Failure Mode and Effects Analysis (FMEA): A Practical Approach to Improving Patient Safety

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Disclosures

• None
Finding mistakes *before* they happen

*BP, Thunderhorse Rig, 2005*
Overview

• A method of prospective risk analysis: FMEA
• Some pitfalls and warnings
• Error-proofing methods and examples
• How well does FMEA work?
Are we overreacting?

Some statistics

621 “events”
2001-2009
NY State
(NY Times, Jan 2010)

1220 events / year
US

740,000 patients
treated / year

Event rate:
1 in 500

Airline industry: 1 in 10 million

Ford & Terezakis, Int J Radiat Oncol Biol Phys, in press, 2009
External Beam Process Map

High-risk areas
- Scattered throughout process
- Traditional QA does not address these
- How to find them?

*Ford et al. Int J Radiat Oncol Biol Phys, 74(3), 852-858, 2009*
FMEA

Failure Mode and Effects Analysis

A (semi-quantitative) way to identify and prioritize risks before they turn into errors.
Failure Mode and Effects Analysis (FMEA): A Recipe

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies
Process Map

**Notes and Observations**
- Valuable but time-consuming
- Avoid too much detail
  - e.g.: “doc contours GTV”
- Get everyone involved
- Start with a general template
A general template for RT process
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies
Identify weak points “Failure Modes”

- **Failure Mode**: Wrong data in treatment planning system
  - **Cause**: Wrong CT transferred into TPS: Patient re-simmed but old scan loaded in
  - **Effect**: Incorrect GTV delineated / treated

**Notes and Observations**
- Typical approach: brain storming sessions
- Record lots of detail
- Get everyone involved
- Each failure mode can have more than one cause
- Find *all* important failure modes
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies
FMEA scoring

Scoring:

- **S**: Severity  
  (No Harm 1 … 10 Severe Harm)
- **O**: Frequency of occurrence  
  (Low 1 … 10 High)
- **D**: Detectability  
  (Easily Detected 1 … 10 Undetectable)

Risk Priority Number, \( RPN = S \times O \times D \)

**Notes and Observations**

- Consensus opinions on all scores
- Decide on clear scoring scale first

*Stamatis, DH, Failure mode and effect analysis : FMEA from theory to execution*, 2003
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies
FMEA ranking

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Area</td>
<td>ID</td>
<td>Threat</td>
<td>Description</td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td>planning</td>
<td>place beams</td>
<td>incorrect placement of beams</td>
<td>wrong radiation dose</td>
</tr>
<tr>
<td>3</td>
<td>77</td>
<td>DRR flow</td>
<td>export DRR to R&amp;V</td>
<td>wrong DRR exported</td>
<td>failure of double check</td>
</tr>
<tr>
<td>4</td>
<td>143</td>
<td>pos'n / Tx</td>
<td>remark patient, note on green sheet</td>
<td>fail to note on green sheet</td>
<td>wrong location</td>
</tr>
<tr>
<td>5</td>
<td>134</td>
<td>pos'n / Tx</td>
<td>verify on green sheet patient's marks still valid</td>
<td>fail to happen</td>
<td>wrong location</td>
</tr>
<tr>
<td>6</td>
<td>54</td>
<td>planning</td>
<td>generate treatment plan</td>
<td>wrong dose, curves, DVH, isocurves</td>
<td>wrong location</td>
</tr>
<tr>
<td>7</td>
<td>31</td>
<td>sim</td>
<td>sim tech creates pinnacle patient file</td>
<td>created for wrong patient</td>
<td>delay in care; wrong location</td>
</tr>
<tr>
<td>8</td>
<td>53</td>
<td>planning</td>
<td>generate treatment plan</td>
<td>wrong dose, curves, DVH, isocurves</td>
<td>wrong location</td>
</tr>
<tr>
<td>9</td>
<td>59</td>
<td>planning</td>
<td>generate treatment plan</td>
<td>plan for wrong patient</td>
<td>wrong dose, wrong location</td>
</tr>
<tr>
<td>10</td>
<td>103</td>
<td>register</td>
<td>Treatment plan and DRR pulled to machine</td>
<td>not most current plan/DRR</td>
<td>wrong dose</td>
</tr>
<tr>
<td>11</td>
<td>106</td>
<td>register</td>
<td>RT looks at green sheet for set up information</td>
<td>wrong version of treatment plan</td>
<td>wrong location</td>
</tr>
</tbody>
</table>

- Typically ranked by *RPN* score
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score
- Develop mitigation strategies

Read Task Group 100 report (due out soon)!
FMEA results

• External beam review task group convened 1/7/2009
• FMEA scoring complete June 2009

Results
131 failure modes
RPN scores ranging up to 240

- Large variability in scores

- Scoring in a group setting or by individuals is similar
• Different groups have different views of scores
FMEA: RPN and Severity are correlated

R = 0.50
p < 0.001
FMEA results

**Notes and Observations**

- Takes a long time
- Group or individual scoring show little difference
  - Do whatever is fastest
- Wide variability in scoring
  - Don’t over-interpret scores
  - Don’t spend too much time
  - Get everyone involved
- Severity may be a good surrogate score
  - Consider severity-only scoring as a quick first-pass
Recipe for FMEA

- Create a process map
- Identify weak points
- Score each weak point
- Rank and prioritize by score

- Develop mitigation strategies
Example 1: Wrong scan loaded into TPS

*RPN* score: 168 \( (RPN=S \times O \times D = 8 \times 3 \times 7) \)

- How to prevent this error?
  - QA check: human check before proceeding
Principles of Error Proofing

- **Mitigate** – control damages
- **Detect** – make problems more obvious
- **Facilitate** – make work easier
- **Replace** – more reliable process
- **Eliminate** – make mistake impossible
Examples of facilitation

- Retrain staff
- Rewrite policy
- Color coding / templates
- Standardize processes
Example 1: Wrong scan loaded into TPS

*RPN* score: 168 \( (RPN= S \times O \times D = 8 \times 3 \times 7) \)

- How to prevent this error?
  - QA check
  - Software double check on demographics
Best strategies for error proofing
Example 2:
Treatment plan and DRR (film) pulled up in R&V system

Failure mode: Plan pulled up for wrong patient
RPN score: 96

Solutions:
• Standardize beam names and include course e.g., “CD”
• Display patient picture in Tx room
• Scan patient ID card just prior to treatment
Example 2:
Treatment plan and DRR (film) pulled up in R&V system

- Patient ID card scanner
- Pulls up electronic record in R&V system

- An unanticipated problem
  - bar code can rub off
- Solutions to **eliminate** this problem?
  - RFID bracelet
  - Require changes in software
Recipe for FMEA

☐ Create a process map

☐ Identify weak points

It is difficult to identify problems before they occur

- Does FMEA actually capture what is occurring in the clinic?
- Compare FMEA to actual incidents in the clinic
Incident reporting system

- In-house web-based system available since 2007
- Includes near-misses

<table>
<thead>
<tr>
<th>Role</th>
<th># reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation therapy technologists (RTT)</td>
<td>150</td>
</tr>
<tr>
<td>Physicists</td>
<td>30</td>
</tr>
<tr>
<td>Dosimetrists</td>
<td>13</td>
</tr>
<tr>
<td>Attending physicians</td>
<td>0</td>
</tr>
<tr>
<td>Resident physicians</td>
<td>0</td>
</tr>
<tr>
<td>Nurses</td>
<td>0</td>
</tr>
<tr>
<td><strong>total</strong></td>
<td><strong>193</strong></td>
</tr>
</tbody>
</table>
FMEA vs. Actual Near-Misses

**Example incident not identified in FMEA:**

*Collimator/gantry angle not correct in R&V system*

- Clinical electron setup on weekend. Correct information was on a sticky note but did not get entered into R&V system.
- Not caught at physics check.
- Caught by RTT checking chart.
- Possible large underdose to part of tumor.
Conclusions

- FMEA: one of the few prospective error tools
- FMEA can be improved
  - Learn from others
  - Keep updating it
- Future directions
  - A clearinghouse for failure mode data?
  - A national voluntary incident reporting system?
Monitoring system for errors and near misses: ASRS

Synopsis

B777-200 CREW RETURNED TO THE GATE AFTER A PAX URGENTLY NEEDED TO GO TO THE LAVATORY, JUST BEFORE TKOF.

ACN: 604485 (5 of 10)

Time / Day
Local Time Of Day : 0601 To 1200
Date : 200401

Place
Locale Reference, Airport : BOS, Airport
State Reference : MA
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Lilly Engineer, MD
Bruce Vanderver, MD
FMEA vs. Actual Near-Misses

Incident report logs
24 total deviations reported

FMEA analysis: Jan 2009 – Jun 2009
131 failure modes identified

10/24 (42%) incidents not identified in FMEA

➢ BOTH FMEA and incident reporting needed