Management of Medical Technology under the New Medical Policy Background in China

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INTRODUCTION

The National Health and Family Planning Commission of People's Republic of China released the "Regulations on canceling the admission approval of the third class medical technologies and relevant works" in July 2015. According to the new regulation, the obligations and responsibilities of health administration departments for the admission approval of the clinical applications on the third- and the second-class medical technologies will be transferred to medical institutions that perform the operations. Upon the changes of the policy, this study aimed to analyze into the characteristics as well as the current situation, obstacles in medical technology management, and research into the practical experiences of various management patterns to provide recommendations and suggestions for medical institutions as well as health administration departments in improving the mechanism of medical technology management and strengthening the clinical application management of medical technologies.

DEFINITION, CLASSIFICATION, AND CURRENT SITUATION AS WELL AS OBSTACLES IN THE MANAGEMENT OF MEDICAL TECHNOLOGIES IN CHINA

Medical technologies refer to the measures taken for the purpose of diagnosing and curing diseases, alleviating illnesses, reducing the pain, as well as helping patients restore health and prolonging their lives.[1]

According to the regulation on the clinical application of medical technologies published by the Ministry of Health in 2009, medical technologies in China are divided into three classes based on their safety and effectiveness at present.[2] The first-class technologies are accurate in security and effectiveness; the second-class technologies are relatively safe and effective with potential ethical issues or risks might be involved, such as endoscopic diagnoses and treatments, artificial joint replacement surgeries as well as interventional therapies; and the third-class technologies may relate to the significant ethical issues and higher risks, whose safety and effectiveness are yet to be proved, such as tumor ablation therapies, radioactive particles implantation therapies as well as hematopoietic stem cell therapies.

The technologies of different classifications also vary greatly in the management of clinical application in China. For the first-class technologies, the medical institutions are in charge of the management of the admission and operations. The admission and application management of the second- and third-class technologies used to be carried out by health administration departments, while now medical institutions will take up the major responsibilities instead according to the new policy. The reason may lie in the disconnection between management and application of health administration departments due to previous experiences, which make the management of new technologies after the admission approval process

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hard to track. Inadequate operation and the deficiency of management of medical technology may lead to potential risks in safety, and even cause medical accidents such as the recent death case of the cancer patient Ze-Xi Wei. With the introduction of the new policy, the primary change in the management of medical technologies is that health administration departments will cancel the admission approval of the second- and third-class technologies, replaced by medical institutions accomplishing the overall process and registered in the management system of the administration department thereafter. This transition from examination and approval system to registration and recording system in the management pattern of medical technologies has already been adopted by many developed countries such as France, Britain, and Canada. Since the second- and third-class technologies are less accurate in safety and effectiveness compared with the first-class technologies, it would be harder to control the application process and may cause medical safety issues or even accidents if were not handled carefully enough. Therefore, it would be imperative for medical institutions as well as the health administration departments to establish comprehensive mechanisms and adopt practical measures to strengthen the management of medical technologies. Only in this way, the safety and effectiveness of the operations can be fully ensured.

SUGGESTIONS ON STRENGTHENING THE MANAGEMENT OF MEDICAL TECHNOLOGY FOR MEDICAL INSTITUTIONS

As the former policies on medical technology management showed a characteristics of "strict in admission, loose in supervision as well as vacant in abolish mechanism," now the seemingly leniently registration measures of the cancellation on the admission approval of the second- and third-class technologies are not meant to be interpreted as relaxing the regulations on management.[3] On the contrary, its original intention was to transfer the key point of management from admission approval to procedural supervision and to make duties clear for each section so that the administrative functions will be much more promoted and highlighted. Therefore, the following suggestions are provided for medical institutions under the current situation.

Improving systems and regulating procedures for the admission approval of new technologies

Admission approval is the first phase in the management of medical technology, thus it is of great significance in improving the systems and regulating the procedures for medical institutions under the current policy background. In general, there are three major aspects involved in the process. The first aspect is the admission of technologies, which exclusively refers to the assessments made on the technological operations. The key issues of the assessment are the safety, effectiveness, as well as the clinical practicality of technologies concerning whether they were suitable to be

applied in clinical practice based on their scientific natures.[4] The second aspect is the evaluation to the departments and personnel that would perform the operations. The crucial part is to adopt comprehensive assessment into the qualification of the personnel and external condition such as the equipment, devices as well as the materials needed in the process. Besides, the qualifications in conducting a certain technology should be strictly limited to departments and personnel that obtain the approval. The third aspect is ethical evaluation, which means the assessments on whether the technology (especially for third-class technology) will comply with ethical norms should be accepted by the society.[5] In this period, the Ethics Committees of the medical institutes should pay great attention to the ethical attributes of the objectives, tools, and behavior of the new operation.

When all the three parts of assessments are accomplished and approved by the medical institution, certain technologies are considered qualified to be operated in clinical practice. First-class technologies can be carried out according to the operation procedures in clinical practice thereafter. As for the second- and third-class technologies are considered, registrations should be also made according to the requirement of the health administration departments before the official application.

In summary, only when a new technology went through the overall process of the evaluations and registrations, it can officially be applied to clinical practice.

Strengthening procedural supervision of new technology in clinical practice

After new technologies are adopted in clinical practice, medical institutions should also pay great attention in strengthening the procedural supervision to ensure their safety and effectiveness during the operations.[6] Specific management measures should be performed through periodically investigating and inspecting on the practical implementation of the technology, finding solutions to the problems encountered in the process of its development as well as making possible improvements. For example, summaries (including the number of cases performed, quality control of the operations, complications, and side effects) of the new technologies are required to be reported on a periodical basis.[7] In addition, it is also necessary in enhancing personnel training on technical operations and carrying out dynamic control of the qualification through authorization in information systems. Furthermore, it is necessary to reevaluate the equipment and facilities once in a while to ensure that all the external factors related to the quality of the new technology are in suitable conditions.

Adopting the close-loop management mechanism of medical technology

The reassessment as well as the withdrawal mechanisms of medical technologies are not only indispensable supplements to the admission management, but also an effective promoter for the procedural supervision.[8] As for the new technologies

that rare cases were performed in clinical practice during a certain period of time, or those whose clinical effects are not so promising, as well as those appeared to be obvious medical security risks or adverse events according to the procedural assessments, should be reevaluated, and decide whether to be suspended according to the results of the evaluation. When sufficient improvements are made, those technologies could be reapplied in clinical application according to the admission approval procedures. This management structure is called close-loop mechanism which involves the course of "admission-process-exit," which is a realization of the full-scale control of technological management.[8]

SUGGESTIONS ON STRENGTHENING THE MANAGEMENT OF MEDICAL TECHNOLOGY FOR HEALTH ADMINISTRATION DEPARTMENTS

The introduction of the current policy apportioned the duties and responsibilities of medical technology management from health administration departments to medical institutions that carry out the operations.[9] Nevertheless, as the top-level design department of medical technology management, the health administration departments will still undertake the important obligations for constructing supporting policies as well as providing guidance for subordinate organizations to follow. The article below would elaborate on the suggestions and discuss in detail about the measures for health administration departments on medical technology management according to advanced experiences in combination with the current situation as follows:

Promoting the development and emphasizing the function of third-party evaluation in medical technology assessment

At present, many countries in Europe and America have introduced the concept of third-party evaluation into the field of medical technology assessment.[10] Medical technology assessment, which belongs to the category of health technology assessment, began in the 1960s in the United States, followed by Britain, Sweden, France as well as some other European countries in the 1980s. On this basis, the admission systems and management patterns of new medical technology were implemented in those countries.

Medical technology assessment is a comprehensive research approach for short- and long-term clinical as well as social effects of the applications of medical technologies.[11] The contents of the assessment include safety, effectiveness, costs, and benefits as well as social effects (such as politics, laws, ethics, and moralities). The mainstream pattern of international third-party evaluation of medical technologies can be classified into three categories according to the subject of the promoters and the assessment procedures.[12] The first is unified evaluation pattern (such as Britain, France), in which the governments are in charge of setting up third-party health technology assessment agencies to implement uniform

evaluation and supervision management. The second type is multi-subjects evaluation pattern (such as Canada and Australia), in which multiple evaluation institutions are set up between national, provincial, and institutions levels. The third category is market evaluation pattern (such as the United States and Germany). In those cases, health technology assessment agencies are established and funded by private medical insurance institutions, enterprises, and foundations to carry out the evaluation procedures on medical technologies.

The concept of medical technology assessment in China was first introduced in 1994 when Shanghai Medical University established the first medical technology assessment center.[13] Since then, a number of medical technology assessment agencies were funded in other parts of the country. However, the overall development of the system is still in its initial stage since there are many bottleneck factors and limitations.[14] The main obstacles are the absence of legislation and mechanism supports; the insufficiency in transformation from academic research to market application; the incompleteness in the construction of the organizations as well as the lack of industry standards and specific operation procedures. Thus, based on the current policy background and actual situation, it is suggested to strengthen the construction of medical technology assessment in China and develop its functional role in the evaluation and supervision of medical technologies step by step.[15] First, providing medical technology assessment mechanism policy support in the legislation and institutions to make clear its administrative obligations.[16] Second, enhancing the construction of medical technology assessment systems, procedures as well as standards, and developing industry guidance that are suitable and operable.[17] To achieve this goal, it is suggested to establish close cooperation ties with foreign medical technology assessment agencies so that we are able to absorb the experiences in combining with the actual situation in the industry. Last but not the least, promoting personnel training to build a team of professionals.[18] By simultaneously propelling varieties of measures mentioned above, the medical technology assessment mechanism and working pattern of China will gradually be developed, while the management of medical technology will be further standardized.

Developing public notification system and establishing the public information platform of medical technology management

Moreover, another proposal for health administration departments on enhancing the management of medical technology is to be more transparent and open in information publication. To be specific, it is suggested to set up a public information platform for medical technology management.[19] The platform could be designed into three versions for health administration departments, medical institutes as well as public patient users, respectively. Users of different attributes can be logging onto the varied panels of the information platform

according to their identity accounts. The accounts for health administration departments have the authorization in information updating, system managing as well as news publication on the platform. Medical institute accounts obtain the administrative access in reporting the operating information of medical technologies that it has developed or about to develop. The accounts for public will be granted the access of browsing and checking the information of medical technologies of different institutes and the operators, including the basic information of the technologies (such as the name and introduction of the operations, personnel, equipment, and devices) as well as treatment information (such as the number of cases operated, curative rates, improvement rates, deaths rates, possible complications as well as adverse events). In addition, the followed-up survey on the satisfaction rate of patients and their families for each institute and operator of a certain technology could also be carried out on the platform and the results could be revealed on a regular basis. As far as we know, a trial version of the medical technology information platform designed by the National Health and Family Planning Commission will be released in the end of this year. So far, a few medical institutions were granted the function of information trial reporting. The well-established platform will be gradually open to the public to check on the information of medical technologies. Moreover, it is foreseeable that this platform, when well established, would be a great help for patients and their family in obtaining objective information for choosing hospitals, doctors as well as operations and therapies in times of illnesses. In addition, by this means, we are able to promote the transparency and equity of the management of medical technology.

Perspective on the Management of Medical Technology Nowadays

In conclusion, it is hoped by remodifying the structure of management system and procedures in combination with the promotion on the evaluation of professional third-party institutions, as well as establishing the public information platform, the management of medical technology in China will be further standardized and improved under the new policy background. While there is still a long way to go which calls for the joint efforts of medical administration departments, medical institutes, patients as well as public forces.

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Conflicts of interest
There are no conflicts of interest.

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