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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Cedar Rapids Healthcare Alliance
Working Together for Patient Safety.

Partnerships in Implementing Patient Safety RFA
Grant No: U18 HS15830-01

Cedar Rapids Healthcare Alliance

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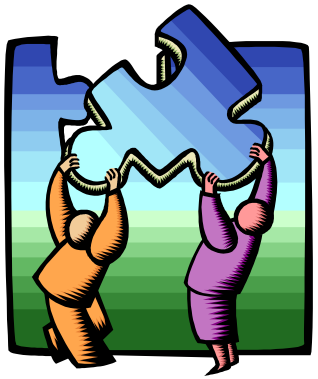

Vision:

To create a community model of care delivery and patient safety using ISO 9001 principles as a quality framework for cooperation.

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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.

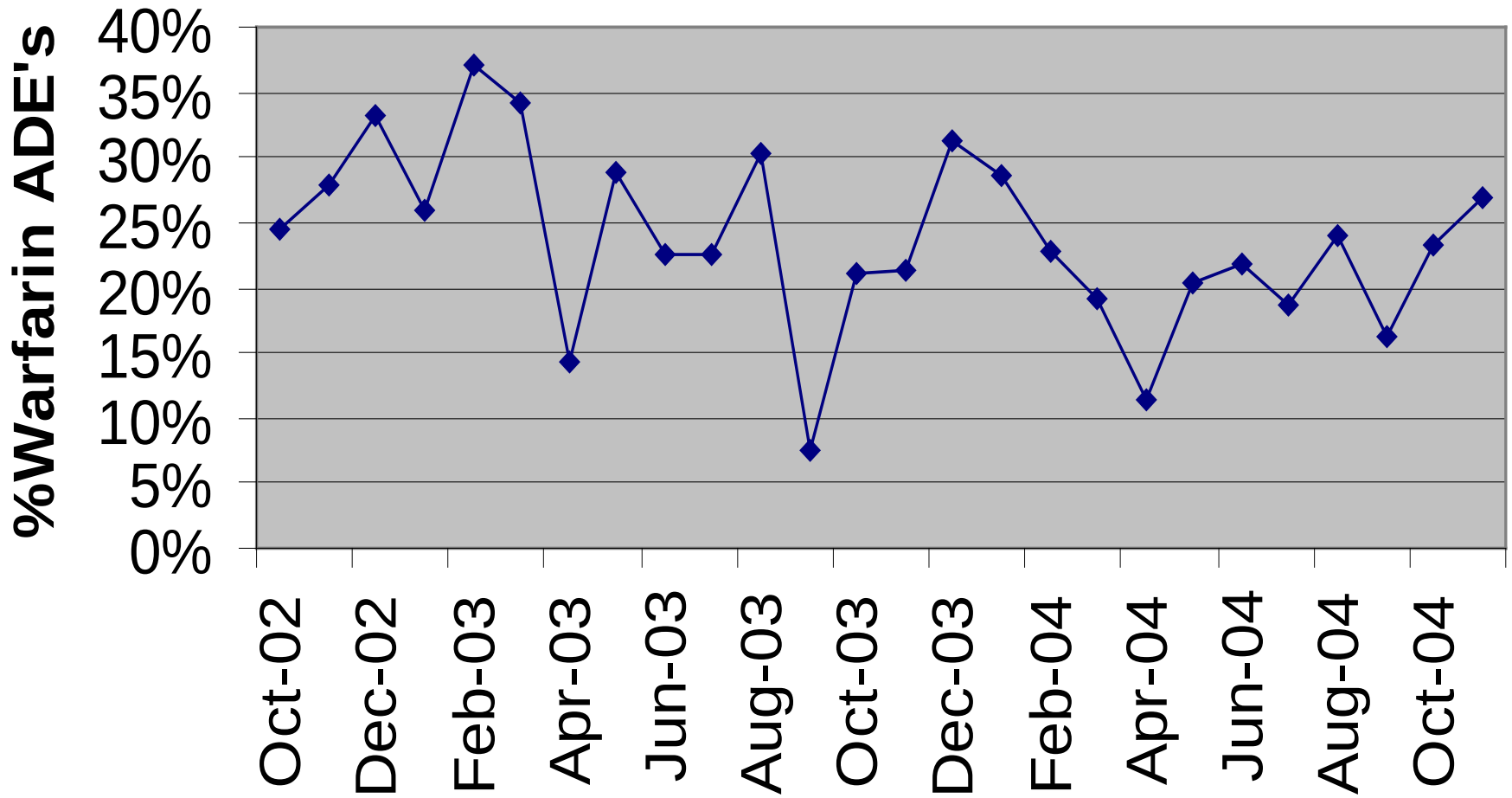
Overview

- 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)

Cedar Rapids Healthcare Alliance

Working Together for Patient Safety.

Quality Management System "Structure" in Healthcare to Optimize Care Delivery

*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

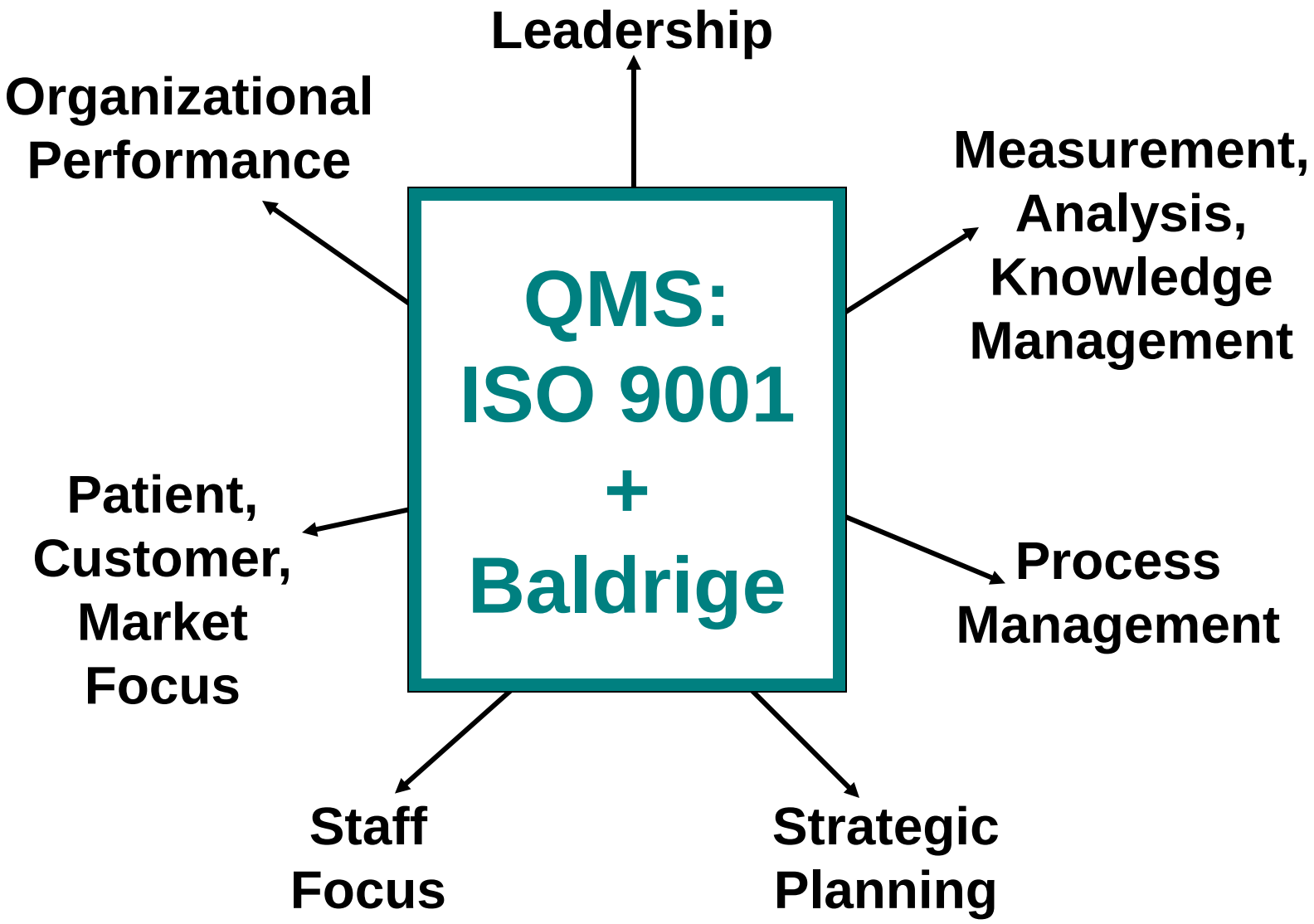
Quality Management Systems

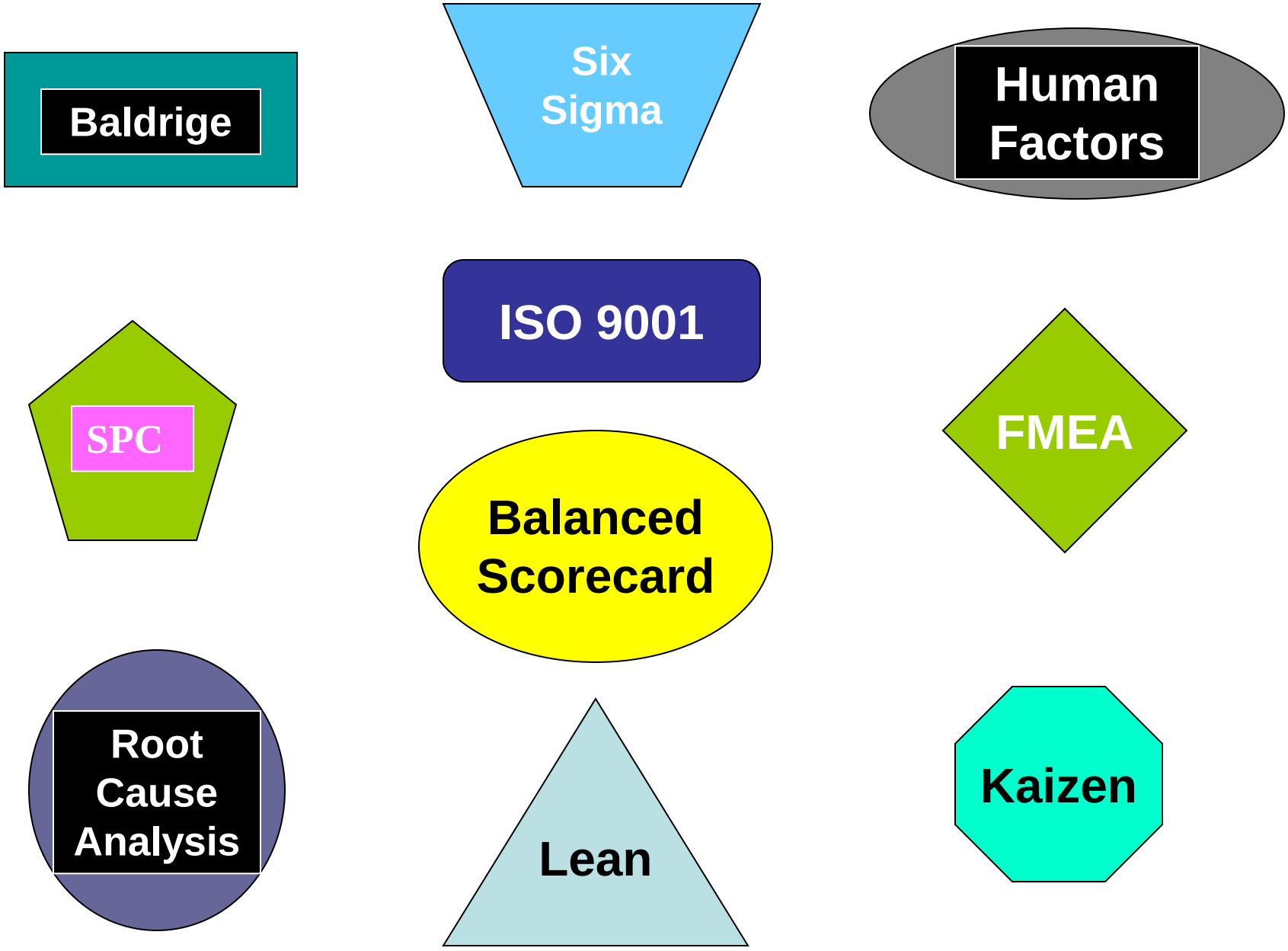
National Baldrige Award

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

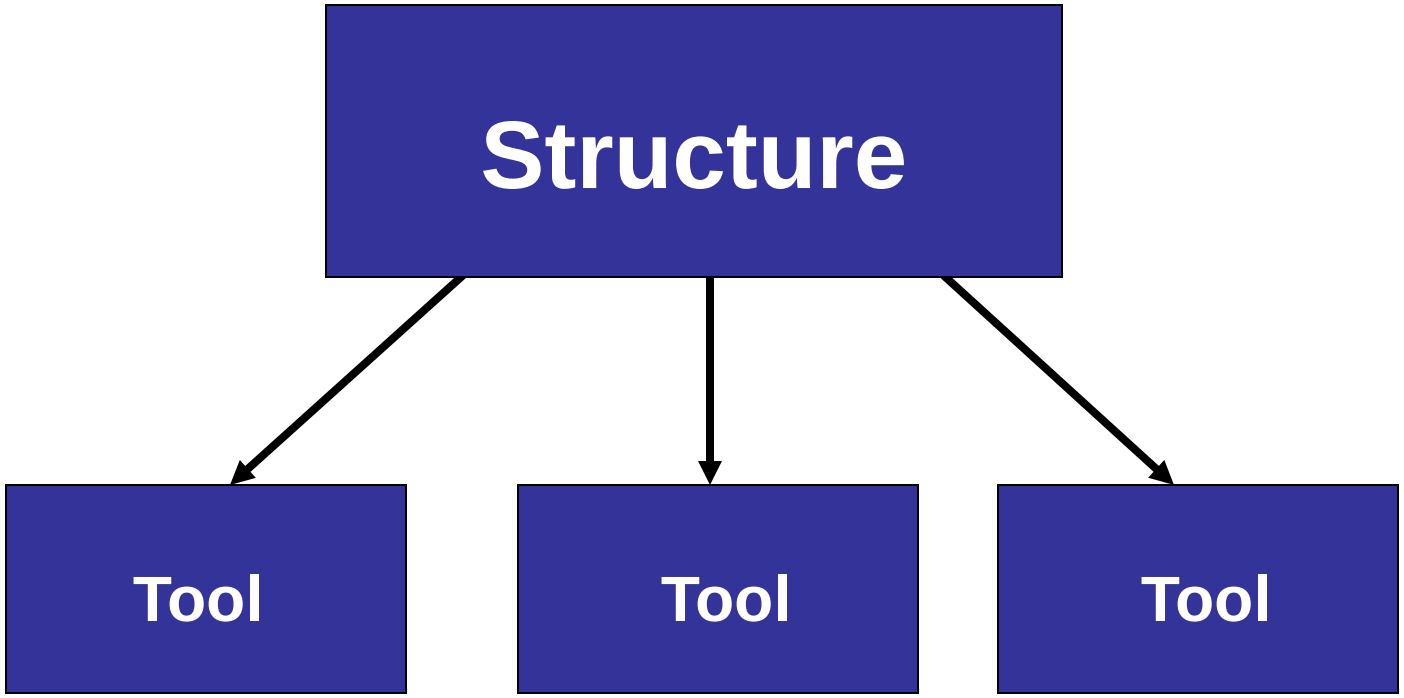
ISO 9001

- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continuous Improvement
- Decision-Making on Facts
- Mutually Beneficial Supplier Relationships

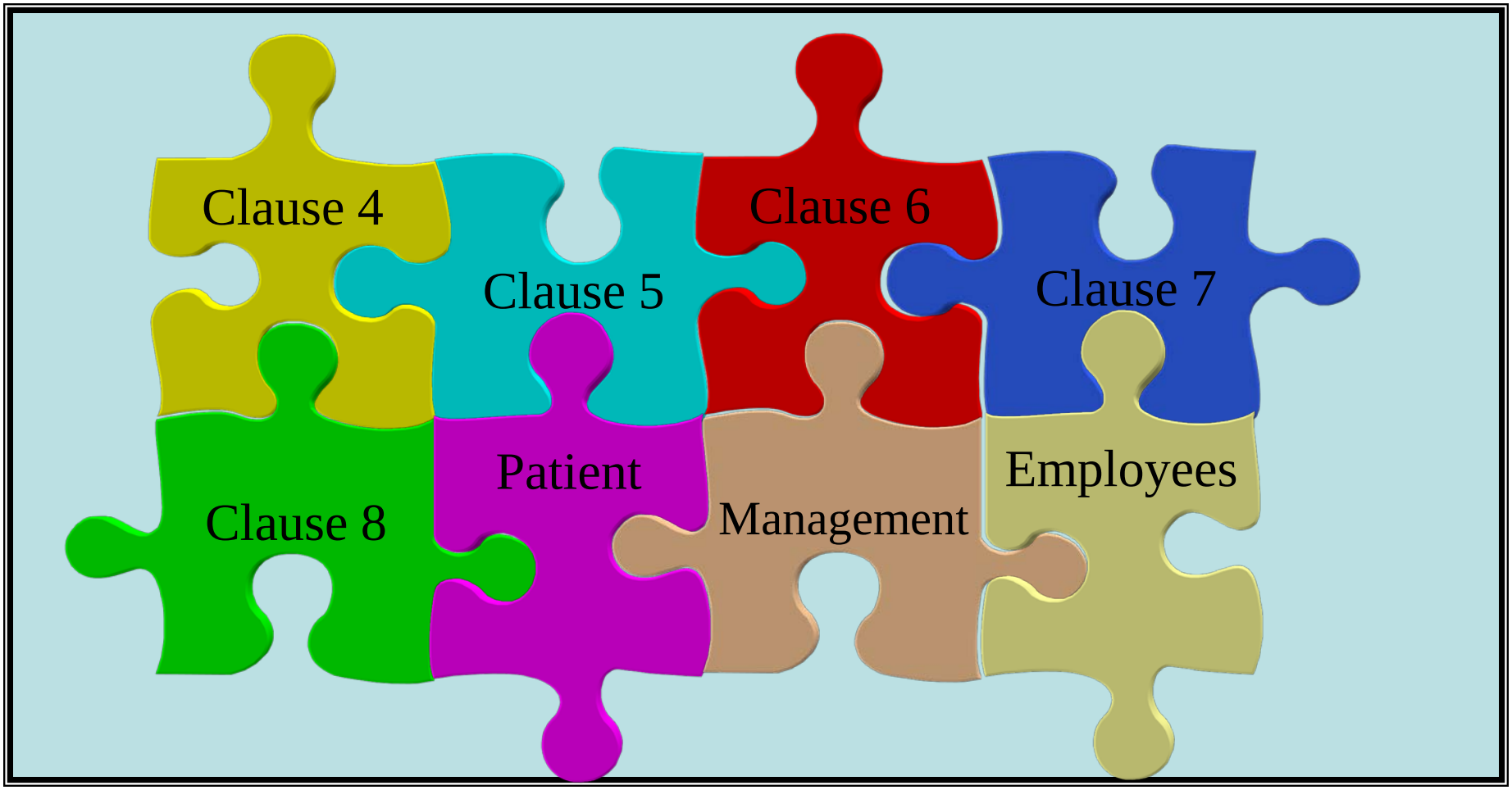

Leadership
Organizational Performance
Measurement, Analysis, Knowledge Management
QMS: ISO 9001 + Baldrige
Patient, Customer, Market Focus
Process Management
Staff Focus
Strategic Planning


Baldrige
Six Sigma
Human Factors
ISO 9001
SPC
FMEA
Balanced Scorecard
Root Cause Analysis
Lean
Kaizen

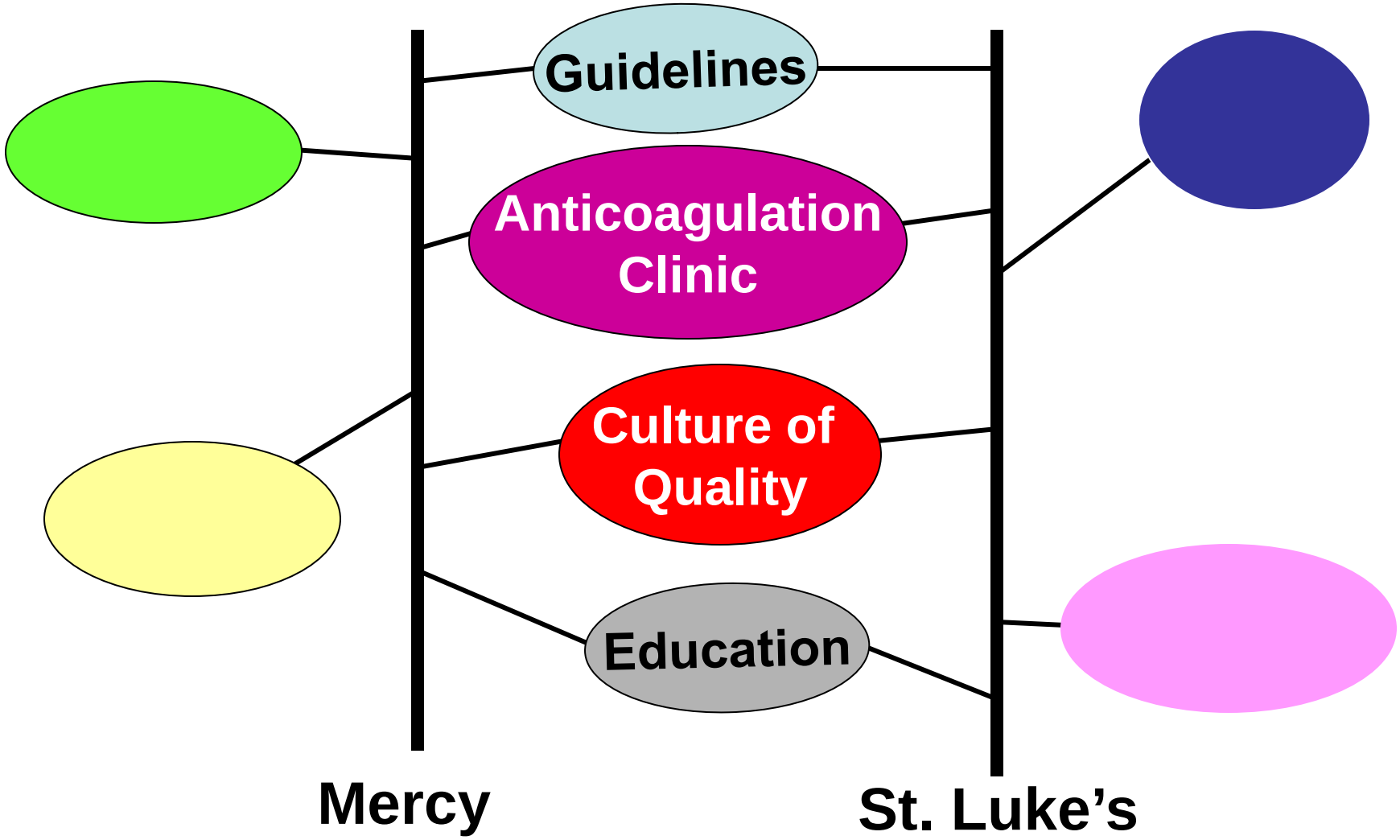
QMS: Structure



Quality Management System



Community Framework for ISO 9001



Applicable ISO Principles

- Auditing, internal and external
- Corrective and preventive action plans
- Document system, controlled and shared

Example of Shared Documents

Inpatient	Anticoagulation record
Outpatient	Anticoagulation guidelines/protocols
Transition	Inpatient to outpatient

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