EVALUATION AND COMPARISON OF QUALITY MANAGEMENT SYSTEMS

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Quality Management Systems: Which is Right for You?

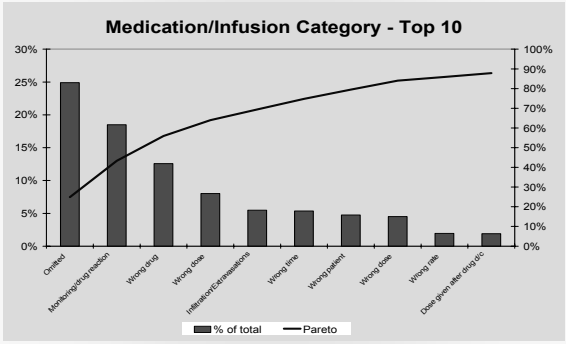
- Institutional Commitment
- Leadership Support
- Training
- Cost
- Buy in: frontline staff
- There is no system that will be 100% successful 100% of the time

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

Pareto

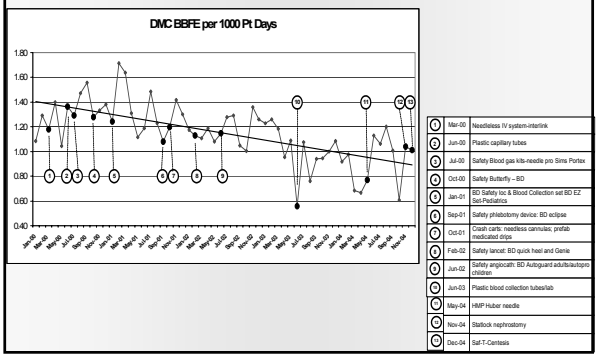
- Displays data in a way that focuses on top opportunities for improvement
- Display moves from greater to lesser percentage of total as move from left to right



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

SAFETY DEVICE IMPLEMENTATION



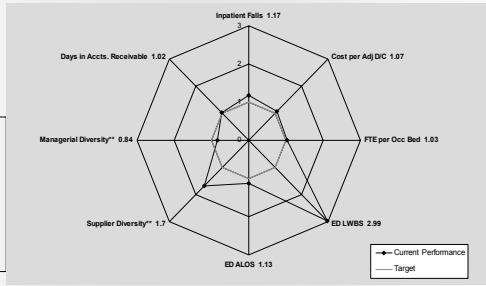
Control Charts

- 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

DMC Quality Dashboard February 2002

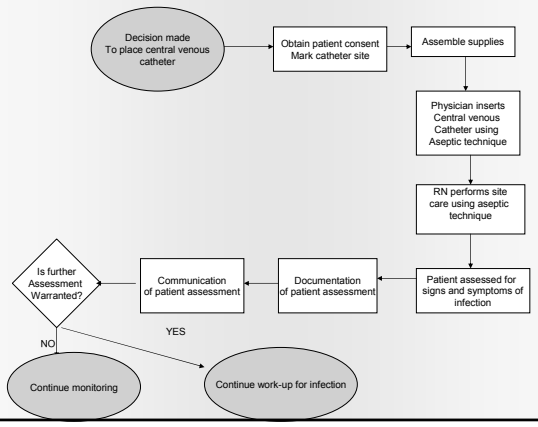


Radar graph indicates the variance from current performance to assigned target as a percentage. For example, 0.95 indicates that a given metric is 5 percent below target; 1.0 indicates on target performance; 1.2 indicates that the given metric exceeds target by 20 percent.

** indicates Quarterly Data

Process Flow Diagram

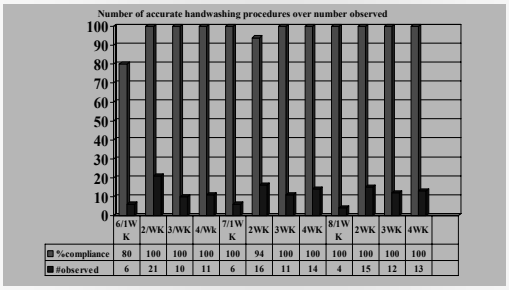
- Maps steps and sub-steps in a process
- Often used to compare process as written versus process as performed
  - Ideal versus real world
  - Modification to improve safety or reduce unnecessary steps (simplify)



Histograms

- Demonstrates frequency distribution
- Commonly used to diagram outbreaks

NICU HANDWASHING WEEKLY COMPLIANCE
JUNE to AUGUST 2004



	6/1WK	2/WK	3/WK	4/Wk	7/1WK	2WK	3WK	4WK	8/1WK	2WK	3WK	4WK
%compliance	80	100	100	100	100	94	100	100	100	100	100	100
#observed	6	21	10	11	6	16	11	14	4	15	12	13

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 then 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

FAILURE MODE EFFECT ANALYSIS FMEA
DEVELOPMENT AND METHODOLOGY

Prepared by:_____**Phone/Page**_____**Date:**_____

Estimated Time Frame: _____

FMEA Process Steps

1. Define the scope and the process to be studied: (You need to keep the scope of your topic specific to the area you are going to study – not too narrow, not too broad. If the process is complicated, pick one area to focus on)

Rationale for the high-risk topic: (attach data – that support rationale for high risk topic when applicable)

Check all that apply:

- ☐ Near misses have identified the potential for risk issues that may impact patient safety
- ☐ Internal data – occurrences reveal frequency or severity for topic chosen
- ☐ External data indicates frequency or severity for topic chosen
- ☐ Introducing a new system process, procedure or technology
- ☐ Other - explain

FMEA
Information

- Gather relevant information needed to conduct the FMEA.

2. List the information needed to conduct the FMEA process

		Assigned to:	Estimated date of completion:
A	Internal procedures, guidelines, protocols specific to the subject matter:		
B	External procedures, guidelines, protocols specific to the subject matter:		
C	Literature search for standards/best practices – results:		
D	Professional organizations/societies for resources – list:		
E.	Staff/Departments to interview regarding process:		

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?

Team Leader:	Date Started:
Core Team:	Date Completed:

Step #	Processes and sub-processes	Failure Mode(s) (What might happen) (What could fail in this step) (What could go wrong)	Likely cause(s) (Why it happens) (Why would this failure occur)	Effect(s) (What happens when it occurs)	Severity	Probability	Hazard score	Action(s) to eliminate or reduce failure mode

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

SEVERITY RATING	
4	**Catastrophic Event**
	Patient Outcome: Death or major permanent loss of function (sensory, motor, physiologic, or intellectual), suicide, rape, hemolytic transfusion reaction, surgery/procedure on wrong patient or wrong body part, infant abduction or infant discharge to wrong family.
	Visitor Outcome: Death; or hospitalization of 3 or more visitors.
	Staff Outcome: Death; or hospitalization of 3 or more staff.
	Equipment or facility: Damage equal to or more than $250,000
3	**Major Event**
	Patient Outcome: Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients.
	Visitor Outcome: Hospitalization of 1 or 2 visitors.
	Staff Outcome: Hospitalization of 1 or 2 staff or 3 or more staff experiencing lost time or restricted duty, injuries or illnesses.
	Equipment or facility: Damage equal to or more than $100,000
2	**Moderate Event**
	Patient Outcome: Increased length of stay or increased level of care for 1 or 2 patients.
	Visitor Outcome: Evaluation and treatment for 1 or 2 visitors (less than hospitalization).
	Staff Outcome: Medical expenses, lost time or restricted duty injuries or illnesses for 1 or 2 staff.
	Equipment or facility: Damage more than $10,000 but less than $100,000.
1	**Minor Event**
	Patient Outcome: No injury, nor increased length of stay nor increased level of care.
	Visitor: Evaluated and no treatment required or refused treatment.
	Staff Outcome: First aid treatment only with no lost time, nor restricted duty injuries or illnesses.
	Equipment or facility: Damage less than $10,000 or loss of any utility without adverse patient outcome (e.g. power, natural gas, electricity, water, comunications, transport, heat/air conditioning.

FMEA
Probability Scoring

PROBABILITY RATING		
4	Frequent	Likely to occur immediately or within a short period (may happen several times in one year).
3	Occasional	Probably will occur (may happen several times in 1-2 years.
2	Uncommon	Possible to occur (may happen sometime in 2-5 years).
1	Remote	Unlikely to occur (may happen sometime in 5-30 years).

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

	Severity Effect			
Probability	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occassional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

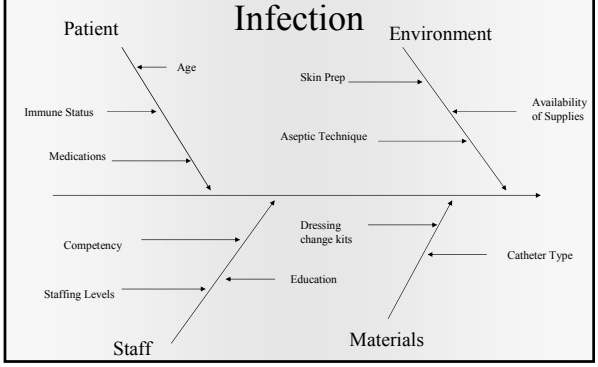
FMEA
Step by step

- 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

Central Venous Catheter Infection



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

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

McGlynn 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

TSL

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

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

TSL

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 heal care 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

J. Womack, D. Jones, Lean Thinking: Banish Waste and Create Wealth in Your Corporation- 2nd edition

www.iso.org

"Getting Started with the Baldridge National Quality Program" **www.baldridge.nist.gov**

The Next Few 2006 Teleclasses

May 16	***Product Evaluation and Selection*** … with Robert Garcia (A British Teleclass)
May 18	***Antibiotic Prescribing Practices*** … with Dr. Dick Zoutman
May 25	***Infection Control on Cruise Ships*** … with Dr. Robert Wheeler
June 1	***Infection Control in Healthcare Construction*** … with Dr. Andrew Steifel

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