

## Driving factors and mode transformation regarding health technology assessment (HTA) in China: Problems and recommendations

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### Summary

As the reform of Chinese medical and health undertakings has advanced (since 2015), the admission, pricing and payment policies regarding the new health technologies of China have undergone significant changes, and health technology assessment (HTA) has gradually become one of the current reform and research hotspots in China. Based on the perspective of HTA driving factors and the development mode, this paper proposes a two-stage mode of HTA development in China, namely, the mode driven by the management of new health technology admission and another one driven by new health technology pricing and medical insurance payment. In addition, the paper also proposes the challenges that HTA faces in China under the current mode, including the development system, process standard, data mechanism, and policy application. Besides, recommendations are provided for the further development of HTA construction in China, including strengthening the development system of regional HTA centers, formulating HTA process guidance, building a database, improving evaluation quality and intensifying policy integration.

**Keywords:** Health technology assessment, China, driving factors, development mode, issues, recommendations

### 1. Introduction

Health technology assessment (HTA) is a comprehensive policy research method for systematically evaluating the characteristics, effects and impacts of health technologies. HTA's main goal is to support decision making regarding health technology management (1). After more than 40 years of development, health technology assessment has been widely adopted by countries around the world, especially in most middle- and high-income countries where formal HTA procedures have been established. The application areas of HTA include fundraising and planning, pricing and payment, clinical guidelines,

and service quality (2,3). In recent years, HTA has been widely developed and applied in Thailand, South Korea, Vietnam, and Chinese Taipei in Asia (4). HTA has also played an important role in the allocation and management of health technology resources.

China introduced HTA in the 1990s under the support of key decision makers from the Chinese Ministry of Health followed by the development and application in Chinese academic and research institutions (5). However, overall, HTA in China is still in slow development and has not been incorporated into policy procedures, with only a small number of studies being translated into policy decisions (6), which lags far behind European and neighboring countries and regions. The main problems faced by HTA in China include a lack of legal support, national HTA centers, relevant process mechanisms, discipline talents and funding inputs (7). Since 2015, with the advancement of China's medical insurance payment methods and the reform of the compensation mechanism of public hospitals (8,9). HTA has been applied for the first time in such fields as price negotiation regarding high-priced

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drugs in China, centralized procurement of high-value consumables and evaluation of new technologies, which has enabled HTA in China to enter a new development stage.

New health technologies refer to new technologies that have entered the market while not yet entering the pricing directory and reimbursement payments and include drugs, equipment and surgical plans. Access, payment and pricing of new health technologies are all important application areas of HTA. In recent years, China has undergone significant changes in the admission, payment and pricing management modes of new health technologies, such as accelerating the admission and adjustment of the directory of new health technologies, liberalizing the price control over some new health technologies and empowering public hospitals to take charge of the admission of new health technologies. These policy changes are highly consistent with the development of HTA in China in recent years, which suggests that the admission, payment and pricing of China's medical technologies may be the key driving factors for the development of HTA in China.

With the admission, payment and pricing management policies regarding new health technologies as the entry point, this paper analyzes the key elements driving the development of HTA and their respective development characteristics before and after the changes of such policies. This paper also summarizes the development rules and modes of HTA in China and the current development of HTA in China and proposes corresponding reform suggestions in the hope of providing empirical support for the development of HTA in China and other Asian countries and regions.

## 2. Driving factors and development modes of HTA in China

Since 2015, the strategy for admission of new health technologies to public hospitals in China has transformed from admission granted by the government and based on grades and categories (Grade-I technologies are subject to the management of hospitals themselves, and Grade-II and Grade-III are subject to provincial and national examination and approval, respectively; the grading of technologies is mainly based on such issues as difficulty, risks and ethics) to "instant admission without forbiddance" (public hospitals can independently determine the admission of new health technologies beyond the restriction list formulated by the central government) (10). In addition, the management subject of new health technologies has also transformed from the government to public hospitals. Furthermore, the pricing of new health technologies in China has also been gradually liberalized. In 2015, the Chinese government canceled pricing on a majority of drugs, and new medical service

projects also adopted a strategy "integrating adjustment and liberalization" (adjustment of medical service prices and liberalization of the pricing on certain medical service prices) (11,12). For example, the prices of new medical services in such areas as Beijing and Guangzhou were independently formulated by the hospitals in those cities. At the same time, the medical insurance payment mode in China was also gradually transformed from payment by items to payment by diseases (13).

From the perspective of driving factors, driving forces and content characteristics of HTA in China, the development of HTA in China can be divided into two stages based on the driving factors. The first stage is the period from 1993 to 2015, during which the main driving factor was the management of the admission of clinical new health technologies; the main driving force was the Ministry of Health of the People's Republic of China. The second stage is the period from 2015 to the present, during which the main driving factors are the adjustment of the directory of medical insurance drugs and the negotiation-based pricing on drugs and high-value consumables; the main driving departments are the China Human Resources Security Bureau and the China Development and Reform Commission (adjusted as the China Medical Insurance Bureau subjected to 2018 institutional reform).

### 2.1. Mode driven by the management of admission of new health technologies

The main driving force for the development of HTA at this stage is the management of health technology admission, during which the Ministry of Health of the People's Republic of China, according to the *Measures for Management and Application of Clinical New Technologies* issued in 2009, assumed responsibility for the evaluation on Grade-III technologies, which mainly involve such contents as safety, effectiveness, risks and ethical social impacts. At the same time, the management of admission configuration was also adopted for large-scale equipment, and the Ministry of Health of China conducted HTA for Grade-A equipment, which was mainly involved in economic evaluation and effect evaluation. Therefore, at this stage, the Department of Science and Education and other departments of the Ministry of Health of the People's Republic of China actively promoted the pilot project and selected key technologies and equipment for technology assessment every year. These cover such new medical technologies as assisted reproductive technology, newborn screening and cervical cancer screening and such large-scale equipment such as gamma knife, MRI and Leonardo's robot (14).

Under this mode, HTA mainly focuses on the safety, effectiveness, and feasibility of new medical technologies and the qualification of relevant

institutions. In addition, most research focuses on the concept of HTA and relevant domestic and international development experience. A system evaluation is the main method that was adopted with cost-effectiveness and other health economic evaluation methods being less frequently used (15). In April 2011, the *Guideline for Pharmacoeconomics Evaluation in China* was issued and showed a basic failure in incorporating pharmacoeconomic research into the decision-making scope of the government for applications not being compulsorily required by the state or recommended by the government (16).

Under this mode, HTA research institutions are mainly colleges and universities with only a few governmental HTA centers. For example, 4 national HTA institutions were established in the 1990s, and another 5 were established by 2015, of which only 3 belonged to the government (17) (Table 1).

2.2. Mode driven by new health technology pricing and medical insurance payment

At this stage, the main driving forces for the development of HTA are medical insurance payments and negotiation-based pricing. During this time, the government liberalized the pricing of medicines and the admission of medical technologies and the Ministry of Human Resources and Social Security and the National

Health Commission of the People's Republic of China explored the adjustment on the directory of medical insurance medicines and introduced HTA evidence in pricing negotiation regarding costly medicines and high-value consumables (Table 2). Meanwhile, the implementation of HTA in the procurement of consumables for medical devices is also under exploration in hospitals (18).

At this stage, HTA focuses on the cost-effectiveness, budget influence and payment standard of medical technologies. For example, during the initial negotiation on the pricing of 44 medicines implemented in 2017, the Ministry of Human Resources and Social Security of the People's Republic of China based on the extensive collection of information with regard to such aspects as the efficacy, prices, economy and medical insurance payments of negotiating medicines and referencing ones, established two assessment expert panels for an assessment measurement perspective of two aspects, namely, the economy of medicines and the affordability of medical insurance funds. Based on the assessment results of the two expert panels, the working group finally determined the expected medical insurance payment standard according to established principles (19) (Figure 1).

At this stage, HTA institutions and networks acquire a further development. For example, in 2016, the China Health Policy and Technology Assessment Research

**Table 1. HTA institutions under the new medical technology admission management mode**

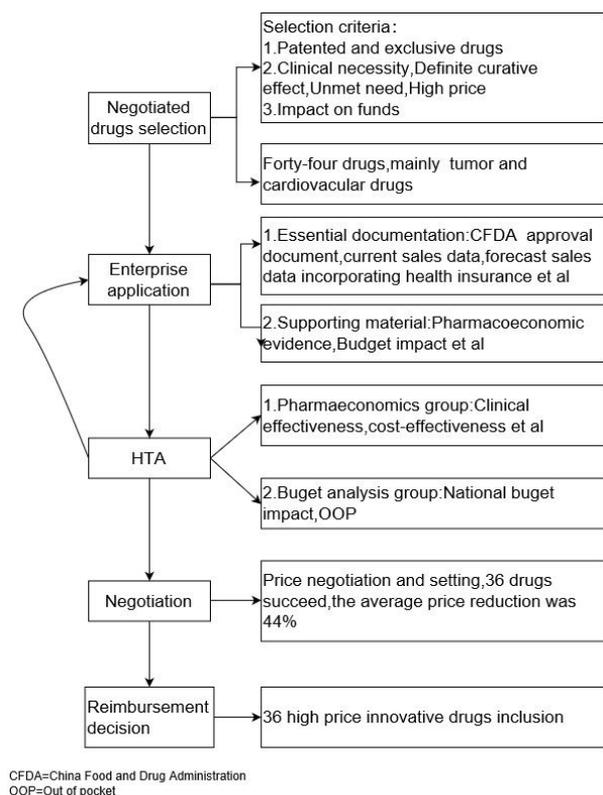
Year	Place	Name
1993	Beijing	China Medicinal Biotechnology Association.
1994	Shanghai	Key HTC Laboratory of the Department of Health in Fudan University.
1994	Beijing	Assessment and Transformation Research Office of the Health Economics Institute of the Ministry of Health of the People's Republic of China.
1999	Chengdu	Chinese Cochrane Center (West China University of Medical Sciences).
2002	Shanghai	Pharmacoeconomics Evaluation and Research Center of Fudan University.
2004	Shanghai	EBM (evidence-based medicine) Center of Fudan University.
2005	Lanzhou	EBM Center of Lanzhou University.
2007	Beijing	Health Policy and Technology Assessment Research Office of National Health Development Research Center of China.
2011	Shanghai	Shanghai HTA Research Center.

HTA, health technology assessment.

**Table 2. HTA applications in China since 2015**

Year	Published by	Policy practices	HTA applications
2017	Ministry of Human Resources and Social Security of the People's Republic of China.	Adjustment on the directory of medical insurance medicines in 2017.	Compare similar medicines following the principle of pharmacoeconomics and preferentially select medicines whose clinical necessity, safety and effectiveness as well as reasonable pricing are fully proved.
2017	Ministry of Human Resources and Social Security of the People's Republic of China.	Negotiation on the pricing of 44 original medicines.	HTA was determined as optional submission material for the first time.
2017	National Health Commission of the People's Republic of China.	Negotiation on the pricing of 4 high-value consumables.	Submit HTA evaluation materials.
2018	National Medical Insurance Administration.	Negotiation on the pricing of 17 anti-cancer medicines to be incorporated in the scope of medical insurance.	HTA was determined as optional submission material.

HTA, health technology assessment.



**Figure 1. Negotiations on the pricing of 44 medicines by the Ministry of Human Resources and Social Security of the People's Republic of China in 2017.**

Network was established under the guidance of the Health Development Research Center of the National Health of Family Planning Commission of the People's Republic of China. In total, 37 relevant institutions applied to join; in 2017, the HTA research center was established in Hubei Province and Peking University; in 2018, the National Integrated Assessment Center on Medicines and Health Technologies was established under the approval of the National Health Commission of the People's Republic of China, which marked the formal establishment of the state-level HTA center in China (20) (Table 3).

At this stage, HTA was also gradually clarified in policy and legal documents. In 2016, the five ministries and commissions (including the National Health and Family Planning Commission and the Ministry of Science and Technology) jointly issued the *Guiding Opinions on Comprehensively Promoting Health-related Science and Technology Innovations* and the *Guiding Opinions on Strengthening the Transfer and Transformation of Health-related Science and Technology Achievements*. It was stated that "we should establish an HTA system, formulate the opinions on the implementation of HTA, develop evidence-based medicine, and strengthen health technology assessment" (21). The Basic Law of Medical Health, which was drawn up in 2017, has HTA incorporated into the scope of the draft legislation. In the *Guiding Opinions on the Reform and Improvement of the Comprehensive*

**Table 3. Establishment of HTA institutions in China since 2016**

Year	Place	Name
2016	Beijing	China Health Policy and Technology Assessment Research Network.
2017	Wuhan	Hubei HTA Research Center.
2017	Chengdu	IDEAL China Center.
2017	Beijing	Health Policy and Technology Assessment Center in Peking University Health Science Center.
2018	Beijing	National Integrated Assessment Center on Medicines and Health Technologies.

HTA, health technology assessment.

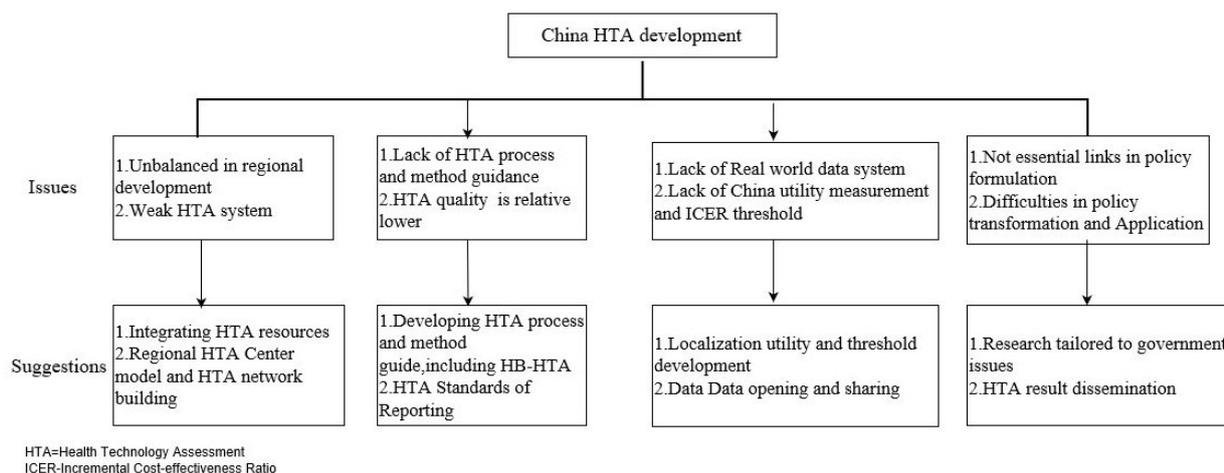
*Supervision System of the Medical and Health Industry* promulgated by the State Council in 2018, it is proposed that full play be given to the decision-making support role of HTA in clinical admission, standardized application, disuse and elimination of medical technologies, drugs and medical devices (22). The reform plan of the National Medical Security Administration newly established in 2018 proposes to carry out and organize the economic evaluation on health. In addition, the guidance opinions on promoting the HTA work organized by the Department of Science and Education of the National Health of the People's Republic of China, is under formulation and involves establishing and perfecting the HTA organization and team, establishing a topic selection mechanism and assessment process, methodology and evaluation results as a releasing mechanism for HTA, and promoting the transformation and application of HTA achievements.

### 3. Problems remaining from the development of HTA in China and corresponding development recommendations

The key driving factors of HTA in China have transformed from admission management to payment and pricing of health technologies followed by the gradual transformation of HTA research to decision-making applications; from safety and effectiveness to cost-effectiveness and budget impact analysis and from the institutional individual development to national system construction, the development characteristics of HTA in China have undergone great changes. Although HTA in China has made progresses in many aspects since 2015, it still faces some key problems and challenges that have not been solved to date (Figure 2).

#### 3.1. Under unbalanced development, HTA in China is in urgent need of system construction

The provinces, municipalities directly under the central government and autonomous regions in China are responsible for setting the prices of medical services and the formulation of a medical insurance directory. However, the development of HTA in different regions



**Figure 2. Problems existing in the development of HTA in China and corresponding countermeasures.**

is significantly unbalanced. Existing HTA institutions are mainly concentrated in economically developed regions, and there is a large gap between central and western regions in the development and application of HTA concepts (23). HTA at the hospital level is mainly implemented in such developed regions as Shanghai and Beijing and is still in the preliminary exploration stage (24-26). Therefore, it is not mature to construct a national, provincial and hospital HTA system in the short term. At the current stage, it is suggested to fully integrate existing resources, such as enterprises, public hospitals, research institutions and universities, to guide all parties in understanding and applying HTA and form a good HTA development environment. Thus, a national HTA development system based on regional HTA centers should be gradually established to form a development system featured by the linkage of HTA in national centers, regional centers and hospitals and the sharing of resources among all stakeholders, including medical security bureaus and health commissions.

### 3.2. Imperfect HTA application mechanism entails the development of Chinese HTA processes and methods

Currently, the imperfection of the HTA application mechanism is mainly reflected in the lack of norms for HTA evidence submission in price negotiation and medical insurance payments (27), such as a lack of clear definitions and evaluation standards for HTA data submitted by enterprises. The state has not promulgated HTA processes and norms for reference in China, and there are few domestic studies on this aspect (28). Existing HTA centers in China are less experienced in the establishment of process systems and expert evaluation mechanisms for topic selection, assessment and evaluation, and the research quality of the evaluation of health economics is relatively low (29). It is suggested that China accelerated the construction of the HTA evaluation process and method guidelines, including two

dimensions, namely, hospital HTA to form a referable practice mode, improve the transparency and objectivity of HTA, and ensure the quality of HTA research.

### 3.3. Lack of an HTA data support system entails strengthening the construction of data collection and sharing mechanisms for HTA in China

Presently, it is difficult to obtain and share real world data between public hospitals in China (30). Research on the life quality of people suffering diseases in China, especially the health utility values of various disease states, are currently an urgent need. Localized utility measurement tools and transformation need to be developed, and there are few studies on the threshold setting based on different populations in different regions of China (31). Improvement of the localization of life quality tools and utility transformation tools in China strengthening the construction of data opening and the sharing mechanism in different regions and public hospitals, building an HTA sharing database, and forming a timely and high-quality data guarantee system is recommended.

### 3.4. Lack of HTA research and decision-making practice transformation channels entails the enhancement of policy integration

HTA research in China has not become a necessary part of policy making to date; for example, it is still uncommon to see the application of HTA in decision making regarding medicines and other health technologies (32). The policy transformation capability of HTA research is relatively weak with only 30-40% of HTA research published in journal articles and submitted to relevant policy makers, and the government also has limited access to HTA evidence (33). Reliance on national and provincial HTA platforms to strengthen topic selection, focus on the key demands of price and

payment, conduct HTA based on problem-oriented entrustment, improve decision-making transformation and application and implementation of monitoring and assessment is recommended.

#### 4. Conclusion

The driving factors for the development of HTA in China have undergone important changes, which makes the dominant development mode of HTA in China transform from technology admission to medical insurance payment and pricing. The transformation of admission, payment and pricing policies regarding new health technologies is an important driving factor for HTA reform in China. HTA in China is moving toward policy application under many challenges, such as the HTA development system, HTA process and methodology, data and standard development, and policy transformation channel, which are all core issues in the development solution for HTA in China. On the basis of China's practical environment, HTA in China needs to establish an integrated development strategy, collect resources from public hospitals, enterprises, universities and research institutions, and establish a decision-making mechanism and environment based on HTA and thus promote and develop HTA in China.

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