Failure Mode and Effects Analysis (FMEA)

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and
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Disclosures

• I am the Secretary Treasurer of the non-profit Center for the Assessment of Radiological Sciences, an organization dedicated to improving the safety of radiotherapy
Learning Objectives

• Introduction to FMEA
• Risk assessment, process improvement and the basics of Process FMEA
• How to perform a Process FMEA
• Process FMEA outputs
• Process FMEA exercise
• Wrap up and questions
Quality Management in Industry

• Systematic application of specific tools that improve process controls producing more consistent and closer to optimal outcomes and reduce the risk of mistakes, errors or hazardous outcomes.
Process Controls

- Process controls for grilling a steak
  - Experience/training – how much charcoal to pile in the middle of the grill, etc.
  - Measurement tools – watch (steak goes on the grill 20 minutes after igniting the coals)
  - Because there are some variables that are difficult to control – meat thermometer (135 deg. F)
FMEA

• A risk assessment tool used to identify weaknesses or deficiencies (inadequate controls) in processes that could lead to mistakes, errors, and potential hazardous outcomes
FMEA

• Four separate and independent types of FMEA
  – Design FMEA – Focus on the product development and design process
  – Process FMEA – Focus on the manufacturing, production, office or healthcare process
  – Application FMEA – Focus on your product as used by your customers
  – Service FMEA – Focus on the service of your products
Design FMEA

- FDA requires that equipment manufacturers demonstrate design control – Quality System Requirements (QSR)
  - Recommend D-FMEA
  - Equipment performs (functions) as defined
  - However......
  - Equipment manufacturers almost never complete Application FMEA
  - FDA regulatory oversight somewhat lacking in this area
Radiation treatments can be powerful and complex machines offer new ways to heal—and to harm. http://www.nytimes.com/2010/01/24/health/4radiation.html

By Walt Bogdanich
The New York Times
updated 12:59 p.m. CT, Sun., Jan. 24, 2010

As Scott Jerome-Parks lay dying, he clung to this wish: that his fatal radiation overdose—which left him deaf, struggling to see, unable to swallow, burned, with his teeth falling out, with ulcers in his mouth and throat, nauseated, in severe pain and finally unable to breathe—be studied and talked about publicly so that others might not have to live his nightmare.

Sensing death was near, Mr. Jerome-Parks summoned his family for a final Christmas. His friends sent two buckets of sand from the beach where they had played as children so he could touch it, feel it and remember better days.

Mr. Jerome-Parks died several weeks later in 2007. He was 43.
A Proactive Strategy for Improving Patient Safety and Healthcare Quality through the use of FMEA and FTA

• Begins with a complete and thorough understanding of the process – flow charts, value stream mapping, process maps
• Perform a Process FMEA (P-FMEA) to identify weaknesses or inadequate controls in the process
• Develop process controls that either reduce the risk or improve the process
• Use FTA to identify root causes of potential process failures and develop recommendations to improve quality control of the process
Completing an Process FMEA

- Create a team
  - Ideally cross functional representing every function involved in the process
  - Nurses, imaging technicians, oncologists, medical physicists, treatment planners, others (administrative staff, social workers, etc.)
  - Effort should be led by a facilitator trained in or familiar with the tools used in the analysis
  - Consider providing training
Completing an Process FMEA

• Select a process – key step
  – Opportunity – Quality issues, past problems, not happy with the level of success, ...
  – Realistic opportunity to make improvements
  – Complexity or size
Completing an Process FMEA

• Defining the current process
• “One picture is worth ten thousand words”
• Flow charts, process trees, and value stream maps
Process FMEA – for each step in a process

- Detect
- Failure Modes
- Cause
- Effects
High Level Flow Chart - Physician Completing Rounds

1. Enter Patient’s Room → Review Chart
2. Question Patient → Examination Required
   - Yes
   - No
3. No → Examine Patient → Wash Hands to Sanitize
4. Yes → Find Sanitizer
5. Spread Sanitizer to Cover Surface of Hands, Etc.
6. Dispense Sanitizer into Palm of Hand
7. Leave Room
<table>
<thead>
<tr>
<th>Review Process Step Name &amp; Seq #</th>
<th>Review Process Step Function</th>
<th>CSC</th>
<th>Potential Failure Modes</th>
<th>Potential Causes of Failures</th>
<th>Potential Effects of Failures</th>
<th>Current Controls</th>
<th>Existing Conditions</th>
<th>Recommended Actions</th>
<th>Responsible Party And Date of Completion</th>
</tr>
</thead>
<tbody>
<tr>
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</table>
Completing an FMEA

1. For each process step – identify all potential failures – always best to define failure modes as “not” meeting process requirements

2. For each potential failure – identify all of the causes that could produce that failure
   a. Focus on process related causes of failure modes
Completing an FMEA

3. For each potential failure – identify the effects of that failure mode
   a. Priority of effects (safety, function, convenience)
Completing an FMEA

4. Current controls – judge the current capabilities of the process controls to:
   a. Prevent the cause of a failure from occurring
      – Documented work procedures or instructions, standard work, formal training programs, visual work instructions, skill set certification program, resource modeling and planning, formal process development programs, process capability studies, Statistical Process Controls, etc.
Completing an FMEA

b. Detect a failure when it occurs
   - Inspection
   - Radiation dose/location monitoring technology (21st Century Oncology)
   - Error, incident or accident detection/reporting
Completing an FMEA

c. Moderate the severity of a failure when it occurs
   – Almost impossible for radiation therapy
Completing an FMEA

• Most effective and lowest cost controls are those that prevent causes of failure modes
High Level Flow Chart - Physician Completing Rounds

1. Enter Patient's Room
2. Review Chart
3. Question Patient
4. Examination Required
   - Yes
   - No
5. No
   - Examine Patient
   - Wash Hands to Sanitize
   - Yes
   - Find Sanitizer
   - Spread Sanitizer to Cover Surface of Hands, Etc.
   - Dispense Sanitizer into Palm of Hand
   - Leave Room
   - No
# POTENTIAL FAILURE

<table>
<thead>
<tr>
<th>Check Type</th>
<th>System</th>
<th>Subassembly</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Design FMEA</td>
<td></td>
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<tr>
<td>☒ Process FMEA</td>
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</table>

**Design Responsibility:**

<table>
<thead>
<tr>
<th>Item / Function</th>
<th>Potential Failure Mode</th>
<th>Potential Cause(s) / Mechanism(s) of Failure</th>
<th>Potential Effect(s) of Failure</th>
<th>Current Design Controls</th>
<th>OCCUR</th>
<th>SEV</th>
</tr>
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<tbody>
<tr>
<td>Wash hands to sanitize</td>
<td></td>
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Occurrence of the cause of failure mode
Detection of failure mode
Severity of the effect when a failure mode occurs

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remote probability</td>
<td>Always</td>
<td>No effect</td>
</tr>
<tr>
<td>2</td>
<td>Low probability</td>
<td>High likelihood</td>
<td>Minor effect</td>
</tr>
<tr>
<td>3</td>
<td>Moderate probability</td>
<td>Moderate likelihood</td>
<td>Moderate effect</td>
</tr>
<tr>
<td>4</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
</tr>
<tr>
<td>5</td>
<td>Very high probability</td>
<td>Very low likelihood</td>
<td>Injury</td>
</tr>
<tr>
<td>10</td>
<td>100% probable</td>
<td>Never</td>
<td>Death</td>
</tr>
</tbody>
</table>

FMEA ranking scales for Occurrence, Detection and Severity.
• Completing an FMEA

• Risk Priority Number (RPN) –
  – Occurrence ranking \( \times \) Severity ranking \( \times \) Detection ranking
  – Range of RPNs (1 -1000)
  – RPN of 125 or higher is problematic either in terms of safety or process capability
  – Typical scenario – RPNs over 400!
  – Highest RPNs must be addressed first
  – Then work down to lower risk process steps
Completing an FMEA

- Risk Priority Number (RPN) –
  - Beware of patterns potentially hidden by low overall RPNs
    - Occurrence = 10, Severity = 10, Detection = 1 - RPN of 100 but ....
    - Occurrence = 1, Severity = 10, Detection = 10 – RPN of 100 but ....
    - Severity of 10 – even if Occurrence and Detection are both a 1 can you or do you want to risk it?
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Next – Perform a Fault Tree Analysis to Identify Root Causes of High Probability Failures Identified in FMEA

• Fault tree analysis (FTA) is a top-down approach to failure analysis, starting with a potential undesirable event (accident) called a TOP event, and then determining all the ways it can happen

• TG100 “poured” the Process FMEA into a Fault Tree to get a visual representation of the most frequent root causes of failure modes
  – Most common root causes were lack of formal procedures or work instructions, lack of communication and lack of time/stress
Case Study

• Radiotherapy & Oncology
  – Journal of the European Society for Therapeutic Radiology and Oncology and affiliated to the Canadian Association of Radiation Oncology
  – Applying failure mode effects and criticality analysis in radiotherapy: Lessons learned and perspectives of enhancement; Radiotherapy and Oncology, Marta Scorsetti, Chiara Signori, Paola Lattuada, Gaetano Urso, Mario Bignardi, Pierina Navarria, Simona Castiglioni, Pietro Mancosu, Paolo Trucco
From the Discussion Section of this Article

Our study attempted to enhance patient safety performance in a radiation oncology department by introducing clinical risk management principles and techniques, achieving the following goals:
(1) to set up an efficient and systematic procedure to assess the risk of the entire RT process;
(2) to disseminate patient safety and risk management culture among all the professionals involved (physicians, physicists, technicians and clerks).

It is likely that the study contributed to an observed reduction in the number of errors reported, mainly by means of the improvement of technical procedures, quality checks and communication flows. This reduction was particularly evident as regards errors in patient identification, that had been evaluated as the FM with the highest CI by the experts.

As an example we report the fact that, after the present study, the adverse events registered by the hospital incident reporting system, showed an important decrease in the RT unit, in terms of severity of the event.

In fact, while the criticalities or near misses reported and corrected together with the risk management team increased, thanks to the strict involvement and awareness of the RT operators, the adverse events and near misses that could be classified as dangerous for the patient were set at zero. For example, errors in patient identification during the treatment, happened a pair of times in the months before the present study, were never pointed out in the following year.

This was probably due to the implementation of new procedures introduced as corrective actions derived from the FMECA analysis.

Besides this, the FMECA study was very well accepted by the operators and further increased their commitment to patient safety, mainly thanks to an improved understanding of clinical risk: they became very proactive during FMECA sessions and after that they showed a continuous effort in promoting patient safety. Thus our experience further supports one of the major reported benefits of prospective analysis in clinical risk management, that is the promotion of organisational learning and the enforcement of safety culture among healthcare professionals [15].
Questions?