ORIGINAL RESEARCH

Application of Multidimensional Quality Management Tools in the Management of Medical Adverse Events

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Purpose: This study aims to investigate the impact of multidimensional quality management tools in establishing a medical adverse event management system, with the aim of continuously improving medical quality and safety while ensuring patient well-being.

Methods: This study introduces risk management theories, such as the "Gray Rhino Theory", and employs quality management tools like the Plan-Do-Check-Act (PDCA) cycle, Quality Control Circle (QCC), and Root Cause Analysis (RCA), to provide relevant quality management education and training to employees. This approach facilitates the establishment of a medical adverse event management system that encourages reporting and fosters a blame-free reporting culture, while simultaneously implementing quality management across the entire process. The regular utilization of the QCC facilitates ongoing quality improvement. Furthermore, for sentinel events and patient harm incidents with educational values, the study employs the Incident Decision Tree (IDT) to determine appropriate actions. Additionally, the hospital initiates RCA for system-wide improvements, focusing on areas such as management, institutional processes, and environmental aspects. Moreover, an internal medical quality improvement case competition is organized, with outstanding cases being selected to participate in the multidimensional quality management competition organized by the National Quality Management Alliance.

Results: The study reveals a significant improvement in employees' awareness of adverse events, the percentage of employees reporting adverse events increased significantly from 39.15% in 2019 to 49.77% in 2022, P=0.002. Furthermore, the adverse event reporting rate has risen significantly from 2.78% (2019) to 5.96% (2022), P=0.002. Additionally, each department has been able to utilize QCC or RCA tools for quality improvement, thereby further reinforcing the development of a patient safety culture.

Conclusion: Multidimensional quality management tools play a crucial role in establishing a hospital's adverse event management system, promoting continuous improvement in medical quality, ensuring patient safety, and effectively implementing a culture of patient safety.

Keywords: multidimensional quality management tools, adverse events, management system, patient safety

Introduction

Patient Safety Culture (PSC) denotes a collective behavioral pattern within an organization, where members share common values and behaviors aimed at minimizing harm to patients through ongoing education, training, and process optimization.[1] In both 2021 and 2022, the National Health Commission of China issued documentation for "Goals for Improving Medical Quality and Safety", which emphasized the objective of increasing the reporting rate of adverse events. This underscores the significance of patient safety as a critical challenge in the medical services domain, garnering considerable attention at the national level. To address this, embracing modern hospital quality management concepts and establishing a scientific adverse event management system, fostering proactive reporting, and adopting a non-punitive approach holds immense importance in enhancing medical quality, boosting patient satisfaction, and ensuring patient safety.

The current understanding of PSC in the healthcare system, as well as the tools that have been utilized for the evaluation of PSC is limited.[2] An inappropriate medical practical could lead to disability or even death to patients.[3] Currently, several instruments commonly used for the evaluation of PSC in a hospital scenario, including the Hospital Survey on Patient Safety

Culture (HSPSC),[4] the Safety Attitudes Questionnaire (SAQ),[5] the Patient Safety Climate in Health Care Organizations (PSCHO),[6] the Modified Stanford Health Assessment Questionnaire (MSHAQ),[7] and the Scottish Hospital Safety Questionnaire (SHSQ).[8] However, considering the differences in beliefs, attitudes, norms, and values between China and other countries, a Chinese version of the Hospital Survey on Patient Safety Culture (HOSPSC) may be more suitable for our study.[9]

Apart from the suitable instrument, education on PSC is also important. Ziema et al showed that patient safety education remained the priority for medical workers, and they suggested that an online and freely accessible curriculum is required.[10] Han et al evaluated the PSC in a nurse population and showed that a higher score on "communication openness" was correlated with fewer pressure ulcers and falls, while a better "working in teams with other health professionals" was significantly correlated with reduced pneumonia in patients. These results indicated that PSC is correlated with adverse medical events, and education on PSC is of urgent need.

To conduct an investigation into the PSC at our hospital, we performed a comprehensive and in-depth analysis from various aspects, including medical quality, related processes, patient demands etc. This investigation revealed deficiencies in the awareness of adverse events, adverse event management systems, adverse event management processes, quality indicator evaluation systems, and continuous improvement of adverse events among employees. These deficiencies impeded the timely detection and management of quality defects and potential risks through adverse event management. Therefore, it becomes imperative to introduce multidimensional quality management tools and establish a scientific adverse event management system. This study presents a summary of the management experience in improving the rate of adverse event reporting at our hospital from 2019 to 2021, with the aspiration of providing ideas and practical methods to other psychiatric hospitals in the realm of adverse event management and patient safety management.

Materials and Method

Study Design and Population

This cross-sectional study enrolled PSC among employees at the Guizhou Mental Health Center (Guizhou, China). Two surveys were conducted, one before program implementation and the other after the program implementation. The distribution and collection of questionnaires were preformed using QuestionStar, an online questionnaire platform. The Inclusion criteria were: (1) have obtained the corresponding practice certificate; (2) A labor contract has been signed with the unit; (3) Informed consent, willing to participate in the investigation. The Exclusion criteria were: (1) rehired employees; (2) Employees on probation; (3) Employees who are not on the job for further study, sickness, maternity, personal leave, etc. This study was approved by the Ethics Committee of the Second People's Hospital of Guizhou Province (ID: Human ethics [2021]99).

Research Methods

Questionnaire

General Information. In January 2019 and February 2022, two surveys on PSC were conducted, resulting in 401 and 426 valid questionnaires, respectively. The survey questionnaires comprehensively covered basic information about employees, including gender, age, education level, professional title, position, workload, years of professional experience, and direct patient contact status. PSC Survey Questionnaire. For this study, we used the Chinese version of the Hospital Survey on Patient Safety Culture (HOSPSC), which was developed by the Agency for Healthcare Research and Quality (AHRQ) in the United States.[9] This questionnaire has demonstrated good reliability and validity. The questionnaires was distributed and rated on a Likert 5-point scale, from "strongly disagree" to "strongly agree". "Strongly agree" or "always agree" or "often" in the options are positive responses, and the positive response rate (number of positive responses/number of responses) was calculated for each entry. Areas of advantage were identified by a positive response rate higher than 75% and a total score of ≥4. On the other hand, areas requiring improvement were determined by a positive response rate lower than 50% and a total score of ≤3.5.[11] The dimensions assessed in the survey included the frequency of reporting adverse events and the overall awareness of patient safety.

Related Definition. As defined by the "Group Standard of the Chinese Hospital Association", medical safety (adverse) events, commonly known as adverse events, encompass incidents that have caused or have the potential to cause adverse effects on patient safety, healthcare personnel safety, and the safety of medical institutions during the operation and medical activities of a medical institution.[12] The adverse event reporting rate is calculated by dividing the number of actively reported adverse events within a specific period by the total number of discharged patients during the same period. This result is then multiplied by 100% to express the reporting rate as a percentage.

Implementation Method

The first questionnaire investigation commenced in January 2019, based on its findings, a series of continuous education courses were implemented to address various issues, including the frequency of adverse event reporting, non-punitive responses, and overall awareness of patient safety. These improvements aimed to establish a comprehensive adverse event management system within our hospital. In February 2022, the second investigation was launched, and results were used for the analysis of the effectiveness of the implemented improvements. Additionally, this investigation assessed the value of employing multidimensional quality management tools in medical adverse event management.

The specific process of constructing the adverse event management system involved four stages: introducing multi-dimensional quality management tools, providing education and training, implementing the system in departments, and ensuring continuous improvement. Throughout this process, the Plan-Do-Check-Act (PDCA) was integrated, ensuring a systematic and iterative approach to building the adverse event management system. The Quality Control Circle (QCC) was used to improve the quality of common defects in the process, while Root Cause Analysis (RCA) was employed to investigate and improve incidents after they occurred.

Theoretical Introduction

We conducted comprehensive lectures for all hospital staff, introducing the "Gray Rhino Theory", "Hein Principle", and "Accident Iceberg Theory". The purpose of these lectures was to raise the awareness that medical quality can be measured, and defects can be detected among employees. By promptly identifying, reporting, and actively managing minor incidents in the early stages, a significant reduction of the potential impact of later severe patient harm incidents which is often referred to as "Black Swan events" could be achieved. These proactive approaches to incident management can also help control medical risks at minimal costs. We emphasized the crucial value of proactive reporting of adverse events in medical quality and safety management.

Tool Training

A series of quality management training and education sessions were conducted within the hospital to cultivate professionals in each department specializing in quality management. The training program included courses such as "Introduction to Hospital Quality Management", "Design and Monitoring of the Medical Quality Indicator System", "Statistical Analysis of Medical Quality", "Medical Document Review", "New and Old Seven Quality Management Tools", "Adverse Event Management", "Root Cause Analysis", and "Quality Control Circle", among more than twenty other courses.

Project Implementation

Information Transformation: The hospital implemented a management information system for adverse events, replacing the previous manual paper-based reporting system with a more efficient system-based reporting mechanism. 2) Revision of the "Adverse Event Reporting Management System": In alignment with the new information system, the reporting process was optimized to encourage non-punitive reporting. To incentivize reporting, a reward of 20 yuan was given for each reported adverse event. 3) Practical Application of Quality Improvement Tools: Following training, the Quality Management Office guided each department on quality improvement projects, with a focus on utilizing quality control circles as the main tool. Specialized guidance was tailored to each department based on their project implementation progress, ensuring effective application of quality control tools. Additionally, an annual internal quality improvement case competition was organized, and outstanding projects were selected to participate in the annual Quality Control Circle competition organized by the China Quality Management Association. In case of internal incidents during the

implementation process, a root cause analysis team was promptly formed, and the Quality Management Office supervised the analysis process, ensuring comprehensive evaluation and sharing of analysis reports internally.

Hosting an Internal Medical Quality Improvement Case Competition

As part of the implementation process of multidimensional quality management tools and the establishment of the adverse event management system, we conduct an annual internal medical quality improvement case competition. Each year, nearly 30 teams representing various departments, including clinical, nursing, administrative, and logistics units, participate in the competition. Our hospital's project titled "Reducing the Rate of Suicides and Self-harm among High-Risk Patients" received the Excellent Award in the 7th National Quality Management Circle Competition, showcasing the effectiveness of our efforts in improving medical quality and safety.

Statistical Analysis

Statistical analyses were performed with SPSS 24.0 (IBM Corp., Armonk, N.Y., USA). Counting variables are presented as n, (%). Continuous variables were described as mean±SD for normally distributed variables. For nonnormally distributed variables (tested with the Shapiro–Wilk test), median and interquartile range with equivalent comparison tests were used. Categorical/binomial variables were expressed as absolute values and percentages and compared with $\chi2$ or Fisher exact test as appropriate. Student's *t*-test was used to analyze the data before and after the investigation, A 2-sided value of $P<0.05$ was considered significant.

Results

Implementation Effects

Cognitive Improvement

After three years of project implementation, we conducted another survey on PSC in February 2022. The investigation data on the number of adverse event reports in the past 12 months indicated significant improvements. In 2019, 39.15% (157/401) of employees reported one or two adverse events, and 10.97% (44/401) of employees reported three or more adverse events. In the 2022 survey, 49.77% (212/426) of employees reported one or two adverse events, and 14.55% (62/426) of employees reported three or more adverse events, respectively, reflecting a 14.2% increase in the proportion of employees actively reporting adverse events. Also, from 2019 to 2022, the positive response rate for overall evaluation increased from 64.33% to 82.63%, the positive rate for the perception of safety increased 11.1% (72.76% in 2019 vs 83.86% in 2022) while the positive rate for Frequency of Adverse Event Reporting increased 11.57% (56.11% in 2019 vs 67.68% in 2022). The improvement effects on PSC survey dimensions is shown in Table 1. A *T*-test was used to analyze the item scores in 2019 (3.66±0.22) and 2022 (4.04±0.21), the P-value was 0.002, which indicated a significant improvement in item score in 2022 (Table 2).

Implementation and Reporting Quantity

During the project implementation period, the number of reported adverse events increased gradually to approximately 200 per quarter. After the project, the adverse event reporting rate and the adverse event reporting rate in our hospital were compared to the data from the annual Medical Quality and Safety Report released by the National Health and Health Commission. The comparison showed that the reporting rate in our hospital far exceeded the nationwide average levels. From 2019 to 2022, the adverse event reporting rates in our hospital were 2.78%, 5.73%, 5.96% and 3.67%,

Table 1 Comparison of Improvement Effects on PSC Survey Dimensions

Dimension	Item Score		Positive Response Rate	
	2019 (n=401)	2022 (n=426)	2019	2022
Overall Evaluation of Safety	3.85±0.86	4.28±0.84	64.33%	82.63%
Perception of Safety	3.66±1.11	4.04±1.09	72.76%	83.86%
Frequency of Adverse Event Reporting	3.57±1.19	3.88±1.18	56.11%	67.68%

Table 2 *T*-Test of Item Score Between 2019 and 2022

	2019	2022	t	P
Item score, mean±SD	3.6635±0.2179	4.0416±0.2145	−3.3033	0.0016

respectively. From January to June 2022, after the implementation of the project, the adverse event reporting rate remained high at 3.15%. These results indicated that after the introduction and continuous implementation of the multi-dimensional quality management tool, adverse event reporting can be maintained at a high level. Figure 1 illustrates the quantity of proactive reporting of adverse events before and after the implementation of the project (from January 2019 to June 2023).

## Comparison of Adverse Event Reporting by Severity Level

We further conducted a categorization of the adverse events reported by employees based on their severity levels. From July 2019 to December 2022, the number of adverse events reported gradually increased, especially for Grade III and IV adverse events, and this trend was maintained from January to June 2023. Figure 2 presents the distribution of adverse events by severity level over the past five years.

Analysis of Employees Who Actively Reported Adverse Events

From a job type perspective, in both 2019 and 2022, nurses contributed most actively reported adverse events, the proportion was 69.43% in 2019 and 74.06% in 2022. This was followed by doctors of 17.20% in 2019 and 19.34% in 2022. These results indicated that nurses and doctors are still the main providers of reported adverse events, and the active reporting of adverse events still relies on clinical work.

According to the analysis of working years, employees with working experience of 4–10 years in both the 2019 survey and 2022 survey reported the most adverse events (56.69% in 2019 and 49.06% in 2022), followed by employees with working experience of 1–3 years and employees with working experience less than 1 years. We also noticed that medical workers with more than 15 years reported the least adverse events. Previous analysis showed that employees with a working life of less than 1 year exhibit a low proportion of reports rate, which was partially due to a lack of working experience, understanding of patient safety and concerns about active reporting of adverse events without responsibility. However, employees with a working experience of more than 11 years, they tend to report fewer adverse events because they are skilful and can handle most adverse events. Therefore, we recommended that in the future patient
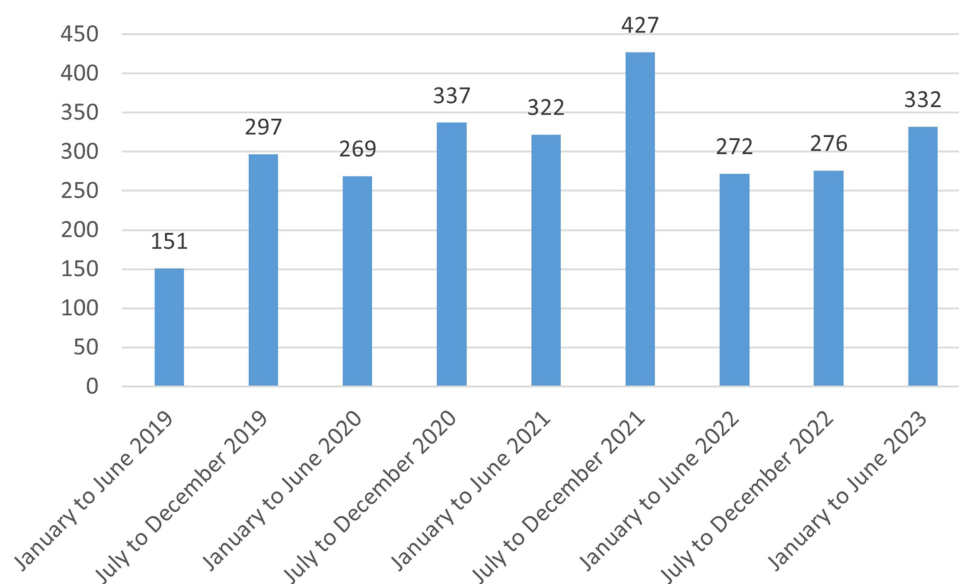
Figure 1 Number of adverse event reports before and after implementation.
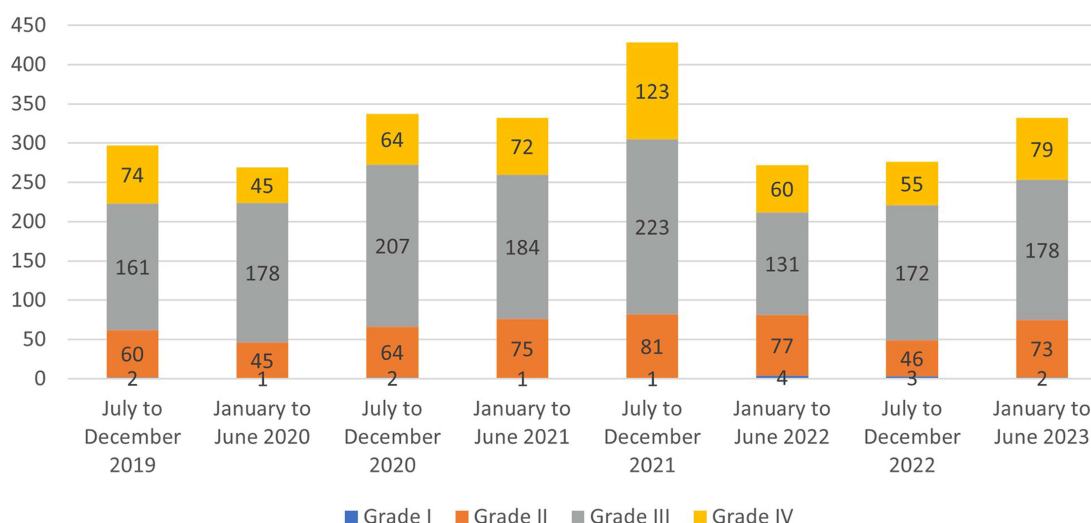
Figure 2 Number of reported adverse events by severity level over the past five years.

safety-related education and training should be focused on young employees with less than 1 year of working experience and experienced workers with more than 11 years of working experience. The specific distribution of reports is shown in Table 3.

RCA Case

During the establishment of our hospital's adverse event management system, a severe adverse event occurred, an inpatient chose to end his life by hanging himself. A RCA team within that department was formed immediately after the incident, and technical guidance was provided by the Quality Management Office. This team consisted of members from the involved department, as well as personnel from the medical, nursing, administration, logistics, and security departments.

The event was classified as a sentinel event based on the Sentinel Adverse Event Classification (SAC) matrix, which necessitated an RCA. According to the Incident Decision Tree (IDT) method, the event was identified as a system problem, ruling out any individual factors contributing to its occurrence.

Table 3 Distribution of Actively Reported Adverse Events

Survey Category	2019 (n/%)	Proactive Reporting (%)	2022 (n/%)	Proactive Reporting (%)
Job Type				
Doctor	110 (27.43)	17.20	119 (27.93)	19.34
Nurse	230 (57.36)	69.43	221 (51.88)	74.06
Medical technician	19 (4.74)	7.01	31 (7.28)	5.19
Hospital Manager	20 (4.99)	5.10	14 (3.29)	2.83
Logistical personnel	21 (5.23)	1.27	41 (9.62)	0.47
Years of Work in Department, years				
≤1	37 (9.23)	3.82	33 (7.75)	4.25
1–3	68 (16.96)	36.30	84 (19.72)	41.51
4–10	173 (43.14)	56.69	153 (35.92)	49.06
11–15	55 (13.72)	2.55	59 (13.85)	2.83
>15	68 (16.96)	0.63	97 (22.77)	2.36
Contact with Patients				
Yes	362 (90.27)	95.54	388 (91.08)	93.40
No	39 (9.73)	4.46	38 (8.92)	6.60

Subsequently, the RCA team identified the following underlying problems: inadequate identification of patients with suicidal plans, the absence of a comprehensive chronic disease joint consultation and evaluation system, insufficient staff proficiency in emergency resuscitation procedures, safety hazards in the ward environment, and a lack of expertise among physicians who are not psychiatrists in managing patients with comorbid psychiatric conditions. After comprehensive discussions and a review of relevant literature, the team determined the root causes and devised a series of corrective measures. These measures included providing additional training on emergency resuscitation procedures for all hospital staff, educating non-psychiatrist physicians on psychological knowledge, establishing a multidisciplinary joint consultation system, and conducting inspections to identify safety hazards in all hospital wards, such as installing limiting devices on windows and ensuring the evenness of the hospital premises. Subsequently, the RCA team compiled a report on the root cause analysis, which was presented during a meeting of the Medical Quality Management Committee. The department also submitted a report detailing the incident correction process and participated in an internal medical quality improvement case competition held at the end of the year, receiving the second prize.

Discussion

In this study, we evaluated the multidimensional quality management tools of PSC in a Chinese hospital. Our results proved that after a 3-year PSC education project, the scores for overall evaluation of safety, perception of safety and Frequency of Adverse Event Reporting were significantly improved. The positive response rates also increased about 10%-15%. This study also showed that young employees and experienced employees reported fewer adverse events, so a reinforced PSC education could be beneficial.

The implementation of multidimensional quality management tools has proved highly effective in enhancing employees' awareness of adverse events and promoting comprehensive quality management. Our use of various tools, such as the Quality Circle, RCA, and the Quality Loop, has enabled proactive prevention of adverse events. Boussat et al evaluated the efficacy of RCA methods in more than 3800 healthcare providers and concluded that RCA in team routine could improve PSC.[13] By conducting an RCA analysis of sentinel events and patient harm incidents with educational values, we can better identify latent hazards in hospital management processes and structures and continuously improve them.[14,15] In our study, we noticed that RCA has been instrumental in analyzing patient harm incidents within the hospital, alleviating employees' fears of punitive actions following such incidents.

Our practical experience also confirmed that the QCC is a preferred and effective management model for conducting quality management.[16] A previous study showed that QCC promotion strategies in China can offer valuable insights for improved healthcare quality,[17] while quality loop has shown its efficacy in an endoscopist training program.[18] In our study results, we also encouraged employees to actively engage in the QCC for ongoing quality improvement initiatives. The integration of the Quality Loop into the adverse event management system and the overall hospital-wide quality management process highlights the significance of adverse event management.[19]

Information management has played a crucial role in the construction of our adverse event management system. By implementing the "Kejin Adverse Event Management System", the Quality Management Department can monitor the flow of adverse events in real-time at various stages, significantly improving our information management capabilities for adverse event management. The system ensures point-to-point management and full anonymization of adverse event reports, addressing employees' concerns about identity disclosure when reporting adverse events.[20] The establishment of a closed-loop process for adverse event reporting, handling, and review has further enhanced our information management capabilities for adverse event management.

In this study, we also examined the relation between working experience and adverse events reporting rate, we found that young workers tend to report fewer adverse events which is in alignment with a previous study, where less experience is associated with a higher prescribing error rate.[21] Surprisingly, we found that experienced workers also reported fewer adverse events, and the underlying reason could just be their experience, which indicated that abundant experience could be a double-edged sword.

Analyzing the reported adverse events in our hospital reveals that the absolute number of Grade III events surpasses that of Grade IV events. According to Hein's Law, behind every serious accident, there are inevitably 29 minor accidents, 300 near misses, and 1000 potential hazards.[22] This suggests that reporting of Grade IV events is significantly lacking.

Combining the results of our PSC survey, which showed that 50% of employees have not reported adverse events in the past year and 63.37% of employees are concerned about potential consequences after reporting adverse events, it is evident that efforts must be directed towards enhancing employee education and training regarding adverse events to improve their awareness. Additionally, promoting internal recognition and rewards for reporting adverse events will help foster a blame-free reporting culture throughout the entire hospital. By addressing these reporting gaps, we can further strengthen our adverse event management system and ensure a culture of patient safety.

This study still possessed limitations: first, this is a single-centre study focused on psychiatric diseases, and the generalization ability of our experience in a general hospital required further validation; second, the sample size in this study is quite small, with only 400 employees include; third, during 2019 to 2022, the COVID-19 significantly affected the medical system in China, long-term observation and PSC education are required for a more precise analysis.

Conclusion

This study focused on the PSC development in a Chinese psychiatric hospital. A modified PSC instrument and multi-dimensional quality management tools were used for analysis. Our results proved the effectiveness of quality management tools in improving adverse events reporting rate and awareness of PSC concepts. More importantly, through analysis of results, we could provide suggestions for the development of PSC.

Ethics Approval and Informed Consent

Informed consent Informed consent was obtained from all individual participants included in the study. This study was approved by the Ethics Committee of the Second People's Hospital of Guizhou Province (ID: Human ethics [2021]99). Employees can only conduct questionnaire survey after fully informed consent.

Acknowledgments

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.

Disclosure

The authors report no conflicts of interest in this work.

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