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# Failure Mode and Effects Analysis (FMEA) applied to High-Dose-Rate Prostate Brachytherapy Treatment Planning and Delivery

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## INTRODUCTION

### WHAT IS FAILURE MODE AND EFFECTS ANALYSIS

Failure Mode Effects Analysis (FMEA) is a risk assessment tool for systematically identifying all potential failures in a process. It analyses why the process might fail, the effects of each failure and how the process can be made safer. The objective of an FMEA is to evaluate and improve system safety by taking actions to eliminate or reduce failures, starting with the highest-priority ones.

### HIGH-DOSE-RATE PROSTATE BRACHYTHERAPY PROCESS

High-dose-rate (HDR) prostate brachytherapy consists of simulation, treatment planning, dose/time calculation and followed by treatment all in a short period of time. This condition added to regimens with high doses in a few fractions implies significant risk. The FMEA technique is well-established tool for safety analysis and improvement<sup>1</sup>.

As errors during HDR process have the potential to cause considerable patient harm, evaluation of the process by FMEA is highly applicable.

## OBJECTIVES

1. Conduct an FMEA of High Dose Rate Prostate Brachytherapy Treatment Planning and Delivery at NCCS.
2. Identify Risk Priority Number (RPN) for every possible failure mode and its causes, and determine the total RPN for the process.
3. Propose controls which can reduce total RPN for the process.

## METHODOLOGY

### FMEA PROCESS STEPS

1. Select an appropriate process (see Figure 2).	5. Identify possible causes and effects of all failure modes.
2. Assemble a multidisciplinary team (see Figure 1).	6. Assign a numerical value for each failure mode according to three characteristics: occurrence (O), severity (S) and detectability (D) (see Figure 3 and 4).
3. Develop a process flow diagram.	7. Prioritize failure modes and determine where process improvements are most needed.
4. Determine all possible failure modes.	8. Propose controls for selected failures.

Figure 1: HDR Prostate Brachytherapy Process

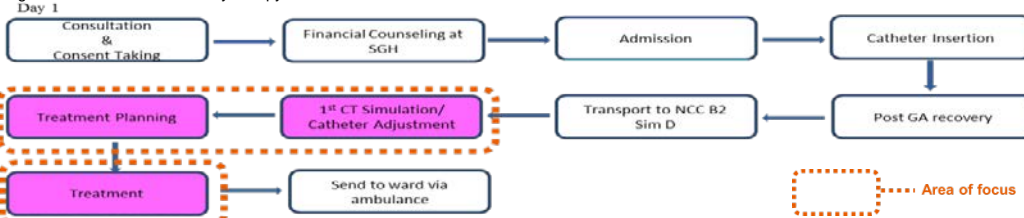


Figure 3: FMEA Scoring Matrix (Adapted from VA National Center for Patient Safety's Prospective Risk Analysis System)

Score	Description
<b>Occurrence (O)</b>	
1	<i>REMOTE</i> : no known occurrence; or happens < 10% of the time
3	<i>LOW</i> : possible, but no known data; or happens 10-30% of the time
5	<i>MODERATE</i> : documented but less frequent; or happens 40-60% of the time
7	<i>HIGH</i> : documented and frequent; or happens 70-80% of the time
10	<i>VERY HIGH</i> : documented, almost certain, or happens 90-100% of the time
<b>Detectability (D)</b>	
1	<i>VERY HIGH</i> : error almost always detected; detected 9 out of 10 times
3	<i>HIGH</i> : error likely to be detected; detected 7 out of 10 times
5	<i>MODERATE</i> : moderate likelihood of detection; detected 5 out of 10 times
7	<i>LOW</i> : low likelihood of detection; detected 3 out of 10 times
10	<i>REMOTE</i> : detection not possible at any point, detected 0 out of 10 times

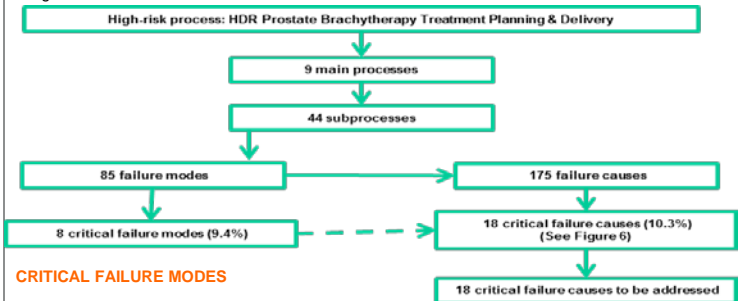
Score	Description
<b>Severity (S)</b>	
1	<i>Minor Event</i> Patient Outcome: No injury Staff Outcome: First aid treatment only with no lost time Equipment or Facility: Damage < \$10,000
4	<i>Moderate Event</i> Patient Outcome: Increased length of stay Staff Outcome: Medical expenses Equipment or Facility: Damage > \$10,000 but < \$100,000
7	<i>Major Event</i> Patient Outcome: Permanent lessening of bodily functioning Staff Outcome: Hospitalization of 1 or 2 staff Equipment or Facility: Damage equal to or more than \$100,000
10	<i>Catastrophic Event</i> Patient Outcome: Death or major permanent loss of bodily functioning Staff Outcome: Death or hospitalization of 3 or more staff Equipment or Facility: Damage equal to or more than \$250,000

Figure 2: Seven-member FMEA team

Department/ Role	Count
Team leader (Radiation Oncologist)	1
Division of Radiation Oncology (Radiation Therapist)	4
Division of Radiation Oncology (Physicist)	1
Institutional Risk Management	1
<b>Total</b>	<b>7</b>

## RESULTS

Figure 4: Overview of FMEA results



### CRITICAL FAILURE MODES

Of the 85 failure modes identified, 8 were identified as critical failures (9.4%).

They were associated with:

- ✓ Incorrect placement of localised copper wires in selected catheters
- ✓ Incorrect catheter depth
- ✓ Incorrect connection of source guide tubes to both catheters on patient and the afterloader

### Five recommendations for process improvement

#### Enhancing Care

- To allocate sufficient time for the procedure
- Dedicate a brachytherapy team consisting of 1 radiation oncologist, 3 radiation therapists, 2 physicists and 1 oncology nurse

#### Knowledge based Competency Assessment

- Development of Protocol & Work Instruction
- Development of Unit & Area Specific competency assessment

#### Safe & Accurate Treatment Delivery

- Identify high risk processes that require two independent checks

Staff @ CT for Prostate HDR (2 hours)

4 hours for Prostate HDR procedure

PERFORMANCE STANDARD	COMPETENCY ASSESSMENT		COMPETENCY REASSESSMENT (if applicable)	
	DATE	COMMENTS	DATE	COMMENTS
A. General Professional Duties				
1. Correctly identify patients according to organizational protocol				
2. Utilize patient case notes and patient management system				
3. Inform the patient on the procedure to be undertaken, pre-procedure preparation and any possible side effects in a manner to assist their understanding and encourages them to ask any questions				
4. Assessment and proper documentation of patient's emotional and physical state inclusive of pain scores. Appropriate action taken to ensure that patient is suitable for treatment.				

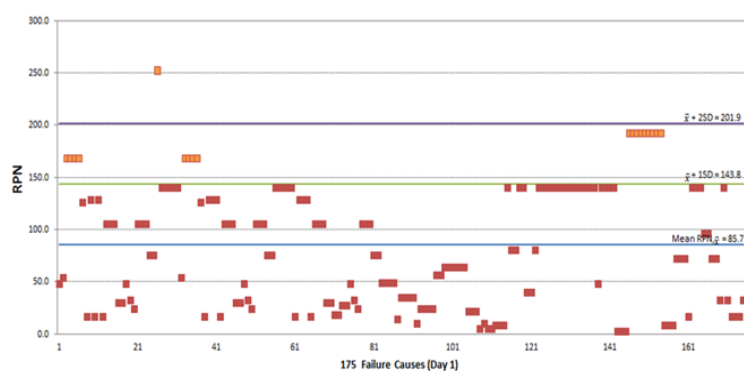
Figure 5: Overview of Scatter Plot results

Total PRN	15004
Minimum RPN	2
Standard deviation, SD	58.1
Mean RPN	85.7
Maximum RPN	252
Critical RPN ( $\geq \bar{x} + 1SD$ )	143.8

Critical failures are defined as those with a RPN of greater than or equals to 1 standard deviation away from the mean. This will enable comprehensive evaluation of the process and give greater focus on the failure causes with higher priority.

Note: The 18 critical failure causes are indicated by bolded orange markers

Figure 6: Scatter Plot of Risk Priority Numbers



## CONCLUSION

- ✓ A total of 85 failure modes and 175 failure causes were identified and quantitatively assessed for risk. 8 of the 85 failure modes (9.4%) were determined to be critical failures. Five recommendations were proposed for the purpose of maintaining quality and ensuring patient safety during brachytherapy treatment.

- ✓ Benefits of conducting the FMEA:

- ✓ Enabled an in-depth analysis of HDR prostate brachytherapy process
- ✓ Brought about an increased understanding among the team members relating to the identified critical failures
- ✓ Quantitatively identified critical areas of concern, leading to practical recommendations for significant improvement.
- ✓ With strict involvement and awareness of these identified critical failures, the HDR Brachytherapy team had identified 2 Near Misses before actual harm can occur to patient resulting in dire consequences since implementation of the recommended measures.

### REFERENCES

Stamatis DH. Failure mode and effect analysis: FMEA from theory to execution. 2<sup>nd</sup> ed. Milwaukee, WI: ASQ Quality Press; 2003.

