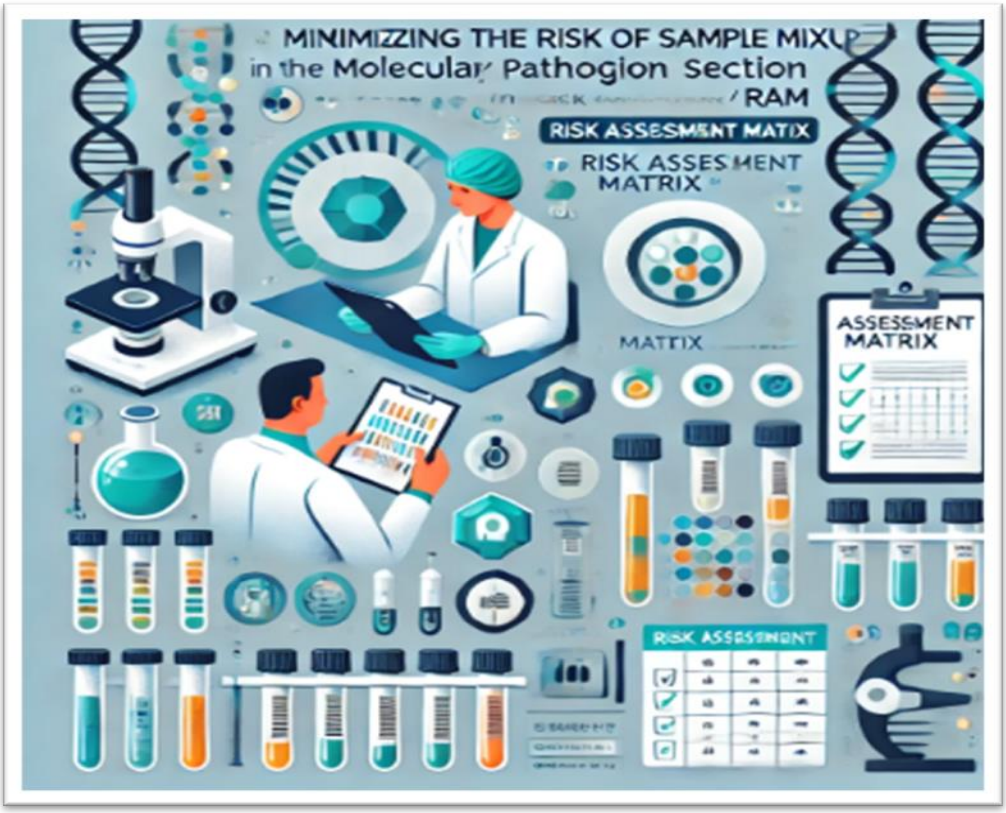
Chapter 3: Minimizing the risk of Sample Mix-ups in the Molecular Pathology Section in Oncology Center using Risk Assessment Matrix (RAM)



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Summary

This project aimed to minimize the risk of sample mix-ups in the Molecular Pathology section of the Sultan Qaboos Comprehensive Cancer Care and Research Centre by employing a Risk Assessment Matrix (RAM) to identify, evaluate, and mitigate potential risks. Through a systematic approach involving multidisciplinary collaboration, key risks such as incorrect labeling, unattended sample transport, and manual data entry errors were identified and addressed with targeted interventions, including electronic tracking systems, secure transport protocols, and standardized electronic data entry procedures. These measures resulted in a significant reduction in Risk Numbers (RNs), enhancing the accuracy and reliability of molecular diagnostics in oncology and establishing a model for improving safety and quality standards in molecular pathology laboratories.

Key Points

- Sample mix-ups pose significant risks in molecular pathology, potentially leading to misdiagnoses and inappropriate treatments.
- A systematic approach using the Risk Assessment Matrix (RAM) was applied to identify, evaluate, and mitigate risks related to sample handling.
- Key interventions included automated labeling, secure transport protocols, and enhanced staff training to reduce sample handling errors.
- The project successfully reduced risk levels and improved the accuracy and reliability of molecular diagnostics, enhancing patient safety and care quality.

Project Charter

Project Charter	Details
Project Title	Minimizing Sample Mix-Up Risks in the Molecular Pathology Section at Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC)
Project Sponsor	Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC), Muscat, Oman
Project Start Date	Q3 2023
Project End Date	Q2 2024
Project Purpose	To minimize the risk of sample mix-ups in the Molecular Pathology section, ensuring the accuracy and reliability of molecular diagnostics and enhancing patient safety through the use of a Risk Assessment Matrix (RAM) to identify, evaluate, and mitigate potential risks.
Problem Statement	The Molecular Pathology section faces significant risks related to sample mix-ups due to the high complexity and precision required in handling biological specimens. Errors such as mislabeling, incorrect data entry, and sample mismanagement can lead to severe consequences, including incorrect diagnoses and inappropriate treatments. A systematic approach using the Risk Assessment Matrix is needed to identify, evaluate, and address these risks effectively.
Project Goals and Objectives	1. Reduce the risk of sample mix-ups by 50% by the end of Q2 2024. 2. Implement electronic tracking systems and secure transport protocols to enhance sample handling accuracy. 3. Establish standardized electronic data entry procedures to minimize manual entry errors. 4. Develop and apply new policies for consistent labeling and secure handling of samples.
Scope	Covers all sample handling processes within the Molecular Pathology section, including collection, transport, analysis, and reporting. Involves developing and implementing interventions such as electronic tracking, secure transport protocols, and standardized data entry procedures. Excludes processes outside the Molecular Pathology section.
Key Stakeholders	Pathologists, Molecular Biologists, Laboratory Technicians, Quality Management Experts, IT Specialists
Resources Required	Budget for new equipment (e.g., electronic tracking systems, automated label printers), staff training, software for data management; personnel from various departments; and data analysis tools.
Risks and Assumptions	**Risks:** Resistance to change among staff, potential technical challenges with new systems, and insufficient resources. **Assumptions:** Availability of necessary resources, stakeholder engagement, and ongoing support from management for risk mitigation efforts.

Success Criteria	Achieving the targeted reduction in sample mix-up risks, as confirmed by the reduction in Risk Numbers (RNs) using the Risk Assessment Matrix, and demonstrating improved safety and quality standards in molecular diagnostics as evidenced by compliance with best practices.

Introduction

In oncology, the Molecular Pathology section is a cornerstone of cancer diagnosis and management, providing precise molecular diagnostics essential for identifying genetic mutations, guiding targeted therapies, and monitoring disease progression. Given the complexity and sensitivity of molecular testing, the risk of sample mix-ups is heightened, potentially leading to serious consequences such as misdiagnoses and inappropriate treatments. Accurate sample handling and processing are, therefore, critical to maintaining the reliability of these diagnostic procedures and ensuring patient safety (Duntsch et al., 2022).

Sample mix-ups in molecular pathology can occur at multiple points, including during collection, transportation, analysis, and reporting. Even minor errors, such as incorrect labeling or manual data entry mistakes, can have catastrophic effects by producing incorrect diagnostic outcomes. In the context of oncology, where timely and accurate diagnoses are crucial for effective treatment, these errors are particularly detrimental. They can lead to delayed or inappropriate therapy, increased patient anxiety, and potentially poorer clinical outcomes (Zhou et al., 2022).

To mitigate these risks, this project focused on minimizing the likelihood of sample mix-ups in the Molecular Pathology section of the oncology center at Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC). The project utilized a Risk Assessment Matrix (RAM) as the primary tool for identifying, evaluating, and addressing potential risks associated with the sample

handling process. The RAM method categorizes risks based on their severity and likelihood, enabling healthcare professionals to prioritize interventions for the most significant threats to patient safety and diagnostic accuracy.

The purpose of this initiative is to enhance the reliability of molecular diagnostics by implementing stringent controls and best practices. By conducting a thorough risk assessment and applying targeted interventions, the project aimed to reduce the incidence of sample mix-ups, thereby improving overall patient care quality. The successful application of the Risk Assessment Matrix serves as a model for improving safety and quality standards in molecular pathology laboratories, setting a benchmark for best practices in the field (Duntsch et al., 2022).

The findings of this project demonstrate that systematic risk management approaches, such as RAM, can effectively identify and mitigate key risks, leading to significant improvements in sample handling accuracy and reliability. This initiative underscores the importance of proactive risk management in specialized healthcare environments and provides valuable insights for other institutions seeking to enhance their molecular pathology services (Zhou et al., 2022).

Problem Statement

The Molecular Pathology section faces significant risks related to sample mix-ups due to the high complexity and precision required in handling biological specimens. Minor errors, such as mislabeling or incorrect data entry, can have severe consequences, including the delivery of incorrect patient results. These mistakes can occur at various stages, from sample collection and transportation to processing and reporting. Given the critical role of molecular diagnostics in oncology, where accurate and timely information is essential for guiding treatment decisions, any lapse in sample handling can adversely affect patient outcomes and safety (Duntsch et al., 2022).

Additionally, the absence of robust protocols and inadequate staff training further exacerbate the risk of errors. This environment presents a significant challenge for maintaining the reliability of molecular diagnostics, highlighting the need for a systematic and comprehensive approach to risk management. Without such an approach, the potential for catastrophic errors remains high, underscoring the urgency of addressing this issue through targeted interventions.

Methods

Setting:

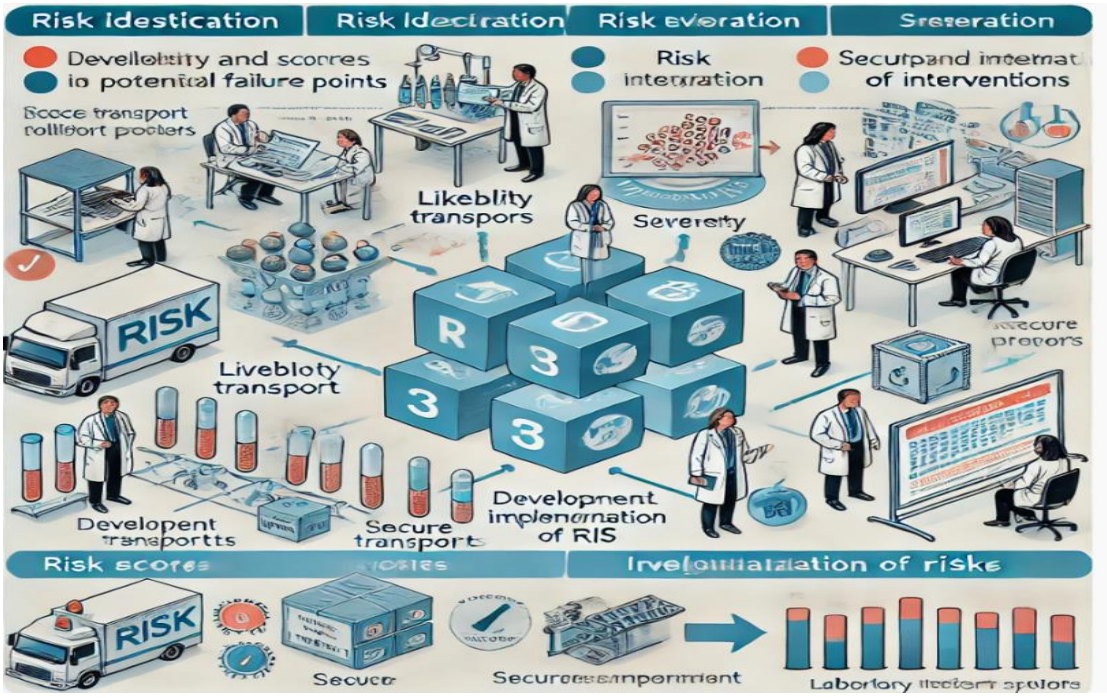
The study was conducted in the Molecular Pathology section of the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC), University Medical City in Muscat, Oman. The study spanned from the third quarter of 2023 to the second quarter of 2024, focusing on improving the integrity and accuracy of sample handling processes to minimize the risk of mix-ups.

Design:

A one-group pretest-posttest design was utilized to evaluate the effectiveness of the interventions in reducing the risk of sample mix-ups. This design enabled a comparative analysis of key performance indicators, such as sample misidentification and labeling error rates, before and after implementing the interventions. The study included all samples processed during the designated timeframe to ensure a comprehensive evaluation of the interventions' impact (Getawa et al., 2023).

Risk Assessment Matrix (RAM):

The Risk Assessment Matrix (RAM) was employed as the primary tool for identifying and prioritizing risks associated with sample handling in the Molecular Pathology section. The RAM framework categorizes potential risks based on their likelihood of occurrence and the severity of their consequences, allowing for a structured approach to risk management.



The methodology involved several key steps:

- **Risk Identification:**

A multidisciplinary team, comprising pathologists, molecular biologists, laboratory technicians, quality management experts, nursing, and IT specialists, conducted a comprehensive review of existing sample handling processes to identify potential failure points. Key data sources included process flowcharts and staff interviews (Figure 1).

- **Risk Evaluation:**

Identified risks were assessed using the RAM, which involved assigning scores for the likelihood and severity of each risk. Likelihood scores ranged from 1 (rare) to 5 (almost certain), while severity scores ranged from 1 (insignificant) to 5 (catastrophic). The product of these scores provided a Risk Number (RN) for each identified risk, guiding the prioritization of mitigation efforts.

- **Development and Implementation of Interventions:**

Based on the RNs, the team developed targeted interventions to address the highest-priority risks. These included new policies for consistent labeling, secure transport protocols, eliminating Excel-based registrations, and introducing automated label printers integrated with the Laboratory Information System (LIS).

- **Re-evaluation of Risks:**

The team re-evaluated the risks post-intervention to assess the effectiveness of the actions taken, using the RAM framework to measure improvements in risk management

Figure 1: ***Flow Chart of Sample Handling Process in Molecular Pathology***

Results

The initial assessment identified several critical risks, such as the use of free labels, samples sent unattended, and manual data entry, all of which had high Risk Numbers (RNs). The application of the Risk Assessment Matrix (RAM) allowed for a structured evaluation of these risks, leading to targeted interventions that significantly reduced the RNs (Table 1). For example:

- **Printing Extra Labels Indicating Sending Samples:** The initial assessment showed a moderate risk with an RN of 6 (likelihood 3, severity 2). The intervention involved discontinuing the use of extra labels and replacing them with electronic tracking systems, reducing the risk to an RN of 2 (likelihood 2, severity 1).
- **Samples Sent Through PTS Unattended:** This risk was initially rated very high, with an RN of 16 (likelihood 4, severity 4). Implementing secure transport protocols, including tamper-evident containers and monitoring systems, reduced the RN to 6 (likelihood 2, severity 3).
- **Combining Samples from Different Locations with Free Labels:** Initially, this risk had an RN of 16 (likelihood 4, severity 4). Introducing separate handling and labeling for samples from different locations, along with an integrated Laboratory Information System (LIS), reduced the RN to 6 (likelihood 2, severity 3).
- **Registration in Excel and Handwriting Section Sample Numbers:** Initially rated with an RN of 16, this risk was addressed by transitioning to an LIS for all registration and labeling processes, effectively reducing the RN to 2 (likelihood 1, severity 2).

- **Manual Entry of Sample Details into LIS System:** The risk of manual data entry errors had an initial RN of 12. The intervention involved standardizing electronic data entry procedures and introducing double-checking and validation processes, reducing the RN to 4.
- **Handwriting Labels on All Tubes:** This practice had an initial RN of 12. Adopting automated label printers integrated with the LIS eliminated handwritten labels, reducing the risk to an RN of 2.
- **Nursing Non-compliance with ID Identification (Two Identifiers):** Initially, this risk had an RN of 16. Implementing strict adherence to ID policies, supported by education and disciplinary measures, reduced the risk to an RN of 6.
- **Loading/Unloading Samples Without Proper Witness:** Initially assessed with an RN of 6, implementing a formalized witness protocol reduced the risk to an RN of 2.
- **Incomplete Patient and Sample Location Data:** The initial RN was 9. Ensuring the LIS included mandatory fields for critical information reduced the risk to an RN of 2.

Overall, the interventions effectively lowered the risk priority numbers across all identified risks, reflecting significant improvements in managing and controlling sample handling processes within the molecular pathology section, and enhancing the accuracy and reliability of laboratory results (Zhou et al., 2022).

Table 1: ***RAM Results for Main Risks***

Main Risk	Likelihood (L)	Severity (S)	Initial RN (L*S)	Intervention	New Likelihood (L)	New Severity (S)	New RN (L*S)
Printing extra labels indicating sending samples	3	2	6	Discontinue the use of extra labels; replace them with electronic tracking systems.	2	1	2
Samples sent through PTS unattended	4	4	16	Implement secure transport protocols with tamper-evident containers and monitoring systems.	2	3	6
Combining samples from different sources with free labels	4	4	16	Ensure separate handling and labeling for samples; use an integrated LIS.	2	3	6
Registration in Excel and handwriting section sample numbers	4	4	16	Transition to LIS for all registration and labeling processes.	1	2	2
Manual entry of sample details into LIS system	3	4	12	Standardize electronic data entry; implement double-checking and validation processes.	2	2	4
Handwriting labels on all tubes	4	3	12	Use automated label printers integrated with LIS.	1	2	2
Nursing non-compliance with ID identification	4	4	16	Enforce strict adherence to ID policies with education and disciplinary actions.	2	3	6
Loading/unloading samples without proper witness	2	3	6	Establish a formalized witness protocol.	1	2	2
Incomplete patient and sample location data	3	3	9	Ensure LIS includes comprehensive patient and sample location information.	1	2	2
Inaccurate documentation in HIS/LIS	3	4	12	Enforce accurate documentation protocols; restrict unauthorized edits.	1	2	2

Discussion

The application of the Risk Assessment Matrix (RAM) in the Molecular Pathology section at SQCCCRC successfully identified and mitigated key risks associated with sample handling, demonstrating its effectiveness in enhancing the quality and safety of molecular diagnostics in oncology. The significant reduction in Risk Numbers (RNs) across all identified risks underscores the value of this systematic approach to risk management in healthcare settings (Zhou et al., 2022). By categorizing risks according to their likelihood and severity, the RAM method provided a structured framework for prioritizing interventions, enabling targeted and efficient responses to the most significant threats to patient safety.

The interventions implemented in response to the identified risks led to marked improvements in the accuracy and reliability of sample handling processes. For instance, the transition from manual data entry to electronic systems, the elimination of handwritten labels, and the introduction of secure transport protocols collectively reduced the potential for errors and mix-ups, thereby minimizing the risk of incorrect diagnoses and treatment plans (Duntsch et al., 2022). These results align with previous findings in similar healthcare contexts, where systematic risk management approaches have proven effective in reducing error rates and enhancing patient safety (Getawa et al., 2023).

Furthermore, the project highlights the importance of a multidisciplinary approach to risk management. By involving pathologists, molecular biologists, nurses, laboratory technicians, quality management experts, and IT specialists, the initiative benefited from a comprehensive understanding of the sample handling process, which facilitated the identification of vulnerabilities

and the development of robust solutions. This collaborative approach is essential in complex healthcare environments where multiple factors can contribute to errors, and diverse expertise is needed to address them effectively (Duntsch et al., 2022).

The findings also emphasize the need for continuous monitoring and reassessment to ensure sustained improvements in quality and safety standards. While the interventions led to significant reductions in risk levels, ongoing evaluation is necessary to identify any emerging risks and maintain the effectiveness of the implemented measures. Regular audits, staff training, and updates to protocols should be integral parts of the risk management strategy to ensure long-term success (Zhou et al., 2022).

Conclusion

The application of the Risk Assessment Matrix (RAM) in the Molecular Pathology section successfully identified and mitigated key risks, resulting in improved sample handling accuracy and reliability. The significant reduction in Risk Numbers (RNs) across all identified risks highlights the effectiveness of the interventions, enhancing the quality and safety of molecular diagnostics in oncology. This approach serves as a model for improving quality and safety standards in molecular pathology laboratories, underscoring the importance of systematic risk management in healthcare environments.

References

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