An ISO 9001 quality management system in a hospital

Bureaucracy or just benefits?

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Abstract

Purpose – To describe how The Red Cross Hospital in Beverwijk, The Netherlands implemented an ISO 9000 quality management system throughout the entire organisation, obtained an ISO 9002:1994 and subsequently an ISO 9001:2000 certificate.

Design/methodology/approach – First, a global implementation plan was written concerning the process obtaining in each department. Once improved, each process was subjected to a procedure, and specific protocols effected. On completion the *Quality Manual* was put together. Quality management was completed by implementing an internal audit system involving 50 co-workers.

Findings – 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 results. Measurements subsequently lead to improvement of quality of care and to quality system improvements. The documentation system serves the organization's needs without leading to bureaucracy. Positive effects on patient safety could be demonstrated compared with ten other hospitals.

Originality/value – Given the need for adequate quality management tools in health care and the need for demonstrating quality, the positive effects reported in this article show how ISO is expected to become more prevalent in health-care organisations.

Keywords Quality management, Quality standards, ISO 9000 series, Hospitals

Paper type Case study

Introduction

Health care organisations are expected to deliver an adequate level of quality of care. Furthermore, society demands transparency, efficient usage of public funding, and

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accountability (Relman, 1988). The Institute of Medicine (IOM), however, states that health care today harms too frequently and routinely fails to deliver its potential benefits (Institute of Medicine, 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 benign intention of employees (Berwick, 1989). The IOM also emphasized the necessity to redesign the health care 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 organisation (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, b). The International Organisation for Standardisation (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 organisation, large or small, whatever its product or service, in any sector or activity whether it is a business enterprise, a public administration of 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 organisation can continuously deliver the product or service that (see "ISO for busy managers" at www.iso.org):

- Meet the customer's quality requirements.
- Meet applicable regulatory requirements.
- Enhance customer satisfaction.
- Achieve continuous improvement of its performance in pursuit of these objectives.

ISO takes a systems and process approach to improve organisational 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 organisations (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, 2002). In the Netherlands, more than 13,000 companies have acquired an ISO 9000 certificate of conformity. In health care, the application of the ISO standards is not yet very common and subject for debate. Recently the usefulness of ISO 9000 standards in health care was outlined (Carson, 2004). A small number of Dutch health care organisations have been reported to use ISO 9000 standards (Sluijs and Wagner, 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 world-wide application of ISO 9001:2000 in hospitals can only be obtained by organisations 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 50 beds) hospitals that are related to BUPA, a health care insurance company, have an ISO 9001:2000 certificate (see www.bupahospitals.co.uk). Several US certification organisations claim to have achieved successful certifications in hospitals (see SGC ICs at www.ics.sgsna.com; Quality Paradigms at www.qualityparadigms.com and TUV America at 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 USA to have earned an ISO 9001:2000 certificate in October 2003 (see Freeman: one of the nation's 100 top hospitals, at 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 to ISO 9002 in 1994 (see www.eastshore.comsg "ISO 9001:2000 quality system). The Alexandra Hospital in Singapore, a 400-bed general hospital, achieved ISO 9001:2000 certification on 16 January 2001 (see www.alexhosp.com.sq "News and events archived news"). 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 world-wide 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 organisation in the country (see www.tisi.go.th). This internet site reports 240 hospitals having an ISO 9000 certificate for parts of the organisation 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 the core processes in our hospital we needed approximately 60 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 organisation were described, the hospital management put together the *Quality Manual*. This manual contains descriptions of the organisation, 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 50 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 the required elements of our ISO quality management system were designed and implemented, the system had to "come alive". 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. Finally the internal and external audits have to either confirm that the system functions 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 focussed 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 health care

The IOM has pointed out that quality of care is often not sufficient because heath care processes are poorly designed and characterised by unnecessary duplication of services and long waiting times and delays. In our quality management system all processes have been identified described and optimised. 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 health care processes and improvement of the quality of health care. 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 analyses 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 (Kohn *et al.*, 2000).

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 the core processes of our organisation. 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 16 procedures related to the health care 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 health care. 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 years 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 organisation. 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. Until this moment we are the only hospital in The Netherlands that obtained an ISO certificate for the entire organisation.

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 and de Koning, 2001). The Centrameter consists of 29 different questionnaires, one for every group of employees in and around the hospital. Patient safety is given a 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, 11 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 from 33 percent to 46 percent with an average 41 percent. In 2001, our hospital scored a 63 percent match where the other hospitals ranged from 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 the centre of our attention and receive positive feedback. This motivates us to pick up the remaining shortcomings in health care 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, health care 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 organisations 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 health care 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 health care 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 organisation as a starting point can, despite using the same standard, lead to different quality management system in different organisations. This observation has been made in health care and was considered a disadvantage of ISO (Sweeney and Heaton, 2000). The intention of ISO however is not to create identical quality management systems in different organisations, but only to establish conformity to (minimal) requirements.

The ExPeRT project, a study on external quality mechanisms for health care, has identified four principal models and national variants, of external quality improvement in health care (Shaw, 2000). These models are; the medical speciality-driven "visitation" 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 health care (Nabitz *et al.*, 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 (van Dijen and de Koning, 2001). In Switzerland, an attempt has been made to adapt the ISO 9000 standards to health care. This resulted in an interpretation guide of ISO 9001:1994 (Cranovsky *et al.*, 1997). Although a number of different kinds of health care 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 health care providers are not yet forced to prove the quality of their work (Schilling *et al.*, 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 health care, called ISO IWA 1, that have been developed can perhaps contribute to a better appreciation and wider use of ISO 9001:2000 in health care (ISO, 2001b). The first revision has appeared in 2004 (Reid, 2004).

Serious quality and safety problems have been described by the Institute of Medicine. Health care relies on outmoded systems of work and systems of care have to be redesigned. The IOM suggests health care adopt quality tools from 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 health care as a basic step in the road of quality management.

Conclusion

We successfully implemented a quality management system according to the ISO 9001:2000 standard and obtained a certificate of conformance for our entire hospital organisation. 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 led 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 health care, 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 health care organisations.

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