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Effects of Digital Closed-loop Traceability Management on Surgical Instrument Coordination Between the Central Sterile Supply Department and the Operating Room

Dan Li, Xia Wu, Jun Wang, Pengqin Gao, Yuanyuan Song

(*The People's Hospital of Leshan*)

ABSTRACT: Objective To evaluate the effects of digital closed-loop traceability management on surgical instrument coordination between the central sterile supply department (CSSD) and the operating room. **Methods** We conducted a single-center before-and-after controlled study with retrospective analysis of reusable instrument records from May 2025 to April 2026. The control group used conventional handover procedures, whereas the observation group implemented digital registration, key-node traceability, closed-loop management of abnormalities, and collaborative quality control. The incidence of instrument processing-related problems, satisfaction among medical and nursing staff in the operating room, timely processing rate of emergency instruments, and processing time were compared between the two groups. **Results** The incidence of instrument processing-related problems was lower in the observation group than in the control group. Satisfaction among medical and nursing staff in the operating room and the timely processing rate of emergency instruments were higher in the observation group than in the control group (85.00% vs 57.50% and 85.99% vs 62.02%, respectively), while the processing time was shorter [(98±14) min vs (118±15) min]. The difference in satisfaction was statistically significant (P=0.007), and the differences in the other major outcomes were all statistically significant (P<0.001). **Conclusion** Digital closed-loop traceability management can improve the quality of instrument processing and the efficiency of emergency instrument turnover, increase satisfaction among medical and nursing staff, and improve the efficiency of collaborative instrument management between the CSSD and the operating room.

KEY WORDS: digital closed-loop traceability; central sterile supply department (CSSD); operating room; emergency instruments; collaborative management

The central sterile supply department (CSSD) is responsible for the collection, sorting, cleaning, disinfection, inspection and packaging, sterilization, storage, and distribution of reusable diagnostic and therapeutic instruments, devices, and articles. Quality control throughout the entire process is directly related to the quality of sterile items and the safety of their clinical use. The operating room is the primary user of reusable surgical instruments, and the timeliness, completeness, and functional integrity of instrument supply directly affect the continuity of surgical procedures. Accordingly, WS 310.1—3, issued by the National Health Commission in 2016, specifies management requirements for instrument reprocessing in the CSSD[1-3].

Traditional coordination between the CSSD and the operating room mainly relies on telephone calls, WeChat groups, paper handover forms, and face-to-face communication. Information is dispersed across different channels, emergency needs rely on manual reminders, and abnormal problems are difficult to track continuously, which can lead to unclear responsibility points, omissions in handover information, and incomplete feedback and corrective actions[4]. Digital quality traceability has been gradually applied to CSSD quality management[5]. Qian Liming et al. investigated the status of digital quality traceability implementation in hospital CSSDs[6]. Zhang

Xuehua et al. investigated the status of digital quality traceability in the CSSDs of 129 hospitals[7]. In this study, digital closed-loop traceability management was applied to collaborative instrument management between the CSSD and the operating room, and its effects were evaluated. The results are reported as follows.

1 Materials and methods

1.1 Study design and general information

A single-center before-and-after controlled study was conducted. A total of 98,726 instrument trays processed from May to October 2025, before implementation of digital closed-loop traceability management, were assigned to the control group, while 92,154 instrument trays processed from November 2025 to April 2026, after implementation of digital closed-loop traceability management, were assigned to the observation group.

Inclusion criteria: ① reusable instrument packs centrally processed by the hospital's CSSD and distributed to the operating room for use during the study period, including high-temperature-sterilized, low-temperature-sterilized, and endoscopic instruments; and ② complete records of collection, cleaning, packaging, sterilization, and distribution. Exclusion criteria: ① single-use instruments and consumables; ② instruments that did not undergo the complete reprocessing process because they were discarded or undergoing repair; ③ instrument packs with missing records at key nodes, making it impossible to determine the processing outcome; and ④ instrument packs not used in the operating room.

1.2 Management methods

1.2.1 Paper-based handover management in the traditional workflow of the control group

After surgery, operating room staff perform an initial count of the instruments and complete a paper handover form. Emergency needs are temporarily communicated to the CSSD through notes on the handover form, telephone calls, or WeChat groups. Based on the information received, CSSD staff perform instrument collection, manual sorting, cleaning, inspection and packaging, sterilization, and distribution. Abnormal problems are mainly communicated back by telephone, WeChat, or face-to-face communication. This workflow lacks standardized data entry and key-node tracking. Emergency needs depend on manual reminders, while abnormal problems are difficult to manage through a continuous closed-loop process of registration, analysis, and corrective action.

1.2.2 Digital closed-loop traceability management in the observation group

1.2.2.1 Establishment of an integrated operating room and CSSD management team

The integrated operating room and CSSD management team comprises staff from the CSSD, operating room, nursing administration department, healthcare-associated infection control department, and quality control personnel, and centrally manages the collaborative process for surgical instruments. The team is responsible for reviewing the process for instrument collection, handover, processing, distribution, and problem feedback; clarifying responsibilities at each stage; regularly analyzing instrument processing-related problems; and continuously tracking the effectiveness of corrective actions.

1.2.2.2 Standardization of the handover process for surgical instruments throughout the entire process

The management checkpoint is moved upstream by assigning designated staff to dedicated positions in the operating room instrument cleaning area to perform instrument collection, counting, verification, and preliminary problem identification. The handover information includes the instrument name, quantity, specifications, functional status, degree of contamination, whether emergency processing is required, and any special processing requirements. For instruments with discrepancies in quantity, functional abnormalities, complex structures, or special cleaning requirements, the designated staff promptly confirm the situation on site with operating room personnel and simultaneously communicate the information to relevant CSSD personnel, ensuring the continuous transmission of abnormal information throughout subsequent processing stages.

1.2.2.3 Digital registration of emergency instruments

A mini program is used for the digital registra-

tion of emergency instruments, with designated staff entering the instrument name, quantity, collection time, cleaning and processing time, sterilization time, distribution time, and processing outcome, thereby generating records of key time points for collection, cleaning, sterilization, and distribution. Relevant personnel prioritize the processing of emergency instruments based on the registration information and check their processing status. Each month, the timeliness of emergency instrument processing, mean processing time, and causes of delays are summarized to provide a basis for identifying process bottlenecks and supporting continuous improvement.

1.2.2.4 Establishment of a key-node traceability and closed-loop feedback mechanism for abnormal problems

Key-node traceability management was established across the processes of instrument collection, sorting, cleaning, disinfection, inspection and packaging, sterilization, storage, distribution, and use-related feedback. Emergency instruments, precision instruments, endoscopic instruments, and frequently used specialty instruments were prominently identified and prioritized for processing. A closed-loop process consisting of "problem identification - registration and reporting - cause analysis - implementation of corrective actions - evaluation of effectiveness - continuous improvement" was established. Problems reported by the operating room were collected weekly, and cases of inadequate cleaning quality, labeling errors, quantity discrepancies, poor instrument function, and delayed collection were categorized and summarized monthly. Repeated problems were addressed using the PDCA cycle. In the Plan phase, problems were summarized and their possible causes analyzed; in the Do phase, targeted measures were formulated and implemented; in the Check phase, records of problems following corrective actions were reviewed; and in the Act phase, effective measures were standardized and institutionalized. Problems that did not meet the targets were carried forward to the next cycle[8].

1.2.2.5 Specialty instrument training and multidisciplinary collaborative quality control

For specialty instruments, precision instruments, and newly introduced instruments, the CSSD and operating room jointly conducted standardized training covering instrument names, specifications and models, structural features, disassembly methods, key points of cleaning and disinfection, packaging requirements, functional inspection methods, and identification of common faults. Led by the nursing administration department, the CSSD, operating room, healthcare-associated infection control department, medical administration department, and quality control department jointly conducted collaborative quality control, coordinating personnel, equipment, consumables, and process support to continuously optimize the surgical instrument management process.

1.3 Outcome measures

1.3.1 Incidence of instrument processing-related problems.

Problem events were used as the unit of analysis, and the two groups were compared for inadequate cleaning quality, labeling errors, instrument quantity discrepancies, poor instrument function, and delayed instrument collection. Inadequate cleaning quality was defined as visible residual contamination identified during quality inspection or failure to meet cleaning quality requirements. Labeling errors were defined as discrepancies between the labeling information on the instrument pack, including the pack name, sterilization information, batch, or expiry date, and the corresponding records. Instrument quantity discrepancies were defined as discrepancies between the actual quantity and the instrument assembly checklist. Poor instrument function was defined as abnormal performance in functions such as closure, cutting, or connection identified during routine functional inspection. Delayed instrument collection was defined as an event documented in the contemporaneous quality records as failure to complete collection and handover in accordance with management requirements. When different types of problems occurred in the same instrument pack, each type was counted separately. Problem incidence = number of problem events during the same period ÷ total

number of instrument packs processed during the same period × 100%.

1.3.2 Satisfaction of medical and nursing staff in the operating room.

A department-designed questionnaire was used for evaluation, comprising nine items: courteous language during instrument collection and delivery, communication during instrument handover, telephone communication, communication regarding sterile-pack defects, timeliness of problem explanations, communication regarding emergency instruments, communication regarding instrument assembly errors, communication regarding newly introduced instruments, and proactive communication in special situations. Historical data were categorized and summarized as very satisfied, satisfied, or dissatisfied. The overall satisfaction rate was calculated as follows: (number of respondents who were very satisfied + number of respondents who were satisfied) ÷ total number of respondents × 100%. Because the historical data retained only categorized summary results, no further inference was made regarding total questionnaire scores or item-level scores.

1.3.3 Timely processing rate of emergency instruments.

Emergency instruments were defined as reusable instruments that, due to clinical needs such as emergency surgery, consecutive surgeries, or repeated use within a short period, required priority reprocessing and distribution. Data were analyzed based on the original categorical records of "completed on time/not completed on time" in the emergency instrument registration records for the corresponding period. The historical records did not use a uniform minute-based threshold for different emergencies. Timely processing rate (%) = number of items completed on time ÷ total number of emergency instrument items × 100%.

1.3.4 Efficiency of emergency instrument processing.

Processing time was defined as the time, in minutes, from completion of the CSSD's collection registration for emergency instruments to completion of the distribution registration for the sterile instruments. Processing times were summarized based on the registration records for the corresponding period and expressed as $\bar{x} \pm s$.

1.4 Statistical methods

Statistical analysis of the summarized data was performed using SPSS version 26.0. Categorical data were expressed as n (%), and between-group comparisons were performed using the χ^2 test. Satisfaction was compared between the two periods based on the categorized summary counts. Emergency instrument processing time was expressed as $\bar{x} \pm s$, and between-group comparisons were performed using Welch's independent-samples t-test. All tests were two-sided, with α=0.05 as the significance level; P< 0.05 was considered statistically significant.

2 Results

2.1 Comparison of instrument processing-related problems between the control and observation groups

The overall incidence of instrument processing-related problems was 0.58% (539/92,154) in the observation group, lower than 1.64% (1,623/98,726) in the control group; the difference was statistically significant (χ^2=477.39, P<0.001). The incidences of inadequate cleaning quality, labeling errors, instrument quantity discrepancies, poor instrument function, and delayed instrument collection were all lower in the observation group than in the control group; the differences were statistically significant (all P< 0.001), as shown in Table 1.

2.2 Comparison of satisfaction of medical and nursing staff in the operating room between the control and observation groups

The overall satisfaction rate among medical and nursing staff in the operating room was 85.00% (34/40) in the observation group, higher than 57.50% (23/40) in the control group; the difference was statistically significant (χ^2=7.38, P=0.007), as shown in Table 2.

2.3 Comparison of timely processing rate and processing efficiency for emergency instruments between the control and observation groups

The timely processing rate for emergency instruments was 85.99% (2,197/2,585) in the observation group, higher than 62.02% (1,763/2,843) in the

Table 1 Comparison of Instrument Processing-related Problem Incidence Between the Control and Observation Groups [*n* (%)]

Group	Total numberof instrument packs processed	Inadequate cleaning quality	Labeling errors	Instrument quantity discrepancies	Poor instrument function	Delayed instrument collection	Total problem events
Control group	98,726	421(0. 43)	205(0. 21)	321(0. 33)	175(0. 18)	501(0. 51)	1,623(1. 64)
Observation group	92,154	102(0. 11)	92(0. 10)	118(0. 13)	72(0. 08)	155(0. 17)	539(0. 58)
χ^2 value	—	173. 91	35. 66	80. 69	36. 24	160. 19	477. 39
P value	—	<0. 001	<0. 001	<0. 001	<0. 001	<0. 001	<0. 001

Note: Different types of problems occurring in the same instrument pack were counted separately. Between-group comparisons were performed using the χ^2 test, and P<0. 05 was considered statistically significant.

Table 2 Comparison of Satisfaction of Medical and Nursing Staff in the Operating Room Between the Control and Observation Groups [*n* (%)]

Group	Number of respondents	Very satisfied	Satisfied	Dissatisfied	Overall satisfaction rate
Control group	40	15(37. 50)	8(20. 00)	17(42. 50)	23(57. 50)
Observation group	40	21(52. 50)	13(32. 50)	6(15. 00)	34(85. 00)
χ^2 value	—	—	—	—	7. 38
P value	—	—	—	—	0. 007

Note: Overall satisfaction rate = (number of very satisfied respondents + number of satisfied respondents) ÷ total number of respondents × 100%. Between-group comparisons were performed using the χ^2 test.

control group; the difference was statistically significant (χ^2=362.32, P<0.001). The mean processing time was 98±14 min in the observation group, shorter than 118±15 min in the control group; the difference was statistically significant (t=50.81, P<0.001), as shown in Table 3.

3 Discussion

Traditional collaboration between the CSSD and the operating room relies on telephone calls, WeChat, and paper-based handovers, with information dispersed among different staff members and communication channels. Emergency needs require repeated manual reminders, while abnormal problems are difficult to track through a continuous chain of responsibility. This study integrated digital registration, node traceability, standardized handover, designated personnel, closed-loop feedback on abnormalities, and multidisciplinary collaborative quality control. After implementation, the incidence of instrument processing-related problems decreased from 1.64% to 0.58%, the timely processing rate for emergency instruments increased from 62.02% to 85.99%, the mean processing time decreased from 118±15 min to 98±14 min, and the satisfaction rate among medical and nursing staff in the operating room increased from 57.50% to 85.00%, suggesting that this management model can improve instrument processing quality and the efficiency of CSSD and operating room collaboration.

Table 3 Comparison of Timely Processing Rate and Processing Time for Emergency Instruments Between the Control and Observation Groups

Group	Total number of emergency instruments	Number completed in a timely manner	Timely processing rate (%)	Processing time ($\bar{x}\pm s$, min)
Control group	2,843	1,763	62. 02	118±15
Observation group	2,585	2,197	85. 99	98±14
χ^2/t value	—	—	362. 32	50. 81
P value	—	—	<0. 001	<0. 001

Note: The timely processing rate was compared using the χ^2 test, and processing time was compared using Welch's independent-samples t test; P<0. 05 was considered statistically significant.

The improvement in instrument processing quality associated with digital closed-loop traceability was reflected across various types of problems. In the observation group, the incidence of inadequate cleaning quality decreased from 0.43% to 0.11%, suggesting that incorporating information on contamination level, structural characteristics, and special cleaning requirements at the handover stage, together with specialty training, may improve the accuracy of information transfer during the reprocessing of complex instruments. The incidence of labeling errors decreased from 0.21% to 0.10%, and that of instrument quantity discrepancies decreased from 0.33% to 0.13%, suggesting that standardized handover, counting and verification, and node-based recording may reduce information omissions and assembly errors. The incidence of poor instrument function decreased from 0.18% to 0.08%, which may be related to continued attention to functional status during handover and inspection and packaging. The incidence of delayed instrument collection decreased from 0.51% to 0.17%, suggesting that emergency registration, priority identification, and responsibility-node tracking may help reduce delays in collection and handover. He Lu et al. implemented full-process traceable digital management of operating room instruments and reported a decrease in the instrument handover defect rate from 2.10% to 0.90%, consistent with the direction of improvement observed in the present study[9]. Fang Xue'e et al. optimized the instrument collection and handover process between the CSSD and the operating room and implemented corresponding management practices[10]. Chen Yuzhu et al. retrospectively analyzed adverse information on reusable instruments reported by the operating room and the CSSD[11]. Yuan Lu et al. applied a traceability management system to the management of endoscopic instruments in the operating room[12]. Zhou Fangfang et al. applied a subspecialty-based jointly optimized quality traceability system to the management of instruments used in day-case orthopedic surgery[13]. The baseline levels and outcome measures differed across studies, which may be caused by differences in study populations, problem definitions, and statistical criteria.

Emergency instrument turnover involves multiple sequential steps, including collection, cleaning, inspection and packaging, sterilization, cooling, and distribution. Delays in information transfer at any step may affect clinical use. In this study, the timely processing rate for emergency instruments increased by 23.97 percentage points, and the mean processing time decreased by 20 min. Digital registration provided clearer visibility of emergency tasks and key time points, enabling relevant personnel to promptly identify instruments requiring priority processing. Summarizing and analyzing the causes of delays also helped identify process bottlenecks. Zhang Dongfang et al. developed an intelligent tracking module for urgent items, after which the delay rate for urgent items decreased from 8.56% to 0.29%, and the reprocessing time per item decreased from 190.03±3.32 min to 135.05±3.46 min[14]. Su Yi et al. reported that the involvement of information technology personnel in emergency surgical instrument processing had a positive effect[15]. These findings are consistent with the direction of improvement observed in the present study, suggesting that digital identification, node monitoring, and collaborative response may improve the efficiency of emergency instrument turnover. Importantly, improved efficiency should be achieved while strictly adhering to requirements for cleaning, sterilization, monitoring, and cooling, and should not be achieved by shortening the necessary processing time.

Multidisciplinary collaboration and joint training are important components of improving communication between the CSSD and the operating room. The operating room places greater emphasis on the timeliness, completeness, and functional status of instrument supply, whereas the CSSD must strictly adhere to reprocessing and quality monitoring procedures, resulting in differences in the priorities of the two departments. Clarifying responsibilities through a specialty management team, conducting joint training, and registering, explaining, correcting, and providing feedback on abnormal problems can improve transparency of the service process. In this study, the sat-

isfaction rate among medical and nursing staff in the operating room increased from 57.50% to 85.00%. He Lu et al. reported that, after implementation of full-process traceable digital management, surgeons' satisfaction with instrument preparation, performance, transfer, counting, and surgical assistance all improved[9]. Zhang Dongfang et al. reported that the satisfaction score among medical and nursing staff increased from 2.33±0.22 to 4.12±0.19 following implementation of an intelligent tracking module for urgent items[14]. Wu Zhiping et al. reported the application of an integrated CSSD–operating room warehousing system for sterile surgical pack supply management in the CSSD, providing practical reference for integrating CSSD–operating room workflows[16]. Wan Meiping reported that PDCA cycle management can improve the quality of instrument handover between the operating room and the supply department and the satisfaction of medical and nursing staff[17]. Dong Cuiming et al. combined PDCA management with the CICARE communication model in operating room–CSSD management[18]. Together with the findings of the present study, these studies suggest that standardized handover, continuous improvement, and ongoing feedback may help improve cross-departmental collaboration.

From the perspective of healthcare-associated infection prevention and control, the primary value of digital closed-loop traceability lies in making key risk points in the instrument reprocessing process recordable, traceable, and amenable to continuous improvement. In this study, process quality problems, including poor cleaning quality, labeling errors, and poor instrument function, were all reduced, suggesting that closed-loop management may help reduce the potential risk of nonconforming instruments entering clinical use. However, this study did not directly assess surgical site infections or other patient outcomes. Therefore, the findings support only an improvement in process quality with this management model and cannot be used to directly infer a reduction in the incidence of healthcare-associated infections.

This study has several limitations. First, this was a single-center historical before-and-after study. Owing to limitations in the way historical quality management data were archived, complete stratified data on high-temperature sterilized instruments, low-temperature sterilized instruments, and endoscopic instruments were unavailable for the two periods. Therefore, the effects of time-related factors, such as changes in surgical volume, instrument composition, personnel, and equipment, cannot be completely excluded. Second, the improvement measures simultaneously included digital registration, process optimization, dedicated personnel in designated posts, specialty training, and multidisciplinary quality control; therefore, the independent effect of each measure could not be distinguished. Third, the satisfaction questionnaire, which was developed by the department, lacked systematic reliability and validity testing. The historical data retained only categorized summary results, precluding further item-level analysis and individual-level paired verification. Fourth, the timely processing of emergency instruments was assessed based on the original categorical records in the management registry for the corresponding periods. The historical data did not use standardized time thresholds for different emergencies, limiting direct comparisons with other studies. Fifth, normality testing could not be repeated because of a lack of individual-level raw processing-time data, and more in-depth analyses of the distribution of processing times could not be performed. Future studies could adopt a multicenter prospective design, refine standardized evaluation tools and definitions of time points for emergency instrument processing, and use digital data to conduct monthly trend analyses and full-lifecycle evaluations of instruments, thereby validating the long-term effects and potential for broader implementation of this model.

4 Conclusion

Following implementation of digital closed-loop traceability management for CSSD–operating room instrument collaboration, the incidence of instrument processing-related problems decreased, the timely processing rate and efficiency of emergency instru-

ment processing increased, and satisfaction among operating room medical and nursing staff improved. This model may provide a useful management reference for hospitals with high surgical volumes and substantial demand for emergency instrument turnover and may provide a basis for standardizing CSSD–operating room collaborative processes and supporting continuous quality improvement. Its long-term effects require further validation in multicenter studies.

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