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

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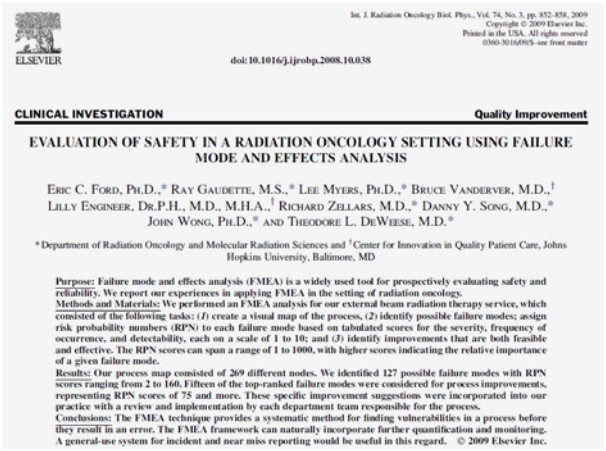
FMEA in RadOnc



Int. J. Radiation Oncology Biol. Phys., Vol. 74, No. 3, pp. 852–858, 2009
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0360-3016/09/$–see front matter

ELSEVIER

doi:10.1016/j.ijrobp.2008.10.038

CLINICAL INVESTIGATION **Quality Improvement**

EVALUATION OF SAFETY IN A RADIATION ONCOLOGY SETTING USING FAILURE MODE AND EFFECTS ANALYSIS

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Purpose: Failure mode and effects analysis (FMEA) is a widely used tool for prospectively evaluating safety and reliability. We report our experiences in applying FMEA in the setting of radiation oncology.
Methods and Materials: We performed an FMEA analysis for our external beam radiation therapy service, which consisted of the following tasks: (*1*) create a visual map of the process, (*2*) identify possible failure modes; assign risk probability numbers (RPN) to each failure mode based on tabulated scores for the severity, frequency of occurrence, and detectability, each on a scale of 1 to 10; and (*3*) identify improvements that are both feasible and effective. The RPN scores can span a range of 1 to 1000, with higher scores indicating the relative importance of a given failure mode.
Results: Our process map consisted of 269 different nodes. We identified 127 possible failure modes with RPN scores ranging from 2 to 160. Fifteen of the top-ranked failure modes were considered for process improvements, representing RPN scores of 75 and more. These specific improvement suggestions were incorporated into our practice with a review and implementation by each department team responsible for the process.
Conclusions: The FMEA technique provides a systematic method for finding vulnerabilities in a process before they result in an error. The FMEA framework can naturally incorporate further quantification and monitoring. A general-use system for incident and near miss reporting would be useful in this regard. © 2009 Elsevier Inc.

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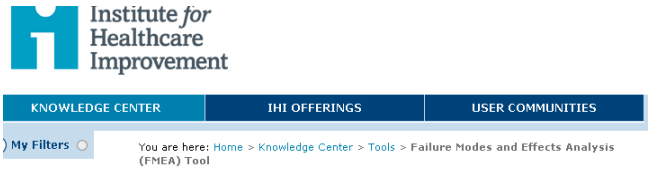
FMEA: Definition – relevant source

- 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.



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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

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Process FMEA

EXAMPLE SLIDES FOR RADONC TEAM

- 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.

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FMEA – basic hypothetical example

EXAMPLE SLIDES FOR RADONC TEAM

1	2	3	4	5	6
Wake Up	Get Dressed	Start the Car	Drive the Car	Park the Car	Walk into Work
1a. Hit snooze on alarm	2a. Make Coffee	3a. Find Keys	4a. Coffee in cup holder	5a. Notice and take exit	6a. Collect coffee, bag, computer
1b. Again, hit snooze on alarm	2b. Take Shower	3b. Find Bag	4b. NPR on Radio	5b. Negotiate turn	6b. Close and lock doors
1c. Get out of bed	2c. Find clothes	3c. Look for Coffee	4c. Phone accessible	5c. Find spot	6c. Walk to work
1d. Find Slippers	2d. Find Shoes	3d. Find Car	4d. Drive to Work	5d. Hang up phone	

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Cindy Pope, Beth Israel – Plymouth MA

FMEA example cont

EXAMPLE SLIDES FOR RADONC TEAM

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.

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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

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Creating a process map

Consensus recommendations for incident learning database structures in radiation oncology

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(Received 29 June 2012; revised 16 August 2012; accepted for publication 15 October 2012; published 26 November 2012)

Medical Physics, Vol. 39, No. 12, December 2012

LAHEY HEALTH - RADIATION ONCOLOGY
BRACHYTHERAPY PROCESS MAP
4-8-2013 P. HALVORSEN

Main branch #	Domain	Secondary branch #	Process	Safety barrier?	Hard stop?
1	Patient Assessment	1.1	Verification of patient ID by two methods		
		1.2	Diagnosis definition including imaging and outside records		
		1.3	Review and verification of pathology report		
		1.4	Physical exam		
		1.5	Clinical staging		
		1.6	Evaluation of patient medical conditions		
		1.7	Evaluation of special needs for radiotherapy (e.g. pacemaker)		
		1.8	Evaluation of previous radiotherapy (including port images and planning records)		
		1.9	Evaluation of other treatment modalities (e.g. chemo, radiation)		
		1.10	Decision to treat		
		1.11	Entering patient information into radiation oncology EMR (Aria)		
		1.12	Selection of clinical protocol (incl. HDR modality, intended dose regimen)		
		1.13	Patient education & consent		
		1.14	Insurance evaluation		
		1.15	Appointment scheduling (OR if applicable, simulation, treatment dates)		
		1.16	Source ordering if permanent implant or non-Cesium LDR (based on nomogram)		
		1.17	Peer review of treatment decision (e.g. tumor board)		
		1.18	Fiducial placement		
		1.19	Evaluation/ordering of workup for IV contrast		
		1.20	Social work and nutrition assessment		
2	Imaging for RT Planning	2.1	Imaging and applicator decisions (type and technique)		
		2.2	Physician directive for imaging technique and immobilization		
		2.3	Verification of patient ID, site, procedure and consent		
		2.4	Patient positioning		

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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

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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

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Ranking each step in the process

Assign a Risk Priority Number (RPN):

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

- RPN = O*S*D

Lahey ranking scales

Rank	Occurrence (O)	Severity (S)		Detectability (D)
		Qualitative	*Metrics*	
1	Less than once every 5 years	No effect		Obvious
2	Once every 2-5 years	Inconvenience	Dose change ≤ 5%	Very easy to detect
3	Once a year			
4	Several times a year	Minimal impact or delay in care		Easy to detect
5	Once a month			
6	Several times a month	Limited toxicity or tumor dose discrepancy	≥ 1 week interruption in treatment due to toxicity caused by the error	Mildly difficult to detect
7	Once a week			
8	Several times a week	Potentially serious toxicity or tumor dose discrepancy	Dose change ≥ 20%; reportable as Medical Event	Difficult, but possible, to detect
9	Once a day	Possibly very serious toxicity or tumor dose discrepancy		
10	Several times a day	Catastrophic	Death or permanent and debilitating disability	Impossible to detect

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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

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FMEA – Lahey results from Phase I

Process Tree Branch	Step	O	S	D	RPN
1: Patient Assessment/Consultation	1.1	1	8	2	*16*
	1.2	4	8	6	*192*
	1.3	3	8	6	*144*
	1.4	2	8	8	*128*
	1.5	4	8	4	*128*
	1.6	4	8	5	*160*
	1.7	3	9	6	*162*
	1.8	2	9	8	*144*
	1.9	4	7	5	*140*
	1.10	2	8	6	*96*
	1.11	5	6	7	*210*
	1.12	2	4	6	*48*
	1.13	3	2	2	*12*
	1.14	2	5	3	*30*
	1.15	4	8	6	*192*
	1.16	4	4	2	*32*
	1.17	4	7	2	*56*
2: Imaging for RT Planning (Simulation)	2.1	3	6	6	*108*

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

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FMEA – Lahey results from Phase I

- 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 this 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 as recommended by Task Group 100 of the American Association of Physicists in Medicine[1] [AAPM] and as reported by Ford[2]. The team's initial report on this topic was submitted in March 2014, 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 (qualitative) expectation 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 commit to substantively addressing 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

Recommendations

For each recommendation below, the "Implementation difficulty" rating is a subjective score on a 1-10 scale as agreed 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 timeline.

Step 3.3 – Planning: Registration of image sets.

Recommendation	Implementation Difficulty	Target date	Lead(s)
Consistently perform a "big picture" check – are the correct data sets fused? Scroll through the entire image volume – anything look odd?	1	1/1/15	MD
Ensure that MD reviews the registration before proceeding with target delineation & planning	3	1/15/15	Dosimetry - Rob

Step 3.4 – Planning: Delineation of target(s).

Recommendation	Implementation Difficulty	Target date	Lead(s)
Dosimetrist opens CTPN with MD present, asks to review CTPN to confirm that target delineation is correct.	3	2/1/15	Dosimetry – Rob
Second physician to review consult note, path, and target delineation prior to dosimetric planning.	10	?	?

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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.

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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

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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

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