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Revisiting Roles of Health Technology Assessment on Drug Policy in Universal Health Coverage in Thailand: Where Are We? And What Is Next?

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ABSTRACT

Objectives: To describe the process, challenges, and future direction of health technology assessment (HTA), focusing on the drug selection of the National List of Essential Medicines (NLEM) in Thailand. **Methods:** Literature and government documents were reviewed and analyzed by authors with experiences in HTA and drug policy in the country. **Results:** The structure of HTA and its process in the drug selection of the NLEM were described, followed by the outcomes of the use of HTA. Examples of lowering drug prices, as a result of price negotiation using HTA, were presented. A few examples were also provided to demonstrate how decisions were made from considering factors beyond cost-effectiveness findings. Finally, challenges on various issues including improvement of HTA structure and process were discussed for the future direction of HTA in Thailand. **Conclusions:** HTA has been adopted as a tool for the drug selection of the NLEM to help Thailand achieve universal health coverage. Nevertheless, various challenges exist and need to be addressed.

Keywords: drug policy, health technology assessment, Thailand, universal health coverage

Introduction

The achievement of Thailand's healthcare financial risk protection by pushing forward the national universal health coverage (UHC) in 2002 led to a reduction in out-of-pocket payments and an improved access to healthcare for all Thai citizens.[1–3] Under the national UHC, the country primarily has 3 major health insurance schemes: the Civil Servant Medical Benefit Scheme (CSMBS), the Social Security Scheme (SSS), and the Universal Coverage Scheme (UCS). Nevertheless, both CSMBS and UCS covered more than 80% of the population and they relied heavily on general taxation as the main source of financing.[3] As a result, the Thai government had significantly increased spending from $4.95 billion to $15.16 billion for total health expenditures in 2000 and 2012.[3] The National Health Security Office (NHSO), which is responsible for UCS and is the largest healthcare payer in the country, has experienced the underfunding and financial pressure. In the period 2010 to 2012, the cumulative gap between the funding requested by the NHSO and the approved amounts was $14.81 billion ($1 =33 baht) in excess of expenditures, or about 7% of the requested funding.[2]

Globally, health technology assessment (HTA) has been recognized as an important tool used to support policy decisions.[4] HTA is a multidisciplinary activity that systematically examines the technical performance, safety, clinical efficacy, effectiveness, cost, cost effectiveness, organizational implications, social consequences, and legal

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and ethical considerations of the application of a health technology.[5] In this context, health technology includes drugs, devices, procedures, and the organizational and support systems that provide healthcare.[6,7] The goal of HTA is to provide clinicians, payers, and policy makers information that assists an evidence-based decision making in clinical care, coverage in benefit package, national investment planning, and market licensure of new health technology, for example, whether the adoption of a specific technology is worth the investment.[7]

In response to increasing healthcare expenditures and limited fiscal constraints, Thailand has increasingly used HTA to inform resource allocation decisions. It became one of the crucial mechanisms to contain costs, especially in national drug policy, because the curative expenditure was 70% of total health expenditures,[3] of which about 25% was for medicines.[3,8] The overall objective of this article was to provide overall description of HTA and future direction of HTA, focusing on the drug selection of the National List of Essential Medicines (NLEM) in Thailand. We began with general descriptions of the current situation of HTA in Thailand in terms of structure, process, outcomes, and its challenges ("Where are we?"). We also shared our insights on future direction, including what should be done for the next stage of HTA in Thailand ("What is next?").

Where Are We?

Structure

The conducting of HTA in Thailand can be traced back to the early 1980s when the first HTA literature was published. Nevertheless, the use of HTA in facilitating decision making in Thai UHC had not become official until the revision of the 2004 NLEM, which included economic aspects as a criterion for drug selection.[9] The NLEM is a list of drugs, vaccines, radioactive substances, and disinfectant agents referred to as a reimbursement list for all 3 health coverage schemes in the country. The list is endorsed by the NLEM subcommittee, which comprises clinicians, health economists, and other experts selected by the Thai Food and Drug Administration.

With increasing demand or HTA evidence to support the inclusion of high-cost technologies in the NLEM, the Health Intervention and Technology Assessment Program (HITAP) was established in 2007, with its major mission being to efficiently and transparently assess health interventions and technologies. National methodological guidelines for HTA and the willingness to pay for a quality-adjusted life-year (QALY)-gained threshold were then first developed in 2008 to standardize and ensure high-quality, reliable, and relevant HTA data for making decisions in the country. At present, HITAP has about 27 researchers primarily conducting the assessment part of HTA. Some researchers from HITAP are also members of the NLEM subcommittee. In addition, HTA in Thailand has made significant progress with an increasing number of economic evaluation researchers in pharmaceutical industry and independent researchers from academia.

An important structure of HTA is its high-quality data. Progress has been made regarding both the availability and the quality aspects of data. HITAP developed the Thai national database for HTA, aiming to collect all HTA studies conducted in the country, the Thai version of the EuroQol 5-dimensional questionnaire to measure utility and quality of life, and a standard cost list for HTA, as part of its strategies.

There have been limited sources of HTA funding in Thailand. HITAP is a semiautonomous research unit under the Ministry of Public Health; nevertheless, besides financial support from the government, HITAP obtains funding from other organizations, for example, the Thai Health Promotion Foundation and international agencies. Independent researchers could obtain government funds on working with HITAP and the NLEM subcommittee and some private funds from the pharmaceutical industry. Also, some pharmaceutical companies fund their own in-house HTA capacity.

Process

Basically, the selection process of NLEM begins with drug nomination. Stakeholders including healthcare providers, healthcare professional organizations, pharmaceutical companies, and patients or patient advocacy groups can submit a dossier of evidence of any drug product to be considered by the NLEM subcommittee. The subcommittee secretariats screen the dossier for completeness and accuracy. The product is then assigned to be evaluated by 1 of the 23 therapeutic working groups. The experts in each working group consider quality, efficacy, and safety of the drug product for the proposed indications. Once drugs are selected by the working groups, they are compiled by a screening working group, which is responsible for coordinating results of drug selection and making recommendations to be considered by the NLEM subcommittee. On the basis of the drug prices and their potential high budgets, the NLEM subcommittee identifies drugs that may require economic evaluation and budget impact analysis (BIA) evidence, and passes them to the Health Economic Working Group (HEWG). The HEWG asks nonprofit organizations or researchers, such as HITAP, academic researchers, and university research centers, to conduct economic evaluation and BIA within 24 weeks. The quality of studies or evidence is assessed through internal (HEWG members) and external (experts outside the HEWG) review processes. None of the economic evaluation studies submitted to the NLEM subcommittee is from pharmaceutical companies. All studies submitted for reimbursement decision need to follow the national methodological guidelines for HTA. Previously, the NLEM subcommittee announced the cost-effectiveness threshold at 1 time the gross national income per capita, equal to $3554 per year.[10] Nevertheless, currently Thailand has an economic status of an upper middle-income country according to the World Bank. The per capita income of the Thai population according to the Atlas method was $3875 (Thai baht was converted into 2017 US dollars).[11] After being adjusted by the consumer price index of medical goods, the national income per capita in 2013 was $3942. The results from the national survey study by Thavorncharoensap et al[12] in the Thai population revealed that the willingness to pay per 1 QALY without extending life expectancy for the Thai society was approximately $4620 (156 000 baht). Therefore, the willingness to pay for 1 QALY for the Thai society was implicitly set up to be $4738 or 160,000 baht or about 1.2 times since 2013.

The NLEM subcommittee considers all recommendations made by the screening working group and the therapeutic working groups as well as economic evidence supplied through the HEWG and takes into account all other relevant issues such as acceptability, feasibility, and equity. Once drugs are considered high potential for being listed in the NLEM, price negotiation is conducted by a price negotiation working group to ensure affordable prices of drugs to be included in the NLEM. To ensure financial sustainability as a whole for the healthcare system in Thailand, the NLEM subcommittee also aligns its potential decisions with 3 major healthcare payers (the NHSO for UCS, the Ministry of Labor for SSS, and the Ministry of Finance for CSMBS) and makes a final decision on listing drugs in the NLEM. Detailed description of the process and experiences can be found in previously published articles.[13,14]

Outcomes

HTA information focusing on economic evaluation and BIA in addition to clinical efficacy and safety has been continuously used

for the selection of new and expensive drugs to the NLEM for a decade.[15] In addition, the role of HTA in Thailand has successfully been applied in policy decision making for the development of the supplementary list of medicines within the benefit package of the USC. As a result of the societal willingness to pay per QALY in Thailand that was endorsed by the NLEM subcommittee as the threshold to consider whether the medicines should be listed in the NLEM according to the incremental cost-effectiveness ratio (ICER) values, drugs can be classified into 4 categories: cost-saving, cost-effectiveness, cost-ineffectiveness, and cost-effectiveness with price negotiation.[13]

Some examples of cost-saving drugs included peg-interferon alpha-2b or -2a plus ribavirin for chronic hepatitis C subtypes 2 and 3, lamivudine or tenofovir for the treatment of chronic hepatitis B, bevacizumab for age-related macular degeneration and diabetic macular edema, and intravenous immunoglobulin for dermatomyositis; thus, they were included in the NLEM.[13] Intravenous immunoglobulin for chronic inflammatory demyelinating polyneuropathy and idiopathic thrombocytopenic purpura and sildenafil for pulmonary arterial hypertension were cost-effective at their prices at the time of submission, therefore they were included in the NLEM.

Nevertheless, galantamine, donepezil, or rivastigmine for mild to moderate Alzheimer disease (ICER = $4,650-$7,108/QALY gained), risedronote or raloxifene for osteoporosis (ICER = $8,885-$23,692/QALY gained), rituximab plus the CHOP regimen for diffused large B-cell lymphoma (ICER = $17,769/QALY gained), bosentan or iloprost for pulmonary arterial hypertension after failing sildenafil (ICER = $29,616-$133,270/QALY gained), sunitinib for metastatic renal cell carcinoma (ICER = $71,077/QALY gained), rituximab for rheumatoid arthritis (ICER = $32,577/QALY gained), gefitinib or erlotinib for second-line treatment for non–small cell lung cancer (ICER = $44,423-$59,231/QALY gained), and ustekinumab for chronic plague psoriasis (ICER = $29,616-$103,655/QALY gained) were clinically effective but cost-ineffective because of their prices. Rituximab, however, underwent the price negotiation process and was eventually included in the NLEM. In addition, HMG-CoA reductase inhibitors except generic simvastatin, recombinant human erythropoietin for the treatment of anemia among patients with cancer, and adefovir, entecavir, telbivudine, and peg-interferon alpha-2a for the treatment of chronic hepatitis B had an ICER with negative dominant, meaning that these drugs had lower effectiveness but higher costs compared with simvastatin, blood transfusion, and lamivudine or tenofovir, respectively. Consequently, these drugs were not listed in the NLEM.

Because of the cost-ineffectiveness results of high-cost medicines, price negotiation mechanisms have been successfully implemented in the Thai healthcare system. Thai HTA guidelines recommend estimating the prices at the cost-effective threshold when cost-ineffectiveness results were found. The price negotiation working group used these prices to bargain with pharmaceutical companies.[13] For instance, the country saved more than $29.62 million from the price negotiation of tenofovir, oxaliplatin, and pegylate interferon alpha-2a. Later, such price negotiation mechanisms used in Thailand have been recognized as a role model in low- and middle-income countries. Nevertheless, sometimes even the prices of drugs were considerably reduced, resulting in cost-effective results. But they were still not listed in the NLEM because of their large budget impact. Therefore, it is noteworthy that BIA also plays an important role in the selection of drugs for the NLEM.

Similarly, HTA results were also applied to remove drugs from the NLEM during the selection process. For instance, atorvastatin was previously listed in the NLEM, but later the HTA results demonstrated that atorvastatin was not cost-effective, and so subsequently it was unlisted from the NLEM.[13] In addition, medicines used for the treatment of mild to moderate Alzheimer disease (i.e., galantamine, donepezil, and rivastigmine) and the treatment of osteoporosis (i.e., alendronate, risedronate, and raloxifene) were not cost-effective, and so these medicines were excluded from the NLEM.

Because the cost-effectiveness result is only a part of the HTA, it was not used as the only criterion for consideration of drug selection of the NLEM. For instance, although imiglucerase used for the treatment of Gaucher disease type 1 was not cost-effective, it was still included in the NLEM because of 2 reasons. The first reason was that the number of patients with Gaucher disease, a very rare disease, was not more than 5 per year. Therefore, it was considered affordable. Another reason was that patients should receive imiglucerase for 1 to 2 years before undertaking bone marrow transplantation, which is a curable intervention and currently is covered by the UCS. As a result, imiglucerase has been included in the NLEM, even though the ICER was much higher than the cost-effectiveness threshold of $4738/QALY.

Furthermore, in case of renal replacement therapy, the results indicated that providing peritoneal dialysis (PD) or hemodialysis (HD) as the initial treatment for patients with end-stage renal disease was not cost-effective, but PD seemed to be a better choice than HD.[16] Nevertheless, the subcommittee for the Development of the Benefit Package decided to implement the "PD First" policy since 2008 under the UCS because of it being a life-saving intervention. Another example was hematopoietic stem cell transplantation, which is a curable intervention for severe thalassemia. It was found to be cost-effective only for patients younger than 10 years.[17] Finally, hematopoietic stem cell transplantation was included in the benefit package for patients with severe thalassemia.

Challenges

HTA in Thailand faces various challenges. Thai researchers and decision makers were aware that economic evaluation could be used for health policy decision making, but the country still lacked economic evaluation knowledge and skills. It was recommended that economic evaluation training would help in building HTA human capacity among both groups in public and private sectors.[18] Although the number of economic evaluation researchers has been increasing in the last decade, they are still in short supply when compared with the need for HTA evidence. Recently, HITAP was capable of only 15 studies a year.[19] HITAP has continuously provided short course trainings, and academic institutes have offered both short- (eg, workshop) and long-term trainings (eg, undergraduate and graduate levels especially at the Faculties of Medicine and Pharmacy across the country). HTA capacity building has, however, been a challenge.

In addition, good-quality economic evaluation studies rely heavily on good data. Nevertheless, such data at the national level are still limited and are not linked among healthcare facilities in the country. Some HTA data structures were developed, but their maintenance is questionable. For instance, HITAP developed the standard cost list that has been widely used by HTA studies in the country, but it has not been updated for almost 10 years. Moreover, the financial support for HTA studies has been limited and it is a hindrance for independent researchers at universities to conduct HTA research. Stakeholder engagement is another HTA challenge in the country. Currently, third-party payers, healthcare providers, clinical experts, and pharmaceutical industries have been invited to participate in the NLEM listing process. Nevertheless, patients have been slightly engaged in HTA.

Another challenge, which has never been addressed, is the health impact or consequence of the HTA. The HTA could possibly delay access to new technologies with less cost-effective and high budget impact. The case of human papillomavirus (HPV) vaccines

was an example, although the HTA might not be the only reason for the delay. The evidence suggested that cervical cancer screening was cost-effective, whereas the HPV vaccines in Thailand were not.[20] Consequently, a massive campaign on cervical cancer screening was launched at public healthcare facilities, whereas HPV vaccines were not included in the public program for cervical cancer prevention.[20] The economic evaluation results suggested that the prices of HPV vaccines should be decreased by 60% to become cost-effective. At that time, 2 pharmaceutical companies agreed to reduce the price on the basis of the findings. Nevertheless, HPV vaccines were not included because of a high budget requirement.[21] Although the cervical cancer screening rate had been improved, it plateaued. A study reported that the implementation of the screening program was not effective.[22] The Global Alliance for Vaccines and Immunizations, however, successfully negotiated the vaccine prices and provided the HPV vaccines a few years earlier in several countries with lower national incomes than Thailand's. Nevertheless, the health impact from this delayed access was unknown.

What Is Next?

What is next for HTA in Thailand should center on improving HTA agency and capacity building to overcome the challenges. Although HITAP is known as an active body in the HTA and has also conducted the economic evaluations of several technologies, it is not a sole HTA agency. Nevertheless, the HEWG, the therapeutic working group, and the NLEM subcommittee indeed also play the appraisal role of HTA. This unclear HTA structure did not accommodate the growth of HTA in Thailand. It also led to 2 major criticisms including transparency and monopoly of power. The country should have an immediate review of its structure, strategic plan, and implementation. It can learn from countries that have a well-established HTA system and adapt it to Thai context to attain a higher achievement level of HTA. Primarily, the country should aim for 2 separate bodies for the assessment and appraisal roles of HTA. The assessment body is responsible for reviewing and synthesizing clinical, economic, and other evidence, for example, budget constraint, ethics, and equity, whereas the appraisal body examines these evidences and incorporates them in decision making.

One can argue that Thailand is a small country with a limited number of HTA researchers and it is not possible to afford 2 separate bodies of HTA. Nevertheless, the argument is somewhat invalid and too conservative. It never allows the improvement of the HTA system in the country. In fact, one should expect a negative consequence from the current HTA model in Thailand. Currently, there is a clear policy that health economic evidence generated solely by the industry cannot be used to support the decision-making process unless its conduct has been endorsed by the HEWG. The industry would consider that their attempt to generate economic evidence is meaningless and a waste of their investment. Intuitively, they would rather wait and use pricing strategies to push back after the economic evaluation evidence becomes available. Different approaches need to be discussed. For instance, currently a number of researchers at HITAP have spent a great amount of time to generate clinical and economic evidence. This function is important, but could be transferred to the pharmaceutical industry and its consulting firms at their own costs. The researchers at HITAP could spend time to review and examine the evidence instead or HITAP could be transformed to be an appraisal body. This approach would transfer some costs of HTA to the industry and also overcome the issue of trusting the evidence generated or submitted by the industry at the same time. It should be noted that this approach is not alienated because most clinical trials of new technologies have been done or financially supported by the industry and the results have been assessed and still used in clinical practice. This approach would also potentially accelerate the capacity building because it could draw more resources for training more researchers in the field.

The capacity building has been a long-haul challenge of HTA in Thailand. This type of training requires not only technical skill sets but also resources and opportunities. Only a few major graduate programs have had formal training for the economic evaluation. Although the country recognized the impact of HTA, only some of the training programs could obtain financial support from getting involved in the economic evaluation of healthcare technologies more than the others did. As previously mentioned, a public-private partnership model has been discussed and suggested to resolve this challenge. Nevertheless, it did not seem to work well because of inadequate trust. Under the current HTA model, it is almost impossible to overcome the problem of capacity building. Thailand needs to mimic the academic fellowship model under nonrestricted support from either the industry or the government. Besides capacity building, the fellowship program would generate HTA evidence at the same time. It is noteworthy that capacity building should also include those that generate quality of life and other evidence (eg, ethics) used in HTA as well.

Another problem with the current HTA structure is the lack of the engagement of stakeholders, especially patients, in the HTA process. Although the HTA process has included patient representatives, it is unclear how they were selected or whether they were qualified or trained to appraise the evidence to ensure that no party in the HTA process could overshadow them.

Although the data for HTA use have been improved for both availability and quality, access to data is another challenge in Thailand, primarily because of lack of trust. Access to data requires not only willingness to share but also law and regulation. The country should take several small steps to finally open access to data. The easiest step is that the country should accommodate data sharing among governmental agencies, including public universities. Certainly, law and regulation need to be set up and enforced to protect data secrecy. With the permissions from patients and the law and regulation, there should be no reason for any government agency to consider that they own data or to build barriers to limit others' access to the data. The accessibility of the data needs to be assessed. It should be considered unethical or wrongful if the existing data are not shared for the benefits or the best interest of the patients or the country, especially the agency that specifically receives financial support from the government to collect or manage data. Nevertheless, one should not expect to succeed overnight because the willingness to share data is indeed an issue of cultural change in Thailand.

Opportunities

The opportunities of HTA in Thailand could be viewed at 2 levels: national and international. As previously mentioned, a well-established example of HTA in the country is the drug selection of the NLEM. Nevertheless, the flood of more advanced technologies, for example, biological products and precision therapies, could be more opportunities for the country's HTA. Routinely, HTA has been applied to other health technologies and programs, including medical equipment, health prevention, and health promotion, but certainly they are opportunities of HTA in Thailand, because they are also parts of the UCS.

At the international level, HITAP has done an excellent job in expanding its horizon to help other countries inside and outside the Association of Southeast Asian Nations.[23–26] Undoubtedly, this created a potential opportunity for Thailand to be a leading

nation for HTA. Once Thailand has well established its own HTA agency and has built enough capacity, the country should have opportunity to play a major role in HTA globally.

Conclusions

Thailand has used HTA as a tool for the drug selection of the NLEM. It helps the country achieve universal health coverage. However, further development of the country HTA is still needed.

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