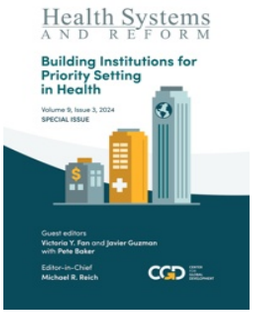

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RESEARCH ARTICLE

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Health Technology Assessment in China's Health Care Sector: Development and Applications

Wudong Guo[a], Peimeng Wang[a], Yuzheng Zhang[a], Xue Li[a], Yaoling Wang[a], Kun Zhao[a], Francis Ruiz[b], Rui Li[a], Feiyi Xiao[a], Xuefei Gu[a], Mao You[a], and Qiang Fu[a]

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ABSTRACT

China's health system is facing severe challenges from social transition and the double burden of population aging and non-communicable diseases. Addressing the tension between the public's increasing demand for health services and the limited availability of medical resources has become a critical issue for health care policymakers and medical insurance fund administrators. In promoting its medical insurance system reform, China is actively developing health technology assessment (HTA) with principles and applications adapted to the Chinese context. This study aims to analyze the evolution of HTA in China with a focus on context, actors, process, content, and challenges encountered through applying a modified verson of Walt and Gilson's policy triangle framework. Currently, HTA plays an indispensable part in the reform of China's health care and medical insurance system, especially in the formulation and adjustment of the National Reimbursement Drug List (NRDL). While HTA is increasingly used in China, there remain challenges, such as the slow development of HTA related disciplines, lack of an independent national HTA authority, and limited scope in the use of HTA. Despite the identified challenges, HTA has the potential to support a wide range of applications in China's health care sector, building on the progress achieved over the last three decades.

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KEYWORDS
China health technology assessment; health care policy making; medical insurance; National Reimbursement Drug List

Introduction

China is undergoing significant economic and social transition, with its health system facing critical challenges such as an aging population and an increase in non-communicable diseases.[1,2] The prominent feature of China's state-sponsored medical insurance system is its commitment to "broad coverage and basic protection," aiming to cover over 95% of citizens and fulfill their fundamental health care needs.[3,4] Currently, China's basic health care insurance framework is divided into two main components: Urban Employees Basic Medical Insurance (UEBMI) and Urban and Rural Residents Basic Medical Insurance (URRBMI).[5,6] Addressing the tension between the public's increasing health care demands and the limited medical resources available has become a critical concern for health care insurance policymakers in China. Implementing value-based purchasing of medical services is one important aspect to ensure appropriate and equitable use of medical insurance funds, improving insurance coverage for the broader Chinese population, and solidifying the state's negotiating capacity as a strategic purchaser.

In accordance with international experiences, health technology assessment (HTA) represents a valuable tool to support effective priority-setting and value-based decision-making, including value-based purchasing strategies. The International Network of Agencies for Health Technology Assessment (INAHTA) has defined HTA as a multidisciplinary assessment process designed to assess the value of health technologies at various stages of their lifecycle. This process aims to guide decision-making and promote health systems that are equitable, efficient, and high-quality.[7] HTA was introduced in China in the early 1990s and steadily became an important decision-making tool in the health care sector.[8] The present study aims to examine the development and current applications of HTA in China with a focus on context, actors, processes, and content. It also aims to outline the current HTA application challenges in China and propose strategic recommendations. This study also seeks to draw insights to support the further reform of China's health care insurance system.

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Methods

Using a modified version of Walt and Gilson's policy triangle framework, this study aims to provide a comprehensive qualitative analysis of the evolution of HTA in China. The policy triangle framework is a tool for analyzing policies originating from health care departments.[9] In contrast to earlier policy analysis frameworks that predominantly concentrated on the examination of policy content, Walt and Gilson's policy triangle framework encompasses an analysis of policy content in conjunction with the roles of actors, the contextual background, and processes used, providing a holistic perspective for policy analysis.[10]

The exploration of HTA's development in China encompasses various dimensions: context, actors, process, content, and challenges encountered. A core focus is the application of HTA in the adjustment of the National Reimbursement Drug List (NRDL), leveraging HTA evidence to inform decisions on the inclusion or exclusion of drugs in the coverage provided by China's basic health insurance.

Documents Sources and Search Strategy

Officially released policy documents and related gray literature were used as key data sources. The information was obtained through a manual online search of government web portals including Chinese official website of the State Council, the National Health Commission, and the National Healthcare Security Administration. The search terms include health technology assessment, health system reform, National Reimbursement Drug List, and combinations thereof. In addition, wide searches on Baidu, a dominant search engine in China, were conducted to identify relevant gray literature.

Eligibility Criteria

Policy documents or gray literature were included that met the following three inclusion criteria: (1) the policy documents or gray literature were published from January 2016 to July 2023, reflecting the period when HTA activities became more integrated with policy-making units, with the government clearly indicating an objective of building an HTA system to promote dissemination and policy transformation in this space[11]; (2) the issuing institution or author was either a national-level government department or an independent third-party consulting agency, as the document review of the study predominantly concentrates on policies and regulations; and (3) the body of the policy documents or literature covered any information on context, actors, processes, or content of HTA in China, as the study aimed to use a modified version of Walt and Gilson's policy triangle framework. Overall, eight identified documents met the predefined inclusion criteria. The list of these materials is presented in Supplementary File 1.

Results

The health policy triangle framework was used to analyze the content of the selected policy documents and other items of gray literature. Key findings are summarized in Figure 1. The results are discussed within four

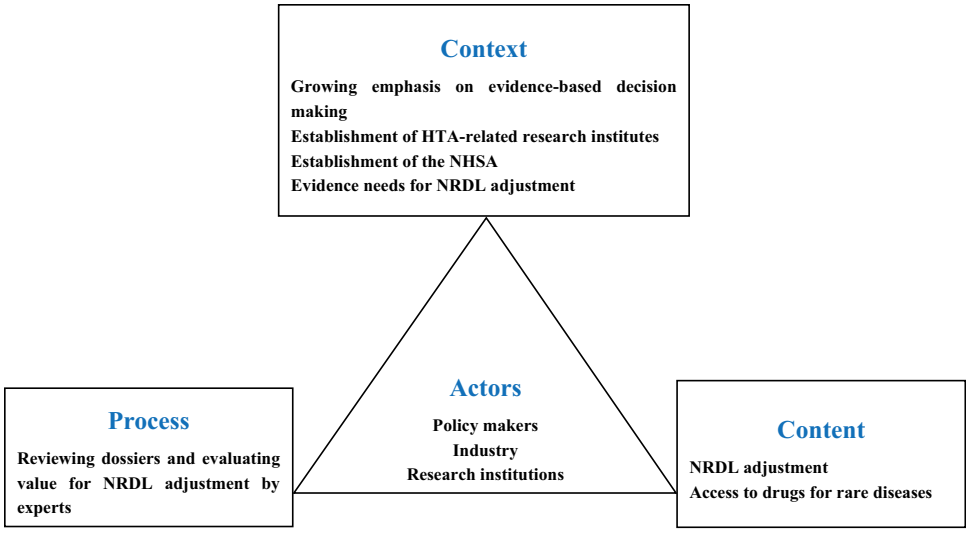

Figure 1. Policy triangle framework of HTA development and application in China. Figure prepared by authors. HTA, Health Technology Assessment. NHSA, National Healthcare Security Administration. NRDL, National Reimbursement Drug List.

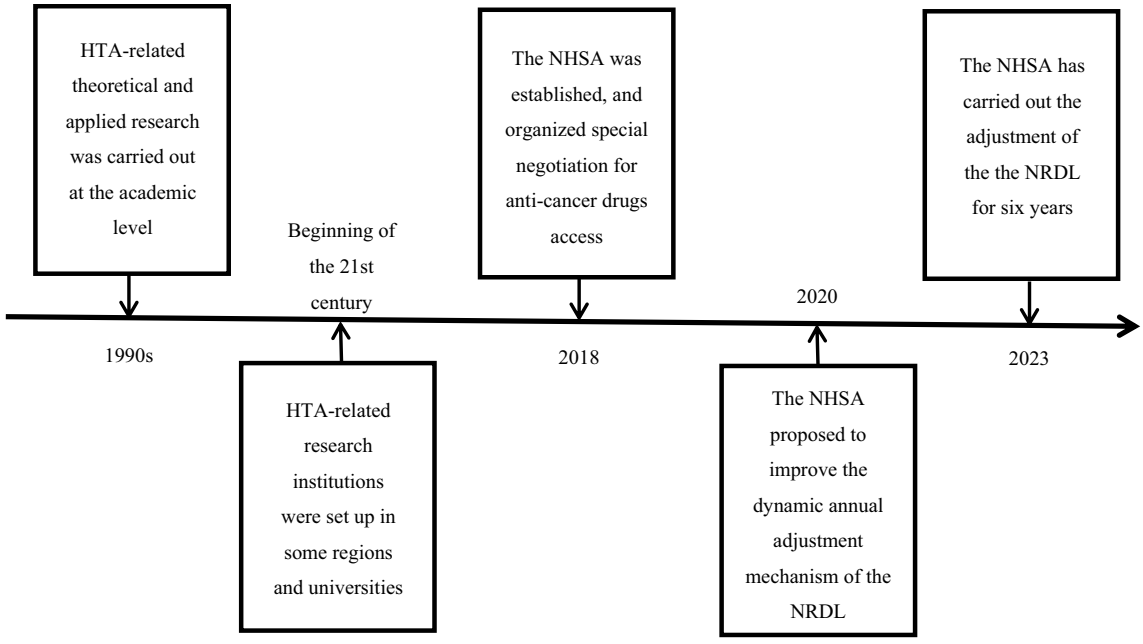

Figure 2. Milestones in HTA development in China. Figure prepared by authors. HTA, Health Technology Assessment. NHSA, National Healthcare Security Administration. NRDL, National Reimbursement Drug List.

main areas: the context of HTA development in China; the actors involved in policy design and implementation; the process of value-based drug evaluation; and the content of the HTA application.

Context

During the 1990s, theoretical and applied HTA research was conducted in academic settings in China. This work laid the foundations for developing an institutional HTA framework to inform decision-making, including by policy makers. Since the beginning of the 21st century, fueled by a growing appreciation of the role of evidence-based decision-making, several regions and universities established research institutions focusing on HTA. Over time, HTA-related research transitioned from purely academic settings to applied work addressing specific policy questions. An early example of an HTA research institution was the Research Center for Medical Technology Assessment at Shanghai Medical University in 1994, which subsequently became the "National Key Laboratory of HTA" at Fudan University in 2004. Another key milestone was the establishment of the HTA Division at the China National Health Development Research Center (CNHDRC) in 2007, affiliated with the National Health Commission of China (NHC), akin to a Ministry of Health in other countries. In 2018, the CNHDRC was selected to host the National Center for Medicine and Health Technology Assessment, acting as a national think tank providing technical advice on HTA to policymakers.[12]

HTA has become an integral part of the reform of China's medical and health system, particularly in updating the NRDL. The NRDL includes drugs eligible for reimbursement through China's basic health care insurance schemes.[13] Since 2018, the National Healthcare Security Administration (NHSA) was established under the State Council of China and conducted annual negotiations with pharmaceutical companies to support adjustments to the NRDL. Simultaneously, the regulatory framework for updating the NRDL evolved. In July 2020, the NHSA proposed improvements to the dynamic adjustment mechanism of the NRDL and the approach to drug access negotiations with the drug manufacturers.[14] As a result, this mechanism currently involves an annual update of the NRDL based on the NHSA's evaluation of a drug's value. The drug access negotiation system involves NHSA organizing on-site discussions with drug manufacturers to determine the listing price within the basic medical insurance system. Figure 2 summarizes the major milestones of HTA development in China, especially its role in supporting NRDL decision-making.

Actors

In 2018, the NHSA was established, integrating responsibilities that were previously held in several

different ministries and reporting directly to the State Council (Figure 3). The NHSA is responsible for formulating and overseeing the implementation of laws, regulations, and policies for the Chinese health care insurance system.[15] Given the complex factors that affected drug prices, public interest in health services, and broader societal impacts, HTA-based research played a critical role to support decision-making within the NHSA.

Currently, the participants in this HTA process consist of mainly supply-side stakeholders represented by pharmaceutical companies, and demand-side stakeholders represented by the NHSA, acting as the third-party medical services purchaser. Although active patient engagement in HTA is considered to be best practice for capturing the perspectives of those directly affected by healthcare decisions, currently they are less involved in the process compared to pharmaceutical companies and the NHSA.

Process

HTA plays a key supporting role during the negotiation of drug's listing price and access arrangements, integral to the NRDL's dynamic annual adjustment.[16] By introducing the concept of HTA and adhering to value-based evaluations, drugs with significant value benefits are included in the NRDL, while those lacking are excluded. The NRDL adjustment process involves five stages: preparation, application, expert review, negotiation, and results announcement (Figure 4). At the preparation stage, the NHSA updates the expert database, the annual adjustment principles, such as declaration conditions, and upgrade of information system. During the application stage, manufacturers submit brief value dossiers to the NHSA. Technical HTA methods are then applied during the expert review and negotiation stages to assess the value claims and estimate prices.[17,18] The annual negotiation results are generally announced and implemented at the beginning of the following year, usually in January.

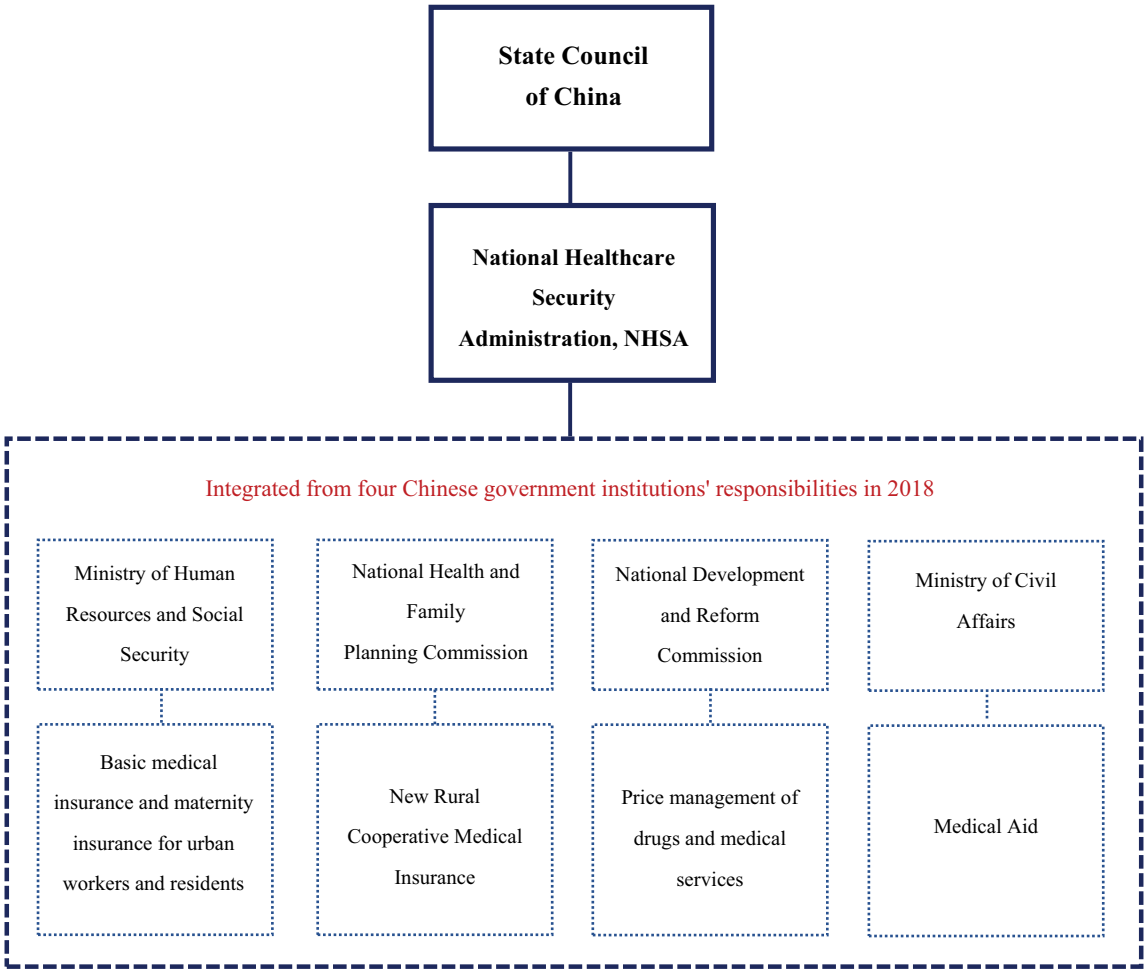

Figure 3. Establishment of the National Healthcare Security Administration in 2018. Figure prepared by authors.

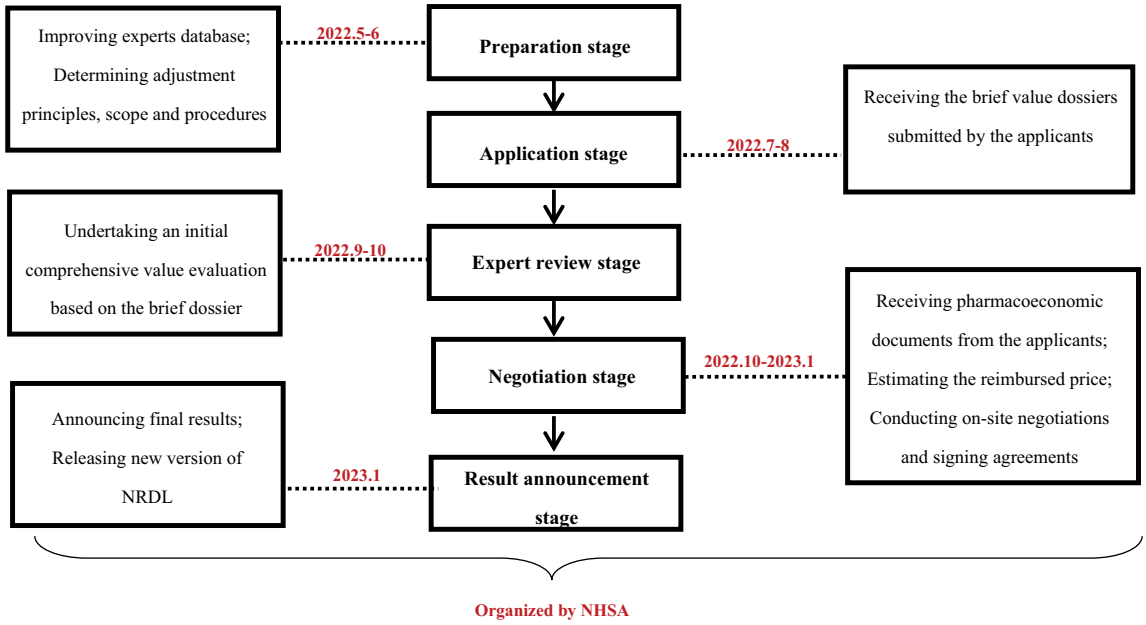

Figure 4. Process of adjusting the NRDL in 2022. Figure prepared by authors. NRDL, National Reimbursement Drug List. NHSA, National Healthcare Security Administration.

Content

Application of HTA in the adjustment of the NRDL

During the adjustment of the NRDL, HTA-informed methods are prominently used during the expert review and negotiation stages.

Expert Review Stage. During this stage, experts from various fields, including clinical medicine, pharmacy, pharmacoeconomics, medical insurance management, and work-related injury, are convened by the NHSA to conduct a comprehensive value evaluation based on brief dossiers submitted by manufacturers. The evaluation covers five dimensions: safety, efficacy, economy, innovation, and equity (Table 1). The expert team scores each drug against these dimensions and considers the views from drug manufacturer representatives. The expert team then develops preliminary recommendations on whether the medicine can be included directly into the NRDL without conditions, conditionally included following a negotiation with the manufacturer, or else rejected directly.[12] The expert review stage also involves defining drug use indications, available comparators, and the restrictions of the medical insurance payment, all of which will be used to inform the negotiation stage.

Negotiation Stage. The negotiation stage includes three sub-phases. Initially, manufacturers who passed the preceding expert review stage submit detailed dossiers, including cost-effectiveness and budget impact analyses. The expert group then estimates an appropriate listing price for each drug, considering cost-effectiveness and affordability from the healthcare insurance fund's perspective.[20] This estimation process involves the implementation of what has been described as a "double back-to-back" mechanism, where parallel estimations by pharmacoeconomics and medical insurance fund expert sub-groups occur. In addition, two experts from the pharmacoeconomics sub-group independently estimate prices to minimize bias and enhance the process's credibility and fairness. Table 2 summarizes the principles followed by the NHSA in this price

Table 1. Five dimensions of comprehensive value evaluation of expert review stage.

Dimensions	Description
Safety	A review of safety information from pre-market randomized controlled trials (RCTs) and adverse event reports sourced from realworld data
Efficacy	A comparison of clinical effectiveness of the applicant drug with that of its comparator
Economy	There is a need for a cost-effectiveness analysis, including identifying the most likely expected incremental cost-effectiveness ratio. Alongside this, a budget impact analysis model should be developed to predict the financial impact on health care insurance funds
Innovation	This is based on whether the technology can improve adherence or enhance clinical applicability
Equity	An assessment of whether the cost of the drug is considered affordable from the perspective of the Chinese medical insurance system, and whether it can effectively address any gaps in the current provision of medicines

Referred from.[19]

Table 2. Principles followed in the price calculation process of negotiation stage.

Principles	Description
Enhancing the quality of evidence	The evidence for the reviewed drugs follows the principles of the Evidence Pyramid, which supports an assessment of reliability.[21] In addition, priority is given to evidence-based studies involving Chinese populations.
Emphasizing authoritative clinical guidelines	The availability of authoritative guidelines (domestic or foreign) that can help contextualize the appropriate use of the medicines.
Uniform parameter selection	Key parameters that influence the establishment of negotiated prices, such as the incremental cost-effectiveness ratio (ICER) threshold, have been standardized to mitigate the potential for expert subjective bias.

Adapted from.[22]

calculation process. Based on these estimated prices, representatives of the NHSA lead negotiations with drug manufacturers that lead to the drug's inclusion in the NRDL and determination of its listing price in Chinese market.

Application of HTA in the evaluation of medicines for rare disease drugs and their inclusion of the NRDL

In China, there are at least 16.8 million patients with rare diseases. The majority of these diseases are genetically inherited, which can negatively impact quality of life and lead to substantial economic burden for both affected individuals and their communities.[23] In May 2018, the NHC issued China's First List of Rare Diseases, including 121 rare diseases, marking the first time the Chinese government has defined the scope of rare diseases.[24]

The conduct of HTA can be challenging with respect to the evaluation of interventions for rare diseases. The relatively limited number of patients affected by such conditions poses challenges for undertaking conventional clinical trials and accurately evaluating long-term efficacy and costs. Nevertheless, there remains a need to provide comprehensive assessments of treatments for rare diseases that consider broader social values and ethics, unmet treatment needs, as well as standard evaluations of clinical and cost-effectiveness. In 2019, the *Expert Consensus on Health Technology Assessment of Rare Disease Drugs (2019)*, a report initiated by the China Rare Disease Alliance and jointly formulated by the Peking Union Medical College Hospital and the CNHDRC, was released at the China Rare Disease Conference.[25,26] The research team formalized definitions of research questions when applying HTA approaches for rare disease medicines in the context of safety, efficacy, and cost-effectiveness, in addition to ethical and social value considerations.

As of 2022, among the 121 rare diseases defined by the NHC, 103 drugs for 47 rare diseases were approved in China, and 73 drugs for 31 rare diseases were evaluated and subsequently included in the NRDL. Of the 73 drugs covered by the Chinese national reimbursement program, 17 are fully reimbursed, and 56 drugs are partially reimbursed, with reimbursement rates varying between 70% to 80%, depending on provincial-level decisions.[27] Many life-saving drugs for rare diseases were included in the NRDL list, which dramatically reduced the financial burden on patients and their families.

Discussion

Current HTA research in China primarily supports the NRDL decision-making process, with medical insurance as a significant driver for HTA's development in the country. Although HTA is increasingly applied in China, previous work has highlighted important challenges, including issues related to low-quality reporting and fragmented application of HTA in the Chinese health policy making process.[12,28] There are additional factors that are impacting on its future development as set out below.

Context

The Slow Development of HTA-Related Disciplines

With the increasing demand for HTA approaches to support decision-making, expertise in China continues to grow, and context-specific assessment methods and tools are gradually being developed. However, there is a concern about the slow pace of capacity building and training for the next generation of HTA practitioners and users.[28] At present, only one university independently grants master's level and doctoral degrees in pharmacoeconomics. Most researchers engaged in HTA research are majoring in health economics, health management, or pharmaceutical management, while HTA may be a minor component of their curricula. As such, the number of domestic experts in more applied methods, especially in the field of modeling and econometrics is still relatively small, and urgent attention is needed in support skills development in HTA-related disciplines. There is a need to expand the availability of HTA-related courses or programs at universities and offer continuing education and training to foster domestic HTA expertise.

Actors

Lack of an Independent National HTA Authority

There is currently no fully independent HTA institution at the national level. Annually, when the NRDL adjustment work begins, NHSA recalls and selects qualified experts to conduct the expert review and negotiation stage involving the application of HTA ideas and methods. This process typically takes place in a centralized, closed setting, followed by the dissolution of the expert panel after the evaluation. In other words, the plausible institutionalized mechanism carries the potential risk of expert annual turnover, inconsistency of evaluation standards, and unconvincing endorsement. Thus, establishing an HTA regulatory authority is essential for standardizing its conduct and supporting consistent decision-making. Existing HTA research and policy platforms are distributed among national and local government bodies and universities, including the CNHDRC, Fudan University, and Peking University.[28,29] National authorities should consider establishing a UK National Institute for Health and Care Excellence-like independent and government-supported third-party assessment agency. Such an entity could have a pivotal role in setting nationally applicable technical standards, ensuring assessment quality, and supervising regional HTA agencies.

Insufficient Patient Engagement in HTA

Arguably, a key element of an effective HTA system is the incorporation of multi-stakeholder participation within the evidence-to-policy decision-making process.[30] In the United Kingdom, NICE identifies patients and their organizations as main stakeholders in the HTA process, and their treatment needs as important considerations in the assessment process.[31]

In China, patient and consumer organizations are notably less involved in the HTA process, limiting the insights and perspectives available to decision makers regarding the impact of new technologies on the target populations. The lack of patient or public involvement may also affect the perceived fairness and legitimacy of the HTA process. Currently, despite being the ultimate user of health care technologies, patients do not directly participate in the HTA process in China. Instead, their interests are often represented by health policy makers or health care institutions that act as their agents. A broader range of stakeholder groups, especially patients, should be encouraged to participate in HTA processes. Patients and their representatives should additionally be invited to communicate directly with other stakeholders (e.g., health care providers, health insurance payers, and manufacturers), and the views of different stakeholders should be integrated in the development of HTA evidence.

Process and Content

Limited Scope in the Use of HTA

Currently, most HTA activities in China are focused on generating evidence to support pharmaceutical reimbursement decisions. HTA-based evaluations of non-drug medical technologies, such as assisted reproductive technology, cervical cancer screening, gamma knife, robot-assisted surgery, and diagnostic imaging modalities, are still at an early stage of development. The assessment and appraisal of non-drug interventions, such as medical devices and medical disposables, are a challenge in many settings.[32] Gathering the necessary local evidence and developing dedicated skills may require additional resources. In the longer term, it is critical to expand HTA processes to include the routine assessment of non-drug interventions. This expansion is important for addressing a key gap in evidence-informed decision making, especially with the increasing use of advanced medical technologies.

Reassessment and Updating Prices

Currently, HTA in China lacks a formal mechanism to support reassessment. Although the price of a drug included on the NRDL is renegotiated with the NHSA every two years, that renegotiation is mainly based on the manufacturer sales volume instead of an evaluation of the drug's actual performance based on real-world evidence. The concept of life-cycle HTA could bring insights to the China setting, as this framework builds on standard HTA methods and contains a systematic process from the preassessment to the reassessment stage for informing adoption decisions of medical products.[33]

Insufficient Context Relevant HTA Data

Limited availability of quality data that reflects the Chinese context is a key challenge affecting the conduct of HTA and its future development in the country. This issue can be explored further by noting that HTA usually requires three main types of data:

(1) Epidemiologic information. Due to the heterogeneity of epidemiologic research in China, there are inconsistencies in reported evidence on prevalence and incidence. Consequently, HTA research in China has often relied on national survey data or patient registry data for key epidemiological inputs, but update frequency to

national survey databases may affect data availability.

(2) Effectiveness data on short- and long-term health outcomes. On the one hand, there is a lack of locally relevant trial-based evidence, especially from randomized controlled trials.[34] On the other hand, there is limited patient self-reported health outcomes data including the use of health-related quality of life measurement tools. Clinicians in China do not emphasize the importance of collecting data on patient-reported health outcomes, and data conversion between disease-specific scales and general utility scales can be challenging.[35,36]

(3) Resource use and cost data. These can be difficult to obtain despite the existence of relatively advanced electronic health records and data systems. The difficulty in obtaining cost data is mainly because of data silo problems. There are weak linkages between various information systems; for example, if a patient visits multiple medical service providers during a given period, the doctors and other clinical providers may not be able to access information from different medical institutions.[37]

To address these informational gaps, efforts should be expedited to establish a comprehensive medical data platform in China with standardized patient data. Additionally, it is crucial to improve national-level patient registry databases and link them with medical claims data and electronic health records.

Lack of Technical Standards for Conducting HTA

Typically, judgments of cost-effectiveness can be made with reference to a willingness to pay threshold that aims to quantify the maximum amount of money that an individual or society is willing to pay for a specific health care intervention or technology to achieve a certain health outcome.[38] There is currently no uniformly applied cost-effectiveness threshold in China to support decision making on relative value and the opportunity costs of adoption. Studies, however, have estimated a threshold equivalent to 0.44–1.5 times GDP per capita for the Chinese setting.[39,40] Thresholds can be established in various ways, although it is usually critical that a threshold appropriately reflects the opportunity costs of new health investments. Some countries, such as the UK, have well-established thresholds that are used as part of HTA and guideline development. There is an urgent need to establish a threshold that is relevant for the medical insurance systems in China, with linked decision criteria that align with the goal of "broad coverage and basic protection."

Another area of ongoing debate relates to valuing health outcomes, specifically, the use of utility values in cost-effectiveness analysis and the role of standard generic questionnaires such as EQ-5D and SF-6D. Sociocultural differences may affect individuals' interpretation of these tools, even when appropriately translated, given that they were designed originally for use in high-income European or North American settings. Given these concerns and the potential impact on the validity of any utility estimates obtained using those tools in a Chinese setting, efforts have been made to develop a generic-preference based measures more suitable for Chinese populations.[41]

In brief, it will be important for authorities in China to validate existing studies aiming to estimate a locally relevant cost-effectiveness threshold so that one can be established that is suitable for China's health insurance reimbursement decisions. In addition, there remains a need for further development of disease-specific health-related quality of life measurement tools suitable for the Chinese population.

Conclusion

Following three decades of development and success in implementation, particularly for drug reimbursement decisions, HTA in China holds the potential to support broader applications in the health care sector. Further progress is needed in developing the institutional context of HTA, including improving procedural aspects such as better stakeholder engagement and ongoing strengthening of methods and capacity.

Disclosure Statement

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