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# CHAPTER THREE

## Organizational excellence in healthcare

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### Introduction

Healthcare, as any other service operation, requires systematic innovation efforts to remain competitive, cost efficient and up to date. In this paper, we outline a methodology and present how principles of two improvement programs, i.e., Lean Thinking and Six Sigma, can be combined to provide an effective framework for producing systematic innovation efforts in healthcare. The benefits of this approach are that healthcare cost increases can be kept in control, while quality is improved, and better healthcare is provided. The approach is illustrated by a longitudinal case study of a period of five years in a hospital.

The Institute of Medicine (established in 1970 under the charter of the National Academy of Sciences to provide independent, objective, evidence-based advice to policymakers, health professionals, the private sector, and the public in the United States) has produced two reports demonstrating healthcare has serious patient safety and quality problems and is in need of fundamental change (Institute of Medicine, 2000 and 2001). 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 to meet patient's needs. To better serve the needs of patients, healthcare systems have to be redesigned. By issuing the reports, the Institute of Medicine has put quality management strongly on the agenda of healthcare organizations. Delivering low quality of care was considered unacceptable. This obligation may cause more (financial) stress because for

example in the Netherlands the hospital funding system pays fixed prices per patient regardless the quality of care delivered. Hence delivering high quality does not generate more income. However, the observations of the Institute of Medicine with respect to process optimization and waste reduction offered opportunities for healthcare organizations with respect to cost containment.

World wide the cost of medical care is also increasing at an alarming and unsustainable rate. Admittedly, a significant percentage of these cost increases can be attributed to aging populations and technological advances. Those two causes are inevitable facts of the technological and demographical developments of modern society. As such, they are largely beyond our control. However, another significant source of healthcare cost increases can broadly be characterized as unnecessary operational inefficiency. This we have more control over. Inefficiency we can change. If we do, we can provide more affordable and better healthcare for a large percentage of the population. Some operational inefficiencies are associated with the direct medical service delivery process. Others are associated with the administrative, logistical and operational side of the healthcare delivery system. Both areas can benefit from systematic process innovation activities.

We would not be surprised if some object to the notion of industrialized healthcare delivery. However, industrialization is essentially a conversion of artisan methods to more efficient, cost effective, streamlined systems for the delivery of products or services (Levitt, 1976; Heskett, Sasser, and Schlesinger, 1997). During the past century, industry deployed a large arsenal of tools and innovation approaches to achieve high levels of operational efficiency. Economic history indicates that efficiencies in industry were obtained primarily as the cumulative effect of a large number of incremental improvements (Rosenberg, 1982 and Bisgaard, 2006). Lean Thinking and Six Sigma are two process innovation approaches that currently are popular in industry (Womack, Jones and Roos, 1990; Harry, 1997). Both provide a systematic approach to facilitate incremental process innovations. Lean Thinking emerged within the Japanese automobile industry after World War II (Ohno, 1988), but can be traced back to the early days of the Ford Motor Company (Ford and Crowther, 1926). Similarly, Six Sigma, originally introduced by Motorola, is the culmination and synthesis of a series of century long developments in quality management (Snee, 2004) building on a number of other approaches, in particular, Juran's Trilogy (Juran, 1989). Lean and Six Sigma have gone through parallel developments in recent years. Originally applied to the

manufacturing environment, both approaches are now also used widely in administration and service areas (George, 2003; Snee and Hoerl, 2004; De Mast, Does and De Koning, 2006). The latest development is a synthesis of the two approaches (Hoerl, 2004; De Mast, Does and De Koning, 2006). In this paper, we explore the integration of these two approaches in the healthcare setting.

In the remainder of this paper, we first briefly outline the key principles of Lean Thinking and Six Sigma. Next, we explore the concept of quality in healthcare. Based on these two sections, we discuss how in healthcare we may organize quality management. We demonstrate that Lean Six Sigma can solve the problems mentioned by the Institute of Medicine by improving care processes, eliminating waste, reducing costs and enhancing patient satisfaction. Finally, we draw some conclusions about the future possibilities of Lean Six Sigma.

### **The integration of Lean Thinking and Six Sigma**

Lean Six Sigma is a widely applied program for company wide quality improvement (see for an introduction De Mast, Does and De Koning, 2006). It is the synthesis of Six Sigma and Lean. Six Sigma was developed by Motorola in the 1980s, but gained momentum after its adoption by General Electric in the mid 1990s (Harry, 1997). Lean is an outgrowth of the Toyota Production System (Ohno, 1988).

We start with a description of Six Sigma. We first elucidate the organizational structure prescribed by Six Sigma. The key principle is that projects are run by people with intimate and detailed understanding of the process and problem at hand. That implies that mostly projects are executed by people from the line organization (typically operations), and not by staff personnel (let alone external consultants). The motivation is of course that line persons are aware of the treacherous details that are part of the problem, its solution, and that pose limitations on improvement directions. Moreover, since improvement actions ultimately are handed over to the line (to the employees, operators and process engineers), it is important that the solution is such that they can work with it, and that they accept it. Typically, a Six Sigma project is run by a team consisting of:

- One or more Black Belts (BBs) and/or Green Belts (GBs), who are typically selected from middle management. They are thoroughly trained in becoming effective project

leaders, and they work either full-time or at least a considerable part of their time on the project.

- Several Yellow Belts (YBs): persons that the BB or GB calls in as advisors, typically operators or employees who execute the process, but YBs could as well be technical specialists, marketing specialists, or whoever the BB or GB thinks could bring in relevant knowledge. On a limited number of occasions input from the YBs is requested, and they may be called upon to collect data.

The difference between a BB and a GB is interpreted differently in various organizations, and the precise role of a BB and a GB should be adapted to the situation in one's own organization. In some companies, a BB refers to project leaders who work full-time on their project, whereas GBs work two or three days per week on their project. BBs then run the tougher projects. But a different approach is to have projects executed by a full-time BB from a staff department, assisted by one or two part-time GBs from the line.

The above implies that improvement projects are not run from a central staff department (such as quality assurance or troubleshooting). Rather, the idea is that GBs and BBs are dispersed over the organization. The danger of such a decentralized approach to improvement is that there is no integration of activities, and that efforts are wasted on issues that are not of strategic importance. For this reason, projects are selected and monitored by so-called Six Sigma champions. The champion is the project owner, in the sense that he is responsible for the process that the project aims to improve. Preferably, the champion is also the hierarchical superior of the BB or GB. Loosely said, the champion owns the problem, and hires the BB and GBs to solve it. Given his position in the company, the champion should be able to relate the project to the bigger picture of the company's strategy and other initiatives. During its execution, a project is reviewed several times by the champion, thus allowing him to adjust the direction that the BB or GB chooses. This control mechanism is intended to assure that the project remains focused on issues of critical importance to the company. The structure just described has firm roots in the scientific literature about theory of the firm. Jensen (1998) discusses the merits of this organizational structure in dealing with quality improvement (albeit in the case of Total Quality Management).

Part of theoretical grounding of Six Sigma may be found in De Mast and Bisgaard (2007). They show that several elements in Six Sigma's methodology constitute its sound basis in scientific methodology. Central to a scientific attitude towards process improvement is the idea that to control a system we have to understand how it works. Without understanding of the mechanics of a problem, we are likely just fighting symptoms and applying makeshift solutions. To understand a system means: to have a theory that relates the system's behavior to its causal factors. De Koning and De Mast (2007) draw the conclusion that "Six Sigma does not offer standard cures, but a method for gaining understanding of the causal mechanisms underlying a problem".

The next principle is that we have to define problems in a crystal clear, operational form before attempts at finding a solution are made. Targets and objectives are often formulated in abstract terminology: "to become a number one supplier", "to be best in class", "to become an empowered organization". Although such objectives are useful in stating an intention and providing a sense of direction, they are too vague to manage upon. Objectives should be translated into a tangible and measurable form. An objective is operationally defined if its formulation is so tangible, that one can determine precisely and unambiguously whether the objective is met. In Six Sigma problems are translated into measurable quantities, called critical to quality characteristics (CTQs). A commonly used tool to go from a project definition to these specific and measurable CTQs is the CTQ flowdown (De Koning and De Mast, 2007). It aims to make explicit and structure the rationale underlying the project. Furthermore, it shows how CTQs relate to higher level concepts such as performance indicators and strategic focal points. Downward it shows how CTQs relate to measurements.

A third cornerstone of Six Sigma's methodology is the emphasis on quantification. Customer satisfaction versus production costs, crime prevention versus privacy of citizens, pollution and noise nuisance of airports versus economic interests: most interesting problems are trade-off problems. The issue is not "either / or", but "how much of one, and how much of the other?" If problems are not quantified, their trade-off nature is obscured, and people tend to treat them as either/or-problems (and frequently politicize them in addition).

The fourth principle indicates that before attempts are made to solve the problem, a data-based diagnosis is needed. In Six Sigma this takes the form of a process capability study. This shows the nature and size of the problem. The nature of the problem guides the

direction of the improvement actions, and the magnitude of the problem facilitates prioritization. The importance of prioritization cannot be overemphasized. The saying has it that “every ounce helps”, but this proverbial wisdom does not work in business. With unlimited time and resources one could bother about ounces, but in reality one must focus on the strategically important issues. Or in Six Sigma’s terminology: each minute spent on the trivial many issues is a minute lost; it is the vital few issues that determine the success of a project. Without data-based diagnosis improvement actions are likely to be wasted on many trivialities, not on the few drivers of performance.

A final element of Six Sigma is its emphasis on data-based testing of ideas and improvement actions to reality. In a world where no-one is likely to have sufficient knowledge to be consistently right the first time, feedback is crucial. One should experimentally verify one’s ideas for two reasons. In the first place, to get rid of misconceptions, misjudgments and myths. And secondly (and equally important), to fine-tune a coarsely developed idea to the specifics and complications of the real life situation. Ideas that are not tested before they are implemented are often either misconceived, or appear to be based on a wrong notion of proportions and priorities, or fail because of the many ignored growing pains.

The principles outlined above were put in an operational form in the form of the DMAIC roadmap. It employs five phases: Define (D), Measure (M), Analyze (A), Improve (I) and Control (C). The roadmap guides BBs and GBs through their projects, helps them ask the right questions, shows them when certain tools and techniques can be used, and forces them to organize their findings in a structured manner. The five phases are briefly characterized as follows:

1. Define: Select project and BB or GB.
2. Measure: Make the problem quantifiable and measurable.
3. Analyze: Analyze the current situation and make a diagnosis.
4. Improve: Develop and implement improvement actions.
5. Control: Adjust the quality control system and close the project.

In the Define phase, a charter is drafted which includes a cost-benefit analysis. If the cost-benefit analysis meets the company-established thresholds, the charter will be accepted and the project will continue through the DMAIC process, i.e., the project becomes scheduled for solution and assigned to a team headed by a Green or Black Belt and reporting to a

Champion. In the subsequent Measure phase, baseline data is assembled and the diagnosis is started in earnest. The problem is translated into quantifiable terms via Critical-To-Quality (CTQ) characteristics. The analysis phase continues the diagnosis and involves an identification of possible causal relationships between inputs and the CTQs. Once the diagnosis is completed, the team proceeds to the Improve phase and suggests a solution to the problem. The Green or Black Belt designs and implements process changes or adjustments to improve the performance of the CTQ. Finally, in the Control phase, control systems are developed to assure that improvements are maintained and the new improved process can be handed over to the day-to-day operations. Each of the five phases of DMAIC involves detailed roadmaps that help to guide project leaders through the execution of an improvement project. These phases are discussed in depth in De Mast, Does and De Koning (2006). Each of the MAIC phases is broken down in three steps. For each step a list of end terms is defined as well as a set of techniques that are typically used to achieve them. BBs and GBs report the progress of their projects following these steps, which makes it easy for program management to track progress.

Hence Six Sigma elevates problem-solving and quality improvement to a more professional level by providing a method that follow scientific method and by training BBs and GBs in an attitude that can be described as scientific. Improvement actions are not based on perception and anecdotal evidence. But neither are they based on the notion of the omniscient specialist who, sitting behind his desk, derives a remedy by making clever deductions from his expert knowledge. The attitude that Six Sigma represents, is an adventurous and open-minded eagerness to go out to the process under study and learn from it, and the willingness to correct one's own misconceptions on the basis of experimental results and empirical feedback. That is in a nutshell the tenor of Six Sigma's methodology.

Lean is not a method such as Six Sigma's DMAIC method. Lean offers only very limited techniques for analysis and diagnosis. Instead, Lean should be seen as a collection of best practices, which have mainly been copied from the Toyota Production System (Ohno, 1988). The book by Womack, Jones and Roos (1990) introduced these best practices in the Western world. The analysis part of Lean consists of the identification of waste in the process. Following the steps of the process, one identifies redundant work, overcapacity, needless complexity, inefficient routing, and so on. The results are visualized in a value stream map. A value stream map is a process flowchart extended with information about speed,

continuity of the flow, work in process, et cetera. Moreover, it specifies which work adds value and which does not. Upon identification of instances of waste, Lean applies standard solutions such as visual management, 5S, cellular production, pull systems, line balancing, single-piece flow and rapid changeover (Womack and Jones. 2003).

Lean and Six Sigma are complementary. Lean can benefit from the management structures that Six Sigma offers: Six Sigma's project-by-project approach, led by BBs and GBs from all over the organization, is an effective organization form for getting Lean principles applied. 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 it tries to solve 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. Six Sigma is a general problem solving framework, however. Given the ubiquity of process inefficiencies, Six Sigma projects — especially the ones pursuing 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.

From now on we shall not make a difference between the programs Six Sigma and Lean Six Sigma.

### **Concept of quality in healthcare**

Quality in healthcare can be traced back to Hippocrates (450-370 B.C.) who formulated the oath for medical practice in ancient Greece (see for an overview Nabitz, 2006). With the oath, the teacher-student relation was defined, specific medical procedures were included and excluded and privacy and rights of patients were formulated. In the renaissance Vesalius (1514-1564) and Paracelsus (1494-1541) represented a rational, analytical and observational approach to medicine and also proclaimed an oath to guarantee the integrity of doctors. During the 19<sup>th</sup> century the oath was modified with more emphasis on patient rights and

humanistic aspects and a code of conduct for the medical professional was added. After World War II, the World Medical Association formulated nine prescriptive rules of conduct and in 1995 patient centeredness and standard of practice and care were introduced which turned the oath into a professional quality manifest. Besides Hippocrates, the English nurse Florence Nightingale (1820-1910) is seen by many experts as an important figure for the roots of quality in the field of healthcare.

Apart from these issues of quality in healthcare, it is generally accepted that there is no single or ultimate definition. Each industry or research branch has its own definition. Garvin (1984) has identified five major approaches of defining quality in industry; and most existing definitions of quality fall into one of these approaches:

- Transcendent approach of philosophy: Quality is innate excellence and cannot be defined;
- Product-based approach of economics: Quality reflects the presence or absence of measurable product attributes, and more quality (attributes) means more costs;
- User (client)-based approach of economics, marketing, and operations management: Individual consumers have different wants or needs, and those goods that best satisfy their preferences have the highest quality;
- Manufacturing-based approach: Quality as conformance to requirements, so that improvements in quality (reductions in defects) lead to lower costs;
- Value-based approach of operations management: A quality product provides performance at an acceptable price or conformance at an acceptable cost.

Garvin concluded that a company should not rely on a single definition of quality but rather should cultivate all five quality approaches. Consideration of the five approaches to quality in healthcare can illustrate the power of Lean Six Sigma. The transcendental approach, unfortunately, is often used by healthcare professionals, but an inability to define or measure quality will severely impede quality improvement initiatives. Lean Six Sigma stimulates healthcare workers to define, measure, and improve aspects of quality. Our experiences with Lean Six Sigma at several hospitals have shown that its focus on data and statistical verification is an excellent counterbalance to the subjective and intuitive (transcendental) approach.

In terms of the product-, user-, and manufacturing-based approaches in healthcare, we observe a very interesting phenomenon. A patient is not only our client but also our product (we replace parts), and is the most important element of our manufacturing (i.e., healthcare) process—thereby representing three approaches to quality at the same time. Therefore, we are obliged to manage all three quality approaches 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 the Master Black Belt in a hospital, who had had five years' 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, making new requests, adding new wishes, and being annoyed by waiting times and paint spilled on his trousers?" He admitted that the entire plant would become a mess! This, however, represents daily practice in every hospital, and explains much about the origins of a "quality chasm" in healthcare (cf. Institute of Medicine, 2001).

Because the patient is part of the manufacturing process, improving the quality of the healthcare process will manifest by e.g., shorter waiting times and length of stay, a reduced number of examinations and a decrease in the number of defects, such as errors, unnecessary interventions and complications. Hence improving quality will lead to lower costs and higher quality of care. Furthermore, Lean Six Sigma links the demands of the patient 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 Lean Six Sigma seems to work both ways; costs are eliminated and quality is improved.

The fact that the patient is part of the manufacturing process also provides an explanation for the kinds of patient safety problems cited by the Institute of Medicine reports. 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 of nor affected by the undesired output of an imperfect manufacturing process. Yet unlike industry, where a defective product can be rejected without any problem, in healthcare an imperfect process that produces defects and rework directly affects the patient's safety. Therefore, Lean Six Sigma can be used to improve

patient safety by reducing the number of defects (for example, medical errors, see Buck, 2001) produced by healthcare processes.

Finally, in terms of the fifth, value-based approach, it is evident that contrary to industry, pricing mechanisms do not function well in healthcare. In general, patients just want maximum quality and insurance companies, government, and other payers want to pay the lowest price. In general, reimbursement systems do not generally explicitly reward additional quality of care. As a result, the hospital is torn between these conflicting demands. The only sensible policy for any hospital to pass both Scylla and Charybdis is to maximize efficiency while at least preserving quality of care. Again, this means investing in healthcare process improvement, which, we contend, will invariably lead to lower costs and higher quality of care. Improvement of patient safety can be viewed as a valuable “side effect” of Lean Six Sigma. In the Netherlands, policy makers have defined patient safety as an issue on its own requiring separate management systems. Yet by taking the patient as the starting point, Lean Six Sigma provides a balanced approach to quality and safety.

### **Quality management in healthcare**

There are many activities in organizations relating to quality and efficiency, and they should not all be organized in the same way. Juran (1989) proposed a generally accepted distinction of activities related to quality into planning, control and improvement.

- *Quality planning* consists of the determination of what customers want and the development of the products, services and processes which are required to comply with these needs. This work is typically organized in specialized staff departments.
- *Quality control* consists of the on-line and real time monitoring of production or service delivery, the detection of irregularities, and the reaction to these irregularities. A typical control system encompasses elements such as a control plan (or quality control handbook), control points and loops, and inspections. Quality control is reactive in nature and deals particularly with what Juran (1989) calls *sporadic problems*. Its organization should be integrated with the regular (production, backoffice, service delivery, or other) process, and nowadays its execution is typically the responsibility of the people who execute the process (Does, Roes and Trip, 1999).

- *Quality improvement*, finally, is the organized and systematically pursued improvement to increase quality and efficiency to unprecedented levels (Juran (1989) calls this *breakthroughs*). Unlike quality control, quality improvement is not an on-line affair, but should be executed in the form of projects (what Juran (1989) calls the *project-by-project nature* of quality improvement). Such improvement projects typically tackle what Juran (1989) calls *chronic problems*. They (e.g., recurring stagnations, constant levels of waste, poor service, scrap) should be eliminated once and for all.

A major part of the problems in processes can be prevented, however, by taking possible problems during manufacturing and operations into account during product and process development. In order to apply the basic principles of Lean Six Sigma in product and process development, an adaptation of the methodology has been developed. This adapted methodology is called Design for Six Sigma (DfSS). DfSS is the methodology for quality planning.

The distinction between control and improvement, sometimes described as on-line vs. off-line quality management, is important. Quality control's main intent is to defend the status-quo by reacting to problems ("fire fighting"). If, in the course of this operation, an opportunity is encountered to improve the process then it is of course seized, but the reactive and opportunistic approach of control is completely different from improvement, which searches for improvement opportunities systematically. Examples of approaches for quality improvement are Taguchi's off-line quality control, process optimization using design of experiments, business process reengineering (BPR), and Lean Six Sigma's DMAIC methodology. Regular Lean Six Sigma projects are mainly conducted in the operational part of organizations (e.g., manufacturing, nursing, accounting and sales), where the routine tasks are carried out. Stagnations and structural problems are tackled; improvements often are found in the form of a control system or modifications in the standard way of working. Occasionally a redesign of part of the process is needed.

Hence according to Juran (1989), quality management consists of three aspects; quality planning, quality control and quality improvement. In healthcare a similar approach has been

suggested (Donabedian 1985). Next we discuss how the three aspects of quality management may be implemented in a hospital.

### **Quality Planning in Healthcare**

Quality planning is a structured process for developing (healthcare) products that ensure that customer needs are met by the final results (Juran and Godfrey, 1999). Looking at the “bi-personality” client and the five approaches to define quality, a hospital has choices to determine the level of quality it wants to deliver. First according to the value-based approach a hospital has to contain its prices regardless the level of quality it intends to deliver. It is nearly impossible for any insurance company to charge their clients higher insurance contributions to pay higher prices to the 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 the 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 pace makers, 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, et cetera, directly increases the 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 the 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 like to find during their stay in a 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 a hospital can create a major competitive edge with limited investments.

## **Quality Control in Healthcare**

Quality control is the universal managerial process for conducting operations to provide stability, to prevent adverse change and to maintain status quo (Juran and Godfrey, 1999). The ISO 9000 series are standards that define requirements (9001) and guidelines (9004) for quality management systems. 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:

- Meets the customers' quality requirements;
- Meets applicable regulatory requirements;
- Enhances customer satisfaction;
- 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). World wide application of ISO in hospitals has been reported on a limited scale (Van den Heuvel, Koning et al., 2005). The ISO 9000 guidelines for healthcare, called ISO IWA 1, can perhaps contribute to a better appreciation and use of ISO 9000 in healthcare (Reid, 2004).

The scope of ISO 9000 is much broader than quality control and quality assurance. Representing consensus on good management practices it covers in fact 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, it does not offer a real methodology. Hence, the need to implement an additional system exists. Six Sigma and ISO have proven to be highly complementary in other organizations (Warnack, 2003).

### **Quality Improvement in Healthcare**

As we have explained before, Lean Six Sigma is a company wide quality improvement approach that aims at optimizing processes while reducing defects and costs. It is developed and widely used in industry. Recently, the application of (Lean) Six Sigma has also been suggested in healthcare (Barry, Murcko and Brubaker, 2002). A number of healthcare systems have implemented (Lean) Six Sigma (Thomerson, 2001; Sehwal and De Yong, 2003; Van den Heuvel, Does and Bisgaard, 2005; Christianson et al., 2005; De Koning, Verver et al., 2006). Especially, in healthcare (Lean) Six Sigma works both ways; costs are eliminated and quality is improved (Kooy and Pexton, 2002).

### **A real life example: Implementation of ISO 9000 and Lean Six Sigma in a hospital**

The Red Cross Hospital (RCH) is a middle sized general hospital with 384 beds and about 1,000 employees located in Beverwijk in The Netherlands with an annual budget in 2004 of 90 million US Dollars. The RCH is located 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 the RCH has chosen as main strategic goals a moderate growth and minimization of

costs, both to provide continuity. Furthermore, the RCH aims 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 (Bliersbach, 1988; Blumenthal, 1996). 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 the strategic goals, implementing a well functioning quality management system was considered of vital strategic importance to the RCH.

The implementation of the ISO quality management system started in January 1999. Processes were described and analyzed by 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. The outcomes were put together in a Quality Manual which contains descriptions of the organization, the divisions, the quality system, the policies of the RCH and its current set of performance indicators. To complete the quality management system the RCH implemented an internal audit system. Approximately fifty co-workers were trained 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 the RCH 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 the RCH obtained an ISO 9001:2000 certificate in October 2003. Until this moment the RCH is the only hospital in the Netherlands that obtained an ISO certificate for the entire organization.

Initially, the quality improvement approach appeared to work reasonably well. A number of projects were completed successfully. However, it was recognized that management control

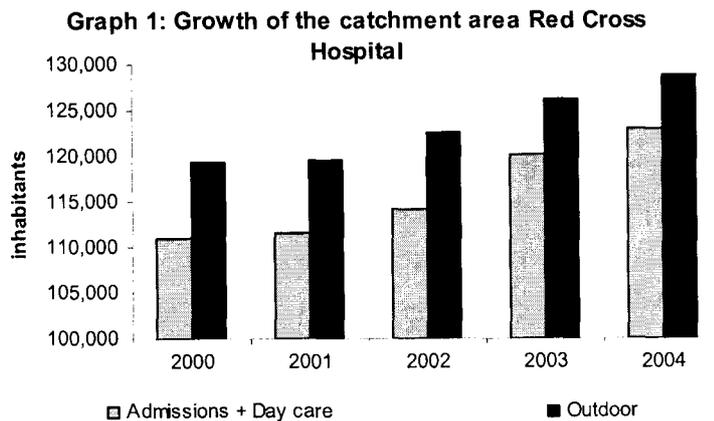
of the projects was not effective. Frequently, the project goals were poorly aligned with the hospitals strategic goals. There was no systematic way to determine the relevancy of a project and its contribution to the long-term strategy. Furthermore, it was difficult to make go/no go decisions for the projects. Most of the time projects were initiated because it was “felt” that they would make a contribution to quality of care. RCH was also not able to assess potential savings of alternative projects. Once a project was started, management did not have reliable information about its status until it was finished. In summary, management was navigating blindfold (Van den Heuvel, Does and Bisgaard, 2005 and Van den Heuvel, Does and De Koning, 2006).

RCH then decided to implement Lean Six Sigma as the quality improvement method. The Institute for Business and Industrial Statistics at the University of Amsterdam supported the implementation of Lean Six Sigma in the RCH. It was started in 2001 with a one-day introduction training for management and directors. In order to implement Lean 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 co-ordination and management of the Lean Six Sigma program became evident. It was observed that Green Belts faced difficulties with closing their projects. Therefore RCH 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 the Green Belt training. RCH has consistently started new groups of approximately fifteen employees every six months. Participants emerge from different departments and disciplines within the organization. RCH has been able to initiate Lean Six Sigma projects in almost any unit and related to every discipline in our hospital (Van den Heuvel, Does, Bogers and Berg, 2006). The introduction of Lean Six Sigma in the RCH 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 Lean Six Sigma, co-workers take responsibility and provide management with solutions based on facts and data.

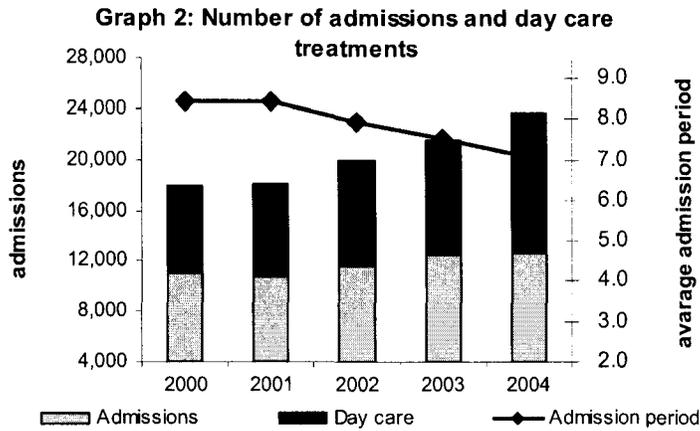
At the end of 2004 RCH had 63 employees that were fully trained as Green Belt. At that moment 44 projects were started and 21 projects were completed successfully. The total net savings amount to 1.4 million US Dollars. These amounts are cumulative savings on an annual basis. At the beginning of 2004 the RCH anticipated serious financial problems. Management embraced the Lean 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, Bogers et al., 2006).

Quality management using ISO and Lean Six Sigma enhanced the performance of the RCH and helped RCH to achieve the strategic goals. We will show the results of a set of performance indicators from 2000 through 2004. A complete account of the results is given in Van den Heuvel, 2007.

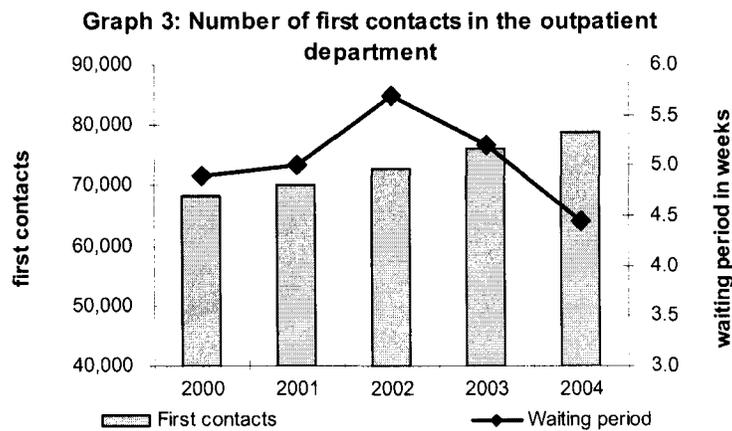


Graph No 1 demonstrates the growth of the catchment area of the RCH, or in other words the number of people that are inclined to go to the RCH. The catchment area is a calculated parameter based on the number of admissions and outdoor contacts and gives an indication

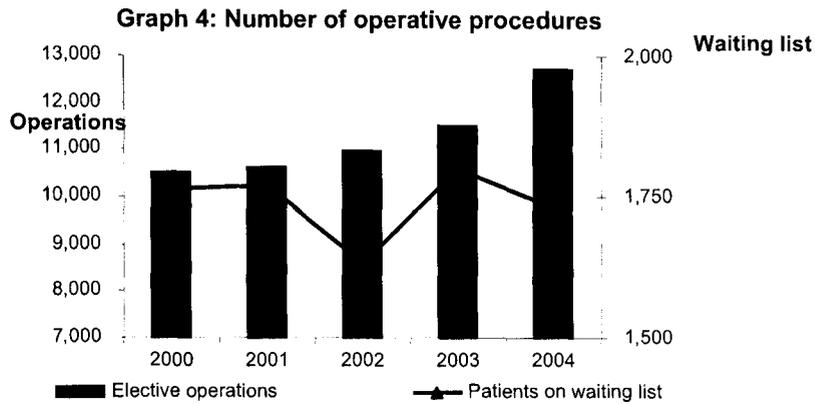
of the size of the market share. The growth as seen in this graph demonstrates RCH has been able to achieve one of its major strategic goals.



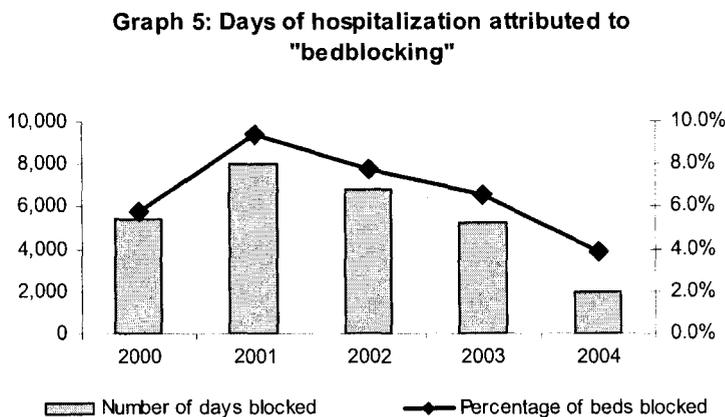
Graph No 2 demonstrates the number of admissions, day care treatments and the overall length of stay. The growth in the last three years has been made possible by a substantial reduction of the length of stay. This could be achieved by a number of Lean Six Sigma projects and the implementation of Clinical Pathways (guidelines to cure and care patients).



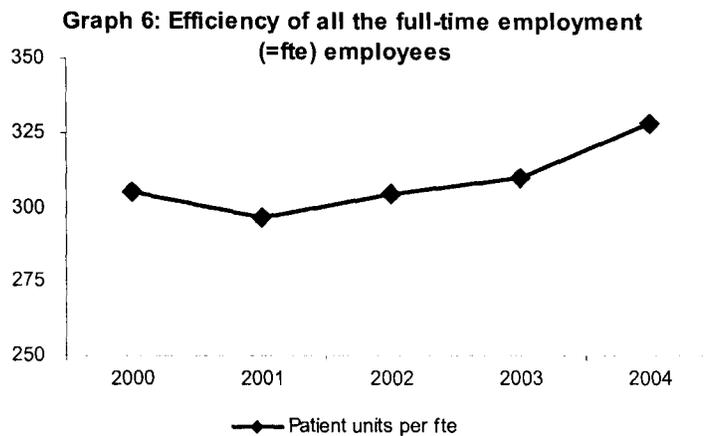
Graph No. 3 demonstrates the growth of the number of first contacts in the outpatient department and the waiting period (admission time). This growth has been made possible mainly by projects related to reducing the number of revisits and introducing elements of one stop shopping (i.e., all treatments on the same day).



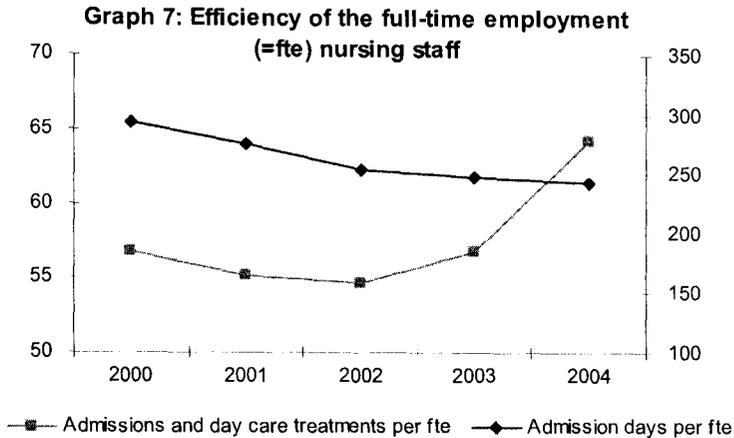
Graph No. 4 demonstrates the number of operative procedures and the number of patients waiting for an operation. In 2001 management stated that the number of surgical operations could not be increased any further. By starting a Lean Six Sigma project, however, it appeared possible to increase the number of surgical operations with 11%. 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 RCH did also receive some unwanted help of a multi resistant staphylococcus aureus that forced RCH to close its Intensive Care unit for a period of time, thus enabling RCH to treat more low care patients. Over a period of five years RCH was able to increase the number of surgical operations by more than 20 percent.



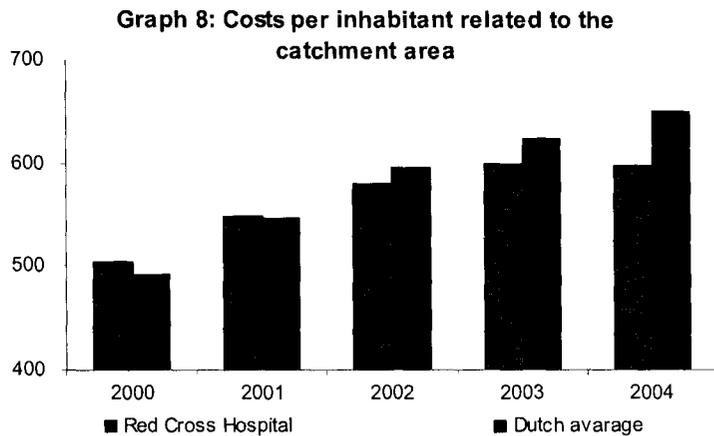
Graph No. 5 demonstrates the number of beds that were blocked by patients waiting for a nursing home. Beds that are blocked seriously impede the available capacity and therefore our output. RCH was aware that it had a problem in 2001 but RCH was not aware of the magnitude or the financial impact. RCH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



Graph No. 6 demonstrates the number of patients 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 a hospital. Therefore the number of patient units per fte gives an impression of the efficiency of a hospital. In 2000 there was a high sick rate (see graph no 10) and a general (but not substantiated) idea that the workload was much too high. Given the sick rate RCH then decided to increase the number of employees which explains for the drop in efficiency in 2001. From that time on RCH had its quality management system fully operational and from 2003 RCH could give efficiency an extra impulse with the first tangible results of Lean Six Sigma.

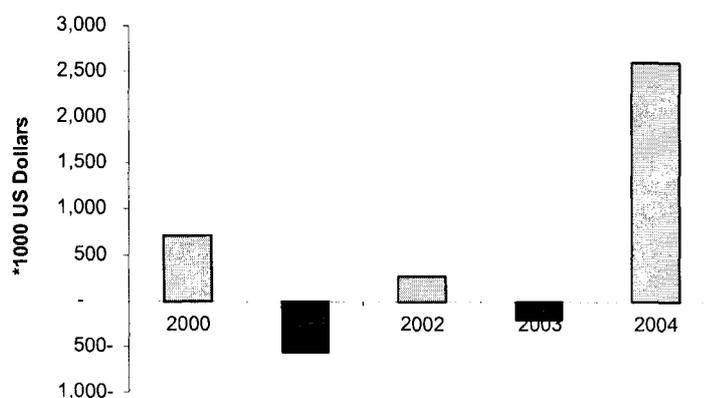


Graph No. 7 demonstrates the number of admissions and day care treatments per full time equivalent (FTE) nursing staff. It also demonstrates the number of admission days per fte nursing staff. The graph clearly shows that a number of projects and the implementation of clinical pathways firmly increased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



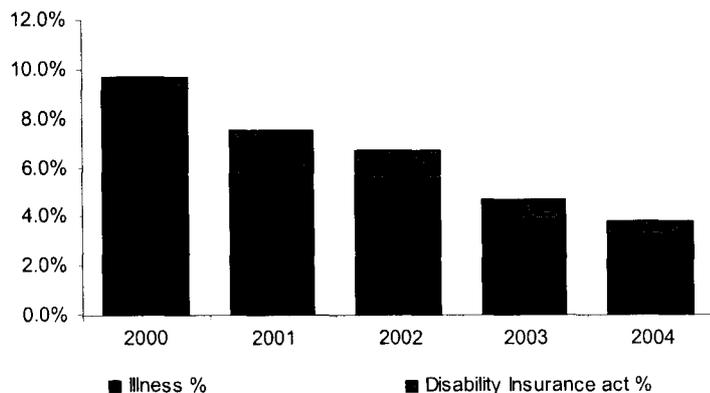
Graph No. 8 demonstrates the costs per inhabitant related to the catchment area of the RCH and of all Dutch (non-academic) hospitals. This graph relates the overall output of the RCH to the total costs. In 2000 RCH was less efficient than the Dutch average. The quality management system and Lean Six Sigma made RCH 8.3% more efficient on costs per inhabitant than the Dutch average in 2004. This graph perhaps shows best the effects of quality management in the hospital.

**Graph 9: Income from continuing operations**

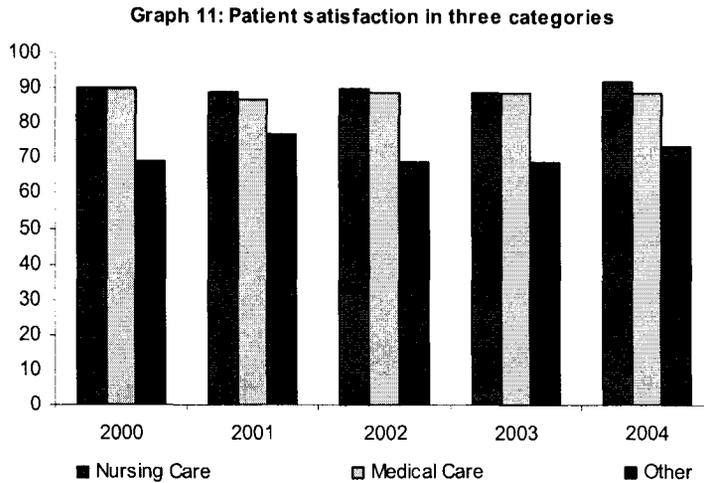


Graph No. 9 demonstrates the income from continuing operations. Here it can be seen that the earnings from the projects in 2004 correspond directly with the income of the RCH in that same year. This income differs significantly from the years in which Lean Six Sigma was not fully operational.

**Graph 10: Absence due to illness**



Graph No. 10 demonstrates the absence through illness. This graph shows clearly that despite the increase in efficiency RCH was able to control the absence through illness as well.



Graph No. 11 demonstrates patient satisfaction. Perhaps one of the most important indicators is related to patient satisfaction. This graph demonstrates three main categories of patient satisfaction; nursing care, medical care and all other service and care. RCH uses 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 the RCH. RCH distributes more than 2,000 forms a year and the response rate is nearly 50%. On every item, patients can rate four categories; “good”, “reasonable”, “can be improved” and “must be improved”. RCH has been able to achieve consistent rates of more than 80% “good” every year for the entire hospital and 90% “good” on nursing care and medical care.

When we look at the development of the performance indicators of the RCH we can draw the following conclusions. In the first place RCH has been able to realize its two main strategic goals: RCH achieved continuous growth over the past five years and RCH was able to increase efficiency from below to above the Dutch average. Furthermore, RCH was able to consistently lower our sick rates. This might indicate that the raise in efficiency did not inflict the well-being of our employees. Its third strategic goal to deliver an adequate level of quality of care in order to stay attractive to its patients has been achieved as well because its patient satisfaction scores were constant (and high) over the past five years. Based on its achievements we dare to state that quality management indeed has paid off in RCH.

## **Conclusions**

Quality management according Juran consists of three aspects; quality planning, quality control and quality improvement (Juran, 1989). In addition, measuring quality is considered the core of quality management. 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 a quality improvement program. The most important quality standards are the International Quality Standards ISO 9000 series. Currently, the state of the art quality improvement program is called Lean Six Sigma. In this paper we discuss both aspects and we show the results of the implementation of ISO and Lean Six Sigma in a hospital over a period of five years. Both Lean Six Sigma and ISO offer explicit structures and approaches so there is little room for debate among employees about the relevancy and subsequent actions needed to achieve quality. Finally, Lean Six Sigma and ISO are highly complementary. They both focus on: processes, client wishes, continuous improvement, employee involvement, fact-based decisions and a systems approach on management. So an ISO quality management system and Lean Six Sigma are virtually zipped together thus integrating the full spectrum ranging from quality control via quality assurance to quality improvement.

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

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