics of the items of BRF Procedure on a scale from 1 to 5

Tripod Delta HC			
Basic Risk Factor	***mean (SD)***	***Range***	***n***
BRF Procedures	2.70 (0.52)	1.0-5.0	395
BRF Training	2.27 (0.45)	1.0-3.7	412
BRF Communication	2.22 (0.40)	1.1-3.6	412
BRF Incompatible Goals	2.53 (0.45)	1.1-3.9	408
BRF Organization	2.35 (0.42)	1.0-3.4	411

BRF Procedures ***Items***	***mean (SD)***
I have sometimes not been able to find a procedure which I needed at that time.	3.39 (1.00)
There are rules in the hospital which can be interpreted in different ways.	2.99 (0.83)
I have sometimes ended up in a situation whereby it was unclear if a procedure existed about how to act in such a situation.	2.99 (0.93)
I sometimes have had extra work for a relatively simple task because I had to follow a cumbersome procedure.	2.94 (0.96)
I have sometimes searched for information which I subsequently found spread over different places.	2.91 (1.00)
Because procedures are insufficiently clear, I sometimes have to act according to my own discretion.	2.85 (0.93)
I sometimes work with instruments or equipment for which a clear manual is lacking.	2.62 (0.94)
I sometimes have had to deal with procedures the authors of which clearly had no understanding of how it would function in practice.	2.61 (0.87)
There have sometimes been procedures concerning my work which had been changed without me being informed about this.	2.58 (0.91)
I have sometimes been confronted with a procedure, the meaning of which was completely unclear to me.	2.55 (0.81)
I have sometimes had to use a procedure which was so unclear that I had to determine myself how I had to act.	2.50 (0.81)
I have sometimes been confronted with new procedures which were not workable.	2.46 (0.75)
It has happened that I did not understand a procedure due to the unclear lay-out.	2.38 (0.78)
I have sometimes been confronted with a procedure which was formulated in such a complex way that I could not oversee what would happen if I would follow the procedure.	2.31 (0.72)
The procedures which I need for my work link up with practice.	2.29 (0.66)

Table 4. Percentage of healthcare professionals who indicated a high risk on the items of the BRF Procedures of Tripod Delta HC, per department.

		Departments*										
	Item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	***TOTAL***
1	I have sometimes not been able to find a procedure which I needed at that time.	40.9	56.0	44.7	34.3	38.7	31.7	32.6	16.3	27.5	39.3	34.3
2	There are rules in the hospital which can be interpreted in different ways.	9.5	50.0	32.4	28.6	37.5	35.0	2.3	20.5	28.0	26.7	31.4
3	I have sometimes ended up in a situation whereby it was unclear if a procedure existed about how to act in such a situation.	14.3	26.1	18.4	21.2	12.9	16.7	13.6	12.2	12.5	24.1	16.6
4	I sometimes have had extra work for a relatively simple task because I had to follow a cumbersome procedure.	20.0	39.1	37.8	33.3	43.3	42.4	36.4	39.5	28.0	46.7	37.1
5	I have sometimes searched for information which I subsequently found spread over different places.	25.0	60.9	51.4	41.2	46.7	35.0	34.1	21.0	25.5	40.0	36.7
6	Because procedures are insufficiently clear, I sometimes have to act according to my own discretion.	0	18.2	9.1	10.4	10.0	7.1	7.0	2.7	0	13.3	7.3

- table 4 continues -

		Departments*										
	Item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	***TOTAL***
7	I sometimes work with instruments or equipment for which a clear manual is lacking.	31.8	16.0	7.9	5.7	12.5	8.2	4.6	4.3	5.6	6.7	7.0
8	I sometimes have had to deal with procedures the authors of which clearly had no understanding of how it would function in practice.	50.0	37.5	25.6	22.6	38.7	22.0	34.9	6.8	11.5	31.0	25.3
9	There have sometimes been procedures concerning my work which had been changed without me being informed about this.	36.8	45.5	38.9	31.0	50.0	46.7	58.5	26.3	15.7	39.3	38.4
10	I have sometimes been confronted with a procedure, the meaning of which was completely unclear to me.	11.1	19.1	17.1	22.2	10.3	6.6	9.5	2.6	11.8	10.7	11.1
11	I have sometimes had to use a procedure which was so unclear that I had to determine myself how I had to act.	68.4	88.0	75.7	48.5	78.1	66.7	75.0	48.8	38.8	70.0	64.0

-table 4 continues-

		Departments*										
	Item	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	***TOTAL***
12	I have sometimes been confronted with new procedures which were not workable.	15.8	28.6	19.4	16.7	22.6	20.3	11.4	0	10.0	16.7	15.3
13	It has happened that I did not understand a procedure due to the unclear lay-out.	30.0	47.8	8.3	45.5	20.0	21.7	18.2	9.3	20.4	23.3	22.6
14	I have sometimes been confronted with a procedure which was formulated in such a complex way that I could not oversee what would happen if I would follow the procedure.	16.7	30.4	36. 1	29.0	16.1	15.3	16.7	7.5	22.0	26.7	20.8
15	The procedures which I need for my work link up with practice.	11.1	13.0	10.5	23.3	23.3	8.3	11.6	4.7	8.2	33.3	11.5

*Departments: 1= Surgical department; 2= Internal department; 3= Neurology; 4= Short-stay nursing department; 5= Lung diseases & cardio department; 6= Gynecology; 7= Intensive care department; 8= Pediatric department; 9= Operating rooms; 10= Emergency room.

Interviews

Table 2 describes the characteristics of the sample of interviews. All participants were female and the majority (29 of 34 participants) worked in the hospital as a registered nurse. On average, the participants had been working at the hospital for ten years. All participants indicated that they use procedures in their daily work. The majority of participants indicated that there are enough procedures to cover their daily work and that the number of procedures did not need to be expanded. Several participants indicated that there are too many procedures. Three themes and several sub-themes were identified in the interviews by the two researchers (SVS and JT): preconditions, added value and compliance. The results for each theme are described below. Figure 1 describes the themes and sub-themes.

Preconditions

The participants indicated several preconditions for following procedures in their daily work of which the *availability* of procedures was most often mentioned. According to the participants, the search engine should be designed in a way that it is easy to find and access the procedures, as this was currently not the case. In order to find the appropriate procedure, a very specific search term needed to be entered; otherwise the search results would give too many hits resulting in lost time. The name of the procedure should be suitable and should cover the content of the procedure. Several participants stated that procedures should be available from home so that they can be accessed outside working hours.

> *"The search engine needs to be improved; the names of the procedures are difficult to figure out. The search terms we have in our minds often don't match the names of the procedures."*

Other preconditions were related to the *form* of the procedure. Most often mentioned was the fact that a procedure should be a chronological description of all the necessary steps of the task. Furthermore, a procedure should be clearly written, the length should be appropriate (a balance between limited length and providing enough detail), the layout should support the text and provide structure, abbreviations should be avoided and illustrations should be used when appropriate, with the aim of simplifying the content. Participants named several characteristics of what they believe makes an understandable and workable procedure. Participants stated that a procedure should be short and simple, unambiguous, feasible and should describe the responsibilities and prerequisites (for example people, materials/equipment or forms).

"It needs to be clear what benefit there is to working in a certain way, the advantage. It should be feasible, easy to fit into your daily work. It should be short and clearly written and it must summarize who should be doing what."

Figure 1 Themes and sub-themes extracted from the interview data.

Preconditions	***Added value***	***Compliance***
Availability of search engine, name, up-to-date, from home.	*Uniformity* everyone works in the same way, patients know what to expect.	*Patient characteristics* no two patients are identical.
Form clearly written, appropriate length, layout, illustrations, language, abbreviations.	*Evidence-based* according to latest scientific research.	*Work conditions* acute situation, time constraints, physician, other department.
Relates to practice applicable in practice, possibility for providing feedback. and suggest changes.	*Confidence* that work gets done in the right way.	*Experience vs. guideline* following guideline by heart.
	Education/training for new employees	*Justification in case of non-compliance* yourself, colleague(s), physician, head of department.
	Backup for uncommon circumstances, in case of incidents.	*Documentation of non-compliance* oral or written, patient record, multi-disciplinary record, activity plan.

Lastly, the *relationship with practice* of a procedure was mentioned as a precondition. Participants stated that the procedure should be applicable in practice in the sense that the procedure must describe the practical working situation. There should be possibilities for providing feedback and suggesting changes in cases where there was a gap between the description in the procedure and practice. Participants mentioned that there is often a mismatch between procedure and practice, making it impossible to follow it. Changes were made regularly to procedures and these changes lead to confusion and contradictions in the way tasks were carried out. Participants also indicated that more education/training in the use of procedures is needed.

> *"When just a single sentence gets changed in a procedure, I get the whole procedure in my e-mail. I'd like to see just the change. If it's something important, it will be much clearer if it is explicitly highlighted."*

Added value of procedures

Participants named a wide range of added value of working with procedures. The aspect listed most often was the objective of creating uniformity in the care delivered to patients. When everyone works in the same way, this reduces variation in the processes and patients know what to expect. Another important aspect was the evidence-base of procedures and the fact that they are based on the latest scientific insights. This should, in their opinion, result in the best possible care for specific clinical conditions. Furthermore, healthcare professionals mentioned that procedures give them the confidence that they are doing their job as they are supposed to do it. For new healthcare professionals, procedures work as a form of education and for other healthcare professionals as a backup in uncommon circumstances or in cases where an accident has happened.

Compliance

The participants stated that non-compliance with procedures occurs regularly and there was a shared acceptance that this was unavoidable. Reasons for non-compliance could be related to *patient characteristics*, not all patients are alike and different patient characteristics ask for different approaches. Certain *working conditions* could lead to deviations from procedures such as acute situations and time constraints. Or the physician could demand deviations from procedures for clinical reasons. Non-compliance could also be initiated by healthcare professionals from other departments in the case of multi-disciplinary treatment of a patient. Participants mentioned that over time and when tasks become more routinized, healthcare professionals know the procedure by heart they don't

have to look up the procedure anymore. Participants used several reasons to justify non-compliance. In cases of intentional small deviations they did this according to their own insight or discussed it with colleagues. When the deviation was for a medical reason, it was discussed with the physician before the task was performed. In more complex cases or when incidents happened, the deviation was discussed with the head of the department. Participants described several ways to communicate about non-compliance, this could be verbally or in writing. In the case of written communication it was recorded in the patient record, the multi-disciplinary record (when information needed to be available to others) or in an activity plan.

> *"In the end, it's about the healthcare professional's clinical view. You want to provide good care that is tailored to the patient. The procedures describe the main aspects of what is needed, they describe 80-90% of the situations. But there will always be exceptions. You have to be aware of that; you have to keep on thinking for yourself."*

Discussion

In this study we found that healthcare professionals report a considerable amount of perceived risk related to procedures in their daily work. Furthermore, results showed that there are large differences between hospital departments in those perceived risks.

According to healthcare professionals important preconditions for the use of procedures in terms of availability, form and the relationship with practice are not always met and not met to the same extent in every department. This is the first study in healthcare that gathered information about preconditions for the use of procedures, and is important because it gives insight in reasons why procedures are not always being used or cannot always be used as intended.

Healthcare professionals specified multiple objectives for following procedures: uniformity, evidence-based treatment, increase of healthcare professionals' confidence, education of new healthcare professionals and a library to look up information. These objectives show that in general, healthcare professionals do perceive an added value to working with procedures and that this goes beyond the original objective of procedures: a reduction in the variation of outcomes for patients by standardizing the behavior of healthcare professionals. This shows that healthcare professionals are not reluctant to the use of procedures in general, but that

this reluctance is related to procedures that, in their opinion, do not contribute to these objectives.

Non-compliance is accepted amongst healthcare professionals and depends on patient characteristics, work conditions and experience. This is consistent with studies in healthcare that found low compliance rates with clinical guidelines, for example.[9,13,19] However, most of these studies focused on compliance with specific clinical guidelines and not on the more broad concept of procedures as referred to in hospital quality systems. This study showed that non-compliance is not just restricted to narrowly defined clinical guidelines, but also occurs with more general procedures.

This study provides a better understanding of the constraints that healthcare professionals experience in working with procedures and why hospitals are not always optimally effective in translating the requirements of the management system into effective implementation and compliance with procedures. For the quality system to operate optimally, these constraints need to be acknowledged and dealt with by hospital managers and policy makers in order to obtain the desired effect: to reduce the variation in processes and outcomes. This can be achieved for example by using uniform clinical terms in procedures, clearly highlighting changes in amended and updated procedures or by using the input of healthcare professionals to build search engines that reflect their search strategies. Furthermore, hospitals could perform 'rule management', in order to determine which standards and procedures are superfluous or need to be revised to close the gap between the practical working situation and the written standards and procedures. The framework of Hale and Borys (2013)[24] that was adapted from Larsen (2004)[25] provides a categorization of steps that are necessary for rule management. The framework is cyclical and reflects a dynamic process of adapting the rules to the existing working environment.

Strengths and Limitations

This study used a mixed methods approach, combining data from a prospective risk analysis questionnaire and interviews with healthcare professionals. Despite the call for more mixed-method research in health services research literature[26,27], such studies are, to date, scarce. Several limitations must however be mentioned. Firstly, the results of this study were based on data from one general hospital in the Netherlands. Although the attitudes and perceptions obtained might not be present to the same extent in other hospitals, we believe that they can be meaningful in understanding why and under what conditions healthcare professionals use

procedures in their daily work and how these attitudes relate to risk perceptions about procedures. The hospital in this study worked with a database of procedures and protocols, which is common in most Dutch hospitals. Secondly, the selection of the interviewees was made by the head of department. Every head of department was asked to approach one senior and one junior healthcare professional from their department. No additional criteria for selection were set by the researcher and this could have resulted in more positive answers. To constrain this potential selection bias, participants were informed at the beginning of the interview that there were no right or wrong answers and that results from the interviews would not in any way be traceable to individual respondents.

Conclusions

Healthcare professionals report a considerable amount of perceived risk for patient safety in the procedural domain and there are large differences between hospital departments in this risk evaluation. Differences in preconditions, perceived added value and compliance with procedures contribute to our understanding why hospitals are not always optimally effective in translating the requirements of a quality system into effective implementation of, and compliance with procedures. Understanding how healthcare professionals evaluate the risk of operational disruptions related to procedures and how they perceive procedures in their daily work is important, as procedures play an important role in the reduction of variation in outcomes for patients. Future research should examine the link between risk evaluations and attitudes towards procedures and actual behavior of healthcare professionals in order to understand how healthcare professionals make different risk assessments and how they use them as the basis for deciding whether or not to comply with a procedure.

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8

General discussion

Introduction

The aim of this thesis was to gain insights in the working mechanisms of hospital quality systems and more specifically into determining factors of effective quality systems and their long-term added value. The main research questions of this thesis were:

(1) *Does having a hospital quality system lead to higher quality of care?*
(2) *What are the working mechanisms of hospital quality systems that lead to higher quality of care?*

In this chapter, the main findings of the research in this thesis are summarized and reflected upon. Also, methodological considerations are discussed along with implications for practice and for future research.

Main findings and their interpretation

The first study in this thesis examined the development stage of hospital quality systems in Dutch hospitals. Development is divided in four stages, where stage 0 is the most 'immature' stage and stage 3 is the most 'mature'. By stage 3, the quality system encompasses all necessary elements of quality assurance and quality improvement and the results of that system are being used by the hospital to adjust input of and resources for the system. Our study showed that, more hospitals had reached this stage of development by the last measurement in 2011 than in 2007: 35% of Dutch hospitals had reached this highest stage in 2007 and this percentage had risen to 45% in 2011. This increase indicates that hospitals have continued to strive for enhancement of their quality systems. However, our results also showed that 5% of the hospitals moved from stage 1 to stage 2 but for a majority of Dutch hospitals (55%) the development of their quality system stagnated in stage 2. These hospitals have all the elements of the quality system in place, but outcomes of the quality system are not (yet) used to improve their system and processes further. This prevents the emergence of an important element of quality improvement: the continuous cycle of quality improvement. It is known from the literature that the implementation of a quality system takes time. The actual achievement of the results targeted by implementing a quality system may require more than a decade of disciplined use.[1] A considerable amount of time is needed to fully comprehend the benefits of a properly implemented quality system.[2] Doeleman's studies showed that for example the EFQM Excellence Model needs to be consistently applied over a lengthy period of time (5-10

years) before the effects of its use became evident.[3] Furthermore, we found that when all the various elements of the quality system are considered separately, the element of patient involvement is the least developed. The results from this study can be seen as defining a baseline needed for answering the research questions of this thesis.

The second study in this thesis examined the relationship between the development stage of the quality system and perceived organizational outcomes over a period of fifteen years (1995-2011). Based on Donabedian's quality improvement model, we hypothesized that having achieved a more advanced stage of quality system development is related to better organizational outcomes (*hypothesis 1*). Results showed that hospitals with more developed quality systems did indeed have better perceived organizational outcomes and that this positive relationship was consistent over time, thereby confirming *Hypothesis 1: A higher degree of implementation of the hospital quality system leads to improved outcomes of the organization.* In this study, we had measurements from multiple moments in time and linked the measures of the quality system to the organizational outcomes of the *next* measurement point. This was based on the assumption that structural measures do not have an immediate effect on organizational outcomes but that this process needs time to become visible. In this respect, since most previous studies used cross-sectional data, our study expands the theoretical understanding of quality systems by adding a longitudinal approach. It must however be noted that the effects that were found were relatively small and that the measured outcomes were perceived rather than clinical.

The relationship between organizational structure and organizational outcomes is assumed to be established through interrelation of the structure of the organization and organizational processes. In other words, the structure influences the processes in the organization and these in turn affect the organizational outcomes. This assumed interrelatedness of structure and outcome was translated into the following hypothesis. *Hypothesis 2: A higher degree of implementation of the hospital quality system leads to improved processes in the organization. W*e examined the relationship between the development of the hospital quality system and process indicators taken from a national patient safety programme. It was assumed that hospitals with more highly developed quality systems would perform better on process indicators as they would reflect measures of the performance of an organization at the department level (process level). However, an inconsistent pattern of relationships between the development of the hospital quality system and the process indicators was found. Some positive associations were found

between the development stage of the quality system and several process indicators and some negative associations were found as well. Most of the process indicators in our study did not seem to be influenced by the quality system at all.

Consequently, we studied differences in the risks perceived by healthcare professionals in several organizational areas at the department level within the organizational domains (1) Procedures, (2) Training, (3) Communication, (4) Incompatible Goals and (5) Organization. This study was carried out in a general hospital that had been accredited for many years. It was therefore expected that healthcare professionals from this hospital would perceive little risks in the various organizational domains and that differences between healthcare staff from different departments in risk perceptions would be small to non-existent. Ideally, the quality system would have standardized the processes resulting in departmental processes becoming more similar (less between-groups variation) and reducing the amount of risky processes. However, we found that the hospital reported a high level of perceived risk for patient safety in most of the five organizational domains, especially in the procedures domain. Furthermore, inter-departmental converging effects of quality systems on organizational areas were not found, which can be seen as another contradiction of *Hypothesis* 2.

Both these studies contradict the idea that a quality system improves the processes of an organization. These findings contradict the results from the European research project DUQuE.[4] Within this large study on the effectiveness of quality improvement systems in hospitals from different European countries, researchers found no relationship between quality management systems at hospital level and patient outcomes. However, they did find a positive relationship between quality management systems at hospital level and quality improvement at department level and between quality improvement at department level and patient outcomes.[5-8] These contradictory findings can (at least partially) be explained by the use of different type of outcome measures that were used: where DUQuE used patient outcomes measures in this thesis perceived outcomes were used. Furthermore, another explanation can be found in the process indicators used in this study. These were part of a national safety programme that was designed separately from the existing quality system of the hospitals and therefore possibly less integrated in the hospital organization than the indicators used in the DUQuE project.

Based on our findings, we cannot rule out the possibility that a quality system does not contribute to improvement of process-level measures. This would contradict the first part of Donabedian's theoretical model of quality improvement. However, we have proposed several alternative explanations for these findings. One of these explanations was examined further in our study that examines the attitudes of healthcare staff towards procedures, an important aspect of a quality system, reasoning that this might play an important role in the extent to which parts of the quality system are adopted and adhered to at the clinical level. Attitudes of healthcare staff might mediate the relationship between quality systems and processes, making it complex to measure and attribute to the variation of scores for process indicators that we found. We will come back to this when we discuss the results of the study into attitudes of healthcare staff.

In a developed quality system, quality activities are integrated into daily working processes throughout the organization. Policy and management of the organization ensure that this is carried out at the process level of the organization as well and this becomes visible in a reduction of variation in processes of the organization (over departments) and improvement of these processes over time. This led us to hypothesis 3*: Improved processes of the organization lead to improved outcomes of the organization.* We studied the compliance of healthcare professionals with a procedure intended to prevent wrong surgery. Compliance with this safety procedure can be seen as an outcome of the organization because compliant behaviour is thought of to result from a procedure developed to standardize processes at the departmental level of the organization and implemented similarly in all participating hospitals. We found that compliance with this specific procedure was generally low and influenced by a multitude of factors. Based on our hypothesis, we would have expected high compliance in general. Our research suggests that hypothesis 3 must be rejected. As discussed in previous chapters, existent research findings on compliance with quality and safety procedures indicated low compliance rates as well.

In the second study, mentioned earlier in the description of the results under hypothesis 2, we also examined the influence of organizational outcomes on the structure of the quality system over time (1995-2011). We hypothesized that hospitals with a more developed quality system (stage 3) would use their organizational outcomes as input to further improve their quality system. This is a feedback loop intended to effect continuous quality improvement over time. In this study we found that hospitals with a more developed quality system do indeed use organizational outcomes to

improve the structure of their quality system. *Hypothesis 4: In a more developed quality system, the outcomes of an organization feed back into the structure of the organization and this forms a cycle of continuous quality improvement.* This study revealed a positive relationship between organizational outcomes and measures of the structure of the quality system at a later point in time. Hypothesis 4 is confirmed by these results. Unique to this study is that it is the first to measure quality improvement over a longer period of time and test whether the results of an organization are being used to improve the structure of the system, which is an important assumption in quality improvement theory. The results obtained in this study can therefore be seen as a contribution to existing theoretical knowledge about quality improvement. It shows the results of a continuous cycle of quality improvement and confirms the theoretical idea of a feedback loop of improvement. However, the effects we found were smaller than the effects we found in the relationship between structure of the quality system and organizational outcomes. Furthermore, not all of the effects between organizational outcomes and structure were statistically significant. One explanation is that the relationship between results of an organization and the quality system is weaker because such a feedback loop is more difficult for organizations to obtain.

Hypothesis 5: The relationship between the level of development of a quality system and the processes, and the relationship between the processes and outcomes of a hospital are modified by the degree to which healthcare professionals are aware of the importance of standards and procedures set by the quality system and act accordingly. In this thesis we considered two aspects of this hypothesis: 1) healthcare professionals' attitudes towards working with procedures and 2) healthcare professionals' compliance with these procedures. We acknowledge that this is only a fraction of the many different ways that healthcare professionals interact with the quality system. In one study we examined compliance with a surgical checklist intended to reduce the incidence of wrong surgery. Overall compliance was found to be 71.3%. However, differences between hospitals and different departments within the same hospitals were large. Furthermore, actual execution of this procedure was suboptimal because healthcare professionals performed all kinds of tasks simultaneously. The study showed that having implemented procedures in a hospital is no guarantee for procedural compliance. Therefore, the intended effect of procedures on standardization of care and outcomes of treatment is suboptimal. Further examination of professionals' attitudes aimed to find reasons for non-compliance. From interview data it was shown that (according to the healthcare professionals) preconditions for

procedures are not always met and tend to vary between departments. The availability of procedures is limited, mostly due to technical problems such as inadequate search engines. Procedures are sometimes described too generally or on the contrary are too detailed to work with and often do not relate to practice. This indicates a gap between what the procedure prescribes and the actual work situation. Healthcare professionals acknowledged the importance of procedures and specified multiple objectives of compliance with procedures: uniformity, evidence-based treatment, increase of healthcare professionals' confidence, education of new healthcare professionals and a library. Non-compliance is accepted amongst healthcare professionals, mostly due to the fact that most procedures are not uniformly applicable to every individual patient. Also, specific work conditions, such as acute situations or time constraints, can lead to non-compliance. Non-compliance can also be (implicitly) demanded by the leading physician or derive from collaboration with other departments. Non-compliance looms when tasks become more routinized, a situation under which experience subjugates procedural piety. The decision to deviate from a procedure is often justified by the person's own clinical insight or discussed with colleagues, physicians or the head of the department. This information is important since it helps understand how healthcare professionals perceive the added value of quality procedures and how these procedures are applicable (or often not) in daily practice. Based on these two studies hypothesis 5 can neither be confirmed or rejected as they reveal only a part of the complicated relationship between healthcare professionals and the working mechanisms of quality systems. However, it seems safe to assume that the relationship between structure, process and outcomes is indeed modified by the attitudes of healthcare professionals towards procedures and the way in which they choose to work with them. This could also explain why we did not find the hypothesized positive relationship between the development stage of a quality system and higher scores of the process indicators.

To summarize our main findings, Table 1 describes the five hypotheses in this thesis, their working mechanisms and the conclusions based on research in this thesis.

Table 1 Hypotheses, working mechanisms and conclusions of this thesis.

	Hypothesis	**Working mechanism**	**Conclusion**
1	A higher degree of implementation of the hospital quality system leads to improved outcomes of the organization.	In a developed quality system, the quality activities are integrated in daily working processes throughout the organization. This leads to broad and systematic quality improvement. This is visible through a reduction of variation in results of the organization and improvement of these results over time.	Confirmed.
2	A higher degree of implementation of the hospital quality system leads to improved processes in the organization.	In a developed quality system, the relationship between the structure of the organization and results of the organization is assumed to be established through interrelation of the structure of the organization and organizational processes. This is visible in a reduction of variation in processes of the organization and improvement of these processes over time.	Rejected.

Table 1 Hypotheses, working mechanisms and conclusions of this thesis. (*Continued*)

3	Improved processes of the organization lead to improved outcomes of the organization.	In a developed quality system, the quality activities are integrated into daily working processes throughout the organization. Policy and management of the organization ensure that this is carried out at the process level of organizations as well. This is visible in a reduction of variation in processes of the organization leading to improvement of results of the organization over time.	Rejected.
4	In a more developed quality system, the outcomes of an organization feed back into the structure of the organization and this forms a cycle of continuous quality improvement.	The key aspect of a developed quality system is the feedback loop of organizational learning. Results of the organization are being used to adjust policy and strategy at the structure level. This creates a cycle of continuous improvement which is visible not only in an improvement of results but also improvement of the system itself over time.	Confirmed.
5	The relationship between the level of development of a quality system and the processes, and the relationship between the processes and outcomes of a hospital are modified by the degree to which healthcare professionals are aware of the importance of standards and procedures set by the quality system and act accordingly.	Awareness of the importance of quality and safety creates an environment where it becomes natural to act according to the standards and procedures set by the quality system. This is a prerequisite for quality policy and strategy at the system level to seep through to the results of the organization and thereby optimize the functioning of the quality system.	Confirmed.

In conclusion, the results of this research show the complexity of the relationship between hospital quality systems and high quality of care. We showed that a higher degree of implementation of the hospital quality system leads to improved outcomes, and that these improved outcomes can in turn have a positive effect on the structure of the hospital quality system. However, contrary to expectations based on the idea of quality improvement, we did not find a positive relationship between the degree of implementation of the quality system and improved processes of the organization. Furthermore, we did not observe a positive relationship between improved processes and outcomes of the organization. Based on our findings it seems that hospitals don't systematically use the data and results from the quality system to improve their quality system, processes and outcomes. A key aspect for optimal functioning of the quality system is the commitment and input to quality and quality improvement of healthcare professionals.

Methodological considerations

This thesis combined quantitative and qualitative research methods in order to answer the main research questions. More specifically, we used questionnaires, interviews, observations and record reviews. Data triangulation is seen as a way to obtain a broad understanding of the phenomenon being studied, in this case the hospital quality system. Data was measured at the structure, process and outcome levels in order to gain insight into all the levels involved in quality improvement. This study used data from fifteen years of quality management in Dutch hospitals, a unique dataset that enables to consider long-term development of both quality systems and organizational outcomes. Multilevel statistical techniques were used to analyse the results.

Despite these methodological strengths, several limitations should be mentioned. For a more detailed overview of limitations per study we refer to chapters 2 to 7. The first two limitations necessary to mention here are related to the way in which the development stage of quality systems was measured. These limitations were reported by other researchers in previous publications as well.[9-11] First, the development of quality systems and the results of the quality system were measured by means of self-reported questionnaires with a risk of socially desirable answers. However, the wide range of scores, the general tendency of quality systems to shift towards higher stages of development over the years of measurement, the guaranteed anonymity of the respondents and the provision of feedback

reports for benchmarking do seem to minimize biased results due to socially desirable response tendencies.

Second, the quality system questionnaire portrays the hospital as a whole, without providing any insights into differences between and/or within departments. The possibility that differences do exist between parts of the hospital cannot be ruled out. Therefore, this should be taken into account when interpreting the results. The use of a second questionnaire, Tripod Delta HC, that measures risk perception at department level gives more insight in these differences between departments and can be seen as complementary to the quality system questionnaire.

A third limitation is that the organizational outcomes were based on perceived outcomes, allowing some form of subjectivity. Ideally more objective measures such as clinical outcome data should be used to measure the performance of hospitals. However, no stable and reliable clinical outcome data were available, partly due to the length of the study period (1995-2011).

Implications for practice

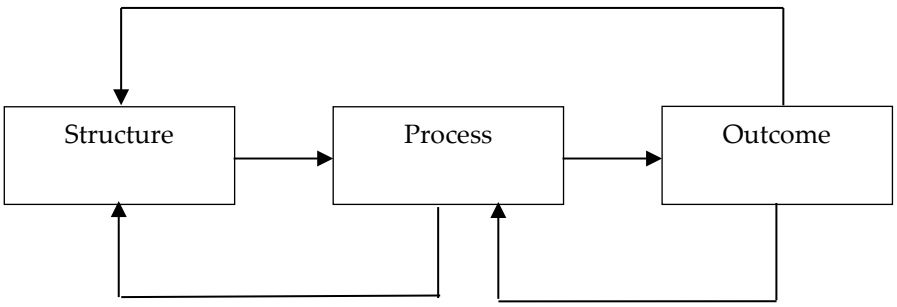
In order to achieve continuous quality improvement, hospitals need to use their outcomes to improve the structure and processes of their organization

Our research showed that within our observation period most hospitals did not manage to establish a feedback loop of continuous quality improvement.[12] Without such a feedback loop, hospitals do not use their outcomes to systematically improve their quality system (structure). It is important to establish this feedback loop since outcomes of the hospital organization can have a positive influence on the structure. The research in this thesis showed that over 50% of Dutch hospitals have not reached the highest stage of development of their quality system.[12] It is important that hospitals continue their efforts to develop their quality systems further. Only a fully developed quality system has the potential to contribute to better quality of care for patients. Hospitals that do have all the elements of the quality system in place but are struggling to get all these elements integrated into the daily working processes (the highest stage of development) could learn from the experiences of hospitals that have managed to do so. This requires a transparent and open culture of sharing and learning between hospital organizations. Some collaborations between hospitals have already

been formed in the Netherlands, for example a group of six teaching hospitals that started an open collaboration to improve their quality of care in 2010.[13] Within this collaboration, quality information of the individual hospitals and hospital departments is shared and used for benchmarking and quality improvement. Quality information is made publicly available in other countries as well. For example, in the United Kingdom the NHS publishes results using quality indicators.[14] Multiple purposes are being served: it can be used by the public to choose healthcare providers based on their quality of care and it can be used by the healthcare providers to share and detect best practices and learn from each other.

Moreover, it is not only the feedback loop from outcomes of the organization to structure that is important: a feedback loop from organizational processes to the structure is also needed and currently missing. We have shown that wide variation exists in organizational processes between hospitals and that the results of these processes are not always used to improve the quality (system) of care. For example, hospitals can perform numerous quality improvement projects but the results of those projects are not always used as feedback to shape future quality improvement projects. This entails a danger of repeating inefficient ways of working. Figure 1 shows the two proposed feedback loops.

Figure 1 Quality improvement through a feedback loop of continuous learning.



Patient involvement should be developed further

The results of this thesis showed that there is variation in the degree to which the different elements of the quality system are developed. Least developed is the element of patient involvement. This is consistent with

research into patient involvement in European hospitals that shows that patient involvement in European hospitals is generally low.[5,15] Patients are an important actor in the quality system as they not only interact with the system but are also the outcome of the system: patient safety and quality of care. It is therefore important to develop patient involvement in hospitals further. Patient involvement is defined by the European Patients Forum (EPF) as *'the extent to which patients and their families or caregivers, whenever appropriate, participate in decisions related to their condition (e.g. through shared decision-making, self-management) and contribute to organizational learning through their specific experience as patients (e.g. patient reporting of adverse events or participation in root cause analysis related to their care)'*.[16] During the last decade, emphasis has been placed on the idea that patients should be involved in care in general but also in for example factual decisions and medical procedures concerning their own disease and treatment. This is also apparent from the growing body of literature on patient involvement (for example [17-23]). This literature also highlights several difficulties in patient involvement, such as the high level of institutionalisation of participation, and increase in proto-professionalization of patients.[21,22] Both aforementioned benefits and threats of patient involvement can be taken as a starting point for developing efficient techniques to involve patients in a more systematic manner than is currently the case.

Hospitals need to find the balance between bureaucracy and quality improvement

From our interviews with healthcare professionals it became clear that a general feeling exists of an abundance of rules and procedures interferes with daily work. As quality systems develop, so do the numbers of procedures, rules and guidelines within the system. The next step should be to take the time to take a step back and consider the purpose of these rules and procedures. Rules and procedures are not intended to increase the bureaucratic burden but to improve the quality of care by standardizing the way in which healthcare professionals work. When a procedure does not contribute to this purpose, or when it even has a corroding effect, it should be eliminated from the system.

Involvement of healthcare professionals in quality improvement is essential for good functioning of the hospital quality system

A key aspect of quality improvement is the involvement of healthcare professionals in quality management. Attitudes of healthcare professionals

towards protocols are a potential source of resistance to quality initiatives.[24] It is known that professional autonomy plays a key role in the decision whether to engage in quality improvement activities.[25] Failing to engage healthcare professionals in the development and implementation of interventions is seen as one of the most important barriers to successful quality improvement.[26] Objections of healthcare professionals to standards and procedures should be taken seriously in order to keep them committed to safety and quality. But listening and trying to understand the resistance of healthcare professionals could also provide meaningful insights into the added value of certain standards and procedures. Healthcare professionals are the people most able to determine the merits of standards and procedures where it matters the most: patient care at the front line. This could contribute to the balance between bureaucratization and quality improvement. What should to be taken into account in this respect is the increasing pressure that is being put on resources in healthcare in combination with the increasing numbers of new standards and rules that professionals need to work with, as was mentioned in the previous section. It is not surprising that new rules and procedures probably meet more resistance in an environment where there is a lot of time pressure on professionals to get their work done with less manpower available.

Implications for future research

Several implications for future research can be derived from this thesis. These implications take the form of proposed research questions for future research. The aim of these questions is to add to knowledge about how quality systems work and develop existing theories about quality improvement.

What role do processes play in hospital quality improvement?

The results of this thesis showed that the role of processes in hospital quality improvement is contradictory to our expectations based on the idea of quality improvement. Future research is needed to confirm whether this contradiction has theoretical or methodological origins. In this thesis we already suggested several theoretical explanations which mainly focused on aspects of implementation of quality improvement initiatives on the process level and the attitudes and behaviours of healthcare professionals. A first step in further developing our theoretical understanding of quality improvement would be to examine these possible explanations and gain

more insights into the role processes seem to play in quality improvement. Another possibility is that our method of measuring processes was not optimally suited to reveal a possible relationship between the structure of the quality system and processes, and a relationship between processes and outcomes of the organization. In this thesis we mainly focused on variation in processes, and assumed that improvement of processes is reflected in a reduction of variation in these processes. However, future research could define other ways of operationalizing improvement in processes and decide whether these relate to structure and outcome measures of the organization.

What obstacles do hospitals face in trying to reach the highest stage of development of their quality system?

The results of this thesis showed that organizations find it difficult to reach the highest stage of development of a quality system. The stage where quality is integrated into the normal operational processes and organizational outcomes are being used to improve the quality system. What could explain why hospitals experience difficulties in taking this step in development? And what type of resources and/or support would these hospitals need to move their quality system to this desired stage of development? A good starting point for answering these questions could be to study the hospitals that did manage to develop their quality system optimally and reached the highest stage of development of their quality system.

Can the quality system be designed in such a way that a maximum level of quality can be reached with a limited amount of resources? What should a selection of the essential elements of the system be based upon?

Related to the previous question, there is a contradiction that is worth examining in future research. On the one hand the quality system produces a growing number of rules, procedures, protocols and guidelines and calls for registration and data collection. However, this contrasts with fewer (financial and human) resources, which places a lot of time pressure on healthcare professionals. In order to maintain a balance between the competing demands (high quality with fewer resources) it would be interesting to provide a minimum set of requirements for their quality systems so that hospitals can focus on the essential elements that are needed to obtain high quality of care. It would be therefore important to examine whether there are specific rules, procedures and registrations that do not contribute (or only do so to a minimal extent) to higher quality of care. And

how can the contribution of rules and procedures be assessed? In other words: if policy makers want to make a selection of the aspects that are really necessary, what should this selection be based upon? Future research could provide insights that are valuable for research and practice, and help organizations to focus their resources and organize their processes in the most efficient way. As a first step to reduce the numbers of procedures carried out in an organization and give more autonomy to professionals working with procedures, the classification of Hale and Swuste[27] can provide guidance in determining which procedures allow space for interpretation. Hale and Swuste categorize rules into three types that are based on the amount of autonomy, or freedom of choice, that the rule allows for: (1) goal rules, which define goals that need to be achieved - goal rules leave a large amount of autonomy with the professional; (2) procedural rules, which define the way to arrive at a decision about a course of action; (3) action rules, which define concrete actions. Action rules remove almost all autonomy from the professional.[27] Certain organizational factors are relevant for determining the level of the constraint of the rules, for example a more unpredictable system needs goal rules.[28]

How can healthcare professionals stay connected to the hospital quality system?

How can hospitals avoid losing the commitment of healthcare professionals to quality management? How can the input of healthcare professionals be used to improve quality of care? What do healthcare professionals need in order to be able to work according to the rules and procedures set by the quality system? A key aspect of the functioning of quality systems is the healthcare professionals who need to work within the system. Quality management is often performed using a top-down approach, with little involvement and input from healthcare professionals at the structure level. This creates a risk of healthcare professionals feeling passed over and in turn they might not feel connected with the quality system. In order to avoid losing the valuable contribution of healthcare professionals to quality improvement, it is important to know exactly how healthcare professionals can stay motivated, connected, involved and committed to quality management. Future research should focus more on the needs of healthcare professionals and point to solutions for existing barriers for them, facilitating more interaction with the hospital quality system and more bottom-up input.

Future methodological approaches

As well as pointing to relevant future research questions that could contribute to the theoretical understanding of quality systems, it is also relevant to consider different methodological approaches. With regard to the *study population*, future research should try to study the effectiveness of quality systems in larger hospital populations, for example within a European context. A recent example of one such valuable approach was the European research project DUQuE.[4] Furthermore, it would be worthwhile to see whether the mechanisms for quality systems show a similar pattern in different healthcare sectors, such as long-term care. Long-term care is a relevant sector given the rapidly ageing population worldwide. Researchers should favour *study designs* that are longitudinal in nature. Even though a longitudinal design is in practice often very difficult to realize, it does provide more meaningful insights when researchers want to determine causal relationships between quality systems, organizational processes and organizational outcomes. Complementary, in-depth studies that are more qualitative in nature could be used to provide insights into the attitudes and needs of healthcare professionals. The complexity of the human mind, cognition, decision-making and attitudes might be better captured with these kinds of in-depth qualitative methodologies. Replication of results of previous studies might sound trivial and is often mentioned in published papers, but in practice replication is not common at all, even though it is an important cornerstone of science.[29] Future research in the field of quality management could benefit from *other scientific disciplines* such as safety science (for example to learn about the working of safety systems in other high risk industries, e.g., aviation), human factor engineering (for example to learn how a system can be designed around humans instead of how the system should be 'forced upon' them) or social psychology (for example to understand the decision-making processes of healthcare professionals). At the measurement level, future research should develop valid and stable clinical outcome measures. There are not many clinical outcome indicators available and the measures that are available are often unreliable or not validated. These clinical outcome measures should not replace the currently used process indicators but should be seen as supplementary to them.

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Summary

The implementation of quality systems in healthcare organizations is a strategy for quality assurance and quality improvement. The underlying assumption is that a quality system will improve the performance of an organization by facilitating and improving the processes within the organization. Although implementing quality systems in healthcare aims to improve the quality of care and patient safety by improving the processes, no clear evidence can be found in the literature that this is actually the case. Furthermore, little is known about the mechanisms through which a quality system can lead to high quality of care.

The research in this thesis was set out to gain a better understanding of the conditions under which a hospital quality system can result in higher quality of care. Furthermore, we aimed to gain insights into the determinants of effective quality systems and the long-term added value of quality systems for hospitals. The main research questions were:

(1) Does having a hospital quality system lead to higher quality of care?
(2) What are the working mechanisms of hospital quality systems that lead to higher quality of care?

According to Donabedian's model of quality improvement, quality can be achieved by means of a structure-process-outcome relationship in which the quality system –the structure– is thought of as improving the organizational processes that in their turn should positively influence quality of care –the outcomes. The quality system is the structure within which quality improvement policies and quality improvement activities can be embedded and this quality system is hypothesized to have an influence on quality improvement activities at the process level. The improved processes in their turn influence the outcomes of the organization. Based on this model five hypotheses were formulated and tested in the studies that were described in the different chapters of this thesis:

- *Hypothesis 1: A higher degree of implementation of the hospital quality system leads to improved outcomes of the organization.*
- *Hypothesis 2: A higher degree of implementation of the hospital quality system leads to improved processes in the organization.*
- *Hypothesis 3: Improved processes of the organization lead to improved outcomes of the organization.*
- *Hypothesis 4: In a more developed quality system, the outcomes of an organization feed back into the structure of the organization and this forms a cycle of continuous quality improvement.*

- *Hypothesis 5: The relationship between the level of development of a quality system and the processes, and the relationship between the processes and outcomes of a hospital are modified by the degree to which healthcare professionals are aware of the importance of standards and procedures set by the quality system and act accordingly.*

Chapter 2 describes the development of quality systems in Dutch hospitals between 1995 and 2011. Research using longitudinal questionnaire surveys among all Dutch hospitals in 1995, 2000, 2005, 2007 and 2011 measured how the quality systems have progressed. In 1995, 52% of the hospitals taking part were still in the preparation stage of their quality system development, whereas 53% of participating hospitals had all the requisite components of a quality system by 2011. By 2011, 45% of the hospitals had also succeeded in integrating these elements into a system for continuous quality improvement, meaning that the highest level of quality system development had been achieved. If the development of quality systems is examined in terms of the separate quality system components, it can be seen that this development did not progress in the same way for all elements. It is also possible to see that quality systems at larger hospitals have developed further. Future research should focus on additional explanations of differences between hospitals in the development stages of their quality systems and the effects that these systems have on the quality of care.

In Chapter 3, the same longitudinal questionnaire survey data was used in a different manner. The questions from the questionnaire were regrouped in order to reflect the five enabler and the four results criteria of the European Foundation for Quality Management model (EFQM Excellence Model). This data was then used to measure the performance of hospitals on enabler and results criteria over time (1995-2011), to see whether high scores on enabler criteria would lead to higher scores on results criteria, and to test a feedback loop of the results criteria into the enabler criteria. The results of this study showed that applying the EFQM Excellence Model in hospitals is related to improvement in organizational performance over time, a feedback loop in which hospitals use their results to further improve their organizational processes is established, and improvement is stronger when all the model's elements are considered simultaneously.

In the study in **Chapter 4,** data from a national survey on the development stage of quality systems in Dutch hospitals with results from an evaluation study of the Dutch Hospital Patient Safety Programme were combined. Data on the development stage of quality systems were collected in Dutch hospitals in 2011.

A total of 73 quality coordinators completed a questionnaire (response rate 77%) covering five quality system domains: policy and strategy, human resource management, patient involvement, practice guidelines, and systematic quality improvement. Data were included on the implementation of five patient safety themes from the Dutch Hospital Safety Programme. Process indicators for each theme were measured every four to six weeks, resulting in ten measurements in each hospital. Data were analyzed using multilevel analysis. This study found no association between the development stage of a hospital quality system and the implementation of patient level safety themes at the process level. This contradicts the hypothesis that quality improvement is caused by a positive relationship between structure (the quality system) and processes (the safety programme implementation), which in their turn mold the quality of care at the patient level.

Chapter 5 describes the development and validation of an instrument for prospective risk analysis at the department level in hospitals. The questionnaire that was used is called Tripod Delta and was originally developed for the petrochemical industry. The questionnaire asks the healthcare professional questions about perceived risks in five organizational domains: (1) Procedures, (2) Training, (3) Communication, (4) Incompatible Goals and (5) Organization. In our study we modified the questions slightly so that they were applicable in the healthcare sector. This altered version was named Tripod Delta Health Care and was administered in thirteen departments of two Dutch hospitals. A multilevel method called ecometrics was used to evaluate the validity and reliability of the questionnaire. An ecometrics approach allows differences between departments and individual perceptions to be distinguished so as to ensure that differences in risk analysis between departments are really reflecting differences between departments and not between individuals. A total of 626 healthcare staff completed the questionnaire, resulting in a response rate of 61.7%. The results of this study show that Tripod can be used as a method for prospective risk analysis in hospitals. Results of the questionnaire provide information about latent risk factors in hospital departments. However, this study also shows that there are indications that the method is not sensitive enough to detect differences between hospital departments. Therefore, it is important to be careful when interpreting *differences* in potential risks between departments when using Tripod.

Chapter 6 uses data from a larger evaluation study of the Safety Programme, focusing on one of these patient safety themes: the prevention of wrong

surgery. The goal was to have ten observation days per hospital at intervals of four to six weeks, and to observe six to ten surgical procedures per day, preferably involving different surgeons and different surgical procedures. One observer per surgical procedure evaluated whether the Time- Out Procedure (TOP) was carried out before anesthesia, using a standardized recording form that covered the various aspects of doing the TOP: checking the patient, procedure and side/site, attention of the team (focus), completeness of the team and interruptions, plus several background variables such as the type of surgical procedure, the patient's age and sex. Mean compliance with the TOP was 71.3%. Large differences between hospitals were observed. No linear trend was found in compliance during the study period. Compliance at general and teaching hospitals was higher than at academic hospitals. Compliance decreased with the age of the patient, general surgery showed lower compliance in comparison with other specialties and compliance was higher when the team was focused on the TOP.

Chapter 7 uses a mixed method approach: the validated Tripod Delta Health Care was measured in ten departments of one general Dutch hospital and this was complemented by interviews about the attitudes of healthcare professionals towards the use of procedures in their work. These two data sources were combined to give a broad overview of risk perceptions and attitudes concerning procedures in the daily work of healthcare professionals. Procedures are a cornerstone of a hospital quality system as they include all the relevant (clinical) guidelines, protocols and procedures that a hospital has in place to guide the organization and its healthcare professionals towards good quality of care. Based on the assumption that implementing and working according to procedures reduces risks for patients, it is expected that healthcare professionals working in hospitals with a more developed quality system will experience lower risk at operational failures in processes and therefore less risk at patient harm. The aim of this study was to describe how healthcare professionals evaluate risks of operational disruptions related to procedures and to describe their attitudes towards the use of procedures in their daily work. 413 prospective risk analysis questionnaires were returned by healthcare professionals and 34 interviews with nurses from the different departments were conducted. Healthcare professionals reported a considerable amount of perceived risk in the procedural domain and there are large differences between hospital departments. Differences in preconditions, perceived added value and compliance with procedures contribute to our understanding why hospitals are not always optimally effective in translating the requirements of a

quality system into effective implementation of, and compliance with procedures.

Conclusion

In conclusion, the results of the research in this thesis show the complexity of the relationship between hospital quality systems and high quality of care. We showed that a higher degree of implementation of the hospital quality system leads to improved outcomes, and that these improved outcomes can in turn have a positive effect on the structure of the hospital quality system. However, contrary to expectations based on the idea of quality improvement, we did not find a positive relationship between the degree of implementation of the quality system and improved processes of the organization. Furthermore, we did not observe a positive relationship between improved processes and outcomes of the organization. Based on our findings it seems that hospitals don't systematically use the data and results from the quality system to improve their quality system, processes and outcomes. A key aspect for optimal functioning of the quality system is the commitment and input to quality and quality improvement of healthcare professionals.

Implications for practice:

- In order to achieve continuous quality improvement, hospitals need to use their outcomes to improve the structure and processes of their organization.
- Patient involvement should be developed further.
- Hospitals need to find the balance between bureaucracy and quality improvement.
- Involvement of healthcare professionals in quality improvement is essential for good functioning of the hospital quality system.

Proposed research questions for future research:

- What role do processes play in hospital quality improvement?
- What obstacles do hospitals face in trying to reach the highest stage of development of their quality system?
- Can the quality system be designed in such a way that a maximum level of quality can be reached with a limited amount of resources? What should a selection of the essential elements of the system be based upon?
- How can healthcare professionals stay connected to the hospital quality system?

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About the author

Steffie Marijke van Schoten was born on the 3rd of May 1984 in Oegstgeest, the Netherlands. She grew up in Hilversum where she finished secondary education at Adriaan Roland Holst College. She studied Sociology and Social Psychology at the University of Tilburg and graduated in 2006 (MSc Sociology) and 2008 (MSc Social Psychology). During her studies she worked as an intern at an employee assessment company. After finishing Social Psychology in 2008 she worked as a product developer at an international publisher for clinical testing instruments. In February 2010 she started working at NIVEL as a PhD student on the research described in this thesis. During this period she was also involved in the European Union network for patient safety and quality of care (PaSQ) and she was secretary for the internal quality committee of NIVEL for almost two years. Currently she is employed at NIVEL as a post-doc researcher, where she will continue to work on research related to quality of care.