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ORIGINAL RESEARCH

Effect Analysis of the HFMEA Model Applied in Sputum Specimen Management Among Patients with Tuberculosis

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Objective: Accurate diagnosis is very important to block the transmission of tuberculosis. The quality of sputum culture affects the diagnostic accuracy. The quality of sputum samples is not optimistic. Therefore, this study investigated whether health care failure mode and effect analysis (HFMEA) can improve specimen quality and detection efficiency in sputum specimen management in tuberculosis departments.

Methods: This study is a non-randomized controlled trial study. A convenience sampling method was used to select 110 patients who visited the Department of Tuberculosis of the Second Hospital of Nanjing from September to November 2022 and December 2022 to February 2023 as the control group and the experimental group. Control groups followed standard operating procedures for sputum specimen collection. In the experimental group, HFMEA model was used to control the quality on this basis. After 3 months of intervention, the qualified rate and positive detection rate of sputum samples were compared between the two groups.

Results: A total of 634 sputum specimens were included in the experimental group and 647 in the control group. Compared with the control group, the qualification rate of sputum specimens was higher in the experimental group (84.54% vs 79.13%); the positive detection rates of the X-Pert assay (27.88% vs 16.19%), sputum culture (20.29% vs 12.68%), and sputum smear (22.29% vs 15.81%) were all higher in the experimental group (all $P < 0.05$). Patients in the experimental group had higher knowledge mastery and nurse sputum sample management scores ($P < 0.05$). However, patient satisfaction with sputum specimen management in the experimental group was lower than in the control group (7.72 ± 0.74 vs 8.38 ± 0.85, $P < 0.001$).

Conclusion: The application of the HFMEA model in sputum specimen management can effectively improve specimen quality and positive detection rates.

Keywords: healthcare failure mode and effect analysis (HFMEA), tuberculosis, sputum, nursing care, risk management

Introduction

China is one of the countries with a high burden of tuberculosis (TB) and latent *Mycobacterium tuberculosis* (MTB) infection, making TB prevention and control a herculean task. According to the 2023 Global TB Report released by the World Health Organization, it is estimated that in 2022, China had 748,000 new TB cases, 30,000 TB-related deaths, a mortality rate of 2.0 per 100,000, and the third-highest incidence rate worldwide.[1] One of the main challenges in TB management is early and accurate diagnosis. Rapid and precise laboratory diagnostic methods are crucial for the early detection and treatment of patients with TB and for preventing community transmission. Domestic research[2] has demonstrated that etiological detection and diagnosis of TB are essential for screening patients with TB, primarily involving sputum smear, sputum culture, and X-Pert MTB/RIF (rifampicin) assay, with X-Pert showing high positive detection rates, sensitivity, and specificity, thus having substantial value in TB diagnosis.

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For a long time, international guidelines for TB prevention and treatment have recommended naked-eye sputum quality as an important determinant of smear microscopy and culture performance.[3] In clinical practice, the quality of sputum specimens directly affects the accuracy of detection results, which is crucial for diagnosing diseases and prescribing medication.[4] Poor sputum samples may lead to missed TB diagnoses in all examinations because diagnostic sputum samples inevitably contain respiratory secretions from healthy airways and diseased lungs, along with varying amounts of saliva.[5] Collecting qualified sputum specimens can increase the positive rate in bacteriological tests of sputum, thereby enhancing the diagnostic rate of pulmonary tuberculosis (PTB).[6] It has been shown that the positive rate of laboratory tests for the same patient often varies, and erroneous diagnostic results are mostly caused by sticky sputum, incorrect sample size, improper filling of minicolumn reaction tubes, and issues with bubble or probe integrity.[7] Diagnostic errors not only result in valuable treatment time loss for patients but also bring financial loss to the laboratory.[8] Consequently, high-quality sputum collection training and patient nursing education play an important role in improving sputum quality, thereby minimising these errors.

The quality of submitted sputum specimens from patients with TB in China is not promising. A survey conducted in eight regions of China in 2019 showed that the qualified rate of sputum specimens was only 60%.[6] In clinical practice, sputum specimens are usually collected and submitted to the specimen cabinet or laboratory by the patients themselves after receiving oral education and sputum cups from nurses. This process is prone to errors, such as retaining unqualified specimens with insufficient salivary and sputum volume, which affects the positive rate of etiological examination.[9] Research has suggested that the lack of pre-job training for staff in the outpatient department of TB in Centers for Disease Prevention and Control and medical institutions, self-retention of sputum, inadequate nursing education, and low patient compliance are risk factors for substandard sputum quality.[10] Currently, some studies[11,12] mainly improve the quality of sputum culture through health education for nurses and patients. Although these methods show some results, they cannot intervene in the entire sampling process, and their effects are not lasting. Other studies have used the PDCA cycle,[13] the link quality management method,[14] and integrated medical and nursing concepts[15] for the management of sputum culture. Although these methods are effective, most are single-centre samples with small sample sizes, and their methods may not be applicable in this hospital. Therefore, the management model of sputum samples needs to be adjusted and updated according to local hospital conditions, and the appropriate model needs to be selected for intervention.

Healthcare failure mode and effect analysis (HFMEA) is a prospective and systematic quantitative analysis method for identifying possible failure modes of a process that can reduce potential risks through standardised assessment of risk factors.[16] Healthcare failure mode and effect analysis focuses on the modification of systematic processes, including the establishment of a failure mode and effect analysis team, drawing flow charts, exploration of potential causes and risk analysis, development of improvement plans, and effect evaluation. With the core of 'proactive prevention', it evaluates potential risks in each step of the process, detects and quantitatively analyses difficulties, and finally develops targeted improvement methods.[17] Currently, this model has been widely applied in nursing practice in areas such as needlestick injury, intravenous infusion, and radiotherapy safety, achieving substantial results.[18] To further improve the quality of sputum specimens, The Second Hospital of Nanjing has innovatively applied the HFMEA model in the management of sputum specimens from patients with TB since December 2022. This study aims to explore the effect of the HFMEA model in sputum specimen management and analyse the quality and detection efficiency of sputum specimens before and after its implementation.

Materials and Methods

Clinical Data

Sample size calculation: $n=Z_{\alpha/2}^2 p(1-p)/E^2$. n is the sample size; Z is the quantile of the standard normal distribution at the confidence level, taking 1.96; p is the possible proportion of qualified rate of sputum samples in the two groups, taking 0.8; E is the error range, taking 0.05. Finally, the required sample size for the two groups was calculated to be 246 sputum samples, respectively.

This study is a non-randomized controlled trial study. Using the convenience sampling method, we selected 110 patients who visited the Department of TB at The Second Hospital of Nanjing between September and November 2022 as the control group and another 110 patients who visited the same department between December 2022 and February 2023 as the experimental group. The inclusion criteria for the patients are as follows: (1) patients were

diagnosed with TB according to the *Diagnostic Criteria for Pulmonary Tuberculosis (WS 288–2017)*[19] prior to admission; (2) patients underwent sputum specimen testing during their hospital stay; (3) patients aged between 18 and 65 years; and (4) patients were conscious, willing to participate in this study, and signed the informed consent. The exclusion criteria included: (1) patients in a coma who could not spontaneously excrete sputum, as well as those with endotracheal intubation or tracheostomy who required sputum to be suctioned using a disposable sputum suction apparatus; (2) patients with no sputum or insufficient sputum who required induced expectoration; (3) patients with mental illness or an inability to cooperate during educational sessions provided by nurses; (4) patients who coughed up bloody sputum or had other special types of sputum; and (5) patients who refused to participate in the study.

This study adheres to the Declaration of Helsinki and received approval from the Medical Ethics Committee of The Second Hospital of Nanjing. All participants provided signed informed consent.

Intervention Methods

The control group adhered to standard operating procedures for sputum specimen collection and received routine nursing interventions. Prior to collecting sputum, a nurse provided oral health education to the patients and guided them to retain morning sputum. Patients were instructed to rinse their mouths with clean water and expectorate sputum immediately upon waking. During expectoration, patients should first take a deep breath and then cough forcefully while exhaling to expel sputum from deep within the trachea. Sputum specimens were to be submitted promptly. Nurses distributed sputum bottles to the patients, who then collected and submitted their sputum specimens directly to the specimen room or laboratory. Each patient provided three sputum specimens.

In the experimental group, interventions were made in the sputum specimen collection and transportation processes, as well as in quality control, using the HFMEA model (refer to Figure 1). The specific methods included:

1. Formation of an HFMEA team, named ‘Guardian Circle’, comprising six members from the nursing department (including two directors, one head nurse, one chief nurse, and two clinical nurses), one public health department worker, one laboratory physician, and the chief physician from the Department of TB, making a total of nine members. All team members were trained in HFMEA knowledge and passed a theoretical assessment with a score of ≥85%.

2. After conducting a literature search for the best evidence-based practices in both Chinese and English databases, the team employed brainstorming to sort and revise the procedures for sputum specimen collection, management, and quality standards. The process steps were further refined, culminating in the identification of three main processes and 16 sub-processes, as illustrated in Figure 2.

3. The HFMEA team performed a failure analysis to identify the causes and processes involved in the failures. Through brainstorming, potential failure modes were identified, and the risk priority number (RPN) was calculated by multiplying the severity (S), occurrence (O), and detectability (D) of each failure mode, ranging from a minimum of 1 to a maximum of 1,000. For each failure mode, team members jointly evaluated the S, O, and D values and calculated RPN = S × O × D. Failure modes with RPN values ≥125 were prioritised for the control, as depicted in Table 1.

4. Improvement plans and measures were developed using root cause analysis: (1) After being retained by the patients or collected by nurses, sputum specimens were placed in a specialised specimen transport box and submitted to the TB laboratory within 1 hour. In cases where timely submission was not possible, the specimens were temporarily stored at 4°C in a refrigerator for no more than 24 hours. The person submitting the specimens ensured their handover to laboratory staff, an accountability system was established, and regular inspections were conducted to optimise the process of collecting and transporting sputum specimens. Subsequently, the sputum specimen management system was revised. (2) A quality control process for sputum specimens was established, including standardised continuous observations at 24, 48, and 72 hours after specimen retention or collection. A quality control inspector (charge nurse) was assigned to visually inspect the sputum specimens daily to confirm their qualification before submission. (3) Patients were urged to retain two spot sputum specimens as needed on the day of admission.[20] Within 1 week of admission, tests, including sputum smear testing, MTB DNA detection, X-Pert assay, and detection of drug-resistant genes in MTB, were performed. A tracking and feedback system was also established. (4) A comprehensive sputum specimen control form was prepared, and daily inspections were carried out by the charge nurse, covering four areas: knowledge education (explaining the purpose and significance of retaining sputum and methods for 24-hour and spot sputum retention); specimen collection (use of specialised containers,

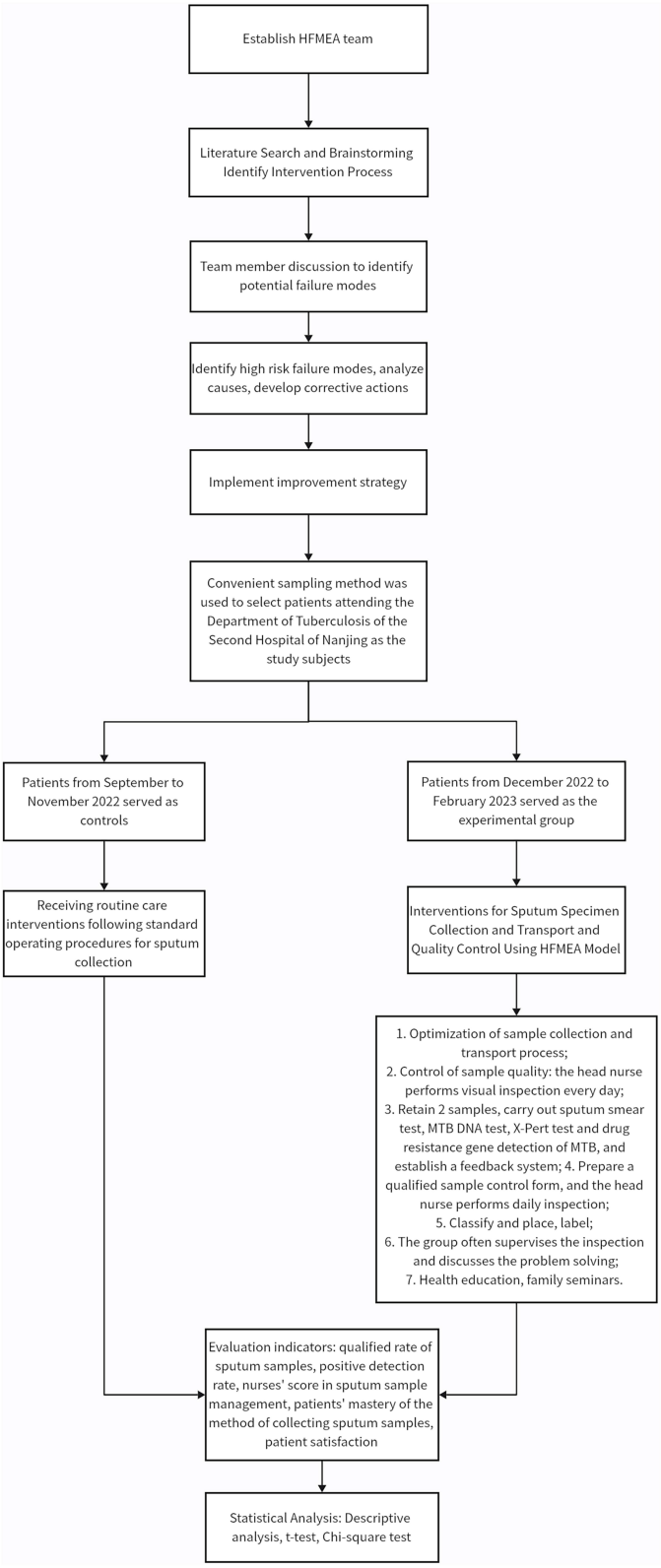

Figure 1 Experimental Flow Chart.

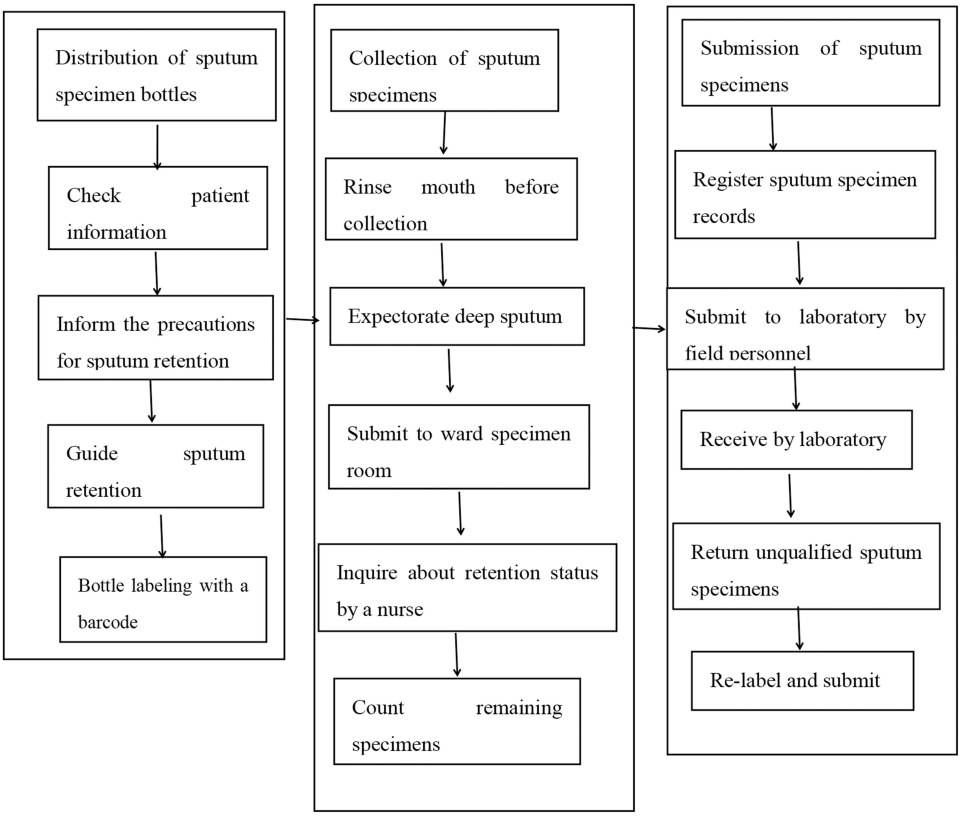

Figure 2 Sputum specimen distribution, collection, and submission process in HFMEA mode.

mouth rinsing prior to retention, methods of sputum retention, and sample size necessary); specimen submission (visual inspection prior to submission and timely submission of various sputum specimens); and tracking and feedback (managing the retention, submission, and inspection of specimens, promptly reprinting barcodes for unqualified specimens, and swiftly implementing corrective actions when necessary). (5) For patients with no sputum or only small amounts, medical staff intervened early and employed techniques such as sputum induction, fiberoptic bronchoscopy, and chest physical therapy-assisted sputum aspiration to facilitate collection.[21] (6) Based on practical clinical needs, a sputum specimen storage box was used to categorise and store specimens, equipped with labels indicating sputum volume. Specimens were prioritised according to medical advice, incorporating tests such as gene detection in MTB, ordinary sputum fungal culture, drug sensitivity, and drug-resistant gene detection in MTB. This method was simple and clear, preventing errors such as specimen mix-ups and labelling mistakes typically caused by storing specimen bottles in sealed plastic bags. (7) Specific sensitive indicators for TB were defined, prompting regular supervisory visits, discussions, and timely provision of solutions to any emerging issues. Regular assessments of nurses' knowledge related to sputum specimens were conducted to ensure competency. (8) Multiple educational methods were adopted to enhance patient and family cooperation, including the development of educational videos on sputum specimen procedures and aerosol inhalation techniques. Regular symposia for patients and their families were held to stress the importance of timely sputum specimen retention, thereby increasing awareness and engagement.[22,23]

Detection Methods

International universal sputum bottles with screw caps were uniformly adopted as containers for retained sputum specimens. After the collection and submission of sputum specimens from participants, qualified inspectors conducted sputum smear microscopy, solid culture of MTB in sputum specimens, and an X-Pert assay. The results were recorded and determined based on the *Diagnostic Criteria for Pulmonary Tuberculosis (WS 288–2017)*.[19]

Table 1 Analysis of failure modes of sputum specimens

High-risk process	Failure mode	Failure cause	Risk analysis before improvement			
			S	O	D	RPN
1D. Bottle labeling with a barcode	1D1 Labeling error	Failure to conscientiously implement the checking system	7.9	8.0	6.4	404.48
1E. Bagging of sputum specimen bottles	1E1 Bagging error	Lack of clearly labeled carrier for specimen bottles	8.9	7.8	6.4	444.29
2B. Mouth rising before collection	2B1 No mouth rising	Inadequate education on sputum retention	6.4	7.7	3.7	182.34
2C. Deep sputum expectoration	2C1 Insufficient sputum expectoration	Patient with an inability to cough or no sputum	8.0	6.4	2.9	148.48
2F. Remaining specimen counting	2F1 No counting	Nurse with a lack of a sense of responsibility	6.3	7.8	3.7	181.81
3C. Reception by laboratory	3C1 No timely reception of sputum specimens	Human factor	6.2	7.8	4.9	236.96
	3C2 Long submission duration of sputum specimens	Systemic factor				
3D. Returning of unqualified sputum specimens	3D1 Unqualified sputum specimens	Inadequate education and insufficient sputum	9.2	3.8	4.4	153.82

Abbreviation: RPN, Risk Priority Number; S, Severity; O, Occurrence; D, Detectability.

Observation Indicators

1. Qualification rate of sputum specimens: This rate was calculated by dividing the number of qualified sputum specimens submitted by patients by the total number of sputum specimens submitted. Qualified sputum specimens were defined as purulent, cheese-like, or mucopurulent, with a volume of 3–5 mL and no contamination.[19]
2. Positive detection rate: The positive detection rate was calculated by dividing the number of positive sputum specimens identified in sputum smear microscopy, solid culture of MTB, and X-Pert assay by the total number of submitted sputum specimens.
3. Nurses' scores in sputum specimen management: Theoretical and practical skill assessments were conducted for nurses involved in sputum specimen management using self-designed questionnaires and assessment items. The theoretical assessment covered sputum specimen collection methods and precautions, whereas the practical skill assessment included throat swab operations and sputum specimen collection. To mitigate learning effects, the nursing staff in the control and experimental groups did not overlap.
4. Patients' mastery of sputum specimen collection methods: Patients in both groups were surveyed using a unified self-made questionnaire on sputum specimen collection knowledge. This mainly covered methods of mouth rinsing before sputum retention, coughing techniques, and sputum retention, as well as the timing of specimen submission. Each item was scored out of 100, ensuring high reliability and validity.
5. Patient satisfaction: Patients in both the control and experimental groups rated their overall satisfaction with the management of sputum specimens using anonymous scoring. The total score was out of 10, where a score ≥6 indicated high satisfaction, a score of 3–5 indicated satisfaction, and a score ≤2 indicated dissatisfaction. Overall satisfaction was calculated as ([the number of highly satisfied patients + the number of satisfied patients] / the total number of patients) × 100%.

Statistical Methods

Data were analysed using SPSS version 19.0. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$) while counting data were expressed as either a number (n) or percentage (%). The independent sample *t*-test was utilised for inter-group comparisons of measurement data that conformed to normal distribution. Inter-group comparisons of counting data were performed using the χ^2 (chi-square) test. All tests were two-tailed, and a *P-value of less than 0.05* was considered statistically significant.

Results

General Demographic Characteristics

A total of 110 patients, contributing 634 sputum specimens, were included in the experimental group, whereas another 110 patients, contributing 647 sputum specimens, comprised the control group. Baseline data, including gender, age, educational level, BMI, marital status, course of disease, time of onset, and underlying diseases, showed no statistically significant differences between the two groups ($P > 0.05$), as indicated in Table 2.

Comparison in Qualification Rate of Sputum Specimens

Inter-group comparison results demonstrated that the qualification rate of sputum specimens in the experimental group was higher than that in the control group (84.54% vs 79.13%), with a statistically significant difference ($P < 0.05$), as shown in Table 3.

Comparison of Positive Detection Rate

Comparisons of the positive detection rates revealed that the rates for X-Pert assay, sputum culture, and sputum smear in the experimental group were all higher than those in the control group, with statistically significant differences (27.88% vs 16.19%, 20.29% vs 12.68%, and 22.29% vs 15.81%, respectively; $P < 0.05$), as displayed in Table 4.

Table 2 General demographic characteristics between the two groups

Basic information	Experimental group (n=110)	Control group (n=110)	t/X^2	*P*
Gender			0.294	0.587
Male	63(57.27%)	59(53.64%)		
Female	47(42.73%)	51(46.36%)		
Age (year)	48.39±20.46	46.44±19.13	4.311	0.233
BMI (kg/m^2)	22.13±5.62	23.02±4.23	2.787	0.656
Educational level			4.242	0.236
Primary school	12(10.91%)	22(20.00%)		
Junior high school	28(25.45%)	23(20.91%)		
Senior middle school	36(32.73%)	29(26.36%)		
Bachelor's degree or above	34(30.91%)	36(32.73%)		
Marital status			2.055	0.358
Unmarried	24(21.82%)	24(21.81%)		
Married	83(75.45%)	82(74.55%)		
Others	3(2.73%)	4(3.64%)		
Course of disease (month)	6.32±5.41	7.11±5.21	2.653	0.566
Time of onset			0.33	0.565
Initial onset	76(69.09%)	72(65.45%)		
Recurrent onset	34(30.91%)	38(34.55%)		
Complication			0.018	0.893
No complication	51(46.36%)	52(47.27%)		
Other complications	59(53.64%)	58(52.73%)		

Abbreviation: BMI, Body Mass Index.

Table 3 Comparison in qualification rate of sputum specimens between the experimental group and the control group

Group	Total number of sputum specimens		Total
	Unqualified	Qualified	
Control group	135(20.87%)	512(79.13%)	647
Experimental group	98(15.46%)	536(84.54%)	634
X^2	6.961		
P	0.008*		

Note: *indicates that there is statistically significant difference in this observation indicator between the two groups(*P* <0.05).

Table 4 Comparison in positive detection rate of sputum specimens between the two groups

Item	X-Pert		Sputum culture		Sputum smear		Total number of sputum specimens
	Positive	Negative	Positive	Negative	Positive	Negative	
Control group	17(16.19%)	88(83.81%)	27(12.68%)	186(87.32%)	52(15.81%)	277(84.19%)	647
Experimental group	29(27.88%)	75(72.12%)	42(20.29%)	165(79.71%)	72(22.29%)	251(77.71%)	634
X^2	4.163		4.432		4.451		
P	0.041*		0.035*		0.035*		

Note: *indicates that there is statistically significant difference in this observation indicator between the two groups(*P* <0.05).

Comparison of Nurses' Comprehensive Scores in Sputum Specimen Management

A comparison of the comprehensive scores for sputum specimen management between the two groups indicated that the theoretical scores, throat swab operation scores, and sputum specimen collection operation scores in the experimental group were all higher than those in the control group, showing statistically significant differences ($P < 0.05$), as seen in Table 5.

Comparison of Patients' Mastery of Sputum Specimen-Related Knowledge

A comparison between the two groups showed that the experimental group scored higher in the areas of mouth rinsing method, effective coughing method, correct sputum retention method, and timely specimen submission. These results were significantly higher than those of the control group, with statistical significance noted ($P < 0.05$), as detailed in Table 6.

Comparison of Patient Satisfaction with Sputum Specimen Management

Patient satisfaction with sputum specimen management was compared between the two groups. The satisfaction score for the experimental group (8.38 ± 0.85) was higher than that of the control group (7.72 ± 0.74), showing a statistically significant improvement ($P < 0.001$), as shown in Table 7.

Table 5 Comparison of nurses' comprehensive scores in sputum specimen management between the experimental group and the control group ($\bar{x} \pm s$)

Item	Theoretical score of sputum specimens	Throat swab operation score	Sputum specimen collection operation score
Control group	77.06±12.27	88.40±9.87	88.9±11.72
Experimental group	88.26±18.42	92.36±10.11	97.66±14.35
t	6.182	3.271	5.338
P	0.002*	0.039*	0.003*

Note: *indicates that there is statistically significant difference in this observation indicator between the two groups(P <0.05).

Table 6 Comparison of patients' mastery of sputum specimen-related knowledge between the two groups ($\bar{x} \pm s$)

Item	n	Mouth rinsing method	Coughing method	Sputum retention method	Submission duration
Control group	110	91	74	73	91
Experimental group	110	104	91	99	103
X^2		7.627	7.006	18.014	6.281
P		0.006*	0.008*	<0.001*	0.012*

Note: *indicates that there is statistically significant difference in this observation indicator between the two groups(P <0.05).

Table 7 Comparison of patient satisfaction with sputum specimen management between the two groups

Group	Satisfaction	t	P
Control group	7.72±0.74	-6.181	<0.001*
Experimental group	8.38±0.85		

Note: *indicates that there is statistically significant difference in this observation indicator between the two groups(P <0.05).

Discussion

HFMEA is a management method that reduces the occurrence of medical risk events and enhances the quality of medical services by verifying and optimising the risk processes in medical services.[24] Characterised by proactive prevention, it has been widely applied in medical fields such as the management of patients undergoing dialysis, control of multidrug-resistant bacterial infections in ICUs, management of emergency patient transfers, treatment of stroke emergencies, operating room management, and safety management in radiotherapy, among others. It is one of the most effective methods for optimising workflow. In previous quality control management of sputum specimens from patients with TB, integrated medical care, comprehensive and reasonable intervention, and quality control circles were adopted.[25–28] However, there has been no relevant research on the application of the HFMEA model. The present study innovatively applied this model to the quality control management of sputum specimens from patients with TB. The results demonstrated that this model had certain advantages in improving the qualification rate and positive detection rate of sputum specimens, the knowledge mastery level of nursing staff and patients, and patient satisfaction.

Sputum examination is crucial for the diagnosis of TB.[29] Timely detection of patients with TB who test positive for MTB and drug-resistant MTB can facilitate the early implementation of the directly observed therapy short-course strategy and treatment for drug-resistant TB, thereby controlling the disease's development at an early stage.[30] Our results revealed that after implementing HFMEA management, the qualification rate of sputum specimens substantially increased. Previous studies have shown that the implementation of targeted interventions and precise health education programmes for patients with PTB before sputum collection is essential for enhancing the quality of sputum specimens and the accuracy of diagnoses. Traditionally, sputum specimen management involved a single session of health education conducted by nurses, often perfunctorily, resulting in patients struggling to master effective coughing and expectoration techniques, lacking TB-related knowledge, showing poor compliance with sputum collection, and producing low-quality sputum samples. Furthermore, the coordination and division of responsibilities within traditional management departments are often inadequate, making the sputum specimen management process unreasonable. This can lead to delays in sputum collection, delayed intervention measures, and nurses' inability to supervise effectively. Under the HFMEA model, complex, high-risk failure modes are quantified and graded through RPN calculation, and potential high-risk factors are identified predictably and corrected, thereby maximising the safety of the medical process and mitigating the impact of risk factors.[31] All team members in this study had extensive experience in sputum specimen management, participated in HFMEA training, and passed assessments before its implementation. During the HFMEA implementation, the team members analysed and discussed the processes of sputum specimen retention and submission for patients with TB through brainstorming. Three main processes and eight high-risk failure modes were identified, including incorrect labelling of sputum specimen bottles, improper packaging of sputum specimen bottles, patients failing to rinse their mouths before collection, inadequate coughing by patients, failure of nurses to account for remaining sputum specimens after collection, delays in submitting and receiving sputum specimens, and unqualified sputum specimens. For these high-risk issues, the team members proactively raised awareness to avoid problems. This management strategy now appears to fully engage the nurses, thereby improving the quality of sputum specimens.

In the control group, the positive detection rate of the X-pert assay was only 16.19% (17/105), whereas the positive detection rate of the sputum smear for MTB stood at 15.8% (52/329). In the experimental group, the positive detection rate of the X-Pert assay increased to 27.88% (29/104), and that of the sputum smear for MTB rose to 22.29% (72/323). The positive detection rate and qualification rate of sputum specimens in the experimental group were both substantially higher than those in the control group, underscoring that HFMEA management effectively improves both the quality and positive detection rate of sputum specimens. In this study, not only were the collection and transport processes of sputum samples optimised, but the sputum sample management system was also revised, and a sputum sample quality control process was established, rendering the sputum culture management process more scientific and standardised, thus enhancing the positive detection and qualification rates of sputum samples. Simultaneously, this study established specific sensitive indicators for TB, organised groups for regular supervision and inspection, held discussion meetings, and provided timely countermeasures and solutions to any emerging problems. Through regular summarisation and feedback by the group, the focus of improvement at each stage was clarified, enabling continuous enhancement of nursing quality.[32] Although previous studies have not applied the HFMEA model to sputum

culture management of TB, they have demonstrated substantial improvements in other areas, enhancing the quality of care and nursing satisfaction. Jin Yanling et al[33] applied the HFMEA management model in mechanically ventilated children, showing that this approach could shorten the duration of mechanical ventilation and hospital stay, improve blood gas analysis indicators, reduce the incidence of complications, and enhance parental satisfaction, outperforming conventional nursing. Wang Huan[34] utilised the HFMEA model to prevent medical adhesive-related skin injury during PICC catheterisation in patients with breast cancer. The results indicated that the HFMEA model could minimise the occurrence and severity of MARSI, delay the onset of MARSI, and improve both patient satisfaction and nursing quality. The HFMEA model enhances the quality of sputum specimen management by optimising management processes and integrating optimal solutions, benefiting both patients and hospitals and holding promotional value in clinical practice. Moreover, in our study, the comprehensive performance of nurses in sputum specimen management and patient satisfaction with sputum specimen management exhibited substantial differences before and after implementing this model, reflecting the personalised and patient-centred nursing principle and enhancing both nursing care technology and patient satisfaction. Regular seminars were held for patients and their families to communicate relevant precautions and strengthen communication with their families, thereby improving the communication effect and increasing trust and cooperation with nursing staff, thus enhancing nursing satisfaction.

This study has several limitations. First, it is a single-centre study with all samples sourced from the same hospital, which may limit the generalisability of the findings. Additionally, the study did not include other types of specimens, such as blood and other pathological samples, in the process management. Finally, the participants of the experimental and control groups were not recruited during the same period, which could introduce biases in the results. In future work, we aim to enhance the tracking management of HFMEA processes and conduct studies across multiple departments and with various sample types to ensure the scientific integrity of process quality improvements.

Conclusion

In conclusion, the optimisation of the sputum specimen management process for patients with TB, based on HFMEA, can identify the failure points in the existing sputum specimen management process and formulate corresponding process improvement measures. This approach effectively improves the qualification rate and detection accuracy of sputum specimens. Additionally, it enhances patients' understanding of sputum specimen-related knowledge and their satisfaction, ensuring the quality of the specimens. Consequently, this can improve the accuracy of TB diagnosis and help to prevent the transmission of the disease.

Data Sharing Statement

All data generated or analyzed during this study are included in this published article.

Ethics Approval and Consent to Participate

This study was conducted in accordance with the declaration of Helsinki.This study was conducted with approval from the Ethics Committee of The Second Hospital of Nanjing, Nanjing University of Chinese Medicine.Written informed consent was obtained from all participants.

Consent for Publication

The manuscript is not submitted for publication or consideration elsewhere.

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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.

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Disclosure

The authors declare that they have no competing interests in this work.

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