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A Comprehensive Risk Management Framework Incorporating FMEA and Quality Indicators for Enhancing Safety during Radiation Therapy System Upgrades

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ABSTRACT

Purpose: This study aimed to enhance safety during system upgrades of radiation therapy equipment by developing a comprehensive risk management framework that incorporates Failure Modes and Effects Analysis (FMEA) and Quality Indicators (QIs). The clinical applicability and utility of this framework as a quantitative approach for evaluating operational improvements were investigated.

Methods: The proposed framework was applied to a system upgrade from TomoTherapy (Accuray) to Radixact (Accuray). A multidisciplinary team consisting of a radiation oncologist, nurse, radiation therapist, and medical physicist performed an FMEA in accordance with AAPM TG-100 and constructed a process map spanning machine acceptance through treatment initiation. Failure modes (FMs) were identified at each process step, and Risk Priority Numbers (RPNs) were calculated based on occurrence, severity, and detectability. The top 20% of high-risk FMs were selected for risk-reduction interventions. Concurrently, radiation-therapy-specific QIs proposed by Mizuno et al. were assessed before upgrade and again two months after clinical implementation, and improvement measures were undertaken for indicators with insufficient achievement. Changes in RPNs and QI achievement rates before and after the upgrade were compared, and their relationship was evaluated.

Results: Twenty processes were identified, yielding 214 FMs. Among these, 42 high-risk FMs were prioritized, and their mean RPN decreased markedly from 149.4 to 68.3 following the upgrade, demonstrating substantial risk reduction. The QI achievement rate improved from 46% pre-upgrade to 77% post-implementation. Moreover, the trend in RPNs sreduction was consistent with improvements in QI performance.

Conclusions: The comprehensive risk management framework that incorporates FMEA and QIs demonstrated clinical value by improving safety during a system upgrade and enabling quantitative assessment of risk-reduction effects. This methodology may be applicable to new equipment installations and operational transitions, contributing to continuous quality management in radiation therapy.

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INTRODUCTION

Advances in radiotherapy technology have improved treatment accuracy and clinical outcomes; however, increasing system complexity has also increased the risk of errors related to insufficient verification and communication failures among healthcare professionals. System upgrades, including software updates, hardware modifications, and workflow changes, may introduce new risks and require enhanced safety management.

Failure Modes and Effects Analysis (FMEA), recommended by AAPM TG-100, is widely used to identify and prioritize potential risks within radiotherapy processes[1]. However, FMEA primarily focuses on process-related failure modes and provides limited assessment of organizational performance and operational compliance. In contrast, Quality Indicators (QIs) can quantitatively evaluate organizational structures, workflow management, and adherence to procedures, but they are not designed to comprehensively identify latent risks embedded within clinical processes. Therefore, the limitations of one approach may be complemented by the strengths of the other.

Because radiotherapy involves multiple professionals and complex workflows, a comprehensive approach to risk management is essential. This study developed an integrated framework combining FMEA and QIs for radiotherapy system upgrades and evaluated its usefulness for enhancing patient safety and supporting operational improvement.

METHODS AND MATERIALS

This single-center before-and-after study evaluated a comprehensive risk management framework combining Failure Modes and Effects Analysis (FMEA) and Quality Indicators (QIs) during the upgrade of a radiotherapy system from TomoTherapy to Radixact (Accuray Inc.).

A multidisciplinary team consisting of a radiation oncologist, two nurses, two radiation therapists, and a medical physicist conducted FMEA according to AAPM TG-100. The clinical workflow was mapped , and potential failure modes were identified and scored for occurrence (O), severity (S), and detectability (D).

The Risk Priority Number (RPN) was calculated as the product of these three scores.

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

Top 20% of RPNs → Corrective actions

Quality Indicators (QIs) proposed by Mizuno et al. were used to evaluate organizational structure, workflow management, and compliance with recommended practices[2].

Unachieved QIs → Corrective actions

RPNs and QI achievement rates were compared before the upgrade and two months after clinical implementation. Overall effectiveness was assessed by integrating changes in process-related risks identified by FMEA and changes in organizational and operational performance measured by QIs.

RESULTS

The overall risk management framework is shown in Fig. 1.

FMEA results: Twenty clinical processes were identified, yielding 214 failure modes (FMs). Among these, 42 high-risk FMs (top 20% by RPN) were prioritized for mitigation (Table 1). Following implementation of corrective actions, the mean RPN of high-risk FMs decreased from 149.4 to 68.3.

QI results: The overall QI achievement rate improved from 46% before the system upgrade to 77% after clinical implementation. Improvements were observed following interventions targeting unachieved indicators, including procedure standardization, checklist implementation, and enhanced multidisciplinary communication. Reductions in RPNs were accompanied by improvements in QI achievement rates.

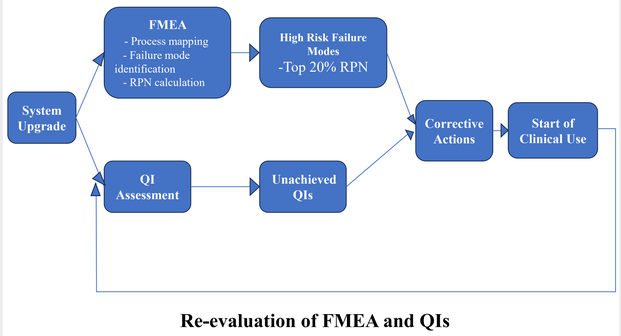

Fig. 1 Overview of the Comprehensive Risk Management Framework.

Table 1. List of the Top 20% of RPNs Identified by the Pre-upgrade FMEA.

No.	Process	Failure mode	Before		After	
			Mean	SD	Mean	SD
1	Acceptance	Scope of QA testing is insufficient.	219.2	141.2	80.5	51.3
2	Acceptance	Acceptance testing of equipment is inadequate, resulting in missed initial defects.	200.2	152.9	92.5	32.8
3	Staff Training (Equipment Operation)	Equipment operation procedures are not properly taught to staff.	187.8	172.8	85.2	58.9
4	Staff Training (Equipment Operation)	Training participation is inconsistent, and some staff have not completed required training.	184	146.1	90.7	58.4
5	Staff Training (Equipment Operation)	Trainers lack sufficient knowledge and clinical experience.	180	85.9	50.3	39.4
6	Commissioning	Clinical procedures and workflows are not standardized.	172.5	100.2	73.3	45.0
7	CT Simulation for Treatment Planning	CT simulation setup errors occur (e.g., incorrect patient positioning).	166.7	212.4	58.2	56.5
8	Quality Assurance (Regular)	Resources for quality management are insufficient.	165.8	184.7	50.3	37.9
9	Commissioning	Incorrect configuration of software or auxiliary tools.	165.7	161.4	101.3	70.2
10	Commissioning	Verification and independent check processes are insufficient.	164.7	97.7	100	78.5
11	Quality Assurance	Variability in standards among staff leads to inconsistent management practices.	164.2	154.1	78.2	69.8
12	Quality Assurance (Regular)	No defined process for responding to QC results that fall outside tolerance limits.	163.2	182.6	73	44.0
13	CT Simulation for Treatment Planning	Limited time allocated for respiratory motion management training, resulting in unstable breathing during planning CT acquisition.	162	78.9	90	44.1
14	Regular Staff Training	Training for newly assigned staff is insufficient.	157.8	189.5	53	36.9
15	Radiation Treatment	Patient motion causes setup displacement.	156.8	105.2	62.7	23.2
16	Treatment Plan Approval	Planning verification checklist is incomplete.	155.8	152.3	40.8	14.9
17	Staff Training (Clinical Operation)	No post-training follow-up or competency assessment is performed.	152	178.3	54.2	38.5
18	Staff Training (Equipment Operation)	Training records are not properly maintained, resulting in unclear training history.	150.5	109.8	79.7	87.6
19	Post-Treatment Plan Review	Unexpected issues (e.g., patient movement) are not reviewed retrospectively.	150.5	120.5	91.5	69.3
20	Treatment Planning	Staff lack sufficient experience in treatment planning.	144	116	55.8	41.8
21	Treatment Plan Approval	Inadequate communication among treatment team members.	142.3	143.8	75.5	67.8
22	Radiation Treatment	Lack of information sharing may result in accidental irradiation of cardiac pacemakers.	141.7	208.5	55.7	36.1
23	Staff Training (Equipment Operation)	Local operating manuals are not updated, and outdated procedures remain in use.	141.5	105.8	93	101.3
24	Treatment Planning	Dose constraints are not achieved in treatment plans.	140.8	114.3	108.8	73.6
25	Consulting	Referring physicians do not adequately communicate clinical background or referral intent to radiation oncology.	139	135.2	80.7	89.3
26	Staff Training (Equipment Operation)	Timing and duration of training programs are inappropriate.	138.2	88.1	47.7	38.0
27	Staff Training (Clinical Operation)	Participation in training opportunities is limited among staff.	137	162.1	45.7	23.5
28	Radiation Treatment	Individualized radiation treatment order sheets are unavailable for some patients.	135.5	89	52.7	28.6
29	Staff Training (Clinical Operation)	Staff misunderstand the clinical operation or workflow of the equipment.	134	83.7	52.3	45.1
30	Commissioning	Inconsistencies exist between treatment planning system settings and machine configuration.	132.5	134.5	52.5	30.1
31	medical examination	Staff knowledge and clinical competency are insufficient.	131.8	156.5	40.8	34.5
32	Radiation Treatment	Equipment failure or malfunction occurs.	131.8	113	64.7	39.3
33	Radiation Treatment	Power outages interrupt treatment delivery, preventing irradiation data from being recorded.	131.3	123.4	63	43.6
34	Quality Assurance (Regular)	Human error impacts quality assurance and treatment accuracy.	129.7	124.7	47.7	44.4
35	Commissioning	Training and education related to radiation therapy workflow are insufficient.	128.8	81.7	62.2	40.7
36	Quality Assurance	Routine testing and QA checks are not consistently performed.	128.3	104.1	79.5	71.9
37	Patient-Specific Dose Verification	Verification records are incomplete, preventing retrospective review.	127.7	152.4	43	28.8
38	Treatment Planning	Incorrect CT-to-ED (electron density) conversion table is used.	126	90.5	79.7	37.4
39	Quality Assurance	Initial beam data collection for commissioning is incomplete.	125.2	75.5	73.3	55.0
40	Commissioning	Treatment environment and working conditions are not properly evaluated.	124.7	106.9	67.7	53.5
41	Staff Training (Clinical Operation)	Education and competency training for staff are inadequate.	123.2	92.2	54	36.1
42	Staff Training (Equipment Operation)	Information sharing among staff is insufficient, and training content is not widely communicated.	119.8	119.3	68.8	94.7

DISCUSSION

Twenty clinical processes associated with the upgrade from TomoTherapy to Radixact were identified, resulting in 214 failure modes (FMs), of which 42 high-risk FMs were mainly related to staff training, communication, quality assurance, and commissioning rather than equipment issues, highlighting the importance of organizational and human factors.

After mitigation strategies such as standardization, checklists, and improved communication, the mean RPN decreased from 149.4 to 68.3, while QI achievement increased from 46% to 77%, indicating improved workflow reliability and compliance.

FMEA and QI showed consistent trends, with FMEA identifying latent risks and QI reflecting implementation effectiveness, suggesting their complementary role in safety evaluation.

These findings indicate that system upgrade risks are largely driven by organizational factors; however, this was a single-institution study with limited follow-up, and further validation is required.

CONCLUSIONS

Radiotherapy system upgrades are associated primarily with organizational and human-factor–related risks rather than technical failures.

The combined use of FMEA and QIs effectively identified latent risks and verified the impact of mitigation strategies, demonstrating their complementary value in improving clinical safety during system transitions.

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