Technical Report on Study of Policy Evaluation on Hi-tech Medical Devices （HTMDs） Management and Planning in China

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Abstract: Literature review, focus discussion and in-depth interview method were used in this study. Based upon the review of the historical change and development in management of HTMDs in China and other international lessons, recommendations were suggested by the team. Some of the recommendations have been adopted by the MOH and a new regulation framework is in process in China. We strongly suggest that evidence-based approach should be employed in the future for decision-making.

In China, there are very few researches on the management and regulation policies of High-tech Medical Devices (HTMDs). As identification of poor regulation on HTMDs, in 1995, the MOH of China has enacted a national act on the allocation and management of HTMDs and put forward the management framework and guidelines. With the

method of population to HTMDs ratio, the MOH has set up the allocation criteria for CT, MRI and X knife for the period of 1996 to 2000. In 1999, a national guideline on regional health planning was also introduced, it emphasized the regulation on HTMDs. However, as regulation on HTMDs was very new and the authority is short of experiences, there are still some problems in the implementation process. After 10 years of regulation practice, there is a need to know the situations and evaluate the effects of relevant policies.

Enhancing the macro management of HTMDs is not only helpful to reach the cost-effectiveness goal of the investment but also promote the overall allocation of HTMDs. It will improve the geographical access and the technical efficiency of HTMDs, which will enhance the role of HTMDs in service delivery. However, there are still some problems due to the time constrain and technical limitations. We are short of researches and evidences on assessment of HTMDs management and policy analysis. So, international information and lessons will be helpful to China's regulation on HTMDs.

Literature review method was used to collect international experiences in HTMDs regulation. In some developed countries, some technology assessment agencies have been set up in USA, France, Sweden, Holland, Canada, and Japan etc. The assessments have been conducted on the method of clinical treatment, diagnosis, new drug and medical equipment application in these countries. The technology assessment activities in

HTMDs also could be divided into macro and micro levels. Macro assessment relates to the allocation and distribution of equipments as well as equity and access issues. Micro assessment includes the feasibility study on the adoption of HTMDs, selection of equipment model, assessment of safety and validity, and cost-benefit analysis within hospitals. In order to improve safety and validity of equipment, many countries have established more certification and licensure on HTMDs. The certification mostly aims at technical indicators, validity and safety. It will be permitted into the market only at the time when it is in accord with all of the standards, and then the HTMDs could be financed by insurance schemes. The certification and licensure not only restrains the over expansion of the medical device market, but also assures that the products would not harm the patients. Ministries of health in many countries participate in management directly or indirectly, for example FDA of USA is in charge of checkup and authorization of the medical device entering the market. Moreover many developed countries managed the growth in the quantity of HTMDs as a whole. At present, the quantity of CT and MRI is 4.3 and 0.9 per million populations in UK. The measure used in Italy is to control the quantity of HTMDs based on population ratio. Canada and France's methods are like this, and they also carries out a "planned ceiling" for HTMDs.

Here is the some information in the development about HTMDs in China in the recent years. Since 1995, the MOH of China initiated regulation on HTMDs and a National Act was issued on management and utilization of HTMDs. Since then, some specific regulation policies were formed to control CT, PET-CT etc. Under the regulation, the hospitals should make an application to the local health authority when they plan to purchase a

HTMD and the final decision was made by MOH. There are 8 items of HTMDs were under the regulation by MOH. The MOH has also issued national plan (1996-2000) for CT, MRI and X-knife.

The team initiated a investigation in 10 provinces to assess the technical efficiency of HTMDs. Results showed that the technical efficiency was not very good. For CT, the technical efficiency was only 37%, for MRI, it was only about 40%. Based on the survey, research has been done on the basic working situations for hospitals which possessed HTMDs, then tried to find the variables that were related with the HTMDs' adoption as the qualification standard for health institutions to purchase high-tech medical equipments. Further more, the econometrics models were also established. For example, based on the dependent variable which is workload of a specific HTMD, the independent variables which are basic workloads of hospitals, then the significant independent variables could be identified using the stepwise multi-regression model. By using the model, policy makers can make decisions about whether to give a licensure or not to a hospital based on the calculation results on the expected efficiency. As the regional health planning is being carried out in China, government began to give higher priorities for the management of HTMDs. Therefore, it is the key that scientists can project the amount of equipment in the future years in different province by using scientific method. Domestic scientists ever had a try on these aspects by building

up a time-lag stepwise multi-regression model. The models can tell the relationships among social economic, population, health and the amount of medical equipments. By establishing the medical equipment allocation planning, the health policy makers could find the evidences for future policy interventions.

The research on HTMD allocation model which was developed by the team is suitable to the occasion of China at present. Although No. 43 Minister Act in 1995 on HTMDs has a good effect on control the over growth of equipments, the local administrative institutions generally feel that there are still lack of tools to set the qualification for health institutions. It is difficult to judge the application from the health institutions, which might resulted in low utilization efficiency in some hospitals. This would also result in resource waste and other serious problems.

The present situations urgently need to be studied on how to control the health institutions to adopt equipments wisely, and how to control the equipment's total amount in a scientific development view, and then we can deal with HTMDs allocation under the principles of equity and efficiency. In addition, we proposed that the management of HTMDs should be emphasized with the tool of sector-wide regulation. All of the health institutions, no matter how it is belonged to or owned by, they must abide by the rules and serve the local people. Only in this way, can

we really better the resource's efficiency. The macro-management of HTMDs should combine with the regional health resource planning, especially in the process of drafting the 11th Five-Year Plan across the country. We should make the health resource as a key component in health sector development, which can strengthen the government's roles in services delivery and quality assurance.

Based on the HTMDs management situations in nowadays, there are two serious problems in front of us, low efficiency and induced demand, which puzzled the management of HTMDs. In China the market failure in HTMDs allocation is obvious and we need the government intervention to correct it. Then we can enhance the macro adjustment and control over HTMDs. Therefore we should enhance the government's macro management and deepen the health system reform. Based upon the understanding of the current situations in China and experiences and lessons drawn in recent years, some potential options should be considered:

1. To adjust the HTMDs management list according to the development level of social-economic level and the trend of technical improvement. The team suggests that Proton-knife, Neutron-knife, MM50, DSA (above 800mA) and SPECT should be included into the regulation list so as to deal with the new situations in technology development.

2. To reform the management system and re-allocate the administrative power rationally so as to increase the participation and enthusiasm of the local health authorities in HTMDs regulation. The local health bureaus were not very active and with less responsibility in HTMDs management, the MOH was burdened with a lot of tasks. So, local participation should be encouraged. The team suggests that two-tired management system should be established with more involvement of the provincial health bureaus. In order to increase the positive participation of local governments in supervising the medical equipments and improve the overall performance of regulation in medical devices, decentralization reform is recommended by the team. Some very expensive and high-tech medical devices such as Proton-knife, Neutron-knife, MM50 PET-CT and γ knife should be regulated by MOH directly. Other less expensive technology like CT, MRI, Linear Accelerator, SPECT etc could be controlled by the provincial bureaus, but they should report to the MOH about planning and management. Provinces should be encouraged to include some other new technology into the regulatory list and take an active role in the regulation practice. This will release the burden of MOH in regulating medical devices market and will better the overall management situation in HTMDs. MOH should be responsible for the licensure of the 1st entry-to-market technology to guarantee the safety, quality and cost-effectiveness.

3. To improve the administrative efficiency, three licenses should be merged together. Since 1995, MOH of China used three licenses in the regulation of HTMDs, they are license for procurement and installment, license for staffs, license for practice. The three licenses are under the different management bodies. This make it too complicated and even exhausts the hospitals who hopes to install a high-tech medical device. Some of hospitals did not apply for any of three licenses to avoid the administrative process. So the MOH should combine the three licenses together to relieve the unnecessary burdens of hospitals. MOH should focus on license for installment. This will highlight the role of the government in the regulation practice.

4. To issue the national plan and guidelines quickly to meet the practical demand. The national plan for CT, MRI and X-knife was now out of date and the local provinces are waiting for the new plan so that they can deal with the new applications from the hospitals. Moreover, under the suggested decentralized management framework, MOH should initiate the study on the planning of Proton-knife, Neutron-knife, MM50, PET-CT and γ knife. For CT, MRI and Linear Accelerator and SPECT, MOH should give some principals and guidelines on how to regulate these devices. Management in HTMDs should be included into the health plan as they are the important health resources.

5. Besides the national plan and guidelines, the standard on the adoption

of new technology for hospitals should be established. In practice, the macro-plan on HTMDs can not be of help to deal with the specific application of a hospital, it is very difficult for the health authority to determine whether the application is suitable or not due to poor information and lack of comparison. So, it is necessary to establish the criteria on the adoption of medical device by the hospitals, it will in practice help the health authority to deal with the application. As there are general hospitals and other different types of hospitals in China, so different criteria should be studied for further regulation practices. The team has developed a method for the standards for hospitals to adopt HTMDs and it was proved to be successful and useful, we need to test the methods in large samples and help the government to establish the criteria.

6. Use evidence-based medicine approaches to improve the management performance. Research of HTMDs management is limited in China. The technical evaluations are also far behind of the developed country, and the researchers are too limited to fulfill the work required by real situation. This has led to the management practice to be based upon experiences rather than evidences and scientific information. More works and studies should be done to provide more information to help make sound decisions. Evidence-based approaches will improve the regulation and management in HTMDs in China..

Some latest development and influences on policy:

The MOH of China has issued the latest "Regulations on HTMDs management and allocation" in December, 2004. The guideline for Class B HTMDs management and allocation was released in April, 2005. The result and outcomes of our study were well presented in the newest regulation and guideline. It was clearly represented in those files that the decentralized management is now in place. Management of Class B HTMDs was transformed to provincial health bureaus. These devices include CT, MRI, DSA, SPECT and LA. The provincial government should establish total quantity controlling standard of HTMDs and establish the entry standard for hospitals to adopt Class B devices. Our econometrics model was recommended by MOH to the provinces to help them make decisions.

The total quantity standard should based on the regional health planning and also consider the local social-economic development level and the residence's health demands. For each kind of device, there are different directions and guidelines in details. For example as CT, the total number in a province should consider the quantity of doctors, population density, location of the province, salaries and numbers of counties. The entry standard of hospitals includes annual outpatient visits, annual quantity of inpatient bed-days, annual X-ray photo numbers.

Now, the MOH and the provincial health bureaus are working under the new management frameworks and some national plan for Class A devices like PET-CT and γ knife will come out soon.