Journal of Clinical and Nursing Research, 2026, Volume 10, Issue 7
http://ojs.bbwpublisher.com/index.php/JCNR
Online ISSN: 2208-3693
Print ISSN: 2208-3685

Research on the Application of Refined Management Model in Quality Control of Hospital Central Sterile Supply Department (CSSD)

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Abstract: This study explores the application approaches of refined management methods in the quality control of the Hospital Central Sterile Supply Department (CSSD). In accordance with the requirements of the WS310 series of industry standards, the Supplementary Indicators for Quality Control of Disinfection Supply issued by the National Health Commission's Institute of Hospital Management (2025 edition), and the special action plan of the provincial disinfection supply quality control center, this study systematically organizes practical approaches from four aspects: standardization of systems and processes, quality monitoring and data-driven improvement, application of information traceability systems, and job training and performance evaluation, starting from the concept of refined management. Refined management relies on specific means and institutional constraints to improve the operational standardization of all links in disinfection supply, achieving the goal of transforming quality control from extensive to precise. Practice has proven that this model can effectively enhance the quality control level of the CSSD and is worthy of promotion.

Keywords: Refined management; Central sterile supply department; Quality control; Traceability system; Standardized process

Online publication: Jul 31, 2026

1. Introduction

The Central Sterile Supply Department (CSSD) serves as the first line of defense in hospital infection control, primarily responsible for the recovery, cleaning, disinfection, sterilization, and supply of reusable medical devices throughout the hospital. The quality of its work directly impacts surgical safety and the lives and health of patients. Traditional extensive management methods suffer from issues such as poor process connectivity, inadequate quality tracking, and insufficient personnel training. Refined management

emphasizes standardization, quantification, and continuous improvement, and integrating it into the quality control system of the CSSD holds significant practical importance. Based on the WS 310 series of industry standards, the "Basic Dataset for Monitoring Hospital Disinfection Supply" (WS/T 879—2025), and the "Supplementary Indicators for Quality Control of Disinfection Supply (2025 edition)" issued by the National Health Commission's Institute of Hospital Management, this paper systematically elaborates on the application of the refined management model in the quality control of the CSSD [1].

2. Standardized construction of systems and processes in the sterilization and supply center under a refined management model

2.1. Establishing comprehensive operational procedures based on the WS 310 series of standards

Standardization is the foundation of refined management. The WS 310 series of standards outline management requirements, technical operating specifications, and effectiveness monitoring criteria for sterilization and supply centers, providing a basis for refined management. According to the requirement in WS310.1-2016 that "all medical devices, instruments, and items requiring reuse after disinfection or sterilization should be centrally collected, cleaned, disinfected, sterilized, and supplied by the CSSD", the hospital's sterilization and supply center incorporates all reusable medical devices across the hospital into centralized management. Following the technical operating specifications in WS310.2, refined management establishes standardized operating procedures (SOPs) for nine key processes: collection, classification, cleaning, disinfection, drying, inspection and packaging, sterilization, storage, and distribution. Each process specifies operational essentials, equipment parameter standards, and quality inspection requirements. The cleaning process requires distinguishing between manual cleaning, ultrasonic cleaning, and automatic cleaning machine conditions and procedures, providing operators with clear guidelines and evidence.

2.2. Establishing quantitative assessment criteria based on a quality control indicator system

Refined management demands quantifiable and assessable quality objectives. Based on the three-level indicator system (structure, process, and outcome) established in accordance with the Sterilization and Supply Quality Control Indicators (2022 edition), quality assessments are refined to specific indicators. According to WS 310.3, cleaning pass rates, packaging pass rates, and sterilization pass rates are used as primary assessment indicators. The benchmarks of ≥ 97% cleaning pass rate, ≥ 98% packaging pass rate, and 100% sterilization pass rate for medical devices in healthcare institutions in Zibo City, Shandong Province, are used as references for refined management [2]. Refined management sets quality control points for each operational process, including cleaning quality sampling for the cleaning process and packaging seal integrity and item verification for the packaging process. Operational data such as process times, equipment parameters, and consumable usage are recorded and analyzed to identify efficiency bottlenecks and quality weaknesses, supporting continuous improvement.

3. Refined quality monitoring system and data-driven continuous improvement mechanism

3.1. Multi-level monitoring methods based on WS 310.3

In accordance with the revised WS 310.3-2024, a multi-level monitoring system combining physical, chemical, and biological monitoring is established. Based on the newly added clauses in the standard regarding handling non-conformities in cleaning, disinfection, and sterilization quality monitoring, refined management develops detailed non-conforming product handling procedures and closed-loop feedback mechanisms for each monitoring process.

3.1.1. Physical monitoring

Detailed records of temperature, pressure, and time parameters for each sterilization batch are maintained and compared with standard curves to identify and correct deviations promptly. According to WS 310.3-2024 Clause 4.4.2, the temperature fluctuation range for pressure steam sterilization should be controlled within ± 1 ℃ of the set value, pressure fluctuations should not exceed ± 0.1 kPa, and sterilization time errors should not exceed ± 1%. Refined management requires a BD test before each use of sterilization equipment, and equipment failing the test cannot be used that day.

3.1.2. Chemical monitoring

Standardized placement positions, quantities, and judgment criteria for chemical indicators inside and outside packages are established. Each package includes an internal chemical indicator card, and each sterilization batch includes batch monitoring chemical indicators at the equipment exhaust port.

3.1.3. Biological monitoring

In accordance with standard requirements, weekly monitoring using *Geobacillus stearothermophilus* spore biological indicators is conducted, with each implant batch undergoing biological monitoring. Results are reported within 3 hours before release.

Refined management registers the results of multi-level monitoring in the “Sterilization Effectiveness Monitoring Record Form”, with a retention period of no less than three years.

3.2. Goal-oriented quality control initiatives and data-driven improvements

Refined management requires quality management improvements to have goals, plans, and follow-ups. Implementation details are carried out in accordance with the special action plan for improving the regular sampling pass rate of medical device cleaning effectiveness issued by the Henan Provincial Hospital Sterilization and Supply Quality Control Center.

3.2.1. Goal setting and sampling system standardization

By 2025, the regular sampling pass rate for medical device cleaning effectiveness in healthcare institutions at or above the secondary level across the province should not be lower than 98%. To achieve this goal, a regular sampling system for cleaned reusable medical devices must be established, specifying sampling types, frequencies, sample sizes, and judgment criteria. The sampling system details that at least 30 devices of various types should be sampled each quarter for cleaning effectiveness testing, using two unified methods: magnifying glass visual inspection (checking for residues in teeth, lumens, etc., under a 5 ×

magnifying glass) and ATP biological fluorescence detection (relative luminescence value ≤ 150 RLU deemed qualified). All sampling results must be recorded and archived by designated personnel for quality improvement purposes.

3.2.2. Daily-weekly-monthly data analysis and problem tracing

Under refined management, the sterilization and supply center establishes a three-level analysis system for quality data: "daily summary, weekly analysis, and monthly evaluation". Each shift member records quality data for their respective processes (collection, cleaning, packaging, sterilization, etc.) and enters it into an electronic ledger. The quality control nurse collates all data weekly, analyzes non-conforming items by department, common device types, and trends, and generates a weekly report. At the end of each month, the department head organizes a quality evaluation meeting with doctors, nurses, and technicians to conduct a thematic analysis of device cleaning and sampling results, tracing the root causes of quality issues using methods such as fishbone diagrams and 5W1H analysis to ensure problems are attributed to specific processes and positions.

3.2.3. Closed-loop rectification and effectiveness review mechanism

Specific improvement measures are developed for each non-conforming item identified during monitoring, with assigned responsibilities and completion deadlines. The quality control team follows up on rectification progress weekly to ensure timely completion. After rectification, the quality control nurse conducts on-site reviews of the rectification effects and records them. According to the requirements of the Henan Provincial Quality Control Center, a comprehensive review should be conducted 30 days after implementing rectification measures. If the sampling pass rate remains below 98%, a new rectification plan should be formulated, and the rectification process restarted until the pass rate meets the standard. Each rectification plan, process record, and review result is included in the quality archives, forming a closed loop from problem identification, measure formulation, rectification implementation, effectiveness review, and re-rectification if unqualified, ensuring continuous and effective quality improvement [3].

4. In-depth application of information traceability systems in refined quality management

4.1. Technical implementation of full-process closed-loop traceability

In accordance with the newly added clause in the revised WS 310.3-2024, which stipulates "requirements for information-based quality traceability in medical sterilization and supply centers or hospitals providing services to other medical institutions", the refined management model regards information-based traceability systems as the primary technological means for quality control. According to the requirements of the "Basic Dataset for Monitoring Sterilization and Supply in Hospitals" (WS/T 879-2025), the traceability system should be capable of recording, storing, sharing, tracking, and responding to data related to sterilization and supply, including 24 data items such as device name, unique identifier, operator ID, operation time, equipment number, and sterilization parameters [4].

From a technical architecture perspective, refined management typically employs QR codes or RFID technology to assign a unique digital identifier to each device and each package of sterile items, facilitating scanning operations throughout the entire process using wireless handheld terminals (PDAs). In accordance

with the "Requirements for Item Information Traceability Systems in Sterilization and Supply Centers of Medical Institutions" (T/WSJD 39-2023), the traceability system should retain information on the entire lifecycle of devices, from clinical use and subsequent collection, cleaning and disinfection, packaging and sterilization, storage and distribution, to reuse. Details such as the operator, operation time, and key equipment parameters for each step should be recorded. Taking Chongqing University Cancer Hospital as a case study, under the management of the traceability system, all device packages (totaling 12,000) can be traced, with each package having more than 28 data record entries, thereby achieving the goals of traceable origins, trackable destinations, and accountable responsibilities. Refined management should also feature offline caching functionality, capable of storing over 500 operation records during network outages and automatically uploading them once the network is restored, ensuring no data loss.

4.2. Precision upgrade of intelligent data analysis and quality control

Refined management aims to achieve full-process recording and incorporate intelligent data analysis and early warning capabilities. According to the supplementary quality control indicators for sterilization and supply (2025 edition) issued by the National Health Commission's Institute of Hospital Management under the document No. Guoweiyiyanhan [2025] 103, refined management can automatically generate statistical reports for 12 tertiary indicators, including cleaning pass rate, packaging pass rate, sterilization loading pass rate, wet pack incidence rate, and sterilization effectiveness monitoring pass rate.

The intelligent early warning module incorporates compliance verification rules for sterilization parameters based on WS 310 standards, with a lower temperature limit of 132 ℃, an upper limit of 135 ℃, a pressure range of 184–210 kPa, and an exposure time of no less than 4 minutes. When the sterilization temperature falls below 132 ℃, pressure is abnormal, or the time deviation exceeds ± 1%, the system will lock out non-compliant devices within 0.5 seconds and issue a red alarm signal, preventing their clinical use. The expiry early warning system provides advance reminders for sterile items expiring within 7 days, preventing expiration issues caused by delayed inspections during traditional storage. According to practical data from Jiangmen Central Hospital in Jiangsu Province, refined management has reduced the time required to trace and locate quality anomalies from an average of 45 minutes to less than 10 minutes. Refined management has broken down data barriers between the sterilization and supply traceability system and the hospital HIS and operating room management systems, enabling collaborative and interconnected operations among multiple systems. Scanning surgical instruments after use triggers the collection process, reducing the collection response time from an average of 2 hours to just 15 minutes.

5. Closed-loop personnel training system and performance evaluation under refined management

5.1. Hierarchical training and evaluation system based on job competency

Refined management necessitates a systematic, standardized, and evaluated personnel training approach. In accordance with the two human resource indicators stipulated in the "Quality Control Indicators for Sterilization and Supply (2022 Edition)"—job training rate (100%) and continuing education rate (≥ 95%)—these metrics are integrated into the departmental quality management system. According to Article 6.2 of WS310.1-2016, CSSD staff should participate in training relevant to their job duties, covering knowledge and skills in cleaning, disinfection, and sterilization of various medical devices, equipment operation procedures,

occupational safety protection principles and methods, hospital infection prevention and control knowledge, and relevant laws, regulations, and standards.

New employees should undergo a minimum of 40 hours of training, including 16 hours of theoretical instruction and 24 hours of practical coaching, with passing scores set at ≥ 85 for theory and ≥ 90 for practical skills. Training methods combine "one-on-one" on-site guidance, theoretical lectures, practical operations, and self-study improvement. Both new and transferred employees undergo training at both hospital and departmental levels. In line with the requirements of the Henan Sterilization and Supply Quality Control Center, refined management has formulated specific training plans for new employees, sterilization personnel, and contract workers. Sterilization personnel receive additional specialized training on pressure vessel operation certificates (minimum 16 hours), new employees undergo monthly skill reassessments in the first three months, and contract workers focus on training in device classification and cleaning standards (minimum 8 hours). Training content should reflect the characteristics of sterilization and supply specialization and the requirements for continuous quality improvement, with training records retained for at least two years.

5.2. Refined quantification and continuous improvement closed-loop of performance evaluation

Refined management directly links performance evaluation with quality indicators, establishing a quantified performance evaluation system based on the "Quality Control Indicators for Sterilization and Supply (2022 Edition)" and supplementary indicators from the National Health Commission Medical Research Letter [2025] No. 103. Key quality indicators such as device cleaning pass rate (target ≥ 97%), packaging pass rate (target ≥ 98%), and sterilization effect monitoring pass rate (target 100%) are broken down into a chain of "quality indicators—job objectives—personal performance" for each job position and individual.

(1) Cleaning position

The weight of the device cleaning pass rate in personal performance accounts for 35%.

(2) Packaging position

The weight of packaging pass rate accounts for 30%.

(3) Sterilization position

The weight of sterilization monitoring pass rate accounts for 40%.

Refined management requires monthly evaluations of theoretical knowledge and practical skills. Theoretical exams utilize a standardized question bank, with each exam consisting of 50 questions and a passing score of 80. Practical evaluations randomly select three operations, each scored out of 100, with a re-exam required for any single score below 90. Evaluation results are linked to personal performance pay, with a 5% deduction for those failing the exam in a given month. Those failing twice consecutively have their independent work qualifications suspended and must undergo 15 hours of intensive retraining. Based on quality monitoring data and quality control feedback, specialized intensive training and re-evaluation are conducted for positions or personnel with recurring quality issues, with those still failing having their independent work qualifications suspended. In accordance with the continuous improvement requirements of the revised WS 310.3-2024, monthly and quarterly quality analysis meetings serve as platforms to feedback the results of quality defect statistical analysis to relevant responsible parties, fostering a positive cycle where the updating and improvement of the training system align with the continuous improvement of quality issues, thereby promoting the enhancement of personnel's professional capabilities from "compliant

operation" to "precise operation" [5].

6. Conclusion

The refined management model relies on the synergistic effects of standardized systems, quantifiable processes, information-based traceability, and closed-loop evaluations to transform quality control in the sterilization and supply center from post-hoc spot checks to precise interventions throughout the entire process, shifting quality control from a coarse to a systematic and refined approach. In accordance with the WS310 series standards, a standardized operation system covering the entire process of recovery, sterilization, and distribution has been established. Relying on an information-based traceability system and intelligent data analysis, real-time monitoring of quality parameters and deviation warnings have been achieved. The closed-loop of job training and performance evaluation ensures the homogenization level of personnel operations. The refined management model provides a feasible technical approach and management paradigm for achieving precise quality control in hospital sterilization and supply centers.

Disclosure statement

The author declares no conflict of interest.

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