Evaluation of Quality Management Systems in Infection Control
Dr. Tammy Sue Lundstrom, Wayne State University
A Webber Training Teleclass

EVALUATION AND COMPARISON OF QUALITY MANAGEMENT SYSTEMS

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SVP, Chief Quality and Safety Officer
Detroit Medical Center - Wayne State

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paul@webbertraining.com

Quality Management Systems: Which is Right for You?

- Institutional Commitment
- Leadership Support
- Training
- Cost
- Buy in: frontline staff
- There is no system that will be 100% successful 100% of the time

Systems Use Similar “Toolbox”

- Pareto Charts
- Run Charts
- Control Charts
- Radar (Spider) Graphs
- Process Flow Diagrams
- Histograms
- Failure Mode and Effects Analysis
- Ishikawa (Fishbone) Diagram

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Pareto

- Displays data in a way that focuses on top opportunities for improvement
- Display moves from greater to lesser percentage of total as move from left to right

Run Charts

- Focuses on performance trends over time
- Good way to display data to show improvements (or not) when actively intervening with performance improvement initiatives

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Control Charts

- Focus on detecting process variation over time
- Generally displays upper and lower control limits
  - 2 Standard Deviations above and below the mean
- Helps to differentiate Special Cause from Common Cause variation

Radar (Spider) Graph

- Snapshot of data at one point in time
- Useful to show positive and/or negative deviation from target
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DMC Quality Dashboard February 2002

<table>
<thead>
<tr>
<th>Metric</th>
<th>Current Performance</th>
<th>Target</th>
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</thead>
<tbody>
<tr>
<td>Inpatient Falls</td>
<td>1.17</td>
<td></td>
</tr>
<tr>
<td>Cost per Adj D/C</td>
<td>1.07</td>
<td></td>
</tr>
<tr>
<td>FTE per Occ Bed</td>
<td>1.03</td>
<td></td>
</tr>
<tr>
<td>ED LW BS</td>
<td>2.99</td>
<td></td>
</tr>
<tr>
<td>ED ALOS</td>
<td>1.13</td>
<td></td>
</tr>
<tr>
<td>Supplier Diversity**</td>
<td>1.7</td>
<td></td>
</tr>
<tr>
<td>Managerial Diversity**</td>
<td>0.84</td>
<td></td>
</tr>
<tr>
<td>Days in Accts. Receivable</td>
<td>1.02</td>
<td></td>
</tr>
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</table>

** Indicates Quarterly Data

Process Flow Diagram

- Maps steps and sub-steps in a process
- Often used to compare process as written versus process as performed
  - Ideal versus real world
  - Modification to improve safety or reduce unnecessary steps (simplify)

Decision made
To place central venous catheter

- Physician inserts central venous catheter using aseptic technique
- RN performs site care using aseptic technique
- Patient assessed for signs and symptoms of infection

Is further assessment warranted?
- NO
  - Continue monitoring
- YES
  - Continue work-up for infection

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Histograms

- Demonstrates frequency distribution
- Commonly used to diagram outbreaks

NICU HANDWASHING WEEKLY COMPLIANCE
JUNE to AUGUST 2004

<table>
<thead>
<tr>
<th>Date</th>
<th>#observed</th>
<th>%compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/1W</td>
<td>62</td>
<td>100</td>
</tr>
<tr>
<td>2/WK</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>3/WK</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>4/WK</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>7/1W</td>
<td>161</td>
<td>100</td>
</tr>
<tr>
<td>2WK</td>
<td>6</td>
<td>100</td>
</tr>
<tr>
<td>3WK</td>
<td>1</td>
<td>100</td>
</tr>
<tr>
<td>4WK</td>
<td>1</td>
<td>100</td>
</tr>
</tbody>
</table>

Failure Mode and Effect Analysis
FMEA

- FMEA is a proactive risk analysis; a tool or technique to prevent errors before they reach the customer:
  - FMEA looks to find the source of problems before they occur so performance improvement processes can be implemented proactively rather than reactively like in a root cause analysis.
  - It identifies where re-design of a process must occur to reduce/minimize risk and prevent an adverse outcome or incident.
FMEA
Development and Methodology

- Define the scope of your FMEA
- Establish a time frame
- Document rationale
- Establish team
- Establish Leadership support
- Identify information needs
- Document communication plan

FMEA
Information

- Gather relevant information needed to conduct the FMEA.
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FMEA
Step by step

Step 1: Construct a flow diagram
• This is a process flow as opposed to a chronological flow used in a root cause analysis.
  • Be sure your process flow is the actual process that occurs at your hospital.
• If the process is complex, identify the area of the process to focus on.
  • The scope of your process needs to be manageable.
  • Clearly state the process start and end points.
• Identify all sub processes under each process step.

FMEA
Step by step

Step 2: Identify Failure Modes
• Identify the possible failures and errors
  • What might happen, what could go wrong?
• Determine the likely causes of failures and errors
  • Why would this failure occur?
• Describe the effect of the failure or error on the system
  • What happens if it were to occur?

<table>
<thead>
<tr>
<th>Team Leader:</th>
<th>Core Team:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Started</td>
<td>Date Completed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step</th>
<th>Processes and sub-processes</th>
<th>Failure Mode(s)</th>
<th>Likely cause(s)</th>
<th>Effect(s)</th>
<th>Action(s) to eliminate or reduce failure mode</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
FMEA Step by step

- Step 3: Prioritize failure modes by assigning a Hazard Score,
  - Score the Severity of the failure mode
  - Score the Probability of the failure mode
  - Calculate the Hazard score

FMEA Severity Scoring

<table>
<thead>
<tr>
<th>SEVERITY RATING</th>
<th>Visitor Outcome</th>
<th>Equipment or facility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Event</td>
<td>Evaluation and treatment for 1 or 2 visitors (less than hospitalization).</td>
<td>Damage more than $10,000 but less than $100,000.</td>
</tr>
<tr>
<td>Moderate Event</td>
<td>Temporary disability or loss of function (sensory, motor, physiologic, or intellectual).</td>
<td>Moderate damage more than $10,000 but less than $100,000.</td>
</tr>
<tr>
<td>Catastrophic Event</td>
<td>Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, transfusion reaction, wrong patient or wrong body part, infant abduction or infant discharge to wrong family.</td>
<td>Damage equal to or more than $250,000.</td>
</tr>
</tbody>
</table>

FMEA Probability Scoring

<table>
<thead>
<tr>
<th>PROBABILITY RATING</th>
<th>Event Probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote</td>
</tr>
<tr>
<td>2</td>
<td>Uncommon</td>
</tr>
<tr>
<td>3</td>
<td>Occasional</td>
</tr>
<tr>
<td>4</td>
<td>Frequent</td>
</tr>
</tbody>
</table>

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FMEA
Hazard Score

• Hazard score = Severity score x Probability score
• Prioritize “failure modes” that require action:
  – Failure modes with hazard score of 8 or greater must be addressed
  – Failure modes with hazard score of less than 8 may be considered

<table>
<thead>
<tr>
<th>Probability</th>
<th>Catastrophic</th>
<th>Major</th>
<th>Moderate</th>
<th>Minor</th>
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</thead>
<tbody>
<tr>
<td>Frequent</td>
<td>16</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Occasional</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Uncommon</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Remote</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

FMEA
Step by step

• Step 4: Action and Process re-design
  – Describe how the failure mode or error can be eliminated or reduced.
  – Construct the re-designed process flow.
  – Communicate the action plan and include a time frame.

Ishikawa (Fishbone) Diagram

• Cause and effect diagram
• Displays causes of a problem in order to identify the root causes
Six Sigma

- Goal is to eliminate defects in existing processes
- Focus on achieving 3.4 defects/million or less
- Focus on achieving customer expectations
- Goal to pick projects that will achieve savings of more than $250,000

Health Care Reliability

<table>
<thead>
<tr>
<th>Reliability</th>
<th>Failures</th>
<th>Examples</th>
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<tbody>
<tr>
<td>$10^{-1}$</td>
<td>1-2 per 10</td>
<td>Beta Blocker/AMI</td>
</tr>
<tr>
<td>$10^{-2}$</td>
<td>per 100</td>
<td>Medications</td>
</tr>
<tr>
<td>$10^{-3}$</td>
<td>per 1000</td>
<td>Gen. Surgery Deaths</td>
</tr>
<tr>
<td>$10^{-4}$</td>
<td>per 10,000</td>
<td>Routine Anesthesia</td>
</tr>
<tr>
<td>$10^{-5}$</td>
<td>per 100,000</td>
<td>RT machine failures</td>
</tr>
<tr>
<td>$10^{-6}$</td>
<td>per million</td>
<td>SIX SIGMA GOAL</td>
</tr>
</tbody>
</table>

McGinnis NEJM 2003: 348
Six Sigma Structure

- Process owner
- Master Black Belt
  - external consultant
- Black Belt
  - full- time on 4-6 projects annually
  - Training $25,000/black belt
- Green Belt/White Belt
  - Assists Black Belt while maintaining usual job responsibilities

Six Sigma Process

- Define the problem
- Measure current performance
- Explore root causes, best practices
- Design new process
- Validate
- Implement and measure success

Utilizes process flow, FMEA

Toyota Production Model

- Focus is to eliminate waste/redundancy
- Focus on customer needs: eliminate steps that do not add value from the customer perspective
TPM: Sources of Waste

- Transportation: Transporting samples to lab
- Motion: Searching for equipment
- Waiting: Admission delay
- Processing: Unnecessary testing
- Inventory: Supplies
- Overproduction: Early testing to avoid lab delays
- Corrections: Retesting due to error
- Defects: Falls/Medication Errors

TPM: Process Principles

- Eliminate waste
- Improve work flow
- Optimize inventory
- Change work environment to eliminate waste
- Enhance customer relationships; focus on customer needs
- Manage time
- Manage variation
- Design systems to avoid waste

TPM Toolbox

- Process mapping- eliminate unneeded steps
- Pareto charts
- Control charts
- Cause and effect diagrams
- FMEA
TPM Lingo
Managing Variation

• Kai= to break apart, modify, change
• Zen= to make better

• Kaizen= Utilize process flow to identify unnecessary steps, change process to eliminate/reduce those unnecessary steps: identify and implement standardized processes

Malcolm Baldridge Award

• National Quality Award bestowed by the President
• 1999 Applied to Health Care
• First healthcare facility took 7 years to achieve success
• External examiners

Baldridge Focus

• Leadership
  – Address responsibilities to public/good citizenship
• Strategic planning
  – Setting strategic direction and action plans
• Customer and market focus
  – Determine expectations of and builds relationship with customers; customer satisfaction
• Measurement, analysis, and knowledge management
  – How the organization uses data to improve processes and attains management objectives
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Baldridge Focus

• Human resource focus
  – Enabling workforce to develop its full potential
  – Aligning work force with objectives
• Process management
  – Process design, management and improvement
• Business results
  – Examine organization performance in key business areas and relative to competition

Baldridge Process

• Generally consultant to assist with assessment and application
• Identify gaps between current business performance and criteria
• Examiners provide feedback to organization for improvement

International Organization for Standardization (ISO)

• Quality Management System
• Standards based
• Highly utilized in Europe for Health care organizations
• Series of internal and external audits for continuous improvement
ISO Focus

- Customer focused
- Emphasis on process design and planning
- Focus on providing employees work instructions/guides to minimize variation
- Focus on Leadership/Management communication of expectations to employees
- All employees must know their role in achieving quality objectives

ISO Process

- Adapted from manufacturing industry
- IWA document interprets standards for utilization in healthcare industry
- Facilities generally hire consultant for training and education
- Utilizes process flow, FMEA, run charts, pareto, etc

ISO Audits

- Internal
  - Train internal auditors to perform scheduled audits of all standards/all departments
  - Corrective Action for each nonconformance
- External
  - At least annually have external surveillance audits (sampling)
  - Every three years full registration audit
Conclusions

• All quality management systems utilize same toolbox
• Each has own “lingo” that needs to be adapted for health care
• None will be successful without leadership commitment
• Costs/focus varies depending upon system chosen

Additional Resources

J. Goodman, J. Theuerkauf, What’s Wrong with Six Sigma? Quality Progress, January 2005

D. Vonderheide-Liem, B. Pate, Applying Quality Methodologies to Improve Healthcare

American Society for Quality www.asq.org

Additional Resources

Six Sigma
www.sixsigmamainstreet.com/home.asp


www.iso.org

“Getting Started with the Baldridge National Quality Program” www.baldridge.nist.gov
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The Next Few 2006 Teleclasses

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Speaker</th>
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<tbody>
<tr>
<td>May 16</td>
<td>Product Evaluation and Selection</td>
<td>Robert Garcia (A British Teleclass)</td>
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<tr>
<td>May 18</td>
<td>Antibiotic Prescribing Practices</td>
<td>Dr. Dick Zoutman</td>
</tr>
<tr>
<td>May 25</td>
<td>Infection Control on Cruise Ships</td>
<td>Dr. Robert Wheeler</td>
</tr>
<tr>
<td>June 1</td>
<td>Infection Control in Healthcare Construction</td>
<td>Dr. Andrew Steifel</td>
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