

REVIEW ARTICLE

Practice and effectiveness of medical technology management in specialized hospitals based on the concept of total quality management

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ABSTRACT

Background and Objectives: This study explores the practice and effectiveness of medical technology management in specialized hospitals based on the concept of total quality management (TQM). **Methods:** Focusing on a specialized tertiary respiratory hospital and guided by the framework of TQM theory, this research takes robotic surgery as an example to delineate whole-process management measures and systems for medical technologies, especially restricted technologies, and analyzes the technology's practical performance. **Results:** In 2021, the filing of robotic surgery technology for record was officially approved, marking the start of its clinical use; throughout the year, a total of 710 surgeries were performed. Robotic surgery outperformed traditional surgical approaches in terms of unplanned reoperation, intraoperative and postoperative blood transfusion, and 14-day readmission rates. **Conclusion:** Implementing relevant measures in technology access management, quality supervision, and performance incentives for robotic surgery may not only promote the vigorous development of the technology but also enhance medical quality and ensure patient safety.

Key words: specialized hospital, medical technology management, robotic surgery, total quality management

INTRODUCTION

New medical technology is a key driver of innovation and development in hospitals, and acts as the leading force behind hospitals' high-quality and sustainable growth, with the government and medical institutions strongly supporting medical technology. China's National Health Commission officially enacted the "Management Measures for the Clinical Application of Medical Technologies" on November 1, 2018, to bolster the clinical application of medical technology and to advance medical science and technological progress. The policy's introduction marks a move toward a significant strengthening the principal responsibility of medical institutions and the supervisory responsibility of health administrative bodies. Medical institutions now face the challenge of assuming full responsibility for the

competent management of the clinical application of medical technologies.^[1] To clarify the policy's intent, the Shanghai Municipal Health Commission published the "Detailed Implementation Rules of Shanghai Municipality for the Management Measures for the Clinical Application of Medical Technologies" (referred to as the "Implementation Rules") on July 1, 2019. These rules meticulously specify procedures for the registration of medical technologies, application information for submissions, and both ongoing and post-event supervision within Shanghai. The above documents have established a theoretical and regulatory foundation for medical technology management.


With the development of minimally invasive surgery and the concept of rapid recovery, robotic surgical systems (da Vinci surgical systems) are becoming increasingly

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popular in various clinical areas.^[2] Compared to traditional minimally invasive surgery, robotic surgery systems offer clearer 3D imaging and more flexible wristed instruments, the ability to eliminate hand tremors, enhanced hand–eye coordination, and significantly improved operability and safety. To strengthen the management of this technology and standardize clinical diagnostic and treatment behaviors, the National Health Commission has classified robotic surgery as a national restricted medical technology and formulated the “Management Norms for Artificial Intelligence-Assisted Therapeutic Technology.” Total quality management (TQM) is an important quality-centered management activity that emphasizes prevention and whole-process quality control, and adheres to a philosophy of comprehensive, whole-process, and all-member participation, which has evolved into an important management concept for hospitals.^[3] This study, taking the implementation and management of da Vinci surgeries in a specialized respiratory hospital as an example, demonstrates the practice and effectiveness of medical technology management in specialized hospitals based on the TQM concept.

MEDICAL TECHNOLOGY MANAGEMENT PRACTICES

Technology access

In the technology management system, an application for the use of medical technology must be submitted and processed in a three-level management system that includes a clinical department, medical affairs department, and a medical technology committee. According to the requirements of the Implementation Rules, different processes for submitting applications and filing records are established for different categories of medical technologies. Robotic surgery, as a nationally restricted medical technology, requires the applying department to first submit an application form for da Vinci surgical technology according to the corresponding procedure (Figure 1), and the application form must provide evidence of the medical technology's safety and effectiveness.^[4] After a preliminary review by the medical affairs department and a subsequent review in a vertical medical team meeting, the application materials are submitted to the medical technology committee for a further review that covers actual needs, personnel qualifications, conditions for implementation (site and equipment, *etc.*), management standards, and informed consent. After passing this review, the application must also be submitted to the hospital's ethics committee for an ethical review. Once the hospital's review process is complete, it must be submitted to a superior health administrative department for filing as required by the Implementation Rules. Only

after successfully filing for recordkeeping can clinical implementation proceed.

Other technology categories, such as non-restricted technologies, can be implemented immediately after the hospital review without the need for filing with the superior health administrative department. Technologies that are to be implemented for the first time in Shanghai, must also be subjected to a technological assessment by the city's medical association/clinical inspection center based on the classification (non-restricted *vs.* restricted) determined in the assessment process. They then proceed with the corresponding processes of submitting the application and filing it for the record. In the clinical application, prohibited technologies (medical technologies with major ethical issues, those that are clinically being phased out, and new medical technologies not proven by clinical research) are strictly forbidden.

Following the required procedure, the hospital filed da Vinci surgeries with the superior administrative department in January 2021, the date on which the hospital officially started to charge for this service.

Pre-, intra-, and post-event management based on the TQM concept

Establishing systems and organizational frameworks: As level of management is an important factor affecting the implementation of new technologies, medical institutions should first establish corresponding new technology management systems and organizational frameworks.^[5] For all medical technologies, the hospital compiled hospital-level operation manuals for medical technology management, including “Clinical Application Management System of Medical Technologies”, “Early Warning Mechanism for the Risks Associated with Clinical Application of Medical Technologies”, and “Response Plan for Medical Technology Damages.” For high-risk technologies, the hospital formulated specific technical management measures for da Vinci surgeries such as “Management Regulations for Da Vinci Surgical Robot Technology” that specify that the thoracic surgery department is responsible for the management of da Vinci surgical robot technology, with the department head as the person in charge of the technology. Corresponding job responsibilities are clarified for different departments. Operating room nurses are responsible for the use, storage, and disinfection of the da Vinci surgical robot. They are also responsible for charge management and the overall arrangement of the operating rooms of da Vinci surgical robot, keeping records of the use of the da Vinci surgical robot, and designating a person as the administrator. The thoracic surgery department selects patients with indications for da Vinci surgeries based on their conditions. The medical equipment department is responsible for conducting regular maintenance, repair,

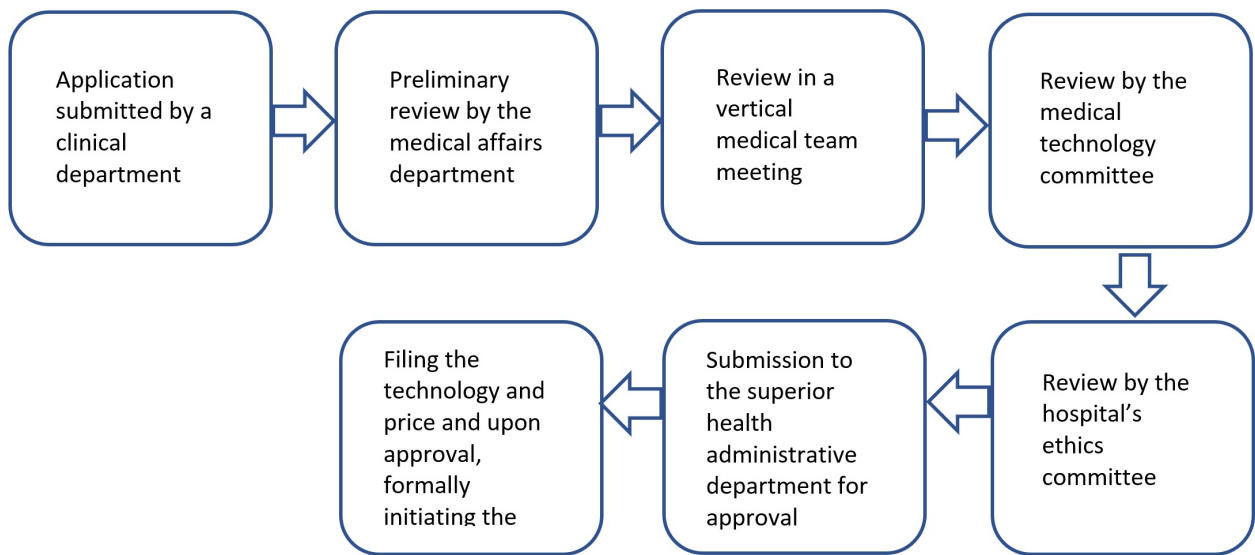


Figure 1. Flowchart for to perform da Vinci robotic surgeries.

quality control, and the consumable procurements of da Vinci surgical robot, as well as organizing personnel training for this equipment. The finance and the operation management departments are responsible for applying for the approval of related charge items and managing health and economic accounting. The medical affairs office is responsible for technology management, personnel access, and the overall coordination of the operational management of da Vinci surgical robot.

Strengthening process and dynamic supervision:

Obtaining technology access and successfully filing mark the legality, compliance, and capacity of a medical institution to use a technology. The whole-process dynamic supervision of medical technology is an effective means to ensure medical quality and patient safety, but it is also challenging to manage the new technology.^[6,7]

Whole-process dynamic supervision includes personnel authorization, information management, archive management, monitoring of clinical performance, inspections by medical departments, and data reporting, *etc.* To ensure proper pre-operative management for robotic surgery, whole-process dynamic supervision is incorporated into the hospital's surgical standards library. Technical authorization and management are facilitated through the surgery application system, which prevents physicians without the necessary qualifications from applying for such surgeries. Both technical and personnel files are managed through dynamic archiving, with effective integration with the information system to ensure real-time updates of personnel qualifications

whenever changes occur.

The hospital has developed an indicator system for process monitoring. The thoracic surgery department, as the responsible department, regularly summarizes and analyzes the clinical performance of the technology, including the number of cases, outcomes, complications, and adverse events to ensure its appropriateness and safety. Additionally, there is an emphasis on improving the accuracy of medical record documentation, including the detailed completion of the medical record's first page and surgical records. To protect patients' right to be informed, the chief surgeon must also fully inform the patient of the technical characteristics of da Vinci surgeries and related costs, and obtain patients' written informed consent before the surgery. As robot surgery is a nationally restricted technology, the medical specialty department must complete related information reporting in the national management information system for the clinical application of medical technologies after each surgery. Meanwhile, the medical affairs department is obliged to periodically retrieve detailed records from the system to verify both the thoroughness of the submissions and the accuracy of the reported information.

The medical management department strengthens the intensity and frequency of regular inspections, including regular on-site inspections to verify the qualifications of the lead surgeon, primary assistant, and nursing personnel. In addition, information on the implementation of the technology is obtained through the surgery system and medical record system, and

complements the information reported by the thoracic surgery department, thereby achieving timely and effective quality control. Regular inspections of medical histories are also carried out, focusing mainly on the adequacy and objectivity of pre-operative doctor-patient communication, intraoperative risks, and prevention plans.

New technology promotion and incentives

The hospital promotes medical technologies that have been approved for use through various forms of publicity, such as internal documents, announcements on the OA intranet, and presentations at weekly hospital meetings. This ensures that clinical departments have comprehensive access to information about new technologies, including their scope of application, prescription names, and payment policies. To encourage applications for and the use of new technologies, the hospital annually presents a New Technology Award with prizes for first, second, and third places, and publicly commends the prize winners in the form of a document issued by the hospital on the OA intranet. Da Vinci surgeries were awarded the first prize in the 2021 New Technology Award. The human resources and performance management departments work together to develop assessment plans that consider both technical difficulty and risk levels,^[8] linking the use of new technologies to development policies, work performance, and the promotion policies of clinical departments. Each quarter, the performance management department provides additional subsidies to the lead surgeons, surgical nurses, and anesthesiologists based on the implementation of da Vinci surgeries.

Effective utilization of assessment techniques and management tools

The adoption of health technology assessment methods is advocated for medical technologies, especially restricted medical technologies, or the medical technologies newly approved for use in Shanghai.^[9] These methods employ multidisciplinary evaluation approaches, including evidence-based medicine, epidemiology, and health economics, to assess the value of medical technologies at different stages of their lifecycle. These evaluations mainly cover the technical characteristics, safety, effectiveness, economic aspects, and social adaptability of the medical technologies. In pre-, during-, and post-event management, proactive pre-event preventive management is conducted using failure modes and effects analysis (FMEA). The plan-do-check-act (PDCA) cycle is integrated throughout the intra-event management. Last, a root cause analysis (RCA) is utilized to identify the causes of an adverse event so that the hospital can improve its management practices.^[10,11] Additionally, management tools, such as flowcharts, fishbone diagrams, and cause-and-effect

diagrams, can also be used to solve specific problems.

APPLICATION PERFORMANCE

The data showed that a total of 710 da Vinci surgeries were performed in 2021. The monthly performance data are summarized in Table 1. In May 2021, the hospital led the nation for the first time in the number of robotic-assisted thoracoscopic surgeries; thereafter, the monthly surgery volume has always been at a leading level nationally. The performance of da Vinci surgeries by disease type is summarized in Table 2, with surgeries (thoracoscopic) for malignant lung tumors accounting for the highest proportion at 72.25%, followed by surgeries for benign lung diseases (thoracoscopic) and mediastinal surgeries.^[12]

In terms of quality indicators, da Vinci surgeries showed significant advantages over conventional surgeries in unplanned reoperation rates, intraoperative and postoperative blood transfusion rates, and 14-day readmission rates, demonstrating the greater safety of da Vinci surgeries (Table 3). Among surgeries (thoracoscopic) for malignant lung tumors, the da Vinci group had a 0% rate of unplanned reoperation and a 1.58% rate of intraoperative and postoperative transfusions, with both indicators outperforming those of the conventional surgery group. Among surgeries for (thoracoscopic) benign lung diseases, the da Vinci group had a 0% rate for unplanned reoperation, a 3.09% rate for intraoperative and postoperative transfusions, and a 0% 14-day readmission rate, with all three indicators outperforming those for the conventional surgery group. Among mediastinal surgeries, da Vinci surgeries achieved lower values of all three quality indicators and shorter overall hospitalization duration and postoperative hospitalization duration than the conventional group. The results indicate that the da Vinci surgery system can reduce hospitalization duration and improve bed utilization efficiency in mediastinal surgeries. Moreover, the age of patients in the da Vinci group was higher than that of the conventional group, reflecting the technical advantage of da Vinci surgery in treating older patients.

DISCUSSION

With the shift from an administrative approval system to a filing system for medical technologies, management faces challenges such as an incomplete management system, insufficiently strict technical review and gatekeeping procedures, and inadequate process management.^[6] The medical institution promotes the development of technology and ensures medical quality and patient safety through the implementation of a series of measures based on the TQM concept, including

Table 1: Number of da Vinci surgeries performed from January 2021 to December 2021

Month	Number of surgical cases	Percentage (%)
1	15	2.11
2	17	2.39
3	79	11.13
4	57	8.03
5	77	10.85
6	77	10.85
7	69	9.72
8	78	10.99
9	62	8.73
10	56	7.89
11	68	9.58
12	55	7.75
Total	710	100.00

Table 2: Number of da Vinci surgeries performed by disease type in 2021

Type of disease	Number of surgical cases	Percentage (%)
Surgeries for malignant lung tumors (thoroscopic)	513	72.25
Surgeries for benign lung diseases (thoroscopic)	97	13.66
Mediastinal surgeries	93	13.10
Tracheal surgeries	3	0.42
Biopsy surgeries	1	0.14
Surgeries for empyema	1	0.14
Surgeries for malignant esophageal tumors	1	0.14
Pleura, chest wall, and diaphragm surgeries	1	0.14

Table 3: Comparison of quality indicators between da Vinci and conventional groups

Surgical classification	Number of cases	Age (years)	Hospitalization duration (d)	Postoperative hospitalization duration (d)	Unplanned reoperation rate (%)	Intraoperative and postoperative blood transfusion rate (%)	14-d readmission rate (%)
Surgeries for malignant lung tumors (thoroscopic)							
Da Vinci group	513	59.6	6.0	4.0	0	1.58	0.20
Conventional group	16 689	55.6	5.0	3.8	0.26	1.73	0.20
Surgeries for benign lung diseases (thoroscopic)							
Da Vinci group	97	58.2	6.9	4.5	0	3.09	0
Conventional group	2 281	53.1	5.3	3.8	0.13	3.68	0.09
Mediastinal surgeries							
Da Vinci group	93	55.4	5.1	3.1	0	2.17	0
Conventional group	304	51.8	5.4	3.4	0	4.28	0

medical technology access management, whole-process supervision, and performance incentives. In managing medical technologies, different medical institutions have adopted and utilized management methods and tools with distinctive characteristics.

The First Affiliated Hospital of Soochow University has explored and established a new system for the management of clinical applications of new technologies, and strengthened management and dynamic supervision at various stages such as application, approval, author-

ization, implementation, reauthorization, and inspection. Through the PDCA method, continuous improvement and evaluation are integrated into the whole-process management. The results show that the system helps to standardize the whole-process management of the implementation of new clinical technologies, promotes the positive development of new technologies, and improves the level of medical services.^[5] Northern Jiangsu People's Hospital has drawn on existing project management theories and methods to manage medical technologies through five phases: medical project initiation, planning, implementation, supervision, and summary.^[13] Relying on project management, Northern Jiangsu People's Hospital has achieved breakthroughs in new technologies and enhanced its brand influence. The First Affiliated Hospital of Tsinghua University has used the quality control circle method and fishbone diagrams to identify the obstacles to the development of new medical technologies and propose solutions.^[14] After implementing a series of measures, the hospital has seen a good number of new technology cases. The introduction of new technologies has effectively shortened patients' surgery time and average hospitalization duration, reducing their financial burden.

Additionally, it is necessary to strengthen the construction of information technology (IT) and make full use of IT management tools for intelligent supervision, so as to improve the precision and efficiency of supervision, and ultimately achieve refined management.

Medical technologies, especially restricted ones, typically consume substantial medical resources; therefore, cost-effectiveness, operational costs, and health insurance payment policies are also important factors influence the promotion of technologies.

In Shanghai, multiple departments have simplified the process for new technologies to apply for determining prices and explored supportive paths for health insurance payment models, vigorously developing cutting-edge medical technologies to enhance hospital diagnostic and treatment capabilities.^[15] Specific measures include accelerating the speed of the review process for new technology approval, changing the "one hospital, one approval" system to a citywide unified pricing system, optimizing the scope of newly permitted medical projects, aligning their prices with national standards more swiftly, and simplifying the recognition process.

Regarding payment policies, the Shanghai Municipal Health Insurance Bureau aims to reduce patient burdens and improve the quality of medical services by exploring a pilot reform for performance evaluation-centered payments and testing a performance-based payment

approach on some diagnostic and treatment items. Full payment by the health insurance department is made only if the items meet assessment requirements, such as items' positive testing rate, treatment technologies' success rate, and the incidence rate of complications. If the requirements are not met, a prescribed deduction is made, thereby encouraging medical institutions to focus more on the management of quality of medical services.

Currently, in alignment with national directives aimed at fostering the high-quality advancement of medical institutions, both the robust development of medical technologies and the augmentation of medical service capabilities have emerged as effective strategies for healthcare institutions to gain core competitiveness. Therefore, more effective management measures and mechanisms are needed to ensure and enhance the quality and safety of medical care.

DECLARATIONS

Author contributions

All authors have accepted responsibility for the entire content of this manuscript and approved its submission.

Conflicts of interest

There is no conflict of interest among the authors.

Data sharing statement

No additional data is available.

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