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A Novel Swiss Cheese Model-Based Safety Chain Management System for Central Sterile Supply Department

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ABSTRACT: Objective This study aimed to develop and implement a safety chain management system for the Central Sterile Supply Department (CSSD) based on the Swiss Cheese Model. **Methods** Based on literature analysis and case studies, a safety chain management system was developed by integrating the multi-layer defense concept of the Swiss Cheese Model into CSSD management. The system encompassed ten key components related to processes, equipment, personnel, and supervision. To evaluate its effectiveness, comparisons were made before and after the intervention in terms of instrument cleaning efficacy, standardized acceptance rate of high-risk instruments, sterilization qualification rate, and adverse event reporting rate. **Results** Following the intervention, the qualified rate of instrument cleaning increased from 99.74% to 99.94% ($P<0.001$), the standardized acceptance rate of high-risk instruments rose from 99.6% to 99.81% ($P<0.001$), and the sterilization qualification rate improved from 99.56% to 99.90%. Notably, the number of sterilization process interruptions caused by incomplete instrument drying decreased from 4 to 1, positive biological monitoring results declined from 2 to 1, wet packages were reduced by 2 cases, and cycle interruptions due to equipment failure decreased by 3. In addition, the adverse event reporting rate increased markedly from 24.49% to 75.00% ($P<0.001$). **Conclusion** The proposed safety chain management system effectively reduces the risk of healthcare-associated infections and improves the quality of instrument reprocessing in the CSSD. It also offers a novel theoretical framework and practical guidance for advancing safety management practices in the CSSD.

KEY WORDS: Swiss cheese model; Central Sterile Supply Department (CSSD); Safety chain management; Medical infection control; Quality management

With the rapid advancement of medical technology and the growing emphasis on patient safety, the Central Sterile Supply Department (CSSD), as a cornerstone of hospital infection control, plays a critical role in ensuring medical safety and patient well-being. The CSSD manages a series of complex processes, including instrument retrieval, cleaning, sterilization, and distribution. Traditional single-point quality control measures are often insufficient to address systemic risks comprehensively. To tackle this challenge, the present study introduces the Swiss Cheese Model, originally proposed by James Reason[1]. This theoretical framework conceptualizes a system's defenses as multiple slices of Swiss cheese, where each slice represents a layer of defense, and the holes symbolize latent flaws. When holes across different layers momentarily align, a trajectory of risk can penetrate all defenses, potentially resulting in an adverse event. Hence, establishing multi-layered and complementary defense mechanisms is essential. Concurrently, the chain management model emphasizes precise vertical and horizontal coordination across all process links, thereby ensuring workflow continuity and integrity[2]. The integration of these two approaches facilitates the development of a safety chain management system

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within the CSSD that reinforces both localized control and systemic interconnection. At present, research on combining the Swiss Cheese Model with chain management for safety optimization in the CSSD remains limited. Accordingly, this study seeks to integrate the Swiss Cheese Model into CSSD management practices and to construct a comprehensive safety chain management system. By implementing multiple error-proofing barriers and link-based complementary mechanisms, this system aims to systematically intercept potential risks, thereby shifting the safety paradigm from reactive handling to proactive prevention and ultimately enhancing the overall quality and safety of CSSD operations[3].

1 Construction of a CSSD safety chain management system based on the Swiss Cheese Model

To establish an active, forward-looking, and self-improving safety defense line, we departed from traditional quality control paradigms by introducing the concept of "system resilience" and benchmarking against advanced international practices in hospital infection control. Based on this approach, a CSSD chain safety management system was developed. This system is explicitly designed to interconnect previously isolated risk control points, thereby forming a three-dimensional protective network capable of active warning, dynamic adaptation, and continuous learning. The resulting safety chain management system is illustrated in Figure 1.

1.1 Top-level design and institutional resilience: establishing a "vertically integrated and horizontally coordinated" management framework

1.1.1 Vertical responsibility system: A four-tier quality control structure was established, consisting of the Head Nurse, Quality Control Team Leader, Specialty Team Leader, and Operating Nurse. This hierarchy ensured clearly defined lines of authority and responsibility, enabling the transmission of quality and safety imperatives without attenuation throughout the organization.

1.1.2 Horizontal coordination mechanism: A Joint Committee for Instrument Lifecycle Management was formed in collaboration with key departments, including the Infection Control Department and the Operating Room. This committee was responsible for jointly reviewing standard operating procedures (SOPs) and establishing a collaborative root cause analysis (RCA) mechanism for investigating medical device-related adverse events.

1.1.3 Proactive risk management: The Failure Mode and Effects Analysis (FMEA) methodology was introduced to conduct pre-processing risk assessments for new and precision instruments. This approach enabled the transition from reactive incident management to proactive risk prevention[4].

1.2 Process reengineering and closed-loop control: pursuing "zero defects" through integrated workflow design. To achieve the goal of "zero defects", core processes were reengineered to ensure interlocking coordination, traceability, and controllability across all stages.

1.2.1 Critical control points: Mandatory quality gates were established at key stages of the reprocessing workflow, including decontamination, inspection and packaging, and sterilization. These gates incorporated mechanisms such as double-checking and immediate verification of cleaning quality, ensuring that nonconforming items could not proceed to subsequent stages[5].

1.2.2 Closed-loop traceability management: Leveraging information systems, a full data closed loop was achieved throughout the entire process from instrument retrieval to distribution. Specifically for implants, a dual assurance strategy was strictly implemented, combining 24-minute rapid biological monitoring with 24-hour physical retention of implants pending test results.

1.3 Smart empowerment and technical support: leveraging technology to address the "holes in the cheese"

1.3.1 Intelligent traceability system: The application of mobile PDAs and QR codes enabled the establishment of a full lifecycle electronic file for each instrument, allowing for one-click traceability throughout the reprocessing workflow.

1.3.2 Data-driven decision making: A dynamic dashboard for quality indicators was developed to auto-

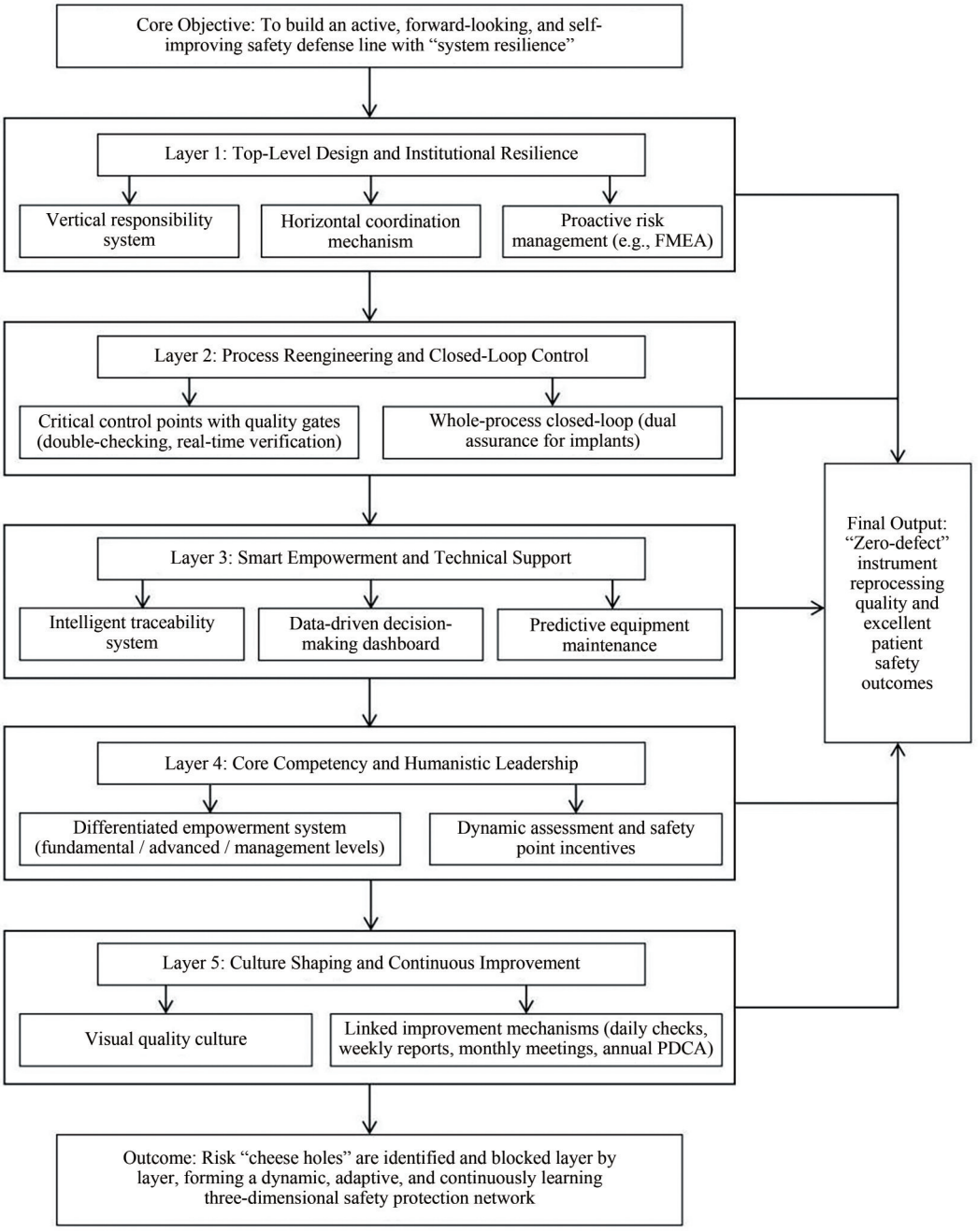

Figure 1 CSSD chain safety management system based on Swiss Cheese Model

matically collect and analyze key metrics, including cleaning pass rates and sterilization failure rates. This facilitated the precise identification of risk nodes and supported the execution of Plan-Do-Check-Act (PDCA) cycles for continuous improvement.

1.3.3 Predictive equipment maintenance: Moving beyond traditional preventive maintenance, the system explored predictive maintenance models by continuously monitoring equipment operational data, thereby minimizing unplanned downtime and enhancing workflow reliability.

1.4 Core competency and humanistic leadership: empowering personnel as the most dynamic defense layer through safety culture cultivation

1.4.1 Differentiated empowerment system

At the fundamental level, competency-based access protocols and training modules were established. Micro-videos, mind maps, and QR codes were employed to facilitate on-demand, ubiquitous access to SOPs[6].

At the advanced level, specialized certification training was introduced for high-precision instruments, including micro-instruments and Da Vinci robotic surgical systems.

At the management level, key personnel were trained in RCA and lean management methodologies to strengthen their capacity for leading quality improvement initiatives.

A dynamic assessment framework, incorporating theoretical, practical, and emergency response evaluations, was implemented and linked to individual competency files and quality safety points, thereby establishing a positive incentive cycle.

1.5 Culture shaping and continuous improvement: fostering the internalization of quality and safety into daily practice

1.5.1 Visual quality culture: A "Quality Safety Culture Wall" and visual dashboards were established to publicly display quality data and improvement cases, thereby enhancing staff engagement and operational transparency.

1.5.2 Linked improvement mechanisms: Through daily spot checks, weekly quality briefings, and monthly multi-departmental joint meetings on quality and safety, departmental silos were progressively dismantled. These coordinated efforts facilitated the collaborative implementation of annual strategic PDCA projects, enabling continuous, spiral improvement of the management system[7].

2 Implementation and effectiveness of CSSD safety chain management system

2.1 Management system implementation and deepening

To systematically address potential risks in the CSSD related to instrument traceability, process control, and consistency of personnel operations, the department, in December 2023, in collaboration with hospital leadership and multiple departments (including the Nursing Department, Information Department, Operating Room, and Logistics Support Department), jointly developed a CSSD safety chain management system based on the Swiss Cheese Model. Following comprehensive preparation and pilot verification, the system was formally implemented in February 2024. Throughout the implementation process, guided by the principles of evidence-based decision-making, phased advancement, and closed-loop management, the following core strategies and measures were adopted:

2.1.1 Precision assessment and risk insight (problem identification phase)

During the initial implementation stage, a special task force was established to conduct multiple rounds of comprehensive assessment covering the entire instrument processing workflow from retrieval to distribution. Through historical data analysis and on-site tracking, several key risk points were precisely identified: (1) manual records were error-prone and subject to omissions, resulting in fragmented information chains; (2) adherence to high-risk instrument processing standards relied heavily on individual experience, introducing variability and potential deviations; and (3) inconsistencies in standardization and proficiency levels across different personnel positions compromised overall quality homogenization[8].

2.1.2 Building multi-layered defense barriers (system design phase)

To address the identified challenges, a set of interlocking, multi-layered defense measures was designed based on the principles of the Swiss Cheese Model, with the objective of systematically closing each potential "hole" in the safety framework:

2.1.2.1 Technology defense layer: building an intelligent traceability ecosystem through information technology integration. Information technology was actively introduced and integrated to construct an intelligent traceability ecosystem. Mobile PDA scanning replaced manual record-keeping, ensuring precise identification of each instrument throughout the reprocessing workflow. Barcode tracking systems, combined with high-risk instrument node control modules, enforced mandatory quality checks at all critical stages, including cleaning, disinfection, inspection, packaging, and sterilization, thereby locking down non-conforming instruments and preventing their progression to subsequent steps. Concurrently,

the hospital logistics system was integrated with the CSSD traceability system, enabling seamless instrument transfer and uninterrupted data connectivity between clinical areas and the CSSD. An "Instrument Processing Risk Assessment Form" (Table 1) was developed and implemented to systematically evaluate instruments across three key dimensions: material sensitivity, structural complexity, and post-use contamination level. Each dimension was stratified into defined grading standards (e.g., low, medium, or high risk). Following individual assessment, the ratings from all three dimensions were integrated and analyzed within a risk matrix model. This matrix, presented in either two- or three-dimensional format, visually cross-referenced the dimensional ratings to automatically generate a comprehensive risk level for each instrument. This approach transformed previously experience-based subjective judgments into a quantifiable, reproducible, and scientifically grounded decision-making process. Based on the assigned risk level, differentiated processing protocols could be precisely formulated, effecting a paradigm shift from a "one-size-fits-all" approach to risk-stratified precision management. This strategy effectively focused resources on critical control points while enhancing overall work efficiency and quality safety levels.

2.1.2.2 Process defense layer: implementing subspecialty grouping and standardized procedures

A "Surgical Instrument Subspecialty Grouping" management model was implemented, in which dedicated teams assumed responsibility for specific categories of instruments. This approach enhanced management granularity and allowed personnel to develop specialized expertise. Building on this structure, SOPs were established covering all instrument categories, thereby consolidating best practices and ensuring consistency across the department[9-10].

2.1.2.3 Personnel defense layer: ensuring standardized execution through competency-based training and assessment

To guarantee effective implementation of the SOPs, a standardized training and assessment mechanism was developed. This mechanism comprised theoretical instruction, simulated operations, on-the-job mentoring, and independent on-duty assessments. An information system was utilized to document each employee's training progress and assessment outcomes, ensuring that all staff members proficiently mastered and consistently executed the new management processes and operating standards. This approach facilitated the achievement of both standardization and homogenization of technical operations across the workforce.

2.2 Data collections and statistics

Data were collected during two distinct periods: the pre-implementation phase (February 2023 to December 2023), during which the new model had not yet been introduced, and the post-implementation phase (February 2024 to December 2024), following the full deployment of the CSSD safety chain management system. The collected data encompassed the following indicators: instrument cleaning pass rates, standardized acceptance rates for high-risk instruments (including loaner instruments, new instruments, and operating room surgical instruments), sterilization pass rates, and adverse event reporting rates.

2.2.1 Instrument cleaning pass rate

Quantitative test: Cleaning efficacy was assessed using ATP bioluminescence testing (measured in relative light units, RLU) or protein residue testing, with a passing result defined as a value equal to or below the institution's predefined threshold.

Visual inspection: Instruments were examined under an illuminated magnifying lamp to confirm that all surfaces, including joints, serrations, and lumens, were free from any visible contaminants, blood stains, scale, or rust spots.

Judgment criteria: An instrument was classified as "pass" only when it satisfied both of the above criteria simultaneously. A "fail" was assigned if the quantitative test result exceeded the established threshold, or if any visible contaminant was detected during visual inspection.

2.2.2 Standardized acceptance rate for high-risk instruments

Routine check: For each high-risk instrument received, a double-checking procedure was per-

Table 1 Instrument Processing Risk Assessment Form

Comprehensive Risk Level	Material Risk Criteria	Structural Risk Criteria	Contamination Risk Criteria	Evidence-Based Core Management Strategy
Extremely high risk	High: Material is precision or extremely sensitive to processing parameters. Examples: 1. Active metal implants such as titanium alloy (sensitive to scratches and chloride corrosion) 2. Precision optical components (e. g. , endoscope lenses) 3. Polymer materials (e. g. , insulation on certain electrosurgical instruments, not heat resistant)	High: Extremely complex structure, difficult to clean and dry. Examples: 1. Long narrow lumens (inner diameter < 2 mm, length multiple times the instrument width) 2. Multi-layered structures, tight joints, or precision serrations 3. Powered tools with non-removable components	High: Contacts patient sterile tissue or body fluids, or carries highly resistant pathogens. Examples: 1. All implants 2. Instruments contacting patient blood or sterile body cavities 3. Instruments contaminated by prions, gas gangrene, or unidentified infectious disease pathogens	Dedicated Process, Full Traceability: 1. Designated personnel handling, execution of dedicated SOP. 2. Enhanced cleaning verification: Mandatory use of lumen brushes, high-pressure water guns; quantitative verification using ATP or specific protein residue tests. 3. Sterilization assurance: Physical, chemical, biological monitoring for every load; release only upon negative results. 4. Informational full traceability, recording all processing parameters.
High risk	Medium/High: Material has certain specificities requiring attention. Examples: 1. Certain coated instruments (anti-rust layer may be damaged by strong acids/ alkalis) 2. Rubber or silicone products (aging issues)	Medium/High: Complex structure with hard-to-clean areas. Examples: 1. Instruments with joints, crevices, holes (e. g. , hemostats, needle holders) 2. Short, wide lumens 3. Instruments with textures or grooves	Medium/High: Contacts patient mucous membranes or non-intact skin, or from infectious surgeries. Examples: 1. Flexible endoscopes (gastroscopes, bronchoscopes) - high biofilm risk 2. Instruments used on patients with infectious diseases (e. g. , Hepatitis B, HIV)	Standard Process, Focused Attention: 1. Execute WS310 standard process, no simplification. 2. Enhanced manual cleaning and visual inspection: Use illuminated magnifying lamp, focus on joints and teeth. 3. Ensure drying: Use drying cabinet or dedicated drying equipment. 4. Packaging and sterilization: Standard packaging, primarily pressure steam sterilization, include internal chemical indicators.
Medium risk	Low/Medium: Material sturdy, stable, widely compatible. Examples: 1. High-quality stainless steel (e. g. , Austenitic 316L) 2. Ceramic or glass (heat-resistant but fragile)	Low/Medium: Relatively simple structure, no significant hard-to-clean areas. Examples: 1. Smooth-surfaced instruments (e. g. , treatment bowls, trays) 2. Simple cutting instruments (e. g. , straight scissors)	Medium: Contacts only patient intact skin. Examples: 1. Container items in dressing change kits or nursing packs 2. Low-risk items such as blood pressure cuffs	Standard Processing, Efficiency Priority: 1. Mainly mechanical cleaning possible, but ensure correct loading. 2. Routine visual inspection, no visible soiling. 3. Choose intermediate-level disinfection or sterilization based on intended use.
Low risk	Low: Material durable, no special requirements for routine processing. Examples: 1. General-purpose stainless steel or plastic	Low: Very simple structure, easy to clean and dry. Examples: 1. Flat instruments (e. g. , instrument trays) 2. Simple items without joints or lumens	Low: No patient contact or only contacts clean environment. Examples: 1. Transfer containers or equipment surfaces 2. Packaging auxiliary materials	Routine or Simplified Processing: 1. Routine cleaning and disinfection acceptable. 2. Processes can be optimized for efficiency while ensuring safety. 3. Periodic spot checks to ensure quality.

formed to verify that all relevant information, including instrument name, specification, quantity, and associated patient or surgical procedure details, was complete and accurate.

First-time receipt of instrument: For instruments received for the first time, it was ensured that the instruction manual had been obtained, that relevant staff had completed appropriate training, and that a reprocessing compatibility assessment had been conducted.

Loaner instruments: Loaner instruments were managed in strict compliance with the requirements of the national standard *Central sterile supply department (CSSD) — Part 2: Standard for operating procedure of cleaning, disinfection and sterilization* (WS 310.2—2016). Specifically, it was confirmed that appropriate cleaning and sterilization methods had been assessed and validated; Process Challenge Device (PCD) testing was performed as required for implants and in emergency situations; and all loaner instruments were cleaned and disinfected in the CSSD prior to their return.

Judgment criteria: A case was classified as "pass" when it met all of the above requirements. A "fail" was assigned under any of the following conditions: information was missing or incorrect; the double-checking procedure was not performed; a new instrument was accepted without the accompanying manual or without completed training and assessment; or a loaner instrument was accepted or returned without the required assessment, testing, acceptance verification, cleaning, or disinfection.

2.2.3 Sterilization pass rate

Physical monitoring: Key process parameters, including time, temperature, and pressure, were required to remain within the predefined ranges throughout the entire sterilization cycle.

Chemical monitoring: Both external and internal chemical indicators—the latter placed at the most difficult-to-sterilize site within each package—were required to display color changes consistent with specifications.

Biological monitoring: Biological indicator cultures, performed in accordance with established protocols (e.g., weekly and for each implant load), were required to yield negative results.

Judgment criteria: A sterilization cycle was classified as "pass" only when all three of the above criteria were met simultaneously. A "fail" was assigned in any of the following circumstances: physical monitoring parameters deviated from the specified ranges; any chemical indicator failed to meet specifications; a positive biological monitoring result was obtained; or improper use of monitoring materials led to invalid test results.

2.2.4 Adverse event reporting rate

Proactive identification and reporting: Staff were required to clearly identify whether an event fell within the scope of CSSD adverse events, including but not limited to wet packs, cleaning or sterilization failures, and incorrect instrument distribution.

Timely and standardized reporting: Adverse events were to be reported through the hospital's internal reporting system within the prescribed timeframe, with complete documentation of key elements, including time of occurrence, event description, contributing causes, and actions taken.

Judgment criteria: A "pass" was defined as meeting all of the above criteria. A "fail" was assigned in any of the following circumstances: occurrence of a reportable event that was concealed and not reported; significant delay in reporting beyond the specified timeframe; or critical information missing from the report that hindered subsequent analysis and root cause identification.

2.3 Statistical analysis

Descriptive statistics were used to summarize all collected data. Count data are expressed as frequencies or rates (%), and the comparison between pre-implementation and post-implementation group was conducted by the χ^2 test or Fisher's exact test. If P Value <0.05, the difference is statistically significant. Statistical analyses were performed using SPSS version 26.0.

2 Results

2.1 Comparison of CSSD instrument cleaning effectiveness, standardized acceptance rate of high-

risk instruments, sterilization qualification rate, and adverse event reporting rate before and after implementation are shown in the tables below.

3 Discussion

This study integrated the multi-layered defense principles of the Swiss Cheese Model with the whole-process collaboration approach of chain management to develop and implement a safety management system tailored to the CSSD. The findings demonstrate that the system led to statistically significant and clinically meaningful improvements in instrument cleaning pass rates, standardized acceptance rates for high-risk instruments, sterilization process stability, and the culture of adverse event reporting. These outcomes were not attributable to any single intervention but rather resulted from a comprehensive and structured risk prevention and control strategy.

Table 2 Comparison of CSSD instrument cleaning pass rates before and after implementation

Instrument Category	Total Tested	Pre-Implementation Passes (Pass Rate, %)	Post-Implementation Passes (Pass Rate, %)	χ^2 Value	*P* Value
Forceps	1 297 790	681,280(99. 71)	614,175(99. 94)	387. 2	<0. 001
Clamp/Pick	973 342	511,169(99. 75)	460,611(99. 94)	312. 5	<0. 001
Knife handle	324 447	170,459(99. 79)	153,537(99. 94)	187. 4	<0. 001
Scissors	648 895	340,710(99. 73)	307,058(99. 93)	256. 8	<0. 001
Retractor	194 668	102,328(99. 85)	92,122(99. 94)	45. 6	<0. 001
Puncture	324 447	170,459(99. 79)	153,558(99. 95)	210. 3	<0. 001
Lumen	778 674	408,599(99. 67)	368,537(99. 95)	525. 7	<0. 001
Container	519 116	273,017(99. 90)	245,686(99. 95)	58. 9	<0. 001
Endoscopes	6 489	3,409(99. 79)	3,071(99. 93)	8. 2	0. 004
Precision instruments	1 421 080	745,848(99. 69)	672,493(99. 94)	612. 4	<0. 001
Total	6 488 948	3,407,280(99. 74)	3,070,844(99. 94)	3878. 5	<0. 001

Table 3 Comparison of standardized acceptance rates for high-risk instruments before and after implementation

Item Category	Total Accepted	Pre-Implementation Standardized Acceptance (Rate, %)	Post-Implementation Standardized Acceptance (Rate, %)	χ^2 Value	*P* Value
New instrument handover	39 287	6,208(98. 71)	6,226(99. 84)	70. 25	<0. 001
Loaner instrument handover	735 034	113,576(99. 14)	113,624(99. 96)	485. 33	<0. 001
Professor's own surgical instruments	6 552	118(98. 03)	120(99. 69)	9. 09	0. 003
Operating room surgical instruments	1 030 369	1,945,538(99. 84)	1,946,405(99. 97)	352. 94	<0. 001
Total	1 811 242	75,440(99. 60)	346,971(99. 81)	907. 61	<0. 001

Table 4 Comparison of sterilization pass rates before and after implementation

Non-Conformance Item	Total Sterilization Loads	Pre-Implementation Non-Conformance Count (Pass Rate, %)	Post-Implementation Non-Conformance Count (Pass Rate, %)	χ^2 Value	*P* Value
Interruption due to incomplete drying	25206	41(99. 67)	4(99. 97)	29. 42[c]	<0. 001
Positive biological monitoring	25206	2(99. 98)	1(99. 99)	-[a]	0. 564
Wet pack	25206	3(99. 98)	2(99. 98)	-[a]	0. 658
Interruption due to equipment failure	25206	9(99. 93)	6(99. 95)	0. 65	0. 421
Total	25206	55(99. 56)	13(99. 90)	26. 66	<0. 001

Note: [a], Fisher's exact test used; [c], Continuity corrected χ^2 test used.

Table 5 Comparison of adverse event reporting before and after implementation

Time Period	Total Adverse Events Occurred	Actual Reported Events	Reporting Rate (%)	χ^2 Value	*P* Value
Pre-implementation	49	12	24. 49	21. 61	<0. 001
Post-implementation	36	27	75. 00		

This strongly supports the necessity and effectiveness of transitioning from isolated point-based error correction to a systemic approach to safety defense.

3.1 Addressing core risks systematically: from experience-based judgment to scientific decision-making

We developed and applied the Instrument Processing Risk Assessment Form as an innovative tool to enhance risk stratification in CSSD operations. This instrument translates three previously abstract dimensions, including material sensitivity, structural complexity, and contamination risk, into quantifiable and actionable grading criteria. By integrating these dimensions within a risk matrix, the tool enables automatic determination of the comprehensive risk level for each instrument. It thereby redefines the concept of "high-risk instruments" from a subjective notion to an objective, evidence-based standard. This advancement directly contributed to the significant improvement in the standardized acceptance rate of high-risk instruments, which increased from 99.6% to 99.81% (P<0.001). Moreover, the tool shifts pre-processing risk assessment from an experience-driven to a data-driven paradigm, providing a scientific foundation for implementing differentiated processing protocols. For instance, instruments classified as "extremely high risk" are subject to dedicated processing pathways, enhanced cleaning verification, and full traceability. This represents a core manifestation of precision management within the CSSD safety system.

3.2 Specific effectiveness and synergistic mechanisms of multi-layered defense strategy

The observed improvements can be attributed to the synergistic interplay among the various defense layers within the system.

Technology defense layer lays the data foundation: The comprehensive implementation of mobile PDA scanning and traceability systems effectively addressed the limitations of manual record-keeping, thereby establishing a closed-loop information chain. This advancement not only enhanced the accuracy and traceability of operational data but, more importantly, enabled real-time monitoring of quality indicators (e.g., cleaning pass rates) and facilitated data-driven decision-making. The increase in cleaning pass rates from 99.74% to 99.94% (P< 0.001) was underpinned by the information system's capacity to monitor cleaning parameters, automatically intercept non-conforming items, and support continuous process optimization through data feedback.

Process and personnel defense layers ensure execution consistency: The adoption of surgical instrument subspecialty grouping, together with the standardization of operating procedures (SOPs), constituted a targeted process redesign aimed at addressing operational complexity and human variability. A correspondingly standardized training and assessment mechanism ensured high adherence to SOPs. Through systematic competency development and performance evaluation, the personnel defense layer significantly reduced inter-operator variability and reinforced best practices. The combined effect of these two layers minimized quality fluctuations arising from inconsistent understanding or discretionary practices, thereby contributing to improved sterilization pass rates and a reduction in interruptions caused by incomplete drying or equipment failure.

Culture defense layer stimulates system introspection capability: The marked increase in adverse event reporting rates from 24.49% to 75.00% (P< 0.001) serves as a compelling indicator of the system's cultural transformation. Consistent with the Swiss Cheese Model, which emphasizes that reporting and analyzing near misses is essential for addressing latent systemic vulnerabilities, the present system fostered a non-punitive reporting environment. Through mechanisms such as multi-departmental joint RCA and incentive structures linked to quality safety points, the act of reporting shifted from being perceived as a burden to being recognized as a contribution to safety and a professional responsibility. The cultivation of this positive safety culture endowed the system with continuous self-learning and improvement capabilities, enabling it to draw lessons from minor events and prevent small gaps from

evolving into major failures[11-12].

3.3 Theoretical significance, practical value, and future prospects

This study integrates the classic safety theory of the Swiss Cheese Model with CSSD-specific practices and the chain management framework. It not only validates the applicability of this theoretical model in the risk management of medical support systems but also extends its scope by offering a comprehensive practical solution that includes specific tools (e.g., the instrument processing risk assessment form), implementation pathways, and evaluation indicators. Consistent with previous findings by Xia and colleagues, who demonstrated that chain management enhances the controllability of process links[11], this study further reveals that when chain management is embedded with the multi-layered defense core of the Swiss Cheese Model, the efficacy of risk prevention and control achieves a qualitative improvement.

In summary, the Swiss Cheese Model-based safety chain management system for CSSD, by constructing a multi-layered and dynamic defense network encompassing proactive risk assessment, intelligent process control, standardized personnel empowerment, and a learning safety culture, effectively enables systematic risk control throughout the entire instrument reprocessing process. It successfully shifts quality management from end-point monitoring toward source prevention and precision process control, thereby significantly enhancing both the quality of work and the safety resilience of the CSSD. This provides a valuable theoretical framework and a practical reference for ensuring patient safety and improving the overall operational reliability of healthcare institutions.

Nevertheless, this study has certain limitations. The effectiveness of the system may be influenced by contextual organizational factors, such as hospital size and the level of information technology infrastructure. Future research should further explore the adaptability and optimization pathways of this system across different types and tiers of medical institutions. In addition, with the advancement of technologies such as the Internet of Things and artificial intelligence, the integration of these technologies into the system to enable proactive risk prediction will represent a key direction for optimizing the "smart defense layer" in the next phase.

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