Utilization of ISO 9001 Principles as a Model for Community Cooperation in Establishing an Anticoagulation Clinic

Kirkwood Community College
Lead Organization

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Partnerships in Implementing Patient Safety RFA
Grant No: U18 HS15830-01
Vision:
To create a community model of care delivery and patient safety using ISO 9001 principles as a quality framework for cooperation.
Immediate Objective:
The project partners have established a community anticoagulation clinic (CAT Clinic) to facilitate management of patients on warfarin and to promote the continual improvement of healthcare within our community.
Overview

- What we hope to accomplish
- Background of ISO 9001
- Review of first year activities
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 our community.
% Warfarin of All ADE's 04/02 through 11/04
A Community Partnership
Grant Partners

- Cardiologists, P.C.
- Cedar Rapids PHO
- Delta Group
- Iowa Quality Center
- Iowa Healthcare Collaborative
- Iowa Health Information Project
- Kirkwood Community College
- Linn County Medical Society
- Mercy Medical Center
- Physicians’ Clinic of Iowa
- Rockwell Collins
- St. Luke’s Hospital
- United Heart Associates
- Wellmark Blue Cross/Blue Shield and Foundation
Cedar Rapids Healthcare Alliance

- Not-for-profit corporation
- Seeking 501(c)(3) designation
- Potential Patient Safety Organization (PSO)
- Framework for Regional Health Information Organization (RHIO)
Quality Management System “Structure” in Healthcare to Optimize Care Delivery

Customer Care and Satisfaction

Process and Service PERFORMANCE

ISO 9001 and Baldrige

*SME-Subject Matter Expert, e.g., Six-Sigma Blackbelt, Process/Quality Analyst
What is ISO 9001?
International Organization of Standardization

- ISO 9001 and other quality standards are developed and controlled by this organization

- “ISO” means: “equal standards throughout the world”
ISO 9000 Quality Standards

- Technical specifications initially
- Generic management system standards later
- ISO 9000 family developed in 1987
- Revised in 1994 and 2000
- Can be used across all types of organizations, including healthcare
- Organizations are certified to the ISO 9001 requirements
ISO 9001 Requirements

- Based on eight quality management principles
- Suggest the use of a process approach in developing the Quality System
- Designed to increase customer/patient satisfaction
- Requires continuous improvement
Quality Management Systems

**National Baldrige Award**
- Strategic Planning
- Leadership
- Focus on Customers, Markets
- Measurement, Analysis & Knowledge Management
- Staff Focus
- Process Management
- Performance Results

**ISO 9001**
- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continuous Improvement
- Decision-Making on Facts
- Mutually Beneficial Supplier Relationships
QMS: ISO 9001 + Baldrige

Leadership

Organizational Performance

Measurement, Analysis, Knowledge Management

Patient, Customer, Market Focus

Process Management

Staff Focus

Strategic Planning
QMS: Structure

Structure

Tool
Tool
Tool
Quality Management System

Clause 4
Clause 5
Patient
Management
Clause 6
Clause 7
Employees
Clause 8
Community Framework for ISO 9001

Guidelines

Anticoagulation Clinic

Culture of Quality

Education

Mercy

St. Luke’s
Applicable ISO Principles

- Auditing, internal and external
- Corrective and preventive action plans
- Document system, controlled and shared
## Example of Shared Documents

<table>
<thead>
<tr>
<th>Inpatient</th>
<th>Anticoagulation record</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td>Anticoagulation guidelines/protocols</td>
</tr>
<tr>
<td>Transition</td>
<td>Inpatient to outpatient</td>
</tr>
</tbody>
</table>
Teams

- Clinic Evaluation and Process Mapping
- Health Literacy
- Hospital Coordination Team
- Management
- Metrics
Teams

- Patient Educational Material Development
- Survey
- Tool Kit
- Training Design and Evaluation
- Web Design
Process Metrics

- Number of dose changes
- Number of times physician contacted
- Incidence of values outside protocol
- Length of time on warfarin therapy
- Number of corrective action plans
- Time in therapeutic range
Outcome Metrics

- Reduction in patient complications and readmissions related to bleeding, thromboembolic events, and adverse drug events
- Risk profile of patients developing complications
- Reduction in deaths
- Reduction in length of time on warfarin, number of dosage changes, and improved patient time in therapeutic ranges
- Reduction in missed lab reports
Outcome Metrics

- Clinically Adjusted Charge/Cost & LOS
  - Reporting Variables: Service Line, DRG, Physician, Diagnosis, Procedure, Trending
  - Including ICD-9 codes used in risk assessment: Adverse Effects of Anticoagulation (E934.2) and Abnormal Coagulation Profile, (790.92).

- Risk Adjusted Complications, Mortality, Readmissions
  - Reporting Variables: Service Line, DRG, Physician, Trending

- Clinically Adjusted Episodes of Care
  - Reporting Variables: Major Practice Category, ETG, Physician, Trends, Office Processes, CPT-4 Codes, NDC Codes
Tools: Anticoagulation Clinic

- **Process patient flow chart:** This flow chart documents the overall process and protocols for patient care in the clinic.
- **Risk assessment form:** This form will record risk factors of patients on warfarin therapy.
- **Clinical risk assessment tool:** This tool will characterize and profile patients at risk for adverse outcomes. The tool will describe patient characteristics related to complications, particularly in the elderly population served.
Tools: ISO 9001

- **ISO 9001 Healthcare Leadership Program:** Course materials, guides, and a PowerPoint® presentation, delivered in four, two-hour training sessions.
- **ISO 9001 Basic Training:** Curriculum, guides and a PowerPoint® presentation, delivered in three, four-hour training sessions.
- **ISO 9001 Internal Auditor Training:** Curriculum and guides, delivered during a three-day training session.
Database and Website

- Access clinic database
- Clinic website
- Link data input from labs
Health Literacy

- Teaching materials
- Work with local senior center to validate material
- Application in clinic setting
Results of Grant Process

- Establish anticoagulation clinic
- Establish partnerships within community
- Improve communication
- Provide improved patient care
- Utilize ISO concepts within the community of healthcare providers
Results of Grant Process

- Establish legitimacy of the quality system
- Establish the concept as a community model
- Develop long-term sustainability for clinic
- Develop tools and report our experience
ISO Websites

- asq.org       American Society for Quality
- iso.org       Int’l Org. for Standardization
- isoeasy.org   General ISO information