The Effectiveness of ISO 9001 and Six Sigma in Healthcare

Jaap van den Heuvel

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The patient is the centre of the medical Universe, around whom all our activities revolve and towards whom all our energies are directed.

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The true voyage of discovery lies not in finding new landscapes but in having new eyes.
(Marcel Proust)

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Introduction

Subject of this thesis

All over the world healthcare is facing serious problems. Costs are exploding and quality of care consistently fails to meet justified expectations (IOM 2001). Quality management therefore is a major strategic issue in healthcare organizations. Unfortunately there is little agreement on the precise definition and content of quality and quality management in healthcare. Many concepts and tools originate from industry. There are, however, some fundamental differences between healthcare and industry that have to be taken into account before transferring those concepts and tools. The subject of this thesis is the transfer to a hospital of two quality management tools; the ISO 9000 standards and Six Sigma. General conclusions will be drawn that may assist other healthcare institutions to face their challenges in quality management.

Quality management

Quality management consists of three aspects: quality planning, quality control and quality improvement (Juran 1989). In addition, measuring quality is considered the core of quality management (Shewhart 1931). In healthcare similar aspects of quality management have been defined (Donabedian 1987). An important way in which quality management is put into practice is through the implementation of quality standards and quality awards. The most important quality standards are the International Quality Standards ISO 9000 series. For many organizations the next step after ISO certification is the achievement of a quality award. This is because awards are more comprehensive than ISO 9000 (Conti 1993). A well known quality award is the European Quality Award, instituted in 1992 by the European Foundation of Quality Management (EFQM). The Dutch equivalent of this award is created by the Dutch Quality Institute (Instituut Nederlandse Kwaliteit), the INK-award. The Malcolm Baldrige National Quality Award is the American equivalent of the European Quality Award and was created in 1987. Evidence suggests that the new ISO 9000:2000 standard can be implemented complementary to the EFQM model (Kelemen 2003). Compared with the EFQM model however, the ISO 9000:2000 standard is a necessary but not sufficient criterion for the achievement of excellence (Russell 2000). The ultimate goal of quality management is Total Quality Management (TQM). Unfortunately there are numerous definitions of TQM, and despite thousands of articles and books written on it, TQM remains a highly ambiguous concept (Kelemen 2003). This can be illustrated by the following definition: "TQM is the vast collection of philosophies, concepts, methods and tools now being used throughout the world to manage quality" (Godfrey 1999). Despite the theoretical attractiveness, the success of implemen-

ting TQM programmes is limited (Choi and Behling 1997). Most explanations regarding TQM failure emphasize problems with its implementation (Redman and Grieves 1999). In recent years new concepts are created as an extension of TQM (Godfrey 1999). One such concept is Six Sigma, a program aimed at the near elimination of defects from every product, process and transaction (Tomkins 1997). Six Sigma differs from TQM with respect to the part-time and full-time assigning and training of staff, a sound scientific method, and the strong focus on financial results (Hoerl 1998).

Aims of this thesis

- The first question to be answered in this thesis is: Do the ISO 9000 standards provide a useful tool to implement a quality management system in a hospital?
- The second question in this thesis is: Does the implementation of Six Sigma in a hospital provide a quality improvement system equally powerful as in industry?
- The third question in this thesis is: Does quality management, by using ISO 9000 and Six Sigma, contribute to the strategy of a hospital?
- The final question in this thesis is: Can Lean principles, when combined with Six Sigma, provide an additional positive effect on the quality improvement system?

Methodology

The empirical bases for this study include our own experiences in the Red Cross Hospital in Beverwijk, the Netherlands. The process of organizational change and the development of quality management in the hospital were studied from 1998 to 2004. Therefore we have applied the (longitudinal) "case study research" method. This method can be defined as an empirical study that investigates a contemporary phenomenon (i.e. quality management) within its real-life context investigated over a period of time (Yin 1984). Our methodology is also strongly based on the principles of "action research" because organizational change and research have been performed simultaneously and have provided input to each other (Cronholm and Goldkuhl 2003).

A frequent criticism of case study methodology is that its dependence on a single case renders it incapable of providing a generalizing conclusion (Tellis 1997). Generalizing and theory development are thought to be facilitated only by means of quantitative methods and deduction. To eliminate these shortcomings we added principles of "grounded theory" to our case study method. Grounded theory is an inductive approach aiming at generating theory that is grounded in

mainly qualitative data (Glaser and Strauss 1967). The researcher is supposed to start with hardly any a priori constructs, to inquire deeply into organizational behaviour and events and to gradually test and form theories (Strauss and Corbin 1990). Over the years grounded theory has been further developed into different variants. The latest modification "multi-grounded theory" combines an inductive approach with the theory driven deductive analysis. Multi-grounded theory includes a more systematic use of pre-existing theories than pure grounded theory (Goldkuhl and Cronholm 2003). Although grounded theory has initially been developed within the social sciences, successful application of (multi-)grounded theory in Information System research has been reported as well (Goldkuhl 2004).

Management research is predominantly based on deductive theory testing and empirical research (Alvesson and Willmott 1996). Research for TQM, following this approach, fails to give deep insight and rich data related to TQM in practice within organizations. So there is a lack of practice-based research studies from which TQM theories can be developed. A methodology like grounded theory which inquires more deeply into TQM related events within the organization is needed to develop a coherent and firmly founded set of TQM theories (Leonard and McAdam 2001). Case studies are especially appropriate within grounded theory methodology (Van de Ven 1992; Yin 1989). Thus any grounded theory research methodology for TQM is likely to benefit from incorporating a longitudinal case study approach (Leonard and McAdam 2001).

Summarizing, in the Red Cross Hospital we applied longitudinal case study principles combined with action research to study quality management. In addition we used the grounded theory methodology to enable generalization of our conclusions. Since we used pre-existing concepts and tools from industry we have, by definition, used the multi-grounded theory approach.

Content of this thesis

This introduction describes the subject, the questions to be answered and the methodology of the study that has been performed. A survey of this study is provided by chapter 1. This part demonstrates and accounts for the design, the actual way the study has been performed and the choices that have been made. The chapters 2 to 9 are all based on published articles and give a more detailed but fragmented description of our findings and conclusions. Finally a General Discussion is provided, which relates the four questions to be answered in this thesis with our findings and conclusions.

Structure of this thesis

Subject	Chapter
Description of the subject of this thesis; Short introduction in Quality management; Aims of this thesis formulated in four questions; Methodology	Introduction
Survey of the research; Description and account for the design of the study	Chapter 1
Research material to answer the first question	Chapters 2; 3 and 8
Research material to answer the second question	Chapters 4; 5; 6; 7 and 8
Research material to answer the third question	Chapter 8
Research material to answer the fourth question	Chapter 9
Answers to the four questions and Conclusions; Concluding remarks and possible impact of the results	General Discussion
Summary	Summary and Samenvatting

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Chapter 1

Design and Execution of the Study

Overview

The subject of this thesis is the transfer from industry to a hospital of two quality management tools; the ISO 9000 standards and Six Sigma. Our research was performed parallel to the actual organizational change related to quality management in the Red Cross Hospital. In this chapter we describe the way the study has been executed and we account for the choices that were made along the way. The main body of the study started in 1998 in the Red Cross Hospital in Beverwijk. Based on a strategic analysis we decided to implement a quality management system in our hospital based on ISO 9002:1994. After a while we observed that quality improvement did not meet our expectations. We decisively introduced Six Sigma, a quality improvement methodology from industry, and assessed its potential in healthcare. The expectations were promising so we decided to implement Six Sigma complementary to our ISO quality management system. The integration of ISO and Six Sigma showed additional benefits: we were able to demonstrate positive trends on all relevant strategic performance indicators of our hospital and to provide a theoretical explanation for our results. Finally, we will point out the advantages of integrating Six Sigma with principles of Lean Manufacturing, which in our opinion is an interesting subject for further research.

First experiences with ISO in healthcare

Our study started with a "prologue" in 1994 in the Academic Hospital in Utrecht where we first succeeded to implement an ISO 9000 quality management system in a radiology department. In 1994, the year in which the ISO 9000:1994 standards were published, the radiology department of the university hospital in Utrecht produced a strategic plan in which TQM played an important role (Deming 1986). Three considerations prompted this conclusion. Firstly, there was an increasing demand for radiological investigations combined with decreasing budgets. Therefore, it was essential to control both quality and costs. Secondly, the department was used to perform a large number of quality-improvement projects and the growing interrelations among the different projects made it clear that an integral and systematic approach was needed (Hendriks 1995). Finally, the Dutch government had enacted a law which obliged healthcare organizations in The Netherlands to have a demonstrable quality control system. After reviewing available methods for designing a quality control system and with the help of our industrial partner Philips, we chose to implement the model for quality assurance outlined by the International Organization for Standardization (ISO 1994). At that time there were no real alternatives for implementing a quality management system. The Dutch Hospital Accreditation System (NIAZ) was still under development and the EFQM-model (in Dutch; INK) lacked focus on process control and quality assurance. Since a radiology department shares many characteristics with

an industrial production unit we believed that ISO 9000, being an industrial standard, could match our needs. In January 1996 the implementation of the quality system was completed and an ISO 9002 certificate was obtained. We could report a number of advantages related to the implementation of ISO 9000, such as an excellent document control system, an increase in production and a decrease in costs (Van den Heuvel et al 1998). To our knowledge this was the first implementation of an ISO 9000:1994 quality management system in healthcare.

Policy deployment as a starting point of quality management in the Red Cross Hospital

The Red Cross Hospital is a middle sized general hospital with 384 beds located in Beverwijk in The Netherlands with an annual budget in 2004 of 72 million euros. The hospital is situated in a very competitive environment having five other hospitals within a 20 kilometers range. The Dutch hospital funding system pays fixed prices for admissions, first contacts and day care treatments. Recently the government initiated the gradual introduction of a new funding system based on so-called Diagnose Treatment Combinations which is similar to the Diagnose Related Groups (DRG) system. Both systems are applied simultaneously at this moment and show great resemblance with a capitation system. The consequences of both systems are that treating more patients provides more income, but delivering more care, higher quality or better service, does not. Considering the competitive environment and the characteristics of the Dutch funding system we have chosen as our main strategic goals a moderate growth and minimization of costs, both to provide continuity. Furthermore we aimed at optimizing quality of care, within the limitations of the fixed prices per episode, in order to attract more patients. Capitation systems are thought to be successful in containing costs, but might be a threat to healthcare quality (Berwick 1996). Cost containment without effective quality assurance systems can endanger quality (Blumenthal 1996; Bliersbach 1988). To be effective, (total) quality management is considered an essential part in the strategic plan of any organization (DeFeo 1999). Thus given the characteristics of the Dutch funding system and our strategic goals, implementing a well functioning quality management system was considered of vital strategic importance to our hospital.

Quality management system selection

Quality management consists of three aspects; quality planning, quality control and quality improvement (Juran 1989). In healthcare a similar approach has been suggested (Donabedian 1987). To put quality management in practice a quality management system should be implemented. We have evaluated three possible quality management systems; ISO 9000, the INK-model (based on the EFQM-

model) and the Dutch Hospital Accreditation System (NIAZ). A short description of these three systems include:

ISO 9000

The ISO 9000 series are standards that define requirements (9001) and guidelines (9004) for quality management systems (ISO 2000a; ISO 2000b). ISO 9000 standards are successfully used and adopted worldwide in industry and service organizations (Marquardt 1999). The International Organization for Standardization (Geneva, Switzerland) first issued the standards in 1987. In 1994 and in 2000 the ISO 9000 series were revised. The standards are generic, which means that the same standards can be applied to any organization. The ISO 9000 standards are founded on the concept that the assurance of consistent product or service quality is best achieved by simultaneous application of product standards and quality management system standards. ISO takes a systems and process approach to improve organizational and financial performance with a specific focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory performance or non-conformance. The standards represent an international consensus on good management practices with the aim of ensuring that the organization can continuously deliver the product or service that:

- meets the customers' quality requirements;
- meets applicable regulatory requirements;
- enhances customer satisfaction; and
- achieves continuous improvement of its performance in pursuit of these objectives.

Representing consensus on good management practices ISO 9000 in fact covers all aspects of quality management as mentioned above. Quality control and assurance, however, are perhaps the most significant characteristics of an ISO quality management system. Quality planning is covered equally well because ISO is almost synonymous with meeting customer requirements. In healthcare, the application of the ISO standards is not yet very common and subject for debate. The usefulness of ISO 9000 standards in healthcare was outlined earlier (Carson 2004). Worldwide application of ISO in hospitals has been reported on a limited scale. The ISO 9000 guidelines for healthcare, called ISO IWA 1, can perhaps contribute to a better appreciation and use of ISO 9000 in healthcare (ISO 2001b; Reid 2004).

The INK-model

The INK-model (EFQM) has been applied in healthcare (Nabitz 2000). The INK-model aims at creating an excellent organization and basically looks at nine organizational elements. The first element is leadership, which drives the next

group of elements; people management, policy and strategy, and management of resources. These in turn drive all operational processes which subsequently drive people satisfaction, customer satisfaction and impact on society. These three elements, in the end, drive business results. The actual performance on all nine organizational elements is scored in a structured manner based on a five level process management approach resulting in a maximum score of 1,000 points. Self assessment is required to enter the formal evaluation process. Every company that earns more than 450 points qualifies for a prize (INK-onderscheiding) and once a year the best company in The Netherlands may receive the award. Until now, only one hospital in The Netherlands has obtained the INK-prize.

NIAZ Accreditation

The NIAZ is a Dutch institute that has developed an accreditation system to evaluate hospitals. The NIAZ accreditation system contains elements from a number of foreign hospital accreditation systems. A major advantage of the NIAZ-model is the fact that it has been developed to be implemented in hospitals. Since its start in 1995 several alterations have been presented. At first the system was department oriented and processes were regarded within the scope of the departments. After several years a hospital wide process oriented approach was introduced. Recently the NIAZ accreditation system has been fit in the INK-model. This year alterations have been implemented after some serious quality incidents in two hospitals that possessed an accreditation certificate. In one hospital it was clear that process management and process control had failed. Especially the requirements related to the system of internal audits were enforced by NIAZ. Most recently NIAZ and Medirisk, a liability insurance company, have decided to combine their external audits.

Comparing the three systems

First, it must be stated that all three systems have their own merits so there is no good or wrong choice. The strategic choices of the Red Cross Hospital; growth, cost containment and optimizing quality, therefore are the main criteria to evaluate the three quality management systems.

Growth

To enhance growth, a strict customer orientation is required. So customer's demands have to be transformed into organizational performance. When we look at ISO we see that client orientation and conformance to requirements are the core of the ISO 9000 standards. ISO's focus on customer's demands has often been ridiculed. It was thought possible to make insane products (for example a concrete

life jacket) just because the wishes of the customers are incoherent. This, however, mainly demonstrates disdain for the customer more than any knowledge of ISO. The INK-model's prime intention is to make an excellent organization. Such an organization will most likely produce excellent products. In this way ISO and INK have the same objective, only ISO takes the shortcut from customer's demands to product specifications and INK takes the longer and more comprehensive road via an excellent organization. NIAZ is designed by hospital management and professionals. Professional organizational standards therefore play an important role and customer's demands are not the prime focus of NIAZ.

Cost containment

The first step to contain costs is to produce products which features closely meet demands and needs of the customers. To add more features means more costs without additional income. Too little features means clients' complaints, so more costs and diminishing sales and income. The second way to contain costs is to optimize processes. We already addressed the subject of customer's demands above. When we look at optimizing processes we see that the NIAZ-model is department oriented. This seriously impedes the opportunity to optimize processes ranging from client to product. Departments are most likely to sub-optimize on the organizational level while optimizing there own processes. ISO and INK both aim at efficiency improvement.

Optimizing quality

Optimizing quality is a requirement related to the fact that fixed prices are paid for the same (groups of) products despite additional features in a given product. In this respect healthcare differs from industry. Consequently, customer's demands have to be made very clear to deliver just what is needed within the constraints of the fixed price. In this respect the NIAZ-model is inclined to allow more healthcare features to be delivered because of professional organizational standards. ISO and INK are more inclined to create a sharp edge between costs and, in case of healthcare strictly necessary, features.

Miscellaneous

Internal and external audits are a very powerful instrument in quality management. The master's eye makes the horse fat. In ISO a substantial amount of internal audits have to be performed to obtain a certificate. External audits take place every half year during the first three years. The NIAZ accreditation is valid for four years, no intermediate audits take place. As related to internal audits, there are no required numbers of audits that have to take place. It is even possible to obtain an

accreditation without any internal audits performed. Only after two recent major incidents in NIAZ accredited hospitals especially the requirements to internal audits were enhanced. INK also does not put great emphasis on internal audits. When we look at the external audit more closely we see that there are a number of companies that are allowed (accredited) to perform ISO certifications. They have a large number of highly trained professional auditors and they have no waiting lists. The organization to be audited may expect to receive high quality feedback on its quality management system. A NIAZ accreditation is a peer to peer system. Audits are performed by colleagues from other hospitals trained in the NIAZ-model but with limited knowledge of quality management systems and principles.

Evaluation and selection

Looking at the three strategic choices it is obvious that ISO 9000 provides the best fit. Especially related to growth objectives the focus to the client and conformance to requirements are an Achillus' heel in healthcare that can be supported by ISO. Despite the advantage of being dedicated to hospitals, the changes of the NIAZ-model during its existence from department oriented to process oriented and finally the incorporation of elements of the INK-model, are confusing. The scope of ISO, dedicated to quality management, the intense process of internal and external audits, and compared to the other two systems, limited efforts of implementation, supported the selection of ISO. As we mentioned above, the next logical step after ISO could be implementing the, more comprehensive, INK-model (Russell 2000).

Implementation of ISO 9000

We implemented an ISO 9000 quality management system from 1999 to 2000 in a period of one and a half year (Van den Heuvel et al. 2005a). Processes were identified and described in a standardized manner called procedures. We then identified and implemented quick wins in process improvement. All core processes in our hospital were described in approximately sixty procedures. The next step was to make protocols related to each procedure. Protocols in our quality system give a detailed description of a specific task, i.e. how to remove stitches or how to enter specific data in the computer. Processes and activities were only described when this was necessary to provide sufficient quality assurance. This kept the number of activities and procedures that actually had to be documented, limited to a minimum. Once all essential processes and activities of our organization were described, the hospital management put together the Quality Manual. This manual contains descriptions of the organization, the divisions, our quality system, the policies of our hospital and our current set of performance indicators. To complete our quality management system we implemented an internal audit

system. We trained approximately fifty co-workers to audit procedures and protocols in various departments. The internal audits resulted in a large number of improvements to our quality management system. When all required elements of our ISO quality management system were designed and implemented, the system had to "come alive". Processes had to perform the way they should and if not, corrective actions had to be taken. The flow of opportunities to improve the system had to lead to actual improvements. Finally the internal and external audits had to either confirm that the system ran properly or provide input to further improvements. We have been able to implement ISO 9002:1994 and subsequently ISO 9001:2000 without support of external consultants or an increase in personnel. External audits and certification have cost approximately 77.000 euros. Every year two external audits are required with total costs of 14.000 euros. We could report a number of positive results. The foundation of these results was provided by findings during the process analysis and description in which many employees were involved. Furthermore, the internal and external audits provided a large amount of information about the functioning and the added value of our ISO 9000 quality management system.

Patient and client orientation

Our ISO quality management system keeps us focused on the needs of our patients and clients. We have to assess our patients' needs in advance and evaluate patient satisfaction on a structural base afterwards. Our processes are all identified and have to be improved continuously to consistently meet patients' needs. Due to these ISO requirements, we are confident that we are doing the right things and move in the right direction of quality improvement. The explicit focus of ISO 9001:2000 on the client, our patients, appeared to be very stimulating. In the past, due to external demands, our attention has gradually shifted towards efficiency parameters and administrative procedures such as filling out forms and medical files. We have put the patient back in the centre of our attention and receive positive feedback. This motivates us to pick up the remaining shortcomings in healthcare delivery.

Process oriented healthcare

The Institute of Medicine (IOM 1999) has pointed out that quality of care is often not sufficient because healthcare processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays. In our quality management system all processes have been identified, described and optimized. Although we still have a long way to go, performance indicators on process level are developed and monitored. Department heads in their responsibility as "process owner" have to ensure optimal process performance.

Continuous improvement

An important feature of ISO 9001:2000 is its systems approach in relation to process management. We gather information from a number of sources such as: patient satisfaction surveys, complaints, faults accidents and near accidents, quality measurements, internal and external audits. These measurements have to lead to improvements of the quality system, improvement of the design and performance of the healthcare processes and improvement of the quality of healthcare. Performing risk analyses on every process and design improvements, as required after the 2000 revision of ISO 9000, created a significant amount of awareness and commitment to quality of care and patient safety. These risk analyses and subsequent improvements can be considered an important step in eliminating the flaws in patient safety as stated by the Institute of Medicine (IOM 1999).

Performance measurements

We have developed a set of performance indicators as required by ISO 9001:2000 which is an essential part of our quality management system. This set of indicators is published every year in our Annual Quality Report. The most important indicator is related to patient satisfaction. We use approximately 50 different types of questionnaires, one for each department. The structure of all these assessment forms and the rating systems are identical so all the results can be added up to give our hospital a total score on patient satisfaction. We distribute more than 2.000 forms a year and the response rate is nearly 50 percent. On every item, patients can rate four categories; “good”, “reasonable”, “can be improved” and “must be improved”. We have been able to achieve consistent rates of more than 80 percent “good” every year.

Document system

The quality documents are the most tangible part of our quality management system. The first document layer consists of the Quality Manual. The second layer consists of approximately 60 procedures describing all core processes of our organization. There are processes related to the quality management system itself, for instance Documentation management, Internal audits, Complaints and Risk management. There are management procedures, such as Budgeting and Investments. The largest group consists of sixteen procedures related to the healthcare process such as “Day care treatment”, “Emergency care”, “Preoperative screening” and “Medication provision”. The third layer of our quality document system consists of protocols and work instructions. These types of documents are typical of those generated by ISO 9001:2000 requirements. ISO is often thought to be synonymous with bureaucracy. The fact, however, is that hospitals, due to a

number of reasons such as government regulation, healthcare inspection etc., have to maintain a considerable level of registration and documentation. This resulted in a large and uncontrolled number of documents with many duplicates with only minor differences that were relatively inaccessible. For example, there were more than five protocols to insert an intravenous drip. The paradox therefore is that ISO due to its well-described document control system can reduce bureaucracy in organizations especially in hospitals where a certain degree of documentation is required.

Certification

At the end of 2000, one and a half year after starting the implementation, KEMA, a Dutch certification institute, performed the first external audit. After correcting a number of shortcomings, we received the ISO 9002:1994 certificate for the entire hospital organization. This certificate was valid for three years. During that period, KEMA performed an external audit every six months. In the meantime we adapted our quality management system to fit the requirements of the revised ISO 9000:2000 standards. These efforts were successful and we obtained an ISO 9001:2000 certificate after the external audit in October 2003. Currently we are the only hospital in The Netherlands that obtained an ISO certificate for the entire organization.

ISO 9000 standards and patient safety

Compared to ten other (non ISO) hospitals that participated in the Centrameter, an instrument to assess patient safety developed by our liability insurance company, we were able to demonstrate that the implementation of an ISO 9002 quality management system in the Red Cross Hospital resulted in the highest improvement rate on patient safety. Furthermore, the hospital achieved the highest score and highest improvement rate in the category policy and management.

Applicability in healthcare

Since the ISO 9000 standards originate from industry, they were considered not to be applicable to healthcare quality management systems. Applications therefore were mainly seen in non-clinical environments such as the radiology and laboratory departments (Klazinga 2000). We have been able to include all core processes of our hospital in our quality management system including the processes concerning healthcare delivery. Our first intention was to develop and implement a quality management system that was best suited for our hospital. Only after completing our quality management system, we verified conformity with the ISO standard. We strongly recommend this sequence. Taking one's own organization as a starting

point can lead to different quality management systems in different organizations, despite using the same standard. This observation has been made in healthcare and was considered a disadvantage of ISO (Sweeney 2000). However, the intention of ISO is not to create identical quality management systems in different organizations, but only to establish conformity to (minimal) requirements.

Our experiences with ISO 9000 and quality improvement

Continuous quality improvement is an essential element of an ISO quality management system. We therefore developed a procedure in which we described the way quality improvement was performed in our hospital. All managers had to initiate quality improvement projects within their organizational unit. A project plan had to be made and during our monthly "improvement" meeting progress was monitored. The progress was expressed in terms of percentage of the completion rate. We were able to run quality improvement projects and were successful in completing a number of them. There were, however, some deficiencies:

- Most of the time, we had no accurate way to determine the relevancy of a given project and its contribution to our organizational goals.
- We did not have a standardized procedure to evaluate the cost effectiveness of a project in advance.
- Once a project was started we had no reliable information about the progress.

Employees who had to complete improvement projects also experienced some problems. For them the fact that there was no standardized project management approach was a major problem. A lot of time was wasted initiating and running a project because the project approach, the project documents, the planning et cetera, had to be developed every time and again. Another problem for our employees was the fact that they rarely had the opportunity to be relieved of other tasks, so they had to complete their project in addition to all their other activities (Van den Heuvel et al. 2005b). In 2001 our attention was drawn by Six Sigma, a quality improvement approach from industry (Harry 1997).

Quality improvement using Six Sigma

Six Sigma is a company wide quality improvement approach that aims at optimizing processes while reducing defects and costs (Snee 2004). It is developed and widely used in industry (Breyfogle et al. 2003). The application of Six Sigma has also been suggested in healthcare (Barry 2002). A number of healthcare systems have implemented Six Sigma (Thomerson 2001; Sehwail 2003; Van den Heuvel et al. 2004; Christianson et al. 2005). Especially in healthcare Six Sigma works both ways; costs are eliminated and quality is improved (Kooy and Pexton 2002). In order to quantify the performance of a given process a Six Sigma project starts by

defining and implementing relevant measures and metrics, the so-called Critical To Quality characteristics. Six Sigma tackles performance problems in five phases: Define, Measure, Analyze, Improve and Control. In addition to this stepwise project approach Six Sigma contains an organizational structure. Project leaders, called Black Belts or Green Belts, are trained in project management, problem solving methodology and statistical methods. The stepwise strategy that Black Belts and Green Belts follow enables them to make a proper problem definition and diagnosis based on facts and data before undertaking attempts at solving the problem. Tools used in Six Sigma, such as quality function deployment and Pareto analysis, link customer demands to product features and establish the relative importance of various problems. Managers in their role of "Champion" review the progress of a project and ensure that the Black Belts and Green Belts focus on the interests of the organization. Experts on the Six Sigma methodology are called Master Black Belts and they are responsible for managing the Six Sigma organization.

The implementation of Six Sigma in the Red Cross Hospital

After having studied the methodology we decided to implement Six Sigma as our major quality improvement tool in our hospital. We started with the one-day introduction training for management and directors. In order to implement Six Sigma successfully, some apparent minor adaptations were necessary. The first group of fifteen Green Belts started their training in September 2002. Seven projects were initiated. To create commitment, participants were allowed to choose the subject of their projects. In February 2003 the second group of Green Belts started. The hospital directors stimulated managers to train a sufficient number of Green Belts and maintain a substantial program of new projects. Gradually project selection was taken over by management to ensure alignment with the strategic goals of the hospital. As the number of projects increased the necessity for co-ordination and management of the Six Sigma program became evident. We observed that Green Belts faced difficulties with closing their projects. We therefore appointed a Master Black Belt to set up a management control system to evaluate progress and to support Green Belts in finishing their projects. The Master Black Belt organized the necessary training programs and ascertained that once Green Belts completed a project they initiated another project. In September 2004, the fifth group of Green Belts began their projects. Co-workers showed increasing interest in following a Green Belt training. We have consistently started new groups of approximately fifteen employees every six months. Participants emerge from different departments and disciplines within the organization. We have been able to initiate Six Sigma projects in almost any unit and related to every discipline in our hospital (Van den Heuvel et al. 2005c).

Our results related to Six Sigma

At the end of 2004 we had 63 employees that were fully trained as Green Belt. At that moment 44 projects were started and 21 projects were completed successfully. The total net savings amount to 1.0 million Euro. These amounts are cumulative savings on an annual basis. At the beginning of 2004 the Red Cross Hospital anticipated serious financial problems. Management embraced the Six Sigma organization to initiate an additional number of smaller "quick win" projects instead of discharging personnel. This additional program resulted in extra savings up to 1.0 million Euro. The Annual Report of 2004 consequently showed an, in our history, extraordinary positive net result of 2.0 million Euro (Van den Heuvel et al. 2006a). The focus of Six Sigma on data and the statistical substantiation of conclusions have proven to be an excellent counterbalance to the often subjective and intuitive way of working in healthcare. The introduction of Six Sigma in our hospital has stimulated a culture of awareness to find opportunities to improve healthcare delivery and also to take responsibility to eliminate shortcomings. In the past, decisions were too often based on assumptions and feelings as well as inaccurate and incomplete information. By using Six Sigma, today co-workers take responsibility and provide management with solutions based on facts and data.

Why industry and healthcare differ and Six Sigma works even better in healthcare

To fully understand the potential of Six Sigma in healthcare quality management we have to take a closer look at the way quality is defined (Donabedian 1987). Garvin has identified five major approaches of defining quality in industry (Garvin 1984). Most existing definitions of quality fall into one of these approaches. The first one is the transcendent approach of philosophy, which states that quality is innate excellence and cannot be defined. The second one is the product-based approach of economics, which states that quality reflects the presence or absence of measurable product attributes. In this approach more quality (attributes) means more costs. Thirdly, the user based approach of economics, marketing and operations management states that individual consumers have different wants or needs and those goods that best satisfy their preferences have the highest quality. The fourth, manufacturing based approach defines quality as conformance to requirements. Designs of the product and the manufacturing process have to lead to the lowest possible costs. Improvements in quality, so reductions in defects, lead to lower costs. The fifth approach is called the value-based approach of operations management. According to this approach, a quality product is one that provides performance at an acceptable price or conformance at acceptable costs. Garvin concluded that reliance on a single definition of quality is a frequent source of problems for any company. Companies need to cultivate these different approaches.

The power of Six Sigma in healthcare can be illustrated by looking at the different quality approaches. The transcendental approach, unfortunately, is often used by healthcare professionals. However, neither to be able to define nor to measure quality will severely impede quality improvement initiatives. Six Sigma stimulates healthcare workers to define, measure and improve aspects of quality. The focus of Six Sigma on data and statistical verification have in our hospital proven to be an excellent counterbalance to the often more subjective and intuitive (transcendental) way of working in healthcare. Looking at the product based, client based and manufacturing based approaches in healthcare we observed a very interesting phenomenon. Our patients are not only our clients, but they also are our product and they are the most important element of our manufacturing (i.e. healthcare) process. So there are three quality definitions applicable at the same time. Therefore we are obliged to manage all three quality approaches in relationship to each other during the entire healthcare process. This largely explains the complexity of our work and the vast challenges we face in quality management in healthcare.

Due to the fact that the patient is part of the manufacturing process, improving the quality of the healthcare process will by definition lead to lower costs and higher quality of care. This quality of care will manifest by shorter waiting times and length of stay, reduce the number of examinations and a decrease in the number of defects, such as errors, unnecessary interventions and complications. Furthermore, Six Sigma links client demands to product attributes. This prevents healthcare workers to deliver care that patients do not expect to be delivered, and this also reduces costs. So especially in healthcare Six Sigma seems to work both ways; costs are eliminated and quality is improved (Kooy and Pexton 2002). The fact that the patient is part of the manufacturing process also provides an explanation for patient safety problems as pointed out by the Institute of Medicine (IOM 1999). In industry a high quality product can be manufactured regardless or even because of the fact that a large number of (imperfect) products are rejected. The customer only experiences the high quality product and is neither aware nor inflicted by the undesired output of an imperfect manufacturing process. Unlike industry where a defective product can be rejected without any problem, in healthcare an imperfect (healthcare) process that produces defects and rework directly affects our patient's safety. The positive effect of Six Sigma on reduction of medical errors has been described earlier (Buck 2001). Therefore Six Sigma is a powerful instrument to improve patient safety by reducing the number of defects produced by the healthcare processes.

Considering the fifth and final value-based approach, we see that contrary to industry, pricing mechanisms do not function very well in healthcare. In general, patients

just want maximum quality and meanwhile insurance companies want to pay the lowest price. We do not know of hospital imbursement systems that explicitly reward additional quality of care. As a result the hospital, and especially the quality of care, is torn between these conflicting demands. The only sensible policy for any hospital in order to pass both Scylla and Charybdis, is to maximize efficiency while at least preserving quality of care. The best way to achieve this, as we stated above, is to invest in healthcare process improvement because this will invariably lead to lower costs and higher quality of care. In this respect Six Sigma with its primary focus on process improvement provides the best quality management tool to healthcare organizations.

The success of combining ISO 9000 and Six Sigma

In the past years Total Quality Management (TQM) was considered the most important concept to help companies deliver quality and gain competitive advantage (Godfrey 1999). For this reason TQM has also been promoted in healthcare (Gaucher and Coffey 1993). As we mentioned earlier, there are no generally accepted definitions of TQM and there is also some debate about the effectiveness of using TQM (Kelemen 2003). In most cases TQM failure is related to problems with its implementation and not with theoretical weakness of the model (Redman and Grieves 1999). This has also been our experience. TQM helped us to develop our strategic quality goals, but we needed more practical tools to enable us to attain these goals. ISO 9001, as well as Six Sigma contain most of the elements, tools and concepts of TQM. However, contrary to TQM, they both involve and mobilize large numbers of employees. ISO requires employees to describe their working processes, to perform internal audits and to suggest improvements. In Six Sigma large numbers of employees are trained and coached to achieve improvements. Furthermore both Six Sigma and ISO offer explicit structures and approaches, leaving little room for debate among our employees about the relevancy and subsequent actions needed to achieve quality. Finally Six Sigma and ISO are highly complementary. They both focus on: processes, customers' demands, continuous improvements, employee involvement, fact based decisions and a systems approach on management. So our ISO quality management system and Six Sigma are virtually zipped together, thus integrating the full spectrum ranging from quality control via quality assurance to quality improvement. This integration offers the benefits of the TQM concepts and lacks the shortcomings of TQM related to the implementation. One could say that TQM helped us to develop ideas about quality management top down and ISO combined with Six Sigma enabled us to implement these ideas bottom up.

Five years of Red Cross Hospital performance

We will now demonstrate how quality management using ISO and Six Sigma

enhanced the performance of our hospital and helped us to achieve our strategic goals; growth, cost containment and optimizing quality (Van den Heuvel et al. 2006b). We will do so by showing a set of performance indicators.

The achievements related to the growth of our hospital

- We were able to increase our catchment area by 10.9 percent in five years. The catchment area is a calculated parameter based on the number of admissions or outdoor contacts and gives an indication of our market share.
- We were able to increase the number of admissions by 14.7 percent and the number of day care treatments by 60.9 percent in five years. The growth in the past three years has been facilitated by a substantial reduction of the length of stay by 15.5 percent. This could be attributed to a number of Six Sigma projects and the implementation of Clinical Pathways.
- We were able to increase the number of first contacts in the outdoor department by 15.6 percent in the past five years. This growth has been made possible mainly by projects related to reducing the number of revisits and introducing elements of one stop shopping.

The achievements related to cost containment

- We were able to increase the number of patient units per Full Time Equivalent (FTE) by 7.9 percent in 2004. A patient unit is a measure of our work load calculated by multiplying the number of admissions, day care treatments and outdoor contacts each by their own weight factor. The total summation of patient units gives a fair impression of the workload of our hospital. Therefore the number of patient units per FTE gives an impression of the efficiency of our hospital.
- We were able to increase the number of admissions and day care treatments per full time equivalent (FTE) nursing staff by 12.3 percent.
- When we look at the costs per inhabitant related to the catchment area of our hospital we noticed in 1999 that we were less efficient than the Dutch average. In the next four years our quality management system and Six Sigma made us 8.3 percent more efficient on costs per inhabitant than the Dutch average. This observation shows best the effects of quality management in our hospital.

The achievements related to quality

We were able to maintain constant scores on patient satisfaction which we measure in three main categories; nursing care, medical care and all other service and care. We use approximately 50 different types of questionnaires, one for each department. The structure of all these assessment forms and the rating systems

are identical, so all results can be added to produce one score for patient satisfaction in our hospital. We distribute more than 2.000 forms a year and the response rate is nearly 50 percent. On every item, patients can rate four categories; “good”, “reasonable”, “can be improved” and “must be improved”. We have been able to achieve consistent rates of more than 80 percent “good” every year for the entire hospital and 90 percent “good” on nursing care and medical care. In 2004 we were able to produce a 3 percent increase of the overall score on “good”.

We could demonstrate that the earnings from our projects in 2004 correspond directly with the income from continuing operations of our hospital in that same year. This income differs significantly from the years in which Six Sigma was not fully operational. The extra income offered the opportunity to invest in quality improvement projects.

When we look at the development of the performance indicators of our hospital we can see that we have been able to attain our two main strategic goals. We achieved continuous growth over the past five years and we were able to increase efficiency from below to above the Dutch average. Our third strategic goal to deliver an adequate level of quality of care in order to stay attractive to our patients has been achieved as well because our patient satisfaction scores remained constant (and high) over the past five years. In 2004 we could demonstrate a slight increase of 3 percent in patient satisfaction.

The next logical step: Lean Six Sigma

The latest development related to Six Sigma is the integration of Lean Manufacturing principles into the framework of Six Sigma, which is called Lean Six Sigma. The proliferation of Lean in the Western World started in 1990 with the publication of a seminal work on Lean Manufacturing entitled “The Machine that Changed the World” (Womack et al. 1990). Lean Manufacturing is based on the Toyota Production System (Ohno 1988; Shingo 1989). The primary focus of Lean is on reducing waste, synchronizing flows and managing variability in (process) flows. It offers a framework for analysis of processes within an organization (Standard and Davis 1999). A core element of this framework is the distinction between value-adding and nonvalue-adding activities. Value-adding activities contribute to what the customer wants of the product or service and that they would be willing to pay for (George 2003). The primary analysis tool of Lean is the value stream map. A value stream map is a process flowchart, extended with information about speed, continuity of the flow, work in process (WIP) et cetera. Moreover, it specifies which steps add value and which do not. It helps to identify bottlenecks and is used to focus the improvement

activities. The value stream map stretches the entire value chain, providing a holistic picture of companies' processes. Furthermore, Lean offers a set of standard solutions to common organizational problems. Despite the attractiveness it is unclear how to launch Lean effectively into an organization. In the Red Cross Hospital an introduction of a similar methodology prior to the introduction of Six Sigma failed. Roles and responsibilities of Lean key players are not specified clearly. Moreover, where to start value stream mapping, is also a crucial question. Guidelines for quality assurance and control are missing within Lean. Finally, in complex cases one needs tailor-made solutions, not just copies from other companies.

Lean and Six Sigma appear to have complementary benefits. Lean can benefit from the management structures that Six Sigma offers: Six Sigma's project-by-project approach provides an effective embedding framework to apply Lean principles. Further, Lean lacks a method for diagnosis, and has only limited methods for analysis. It is rather one-sidedly focused on problems with process throughput, which are solved with a set of standard solutions. Lean does not analyze the economic performance indicators of a process to establish where the main points of improvement are, but focuses on inefficiencies in process flow, even if that is not where the main opportunities for improvement are. Six Sigma's DMAIC method offers a thorough roadmap for analysis and diagnosis, driven by powerful tools and techniques. The key to a successful integration of Lean and Six Sigma is to regard Six Sigma's project management and its roadmap as a general framework for problem solving and process improvement. Within this framework, Lean's standard solutions and mindset have found their place. Several hospitals have started to work with Lean Six Sigma (George 2003; Chalice 2005; De Koning et al. 2006).

An application of Lean Six Sigma in the Canisius Wilhelmina Hospital

The Canisius Wilhelmina Hospital is located in Nijmegen, The Netherlands. It is a 650 bed hospital with an annual budget of 145 million euros. At the beginning of 2005 the Canisius Wilhelmina Hospital started to implement Lean Six Sigma (Van den Heuvel et al. 2005b). This was done by the same team that was responsible for the implementation in the Red Cross Hospital. In 2005 we trained two teams of twenty Green Belts each in Six Sigma. This time the training also included the key principles of Lean. An exercise was added in which the participants could experience directly the powerful effects of Lean tools. In 2006 we trained another team of Green Belts and we plan to start two more groups. Employees are very enthusiastic about the training especially because they are given the means and tools to solve problems in their own department which they faced for a long time. Since the Canisius Wilhelmina Hospital is twice as big as the Red Cross Hospital

we also trained more than sixty Yellow Belts to make more employees familiar with Lean Six Sigma and to support the Green Belts in their projects. Furthermore we did an additional Lean training of one day for all our managing medical specialists and the directors. In April 2006, we conducted a survey among employees to evaluate the organizational structure. The results where that Lean Six Sigma was appreciated as a very useful instrument.

A roadmap to the answering of the questions in this thesis

The main body of this thesis consists of eight articles published in various peer-reviewed Journals. In action research knowledge is developed parallel to and in interaction with the organizational change and therefore over a period of time. Consequently, we published our growing understanding of quality management over a period of several years. In this paragraph, for each of the four questions in this thesis, we will indicate the chapters in which (elements of) the answers can be found.

The first question is: Do the ISO 9000 standards provide a useful tool to implement a quality management system in a hospital? This question is answered in chapter 2, chapter 3 and chapter 8. In chapter 2 we report positive results of the implementation of the ISO 9000 standards in a hospital department. These results incited us to consider the implementation of ISO 9000 standards in an entire hospital organization. In chapter 3 we report the results of implementing ISO 9000 in the Red Cross Hospital. The results are confined to quality management subjects such as enhancement of the customer focus, identification and improvement of processes, introduction of performance measurements and improvement of the documentation system. In chapter 8 we report results of the Red Cross Hospital related to the overall hospital performance. Although these results have to be contributed to the combination of ISO 9000 and Six Sigma, they illustrated at least partly the usefulness of ISO 9000 in a hospital.

The second question is: Does the implementation of Six Sigma in a hospital provide a quality improvement system equally powerful as in industry? The answer to this question can be found in chapters 4 to 8. In chapter 4 we provide a rationale for implementing Six Sigma and we show some early results. In chapter 5 we describe three improvement projects in more detail to give a deeper insight in the Six Sigma methodology and its effectiveness in healthcare. Chapter 6 demonstrates the results of Six Sigma at a hospital level. Chapter 7 describes in a more qualitative manner why Six Sigma, due to its focus on process improvement, is even more effective in healthcare than in industry. In chapter 8, as we mentioned above, we report results of the Red Cross Hospital related to the overall hospital

performance. These results have to be contributed to the combination of ISO 9000 and Six Sigma. The results related to the overall hospital performance, however, match our findings in chapter 6.

The third question is: Does quality management, by using ISO 9000 and Six Sigma, contribute to the strategy of a hospital? This question is answered in chapter 8.

The final question is: Can Lean principles, when combined with Six Sigma, provide an additional positive effect on the quality improvement system? This question is answered in chapter 9.

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Chapter 2

An ISO 9002:1994 Quality Management System in a Hospital Department

This chapter is based on:

An ISO-Quality System in the Radiology Department: A Benefit Analysis. Acad Radiol. 1998: 5(suppl 2): S441-S445.

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Rationale and objectives

In 1994, as part of a strategic planning process in our department, mission and vision statements were defined. During the process, it was concluded that the introduction of the principles of Total Quality Management (TQM) (Deming 1986) and the development of an integrated quality system were of great strategic importance to our department. Three considerations prompted this conclusion. First, due to government policy, the department is faced with an increasing demand for radiologic investigations and decreasing budgets. Therefore, it is essential to control quality and costs. Second, traditionally the department had a large number of quality-improvement projects (Hendriks 1995). However, the growing interrelations among the different projects made it clear that an integral and systematic approach was needed. Finally, the Dutch government has recently enacted a law which states that healthcare organizations in The Netherlands are obliged to have a verifiable quality control system.

Radiologists in the United States have a profound interest in applying principles of quality management in radiology (Deitch 1994). Management participation is also on the rise in The Netherlands. In their study, Deitch et al. found that 86 percent of the radiology departments have programs to monitor and evaluate physician performance. The questionnaire used by Deitch gives a good overview of the relevant items that can be of help in evaluating one's own department. Seltzer et al. (Seltzer, 1994) describes the use of quality management techniques to improve the turnaround time of radiology reports. Crabbe et al. (Crabbe 1994) performed the same task by using workflow analysis techniques. They also discuss the use of indicators, based on data from the Radiology Information System (RIS) in their department. After reviewing available methods for designing a quality control system, we selected the model for quality assurance outlined by the International Organization for Standardization (ISO) (ISO 1994).

In January 1996, implementation of the quality system was completed, and an ISO 9002 certificate was obtained. This article discusses the structure, design, and implementation of our quality system. In addition, revenues accrued during the first year of operation of the new quality system are reported.

Materials and methods

TQM

Total Quality Management (TQM) is a structured, systematic approach in which all employees are utilized as a source of ideas in order to continuously improve

processes, services, and products (Adams and Arora 1994). Since the concept of quality in healthcare is hard to define, the principles of TQM (Cascade 1990) can be of great help in developing a quality system in a healthcare organization. TQM can also be seen as a set of management tools — such as Quality Assessment (QA) and Continuous Quality Improvement (CQI) — which are part of a method which uses a system approach with feedback loops, a process approach, and a client-centered approach in order to provide quality assurance.

ISO quality system

The International Organization of Standardization has developed standards for the design of quality systems. These standards, originally designed for product manufacturing, are independent of any special industrial branch or specific economic area. The standards offer sufficient flexibility to apply them in healthcare organizations. Furthermore, a radiology department also has some characteristics in common with a production company. A quality system according to the ISO standards has three main characteristics:

- The main focus is on the process of delivering the service and not primarily on the outcome.
- There is a system approach. This implies that working processes and authorized and accountable staff are identified, performance measured on a regular basis through indicators, and finally a feedback loop-defined as transparency.
- The quality system has to be verifiable by means of a number of documents such as the quality handbook of the organization, procedures describing the most important working processes, protocols, and the measurement results of the indicators.

Design and implementation

The workflow in our department has been studied by means of standard tools and has been divided into logical processes. The processes were analyzed and represented by means of flowcharts, and every process has been described in a procedure and protocols handbook. Each detail of a process is not, however, written down in a procedure. Parts of a process are described only when their description directly affects quality control in the department. In this way, bureaucracy is kept to a minimum. After descriptions of the procedures were finished, protocols were produced. Protocols provide a more detailed description of a specific part in a process and are created for the express purpose of contributing to quality control. It was convenient that in our department most of the clinical processes had already been recently defined in a large number of protocols. These protocols were all updated to fit in a system of periodical updating, authorization, and distribution.

Quality indicators

A major element in quality control and quality improvement is the use of quality indicators. In a number of procedures, indicators were defined to quantify specific aspects of care. Information systems were developed to measure and report quality indicators periodically.

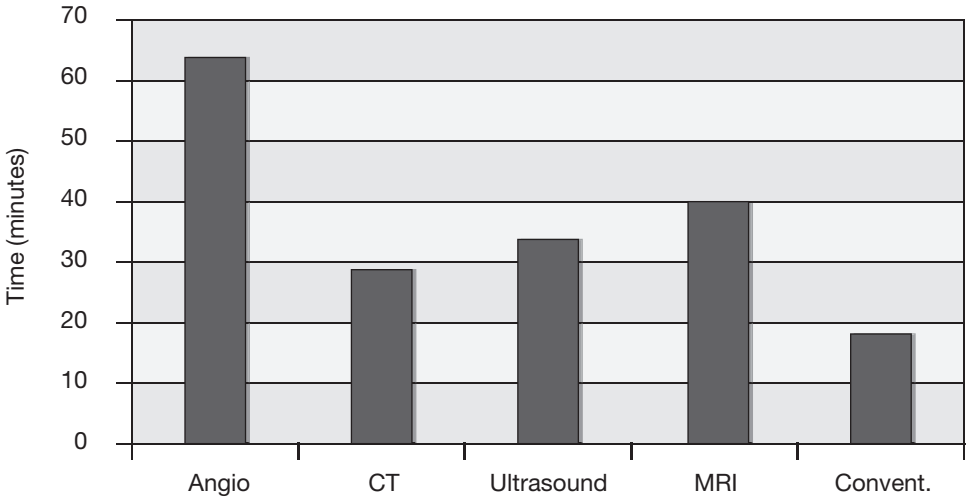

Figure 1. Examination time per modality in 1996.

Results

Structure of the quality system

The quality system of the department has been described in three types of document: the quality handbook, procedures, and protocols. The quality handbook gives a description of the organization, the quality system, and the quality policy of the department. The procedures describe the relevant aspects of the working processes. At this moment, there are 40 defined procedures, which can be divided into the following five categories:

1. Procedures of the quality system itself.
   This category consists of five procedures: document control, internal audits, statistical techniques/management information, measurement of customer satisfaction, and quality registrations.
2. Procedures of the radiologic modalities.
   In this category there are 16 procedures. The most important are CT, MRI, ultrasound, angiography and bucky.
3. Procedures of patient scheduling, transcription and file room.

4. Procedures of management activities.
   There are seven procedures in this category, the most important of which are staffing management, investments and management of complaints.
5. Procedures of the photography department.
   These three procedures are related to photographic material management, maintenance of developing machines and laser printers, and production of manuscripts and audiovisuals.
6. Six procedures — including safety and environment, system management, stock management and privacy — did not fit in the above categories.

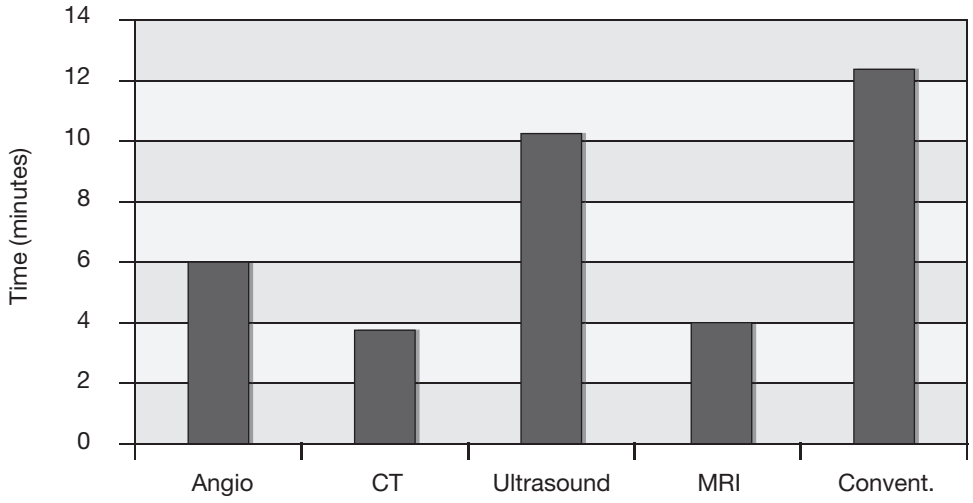

Figure 2. Waiting time in 1996.

All procedures are updated, authorized, and distributed as described in the document control procedure. Any improvement in workflow results in an update of that specific procedure. Employees are informed instantaneously when they receive the updated procedure.

Protocols give a more detailed description of a specific task within a procedure. A large number of protocols have been developed for MRI, CT, and other modalities. At this moment, there are about 150 MRI protocols, 80 CT protocols, and 40 angiography protocols. These protocols can also be updated and sent to users whenever changes due to new insights are required. Having an effective update procedure is a key success factor in using protocols and procedures.

Performance measured by quality indicators

Quality indicators also have to be evaluated and possibly updated periodically. The indicators are divided into four categories:

1. Production.
   Comparison of monthly production for each modality with the predicted production for a whole year: comparison with production for the previous year;
2. Costs and efficiency;
3. Quarterly reviews of staffing and material budgets, average number of FTE's, production hours per FTE, and absence due to sickness;
4. Process quality.
   Reviews of average examination time per modality, film usage and waste and percentage of available old examinations; and
5. Customer orientation.
   Determination of waiting time (reception and telephone), reporting time, waiting time for examination after arrival and customer satisfaction.

Indicators related to the productivity of the department give a fair indication regarding the workload and the degree to which production agreements within the hospital are met. A very useful indicator appeared to be the number of production hours per FTE. Mismatches between required production and available personnel can be detected instantaneously. The indicators of process quality played an important

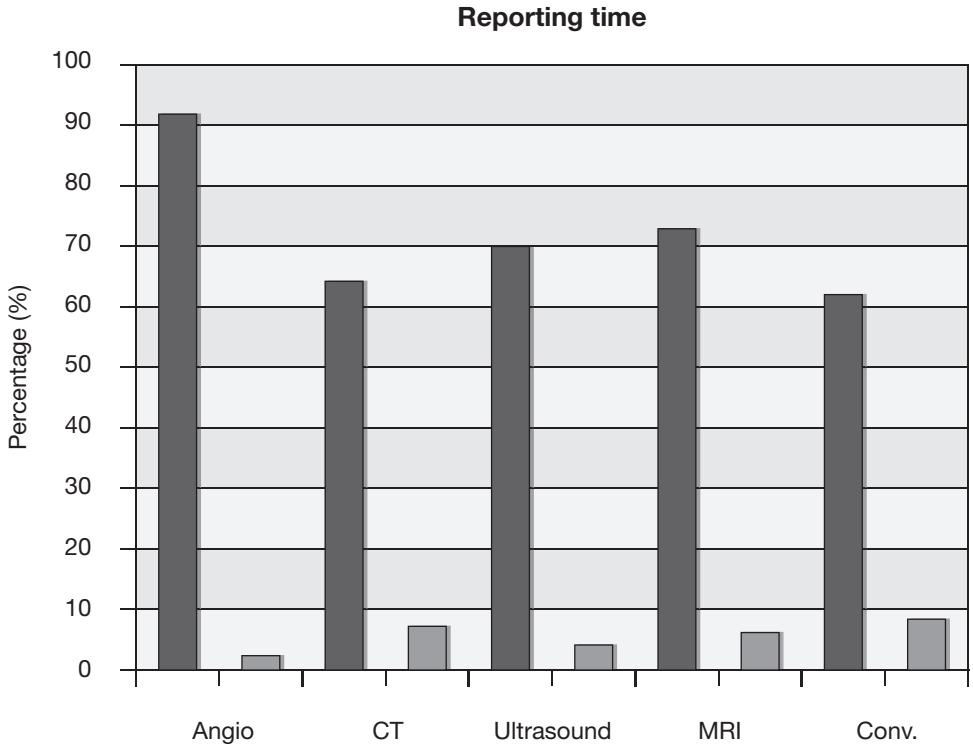

Figure 3. Percentage of reports finished after 2 days and not finished after 5 days (1996).

role in improving the efficiency of the department. The average examination time per modality is measured periodically by means of a Radiology Information System (figure 1). Waiting times and reporting times are monitored intensively (figure 2). The reporting time is measured and represented by means of two percentages. The first percentage figure shows how many reports are available on the network within 2 days. The second percentage figure shows how many reports are still not available after 5 days (figure 3). Customer satisfaction is measured quarterly by means of a patient questionnaire. In general, patients were very satisfied, but many expressed the need for more information about the examination procedures and waiting times. These findings led to the initiation of several changes to improve patient satisfaction in these areas. Referring physicians were also asked to evaluate the service levels of the department. They appeared to be satisfied, and there were no clues for further improvements. The development of quality indicators is an ongoing process, and more indicators will be developed to facilitate management, quality control and improvement.

Continuous improvement

Being engaged in the process of continuous improvement implies that the entire department is forever aware of possibilities for improving the quality of care. This awareness often generates improvement projects. Some illustrative improvement projects completed last year are the following:

- Improved patient information. Analysis of patient satisfaction questionnaires indicated a need for more detailed information prior to the examination. Information folders, covering most of the procedures, were therefore made for distribution to patients.
- Reduced film usage. After analyzing and quantifying film-usage patterns, the use of film material diminished. In 1996, the total amount of film costs did not increase, whereas the number of examinations showed a 6 percent increase.
- Shortened MRI examination time. The average length of a MRI examination was 45 minutes. After optimizing workflow, the examination time was decreased to 40 minutes. Last year it even appeared possible to further reduce the examination time to 35 minutes. Quality levels were maintained by the use of a consistent number of protocols.

Costs and benefits of TQM and ISO implementation

In their study, Deitch et al. (Deitch 1994) found that 58 percent of radiologists believe that the introduction of QA and/or CQI/TQM programs contributed to the improvement of patient care. On the other hand, only 19 percent believe that efforts concerning quality result in a positive cost-benefit effect to their organization.

Improvements in cost-benefit ratio are very hard to detect, mainly because it is virtually impossible to determine all changes in costs and aspects of quality. In our opinion, the best strategy is to improve quality by means of improving the scores of the chosen indicators at the same level of costs. The direct costs related to the implementation of our quality system included Dfl. 23.000.- for consultation for planning, implementation, and teaching of the audit system and Dfl. 37.000.- for actual certification costs, a total of Dfl. 60.000.-. No extra staff had to be hired, since describing and analyzing workflow increased efficiency sufficiently. Since the department operates as a nonprofit agency within a closed budget system, a capital gain cannot be shown. However, in the first year our quality system was fully operational, we experienced a 4 percent increase in the number of examinations, resulting in a 9 percent increase in workload. This increase in examinations is equal to a capital gain of Dfl. 900.000.-. We also achieved a high score (130 percent) on production hours per FTE, the major efficiency indicator. We even exceeded the average efficiency rate of non-academic hospitals. Unfortunately, we also detected organizational stress by means of other indicators, such as absence due to sickness. We concluded that too many demands were being made in the name of efficiency and employed a limited number of extra employees. This experience provided us with a standard for efficiency levels but also showed us that efficiency improvement has limits.

It is not easy to give an exact quantification of the revenues of our certification project. Certain aspects of quality cannot be translated into a dollar amount. Quality improvements should, however, always lead to an increase in service level and/or lower costs. Two achievements can be mentioned here. First, our improvement project to reduce film usage resulted in an estimated yearly savings of Dfl. 40.000.-. After improving our MRI procedure and implementing a large number of scanning protocols, we were able to increase MRI production to 13.000 examinations per year, a 4 percent increase in investigations without extra costs.

The real benefits of our new system are a better quality of service rendered, as measured by quality indicators and successful improvement projects.

Conclusions

This paper describes an integrated quality system, based on ISO standards. Although the principles of quality management and TQM have found their way into the practice of radiology and a variety of quality improvement projects have been successfully implemented in radiology departments, an integrated quality system is a major step forward on the road to total quality management. With TQM, all relevant

aspects that influence the quality of service are known and controlled. This does not necessarily mean that maximum quality is delivered, but it does allow choices to be made which optimize the quality of services provided given the means available. To maintain as high a level of quality as possible, there must be no unknown "quality leaks". We achieved this by creating transparency in the workflow by means of procedures and quality indicators. Transparency and quality indicators are also essential in the success of improvement projects. Insight into the present state, by means of procedures, is an excellent starting point for any improvement project. In this environment, the usefulness and revenues of proposed improvements can be confirmed and measured by their effect on specific indicators, creating the positive atmosphere of a competitive department eager to respond to demands for quality cost-effectively.

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Chapter 3

An ISO 9001:2000 Quality Management System in a Hospital

This chapter is based on:

An ISO Quality Management System in a Hospital: Bureaucracy or just Benefits. International Journal of Health Care Quality Assurance. 2005: 18 (5): 361-369.

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Introduction

Healthcare organizations are expected to deliver an adequate level of quality of care. Furthermore, society demands transparency, efficient usage of public funding, and accountability (Relman 1988). The Institute of Medicine (IOM), however, states that healthcare today harms too frequently and routinely fails to deliver its potential benefits (IOM 1999, 2001). Bad quality, and therefore the opportunity to improve quality, is usually related to the design of complex production processes and not to lack of will, skill, or being intention of employees (Berwick 1989). The IOM also emphasized the necessity to redesign the healthcare delivery system to improve the quality of care, because it is highly fragmented and care processes are poorly designed. Quality management and the implementation of a quality management system, emphasizing process control and process improvement, are therefore essential to any hospital organization (Casparie 1993). In this article, we describe how we designed and implemented a quality management system according to the ISO 9000 standards in the Red Cross Hospital in Beverwijk, The Netherlands.

ISO 9000

The ISO 9000 series are standards that define requirements (9001) and guidelines (9004) for quality management systems (ISO 2000a) (ISO 2000b). The International Organization for Standardization (Geneva, Switzerland) first issued the standards in 1987. In 1994 and in 2000 the ISO 9000 series were revised. The standards are generic, which means that the same standards can be applied to any organization, large or small, whatever its product or service, in any sector or activity whether it is a business enterprise, a public administration or a government department. The ISO 9000 standards are founded on the concept that the assurance of consistent product or service quality is best achieved by simultaneous application of product standards and quality management system standards (Marquardt 1999). The standards represent an international consensus on good management practices with the aim of ensuring that the organization can continuously deliver the product or service that:

- meet the customer's quality requirements;
- meet applicable regulatory requirements;
- enhance customer satisfaction; and
- achieve continuous improvement of its performance in pursuit of these objectives.

ISO takes a systems and process approach to improve organizational and financial performance with a specific focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory performance or non-conformance.

ISO 9000 standards are successfully used and adopted worldwide in industry and service organizations (Marquardt 1999). At the end of December 2002 more than 560,000 conformity to ISO 9000 standards have been issued in 159 countries. This is an increase of more than 10 percent compared to 2001 (ISO Survey). In The Netherlands, more than 13,000 companies have acquired an ISO 9000 certificate of conformity. In healthcare, the application of the ISO standards is not yet very common and subject for debate. Recently the usefulness of ISO 9000 standards in healthcare was outlined (Carson 2004). A small number of Dutch healthcare organizations have been reported to use ISO 9000 standards (Sluijs 2000). The application of ISO 9000 in hospitals was until recently limited to certification of departments (Van den Heuvel et al. 1998).

Information about the worldwide application of ISO 9001:2000 in hospitals can only be obtained by organizations that are allowed to perform certification or through announcements by the hospitals themselves. A survey on the internet shows that in most European countries a limited number of hospitals have obtained an ISO certificate. In Great Britain, ten smaller (around fifty beds) hospitals that are related to BUPA, a healthcare insurance company have an ISO 9001:2000 certificate (BUPA website). Several US certification organizations claim to have achieved successful certifications in hospitals (www.ics.sgsna.com; www.qualityparadigms.com; www.tuvamerica.com). The American Legion Hospital in Crownley, Louisiana, USA is believed to be the first acute care hospital in North America to be certified to ISO 9002 (ISO 2001a). Freeman Health System reports to be the first healthcare system in Missouri and the sixth in the US to have earned an ISO 9001:2000 certificate in October 2003 (www.freemanhealth.com). The East Shore Hospital with 123 beds together with Mount Elizabeth Hospital in Singapore claim to be the first private hospitals in the Asian Pacific to be certified according tot ISO 9002 in 1994 (www.eastshore.com). The Alexandra Hospital in Singapore, a 400 beds general hospital, achieved ISO 9001:2000 certification on 16 January 2001 (www.alexhosp.com.sq). De La Salle University Medical Center in Manila in 2001 claims to be the first ISO 9001 certified hospital in the Philippines (Edralin 2001). So worldwide application of ISO 9000 in hospitals has been reported but up to now only on a limited scale. An interesting exception is Thailand, having an internet site that reports all ISO 9000 certificates in every possible type of organization in the country (www.tisi.go.th). This internet site reports 240 hospitals having an ISO 9000 certificate for parts of the organization or the entire hospital.

Implementation

The Red Cross Hospital is a general hospital with 384 beds located in The Netherlands with an annual budget of 72 million euros. We began our project in January 1999 by

writing a global implementation plan. The department heads analysed and described processes within their own departments. The analyses were first used to identify and implement quick wins in process improvement. Once the process was improved, it was described in a standardised manner called a procedure. To describe all core processes in our hospital we needed approximately sixty procedures. The next step was to make protocols related to each procedure. Protocols in our quality system give a detailed description of a specific task, i.e. how to remove stitches or how to enter specific data in the computer. Processes and activities were only described when this was necessary to provide sufficient quality assurance. This kept the number of activities and procedures that actually had to be documented limited to a minimum.

Once all the essential processes and activities of our organization were described, the hospital management put together the Quality Manual. This manual contains descriptions of the organization, the divisions, our quality system, the policies of our hospital and our current set of performance indicators. To complete our quality management system we implemented an internal audit system. We trained approximately fifty co-workers to audit procedures and protocols in various departments. The internal audits resulted in a large number of improvements to our quality management system.

When all required elements of our ISO quality management system were designed and implemented, the system had to "come alive". Processes had to perform the way they should and if not, corrective actions have to be taken. The flow of opportunities to improve the system had to lead to actual improvements. Finally the internal and external audits had to either confirm that the system ran properly or provide input to further improvements. We have been able to implement ISO 9001:2000 without support of external consultants or an increase in personnel. External audits and subsequent certification have cost approximately 77,000 euros. Every year two external audits are required with total costs of 14,000 euros.

The results

Patient and client orientation

Our ISO quality management system keeps us focused on the needs of our patients and clients. We have to access our patients' needs in advance and evaluate patient satisfaction on a structural base afterwards. Our processes are all identified and have to be improved continuously to consistently meet patients' needs. Due to these ISO requirements, we are sure that we are doing the right things and move in the right direction of quality improvement.

Process oriented healthcare

The IOM has pointed out that quality of care is often not sufficient because healthcare processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays. In our quality management system all processes have been identified, described and optimized. Although we still have a long way to go, performance indicators on process level are developed and monitored. Department heads in their responsibility as "process owner" have to ensure optimal process performance.

Continuous improvement

An important feature of ISO 9001:2000 is its systems approach in relation to process management. We gather information from a number of sources such as; patient satisfaction surveys, complaints, Faults Accidents and Near Accidents, quality measurements, internal and external audits. These measurements have to lead to improvements of the quality system, improvement of the design and performance of the healthcare processes and improvement of the quality of healthcare. Performing risk analysis on every process and design improvements, as required after the 2000 revision of ISO 9000, created a significant amount of awareness and commitment to quality of care and patient safety. These risk analysis and subsequent improvements can be considered an important step in eliminating the flaws in patient safety as stated in the first report of the IOM (IOM 1999).

Performance measurements

We have developed a set of performance indicators as required by ISO 9001:2000 that is an essential part of our quality management system. This set of indicators is published every year in our Annual Quality Report. The most important indicator is related to patient satisfaction. We use approximately 50 different types of questionnaires, one for each department. The structure of all these assessment forms and the rating systems are identical, so all the results can be added up to give our hospital a total score on patient satisfaction. We distribute more than 2000 forms a year and the response rate is nearly 50 percent. On every item, patients can rate four categories; "good", "reasonable", "can be improved" and "must be improved". We have been able to achieve consistent rates of more than 80 percent "good" every year.

Document system

The quality documents are the most tangible part of our quality management system. The first document layer consists of the Quality Manual. The second layer consists of approximately 60 procedures describing all core processes of

our organization. There are processes related to the quality management system itself, for instance Documentation management, Internal audits, Complaints and Risk management. There are management procedures, such as Budgeting and Investments. The largest group consists of sixteen procedures related to the healthcare process such as "Day care treatment", "Emergency care", "Preoperative screening" and "Medication provision". The third layer of our quality document system consists of protocols and work instructions. These documents of one or two pages describe small parts of a process and sometimes only a single action. They are valid within a single department or distinctive to one group of professionals. The type of documents that we have mentioned so far are typical of those generated by ISO 9001:2000 requirements. We added two types of documents we felt were necessary in healthcare. The first one called "house protocol", is a protocol that concerns several departments. We have 137 house protocols at this moment and the most important group contains descriptions of 44 nursing procedures of which performance is restricted to registered nurses. The second group of documents we added are descriptions of so called Clinical Pathways. We have approximately 40 approved and documented clinical pathways and they have proven to be a promising extension of our quality management system.

Certification

At the end of 2000, one and a half year after starting the implementation KEMA, a Dutch certification institute, performed the first external audit. After correcting a number of shortcomings, we received the ISO 9002:1994 certificate for the entire hospital organization. This certificate was valid for three years. During that period, KEMA performed an external audit every six months. In the mean time we adapted our quality management system to fit the requirements of the revised ISO 9000:2000 standards. These efforts were successful and we obtained an ISO 9001:2000 certificate after the external audit in October 2003. Until this moment we are the only hospital in The Netherlands that obtained an ISO certificate for the entire organization.

ISO 9000 standards and patient safety

In 1998 and 2001 we performed an assessment on patient safety by using a tool developed by our insurance company called the Centrameter (Van Dijen 2001). The Centrameter consists of 29 different questionnaires, one for every group of employees in and around the hospital. Patient safety is given score in five categories; the Care Process, Prevention of Incidents, Complaints and Claims, Client Orientation, Policy and Management. Each category is subdivided in characteristics and each characteristic is subdivided in indicators. At the bottom

level, the Centrameter consists of more than 700 different questions. The answers are processed and interpreted by an expert system. This expert system, that is also a part of the Centrameter, is a computer program designed to process knowledge. The knowledge that has been put into the Centrameter reflects an expert opinion on patient safety based on a panel of human experts. Patient safety is scored as a percentage of resemblance to an imaginary hospital that, according to the human experts, is considered outstanding. At present, eleven hospitals have been assessed with the Centrameter.

In 1998, the Red Cross Hospital distributed 276 questionnaires. The response rate was 77 percent. In 2001 we repeated the Centrameter, this time 266 questionnaires were distributed and the response rate was 82 percent. By repeating the Centrameter, we obtained an assessment on patient safety before and after the implementation of our quality management system. Thus, we were able to measure the effects of an ISO 9000 quality management system on patient safety in our hospital compared to ten other hospitals that did not develop such a system.

In 1998, our hospital scored on integral patient safety a 35 percent match with a hospital that is considered "outstanding". The scores of the other hospitals ranged form 33 percent to 46 percent with an average 41 percent. In 2001, our hospital scored a 63 percent match where the other hospitals ranged form 38 percent to 72 percent with an average of 61 percent. The improvement rate of our hospital, from 35 percent in 1998 to 63 percent in 2001, was 80 percent, with an average improvement rate of 50 percent for all hospitals. Our most significant improvement occurred in the category Policy and Management. In 2001, we scored a 95 percent match with an outstanding hospital and obtained the highest score in this category. Our improvement rate was 58 percent, with an average of 5 percent for all hospitals.

Compared to ten other hospitals that participated in the Centrameter, the implementation of an ISO 9002 quality management system in the Red Cross Hospital resulted in the highest improvement rate on patient safety. Furthermore, the hospital achieved the highest score and highest improvement rate in the category policy and management.

Discussion

The explicit focus of ISO 9001:2000 on the client, our patients, appeared to be very stimulating. In the past, due to external demands, our attention has gradually shifted towards efficiency parameters and administrative procedures such as filling out forms and medical files. We have put the patient back in the centre of our

attention and receive positive feedback. This motivates us to pick up the remaining shortcomings in healthcare delivery.

ISO is often thought to be synonymous with bureaucracy. The fact, however, is that hospitals due to a number of reasons, such as government regulation, healthcare inspection, etc., have to maintain a considerable level of registration and documentation. In our hospital, this resulted in a large and uncontrolled number of documents with many duplicates with only minor differences that were relatively inaccessible. There were more than five protocols to insert an intravenous drip. The paradox therefore is that ISO due to its well-described document control system can reduce bureaucracy in organizations especially in hospitals where a certain degree of documentation is required.

Since the ISO 9000 standards originate from industry, they were considered not to be applicable to healthcare quality management systems. Applications therefore were mainly seen in non-clinical environments such as the radiology and laboratory departments (Klazinga 2000). We have been able to include all the core processes of our hospital in our quality management system including the processes concerning healthcare delivery. Our first intention was to develop and implement a quality management system that was best suited for our hospital. Only after completing our quality management system, we verified conformity with the ISO standard. We strongly recommend this sequence. Taking one's own organization as a starting point can, despite using the same standard, lead to different quality management systems in different organizations. This observation has been made in healthcare and was considered a disadvantage of ISO (Sweeney 2000). However, the intention of ISO is not to create identical quality management systems in different organizations, but only to establish conformity to (minimal) requirements.

The ExPeRT project, a study on external quality mechanisms for healthcare, has identified four principal models and national variants of external quality improvement in healthcare (Shaw 2000). These models are; the medical speciality-driven "visitatie" in The Netherlands, traditional accreditation, European Quality Awards (EFQM and national variants) and finally certification using ISO 9001:2000. A convergence between the four models has been observed (Klazinga 2000). The EFQM-model can be best seen as management model to support top management in pursuing Total Quality Management. ISO 9001:2000, like EFQM a generic model, is focussed on quality management and developing quality management systems. The EFQM-model has proven its value in healthcare (Nabitz 2000). We have used the EFQM-model (in The Netherlands: the INK-model) as

a management model for several years. However, we gradually felt the need to improve process management and quality assurance on the tactical and operational level of our hospital. With ISO 9001:2000 we were able to achieve these goals and most of all involve our employees in quality management.

A number of countries have developed guidelines for the interpretation of ISO 9002:1994. In Switzerland, an attempt has been made to adapt the ISO 9000 standards to healthcare. This resulted in an interpretation guide of ISO 9001:1994 (Cranovsky 1997). Although a number of different kinds of healthcare institutions obtained a certificate, breakthrough applications have not occurred so far. This was possibly due to the complexity and costs of the introduction but also because healthcare providers are not yet forced to prove the quality of their work (Schilling 2001). In our experience, the possible complexity of implementing ISO 9000 has been reduced by the 2000 version that is far more comprehensive. The ISO 9000 guidelines for healthcare, called ISO IWA 1 that have been developed can perhaps contribute to a better appreciation and wider use of ISO 9001:2000 in healthcare (ISO 2001b). The first revision has appeared in 2004 (Reid 2004).

Serious quality and safety problems have been described by the Institute of Medicine. Healthcare relies on outmoded systems of work and systems of care have to be redesigned. The IOM suggests healthcare to adopt quality tools form industry because it has a long standing experience in quality management. In our opinion ISO 9000 is such a tool that can be applied successfully in healthcare as a basic step in the road of quality management.

Conclusions

We successfully implemented a quality management system according to the ISO 9001:2000 standard and obtained a certificate of conformance for our entire hospital organization. Our experiences with ISO are very positive and we experienced a number of advantages. The focus on our patients has been re-established and all processes are identified and subject to continuous improvement. We introduced performance measurements that give an overall and integrated picture of our results. Measurements subsequently lead to improvement of quality of care and to improvement of our quality management system. Our documentation system has been optimised largely and serves our needs without leading to bureaucracy. Positive effects on patient safety could be reported. Given the need for adequate quality management tools in healthcare, the increasing need for demonstrating quality of care and the positive effects reported in this article, we expect ISO 9001:2000 quality management systems to become more common in healthcare organizations.

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Chapter 4

Why Implement Six Sigma in a Hospital?

This chapter is based on:

Dutch Experiences Implementing Six Sigma in Healthcare.
Six Sigma Forum Magazine. 2004: 4(2): 11-14.

By:
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Søren Bisgaard

Introduction

Six Sigma is increasingly applied to a wide variety of non-manufacturing operations. In a previous chapter, we discussed the use of Six Sigma in industrial non-manufacturing operations and specifically reviewed eight projects conducted in Dutch industry facilitated by a team from the University of Amsterdam (Does et al. 2002). In this article we discuss the implementation of Six Sigma in healthcare focusing on the decision making process. Specifically, we will discuss the process that led to the application of Six Sigma at the Red Cross Hospital in Beverwijk, The Netherlands. We focus on managerial issues related to the implementation of Six Sigma in healthcare and report on preliminary results.

In the first section of this chapter we provide background for the introduction of Six Sigma and in the following section we review our pre-Six Sigma quality initiatives. Then we discuss the implementation of Six Sigma followed by a section with illustrative examples of successful Six Sigma projects. The final section provides a conclusion. The intent of this article is to stimulate further applications of Six Sigma in the healthcare sector (Barry 2002; Kabcenell 2002; Stahl 2003).

Background

The Red Cross Hospital in Beverwijk is a 384-bed medium size general hospital in The Netherlands employing a staff of 930 with a current budget of $70 million. In addition to being a general healthcare provider, the Red Cross Hospital is the base for a national Burn Care Center with 25 beds that provide services to all of The Netherlands. In 2002, the Red Cross Hospital made 11.632 admissions, performed 8.269 outpatient treatments, and received 190.218 visits to its outpatient units of which 72.500 were first contacts. During the past four years, management and employees have invested significant resources in quality management resulting in a system for quality assurance. At the end of 2000, an external audit resulted in an ISO 9002 certification. After the certification we began considering quality improvement projects on a regular basis, but initially without the benefit of Six Sigma's project management system.

Pre-Six Sigma quality improvement initiatives

During the initial pre-Six Sigma phase, our quality improvement approach appeared to work reasonably well. A large number of quality improvement projects were successfully completed. However, we recognized that our management control of projects was not effective. Frequently the project goals were poorly aligned with the hospitals strategic goals. We lacked a systematic way to determine a project's relevance and contribution to our long-term strategy. The lack of a standardized procedure for evaluating the cost-effectiveness of a project was also an impediment. Further we had difficulty making project go/no go decisions. Most of the time projects were initiated

because we "felt" they would make a contribution to quality of care. We were also not able to access potential savings of alternative projects. Once a project was started, we did not have reliable information about its status until it was finished. This, of course, was the result of not having a standardized project management approach. Each project had different milestones, and progress could not be evaluated and compared to other projects. In summary, management was navigating in the dark!

The management team and the employees were frustrated about the lack of a standardized project management approach. Time was frequently wasted; each time the approach, the project documentation, the planning, etc. had to be developed from scratch. For that and other reasons, we could not properly train our employees in project management. We did have organized training, but with meagre and disappointing results. Another problem for our employees was that management expected them to work on their project in addition to their usual duties. This might at first appear to be a "cheap" approach. But it seriously delayed potential savings. Ironically, we were mostly unaware of this unfortunate situation because of our poor management controls. Had management been in a position to determine the results of a project in advance, they would have been able to make more appropriate decisions about employee time allocations to projects. Further we now have learned that employees should be relieved of some of his or her other duties when working on a project. Fortunately, we also quickly realized that there were many more potential savings. We were just missing them because of a poor project management system.

The implementation of Six Sigma

Six Sigma as a system incorporates a number of quality management techniques. These help resolve some of the problems discussed in the previous section. Specifically, we consider the following main reasons for success:

Philosophy

Six Sigma is based on scientific principles; decisions are primarily based on facts and data and less on feelings and intuition. Projects are not initiated when estimated savings are below management-defined thresholds.

Project management

Projects are managed strictly according to the five phases of Define-Measure-Analyse-Improve-Control (DMAIC). Each phase is completed only when specific milestones are reached (Harry 1997). At any given time it is possible to determine specific project's progress in an unified way within departments and across the entire organization.

Well-defined roles and responsibilities

Six Sigma assigns specific roles — Yellow Belt, Green Belt, Black Belt, Champion and Master Black Belt — to those involved. Clarity of roles and expected contributions is important during an organizational change effort. Explicitly defined roles contribute to the success of a project.

Tools and techniques

Six Sigma employs a variety of tools and statistical techniques. Software tools are used to make the techniques available and accessible to people with little or no training.

Well-defined interfaces with the existing organization

Six Sigma provides a detailed blueprint that links it to the existing organization in a "matrix like" fashion. Specifically, Six Sigma's tight project organization operates across all hierarchical layers of the organization. All relevant information and responsibilities can be brought together while the business continues to operate.

In conclusion, Six Sigma is not just an idea, or another trick to organize improvement projects. It is a set of managerial instruments, well defined and well tuned to enhance the results of improvement projects with the ultimate goal of maximising the performance of the entire organization.

To implement Six Sigma at the Red Cross Hospital we had to customize and adapt some of the standard Six Sigma management concepts so they apply better to the healthcare industry. Companies that typically use Six Sigma are large organizations. Because of the much smaller scale of our organization, we had to make adjustments. As it turned out, that was not difficult. Further, we are a service organization and, as all Dutch hospitals, organized as a non-profit organization. Again during the implementation phase we found that this was not a major issue. There were discussions concerning the culture of our organization as a non-profit organization versus an industrial for-profit company, and especially about the explicit focus on financial results. However, it was relatively easy to explain that more money for our hospital means happier and healthier patients, convincing the few remaining skeptics. In this respect our experience parallels that of the implementation of Six Sigma at the Thibodaux Regional Medical Center, Louisiana, USA (Kabcenell 2002).

The implementation of Six Sigma was initiated with a one-day training session for the upper management team at the end of 2001 provided by an external consulting company with broad experience in introducing Six Sigma. The management

team consisted of two directors and the managers of the hospital's four divisions. Our quality manager was introduced to Six Sigma in January 2002 and she enthusiastically went through intensive Black Belt (BB) training during the spring. After she completed her BB course, sixteen employees enrolled in in-house Green Belt (GB) training provided by the external consulting company in September 2002. During the GB training period, every participant was required to participate in a Six Sigma project. One hospital director also participated in this first wave of GB projects. During the course, consisting of two separated periods of three days, every participant was required to produce documented results. No GB project was allowed to proceed to the subsequent phase without completing the preceding phase. Participants had to present their results twice in front of the entire group, the second being a presentation of their final results. Because of the size of our organization, we exclusively used GBs as team members, each typically spending two days a week on the project. We used $25.000 estimated savings as our financial threshold for initiating a project. This amount was appropriate considering the budget and savings potential of our organization. After completing the first wave, we immediately started a second group of 15 GBs in February 2003, a third group of 13 GBs in September 2003, a fourth group of 14 GBs in February 2004 and a fifth group of 17 GBs is scheduled to start training in September 2004.

The Six Sigma approach was well received. The teams felt it supported them well throughout the entire process of a project. The data driven approach was considered helpful in establishing support during the implementation of the results. The data proved convincing and in many cases minimized emotional resistance. Initially our BB performed the role of Master Black Belt on a part-time basis. As the number of GBs increased, this proved inadequate. Since we wanted to deploy Six Sigma relatively quickly, we decided to look for a full time Master Black Belt (MBB) from outside our organization. Fortunately, we were able to hire a highly experienced BB with previous experience from DAF, a Dutch truck manufacturer now owned by Paccar. Successfully employing a MBB with previous experience from outside the healthcare sector was possible because the Six Sigma "language" is universal and independent of the type of industry. More recently, we received an offer from 3M, a company with a reputation for having successfully implemented Six Sigma throughout its worldwide organization, to support us in further developing our Six Sigma organization.

A sample of our results

The first group of GBs consisted of 16 employees involved with seven projects. One project was terminated during the course because it did not run well. In the

"pre-Six Sigma" phase such a project would have dragged on forever. The other six projects were successfully completed in February 2003. They are described briefly below. More details about these and other projects can be found in Six Sigma in a Dutch Hospital: Does It Work in the Nursing Department? (Van den Heuvel et al. 2004).

Shortening the length of stay of COPD patients

Patients with Chronic Obstructive Pulmonary Disease (COPD) were admitted to either the pulmonary or the internal medicine department due to capacity problems in the former. A statistical analysis showed a significant difference in the admission time between the two departments. The average stay in the pulmonary department was 2 days shorter than the internal medicine department. A further statistical analysis showed that this difference was not due to patient characteristics or physicians. Presumably, the pulmonary department was better at treating pulmonary patients! Consequently, we rebalanced the bed capacity so that it became possible for all COPD patients to be admitted to the pulmonary department. After this change, in-patient days were saved and more admissions were possible. The annual savings were estimated at $40.000.

Improved checks on invoices from temp agencies

After intensive investigations, we found that a considerable number of invoices from temp agencies were incorrect. Furthermore, the errors were consistently in the temp agencies favors and cost us a lot of money to fix. We designed and implemented an improved declaration form that is now required by all agencies contracting with us. In addition to the annual savings estimated at $75.000, we experienced a one-time saving of $35.000 due to a refund.

Revision of the terms of payment

An analysis revealed that there were a large number of different terms of payment for our suppliers. The cause was traced to the lack of a uniform payment policy. A standard policy was established and a number of improvements implemented. The total savings so far are $35.000 and continues to increase.

Reducing the number of mistakes in invoices

The Red Cross Hospital issues yearly 250.000 invoices to our patients and their insurance companies. We found that 9 percent of our invoices were refused and sent back due to our mistakes. Given the large number of invoices (and mistakes) the true lovers of statistics had their finest hours during this project. More than a hundred percentage points of improvement could be identified! A number of them are still

being worked on. At this moment less than 1 percent of the invoices are refused. We estimate that the savings so far exceed $200.000.

Rooming-in in the children's department

Our data analysis revealed that when parents are permitted to stay with their hospitalized children during the night, the length of stay decreased. Observing this, measures were implemented to facilitate the presence of parents. Armed with the data the insurance company agreed to pay 80 percent of the cost for the extra services. Consequently, because of the significant decrease in the number of admission days, we will be able to admit more children and hence boost our revenue. The total annual savings is estimated to be around $30.000.

Reducing the number of patients with intravenous antibiotics

Intravenous antibiotics are much more expensive than oral medication. We found that a number of patients that used intravenous antibiotics could be transferred earlier to oral medication. An analysis showed that the internal medicine department was much better than the surgical department in managing this process. Further analysis revealed that the internal medicine department had a strictly followed protocol (SOP) for switching between intravenous and oral medication whereas the surgical department did not have a SOP. Consequently the protocol developed and used by the internal medicine department was adopted as the SOP throughout the hospital. The total annual saving was estimated at $25.000.

Although each of these savings individually may seem relatively modest, collectively they added up to a significant amount. Further, they required only minor changes and adjustments to the operation and management of our hospital. More importantly, all of these improvement projects provided significant but less tangible benefits both to our hospital management and our customers — the patients. The projects above illustrate that a minimum level of revenues per project of $25.000 is relatively easily met. However, we found that much larger amounts (e.g. $200.000) were possible. Projects are possible in patient care as well as in the administrative departments. Because employees are relatively free to suggest ideas for projects, we expect that an improved selection of projects can further enhance revenues. Indeed, we are very optimistic about the future.

Conclusions

The Red Cross Hospital in The Netherlands is an ISO 9000 certified hospital that has introduced Six Sigma as a major quality management approach. The results have been encouraging. Without major difficulties, Six Sigma was implemented

and made operational. We experienced no significant problems implementing Six Sigma in a non-profit service organization. Employees working with Six Sigma were enthusiastic and considered it a major advantage in managing and executing improvement projects. The savings far exceeded initial expectations. There is no doubt that the Red Cross Hospital will continue to institutionalize Six Sigma in its organization. ISO 9000 and Six Sigma were highly complementary and compatible. These two instruments will continue to be the core of our quality management system in our hospital.

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Chapter 5

Description of Three Six Sigma Projects

This chapter is based on:

Six Sigma in a Dutch hospital: Does it work in the nursing department? Quality and Reliability Engineering International. 2004: 20: 419-426.

By:
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Introduction

The Six Sigma approach has in the past predominantly been used to improve manufacturing processes. However, Six Sigma is now increasingly also applied to a wide variety of non-manufacturing operations (Does 2002). In this chapter, we discuss the application of Six Sigma in a healthcare environment (Barry 2002). Most recently, Merry (Merry 2003) pleads for a change in thinking, structures and processes in healthcare. In our opinion, Six Sigma might be this new way of thinking. The Red Cross Hospital is a medium size general hospital with 384 beds located in Beverwijk, The Netherlands. A national Burn Care Center with 25 beds is part of our hospital. In 2002 the Red Cross Hospital had about 12.000 admissions, 8.300 day-care treatments, 190.000 visits in the ambulatories of which 72.500 were first contacts. The total budget of the hospital is 64 million euros and the hospital employs 930 full time equivalent employees. During the past four years management and employees have put a lot of effort in implementing quality management in the hospital. A quality system was designed and implemented to support quality assurance. At the end of 2000, an external audit resulted in an ISO 9002 certification for the entire quality system of the hospital. In addition to quality assurance, we started a project organization to support quality improvement. Initially quality improvement seemed to work reasonably well in our hospital. We were able to run quality improvement projects and were successful in completing a number of them. There were, however, some deficiencies:

1. Most of the time, we had no accurate way to determine the relevancy of a given project and its contribution to our goals.
2. We did not have a standardised procedure to evaluate the cost effectiveness of a project in advance.
3. Once a project was started we had no reliable information about the progress.

Employees who had to do improvement projects also experienced some problems. For them the fact that there was no standardized project management approach was a major problem. A lot of time was wasted initiating and running a project because the project approach, the project documents, the planning, et cetera, had to be developed time and time again. Another problem for our employees was the fact that they rarely had the opportunity to be relieved of other tasks, so they had to do their project in addition to all their other activities.

The implementation of Six Sigma

Six Sigma is a scientific method to solve problems, made operational in business and industry. It gives a methodological framework to tackle quality problems, but it also offers an organizational structure to implement the required change. Six Sigma is an

integrated approach best characterized by its emphasis on data, and by its focus on financial results (Harry 1997). Originally developed at Motorola in 1987, Six Sigma became well known in the USA, with important multinationals such as American Express, Boeing, Citibank, Dow, Ford and General Electric. These companies were able to produce multibillion dollar saving by utilizing this program. In recent years Six Sigma had been implemented in Europe within companies such as, DAF Trucks, Nokia and Philips.

All quality improvement takes place project by project and in no other way (Juran 1989). Chronic problems will linger unless they are put on the agenda and scheduled as projects for improvement by upper management. To make sustained progress it is widely recognized that projects should follow a logical sequence of steps: first define the project, then diagnose the problem followed by a proposed remedy, check that the remedy is effective and finally institute controls to hold on to the gains. This structure is incorporated in the Six Sigma DMAIC sequence of Define, Measure, Analyze, Improve and Control. Six Sigma projects are conducted by individuals who are thoroughly trained in the Six Sigma approach, statistical tools, and techniques for problem solving, called Black or Green Belts. Typically, a Black Belt training consists of four modules of four days each, which is taught within a six month period. Green Belt training has two modules of each three days, within the same period.

For several reasons we had to do some customizing to the Six Sigma concept when we decided to implement it in our hospital. The main reason was that companies using Six Sigma are mainly large multinationals. Therefore we use Green Belts instead of Black Belts to perform the projects. Our Green Belts may spend one to two days in a week on their project. As a financial threshold, we choose 20.000 euros for each project. Some people felt uncomfortable about the explicit focus of Six Sigma on financial results. Fortunately we were able to convince these people that cost containment is also in the best interest of our patients. It turned out that our approach was comparable with the implementation of Six Sigma in Thibodaux Regional Medical Center in southern Louisiana, USA (Stock 2002). A full account of the decision process to implement Six Sigma in the Red Cross Hospital has been described earlier (Van den Heuvel et al. 2004).

At the end of 2001, we started the implementation of Six Sigma with a one-day training of our management team that consisted of two directors and the managers of the four divisions. After that our quality manager started in January 2002, the intensive Black Belt training. In September 2002 sixteen employees started an in-company Green Belt training. During the Green Belt training, teams of two

or three Green Belts worked together on one Six Sigma project. Every team had to produce the specific results that characterize a Six Sigma project. No one is allowed to go to the next phase until the preceding phase is completed. Teams have to present progress twice before the entire group. In the second presentation, they demonstrate the results of their project. When the first group completed their projects in February 2003, we immediately started a second and in September 2003 a third group of Green Belts. For 2004, a fourth and fifth group of Green Belts have been scheduled. Participants are very enthusiastic about the Six Sigma approach. It supports them very well during the entire project. Furthermore, the scientific "data driven" approach is helpful in dealing with resistance during the implementation of the results. Data appears to be very convincing and in many occasions, leaving little room for resistance driven by emotions. Our Black Belt performed the role of Master Black Belt. Two experienced trainers from a consultancy agency supported her.
Most of the projects had to deal with problems in the areas of accounts receivable, patient logistics, invoicing, medication, temporary workers, and length of stay in the hospital. Three projects all concerning the nursing departments will be presented in the next sections as case studies. They all show that Six Sigma, despite its origin from industry, can work equally well in healthcare. One project had to do with shortening the length of stay of gynecology patients, another project dealt with reducing preparation time of intravenous medication, and the third project had to do with reducing costs for temporary workers. In the description of the projects we will follow the DMAIC cyclus (Harry 1997).

Shortening the length of stay of gynaecology patients

In The Netherlands hospitals receive, as part of their budgets, a fixed amount of money for every admission. Therefore reducing the length of stay of patients has a direct impact on the financial results of the hospital because more patients can be admitted. The head of the department of gynecology, one of the participants of the second Green Belt group, has chosen this project.

Define phase

The objective of this project was shortening the stay of gynecology patients that had to undergo an Abdominal Uterus Extirpation (AUE) or a Vaginal Uterus Extirpation (VUE). The financial benefits of this project were estimated to be 57.800 euros. An additional benefit was the possible reduction of the waiting list of this type of gynecology patients. The duration of the project was estimated to be 6 months. The project was carried out by two Green Belts in training. Both Green Belts had one day per week available to spend on the project. Before starting the project a contract has been made in which the appointments between the Green Belts and the

Champion (in this project the managing director) were formalized. The Green Belts, the Champion, and the controller signed this contract.

Measure phase

The so-called Critical To Quality characteristic (CTQ) is the length of the stay of patients with AUE or VUE. This CTQ was defined as: the length of the stay measured in days. Only patients that had to undergo an AUE or a VUE were included. The requirement on the CTQ is to shorten the stay of these patients as much as possible with no additional discomfort for the patients. The measurement of the length of stay by means of the computer system had to be validated. This was done by comparing the length of stay measured with the help of thirty patient dossiers with the results from the computer system. There were no differences found in this sample. Based on these observations we concluded that the measurement system was valid.

Analyze phase

Data of the year 2002 were available. There appeared to be a few outliers. These outliers were analyzed and excluded from the data to perform a capability analysis. The average stay in the hospital of patients with VUE or AUE equaled 7 days, and the standard deviation equaled 2 days. Based on the current performance the Green Belts decided that the objective of this project was to reduce the length of stay for AUE or VUE patients to 4.5 days with a standard deviation equal to 0.6 days. This objective should result in a financial benefit of 63.520 euros. Factors influencing the length of stay were listed by using a cause and effect diagram and a Failure Mode and Effect Analysis (FMEA).

Improve phase

The most relevant factors influencing the length of the stay were:

- treatment protocols of patients with AUE or VUE; and
- situation at home, i.e. are there relatives that can take care of the patients after discharge.

Changes in the protocols of AUE or VUE patients such as skipping the pre-surgery day directly reduced the length of stay of the patient. The other most fruitful improvements were:

- an out-patient clinic to prepare the patient for the operation (this action reduces the length of stay of patients with one day);
- improved protocols;
- check on the situation at home and offer home care if needed; and
- information about the length of the stay given to the patient in advance.

Control phase

All above-mentioned improvements have been implemented in March 2004. At this moment (May 2004) the average length of stay equals 5.2 days and the standard deviation equals 0.9 days (based on 15 patients). Further reduction of the length of stay is expected after this initial phase.

Shortening the preparation time of intravenous medication

In our hospital every nursing department has facilities to prepare intravenous medication. When a patient needs intravenous medication, it is prepared in the nursing department by a registered nurse. The medication is admitted by means of an intravenous drip. This procedure was rather inefficient.

Define phase

The objective of this project was to shorten the preparation time of intravenous medication. The financial benefit of this project was estimated to be around 20.000 euros. Furthermore, in the near future due to new Dutch legislation it will be necessary to prepare intravenous medication under strict controlled conditions in a flow closet. An additional one-time benefit of 21.000 euros could be realized, when the installation of flow closets was minimized. The duration of the project was estimated to be six months. The project was carried out by two Green Belts in training. Both Green Belts had one day a week available to do the project. One Green Belt is a nurse and the other one an employee of the pharmacy department. A contract has been made wherein the appointments between the Green Belts and the Champion are formalized. This contract was signed by the Green Belts, the Champion (in this case the managing director), and the controller.

Measure phase

The CTQ was the preparation time of one dose of intravenous medication. The total preparation time of the dose was measured using a stopwatch. A Gage R&R study on the stopwatches was successfully carried out in an earlier Black Belt project. The unit is a medication order and the population consists of all medication orders. The requirement on the CTQ is that the preparation time has to be as small as possible.

Analyze phase

Data analysis revealed that the process is in control with mean preparation time equal to 165 seconds and standard deviation equal to 50 seconds. The objective of this project was to reduce the mean and the standard deviation of the preparation

time as much as possible. Brainstorming techniques were used to find the relevant factors that influence the preparation time.

Improve phase

The most important influence factors of preparation time of the injection on the nursing department are:

- interruptions;
- absence of a supervisor;
- number of injections to be prepared; and
- workload in the department.

An experiment was carried out to prepare intravenous medication in the pharmacy department. Eight runs of 30 doses were prepared. This resulted in a mean preparation time per injection of 104 seconds and a standard deviation of 12 seconds. Based on these results it was decided to transfer the preparation activities from the nursing departments to the pharmacy. The new approach also solved the problems of interruptions, workload at the nursing department and the absence of the supervisor. Improvement actions were also set up to further reduce the preparation time at the pharmacy.

Control phase

New instructions to the nurses are introduced. A training program has been scheduled and executed. At the pharmacy the medication is injected directly in infusion fluid. The annual savings compared with the procedure at the nursing departments are 33.600 euros.

Improved checks on invoices of temp agencies

The Red Cross Hospital spends more than one million euros a year on hiring temporary personnel. There was no circumscribed procedure for hiring temp workers. The different departments all had their own contacts with temp agencies. Every temp agency used its own worksheet and it was very hard to verify the corresponding invoices. This situation led to a substantial administrative workload. Once reviewed, we discovered a significant number of invoices that contained discrepancies. Most of the time these mistakes were in favor of the temp agency (reasons unknown).

Define phase

The objective of this project was to reduce the number of mistakes on the invoices. The CTQ was the number of invoices we received from the temp agency that were

correct. The financial benefits of this project were estimated to be 20.000 euros. The expected duration of the project was six months. The project was carried out by two Green Belts in training. Both Green Belts had one day per week available to do the project. Both Green Belts were involved in hiring temporary workers. The Green Belts, the controller and the Champion (the managing director) signed a contract.

Measure phase

A declaration form is used by the temp agency to produce an invoice. The project has focused on both the accuracy of declaration forms and invoices. To make the CTQ, the number of correct invoices, operational the Green Belts used the following criteria to check the declaration form:

- Are the breaks registered?
- Are the total working hours in accordance with the agreement?
- Are there any other obvious mistakes?

The invoices were checked on:

- Is the number of hours spent by the temp worker correct?
- Is the irregularity bonus applied correctly?
- Are there any arithmetical mistakes?

With these checks five categories of the CTQ can be distinguished:

I. Both the declaration form and the invoice are correct.
II. The declaration form is correct and the invoice is incorrect.
III. The declaration form is incorrect and the invoice is correct.
IV. The declaration form is incorrect and the invoice may be easily corrected (i.e. the mistakes in the declaration form are corrected in the invoice).
V. The declaration form is incorrect and the invoice is incorrect (i.e. beside the mistakes in the declaration form additional mistakes have been made in the invoice).

The validation of the measurement system is achieved by executing an experiment. Two operators independently judged 25 declaration forms on two separate occasions. The results of the experiment were that every declaration form was judged four times in exactly the same way. We could conclude that the measurement system is precise enough to meet our expectations.

Analyze phase

Declaration forms of the last three months (117 forms) have been analyzed. In the table an overview of the results are given.

The current performance is that only 15 percent of the declarations forms and the corresponding invoices are correct. The objective is to improve this percentage to 100 percent. This implies a financial impact of 36.000 euros annually. Influence factors are usually found by specific knowledge, an exploratory study and brainstorming. These three methods delivered a great variety of possible influence factors. Based on an exploratory analysis it was discovered that the irregularity bonus did not fit with the collective wage agreements because the temp agencies did not use the maximum allowed percentage. So the amount on the invoice was often too high. A brainstorm session led to the following influence factors:

Category	Percentage
I	15 percent
II	21.5 percent
III	15 percent
IV	26.5 percent
V	22 percent

Table: Results of the analysis of declaration forms and corresponding invoices.

- signature of the head of the department is missing;
- no check on the hours worked;
- breaks not registered;
- mistakes made by the temporary worker with respect to hours worked and traveling costs;
- no check on the number of years experience of the temporary worker; and
- the hourly wage on the invoice is incorrect.

Improve phase

The relation between the influence factors and the CTQ appeared to be very close. We choose the following actions to diminish the number of mistakes.

- We introduced a standardized worksheet for every temp worker.
- The requests for temp personnel are centralized.
- We introduced an administrative system to check the irregularity bonus and the invoice.
- We reduced the number of temp agencies.

With these improvements the majority of mistakes can be eliminated.

Control phase

A new procedure has been introduced for hiring temp personnel. The heads of the department are required to use the new standard worksheet. With this worksheet one can easily check all the relevant data. The corresponding invoice can be made in advance and compared with the invoice sent by the temp agency to establish the discrepancies.

Conclusions

Six Sigma has been introduced in the Red Cross Hospital as quality improvement system in addition to our ISO 9000 quality management system. We have chosen to run the projects with Green Belts. Employees were very enthusiastic about the Green Belt training itself, moreover how the training supported them during their projects. We have showed three projects in the nursing departments all rendering more savings than were estimated at the beginning. Until recently, Six Sigma was predominantly used in industry. Based on our experiences, it can be concluded that Six Sigma, is also applicable in healthcare.

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Chapter 6

Six Sigma: The Results

This chapter is based on:

Six Sigma in Healthcare: Lessons Learned from a Hospital.
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By:
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Ronald J.M.M. Does
John P.S. Verver

Introduction

Six Sigma is an integrated approach for pursuing continuous improvement of customer satisfaction as well as organizational profits (Snee 2004). Six Sigma was developed at Motorola in 1987. In the mid-1990s General Electric started implementing Six Sigma. The GE 1997 Annual Report states that Six Sigma delivered more than 300 million US dollars to its operating income. Subsequently many companies, such as, American Express, Boeing, Citibank, Ford, and 3M have followed General Electric (Breyfogle 2003). More recently application of Six Sigma has also been suggested in healthcare (Barry 2002; Stahl 2003). We introduced Six Sigma at the Red Cross Hospital with the purpose of enhancing continuous improvement in combination with our ISO quality management system. ISO and Six Sigma have proven to be highly complementary in other organizations (Warnack 2003). In this chapter, we first describe Six Sigma. We then demonstrate the implementation of Six Sigma in our hospital. Finally we present our results and discuss our experiences.

Six Sigma

Organizations that implement Six Sigma invest in quality improvement, cost reduction and efficiency improvement. The term Sigma, used by statisticians, defines the standard deviation of a random variable. A number of times sigma indicates the amount of defects that are likely to occur in a given (production or service) process. A three sigma process, for example, has a defect rate of 6.7 percent, while a Six Sigma process has only 3.4 defects per million opportunities. The objective to achieve processes to perform at Six Sigma-level symbolizes the systematic pursuit of breakthroughs. Defects cause an increase in costs. Six Sigma reduces costs by reducing the number of defects (Bisgaard, 2000). Several variants of the program are current (e.g. Harry 1997; Breyfogle 2003).

In order to quantify the performance of a given process a Six Sigma project starts by defining and implementing relevant measures and metrics, the so-called Critical To Quality characteristics (CTQs). Six Sigma tackles performance problems in four phases: Measure (M), Analyse (A), Improve (I) and Control (C). These phases consist of twelve steps that guide a project leader in the execution of a quality improvement project (Harry 1997). In addition to this stepwise project approach Six Sigma contains an organizational structure. Project leaders called Black Belts or Green Belts are trained in project management, problem solving methodology, and statistical methods. The stepwise strategy that Black Belts and Green Belts follow enables them to make a proper problem definition and a data based diagnosis before undertaking attempts at solving the problem. Tools used in Six Sigma, such as Quality Function Deployment (QFD) and Pareto analysis, link customer demands

to product features and establish the relative importance of various problems. Managers in their role of coach (the so-called Champions) review the progress of a project and ensure that the Black Belts and Green Belts focus on the interests of the organization. Experts on the Six Sigma methodology are called Master Black Belts and they are responsible for managing the Six Sigma organization. Through this structure, Six Sigma is able to combine the available knowledge from the various functions in an organization to achieve the best possible process improvements (Jensen 1998). The focus of Six Sigma on data and the statistical verification of conclusions have proven to be a good counterbalance to the often more subjective and intuitive way of working in healthcare.

Experiences with Six Sigma in healthcare

One of the first healthcare organizations to fully implement Six Sigma was Commonwealth Health Corporation in 1998 (Thomerson 2001). This was achieved with the help of consultants from General Electric. The Commonwealth Health Corporation has 500 plus beds and is a multi-site health system with headquarters in Bowling Green, Kentucky, USA. The implementation gave positive results. Throughput in the radiology department was improved by 33 percent and costs per radiology procedure decreased by 21.5 percent. At the beginning of 2002 Commonwealth had invested about 900.000 US dollars in Six Sigma which lead to improvements in excess of 2.5 million US dollars (Lazarus 2002a). A number of healthcare organizations have followed the example of Commonwealth Health Corporation with even better results (Sehwail 2003). Mount Carmel Health System, a three-hospital system in Columbus, Ohio with 7.300 employees reported a financial return of 3.1 million US dollars with expectations for these financial returns to grow rapidly as more Six Sigma projects are completed (Lazarus and Stamps 2002a). Charleston Area Medical Center, a 919-bed three-campus medical center in West Virginia, achieved 841.000 US dollar savings on supply chain management by using Six Sigma (Lazarus 2002b). Thibodaux Regional Medical Center, a non-profit 149-bed hospital in Louisiana, started implementing Six Sigma in 2001. In May 2002 they reported a savings of more than 475.000 US dollars per year (Stock 2002). Earlier reports of our own experiences at the Red Cross Hospital in Beverwijk, the Netherlands, were equally convincing (Van den Heuvel et al. 2004).

Implementation and results at the Red Cross Hospital, Beverwijk

The Red Cross Hospital is a general hospital with 384 beds located in The Netherlands with an annual budget of 72 million euros. The Institute for Business and Industrial Statistics at the University of Amsterdam supported the implementation of Six Sigma in this hospital. It started with the one-day introduction training for management

and directors. In order to implement Six Sigma successfully, some apparent minor adaptations were necessary. First we reduced the threshold for initiating a project from 100.000 to 20.000 euros. Secondly, we only used Green Belts to run the projects. Finally, Green Belts were allowed to run the projects in couples, rather than one Belt per project.

The first group of fifteen Green Belts started their training in September 2002. Seven projects were initiated. To stimulate commitment, participants were allowed to choose the subject of their projects. In February 2003 the second group of Green Belts started. The hospital directors incited managers to train a sufficient number of Green Belts and maintain a substantial program of new projects. Gradually project selection was taken over by management to ensure alignment with the strategic goals of the hospital. As the number of projects increased the necessity for co-ordination and management of the Six Sigma program became evident. We observed that Green Belts faced difficulties with closing their projects. Decisively we appointed a Master Black Belt to set up a management control system to evaluate progress and to support Green Belts in finishing their projects. The Master Black Belt organized the necessary training programs and ascertained that once Green Belts completed a project they initiated another project. In September 2004, the fifth group of Green Belts began with their projects. Co-workers show more and more interest in following a Green Belt training. We have consistently started new groups of approximately fifteen employees every six months. Participants emerge from different departments and disciplines within the organization. We developed a special training for medical specialists. Recently we started training employees from partner-organizations, such as home care and a nursing home, to initiate projects that improve co-operation, communication and quality of care.
Table 1 shows the cumulative number of Green Belts trained and the number of projects that have been initiated.

Six Sigma	2002	2003	2004
Green Belts	15	38	63
Projects	7	19	44

Table 1. Numbers of Green Belts and Six Sigma projects.

Currently 44 projects have started and 21 projects are closed. The total savings amount to 1.2 million euros. The expected total net annual savings of all running projects are estimated at 3 million euros. These amounts are cumulative savings on an annual basis.

Table 2 shows the development of savings and costs per year.

Six Sigma	2002	2003	2004	Total
Costs	40.000	88.000	101.000	229.000
Savings	0	0	1.268,000	1,268.000
Results	-/- 40.000	-/-88.000	1.167.000	1,039.000

Table 2: Savings and Costs in euros of the Six Sigma approach.

Costs are related to training, consultancy and hospital personnel that have been employed to support the Six Sigma organization. The salaries of Green Belts were only included when extra personnel had to be employed to replace them. Savings are actual achieved total net savings from all running and completed projects. They include reductions in labor time spent by employees; only if this time could be utilized elsewhere.

Table 3 shows a number of projects and their estimated target savings and actual annual savings.

Project	Target savings	Annual savings
Improving patient scheduling Operating Theatre	50.000	229.000
Reducing accounts receivable	20.000	225.000
Optimizing technical maintenance	20.000	211.400
Reducing formation of physiotherapists	25.000	64.400
Revision of terms of payment	20.000	60.000
Reducing admission time hip replacement	46.000	56.000
Reducing admission time after delivery	25.000	56.000
Improving logistics linen distribution	50.000	44.000
Availability ambulatory files	37.000	37.000
Reducing waiting times first contacts cardiology	34.000	34.000

Table 3. A selection of Green Belts projects (savings in euros).

We have been able to initiate Six Sigma projects in almost any unit and relate it to every discipline in our hospital (Van den Heuvel et al. 2005). As mentioned before we use an amount of 20.000 euros as a threshold for initiating projects. Based on 21 projects the average savings per project mount to 68.000 euros.

Lessons learned from the implementation of Six Sigma in a hospital

A number of areas can be identified that are particularly profitable to initiate projects.

The first group of projects where substantial savings can be realized quite easily are related to reducing admission time. To achieve this, the clinical pathway of a given disease has to be described and optimized using various Six Sigma and Lean tools (George 2003). This will invariably lead to considerable cost reductions because currently the full content of a clinical pathway is seldom analyzed and evaluated from the perspective of every participating healthcare provider. Therefore, redundancy in activities, examinations and administration resulting in unnecessary costs is most likely to occur in many clinical pathways. In the end, optimizing a clinical pathway as described above will lead to a shortening of admission time or at least in reducing variability of admission time. Shortening admission time, due to the nature of the Dutch funding system, has a positive net effect on the budget because more patients can be admitted using the same capacity. Reducing variability in length of stay facilitates planning and subsequent optimal usage of the available bed capacity also. Financial savings related to reducing variability have until now been underestimated in our hospital.

A second group of projects has to do with minimizing the use of materials and devices. For example, intravenous medication is changed in oral medication at the earliest possible moment, or reducing the number of intravenous pumps by pooling.

A third group of projects pertained with the optimal use of available capacities such as the capacity of the operating theatre. Starting operations on time and making the most of available timetables through flexible planning can do this. The same goes for optimizing the use of costly diagnostic scanners such as MRI and CT.

The fourth group of favorable Six Sigma projects is related to reducing the amount of staff that has to be employed. Approximately seventy percent of our annual budget consists of costs related to personnel. Therefore reducing the number of employee activities or tasks within a given process and optimizing personnel scheduling can lead to substantial savings.

The fifth group consists of all activities that are directly related to improve cash flow. Reducing accounts receivable, which produced 225.000 euros annual savings, appeared to be a very successful project in this category. Also a revision of terms of payment was quite beneficial.

Apart from the financial benefits, Six Sigma made an important contribution to the improvement of quality of healthcare. Unlike in industry where a defective product

can be rejected without any problem, in healthcare defects and rework directly affect the patient and therefore the patient's perception of quality. Shorter waiting lists, elimination of unnecessary examinations, reducing the number of defects as well as complications and improving the output of the care process directly contribute to the improvement of the quality of healthcare. Every Green Belt needs to indicate the amount of savings before starting his project and monitor progression. This explicit focus on savings caused some resistance. One got the impression that quality of healthcare had been made subordinate to money. In fact, we noticed that Six Sigma made an important contribution to the improvement of quality of healthcare. Especially in healthcare Six Sigma seems to work both ways; costs are eliminated and quality is improved (Kooy 2002). The introduction of Six Sigma in a hospital stimulates a culture of awareness to find opportunities to improve healthcare delivery and to take responsibility to eliminate shortcomings. In the past, decisions were too often based on assumptions and feelings as well as inaccurate and incomplete information. By utilizing Six Sigma, today co-workers take responsibility and provide management with solutions based on facts and data.

In the Red Cross Hospital a quality improvement system was already developed and functioning, within the framework of our ISO 9000 quality management system. Project selection, however, appeared to be difficult. We did not have at our disposal a standardized project management approach, which lead to significant waste of time and effort with initiating and running projects. Since we combined projects with regular tasks without giving employees time off to focus on running their projects, results were delayed. This in fact cost more money because savings were postponed. In Six Sigma possible savings of every project are estimated in advance. Based on our estimations, we determine which project requires highest priority. The progress of Six Sigma projects is very easy to manage due to the uniformity of the project approach with twelve steps and well defined outcomes. This transparency has proven to be a very powerful management tool supporting directors and managers in defining and accomplishing the right projects. Cost reductions bear the risk to affect quality of healthcare in negative way. Therefore ISO 9001:2000, with a strong emphasis on quality assurance, combined with Six Sigma emphasizing efficiency improvement, was an excellent combination in our hospital. Further integration of our ISO quality management system and Six Sigma was advantageous because both systems are focused on processes, are client oriented and data driven.

As in other service organizations, we also encountered some difficulties in introducing quantitative methods (Does 2002). Now, when employees in our

hospital face an opportunity for improvement they will often make quantitative analyses and calculations themselves. They will also give indications as to how the improvement will contribute, for instance to the financial aims of the hospital. Facts based on data prove to be strong arguments to convince medical specialists to change to a different method of working.

Quality improvement programs often focus on realizing the larger and prestigious improvement projects. Furthermore, only few privileged employees are allowed to participate in the program. In our experience employees attention returns to daily tasks after a while and they inevitably lose interest in the program. With Six Sigma we have invested in an infrastructure and do not promote specific projects. Thanks to this infrastructure, every trained employee can start and accomplish any improvement project within a short time and with little effort.

At the beginning of 2004 our hospital faced a budget deficit threat of 1.5 million euros. Instead of discharging employees, managers were asked to define and start enough projects for 2004, resulting in savings that could eliminate the deficit. As we had gained enough experience with Six Sigma and a sufficient number of trained Green Belts were available, we managed to find the required amount of savings. Presently, we are ahead of reaching this goal. This outcome clearly proves how Six Sigma is a major contribution to the continuity of our hospital.

The Institute of Medicine (IOM) produced in 2003 a report demonstrating that healthcare has serious safety and quality problems and is in need of fundamental change. Care processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays. Waste is identified as an important contributor to the increase in healthcare expenditures. To better serve the needs of patients, healthcare systems have to be redesigned (Institute of Medicine 2001). In our opinion, Six Sigma is able to address a number of the problems mentioned by the IOM by improving care processes, eliminating waste and enhance patient satisfaction.

Conclusions

The Red Cross Hospital has successfully implemented Six Sigma and integrated it within the ISO 9001:2000 quality management system. In doing so, we have produced 1.2 million euros in annual savings. Training employees and have them initiate Six Sigma projects reduced costs and improved quality of healthcare. The results are comparable with those in industry and other hospitals. Since the Six Sigma organization in our hospital is still expanding, we expect to achieve

greater substantial savings in the near future. The fact that Six Sigma successfully combines quality improvement and cost reduction substantiates that it could be a solution to present day financial problems in healthcare.

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Chapter 7

Six Sigma: Why does it work even better in Healthcare?

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Today's healthcare problems

The Institute of Medicine (IOM) produced two reports demonstrating healthcare has serious patient safety and quality problems and is in need of fundamental change. Care processes are poorly designed and characterised by unnecessary duplication of services and long waiting times and delays. Costs are exploding and waste is identified as an important contributor to the increase in healthcare expenditures. As a result healthcare consistently does not succeed to meet patient's needs. To better serve the needs of patients, healthcare systems have to be redesigned (IOM 1999; IOM 2001). Despite these dazzling conclusions very little has been achieved in the past years. In this chapter we demonstrate that Six Sigma can solve the problems mentioned by the IOM by improving care processes, eliminating waste, reducing costs and enhancing patient satisfaction. First we will describe Six Sigma. Then we demonstrate some examples of successful Six Sigma implementations in healthcare. Next we illustrate why Six Sigma is especially powerful in healthcare. Finally, we draw some conclusions about the future possibilities of Six Sigma.

What is Six Sigma?

Six Sigma is a philosophy for company wide quality improvement. It was developed by Motorola in 1987 and popularized by General Electric in the late Nineties (Snee 2004). Subsequently, many companies such as American Express, Boeing, Citibank, Ford, and 3M have followed General Electric (Breyfogle 2003). More recently application of Six Sigma has also been suggested in healthcare (Barry 2002; Stahl 2003). Organizations that implement Six Sigma invest in quality improvement, cost reduction and efficiency improvement. The Sigma level indicates the defect rate in a given (production or service) process. Defects have serious implications: they increase costs, increase lead time and reduce quality. Six Sigma tackles these problems by reducing the number of defects (Bisgaard 2000). Several variants of the program are current (Harry 1997; Breyfogle 2003).

Six Sigma entails an elaborate organizational structure of project leaders and project owners. Six Sigma project leaders are called Black Belts and/or Green Belts and constitute a well-trained task force. The scale and resources committed to Six Sigma projects are unprecedented in the history of quality improvement. An experienced Black Belt can be appointed as a Master Black Belt. The Master Black Belt is fully dedicated to coaching and training Black and Green Belts, while having expertise in advanced (statistical) tools. Apart from Green — and Black — Belts, (top) management plays the role of project owner/coach and they are called Champions. Through this structure, Six Sigma is able to combine the

available knowledge and experience from various functions in an organization to achieve the best possible process improvements (Jensen 1998).

Deployment of the Six Sigma program is done by carrying out improvement projects. Part of the Six Sigma program is a twelve step 'Breakthrough Cookbook', a problem-solving method "specifically designed to lead a Six Sigma Black or Green Belt to significant improvements within a defined process" (Harry 1997). It tackles problems in four phases: Measure (M), Analyze (A), Improve (I) and Control (C). In more recent accounts of the methodology a Define (D) phase precedes the other four in which projects are defined in three steps (Breyfogle 2003). First suggestions for potential projects are collected. Suggestions can be made bottom up by for instance (Black) Green Belts who are familiar with operational problems and flaws, or top down related to strategic issues by senior management, i.e. Champions. Projects may be related to problems in healthcare processes, hospital strategy, customer (patient) demands or costs of poor quality. For each suggested project, a Black (Green) Belt is selected. The Black (Green) Belt is the intended person for conducting the project. He should have context knowledge about the problem and relevant hands-on experience. In the second step in the Define phase the Black (Green) Belt makes the project proposal which consists of a business case, a planning, and an organizational context. Finally the Master Black Belt and the Champions prioritize the proposed projects and select the most promising ones. The prioritization is based on quality improvement potential, financial benefits, positive side effects, strategic impact and feasibility to complete the project within 4 to 6 months. A project is only started if a certain amount of net savings can be achieved.

Note that in a Six Sigma project a problem is studied to find its causes, and to develop a solution. Problems that have a known cause or a known solution do not require a Six Sigma approach but just need someone to implement the solution. In the Measure phase the problem is translated into a measurable form by means of a so-called Critical To Quality (CTQ) characteristic. The analysis of the current situation and the identification of influence factors of the CTQ take place in the Analyze phase. In the Improve phase Black (Green) Belts design and implement adjustments to the process to improve the performance of the CTQ. Finally, in the Control phase the process management and quality control system are adjusted to assure that improvements are sustainable. Each of the four phases M, A, I and C consists of several steps, as shown in the scheme on the next page, which guide a project leader through the execution of an improvement project (Harry 1997).

DEFINE	Project identification, Project proposal, Project selection
MEASURE	1. Select internal Critical To Quality (CTQ) 2. Operationalize the CTQ 3. Validate measuring procedure
ANALYZE	4. Determine process performance 5. Determine project goals 6. Identify potential influence factors
IMPROVE	7. Select most important influence factors 8. Establish relationship between CTQ and influence factors 9. Design improvement actions
CONTROL	10. Adjust quality control system 11. Determine new process performance 12. Close the project

Six Sigma Breakthrough Cookbook.

Tools used in Six Sigma, such as Quality Function Deployment (QFD) and Pareto analysis, link customer demands to product features and, supported by various statistical techniques, establish the relative importance of various problems. Managers in their role of coach, the so-called Champions, review the progress of a project and ensure that the Black Belts and Green Belts focus on the interests of the organization.

Experiences with Six Sigma in healthcare

One of the first healthcare organizations to fully implement Six Sigma was Commonwealth Health Corporation in 1998 (Thomerson 2001). This was achieved with the help of consultants from General Electric. At the beginning of 2002 Commonwealth had invested about 900.000 US dollars in Six Sigma which lead to improvements in excess of 2.5 million US dollars (Lazerus 2002a). A number of healthcare organizations have followed the example of Commonwealth Health Corporation with even better results (Sehwail 2003). Mount Carmel Health System, a three-hospital system in Columbus, Ohio with 7,300 employees reported a financial return of 3.1 million US dollars (Lazerus 2002a). Charleston Area Medical Center, a 919-bed three-campus medical center in West Virginia, achieved 841.000 US dollar savings on supply chain management by using Six Sigma (Lazerus 2002b). Thibodaux Regional Medical Center, a non-profit 149-bed hospital in Louisiana, started implementing Six Sigma in 2001. In May 2002 they reported a savings of more than 475.000 US dollars per year (Stock 2002). Fairview Health Services (FHS) in Minneapolis, one of the four major healthcare providers in the Twin Cities area, had begun with a partial deployment of Six Sigma in February 2002. Even before completing

analyses of the pilot projects, FHS decided to proceed with full deployment. Leaders developed strategic and communication plans, allocated resources, and provided for further training. In 2005, three years after the initial implementation period, Six Sigma has resulted in a system wide method for setting priorities for performance improvement projects, supported by a web-based system for managing, tracking, monitoring, and communicating results (Christianson, 2005).

The Red Cross Hospital in Beverwijk, The Netherlands, is a 384-bed medium sized general hospital. With an annual budget of 90 million US dollars in 2004 the hospital admitted 12.669 patients, treated 11.064 in its day care facilities and performed 78.832 outdoor first contacts. A national 25 bed burn care center is part of the hospital. Six Sigma was introduced at the Red Cross Hospital with the purpose of enhancing continuous improvement. This was done after completing and complementary to the ISO 9001 quality management system which was certified in 2000 in our hospital (Van den Heuvel et al. 2005a). ISO and Six Sigma have proven to be highly complementary in other organizations (Van den Heuvel et al. 2005b; Warnack 2003).

Six Sigma was initiated at the Red Cross Hospital by an external consulting company during a one-day training for the management team consisting of two directors and the managers of four divisions at the end of 2001. Topics in the one-day training were: Six Sigma in relation with other quality improvement programs; project identification and selection; roles of Black and Green Belts and Champions; the Six Sigma methodology DMAIC; case studies. Our quality manager attended in the first half of 2002 the intensive Black Belt training and in September 2002 sixteen employees started an in-company Green Belt training. During the Green Belt training every participant was required to participate in a Six Sigma project. One director and the managers of the divisions also participated in this first wave of Green Belt training. During the course, consisting of two separated periods of three days, every participant had to produce specific results. No Green Belt project was allowed to pass to the next phase until the preceding phase was completed. The participants had to present their results twice before the entire group. In the second presentation they presented the final results of their project. Because of the size of our organization we used Green Belts instead of Black Belts to perform the projects. Projects were carried out by two or three Green Belts. Our Green Belts typically spend one or two days a week on their project. We use a 25.000 US dollars estimated savings as our financial threshold for initiating a project. This amount was appropriate considering the actual budget and the savings potential of our organization. After the first group we immediately started a second group of 15 Green Belts in February 2003, a third group of 13 Green Belts in September 2003,

a fourth group of 14 Green Belts in February 2004 and a fifth group of 17 Green Belts in September 2004.

Participants are enthusiastic about the Six Sigma approach. It supported them well during the entire project. The scientific "data driven" approach is helpful in establishing sufficient support to implement the results of a project. The data can be convincing and in many occasions they leave little room for resistance driven by emotions. Initially, the hospital's Black Belt performed the role of Master Black Belt on a part-time basis. Because we wanted to deploy Six Sigma relatively fast, we decided to employ a full time Master Black Belt from outside our organization. Fortunately, we were able to contract a highly experienced Black Belt from DAF, a Dutch truck manufacturer now owned by Paccar. Successfully employing a Black Belt with previous experience from outside the healthcare sector was only feasible because the Six Sigma "language" is universal and independent of the type of industry. More recently, we received an offer from 3M, a company with a reputation for having successfully implemented Six Sigma throughout its worldwide organization, to support us in further developing our Six Sigma organization. The total savings in 2004 amount to 1.4 million US dollars. Based on 21 projects completed in 2004 the average savings per project totals 67.000 US dollars. The expected total net annual savings of all running projects are estimated at 3.6 million US dollars (Van den Heuvel et al. 2005c). We have been able to initiate Six Sigma projects in almost any unit and relate it to every discipline in our hospital (Van den Heuvel et al. 2004).

At the beginning of 2004 our hospital anticipated serious financial problems. Management embraced the Six Sigma organization to initiate an additional number of smaller "quick win" projects (low hanging fruit) instead of discharging personnel. This program resulted in extra savings up to 1.2 million US dollars. The Annual Report of 2004 consequently showed an, in our history, extraordinary net result of 2.4 million US dollars. Six Sigma was a fact.
It needs leadership to start Six Sigma, coming from a totally different environment, in your healthcare organization. This leadership, however, produces substantial results in less than half a year when the first group of Green Belts appears to be very enthusiastic and presents their achievements on quality and costs. When more and more results are produced, as shown above, and an increasing number of employees want to be trained as a Green Belt, motivation is no longer the issue.
Special attention is required to expand the Six Sigma organization in a controlled manner as was done by our Master Black Belt. The ingredients of Six Sigma are very similar to those of Total Quality Management (TQM). Leadership, culture, philosophy, technical and analytical skills, structure and organization, people skills and above all customer focus are the key elements of TQM as well as Six Sigma

(Gaucher 1993). Although we tried to implement TQM in our hospital, it never produced the turn around and results we achieved with Six Sigma. In our opinion there are two reasons that can account for this observation. First, Six Sigma gives very detailed prescriptions about the way it should be implemented and tools that have to be used. After starting with Six Sigma one could say that everyone's role, tasks and activities are defined for the coming year. TQM is much less specific and more philosophic. Second, TQM focuses on management first to promote the philosophy and motivate employees. Six Sigma focuses on employees, teaches them and gives them the proper tools to solve their every day problems. This is all embedded within a larger organizational framework and overall philosophy and culture. So compared to TQM, Six Sigma works the other way around and creates a large number of motivated and successful ambassadors of quality.

Why industry and healthcare differ and Six Sigma works even better in Healthcare

To fully understand the potential of Six Sigma in healthcare quality management we have to take a closer look at the way quality is defined (Donabedian 1987). Garvin has identified five major approaches of defining quality in industry (Garvin 1984). Most existing definitions of quality fall into one of these approaches. The first one is the transcendent approach of philosophy, which states that quality is innate excellence and cannot be defined. The second one is the product-based approach of economics, which states that quality reflects the presence or absence of measurable product attributes. In this approach more quality (attributes) means more costs. Thirdly the user based approach of economics, marketing and operations management states that individual consumers have different wants or needs and those goods that best satisfy their preferences have the highest quality. The fourth, manufacturing based approach defines quality as conformance to requirements. Designs of the product and the manufacturing process have to lead to the lowest possible costs. Improvements in quality, so reductions in defects, lead to lower costs. The fifth approach is called the value-based approach of operations management. According to this approach, a quality product is one that provides performance at an acceptable price of conformance at an acceptable cost. Garvin concluded that reliance on a single definition of quality is a frequent source of problems for any company. Companies need to cultivate these different approaches.

We will now illustrate the power of Six Sigma in healthcare by looking at the different quality approaches. The transcendental approach, unfortunately, is often used by healthcare professionals. However, neither to be able to define nor to measure quality will severely impede quality improvement initiatives. Six Sigma stimulates healthcare

workers to define, measure and improve aspects of quality. The focus of Six Sigma on data and statistical verification have in our hospital proven to be an excellent counterbalance to the often more subjective and intuitive (transcendental) way of working in healthcare. Looking at the product based, client based and manufacturing based approaches in healthcare we observe a very interesting phenomenon. Our patients are not only our clients, but they also are our product (we replace parts) and they are the most important element of our manufacturing (i.e. healthcare) process. So there are three quality definitions applicable at the same time. Therefore we are obliged to manage all three quality approaches in relationship to each other during the entire healthcare process. This largely explains the complexity of our work and the vast challenges we face in quality management in healthcare.

We once asked our Master Black Belt having five years of experience at a large truck manufacturing company the following question: "What would happen if the future truck driver is on the truck you are assembling during the entire production process, asking questions, adding new wishes and being annoyed by waiting times and paint spilled on his trousers?" He admitted; the entire plant would become a mess! This, however, is daily practice in every hospital and explains the origin of a quality chasm in healthcare.

Due to the fact that the patient is part of the manufacturing process, improving the quality of the healthcare process will by definition lead to lower costs and higher quality of care. This quality of care will manifest by shorter waiting times and length of stay, reduce the number of examinations and a decrease in the number of defects, such as errors, unnecessary interventions and complications. Furthermore, Six Sigma links client demands to product attributes. This prevents healthcare workers to deliver care patients do not expect to be delivered and this also reduces costs. So especially in healthcare Six Sigma seems to work both ways; costs are eliminated and quality is improved (Kooy 2002). The fact that the patient is part of the manufacturing process also provides an explanation for patient safety problems as pointed out by the IOM. In industry a high quality product can be manufactured regardless or even because of the fact that a large number of (imperfect) products are rejected. The customer only experiences the high quality product and is neither aware nor inflicted by the undesired output of an imperfect manufacturing process. Unlike industry where a defective product can be rejected without any problem, in healthcare an imperfect (healthcare) process that produces defects and rework directly affect our patient's safety. The positive effect of Six Sigma on reduction of medical errors has been described earlier (Buck 2001). Therefore Six Sigma is a powerful instrument to improve patient safety by reducing the number of defects produced by the healthcare processes. Looking

at the fifth and final, value-based approach, we see that contrary to industry, pricing mechanisms do not function very well in healthcare. In general patients just want maximum quality and insurance companies want to pay the lowest price. We do not know of hospital imbursement systems that explicitly reward additional quality of care. As a result the hospital, and especially the quality of care, is torn between these conflicting demands. The only sensible policy for any hospital in order to pass both Scylla and Charybdis, is to maximize efficiency while at least preserving quality of care. The best way to achieve this, as we illustrated above, is to invest in healthcare process improvement because this will invariably lead to lower costs and higher quality of care. In this respect Six Sigma with its primary focus on process improvement provides the best quality management tool to healthcare organizations.

Three examples of successful projects

The first example is a project that aimed at optimizing the usage of our operating rooms just by starting on time in the morning and utilizing all available time. Our official starting time is 8:00 am. Data collected in the Measure phase showed that the average starting time was 8:33 am. During the Analysis phase the Green Belt team identified a number of causes for starting too late:

- patients were brought in late or had not yet been given the proper medication;
- nursing staff was lacking;
- surgeons wanted to make their rounds first;
- anesthesiologists were too late.

The Green Belt team discovered that there was no unique straightforward reason for starting too late but that the underlying problem was a poorly defined planning process. They designed a new admission process based on a few simple rules. First patients must be present at the Operating Theatre no later than 7:35 am. Secondly measurements have to be taken to assure that before arriving at the Operating Theatre patients have received pre-operative medication. Finally the referring department and the anesthesiologist have to be informed one day in advance of a procedure. To control this new planning process visual management was introduced, showing the starting times of the past week. The resulting graph is reviewed weekly. The Six Sigma approach was very helpful to provide real insight in the problem and to avoid the classical blaming of the other party. After one year the starting time appeared to be 8:24 am. With this relatively minor improvement in starting time and better usage of the available time on eight Operating Theaters we were able to increase the number of patients that were operated with 400 and we achieved structural net savings of more than 273.000 US dollars without additional resources. This project clearly shows that lower costs can be combined with an increase of quality by, in this case, reducing waiting times and

especially reducing canceling of operations at the end of the day. Note that every day all over the world operations start too late due to a complex of reasons.

Compared to oral medication, intravenous admission is more prone to produce errors, takes more preparation time of nurses and pharmacy employees, is more expensive and is not very patient friendly. The second example is a project that aimed to reduce the number of intravenous admissions of antibiotics, by switching to oral admission as soon as possible. The CTQ was defined as the percentage of unnecessary intravenous admissions per week. Criteria were developed to determine whether intravenous admission was necessary or not. Measurements were performed at two departments during three months. One department showed 19 percent unnecessary intravenous admissions and the other one showed none. A number of causes were determined such as lack of structured evaluation, i.e. transfer to oral medication was not part of the treatment protocol, criteria to switch were unknown, lack of information about (oral) alternatives and workload at the nursing department. A number of improvements were designed and implemented such as new protocols containing switch criteria and an automatic alert to evaluate medication. Because evaluation through examination of medical files is very time consuming, the results of this project were monitored by measuring the usage of intravenous medication (i.e. a specific type of antibiotics). In September 2002 we observed that 291 intravenous admissions were given. In September 2004 we measured 157 intravenous admissions. The annual savings due to these results based on medication costs only were more than 75.000 US dollars.

Our final example deals with the reduction of admission time after delivery. In our hospital we were facing a shortage of delivery room capacity and it was impossible to increase the number of rooms. The average length of stay of mother and child after delivery appeared to be 11.9 hours. We also noticed that 20 percent of the mothers stayed less than four hours, so we concluded that a reduction of length of stay could be attainable. To achieve this we designed a new protocol with discharge criteria, a check list and additional procedures. We provided information leaflets about the discharge procedure to be distributed by midwifes in the outpatient department and an information booklet “the first hours at home with your baby” to be taken by the mother at discharge. Home care facilities were improved and a new discharge letter to the GP was designed. After implementing all these measures, the new procedure was implemented and we were able to reduce the length of stay from 11.9 to 3.4 hours. By doing this we also achieved a 68.000 US dollars saving. It goes without saying that an increase in the number of delivery rooms was no longer necessary. The mother and father were also happy with this new procedure, because they were well informed and could go home and enjoy their baby as soon as possible.

So in every example we see that costs can be reduced and quality is improved. Improvement of patient safety can also be reported as a valuable "side effect" of Six Sigma. The Institute of Medicine considers patient safety an integral part of quality of care. In the Netherlands policy makers have defined patient safety as an issue on its own requiring separate management systems. By taking the patient as a starting point, Six Sigma prevents division of attention and means and provides a balanced approach with maximum results. In every project we could achieve at least two of the three goals, cost reduction, quality improvement and patient safety. Furthermore we see that assessing the financial savings in fact removes an important roadblock to every project because it actually provides the means to perform the project. Finally, performing measurements and agreement on the validity of the measurement system at the start of every Six Sigma project reduces resistance and leads to positive participation of healthcare professionals and produce successful projects.

The ultimate cure?

Berwick has pointed out the value and necessity of continuous process improvement in healthcare. To successfully achieve this he suggested that healthcare workers have to be involved, tools for improvement (from industry) have to be put in use in healthcare and flexible project teams must be created and trained to tackle complex processes that cross departments. He also stresses the value of process data analyses and the willingness of hospitals to really invest in quality improvement (Berwick 1989). In fact Berwick in 1989 described all elements of a Six Sigma organization as it is functioning in a number of hospitals today as well as in our own hospital producing the predicted results. Six Sigma provides a powerful instrument to really face present day challenges of healthcare management by reducing costs and increasing quality of care. Therefore we dare to state that Six Sigma provides the cure and is capable of guiding us out of the present day situation in healthcare as described by the Institute Of Medicine.

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Chapter 8

Results of Five Years of Quality Management

This chapter is based on:

Quality Management; Does it pay off? Quality Management in Healthcare. 2006: 15(3): 137-149.

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Introduction

The Institute of Medicine (IOM) produced two reports demonstrating healthcare has serious safety and quality problems and is in need of fundamental change. Care processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays. Costs are exploding and waste is identified as an important contributor to the increase in healthcare expenditures. As a result healthcare consistently does not succeed in meeting patient's needs (IOM 1999, 2001). Given these findings quality management becomes a major strategic issue in any hospital. In this article we demonstrate how quality management has been developed and implemented in the Red Cross Hospital in The Netherlands. We will first look at the process of strategy deployment in our hospital and take a brief look at the definition of quality. We then go through the three steps of quality management: quality planning, quality control and quality improvement. Our achievements during a period of five years will be demonstrated by presenting the scores of a number of performance indicators. Finally we will provide some explanations that might account for our results and achievements.

Strategy Deployment

The Red Cross Hospital is a middle sized general hospital with 384 beds located in Beverwijk in The Netherlands with an annual budget in 2004 of 72 million euros. We find ourselves in a very competitive environment having five other hospitals within a 20 kilometers range. The Dutch hospital funding system pays fixed prices for admissions, first contacts and day care treatments. Recently the government initiated the gradual introduction of a new funding system based on so-called Diagnose Treatment Combinations which is similar to the Diagnose Related Groups (DRG) system. Both systems are applied simultaneously at this moment and show great resemblance with a capitation system. The consequences of both systems are that treating more patients provides more income, but delivering more care, higher quality or providing better service, does not. Considering the competitive environment and the characteristics of the Dutch funding system we have chosen as our main strategic goals a moderate growth and minimization of costs, both to provide continuity. Furthermore we aim to optimize quality of care, within the limitations of the fixed prices per episode, in order to attract more patients. Capitation systems are thought to be successful in containing costs, but might be a threat to healthcare quality (Berwick 1996). Cost containment without effective quality assurance systems can endanger quality (Blumenthal 1996; Bliersbach 1988). To be effective, (total) quality management is considered an essential part in the strategic plan of any organization (DeFeo 1999). So given the characteristics of the Dutch funding system and our strategic goals, implementing a well functioning quality management system was considered of vital strategic importance to our hospital.

Where to start?

Quality management begins with defining quality (Donabedian 1987). There are five different approaches to define quality (Garvin 1984). The first transcendent approach states that quality is an innate excellence and cannot be defined or measured. This approach is often advocated by healthcare professionals. As a result it severely impedes quality management because measurement and improvement of quality of care are thought to be hard or even impossible. The second approach is product based and states that quality reflects the presence or absence of measurable product attributes. More quality, i.e. more attributes, in this approach means more costs. The third user based approach assumes that those goods that best satisfy customers preferences have the highest quality. The fourth manufacturing based approach defines quality as conformance to requirements. The design of the product and manufacturing process has to lead to the lowest possible costs. So quality improvement by reducing defects leads to lower costs. The fifth value based approach relates costs to quality. A quality product in this approach is one that provides performance at an acceptable price. Reliance on a single definition is considered to be a frequent source of problems for any company.

A widely used definition of quality states that quality is the degree to which customer wishes are met (ISO 1994). So the first step in defining the level of quality that our hospital has to deliver in order to accomplish its strategy is to determine our clients' wishes. Here we encounter an anomaly in healthcare that is not seen in industry or service organizations. Our "client" appears to have two faces that express at least partly conflicting demands. A patient when entering our hospital expects all possible efforts to be done and maximal quality to be delivered. His insurance company, by nature, wants the lowest possible prices and is not inflicted directly by the (quality) consequences of these prices. This "Dr Jeckill and Mr Hyde like" phenomenon greatly influences quality management, and especially quality planning in healthcare. Another interesting difference between healthcare and industry is the fact that the patient is part of and participates in the manufacturing (i.e. the healthcare) process. Participating in the manufacturing process has as a major consequence that the way the care process is designed and performs directly influences the quality perception of a patient. Storage time for an intermediary product in industry does, in the eyes of the customer, not lower the quality of the final product. In healthcare storage time is equivalent with waiting time which as we know severely affects quality perception by our patients. Waste during a manufacturing process and rejected intermediary products are not noticed by the customer who is buying a car. In healthcare, however, waste and rejects are called complications. On top of this the patient constantly interferes with and severely influences the progression of the healthcare process.

The role our patient plays also affects predictability and therefore the controllability of the healthcare process. So compared to industrial manufacturing the design of a healthcare processes requires vast additional measures to achieve the required level of quality and safety. In our opinion these observations explain the difficulties healthcare is facing today as described by the IOM in achieving acceptable levels of quality. Comparing with and learning from industry is necessary but not sufficient. Healthcare professionals and management have to take into account that healthcare is different from industry and requires additional measures and an innovative approach to improve quality.

Quality management

Quality management consists of three aspects; quality planning, quality control and quality improvement (Juran 1988). In healthcare a similar approach has been suggested (Donabedian 1987). We will now demonstrate in which way the three aspects of quality management have been addressed in the Red Cross Hospital.

Quality planning

Quality planning is a structured process for developing (healthcare) products that ensure that customer needs are met by the final results (Juran 1999). Looking at our "bi personality" client and the five approaches to define quality we will now look into more detail at the choices our hospital has made to determine the level of quality we want to deliver. First we can conclude that according to the value based approach we have to contain our prices regardless the level of quality we intent to deliver. It is nearly impossible for any insurance company to have their clients pay higher insurance contributions to pay higher prices to our hospital. This mechanism also affects the product based approach. More quality (so more attributes) can only be delivered within the limitations of the fixed prices paid to our hospital. So in most cases the more expensive and higher quality hip prostheses will not be implanted, in favor of the medium priced, medium quality prostheses. The same goes for high quality pacemakers, costly endoscopic procedures or expensive innovative medication. So product quality (attributes) in healthcare has to be optimized, not maximized. Fortunately, the manufacturing based approach offers much more strategic opportunities. Here we can serve both masters at the same time. Since the patient is participating in the healthcare process, reducing errors, waiting times, waste, etcetera, directly increases our patients' quality perception. In addition, optimizing the healthcare process not only increases quality; it reduces costs as well so we also can satisfy the legitimate demands of healthcare insurers to contain our prices. The user based approach offers some interesting opportunities as well. Patients in most cases are not aware of the exact level of healthcare product quality.

There are, however, a number of features that patients would very much like to find during their stay in our hospital and that can be added without (many) additional costs. The Dutch proverb: "A smile goes for free", perhaps illustrates best how a highly appreciated client friendly approach can be achieved with little effort. The same goes for client friendly visiting hours, quality food, communication facilities and so on. So by exploring the user based approach our hospital can create a major competitive edge with limited investments.

Quality control using ISO 9001

Quality control is the universal managerial process for conducting operations to provide stability, to prevent adverse change and to maintain status quo (Juran 1999). We implemented an ISO 9001 quality management system to obtain an adequate level of quality control (Van den Heuvel et al. 2005a). The ISO 9000 series are standards that define requirements (9001) and guidelines (9004) for quality management systems (ISO 2000a; ISO 2000b). ISO 9000 standards are successfully used and adopted worldwide in industry and service organizations (Marquardt 1999). The International Organization for Standardization (Geneva, Switzerland) first issued the standards in 1987. In 1994 and in 2000 the ISO 9000 series were revised. The standards are generic, which means that the same standards can be applied to any organization, large or small, whatever its product or service, in any sector or activity whether it is a business enterprise, a public administration or a government department. The ISO 9000 standards are founded on the concept that the assurance of consistent product or service quality is best achieved by simultaneous application of product standards and quality management system standards. ISO takes a systems and process approach to improve organizational and financial performance with a specific focus on quality management, process control and quality assurance techniques to achieve planned outcomes and prevent unsatisfactory performance or non-conformance. The standards represent an international consensus on good management practices with the aim of ensuring that the organization can continuously deliver the product or service that (ISO):

- meets the customers' quality requirements;
- meets applicable regulatory requirements;
- enhances customer satisfaction; and
- achieves continuous improvement of its performance in pursuit of these objectives.

In healthcare, the application of the ISO standards is not yet very common and subject for debate. The usefulness of ISO 9000 standards in healthcare was outlined earlier (Carson 2004). Worldwide application of ISO in hospitals has been reported on a limited scale. The ISO 9000 guidelines for healthcare, called ISO IWA 1, can perhaps contribute to a better appreciation and use of ISO 9000 in healthcare (IWA 1 2001; Reid 2004).

The scope of ISO 9000 as we can see is much broader than quality control and quality assurance. Representing consensus on good management practices it in fact covers all aspects of quality management as mentioned above. Quality control and assurance, however, are perhaps the most significant characteristics of an ISO quality management system. Quality planning is covered equally well because ISO is almost synonymous with meeting customer requirements. As we have mentioned above in the user based approach, meeting customer requirements offers great competitive opportunities for any hospital. Although ISO advocates and supports quality improvement as well, we felt the need to implement an additional system (Van den Heuvel et al. 2005a). Six Sigma and ISO have proven to be highly complementary in other organizations (Warnack 2003). We therefore decided, after studying the model, to implement Six Sigma in our hospital.

Quality improvement using Six Sigma

Six Sigma is a company wide quality improvement approach that aims at optimizing processes while reducing defects and costs (Snee 2004). It is developed and widely used in industry (Breyfogle 2003). Recently the application of Six Sigma has also been suggested in healthcare (Barry 2002). A number of healthcare systems have implemented Six Sigma (Thomerson 2001; Sehwail 2003; Van den Heuvel et al. 2004; Christianson 2005). Especially in healthcare Six Sigma works both ways; costs are eliminated and quality is improved (Kooy and Pexton 2002). In order to quantify the performance of a given process a Six Sigma project starts by defining and implementing relevant measures and metrics the so-called Critical To Quality characteristics. Six Sigma tackles performance problems in five phases: Define, Measure, Analyze, Improve and Control. In addition to this stepwise project approach Six Sigma contains an organizational structure. Project leaders called Black Belts or Green Belts are trained in project management, problem solving methodology, and statistical methods. The stepwise strategy that Black Belts and Green Belts follow enables them to make a proper problem definition and diagnosis based on facts and data before undertaking attempts at solving the problem. Tools used in Six Sigma, such as quality function deployment and Pareto analysis, link customer demands to product features and establish the relative importance of various problems. Managers in their role of "Champion" review the progress of a project and ensure that the Black Belts and Green Belts focus on the interests of the organization. Experts on the Six Sigma methodology are called Master Black Belts and they are responsible for managing the Six Sigma organization. The focus of Six Sigma on data and the statistical substantiation of conclusions have proven to be an excellent counterbalance to the often subjective and intuitive way of working in healthcare.

Implementation

The implementation of our ISO quality management system started in January 1999. Processes were described and analyzed by our middle management. If possible quick wins were implemented. Once the process was improved, it was described in a standardized manner called a procedure. The next step was to make protocols that give a more detailed description of a specific task or activity. Processes and activities were only described when this was necessary to provide a sufficient level of quality assurance. We then put together the Quality Manual which contains descriptions of the organization, the divisions, our quality system, the policies of our hospital and our current set of performance indicators. To complete our quality management system we implemented an internal audit system. We trained approximately fifty co-workers to audit procedures and protocols in various departments. Processes are to perform the way they should and if not, corrective actions have to be taken. The flow of opportunities to improve the system has to lead to actual improvements. The internal and external audits have to either confirm that the system functions properly or provide input to further improvements. At the end of 2000, one and a half year after starting the implementation, KEMA a Dutch certification institute, performed the first external audit and we received the ISO 9002:1994 certificate for the entire hospital organization. In the next years we adapted our quality management system to fit the requirements of the revised ISO 9001:2000 standards. These efforts were successful too and we obtained an ISO 9001:2000 certificate in October 2003. Until this moment we are the only hospital in the Netherlands that obtained an ISO certificate for the entire organization.

Initially our quality improvement approach appeared to work reasonably well. A number of projects were completed successfully. However, we recognized that management control of our projects was not effective. Frequently the project goals were poorly aligned with the hospitals strategic goals. We lacked a systematic way to determine the relevancy of a project and its contribution to our long-term strategy. Furthermore we had difficulty making project go/no go decisions. Most of the time projects were initiated because we “felt” they would make a contribution to quality of care. We were also not able to assess potential savings of alternative projects. Once a project was started, we did not have reliable information about its status until it was finished. In summary, management was navigating blindfold (Van den Heuvel et al. 2005b).

We then decided to implement Six Sigma as a quality improvement tool. The Institute for Business and Industrial Statistics at the University of Amsterdam supported the implementation of Six Sigma in our hospital. We started with the one-day introduction training for management and directors. In order to implement Six Sigma successfully,

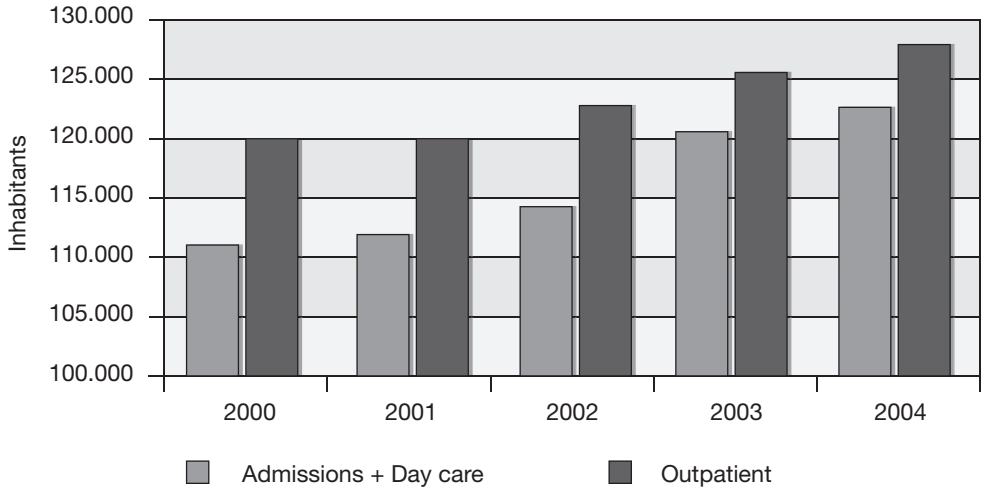
some apparent minor adaptations were necessary. The first group of fifteen Green Belts started their training in September 2002. Seven projects were initiated. To stimulate commitment, participants were allowed to choose the subject of their projects. In February 2003 the second group of Green Belts started. The hospital directors incited managers to train a sufficient number of Green Belts and maintain a substantial program of new projects. Gradually project selection was taken over by management to ensure alignment with the strategic goals of the hospital. As the number of projects increased the necessity for coordination and management of the Six Sigma program became evident. We observed that Green Belts faced difficulties with closing their projects. We therefore appointed a Master Black Belt to set up a management control system to evaluate progress and to support Green Belts in finishing their projects. The Master Black Belt organized the necessary training programs and ascertained that once Green Belts completed a project they initiated another project. In September 2004, the fifth group of Green Belts began with their projects. Co-workers show more and more interest in following a Green Belt training. We have consistently started new groups of approximately fifteen employees every six months. Participants emerge from different departments and disciplines within the organization. We have been able to initiate Six Sigma projects in almost any unit and related to every discipline in our hospital (Van den Heuvel et al. 2005c). The introduction of Six Sigma in our hospital has stimulated a culture of awareness to find opportunities to improve healthcare delivery and also to take responsibility to eliminate shortcomings. In the past, decisions were too often based on assumptions and feelings as well as inaccurate and incomplete information. By using Six Sigma, today co-workers take responsibility and provide management with solutions based on facts and data.

At the end of 2004 we had 63 employees that were fully trained as Green Belt. At that moment 44 projects were started and 21 projects were completed successfully. The total net savings amount to 1.4 million US Dollars. These amounts are cumulative savings on an annual basis. At the beginning of 2004 our hospital anticipated serious financial problems. Management embraced the Six Sigma organization to initiate an additional number of smaller "quick-win" projects (low hanging fruit) instead of discharging personnel. This additional program resulted in extra savings up to 1.3 million US Dollars. The Annual Report of 2004 consequently showed an, in our history, extraordinary net result of 2.7 million US Dollars (Van den Heuvel et al. 2006).

Five years of Red Cross Hospital performance

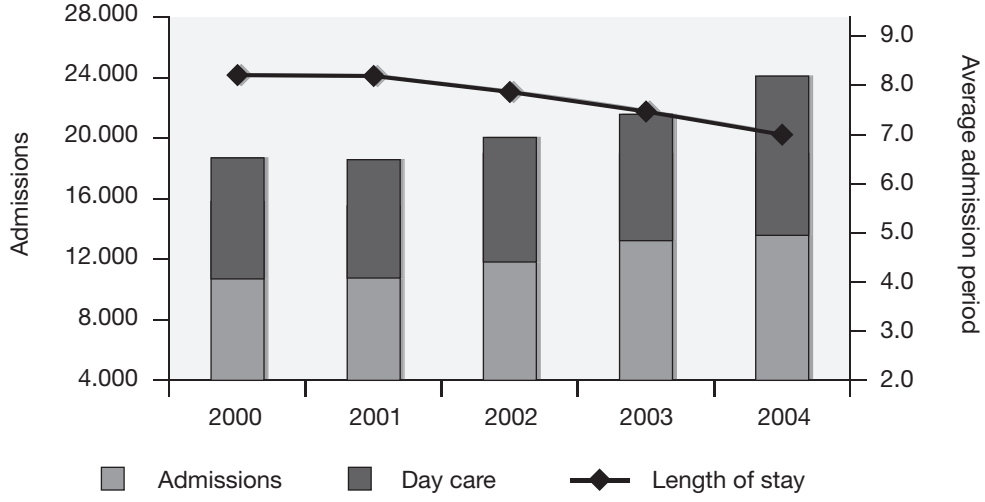
We will now demonstrate in what way quality management using ISO and Six Sigma enhanced the performance of our hospitals and helped us to achieve our strategic goals. We will do so by showing a set of performance indicators.

Graph 1: Growth of the catchment area Red Cross Hospital



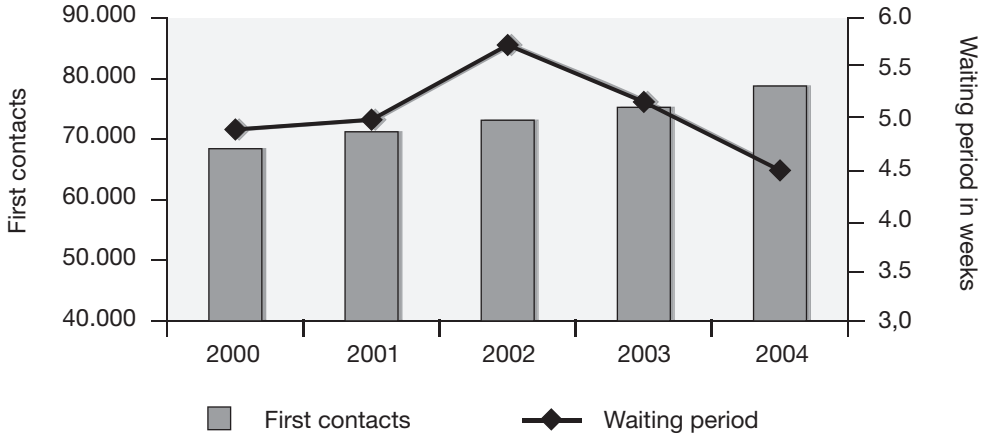
Graph no 1 demonstrates the growth of our catchment area, so the number of people that are inclined to go to our hospital. The catchment area is a calculated parameter based on the number of admissions or outpatient contacts and gives an indication of the size of our market share. The growth as seen in this graph demonstrates we have been able to achieve one of our major strategic goals.

Graph 2: Number of admissions and day care treatments



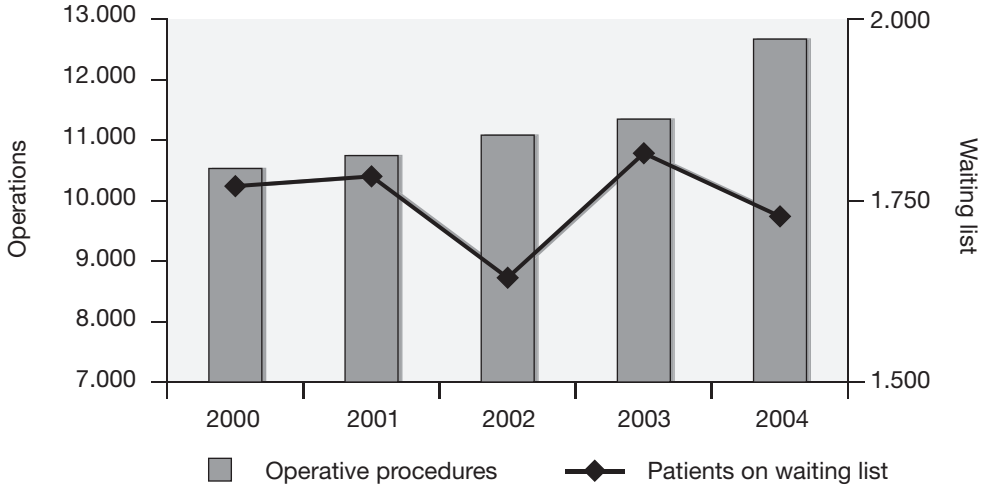
Graph no 2 demonstrates the number of admissions, day care treatments and the overall length of stay. The growth in the past three years has been made possible by a substantial reduction of the length of stay. This could be achieved by a number of Six Sigma projects and the implementation of Clinical Pathways.

Graph 3: Number of first contacts in the outpatient department



Graph no 3 demonstrates the growth of the number of first contacts in the outpatient department and the admission time. This growth has been made possible mainly by projects related to reducing the number of revisits and introducing elements of one stop shopping.

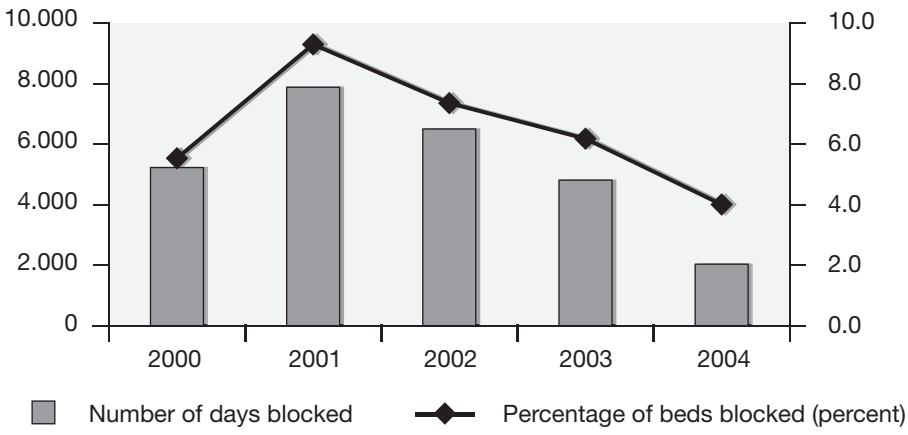
Graph 4: Number of operative procedures



Graph no 4 demonstrates the number of operative procedures and the number of patients waiting for an operation. In 2001 management stated that the number of surgical operations could not be increased any further. By starting a Six Sigma project, however, it appeared possible to increase the number of surgical operations with 11 percent. This project produced specific improvements such as starting on time, but it also created a general focus on optimizing the use of the available capacity. In 2004 we did also receive some unwanted help of a multi resistant staphylococcus aureus that forced us to close our Intensive Care unit for a period of time, thus enabling us to

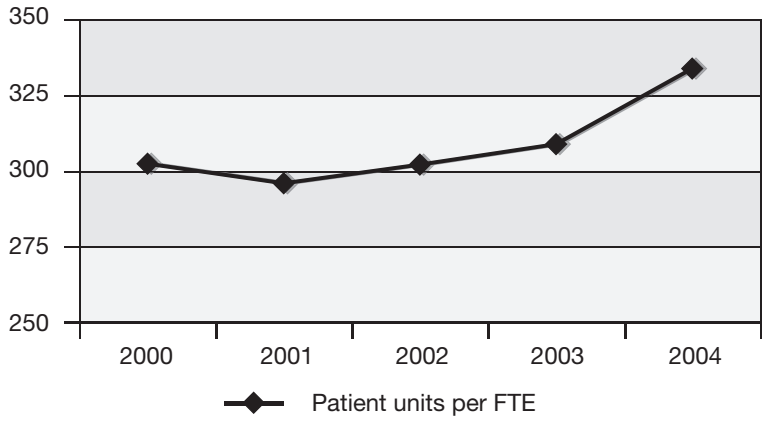
treat more low care patients. Over a period of five years we were able to increase the number of surgical operations by more than 20 percent.

Graph 5: Days of hospitalization attributed to "bedblocking"



Graph no 5 demonstrates the number of beds that were blocked by patients waiting for a nursing home. Beds that are blocked seriously impede our available capacity and therefore our output. We were aware that we had a problem in 2001 but we were not aware of the magnitude or the financial impact. We then decided to add this parameter to our set of performance indicators and monitor it. Together with the healthcare insurance company, responsible for purchasing sufficient nursing home capacity, we could bring down the number of patients waiting for a nursing home to acceptable levels.

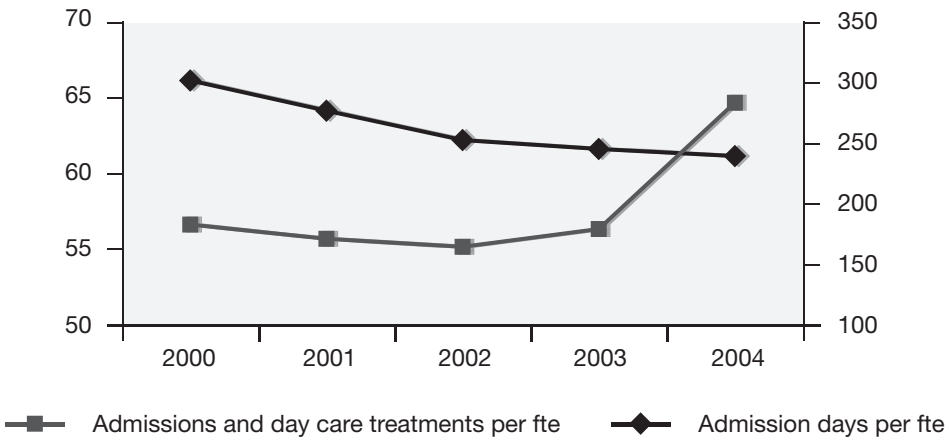
Graph 6: Efficiency of all employees



Graph no 6 demonstrates the number of patient units per Full Time Equivalent (FTE). A patient unit is a measure of our work load calculated by multiplying the number of admissions, day care treatments and outdoor contacts each by their own weight factor. The total summation of patient units gives a fair impression of the workload

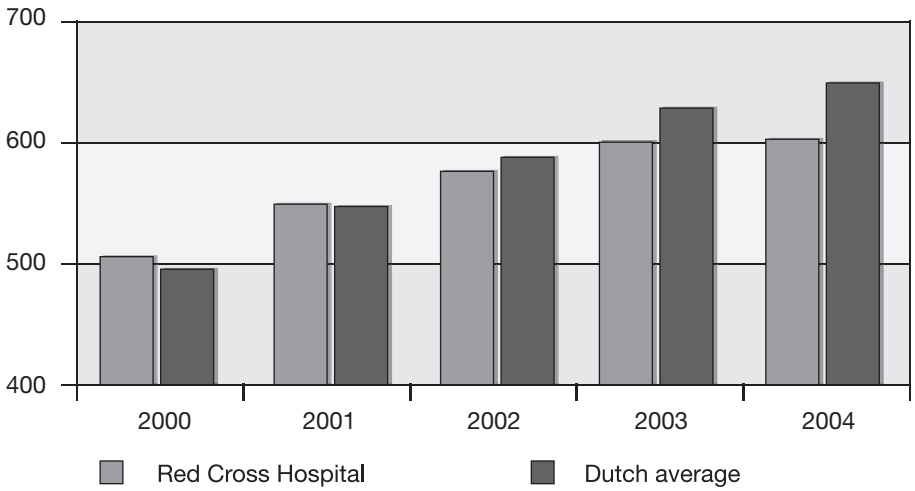
of our hospital. Therefore the number of patient units per FTE gives an impression of the efficiency of our hospital. In 2000 there was a high sick rate (see below) and a general (but not substantiated) idea that the work load was much too high. Given the sick rate we then decided to increase the number of employees which explains for the drop in efficiency in 2001. From that time on we had our quality management system fully operational and in 2004 we could give efficiency an extra impulse with the first tangible results of Six Sigma.

Graph 7: Efficiency of the nursing staff



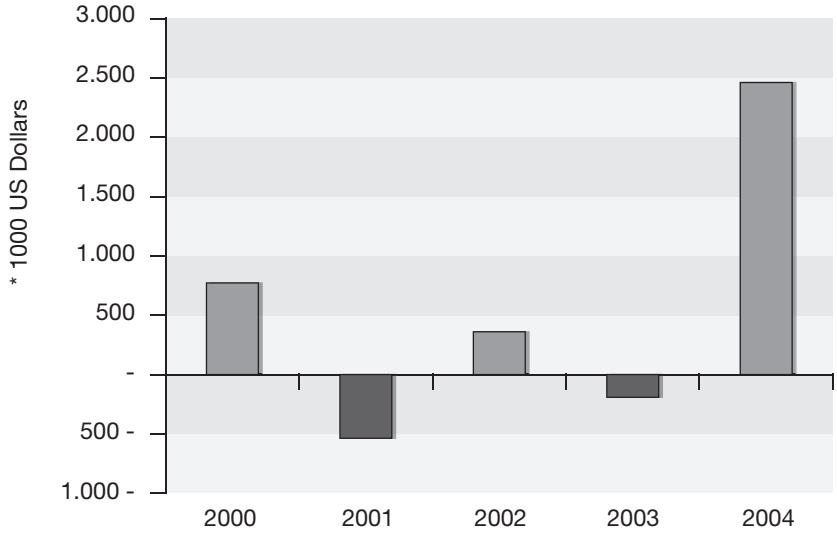
Graph no 7 demonstrates the number of admissions and day care treatments per full time equivalent (FTE) nursing staff. It also demonstrates the number of admission days per FTE nursing staff. The graph clearly shows that a number of projects and the implementation of clinical pathways firmly increased the output per FTE.

Graph 8: Costs per inhabitant related to the catchment area



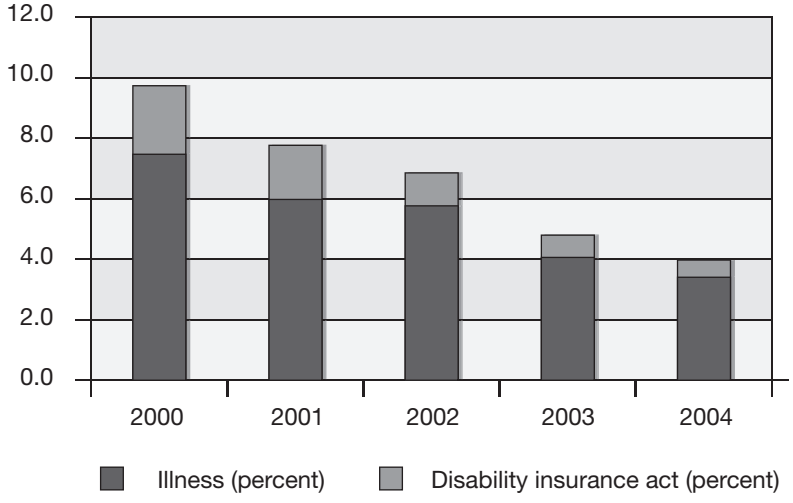
Graph no 8 demonstrates the costs per inhabitant related to the catchment area of our hospital and of all Dutch (non university) hospitals. This graph relates the overall output of our hospital to the total costs. In 1999 we were less efficient than the Dutch average. Our quality management system and Six Sigma made us 8.3 percent more efficient on costs per inhabitant than the Dutch average. This graph perhaps shows best the effects of quality management in our hospital.

Graph 9: Income from continuing operations



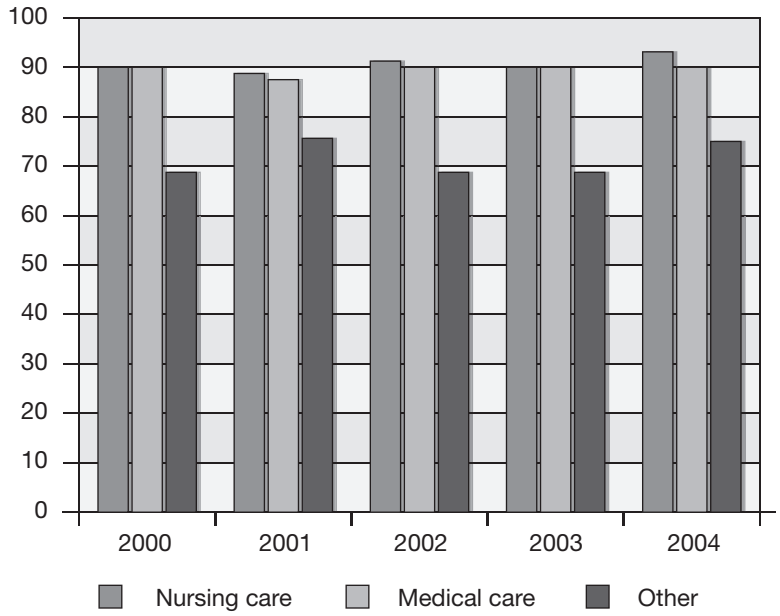
Graph no 9 demonstrates the income from continuing operations. Here we can see that the earnings from our projects in 2004 correspond directly with the income of our hospital in that same year. This income differs significantly from the years in which Six Sigma was not fully operational.

Graph 10: Absence due to illness



Graph no 10 demonstrates the absence through illness. This graph shows clearly that despite the increase in efficiency we were able to control our absence through illness as well.

Graph 11: Patient satisfaction in three categories



Graph no 11 demonstrates patient satisfaction. Perhaps one of our most important indicators is related to patient satisfaction. This graph demonstrates patient satisfaction three main categories; nursing care, medical care and all other service and care. We use approximately 50 different types of questionnaires, one for each department. The structure of all these assessment forms and the rating systems are identical so all results can be added to produce one score for patient satisfaction in our hospital. We distribute more than 2000 forms a year and the response rate is nearly 50 percent. On every item, patients can rate four categories; “good”, “reasonable”, “can be improved” and “must be improved”. We have been able to achieve consistent rates of more than 80 percent “good” every year for the entire hospital and 90 percent “good” on nursing care and medical care.

When we look at the development of the performance indicators of our hospital we can draw the following conclusions. In the first place we have been able to attain our two main strategic goals. We achieved continuous growth over the past five years and we were able to increase efficiency from below to above the Dutch average. Furthermore we were able to consistently lower our sick rates. This might indicate that the raise in efficiency did not inflict the well being of our employees. Our third strategic goal to deliver an adequate level of quality of care in order to stay attractive to our patients

has been achieved as well because our patient satisfaction scores stayed constant (and high) over the past five years. Based on our achievements we dare to state that quality management indeed has paid off in our hospital.

How can we explain these results?

In the past years Total Quality Management (TQM) was considered the most important concept to help companies deliver quality and gain competitive advance (Godfrey 1999). For this reason TQM has also been promoted in healthcare (Gaucher 1993). There is, however, no generally accepted definition of TQM and there is also some debate about the effectiveness of using TQM (Kelemen 2003). In most cases TQM failure is related to problems with its implementation and not with theoretical weakness of the model (Redman 1999). This has also been our experience. TQM helped us to develop our strategic quality goals, but we needed more practical tools to enable us to realize these goals. ISO 9001 as well as Six Sigma contain most of the elements, tools and concepts of TQM. However, contrary to TQM, they both involve and mobilize large numbers of employees. ISO requires employees to describe their working processes, to perform internal audits and to suggest improvements. In Six Sigma large numbers of employees are trained and coached to achieve improvements. Furthermore both Six Sigma and ISO offer explicit structures and approaches so there is little room for debate among our employees about the relevancy and subsequent actions needed to achieve quality. Finally Six Sigma and ISO are highly complementary. They both focus on: processes, client whishes, continuous improvements, employee involvement, fact based decisions and a systems approach on management. So our ISO quality management system and Six Sigma are virtually zipped together thus integrating the full spectrum ranging from quality control via quality assurance to quality improvement. This integration offers the benefits of the TQM concepts and lacks the shortcomings of TQM related to the implementation. One could say that TQM helped us to develop ideas about quality management top down and ISO combined with Six Sigma enabled us to implement these ideas bottom up.

The necessity to improve healthcare organizations has been emphasized strongly by the IOM. The requirements to create a high quality healthcare organization have been described much earlier (Berwick 1989). In our opinion ISO combined with Six Sigma provide the instruments to achieve such organizations.

Acknowledgements

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Chapter 9

Future Developments

This chapter is based on:

Lean Six Sigma in a Hospital. International Journal of Six Sigma and Competitive Advantage. 2006: 2(4): 377-388.

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Introduction

All over the world healthcare is facing serious quality problems while costs are exploding. The Institute of Medicine produced two reports demonstrating healthcare has serious safety and quality problems and is in need of fundamental change (IOM 1999, 2001). Care processes are poorly designed and characterized by unnecessary duplication of services, long waiting time and delay. Costs are exploding and waste is identified as an important contributor to the increase in healthcare expenditures. As a result healthcare consistently does not succeed in meeting patient's needs.

In the Netherlands the government has introduced the healthcare market and reduced direct governmental interference in an attempt to reduce costs and enhance patient satisfaction. As a result hospitals find themselves in an environment that is becoming highly competitive. To attract the same number or preferably more patients, hospitals have to put customer satisfaction first. At the same time, due to competition, insurance companies are confronted with increasingly lower margins that subsequently lead to lower prices paid to the hospitals. Delivering more quality while revenues are going down is the major challenge in healthcare. In this article we demonstrate how implementing Six Sigma combined with Lean principles can help hospitals to enhance quality and to reduce costs. In the first place we will introduce Six Sigma, an improvement program developed in industry. Then we describe the implementation and the results of Six Sigma in a hospital. Subsequently, we will introduce Lean Manufacturing and demonstrate why Six Sigma combined with Lean Manufacturing, better known as Lean Six Sigma, is such a powerful tool in healthcare. Finally, we give an example of a Lean Six Sigma project in the Emergency Room of a hospital.

Six Sigma

Six Sigma is a philosophy for company wide quality improvement. It was popularized by General Electric in the late Nineties. Several variants are current (Harry 1997; Pyzdek 2001; Breyfogle 2003). The program is characterized by its customer driven approach, by its emphasis on decision making based on quantitative data and by its priority on saving money.

Six Sigma is deployed by carrying out improvement projects. Project selection is usually based on a translation of the company strategy to operational goals (Pyzdek 2004). Furthermore, Six Sigma provides an elaborate organizational structure of project leaders and project owners. Six Sigma project leaders are called Black Belts (BBs) and Green Belts (GBs) and constitute a well-trained task force. Apart from GBs and BBs, management plays the role of project

owner and are called Champions. Part of the Six Sigma program is a twelve step 'Breakthrough Cookbook', a problem-solving method "specifically designed to lead a Six Sigma Black Belt to significant improvement within a defined process" (Harry 1997, pp. 21.18–19). It tackles problems in five phases: Define (D), Measure (M), Analyze (A), Improve (I) and Control (C). In the Define phase a problem is selected and a cost-benefit analysis is carried out. Then, in the Measure phase the problem is translated into a Critical To Quality (CTQ) characteristic, and the current situation is measured. Identification of influence factors and causes that determine the CTQ's behaviour takes place in the Analyze phase. In the Improve phase, project leaders design and implement adjustments to the process to improve the performance of the CTQs. Finally, in the Control phase the process management and control system are adjusted. Each of the phases D, M, A, I and C encompasses itself several steps, which guide a project leader through the execution of an improvement project (De Koning and De Mast 2006). Weaknesses of Six Sigma lie in its complexity and its lack of standard solutions. In case of less advanced problems, problem-solving is not very efficient if one has to go through a whole six month spanning Six Sigma project (George 2003). Furthermore, Six Sigma does not use existing solutions to standard problems in these cases. Finally, the danger of sub-optimizing a process, because of not taking into account the entire value chain, is ever present.

Six Sigma in a hospital

A brief overview of healthcare providers that have implemented Six Sigma is given by Van den Heuvel, Does, and Verver (2005). Here we recall our experience in the Red Cross Hospital in Beverwijk, the Netherlands. The Red Cross Hospital is a 384-bed medium sized general hospital. With an annual budget of 72 million Euros in 2004 the hospital admitted 12.669 patients, treated 11.064 in its day care facilities and performed 78.832 outdoor first contacts. A national 25 bed burn care center is part of the hospital. Six Sigma was introduced at the Red Cross Hospital with the purpose of enhancing continuous improvement (Van den Heuvel, Does, and Bisgaard 2005). This was done after completing and complementary to the ISO 9001 quality management system which was certified in 2000 in that hospital (Van den Heuvel, Koning, Bogers, et al. 2005). ISO and Six Sigma have proven to be highly complementary in other organizations (Warnack 2003). The implementation of Six Sigma started with one-day introduction training for management and CEO. The first group of 15 Green Belts started their training in September 2002. Seven projects were initiated. To stimulate commitment, participants were allowed to choose the subject of their projects. The second group of Green Belts started in February 2003. As the number of

projects increased the necessity for coordination and management of the Six Sigma program became evident. We observed that Green Belts faced difficulties with closing their projects. A Master Black Belt was appointed to introduce a management control system to evaluate progress and to support Green Belts in finishing their projects. The Master Black Belt organized the necessary training programs and ascertained that once Green Belts completed a project they initiated another project. In September 2004, the fifth group of Green Belts began with their projects. Co-workers showed more and more interest in following a Green Belt training. We started new groups of approximately 15 employees every 6 months. Participants emerge from various departments and disciplines within the organization. We developed a special training program for medical specialists. We also started training employees from partner organizations, such as home care and a nursing home, to initiate projects that improve cooperation, communication, and quality of care. We have been able to initiate Six Sigma projects in almost every unit and related to every discipline in our hospital (Van den Heuvel, Does, and Verver, 2005). At the end of 2004 we had started 44 projects and 21 projects were completed. The total savings amount to 1.2 million euros and these amounts are cumulative savings on an annual basis. At the beginning of 2004 the Red Cross Hospital anticipated serious financial problems. Management embraced the Six Sigma organization to initiate an additional number of smaller "quick win" projects instead of discharging personnel. This additional program resulted in extra savings up to 1 million Euros. The Annual Report of 2004 consequently showed an, in its history, extraordinary net result of more than 2 million euros (Van den Heuvel, Does, Bogers, and Berg 2006). The introduction of Six Sigma in the hospital has stimulated a culture of awareness to find opportunities to improve healthcare delivery and also to take responsibility to eliminate shortcomings. In the past, decisions were too often based on assumptions and feelings as well as inaccurate and incomplete information. By using Six Sigma, today co-workers take responsibility and provide management with solutions based on facts and data.

Lean

The proliferation of Lean in the Western World started in 1990 with the publication of a seminal work on Lean Manufacturing entitled "The Machine that Changed the World" (Womack, Jones, and Roos 1990). Lean Manufacturing is an outgrowth of the Toyota Production System (Ohno 1988; Shingo 1989). Toyota and other Japanese companies invented a manufacturing paradigm that was superior to the century old mass fabrication paradigm of the West, which was based on employing economies of scale. The Japanese had broken with dogmas like:

- a strong separation of "thinking" and "doing" of the job is most effective;
- defects are unavoidable by-products of production processes;
- organizations should be designed as a hierarchical chain of command; and
- inventories are necessary evils, used to buffer fluctuations in production speed and customer demand.

The Japanese surpassed Western companies on several dimensions simultaneously, while these dimensions were traditionally seen as trade-offs, i.e. quality versus cost and responsiveness versus flexibility. Much of the practices of the Japanese companies are incorporated in the Lean approach. The primary focus of Lean is on reducing waste, synchronizing flows and managing variability in (process) flows. It offers a framework for the analysis of processes within an organization (Standard and Davis 1999).

A core element of this framework is the distinction between value-adding and nonvalue-adding activities. The dividing line between the two is determined by the customer. Value-added activities are these that contribute to what the customer wants of the product or service and that they would be willing to pay for (see George 2003, p.118). The primary analysis tool of Lean is the value stream map. A value stream map is a process flowchart, extended with information about speed, continuity of the flow, Work In Process (WIP), and so on. Moreover, it specifies which steps add value and which do not. It helps to identify bottlenecks and is used to focus the improvement activities. The value stream map stretches the entire value chain, providing a holistic picture of companies' processes.

Because Lean focuses on process throughput the Lead Time is an important variable. The Lead Time tells us how long any item of work will take to be completed. According to Little's Law (Standard and Davis 1999, p. 78) the Lead Time equals the amount of work in process divided by the average completion rate:

$$\text{Lead Time} = \frac{\text{Amount of Work in Process}}{\text{Average Completion Rate}}$$

So according to this equation one can increase process speed either by reducing the amount of work in process or by increasing the average completion rate. We will elaborate on Little's Law in the project related to the Emergency Room. Furthermore, Lean offers a set of standard solutions to common organizational problems. Visual management, complexity reduction, 5S-method, cellular production, pull systems, line balancing, one piece flow, and single minute exchange of dies (SMED) are

some of the more familiar ones. In the Lean literature the advantages of and principles behind these solutions are described in depth (Standard and Davis 1999; George 2003). Lean's strength lies in its offering a set of standard cures and its build-in customer focus. The Lean tools are all proven solutions to problems often encountered in practice. However, it is unclear how to launch Lean effectively into an organization. Roles and responsibilities of Lean key players are not specified clearly. Moreover, where to start value stream mapping is also a big question. Guidelines for quality assurance and control are missing within Lean. Finally, in complex cases one needs tailor-made solutions, not just copies from other companies.

Integration of Six Sigma and Lean: Lean Six Sigma

Lean and Six Sigma have complementary benefits. For integration, Lean may use the management structures that Six Sigma offers: Six Sigma's project-by-project approach provides an effective embedding framework to apply Lean principles. Further, Lean lacks a method for diagnosis, and has only limited methods for analysis. It is rather one-sidedly focused on problems with process throughput, which are solved with a set of standard solutions. Lean does not analyze the economic performance indicators of a process to establish where the main points of improvement are, but focuses on inefficiencies in process flow, even if that is not where the main opportunities for improvement are. Six Sigma's DMAIC method offers a thorough roadmap for analysis and diagnosis, driven by powerful tools and techniques. However, Six Sigma is a general problem-solving framework, however. Given the ubiquity of process inefficiencies, Six Sigma projects — especially the ones pursuing process efficiency improvement and speed — can benefit from the standard solutions that Lean offers. The key to a successful integration of Lean and Six Sigma is to regard Six Sigma's project management and its DMAIC roadmap as a general framework for problem solving and process improvement. But within this framework, Lean's standard solutions and mindset have found their place. Thus, one will find the value stream map as one of the tools used in DMAIC step 4 (*Establish the process capability*) and many of the standard solutions that Lean offers in DMAIC step 9 (*Design improvement actions*) and DMAIC step 10 (*Improve the quality control system*). In Figure 1 we illustrate the integration of the Lean and Six Sigma approach in the DMAIC structure.

Lean Six Sigma

Benefits

- Improvements and redesign of routine tasks (manufacturing, service processes, sales, marketing, healthcare, and accounting)
- Resulting in superior quality and efficiency

Strategic Value

- Superior cost structure
- Competitive advantages derived from customer satisfaction
- Competence building in manufacturing and service delivery virtuosity

Method

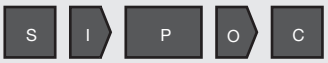
- Professional and science-like problem solving
- Precise and quantitative problem definition
- Data-based diagnosis
- Innovative generation of new ideas
- Empirical testing of ideas

Organization

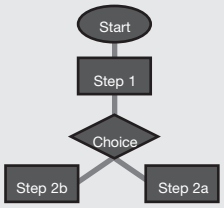
- Projects executed by **Black** and **Green Belts** (line personnel selected for their context knowledge)
- Project monitoring by **Champions** (line management and process owners)
- Project support by **Yellow Belts** (line personnel, shopfloor)
- Coaching by **Master Black Belts** and programme management

Define

0. Select project



SIPOC



Flow Chart

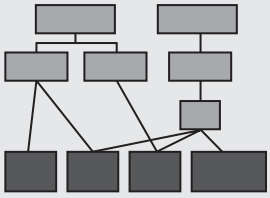
- Process maps (SIPOC)
- External CTQs + stakeholders
- Current performance
- Side conditions
- Benefit analyses

0. Project management

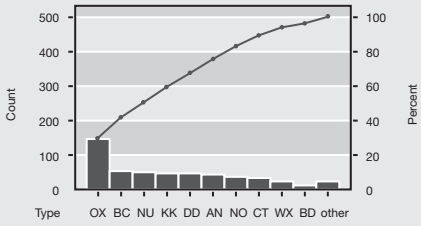
- Project charter
- Stakeholder analysis
- Improvement team (Yellow Belts)

Measure

1. Select the internal CTQ



CTQ Flowdown



Pareto analysis

- Internal CTQs
- Their relationship with the external CTQs
- Current performance

2. Operationalize the CTQ

- Unit and population
- Measurement procedure
- Requirements (target value, specification limits)

3. Validate the measurement system

$$\frac{5.15 \times \sigma_{measurement}}{USL - LSL}$$

Gage R&R study

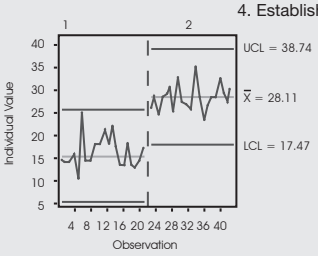
$$\kappa = \frac{P_{obs} - P_{exp}}{1 - P_{exp}}$$

Agreement (Kappa) method

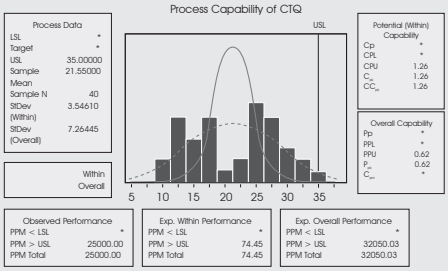
- Validity of the measurements
- Systematic measurement error (bias)
- Random measurement error (R&R)

Analyse

4. Establish the process capability



Control chart



Capability analysis

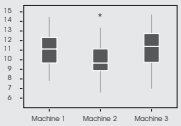
- Process behaviour in time (trends, patterns, outliers)
- Process μ, σ, histogram
- Defect rate, P_{pk}, sigma level
- Value stream map

5. Define the objective of the project

- Benchmarking
- Should be performance (μ, σ, defect rate)
- Calculation of financial benefits

6. Identify potential influence factors

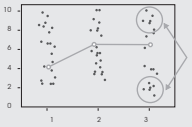
Ishikawa diagram
brainstorming
5M



Exploratory data analysis

Failure mode	S	F	D	RPN
Disturbance 1	3	2	4	24
Disturbance 2	8	5	9	360

FMEA

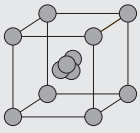


BOB vs. WOW
autopsy

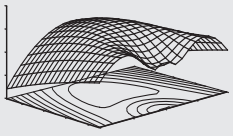
- Control and nuisance variables
- Disturbances + improvement actions
- Process inefficiencies (waste, rework, redundancies)
- Process matrix

Improve

7. Select the important influence factors



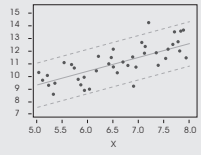
Design of Experiments (DoE manual)



Response Surface methodology

- List the vital few Xs
- Summary of the evidence

8. Establish relationships



Regression analysis

One-way ANOVA: CTQ versus Factor

Source	DF	SS	MS	F	P
Factor	3	35,01	12,03	4,34	0,012
Error	36	101,91	2,83		
Total	39	137,94			

S = 1,683 R-sq = 25,11% R-sq(adj) = 19,95%

Individual 95% CIs for Mean Based on Pooled StDev

Level	N	Mean	StDev
Machine 1	10	11.915	1.417
Machine 2	10	9.665	2.110
Machine 3	10	11.075	1.945
Machine 4	10	9.729	1.035

Pooled StDev = 1.683

ANOVA

- Transfer function (for numerical Xs)
- Level averages (categorical Xs)
- Frequency and impact (disturbances)

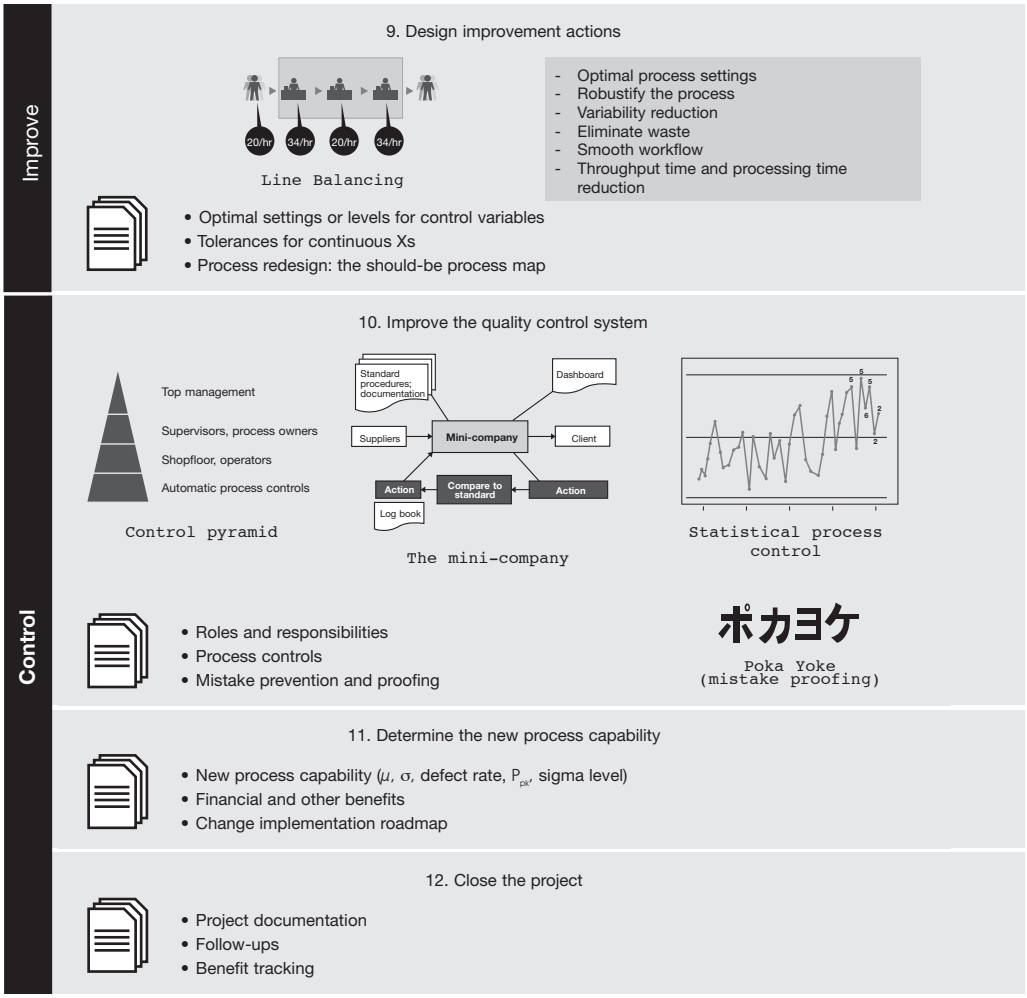


Figure 1. The DMAIC approach for Lean Six Sigma.

In the book of De Mast, Does, and De Koning (2006) details about these issues may be found. Several hospitals have started to work with Lean Six Sigma (George 2003; Chalice 2005; De Koning, Verver, Van den Heuvel et al. 2006). In the last mentioned paper worked examples can be found. It concerns examples with respect to complexity reduction in hiring personnel, improving starting times in an operating theatre, and improving a maintenance system to manage mechanical breakdowns and irregularities. Savings obtained with these projects ranges from 57.000 US dollars to 229.000 US dollars. Additional examples may be found in Van den Heuvel, Does and Verver 2005 and Van den Heuvel, Does, Bogers, and Berg 2006. Tools used in these projects were value stream map, complexity reduction, regression analysis, ANOVA, visual management system, control charts, mistake proofing, critical path analysis, and several elementary statistical techniques.

An application of Lean Six Sigma in the Canisius Wilhelmina Hospital

The Canisius Wilhelmina Hospital is located in Nijmegen, the Netherlands, and has 650 beds and a budget of 145 million euros. At the beginning of 2005 the Canisius Wilhelmina Hospital started to implement Lean Six Sigma. This was done by the same team that was responsible for the implementation in the Red Cross Hospital. In 2005 two teams of 20 Green Belts were trained. This time the training also included the key principles of Lean. An exercise was added in which the participants could experience directly the powerful effects of Lean tools. In 2006 we started to train another team of Green Belts and we plan to start two more groups. Employees are very enthusiastic about the training especially, because they are given the means and tools to solve problems in their own department, which they faced for a long time. Since the Canisius Wilhelmina Hospital is twice as big as the Red Cross Hospital we also trained more than 60 Yellow Belts to make more employees familiar with Lean Six Sigma and to support the Green Belts in their projects. Furthermore, we did an additional Lean training of one day for all the managing medical specialists and the directors. In April 2006, we did a large survey among employees to evaluate the organizational structure. A large number of flaws in our structure were mentioned by our employees. However, Lean Six Sigma was appreciated as a very useful instrument. In the next paragraph, we will demonstrate one project in our hospital that has been conducted in the Emergency Room. This project has not been completed yet, but it illustrates very well the power of Lean Six Sigma in a hospital.

An example: Long waiting times and an over-crowded Emergency Room

The Emergency Room (ER) in the Canisius Wilhelmina Hospital faces three serious and persisting problems. In the first place, our patients complain about the duration of the entire treatment in the ER. In Lean terminology this time, as we have mentioned before, is called the Lead Time. Secondly, employees complain about the limited space in the ER. At peak hours all the treatment rooms were in use as well as the surgeries for doctors and nurses. Finally, employees experience a high workload, partly due to the fact that the ER is over-crowded on peak times. A number of plans have been developed to increase the number of treatments and surgeries. Due to the tight budgeting system, neither the physical space nor the financial means could be provided. The same holds for increasing the number of employees.

The ER is of high strategic importance, because a significant amount of our patients enters the hospital through this gate. We therefore decided to start a Lean Six Sigma project and chose the duration of the entire treatment in the ER as CTQ. Since the duration of the treatment course is identical with the concept of Lead Time, the Green Belt decided to put a number of Lean tools into action. Therefore, the primary goal of

the project was to reduce the Lead Time. According to Little's Law, it is known that there are two ways to do that. In the first place, one can reduce the amount of work in process and secondly one can speed up the average completion rate.

Contrary to industry the reduction of the work amount in process looks counterproductive at first sight. It would mean that we prevent patients to enter the ER or to put them in the waiting room. Since the Lead Time starts from the moment a patient demands the service, there remains a reason to reduce the work in process. If we let more people wait before entering the treatment process, the lead time will decrease, because the actual care process accelerates: the same amount of personnel and equipment are engaged with fewer patients. Therefore, instead of pushing all patients into the ER treatment process one could seek for an optimum in the amount of patients in process. However, one needs also a kind of triage system, because acute patients should be treated in any case and despite the amounts of patients in process. Lead Time will go up but this is inevitable. We therefore implemented a triage system in our hospital. Another way to reduce the number of patients in process is to see a number of patients on the outpatient department instead of in the ER. This looks self-evident but this option has only been considered after we introduced the concept of Lead Time. Physicians were just used to refer every non-scheduled patient to the ER, but we are going to diverse part of these patients to the outdoor department.

The rationale of reducing the amount of work in process may look a bit metaphysical; the positive effect of increasing the average completion rate on reducing the Lead Time is obvious. To increase the average completion rate we have looked at waiting times within the process, nonvalue-added activities and shortening the clinical pathway. We analyzed the entire treatment process in the ER and looked at value- and nonvalue-added activities. We also measured the lead times of the sub-processes and the waiting times between the sub-processes. Most activities were executed after each other so we looked for opportunities (i.e. critical path analysis) to perform some activities, such as X-ray and Laboratory exams, parallel to others. New protocols will be developed that enable the nurses to initiate these exams. An example of non value-added activities is the case that a patient had to be admitted but stayed in the ER to receive additional examinations. These examinations are non value-added with respect to the emergency care process and can be performed equally well in the admitting department. We intend to develop protocols to arrange immediate transfer from the ER as soon as the acute care has been completed. The majority of the waiting times can be attributed to waiting for results from various examinations and waiting for (consulting) physicians. In addition to the critical path intervention

we also asked the Laboratory and X-ray department to improve their lead times. The lead times for the treatment process of different physicians were measured and presented. Physicians were asked to increase their effort in the ER or at least increase the effort of house officers. Given the measurements and the necessity to increase service at the ER our physicians agreed to do this. At this moment the number of physicians that give priority to the ER has been increased. The first results are very promising: the average Lead Time has been decreased with 20 percent.

What can we learn from the experiences?

It is interesting to note that in industry the concept of process speed and Lead Time are related to costs containment and have to do with internal quality. The client is only interested in the end product. In healthcare Lead Time is perhaps one of the most important quality indicators from the perspective of our patients. Our customer, the patient, contrary to industry, is participating in the entire process. So the concept of Lead Time and the consequences of Little's Law offer major opportunities to enhance quality and, by nature, to reduce costs. Especially the concept of work in process or in our case patients in (healthcare) process requires additional attention. Nevertheless it provides insight in the dynamics of our ER and helped us to find ways to reduce the Lead Time. The concept of Lead Time appears to be even more challenging when we look at the other two problems; the shortage of rooms and the workload of our employees. When you increase the average completion time and in addition reduce the number of patients in process, the capacity (rooms, employees) that you require decreases. This is extremely relevant; we solved the most important problem of our patients (long waiting times) and in addition we had two of our own, costly, problems solved as well. Our ER example shows why Lean can be extremely powerful in healthcare.

Waiting times and waste strongly affect the quality perception of our patients. Lean solves these problems. We already noticed in the Red Cross Hospital that Six Sigma by reducing defects also has a positive effect on quality as perceived by our patients (Van den Heuvel, Does, Bogers, and Berg 2006). Defects in healthcare are called complications. They do harm to our patients and cost vast amounts of money. So Six Sigma and Lean both increase quality and reduce costs. They do this by following different strategies and in this sense they are highly complementary. The combination is even more powerful because Six Sigma offers a complete quality improvement program and Lean tools can be integrated neatly within this.

The Lean Six Sigma approach has in the past predominantly been used to improve manufacturing processes. However, Lean Six Sigma is now increasingly applied to a wide variety of non-manufacturing operations. This is an important development;

there are potentially more benefits to be achieved in those areas than in traditional manufacturing where decades of good work have already paid off (Does, Van den Heuvel, De Mast and Bisgaard 2002). The key to understand how Lean Six Sigma can be applied more broadly is to recognize that non-manufacturing operations are also processes; they process inputs from suppliers and provide output to customers. This is the reason that in both areas the same approach can be used. However, there are differences in which tools are used (e.g. Design of Experiments are not frequently applied in healthcare).

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Chapter 10

General Discussion

Quality management as a strategic issue

In 1998 after a strategic analysis in our hospital we concluded that to guarantee continuity we had increase our income by a steady growth and a strong emphasis on cost containment. The Dutch hospital funding system pays fixed prices per patient regardless the quality of care delivered. So treating more patients produces more income, delivering high quality does not. Growth however can be stimulated by delivering higher quality of care and service. When doing so, the net result from more income through growth and higher costs to produce more quality has to be guarded extremely well. Given the complex relationship between growth, costs and quality, we considered quality management as a major strategic issue in our hospital. In 1999 and 2001 the Institute Of Medicine (IOM) produced two reports demonstrating healthcare has serious safety and quality problems and is in need of fundamental change (IOM 1999, 2001). Care processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays. Costs are exploding and waste was identified as an important contributor to the increase in healthcare expenditures. By issuing their reports the IOM has put quality management strongly on the agenda of healthcare organizations. Delivering low quality of care was considered unacceptable. This obligation caused more (financial) stress because, as we stated, quality is not paid for. On the other hand the observations of the IOM with respect to process optimization and waste reduction also offered opportunities for healthcare organizations with respect to cost containment.

How we studied quality management

To implement quality management in the Red Cross Hospital we introduced ISO 9000 and Six Sigma, both originating from industry. We started with ISO 9000 in 1999 and obtained a certificate in 2000. In 2002 we selected and started implementing Six Sigma as our quality improvement tool in addition to ISO. In 2004 Six Sigma was fully operational and we could report excellent financial and quality achievements. Given the fact that quality management is a major issue in every healthcare organization we decided to study and analyze our experiences and findings during the implementation of a quality management system based on ISO 9000 and Six Sigma in the Red Cross Hospital. This setting of course limited the design and the execution of our study to a large extent. The organizational change process was leading and choices were based only on the strategic impact, the performance and continuity of the hospital. So interventions could not be initiated or adapted on behalf of the study. They could however be studied intensely because the change process produced a vast amount of qualitative data, such as process analyses of the entire hospital, process improvement reports, internal and external audit reports, and finally numerous interim and final reports of our improvement projects. In 2005 we started implementing Six Sigma in the Canisius Wilhelmina Hospital. Here we decided to add principles of Lean

Manufacturing to the Six Sigma framework. This integration, called Lean Six Sigma, offers even more benefits than Six Sigma so we decided to report some first results.

During the course of the implementation of ISO 9000 and Six Sigma we formulated four questions which, when answered positively, could benefit other healthcare organizations and more important, their patients. These four questions make up the core of this thesis. We will now discuss the questions and provide the answers that emerge from chapter 2 to chapter 9.

Do the ISO 9000 standards provide a useful tool to implement a quality management system in a hospital?

In chapter 2 we demonstrate the successful implementation of an ISO 9000 quality management system in a Radiology department of an Academic Hospital. A Radiology department combines features of a production based unit and a healthcare department. This hybrid character made the department very suitable for attempting to introduce of ISO 9000 in healthcare. We could report positive results on process improvement, performance measurement, improvement projects and cost/benefit ratios. To our knowledge we were the first healthcare department that implemented ISO 9000. Our next step, described in chapter 3, was the implementation of a quality management system in the Red Cross Hospital according to the ISO 9000 standards. We succeeded to obtain a certificate of conformance for the entire hospital organization. A positive external audit in itself is a strong proof of a successful implementation because external auditors closely examine the system and judge its effectiveness. External audits are repeated every half year so there is little room for any deceit. Our own experiences with ISO were also very positive and we experienced a number of major advantages. The focus on our patients has been re-established. All processes are identified and subject to continuous improvement. We introduced performance measurements that give an overall and integrated picture of our results. Measurements subsequently lead to improvement of quality of care and to improvement of our quality management system. Our documentation system has been optimized largely and serves our needs without leading to bureaucracy. Positive effects on patient safety can be reported. In chapter 8 we demonstrate the positive effects of ISO 9000 combined with Six Sigma on strategy deployment of the Red Cross Hospital. Based on our observations we concluded that the ISO 9000 is an excellent tool to implement a quality management system in a hospital.

Does the implementation of Six Sigma in a hospital provide a quality improvement system equally powerful as in industry?

In chapter 4 we picture the situation after the implementation of ISO 9000 and provide arguments for implementing Six Sigma as a quality improvement tool.

Six Sigma, at that moment, had proven results in industry. We, on the other hand, experienced insufficient support from ISO in running quality improvement projects. Six Sigma's explicit focus on financial results was unique to our knowledge and we expected it to strongly support our cost containment strategy. Without any major difficulties, Six Sigma was implemented and made operational in the Red Cross Hospital. Employees working with Six Sigma were enthusiastic and considered it a major advantage in managing and executing quality improvement projects. In chapter 5 we describe three projects in more detail to illustrate that Six Sigma also functions well in projects directly related to the healthcare process. Projects are preformed by healthcare workers themselves after two episodes of three day training over a period of half a year. In chapter 6 we report the financial results related to a large number of projects. We have generated 1.2 million euros in annual savings in 2004 directly related to Six Sigma projects. Within the same Six Sigma structure we were able to do a large number of smaller projects (low hanging fruit) that produced another 1 million euros of savings. Our results were comparable with those in industry and other hospitals.

To better comprehend the success of Six Sigma in our hospital we analyzed concepts of quality in chapter 7. It appears that more product quality, so more features, leads to more costs. More process quality on the other hand leads to less waste and less defects thus to lower costs. Due to the fact that the patient is part of the manufacturing process, improving the quality of the healthcare process will lead to lower costs but will also lead to a higher quality of care. This quality of care will manifest by shorter waiting times and length of stay, less examinations and a decrease in the number of defects, such as errors, unnecessary interventions and complications. Since Six Sigma is primarily focused on process improvement it will improve quality and lower the costs of healthcare. Furthermore, Six Sigma links client demands to product attributes. This prevents healthcare workers to deliver care patients do not expect or desire to be delivered. This also reduces costs. So especially in healthcare Six Sigma seems to work both ways; costs are eliminated and quality is improved. In addition Six Sigma is also a powerful instrument to improve patient safety because it reduces the number of defects (i.e. complications, death rates, etc) produced by the healthcare processes.

In a hospital the quality of care is torn between conflicting demands. In general patients just want maximum quality and insurance companies want to pay the lowest possible prices. We do not know of hospital imbursement systems that explicitly reward quality of care. The only sensible policy for any hospital is to maximize efficiency while at least preserving quality of care. The best way to achieve this is

to invest in healthcare process improvement because this will invariably lead to lower costs and higher quality of care. The observations made by the IOM that care processes are poorly designed and characterized by unnecessary duplication of services and long waiting times and delays, and that costs are exploding due to waste, support this approach. In this respect Six Sigma with its primary focus on process improvement provides in our opinion the best possible quality improvement tool to healthcare organizations. Due to the direct impact of (healthcare) process improvement on patient satisfaction, we believe that compared to industry Six Sigma offers additional benefits in healthcare.

Does quality management, by using ISO 9000 and Six Sigma, contribute to the strategy of a hospital?

In chapter 8 we demonstrate the development of the performance indicators of our hospital over a period of five years. Looking at these figures we can draw the following conclusions.

When we look at growth we illustrated that we were able to increase our catchment area for admitted patients with 10.9 percent and for the outpatients' clinic with 7.9 percent. This was achieved through a growth of admissions with 14.7 percent, a growth of daycare treatments with 60.9 percent and a growth of first contacts with 15.6 percent. These results were made possible through a better usage of our capacities. We reduced our average length of stay by 15.5 percent. In addition we reduced the number of follow up contacts in relation to the number of first contact in the outpatient department by 9.0 percent. We also achieved an increase in operative procedures of 21.5 percent and a reduction in bed-blocking due to patients waiting for an nursing home from 5.391 days to 2.024 days. The increase in capacity usage has been facilitated by a number of Six Sigma projects as mentioned in chapters 3 to 5, such as a group of projects related to the reduction of admission time and one project in the operating theatre. This project produced specific improvements such as starting on time, but it also created a general focus on optimizing the use of the available capacity. In 2004 we received some unwanted help from a multi resistant staphylococcus aureus that forced us to close our Intensive Care unit for a period of time, thus enabling us to treat more low care patients. When we look at the overall picture of growth rates we can see that growth accelerated when a number of Six Sigma projects started to pay off.

We can demonstrate our achievements related to efficiency improvement and cost containment by looking at three indicators. First, looking at the costs per inhabitant in our catchment area, we can see that in 2000 the Red Cross Hospital was 2.4

percent less efficient than the Dutch average. In 2004 we were 8.8 percent more efficient than the Dutch average. The score on costs per inhabitant perhaps shows best the effects of quality management on efficiency improvement in our hospital. Secondly, the number of admissions per full time equivalent nurse increased with 12.9 percent. Finally the number of patient units, a measure for the overall workload of a hospital, increased with 7.9 percent per full time equivalent employee. During the same period we saw a decrease in absence through illness by more than half, going from 7.4 percent in 2000 to 3.2 percent in 2004. This indicates that efficiency improvement was not achieved by an increase in workload or at least did not inflict the well being of our employees. When we look at the income from continuing operations in 2004, we can see that this income differs significantly from the years in which Six Sigma was not fully operational. We can also see that the earnings from our projects in 2004 correspond directly with the income of our hospital in that same year, being 2 million euros.

We can illustrate our achievements related to optimizing our quality by looking at the results of our patient satisfaction scores. We use approximately 50 different types of questionnaires, one for each department. The structure of all these assessment forms and the rating systems are identical so all results can be added to produce one score for patient satisfaction in our hospital. We distribute more than 2.000 forms a year and the response rate is nearly 50 percent. On every item, patients can rate four categories; "good", "reasonable", "can be improved" and "must be improved". We have been able to achieve consistent rates of more than 80 percent "good" every year for the entire hospital and 90 percent "good" on nursing care and medical care. In 2004 we could demonstrate a 3 percent increase of the score "good" for nursing and medical care. We were also able to demonstrate positive results in external quality surveys. In the national quality enquiry 'Elsevier Questionnaire' 2004 among one hundred hospitals The Red Cross Hospital ended on the fifth place in the overall score. In 2003 our score was way below 50th place. Our hospital was ranked first place in the category organizational quality. In the category patient satisfaction we ranked sixth. The Elsevier survey gives an indication of the appreciation by other healthcare workers. A second survey is performed by the Algemeen Dagblad. This national newspaper collects the scores on quality indicators as required by the Dutch Healthcare Inspection. In 2006 the Red Cross Hospital ranked ninth place of all hundred Dutch Hospitals.

As demonstrated above we have been able to attain our two main strategic goals related to growth and efficiency improvement. We achieved continuous growth over the past five years and we were able to increase efficiency from below to above the Dutch average. Our third strategic goal to deliver an adequate level of quality

of care in order to stay attractive to our patients has been achieved as well. Our patient satisfaction scores remained constant and high over the past five years and we achieved high scores on external quality surveys. We could also link our scores to specific (groups of) projects. Based on our achievements we dare to state that ISO and Six Sigma have largely contributed to the accomplishment of our strategic goals.

Can Lean principles, when combined with Six Sigma, provide an additional positive effect on the quality improvement system?

Finally in chapter 9 we look forward in this thesis by demonstrating the relevancy of adding Lean principles such as process speed and Lead Time to Six Sigma. In industry Lean Manufacturing is about cost containment and internal quality. In healthcare Lead Time is perhaps one of the most important quality indicators from the perspective of our patients. Waiting times and waste strongly affect the quality perception of our patients. Our customer, the patient experiences the entire healthcare process. So the concept of Lead Time and the consequences of Little's Law offer major opportunities to enhance quality and, by nature, to reduce costs. The concept of Lead Time appears to be even more challenging when we look at other problems such as the shortage of rooms and the workload of our employees. When you are able to increase the average completion time and in addition reduce the number of patients in process, the capacity (rooms, employees) that you require decreases. So Six Sigma and Lean both increase quality and reduce costs. They do this by following different strategies and in this sense they are highly complementary. The combination is even more powerful because Six Sigma offers a complete quality improvement program and Lean tools can be integrated neatly within this.

Concluding remarks

How can we explain our results? In the past years Total Quality Management (TQM) was considered the most important concept to help companies deliver quality and gain competitive advantage (Godfrey 1999). For this reason TQM has also been promoted in healthcare (Gaucher 1993). There is, however, no generally accepted definition of TQM and there is also some debate about the effectiveness of using TQM (Kelemen 2003). In most cases TQM failure is related to problems with its implementation and not with theoretical weakness of the model (Redman 1999). This has also been our experience. TQM helped us to formulate our strategic goals related to quality management, but we needed more practical tools to enable us to implement our strategy and achieve these goals. ISO 9001 as well as Six Sigma contain most of the elements, tools and concepts of TQM. However, contrary to TQM, they both involve and mobilize large numbers of employees. ISO requires employees to describe their working processes, to perform internal audits and to

suggest improvements. In Six Sigma large numbers of employees are trained and coached to achieve improvements. Furthermore both Six Sigma and ISO offer explicit structures and approaches so there is little room for debate among our employees about the relevancy and subsequent actions needed to achieve quality. Finally Six Sigma and ISO are highly complementary. They both focus on: processes, client requirements, continuous improvements, employee involvement, fact based decisions and a systems approach on management. Our ISO quality management system and Six Sigma are virtually zipped together thus integrating the full spectrum ranging from quality control via quality assurance to quality improvement. This integration offers the benefits of the TQM concepts and lacks the shortcomings of TQM related to the implementation. One could say that TQM helped us to develop ideas about quality management top down and ISO combined with Six Sigma enabled us to implement these ideas bottom up.

The necessity to improve healthcare organizations has been emphasized strongly by the IOM. Berwick has pointed out the value and necessity of continuous process improvement in healthcare (Berwick 1989). To successfully achieve this he suggested that healthcare workers have to be involved, tools for improvement (from industry) have to be put in use in healthcare and flexible project teams must be created and trained to tackle complex processes that cross departments. He also stressed the value of process data analyses and the willingness of hospitals to really invest in quality improvement. In fact Berwick in 1989 described all elements of a Six Sigma organization as it is functioning in a number of hospitals today as well as in our own hospital producing the predicted results. In our opinion ISO with a strong emphasis on quality assurance combined with (Lean) Six Sigma provide the right instruments to hospitals to face present day quality management challenges.

In this thesis we stated repeatedly that healthcare faces serious problems related to quality and costs. The Institute of Medicine has illustrated and documented these problems very prominently. It is most likely that for several reasons this situation will worsen in the coming years. Governments try to control the ever increasing costs of healthcare. In The Netherlands this was first done by tight budgeting systems which in the end led to unacceptable waiting lists. Subsequently, in the past two years, a healthcare market has been introduced in The Netherlands as another and ultimate effort to stop healthcare expenditures to rise even further. Looking at market theories and also how costs have developed in 2006 one may not expect a miraculous financial turnaround. Furthermore, contrary to industry, pricing mechanisms do not function very well in healthcare. In general patients just want maximum quality of care and on the other hand they are only prepared to pay the

lowest possible insurance costs. Insurance companies, as a consequence confronted with decreasing incomes, as happened in the past year, want to pay the lowest possible price. Quality of care is therefore not much of an issue during negotiations with insurance companies. Costs, however, increasingly become the prime subject. The trade off between quality and costs is also obstructed by the fact that measuring and demonstrating quality of care is fairly complicated. Consequently healthcare providers will continue to face major difficulties in maintaining an acceptable level of quality of care. So how do we get out of this tragedy that will invariably lead to a steady increase in costs, a decline in quality and in increase in frustration of all players, not in the least healthcare providers?

In this thesis we demonstrated that healthcare workers when given sufficient time and provided with the right tools and training can reduce costs and increase quality at the same time. We estimate that by this bottom up approach, equivalent to industry, at least five percent of the total earnings of a hospital can be saved by using Six Sigma combined with ISO. This is about half a billion euros annual savings for The Netherlands. More savings can be expected when Lean Six Sigma is applied for a longer period. In addition measures have to be taken, preferably by the government, to make quality of care much more transparent, measurable and comparable. The Dutch Healthcare Inspection has taken some promising steps in this direction, but much remains to be done. The ultimate goal is to create a level playing field with respect to the quality of care. Only when we know the quality of care that has been delivered, we can compare the costs or preferably the prices hospitals charge.

In this ideal situation healthcare professionals hopefully will never again be confronted with the awkward situation they have to deny their patients costly treatments because budgets are said to be exhausted. Neither will it be an option to misinform the public by saying that a specific type of care cannot be delivered because healthcare professionals are working inefficiently. Only when costs and quality are transparent one could consider introducing elements of a ‘free’ market in healthcare. There are, however, less costly and less risky manners to determine the proper reimbursement a hospital should receive as well as the amount of profit the hospital and the insurance company are allowed to make. If the government wants high quality and no waiting lists, a simple management rule perhaps can help: What gets paid gets done.

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Summary

In our Introduction a description and the relevancy of the subject of this thesis are given. We then provide a brief overview of quality management tools and principles. The aims of this thesis are expressed in four research questions to be answered. Subsequently we account for the methodology that has been applied in this study. The core of the methodology consists of the longitudinal case study research method since we studied quality management over a period of six years in the Red Cross Hospital. In addition we used principles of action research because our study was performed during and in interaction with the process of organizational change, i.e. the implementations of quality management tools. To eliminate shortcomings related to case study methodology we also used principles of multi grounded theory, which allowed us to generate theory grounded in qualitative date. Finally we provide the content and the structure of this thesis.

An overview of this study is given in chapter 1. A more or less chronological description of our activities is given and the various choices that have been made along the course are accounted for. We describe our first positive experiences with ISO in a radiology department. We then picture policy deployment in the Red Cross Hospital based on three strategic goals; moderate growth, efficiency improvement and optimizing quality. Subsequently we describe our considerations related to quality management system selection and the outcome of the selection process. We have chosen ISO 9000 above the INK-model and the NIAZ Accreditation system because ISO supported best the achievement of our three strategic goals. We then describe the implementation of ISO 9000 and our results. This is followed by our, partly disappointing, experiences related to quality improvement that we experienced some years after the implementations of our ISO 9000 quality management system. We then describe the features and the implementation process of Six Sigma, followed by the results we achieved by working with Six Sigma in the Red Cross Hospital. The differences between healthcare and industry with respect to quality management are analysed and described. The main difference is the fact that in healthcare the patient is part of and experiences the manufacturing i.e. the healthcare process. This means that flaws in the healthcare process directly affect the quality from the perspective of the patient. Consequently, improvements of the healthcare process directly enhance quality perception and in addition lower the costs. This observation explains for the positive effect of Six Sigma in healthcare; it improves quality and lowers costs. We then briefly explain why ISO 9000 and Six Sigma are highly complementary. They both focus on processes, customers' demands, continuous improvement, employee involvement, fact based decisions and a systems approach on management. We then describe the results of five years working with ISO 9000 and Six Sigma in the Red Cross Hospital. We were able to grow ten percent in five years and lower the costs per inhabitant with slightly more than eight percent. We were also able to keep our patient satisfaction

scores high and constant for five years, indicating that efficiency improvement did not affect quality. Finally we provide evidence that adding Lean principles to Six Sigma provides an even more powerful quality improvement instrument.

In chapter 2 we demonstrate the implementation of an ISO 9000 quality management system in the radiology department of an academic hospital. This was a serious test case because it was the first time ISO was used in a department directly related to the healthcare process. We found that ISO was very supportive in optimizing performance and quality improvement. Based on our positive experiences we considered the possibility of implementing ISO in an entire hospital.

The opportunity to implement an ISO quality management system in an entire hospital occurred in the Red Cross Hospital and is described in chapter 3. We succeeded to implement an ISO 9000 quality management system throughout the entire organization within a period of one and a half year. The hospital obtained an ISO 9002:1994 and subsequently an ISO 9001:2000 certificate. A number of advantages are found from using ISO. The focus on patients has been re-established. All processes are identified and subject to continuous improvement. Performance measurements were introduced and give an integrated picture of our results. Measurements subsequently led to improvement of quality of care and to improvement of our quality system. The documentation system serves our needs without leading to bureaucracy. Positive effects on patient safety could be demonstrated compared to ten other hospitals.

Although ISO contains elements and requirements related to quality improvement we felt we needed measures to enhance quality improvement in our hospital. In chapter 4 we describe the rationale to implement Six Sigma and we present some preliminary results. Six Sigma is a scientific method to solve problems, made operational in business and industry. It gives a methodological framework to improve quality, but it also offers an organizational structure to implement the required change. Six Sigma is increasingly applied in a wide variety of non-manufacturing operations. Without major difficulties, Six Sigma was implemented and made operational in our hospital. We experienced no significant problems implementing Six Sigma in a healthcare organization. Employees working with Six Sigma were enthusiastic and considered it a major advantage in managing and executing improvement projects. The savings far exceeded initial expectations.

In chapter 5 we describe three Six Sigma projects in more detail. Two projects were done in the nursing department. The projects were related to reducing the length of stay of gynaecology patients, shortening the preparation time of intravenous

medication and improved checks on invoices of temp agencies. The projects appeared to be very successful and demonstrated that Six Sigma can be applied in the primary process of a hospital organization.

In chapter 6 we demonstrate overall results on the hospital level after two years of working with Six Sigma. We were able to train 63 Green Belts and initiate 44 projects. The total annual savings amount to 1.2 million euros. We also initiated a number of smaller Six Sigma projects to reduce an imminent budget deficit. This program resulted in 1 million euros additional savings.

While working with Six Sigma we gradually noticed that it also has a substantial positive effect on the quality of care. In chapter 7 we provide an explanation for this observation. Contrary to industry, in healthcare the patient is not only the client, but he is also part of the production (healthcare) process and the patient can be considered as our product. So for instance reducing defects (i.e. complications, mortality rate), or production times (i.e. waiting times, admission times), not only reduces costs but also enhances the quality of care. We believe that the problems related to quality and costs healthcare is facing today, can be explained partly by the idiosyncratic role (client, product and part of the process) the patient plays. We concluded that Six Sigma, while interfering on all three parts of that role, is an excellent tool to face the present-day problems.

In chapter 8 we look back on the strategy deployment and quality management process of our hospital. Growth, efficiency improvement and optimizing quality of care were chosen as our main strategic goals. To enable achievement of these goals we implemented an ISO 9001:2000 quality management system and integrated it with Six Sigma. The results of five years of quality management illustrated by the scores of a number of performance indicators clearly show that we were able to achieve all our strategic goals. Based on our findings we believe that the combination of ISO and Six Sigma provides the proper instruments to bring healthcare organizations to a higher level of performance.

In the final chapter 9 we illustrate how principles of Lean Thinking and Six Sigma can be combined to provide an even more effective framework for producing systematic improvements in healthcare. Lean aims at improving the entire process (flow) and therefore identifies more opportunities to improve than Six Sigma which aims at improving one or two process parameters. Six Sigma on the other hand offers a tight project management approach, and an effective embedding in the organization. The concept of Lean Six Sigma, by integrating Lean and Six Sigma, is therefore an interesting subject for future research.

Samenvatting

In onze Introductie wordt een beschrijving en een onderbouwing van de relevantie van het onderwerp van dit proefschrift gegeven. Vervolgens geven we een kort overzicht van kwaliteitsmanagement-instrumenten en -principes. De doelstellingen van dit proefschrift worden aangegeven in vier onderzoeksvragen die beantwoord moeten worden. Vervolgens leggen we verantwoording af voor de methodologie die is toegepast in dit onderzoek. De kern van de methodologie bestaat uit een longitudinale "case study" onderzoeksmethode omdat we gedurende een periode van zes jaar kwaliteitsmanagement in het Rode Kruis Ziekenhuis hebben bestudeerd. Aanvullend hebben we principes van "action research" gebruikt omdat ons onderzoek is uitgevoerd tijdens en in interactie met het proces van organisatieverandering, in casu de invoering van kwaliteitsmanagement instrumenten. Om de tekortkomingen die kleven aan de "case study" methode te elimineren hebben we ook principes toegepast van "Multi grounded theory" die ons in de gelegenheid stelden algemene theorieën te genereren op basis van kwalitatieve data. Tot slot geven we de inhoud en de structuur van dit proefschrift.

Een overzicht van dit onderzoek wordt gegeven in hoofdstuk 1. Er wordt een min of meer chronologische beschrijving van onze activiteiten gegeven en er wordt verantwoording afgelegd voor de verschillende keuzes die gedurende het onderzoek gemaakt zijn. We hebben onze positieve ervaringen met ISO op een radiologie-afdeling beschreven. Vervolgens hebben we de beleidsontwikkeling in het Rode Kruis Ziekenhuis geschetst die gebaseerd is op drie strategische doelen; groei, efficiency verbetering en optimalisering van kwaliteit. Daarna beschrijven we onze overwegingen met betrekking tot de selectie van een kwaliteitsmanagementsysteem en de uitkomst van dit selectieproces. We hebben ISO 9000 verkozen boven het INK-model en het NIAZ-accreditatiesysteem omdat ISO het bereiken van onze drie strategische doelen het beste ondersteunde. Daarna beschrijven we de implementatie van ISO 9000 en onze resultaten. Dit wordt gevolgd door onze, deels teleurstellende, ervaringen met de kwaliteitsverbetering die we een aantal jaren na de implementatie van ons ISO 9000 kwaliteitsmanagementsysteem opmerkten. Vervolgens beschrijven we de eigenschappen en de implementatie van Six Sigma, gevolgd door de resultaten die we in het Rode Kruis Ziekenhuis bereikten door te werken met Six Sigma. De verschillen tussen de gezondheidszorg en de industrie in relatie tot kwaliteits-management worden geanalyseerd en beschreven. Het grootste verschil ligt in het feit dat in de gezondheidszorg de patiënt onderdeel uitmaakt van het voortbrengings-proces, in casu het zorgproces. Dit betekent dat tekortkomingen in het zorgproces direct de kwaliteit aantasten vanuit het perspectief van de patiënt. Verbeteringen van het zorgproces hebben tot gevolg dat de kwaliteit stijgt, maar zorgen er ook voor dat de kosten dalen. Deze waarneming verklaart de positieve effecten van Six Sigma in de

zorgverlening; het verhoogt de kwaliteit en verlaagt de kosten. Vervolgens lichten we kort toe waarom ISO 9000 en Six Sigma in hoge mate complementair zijn. Ze richten zich beide op; klantwensen, continu verbeteren, medewerkerbetrokkenheid, op feiten gebaseerde besluitvorming en een systeembenadering van het management. Daarna beschrijven we de resultaten van vijf jaar werken met ISO 9000 en Six Sigma in het Rode Kruis Ziekenhuis. We waren in staat om tien procent in vijf jaar te groeien en de kosten per adherente bewoner met iets meer dan acht procent te verlagen. We waren ook in staat om gedurende vijf jaar onze patiënt tevredenheidscores constant en hoog te houden, hetgeen aangaf dat de efficiency verbetering de kwaliteit niet aantastte. Tot slot geven we bewijzen dat het toevoegen van Lean principes aan Six Sigma een nog krachtiger kwaliteit verbeterinstrument oplevert.

In hoofdstuk 2 laten we de invoering zien van een ISO 9000 kwaliteitsmanagement-systeem op een radiologie-afdeling van een academisch ziekenhuis. Dit was een serieuze test case, omdat het de eerste keer was dat ISO werd toegepast op een afdeling die direct te maken had met het zorgproces. Wij vonden dat ISO zeer ondersteunend was aan het optimaliseren van de prestaties en het ondersteunen van kwaliteit verbeteren. Gebaseerd op onze positieve ervaringen hebben we de mogelijkheid overwogen om ISO in een heel ziekenhuis te implementeren.

De mogelijkheid om een ISO-kwaliteitsmanagementsysteem in een heel ziekenhuis in te voeren deed zich voor in het Rode Kruis Ziekenhuis en wordt beschreven in hoofdstuk 3. We slaagden er in een ISO 9000 kwaliteitsmanagementsysteem in de gehele organisatie in anderhalf jaar in te voeren. Het ziekenhuis verkreeg een ISO 9002:1994 en vervolgens een ISO 9001:2000 certificaat. Een aantal voordelen kon worden vastgesteld door het gebruik van ISO. De focus op de patiënt werd weer teruggebracht. Alle processen zijn geïdentificeerd en onderwerp van continue verbetering. Prestatiemetingen zijn ingevoerd die een integraal plaatje geven van onze resultaten. De metingen leiden vervolgens tot verbeteringen in de kwaliteit van de zorgverlening en verbeteringen in ons kwaliteitssysteem. Het document beheersysteem ondersteunt onze behoefte zonder tot bureaucratie te leiden. Positieve effecten op de patiëntveiligheid konden worden aangetoond in vergelijking met tien andere ziekenhuizen.

Hoewel ISO elementen en vereisten bevat met betrekking tot kwaliteitverbeteringen, hadden we behoefte aan maatregelen die het kwaliteitsverbeteren in ons ziekenhuis konden versterken. In hoofdstuk 4 beschrijven we de redenen om Six Sigma te implementeren en onze eerste resultaten. Six Sigma is een wetenschappelijke methode om problemen op te lossen en wordt gebruikt in het bedrijfsleven en de industrie.

Het bevat een methodologisch raamwerk om kwaliteit te verbeteren, maar het biedt eveneens een organisatiestructuur om de vereiste verandering te implementeren. Six Sigma wordt in toenemende mate toegepast in een breed gebied van de niet-productie gerichte industrie. Zonder grote problemen is Six Sigma in ons ziekenhuis ingevoerd en in werking getreden. We hebben geen bijzondere problemen ervaren bij het invoeren van Six Sigma in de gezondheidszorg. Medewerkers die met Six Sigma werken zijn enthousiast en ervaren het als een belangrijk voordeel bij het managen en uitvoeren van verbeterprojecten. De besparingen overtroffen de aanvankelijke verwachtingen.

In hoofdstuk 5 geven we een meer gedetailleerde beschrijving van drie Six Sigma projecten. Twee projecten zijn uitgevoerd op een verpleegkundige afdeling. De projecten hadden betrekking op het verkorten van de ligduur van gynecologische patiënten, het verkorten van de bereidingstijd van intraveneuze medicatie en een verbeterde controle op de rekeningen van uitzendbureaus. De projecten bleken erg succesvol en toonden aan dat Six Sigma kan worden toegepast in het primaire proces van een ziekenhuis.

In hoofdstuk 6 laten we het totale resultaat zien op het niveau van het gehele ziekenhuis na twee jaar werken met Six Sigma. We bleken in staat om 63 Green Belts te trainen en 44 projecten te starten. De totale besparingen op jaarbasis bedroegen 1,2 miljoen euro. We hebben ook een aantal kleinere Six Sigma projecten gestart om een dreigend exploitatietekort terug te dringen. Dit programma resulteerde in 1 miljoen euro extra besparingen.

Tijdens het werken met Six Sigma kwamen we er geleidelijk achter dat het ook een stevig positief effect had op de kwaliteit van de zorgverlening. In hoofdstuk 7 geven we een verklaring voor deze waarneming. In tegenstelling tot het bedrijfsleven is de patiënt in de gezondheidszorg niet alleen de klant, maar hij is ook onderdeel van het (zorg) proces en kan ook worden opgevat als ons product. Als wij bijvoorbeeld het aantal defecten (zoals complicaties, sterftecijfers), of de productietijden (zoals wachttijden, toegangstijden) dan brengen we niet alleen de kosten terug, maar verbeteren ook de kwaliteit van de zorg. We zijn ervan overtuigd dat de problemen met de kwaliteit en de kosten waar de zorg mee wordt geconfronteerd, voor een deel kunnen worden verklaard door de eigenaardige rol (klant, product en deel van het proces) van de patiënt. Six Sigma, dat inspeelt op alle drie de onderdelen van die rol, is daarom naar onze mening een uitstekend hulpmiddel om de huidige problemen aan te pakken.

In hoofdstuk 8 kijken we terug op de strategieontwikkeling en het kwaliteits-management in ons ziekenhuis. Groei, efficiency verbetering en het verbeteren van de

kwaliteit van de zorg zijn gekozen als onze belangrijkste strategische doelen. Om het bereiken van deze doelen mogelijk te maken hebben we een ISO 9001:2000 kwaliteitsmanagementsysteem ingevoerd en geïntegreerd met Six Sigma. De resultaten van vijf jaar kwaliteitsmanagement geïllustreerd door de scores van een aantal prestatie-indicatoren, laten duidelijk zien dat we al onze strategische doelen hebben gehaald. Gebaseerd op deze bevindingen zijn wij ervan overtuigd dat de combinatie van ISO en Six Sigma de beste instrumenten levert om een gezondheidszorgorganisatie op een hoger prestatieniveau te brengen.

In het laatste hoofdstuk 9 laten we zien dat principes van Lean Manufacturing en Six Sigma kunnen worden gecombineerd tot een nog effectiever raamwerk voor het verkrijgen van systematische verbetering in de gezondheidszorg. Het concept van Lean Six Sigma is daarom een interessant onderwerp voor toekomstig onderzoek.

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Zeynep, seni çok seviyorum.

Curriculum Vitae

Jaap van den Heuvel was born in 1955 in Nieuw Lekkerland. He passed the first-year exam in Chemistry in 1977 and became a MD at the University of Leiden in 1984. In 1988 he obtained his MBA degree at the Erasmus University of Rotterdam. In 2003 he became a Certified Public Controller at the Free University of Amsterdam. In 1985 he was member of the medical team of Alarm Centrale Euro Cross. Then he worked three years as a house officer in Thoracic Surgery and Internal Medicine. After that he became IT consultant specialized in electronic medical records. In 1992 he became management consultant at Bakkenist and worked as interim manager in the radiology department of the academic hospital in Utrecht. During the same period he was the general manager of the nursing home Amstelhof in Amsterdam. In 1997 he started as general director of the Red Cross Hospital in Beverwijk. In this hospital he introduced an ISO 9001 quality management system and Six Sigma. Since 2005 he is the chairman of the board of the Canisius Wilhelmina Hospital. Jaap van den Heuvel is married to Zeynep Poyraz and has three children; Boris, Rick and Roosje.

Niets

Wat is dat eigenlijk?
Als je het ziet wat zie je dan?
Het antwoord: “niets”
Want je kunt het niet beschrijven.
Want er is absoluut niks.
Geen licht, donker, muur, kleur, verandering, geen leven of dood, geen land of zee, geen begin geen eind, maar toch zie je het, maar hoe zie je niets als er niets is, hoe beschrijf je het, hoe zie je het toch
‘t is een wonder…

Rick van den Heuvel (2004) 11 jaar oud

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