Chapter 2: Optimizing Laboratory Processes: A Path to Reduced Rejection and Improve Safety of Samples in Oncology Setting

Authors:

Sara AlSheedi, Omar Ayaad, Rawan Ibrahim, Razzan Al Zadjali, Balaqis Al Faliti, Ossayed Al Awor, Ibrahim Al Haddabi, Huda AlAwaisi, Mohamad Majed, Salim Aldhahli, Haitham Alwaheibi, Abdulhamid A Turkomani, Khalid AlBaimani.

Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC) - University Medical City

Summary

This project aimed to enhance the quality of laboratory processes at the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC) by reducing sample rejection and mislabeling rates. Using the FOCUS-PDCA framework, a systematic approach was implemented to identify critical areas for improvement, assemble a multidisciplinary team, clarify the causes of errors, and develop targeted interventions such as educational sessions, process modifications, and improved communication protocols. The interventions resulted in a substantial reduction in sample rejection rates from 20.85% to 6.05% and mislabeling rates from 1.68% to 0.25%, as confirmed by statistical analysis (ANOVA). These outcomes highlight the effectiveness of the applied strategies in optimizing laboratory practices, improving patient safety, and providing a model for other institutions aiming to enhance laboratory accuracy and reliability in oncology settings.

Key Points

- **The project achieved a significant reduction in sample rejection and mislabeling rates, demonstrating the effectiveness of targeted interventions.**
- **A systematic approach using the FOCUS-PDCA framework enabled continuous quality improvement in laboratory processes at SQCCCRC.**
- **Multidisciplinary collaboration among various healthcare professionals facilitated comprehensive problem-solving and effective intervention development.**
- **Educational sessions and process modifications were critical in enhancing staff competencies and reducing laboratory errors.**

Project Charter

	Details
Project Title	Enhancing Quality of Laboratory Processes 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	Q2 2023
Project End Date	Q1 2024
Project Purpose	To enhance the quality of laboratory processes by reducing sample rejection and mislabeling rates, thereby improving patient safety and care standards in oncology setting.
Problem Statement	High rates of sample rejection (20.85%) and mislabeling (1.68%) are affecting diagnostic accuracy and patient safety at SQCCCRC. Errors are due to improper labeling, workflow inefficiencies, and communication barriers. A systematic approach using the FOCUS-PDCA framework was required to address these issues.
Project Goals and Objectives	1. Reduce sample rejection rate from 20.85% to below 10%. 2. Decrease sample mislabeling rate from 1.68% to below 0.5%. 3. Implement targeted interventions to improve staff training, workflow efficiency, and communication. 4. Establish a sustainable process for continuous quality improvement in laboratory practices.
Scope	Covers all laboratory processes related to sample collection, handling, labeling, transport, and processing at SQCCCRC. Includes interventions such as staff education, process modifications, and communication protocols. Excludes processes outside the laboratory domain.
Key Stakeholders	Oncologists, Nurses, Laboratory Technicians, Quality Management Experts, Informatics Staff
Resources Required	Budget for educational sessions, materials, process modifications; personnel from relevant departments; and data analysis tools (SPSS software).
Risks and Assumptions	**Risks:** Resistance to change, insufficient resources, potential implementation disruptions. **Assumptions:** Availability of necessary resources, stakeholder engagement, and consistent data collection for analysis.
Success Criteria	Achieving the targeted reduction in sample rejection and mislabeling rates, as confirmed by statistical analysis (ANOVA), and improved patient safety and care standards as evaluated through stakeholder feedback and audits.

Introduction

Laboratory sampling is a cornerstone in the field of medical diagnostics, forming the foundation for accurate patient diagnosis, treatment, and monitoring. The integrity and quality of samples are crucial, particularly in oncology, where timely and precise laboratory results significantly impact clinical decisions. Errors in the pre-analytical phase, which includes sample collection, handling, transport, and processing, can lead to significant adverse outcomes. Inaccurate sample handling contributes to misdiagnoses, inappropriate treatments, and delayed therapeutic interventions, ultimately affecting patient safety and care quality (McPherson & Pincus, 2021; Bolton-Maggs et al., 2015).

The pre-analytical phase is considered the most error-prone stage in laboratory medicine, accounting for approximately 60-70% of total laboratory errors (Plebani, 2010). These errors can result from a variety of factors, including improper sample collection, mislabeling, inadequate transport conditions, and incorrect handling procedures. Studies indicate that even minor errors in sample collection or labeling can have catastrophic consequences, particularly in oncology, where treatment decisions often rely on specific molecular and genetic markers (Raab & Grzybicki, 2010; Cadamuro et al., 2017).

At the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC) in Muscat, Oman, the issue of pre-analytical errors has been a persistent challenge. The high incidence of sample rejections and mislabeling incidents has highlighted the need for a systematic approach to enhance laboratory processes. In the last quarter of 2022, blood-related incidents constituted

40% of all reported incidents, underscoring the critical need for improvement in sample handling and management.

Addressing these issues is vital for improving patient safety, ensuring accurate diagnoses, and maintaining high standards of care. Various strategies, including education-based interventions, standardized protocols, and technological enhancements, have been proposed and implemented in different settings to reduce the prevalence of sampling errors (de Mel et al., 2017; Christian et al., 2021). This project, therefore, aimed to optimize laboratory processes at SQCCCRC through a comprehensive approach using the FOCUS-PDCA framework, targeting specific areas of concern to reduce the rate of sample rejection and mislabeling.

By employing a multidisciplinary approach involving oncologists, nurses, laboratory technicians, and quality management experts, this initiative sought to identify root causes, develop targeted interventions, and systematically evaluate their effectiveness. The project demonstrates the potential for significant improvements in laboratory accuracy and reliability through continuous quality improvement measures.

Problem Statement

In the realm of oncology, accurate and timely laboratory results are critical for effective patient management. However, the pre-analytical phase remains fraught with challenges, particularly in high-complexity settings like SQCCCRC, where errors in sample collection and handling can have severe consequences. Issues such as improper labeling, contamination, and delays in transport contribute to a high rate of sample rejections, leading to delays in diagnosis and treatment, increased costs, and potentially adverse patient outcomes.

Despite the crucial role of laboratory diagnostics in cancer care, there is often a lack of standardized protocols and adequate staff training to minimize these errors. This project aimed to address these gaps by implementing a structured, systematic approach to optimize the laboratory.

Methods

This project was conducted at the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC) in Muscat, Oman, from the second quarter of 2023 to the first quarter of 2024. A one-group pretest-posttest quasi-experimental design was employed to assess the impact of targeted interventions on sample rejection and mislabeling rates. The study included all samples processed during the designated timeframe, providing a comprehensive evaluation of the interventions 'effectiveness. The project utilized the FOCUS-PDCA methodology, a widely recognized framework for continuous quality improvement in healthcare settings

1. **Find**

   The initial phase involved identifying critical areas for improvement based on pre-intervention data. Analysis revealed a high rate of sample rejection (20.85 per 1000 samples) and mislabeling (1.68 per 1000 samples). These issues were primarily attributed to improper labeling, inefficient workflows, and communication barriers among staff.

2. **Organize**

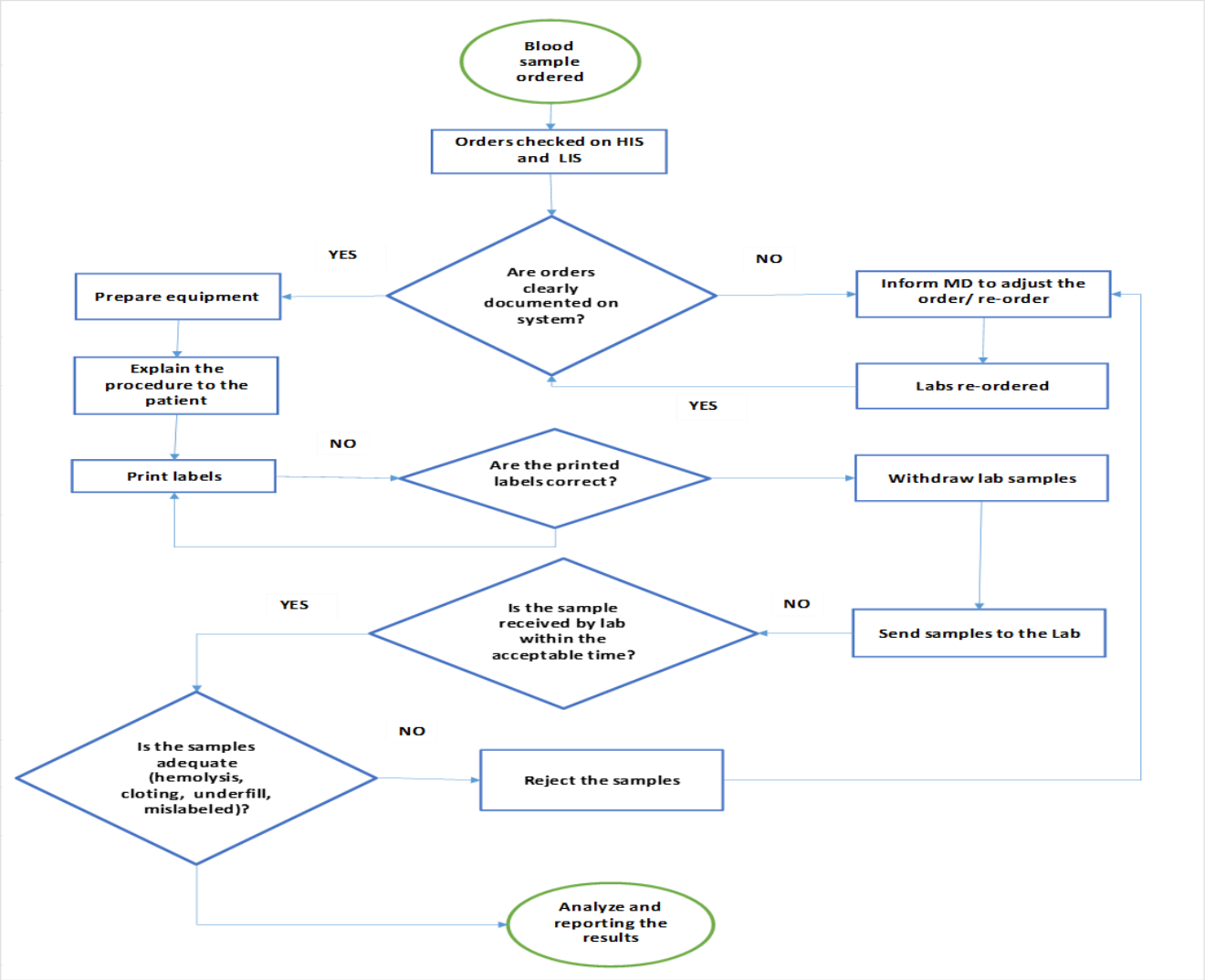
   A multidisciplinary team was assembled, comprising oncologists, nurses, laboratory technicians, quality management experts, and informatics staff. This team was responsible

for conducting a thorough review of current procedures and developing targeted interventions to address identified issues.

3. **Clarify**

Detailed process mapping was performed to analyze existing laboratory workflows, utilizing tools such as flowcharts, checklists, and quality rounds. This phase aimed to identify key barriers contributing to errors, such as improper identification protocols and labeling inaccuracies.

Figure 1: ***Blood Sampling Process***



4. **Understand**

A root cause analysis was conducted using the Fishbone (Ishikawa) diagram to identify the underlying causes of sample errors. This analysis revealed several critical factors, including inadequate staff training, lack of standardized procedures, and poor communication channels.

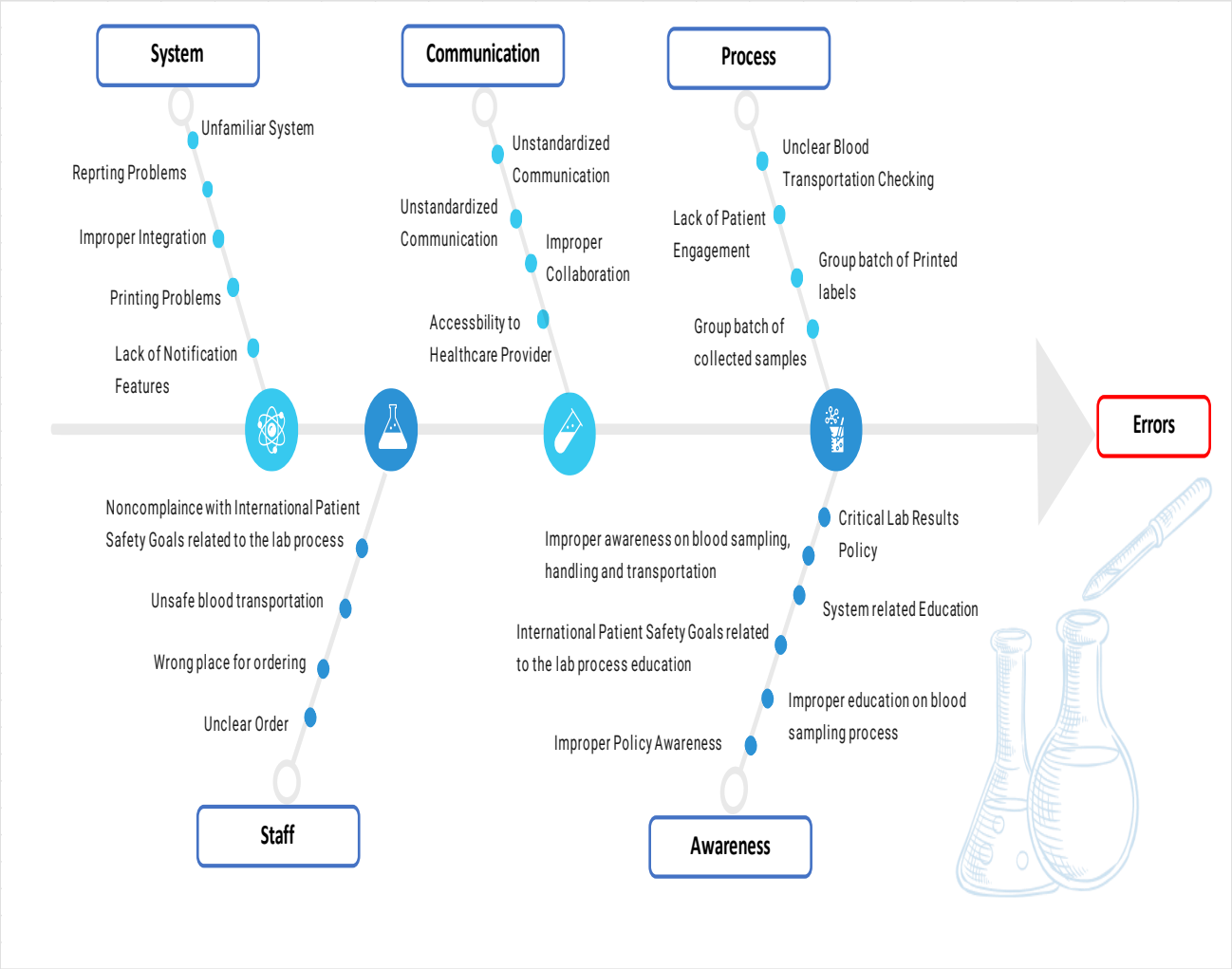


Figure 2: ***Fishbone***

5. Select, Plan, and Do

Based on the findings, specific areas for improvement were selected, and targeted action plans were developed (Table 1). Interventions included educational sessions for staff, process modifications, and the introduction of improved communication protocols. Key measures involved:

- **Ordering Process:** Conducted educational sessions to ensure proper placement of orders in the health information system, even during system downtimes. Features were added to the system to alert nurses about new or pending orders
- **Process Modifications:** Implemented a new protocol for printing labels for one patient at a time to reduce the risk of misidentification. Educational materials were developed to enhance staff competency in blood sampling and data collection
- **Labeling Process:** Developed an instruction manual for nurses detailing the types of tests, suitable vacutainers, and handling procedures. Introduced bedside labeling and double-bagging protocols for patients with suspected communicable diseases
- **Transport and Handling:** Trained medical orderlies on safe transportation criteria for lab samples. Implemented stricter documentation procedures at the laboratory reception to track sample receipts and ensure compliance. Ensured compliance during the transport of the samples through Pneumatic tube systems (PTS).
- **Auditing Process:** Regular audits were conducted by nurse managers and quality champions to monitor adherence to protocols and provide on-the-spot education to staff.

Table 1: Interventions

Process	Implemented action Plan
Ordering process	• 4 educational sessions to ensure. • proper placement for ordering lab samples in the health information system • the ordering process during downtime. • Adding features to alert nurses about new or pending orders in the health information system
Process	• Modifying the process: print the labels for one patient at a time and avoid collecting labels for more than one patient. • Educational sessions for nurses about the new process and best practices for data collection via spot education and educational video. • Developing and validating the blood sampling competency for all staff.
Labeling process	• Preparing an instruction manual for nurses that includes types of tests, suitable vacutainers, and the handling of different samples. • Encouraging the nurses to check the order before printing the label. • Labeling immediately after collection in the patient's bedside • Implement double bagging for patients suspected of having a communicable disease.
Transport and receiving the sample	• Educating the medical orderly about the criteria for safe transportation of lab samples. • Refusing unsafe samples and documenting incidents. • Lab reception staff will document the receiving of samples.
Auditing process	• Nurse manager/leader to perform regular rounds to monitor & educate about the process. • Nursing quality/champion to audit the entire process. • Lab quality will follow the endorsement process documentation for all received samples.

6. **Check and Act**

   The effectiveness of these interventions was evaluated through regular monitoring and data analysis. Adjustments were made as necessary to ensure continuous improvement in laboratory processes.

Data were analyzed using SPSS version 23, with pre and post-intervention data compared using ANOVA to assess the effectiveness of the interventions. Key performance indicators, such as sample rejection and mislabeling rates, were monitored throughout the study period to evaluate the impact of the implemented changes.

Results

The intervention resulted in a substantial decrease in rejected samples from 20.85% to 6.05% and in mislabeling rates from 1.68% to 0.25%. Statistical analysis using ANOVA demonstrated significant differences between the pre-and post-intervention phases for both rejection rates (F-value = 12.3458, p-value = 0.002) and mislabeling rates (F-value = 57.1875, p-value < 0.001) (Table 2). These findings indicate the effectiveness of the targeted interventions in optimizing laboratory processes and reducing errors.

Table 2: *Quality Improvement Results*

Study Period	Quarter 2 2023	Quarter 3 2023	Quarter 4 2023	Quarter 1 2024	F (p-value)
Phase	Pre-intervention	Intervention	Post Intervention	Post Intervention	
Number of Samples	11974	18025	19628	23811	-
Rejected Samples rate	20.85	15	10.76	6.05	12.3458 (0.002)
Mislabeling rate	1.68	0.39	0.25	0.25	57.1875 (<.001)

Discussion

The application of the FOCUS-PDCA framework enabled a structured approach to identify and address critical issues in the laboratory processes at SQCCCRC. The significant reduction in sample rejection and mislabeling rates demonstrates the effectiveness of the interventions and highlights the importance of continuous quality improvement in healthcare settings (Plebani, 2010; Raab & Grzybicki, 2010).

Education-based interventions played a crucial role in reducing sampling errors by improving staff competency and adherence to standardized protocols (de Mel et al., 2017). Moreover, process modifications, such as bedside labeling and secure transport protocols, minimized the risk of mislabeling and contamination, enhancing the overall reliability of laboratory results (Cadamuro et al., 2017; Bolton-Maggs et al., 2015).

The success of this project underscores the importance of a multidisciplinary approach in tackling complex healthcare challenges. Involving various stakeholders, including laboratory technicians, oncologists, and quality management experts, facilitated a comprehensive understanding of the processes and enabled the development of robust solutions (Haroun et al., 2021; Saxena et al., 2004).

Additionally, this initiative provides a model for other institutions seeking to enhance their laboratory processes and improve patient safety. By demonstrating the impact of targeted interventions on reducing errors, the project highlights the potential for significant improvements in clinical outcomes through continuous quality improvement measures (Christian et al., 2021; Misganaw et al., 2019).

Ongoing monitoring and reassessment are essential to sustaining these improvements and ensuring the continued effectiveness of the implemented measures. Regular audits, staff training, and protocol updates should be integral parts of the risk management strategy to maintain high standards of care (Plebani, 2010; Raab & Grzybicki, 2010).

Conclusion

This project successfully optimized laboratory processes at SQCCCRC by significantly reducing sample rejection and mislabeling rates. The systematic approach, guided by the FOCUS-PDCA framework, demonstrates the importance of continuous quality improvement in enhancing laboratory accuracy and patient safety. These findings provide valuable insights for other healthcare institutions aiming to improve their laboratory practices and ensure high standards of care.

References

Bolton-Maggs, P. H., Wood, E. M., & Wiersum-Osselton, J. C. (2015). Wrong blood in tube–potential for serious outcomes: can it be prevented?. British journal of haematology, 168(1), 3-13.

Cadamuro, J., Simundic, A. M., Ajzner, E., & Sandberg, S. (2017). A pragmatic approach to sample acceptance and rejection. Clinical biochemistry, 50(10-11), 579-581.

Christian, S. G., Moore-Igwe, B. W., Jacob, R. B., Odinga, T., & Eze, E. M. (2021). Quality Indicator Measures as It Affects Turnaround Time (TAT) in A Molecular Laboratory in Port Harcourt, Rivers State. European Journal of Clinical Medicine, 2(4), 6-9.

de Mel, S., Lim, S., Soekojo, C. Y., Thow, C., Lang, S. P., Lee, S. Y., & Tan, L. K. (2017). Education-based interventions to minimize sampling errors in transfusion. ISBT Science Series, 12(2), 307-313.

Haroun, A., Al-Ruzzieh, M. A., Hussien, N., Masa'ad, A., Hassoneh, R., Alrub, G. A., & Ayaad, O. (2021). Using failure mode and effects analysis in improving nursing blood sampling at an international specialized cancer center. Asian Pacific Journal of Cancer Prevention: APJCP, 22(4), 1247.

McPherson, R. A., & Pincus, M. R. (2021). Henry's clinical diagnosis and management by laboratory methods E-book. Elsevier Health Sciences.

Misganaw, A. S., Worku, M., Bashea, C., Nigus, M., & Yoseph, Y. (2019). Pre Analytical Errors in the HIV Anti Retro Viral Therapy (ART) Laboratory of Teaching Referral Hospitals in Addis Ababa, Ethiopia. Int J Virol AIDS, 6, 057.

Plebani, M. (2010). The detection and prevention of errors in laboratory medicine. Annals of clinical biochemistry, 47(2), 101-110.

Raab, S. S., & Grzybicki, D. M. (2010). Quality in cancer diagnosis. CA: a cancer journal for clinicians, 60(3), 139-165.

Saxena, S., Ramer, L., & Shulman, I. A. (2004). A comprehensive assessment program to improve blood-administering practices using the FOCUS–PDCA model. Transfusion, 44(9), 1350-1356