Risk Management and Healthcare Policy

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ORIGINAL RESEARCH

Tracing Missing Surgical Specimens: A Quality Improvement Strategy for Adverse Events Based on Root Cause Analysis

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Background: In 2022, a critical incident occurred at a Chinese hospital where a surgical specimen from a rectal prostate procedure was misplaced, necessitating repeat surgery for the patient. This event underscored systemic vulnerabilities in specimen handling processes and catalyzed an investigation into how healthcare systems manage medical errors to uphold patient safety.

Methods: Using root cause analysis (RCA), we dissected the workflow gaps and organizational factors contributing to the specimen loss. Key failures identified included unclear role delineation among staff, inadequate specimen labeling protocols, and lack of real-time tracking mechanisms. Three interventions were implemented: (1) Redesigning specimen handling workflows with explicit role responsibilities; (2) Developing standardized, color-coded specimen bottles and racks to improve visual identification; (3) Integrating an electronic tracking system for closed-loop management of specimens.

Results: Post-intervention, the recognition rate of post-use specimen vials improved from 0% to 100% after implementing a dual-color sealing system (white cap with red ring), enabling visual confirmation of proper sealing. Over two years, no surgical pathology specimens were lost post-intervention.

Conclusion: The RCA-driven reforms effectively addressed systemic flaws in specimen management, demonstrating that targeted process redesign, ergonomic tools, and digital tracking can mitigate risks of medical errors. This case highlights the importance of analyzing localized workflow failures within broader systemic contexts to build resilient, patient-centered medical care systems.

Keywords: rectal prostate specimens, medical errors, root cause analysis, patient safety, quality improvement

Introduction

Patient safety has remained a pivotal concern in healthcare since seminal reports such as the Institute of Medicine's "To Err is Human: Building a Safer Health System".[1] The mishandling of surgical specimens, in particular, poses significant risks, including delayed diagnoses, inappropriate treatments, and unnecessary repeat procedures. Globally, studies estimate that approximately 6% of specimen errors directly result in adverse clinical outcomes.[2] Moreover, over half of these errors can be attributed to identifiable systemic factors, including ambiguous protocols and insufficient safeguards.[2] These challenges persist despite decades of efforts to improve safety frameworks, underscoring the urgency of addressing latent organizational flaws that perpetuate errors.[3]

In 2022, a sentinel event at a Chinese hospital exemplified these systemic gaps: a misplaced rectal prostate biopsy specimen led to a patient undergoing repeat surgery. This incident not only caused physical and psychological harm but also exposed critical weaknesses in specimen management workflows, including inconsistent labeling practices,

Received: 8 March 2025
Accepted: 23 June 2025
Published: 27 June 2025

fragmented role responsibilities, and a lack of real-time tracking mechanisms. Such failures align with prior findings that more than half of errors involve preventable systemic oversights.[2] Yet this case uniquely highlights the cascading consequences of these gaps in a high-stakes clinical setting.

RCA is a structured, systematic process designed to identify the fundamental reasons behind adverse events rather than merely addressing the immediate causes.[4] It typically begins with a detailed reconstruction of the event timeline, involving the collection of data from various sources such as incident reports, interviews with involved personnel, and review of relevant policies and procedures.[5,6] One of the key techniques used in RCA is the "5 Whys" method, where the team repeatedly asks "why" about each identified factor contributing to the event.[5,6] Which categorizes potential causes into groups like people, methods, machines, materials, and environment, allowing the team to visualize and analyze the complex web of factors contributing to the event.[6,7]

In other healthcare contexts, RCA has been highly successful. For example, in the area of hospital - acquired pressure ulcers.[8] Similarly, in surgical site infection prevention, RCA has helped uncover issues like ineffective pre - operative skin preparation, improper sterilization of surgical instruments, and breakdowns in communication among the surgical team. Corrective actions based on RCA findings have led to a substantial decrease in surgical site infections.[9] These examples illustrate the versatility and effectiveness of RCA, highlighting the potential for its application in addressing specimen - related errors. RCA has been recognized as a powerful theoretical tool, capable of identifying fundamental issues such as outdated protocols and technological deficiencies.[10,11]

However, despite its well-established theoretical utility, its practical application to specimen-related errors, which can have significant consequences for patient care, remains notably underexplored. Specimen - related errors, which can lead to incorrect diagnoses, inappropriate treatment, and potential harm to patients, often stem from complex interactions between human factors, such as fatigue, lack of attention and system - level issues, such as inefficient processes and outdated technology. Human factors engineering, which focuses on optimizing the interaction between humans and systems, and digital solutions, which can automate and streamline processes, have the potential to address these root causes effectively.[12,13] However, the practical application of these approaches in the context of specimen - related errors, guided by a rigorous RCA framework, remains largely unexplored. This study aims to fill this gap by demonstrating how a comprehensive RCA can identify the root causes of specimen - related errors and inform the development and implementation of targeted interventions based on human factors engineering principles and digital solutions, thereby contributing to the broader goal of improving patient safety in healthcare systems globally.

Methods

Study Design

This quality improvement project investigated a 2022 sentinel event at a tertiary hospital in Zhejiang Province, China, where a misplaced rectal prostate biopsy specimen necessitated repeat surgery. The hospital, with 1,200 beds and ~17,000 annual surgeries, processes ~8,000 surgical specimens yearly. The RCA followed national guidelines, focusing on systemic failures in specimen handling rather than individual blame.[14]

Team Composition

A multidisciplinary RCA team (vice president, a quality manager, an operating room head nurse, a urologist, and a pathologist), reviewed workflows, and mapped the specimen journey (shown in Figure 1). The head nurse of the operating room was the leader of the team. Staff involved in the incident were excluded to minimize bias.[15] Each team member brought unique expertise to the project. All team members were trained and passed an RCA course of at least 8 hours prior to joining. Regular team meetings were held to discuss findings, share ideas, and make decisions.

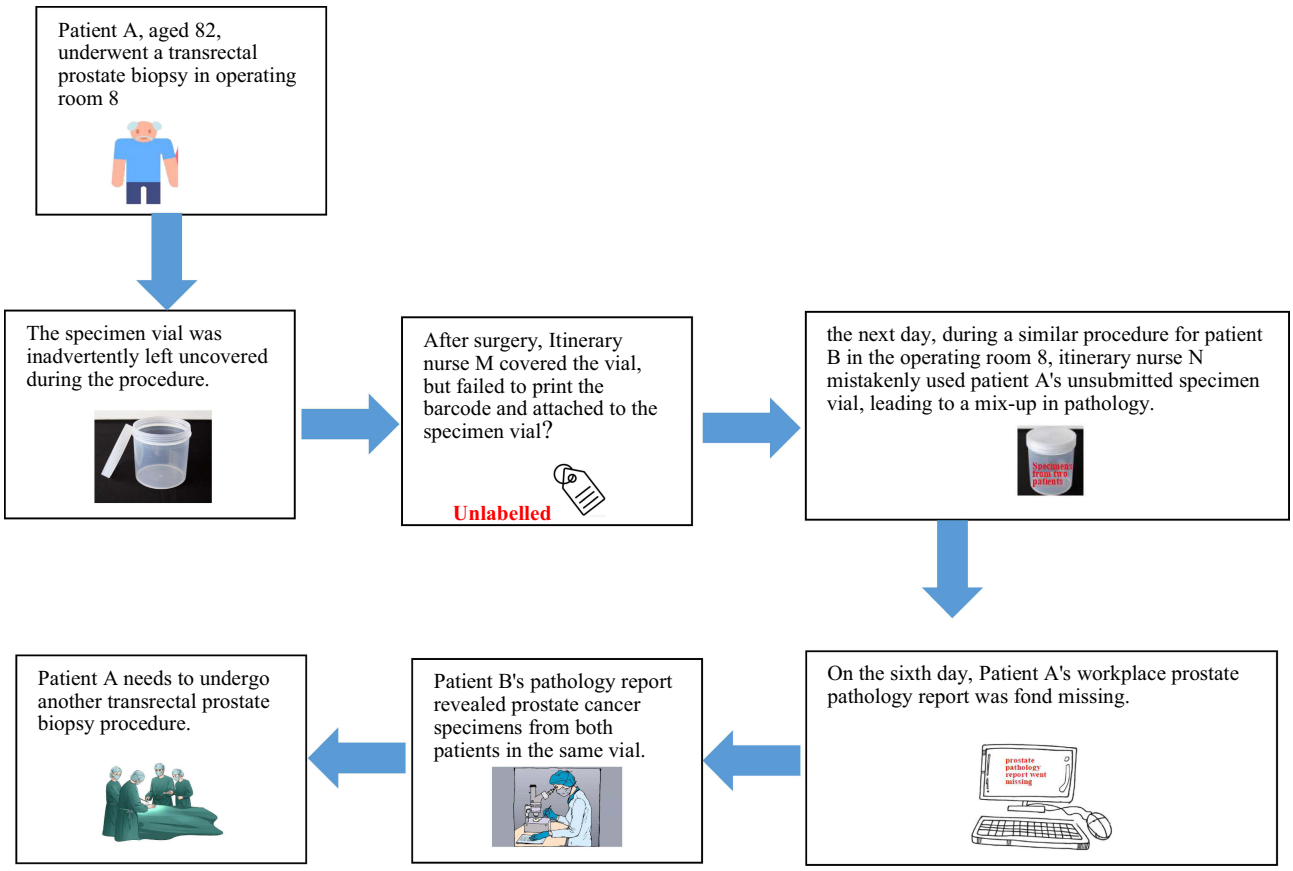

Figure 1 The event story map.

Event-Specific Analysis Framework

System Failure Identification

Using the Incident Decision Tree (IDT),[16,17] we evaluated whether systemic factors rather than individual error enabled the specimen loss. The "substitution test" confirmed that even competent staff would likely err under existing conditions due to:

1. Ambiguous preoperative order protocols.
2. Lack of visual verification tools for specimen bottle sealing.
3. Absence of real-time tracking between operating rooms and pathology labs.

Semi-Structured Face-to-Face Interviews

We conducted semi-structured interviews with 12 hospital staff members, including nurses, doctors, technicians and administrative personnel directly involved in the specimen handling process (excluding those directly related to sentinel incidents to minimize bias). Due to the sensitivity of the issue, no interviews were conducted with the patients and their families in this study. Sample questions included: "Can you describe the steps you take to ensure specimen integrity during the handoff between the operating room and the pathology lab?"; "Have you encountered any challenges with the current specimen labeling or sealing protocols, and if so, what were they?"; and "In your opinion, what aspects of the specimen handling workflow could be improved to prevent errors?" These questions aimed to uncover systemic issues in the specimen handling process, rather than focusing on individual performance.

https://doi.org/10.2147/RMHP.S527015

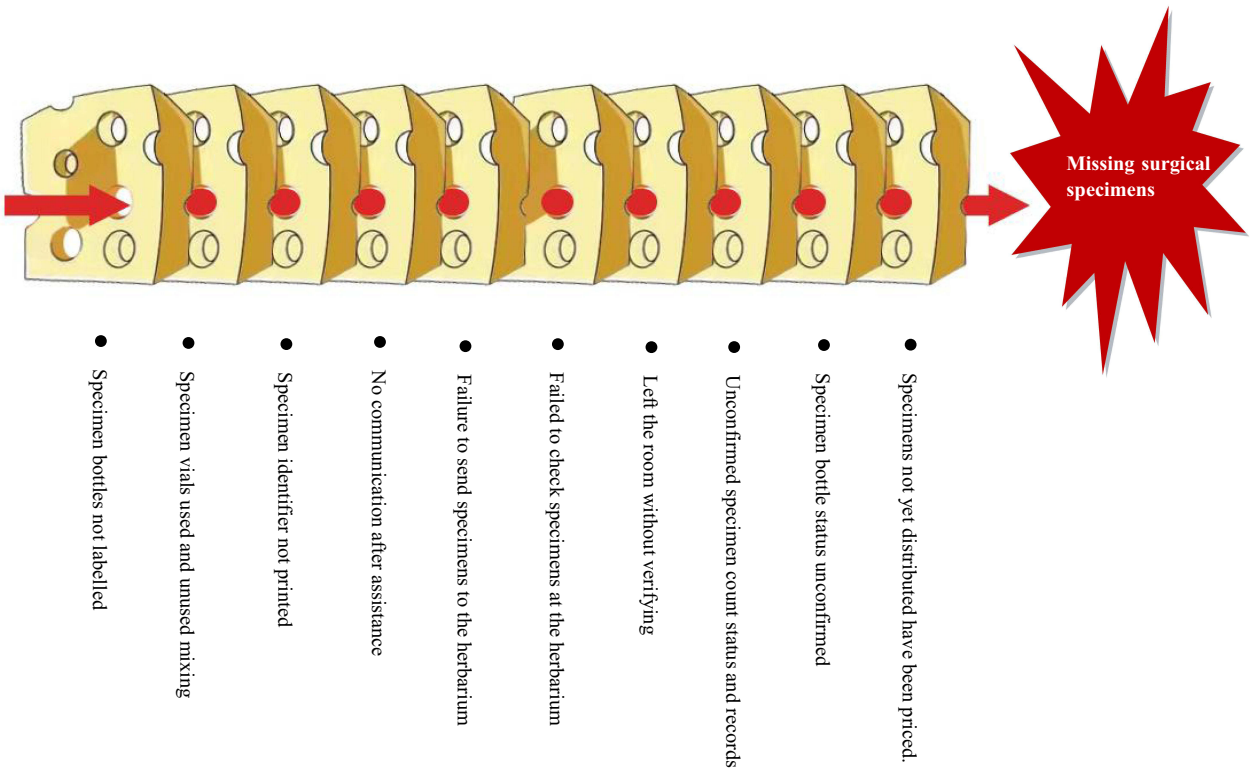

Figure 2 The Swiss cheese conceptual model analysis.

"Swiss Cheese" Conceptual Model Analysis

We conducted a qualitative error analysis using James Reason's "Swiss cheese" model to explore the interaction between surgical specimen loss and its systemic implications.[18,19] In the analysis, by applying the Swiss cheese model, various "holes" that led to the loss of surgical specimens at different system levels were identified, as shown in Figure 2. These included issues such as specimen bottle status unconfirmed, unconfirmed specimen count status and records, failure to send specimens to the herbarium, and specimen bottles not labelled. Each of these represented gaps or failures in specific processes. The model posits that when such holes across different levels (eg, preoperative, intraoperative, postoperative workflows) align, they create a pathway for errors like specimen loss to occur.

Root Cause Identification

We identified 13 systemic root causes (shown in Table 1). The analysis identified three interdependent systemic vulnerabilities contributing to the specimen loss (identify root cause contributing factors as shown in Figure 3). Material deficiencies were evident in non-intuitive specimen labeling designs, which increased the risk of misidentification during high-pressure workflows. Process gaps further compounded risks, as the absence of closed-loop tracking systems allowed specimens to bypass critical checkpoints undetected. Human factor limitations exacerbated these issues, with inadequate staff training on updated protocols leading to inconsistent adherence to safety measures. Together, these flaws created alignment in the system's "Swiss cheese" defenses, enabling the specimen to slip through multiple layers of safeguards.

Interventions

As shown in Table 2, to address the root causes, inspired by previous studies, we have formulated three targeted intervention measures: Process redesign established mandatory preoperative pathology orders, alongside clear cross-departmental role delineation for specimen handling;[20] Ergonomic innovations introduced dual-color sealing rings (white cap/red ring) on specimen bottles, enabling instant visual verification of proper sealing status;[21] and digital closed-loop

Table 1 Systemic Root Cause Analysis

System factor	Question 1	Question 2	Question 3	Root cause
	When this Cause Does Not Exist, Does the Problem Still Occur?	If this Cause is Corrected or Eliminated, will the Problem Occur Again for the Same Reason?	After the Cause has Been Corrected or Eliminated, will it Lead to Similar Incidents?	
Label printing paper size is too large	No	No	No	√
No uniform code of practice in the department	No	No	No	√
The system configuration is unreasonable	No	No	No	√
No shared computers in the operating area for orders	No	No	No	√
The nurse forgot to print	No	No	No	√
The process is not clearly defined	No	No	No	√
No standardized communication protocols established	No	No	No	√
The specimens are too small	Yes	No	No	×
Specimen vials indistinguishable used from unused	No	No	No	√
Inadequate supervision in check	Yes	Yes	Yes	×
Incomplete performance plans without effective constraints	No	No	No	√
The specimen submission policy lacks detail	No	No	No	√
The information system displays are not prominent	No	No	No	√
Permissions are set too broadly	No	No	No	√
Workflows have not been established	No	No	No	√

management integrated barcode tracking into the hospital information system, with automated alerts flagging unlogged specimens to prevent oversight.[22]

However, the implementation of these interventions was not without challenges. For the process redesign, some staff resisted the changes due to concerns about increased workload and the need to adapt to new procedures. To overcome this, we organized in - depth training sessions that included both theoretical explanations of the importance of the new protocols and practical demonstrations of how to follow them. For the ergonomic innovation of dual - color sealing rings, there were initial concerns about the cost implications and compatibility with existing specimen bottles. We addressed these by conducting thorough cost - benefit analyses and collaborating closely with suppliers to ensure that the new sealing rings could be seamlessly integrated into the existing workflow. When implementing digital closed - loop management, technical glitches during system integration emerged as a major hurdle. Our IT department worked closely with the system developers, conducting extensive testing and troubleshooting to optimize the system and ensure its smooth operation. Training sessions were conducted for all these employees to ensure understanding and adherence to the new protocols, ergonomic changes, and digital tracking systems. A total of 287 employees, including surgeons, nurses, lab technicians, and administrative staff, whose roles directly impacted specimen handling workflows, were included in the interventions.These measures collectively fortified safeguards across the entire specimen journey, spanning preoperative protocols to postoperative tracking, thereby closing systemic gaps identified in the RCA.

Evaluation Metrics

The intervention's effectiveness was evaluated through a structured, hierarchical framework aligned with the RCA-identified systemic vulnerabilities.

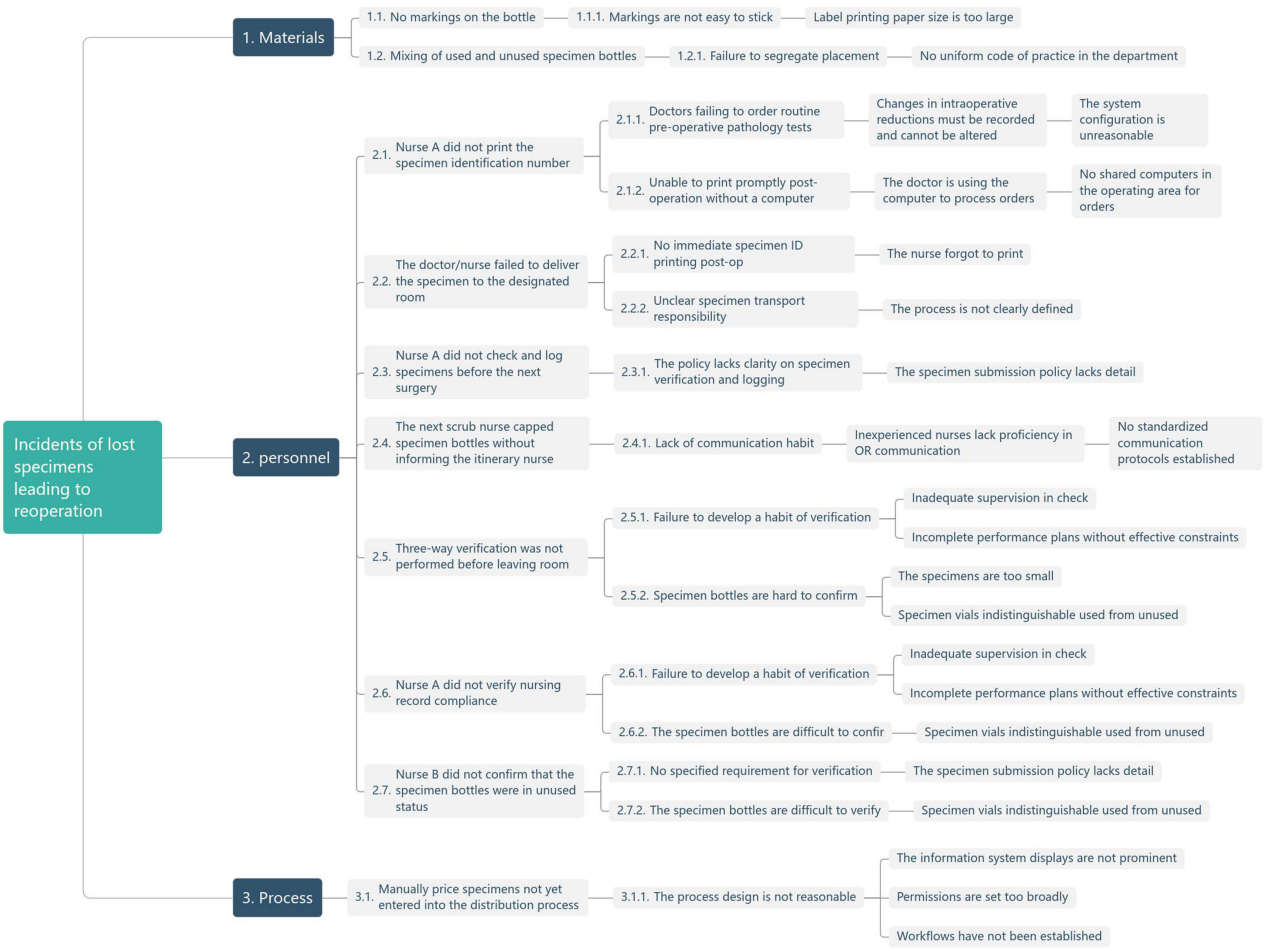

Figure 3 Identify root cause contributing factors.

Clinical Outcome Metrics

Clinical outcome metrics centered on ensuring specimen integrity and safety throughout the handling process. Specimen integrity preservation was evaluated by systematically monitoring recurrence rates of loss events, while safety verification efficacy was assessed through enhancements in the reliability of sealing confirmation mechanisms, ensuring tamper-evident protocols were consistently maintained. These dual metrics collectively validated the intervention's capacity to safeguard specimens from pre-collection to final analysis.

Process Compliance Metrics

Process compliance metrics evaluated specimen workflow standardization. Preoperative protocol adherence was measured through pathology order compliance, while documentation accuracy focused on labeling error tracking to mitigate traceability risks. These metrics ensured procedural fidelity and resolved preoperative-postoperative coordination gaps.

System-Level Impact Metrics

System-level impact metrics focused on organizational and translational impact. Staff competency was tracked through participation in updated protocol training, while scalability was monitored via external partnerships adopting RCA innovations like dual-color sealing systems and closed-loop tracking.

Table 2 Developing and Implementing Improvement Actions

Root Cause	Original Actions	Integration of Actions	Action Number
No public computer processing medical orders in the surgical area	Just one computer for the doctor in the preparation room 8 and room 9	Revised the system process and defined the responsibilities	Action one
The process is not clearly specified	Revise the operating room specimen management process and define the responsibilities		
The specimen inspection system is not detailed enough	Revision of procedure procedure procedure procedure procedure procedure, performed within unit time		
The performance plan is not perfect and fails to restrict each other	Learn the operating room specimen inspection system and the surgical specimen management process		
	Strengthen the specimen management process inspection and implement performance management		
No workflow was developed	Pathology system related work process, the general knowledge		
No institutional communication mode	It is stipulated that the treatment method of surgical specimens shall be handled by the desk nurse personally		
Excessive size needs to be trimmed	Purchase a small size label printer and an indelible small size material label	Innovative research and development and design of specimen bottle, specimen rack	Action two
There is no unified operation standard in the department	Design a special specimen bottle holding rack		
	The specimen bottle department stipulates the daily dosage, and put the allowance back to the designated seat in time		
Used and indistinguishable from unused	Development of a sealed ring specimen bottle		
System design is unreasonable	The doctor issued the pathology application form before surgery, and the intraoperative nurse modified the intraoperative observation according to the doctor's advice	Information assistance to establish a closed-loop management system for pathological specimens	Action three
	Specimen entries can be printed separately by selection		
The system display is not very visible	Information system optimization design, visual management		
The permissions are set too large	Information system redesign pricing authority		
Nurses forget to print	When printing pathology labels, the patient identity code should be scanned to confirm the binding		
	15 minutes after the end of the operation, the system set a pop-up reminder		

Results

Inspection Results

Members of the RCA quality management team collected data on indicators related to the loss of pathological specimens during two sampling periods (9 September to 27 September 2022 and 12 February to 26 February 2023). We examined 96 patients undergoing transrectal prostate biopsy procedures.

https://doi.org/10.2147/RMHP.S527015

Evaluation of Direct Quantitative Indicators Before and After the Implementation of RCA

After adopting the split design for the sealing ring of specimen vials, the post-use recognition rate of specimen vials increased from 0% before the implementation of RCA to 100% after the implementation of RCA, which is an effective improvement measure. Our joint hospital information research and development centre introduced a closed-loop management design based on the existing pathology specimen management information system. After the implementation of the following three measures, ie, the implementation of the information system's anti-defective settings, the setting of the information alert function, and the design of the registration page for pathology specimens using the "colour differentiation method". There has been no adverse event of loss of surgical pathology specimen for 2 years since the occurrence of the adverse event. The printing rate of specimen identification codes has increased from 97% to 100%, the issuance rate of preoperative pathology orders has increased from 14% to 100%, and the rate of pre-pricing surgical pathology specimens has decreased from 100% to 0%. Significant improvements were achieved in all the above quantitative indicators. (The results as shown in Table 3)

Evaluation of Indirect Derived Indicators Before and After the Implementation of RCA

The quality management department, in collaboration with the hospital quality and safety management committee, organized three training sessions for surgeons, nurses, lab technicians, and administrative staff to disseminate the findings of the RCA report on "missing" pathology specimens that led to a patient undergoing a repeat prostate biopsy. A total of 1,500 surgical and clinical managers attended these post - intervention training sessions, The trainings were a part of the post - intervention efforts to enhance awareness and improve practices related to specimen handling across the hospital.

We also promoted the innovative split design of sample vial seals and the application of the color differentiation method on the pathology specimen registration page. These innovations have been shared with 14 healthcare institutions. The RCA report was awarded the gold medal at the 2024 hospital quality management competition in Zhejiang Province, Mainland China, highlighting its practical significance in improving patient safety culture.

To further strengthen the rigor of our study and assess the long term effectiveness of the interventions, we are conducting a follow up evaluation. We plan to collect data six months and one year after the implementation of the interventions, focusing on process compliance, staff feedback, and the recurrence rate of specimen related errors. This follow up will provide more comprehensive evidence of the sustainability of the RCA - based improvements.

Table 3 Evaluation of Direct Quantitative Indicators Before and After the Implementation of RCA

Indicators	Definition	Before RCA Implementation (%)	After RCA Implementation (%)	Degree of Improvement (%)
Outcome indicators				
AEs recurrence rate (2Year)	No further loss of surgical pathology specimens since the adverse event occurred	——	0	——
Process indicators				
The post-use recognition rate of specimen vials	Measures the ability to correctly identify the state of use of each specimen vials after specimen collection	0	100	100
The printing rate of specimen identification codes	Measures how often specimen identification codes are printed correctly during specimen preparation	97	100	3
The issuance rate of preoperative pathology orders	Measurement of timely issuance of preoperative pathology slips prior to surgery	14	100	86
The rate of pre-pricing surgical pathology specimens	Measuring surgical pathology specimens at non-standardised predetermined prices	100	0	100

Abbreviation: AEs, Adverse Events.

Discussion

Clinical Implications

Our study successfully addressed the issue of lost surgical pathology specimens through systematic improvements and innovations. The investigation utilized RCA, a quality improvement tool, to examine how local specimen handling processes interact with systemic medical error management. By implementing a dual-color sealing ring system and integrating closed-loop management into our pathology specimen information system, we achieved a significant enhancement in specimen recognition and management efficiency. Following these interventions, we observed a marked increase in specimen identification accuracy and operational effectiveness across multiple quantitative metrics. Moreover, our comprehensive training initiatives and knowledge sharing efforts further reinforced these improvements within our institution and beyond, impacting a wide range of healthcare facilities. These outcomes underscore the efficacy of proactive quality management strategies in mitigating risks and enhancing patient safety in surgical pathology practices.

Surgical specimen management is a multifaceted and error - prone process from the time the surgeon identifies the need to collect a surgical specimen.[23] There are multiple steps and people involved in the specimen handling process. Errors can occur at any stage of the process, but most occur during the pre - analytical stage, ie, the period before the surgical specimen is collected until it is sent to the laboratory.[2] One study showed that the incidence of errors related to surgical specimens in the pre - analytical phase ranged from 45% to 71%.[24] Further studies have found that the most common error causing loss of surgical specimens is mixing of specimens between two patients.[25] The surgical specimen error addressed in this study also falls under the issue of specimen mixing between two patients. This is an enduring and popular topic that has prompted researchers to continue to explore and make discoveries.

Previous studies have shown that concerns about the problem of lost surgical pathology specimens usually focus on process management and joint multidisciplinary management.[26,27] To reduce this problem, previous studies have focused on measures such as overall process optimisation and improved communication.[26,27] However, these studies have mostly focused on the outcome facet indicator of surgical specimen loss rate in the presentation of results, and less on process facet specific indicators.[26–28] The innovation of this study is that it focuses on the development and implementation of systematic measures that focus on the root causes, not only optimising the process but also focusing on addressing the development of assistive technology at the operational level.

Such innovative reform measures face challenges in implementation.[29] Firstly, technological integration posed a significant hurdle. Integrating the digital closed - loop management system into the existing hospital information system required extensive technical support and coordination between different departments.[30] Compatibility issues with legacy systems led to initial delays, and ensuring data security during the transition was a constant concern. Secondly, staff resistance to change was another major challenge.[31] The introduction of new tools like the dual - color sealing rings and the revised specimen handling protocols meant that employees had to unlearn old habits and adapt to new ways of working. Some staff members were skeptical about the effectiveness of these new measures, and training them to use the new systems proficiently required substantial time and resources. Thirdly, financial constraints played a role.[32] Developing and purchasing the new sealing rings and implementing the digital tracking system required a significant investment, which had to be carefully justified within the hospital's budgetary limitations.

These challenges were highly relevant to our study as they highlight the real - world complexities of translating theoretical RCA - based solutions into practical, sustainable improvements. Understanding and addressing these barriers were essential for the successful implementation of our interventions and for ensuring that the improvements were not only effective in the short - term but also sustainable in the long - run. Unlike previous studies, our study presents findings through a three - level synthesis: outcome - level indicators, process - level indicators, and educational outreach. This multilevel presentation helps to comprehensively understand and assess all aspects of the reform measures, which in turn can more effectively promote the continuous improvement of healthcare quality management and patient safety culture.

Clinical Practices

In previous quality improvement studies of lost surgical specimens, the choice of improvement tools has shown diversity, usually including Failure mode and effect analysis (FMEA),[23] Quality Improvement (QI)[26,27] and Plan-Do-Check-Act (PDCA).[29] In this study, RCA was chosen as an improvement tool, and the methodology for applying RCA emphasises systematic analysis rather than individual responsibility, aiming to accumulate empirical data on the occurrence of events and their causes. Although many healthcare professionals have a broad understanding of RCA, there is a relative lack of practical experience.[33] Therefore, it is necessary to train the team members involved in this project on RCA-related knowledge before the study was initiated to ensure that the team was able to quickly reach a consensus and move forward with the improvement project in a robust manner.[34]

The "Swiss cheese" conceptual model and the brainstorming methodology were applied in the discussions of the quality management team. During the discussion, all team members were actively involved in analysing and determining the causes of missing surgical pathology specimens. This discussion transformed the team members from passive performers to active participants. While RCA can improve closed-loop management of surgical pathology specimens in the short term, we are more concerned with continually tracking the effects of improvement. Our long term goal is to achieve continuous improvement in organisational planning.[35]

The people involved in the RCA process need to have high standards and resource-intensive qualities.[36] This allows for a comprehensive grasp and multiple coordination when optimising the process and coordinating its advancement. The RCA team members for this project included a quality manager with a senior quality manager qualification for healthcare organisations, proficiency in RCA and other management tools, and a background in healthcare education, who was responsible for the overall facilitation and coaching of the project. Therefore, careful trade-offs are required when undertaking a comprehensive RCA improvement project in a staff-constrained organisation.

Limitations

This study has a number of limitations, as described below. First, this study was based on a single case RCA at a hospital level, and the findings are not easily transferable to a different setting or hospital. These strategies can serve as a template for other institutions to diagnose and address analogous systemic failures, even as broader validation is warranted. Future research should prioritize multi-center studies to further assess the interventions' broader feasibility. Second, the evaluation period for the effectiveness of the interventions was limited to six months, which may not fully reflect the long-term sustainability of the improvements. Third, during the research process, we did not interview patients and their families. This was mainly due to ethical and practical concerns. The sentinel event had already brought emotional stress to the patient and family, and we worried that additional interviews might cause further harm. In future research, we will design a more comprehensive approach, guided by ethics committees, to incorporate the perspectives of patients and families, aiming to gain a more complete understanding of the incident and improve our quality improvement measures from the patient - experience perspective.

Conclusion

The RCA-driven reforms effectively addressed systemic flaws in specimen management, demonstrating that targeted process redesign, ergonomic tools, and digital tracking can mitigate risks of medical errors. While the single-hospital setting and short evaluation period limit generalizability, the study highlights the value of systemic workflow analysis and provides a replicable template for other institutions to address similar issues, with broader validation needed via future multi-center research.

Data Sharing Statement

All data underlying the findings are within the paper.

Ethics Approval

The study was conducted in accordance with the Declaration of Helsinki. All research methods were performed in accordance with relevant guidelines and regulations. The study was approved by the Ethics Committee of Taizhou First People's Hospital [Ethical Approval No. 2024-KY034-01]. All participants gave verbal informed consent to participate in this study. The medical ethics committee of the authors' institution approved the verbal informed consent procedure for this study.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

This work was supported from the medical quality (evidence-based) management by the Institute of Hospital Management, National Health Commission (Project Number: YLZLXZ24G132), and the sustainable development of kang'enbei research project of zhejiang provincial hospital association (2023ZHA-KEB335). The funding bodies observed during some data collection but was not involved in the study design, analysis of data, interpretation of fndings, or writing the manuscript. No funding was received. There was no additional financial support from public or private sources.

Disclosure

The authors have declared that there are no conflicts of interest, given their final approval, and agreed to be responsible for all aspects of the work that ensures accuracy and integrity.

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