

RESEARCH ARTICLE

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Using FMEA to Reduce the Risk of Delayed Reporting of Critical Radiological Results in Oncology: A Patient Safety Initiative

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Abstract

Background: Timely communication of critical radiological findings is vital in oncology, where delays may jeopardize treatment and patient safety. Despite existing protocols, challenges such as manual reporting, unclear escalation paths, and resource limitations still contribute to delays. **Purpose:** This study applied Failure Mode and Effects Analysis (FMEA) to identify and address high-risk failure points in reporting critical radiology results at an oncology center. **Methods:** Conducted at a specialized oncology center in Amman, Jordan, this quality improvement project used a pre-and-post intervention design. A multidisciplinary team including radiologists, oncologists, IT staff, quality officers, and nurses applied the FMEA framework to assess the reporting process. Failure modes were scored using Severity, Occurrence, and Detection criteria to calculate Risk Priority Numbers (RPNs). Key interventions included: 1. Automated alerts integrated with the Electronic Health Record (EHR), 2. Standardized escalation protocols, 3. Staff retraining, 4. Structured documentation, and 5. Enhanced interoperability across PACS-RIS-EHR systems. Compliance was monitored monthly over a 12 months period. **Results:** Pre-intervention RPNs ranged from 280 to 350, with major risks identified in unrecognized findings (RPN=320), lack of physician notification (310), unclear protocols (330), and insufficient emergency coverage (350). Post-intervention analysis showed RPN reductions of 54–62%. Recognition of critical findings improved by 55%, notification by 58%, protocol adherence by 62%, and emergency staffing by 54%. Improvements were linked to automation, clearer workflows, and better system integration. Statistical testing confirmed significant compliance improvement and reduced monthly variation. **Conclusion:** FMEA effectively identified and mitigated critical failures in radiology reporting. Integrating technology and cross-disciplinary collaboration enhanced reporting timeliness, compliance, and patient safety in oncology care.

Keywords: Critical results- radiology- oncology- FMEA- patient safety- risk priority number- communication delay

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Introduction

Critical results in radiology refer to findings that indicate severe or potentially life-threatening conditions, such as new malignancies, metastases, or acute complications, requiring immediate communication between radiologists and clinicians to enable timely interventions [1, 2]. This process is particularly vital in oncology, where treatment decisions depend heavily on imaging data. Delays in communication can result in missed therapeutic opportunities and jeopardize patient safety. The Joint Commission International (JCI) emphasizes the need for structured protocols to ensure prompt reporting of critical results [3, 4].

In oncology settings, timely communication of critical

radiological findings is essential due to the aggressive nature of many cancers and the need for rapid treatment adjustments. However, several systemic barriers compromise this objective ranging from radiologist overload and manual reporting systems to inconsistencies in interdepartmental communication [5, 6]. These vulnerabilities increase the likelihood of failure modes that could delay the transmission of urgent findings [7-9].

To systematically assess and mitigate these risks, Failure Mode and Effects Analysis (FMEA) was employed. FMEA is a proactive, structured approach for identifying where and how a process might fail and assessing the relative impact of different failures, thereby prioritizing improvement actions. Within the radiology-to-oncology communication pathway, FMEA helps uncover potential

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failure points such as delayed report transcription, unclear documentation of criticality, and breakdowns in notifying responsible clinicians [10, 11].

Through this methodology, failure modes were scored based on severity, occurrence, and detectability, generating a Risk Priority Number (RPN) for each step in the communication process. High-priority failure modes were then targeted for intervention. For example, implementing automated alert systems integrated into the Electronic Health Record (EHR) significantly reduced notification delays by bypassing manual steps [12-14].

Moreover, FMEA facilitated cross-disciplinary collaboration between radiology, oncology, and IT departments to re-engineer workflows and create redundant systems for high-risk findings. Staff training and role clarification were also introduced to reduce variability in how critical results are handled [10, 11].

Despite technological improvements and established protocols, the process reviews revealed a significant risk of variation in the critical result reporting process. This variation stemmed from inconsistent adherence to communication protocols, differences in how staff prioritize critical findings, and resource constraints. These findings underscore the need for continuous process monitoring and targeted risk mitigation to ensure consistency and timeliness in reporting practices.

This study was initiated in response to observed delays in reporting within our oncology department. While communication protocols were in place, FMEA revealed critical gaps that had not been previously addressed. Addressing these gaps is essential for improving patient safety outcomes and aligning with international standards for timely and accurate diagnosis.

The purpose of this initiative was to use FMEA to assess the current system for critical result reporting, identify high-risk failure modes, and implement targeted, sustainable improvements. By doing so, the goal is to enhance communication efficiency, ensure rapid clinical response, and ultimately improve outcomes for oncology patients.

Materials and Methods

Setting

This study was conducted at a specialized cancer care and research center located in Amman, Jordan. The facility provides comprehensive oncology services and serves as a national referral center for complex cancer diagnoses and treatments. The focus of the study was on optimizing the reporting process for critical radiological findings within this complex clinical environment, addressing specific challenges related to communication delays, reporting quality, and protocol compliance.

Design

A pre-and-post intervention design was employed to evaluate the effectiveness of targeted quality improvement measures. This design enabled a comparative analysis of process performance before and after the implementation of corrective actions. The primary aim was to assess improvements in the timeliness, accuracy, and consistency

of critical radiology result reporting.

Framework

Failure Mode and Effects Analysis (FMEA) was applied to systematically identify and evaluate potential failure points within the critical result communication processes [10, 11]. Each stage from the generation of radiology reports to their receipt by the treating oncology team was analyzed for failure modes. These were rated based on Severity, Occurrence, and Detectability to calculate Risk Priority Numbers (RPNs), which guided the prioritization of process redesign efforts. High-risk areas were addressed through interventions such as staff re-training, the development of clearer escalation protocols, and the introduction of automated alert systems (Table 1).

Identify the process

The flowchart in Figure 1 illustrates the standard process for managing critical radiological findings following the completion of a medical examination. Once the exam is finalized, the first step is to determine whether

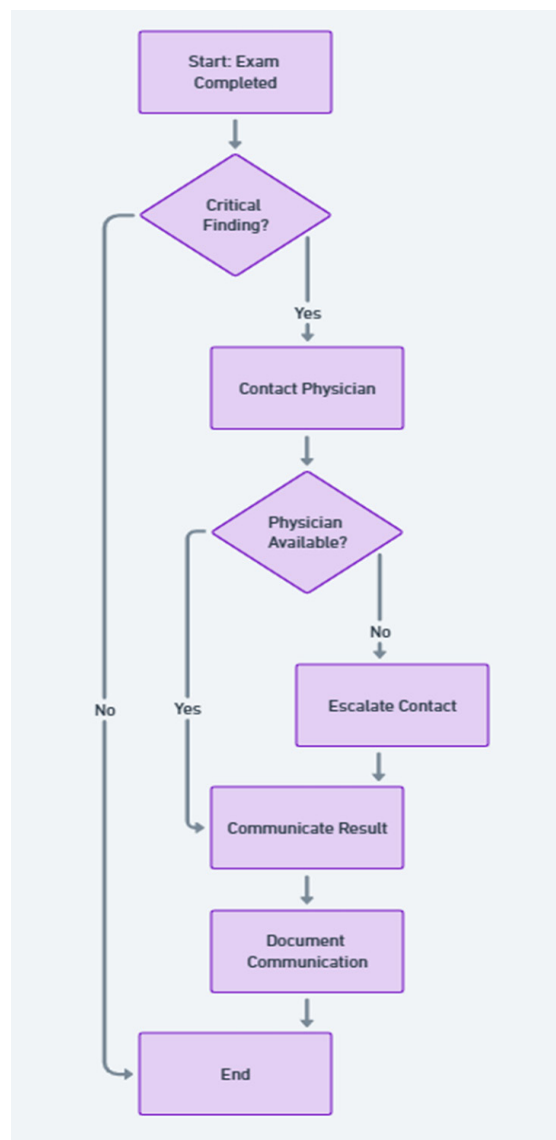


Figure 1. Process for Reporting of Critical Radiology Findings

Table 1. FMEA Steps and Descriptions – Delayed Reporting of Critical Radiological Results

Step	Description
Identify Potential Failure Modes	A multidisciplinary team including radiologists, oncologists, quality assurance personnel, IT specialists, and nurses conducted a structured brainstorming session to identify potential failure modes in the process of reporting critical radiological findings. Issues identified included missed findings, delays in physician notification, poor escalation, and documentation gaps. A fishbone diagram (Figure 2) was used to categorize root causes under people, process, technology, and environment.
Evaluate the Effects of Each Failure Mode	Each failure mode was assessed for its potential impact on patient care, particularly in the oncology setting where treatment decisions are time-sensitive. The team evaluated how each failure could delay diagnosis, affect treatment outcomes, or compromise patient safety, enabling prioritization of the most consequential risks.
Assign Severity Rating (S)	A severity score was assigned from 1 to 10, with higher numbers reflecting greater patient harm. For example, a failure to notify the physician about a critical finding (e.g., new metastasis) was rated high in severity due to the potential for treatment delay or missed intervention opportunities.
Assign Likelihood of Occurrence (O)	Each failure was rated based on how often it was likely to occur. Common issues such as reliance on manual communication, unclear escalation pathways, or high workload received higher occurrence scores due to their frequent appearance in routine operations.
Assign Detection Rating (D)	Detection scores reflected how easily a failure could be identified before causing harm. For example, lack of a real-time alert or monitoring system led to high detection scores, indicating poor visibility into whether the physician had received the critical result.
Calculate Risk Priority Number (RPN)	The RPN for each failure mode was calculated using the formula: $RPN = \text{Severity} \times \text{Occurrence} \times \text{Detection}$. Higher RPNs indicated critical vulnerabilities in the process and helped prioritize where to intervene. These calculations guided resource allocation and improvement focus.
Identify and Implement Corrective Actions	Based on RPN rankings, corrective measures were implemented to reduce high-risk failure modes. These included integrating automated alert systems with the EHR, clarifying escalation protocols, training staff on timely communication standards, and introducing dashboards to track compliance. Post-intervention RPNs were recalculated to confirm the effectiveness of these improvements.

a critical finding is present. If no such finding exists, the process concludes without further action. However, if a critical result is identified such as an urgent or potentially life-threatening condition the responsible radiologist is required to initiate direct communication with the treating physician. If the physician is available, the finding is communicated immediately, and the communication is properly documented in accordance with institutional protocols. In cases where the physician is not available, the process requires escalation, which may involve notifying an alternate provider or following predefined escalation pathways to ensure timely clinical response. After successful communication and documentation of the critical result, the process reaches its endpoint, ensuring that urgent findings are conveyed promptly and accurately to support patient

Safety and timely intervention.

Auditing, incident investigation, and brainstorming to identify Root Causes

The diagram in Figure 2 presents the various risks that can contribute to delayed reporting of critical results, particularly in high-stakes environments such as cancer centers. These risks are grouped into four main categories, each reflecting a different dimension of the reporting process.

The first category, system-related risks, involves technical failures and integration issues. Delays can occur due to system downtimes or malfunctions in

essential platforms like PACS (Picture Archiving and Communication System) and RIS (Radiology Information System), which are critical for accessing and sharing imaging results. Additionally, errors such as incorrect data entry or incomplete documentation can cause critical findings to be overlooked. Another common issue is the lack of seamless integration between different systems or departments, which hampers the efficient transfer of information and interrupts the clinical workflow.

The second category is staff competency and capacity risks, which relate to the human factors influencing performance. These include the misinterpretation of diagnostic results, mistakes in report documentation, and delays caused by staff shortages or heavy workloads. When healthcare teams are overstretched, even high-priority findings may not be communicated in a timely manner. Moreover, insufficient training on timely reporting protocols and the effects of fatigue or burnout can impair staff performance and further increase the risk of delay.

The third group of risks, policy and process-related, refers to gaps in institutional procedures. A lack of clear reporting protocols for critical findings may lead to uncertainty or inconsistency in how urgent results are handled. Similarly, the absence of structured follow-up processes can result in critical findings being overlooked after initial identification. Escalation procedures that are vague or weak also contribute to delays, especially when frontline staff are unsure how or when to elevate urgent



Figure 2. Root Causes of Delay Critical Results Reporting in Radiology

issues.

Lastly, communication and resource risks address challenges in how information is shared and supported. These include the use of ineffective communication methods, failure to prioritize or recognize critical results, and limited access to imaging or diagnostic tools during key times. The absence of backup staff during emergencies, combined with insufficient oversight on reporting accuracy and inconsistent escalation practices across shifts, further increases the likelihood of delayed response.

Ethical consideration

The project was approved by the Institutional Review Board (IRB) under reference number MOH-2025-15425, confirming that all research procedures adhered to established ethical standards. This approval ensures that participant confidentiality, data protection, and overall welfare were safeguarded throughout the study. The IRB's endorsement reflects compliance with national and institutional ethical guidelines, with a particular emphasis on minimizing risk and ensuring responsible data handling in accordance with research ethics principles.

Results

Initial Risk Priority Numbers (RPNs)

The initial Risk Priority Numbers (RPNs) across the identified failure modes in the critical result reporting process ranged from 280 to 350, indicating a high level of risk throughout key steps. The highest initial RPN (350) was observed in the area of staffing during emergencies, reflecting the serious impact of not having backup personnel during off-hours. Other significantly high RPNs included communication tools (340) and escalation protocol weaknesses (330), both of which directly affect the timely transmission of life-threatening findings.

Notably, even routine steps such as documentation (280) and system integration (300) carried high RPNs, revealing that both human and technical factors posed substantial threats to patient safety. These findings confirm that delays in reporting critical radiological results stem from a combination of systemic, procedural, and human reliability issues, necessitating urgent intervention across multiple domains.

Interventions

Table 2 presents a structured plan for addressing the root causes of delayed critical result reporting, detailing targeted improvement areas, corresponding interventions, and the teams responsible for implementation. These interventions were developed based on previous steps and many studies in the literatures [15-33]. The first area, training and competency, focuses on equipping staff with the necessary skills to accurately identify and escalate critical findings. This will be achieved through regular training sessions coordinated by the Radiology Department and the Staff Development Unit. In the domain of communication systems, the intervention involves implementing automated alert systems integrated with the hospital's Electronic Health Record (EHR), a task to be led jointly by the IT Department and the Radiology team to ensure real-time, reliable notifications.

To address delays caused by unclear escalation procedures, the escalation protocols will be standardized with defined response timelines. The Clinical Governance team and Radiology Leadership will oversee the development and enforcement of these protocols. Additionally, the issue of emergency coverage, particularly the lack of available staff during off-hours, will be mitigated by introducing an on-call staffing policy, coordinated by Human Resources in collaboration with the Radiology Department.

Documentation practices will be improved through the

Table 2. Improvement Areas, Interventions, and Responsible Teams

Area	Intervention	Responsible Team
Training & Competency	Conduct regular training on critical result identification and protocols	Radiology Department, Staff Development Unit
Communication Systems	Implement automated alert systems integrated with EHR	IT Department, Radiology Department
Escalation Protocols	Develop standardized and time-bound escalation pathways	Clinical Governance, Radiology Leadership
Emergency Coverage	Introduce after-hours staffing policy with on-call personnel	Human Resources, Radiology Department
Documentation Practices	Create standardized templates for critical result communication	Quality Department, Radiology Admin Team
System Integration	Upgrade PACS-RIS-EHR interface to support seamless data flow	IT Department, Health Informatics
Monitoring & Compliance	Deploy real-time dashboards and conduct regular audits	Quality and Patient Safety Unit
Feedback and Learning	Establish feedback mechanisms and incident review cycles	Risk Management, Clinical Education Unit

creation of standardized templates for recording critical result communications, with the Quality Department and Radiology Administration responsible for this task. Furthermore, the system integration challenges will be addressed by upgrading the interface between PACS, RIS, and EHR platforms to ensure seamless data flow, under the leadership of the IT Department and Health Informatics. To maintain accountability, the monitoring and compliance area will include the deployment of real-time dashboards and regular audits, overseen by the Quality and Patient Safety Unit. Lastly, feedback and learning mechanisms, including incident reviews and structured feedback loops, will be developed by the Risk Management and Clinical Education teams to promote continuous improvement and staff engagement.

Post RPN Post-intervention

The post-intervention analysis revealed a substantial reduction in Risk Priority Numbers (RPNs) across all major failure modes associated with delayed reporting of critical radiological results in oncology. Initially, RPNs

ranged between 280 and 350, indicating a high level of systemic and procedural risk affecting patient safety and timely care delivery. Following the implementation of targeted corrective actions, each failure mode demonstrated notable improvement, with reductions ranging from 54% to 62% (Table 3, Figure 3).

Specifically, the RPN for critical finding identification dropped from 320 to 145 (55% improvement) after reinforcing staff training and managing workload more effectively. The physician notification process improved from 310 to 130, showing a 58% reduction due to the introduction of automated contact alerts and clarified responsibility protocols. The most significant improvement occurred in the escalation protocol, where the RPN fell from 330 to 125, a 62% decrease, driven by the implementation of standardized, time-bound escalation pathways.

Enhancements to communication tools, including integration of automated alerts within the EHR, reduced the RPN from 340 to 150 (56%). Similarly, the documentation process saw a 57% improvement (280

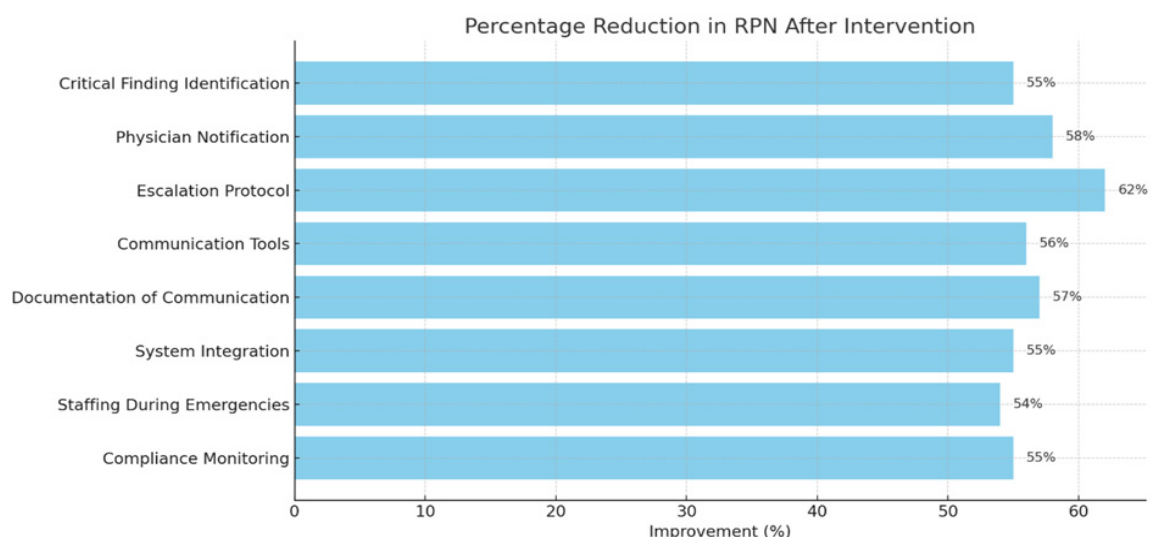


Figure 3. Percentage Reduction in Risk Priority Numbers (RPNs) After Interventions in Critical Radiology Result Reporting

Table 3. Failure Mode and Effects Analysis (FMEA) for Delayed Reporting of Critical Radiological Results

Process Step	Main Failure Mode	Root Cause	Effect	Initial RPN	Post-Intervention RPN	Difference (%)
Critical Finding Identification	Missed recognition of critical findings	Inadequate training; fatigue; high workload	Delay in escalation; compromised patient safety	320	145	55%
Physician Notification	Delay in contacting treating physician	Physician unavailable; lack of escalation protocol	Treatment delays; worsened clinical outcomes	310	130	58%
Escalation Protocol	Escalation not initiated when physician is unreachable	Vague or weak escalation guidelines	Critical finding remains unaddressed; delayed intervention	330	125	62%
Communication Tools	Inconsistent or inefficient communication methods	Use of manual or outdated systems; no automated alerts	Errors or lags in delivering urgent information	340	150	56%
Documentation of Communication	Communication not properly documented	Lack of standard documentation templates; time constraints	Lack of traceability; risk of legal and clinical miscommunication	280	120	57%
System Integration	Radiology system not interfaced with EHR	Poor IT integration; fragmented platforms	Delays in viewing/reporting; duplicate communication	300	135	55%
Staffing During Emergencies	No available staff for result communication during off-hours	No backup system; insufficient shift planning	Missed or delayed result communication during nights/weekends	350	160	54%
Compliance Monitoring	No audit or feedback on timeliness of reporting	Lack of quality monitoring framework	Process gaps persist; no accountability or improvement	310	140	55%

to 120) through the use of structured templates and communication logs. System integration issues, previously rated at 300, improved to 135 (55%) following the optimization of PACS–EHR interoperability. For staffing during emergencies, the RPN decreased from 350 to 160 (54%) after introducing dedicated on-call schedules. Finally, improvements in compliance monitoring lowered the RPN from 310 to 140 (55%) by establishing real-time dashboards and routine audits.

Discussion

This study offers several strengths that underscore its contribution to improving the timely reporting of critical radiological results in oncology. First, it adopts a multidisciplinary approach, involving radiologists, oncologists, IT specialists, quality personnel, and administrative staff, which ensured comprehensive identification of process gaps and the collaborative design of targeted solutions [14–16]. This inclusive approach enhanced the robustness and sustainability of the interventions. Second, the study applied a well-established risk-based quality improvement framework Failure Mode and Effects Analysis (FMEA) to systematically identify, score, and prioritize failure modes. This allowed the team to implement corrective actions tailored specifically to high-risk points within the reporting process and to verify

their effectiveness through recalculated Risk Priority Numbers (RPNs) [9–11]. Third, the use of a pre-and-post intervention design provided measurable evidence of improvement, particularly in compliance and timeliness, as validated through statistical analysis [17–20]. These quantifiable improvements support the effectiveness and relevance of the interventions in a real-world oncology setting.

A major strength of the study was the integration of technology within the intervention package [12–14]. Automated alert systems and enhancements to the Radiology Information System (RIS), including real-time notifications and structured data entry, were instrumental in streamlining communication and minimizing reliance on manual follow-up long identified as a source of delay and error in radiology workflows [12–14]. This technological reinforcement was part of a broader systems-level strategy aimed at addressing procedural inefficiencies, standardization gaps, and human performance variability. By aligning structural, technical, and human resource improvements, the study demonstrates a holistic approach to improving critical result reporting [25–33].

The rationale for these interventions was driven by the core barriers identified during the initial FMEA. One major contributor to delays was inefficiency in the radiology reporting systems. To resolve this, the team implemented automated reminders, faster data entry

protocols, and real-time alerts for critical findings [10-13]. These changes significantly reduced delays by removing the dependence on manual notifications and ensuring that critical results were communicated promptly (. This allowed oncologists to make faster clinical decisions.

Another identified challenge was inconsistent adherence to communication protocols, often due to variability in staff knowledge. To address this, the study introduced multiple training sessions and role-specific guidance to ensure all staff clearly understood the revised reporting procedures and the importance of timely action in oncology care [22–24]. This intervention aimed to empower staff with the competence and confidence to follow protocol, ultimately improving communication accuracy and timeliness.

Furthermore, the lack of standardized reporting templates was a notable source of inconsistency. The study revised institutional policies to define what constitutes a critical finding and implemented standardized escalation and documentation templates to ensure consistency and reduce variation [27, 28]. This step established a clear reporting structure, crucial in high-stakes cancer care settings where delays can have profound clinical implications [29–33].

The implemented interventions collectively addressed critical bottlenecks in the reporting workflow. Automated alert systems ensured real-time communication between radiologists and oncologists [25–27], while reminder functions and streamlined interfaces improved data accuracy and reduced delays. These changes led to measurable improvements in compliance with communication standards [18–19]. In parallel, training and education programs ensured that personnel at all levels were aligned with the updated protocols and better equipped to prioritize critical findings, further boosting compliance and reducing variation [22–24].

Policy revisions, such as standardized reporting templates and well-defined escalation pathways, eliminated uncertainty in communication and ensured that critical findings were acted on even during off-hours or when the primary physician was unavailable [17, 19]. These updates promoted consistency, accountability, and safety in reporting practices.

The use of the FMEA framework also provided a dynamic structure for continuous monitoring and improvement. Through regular review of compliance data and staff feedback, the team was able to identify operational issues that emerged post-implementation such as a temporary dip in compliance during peak workload periods—and respond with targeted adjustments [10-12]. This adaptability reinforced the durability and responsiveness of the intervention model.

Overall, the strength of this study lies in its ability to translate identified risks into targeted, evidence-based interventions, tailored to the oncology radiology environment. The interventions were not only practical and cost-effective but also scalable, offering a sustainable model that can be adapted to other healthcare settings. Grounded in root cause analysis, each action directly addressed the source of delay or error, resulting in measurable improvements in reporting accuracy,

timeliness, and patient safety.

One noted limitation is that the study was conducted in a single oncology center in Amman, Jordan, which may affect the generalizability of findings to other institutions with different resources or workflows. Additionally, reliance on retrospective chart reviews introduces the risk of missing or incomplete data, which could influence the precision of some measured outcomes.

In conclusion, this study demonstrated that the application of Failure Mode and Effects Analysis (FMEA) within an oncology radiology setting is an effective strategy for identifying and mitigating risks associated with delayed reporting of critical findings. By systematically analyzing the process and implementing targeted interventions such as automated alert systems, standardized documentation templates, escalation protocols, and staff training the study achieved significant reductions in Risk Priority Numbers (RPNs), with improvements ranging from 54% to 62%. These changes not only enhanced communication efficiency and compliance but also contributed to improved patient safety and clinical responsiveness in a high-risk, time-sensitive environment.

The success of this initiative underscores the importance of a multidisciplinary, data-driven approach to quality improvement in healthcare. It highlights how structured methodologies like FMEA can drive sustainable process enhancements when paired with technology integration, clear policies, and continuous monitoring. While the study's scope was limited to a single cancer center, its interventions offer a scalable model that can be adapted to similar healthcare environments aiming to optimize the timeliness and reliability of critical result communication.

Author Contribution Statement

All authors contributed equally in this study.

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