

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?