Risk Management and Healthcare Policy

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ORIGINAL RESEARCH

Effect of Quality Control Circle Activities on Reducing the Failure Rate of Surgical Instrument Pre-Treatment

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Background: The quality of surgical instrument cleaning can affect patient safety. Pre-treatment is a key step in cleaning. This study investigated the effect of quality control circle (QCC) activities on reducing the failure rate of surgical instrument pre-treatment.

Methods: A QCC with a topic of reducing the failure rate of surgical instrument pre-treatment was established within the central sterile supply department of our hospital in January 2023. The failure rates of surgical instrument pre-treatment before and after the QCC activities were compared after problem investigation, target setting, critical factor analysis, root cause validation, and development and implementation of countermeasures.

Results: The failure rate of surgical instrument pre-treatment decreased significantly from 2.9% (46/1568) to 1.1% (11/989) after the implementation of QCC activities, with a statistically significant difference ($\chi^2 = 2157$, $P < 0.001$).

Conclusion: QCC activities provide a structured approach to analyzing the root causes of failures in surgical instrument pre-treatment and develop countermeasures, thereby improving the quality of instrument cleaning and ensuring patient safety. QCC activities could also improve team cohesion and develop staff's problem-solving skills.

Keywords: quality control, surgical instruments, problem solving, factor analysis, statistical

Introduction

The Central Sterile Supply Department (CSSD) plays a significant role in the control of nosocomial infections. It is responsible for the cleaning, disinfection and sterilization of all reusable instruments, utensils and articles used for diagnosis and treatment. The goal of CSSD work is to supply high-quality sterile instruments, utensils and articles to other clinical departments of the hospital.[1] Cleaning is one of the 10 steps of CSSD work procedures. The quality of cleaning directly affects the quality of subsequent disinfection and sterilization, thereby affecting patient safety. Both the relevant guidelines issued by Centers for Disease Control and Prevention, United States and those issued by the World Health Organization have pointed out that failure to comply with the relevant guidelines for cleaning and disinfecting reusable medical devices could lead to the outbreak of nosocomial infections.[2,3] Thorough cleaning of medical devices is the key to successful disinfection and sterilization.[4] However, due to several reasons, surgical instruments may not be collected and cleaned within acceptable timeframes after use, and the contaminants on the surface, joints, grooves, apertures and lumens of the instruments may dry up. The longer the time interval between end of use and start of cleaning, the more difficult the contaminants are to remove. Dried organic matter such as blood stains, mucus and proteins attached to the instruments can easily form biofilms, resulting in unsatisfactory disinfection and sterilization effect.[5] Therefore, it is clearly stipulated in various guidelines that medical device users should pre-treat the devices in a timely manner after use.[6–8]

Pre-treatment is a key step in cleaning. It refers to the following aspects: (1) the user removes the visible contaminants from the instruments, utensils and articles in time, during, or after use; (2) the contaminated instruments

Received: 10 February 2025
Accepted: 31 May 2025
Published: 7 June 2025

that cannot be immediately delivered to the CSSD should be kept moist after use, in accordance with the product instructions;[8] and (3) the CSSD staff should classify the instruments according to the level of contamination, degree of instrument precision, and structural characteristics of the instruments. They should conduct pre-treatment before routine cleaning, including flushing, soaking, and brushing, to preliminarily remove contaminants.[9] Pre-treatment can reduce the microbial residues on the instruments, thereby improving the quality of cleaning and the efficiency of instrument reprocessing, increasing the rate of instrument turnover, preventing the corrosion of instruments, extending the service life of instruments, and reducing hospital costs.[10]

In the late 1950s, Professor Deming and Professor Juran proposed the idea of quality control circle (QCC). In 1962, Professor Kaoru Ishikawa, from Japan, started to advocate QCC activities and took the lead in promoting them in the manufacturing sector. This model was subsequently introduced into the healthcare sector.[11] QCC began to be implemented in Taiwan, China in March 1968 and continued to develop for many years. It was first trialed in mainland China in 1993 and mainly involved nursing quality management, pharmaceutical service management, healthcare quality management, improvement of healthcare skills, and patient health education.[12–16] The application of QCC in nursing has been widely reported and promoted in China to achieve the improvement of nursing quality, particularly in quality management, health education, and new nurse training.[12,17,18] Different from other quality improvement methods, QCC focuses more on clear goal setting and detailed execution steps. For example, lean management puts more emphasis on improving efficiency by streamlining unnecessary steps,[19] whilst total quality management is a quality management method with full participation, which emphasizes the assurance of quality at all levels. Based on full participation, process control is taken as the method, and continuous improvement is taken as the goal, then the whole management model is promoted gradually in a systematic and planned way.[20]

The QCC refers to the activities that a work group engaging in the same or similar work on a site, to continuously improve the workplace and manufacturing process, on a voluntary basis, by means of quality control tools.[21] QCC activities can mobilize employee engagement, stimulate their creative thinking, and enable them to actively participate in and integrate into the workplace management.[22]

In this study, a QCC was established with a topic of reducing the failure rate of surgical instrument pre-treatment. This study determined the root causes of surgical instrument pre-treatment failures through problem investigation, critical factor analysis and root cause validation, in order to find solutions. Through comparing the failure rates of surgical instrument pre-treatment before and after the QCC activities, this study was designed to reduce the failure rate of surgical instrument pre-treatment, improve the quality of cleaning, and reduce the risk of nosocomial infections.

Materials and Methods

Ethics Approval

Ethics approval of this study was obtained from the Medical Ethics Committee of Sichuan Friendship Hospital [SCYY-IRB-20231203]. Informed consent was obtained from all study participants prior to study commencement.

General Information

A total of 1568 medical devices pre-treated in our hospital from February 1, 2023 to February 15, 2023 were classified into the control group (before the implementation of QCC activities); 989 medical devices pre-treated in our hospital from October 1, 2023 to October 15, 2023 were classified into the experimental group (after the implementation of QCC activities). Reusable medical devices pre-treated by clinical department staff after use were included in this study. Disposable medical devices were excluded from the study. All reusable medical devices, no matter which group they were classified into and no matter whether they received a pass in the evaluation for pre-treatment quality, could only be used for patients after being strictly cleaned, disinfected, and sterilized. This was to ensure patient safety.

This was a quasi-experimental study. All medical devices that met the inclusion criteria but did not meet the exclusion criteria during the study period were used as samples in this study.

Establish a QCC

A QCC named "cleaning circle" was established within the CSSD of our hospital in January 2023. The member selection criteria for the QCC were as follows: (1) be familiar with knowledge of QCC; (2) be familiar with work procedures for surgical instrument pre-treatment; (3) participate in this study on a voluntary basis. The QCC consisted of 8 members, aged 26–36 years, with an average age of 30.5 years. There was 1 circle leader, 1 facilitator, and 6 ordinary members. Of them, 3 were nurse supervisors and 5 were nurse practitioners. The QCC leader guided and trained the members, formulated plans, and traced the effects of circle activities. The facilitator guided the circle to complete every objective and clearly informed other members of their roles and tasks within the QCC. Tasks were assigned to the other 6 members according to their strengths. The circle meeting was held twice a month. All QCC members gathered in the meeting to report the progress, then evaluate and rate the processes in the activities.

Determine a Topic

The QCC proposed 4 topics after brainstorming. They scored, discussed and voted on each topic from 4 aspects: policy, feasibility, urgency, and competence of circle. According to the scores, the topic for the QCC activities was determined to be "reducing the failure rate of surgical instrument pre-treatment."

Problem Investigation

A problem investigation was conducted in January 2023. The QCC members collected data concerning the problems that occurred in surgical instrument pre-treatment using an inspection form during the group discussion. The inspection form was created using the 5W2H method. The quality controllers conducted on-site inspections of the pre-treated surgical instruments and evaluated their quality. QCC members investigated the causes and distribution of surgical instrument pre-treatment failures in our department. A total of 1568 pre-treated instruments were investigated. Of them, 46 failed instruments were identified, and the pre-treatment failure rate was 2.9%. Among the 46 failed instruments, 20 had visible blood stains and tissue residuals, 10 were disassembled inappropriately, 8 were mixed with sharp instruments, 5 had povidone iodine on the surfaces, and 3 had adhesives on the surfaces. According to the 80/20 rule, the causes leading to failure, namely visible blood stains and tissue residuals, inappropriate disassembly and mixing with sharp instruments, accounted for 82.61% of all causes, so improvement was focused on these 3 causes.

Target Setting

Target index = present value− (present value × key improvement × competence of circle) = 2.9%− (2.9%× 82.61%× 70%) ≈ 1.2%.

Critical Factor Analysis and Root Cause Validation

After brainstorming, QCC members created a fishbone diagram to identify the causes of surgical instrument pre-treatment failures from 5 aspects: manpower, materials, methods, environment, and rules. A total of 20 causes were identified (Figure 1).

All QCC members rated the importance of each cause, according to the following scoring rule: extremely important = 5 points; important = 3 points; and not important = 1 point. Finally, a total of 7 critical factors were identified using the 80/20 rule.[23] The 7 critical factors were as follows: (1) insufficient communication with clinical departments; (2) no training on the methods of surgical instrument pre-treatment; (3) insufficient training on instruments newly purchased by the hospital; (4) lack of instrument disassembly illustration diagrams; (5) surgical instrument users did not know how to pre-treat the instruments; (6) improper training methods; and (7) the instrument was disassembled incorrectly. Then, the 80/20 rule was applied again to validate the root causes. The following 4 root causes were identified: (1) insufficient communication with clinical departments; (2) no training on the methods of surgical instrument pre-treatment; (3) insufficient training on instruments newly purchased by the hospital; and (4) lack of instrument disassembly illustration diagrams.

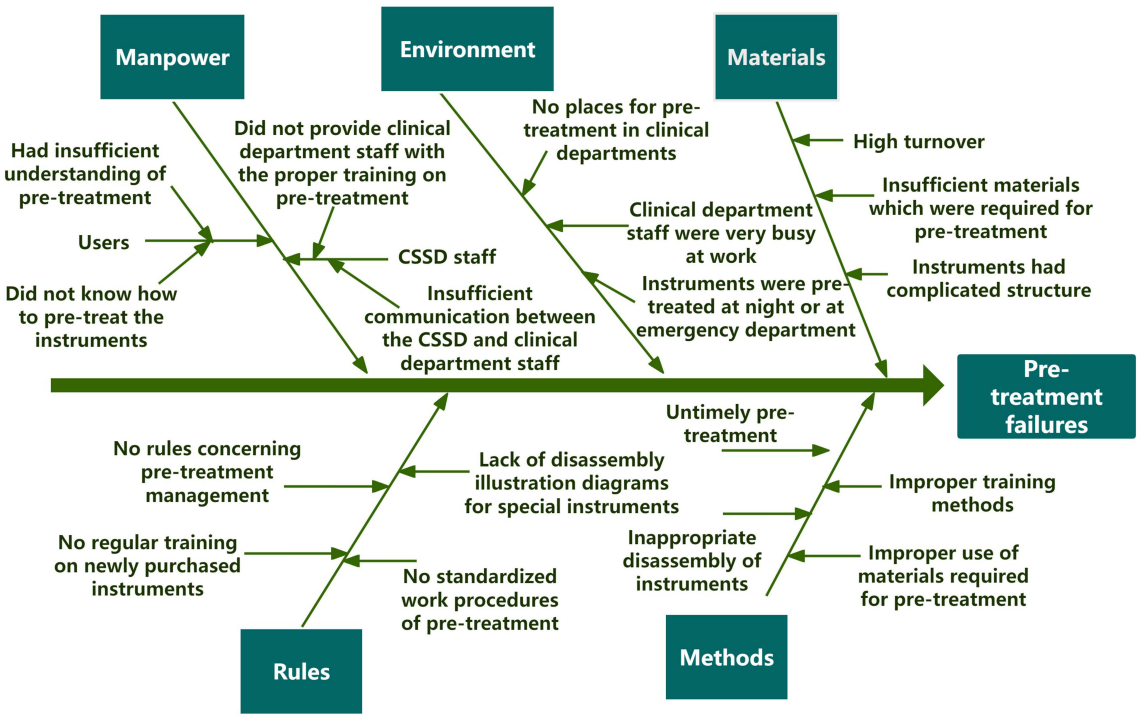

Figure 1 Fishbone diagram for the causes of surgical instrument pre-treatment failures.

Develop Countermeasures

All QCC members discussed the 4 root causes and came up with 4 countermeasures. The circle leader facilitated discussions. The 6 members scored each countermeasure according to feasibility, economy, and benefits. The scoring rule was as follows: excellent = 5 points; acceptable = 3 points; and poor = 1 point. The maximum score for each countermeasure was 105 points. According to the 80/20 rule, countermeasure scored more than 84 points were considered a feasible countermeasure. The 4 intervention countermeasures were:

A Multi-Channel Communication Mechanism with Clinical Department Staff Should Be Established

During the problem investigation, it was found that many clinical department staff did not know the CSSD workflow and the CSSD did not know the demands of clinical departments, leading to poor pre-treatment of surgical instruments. Based on this, the CSSD conducted a questionnaire survey with clinical department staff every month to investigate their satisfaction with CSSD work. The questionnaire was created using the Wenjuanxing, a Chinese online questionnaire survey platform. Moreover, the CSSD head nurse and the optimizing nursing manager of our hospital visited the clinical departments each quarter to conduct a self-check on the cleaning, disinfection, sterilization, storage and pre-treatment of the instruments and to find the obstacles to pre-treatment.[4] The CSSD head nurse and the optimizing nursing manager also communicated with the doctors and nurses of the clinical departments about their demands and coordination. In addition, a face-to-face meeting was held every 6 months for the CSSD and the clinical departments, which used more instruments, such as the operating rooms and the department of plastic surgery. A WeChat group was established for the CSSD and the clinical departments, which used more instruments, so as to provide timely feedback and problem solutions.

Training on Methods of Surgical Instrument Pre-Treatment Should Be Provided

During the problem investigation, it was found that many clinical department staff did not know how and why surgical instruments should be pre-treated, resulting in a large amount of blood stains and tissue residuals remaining on them after use. If surgical instruments are not kept moist after use, the blood stains and tissue residuals remaining on the instruments will become dry, thereby forming biofilms and rust spots on the surfaces. Therefore, the CSSD dispatched nurses to

clinical departments of our hospital and other healthcare institutions receiving our sterile goods. It was done in order to explain the importance and methods of pre-treatment, so as to increase clinical department staff's awareness of the benefits.[4] In addition, the CSSD open day was held to share the knowledge of instrument pre-treatment. Clinical department staff from our hospital and other healthcare institutions were invited to visit the CSSD to know more about the work procedures. Our CSSD collected pre-treatment fee from clinical departments, which did not pre-treat the surgical instruments, so as to make them pay more attention to pre-treatment. After negotiating with the operating room, we agreed the operation room staff should call the CSSD immediately after surgery to come to the operating room to collect the instruments for reprocessing. The instruments that could not be immediately collected by the CSSD staff should be moistened by the operating room staff.

Disassembly Illustration Diagrams for Surgical Instruments Should Be Provided

The problem investigation found that the CSSD nurses had insufficient understanding of the instrument structure. This meant some instruments, which could be disassembled, were not resulting in blood stains and tissue residuals remaining in the joints of the components, so the quality of cleaning was a fail. To solve this problem, the CSSD staff drew the disassembly illustration diagrams for various instruments and saved them into electronic files. The diagrams were then printed out and posted in the decontamination area for check at a convenience. The CSSD provided training and assessment on the disassembly illustration diagrams every week so that the CSSD staff could be familiar with the structural characteristics of the instruments.

Files for Newly Purchased Instruments Should Be Created and Regular Training and Assessment Should Be Performed

The problem investigation found that the CSSD nurses had insufficient understanding of the structure and pre-treatment key points of the newly purchased instruments, which led to the industrial oil remaining in the joints of the components, so the pre-treatment was not thorough. Therefore, the CSSD created a file for newly-purchased instrument management, took photos for each instrument, and then sent the photos to the WeChat group chat. The names of the instruments, which components could be disassembled, and the key points of cleaning, were also sent to the WeChat group chat. One or two inspections on the newly purchased and uncommonly used instruments, and those with complicated structure were performed every month. Assessments were also conducted after the training and for every quarter.

Observation

The failure rates of surgical instrument pre-treatment before and after the implementation of QCC activities were observed. Failed surgical instrument pre-treatment refers to pre-treatment failure by clinical department staff and CSSD staff before cleaning. Surgical instrument pre-treatment by clinical department staff was considered a failure if instruments were not immediately sent to the CSSD after use, or blood stains or tissue residues were found on the surfaces of the instruments at the decontamination area. Pre-treatment by CSSD staff before cleaning was considered a failure if the CSSD quality controllers found that blood stains, tissue residues or industrial oil remaining on the surfaces of the instruments, which was caused by inappropriate disassembly of instruments. The calculation formulation of surgical instrument pre-treatment failure rate is as follows:

Failure rate of surgical instrument pre-treatment = (the number of instrument failed in pre-treatment ÷ the number of investigated instruments) × 100%.

Data Collection

The quality controllers extracted the data concerning the number of surgical instruments in the control and experimental groups from the traceability system, as well as the data concerning the surgical instruments that were recorded as having failed in pre-treatment in both groups. This was to identify the change in the rates of pre-treatment failures in surgical instruments before and after the implementation of QCC activities.

Statistical Analysis

IBM SPSS25.0 was used for data analysis. The enumeration data were represented by percentage. Chi-square test was performed for comparison. A statistically significant difference was identified by $P \leq 0.05$.

Results

Tangible results

The failure rate of surgical instrument pre-treatment achieved the predefined threshold through QCC activities. This rate decreased significantly from 2.9% to 1.1% after the implementation of QCC activities, with a statistically significant difference, as shown in Table 1. After the implementation of the circle activities, visible blood stains and tissue residues were found on the surfaces of 5 separate instruments, inappropriate disassembly was found in 3 instruments, 1 was mixed with sharp instruments, povidone iodine was found on the surface of 1 instrument, and adhesives were found on the surface of 1 instrument.

Intangible Results

After the implementation of the QCC activities, the professional knowledge, communication ability, team spirit, problem-solving ability, sense of responsibility and quality control skills of the QCC members were improved to varying degrees, among which the professional knowledge, team spirit and quality control technique skills of the QCC members were significantly improved, as shown in Table 2.

Table 1 Failure Rates of Surgical Instrument Pre-Treatment Before and After the Implementation of Quality Control Circle Activities

		The Number of Instruments Failed in Pre-Treatment	**The Number of Investigated Instruments**
Before the implementation of quality control circle activities		46	1568
After the implementation of quality control circle activities		11	989
χ^2		2157	
P value		<0.001	
95% confidence interval	Upper limit	<0.001	
	Lower limit	<0.001	

Table 2 Professional Knowledge, Communication Abilities, Team Spirit, Problem-Solving Ability, Sense of Responsibility and Quality Control Skills of Quality Control Circle Members

Items	**Before the Implementation of Quality Control Circle Activities**	**After the Implementation of Quality Control Circle Activities**	**Growth**
Professional knowledge	3.0	4.0	1.0
Communication ability	3.3	3.7	0.4
Team spirit	3.6	4.3	0.7
Problem-solving ability	3.0	3.6	0.6
Sense of responsibility	4.0	4.6	0.6
Quality control skills	3.0	4.1	1.1

Discussion

This study showed that QCC activities was associated with a significant reduction in the failure rate of surgical instrument pre-treatment. This was consistent with the results of Luo.[24] QCC activity is a modern quality management method characterized by a structured, systematic, and incentive-driven approach. It can mobilize the creative thinking of QCC members, enabling them to independently identify problems and implement solutions. This can improve healthcare quality and enhance service level.[25] The QCC activities followed the Plan-Do-Check-Act closed-loop management process and were closely integrated with pre-treatment, a key step in reusable surgical instrument reprocessing. The defects in instrument pre-treatment were identified using an inspection form. Quantitative goals were set based on collected data. A fishbone diagram was used to analyze the factors associated with instrument pre-treatment to determine critical factors. According to the 80/20 principle, those measures with high returns and easy to implement were implemented as a priority. Eventually, the effective countermeasures were transformed into standard operating procedures. QCC activities could effectively promote the standardization, normalization, and continuous improvement of surgical instrument pre-treatment procedures through the structured problem-solving framework and team collaboration mechanism. Through the QCC activities, the failure rate of surgical instrument pre-treatment decreased from 2.9% to 1.1%, reaching the set target value.

This study showed that the QCC activities facilitated the standardization of surgical instrument pre-treatment procedures by implementing structured workflows and quality control measures. A structured management system enhances compliance with standardized procedures, thereby improving the quality of CSSD operations.[26] The CSSD created standardized workflow charts and training and assessment criteria, and specific staff members were assigned to be responsible for the training and assessment of nurses, thereby providing quality control standards for managers, realizing standardization, and improving the quality of work.[27]

This study also showed that QCC activities improved the personal ability and team cohesion of QCC members. Studies by Li et al[28] have demonstrated that QCC activities enhance professional competences, including communication, teamwork, and problem-solving skills. In this study, QCC activities did not lead to an increase in workload. Instead, QCC members actively consulted relevant materials, analyzed the problems, and communicated promptly during these activities. This not only improved QCC members' enthusiasm for work and developed the spirit of unity and cooperation but also further improved the quality of work and overall satisfaction of the department.

This study has some limitations. First, the study's short intervention period limited the ability to assess the sustainability of improvements. Future studies should employ longitudinal designs to evaluate long-term outcomes. Second, this was a single-center study, which might cause bias in research results. Further studies in different hospitals are needed to verify the applicability in different healthcare settings. Third, this was a quasi-experimental study. This study did not strictly follow the principles of random control, and there might be interference from confounding factors. Moreover, instrument pre-treatment failures were determined by quality controllers. Although quality controllers received relevant training, bias might still exist in the results. More rigorous randomized controlled trials should be adopted to validate the research results.

Conclusions

This study provided practical experience of using QCC to reduce the failure rate of instrument pre-treatment. QCC activities provide a structured approach to analyzing the root causes of failures in surgical instrument pre-treatment and develop countermeasures. QCC activities were associated with a significant reduction in the failure rate of surgical instrument pre-treatment, leading to improved cleaning quality and standardized pre-treatment procedures. Additionally, these activities contributed to the professional development of QCC members by enhancing their problem-solving abilities, teamwork, and adherence to quality control protocols.

Data Sharing Statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics Approval

Ethics approval of this study was obtained from the Medical Ethics Committee of Sichuan Friendship Hospital [SCYY-IRB-20231203].

Funding

No funding was obtained for this study.

Disclosure

The authors report no conflicts of interest in this work.

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