Development and evolution of medical technology management in China

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The National Health Commission of the People's Republic of China (NHC) made a revision on the original version of the *Regulation on the Clinical Application of Medical Technology* in November 2018.[1] According to the new policy, medical institutions are endowed with the primary responsibility for the management of medical technology. This study aimed to investigate into the development and evolution of policy reform to explore the changes in the concepts and ideas of medical technology management in Chinese medical institutions.

The general concept of medical technology can be summarized as measures taken for the purpose of diagnosing and curing diseases, alleviating illnesses, reducing the pain, as well as helping patients restore health and prolonging lives.[2] The clinical application of medical technology discussed in this paper mainly refers to those whose operational processes are proven to be safe and effective in clinical diagnosis or treatment. And the development and evolution on the policies and regulations of medical technology management in China can be mainly divided into four stages: before 2009, 2009–2015, 2015–2018, 2018–present.

Before 2009, only a few individual medical technologies (such as the transplantation of hematopoietic stem cells, reproductive assistant technologies and other special technologies) are required for administration.[3] The management on medical technology was isolated and separated, lacking supervision and mainly relied on self-discipline, which lead to disorder in management, as well as the abuse of high-risk technologies involving major ethical issues or hidden dangers (such as limb lengthening technology, cloning technology) that impose threatens on medical safety and resulted in serious social problems. Therefore, the introduction of systematic management policies and regulations on the application of medical technologies was imperative at this stage of time.

On this basis, the NHC initiated the *Regulation on the Clinical Application of Medical Technology* in March 2009, which was China's first political document enacted by the health administration department in systematically regulating the clinical application of medical technology, marking the establishment of the comprehensive management on medical technology in China.[4] The regulation categorized medical technologies into three classes according to their safety and effectiveness. Higher class of medical technologies corresponded to greater risks and difficulties in operation. A classified technological catalog was initiated so that different classes of medical technologies were supervised by varied administrative departments accordingly.[5] In addition, the regulation made clear definitions on the procedures of administration and supervision of medical technology requiring new technologies report to the supervision departments annually within 2 years of admission. The feature of management in this period of time was characterized by the initiation of systematic regulation and supervision.[6] It not only categorized different classes of technology, but also clarified the specific procedure in the whole-rounded-process including the administration, assessment, supervision, and evaluation of medical technology, which was a milestone in the management of medical technology. However, with the implementation of the regulation, problems were gradually emerging. First, the procedures for the approval administration (especially for second and third class technologies) were cumbersome, while the application and suspension of technologies within a medical institution were in dynamic progress.[7] Therefore, the routine procedures added heavy burden to medical institutions and health administrative departments. Even worse, it might lead to regulatory problems. As a result, cases of patients failed to be diagnosed and treated in time which led to seriously medical problems or even caused serious medical accidents due to unreasonable application of medical technology happened frequently (such as the case of Ze-Xi Wei incident, resulted from the abuse of autoimmune cell therapy due to inadequate supervision).

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Besides, due to the inequality of information between material reporting and practical operation of medical technologies, how to carry out objective assessments became a major problem for health administrative departments.[8] Last but not the least, the time span for mid-term assessment of new technologies lacked flexibility and operability. To be specific, the 2-year assessment period was relatively long for well-developed technologies, while might not be enough for those with higher risks or operational difficulties. Based on above issues, changes in the management pattern were essential, and a revision on the clinical application of medical technologies was carried out for the first time in the year 2015.

To simplify the administrative procedures of medical technology management, the 2015 revised edition of *Regulation on the Clinical Application of Medical Technology* abolished the former approval process of medical technology in administration, and adopted the dynamic recording mechanism instead. Thus, the major responsibility of medical technology management application management was delegated to medical institutions. For the second and third class medical technologies, the health administrative departments were supposed to publicize the information of the technologies in time (such as the list of medical institutions capable of clinical operation and related application materials to the society) for the convenience of public inquiry and supervision. In the revision, the establishment of post-operational supervision mechanism of medical technology was also mentioned.[9]

As we look back, the revision of the stage could be regarded as a transitional period for change of perception in medical technology management. The core value of the revolution was to change the approval procedure into recording procedure in admission of new medical technologies, which greatly reduced the cost, improved the efficiency and increased the flexibility in management. Besides, the revised regulation clearly identified that medical institutions were in major charge of medical technology management, which endowed hospitals with greater responsibilities and stricter requirements. Since the new regulation mentioned the establishment of a post-operational supervision mechanism for the clinical application of medical technology and the change of subjects for second and third class medical technology management, the difficulty of management for medical institutions mainly lied in how to carry out specific supervision on these two classes of technology. The absence of explicit definition in specific operational procedures, time interval of supervision in the newly revised regulation might pose risks due to ineffectiveness in management.

Through the smooth transition period as well as the continuous improvement of medical technology management in the previous stage, the NHC revised the *Regulation on the Clinical Application of Medical Technology* for the second time and put into implementation in October 2018. The new regulation was characterized with the complete removal of systematic design for administration approval procedure and the replacement of recording mechanism in the clinical application of new medical technologies. Further, the newly revised version introduced the concept of negative list and restrictive list of medical technologies instead of the former three-classes-technology definition. Moreover, the new regulation made specific requirements on the quality management of medical technology application, the standardization in training and assessment of technical operators, as well as details for public supervision on medical technology, which made further improvement in the whole-rounded-process management system.

First, the new regulation introduced negative technology list management mechanism, prohibited the clinical application of forbidden medical technologies, and put more focus on medical technologies that needed stricter supervision. Prohibited technologies were those inaccurate in safety and effectiveness (eg, pituitary alcohol lesion for intractable pain); involving major ethical issues (eg, clonal therapy, surrogate technology); already been clinically eliminated (eg, radial keratotomy) or new technologies that yet to be proved operable in clinical researches (eg, technologies involving the use of drugs, medical devices, preparations that failed to gain the approval of administrative departments), etc. The operation of prohibited technologies was strictly forbidden in clinical. Restrictive technologies were those with relatively greater operational difficulties and risks, in need of scarce resources, involving major ethical issues that called for close attention. The application of prohibited technologies was strictly supervised by provincial or National Health Administrative Departments, and the scope roughly coincided with the second and third class technology compared with the former classification. The core essence in the transformation from three-classes-technology management to negative list management was to adopt compulsory measures in regulating technologies of high-risk, uncertain and ethical, and radically eliminated the application of technologies whose effectiveness and safety could hardly be ensured in clinical practice, which enhanced the strictness in management. Moreover, the new regulation required all medical institutions about to carry out clinical application of restrictive technologies conduct self-assessment according to relevant clinical instrumentations as the basis of operation. Those who met the standards were seen as qualified for conducting further clinical operation. Afterwards, the recording of the technology should be file within 15 days from the date of its first clinical application in local health administrative department. Meantime, an information supervision platform was established requiring medical institutions report the application of each restrictive technical implementation case timely and accurately to further strengthen the regulation. Health administrative department would publicize the list of medical institutions and the application status of restrictive technologies in its administrative region to accept social supervision. What is more, the new regulation established the quality management and control system on the clinical application of medical technology, meanwhile, enhanced the role of medical quality control organizations at all levels and in all specialized areas to carry out routine monitoring and periodic evaluation. As the major managing department of medical technology, medical institutions should set up specific divisions of technology

management, specify every segment of the process including catalogue management, operation grading, personal authorization, quality control, file management, dynamic evaluation, etc. This helped to clarify the details of contents, cycle and working mode of the after-the-event monitoring in medical technology management, which is more operable than the transitional period.

There are several features in the process of the development and evolution in the management of medical technology. The pattern of management is changing from separate to systematic. Before the enactment of first edition of *Regulation on the Clinical Application of Medical Technology*, the management of medical technology basically focused on individual ones. The regulation of 2009 classified medical technologies into three classes and made the requirement of the administration for each class of technology respectively. Afterwards, the revised edition established the concept of negative technology list in defining prohibited and restricted categories of medical technology. The transition reflected a progress in medical technology management of a disorder and separate mechanism to a more systematic and comprehensive one.

Second, the measures of management are changing from extensive to specific. From a relatively vague definition on technology classification, admission procedures, operational supervision to clear measures, the regulation had become more operable through the evolution.

Third, the range of management is changing from monopolistic to public. The monopoly of medical institutions on the application of restrictive medical technology was broken up since the admission process of new technology changed from approval to recording. The former mode might result in technological monopoly due to the existence of admission barriers, thus some medical institutions failed to have the opportunity in carrying out a restrictive technology because they were not qualified during the period of admission. However, the current recording mechanism eliminated the approval process, which greatly improved the efficiency of management and promoted the popularization of new technologies.

Moreover, the process of management was changing from stationary to dynamic. With continuous development in medical industry, medical technologies had also gone through changes. Operations regarded as high operational difficulties or risks 5–10 years ago may had become regular ones at present, while some might be gradually shifted-out due to poor therapeutic effects or side-effects that had been replaced by other operations. Therefore, the management of restrictive technology was no longer stationary. Instead, they were updating dynamically with time.

Last, the cycle of management was gradually changing from enclosed to transparent. In regards to the evolution of regulation revision, we came to the conclusion that management of medical technology had changed from closed-loop management mode of health administration department – medical institution into the public supervision mode of the health administration department – medical institution – public platform. The public were entitled to make inquiries about information concerning medical technology and the operational institutions, personnel as well as cases in the supervision platform, making the management procedures more open and transparent. On the other hand, the transformation in management also strengthened the requirement for medical institutions.

In conclusion, through years of development and evolution, the management of clinical technology application had gradually changed from separate, extensive, stationary, monopolistic, and enclosed mode to systematic, specific, public, dynamic, and transparent management. Meanwhile, the major responsibility subject had shifted from health administrative departments to the medical institutions, accepting the supervision of health administrative departments and public authorities, which set higher standards and requirements for hospitals in the operation of new technologies. For medical institutions, especially those that had already or intended to carry out restrictive technologies, how to formulate systematic procedures in the administration, evaluation and supervision, improve recording mechanism in the application, enhance authorization management for operational personnel are major priorities to be considered.

Conflicts of interest

None.

References

1. Regulation on the Clinical Application of Medical Technology. National Health Commission, 2018. Available from: http://www.nhfpc.gov.cn/fzs/s3577/201809/ch/. [Last accessed on 2019 March 1].
2. Wu S, Chen T, Wu M, Pan Q, Xuan Y, Wei LY, *et al*. Management of medical technology under the new medical policy background in China. Chin Med J 2016;129:2745–2748. doi: 10.4103/0366-6999.193453.
3. Wu LJ, Pan YL. Problem and countermeasures of clinical application management of medical technology (in Chinese). Chin Health Qual Manag 2015;22:29–31. doi: 10.13912/j.cnki.chqm.2015.22.3.11.
4. Lu B, Lin FF, Li ZY. Reflection and management after the canceling of non-administrative licensing approval to the third rank medical technology (in Chinese). Chin Hosp Manage 2015;35:28–29. doi: 1001-5329(2015)10-0028-02.
5. Wu S, Ge Y, Xu X, Xuan Y, Chen T. Research of admission management standards and working patterns of first class medical technologies. Chin Med J 2014;127:2860–2862. doi: 10.3760/cma.j.issn.0366-6999.20140948.
6. Zechmeister I, Schumacher I. The impact of health technology assessment reports on decision making in Austria. Int J Technol Assess Health Care 2012;28:77–84. doi: 10.1017/S0266462311000729.
7. Weill C, Banta D. Development of health technology assessment in France. Int J Technol Assess Health Care 2009;25 (Suppl 1):108–111. doi: 1010.1017/S0266462309090503.
8. Han L, Yan SJ, Jia YB, Cai J, Zhang C. Practice and exploration of medical technology management in Shanghai (in Chinese). Chin Health Resour 2014;17:169–171. doi: 1007-953X(2014)03-169-03.
9. Wu S, Chen T, Pan Q, Wei L, Wang Q, Song J, *et al*. Establishment of a quantitative medical technology evaluation system and indicators within medical insititution. Chin Med J 2018;131:1327–1332. doi: 10.4103/0366-6999.232804.

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