Chapter 5: Improving Proficiency Tests in a Laboratory Oncology Setting

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Summary

This project aimed to assess and enhance proficiency test (PT) outcomes across various laboratory categories within an oncology setting. A total of 296 tests were analyzed in six laboratory sections: blood bank, hematology, biochemistry, histopathology, molecular pathology, and microbiology. Initially, 11 tests showed improper results. Targeted interventions were implemented to address these deficiencies, including adherence to CAP Kit instructions, addition of quality control (QC) parameters, implementation of a comprehensive Quality Control system, and staff education and training. Following these interventions, the number of tests with improper results dropped from 11 to 1, and the overall PT pass percentage increased from 96.28% to 99.66%. This significant improvement demonstrates the effectiveness of rigorous quality control measures and comprehensive staff training in maintaining high standards in laboratory diagnostics.

Key Points

- Implementing targeted interventions significantly improved proficiency test outcomes in the oncology laboratory.
- The overall PT pass rate increased from 96.28% to 99.66%, reflecting enhanced diagnostic accuracy.
- Significant improvements were achieved across various laboratory sections due to focused interventions.
- Quality control measures, including QC parameters and regular calibration, resulted in a 100% pass rate in multiple test categories.

Project Charter

Project Charter	Details
Project Title	Improving Proficiency Tests in a Laboratory Oncology Setting 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 assess and enhance proficiency test (PT) outcomes across various laboratory categories, ensuring diagnostic accuracy and reliability through targeted interventions, such as adherence to CAP Kit instructions, quality control measures, and comprehensive staff training.
Problem Statement	The oncology laboratories at SQCCCRC have observed challenges in proficiency test (PT) outcomes, with improper test results due to protocol non-compliance, inadequate quality control measures, and insufficient staff training. These issues compromise diagnostic accuracy, patient safety, and the overall quality of care. There is an urgent need to implement targeted interventions to address these deficiencies and enhance laboratory performance.
Project Goals and Objectives	1. Improve the overall PT pass percentage from 96.28% to above 99% by the end of Q2 2024. 2. Adhere to standardized protocols and implement rigorous quality control measures to reduce the number of tests with improper results from 11 to 0. 3. Enhance staff competency through comprehensive training and education programs.
Scope	Includes all laboratory sections within the oncology center: blood bank, hematology, biochemistry, histopathology, molecular pathology, and microbiology. Focuses on implementing interventions to improve PT outcomes, including quality control measures, adherence to guidelines, and staff training. Excludes non-oncology laboratory sections.
Key Stakeholders	Laboratory Technicians, Pathologists, Quality Control Managers, IT Specialists, Laboratory Management Staff
Resources Required	Budget for additional QC materials (control samples, reagents), staff training sessions, equipment calibration, software for data management, personnel from relevant departments, and data analysis tools.
Risks and Assumptions	**Risks:** Resistance to protocol changes, potential technical issues with new QC systems, and limited resources. **Assumptions:** Full support from management, availability of necessary resources, and engagement of all laboratory staff.
Success Criteria	Achieving the targeted increase in PT pass percentages and reduction in improper test results, demonstrating compliance with CAP standards, and enhanced diagnostic accuracy through audits, feedback, and data analysis.

Introduction

Proficiency testing (PT) is a critical component of laboratory quality assurance programs, particularly in oncology settings where diagnostic accuracy directly impacts patient care and treatment outcomes. PT regularly assesses laboratory performance by testing unknown samples sent by external agencies, ensuring the results meet required standards (Dufraing et al., 2021). Inaccurate PT results can lead to diagnostic errors, adversely affecting patient outcomes by delaying or misguiding treatment decisions. Despite implementing stringent protocols, some laboratories face challenges, such as improper test results, due to human error, equipment malfunction, or inadequate quality control measures (Zneimer & Hongo, 2021).

Due to the critical nature of cancer diagnostics, oncology laboratories are constantly pressured to deliver highly accurate results. For example, molecular pathology tests must provide precise information on genetic mutations to guide targeted therapies. Errors in these tests can result in inappropriate treatment choices, affecting patient survival rates and quality of life (Furtado et al., 2023). Therefore, maintaining proficiency in testing is essential to achieving excellence in oncology care.

The need for continuous improvement in PT outcomes is driven by the evolving complexity of diagnostic techniques and the introduction of new technologies. Laboratories must not only meet basic regulatory requirements but also adopt proactive measures to reduce the occurrence of errors and enhance diagnostic reliability (Graden et al., 2021). This project aimed to evaluate current PT outcomes across multiple laboratory sections within an oncology setting and to implement targeted interventions designed to improve these outcomes.

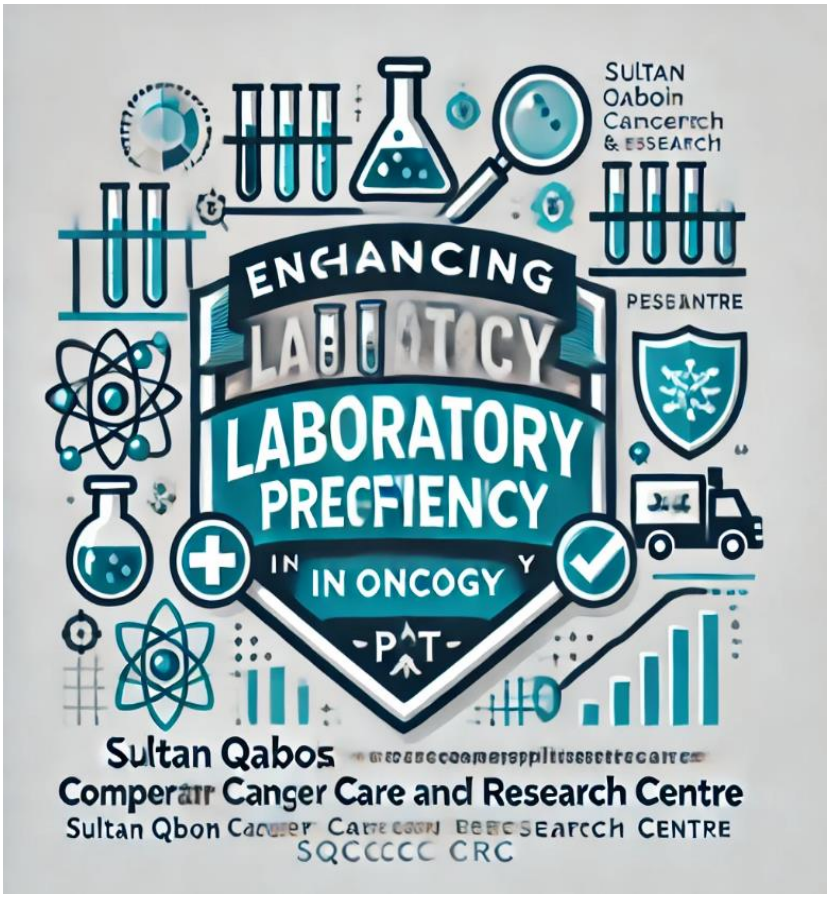
The interventions focused on specific deficiencies identified during initial testing, including adherence to CAP (College of American Pathologists) guidelines, enhancement of quality control measures, and comprehensive staff training. By addressing these critical areas, the study sought to ensure that all laboratory tests meet the highest standards of accuracy and reliability, thereby contributing to better patient care.

Given the high stakes associated with oncology diagnostics, improving PT outcomes is crucial for ensuring patient safety and maintaining high standards of care. This study's results highlight the importance of systematic quality control measures and targeted interventions in achieving optimal laboratory performance.

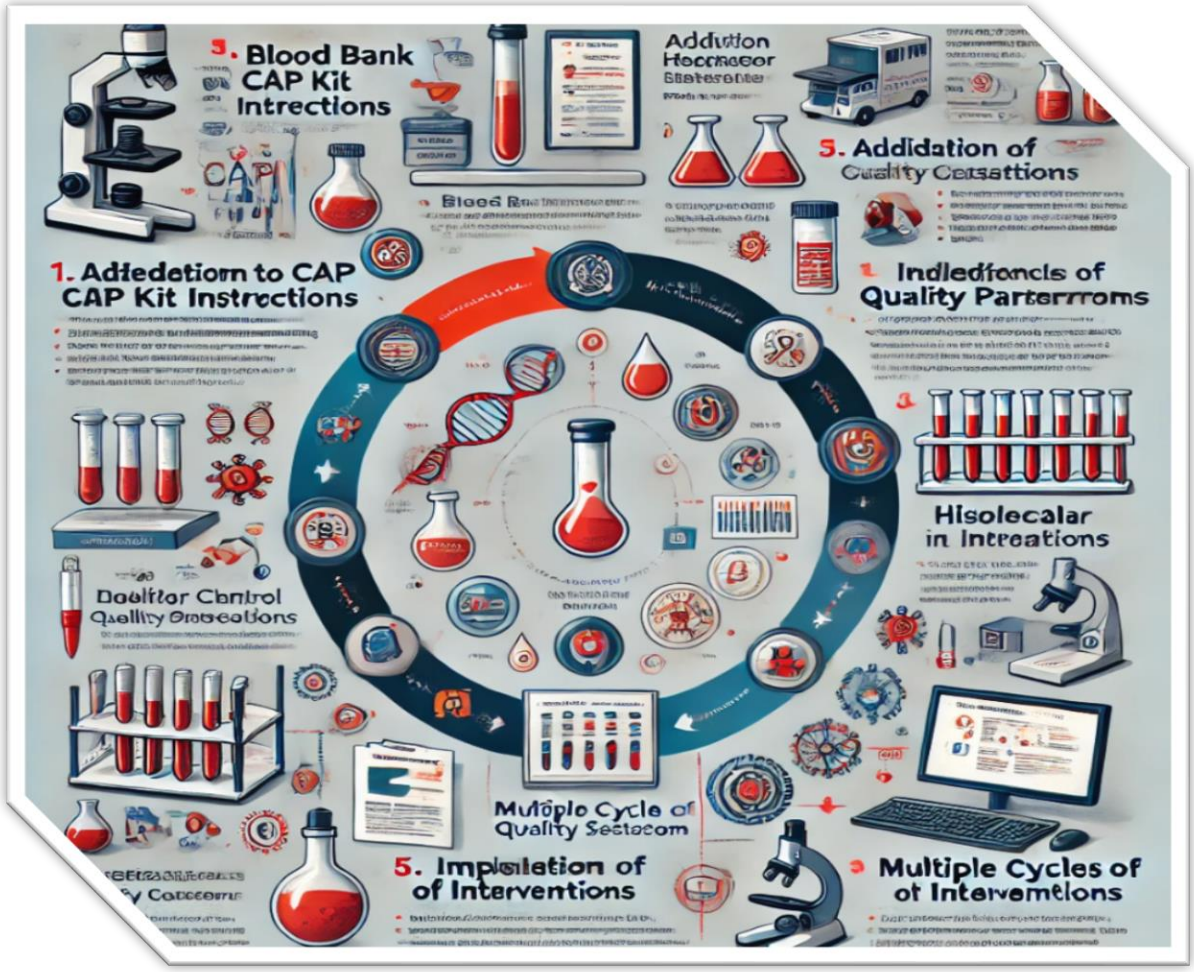
Problem Statement

The accuracy of laboratory results is vital for effective patient management in an oncology setting. However, challenges in proficiency testing (PT) outcomes, such as improper test results, have been observed across various laboratory sections at the Sultan Qaboos Comprehensive Cancer Care and Research Centre (SQCCCRC). These improper results can stem from several factors, including non-compliance with established protocols, lack of quality control measures, and insufficient staff training, leading to potential diagnostic inaccuracies and compromising patient safety.

Given laboratory diagnostics' critical role in oncology, there is an urgent need to address these challenges to maintain the highest standards of care. This study aimed to assess the current state of PT outcomes across six key laboratory categories and implement targeted interventions to enhance diagnostic accuracy and reliability.



Methods



The project was conducted at the SQCCCRC and involved analyzing a total of 296 tests across six laboratory categories: blood bank, hematology, biochemistry, histopathology, molecular pathology, and microbiology. Initially, 11 tests were identified with improper results. To address these deficiencies, several targeted interventions were implemented:

1. Adherence to CAP Kit Instructions:

The CAP (College of American Pathologists) kits provide standardized protocols for conducting specific tests. Laboratory staff were instructed to rigorously follow these guidelines to ensure consistency and accuracy in practices. For example, in the Hematology section, proper reagent handling, accurate timing, and correct interpretation of PTT (Partial Thromboplastin Time) results were emphasized to minimize human error

2. Addition of Quality Control (QC) Parameters:

Quality control parameters were integrated into the testing process to ensure the accuracy and reliability of results. In the Molecular Pathology & Genetics section, control DNA samples were used to validate sequencing processes, and instruments were regularly calibrated to maintain optimal performance

3. Implementation of a Comprehensive Quality Control System

A systematic approach to monitoring and controlling the testing process was established. This involved routine checks, equipment maintenance, and continuous monitoring of test outcomes. In the Routine Chemistry section, daily calibration of analyzers and verification of reagent integrity were conducted to ensure consistent accuracy.

4. Staff Education and Training:

Comprehensive education and training sessions were conducted to enhance staff proficiency in laboratory techniques and protocols. This included workshops, hands-on training, and ongoing

education on quality standards. The Mycological Identification section, for example, focused on training staff in fungal species identification and sample preparation

5. Multiple Cycles of Interventions:

The interventions were applied over multiple cycles, with adjustments made based on the outcomes of each cycle. Continuous monitoring and feedback loops were used to ensure sustained improvement in PT outcomes across all laboratory sections.

Results

The implementation of targeted interventions led to substantial improvements in proficiency test (PT) outcomes across all laboratory sections. The results reflect the effectiveness of systematic measures in enhancing the accuracy and reliability of diagnostic tests in an oncology setting. The key findings are summarized as follows:

1. **Overall Improvement:**
    - The total number of tests with improper results decreased dramatically from 11 to 1, indicating a marked improvement in the overall proficiency testing outcomes.
    - The overall PT pass percentage increased from 96.28% to 99.66%, reflecting a significant enhancement in the quality and reliability of laboratory results.
    - The proportion of tests with improper results was reduced from 3.72% to 0.34%, representing a net improvement of 3.38%.
2. **Hematology Section:**

- For the Hematology section, which included tests such as Partial Thromboplastin Time (PTT), the initial pass rate was 87.50%. After adherence to the CAP Kit instructions, the pass rate slightly decreased to 86.67%.
- Despite the slight decrease, the adherence to CAP guidelines ensured standardization in testing procedures, reducing the likelihood of major errors and highlighting areas needing further improvement.

3. **Molecular Pathology & Genetics Section:**
   - Significant improvements were observed in the Molecular Pathology & Genetics section. The DNA Sequencing Challenges (SEC and SEC1) initially had a pass rate of 66.67%. Following the introduction of additional quality control parameters, the pass rate improved to 100%.
   - This improvement underscores the impact of rigorous quality control measures, such as the use of control DNA samples, regular calibration of sequencing instruments, and stringent monitoring of reaction conditions.
4. **Molecular Identification Section:**
   - The Mycological Identification section showed a notable improvement, with the pass rate increasing from 80.00% to 100%.
   - The success in this section was attributed to focused staff education and training, which enhanced the technical proficiency of laboratory personnel in fungal species identification and sample handling, ensuring accurate results.

5. **Routine Chemistry Section:**

   - Across the Routine Chemistry section, multiple tests, including Cholesterol, Total GGT, Urea Nitrogen, pH, CA 125, and CA 19-9, demonstrated considerable improvements.

   - The pass rates for these tests increased to 100% from a pre-intervention average of around 90.00%, primarily due to the implementation of a comprehensive Quality Control system that included daily calibration of analyzers, verification of reagent integrity, and consistent application of best practice protocols.

Table 1: ***Improvement results***

Laboratory Section	**Test**	**Initial Pass Rate (%)**	**Post-Intervention Pass Rate (%)**	**Improvement (%)**	**Notes on Interventions**
Overall	All Tests	96.28	99.66	3.38	Interventions were applied across all sections, including CAP Kit adherence, QC measures, and staff training.
Hematology	PTT (Partial Thromboplastin Time)	87.50	86.67	-0.83	Strict adherence to CAP Kit instructions; minor decrease suggests the need for further protocol refinement.
Molecular Pathology & Genetics	DNA Sequencing Challenges (SEC & SEC1)	66.67	100	33.33	Additional QC parameters introduced; control samples used, regular calibration, and process monitoring.
Mycological Identification	Fungal Species Identification Tests	80.00	100	20.00	Enhanced staff training in identification techniques, sample

					preparation, and maintaining sterile environments.
Routine Chemistry	Various Tests (Cholesterol, GGT, etc.)	90.00	100	10.00	A comprehensive QC system was implemented, including daily analyzer calibration, reagent verification, and control charting.

Discussion

The study's findings demonstrate the effectiveness of systematic, targeted interventions in improving proficiency test outcomes in an oncology laboratory setting. The significant reduction in improper test results and the overall increase in PT pass rates underscore the importance of adhering to established protocols and enhancing quality control measures (Dufraing et al., 2021; Furtado et al., 2023).

Adherence to CAP Kit instructions proved critical in maintaining high standards of diagnostic accuracy. Despite a slight decrease in the pass rate for Hematology's PTT, this highlights the need for continuous evaluation and adjustment of testing protocols to address any underlying issues (Zneimer & Hongo, 2021).

The addition of QC parameters in the Molecular Pathology & Genetics section was particularly effective, demonstrating how targeted quality control measures can directly improve test outcomes. The increase in pass rates for DNA sequencing challenges illustrates the impact of rigorous QC protocols on diagnostic reliability (Furtado et al., 2023).

Staff education and training played a pivotal role in enhancing technical proficiency and reducing errors. The marked improvement in Mycological Identification pass rates following targeted training sessions highlights the importance of continuous staff development in maintaining high standards of laboratory practice (Graden et al., 2021).

The comprehensive Quality Control system implemented in the Routine Chemistry section resulted in across-the-board improvements, demonstrating the value of routine checks, maintenance, and continuous monitoring in achieving consistent accuracy and reliability (Dufraing et al., 2021).

Conclusion

This study demonstrates that targeted interventions, including adherence to CAP Kit instructions, the addition of QC parameters, a comprehensive Quality Control system, and focused staff education and training, can significantly improve proficiency test outcomes in an oncology laboratory setting. The substantial reduction in improper test results and the increase in PT pass percentages highlight the importance of rigorous quality control measures and continuous process improvement.

Ongoing monitoring, periodic reassessment, and staff development are essential to maintaining high standards in laboratory diagnostics, ultimately enhancing patient care and safety in an oncology setting.

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