

# Prescription for Community-Based Healthcare Includes ISO 9001

by Janet Jacobsen

### At a Glance . . .

- Medical and business leaders in Cedar Rapids, Iowa, joined forces to create a community model of care delivery and patient safety using ISO 9001 principles as a framework for cooperation.
- The initial model is a community anti-coagulation therapy clinic to manage patients who take a common blood-thinning medication.
- A federal healthcare grant provided start-up funds to create the clinic, which utilizes a controlled document system based on ISO 9001, internal and external auditing, and preventive and corrective action plans.
- Customer and provider (referring physician) surveys demonstrate 100% satisfaction. More important, patients now experience fewer side effects from the medication and require fewer hospitalizations and physician visits.

Nearly 2 million people in the United States rely on the prescription anti-coagulant or blood thinner known as Coumadin® or its generic equivalent, warfarin, to prevent blood clots and to allow blood to flow more easily through narrowed blood vessels. Many will need this medication for the rest of their lives. Unfortunately, serious complications such as blood clots, bleeding, and strokes can arise if patients are not closely monitored. Potential interactions with certain foods, alcohol, and other medications make a coordinated team effort involving physicians, hospitals, laboratories, and pharmacists crucial to ensure that warfarin patients are able to live safe, healthy lives.

Could quality principles such as those found in the internationally accepted ISO 9001 quality management system standard play a role in this patient safety issue? Dr. James Levett, a Cedar Rapids cardiothoracic surgeon and chair-elect of the American Society for Quality's Healthcare Division, has set out to prove the following hypothesis:

*ISO 9001 quality principles can serve as a framework to develop a system of care that will improve communication, facilitate establishment of care pathways and safe practice interventions, and enhance the continuity of patient care in the community.*

### About the CAT Clinic

The central testing ground for Dr. Levett's hypothesis, the Community Anticoagulation Therapy (CAT) Clinic, began working with patients in February 2006 as a result of a \$600,000 grant from the Agency for Healthcare Research and Quality (AHRQ), a branch of the U.S. Department of Health and Human Services. Securing the grant was in itself a communitywide effort led by Physicians' Clinic of Iowa (PCI), a multispecialty medical group for which Dr. Levett serves as chief medical officer; Kirkwood Community College; Rockwell Collins, a major employer in this east central Iowa community; two local cardiology clinics, Cardiologists, PC, and United Heart; as well as the city's two major hospitals, Mercy Medical Center and St. Luke's Hospital.

The primary goal of the CAT Clinic is to provide patients with a better quality of service by connecting healthcare providers at a new level of communication and by implementing a process for quality assurance. The clinic offers the following services to approximately 250 patients:

- Anti-coagulation therapy
- Patient education materials
- Feedback to physicians about their patients
- Advocacy coordination



Initially created to provide oversight for the Community Anticoagulation Therapy (CAT) Clinic, the Cedar Rapids Healthcare Alliance (CRHA) soon began focusing on a much

larger picture. "As we wrote the bylaws, we thought this organization should do something broader than the CAT Clinic; it should become an organization with multiple stakeholders comprised of both local hospitals; Wellmark, the largest insurance payer in the state of Iowa; employers; healthcare providers; and patients working together on broad issues of healthcare facing the community," explains Dr. James Levett, president of the CRHA.

This nonprofit organization seeks to create a community model of care delivery and patient safety centered on transparency, accountability, and cooperation. Members of the alliance view the CAT Clinic as the first of many community-centered initiatives with possible additional topics that may include:

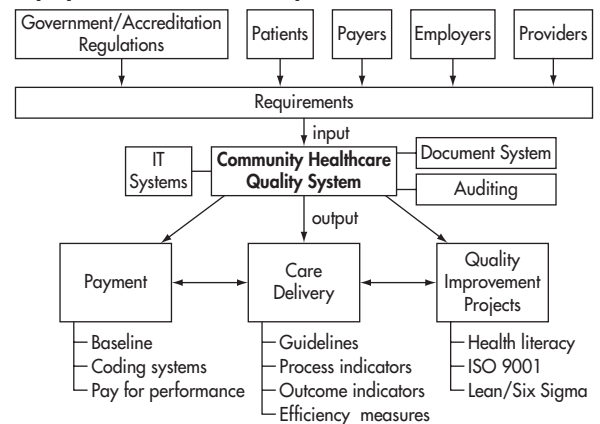
- Decreasing community acquired infections, such as MRSA (methicillin-resistant Staphylococcus aureus) infections, which are resistant to antibiotics
- Reducing childhood obesity and diabetes
- Decreasing adverse drug events in the elderly population by establishing consistent community medication reconciliation at times of transition from one point of care to another
- Increasing access to healthcare quality information that is written in consumer-friendly language

**ISO 9001 Principles May Foster Healthcare Initiatives Across the Nation**

A common thread running through all CRHA activities is the use of ISO 9001 principles. Dr. Levett offers the figure at right to illustrate a potential paradigm of using principles of the internationally accepted quality management system (QMS) standard to support a community quality

system. The process approach helps determine customer requirements and convert them to outputs of care delivery, payment, and ongoing quality improvement projects within the context of a QMS, explains Dr. Levett. The QMS would be supported by IT, an ISO 9001-based controlled document system, and an auditing function.

**A Quality System at the Community Level**



Dr. Levett's confidence in the validity of the model is so strong that he's shared it with U.S. Department of Health and Human Services Secretary Michael Leavitt. Secretary Leavitt has a vision of creating "value exchanges" throughout the country to organize and deliver healthcare locally, supported by an integrated information and learning network based on national standards. Dr. Levett believes the quality system at the community level paradigm offers a strong potential model for Secretary Leavitt's vision.

"We believe that ISO 9001 concepts may have value in the context of community models such as those envisioned for value exchanges. The common framework provided by a QMS would also facilitate the sharing of information and integration of processes with other value exchanges throughout the country," states Dr. Levett.

Patient education is a key objective says Carla Huber, nurse coordinator for the clinic. Once a patient is referred by a physician, Huber conducts an extensive one-on-one visit to assess his or her medical history and completes a "brown bag" review of all other medications the patient takes. Huber, an advanced registered nurse practitioner, also thoroughly discusses the clinic's education booklet, *My Guide to Warfarin Therapy*, with each new patient.

**Using ISO 9001 to Coordinate Healthcare**

Shortly after assuming his post as chief medical officer at PCI, Levett began searching for ways to incorporate quality principles into the clinic's practices. He paid a visit to a team of engineers at Rockwell Collins, a leading supplier of communication and aviation electronic solutions, headquartered in Cedar Rapids. Here, Levett received the following advice: Join the American Society for Quality and participate in local section activities. Acting on this recommendation, he started learning more about quality principles, which ultimately led to PCI earning registration to ISO 9001, the internationally accepted standard for quality management systems.

As he became comfortable with the eight fundamental principles of ISO 9001 that can be applied for organizational improvement, Levett felt that a broader, communitywide application had to be possible. In time, his quest led him to create a community coalition to apply for and eventually receive the AHRQ grant to establish the CAT Clinic. The grant was awarded to fund three specific aims:

- Training in the principles of ISO 9001
- Establishing the CAT Clinic
- Determining additional uses of the ISO 9001 framework within the healthcare community

Levett says that gaining stakeholder buy-in to participate in the grant process was a matter of finding and demonstrating common ground among hospitals, physicians, laboratories, and patients. "We're certainly all interested in lowering healthcare costs and improving delivery of care. Just because there is competition between people or organizations doesn't mean they can't work together," he says. Levett credits the AHRQ grant for helping to garner such widespread stakeholder participation because the grant provides outside funding and allows the clinic to be independent, rather than have an affiliation with one specific hospital or medical practice.

## Coming Together With Quality

With the support of Rockwell engineers, Levett and the coalition employed lean and Six Sigma principles, such as process flow mapping, to study how local cardiology clinics were managing warfarin patients. “We wanted to learn from current practice to better design processes at the CAT Clinic,” Levett explains.

After searching unsuccessfully for a software program that fit the CAT Clinic’s requirements, the group hired local software engineers to create a custom product based on the requirements identified through the lean Six Sigma analysis. This Web-based warfarin management database system, INR Pro, is now sold commercially.

Levett recalls that in the first quarter of the grant operation the need for a community organization to oversee the CAT Clinic became readily apparent. Thus, the Cedar Rapids Healthcare Alliance was established not only to supervise the clinic, but also to identify and resolve other healthcare and patient safety issues in the community. (See sidebar “Community Alliance Focuses on Broad Healthcare Issues” for more information.)

To meet the first aim of the grant, education on the principles of ISO 9001 quality management systems, the Iowa Quality Center provided two levels of training. The first level targeted business and industry leaders and covered ISO 9001, lean, and Six Sigma principles, while the second tier of training was conducted for healthcare employees and focused on basic ISO 9001 and Baldrige concepts.

Levett explains that the process of studying these principles within the community and involving providers at both hospitals and the clinic enabled those involved to identify areas of common interest where standardization was appropriate. For example, common guidelines were developed for managing both outpatients at the CAT Clinic as well as hospitalized patients.

## Utilizing the Process Approach

Levett says the process approach, which is fundamental to most quality systems, is perhaps the most valuable concept to consider when using ISO 9001 principles in a community context such as the CAT Clinic. Using the process approach, the clinic established a controlled document system, auditing plans, and corrective and preventive action plans.

Each day, Huber finds value in the clinic’s controlled document system, which includes 80 policies and procedures. “Everything is in one place with written guidelines on how we treat our patients, collect data, and follow up on that data. It’s a true process from start to finish,” Huber notes.

In addition, the clinic developed auditing plans to monitor activity with quarterly internal audits and annual external audits. Internal auditing by trained hospital and office staff ensures accuracy and validation of data collected as well as standardization of policies, procedures, and guidelines. Corrective and preventive action plans were also implemented to record all safety and error issues as well as to track continuous process improvement.

Levett says the ISO 9001-based system serves as a framework to monitor any adverse reactions and re-admissions for anti-coagulation-related complications by providing a common database for corrective and preventive action plans shared by participating hospitals. By using a common set of documents and an auditing system to maintain quality control, Levett and his team can better understand the overall scope of care within the community, identify safety issues, and ensure that follow-up action is taken.

## Framework for Quality Leads to Patient Safety and Satisfaction

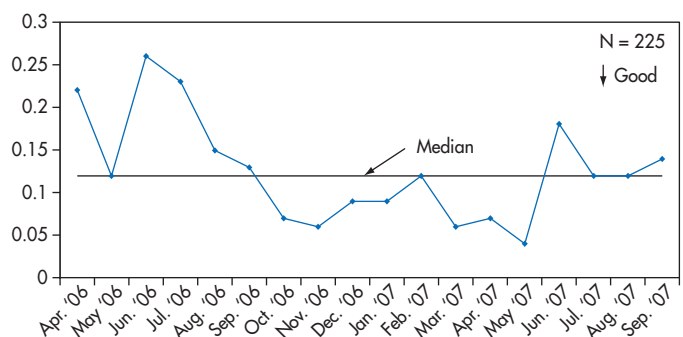
While the CAT Clinic is still relatively new, the results are certainly encouraging, as both patients and providers (referring physicians and their staff members) report 100% satisfaction with the clinic in a series of customer feedback surveys. Huber notes that patient satisfaction rises as patients gain a greater understanding about the medication and how to manage their health—something she believes is happening with CAT Clinic patients.

As the clinic continues to manage each patient’s care more closely, another measure improves: the average CAT score, which measures compliance regarding changes in medications, diet, alcohol use, missed or extra warfarin doses, as well as other medications added or discontinued. Figure 1 shows a decrease in the average patient CAT score, which indicates better compliance with warfarin therapy and typically results in better health.

“What they’ve (the CAT Clinic) accomplished is very statistically significant with the number of patients who are able to be in control of their Coumadin; it’s very impressive,” notes Mary Ann Osborn, vice president and chief clinical officer of St. Luke’s Hospital in Cedar Rapids. She credits the framework and structure put in place with the ISO 9001 policies and procedures for contributing to the reliability of the clinic.

The INR (International Normalized Ratio) range is another key measure for warfarin patients. The INR is a standard unit that represents the results of a test to measure the time required for the blood to clot. Data for each patient are maintained with statistical process control charts to help make decisions regarding warfarin

**Figure 1—Average CAT Score**



This score measures patient compliance regarding changes in medications, diet, alcohol use, missed or extra warfarin doses, and adding or discontinuing another medication. A decrease in the CAT score indicates better compliance with Coumadin®/warfarin therapy.

dosage and prevent unnecessary changes. The greater the time in range and the tighter the range that is maintained, the better for the patient. Figure 2 depicts the percent of time that participants are in an INR range of plus or minus 2%. Patients in the CAT Clinic are in a tighter range 10% to 15% more than prior to enrollment.

As patients maintain a tighter INR range they are less likely to experience symptoms that require additional physician visits, thus lowering healthcare costs. Figure 3 illustrates a decline in physician contacts for CAT Clinic patients.

Data also show that patients participating in the CAT Clinic:

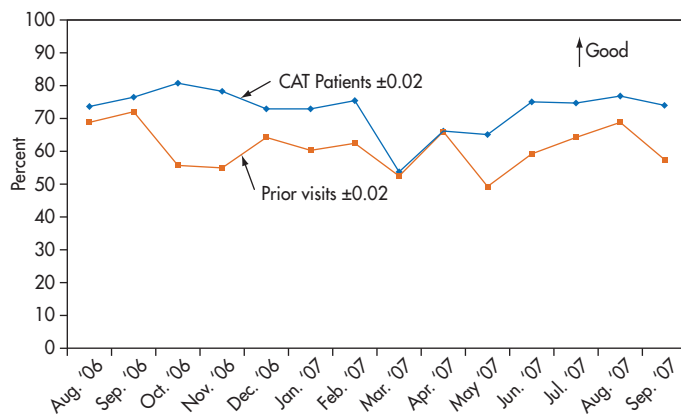
- Are less likely to miss a warfarin dose
- Require fewer dose changes
- Understand the importance of contacting the clinic with health-related questions
- Experience fewer bleeding and clotting events
- Are less likely to require hospitalization or visit the emergency room because of their anti-coagulation medication

Osborn believes one of the biggest challenges is overcoming the reluctance of physicians to refer their patients to the CAT Clinic because it's a new venture and they may question its sustainability. "But now with the good results and track record, Dr. Levett and Carla Huber can have some good conversations with physicians. They have a great story to tell," Osborn remarks.

### Simplifying Processes to Reduce Variation

As the clinic prepares to serve as many as 150 additional patients, plans are under way to begin providing point-of-care INR testing (blood testing) on site at the CAT Clinic by early 2008. Currently, patients visit a lab of their choice to receive a venous draw, meaning a needle is used to access a vein to draw blood. It may then be necessary to send the sample by courier to a main lab for testing where the blood is "spun" by machine. This process introduces variation with the testing machines as well as in having various personnel performing the venous draw, and it can take up to six hours for the results to become available.

**Figure 2—Percent of Time Patients in INR Range  $\pm 0.02$**



This graph shows the percent of time patients are in INR range plus or minus 2%. Patients enrolled in the CAT Clinic are in tighter range, 10% to 15% more than before they were enrolled in the CAT Clinic.

In contrast, with point-of-care testing, Huber will perform a simple finger-stick test with a handheld machine, similar to a glucose-monitoring device. This will further simplify the process as she can easily provide the patient with his or her test results within minutes and can offer in-person consultation if the results indicate variability that requires attention. Once the patient leaves the clinic, Huber will document the visit and send the test results to the referring physician—all within five minutes of the patient's appointment.

### Looking to the Future

As the number of patients served by the CAT Clinic continues to grow, those working closely with the project, such as Tim Charles, president and CEO of Mercy Medical Center in Cedar Rapids, view the clinic as a testing ground for the principles of quality-based community health initiatives. "While the Coumadin clinic is vitally important, what's key is the community commitment to an initiative with the idea of working together using evidence-based protocols to improve quality. The CAT Clinic is a kernel—an opportunity to practice for even broader opportunities to come," Charles predicts.

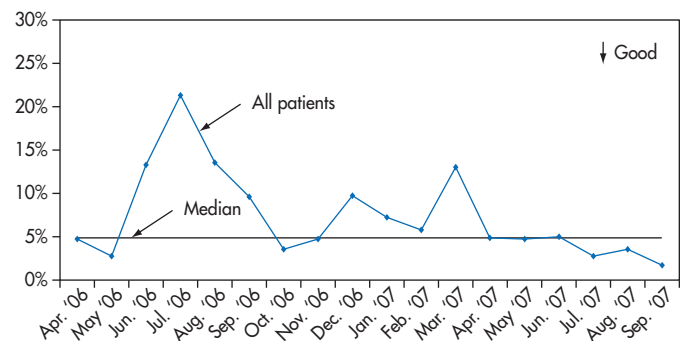
### For More Information:

- Learn more about the CAT Clinic and the Cedar Rapids Healthcare Alliance at <http://www.crhealthcarealliance.org/>.
- Contact Dr. James Levett, medical director of the CAT Clinic and president of the Cedar Rapids Healthcare Alliance, at [jmlevett@hotmail.com](mailto:jmlevett@hotmail.com) or Carla Huber, CAT Clinic nurse coordinator, at [chuber@pcofiowa.com](mailto:chuber@pcofiowa.com).
- For a variety of resources on quality in healthcare visit ASQ's Web site at <http://www.asq.org/healthcare-use/why-quality/overview.html>.

### About the Author

**Janet Jacobsen** is a freelance writer specializing in quality and compliance topics. A graduate of Drake University, she resides in Cedar Rapids, Iowa.

**Figure 3—Physician Contacts**



This graph shows a decrease in the number of physician contacts (the number of times the CAT Clinic nurse needs to contact the referring physician). This number should decrease as patients are in INR range a greater percent of the time.