THE UNIVERSITY OF TEXAS MD Anderson Cancer Center

An FMEA survey of intensity modulated radiation therapy (IMRT) step and shoot dose delivery failure modes

Jacqueline Tonigan Faught, Jennifer Lynn Johnson, Stephen Kry, Peter Balter, Laurence Court, Francesco Stingo, David Followill
IROC Houston QA Center
The University of Texas, M.D. Anderson Cancer Center, Houston, Texas

IROC™ IMAGING AND RADIATION ONCOLOGY CORE
Global Leaders in Clinical Trial Quality Assurance

Introduction

Increasing implementation of the risk mitigation tool failure modes and effects analysis (FMEA) seeks to achieve process-wide risk comprehension and address the ever-increasing quality assurance requirements that come with advanced radiotherapy technologies and techniques.

Objective

This FMEA survey was conducted to assess the perception of TG-142 tolerance level dose delivery failures in IMRT and the application of FMEA process to this specific aspect of IMRT.

Failure Modes and Effects Analysis

Potential points of failure are identified and ranked in order of the Risk Probability Number (RPN):

$$RPN = O \times D \times S$$

Where,

- O = Likelihood of occurrence
- D = Lack of detectability
- S = Severity

Scores O, D, and S are assigned by a team through consensus or average based on a scale such as that in Table 1. The most risky failure modes (high RPN) are evaluated for risk reduction.

Rank	Occurrence (O)		Detectability (D)		Severity (S)	
	Qualitative	Frequency	Qualitative	Est. probability of going undetected	Qualitative	Categorization
1	Failure Unlikely	0.01%	Never undetected	0.01%	No effect	
2		0.02%	Very low likelihood undetected	0.2%	Inconvenience	Inconvenience
3	Relatively few failures	0.05%		0.5%		
4		0.1%	Low likelihood undetected	1%	Minor dosimetric error	Suboptimal plan or treatment
5		< 0.2%		2%	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location or volume
6	Occasional failures	< 0.5%		5%		
7		< 1%	Moderate likelihood undetected	10%	Recordable event, Potentially serious toxicity or tumor underdose	
8	Repeated failures	< 2%		15%		
9		<5%	High likelihood undetected	20%	Reportable event, Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location or volume
10	Failures inevitable	> 5%	Always undetected	> 20%	Catastrophic	

Table 1: FMEA scoring scale adopted from AAPM TG-100 and Ford, *et al.*[1]

Failure Mode	Magnitude of Failure
1. Beam energy	1%
2. Beam symmetry	2%
3. MLC systematically in one bank	2 mm
4. Gantry angle systematically	2.0°
5. Collimator angle systematically	2.0°
6. Couch angle systematically	2.0°
7. MU linearity for < 5 MU systematically	6%
8. MLC transmission and leakage modeling	0.5%
9. MLC tongue-and-groove modeling	0.5%
10. MLC leaf end modeling	0.5%
11. CT number to electron density table systematically	2%

Table 2: Physics-specific failure modes and magnitude of failure evaluated in the survey.

Support: *Work supported by PHS grants CA10953 and CA180803 awarded by NCI, DHHS*

Materials and Methods

An online survey was distributed to approximately 2000 physicists worldwide that participate in quality services provided by the Imaging and Radiation Oncology Core - Houston (IROC-H). The survey briefly described eleven different failure modes covered by basic quality assurance in step-and-shoot Intensity Modulated Radiation Therapy (IMRT) at or near commonly accepted tolerance criteria levels, shown in Table 2. Respondents were asked to estimate the worst case scenario percent dose error to PTVs or OARs that could be caused by each of these failure modes in a head and neck patient as well as the three FMEA scores using the color-coded scale in Table 1. FMEA was not mentioned until the end of the survey to avoid intimidation. Demographic data was also collected.

Results

Demographics

181 individual and three medical physics group responses were submitted. The following figures summarized the demographics of the respondents.

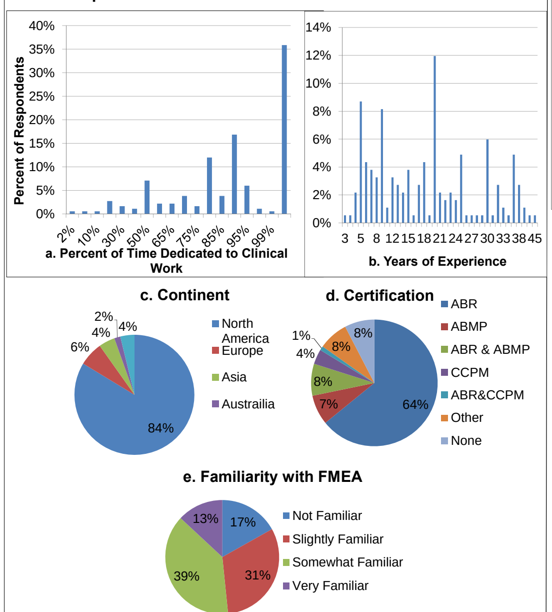

Figure 1: a. The percent of time respondents dedicated to clinical work, b. the years of medical physics experience of respondents, c. the continent the respondents currently practice in, d. the certifications held by the respondents, e. the familiarity of respondents with FMEA prior to the survey.

Occurrence, Detectability, and Severity scores as well as percent errors corresponding to tolerance level failures are reported in Figure 2. . Variability in responses was very high. Overall expected severity was low but potentially consequential, with average S ≤ 5 and average error ≤ 7%. Failure modes were ranked by RPN, resulting in each failure mode being ranked both most risky and least risky by different respondents. Rankings by RPN are shown in Figure 3. No universal relationships were found between the scores and collected demographic data.

Results

Occurrence, Detectability, and Severity scores as well as percent errors corresponding to tolerance level failures are reported below. Variability in responses was very high. Overall expected severity was low but potentially consequential, with average S ≤ 5 and average error ≤ 7%.

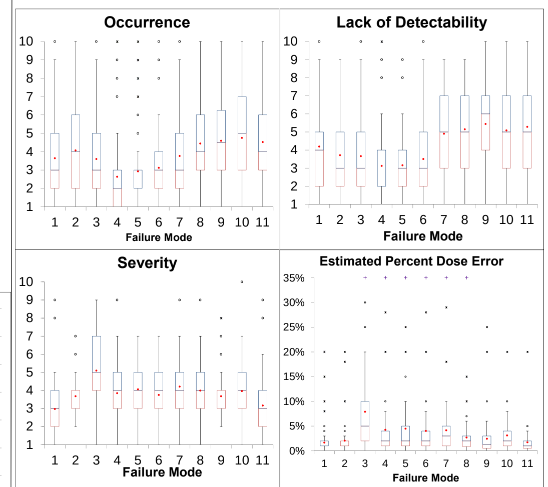

Figure 2: Whisker-Box plots of North American survey results for FMEA scores and estimated percent error for our 11 FMs. Red points show average values, stars show outliers, circles show extreme outliers, purple pluses show larger percent doses were estimated by respondents, up to 105% for failure mode 8. N = 184.

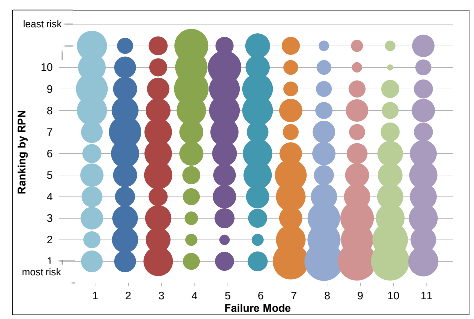

Figure 3. Ranking of failure modes in order of the risk they present using the RPN. The most risky failure mode would have the highest RPN and would be ranked "1". The size of the bubbles in the chart indicate the frequency at which each failure mode was assigned each rank according to the RPNs calculated.

Conclusion

While the perception of tolerance criteria level failures in IMRT tend to indicate low risk as one would expect, large variability in FMEA scores and estimated percent dose errors induced by these failures was found. As FMEA becomes more widely implemented, it is important to grasp the potential for variations in results between users and settings. This is of particular importance when FMEA may be used to eliminate routine QA procedures in the interest of time or for solo physicists.

References
[1] Ford EC, Gaudette R, Myers L, et al. Evaluation of safety in a radiation oncology setting using failure mode and effects analysis. *Int J Radiat Oncol Biol Phys.* Jul 1 2009;74(3):