Failure Mode and Effect Analysis: a practical approach for the clinical professional

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The challenge: toward safer radiotherapy

- 1 in 600 patients experience an “event” during the course of treatment each year in the US\(^1,2\)
  - Based on extrapolation of data collected in NYS from 2001-2009 and assuming ≈750k radiation patients/year
  - Certainly an underestimation: one report estimates only a 1/10\(^{th}\) reporting rate\(^3,4\)
  - cf. 1 in 10,000,000 chance of injury or death in air travel from 2002-2008\(^1\)
The challenge: toward safer radiotherapy

• **Fair play adjustment:** 94% of radiotherapy “events” have “little to no clinical significance”
  – Thus 1 in 10,000 patients/year experience a clinically significant radiotherapy error
  – Still 1000 times more frequent than in air travel, even when we’re underestimating our numbers...

“The challenge: toward safer radiotherapy

“Whatever the actual error rate, it would appear that safety performance in radiotherapy is worse than in some other areas of medicine such as modern anesthesiology. A major initiative is now underway in radiation oncology to improve this situation, with several conferences and sessions at professional meetings dedicated to this topic over the last several years.”

The challenge: toward safer radiotherapy

• Since 2010, our profession produced a huge amount of resources toward safer radiotherapy:
  – “Safety is no accident” (ASTRO, AAPM, etc.)
  – ASTRO: Safety white papers (beginning in Jan 2010)⁶-⁷
  – AAPM: TG-100, TG-275, etc.
  – Hundreds of papers and editorials in major journals
  – RO-ILS national incident learning database launched in 2014

BUT...recent studies confirm that:
A. Clinical professionals either remain unaware of safety resources (e.g., incident learning systems) or do not use them⁸
B. Most new graduates from medical and physics residencies feel inadequately trained and unprepared for ILS, RCA, FMEA⁹
The challenge: toward safer radiotherapy

“The survey results demonstrate that despite increasing interest, residents in radiation oncology have limited exposure to important concepts of patient safety and treatment quality management and do not feel competent to lead clinical patient safety programs in the future. In spite of notable gaps, a sizable minority of residents has either formal training or practical experience with patient safety tools. The programs that do offer formal training may serve as models for program development in radiation oncology.”

– Spraker, Matthew B., PRO 7(4), 2017

A practical approach for the clinical professional

• None of these safety resources are beyond your grasp, even if your department as a whole is not on board.
  – What can you do to evaluate your part of the radiotherapy process flow and build adequate safety barriers?
  – How can you begin advocating for safety and implementing these quality management techniques at the departmental level?
The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

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Failure Mode and Effect Analysis

- Quality Control Program
  - Reactive Analysis
    - Incident Learning System
  - Prospective Analysis
    - Root Cause Analysis
    - Fault Tree Analysis
    - Failure Mode/Effect Analysis
• AAPM TG-100 Risk Analysis Methodology
  – Assemble a multidisciplinary team to perform:

  Process Mapping → Failure Mode/Effect Analysis → Fault Tree Analysis → Quality Management Program
Step 1: Map out the process

**Process map:** illustration to visualize the steps and sequence of a process

**How to escape a Balrog in the Mines of Moria:**

- Make for the Bridge of Khazad-dûm
- Do you have a wizard?
- Cite Secret Fire: “You Shall Not Pass!”
- Fly, you fools!

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Image-Guided Adaptive Radiotherapy

- Diagnostic CT Scan
- Plan Treatment Fields – Compute Dose Distribution
- Initiate Treatment Process
- Perform Image Guidance Scan (Cone-Beam CT)
- Perform nᵗʰ fraction
- Organ deformation?
- Patient setup error?
- Adjust patient
- Re-plan treatment
- Yes
- No
- Yes
- No
Step 1: Map out the process

**Process map**: illustration to visualize the steps/sequences...

- Assemble a multi-disciplinary team *if possible*
- *At least* have a peer review your proposed process map
- Use the smallest number of sub-processes possible to meet the given objective
- Too much detail is unusable; too little detail is unusable

If you will just start small and try this, you will immediately benefit by learning and making your work safer!
Step 2: Failure mode and effect analysis

**FMEA:** Evaluate each step of the process to anticipate what might go wrong and how much risk is involved

- Where do you get this data?
  - *Incident learning system*

“Another way to gather safety-related issues is through prospective risk assessment using Failure Mode and Effects Analysis (FMEA) as described in AAPM Task Group 100. The failure modes gathered in this way can be entered and analyzed in the ILS as “unsafe conditions” or “process improvements”. Risk assessment via FMEA is complementary to the use of ILS. One study reported a set of safety issues that were identified only by FMEA but not by ILS (57% of the total) and noted that another set identified only through ILS and not FMEA (17% of the total). This illustrates the value of combining FMEA risk assessment with ILS.”

Step 2: Failure mode and effect analysis

FMEA: Evaluate each step of the process to anticipate what might go wrong and how much risk is involved

- Where do you get this data?
  - Incident learning system
  - Published reports and databases
  - Professional knowledge, experience, expertise

- Use some metric to distinguish between severe risks and mild risks
  - Helps to prioritize which steps need safety barriers
  - TG-100 suggests common metrics called RPN and Severity

Risk Priority Number (RPN):

RPN = Occurrence x Severity x Detection

- Occurrence: how likely is the failure to occur?
- Severity: how detrimental is the effect on the final outcome if the failure is not detected?
- Detectability: how likely is it that the failure will not be detected in time to prevent an event?

- Result is a value between 1 and 1000
Step 2: Failure mode and effect analysis

TG-100 is immensely helpful to our profession because it provides radiation therapy specific guidance on calculating RPN and S, etc.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Failure</th>
<th>Occurrence (%)</th>
<th>Severity (S)</th>
<th>Detectability (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Failure</td>
<td>0.01</td>
<td>Non-effect</td>
<td>0.01</td>
</tr>
<tr>
<td>2</td>
<td>unlikely</td>
<td>0.02</td>
<td>Inconvenience</td>
<td>0.2</td>
</tr>
<tr>
<td>3</td>
<td>Relatively few failures</td>
<td>0.05</td>
<td>Inconvenience</td>
<td>0.5</td>
</tr>
<tr>
<td>4</td>
<td>Minor dosimetric error</td>
<td>0.1</td>
<td>Suboptimal plan or treatment</td>
<td>1.0</td>
</tr>
<tr>
<td>5</td>
<td>Limited toxicity or tumor underdose</td>
<td>&lt;0.2</td>
<td>Wrong dose, dose distribution, location, or volume</td>
<td>2.0</td>
</tr>
<tr>
<td>6</td>
<td>Occasional failures</td>
<td>&lt;0.5</td>
<td>Potentially serious toxicity or tumor underdose</td>
<td>5.0</td>
</tr>
<tr>
<td>7</td>
<td>Repeated failures</td>
<td>&lt;1</td>
<td>Very wrong dose, dose distribution, location, or volume</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>&lt;5</td>
<td>Catastrophic</td>
<td>&gt;20</td>
<td></td>
</tr>
</tbody>
</table>

Risk Priority Number (RPN):

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Example: DIBH planned on wrong (FB) scan

- **approximate** RPN = 7 x 8 x 5 = 245
Step 2: Fault Tree Analysis

**FMEA:** take a breath, use a metric you like, and do it!
- Identify the steps in your common processes that have gone wrong or might clearly go wrong
- Take a stab at quantifying how severe those failures might be and how likely they would be detected
- Focus on the steps of highest risk and map out what might cause those steps to fail (Step 3)
- Build safety barriers to prevent those failures from occurring (Step 4)

Step 3: Fault Tree Analysis

**FTA:** zoom in on one failure mode and create a visualization (tree diagram) that maps out potential causes of failure
- RCA is retrospective (a posteriori), while FTA is prospective (a priori)
- Very useful in discovering gaps or redundancy (positive) in error prevention
- “Critical facets of treatment should have redundancy. Redundancy gives protection against errors creeping into the systems” (TG-100).
Step 3: Fault Tree Analysis


Step 3: Fault Tree Analysis

Manger, Ryan, et al.

Fig. 3. Fault tree analysis for a top RPN-ranked failure mode of SIG-RS. This failure mode had a RPN of 238 and was associated with step 79.
Step 4: Implement a QM strategy

**QM strategy**: a system of safety barriers that would prevent failures from propagating through the process.
- Improved training (frequency)
- Establishment of standard operating procedures
- Development of checklists
- Clarified documentation (templates, drop-down boxes)
- Redundant checks between professional disciplines
- Improved QA strategies (peer review, measurements, etc.)

At the departmental level

- Be an ambassador for safety in your clinic!
  - Lead by example
  - Honest about mistakes
  - Persistent in seeking participation and solutions
At the departmental level

- Be an ambassador for safety in your clinic!
- Build a multidisciplinary team with comprehensive representation of professional disciplines
- Start with a relatively small project to accommodate the learning curve and avoid burnout
- Helpful to have someone familiar with the FMEA process to facilitate meetings, etc.
- **Read up and use your resources like AAPM TG-100, etc., etc.**

<table>
<thead>
<tr>
<th>2003</th>
<th>2006</th>
</tr>
</thead>
</table>
| “Errors often follow violations in protocols, particularly failures to perform verification procedures, and indicators that things are not correct are often present yet ignored during events.”
| **Radiation Offers New Cures, and Ways to Do Harm**
By WALT BOGDANICH |
References