Study on the centralized management of loaner medical devices and implants in the disinfection supply center

Authors: Shi Yu, Chen Zetao, Du Zhonghe, Yang Suyi

Date: 2026-02-01T16:54:44+00:00

Abstract

Objective To investigate the clinical effect of implementing a centralized management model by the disinfection supply center for external medical instruments and implants, and to verify through a controlled trial its value in improving the quality of instrument handling and staff satisfaction.

Methods A prospective, single-center randomized controlled trial was conducted in the disinfection supply center. External medical instruments and implants received between September 2023 and August 2024 were randomly assigned, according to different management measures, into two groups for comparative analysis: a reference group managed with conventional measures (n=345) and an observation group managed with a centralized model (n=347). Dedicated personnel were responsible for ensuring balance between the two groups in terms of instrument types and surgical categories. Centralized management measures included the establishment of a multidisciplinary collaboration system, optimization of standardized operating procedures, construction of a visualized training system, and implementation of a whole-process quality traceability system. Staff satisfaction was evaluated using a self-designed questionnaire (covering operational norms, workflow, etc.; total score of 100 points) to compare the management value.

Results Compared with the reference group, the observation group showed a 12.18% reduction in the unqualified cleaning rate, a 4.35% reduction in the unqualified sterilization rate, and a 4.64% reduction in the unqualified packaging rate. The observation group was significantly superior to the reference group in the qualified rates of instrument cleaning, packaging, and sterilization quality, as well as in management satisfaction ($P<0.05$).

Conclusion The centralized management model, through standardized process control and a multi-department collaboration mechanism, can significantly im-

prove the handling quality of external medical instruments and implants, while enhancing staff recognition and acceptance of the management processes. It is recommended to promote its application in disinfection supply centers.

Full Text

Author Information

Shi Yu (1987–), male, from Huanggang, Hubei, bachelor' s degree, engaged in Central Sterile Supply Department management.
Corresponding Author: Chen Zetao, Email: 497300853@qq.com

Title: Research on Centralized Management of External Medical Instruments and Implants in Central Sterile Supply Department

Authors: Shi Yu[1−2], Chen Zetao[1−2], Du Zhonghe[1], Yang Suyi[1]
[1] The Fifth Affiliated Hospital of Jinan University, Heyuan, Guangdong 517000
[2] The First Affiliated Hospital of Jinan University, Guangzhou, Guangdong 510630

Abstract

Objective: To investigate the clinical effect of implementing a centralized management model for external medical instruments and implants in the Central Sterile Supply Department (CSSD), and to verify its value in improving instrument processing quality and staff satisfaction through a controlled trial.

Methods: A prospective single-center randomized controlled trial was conducted in the CSSD. From September 2023 to August 2024, received external medical instruments and implants were randomly divided into two groups based on different management measures: a control group (n=345) undergoing conventional management and an observation group (n=347) implementing centralized management. A dedicated staff member was responsible for ensuring balance in instrument types and surgical categories between the two groups. Centralized management measures included multi-disciplinary collaborative system construction, standardized operation process optimization, visual training system development, and full-process quality traceability systems. The main outcome measures were the qualification rates of instrument cleaning, packaging, and sterilization (judged according to WS310-2016 standards). Staff satisfaction was evaluated using a self-developed questionnaire (including operational norms, processes, etc., with a total score of 100 points).

Results: Compared with the control group, the observation group showed a 12.18% reduction in cleaning failure rate, a 4.35% reduction in sterilization failure rate, and a 4.64% reduction in packaging failure rate. The observation group significantly outperformed the control group in the qualification rates

of instrument cleaning, packaging, and sterilization, as well as in management satisfaction ($P<0.05$).

Conclusion: The centralized management model can significantly improve the processing quality of external medical instruments and implants through standardized process control and multi-departmental collaboration, while enhancing staff recognition of management processes. It is recommended for promotion in CSSD.

Keywords: external medical devices; implants; disinfection and supply center; centralized management

---

Main Text

External medical instruments are typically delivered to medical institutions by manufacturers through leasing or free provision. These instruments are usually reusable and often characterized by large size and sophisticated, complex designs. Since they are not considered fixed assets of the hospital, they frequently circulate among different healthcare facilities, which not only increases management complexity but also significantly elevates infection risks [1]. Implants refer to implantable medical devices placed within patient body cavities, commonly used in surgeries to reconstruct human bodily functions. The quality of their cleaning and disinfection directly affects patient recovery outcomes [2]. Therefore, ensuring the cleaning and disinfection quality of external medical instruments and implants has become a critical issue that Central Sterile Supply Departments must urgently address. This study aims to clarify the significant effectiveness of this management model in improving instrument management quality and staff satisfaction through comparative trials, thereby providing robust practical evidence for optimizing management processes in CSSD.

1.1 General Information

This study focused on the management of external medical instruments and implants in the CSSD. The research subjects comprised external medical instruments and implants received by the CSSD, with a final total sample size of n=692. Based on different management strategies, these samples were divided into a control group and an observation group to conduct subsequent research. Throughout the study period, CSSD staff remained stable with no personnel changes. The team consisted of 14 professional healthcare workers aged 23–41 years, with a mean age of $(27.34\$\pm2.76) years, and work experience ranging from 2–19 years, with a mean tenure of (5.83\pm\$0.93)$ years. The male-to-female ratio was 1:6. During the study period, staff remained unchanged, and a quality control team composed of specialty team leaders conducted monthly spot checks of cleaning and sterilization records to ensure data integrity.

1.2 Management Methods

1.2.1 Control Group The control group adopted conventional management: the CSSD managed external medical instruments and implants according to established cleaning and disinfection standards, and conducted irregular spot checks to inspect cleaning quality and other aspects.

1.2.2 Observation Group The observation group implemented a centralized management model, with specific measures as follows:

1.2.2.1 Enhanced Personnel Training. To effectively improve the professional medical operation level of CSSD staff, the department regularly organized training on disinfection technical specifications, hospital infection management standards, and other related content. In response to deficiencies in existing management systems, relevant literature was reviewed to formulate targeted management systems for external medical instruments and implants [3]. Systematic training was conducted to strengthen staff professional ethics, utilizing visual materials such as multimedia and images to explain key information including the names, maintenance and protection methods, and assembly/disassembly procedures of external medical instruments and implants. Staff were ensured to pass assessments before being allowed to work. Furthermore, given that the use of external medical instruments and implants involves multiple departments and units, the hospital clarified the management responsibilities of each department and unit, adopting a multi-department collaborative management model to compensate for the shortcomings of single-department management [4].

1.2.2.2 Standardized Management of Implants and External Instruments.

1.2.2.2.1 Improved Institutional Access. Led by the Hospital Infection Management Office, in collaboration with multiple departments including the Nursing Department and CSSD, in-depth cooperation was conducted to jointly discuss and formulate access systems for external medical instruments and implants. Based on the actual needs and operational characteristics of each department, detailed handover procedures were established, clarifying various requirements such as instrument delivery time and quality standards [5].

1.2.2.2.2 Strict Adherence to Operation Manuals. External medical instruments have sophisticated and complex structures and frequently circulate among multiple hospitals, which significantly increases the difficulty of cleaning. If staff are not familiar with instrument performance, omissions are highly likely during inspection, thereby affecting cleaning and sterilization effectiveness and further increasing the risk of nosocomial infection. Therefore, staff must strictly follow product instructions and operation manuals for standardized processing.

1.2.2.2.3 Standardized Instrument Inventory Management. Each time medical instrument manufacturers deliver instruments, they must attach a detailed inventory list clearly specifying key information such as brand, category, and

specifications to facilitate verification and counting by CSSD staff.

1.2.2.2.4 Establishing a Comprehensive Distribution Management System. For implants and external instruments being used for the first time, strict acceptance inspection of sterilization effectiveness must be implemented, with careful examination of the instruments themselves and their interiors, focusing on identifying any wet pack issues, and detailed recording of sterilization biological test results [6].

1.2.2.3 Optimized Process Management.

a. Reception Management. To strengthen the reception management of external instruments and implants, staff developed a standardized operational procedure to address common issues such as missing registration information and delayed handover during the transfer process. For elective surgeries, relevant personnel were required to complete surgical notification forms one day before surgery and promptly notify the CSSD to receive corresponding instruments, ensuring sufficient time for cleaning and processing to improve sterilization quality [7]. The CSSD designated specific staff members responsible for receiving external medical instruments and implants. During reception, staff first carefully verified whether the instruments and implants fell within the hospital' s scope of use, then jointly counted instrument quantities with suppliers and conducted comprehensive performance checks. Throughout the reception process, staff completed detailed and accurate receiving forms based on actual conditions, ensuring all information was complete and error-free for subsequent traceability and management.

b. Cleaning and Disinfection Management. To ensure medical safety, CSSD staff must strictly follow operational procedures based on product instructions provided by external medical instrument and implant manufacturers to avoid instrument damage, selecting appropriate cleaning and disinfection methods according to instrument performance. Instruments must be strictly disassembled and classified according to product instructions and placed in specific containers with identification tags to prevent loss or confusion [8]. For structurally complex instruments that are difficult to clean, manual pre-processing should be performed first, with enhanced physical monitoring and timely recording of cleaning information to enable traceability management.

c. Standardized Packaging Management. A combination of visual inspection and ATP bioluminescence detection methods was employed. Through direct visual observation, staff preliminarily assessed whether instrument surfaces were clean and free from residual stains. Upon discovering external medical instruments and implants that did not meet cleaning standards, immediate re-cleaning was arranged. If damage was identified during inspection, prompt contact with manufacturers was made for replacement [9]. Given that non-woven fabric sterile barrier systems offer superior performance compared to cotton fabric, appropriate non-woven materials were selected for packaging external medical instruments and implants based on their quantity and specifications. During packaging, a

strict "one person for quality inspection, one person for packaging" protocol was implemented. Specifically, a designated person conducted comprehensive quality inspection of items to be packaged according to quality standards, and only after confirmation, another staff member completed the packaging operation, thereby ensuring packaging quality, effectively reducing contamination risk, and maintaining the sterile status of medical instruments and implants.

d. Enhanced Sterilization Monitoring and Traceability Quality Management. Appropriate sterilization methods were reasonably selected based on the heat and moisture resistance characteristics of items to be sterilized. For oversized and overweight packs, centralized management personnel recommended using heavy-load sterilization programs, with sterilization operators monitoring sterilization parameters in real-time across different batches [10]. Full-process traceability of sterilization procedures and instrument circulation was achieved to ensure quality monitoring.

e. Standardized Distribution Management. After all monitoring of external medical instruments and implants was qualified, distribution was conducted within the validity period, with detailed recording of distribution information. Dedicated personnel and vehicles were arranged to transport instruments from transfer clean elevators to operating rooms.

1.3 Observation Indicators

Compilation of qualification status for cleaning, sterilization, and packaging of external medical instruments and implants; Management satisfaction survey: Professionally trained staff distributed questionnaires to CSSD healthcare workers. Satisfaction was categorized into three levels based on scores: dissatisfied ($ 75*points*), *generallysatisfied*(76–89*points*), *andsignificantlysatisfied*($90 points) [11].

1.4 Statistical Methods

Data were entered and analyzed using SPSS 25.0 statistical software. Count data were expressed as [n(%)], and chi-square tests were performed. For comparisons between two groups of ordered polytomous variables with small sample sizes, Mann-Whitney U tests were used. $P<0.05$ was considered statistically significant.

2.1 Comparison of Cleaning, Sterilization, and Packaging Qualification Rates

Comparison of qualification rates in cleaning, sterilization, and packaging records for the observation group after centralized management intervention. Results showed that the observation group' s qualification rates were significantly higher than the control group in all three aspects ($P<0.05$). Specific proportions are shown in Table 1 .

2.2 Comparison of Management Satisfaction

CSSD staff satisfaction with centralized management in the observation group was significantly higher than in the control group ($P<0.05$). Specific indicators are shown in Table 2 .

3.1 Existing Deficiencies in Management of External Medical Instruments and Implants

With the rapid development of medical technology, the renewal and replacement of implant surgical instruments continues to accelerate. For cost control and improved equipment utilization efficiency considerations, hospitals typically choose to lease these instruments from medical equipment suppliers. However, external medical instruments often have complex structures and frequently circulate among multiple medical institutions. This high mobility poses tremendous challenges to instrument management, leading to substantially increased management difficulty and elevated nosocomial infection risks [12]. Although China has issued and implemented hygiene industry standards for hospital CSSDs, and management of external medical instruments and implants has been gradually strengthened, some medical institutions still have problems with poor management. The main reasons are as follows:

Unclear responsibilities of relevant departments and units. The "Guidelines for External Medical Instrument Operations" has been implemented since 2016. Due to relatively limited management experience in this field across hospitals, the practical applicability of these guidelines for management reference is restricted [13]. Previous management measures for external medical instruments and implants focused primarily on financial accounting. In medical institutions, equipment and consumables management committees are generally composed of staff from equipment departments. Limited by work tasks, when managing leased instruments from medical equipment suppliers, the specific responsibilities for each stage of internal hospital circulation—including instrument reception, storage, allocation, and post-use recovery—were not clearly defined, leading to management loopholes during instrument circulation and affecting overall instrument management effectiveness [14].

Lack of access management for implants and external medical instruments. When equipment departments procure such instruments, decisions are often based solely on clinicians' preferences, lacking comprehensive access systems and effective constraint mechanisms, resulting in excessive introduction of similar types of implants. This is related to unfamiliarity with external medical instruments among users and operators [15]. Additionally, with numerous medical equipment manufacturers, the poor interchangeability of related instruments for the same type of implants causes waste of medical resources to some extent and hinders overall hospital management.

Insufficient personnel training. Field investigations revealed that many hospitals have loopholes in access management for implant and external medi-

cal instrument surgeries. Coupled with inadequate staff training, this directly affects the effective implementation of cleaning and disinfection work [16]. In practice, manufacturer personnel often follow cases, frequently responsible for instrument counting and organization. Due to chaotic management of relevant personnel by hospitals, safety hazards exist.

Inadequate multi-department collaboration. Centralized management of external medical instruments and implants requires coordinated cooperation among multiple departments. If support from higher-level management departments is insufficient, or if management tasks rely solely on the CSSD, management quality will be difficult to achieve expected goals. Additionally, low cooperation from medical equipment suppliers regarding external medical instrument and implant management also affects the smooth progress of management work.

3.2.1 Centralized Management Can Improve Instrument Cleaning and Sterilization Quality

External medical instruments come in numerous varieties, but the number of suppliers is relatively limited, causing these instruments to frequently circulate among multiple hospitals and making it difficult to effectively guarantee their sterilization quality. Furthermore, external medical instruments have complex structures, especially luminal instruments. If cleaning is not performed promptly, biofilm formation can easily occur, increasing the risk of outbreak infections and endangering patient safety. To address this, our hospital specifically introduced a centralized management model, which enhanced the professional skills of CSSD staff through systematic training and implemented targeted management measures for different stages including reception, cleaning, and sterilization, significantly improving management quality. Research data demonstrated that after centralized management, the observation group' s qualification rates for cleaning, sterilization, and packaging were all significantly superior to the control group ($P<0.05$), indicating that centralized management can effectively improve instrument cleaning and sterilization quality. The reasons are as follows: improved management systems effectively prevented potential issues such as insufficient verification and delayed handover. Previously, staff generally emphasized sterilization while neglecting cleaning, but the improved cleaning and disinfection management system prompted staff to strictly follow operational procedures for processing external instruments and implants and to select appropriate cleaning and disinfection methods according to product instructions, thereby reducing instrument damage [17]. Visual inspection and ATP bioluminescence detection methods helped ensure cleaning quality, while strict control of sterilization pack volume and weight according to packaging management systems effectively reduced wet pack rates. Additionally, sterilization monitoring and traceability quality management systems greatly improved work efficiency and guaranteed the sterilization quality of external medical instruments and implants.

3.2.2 Centralized Management Improves Staff Satisfaction

Conventional management models rely on manual implant management with poor overall application effectiveness, exhibiting problems such as lost labels and incorrect information recording. Additionally, with rapid renewal and replacement of medical instruments, CSSD staff lack systematic training opportunities and cannot comprehensively improve their work skills, making them prone to wet pack phenomena due to improper cleaning and disinfection operations. Centralized management provides corresponding measures to address these management difficulties, offering strong support for medical services and strengthening the execution standards of various responsibilities [18]. According to Table 2 research results, satisfaction in the observation group after centralized management was significantly higher than in the control group ($P<0.05$), demonstrating that centralized management is highly favored by staff. The reasons are as follows: clarifying the responsibilities and management requirements of each department and unit during the use of external medical instruments and implants compensated for deficiencies in conventional management measures. Systematic training enhanced legal awareness, standardized medical behaviors, and improved professional ethics levels, ensuring the quality of centralized management. Systematic training using visual materials guided staff to conduct cleaning and disinfection management according to product instructions, reducing instrument damage while greatly improving work efficiency and alleviating work burden.

In summary, implementing centralized management systems in CSSD based on the characteristics of external medical instruments and implants can significantly improve the qualification rates of cleaning, disinfection, and packaging of external medical instruments and implants. The study demonstrates that centralized management not only enhances the cleaning efficiency of reusable medical instruments but also effectively controls nosocomial infection risk and receives widespread recognition from staff, making it worthy of promotion and application in clinical settings.

References

[1] Zhang Gaokun, Li Jiaxin, Yang Lieying, et al. Application effect of standardized management of external medical instrument sterilization packages in CSSD [J]. China Standardization, 2024, (10): 280-283.

[2] Wang Li, Yan Gege, Wu Aiping, et al. Effect analysis of whole-process quality management of external medical instruments in CSSD [J]. Journal of Practical Medical Techniques, 2024, 31(04): 300-302. DOI:10.19522/j.cnki.1671-5098.2024.04.021.

[3] Huang Sudan. Application of risk management in processing external medical instruments in CSSD [J]. Mingyi, 2024, (06): 186-188.

[4] Li Qingling. Effect of PDCA management in CSSD on cleaning quality of external medical instruments [J]. China Medical Device Information, 2024, 30(06): 177-179. DOI:10.15971/j.cnki.cmdi.2024.06.012.

[5] Ye Bihua, Wu Bizhao. Construction and application of sensitive quality indicators for external implant instrument management in CSSD [J]. Contemporary Nurse (Mid-month), 2024, 31(03): 105-108. DOI:10.19792/j.cnki.1006-6411.2024.08.023.

[6] Zhang Yumei, Gao Qin, Diao Chunfei, et al. Application of information traceability system combined with instrument atlas technology in reprocessing external medical instruments in CSSD [J]. Anhui Medical Journal, 2024, 45(02): 230-235.

[7] Zhang Yufeng, Li Xiaoli, Zhuang Lingling, et al. Application of 9S management combined with color management in external medical instrument management in CSSD [J]. Medical Equipment, 2024, 37(02): 69-72.

[8] Yang Yue' e. Difficulties and quality improvement in processing external medical instruments [J]. Marriage and Health, 2023, 29(23): 184-186.

[9] Luo Cen. Application of specialized classification management in hospital external medical instrument classification management [J]. Medical Equipment, 2023, 36(20): 43-45.

[10] Nie Shengnan, Song Donghua, Meng Yingtao. Study on improving processing quality of external medical instruments in CSSD based on failure mode and effect analysis [J]. Chinese Journal of Disinfection, 2023, 40(10): 784-787.

[11] Ma Caiyun, Zhang Chunhua, Wang Yongbo. Effect of refined classification management of external medical instruments in CSSD [J]. Gansu Medical Journal, 2023, 42(09): 841-843. DOI:10.15975/j.cnki.gsyy.2023.09.022.

[12] Liu Runzhi. Application of new circular management model in standardized management of external instruments and implants in CSSD [J]. Medical Equipment, 2023, 36(15): 28-30.

[13] Lv Xiaoxia, Huang Suqiong, Wang Jimei. Application of information quality traceability system in external medical instrument management in CSSD [J]. Chinese Journal of Medical Management Sciences, 2023, 13(04): 60-64.

[14] Guo Qiuyan, Liu Jiali. Effect of PDCA management in CSSD on cleaning quality of external medical instruments [J]. Nursing Practice and Research, 2023, 20(09): 1406-1410.

[15] Li Hui, Yang Tingting, Sun Dongdong, et al. Evaluation of different management processes for external instruments and implants in CSSD [J]. Integrated Traditional Chinese and Western Medicine Nursing (Chinese-English), 2022, 8(03): 184-186.

[16] Wu Mengjuan, Tang Yiling, Fang Xuan, et al. Application of integrated management in disinfection of orthopedic external instruments and implants in

CSSD [J]. Qilu Nursing Journal, 2021, 27(07): 163-165.

[17] Zhang Yayun, He Dongping, Bao Jianfang, et al. Effect of optimized processes in standardized management of orthopedic external instruments and implants in CSSD [J]. Chinese Journal of Disinfection, 2021, 38(01): 69-70.

[18] Zhang Yunying, Lin Qiaoling, You Youlian. Difficulties and solutions in management of external medical instruments and implants in CSSD [J]. Medical Equipment, 2020, 33(18): 59-60.

Note: Figure translations are in progress. See original paper for figures.