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Quality Control Circle Practices to Reduce Specimen Rejection Rates

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Background: Quality assurance in laboratory testing significantly impacts patient care. The pre-analytical phase is particularly error-prone, contributing to around 70% of laboratory errors. High specimen rejection rates can delay diagnosis and treatment, cause patient discomfort, and increase healthcare costs. Quality Control Circles (QCC) have been introduced to medical institutions to improve process efficiency and reduce errors. This study aims to evaluate the effectiveness of QCC practices in reducing specimen rejection rates in a hospital clinical laboratory.

Methods: A QCC initiative was implemented in the clinical laboratory from July 2021 to August 2022. The QCC comprised members from the clinical laboratory, nursing department, and administration. The initiative followed the PDCA (Plan-Do-Check-Act) cycle and involved multiple quality control methods, including flowchart analysis, Pareto analysis, and Fishbone diagrams. The effectiveness of the initiative was evaluated using statistical analyses of specimen rejection rates before and after implementation.

Results: The QCC initiative led to a significant reduction in specimen rejection rates. The monthly specimen rejection rate decreased from an average of 1.13% before the intervention to 0.27% after the intervention. The most significant factors contributing to specimen rejection were identified as lack of sample collection information and blood clotting. Targeted interventions, such as appointing specimen collection liaisons, establishing a quality control team, and providing training on blood collection procedures, were implemented. These measures resulted in a notable decrease in the proportion of rejected specimens due to the identified factors.

Conclusion: The implementation of QCC practices effectively reduced specimen rejection rates in the hospital laboratory. The study highlights the importance of systematic quality control methods and targeted interventions in improving laboratory processes. The success of the QCC initiative demonstrates its potential for broader application in other healthcare settings to enhance quality and efficiency.

Keywords: quality control circle, specimen rejection, quality improvement, PDCA cycle, Pareto analysis

Introduction

Quality assurance remains an enduring concern in laboratory testing due to its impact on patient care and the overall value of the laboratory.[1] Laboratory testing comprises three distinct phases: pre-analytical, analytical, and post-analytical.[2] Notably, the pre-analytical phase is susceptible to approximately 70% of laboratory errors.[3] Laboratory professionals encounter notable challenges during the pre-analytical phase, including patient misidentification, inappropriate container usage, and missing or mislabeled samples.[4,5] Laboratories establish specific technical requirements for each analysis, and specimens failing to meet these criteria are rejected.[6] In such instances, it is crucial to promptly inform the nurse that the sample is unsuitable for testing and request the collection of a new sample.[7] Specimen rejection rate serves as an indicator of the pre-analytical process's effectiveness, encompassing sample collection and transportation within the laboratory workflow.[6] Specimen rejection has significant clinical implications as it can lead to discomfort

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for patients during repeated blood collection and potential risks like hematoma and iatrogenic anemia.[8] Additionally, the rejection of specimens causes delays in conducting and reporting the requested tests.[9] Thus, reducing specimen rejection rates is vital to achieve cost-effectiveness, improve overall quality, and enhance customer satisfaction.[10]

The Quality Control Circle (QCC) concept emerged in the 1950s through the statistical and management teachings of Professor Deming and Professor Juran.[11] In 2001, QCC was introduced to medical institutions in China.[12] Since then, QCC has demonstrated positive outcomes in various hospitals across China, gaining increasing attention. QCC involves individuals who collaborate within a specific field, forming a team to proactively address real problems using quality control methods such as Pareto analysis and fishbone diagrams, aiming to enhance efficiency and personnel competence.[12]

Our analysis between January 2021 and June 2021 revealed an average monthly specimen rejection rate of 1.13%. This rate is higher than the national specimen rejection rate 0.27% reported by the National Center for Clinical Laboratories in our country.[13] These findings highlight the immediate and pressing need for substantial improvements in the quality of pre-analytical specimens. To address this issue and reduce specimen rejection rates in our hospital laboratory, we implemented a QCC initiative from July 2021 to August 2022, with a specific focus on investigating, analyzing, and enhancing specimen management processes. The results achieved through this initiative were highly satisfactory.

Methodology

Ethics Approval and Informed Consent

This study followed the ethical guidelines outlined in the Helsinki Declaration and adhered to the standards set by the quality improvement reporting excellence (SQUIRE, version 2.0).[14] The study was approved by the Chinese Academy of Medical Sciences and Peking Union Medical College Shenzhen Hospital Ethics Committee. As the study involved the retrospective analysis of anonymous secondary data, the requirement for written informed consent was waived by the Chinese Academy of Medical Sciences and Peking Union Medical College Shenzhen Hospital Ethics Committee. Measures were taken to protect the privacy of both patients and staff involved. The analysis was based solely on validated data obtained from our institution's Department of Clinical Laboratory Medicine database.

Context and Formation of QCC

The Cancer Hospital Chinese Academy of Medical Sciences, Shenzhen Center, is a tertiary Grade-A specialized cancer hospital with 880 beds. It was officially inaugurated and commenced operations on March 18, 2017. To address the observed upward trend in specimen rejection rates, the Clinical Laboratory established a QCC. The QCC consists of eight members, including five personnel from the Clinical Laboratory, two personnel from the Nursing Department, and one personnel from the Administration Department. Reducing the specimen rejection rate has been identified as a primary objective due to its impact on sample analysis and subsequent delays in patient diagnosis and treatment. Specimen rejection not only leads to longer turnaround times (TAT) but also hinders the timely provision of patient care.

Planning and Implementation

The improvement process included designing and evaluating of the steps to be implemented. To outline the timeline and ensure a structured approach, a PDCA (Plan-Do-Check-Act) Plan Gantt chart was developed (Figure 1). Following the established plan, the improvement procedure was carried out under the supervision of the clinical laboratory director, who provided oversight and guidance throughout the process.

Process Improvement

For process measurements, our laboratory documents the specimen collection process in a Standard Operation Procedure(SOP) and provides education and training on it. When specimens are received in the laboratory and scanned, the entire process of specimen collection is displayed (Figure S1), including the issuance of medical orders, confirmation of orders by nurses, sample collection, post-collection scanning confirmation, specimen transportation, and other steps. This enables the assessment of whether the specimen collection process is complete and standardized. On the other hand, the intangible results were presented using multiple indicators displayed on a radar map.

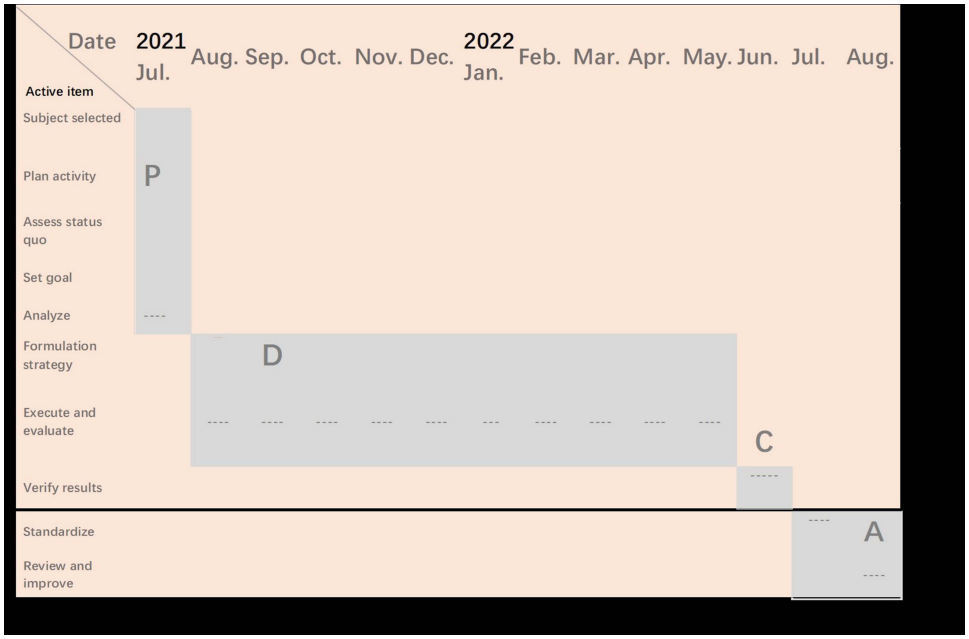

Figure 1 The PDCA (Plan-Do-Check-Act) Plan Gantt chart.

Statistical Processing

The data underwent statistical analysis using SPSS 26.0 software. Count data was presented as percentages and analyzed using the χ^2 test. A significance level of $P < 0.05$ was considered indicative of a statistically significant difference. The Chi-square test for trend was employed to assess the statistical significance of the variation in specimen rejection rates over time. The figures in this paper were generated using Microsoft Excel software and Microsoft PowerPoint software.

Results

Current State Analysis

We conducted a preliminary analysis of the specimen rejection process using a flowchart (Figure 2). Based on the flowchart, the QCC generated a sample rejection cause checklist known as the 5W1H (Who, What, When, Where, Why, How) checklist (Table S1). This checklist was designed to systematically categorize and summarize the reasons for unacceptable samples throughout the entire process. The listed rejection reasons and data in this checklist were compiled based on a randomly selected one-week period from May 3, 2021, to May 9, 2021. During this period, a total of 8473 samples were tested, and 117 samples (1.38%) were rejected. To further depict the data obtained from the checklist, we constructed a Pareto analysis chart (Figure 3) to identify the most significant factors contributing to specimen rejection. Following the 80/20 principle in the Pareto diagram, we determined that a lack of sample collection information and blood clots were the key reason.

Essential Factor Analysis

In order to delve deeper into these main factors, a cause-and-effect analysis was conducted using a Fishbone Diagram (Figure 4). The factors contributing to the issue of "lack of sample collection information" can be categorized into four main factors: medical staff, equipment, policy, and material. Similarly, the factors contributing to the issue of "blood clots" also fall into four major categories: medical staff, equipment, policy, and material.

Strategies and Implementations

Finally, we utilized a Root Cause Analysis (RCA) Scoring Sheet (Tables S2 and S3) to determine the underlying cause and develop strategic interventions. The QCC members summarized and evaluated the different measures (Table S4).

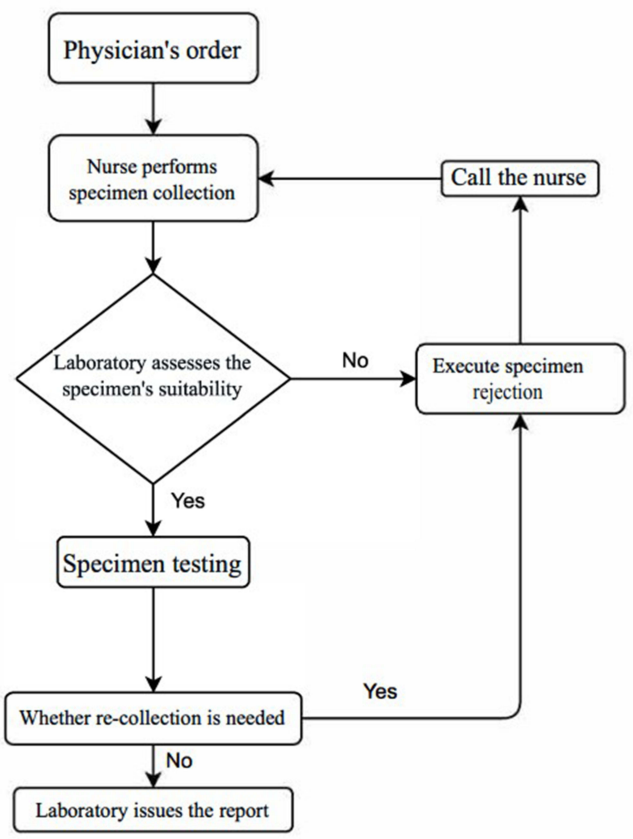

Figure 2 The workflow diagram of the process from the physician's order to the issuance of the laboratory test report.

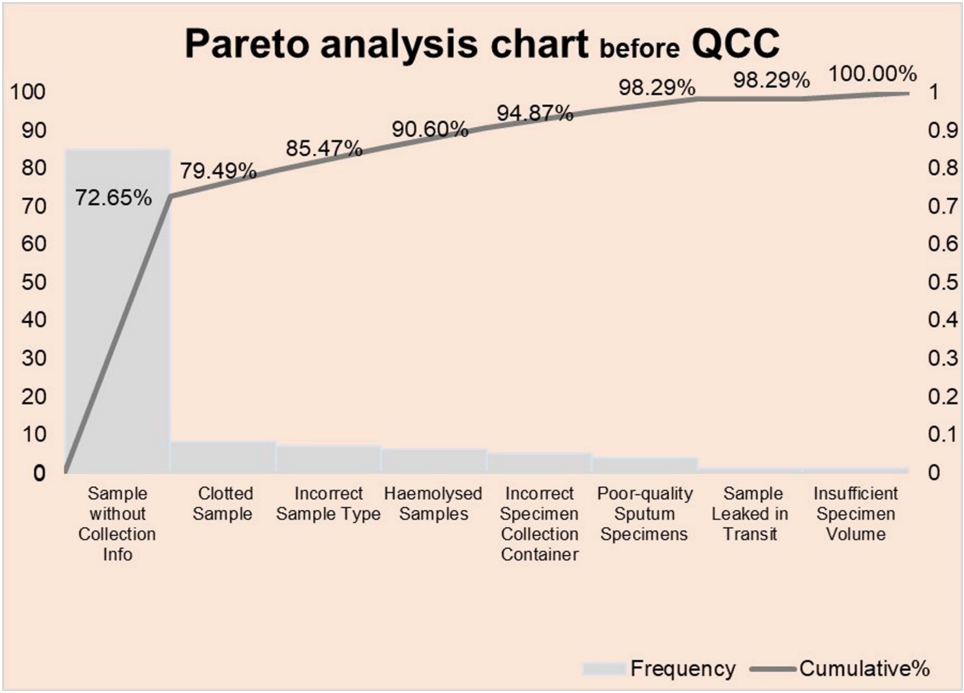

Figure 3 A Pareto analysis chart generated based on the data from May 3, 2021, to May 9, 2021.

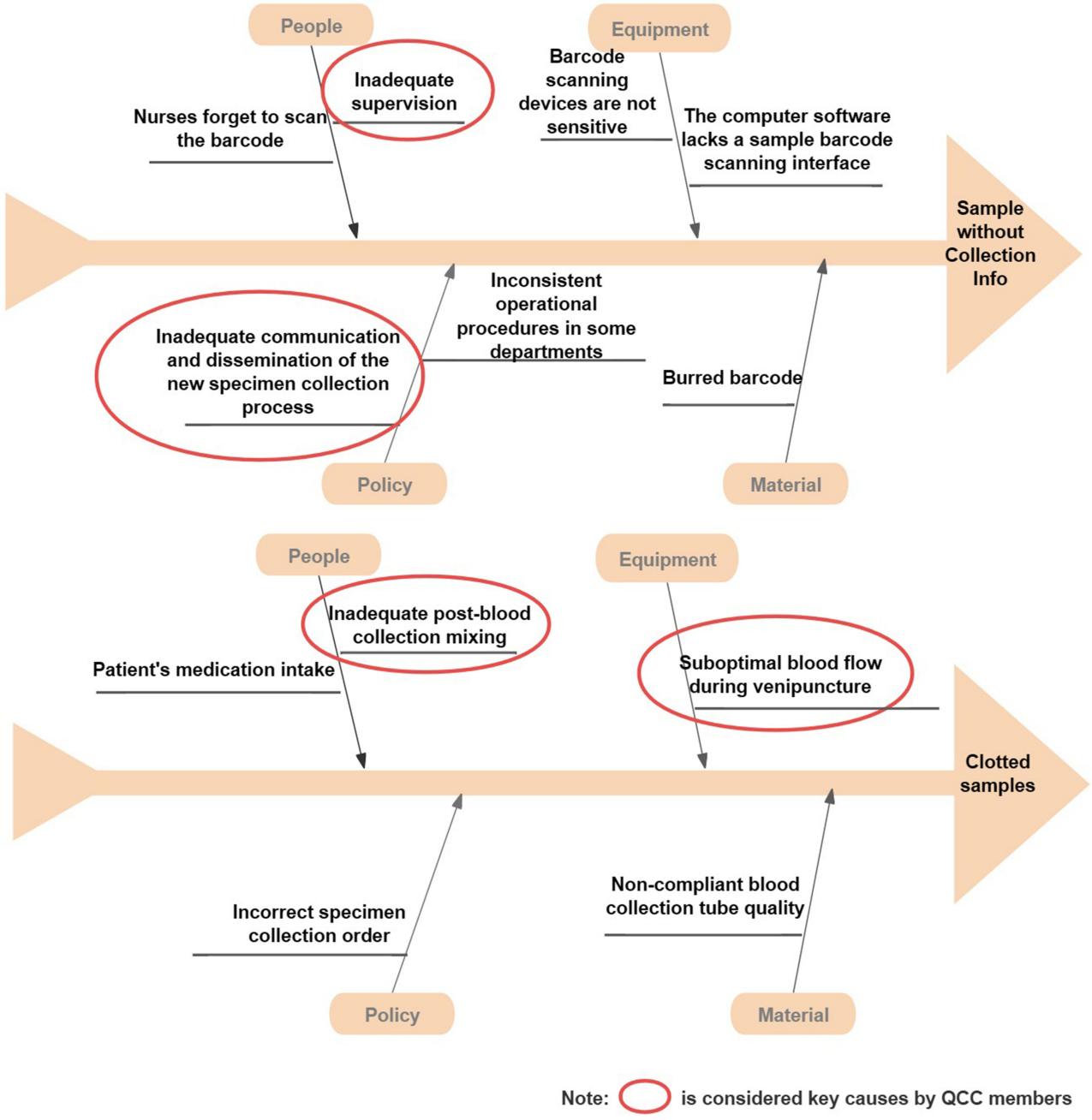

Figure 4 The cause-and-effect (Fishbone) diagrams display the reasons for rejected sample.

The following specific measures were ultimately determined.

Strategy I: Each ward in the Clinical Nursing Department has appointed a specimen collection liaison who is responsible for timely communication. The laboratory promptly communicates any issues with the specimens received, and the nursing department takes corrective actions promptly to reduce the rejection rate.

Strategy II: A quality control team has been established within the nursing department to oversee the quality of specimens before testing. Each month, an analysis is conducted based on the clinical laboratory's compiled records of specimen rejections. Corresponding departments and personnel are penalized with performance evaluation deductions, which may affect their bonuses, as a means to raise awareness and reduce the rate of specimen rejection.

Strategy III: The clinical laboratory provides training to nursing staff on blood collection procedures. The laboratory has standardized the content of the user manual for laboratory testing, specifying the number of inversions for blood collection tubes. The laboratory has also uploaded the user manual to the hospital's OA system for the nursing department's reference and learning.

Standardization of SOP's or Documentation

After evaluating and confirming the results, standardized documents were developed and implemented, including sample collection specifications and a comprehensive guide for common specimen collection procedures. These documents aimed to establish uniform guidelines and procedures for sample collection in the laboratory's quality management of specimens.

Tangible Results

The monthly rates of specimen rejection and the total number of specimens from May 2021 to August 2022 are presented (Table 1). Chi-square test conducted on the monthly specimen rejection rates revealed a statistically significant difference. Trend analysis of the rates indicated a linear trend with $p<0.001$ (Pearson correlation coefficient −0.43), suggesting a decreasing trend in specimen rejection rates over time.

The comparison of Tables S1 and S5 reveals a significant improvement in sample rejection causes after the quality control circle (QCC) interventions. Prior to the intervention (Table S1), the primary reason for sample rejection was "Sample without Collection Info", accounting for 85 rejections, which represented 72.65% of the total, as illustrated in Figure 3. Following the QCC interventions, this issue dropped dramatically to 26 rejections (50%), as shown in Table S5 and Figure 5, reflecting a reduction of nearly 70%. This substantial improvement underscores the effectiveness of

Table 1 Chi-Square Test Results of Specimen Rejection Rates by Month

Time	Specimens Counts	Accepted Specimens (Percentage)	Rejected Specimens (Percentage)	Chi-Square Test		*P* for Trend
				χ^2 Value	*P*	
2021.05	42,331	41,779(98.70)	552(1.30)	2451.98	<0.001	<0.001
2021.06	56,898	56,384(99.10)	514(0.90)			
2021.07	41,872	41,645(99.46)	227(0.54)			
2021.08	48,329	47,614(98.52)	715(1.48)			
2021.09	49,573	48,952(98.75)	621(1.25)			
2021.10	43,596	43,160(99.00)	436(1.00)			
2021.11	55,055	54,586(99.15)	469(0.85)			
2021.12	52,172	51,786(99.26)	386(0.74)			
2022.01	68,381	68,055(99.52)	326(0.48)			
2022.02	45,865	45,637(99.50)	228(0.50)			
2022.03	105,784	105,467(99.70)	317(0.30)			
2022.04	86,402	86,159(99.72)	243(0.28)			
2022.05	79,510	79,246(99.67)	264(0.33)			
2022.06	76,973	76,705(99.65)	268(0.35)			
2022.07	80,170	79,943(99.72)	227(0.28)			
2022.08	86,843	86,607(99.73)	236(0.27)			

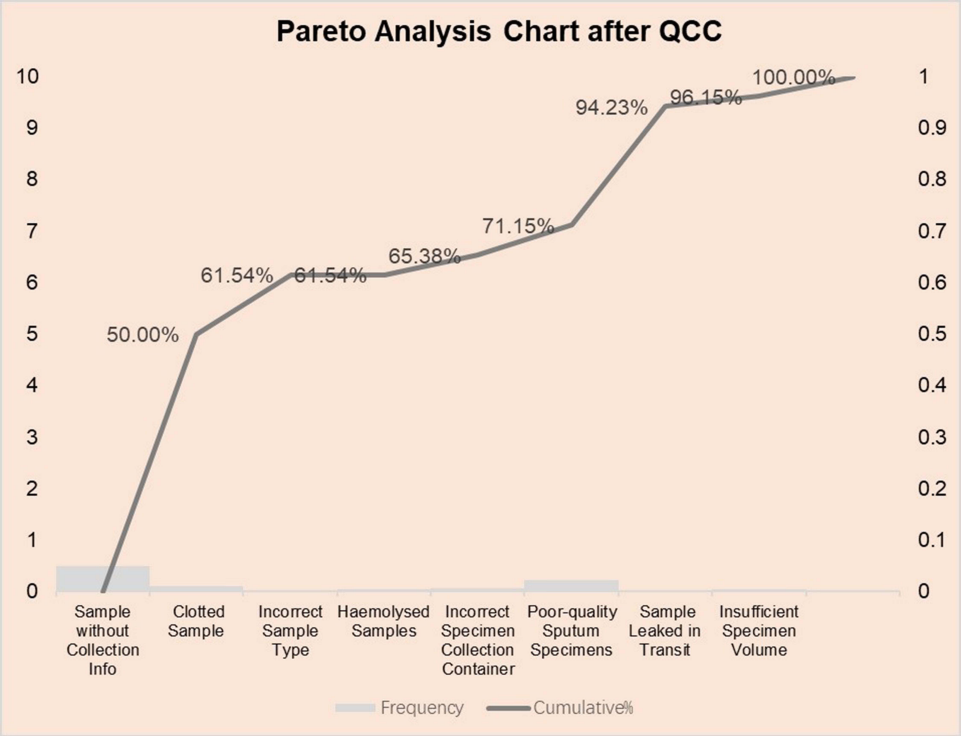

Figure 5 A Pareto analysis chart generated based on the data from June 6, 2022 to June 12, 2022.

targeted measures such as enhanced communication through the establishment of a WeChat group for better coordination, and the maintenance of barcode scanning devices. In addition to the primary issue of missing collection information, other causes of rejection, such as "Clotted Samples", also showed notable improvement. The frequency of clotted samples decreased from 8 cases (6.84%) before the intervention (Figure 3) to 6 cases (11.54%) post-intervention (Figure 5). Although the reduction in this area was less pronounced, the improvement can still be attributed to interventions like standardizing blood collection procedures and improving training on blood mixing techniques, as outlined in Table S4. Other minor issues, such as incorrect specimen types and hemolysed samples, remained relatively stable or showed slight reductions. However, a new issue, "Poor-quality Sputum Specimens", emerged in the post-intervention data, suggesting that while the QCC interventions effectively addressed the primary causes of sample rejection, ongoing attention is needed to identify and manage newly emerging problems.

Intangible Results

During the QCC activity, significant improvements were observed among the circle members in various aspects (Figure 6), including increased confidence, enhanced sense of responsibility, improved communication skills, greater harmony, strengthened team cohesion, heightened motivation, and enhanced quality control skills.

Discussion

The QCC has long been utilized as a scientific approach to quality management in the business sector. In recent years, its application has expanded to hospital management. Participating in a QCC offers valuable opportunities for individuals to acquire scientific quality management concepts, enhance problem recognition awareness, and improve work efficiency. Moreover, QCC facilitates the establishment of harmonious work teams, leading to improved healthcare service quality and reduced hospital operating costs.

In China, QCC has been implemented in hospitals for various purposes, such as improving mask-wearing compliance among tuberculosis patients,[15] promoting early mobilization after cesarean section,[16] providing post-operative care for

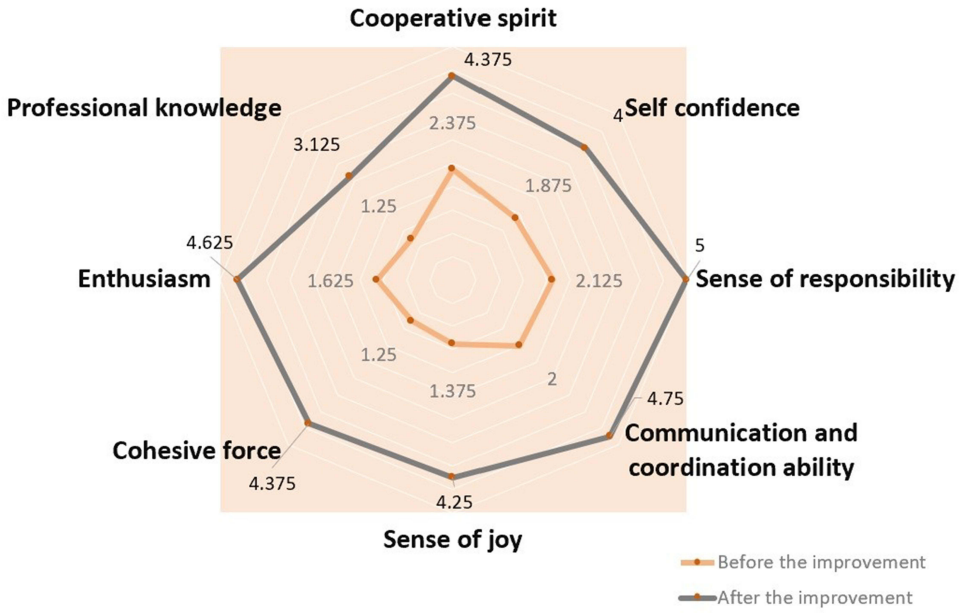

Figure 6 Before and after the implementation of QCC, a radar plot comparing the comprehensive skills of QCC members.

elderly patients undergoing dental implantation,[17] enhancing the quality of laboratory specimens,[12] and raising awareness of patient safety culture among hospital staff.[18] However, applying QCC to improve specimen rejection rates in the clinical laboratory, particularly in a newly established hospital, represents a certain level of innovation in this research.

In this study, the lack of sample collection information was primarily attributed to nurses' unfamiliarity with the newly implemented LIS operating procedures. The sample collection information includes patient ID, as well as the date and time of collection. RCA revealed insufficient training on the use of the new LIS and a lack of supervision during specimen collection, resulting in oversight of information registration. Subsequent measures, such as establishing a dedicated quality control team and developing a SOP for the specimen collection process, significantly improved the specimen rejection rate. Based on randomly sampled data before and after the implementation of these measures, the proportion of specimen rejections due to a lack of collection information decreased from 72.65% to 50%, with the quantity decreasing from 85 to 26. Additionally, the overall specimen rejection rate decreased from 1.30% in May 2021 to 0.27% in August 2022. These findings underscore the importance of conducting context-specific analysis to identify the factors contributing to higher specimen rejection rates and implementing targeted measures accordingly. However, it is important to note that there was a sudden increase in specimen rejection rates in August 2021, which can be attributed to the implementation of a 10-in-1 test policy in the region where the hospital is located. This policy involved combining samples from 10 patients' throat swabs into a single tube. Consequently, if information for any one patient was not registered, the entire tube would be rejected. The abrupt implementation of this policy resulted in an elevated specimen rejection rate for that particular month.

The implementation of QCC in our clinical laboratory has yielded significant intangible results, which can be attributed to several core characteristics of the QCC approach. Firstly, QCC emphasizes teamwork and full participation,[19] forming a team that comprises members ranging from top-level leadership to ordinary employees, thus fostering collaboration among different departments. Throughout the implementation process, every question or suggestion raised by individuals that aligns with the objectives of the QCC is respected, encouraging all members to apply their wisdom and creativity in addressing identified issues. Moreover, the establishment of an open communication platform among personnel from various departments within the hospital enables in-depth analysis of the causes of specific problems, promoting member engagement, enhancing team cohesion, and fostering a sense of responsibility.[18] This

inclusive and mutually inspiring approach helps to reduce hierarchical culture and improve cooperation and coordination among healthcare professionals.[20]

In summary, the implementation of the QCC approach in our hospital laboratory has effectively reduced specimen rejection rates, improved processes, minimized defects, and created a favorable working environment for hospital staff. These outcomes can be attributed to the emphasis on teamwork, full participation, open communication, and the cultivation of a sense of responsibility within the QCC framework. The success of our implementation highlights the potential of QCC as a valuable approach for enhancing quality control in healthcare settings.

There are still several limitations to acknowledge in this study. Firstly, the study was conducted during the COVID-19 pandemic, when the region where the institution is located implemented a zero-tolerance policy for COVID-19 and utilized a 10-in-1 test for screening COVID-19 samples. While the overall specimen rejection rate showed a statistically significant decrease based on the statistical results, the specific impact of this unique situation was not accounted for in the study. Secondly, this study represents the first application of the QCC approach for improving specimen rejection rates in the department of clinical laboratory, and it is a single-center study. Therefore, further validation in a multi-center setting is necessary to confirm the effectiveness of QCC in reducing high specimen rejection rates. Additionally, it is important to note that the study was conducted in a specialized oncology hospital, and thus, the applicability of these findings to general hospitals requires further research. Lastly, previous studies have indicated that the success of QCC implementation can be measured by the duration of QCC projects, typically lasting more than two years.[21] In this study, the duration was slightly over one year, which is also a limitation to consider.

Implications for Policy, Practice and Research

To enhance patient safety and healthcare quality, hospitals must implement effective strategies to improve specimen rejection rates, particularly for newly established hospitals or laboratories that have changed in their LIS. Our study on specimen rejection rates in our institution demonstrates that QCC activities may be an effective strategy for improving specimen rejection rates in new hospitals. These findings hold potential value not only for hospitals in China but also for those in other countries. Therefore, it is recommended that hospitals invest in promoting QCC to continuously improve the entire process of patient specimen testing. Integrating QCC with other CQI tools may lead to more effective resolution of safety issues. Our study provides insights into the implementation process of QCC, which can serve as a reference for other researchers. Further research and evaluation of QCC activities in managing patient safety and identifying additional strategies to optimize patient safety are warranted.

QCC is an ongoing activity that necessitates continuous optimization. The accomplishments attained thus far do not signify the culmination of our efforts. The QCC team must delve deeper into their work, identify emerging issues, and establish new objectives to further enhance specimen quality in subsequent QCC activities.

Conclusions

In conclusion, this QCC activity conducted a comprehensive analysis of the reasons behind the high specimen rejection rate. Corresponding and targeted strategies were formulated and implemented, resulting in a reduction of the specimen rejection rate and a shorter waiting time for patients to receive test results. Furthermore, the promotion of the QCC application can inspire workplace enthusiasm, enhance employee capabilities, and ultimately contribute to improving the timeliness of clinical diagnosis, reducing the likelihood of medical disputes, and enhancing the reputation of the hospital.

Abbreviations

QCC, Quality Control Circle; TAT, Turnaround Times; PDCA, Plan-Do-Check-Act; RCA, Root Cause Analysis; CQI, Continuous Quality Improvement.

Data Sharing Statement

The datasets used and/or analyzed during the current study are available from the corresponding author, Xinjian Cai, on reasonable request.

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Author Contributions

All authors made significant contributions to the work reported, whether in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas.They participated in drafting, revising or critically reviewing the article, gave final approval of the version to be published, agreed on the journal to which the article was submitted, and agreed to be accountable for all aspects of the work.

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Disclosure

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