Implementing an ISO 9001 Quality Management System in a MultiSpecialty Clinic

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In this article…

Take a step-by-step look at how a multispecialty clinic implemented an ISO 9001 quality management system and see the benefits the clinic reaped.

Physicians' Clinic of Iowa (PCI) is a 50-physician multispecialty clinic located in Cedar Rapids, Iowa. Physician specialties include cardiac surgery, otolaryngology, general surgery, neurology, orthopedic surgery, podiatry, rheumatology, thoracic surgery, urology, and vascular surgery.

PCI employs 200 staff at five sites of care. PCI physicians manage approximately 98,000 E and M encounters per year and perform over 52,000 surgical procedures annually. In the spring of 2001, leadership at PCI decided to develop a quality program for the clinic.

After evaluating healthcare options and reviewing industry quality systems, it was decided to pursue ISO 9001 certification for the clinic. PCI leadership had joined the local chapter of the American Society for Quality and participated in chapter events. This relationship enabled PCI leadership to gain insight into quality management systems used in industry, and the information helped in choosing ISO as the quality system for PCI to pursue.

ISO 9001 background

The International Organization for Standardization (ISO) was founded in Geneva in 1947.[1] The original purpose of the organization was to provide standardization of technical specifications for products traded in the international marketplace. The term "ISO" is a word derived from the Greek "isos," meaning "equal."

Over 150 countries are members of ISO, and there are more than 10,000 ISO standards used worldwide. These standards determine how various products and services are produced, and include standards for film speed, thickness of credit cards, compact disc format, and screw thread number. Standardization has served an important role in promoting quality and compatibility of products on a global basis .[2]

The work of standardization is performed by ISO technical committees comprised of representatives from interested member countries to address specific standards. Over the years the concept of standardization has evolved from specific technical specifications to a broader concept of generic quality management system standards.

The concept was first brought to the United States by the automobile industry in the late 1980s because of a need to qualify the thousands of suppliers used by automobile manufacturers. This effort was a concrete example of competitors working together to develop a quality framework that would serve them and their customers.

The ISO 9001 family of quality management system standards was first developed in 1987 and revised in 1994 and 2000.[3] The automobile industry described the specific standards for its suppliers in the QS 9000 system, and other industries have done the same with customized quality management system standards for the particular industry.

In 2001, a set of preliminary standards for healthcare was published by the American Society for Quality in partnership with the Automotive Industry Action Group.[4]

Today, more than 500,000 companies are ISO certified internationally, with approximately 38,000 in the United States. Worldwide, 65 percent of certifications are in manufacturing; 90 percent in the U.S. are in manufacturing. Approximately 100 healthcare entities in North America are certified, including 12 hospitals and 10 medical groups in the U.S.

There are many reasons for a healthcare facility to obtain ISO certification (ISO 9000 is the family of standards; an entity is certified to ISO 9001:2000). Establishing an ISO 9001 quality management system:

- Provides for work performance consistency
- Enables the discovery of causes of poor performance
- Stresses the process approach
- Defines goals and objectives for quality
- Provides benchmarks to measure improvements

Quality management requires customer focus and continual improvement. It provides for accountability within the system and ensures that the most important functions are carried out. It establishes a clear document system throughout the organization, a common language across the organization, and common identifiers for customers/patients .[5]

ISO requirements

An organization seeking ISO certification must describe and implement a quality management system according to the requirements of the American National Standard for quality management systems .

This initially involves utilizing the standard to write a quality policy, quality manual and quality objectives, and then using the process approach to address the other requirements of the standard. The conventional ISO saying is that you:

- Document what you do ("Say what you do")
- Establish a process for the service
- Perform to your documentation ("Do what you say")
- Provide the service based on the process
- Record the results of your work ("Record information")
- Appropriately maintain all recorded information
- Audit the documentation for effectiveness ("Audit effectiveness")
- Audit using the proces s approach

ISO 9001 requirements are based on eight quality management principles. The principals suggest the use of a process approach in developing the quality system and are designed to increase customer/patient satisfaction. The quality system requires continuous improvement. The eight principles are:

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

The principles are imbedded within the eight clauses of ISO 9001:2000 that comprise the quality manual for an organization, and together they describe the quality management system.

An organization may seek certification after it has successfully implemented a quality management system. Certification or registration is awarded after passing an audit by an accredited registrar. Registrars are independent companies that are qualified by a worldwide network of governing bodies.

Costs of ISO Implementation

Documentation of the ISO process at PCI involved maintaining records of all meetings and attendees. Based on this information we calculated the soft costs of implementing the ISO quality management system.

       Soft costs to date of certification (2.5 yr.):

       142 meetings from 3/01 through 9/03
       2,345 hours
       Cost estimate based on each FTE hourly rate $81,895

       Consultant
       Pre-audit, registrar
       Audit, registrar $26,547

       Total costs to date of certification   **$108,443**

       Cost per physician $2,169
       Cost per physician per year (2.5 yr.) $868

Our ISO experience

The experience at PCI was carefully documented over the 2.5 years that we worked to become certified. During the first year we identified a local consultant experienced in ISO certification for businesses. This individual was not experienced in healthcare but was interested in working with PCI to assist in our goal of becoming certified.

The quality improvement director of PCI was given the task of overseeing the project and monitored all aspects of the work, including the documentation of our experience. The consultant delivered several ISO training sessions for PCI employees and identified two local businesses that offered tours of their facilities and shared information about their ISO quality management systems.

Additional support was obtained from the Iowa Quality Center, Kirkwood Community College, and the local chapter of the American Society for Quality. A quality policy, quality objectives, and quality manual were written and circulated to PCI employees. Initial employee uncertainty regarding the meaning of the quality management system was addressed by having employee kick-off meetings in order to describe the ISO concept and clarify employee involvement in establishing the quality management system. Employees were actively engaged in designing the PCI quality management system and in many cases were asked to describe their job responsibilities as ISO documents were written. This employee involvement was key as they learned the quality management system was not a threat to them, but a supporting framework to be used in improving their clinical and business processes.

A controlled document system was developed during the first year using an alpha-numeric numbering system to manage all documents within PCI. Establishing this numbering system was actually considered to be a milestone in our journey to ISO certification.

All PCI policies and procedures were reviewed, revised, and put into a common document format. PCI had over 400 policies and procedures in place when the process began and actually reduced the number of documents to 375 by the time of certification, including the addition of new policies and procedures required by ISO.

Standardizing medical records among different departments and sites of care was a major effort, but was important in our understanding of the value of having a common document system within the organization. It also became apparent that the HIPAA requirements for healthcare providers were much easier to implement with an ISO quality management system in place. During the first year we also established an ISO steering committee comprised of PCI managers and leadership. This committee met on a monthly basis to oversee and provide working support for the ISO implementation effort.

During the second year we interviewed three registrars among the seven registrars in the United States that provided ISO 9001 certification to healthcare organizations. TUV America was selected and initial meetings were held with TUV representatives. Process maps were developed for the overall clinical patient flow process, medical patient care process, and surgical patient care process. The chief medical officer held a quality training retreat for all interested PCI employees and quality literature was provided.

The second milestone was reached with the internal auditor training sessions provided by the consultant. These sessions involved interested employees from each office and were valuable in teaching auditing principles and in clarifying the value of auditing to monitor and improve the quality management system. Internal audits began during the second year as newly trained auditors scheduled and conducted audits of employees in different offices.

Management review meetings were instituted during the second year in accordance with the requirements of the ISO standard. These meetings are held every three to six months and are designed to oversee the quality management system, monitor issues, and provide follow-up to corrective and preventive actions.

A Physician Quality Council was established with representatives from each PCI department. The council was updated regularly on aspects of the ISO process and quality management system, and served as a conduit to keep PCI physicians informed within respective departments.

As our interests in establishing quality metrics within PCI became more refined, we realized that many metrics that we wanted to track were not available in the office setting but were part of the hospital databases. So we established a data collection committee with QI representatives from each of our two community hospitals. The committee agreed to work together and decided to track SIP indicators of peri-operative antibiotic usage that had been outlined by CMS (Surgical Infection Prevention Collaborative).

This collaborative resulted in data sharing and in the development of an ISO document within PCI that is used to track wound infections in the clinic setting following hospital discharge. In this way both PCI and the hospital improve their data integrity and have a better overall understanding of infection rates within our community.

The second year also marked the establishment of a PCI quality newsletter called "PCIntouch." The newsletter was written monthly by the QI director and chief medical officer with articles focused on both HIPAA and ISO 9001 issues.

During the final six months of the journey to become ISO certified, we wrote a series of physician newsletters that served to remind the physicians of the basics of the ISO quality management system and keep them updated.

Our consultant brought several local quality managers within industry to PCI for a practice audit, and a pre-assessment audit was conducted by TUV two months prior to our formal certification audit. PCI became formally registered to ISO 9001:2000 on November 10, 2003, the largest medical group in the U.S. to attain this ISO certification.

Although we believe that the soft costs are accurate, the meetings often involved PCI business and dealt with clinical issues that were not restricted to the ISO implementation. We estimated that approximately half of the soft costs involved time that would have been required from PCI employees without the ISO quality management system. Calculation of costs per physician per year then equate to $540 rather than $868 per physician per year.

Benefits of ISO Implementation

The major benefits of the ISO process relate to the utilization of the process management approach. The process approach initially was used in designing the medical and surgical patient care process maps that were integrated into the ISO system during the first six months. These maps were helpful in understanding the process steps as we evaluated and improved the care processes and incorporated them into the ISO framework.

The process approach was also used in developing a balanced scorecard and strategy map for the organization. These documents were developed as a result of the strategic planning process that is undertaken at PCI biannually. Although the balanced scorecard and strategy maps are not an ISO requirement, they clearly support the ISO management principles and complement the management review activities of the ISO quality management system.

The process approach was used to develop a payer matrix for evaluating payments on proposed insurance contracts. This matrix is employed to document important elements of a proposed contract and assign each contract an overall score.

High value elements such as electronic transmission are awarded bonus points and the resulting score allows evaluation of the overall contract and comparison of contracted rates to other payors. A request for proposal (RFP) process was also written and incorporated into the ISO quality management system as a methodology to use in obtaining information from vendors. PCI is currently evaluating electronic medical record systems and has used the RFP process to ask questions of vendors such as:

- How long has your organization been in existence?
- What differentiates your organization from your competitors?
- Describe your ordering process. Does your organization support an on-line ordering process?
- From order placement to receipt of ordered supplies and/or services, what is your normal delivery timeframe?
- Describe your organization's policy and process for defective and/or damaged products. What is the normal time sequence between product return and replacement?

Both internal and external auditing are ISO requirements. Our internal auditing program requires employee involvement in both maintaining and improving the quality management system and has been well received and supported by PCI employees.

Internal audits are conducted every three to six months, and focus on selected areas based on previous audits and findings of nonconformance. The external registrar audit is required annually.

Corrective and preventive action plans are required procedures within the ISO quality management system. This system requirement ensures follow-up for any problems identified within the clinic setting and have been incorporated into our patient comments to help in addressing patient concerns and complaints. The corrective and preventive action plans are audited and oversight is maintained through the management review process.

Cost savings

Specific cost savings have been identified in the areas of days in accounts receivable, payment on contracted rates, and workers' compensation insurance rates. PCI management recently evaluated our purchasing process using a lean value stream mapping analysis and expects to identify additional cost savings for snow removal, paper shredding, and cleaning. Results of these cost savings initiatives will be evaluated and reported at a later date.

Implementation of an ISO 9001 quality management system has been a definite benefit to our organization. The experience requires time and effort on the part of both employees and management. We initially believed that the process would be completed within a year, and although our efforts required 2.5 years of work, we felt that there was ample time to accomplish the tasks and believe that we had better buy-in from our employees by taking a slower approach and involving them in the effort.

The key learning points that we identified include:

- Leadership must be committed

- Utilize local resources
- Benefits are both tangible and intangible
- Changes the culture
- ISO is a framework to be built upon
- Process management is the key
- ISO systems in healthcare have great potential

Future plans include formal development of a risk management program at PCI that will be incorporated into the ISO quality management system. We recently completed a 20-page risk assessment form at the request of our malpractice carrier. This form was quite comprehensive but the work required to complete the form was reduced significantly because the ISO quality management system framework was already in place within our organization.

The culture of PCI has been positively affected by the ISO quality management system, and marketing efforts to date have been quite favorable, especially with employers who frequently are familiar with ISO concepts.

PCI Quality Policy

The Physicians' Clinic of Iowa, P.C. is a physician-owned and governed multi specialty group whose mission is to deliver the highest quality of multispecialty healthcare to individual patients in Eastern Iowa. We will coordinate this care to be a value to our patients and other purchasers of healthcare.

PCI Quality Objectives

All PCI physicians and employees will strive to:
- Maintain a high level of satisfaction for our patients and other customers
- Contain costs for both patients and the hospitals whom we serve
- Return our patients to active lives with maximal functional capacity
- Monitor clinical outcomes on a regular basis in order to make continued improvements in patient care
- Continually assess issues regarding patient safety in order to ensure patient safety and reduce errors.

The six procedures required by the standard for ISO 9001:2000 include:

1. Control of documents
2. Control of records
3. Control of internal audits
4. Control on nonconformities
5. Control of corrective actions
6. Control of preventive actions

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