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Original Article

Optimizing Laboratory Processes: A Path to Reduced Sample Rejection in Oncology

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Abstract

Background: We aimed to enhance the quality of cancer care by reducing the rate of sample rejection and lowering the incidence of sample mislabeling at the Sultan Qaboos Comprehensive Cancer Care and Research Centre in Muscat, Oman.

Methods: We adopted a one-group pretest-posttest quasi-experimental design from the second quarter of 2022 to the first quarter of 2023, assessing key performance indicators related to sample rejection and mislabeling on quarterly basis before and after implementing targeted interventions. The project utilized the FOCUS PDCA framework for systematic implementation and evaluation. Four FOCUS PDCA sessions were conducted involving a multidisciplinary team of ten participants comprising oncologists, nurses, laboratory technicians, quality management experts, and informatics and cyber security department staff. Ethical clearance was obtained from the Institutional Review Board, ensuring adherence to ethical protocols. Interventions included five educational sessions for nurses and physicians, process modifications, and improved communication protocols.

Results: Analysis revealed a significant decrease in the rate of rejected samples, declining from 20.85% during Pre-Intervention to 6.05% in the Post Intervention phase. Similarly, the mislabeling rate exhibited a substantial reduction, decreasing from 1.68% to 0.25% over the same period. Statistical analysis using ANOVA confirmed significant differences between intervention phases for both the rejected samples rate (F-value = 12.3458, *P*-value = 0.002) and the mislabeling rate (F-value = 57.1875, *P*-value < 0.001).

Conclusion: These results underscored the effectiveness of the interventions in improving blood sample collection and management processes, thereby enhancing the reliability of study outcomes.

Keywords: Rejected samples; Occupation mislabeling; Oman

Introduction

Laboratory sampling is a critical process in medical diagnostics, playing a pivotal role in patient care. This process involves the collection, handling, and processing of biological samples, such as blood, tissue, or bodily fluids. It is a meticulous process encompassing three critical phases, beginning with the pre-analytical phase, which includes sample collection, transport, processing, and storage—all vital steps that can greatly influence the sample's integrity. Following this, the analytical phase takes place, where the actual testing is conducted using various instruments and reagents, and the expertise of technologists is pivotal to ensure accurate results, employing controls and calibrators for quality assurance. The final step, the post-analytical phase, involves the interpretation of the test results (1, 2).

In a clinical setting, these samples are essential for accurate diagnosis, treatment planning, and monitoring of patient health. In oncology, the stakes are particularly high. The field of oncology deals with the diagnosis and treatment of cancer, a complex and often rapidly evolving disease. Accurate and timely laboratory results are crucial in this setting for several reasons. First, they help in the initial diagnosis of cancer, distinguishing between different types of malignancies. Second, lab results are integral in staging the disease and assessing its progression. Finally, they are vital in monitoring the effectiveness of treatments and in making necessary adjustments. In such a sensitive field, any delay or error in laboratory results can have significant implications for patient outcomes (3-5).

Sample rejections occur when a submitted sample fails to meet the required standards for processing and analysis. The reasons for rejection are varied, including improper sample collection, contamination, insufficient sample volume, labeling errors, and degradation due to inappropriate transport or storage conditions (5-7).

Reducing the laboratory sample rejection rate in oncology settings is therefore not only a matter of improving laboratory processes but also a crucial aspect of enhancing patient care, staff efficiency, and organizational effectiveness (5). In our center, several compelling triggers have prompted a re-evaluation of our blood sampling process. Among these, the high frequency of blood-related incidents from the last quarter 2022 stands out, comprising 40% of all incidents.

The high rejection rate of laboratory samples can have far-reaching consequences on patients, healthcare staff, and the organization. For patients, especially those in oncology settings, sample rejection can lead to delays in diagnosis and treatment, increased anxiety, and potentially poorer outcomes. For healthcare professionals, repeated sample rejections can lead to increased workload and stress. It also undermines confidence in laboratory results. At an organizational level, high sample rejection rates can lead to increased costs due to repeat sampling and testing.

This project is thus directed at:

- Reducing the rate of sample rejection.
- Lowering the incidence of sample mislabeling.

Methods

Setting

The project was conducted at the Sultan Qaboos Comprehensive Cancer Care and Research Centre in Muscat, Oman. The timeframe for the study spanned from the third quarter of 2022 through to the first quarter of 2023.

Design

A one-group pretest-posttest quasi-experimental design was utilized to evaluate the impact of targeted interventions on key performance indicators within the laboratory process, particularly concerning sample rejection rates in an oncology context. The goal was to monitor and compare the performance indicators before and after the implementation of the interventions to discern their efficacy. The study included all samples

processed during the project duration for the calculation of these indicators.

The sample cohort was assessed during two timeframes: before the introduction of interventions (pretest) and after their implementation (posttest). This method permitted the observation of changes directly associated with the project's initiatives without the need for a control group. The primary objective was to ascertain if the interventions led to a tangible improvement in the laboratory sample rejection and mislabeling rates.

FOCUS PDCA Approach

FOCUS-PDCA (Find, Organize, Clarify, Understand, Select, Plan, Do, Check, Act) represents a pioneering approach to continuous quality improvement, introduced by American hospital organizations and rooted in the PDCA cycle. It ingeniously merges the FOCUS approach with the principles of continuous cycle improvement (PDCA), resulting in an enhanced management paradigm. This model exhibits distinct characteristics such as a hierarchical structure comprising a primary and secondary ring, incremental advancement, and rigorous statistical analysis. FOCUS-PDCA finds extensive applications in various domains including patient care, pharmaceutical management, and medical record administration (6). Four FOCUS PDCA sessions were conducted involving a multidisciplinary team of 10 participants comprising oncologists, nurses, laboratory technicians, quality management experts, and informatics and cyber security department staff.

Project execution was orchestrated using the FOCUS PDCA framework (Table 1). This structured approach, encapsulating the phases "Find, Organize, Clarify, Understand, and Select" as part of the FOCUS strategy, and "Plan, Do, Check, Act" for the PDCA cycle, offered a clear and systematic pathway for the project's progression and anticipated success.

Finding and selecting critical area for improvement (Find Phase)

Before the intervention, the rejected sample rates were consistently high, at 20.85 per 1000 received samples. Moreover, there was a mislabeling rate of 1.68 per 1,000 samples, a figure that, while seemingly small, can have serious implications for patient safety and diagnostic accuracy.

Organizing the team (Organize Phase)

The project was executed by assembling a collaborative team comprising experts from various departments, which encompassed oncologists, nurses, laboratory technicians, quality management experts, and informatics and cyber security department staff.

Clarifying the situation (Clarify Phase)

A flow chart was created for the current process for referral (Fig. 1). The process for managing blood sample orders within a healthcare environment is delineated in a structured flowchart, which commences with the placement of a blood sample order. Subsequent to this, orders are meticulously verified using the Hospital Information System (HIS) and Laboratory Information System (LIS). If an order is not documented with sufficient clarity, the responsible medical doctor is notified to make the necessary adjustments.

Table 1: FOCUS PDCA Approach Explained

Main Study Purpose: • **Reducing the rate of sample rejection.** • **Lowering the incidence of sample mislabeling.**		
Phase	**Purpose**	**Study Phase and Measures**
Find	Pinpointing critical areas for enhancement within the laboratory processes.	**Pre data collection:** Before the intervention, the rejected sample rates were consistently high, at 20.85 per 1000 received samples. Moreover, there was a mislabeling rate of 1.68 per 1,000 samples
Organize	Forming a team tasked with improving laboratory quality.	The project was executed by assembling a collaborative team comprising experts from various departments, which encompassed oncologists, nurses, laboratory technicians, quality management experts, and administrative staff.
Clarify:	Dissecting current laboratory procedures to identify potential barriers and risks.	A flow chart was created for the current process. a comprehensive checklist, quality rounds, staff interview were used.
Understand	Unearthing the root causes behind inadequate sample processing outcomes.	A systematic approach was employed, leveraging the Fishbone (Ishikawa) diagram tool as a central method to identify the underlying causes contributing to the identified issues
Select	Electing specific aspects of the laboratory process for improvement to upgrade overall efficacy.	The below areas are selected: • Ordering process. • Process • Labeling process • Transport and receiving the sample • Auditing process
Plan	Developing targeted, SMART action plans for process enhancements.	**Interventions:** Interventions included five educational sessions for nurses, process modifications, and improved communication protocols.
Do	Implementing these action plans within the laboratory setting.	
Check	Measuring the efficacy of interventions against key performance indicators.	**Post intervention:** The rates continued to decline in the post-intervention period, reaching their lowest point in March 2023 at 6.55 per 1000 received samples for rejected sample and 0.25 per 1000 received samples for mislabeling.
Act:	Upholding the gains achieved and adjusting strategies based on feedback and data analysis.	

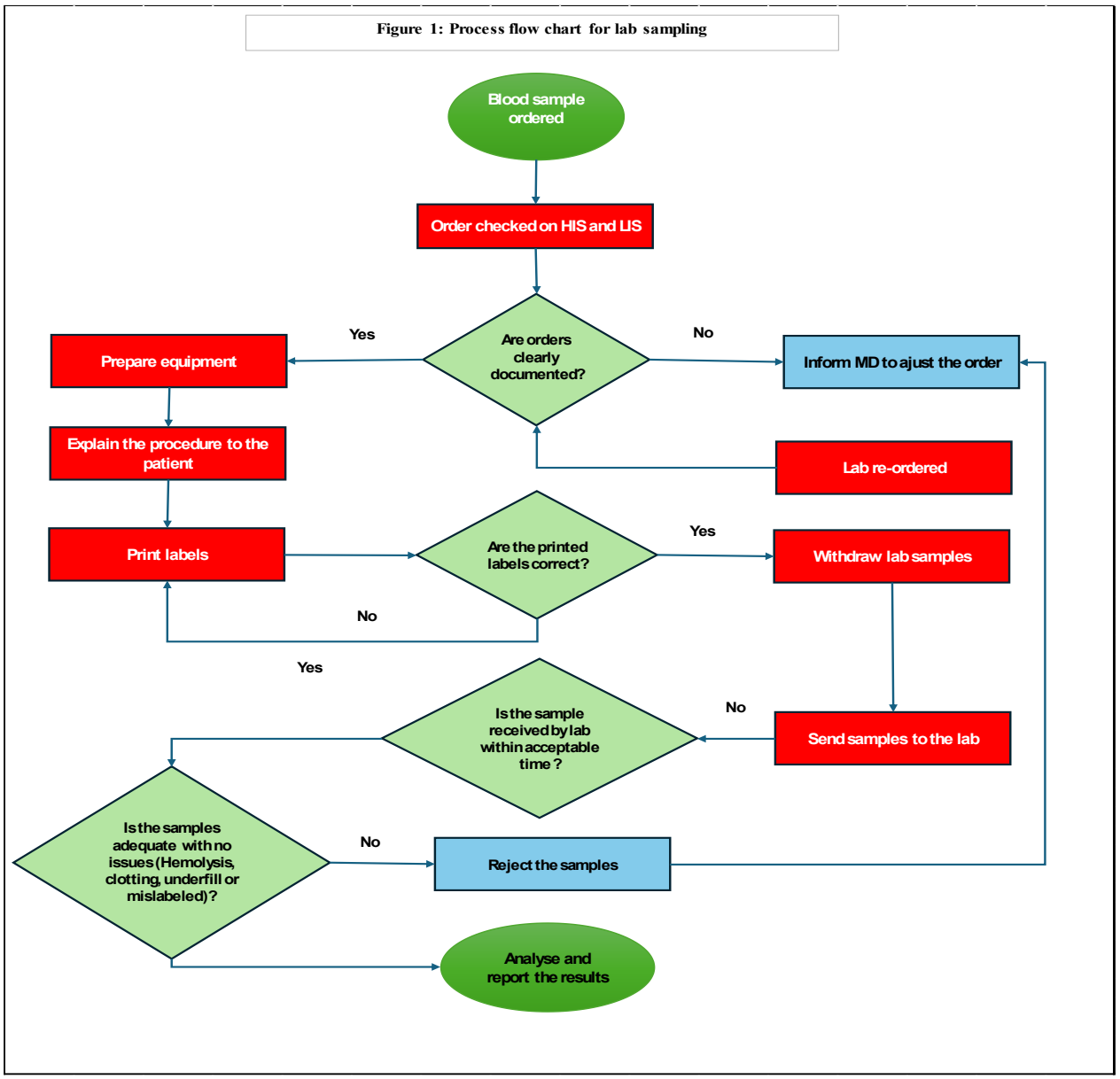

Fig. 1: Blood Sampling Process

Once the order is clarified and documented, laboratory tests are reordered. Equipment for the blood draw is prepared, and the procedure's significance is explained to the patient to ensure compliance. Labels for the sample are printed, and any discrepancies are corrected by reprinting. Collected samples are dispatched to the laboratory, where they are assessed for issues like hemolysis, clotting, underfill, or mislabeling. Unacceptable samples are rejected and corrected, while acceptable samples proceed to analysis. The final stage involves analyzing the samples and reporting the results, essential for diagnosis and treatment planning. During the process audit, team members utilized a comprehensive checklist, quality rounds, staff interview to meticulously review various stages, including:

- The procedure for requesting blood samples,
- The preparation and collection of the blood samples,

For the staff interviews, a purposive sampling technique was employed to select participants with expertise in the relevant processes, including 2 oncologists, 3 nurses, 2 laboratory technicians, and 2 administrative staff involved in sample collection and handling. Semi-structured interviews were conducted, allowing for open-ended question "what are the barriers that you face during the blood sampling process" to explore participants' perspectives, experiences, and insights regarding the identified themes.

Thematic analysis was utilized to extract key themes from the interview data. This involved multiple stages, including data familiarization, coding, theme development, and refinement. Initially, transcripts were reviewed multiple times to gain familiarity with the data. Subsequently, initial codes were generated to label segments. These codes were then organized into broader themes, refined through iterative discussions among the research team. Critical barriers in blood sampling process (Table 2).

Table 2: Critical barriers in blood sampling process

Theme	Critical barriers
Labeling and Identification	• Printing labels for all patients at once: This can increase the risk of misidentification. • Labeling after collection: Increases the chance of labeling errors. • Wrong or extra-label printing: Leads to confusion and potential mislabeling. • Improper Identification (2 identifiers): Not adhering to standard identification protocols. • Unstandardized patient label ID: Lack of consistency in patient identification. • Incorrect position for labels on the sample: Misplacement of labels can lead to processing errors.
Process and Workflow Efficiency:	• Preparing for sampling for many patients at the same time: This can lead to mix-ups and inefficiencies. • Unnecessary motion/rework: Redundant actions that waste time and resources. • Delay in transportation to and within the lab: Slows down the testing process. • Nurses don't mention the blood sampling site in the documentation: Lack of complete documentation affects the integrity of the sample's history. • Blood sample collection date, time, and signature discrepancies: Issues with documentation can lead to accountability problems.
Transportation and Handling:	• Unsafe transportation (in the bags only): Raises concerns about sample integrity and safety. • PTS down leading to delay in the sending of samples: Downtime in pneumatic tube systems or other transportation means can cause delays.
System Usability and Functionality:	• System difficulties (e.g., printing labels through LIS, integration of LIS with HIS): Technical issues can impede the smooth functioning of the process.
Communication	• Time-consuming to run behind doctors for new requests for rejected samples: Inefficient communication leads to delays and increased workloads. • Lab communication practices (e.g., reporting critical values to nurses instead of doctors): Communication protocols may not direct information to the correct individuals. • For blood culture, difficulty in identifying if it needs to be sent peripherally or centrally: Ambiguity in orders can affect the quality of the sample and subsequent results.

Understanding the root causes (Understand Phase)

In order to comprehensively understand the root causes underlying the challenges and obstacles encountered within the referral process, the "Understand Phase" was initiated. During this phase, a systematic approach was employed, leveraging the Fishbone (Ishikawa) diagram tool as a central method to identify the underlying causes contributing to the identified issues (Fig. 2).

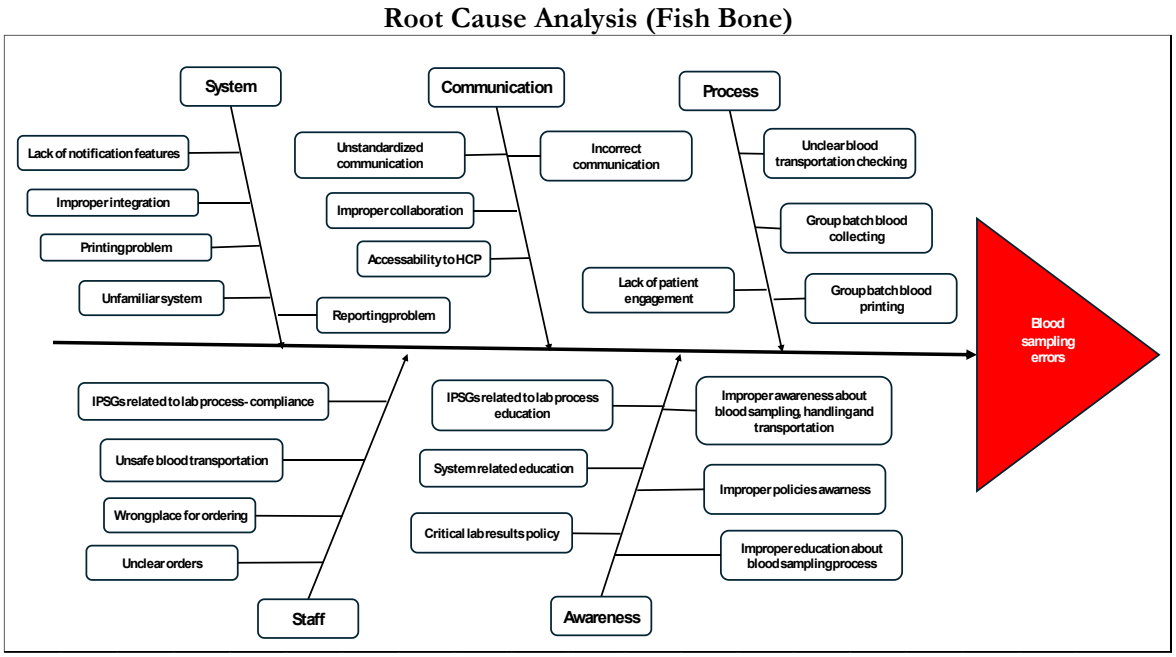

Fig. 2: Root Cause Analysis (FishBone)

Selecting area improvement strategy and developing the plans and implementing them (Select, Plan, Do phases)

Evidenced based improvement strategies were selected based on the previous steps and previous studies (10-20) (Subsequently the operational plans were developed (Table 3).

Data Analysis

SPSS ver. 23 (IBM Corp., Armonk, NY, USA) was used. Average mean was used to measure the pre and post intervention data. ANOVA and p value were conducted to measure the differences in the results and show the effectiveness of intervention.

Ethical Considerations

This project received full clearance from the Institutional Review Board at the Sultan Qaboos Comprehensive Cancer Care and Research Centre. With ethical approval secured and a unique identification number allocated, the research team is set to conduct the project in strict alignment with ethical protocols and regulations.

Scientific Approval: The proposal of the study was reviewed and approved by the research office in Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC), Muscat, Oman

Ethical Declaration: The Institutional Review Board (IRB) approval to conduct the study was taken from the research office in Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC), Muscat, Oman.

Table 3: Improvement areas and Operational plans for the quality Improvement

Process	Implemented action Plan
Ordering process	• 4 educational sessions to ensure. ✓ proper placement for ordering lab samples in the 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, avoid collecting labels for more than one patient. • Educational sessions for nurses about the new process and best practice for data collection via spot education and educational video. • Developing and validating the blood sampling competency for all staff.
Labeling process	• Preparing instruction manual for nurses that includes types of tests and suitable vacutainer 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 • Implementing Double bagging for patients with or suspecting to have a communicable disease.
Transport and receiving the sample	• Educating the medical orderly about criteria for safe transportation of lab samples. • Refusing unsafe samples and document 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 to follow the documentation of endorsement process for all received samples.

Results

The study was conducted over four quarters, spanning from quarter 2 of 2022 to quarter 1 of 2023, encompassing various phases of intervention. Each phase of the study, including Pre-Intervention, Intervention, and Post Intervention, aimed to address specific aspects of sample collection and management. Throughout the study period, data on the number of samples collected, the rate of rejected samples, and the mislabeling rate were meticulously recorded and analyzed.

In terms of sample collection, the study observed a progressive increase in the number of samples gathered over the quarters, with quarter 1 of 2023 recording the highest count of 23,811 samples.

Analysis of the rejected samples rate revealed a notable decline from 20.85% during the Pre Intervention phase to 6.05% in the Post Intervention phase. Similarly, the mislabeling rate exhibited a significant reduction, decreasing from 1.68% at the study's outset to 0.25% by the Post Intervention phase. These declines indicated the effectiveness of the intervention strategies implemented during the course of the study.

Furthermore, statistical analysis using ANOVA demonstrated significant differences between the intervention phases for both the rejected samples rate (F-value=12.3458, *P*-value=0.002) and the mislabeling rate (F-value = 57.1875, *P*-value < 0.001). These findings underscored the impact of the interventions on improving sample collection and management processes, thereby enhancing the overall quality and reliability of the study outcomes (Table 4).

Table 4: The total number of samples, the study period, and the results before and after the intervention

Study Period	Quarter 2 2022	Quarter 3 2022	Quarter 4 2022	Quarter 1 2023	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 study at the Sultan Qaboos Comprehensive Cancer Care and Research Centre, aiming to standardize blood sample collection and labeling, reduce sample rejection rates, and lower the incidence of mislabeling, presents a critical examination of laboratory processes in oncology care. The study's reliance on the FOCUS PDCA framework emphasizes a systematic approach to quality improvement, integrating well-defined steps to identify areas of need, develop and enact plans, and review outcomes (7).

The project's results from the initial Find phase highlight a significant opportunity for improvement, with a considerable rate of sample rejection and mislabeling in the second quarter of 2022. The formation of a multidisciplinary team during the Organize phase underlines the collaborative effort required to tackle such intricate challenges in healthcare processes.

The Clarify and Understand phases are pivotal in pinpointing the specific issues and underlying causes of sample handling inefficiencies. The creation of flowcharts and use of analytical tools such as the Fishbone diagram provide a visual representation of the process, facilitating the identification of critical barriers and enabling targeted interventions (8, 9).

The problems identified—labeling errors, inefficiencies in sample preparation and transportation, communication gaps, and system usability issues—mirror challenges reported in similar studies. For instance, a study on specimen labeling errors in the clinical laboratory reported that a significant proportion of identification errors can be attributed to labeling and requisition problems, which may lead to serious medical errors. This is consistent with the findings of the current study where labeling and identification emerged as critical barriers (9, 15, 16).

In the field of oncology, where precise diagnosis and treatment are crucial, ensuring the integrity of blood samples is of paramount importance. Previous studies have also emphasized the significance of preanalytical phases, which include sample collection and handling, and have identified these as key areas prone to errors, which can impact patient safety and care quality (1, 2,9, 10, 12, 20).

The implementation of evidence-based strategies and operational plans, as outlined in the Select, Plan, and Do phases, are reminiscent of interventions applied in similar contexts. For instance, a quality improvement project also focused on improving the preanalytical phase by providing training, standardizing procedures, and introducing quality checks, which resulted in a decrease in preanalytical errors (7, 13, 17, 21).

Limitations Section for the Project

The study presents several limitations that must be acknowledged:

The project was conducted exclusively at the Sultan Qaboos Comprehensive Cancer Care and Research Centre. This single-center design limits the generalizability of the findings. Different healthcare settings may have varying workflows,

staff competencies, and patient populations, which could influence the effectiveness of the implemented interventions. The study employed a one-group pretest-posttest quasi-experimental design without a control group. This design inherently limits the ability to attribute observed changes solely to the interventions, as external factors could also influence outcomes.

Relying on the internal team for data collection and analysis could introduce bias. The perceptions and expectations of the team members about the desired outcomes might influence their observations and interpretations.

The study focused on specific performance indicators such as sample rejection rates and mislabeling incidents. Other relevant aspects, like turnaround time, staff satisfaction, and patient outcomes, were not measured, which may provide a more comprehensive evaluation of the interventions' impact.

The effectiveness of interventions, especially those involving process changes and educational sessions, may be influenced by the varying levels of compliance and understanding among staff members. This variability can lead to inconsistencies in the application of new protocols.

Future Research Implication

Future research in the field of cancer care quality improvement, particularly focusing on reducing sample rejection and mislabeling rates, can greatly benefit from addressing the limitations identified in the study conducted at the Sultan Qaboos Comprehensive Cancer Care and Research Centre in Muscat, Oman. Expanding the research scope to include multi-center and longitudinal studies can enhance the generalizability and sustainability of the findings.

To delve deeper into the effectiveness of specific interventions, future studies could examine the compliance and understanding of staff members regarding new protocols and educational sessions. Understanding the variability in staff adherence could lead to identifying barriers and strategies for improving compliance.

Finally, including an economic analysis within future research could shed light on the cost-effectiveness of the interventions, aiding healthcare administrators and policymakers in resource allocation decisions. Investigating the role of cultural and organizational factors in the effectiveness of interventions could also reveal valuable strategies for more tailored and effective implementation.

Conclusion

Overall, the methodical approach of this project—encompassing the identification of issues, team organization, understanding root causes, and implementing targeted interventions—aligns with best practices in quality improvement and patient safety. The study's outcomes may not only enhance the sample management process but also contribute valuable insights to the broader field of laboratory medicine and healthcare quality, reaffirming the importance of continual process evaluation and improvement in the clinical laboratory setting.

Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

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Conflict of Interest

The authors have no conflicts of interest to disclose.

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