Outline

- How to introduce the concept to the entire team and cultivate champions
- Importance of safety culture – entire team
- “Narrow & deep” vs “broad & shallow”
- Early lessons – the physicist’s role
- Next phase
FMEA in RadOnc

FMEA: Definition – relevant source

- Failure Modes and Effects Analysis is a systematic, proactive method for evaluating a process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that are most in need of change.
Introducing the concept

- Put it in context
- Avoid physics/technical examples
- Follow the patient care process - inclusive
- “Sell it”
- Learn to be a facilitator for group collaboration

Process FMEA

- Answer key Questions
  - What could go wrong?
  - How badly might it go wrong?
  - Can we easily spot the error?
  - What needs to be done to prevent failures?
- The people involved in the process work together to answer these questions.
FMEA – basic hypothetical example

**Wake Up**
1a. Hit snooze on alarm
1b. Again, hit snooze on alarm
1c. Get out of bed
1d. Find Slippers

**Get Dressed**
2a. Make Coffee
2b. Take Shower
2c. Find clothes
2d. Find Shoes

**Start the Car**
3a. Find Keys
3b. Find Bag
3c. Look for Coffee
3d. Find Car

**Drive the Car**
4a. Coffee in cup holder
4b. NPR on Radio
4c. Phone accessible
4d. Drive to Work

**Park the Car**
5a. Notice and take exit
5b. Negotiate turn
5c. Find spot
5d. Hang up phone

**Walk into Work**
6a. Collect coffee, bag, computer
6b. Close and lock doors
6c. Walk to work

List all Failures:

- 1a. Hit Snooze button
- 1b. Again, hit snooze button
- 1c. Get out of Bed
- 1d. Look for Slippers

Failure Modes:
- 1a(1) - Turn off alarm
- 1a(2) - Unplug Alarm
- 1a(3) - Break alarm clock

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The FMEA team

- Multidisciplinary team with intimate knowledge of each step in the process
- Ideally each member should be an expert in their portion of the process
- Real-life experience is most important – this is a subjective assessment process relying on our collective experience.

The Lahey FMEA team

**Nurse:** Laura Kenda

**Therapist:** Elizabeth Doherty

**Dosimetrists:** Rob Bettinelli, Janel Woodhouse

**Physicists:** Eileen Cirino, Per Halvorsen

**Radiation Oncologist:** Bill O’Meara

**Chief Therapist / Manager:** Angela Tambini
Creating a process map

Consensus recommendations for incident learning database structures in radiation oncology

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Creating a process map: observations

• Invest the time to allow the FMEA team to understand the “generic” process maps

• Collaboratively develop institution-specific process maps, staying as close to the consensus recommendations as possible

• Ensure that the resultant process maps are used for all appropriate purposes in the department’s CQI and safety programs

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“Narrow&deep” vs “broad&shallow”

• Which is the better approach for introducing the concept to the entire RadOnc team?

• An initial “narrow&deep” approach with rigorous FTA would likely have to be physics/technology centered, and would largely preclude active contribution by non-technical members of the team.

• We chose a “broad&shallow” initial approach, to build conceptual understanding & enthusiasm by the entire team.

Pros & cons of “broad&shallow”

• PRO:
  • Helps the entire team understand the concept
  • Promotes active contribution by all team members from the beginning of the project
  • Cultivates “champions”

• CON:
  • Inadequate FTA
  • Findings may not be as actionable as a robust FTA based “deep” FMEA
Assign a Risk Priority Number (RPN):

- Occurrence (1-10)
- Severity (1-10)
- Detectability (1-10)

- \[ \text{RPN} = \text{O} \times \text{S} \times \text{D} \]

RPN scores – who decides?

*Should the subject-matter-expert for each process step assign the RPN, or should it be a group effort?*

- We tried a hybrid approach (all team members assign their RPN values, then a weighted average is applied with 3:1 SME weighting)
- Wide variation in perspectives
- Settled on interactive group scoring – consistent with the “broad&shallow” concept
FMEA – Lahey results from Phase I

Identified the 3 highest and 3 lowest RPN scores in each major process branch.

<table>
<thead>
<tr>
<th>Process Tree Branch</th>
<th>O</th>
<th>S</th>
<th>D</th>
<th>RPN</th>
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<tbody>
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<td>9</td>
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</tbody>
</table>

2: Imaging for RT Planning (Simulation)

- **5 highest risk RPNs overall:**
  - 3.4 – Delineation of target(s)
  - 3.1 – Preliminary Rx, constraints (physician intent)
  - 2.9 – Simulation – marking reference point
  - 2.6 – Simulation – documentation of immob/setup
  - 4.7 – Physician plan peer review (chart rounds)

- **5 lowest risk RPNs overall:**
  - 4.5 – Treatment Approval in Aria
  - 1.13 – Patient education/consent
  - 1.1 – 2 forms of ID
  - A.8 – Documentation of quality management
  - 1.14 – Social work / nutrition assessment

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Communicating the lessons to the team

Lahey Health – Radiation Oncology
Quality Assurance Report 01 December 2014

Initial experience with FMEA – Top 10 recommendations

Executive Summary
The Lahey Health Radiation Oncology (LHRO) team’s Radiation Oncology Safety Initiative (ROSI) focuses on all aspects of the Radiation Oncology service that have an impact on safety. Consistent with its broad mission, the ROSI team decided in mid-2013 to conduct a systematic group assessment of the relative risk associated with every step in the radiation oncology process, using the Failure Mode and Effects Analysis (FMEA) methodology recommended by Task Group 106 of the American Association of Physicists in Medicine (AAPM) and as reported by Fox & Lowe. The team’s initial report on this topic was submitted in March 2013, titled “Initial experience with FMEA”, and the reader is referred to the March report for a review of the analysis process and the LHRO-specific ranking scale and process maps.

Following submission of the initial report, the FMEA Working Group met repeatedly to discuss each of the process steps with the Highest Risk Priority Numbers (RPN) – referred to as the “Top 10” process steps from a risk perspective. For each step, the group debated possible process changes aimed at reducing the risk in the clinical process. Factors considered by the group included the (quantitative) expected impact of risk mitigation as well as the practical limitations inherent in each suggested process change.

This report provides the group’s recommendations for addressing each of the Top 10 process risks. We recognize that some of the recommendations would require a significant commitment by clinical team members to alter their work routines, but we believe all recommendations are realistic and can be achieved without significant direct expense. As such, we recommend that the department continue to substantially address each recommendation in a prudent manner, recognizing that some process changes may take time to plan and implement.

Top 10 process risks

Communicating the lessons to the team

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Recommendations:
For each recommendation below, the “Implementation difficulty” rating is a subjective score on a 1-10 scale agreed to by the Working Group, with 1 being very easy and 10 being extremely difficult. The “Target date” is the Working Group’s recommended goal for an implementation initiative.

<table>
<thead>
<tr>
<th>Step 3.3 – Planning: Registration of Image sets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation</td>
</tr>
<tr>
<td>Consistently perform a “big picture” check—are the correct data sets fused? Scroll through the entire image volume—anything look odd?</td>
</tr>
<tr>
<td>Ensure that MD reviews the registration before proceeding with target delineation &amp; planning</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3.4 – Planning: Delineation of target(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation</td>
</tr>
<tr>
<td>Dosimetrist opens CTPN with MD present, asks to review CTPN to confirm that target delineation is correct</td>
</tr>
<tr>
<td>Second physician to review consultant note, path, and target delineation prior to dosimetric planning</td>
</tr>
</tbody>
</table>
FMEA – physicist’s role:

• Be a constructive facilitator – teach/encourage
• Apply your analytical skills to guide the process
• Summarize findings and recommendations in a cohesive and simple manner
• Keep the project focused and identify opportunities for process improvement.
• Explain it to the institution’s administration.

Impressions from our initial experience

• Very positive response from nurses, therapists, and radiation oncologist
• Has re-energized our CQI Committee
• Has already resulted in “side projects” prompted by the collaborative experience – e.g. working with nurses to revise our HDR emergency procedures to include applicator-specific steps & supplies
Next phase

• “Narrow&deep” approach to a technical portion of the process map → will the findings mirror those from the “broad&deep” approach?

• Determine the longer-term utilization of FMEA in the department’s operations

• Should long-established AAPM-sanctioned QC procedures be modified based on the FMEA findings? → CAUTION