Safety Initiatives in RT
The Role of Process Management

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Conflict of Interest

- Director – TreatSafely.org
- Grant on incident learning in RT - Varian Medical Systems

Learning Objectives

1. Describe use of process management in RT
2. Discuss DMAIC principles and practicality in RT
3. Describe potential benefits of process management in RT
Is there a benefit in every size facility?

Single Machine Facility

- Relatively good communications
- Streamlined processes
- Great collective memory
- Perhaps a limited benefit

Is there a benefit in every size facility?

Large Facilities

- Still silos
- Non-uniform processes
- Unawareness
- Potentially significant benefits

Is there a benefit in every size facility?

Networks

- Non-uniform communications
- Complex processes
- Pockets of reliable memory
- Potentially significant benefits
Errors in Radiation Therapy

- Staff and public exposures
- Misadministrations
  - Underdose
  - Overdose
  - Anatomical misses
- Magnitude
  - From few percent to lethal doses
  - From couple of millimeters to complete misses
- Regulatory
  - Nuclear Regulatory Commission
  - Errors that do not necessarily affect patients but have regulatory/legal consequences

- Sources
  - Staff
  - Software
  - Hardware
  - Random
  - Affect one to few patients
  - Systematic
    - Affect hundreds of patients
    - Potentially in a short period

Error spectrum

- Publicized - One side of the spectrum, usually large dosimetric errors – NY Times Articles
- Semi-publicized – RPC data
  - Approximately 30% of participating institutions fail to deliver IMRT dose indicated in their treatment plans to within 7% or 4mm to an anthropomorphic phantom (IJRDBP. 2008;71(1 Suppl):S71-5).
- Unpublicized/unnoted – everyday occurrences
  - "Small" dosimetric errors and geographic misses
  - Suboptimal treatment plans (contouring and dose distributions)
  - Care coordination issues
  - Unnecessary treatment delays

Event Reporting

- We are not airline industry nor nuclear power
- Perfection in complex systems across hundreds of diverse clinics is impossible
- Reporting systems for sake of reporting alone are a great way to squander resources and demoralize staff
- Error reporting as a part of broader process improvement efforts can be very valuable
DMAIC Cycle

Define
- Step 0: Select a Project

Measure
- Step 1: Establish Performance Parameters
- Step 2: Validate Measurement System for "Y"

Analyze
- Step 3: Establish Process Baseline
- Step 4: Define Performance Goals
- Step 5: Identify Variation Sources

Improve
- Step 6: Explore Potential Causes
- Step 7: Establish Variable Relationship
- Step 8: Design Operating Limits

Control
- Step 9: Validate Measurement System for "X"
- Step 10: Verify Process Improvement
- Step 11: Implement Process Controls

Opportunities
- Better insight into processes
- Education - "I did not know that!"
- Resource and effort allocation
- Overall quality improvement
  - Definition of quality?
  - Safe treatments
  - Minimal variations - Benchmarking
  - Positive patient experience
  - Positive employee experience
- Quality as a revenue center
Process Itself Matters

- Stable and well defined processes enable
  - Standardization
  - Quantification
  - Benchmarking
  - Improvements
  - Quality Control

Two Opportunities

The Goal

1) Timeline
   - Work - Value added
   - Wait - No value
2) Uncertainty

Normative decision theory: Start with efficiency move to efficacy

The Goal

In DMAIC – M and C stand for

- 21% A. Mitigate and Control
- 19% B. Mitigate and Counteract
- 19% C. Measure and Control
- 21% D. Manipulate and Control
- 20% E. Measure and Counteract
Correct Answer: C

A D – Define
A M – Measure
A A – Analyze
A I – Improve
A C - Control

Error Mitigation Strategies

Table 1. Ranking of CMS risk based on the effectiveness in part following the suggestions of NRC 13

<table>
<thead>
<tr>
<th>1. Environmental problem correction (best tool)</th>
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<tbody>
<tr>
<td>Source Control</td>
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<tr>
<td>Visual Control</td>
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<tr>
<td>Testing</td>
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<tr>
<td>Training</td>
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<tr>
<td>Isolation</td>
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<tr>
<td>Environmental Design</td>
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<tr>
<th>2. Automation and computerization</th>
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<tr>
<td>Barriers</td>
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<tr>
<td>Computed order entry with feedback</td>
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<tr>
<th>3. Protocols, standards, and information</th>
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<tbody>
<tr>
<td>Check off forms</td>
</tr>
<tr>
<td>Tailoring Protocol / Clarify Protocol</td>
</tr>
<tr>
<td>Barcodes</td>
</tr>
<tr>
<td>Labels</td>
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<tr>
<td>Signs</td>
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<tr>
<td>Reduce similarity</td>
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<th>4. Independent double check systems and other redundancies</th>
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<tr>
<td>Redundant measurement</td>
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<tr>
<td>Independent audits</td>
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<tr>
<td>Copied orders</td>
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<tr>
<td>Comparison with standards</td>
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<tr>
<td>Increase monitoring</td>
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<tr>
<td>Add status check</td>
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<tr>
<td>Acceptance test</td>
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<th>5. Rules and policies</th>
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<tr>
<td>Essential Audit</td>
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<tr>
<td>Priorities</td>
</tr>
<tr>
<td>Establishing / Clarify, Communication Line</td>
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<tr>
<td>Staffing</td>
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<tr>
<td>Better Scheduling</td>
</tr>
<tr>
<td>Cross-Training</td>
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<tr>
<td>Repair</td>
</tr>
<tr>
<td>PDA (preventive maintenance inspection)</td>
</tr>
<tr>
<td>Establish and Perform QC and QA (planning and software)</td>
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</table>

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<th>6. Education and Information</th>
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<tbody>
<tr>
<td>Training</td>
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<tr>
<td>Experience</td>
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<tr>
<td>Instructions</td>
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Potential benefits - Example

MD SIM AND TREATMENT PLANNING ORDERS
Department of Radiation Oncology
Medical Physics Division

Event Data Use: MD Orders Example

**The Problem:**
- During 19 months - ~500 Events submitted on MD Sim/Treatment Planning Orders - 15% event rate
- ~70% of reported events related directly to the order entry process (MS Word template in MOSAIQ)
  - 28% Incorrect/incomplete simulation instructions
  - 33% Incorrect/incomplete treatment planning orders
  - 6% Scheduling issues
- Solution - Web-based order entry system with business logic and error checking based on the collected event data

Event Data Use: MD Orders Example

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Event Data Use: MD Orders Example
Event Data Use: MD Orders Example

Results:

- 4 Physicians in the pilot group
- 203 events in 19 months with the old system
- New system
- 22 events in 4 months
- 3 events in month 4
- Fully deployed in April 2010
- Drastic reduction in incomplete/incorrect orders
- Currently ~ <2% Event rate

Which of the following is the most effective error mitigation strategy:

21% A. Automation and computerization
20% B. Protocols, standards, and information
20% C. Independent double checks
21% D. Rules and policies
19% E. Forcing functions and controls

Correct Answer: E

Forcing functions and controls includes:
- Interlocks
- Barriers
- Computerized order entry with feedback
Potential benefits - Example

**QA/QC EFFECTIVENESS COMPARISON**

- An analysis of the effectiveness of common QA/QC checks
- IRB between JHU & Wash U
- Both institutions started similar databases at the same time
- Data:
  - Incident reports: 2007-2011
  - 4,407 reports
  - 292 (7%) "high potential severity"

Ford, Mutic, et al. ASTRO & AAPM 2011, Accepted for publication - IJROBP
How effective are combined checks?

For example:
- Pacemaker failure
- Immobilization failure
- Duplicated records

Potential benefits - Example

CHART CHECKS

Physics Checks
- Manually compare paper chart with computer data
- Individual skills
- Alertness
- Consistency

Early 2000's
Paperless RT - Two Phases

- Phase 1: Basic replacement of paper chart with electronic means
- Phase 2: Development of tools and methods for:
  - more efficient,
  - safer,
  - automated,
  - smarter,
  - more effective,
  - better service processes

Return on investment
- Staff buy in
- Number of affected processes
- Use of other tools
- Errors
- Stress

Today
Phase 1
Phase 2
Current IMRT QA Paradigm

1. Transfer patient plan to a QA phantom
   ▶ Dose recalculated (homogeneous) on phantom – any dose calculation errors would not be revealed

2. Perform QA prior to treatment
   ▶ Subsequent data changes/corruption may result in systematic errors for all subsequent patients

3. The volume of data impossible to monitor and verify manually
   ▶ Manual checks do reveal data changes/corruptions, but not reliably

4. The process too laborious with questionable benefits
   ▶ A systematic analysis and redesign demonstrates possibility of a much more robust and automated process
Scope of a Solution

- Shown examples are proportional to the scope of WU operations and commitment to patient safety
- We have examples of simple process changes (check lists, procedural changes, etc.)
- Scope of solutions need to be realistic and commensurate with available resources
- Challenge the system, available resources, and commitment to patient safety
A study has shown that which one of these is the most effective in detecting errors in RT:

- **A. Weekly SSD checks** 18%
- **B. In vivo patient dosimetry** 20%
- **C. IMRT QA** 20%
- **D. Checklists** 21%
- **E. Ongoing checks (chart checks, chart rounds, etc.)** 21%

Correct Answer: E

While all of the listed measures can detect errors in RT, a systematic analysis of events in two similar clinics has shown that continuing checks (chart checks, chart rounds, etc.) have the potential for detecting the largest variety of errors.

Conclusions

- Persistent cultural/organizational emphasis
- Early victories
- Focus studies
- Culture as a broader field emphasis
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