

Exploring the Value of Refined Management Based on Theory of Constraints in the Management of External Medical Devices in Hospital Sterilization and Supply Centers

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Abstract: To explore the value of refined management based on the Theory of Constraints (TOC) in the management of external medical devices in hospital sterilization and supply centers. **Methods:** This study selected external medical devices in a hospital sterilization and supply center from February to August 2023, totaling 9,000 items, and grouped them based on different management methods. The control group followed conventional management, while the observation group implemented refined management based on TOC. The management outcomes of both groups were compared. **Results:** The observation group showed significantly better management data compared to the control group ($P < 0.05$), with clinical statistical significance. **Conclusion:** The combination of the Theory of Constraints and refined management in the management of external medical devices in hospital sterilization and supply centers can demonstrate unique advantages across various dimensions, such as improving efficiency, reducing risks, enhancing quality, and optimizing resource allocation. This approach provides solid support for hospital medical work, helps improve the hospital's overall competitiveness, and better serves patients.

Keywords: Theory of Constraints; Refined Management; Hospital Sterilization and Supply Center; Management of External Medical Devices.

1. Introduction

The hospital sterilization and supply center (CSSD) play a key role in modern healthcare systems by managing the quality of medical devices, directly affecting medical safety and patient health. The management of external medical devices is one of the main challenges faced by hospitals. External medical devices are usually rented to hospitals by suppliers for implant-related surgeries, and their management involves multiple stages, including receiving and checking, cleaning and disinfecting, inspecting and packaging, sterilization monitoring, storage and distribution, and return after use. During the receiving and checking process, the variety of devices makes the task cumbersome and prone to errors. In the cleaning and disinfection stage, ensuring device cleanliness is challenging, with issues such as inadequate cleaning. In the packaging stage, oversized and overweight devices may not comply with disinfection technical standards, increasing the risk of infection. Given these challenges, traditional management methods are no longer sufficient to meet high-quality management requirements. Therefore, this paper proposes the application of refined management principles and the Theory of Constraints (TOC) to address these issues, providing theoretical support for optimization and improvement to enhance management effectiveness.

2. Materials and Methods

2.1. Baseline Data

A total of 9,000 external medical devices from the hospital sterilization and supply center were selected as examples between February and August 2023, grouped according to different management methods. The control group consisted

of 4,500 devices, including 2,100 joint, 1,500 trauma, and 900 spinal devices. The observation group also had 4,500 devices, consisting of 2,500 joint, 1,650 trauma, and 350 spinal devices. There was no significant difference between the groups in baseline data ($P > 0.05$).

2.2. Methods

The control group managed the hospital's external medical devices following the traditional CSSD workflow:

(1) **Information Registration:** Staff primarily relied on manual records or basic electronic spreadsheets to register the essential information of external medical devices, such as device name, model, quantity, source department, and supplier.

(2) **Cleaning:** The conventional cleaning process was followed, starting with preliminary decontamination to remove visible stains and blood. Simple methods such as soaking and brushing were typically used, followed by mechanical cleaning using common cleaning equipment.

(3) **Disinfection:** Standardized chemical disinfectants were used for soaking or wiping disinfection. However, the control over disinfection time and concentration was often not precise, and the varying contamination levels and material characteristics of different devices were not fully considered, leading to inconsistent disinfection results.

(4) **Packaging:** The choice of packaging materials was relatively limited, and the packaging methods were traditional. This may not have provided sufficient protection for devices during storage and transportation, increasing the risk of secondary contamination.

(5) **Sterilization:** Sterilization was performed according to established parameters, mainly using common sterilization equipment such as autoclaves. However, any deficiencies in the cleaning and disinfection stages, as well as insufficient

attention to details such as device loading, could affect the uniformity and thoroughness of sterilization, potentially leading to sterilization failures.

(6) **Storage:** Environmental control was relatively basic, with imprecise regulation of temperature and humidity. Devices were not stored according to their specific requirements, leading to issues such as rust and aging, which affected their performance and service life.

(7) **Issuance:** Devices were issued based on simple requisition records, lacking refined management and real-time monitoring of the issuance process. This made it difficult to ensure the accuracy and timeliness of device issuance, potentially leading to errors such as incorrect or missed issuance, affecting the normal use in clinical departments.

(8) **Post-use Processing:** Devices were collected and initially cleaned according to conventional processes before being returned to the CSSD. However, due to the lack of effective communication and feedback mechanisms with clinical departments, issues such as damage or malfunction during usage were not reported to suppliers for timely repair or replacement. This led to some problematic devices repeatedly entering the cleaning process.

The observation group implemented a refined management model based on the Theory of Constraints:

(1) Identification of Bottleneck Stages:

1) Data collection at each stage of the management process can help identify bottlenecks. For example, the number of discrepancies in device counts during the receiving and checking process each month, or the frequency of errors caused by unclear labeling, can be tracked. If a specific issue occurs frequently and continues to impact subsequent stages, it may indicate a bottleneck. In the case hospital, prior to implementing the new management model, an average of [X] errors per month were caused by the variety of devices and unclear labeling, which severely impacted subsequent surgical scheduling, highlighting a bottleneck in the receiving and checking stage.

2) In the cleaning and disinfection phase, the standardization of staff operations and the compliance rate of device cleaning can be assessed. If certain staff members exhibit a lack of critical thinking or inertia, fail to prioritize device categorization, or mix different types of devices for cleaning, leading to incomplete cleaning, missed items, or improper use of cleaning equipment, and the cleaning failure rate remains high, these would indicate a bottleneck.

3) In the packaging stage, it is necessary to check whether the proportion of over-weight or oversized device packages and the frequency of wet packs are in accordance with the national disinfection technical standards.

4) In the sterilization monitoring phase, attention should be given to the completeness and timeliness of records, as well as whether accurate tracing of sterilization effectiveness is possible. If some records are incomplete or untimely, affecting the control of sterilization quality, it may also be a bottleneck in the management process. Additionally, in the post-use return phase, the frequency of device damage or loss can be used as one of the criteria to determine if this stage is a bottleneck. In the case hospital, occasional damage or loss of devices has occurred, causing complications in cooperation between the hospital and the device suppliers, indicating a need to resolve the bottleneck in this phase as well.

(2) Development of the Refined Management Plan

1) **Staff Training:** Comprehensive and professional

training courses will be provided, focusing on the characteristics of external medical device management. Training content will include device identification, ensuring staff can accurately distinguish between different types and uses of devices, thus preventing management confusion caused by misidentification. The principles of cleaning and disinfection will be explained in detail, teaching staff the appropriate cleaning and disinfection methods for different types of devices and the corresponding parameter settings to improve cleaning quality. Emphasis will be placed on packaging, including adherence to national disinfection technical standards, controlling the volume and weight of sterilized device packages, and specifying the correct selection of packaging materials and methods to ensure no errors in the packaging process. Sterilization monitoring methods, including the specific operations and interpretation of physical, chemical, and biological monitoring indicators, will also be taught to ensure reliable sterilization results. In addition, infection control knowledge will be disseminated to raise awareness of cross-contamination risks and reduce hospital-acquired infections caused by poor device management.

2) **Process Optimization:** The process will be reorganized, starting from the receiving and checking phase, to create a more rational and rigorous reception procedure. For instance, suppliers will be required to provide detailed and accurate device lists in advance, and double-checking will be arranged during reception to ensure that the device quantity, type, and specifications are accurately recorded, minimizing the occurrence of lost or mismatched devices. The cleaning and disinfection process will be further refined based on device characteristics, categorizing devices by material and structure. The cleaning sequence will be defined, such as cleaning simple, non-lumen devices first, followed by more complex devices with lumens. Specific disinfection parameters, such as temperature, time, and the selection of cleaning agents and disinfectants, will be clarified to ensure thoroughness and effectiveness. The packaging stage will strictly follow standard procedures, with detailed specifications for every step, from device assembly and packaging material selection to sealed packaging, to ensure compliance with sterilization requirements and prevent issues like wet packs. Sterilization monitoring processes will be enhanced for rigor and standardization, requiring complete and timely recording of monitoring data, including physical monitoring of pressure, temperature, and time; chemical monitoring of indicator color changes; and biological monitoring of positive or negative results, allowing for accurate traceability of sterilization outcomes. The post-use return process will also be clearly defined, with a detailed device inspection checklist to verify that devices are returned in good condition, facilitating their proper management for reuse.

3) **Quality Control:** A comprehensive quality management system will be established. During device reception, strict checks will be conducted to ensure that devices are not damaged and function properly, ensuring quality at the point of entry. The quality of cleaning and disinfection will be monitored through a combination of routine inspections and random sampling, using advanced testing equipment, such as magnifying lenses, to check for surface cleanliness and microbial residue. Any non-compliance identified in the sampling process will be promptly analyzed, and corrective actions will be taken. Packaging quality will be checked, including ensuring that

packaging is secure, labels are clear and accurate, and the packaging meets sterilization requirements. Non-compliant packaging will be identified and rectified accordingly.

(3) Implementation of the Plan and Resource Allocation

1) **Human Resources:** Staff shifts and positions will be scientifically arranged based on the volume of external medical devices handled during different periods. For example, during peak surgical times, sufficient personnel will be scheduled in advance for the receiving and checking process to ensure that devices are quickly and accurately entered into the sterile supply center. Due to the heavy workload and technical requirements of the cleaning and disinfection stages, experienced and skilled personnel will be assigned, with manpower allocated based on the number of devices, to prevent incomplete cleaning due to excessive workload. In the packaging phase, responsible and knowledgeable staff familiar with packaging standards will be assigned to strictly control packaging quality. In the sterilization monitoring phase, personnel who have received professional training and can accurately interpret monitoring data will be responsible, ensuring effective monitoring of sterilization results. To enhance the professional skills and knowledge of staff, industry experts or experienced trainers will be invited to regularly conduct targeted training courses and operational skill guidance, allowing staff to keep up-to-date with the latest knowledge and key procedures for managing external medical devices.

2) **Physical Resources:** Advanced monitoring equipment will be purchased, such as high-precision magnifying glasses to check for residual stains after device cleaning, and advanced biological monitoring instruments to ensure the accuracy of sterilization monitoring, providing strong technical support for quality control. Appropriate cleaning and disinfection equipment will be supplied, selecting ultrasonic cleaners, high-temperature and high-pressure sterilizers, and other equipment of different specifications and functions based on the characteristics of external medical devices to ensure effective cleaning and sterilization. Packaging materials will be purchased according to the packaging needs of different types of devices, ensuring sufficient stock of materials that meet national standards, such as hard instrument boxes and sterilization wrapping cloth, to prevent issues like wet packs or increased infection risks caused by non-compliant packaging. Additionally, all equipment and facilities will undergo regular maintenance, with a detailed equipment maintenance plan in place. Specialized maintenance personnel will regularly inspect the operation status of equipment, identifying and addressing any potential faults in a timely manner to ensure normal equipment operation and improve operational efficiency.

3) **Financial Resources:** The hospital will establish a dedicated budget to support the implementation of the refined management plan. This budget will cover costs for staff training, equipment acquisition, packaging material purchases, and equipment maintenance. The budget will be carefully allocated to ensure that resources meet the practical needs of each stage of the management plan. For instance, a significant portion of the budget will be used to purchase key monitoring equipment and advanced cleaning and disinfection devices to enhance the hardware capabilities of the management system. At the same time, funding will be allocated for staff training to encourage active participation and improve professional skills, thereby ensuring the solid

implementation of the refined management plan and its role in improving the management level of external medical devices in the hospital's sterile supply center.

2.3. Observation Indicators

2.3.1. Comparison of Management Conditions

(1) **Cleaning Failure Rate:** The cleaning failure rate is determined by strict quality control standards, evaluating whether the device surfaces contain residues such as stains, blood, or microorganisms, thus assessing the effectiveness of the cleaning process. (2) **Device Completeness and Damage:** This involves calculating the proportion of devices that are missing or physically damaged due to various causes, reflecting the management level during the circulation of the devices. (3) **Packaging Non-compliance:** The selection of packaging materials, sealing methods, and labeling are checked to ensure they comply with standard regulations, ensuring that the packaging provides reliable protection and traceability for the devices. (4) **Wet Pack Issues:** Strict monitoring of the dryness of the sterilized device packages is conducted, as wet packs can foster microbial growth, which may compromise the sterility of the devices. (5) **Sterilization Monitoring Failure:** This focuses on monitoring sterilization processes using physical, chemical, and biological methods to ensure the reliability and safety of the sterilization process. (6) **Premature Release of Devices:** The occurrence rate of the premature release of devices is examined, in order to maintain the rigor of the medical process. (7) **Post-surgery Cleaning Rate:** This measures the timely retrieval and reprocessing efficiency of devices after clinical use.

2.4. Statistical Analysis

Data analysis in this study was conducted using SPSS 27.0 statistical software. For continuous data, the mean $\pm$ standard deviation (SD) was used for precise representation, with the t-test applied for comparisons. The Chi-square test was used for inter-group comparisons, and P-values were calculated through rigorous procedures to determine whether the differences in data were statistically significant. A P-value of <0.05 was considered to provide solid and reliable statistical support for the study's conclusions, ensuring the scientific validity and reliability of the results.

3. Results

3.1. Comparison of Management Conditions

The management data for the observation group were significantly better than those of the control group, with $P < 0.05$, indicating clinical statistical significance.

4. Discussion

The Theory of Constraints (TOC), also known as the Bottleneck Theory or Constraint Theory, was developed in the mid-1980s by Israeli physicist Dr. Eli Goldratt, based on his work on Optimal Production Technology (OPT). It is a management philosophy and methodology that emphasizes the identification and resolution of constraints in a system. The core concept of TOC is that any system has at least one constraint, and this constraint determines the rate at which an organization or enterprise achieves its goals.

Table 1. Comparison of Management Conditions [n/%]

Group	Number of Packages	Cleaning Failure	Incomplete Devices	Packaging Non-compliance	Wet Pack	Sterilization Monitoring Failure	Premature Device Use	Post-surgery Cleaning
Observation	4500	38 (0.84)	24 (0.53)	100 (2.22)	19 (0.42)	12 (0.27)	13 (0.29)	3488 (77.51)
Control	4500	82 (2.01)	93 (1.82)	517 (11.48)	48 (1.07)	24 (0.53)	78 (1.73)	1515 (33.67)
X ²		16.354	41.228	30.282	12.645	4.016	46.903	1751.992
P		0.000	0.000	0.000	0.045	0.000	0.000	0.000

Therefore, overcoming the constraint is key to significantly improving the system's output in a shorter time frame. Essentially, TOC provides a systematic problem-solving approach and a management philosophy focused on identifying core issues within the system and continuously improving the limiting factors. In the healthcare management field, TOC plays a crucial role by offering managers a systematic, logical way of thinking and management approach. Traditional healthcare management often focuses on decentralized management of individual processes, without attention to the key constraints within the overall system. TOC, however, guides managers to adopt a holistic view, examining the entire healthcare management system, and identifying the bottlenecks that limit the quality and efficiency of healthcare services. For example, in the management of external medical devices, common issues such as poor control of cleaning quality and the risk of wet packs during packaging may be identified as critical constraints. By optimizing resource allocation, adjusting management processes, and breaking these bottlenecks, TOC enables improvements in overall management effectiveness. This approach shifts away from the traditional "treating the symptoms" model of management, where issues are dealt with individually, and towards a more refined, scientific, and efficient system. It helps ensure better medical safety, meets patient needs more effectively, and enhances the overall operational level and competitiveness of hospitals. The results of this study show that the observation group, which applied the refined management model based on TOC, showed significant improvements in key aspects of medical device management, particularly in reducing failures in cleaning, incomplete devices, packaging non-compliance, and sterilization monitoring. These results confirm the value of integrating TOC into hospital management practices.

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