

Health Technology Assessment in Developing Countries: A Brief Introduction for Vietnamese Health-care Policymakers

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Abstract

As a middle-income country, Vietnam has faced multiple challenges and financial burdens in relation to the health-care sector. In many countries, policymakers make full use of health technology assessment (HTA) to guide decisions concerning health-care resource allocation. The aim of this article is to present perspectives on the historical development of HTA as well as the future of HTA as a tool for making policy decisions in Vietnam. Further, the article also illustrates how HTA can be used effectively and what is needed to establish a successful HTA agency. In addition, the characteristics and conducive factors of an effective HTA agency are thoroughly discussed. Vietnam has witnessed a rapid increase in health expenditure in recent years, which has led to a critical demand to apply HTA to obtain the maximum benefit from new and existing technologies. To meet that demand, the Health Strategy and Policy Institute was established by the Ministry of Health in 2013. Although the use of HTA in Vietnam is still at an early stage, HTA seems likely to become a necessary part of the health-care sector to support policymakers in making difficult decisions in Vietnam.

Key words: Decision-making, developing country, health policy, health technology assessment, Vietnam

OVERVIEW OF HEALTH TECHNOLOGY ASSESSMENT (HTA)

Definition of HTA

The International Network of Agencies for HTA (INAHTA) describes health technology as a wide range of health-care products that can be used for disease prevention, diagnosis, monitoring, or treatment, as well as for health promotion and quality of life improvement.^[1] In this context, “technology” is interpreted broadly to include pharmaceuticals, medical equipment, health-care services, diagnostics, procedures, information technology, and systems of organization in the health-care field.^[2,3] With the rapid growth of medical technology innovations in recent years, an increasing number of health technologies are being invented. As a result, it is vital to implement a system that can effectively direct investments in health technology. For this reason, HTA is progressively used.

According to the World Health Organization, HTA involves the systematic evaluation of

the features, consequences, impacts, and use of health technology.^[4] Similarly, HTA International (HTAi) defines HTA as the evidence-based analysis of related information concerning the direct and intended, as well as the indirect and unintended, results of technologies.^[3] The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) further defines HTA as a process that analyzes the influences of the application of health technology for a short duration as well as in the long run.^[5] More specifically, the INAHTA considers HTA to be a multidisciplinary research process that seeks to comprehensively assess a health-care intervention from the medical, social, economic, legal, and ethical perspectives.^[6] Various other organizations, including

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the European Network for HTA (EUnetHTA), similarly consider that HTA summarizes knowledge regarding the clinical, economic, social, and ethical issues associated with the use of a health intervention using systematic, clear, and equitable methods.^[7]

Role of HTA

The economic evaluation of a new health technology plays a vital role in supporting decision-makers concerned with health-care policy and practice,^[8] especially in terms of pricing, reimbursement, and market access decisions. The impact of this role can be seen in two basic aspects. First, there is the link between HTA and the pricing and reimbursement (P and R) process, that is, whether HTA is a formal part of the P and R process or separate from it. The second aspect concerns the main effects of HTA in terms of pricing, reimbursement, and market access.^[9]

The National Coordinating Center for HTA of the United Kingdom suggests that HTA outcomes provide answers for the following questions concerning health technology: “When compared with existing alternatives, does the technology work, in whom does the technology work, and what is the cost impact?^[10]” This implies that HTA contributes to the determination of the relative “value for money” of a new intervention, thereby helping to guide policymakers and patients as to what is the most appropriate treatment option.^[11] Basically, an effective HTA program ensures the appropriate selection of the latest medical devices/ drug or healthcare services with the most affordable price. To fulfil this role, HTA needs to provide accessible and valuable information regarding the technical characteristics and properties, clinical effectiveness and safety, costs and economic evaluation, and other impacts of new technologies to all concerned stakeholders.

In this way, HTA also contributes to strike a balance between innovation in terms of medical interventions and delivery of adequate and appropriate care to patients, especially in low- and middle-income countries (LMICs) characterized by tight health-care budgets.

Characteristics of successful HTA agencies^[12]

The principal feature of a strong HTA agency is independence. Securing such independence one means that the HTA process can proceed without any political pressure to ensure particular objective outcomes.

The second key characteristic is financial sustainability, which refers to the consistent flow of financial resources into the HTA agency. One suggestion for achieving this is an annual budget allocated by the government. Yet, the operation of HTA agencies, which typically rely heavily on research sponsors, could be threatened if sufficient grants are not available.

The third factor that leads to an effective HTA agency is good management of any potential conflicts of interest (CoI). This is necessary because HTA agencies frequently confront problems when dealing with the different interests of various stakeholders in the health-care sector, for example, health professionals, politicians, civil society, and patient groups. Consequently, good management of any CoI is needed to maintain the neutrality of the HTA agency, which can only be accomplished if HTA agencies coordinate with private industry without receiving financial support from such organizations.

The fourth key characteristic is employing full-time academic staff. HTA is applied in many fields, including pharmaceuticals, medical equipment, health improvement, disease prevention, and health policy. Therefore, when performing HTA, the availability of a multidisciplinary staff who are able to continuously develop their skills is vital.

The fifth feature that contributes to a successful HTA agency is access to an extensive network of local and international partners for the purpose of sharing experiences and best practice.

The sixth element of a successful HTA agency is establishing a methodical process for determining relevant policy topics for assessment. Once interventions have been chosen, their possible effects are examined and then communicated to numerous stakeholders, such as decision-makers, health-care providers, and industry.

The final key characteristic is the ability to produce research with a qualified assurance (QA) mechanism to ensure the high quality of the assessment. Research studies implemented by agencies with a good QA mechanism can be published in academic journals and then widely acknowledged.

Conducive factors for establishing HTA agencies

After acknowledging the key characteristics of any successful HTA agency, it is necessary to consider the conducive factors for establishing an HTA agency. The Health Intervention and Technology Assessment Program (HITAP) has identified six key elements in this regard, which will be thoroughly discussed below.

First, HTA systems with a higher proportion of public investment than private contributions are more likely to be well-established. These systems stand a greater chance of investing in high-quality and cost-effective interventions.

Second, political will, leadership, and legislation all serve as strong encouragement for establishing effective HTA agencies due to legitimizing the role of HTA in the policy-making process, which creates both a requirement and a necessity for more HTA programs.

Third, a high capacity for health information promotes the use of HTA. The HTA process requires a wide range of information and large data sets for analysis. Therefore, an efficient and expansive information infrastructure will make it easier for the government to conduct HTA at an affordable price.

Fourth, the provision of local training in HTA-related disciplines is an essential action before the establishment of formal HTA agencies. Training postgraduates in pharmacoeconomics, health economics, and other relevant HTA disciplines in universities or further education intuitions will result in the availability of skillful and academic staff who can help to strengthen the existing or new capacity of a successful HTA agency.

Fifth, effective coordination between HTA associations and stakeholders serves to establish a link between studies and policy, since these stakeholders, including politicians, medical associations, civil society, and industry, are all involved in every stage of the HTA process. Such partnerships will contribute to widely accepted HTA outcomes and serve to legitimize the produced policies.

Sixth, establishing independence from international support or external assistance compels HTA agencies to spend their limited resources more effectively. The lack of external aid should lead to increased concern on the part of policymakers about making wise and efficient decisions.

Elements of the HTA process and principles of conduct

There are five main activities involved in the HTA process, namely, horizon scanning, topic determination, assessment and preliminary appraisal, dissemination of results and recommendations, and monitoring and evaluation of the organization.^[10] Some experts have suggested a series of 15 principles to be considered when evaluating the available HTA activities or establishing new ones.^[13] All five main activities as well as the application of HTA for policymaking should be conducted according to these principles. Hence, the five main activities will now be considered and the principles that inform them analyzed.

Horizon scanning refers to the early analysis of prominent technologies, potential evidence requirements, and budget allocation.^[10] The first principle that informs this activity is the notion that the aim and range of the HTA should be transparent and relevant to its use. To abide by this rule, the HTA agency's staff should develop a list of questions to be addressed by HTA and then follow-up on those questions.^[13]

Topic determination involves selecting priorities from ranked prominent technologies for assessment or reassessment.^[10] In general, HTA should consider all related technologies due to the existence of potential inefficiencies in all forms of health

care. However, in a situation where not all technologies are assessed, a transparent system for setting the priorities for HTA should be established.^[13]

Assessment and preliminary appraisal require the gathering, evaluating, and systematic examining of all the available data concerning the technology.^[10] Due to the complicated and often controversial nature of HTA-based decisions, the HTA process should be explicit and unbiased, applying suitable methods for evaluation and including a wide range of evidences and results to gain both stakeholder and public trust. In addition, HTA should clearly describe the uncertainty surrounding any estimates. As all information is estimated, the potential errors and limitations of the examination should be recognized. In addition, when conducting HTA, the complete social perspective as well as issues of generalizability and transferability should be considered to maximize efficacy and social benefits.^[13]

Dissemination of results and recommendations allows the HTA findings to be widely and effectively used. To achieve this, the HTA process should be timely, which means that HTA should be implemented when its findings can provide useful information concerning health-care technologies for policy decisions. Further, the assessments should be continuously updated. Moreover, the HTA results need to be communicated appropriately to different stakeholders due to potential CoI. Another principle that informs these activities suggests that the relation between HTA itself and the resulting decisions, as well as the HTA outcomes and policy-making process, needs to be explicitly defined.^[13]

Monitoring and evaluation of the organization ensure that the HTA program runs effectively and generates trustworthy outcomes. A number of issues need to be considered when constructing a monitoring organization for a successful HTA program. First, all the main stakeholders should be involved in all the steps of the HTA program, since this leads to a greater opportunity for outcomes to be implemented as well as serving to guarantee higher quality technology assessments. Second, those conducting the HTA should actively seek out all available data to maintain transparency and gain trust in their decisions. Finally, the HTA process needs to be monitored so as to ensure that it is fairly being implemented and the original investment in conducting HTAs is fruitful.^[13]

Barriers for applying HTA policy decisions

One of the main aims of HTA is to inform decision-makers in relation to policy development. However, a number of problems can prevent HTA from fulfilling its role. The most common barriers to implementation that have been identified in the Asia-Pacific region include the silo-based policy-making process, low quality policy-making standard, limited dissemination of research, and high respect for expert opinions.

A silo-based decision-making process occurs when no other relevant stakeholders besides the chairman participate in making decisions. This means that the leader of the policy-making body often has a greater impact on other committee members than the HTA findings in terms of making decisions, which reduces the use of HTA in policymaking.

Another barrier concerns the fact that policymakers often utilize poor decision-making criteria when allocating resources. More specifically, policy considerations mainly focus on the unit costs of health technologies or safety and short-term outcomes rather than long-term consequences or the link between cost and effectiveness.

At the same time, there is less chance of research results that offer no benefits to policymakers being used during the decision-making process. Simply put, HTA findings that are inconsistent with policy will prove difficult to disseminate to stakeholders. This barrier could represent the main reason for preventing the development of policies that benefit society.

The final common barrier is the fact that expert opinions are generally considered to be more important than evidence-based findings, especially in Asia, where respect for seniors is frequently higher than that seen elsewhere in the world. Therefore, applying strong HTA findings when making decisions may prove challenging.

INTRODUCTION OF HTA IN VIETNAM

Historical development

In March 2013, the Ministry of Health (MoH) of Vietnam decided to establish and operate the Health Strategy and Policy Institute (HSPI) to foster efficient cooperation between policymakers, research agencies, and other stakeholders. The HSPI is responsible for conducting studies to provide scientific evidence that the MoH can use to build and modify health strategies, as well as collaborating with international partners in relation to health policy and the health-care system.^[13] The United Kingdom's National Institute for Health and Care Excellence (NICE), a long-term partner of the MoH of Vietnam, completed the first step in supporting the design of the basic package of health care subsidized at Vietnamese health facilities in November 2013. The NICE International aims to support the HSPI on the journey toward achieving universal health coverage (UHC). However, the health benefit package has not yet been applied, while a link between research institutions and policymakers in Vietnam has also not been completely created.

The HSPI organized a consultation workshop concerning the development of a strategic roadmap for HTA in Vietnam in 2014.^[14] In the same year, the HSPI also participated in the 3rd HTAsiaLink conference held in China in an attempt to further promote international collaboration. In addition, the

NICE International and HITAP Thailand both participated in a week-long training course on HTA that was held in the capital of Vietnam in July 2014.

Health system context in Vietnam

Vietnam is a middle-income country that applies centralized governance of the health-care system. The MoH plays a vital role in planning and implementing all health plans. High-ranking officers from around 20 departments are responsible for making decisions at every level in the health-care sector, which leads to the majority of policy decisions being made personally.^[12]

The Vietnam Social Security (VSS) agency, which is the implementing agency for Vietnam's social health insurance, operates independently under the Vietnamese Government.^[12] In 2014, the health insurance coverage rate in Vietnam was 70% although the aim is to achieve 90% coverage by 2020.^[15,16]

Due to recent increases in the burden of disease and health problems such as non-communicable diseases, as well as the existence of an aging society, Vietnam spent 7% of its gross domestic product on health in 2011, which exemplifies the rapid increase in health expenditure seen in recent years.^[12] In addition, due to the absence of a process for setting relevant health priorities, the use of health technology is generally unwise and incoherent. Indeed, the foundation of the selected health-care services that are paid by the National Health Insurance Fund is not based on scientific evidence or HTA studies, such as a cost-benefit analysis, cost-effectiveness evaluation, or cost-utility analysis.^[14] It can take up to 2 years to make a choice regarding investment coverage and even longer for choices concerning a drug or vaccine.^[12]

Based on the current health system context, there is certainly a need for HTA when establishing health priorities, including building a national list of essential medicines (NLEM) and constructing the official benefits package using HTA evidence. The HSPI is currently at an early stage of development in this regard with support from various international partners.

Current practice

The HTA process is well-established and implemented in developed countries such as the United Kingdom, the United States, and Canada, while in developing countries such as Vietnam, the use of HTA remains limited. Currently, the Vietnamese MoH is the response for conducting HTA as well as reviewing the health system based on all published evidence. However, HTA has not yet been utilized for regulatory and reimbursement decisions.^[16] In addition, a review conducted in a number of LMICs such as Vietnam has revealed that although HTA is increasingly used, the associated research studies are not often used to inform policy-making at the national level in LMICs, with Vietnam being no exception.^[15]

In recent years, due to the demand for advanced health technologies and the rapidly growing pharmaceuticals market, the use of a health benefits package has increasingly been promoted. A health benefit package is defined as the services, activities, and goods reimbursed or directly offered by sponsored public insurance or national health services. The methods, processes, and policies that influence the design of such packages are crucial to accomplishing and sustaining UHC within the insurance field. The International Decision Support Initiative (iDSI) and HITAP engaged with the VSS agency to explore practical ways to achieve efficient and high-quality UHC during their visit to Hanoi in 2017.^[7]

The National Health Insurance Policy Consulting Committee (NHIPCM), which was established in 2016, encompasses an HTA group that is responsible for advising and consulting with the NHIPCM in the technical review of HTA evidence.^[2]

Several HTA studies and systematic reviews have been conducted in Vietnam in recent years, including (i) Cost-effectiveness of peginterferon alfa-2b or alfa-2a with ribavirin for hepatitis C in Vietnam, (ii) cost-effectiveness of magnetic resonance imaging services in Vietnam, and (iii) cost-effectiveness of trastuzumab in metastatic breast cancer in Vietnam.^[2] Although there exists some good individual HTA capacity, HTA and other priority-setting tools still represent new innovations in Vietnam.^[8] Currently, the main HTA aim is to cooperate with other local units to conduct policy-related HTA research with support from external intuitions.

HTA IN VIETNAM: A WAY FORWARD

There are many potential applications of HTA in Vietnam, including supporting policymakers in health reimbursement decisions, providing evidence-based information about new drugs or drug classes for pricing strategies and clinical practice guidelines, and establishing an NLEM.^[10] However, to convert these potential uses into reality, Vietnam needs to establish a strong HTA agency, which should be based on the financial and social contexts and demonstrate characteristics that were mentioned above. Some additional considerations include the annual budget size, sources of funding, professional workforce, reporting system, and capacity of the database.^[11]

How to design the framework for a HTA system

To date, health technology is a vitally important factor in health-care system. However, health technology itself has both pros and cons. It promotes the capacity for prevention, diagnosis, and treatment, but it also has some negative impacts, including the side effects of technology, the increase in health expenditure, and the social and ethical impacts of technology. Vietnam is still a developing country with limited health resources. This situation results in enormous pressure on the health-care system in terms of how to deliver affordable and effective vital health care as well as health technology to

the whole of society. Therefore, HTA represents a significant opportunity to tackle such issues in a transparent, evidence-based fashion. With regard to the development of an HTA system, there are five main strategies available, which are illustrated in Figure 1.

RECOMMENDATIONS FOR DEVELOPING THE HTA CAPACITY

Develop human resources

HTA research agencies and policy-making bodies as well as other related stakeholders that use HTA all require experts and people who are equipped with the appropriate knowledge and skills. One solution for this issue is to implement more HTA training courses within medical and pharmacy universities as well as other related academic institutions in Vietnam.

Establish a core HTA team or institute

The HTA process involves multiple stakeholders, which renders it essential to have a focal HTA agency to coordinate the HTA activities and cooperate with partners. This focal organization not only must be committed to HTA work but also should be responsible for establishing the trust of all stakeholders. The HTA agency in general and the HSPI of Vietnam in particular should also be independent from the government, refuse financial support from private sources, and have an explicit process for dealing with CoI involving different stakeholders. In addition, since conducting HTA is very technical and time-consuming, the HSPI should employ full-time academic staff. Although the necessary number of full-time staff members depends on the scope and responsibility of the core team or HTA institute, the focal organization must have the ability to retain staff to make a significant impact.

Link HTA outcomes to policy-making mechanisms

If they do not serve to support policy-making decisions, all HTA studies and results will become worthless. Therefore, it is essential for the HSPI to have a close connection to policy-making decisions. The appropriate mechanism for establishing this link will vary based on the context and design of the health-care system. For instance, the link between HTA and coverage decisions includes the pharmaceutical reimbursement list or essential drugs list, immunization programs, high-cost medical device packages, and public health programs.

HTA legislation

HTA legislation is not a prerequisite for a well-functioning HTA system, for example, in the case of the HITAP

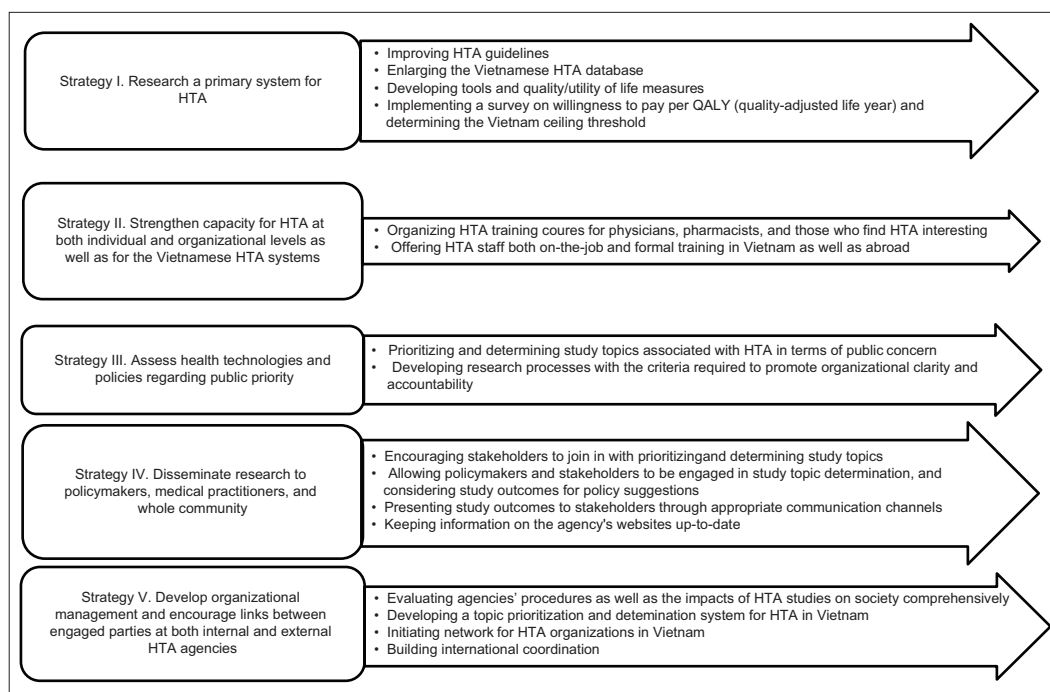


Figure 1: Five suggested strategies for developing the health technology assessment system in Vietnam^[17]

in Thailand. In other words, HTA legislation does not necessarily guarantee the successful implementation and use of HTA. Nevertheless, the existence of appropriate legislation may help to sustain the long-term and successful use of HTA. Such HTA legislation should ensure the presence of key components such as participation, transparency, and systematic application within the HTA process rather than focusing on technical issues.

International collaboration

The HTA agencies of the seven countries all received international support and formal overseas training for staff. International technical support is very useful, especially during the formative stages. As to the establishment of the database, resources are widely available at the international level through international agencies. However, some resources offer policy advice rather than building the capacity of local researchers, and therefore, they are rarely adaptable to local policy questions. As a result, a gap between international support and in-country technical support, which involves hands-on supervision and working closely on local studies, may occur.

Moreover, the experience of using HTA when making policy decisions in one setting can be influenced by the context, especially in places that have similar economic and health infrastructure. Therefore, regional networking, such as HTAsiaLink, is equally important when compared to international or global networking, which is widely available in many forms, including the HTAi, ISPOR, and INAHTA.

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