Policy Forum

Development of health technology assessment in China: New challenges

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Summary Health technology assessment (HTA) is a field of scientific policy research that adopts multidisciplinary approaches to conduct systematic evaluation of health technologies and inform decision making. Although achievements have been made by HTA activities among academics, providers, and policy makers, development of the field of HTA in China is fragmented and not yet formally integrated in health policy making processes. All stakeholders need to make more efforts to strengthen HTA knowledge translation and facilitate a decision making process that is based on evidence including HTA findings. This article reviews how the field of HTA has developed in China, analyzes what factors have been influencing China's HTA development, and proposes policy recommendations.

Keywords: Health policy, policy making, decision making, knowledge translation

1. Introduction

Health technology assessment (HTA) is one of the critical evidence-driven decision making processes to inform policy and clinical decision making on the introduction and use of health technologies. Health technologies include pharmaceuticals, devices, diagnostics, procedures, and other clinical, public health, and organizational interventions. The multidisciplinary field of HTA addresses the clinical, economic, organizational, social, legal, and ethical impacts of a health technology, considering its specific healthcare context as well as available alternatives (*1*). Therefore, HTA is a common policy tool that assists decision makers in using health technology appropriately.

Application of health technology, on the one hand, can create positive social and economic impacts by preventing, diagnosing, and treating diseases, improving quality of life, and caring for people's health. On the other

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hand, inappropriate use of health technology may induce negative consequences that, at the individual level, create safety issues and health problems that aggravate the burden of disease and, at the macro level, waste resources and worsen patient-provider relationships. For example, when a college student with a rare cancer received an immunotherapy that was aggressively advertised but had insufficient evidence of effectiveness and died subsequently, the government and the public saw the importance of HTA in avoiding such tragedies (2). If HTA evidence had been used in the introduction of the immunotherapy and its on-line promotion as the top treatment, patients such as the college student might have not suffered physically, emotionally, and financially. Caution is thus applied when evaluating and adopting cancer therapies, robotic surgery systems, high throughput sequencing technologies, and other technologies with insufficient clinical evidence. In addition, determining the tradeoff between the clinical benefits and high costs of new technologies also requires HTA, specifically cost-effectiveness analysis and budget impact analysis, since health resources are limited. For instance, the effective yet highly expensive drugs for hepatitis C and cancers. Therefore, cultivating strengths and avoiding weaknesses of health technology are crucial in the complicated process of using, managing,

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and monitoring technology development and diffusion, and HTA is the best tool to balance the benefit versus harm, demand versus supply, and appropriateness versus inappropriateness of technology.

HTA has formulated its methodology, including identification of health technology to be assessed, determination of the priority of assessment, implementation of assessment with different methods and highlights, and translation of assessment findings into decisions or policies settings (3).

Since China's most recent round of health reform started in 2009, significant achievements have been made by expanding universal health coverage, improving the access to essential health services, and reducing financial burden. However, new challenges to health status and health system sustainability keep emerging. As the Chinese society goes through the epidemiologic transition, non-communicable diseases (NCDs) which need treatment and management with health technology have become increasingly prevalent in both intensity and extensity. Rapid emergence of cancer and cardiovascular disease has been exerting increasing disease burden on the Chinese population. The prevalence of cancer of all kinds has increased by 63% and that of cardiovascular diseases has increased by 35% from 2006 to 2016 (4), which has been translating into rising dependence on health technologies. Aging has been an integral contributor to the epidemiologic transition. The percentage of population aged 65 and above increased from 8% in 2006 to 11% in 2016 (5), and an aging population contributes to NCD incidences and related technology use significantly. Moreover, due to perverse incentives of technology use in China's health financing scheme, issues of improper use or overuse of technology contribute to rising health care costs and out-of-pocket expenditures and potentially threaten population health (6). As a result, growth rate of health expenditure has been five to ten percentage points higher than that of gross domestic product, and the economic impact of NCDs is projected to be tremendous (7). Confronting such looming cost burdens as well as potential deficit, China's health insurance scheme may not be sustainable. Therefore, the Chinese government established the Healthy China 2030 blueprint in 2016 that places health in the center of the national development agenda and outlines strategies to improve health outcomes, the health industry, and the health system (8). HTA and other policy tools will be increasingly important as the government formulates specific strategies to achieve the Healthy China 2030 goals and improve the insurance package and coverage.

Over the course of HTA development in China, there have been some major activities that contribute to progress, but the policy process still needs to incorporate HTA as routine component. This article reviews HTA development in China, analyzes the factors that influence China's HTA development, and proposes policy recommendations.

2. HTA development in China

Numerous organizations conduct HTA research and provide evidence base for decision making in China, yet no single organization is equivalent to a national archiving center such as the National Institute for Health and Care Excellence (NICE) as a government entity or the Canadian Agency for Drugs and Technologies in Health (CADTH) as an independent nonprofit. HTA organizations in China have different institutional formats, e.g., governmental institutions, universitybased centers, consultant companies, and industry-based centers at both the national and local levels. We surveyed some HTA organizations and browsed their websites in a previous study to understand the development of the field in China (Table 1), but responses were sparse, and there was little information of HTA on the websites. Therefore, we analyzed the HTA-related articles that were written by researchers in China from 1984-2016 to illustrate the changes in the academic realm of HTA (9).

China has made great progress in the field of HTA since its introduction in the 1980s (6). According to Chi's research, a literature retrieval with the keywords "health technology assessment" and "medical technology assessment" in the China Knowledge Resource Integrated Database revealed 351 articles until the end of 2016 (9). Chi categorized HTA activities in China into three stages of development based on the publication year and content of the articles.

The first stage of development in China was from 1993-2000 when several HTA agencies or programs were set up in universities and doing several pilot projects to introduce the concept of HTA to China. The milestone was when Vice Minister of the Ministry of Health advocated policy makers to use HTA at the National HTA Conference in 1999. The main integrated model of HTA and policy translation was assessments of assisted reproductive technology and the Gamma Knife. During this stage only 30 research articles on China's HTA activities were published, on average about four articles were published each year, and the keywords that most articles focused on were "health resources" and "pharmacoeconomics".

The second stage was from 2001 to 2010 when existing HTA organizations formed the engine that drove the development and new ones started to emerge. Compared to the first stage, there was more HTA research on specific technologies such as antenatal screening and large medical equipment such as magnetic resonance imaging scanner and da Vinci surgical system. There were also more articles that introduce or analyze how HTA could serve policy making and how knowledge translation would take place in other countries so that China can learn from them. During this period, 150

Table 1. Examples of health technology assessment (HTA) organizations in China, their institutional format, and year of establishment

Organization	Institutional Format	Year of Establishment
China Medicinal Biotech Association	Industry-based	1993*
Key Lab of Health Technology Assessment (Fudan University), NHFPC	University-based	1994**
Division of Evaluation and Translational Research, Development Center for Medical Science and Technology, NHFPC	Governmental institution	1994
Chinese Cochrane Center	University-based	1999
Center for Pharmacoeconomic Evaluation and Research, Fudan University	University-based	2002
Center for Evidence-Based Medicine, Fudan University	University-based	2004
Evidence-based Medicine Center, Lanzhou University	University-based	2005
Division of Health Policy Evaluation and Technology Assessment, China National Health Development Research Center, NHFPC	Governmental institution	2007
Shanghai Health Technology Assessment Research Center	Governmental institution	2011
Division of Technology Assessment, National Center for Medical Service Administration, NHFPC	Governmental institution	2015
Center for Health Policy and Technology Assessment, Peking University	University-based	2017
Research Center for Health Technology Assessment of Hubei Province	University-based	2017

Note: NHFPC: National Health and Family Planning Commission. * Although the China Medicinal Biotech Association was established in 1993, it did not start conducting HTA until 2007. ** The predecessor, Research Center for Medical Technology Assessment, was established in 1994, and then it was designated as the Key Lab of HTA in 2004 by NHFPC. The World Health Organization (WHO) designated the Key Lab as the WHO Collaborating Centre for Health Technology Assessment and Management in 2007.

research articles on China's HTA activities had been published, on average 15 articles were published each year, and the most popular keywords were "health resources," "antenatal examination," and "alert."

The third stage was rapid development of the field of HTA from 2011 until now. Compared to the second stage, there have been more articles on the safety, cost-effectiveness, and ethical implication of specific technologies as well as more studies on HTA methodologies. From 2011-2016, 171 research articles on China's HTA activities had been published, on average about 34 articles were published each year, and the most popular keywords were "health policy," "public health," and "biguanide." Nine HTA research projects received funding in 2017 from the National Natural Science Foundation, the top public organization that supports scientific research in China. Although HTA projects make up an insignificant proportion of the total number of grants, the number of HTA proposals and grants have been increasing in recent years (10).

Recent changes that took place during the third stage at two key ministries governing the health system also demonstrated clear progress in incorporating HTA to policy making. The National Health and Family Planning Commission (NHFPC) has issued policies to guide and strengthen the implementation and use of HTA in China since 2016. The policies are the *Guidelines* of Developing Health Science and Technology Innovation and Guidelines of Facilitating the Transfer and Translation of Health Science and Technology Outcomes. The NHFPC departments that oversee health technology-related issues are going to adopt HTA and to apply it to decision making in general. NHFPC has also started to incorporate HTA into specific policy making processes. For instance, the Department of Drug Policy and Essential Medicine of NHFPC asked medical device manufacturers to participate in the price negotiation of four groups of high-value medical consumables in 2017 by submitting HTA evidence of the products along with other required information (11). Although NHFPC did not mandate that external parties should conduct the HTA studies, the inclusion of HTA indicated that NHFPC took concrete steps to use HTA to inform policy making.

Moreover, China's national drug reimbursement policy, *i.e.*, the National Reimbursement Drug List (NRDL), has included evidence of HTA or pharmacoeconomic evaluation as one of the criteria of determining whether a drug would be covered by the national health insurance schemes. In 2017 the Ministry of Human Resources and Social Security (MOHRSS) updated NRDL with an evidence-based, value-driven approach rather than repeating the past process of making reimbursement for drugs passively without scientific input (*12*). MOHRSS invited more than 4,000 experts in clinical service delivery, pharmacology, health economics, HTA, and health insurance to vote for the inclusion or exclusion of a preliminary list of drugs. If a drug has high clinical value but is expensive, patented, or exclusive, it could be included in price negotiation before officially becoming part of NRDL (Figure 1). MOHRSS identified 44 drugs to undergo price negotiation and asked the drug companies to provide evidence that supported inclusion of their drugs in NRDL. Two key sections of the evidence, namely clinical value and economic value, coincided with two of the main areas of HTA. This shows MOHRSS was starting to make decisions based on quantitative evidence rather than relying on qualitative expert consensus. After the evidence-based negotiation process, the prices of 36 drugs were successfully reduced (81.8%), and the drugs were added to NRDL. The average price reduction was 44%, and the highest reduction was 70%. The drugs consisted of five traditional Chinese medicines and 31 western drugs; 15 drugs were for cancer (41.7%); and while 21 were imported, 15 were domestic (*13*). This marked a significant milestone for MOHRSS to use HTA in making policies that increase access to effective drugs while maintaining health expenditure at a sustainable level.

The series of policy changes are also catalyzed by researchers' persistent effort of submitting HTA research findings to the government as reference for policy



Figure 1. The process of selecting and adding drugs to the National Reimbursement Drug List (NRDL) by China's Ministry of Human Resources and Social Security (MOHRSS) in 2017.

making. While learning HTA techniques continuously, Chinese scholars and institutions have been conducting HTA research, promoting its application, and expanding research teams. In 2017 alone, at least twenty-seven national and regional academic conferences on HTA took place in 12 major cities throughout China, which made HTA one of the most active fields in terms of knowledge exchange and dissemination (14). As a result, abundant research achievements and academic exchanges have been made to serve health policy making.

However, health policy- and decision making in China still largely relies on experience rather than research evidence, since HTA application remains fragmented, sporadic, and not fully embedded into the policy making process as a mandatory component. Chi's research using the HTA mapping instrument designed by Wija Oortwijn *et al.* shows that China's HTA development score is 75 out of 146 (51.4%), which is lower than the scores of developed countries, and one of the least developed domains is HTA implementation in policy and practice (4 out of 10 points) (9,15).

The core issue is thus the lack of HTA integration into the regulatory, reimbursement, and decision making processes, which results in few pathways for HTA findings to translate into policies or decisions. As old technologies evolve and new ones emerge, the need for translational medicine keeps growing, and requirement of precise, scientific decision making becomes more rigorous. Therefore, the field of HTA in China needs further development to strengthen evidence-based decision making and management, increase the efficiency of resource utilization, and improve health outcomes.

3. Factors influencing HTA development in China

Using John Kingdon's three-stream model of the policy process, we analyze factors that influence issues in the problem, policy, and political streams regarding HTA development in China (*16*).

3.1. Problem Stream

In terms of problems, pharmaceuticals, equipment, and devices still cause safety issues frequently. Effectiveness and affordability of the clinical application of new technologies are sometimes debatable if not unclear. Adjustment of health financing and reimbursement scheme for technology is also largely arbitrary and unreasonable, given little HTA evidence has been taken into account. For example, the proportion of drug costs has been decreased while that of device costs has been increased, even if the appropriateness of individual drugs and devices varies. Market access for innovative technology and the NRDL's slow response to people's needs and technology development are always criticized by the public. As the government simplifies the regulatory process, balancing deregulation of market approval, pricing of health technology, and assurance of safety, effectiveness, affordability, and social acceptability becomes increasingly critical.

3.2. Policy Stream

In terms of the policy stream, there are three issues, namely HTA has little influence on and integration in health policy in China, the policy process that involves HTA is disorganized and fragmented, and the contribution of HTA to policy making has mediocre quality.

First, implementing HTA to provide policy solutions to issues of health technology remains inadequate in China, and HTA is a policy tool that decision makers seldom recognize and acknowledge. According to the report of the 2015 Global Survey on Health Technology Assessment by National Authorities, almost half of the 111 World Health Organization member countries that participated in the survey (46%) have issued legislations to incorporate HTA findings in decision making; two thirds of the countries, not only developed countries but also middle-income ones such as Brazil and Malaysia, have established national HTA agencies; and over 90% of the countries have adopted HTA guidelines (17). China yet needs to take the aforementioned actions and join the common trend across nations of developing HTA as an essential policy tool. Although HTA has become one of the building blocks of China's recent health policies such as NRDL, the government has not required that reimbursement policy making should be based on HTA by an independent third party. The lack of such a requirement may jeopardize fairness and credibility of the evaluation process that informs policy making.

Second, a national HTA organization has not emerged in China to have the authority of setting and implementing HTA-related priorities and standards as well as coordinating participation in policy making among the numerous existing HTA organizations in China. The lack of such an organization contributes to the fact that HTA has not been integrated to the policy process. The governing scheme that oversees health technology-related issues is also fragmented, since it involves at least four ministries and many ministry departments, which makes role determination, coordination, and communication highly challenging. In addition, policies and decisions of market approval and technology selection are based on expert consensus and past experience rather than detailed technology assessments. As market approval undergoes deregulation, more emphasis has been placed on monitoring health technology after market entry, but long-term mechanisms or laws are absent to ensure effective use of HTA in monitoring.

Third, the number of HTA researchers and agencies is low, the scope of application is narrow, and the quality of reports needs improvement, which deters policy makers from considering HTA evidence seriously. HTA activities in China are mostly scientific research projects that are sporadic and confined in disciplinary silos. This makes it difficult for the few HTA researchers to participate consistently in health technology management and policy making, implementation, and evaluation. The needs of HTA researchers are not aligned with those of health policy makers, which further hinders communication between the two parties. Moreover, the amount of HTA research in China is still small, and the quality of the research is uneven across different research teams due to the lack of standards and guidelines.

3.3. Political Stream

Analysis of the political stream and social climate regarding HTA development in China shows multiple constraints. Awareness of HTA among decision makers and health care providers is highly limited. Chi's research shows about 60% of policy makers report that they are not capable of reading and understanding HTA findings, and few agree that HTA has played a significant role in health policy making in China (18). Only 3.5% fully understand the concept of HTA, while 48.5% do not know the concept at all (9). Among the ones who understand HTA, many find navigating HTA research papers and deciphering health economic jargons difficult. Unable to comprehend the implication of HTA for solving real healthcare problems, decision makers often regard HTA as theoretic research that does not produce practical results. Therefore, HTA findings are seldom considered as important evidence for decision making or an integral part of the policy process. Furthermore, the general public, which includes users of health technology, does not possess the basic awareness of HTA, making the social climate unconducive to HTA development. Although the use of HTA may influence the health and need for health technology of every member of the society, very few people know the existence of HTA. Without public participation and support, HTA can hardly draw policy makers' attention.

Lack of awareness results in the fact that government leadership has little acknowledgement of HTA and does not value its importance. During its 30 years of development in China, HTA has only been mentioned in several recent policies rather than playing a significant role in shaping the health reform and guidelines of healthcare management. HTA has had few advocates among senior government leaders who exert great influence on policy making, and HTA researchers have had little resource and few effective channels to reach policy makers and promote the use of HTA.

4. Policy recommendation

While problems with the field of HTA in China are increasingly prevalent and pronounced, solutions are unidentified, and political will remains low. Fortunately, government entities such as NHFPC and MOHRSS have established momentum of using HTA that will affect policy making in at least the next few years. Therefore, China could adopt the following approaches to keep the momentum and apply HTA effectively to meeting the needs of all stakeholders and facilitating evidence-based policy making.

First, China needs an organizing system of health technology assessment and management that promotes implementation and application of HTA and receives external evaluation that holds the government accountable. Exemplars which are worth learning from include the UK NICE, CADTH, and the incorporative system in the US where the government and market compliment and collaborate with each other. China shall adapt successful international experiences to its context and follow the principle that market determines resource allocation so that the government can perform other duties and functions.

An independent consortium of HTA agencies, rather than one single agency, should be established with government funding, and each agency of the consortium would play its unique role while collaborating with each other. The publicly funded independent status of the consortium ensures the objectivity and nonprofit nature of the evaluation research. The consortium helps relevant ministries conduct HTA; suggests HTA findings as reference for decision making; and has the authority to recommend policies and decisions of health technology market approval and selection for public procurement, health insurance, and public health service package. The consortium shall have an HTA expert committee that organizes various ministries and departments to identify key health technologies to assess and coordinate HTA implementation. The consortium shall also promote the development and application of HTA by encouraging all stakeholders of health technology, e.g., health providers, social security that determines health service reimbursement, and manufacturers, to require or provide evidence of external HTA for decision making.

After designating the consortium to implement and develop HTA, China may call for an appraisal mechanism that reviews the health technology reimbursement process and engages stakeholders to critique and discuss HTA reports and recommend the final decision of reimbursement. The appraisal mechanism can only take effect if reviewers are willing to replace isolated observations and experiences with empirical evidence as the basis of policy discussions. HTA reports, the cornerstone of the mechanism, shall synthesize evidence on the safety, effectiveness, affordability, and social implication of a technology to inform the government of technology management. An appraisal committee shall then propose policy recommendations based on thorough discussions of the reports and make the decision. The government agency,

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independent consortium, or professional association responsible for HTA shall initiate the appraisal process and form the appraisal committees that consist of health technology researchers, government officials, and interest group representatives.

Several measures should be taken to improve the quality of HTA research in China so that HTA findings will become increasingly convincing and be translated into policy. An official HTA guideline should be established to dictate the standard of quality and uphold the principle of academic integrity and transparency. Moreover, before publication, HTA reports should undergo peer review by domestic and international experts from related disciplines to gain multifaceted feedback. Technology manufacturers that conduct assessment of their products need to disclose the entire process and findings of the research to the government and the public.

Last but not least, active producers and users of HTA in China should take every opportunity to showcase the value of HTA. The policy climate for HTA development has been improving, as new health technologies emerge, population needs increase and diversify, and the health reform progresses and recognizes the value of scientific evidence in general. Therefore, it is significant for all stakeholders to produce meaningful and influential research with practical implications, propel the momentum, and open the policy window for HTA in China.

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