UPMC CancerCenter
Partner with University of Pittsburgh Cancer Institute

Failure Mode and Effects Analysis (FMEA)

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Disclosures

- I have nothing to disclose
Acknowledgement

• I have used many slides from the presentations that Frank Rath from the University of Wisconsin gave at the 2013 AAPM summer school. Special thanks to him.
Learning objectives

• Introduction to FMEA
• Risk assessment, process improvement and the basics of process FMEA
• How to perform a process FMEA
AAPM TG100 analysis of causes of failure for IMRT

- Human failure: 35%
- Lack of standardized procedures: 15%
- Inadequate training: 15%
- Inadequate communication: 10%
- Inadequate commissioning: 3%
- Design failure: 5%
- Hardware/Software failure: 9%
- Defective materials/tools: 2%
- Lack of resources: 6%
- Design failure: 5%

Saiful Huq – risk based QM: TG100 in action, July 20 – 24, 2014, Austin, Texas
From TG 100’s analysis of causes of failure for IMRT, which of the following causes was the LEAST common?

1. Communication failures (5%)
2. Human error (3%)
3. Hardware or software failure (74%)
4. Lack of standardized protocols (12%)
5. Inadequate training (6%)
From TG 100’s analysis of causes of failure for IMRT, which of the following causes was the LEAST common?

1. Communication failures
2. Human error
3. **Hardware or software failure**
4. Lack of standardized protocols
5. Inadequate training

Reference: Slide no. 5
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
Safety approach in industry

• Hazard identification and control approach is the basis for safety planning procedures for manufacturing

• The safety strategy in the design phase includes
  - identifications of hazards
  - assessment of the associated risk
  - removal of the hazards as much as practicable
Healthcare environment

• Can the concept of risk identification and process control be applied to healthcare to improve the quality of care for patients?
• Yes, of course. Healthcare situations readily lend themselves to a similar risk identification and control approach.
What is risk?

- Risk: frequently defined as the answers to three questions
  - What can go wrong?
  - How likely is it to go wrong?
  - What are the consequences if it goes wrong?
Risk assessment

• Risk assessment is the process of analyzing the hazards involved in a process

• Many risk assessment and analysis tools/techniques exist in industry

• These tools can be easily adapted to radiation therapy to enhance safety and quality of treatment process
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
• FMEA looks at each process and at each step asks the questions

  ➢ What could possibly go wrong (potential failure mode)

  ➢ How could that happen (potential causes of failure)

  ➢ What effects would such a failure produce (potential effects of failure)

  ➢ The overall risks for each identified failure is then scored and prioritized according to RPN

  ➢ A good FMEA then identifies corrective actions to prevent failures from reaching patient
Process FMEA – for each step in a process

FM: Inability of a process step to produce the desired optimal outcome

Detect

Failure Modes

Cause

Effects

Failure Modes: Inability of a process step to produce the desired optimal outcome
Process FMEA

For a given process map:

<table>
<thead>
<tr>
<th>Step</th>
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<th>Potential effects of failure</th>
<th>Current controls</th>
<th>O</th>
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**Current controls**

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**Recommended actions**
Example – physician consult

1. Enter patient’s room
   - Review chart
   - Question patient
     - Examination required
       - Yes
       - No
         - No
         - Yes
           - Wash hands to sanitize
             - Find sanitizer
               - Dispense sanitizer into palm of hand
                 - Spread sanitizer to cover surface of hand
                   - Examine patient
                     - Yes
                     - No
                       - Leave room
# Application of FMEA in washing hands

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\[
\text{RPN} = O \times S \times D \quad [1 \leq RPN \leq 1000]
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**RPN = O x S x D [1 ≤ RPN ≤ 1000]**
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<td>Death</td>
<td>Memo, pictures, sign</td>
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FMEA ranking: Occurrence, Detection, Severity

O: Occurrence of the cause of failure mode  
D: Detection of failure mode  
S: Severity of the effect when failure mode occurs

<table>
<thead>
<tr>
<th>Rank</th>
<th>Occurrence</th>
<th>Detection</th>
<th>Severity</th>
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<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>5</td>
<td>High probability</td>
<td>Low likelihood</td>
<td>Serious effect</td>
</tr>
<tr>
<td>8</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>
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FMEA ranking scales for Occurrence, Detection and Severity.
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RPN = O x S x D [ 1 ≤ RPN ≤ 1000 ]
### Example of FMEA: sub-process RTP planning

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<td>7</td>
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<td>4 3 9 4 24</td>
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File probably would not open
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<tr>
<th>Major Processes</th>
<th>Step</th>
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<th>Potential Causes of Failure</th>
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<th>AVG O</th>
<th>AVG S</th>
<th>AVG D</th>
<th>AVG RPN</th>
</tr>
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<tr>
<td>4 - Other pretreatment imaging for CTV localization</td>
<td>6. Images correctly interpreted (e.g. windowing for FDG PET)</td>
<td>Incorrect interpretation of tumor or normal tissue.</td>
<td>User not familiar with modality or inadequately trained) (Poor inter-disciplinary communication)</td>
<td>Wrong volume</td>
<td>6.50</td>
<td>7.44</td>
<td>8.00</td>
<td>387.75</td>
</tr>
<tr>
<td>7 - RTP Anatomy</td>
<td>&gt;3*sigma error contouring errors: wrong organ, wrong site, wrong expansions</td>
<td>User error</td>
<td>Inattention, lack of time, failure to review own work</td>
<td>Very wrong dose distributions Very wrong volumes.</td>
<td>5.29</td>
<td>8.43</td>
<td>7.86</td>
<td>366.00</td>
</tr>
<tr>
<td>12 - Day N Treatment</td>
<td>Treatment delivered</td>
<td>LINAC hardware failures/wrong dose per MU; MLC leaf motions inaccurate, flatness/symmetry, energy – all the things that standard physical QA is meant to prevent.</td>
<td>Poor hardware design Poor hardware maintenance</td>
<td>Wrong dose Wrong dose distribution Wrong location Wrong volume</td>
<td>5.44</td>
<td>8.22</td>
<td>7.22</td>
<td>354.00</td>
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How does FTA & Quality Management fit?

• After process mapping and FMEA analysis
  - FTA provides visual representation of propagation of failures
  - Quality management: All activities designed to achieve the desired quality in treatments
Summary

• Current QA guidance documents are based on prescriptive approaches evaluating technical performances of radiotherapy equipment

• There has been a growing recognition that quality and safety impairment arises from weakness in radiotherapy processes

• A good QM program should be process centric, prospective and risk based
Which of the following is true about FMEA?

1. It give the probability of a given failure mode.
2. It only works if everyone on the team agrees with each ranking.
3. The average scores are heavily weighted based on the physicians’ responses.
4. The RPN give relative rankings for potential failure modes.
5. The analysis only considers human failure.
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Reference: TG 100
It is useful to report all accidents before consequences appear.

It is impossible to make anything foolproof because fools are so ingenious.

Arthur Bloch, Murphy’s law

Our job is not to prevent errors, but to keep the errors from injuring the patients.

Lucian Leape