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## Application effect of business process management in processing external medical devices and implants

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**ABSTRACT: Objective** The present study aimed to explore the application effect of business process management (BPM) in processing external medical devices and implants. **Methods** The convenience sampling method was applied to select 150 sets of external medical devices and implants used in the Sir Run Run Shaw Hospital affiliated with the Zhejiang University School of Medicine from October to December 2022 as the control group, and 150 sets from January to March 2023 as the experimental group. The traditional manual method of processing information flow was performed in the control group, while BPM was applied in the experimental group. The premium processing rate, the acceptance rate of timely delivery, the closed-loop traceability system of nosocomial infection information, the missed delivery rate, the handover time, and the medical personnel satisfaction with suppliers were compared for same label from same supplier. **Results** The effective acceptance rate, the closed-loop traceability rate, and the satisfaction were higher than those before the application of BPM, and the difference was statistically significant ( $P < 0.05$ ). However, the handover time, the delivery time, the premium processing rate, and the missed delivery rate were lower than those before the application ( $P < 0.05$ ). The satisfaction was 98.7%. **Conclusion** BPM contributes to the standardization of quality surveillance on external medical devices and implants in the hospital, improves the quality control of the whole process, enhances work efficiency and staff satisfaction, and reduces the occurrence of potential safety risks.

**KEY WORDS:** External medical devices; Implant; Business process management (BPM); Hospital; Application effect

### Introduction

The quality of items provided by the central sterile supply department (CSSD) directly affects the medical technology of the hospital and the life safety of patients<sup>[1,2]</sup>. External medical devices, which are used for procedures related to implants, are rented to hospitals by device suppliers and can be reused. Implant refers to an implantable medical device that is placed in body cavities operated surgically upon or physiologically present and retained for 30 days or more<sup>[3]</sup>. According to the requirements of CSSD<sup>[4-6]</sup>, the responsibilities of relevant functional departments, clinical departments, operating rooms, and CSSD should be clarified by the system regard-

ing the management, handover, cleaning, disinfecting, sterilizing, and early release of the devices and implants.

Zhang *et al*<sup>[7]</sup>, Qian *et al*<sup>[8]</sup>, and Li *et al*<sup>[9]</sup> investigated the status of the processing of external medical devices and implants in Chinese hospitals. The results showed that information-based traceability has not been implemented on some devices and implants; no quality control department is set to monitor the items in the hospitals before they are delivered to the CSSD. External medical devices and implants are characterized by significant targeted applications, high prices, and frequent updates<sup>[10]</sup>. Inadequate time to process external medical devices is a common issue as they circulate between hospi-

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tals at all levels<sup>[11]</sup>, which makes quality control and hospital management difficult, thus making them far more risky than surgical instruments circulated internally in hospitals,<sup>[12]</sup> posing a great potential for safety hazards<sup>[24]</sup>.

With the continuous improvement of medical services today, the quality tracing method is hardly able to meet the operational requirements in CSSD. In order to deal with the quality management issues that arise during the processing of external medical devices and implants in CSSD<sup>[8]</sup>, it is necessary to reorganize and redesign the existing business processes, and to integrate the allocation and usage of resources in terms of supply, manpower, material, and financial resources. Business Process Management (BPM)<sup>[17]</sup> effectively solves this issue. BPM is a systematic and comprehensive management model to integrate various business links in the enterprise by standardizing and constructing end-to-end business processes as the core and continuously improving the business performance as the purpose<sup>[18]</sup>. BPM optimizes the integration of personnel, devices, desktop applications, back office, etc., so as to achieve the operation across applications, departments, partners, and customers, and to realize the information convey, data synchronization, business monitoring, and continuous upgrading and optimization of the business processes<sup>[19]</sup>.

In view of the integration advantage of BPM, Sir Run Run Shaw Hospital affiliated with the Zhejiang University School of Medicine (hereinafter referred to as "our hospital") introduced BPM into the whole process management of external medical devices and implants, effectively integrating resources and strengths, promoting the cooperation among subsystems, enhancing the processing capabilities, and improving management efficiency. The present study reports the application effect of BPM.

## 1 Objects and methods

### 1.1 Objects

The convenience sampling method was adopted to select 150 sets of external medical devices and implants used in our hospital from October to De-

cember 2022 as the control group, and 150 sets from January to March 2023 as the experimental group. The inclusion criterion is that the label name from the same supplier and identifier corresponds to the device or implant in both groups; the exclusion criterion is that that does not correspond. The premium processing rate, acceptance rate of timely delivery, closed-loop traceability system of nosocomial infection information, missed delivery rate, handover time between instrument suppliers and Temporary Work Procurement Center (TWPC), handover time between TWPC and CSSD, delivery rate after sterilization of external medical devices and implants, and medical personnel satisfaction with suppliers are compared between the same two groups of labels before and after.

### 1.2 Methods

#### 1.2.1 Management of control group

The control group processed the information flow using a traditional manual method. The specific process is as follows. After the surgery is confirmed, the doctor notifies the supplier offline about the surgery and patient information; the supplier prepares the products, prints the stock list, and delivers them to the hospital. Consumables that need to be sterilized are first sent to CSSD, and CSSD signs for the stock list, sterilizes, packs, and delivers them to the operation room (OR); consumables that do not require sterilizing are sent directly to OR. Consumables that are used up at the end of the procedure or during the procedure are entered into the virtual library by the supplier in the OR medical material management system. The system generates and prints barcodes. The OR personnel scans the barcode or enters it manually into the medical material management system, the latter approach of which is not commonly used; the consumption information is sent to the departmental billing platform for billing, and the *Implant & High-Value Consumables Medical Device Usage Registration Form* is printed; The department gives the registration form provided by the equipment section to the supplier, and the supplier invoices based on the registration form, making product, patient, and invoice associations in the

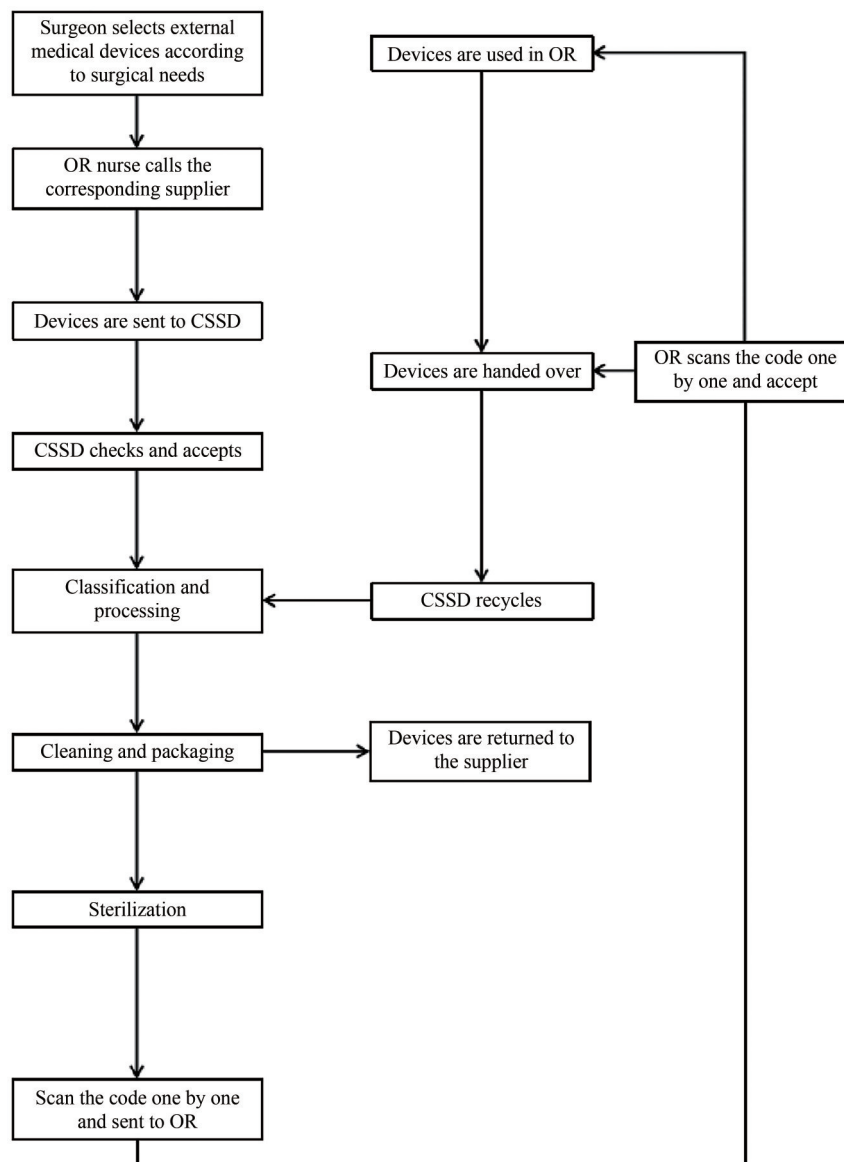
system. After verification by personnel at TWPC, the warehouse personnel enter the invoices and dispense items. Devices and implants are sent to CSSD for cleaning and sterilizing, then printed with identification by the packer in the package inspection area; after passing sterilization, they are distributed to OR. The Details of traditional manual method of processing information flow are presented in Figure 1.

1.2.2 Management of experimental group

The experimental group adopted BMP. Specifically, the department submits the surgery plan application in the system; the warehouse makes the purchase order according to the application and

submits it to TWPC; the TWPC personnel reviews and reports the order through the supply chain; the supplier prepares the products according to the surgery plan from the supply chain system and ships the products to the hospital; the warehouse inspects the products, verifies the information, and prints the virtual warehousing order.

Rental instruments, including implants, which require to be sterilized, as well as lists, are sent to CSSD for processing in accordance with standardized procedures and then delivered to OR on time. After the operation, the consumables used are counted, verified, and billed promptly. Rental instruments that can be reused are routinely pre-



(OR, operation room; CSSD, central sterile supply department)

Figure 1 Traditional manual processing flow of processing external medical devices and implants

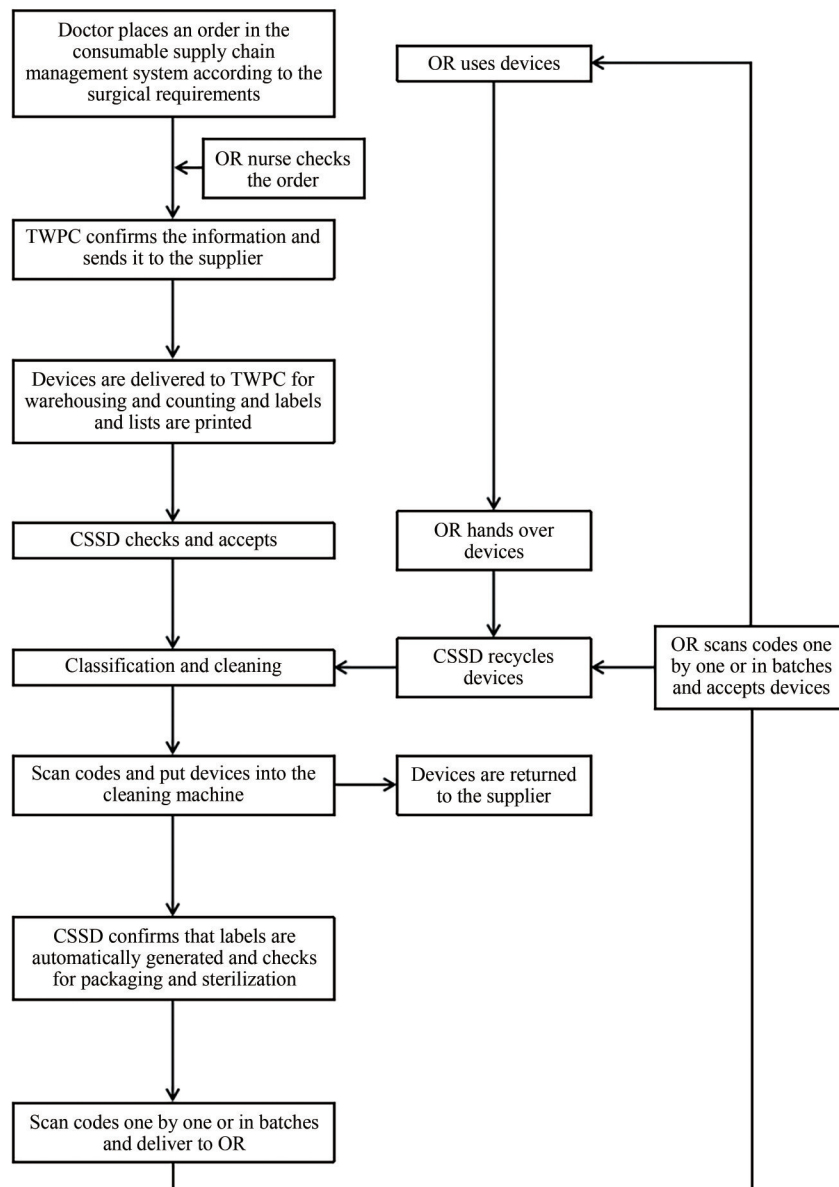
treated and sent to CSSD for cleaning and sterilization, and then returned to the supplier. Details are presented in Figure 2.

1.2.2.1 Optimize business login platform and integrate information management

The overall structure of BPM covers business management, data center, and business applications. The business management includes system supervision, compliance supervision, medical supervision, service supervision, data supervision, and three-party supervision. The data center includes electronic health records, electronic medical records, electronic diagnosis and treatment records,

and electronic basic data. The business applications include medical service, health service, artificial intelligence, third-party assistance, CSSD information system, consumable supply chain management system, OR management system, and clinical warehouse management<sup>[21-22]</sup>.

Hospital Information Platform System Single Sign On (SSO)<sup>[23]</sup> refers to one system in a cluster of multiple applications authorized in all systems without having to log in again. SSO in CSSD is connected to the hospital information system. SSO covers the entire hospital and synchronizes updates and maintenance. The consumable supply chain man-



(OR, operation room; CSSD, central sterile supply department; TWPC, Temporary Work Procurement Center)

Figure 2 BPM flow of processing external medical devices and implants

agement system, OR management system, clinical warehouse management, doctors' and nurses' workstations, third-party maintenance platforms, etc. can all be logged in once authentication and authorization by SSO.

#### 1.2.2.2 Optimize content and processes for entry and exit at TWPC

Login to SSO platform, enter "Delivery Note Entry" program, enter the department code; click Delivery Note No. and scan the QR code on the delivery note; click to get the delivery note, and then click to save the delivery note. If the barcode is not printed in the supplier company, it can be typed in the warehouse. In addition, improve the package module of each supplier company, supplier account on the WEB client of supply chain system, and supplier code in the medical material management system.

The procurement and warehousing processes are optimized. Specifically, the application is made in the medical material management system; the doctor submits the operation plan on the consumable supply chain management system; the system sends the suggestion of consumable requisition; the OR nurse confirms the requisition according to the operation plan; TWPC receives the information and makes a purchase list; the supply chain system in TWPC places an order; the supplier enters the consumable information in the supply chain system and packs the corresponding consumables into boxes. The box is labeled with the name of the consumable package, the name of the surgeon in charge, the patient's medical record number, the box number, and the destination department. Boxes are shipped out to hospitals with delivery notes. Boxes sent to OR and those to CSSD are shipped separately with two delivery notes. TWPC checks and accepts the boxes according to the system order; after acceptance, TWPC signs the delivery note and puts the delivery note and the QR code inside the box; the boxes are sealed and sent to OR or CSSD; OR or CSSD personnel receives the boxes and signs the virtual pre-entry form (two copies, one left behind and one returned to TWPC). The circuit nurse or sterilizer

takes items out for use or cleaning and sterilizing after checking the information outside of the box.

#### 1.2.2.3 Quality control and traceability in whole process

The functions of scanning code before racked and batch scanning code for delivery and acceptance are added to the closed-loop management of the whole process of information-based traceability in cleaning, packing, sterilizing, delivering, receiving, using, and recycling. Programs are set up at each link to reduce human errors.

#### 1.2.2.4 Optimize electronic filing of medical records to correlate devices and implants for nosocomial traceability

The nosocomial traceability allows access to all the instruments and packages of cloth dressings used on one patient based on his/her medical record number. The barcode numbers of the corresponding external medical devices are matched with lists and images stored in the patient's electronic medical record, allowing for more detailed and accurate nosocomial tracing.

#### 1.2.2.5 Simplify business status queries for external medical devices and implants

The information system has three levels that facilitate the query of information related to external medical devices and implants, including the processing status of the device in CSSD, associated personnel information, item information, equipment information, and usage. This information provides the basis for the device budget in the following year and locates the whereabouts of sterilized packages to avoid loss or misuse.

### 1.3 Observation indicators

One QC personnel was responsible for recording the acceptance rate of timely delivery, closed-loop traceability, face-to-face handover time, instrument delivery time, premium processing rate, and missed delivery rate in two groups. The calculation formulas are as follows.

- Acceptance rate of timely delivery=100% - (Number of labels not delivered on time/total number of labels printed) × 100%.
- Closed-loop traceability= (Number of complete

closed-loop labels/total labels printed) $\times 100\%$ .

- Premium processing rate= (Number of temporary expedited labels/total labels printed) $\times 100\%$ .
- Missed delivery rate= (Number of missed labels/total labels printed)  $\times 100\%$ .

In the CSSD decontamination area, QC personnel compared the face-to-face acceptance time between the two groups by timing the individual scanning code and batch scanning code for all sterilized packages in one sterilization rack in the sterile delivery zone.

This project was approved by the Ethics Committee of Sir Run Shaw Hospital, 2024 Study No. 0334 (Approved Ethics No. 2024-2266-01). In May 2024, satisfaction questionnaires were given to 65 nurses and 20 physicians in OR, 36 employees in CSSD, 5 employees in TWPC, and 34 hospital-based personnel from suppliers of external medical devices. The main contents of the questionnaire include receiving efficiency, accuracy, operational convenience, and practicality before and after the application of BPM. A Likert Scale was adopted with the options of “Very dissatisfied”, “Dissatisfied”, “Average”, “Satisfied”, and “Very satisfied”, on a scale of 1 to 5. The questionnaire was completed anonymously to ensure the authenticity and reliability. After the questionnaires were collected, they were entered into the database after being checked for logical errors. A total of 160 questionnaires were distributed and 155 were validly responded (80 from OR, 36 from the CSSD, 5 from TWPC, and

34 from suppliers), with a valid response rate of 96.87%. The calculation formula of satisfaction is Satisfaction=(Very satisfied+Satisfied+Average) Sum/155 $\times 100\%$ .

#### 1.4 Statistical analysis

SPSS 25.0 software was used for statistical analysis. Continuous Data are described as mean  $\pm$  standard deviation, and the t-test was used for comparison. Count data are described by frequency and percentage (%), and the  $\chi^2$  test was adopted for comparison. Differences were considered statistically significant at  $P < 0.05$ .

## 2 Results

### 2.1 Comparison of instrument management before and after application of BPM

Comparison is made on the acceptance rate of timely delivery, closed-loop traceability, premium processing rate, and missed delivery rate of external medical devices and implants in the two groups, as shown in Table 1.

### 2.2 Comparison of handover and delivery time of external medical devices before and after application of BPM

Comparison is made on the face-to-face handover and delivery time of external medical devices and implants in the two groups, as shown in Table 2.

### 2.3 Satisfaction before and after application of BPM

The results showed that satisfaction rate was 83.9% in the control group and 98.7% in the experimental group, and there was a statistical difference

**Table 1 Comparison of instrument management before and after application of BPM (n/%)**

Groups	Premium processing	Acceptance of timely delivery	Closed-loop traceability	Missed delivery
Control group (N=150)	24 (16)	138 (92)	105 (70)	21 (14)
Experimental group (N=150)	4 (2.6)	148 (99)	150 (100)	0 (0)
$\chi^2$	15.756	7.493	52.941	22.581
<i>P</i>	<0.0001	0.006	<0.0001	<0.0001

**Table 2 Comparison of handover and delivery time of external medical devices before and after application of BPM (min)**

Groups	Handover time between instrument suppliers and TWPC	Handover time between TWPC and CSSD	Duration of instrument delivery
Control group (N=100)	90 $\pm$ 5	60 $\pm$ 5	10 $\pm$ 3
Experimental group (N=100)	20 $\pm$ 5	10 $\pm$ 5	1 $\pm$ 0.3
<i>t</i>	9.899	7.071	4.478
<i>p</i>	0.010	0.019	0.046

**Table 3 Satisfaction comparison before and after application of BPM using Likert Scale (n/%)**

Groups	Very satisfied 5 points	Satisfied 4 points	Average 3 points	Dissatisfied 2 points	Very dissatisfied 1 point	Satisfaction
Control group (N=155)	25 (16.1)	55 (35.5)	50 (32.3)	15 (9.7)	10 (6.4)	130 (83.9)
Experimental group (N=155)	95 (61.3)	45 (29.0)	13 (8.4)	2 (1.3)	0 (0)	153 (98.7)

in satisfaction rate between the two groups ( $\chi^2 = 21.46$ ,  $P < 0.0001$ ). The percentage of “Very satisfied” increased from 16.1% to 61.3%, and the difference is statistically significant ( $\chi^2 = 66.62$ ,  $P < 0.0001$ ).

### 3 Discussion

#### 3.1 Intelligent and efficient information integration on external medical devices and implants through BPM

When the traditional manual method is used to process the information flow of external medical devices and implants, the operations are conducted by SSO, and consequently, conflicts may arise between the ideal process and framework initially designed in the original system, or even breakdowns across organizations, departments, or sectors. There is a gap between the management of the devices and implants and the integrated, automated, and intelligent development of processing and management of the whole hospital. Devices and implants are critical but difficult to be managed in sterilization and supply in the hospital because they are circulated among hospitals at all levels and pose a potential threat to quality supervision<sup>[24]</sup>. The upgrading of the information-based traceability system has made the processing of external devices and implants in hospitals more informative and standardized<sup>[25,26]</sup>.

BPM optimizes the traditional process of direct delivery from suppliers to CSSD that items shall be handed over to TWPC for warehousing and supervision before delivered to CSSD. Doctors place orders on the high-value consumable supply chain management system based on their surgical needs. OR nurses log on to the system to select appropriate instruments from a list of pre-prepared packages and confirm information to be conveyed to TWPC. TWPC notifies suppliers to ship prod-

ucts. External medical devices and implants shall be sent to TWPC first. TWPC personnel checks and prints the list details and waterproof code in SSO system, high-value consumable supply chain management system, OR management system, and clinical warehouse management platform. Then items are put into the special box, and sent to the CSSD for processing. Delivery shall be made by 17:00 on the day prior to the day of use after warehousing at TWPC. This optimization effectively reduces the premium processing of the devices and implants by physicians and suppliers, with  $P < 0.05$  being statistically significant, and improves the acceptance rate of timely delivery, with  $P = 0.006 < 0.05$  being statistically significant.

Based on the intelligent SSO platform, a unified information standard is established for all kinds of data. Decentralized applications and data are effectively integrated. One-stop services and intelligent application systems based on the Internet of Things are constructed through the provision of a unified access portal. Authorization is available for designated personnel to log in to the SSO platform and access multiple systems for operation. For example, the operator directly accesses the CSSD information system, the consumable supply chain management system, OR management system, and the clinical warehouse management system once authorized to log in to the SSO platform. BPM contributes to the establishment of macro-strategic awareness, broadens the whole business process including prediction, real-time control, and post-event detection, breaks through departmental boundaries, and realizes intelligent and efficient information management from a business perspective<sup>[27,28]</sup>.

The best practice experience of business processing is accumulated in the BPM system by consolidating the process, standardizing the operation, forming an enterprise knowledge base, and facili-

tating the transformation of the enterprise into a knowledge-based and learning enterprise with the continuous execution and optimization of the process<sup>[19]</sup>. The intelligent, integrated, and informative data processing capabilities of BPM are improved with the assistance of the software system to enhance the management and economic benefits in the operation process<sup>[20]</sup>.

### *3.2 Infection control quality is improved by BPM so that the management of devices and implants is transformed into a systematic process management mode*

It is critical to strengthen the management and supervision of external medical devices because of the high risks to their quality and safety caused by their wide range of sources, high mobility, and frequent use by multiple hospitals<sup>[29]</sup>. External medical devices are complex in structure and thus need to be accepted, cleaned, and sterilized according to the manufacturer's instructions<sup>[13-15]</sup>. The U.S. agencies recommend that external medical devices shall be delivered at least 48 hours in advance, and new devices should be delivered at least 72 hours in advance, to allow for a change of rental supplier in case of validation failure; that sterilization validation of new devices shall be performed so that appropriate cleaning agents, cleaning tools, and rigid containers are prepared on time<sup>[16]</sup>; and that delivery in advance allows sufficient time to perform preoperative processing by CSSD<sup>[7]</sup> for effective sterilization. The application of BPM allows the processing of devices and implants to be transformed from a traditional functional model to a systematic process management model, effectively resolving conflicts and cross-sectoral faults arising from the initial design of ideal processes and frameworks in the system.

The consumable supply chain management system is optimized to simplify the process, automatically identify the unique identification code, and automatically capture the batch number and expiration date of the product. The product business card book with color pictures and the special text boxes for identifying instruments are set up. The special text boxes correspond to various models and sizes of the products horizontally and vertically.

Moreover, the pictures with the product information labels are updated in real-time. Lists and pictures of external medical devices are entered into the information system in CSSD. Fixed waterproof signage is attached. This optimization effectively improves the checking and supplement of consumables in and out of the warehouse by the suppliers and shortens the handover time between instrument suppliers and TWPC as well as between TWPC and CSSD.  $P < 0.05$  is considered a statistically significant difference.

Real-time recording and storage of physical parameters when processing the devices and implants allows data to be queried at any time, facilitating the closed-loop traceability management, thus realizing paperless management and improving the work quality<sup>[30-32]</sup>. The identification code of the device can be traced to each link, including warehousing, cleaning and disinfection, inspection, packaging, sterilization, monitoring, storage, delivery, use, and recovery, as well as the relevant operators. In the event of nosocomial infections, the link and the person concerned can be traced immediately. Only when CSSD manages external medical devices more specialized and standardized, can the efficiency of clinical departments, OR, and CSSD be continuously improved to control nosocomial infections, ensure the service quality of hospitals, and protect the safety of patients<sup>[33,34]</sup>.

### *3.3 Management efficiency is enhanced by the continuous optimization of intelligent, integrated, and information-based BPM*

The information-based traceability system developed continuously plays a crucial role in the management of external medical devices in the CSSD<sup>[35]</sup>. Devices and implants are sent from the CSSD to OR, with the additional functions of batch scanning for delivery and acceptance. When delivering sterilized items, the dispenser can either scan the code and deliver individual packs, or batch scan and deliver. When receiving packs in OR, the operator can either scan individually or in batches. This optimization effectively improves the closed-loop traceability of the information quality of external

medical devices, saves the time of batch scanning and delivering, and reduces the probability of missed deliveries.  $P < 0.05$  is considered a statistically significant difference.

BPM carries out full, real-time, and information-based scientific management of external medical devices and implants in warehousing, receiving, cleaning and disinfecting, inspection, packaging, sterilizing, delivering, and re-cleaning after use. Clear data and information sharing in each business process makes the face-to-face handover and delivery of the devices and implants less time-consuming than traditional management, prevents repeated checking by staff, and improves work efficiency. The processing of accepting and warehousing the devices and implants is optimized through BPM, which improves the on-time delivery rate of the devices, resulting in a significant decrease in the premium processing rate and missed delivery rate. An information-based traceability system is a trend in modern medical services. Making full use of information systems, surgical anesthesia information systems, and color management of the instrument processing realize the whole process monitoring of external medical devices. Information of all links can be traced so that the processing of external instruments becomes informatized, standardized, normalized, functionalized, and programmed<sup>[36,37]</sup>.

#### 3.4 BPM provides basis for budget increases and improve staff satisfaction

Business data is utilized in the application of BPM. Data on commonly-used external medical devices is collected, including statistics on the rented external medical devices and implants in the previous year, and analyzed for supplement. For example, depending on the surgical volume, four sets of long-term spare kits such as lumbar spine instrumentation kits, cervical spine instrumentation kits, extremity joint instrumentation kits, and spinal instrumentation kits are added, thus effectively reducing the usage frequency of renting external medical devices<sup>[38,39]</sup>.

The results reveal that since BPM was applied, satisfaction has increased from 83.9% before

the application to 98.7% after the application. Continuous optimization of the information system and BPM has simplified the handover steps in all links, improved the efficiency of CSSD staff, and shortened the supply time of surgical instruments in OR<sup>[13,40]</sup>. In addition, the originally complicated process of warehousing, sterilization, use, and recycling has been simplified. Each set of external medical devices or implants matches to a fixed identification number and an inventory picture, which makes it easy to order and make additions after use. BPM is initiated once the external medical devices are sent into the hospital in order to accurately trace the whole process and provide safe and sterile devices to OR efficiently and quickly, thus improving the satisfaction of CSSD staff, staff of the suppliers, doctors and nurses in OR, and staff of TWPC<sup>[40]</sup>.

## 4 Conclusion

BPM is applied to manage external medical devices and implants. It is superior to traditional manual information management in terms of quality, efficiency, and staff satisfaction. The whole management process for processing devices and implants becomes paperless, standardized, and modularized for traceability<sup>[41]</sup>, which effectively integrates resources and strengths, promotes the cooperation among subsystems, enhances the processing capabilities, and improves the quality and efficiency of management.

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### Ethical review

This project was approved by the Ethics Committee of Sir Run Shaw Hospital, 2024 Study No. 0334 (Approved Ethics No. 2024-2266-01).

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