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Evaluation of the Impact of Refined Quality Control Management Model on the Qualified Rate of Disinfection and Sterilization of Surgical Instruments in the Sterilization Supply Center

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Abstract: *Objective:* To evaluate the application value of a refined quality control management model for a sterilization supply center. *Methods:* A retrospective analysis was conducted on the work situation of the sterilization supply center from January 2021 to January 2023. The work situation before January 31, 2022, was classified as the control group; a routine quality control management model was implemented, and the work situation after January 31, 2022, was classified as the observation group. The quality of medical device management and department satisfaction between the two groups were compared. *Results:* The timely recovery and supply rate, classification and cleaning pass rate, disinfection pass rate, packaging pass rate, sterilization pass rate, and department satisfaction score in the observation group were all higher than those of the control group ($P < 0.05$). *Conclusion:* Implementing a refined quality control management model in the sterilization supply center can improve the quality management level of medical devices and department satisfaction and is worthy of promotion.

Keywords: Refined quality control management model; Sterilization supply center; Disinfection and sterilization pass rate

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1. Foreword

The sterilization supply center is an indispensable unit of the hospital. Its main function is to perform standardized cleaning, packaging, disinfection, sterilization, and even supply operations for reusable medical devices to realize medical resources recycling and help various hospital departments complete their diagnosis and treatment work orderly [1]. Refined quality control management is a new type of quality control management model. Its core feature is the word "refined"; that is, it has "accurate" and "meticulous" regulations and requirements for many aspects involved in management. Applying "refined" to the sterilization supply center has formulated more detailed rules and regulations for cleaning, packaging, disinfection, sterilization, and other work. It has also conducted standardized training for staff within the management scope to improve the relevant

work processes. It is completed more coherently, smoothly, and with high quality, and significantly enhances the overall quality management level [2,3]. This study explores the benefits of applying the refined quality control management model in the sterilization supply center.

2. Materials and methods

2.1. Materials

A retrospective analysis was conducted on the work situation of our hospital's sterilization supply center from January 2021 to January 2023. Before January 31, 2022, the work situation that implemented the routine quality control management model was classified as the control group. After this date, the work situation that implemented the refined quality control management model was classified into the observation group. 500 medical devices were randomly selected from each group for evaluation. In addition, during the study period, a total of 13 nursing staff in the sterilization supply center were on duty, and all were female; the age range was 30–46 years old, the mean was 38.03 ± 5.46 years; the professional working experience was 1–15 years, the mean was 8.03 ± 2.69 years; in terms of education, the ratio of college to bachelor degree and above was 1:12.

Inclusion criteria: all staff members did not leave their posts for long periods, change posts, or leave their posts during the research period; work experience ≥ 1 year; informed about the research and strongly willing to participate. Exclusion criteria: those who accept other research tasks at the same time; those who study abroad or take leave for ≥ 7 days; those who drop out of the study midway.

2.2. Methods

The control group implemented a routine quality control management model. Based on the relevant systems and processes formulated by the center, the recovery, cleaning, packaging, disinfection, sterilization, and distribution of various medical devices were standardized, and regular inspections of the work quality were conducted during the management period, and focused on the final quality assessment.

The observation group adopted a refined quality control management model. The specific contents are:

Establishing a "refined quality control management team": The team members were composed of the central nurse (1 person serving as team leader), the nurse in charge (1 person), nurses (3 persons), and quality inspectors (2 persons) with more than 5 years of service. The staff in the center was regularly arranged by the team leader to learn the relevant rules and regulations, guidelines, and overall nursing management. Effective supervision was carried out; team members collected past medical device disinfection records, bad nursing practice records, quality management records, and other information, and conducted brainstorming sessions to effectively discover shortcomings and defects in the quality control management process and formulate refined quality control management plan;

Plan implementation:

(1) Improving the quality control management system: The staff improved the existing rules and regulations based on the problems discovered and fully implemented the "personal responsibility system," "reward system," "performance appraisal system," "job rotation system," and other systems. All staff were required to be familiar with relevant regulations and processes, clarify their responsibilities, and work actively.

(2) Organizing training regularly for personnel to participate in: The staff participated in training to learn the relevant knowledge of refined quality control management, clarify all operational points, and pay special attention to cultivating the staff's awareness of laws and regulations, responsibility, and risk prevention, ability to discover and solve problems, teamwork, and other comprehensive qualities.

(3) Scientifically dividing work areas: The staff scientifically divided contaminated areas, clean areas, and office areas, used different colors to distinguish them, and set up eye-catching signs; staff was strictly limited to operating or chatting across areas, and ensured that dedicated personnel was assigned to their posts. The working environment should be regularly disinfected, air monitored, and bacterial cultured. The areas were equipped with a complete ventilation system and personal protective equipment to ensure the safety of the working environment.

(4) Finely managing work processes: Firstly, the staff implemented the "Recycling Responsibility System," assigned dedicated personnel to maintain friendly contact with each department, and reasonably arranged medical device recycling time and sequence. During recycling, the surface of the device was carefully inspected for damage, embroidery stains, blood stains, etc., and the quantity and type of equipment were scientifically classified and carefully recorded; when cleaning, priority was to the types of instruments with a smaller inventory and greater supply demand, and medical instruments with different contamination conditions were addressed in a targeted manner. Medical instruments with embroidery stains and blood stains were cleaned first, by fully soaking them in rust remover and placing them in a special basket for cleaning. Complex instruments that were difficult to clean were disassembled one by one before cleaning. The cleaning was thorough to ensure no residue was left on the surface. Medical devices that were worn or had lost performance after cleaning were recorded promptly and replaced; after cleaning, the quality inspector inspected the devices. If there were still blood stains, proteins, etc., remaining on the surface of the devices, the devices were required to be re-cleaned until the cleaning qualification standards were fully met. The number and type of instruments were carefully checked and recorded, and the labels were pasted before proceeding to the following step.

The second step was disinfection. Medical devices that had passed the cleaning process were classified according to different heat resistance levels. Those with higher heat resistance were disinfected by high-temperature boiling. In comparison, those with lower heat resistance were soaked in 500–1000 mg/L chlorine-containing disinfectant for 30–60 minutes, rinsed thoroughly after disinfection, and then the appropriate drying temperature was selected according to the instrument's material. Metal instruments were dried at 70–90°C, and plastic instruments were dried at 65–75°C, paying special attention to the lumen. The drying process was done with a high-pressure air gun, and heat-intolerant instruments were dried with sterilized low-fiber wadding cloths. After meeting the standards, the next step can be carried out.

The next step was packaging. Professional packaging personnel used a magnifying glass to visually inspect the cleanliness of the device and then conducted occult blood tests, device performance inspections, etc., to ensure that the packaging standards were met. Appropriate packaging materials were selected based on the device's name, type, and quantity. The devices were rechecked before packaging. Quantity was checked by ensuring the chemical indicator card was inside the package and facing outwards. The package was marked with product name, packager number, sterilizer number, sterilization batch (or traceable barcode), sterilization date, expiration date, and other information.

The next step was sterilization. Before sterilization, the integrity and effectiveness of the packaging were confirmed. According to the label outside the package, the sterilization method was selected: ethylene oxide sterilization, pulsating vacuum high-pressure sterilization, or hydrogen peroxide low-temperature plasma sterilization to complete the sterilization operation. The operation was carried out strictly by relevant regulations to avoid secondary contamination; after completion,

the sterilization effectiveness of the equipment, the date of labeling, etc., were reviewed again. Those confirmed to be qualified were placed on the sterile rack, and those unqualified were sterilized again, and the reasons for their non-conformity were carefully recorded so that relevant improvement measures could be formulated in the future.

The last step in this process was supply. The "first in, first out" principle was strictly followed, information such as the number of distributed instruments and sterilization validity period was fully reviewed, and communication with various departments of the hospital was well carried out; the staff also scientifically arranged the supply time and quantity and type of instruments, and placed the distribution list on a special container shelf to facilitate immediate clinical verification.

(5) Continuous quality improvement: In addition to paying attention to final quality, it was also necessary to implement regular inspections and irregular spot inspections to promptly discover problems or hidden risks and then discuss and determine effective solutions to help the continuous improvement of quality management levels.

2.3. Observation indicators

(1) Medical device management quality: The timely recovery and supply rates, classification and cleaning pass rates, disinfection pass rates, packaging pass rates, and sterilization pass rates of the two groups of medical devices were observed and compared.

(2) Department satisfaction: A self-made "Satisfaction Questionnaire" was issued to each hospital department to rate the timeliness of supply, equipment quality, communication, work attitude, etc., of the two staff groups. The scoring range for each item was 0–25 points. The total score was 100 points, and the score corresponded to the level of satisfaction.

2.4. Statistical analysis

Using SPSS25.0 for Windows software as the statistical basis, all the obtained data were divided by nature. If it belonged to measurement data, it was displayed as mean ± standard deviation (SD), and a parallel t-test was performed; if it belonged to count data, it was displayed as %; at the same time, the chi-square test was performed. If the final P value was smaller than 0.05, it indicated that there was a statistically significant difference.

3. Results

3.1. Comparison of medical device management quality between the two groups

As shown in **Table 1**, the quality of medical device management in the observation group was significantly higher than that in the control group, $P < 0.05$.

Table 1. Comparison of medical device management quality [n (%)]

Group	Number of devices	Timely recovery and supply rate	Classification and cleaning pass rate	Disinfection pass rate	Packaging pass rate	Sterilization pass rate
Control group	n = 500	482 (96.40)	491 (98.20)	488 (97.60)	489 (97.80)	485 (97.00)
Observation group	n = 500	500 (100.00)	500 (100.00)	499 (99.80)	500 (100.00)	498 (99.60)
χ^2	-	18.330	9.082	9.430	11.122	10.113
P	-	0.001	0.003	0.002	0.001	0.001

3.2. Comparison of satisfaction levels between the two groups of departments

As presented in **Table 2**, the department satisfaction score of the observation group was significantly higher than that of the control group, $P < 0.05$.

Table 2. Comparison of department satisfaction (mean ± SD, points)

Group	Number of staff	Timeliness of supply	Instrument quality	Communication situation	Work attitude
Control group	$n = 13$	17.52 ± 6.98	17.39 ± 6.58	16.14 ± 5.58	16.25 ± 5.62
Observation group	$n = 13$	24.65 ± 9.79	22.96 ± 8.89	21.99 ± 8.15	22.35 ± 8.65
t	-	2.138	2.142	2.135	2.132
P	-	0.043	0.043	0.043	0.043

4. Discussion

As the hospital's supply department for reusable sterile items, the management quality level of the sterilization supply center largely determines hospital infection rates. Once the management quality of the center does not meet the standards, the reuse of its supplies will not be possible. Sterile medical equipment will cause significant safety risks. Naturally, patients who use related sterile medical equipment will have personal safety problems. In severe cases, it may even endanger patients' lives, and significantly impact the hospital's overall image and reputation. Therefore, it is necessary to attach great importance to the quality management of the sterilization supply center and actively explore methods that can continuously improve its management quality level [4,5].

Previously, the sterilization supply center only standardized medical device recovery, cleaning, and disinfection by existing rules and regulations. The overall quality control management lacked a relatively rigorous and dynamic development mechanism. In addition, its quality control management focuses too much on final evaluation, and many potential risks and hidden dangers in the process are not discovered in time. Hence, it is difficult to effectively improve the overall quality control management level [6,7]. It can be seen from the results of this article that compared with the control group, the quality of medical device management in the observation group was higher, and the satisfaction scores of staff in each department were also at a higher level, suggesting that the refined quality control management model had more application advantages. This model is a complementary and optimized version of the conventional quality control management model. It enables management through refined management measures such as system improvement, personnel optimization, scientific division of work areas, meticulous management of work processes, and continuous quality improvement. Various hidden dangers at work can be discovered and solved promptly, thus the management quality of medical devices can be improved. At the same time, it can also enhance the staff's sense of responsibility and enthusiasm and promote their harmonious connection with the department [8-12].

5. Conclusion

In summary, implementing the refined quality control management model can help the sterilization supply center further improve its sterilization qualification rate and department satisfaction with reusable instruments, utensils, and items, and it is recommended to be promoted vigorously.

Disclosure statement

The author declares no conflict of interest.

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