Application of HTA Research on Policy Decision-Making

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This article provides an overview of the potential uses of health technology assessment (HTA) in health technology or health intervention-related policy decision-making. It summarises the role of HTA in policy planning, health system investment, price negotiation, development of clinical practice guidelines, and communication with health professionals. While the multifaceted nature of HTA means that some aspects of the data can result in conflicting conclusions, the comprehensive approach of HTA is still recommended. To help minimise the potential conflicts within HTA data, a multi-criteria decision analysis (MCDA) approach is recommended as a way to assess a number of decision criteria simultaneously. A combination of HTA with MCDA allows policy decision-making to be undertaken in an empirically rigorous and rational way. This combination can be used to support policy decision-makers in Thailand and help them prioritise topics for assessment and make informed health benefit package coverage decisions. This approach enhances the legitimacy of policy decisions by increasing the transparency, systematic nature, and inclusiveness of the process.

Keywords: *Health Technology Assessment, Multiple-criteria Decision Analysis, Policy decision-making*

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In Thailand, as in many countries nowadays, the availability of high-cost health interventions, including pharmaceuticals and medical technologies, is on the rise. While this has frequently led to an increase in public and patient expectations, the resource-limited nature of government healthcare systems mean that these interventions cannot always be provided for those who wish to have them. There is currently, therefore, a need for rigorous, efficient, and evidence-based approach to help policy-makers decide allocation of limited healthcare budgets. Health Technology Assessments (HTAs) are increasingly recognised as one of the most useful tools that can help inform health technology- or health intervention-related policy-making at individual, institutional, national, and international levels[1,2]. HTA data can improve the quality of health care in multiple ways, and is a valuable resource for the development of a wide spectrum of health care policies[3]. This section provides an overview of the potential applications of HTA for policy-makers when making decisions on the most rational use of health.

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Policy planning and investment in the health system

HTA can be used in policy planning to help determine an appropriate level of health care investment, given the resources and health technologies that are available. HTA can provide information on the budget impact of health technology adoption within a specific country setting, as well as support for decision-makers regarding resource allocation of different health initiatives, including those used in the selection of health interventions for public reimbursement. For instance, HTAs can support decision-makers in deciding which benefit packages they will provide, as shown in case study 1.

Case study 1: Inclusion of allogeneic hematopoietic stem cell transplantation for severely thalassemic patients in the Universal Health Coverage Benefit Package in Thailand[4]

Hematopoietic stem cell transplantation (HSCT) is the only curative treatment currently available to leukaemia and severely thalassemic patients. At the time of the research, HSCT was not included in the benefit package of the Universal Coverage (UC) scheme but was covered in the Civil Servant Medical Benefit Scheme and the Social Security Scheme. This resulted in inconsistent coverage for the population. Of those patients whose insurance did not cover HSCT provision, only those who could afford to pay for the treatment and the associated expenses (around 700,000-

1,500,000 THB per patient) were able to access the treatment. The National Health Security Office (NHSO), which manages the UC scheme, examined a number of health problems/interventions and, through a rigorous selection process facilitated by the Health Intervention and Technology Assessment Program (HITAP) in 2007, identified five that warranted further economic evaluation to determine whether the coverage policy related to each was appropriate. Once the top health problems/interventions had been identified, the Subcommittee for the Development of the Benefit Package and Service Delivery (SCBP) of the NHSO approved the selection. Then, an economic evaluation and budget impact analysis were conducted by HITAP researchers[5]. Of the five health topics/interventions, the intervention that was deemed the top priority for further assessment proposed examining patients with severe thalassemia and their caregivers who were undergoing HSCT.

A cost-utility analysis was performed to evaluate and compare the costs and health outcomes of HSCT compared with standard therapy-in this case, iron chelating therapy (ICT). The results showed that the incremental cost-effectiveness ratios (ICERs) related to HSCT (for patients aged 1 to 15 years) ranged between 80,700 and 183,000 THB per QALY gained, while those associated with the current treatment package (for patients aged 1 to 15 years) ranged from 209,000 and 953,000 THB per QALY gained. Based on a willingness to pay threshold of 100,000 THB per QALY (approximating the Thai GDP per capita), the findings of the analysis indicated that provision of HSCT to severely thalassemic patients with related or sibling donors were likely to be cost-effective only when provided to patients 10 years and under. Moreover, the governmental budget impact of providing HSCT to patients 10 years and under equated to around 90 million THB per year (with only 200 patients requiring treatment per year).

The results of the assessment were subsequently presented to the SCBP for appraisal. The SCBP agreed to provide HSCT coverage for patients aged 10 years and under. This decision was not only based on the fact that the treatment was found to be cost-effective, but also because the subcommittee deemed it socially, ethically, and morally appropriate to do so. However, before including this technology in the UC benefit package, the SCBP asked the researchers to conduct further research on the feasibility of providing this life-saving and cost-effective technology on a large scale in an equitable manner, to examine further whether limited resources should be allocated based on certain criteria, e.g. severity of disease, fair innings, or a lottery model.

Price negotiation

In recent years, HTA data (mostly using ICER information) have been used in drug pricing negotiation. In HTA studies, the price that is used in the analysis is usually the maximum amount that the pharmaceutical company hopes to charge. If the drug demonstrates good value for money the company may be awarded a price similar to that assumed in the assessment. However, the drug price may be negotiated down ward based on the results of the economic evaluation and other relevant information presented in HTA. An example of this can be seen in case study 2.

Case study 2: Using the results of a cost-utility analysis of drug treatments in patients with chronic Hepatitis B for drug price negotiation

An estimated 2 to 3 million people in Thailand are chronically infected with the Hepatitis B virus. Infection with Chronic Hepatitis B (CHB) can cause not only liver inflammation and serious liver damage leading to cirrhosis, hepatic decompensation, hepatocellular carcinoma and death, but may also result in a significant economic burden for patient and caregiver. Six medications-lamivudine, adefovir, entecavir, telbivudine, interferon and pegylated interferon-have been licensed by the Thai Food and Drug Administration (Thai FDA) for the treatment of CHB; only lamivudine has been included in the National List of Essential Medicines (NLEM). To date, no intervention to help manage drug resistance in CHB patients has yet been included in the NLEM. However, tenofovir, approved by the Thai FDA for treating HIV, is currently used for CHB treatment in clinical practice, since it has demonstrated high antiviral efficacy and low rates of resistance in CHB patients.

To assess whether this clinical practice was, indeed, efficient and to help decide which drug should be included in the NLEM, a cost-utility analysis of all treatment options for patients with CHB in Thailand was conducted[6]. The study found that tenofovir was cost-effective when used as a first-line treatment (or second-line treatment in the case of lamivudine resistance), and as such, should be included in the NLEM. However, the inclusion of tenofovir in the NLEM was also found to potentially have a high budget impact for the government, based on the market price (2010). Therefore, the subcommittee of development of the

NLEM negotiated with the pharmaceutical companies to reduce the price of tenofovir. They reduced the price from 43 baht to 12 baht per tablet, resulting in a saving of 375 million baht of government money.

Development of clinical practice guidelines

HTA is one of the most useful tools available when developing clinical practice guidelines. In some developed countries, such as England and Wales, HTA results are always taken into account when developing any guidelines intended to influence health service delivery throughout the country[7].

Communicating with health professionals

It is also widely agreed that HTA is a useful resource for public health authorities involved in communicating and promoting rational health technology use to health professionals.

A cornerstone of many national disease programs is the capacity of interventions to maximise general population health, otherwise known as effectiveness[8,9]. Some national disease programs also propose that cost and cost-effectiveness are also important criteria that should be used to guide choices in health care. These criteria explicitly recognise the economic constraints on the provision of health care, and imply that only those interventions that show value for money should be publicly financed[10,11]. However, over reliance on these kinds of criteria places disproportionate emphasis on the economic aspects of treatment and fails to capture other important aspects of health care that should be taken into account when evaluating interventions. HTAs are more holistic, taking into account different types of evidence, including that related to safety, efficacy, economics (value for money and budget impact), feasibility, societal, and ethical implications of implementing health technologies or interventions within the health system. Because of HTA's multifaceted nature, at times, these different dimensions may conflict with one another. While the HTA model may be more complex that a purely economic evaluation of the intervention, this more comprehensive approach does allow decision-makers to set priorities and allocate limited resources among different health programs[12-15] in the most informed way possible. However, many HTA organisations (such as the National Institute for Health and Clinical Excellence (NICE) in England and Wales) have raised concerns about how best to address all of these issues simultaneously; currently, there is no consensus on how best to resolve this issue[16]. Instead, researchers have suggested that a multi-criteria decision analysis (MCDA)[17] approach, used together with an HTA, might be more appropriate for ensuring that analyses incorporate all relevant issues into their framework, not just effectiveness and cost-effectiveness, to better inform the policy making process.

Multi-criteria decision analysis

A multi-criteria decision analysis (MCDA) is a decision support method that allows the identification of a comprehensive set of criteria, establishes the performance of interventions on those criteria in a so-called performance matrix, and then inspects the performance matrix qualitatively or quantitatively to rank order interventions[17]. In a qualitative inspection, policy-makers simply interpret the performance matrix, and make implicit judgments on the weights of the various criteria. In a quantitative inspection, policy-makers weigh the different criteria on the basis of their relative importance, and multiply the score by the weights to obtain weighted averages for all interventions. Interventions can subsequently be ranked ordered according to these weighted averages. While MCDA reduces the stream of dissimilar information by assessing the interventions' performance according to a set of criteria in the performance matrix, the consideration of other non-quantifiable (or otherwise absent) criteria that did not present in the performance matrix for any reason is captured in the process of deliberation. Decisions on health intervention priorities should be made by using MCDA, on the basis of consultations with the relevant multiple stakeholders through a deliberative process. Therefore, a combination of quantitative and qualitative approaches is recommended[18].

In recent decades, the use of an MCDA approach in HTA has grown in popularity, as a way of improving the evidence upon which healthcare decision-makers base their healthcare policy decisions at all levels, and to ensure better synthesis, communication, and dissemination of HTA results. Combining MCDA and HTA has been found to provide higher quality data that encourages more rigorous policy planning in the long run and allows policy-makers to make informed decisions that are relevant to their specific context, either at the a national, sub-national or institutional level. In Thailand, the lessons learned from the two case studies presented here in provide ample evidence that MCDA has been useful both as a way to select health topics that warrant further HTA studies[19], and as a tool to support health

technology coverage decisions in the Thai UC benefit package[5,20,21].

Due to limited resources, many HTA agencies struggle to keep pace with new technology. As such, priority setting has become a crucial aspect of the process to determine which health products/topics are assessed. Identification of technologies that warrant assessment is now the first step of the HTA process, and it helps ensure that HTAs continue to be relevant and conducted in a transparent, systematic, and socially acceptable manner[22]. Clearly, priority setting is an important process that helps makes sure that HTA offers optimal benefits for society and encourages the use of HTA data in policy decision-making. However, to date, very little research has been conducted into the criteria that should be applied and the process that should be undertaken when selecting HTA topics. Nevertheless, there is some agreement on general topics that should be examined (Table 1) as well as growing acceptance, based on examples, that MCDA can help inform this decision (case study 3).

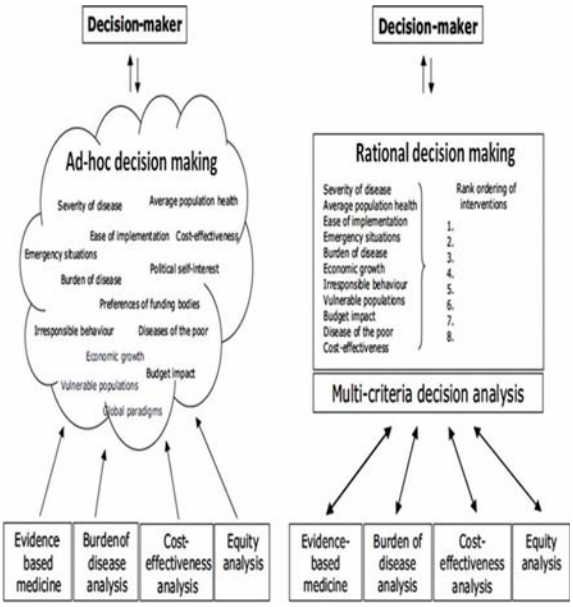

Fig. 1 Ad hoc priority setting and rational priority setting[17].

Case study 3: Selection of health topics for health technology assessment in Thailand, facilitated by HITAP

In 2007, HITAP initiated some research on appropriate methods for identifying priority health topics/technologies that warrant HTA. To ensure that all decision-making resulting from HTA data is systematic, transparent, and efficient[24-26], the MCDA approach was applied to the priority setting process (Fig. 2).

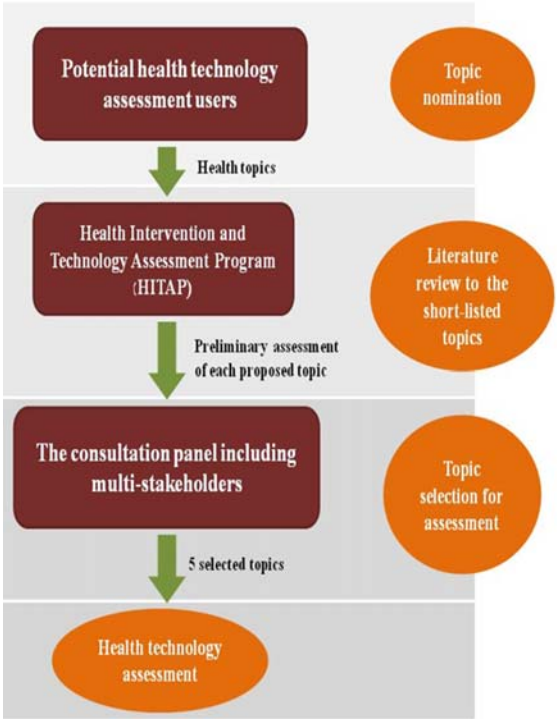

Fig. 2 A schematic representation of HTA topic selection process, facilitated by HITAP.

Step 1. Nomination of health topics/technologies for assessment

As the first step of the process, HITAP invited potential HTA users to nominate a number of health topics/technologies that they considered warranted further assessment. The potential HTA users included health professional councils, health care purchasers (i.e., the National Health Security Office, the Social Security Office, and the Comptroller General's Department), public health agencies (at provincial and national levels), academia, private sector, civil societies, patient groups, and the general population.

Step 2. Short listing and Literature Review

In the second step, HITAP researchers shortened the list of nominated health topics/technologies by excluding all of the following: 1) those that had been assessed within the last five years; 2) those whose assessment was not the responsibility of HITAP but, rather, an officially authorised organisation;

Table 1. Examples of potential criteria used for topic selection of HTA[2,23], by category

Disease burden
High individual burden of morbidity, mortality, or disability
High population burden of morbidity, mortality, or disability
Prevalence or incidence
Disease-adjusted life expectancy or healthy years of life expectancy
Clinical impact
Potential health impact of the proposed technology versus standard care in a person with a clinical condition
Benefits of conducting an assessment in terms of reduced clinical uncertainty
Potential for change in practice to affect patient clinical outcomes
Budget impact
High aggregate cost of a technology or health problem
Potential incremental budgetary impact of adoption of the technology in comparison to the current standard of care
Economic impact
High unit healthcare cost of a technology or health problem
Potential cost-effectiveness of conducting an assessment given resource constraints (e.g., researchers, time, and research funding) of the assessment program
Variation in practice
Variation in rates of use of the proposed technology for the given clinical condition
Substantial variations in clinical practice
Expected level of interest
Public or political demand
Scientific controversy or great interest among health professionals
Need to make regulatory decision
Need to make a health program implementation decision
Need to make payment decision
Social and ethical implications associated with the use of the proposed technology
Evidence
Sufficient research findings available upon which to base assessment
Timing of assessment relative to available evidence
Potential for the findings of an assessment to be adopted in practice

3) those whose performance was already well known; and 4) those that were not directly related to health.

Once the inappropriate health topics/technologies were dismissed, each short-listed topic/technology was reviewed and scored according to a set of criteria, developed by HITAP on the basis of a review of international guidelines used to prioritise HTA topics for assessment (as presented in Table 1). The list of criteria was presented to a number of HTA experts in Thailand, who refined the list to five criteria: 1) disease burden, 2) economic impact on household expenditure, 3) variation in practice, 4) potential for the findings of an assessment to be used, and 5) equity/ethical and social implications (Table 2). The shortlisted topics/technologies were then ranked according to how they scored according to this list of criteria.

Step 3. Topic selection for assessment

Decision-making is a complex process, and resource allocation is always inherently political. Although a comprehensive set of criteria have been developed in terms of how best to undertake the priority setting process, decision-makers should still be permitted room to elaborate their own reasons in the final step, to ensure the process is deliberative. To this end, the shortlisted health topics/technologies were presented to multiple stakeholders in a consultative meeting. The participants were asked to discuss which topics should be assessed by HITAP, and present a final list.

To conclude, HTA is one of the most useful tools for decision-makers involved in healthcare policy. It can help prioritize topics for assessment, and inform coverage decisions of health benefit packages. In addition, the adoption of an MCDA approach when conducting HTAs can help reduce the stream of dissimilar information allowing assessment of intervention performance. The combination of HTA and MCDA can help the policy planning process in the long term and enhance the legitimacy of

Table 2. Selection criteria

Category	Definition	Selection criteria
1. Disease burden	Number of people affected by or severity of the disease or health problem that treated, or prevented by the proposed technology/intervention among Thai population at a specified time.	Prevalence of the disease or health problem >75,000 and/or Patients'quality of life score <0.30
2. Economic impact on household expenditure	Impact on household expenditure as a consequence of providing the proposed technology/ intervention to a family member with consideration of catastrophic illness or health catastrophe.	Direct medical and non-medical house hold expenditure as a consequence of the disease or health problem is estimated to be higher than 28,200 baht per year[1(27-29)]
3. Variation in practice	Variation of implementing the intervention in practice that leads to unequal accessibility to the intervention among Thais. Variation in practice could be identified from the different coverage of the three publicly funded health insurance schemes in Thailand and/or could be identified from the different distribution of the intervention throughout the country.	There is an evidence presenting: - The difference of the benefit packages between the 3 health insurance schemes in Thailand - The difference of health interventions distribution in Thailand
4. Potential for the findings of an assessment to be used	Potential for the findings of an assessment to be used in policy decision-making and/or in changing clinical practice to affect patient outcomes and/or costs	There is evidence that the findings of an assessment can be used
5. Equity/ethical and social implication	Priorities for specific groups of patients i.e. the poor with rare diseases reflect the moral values that should be considered by policy-makers.	Disease of the poor or targeting the poor and prevalence of the disease or health problem <1,000 (Rare disease)

[1] The literature defines catastrophic expenditure as households' spending on direct health care costs (e.g. medicines) which exceeds 10% of household's expenditure.

policy decisions by increasing the transparency, inclusiveness, and accountability of the process.

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Potential conflicts of interest

None.

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การใช้ประโยชน์จากงานวิจัยด้านการประเมินเทคโนโลยีด้านสุขภาพ

ศิตาพร ยังคง

บทความนี้นำเสนอประสบการณ์การใช้ประโยชน์จากการประเมินเทคโนโลยีด้านสุขภาพ สำหรับการตัดสินใจเชิงนโยบายที่เกี่ยวข้องกับเทคโนโลยี หรือมาตรการด้านสุขภาพที่เกี่ยวข้องกับการตัดสินใจเชิงนโยบาย บทความนี้สรุปบทบาทของการประเมินเทคโนโลยีด้านสุขภาพในการวางแผนเชิงนโยบาย การลงทุนในระบบสุขภาพ การต่อรองราคายา การจัดทำแนวทางเวชปฏิบัติ และการสื่อสารกับบุคลากรสาธารณสุข ขณะที่การประเมินเทคโนโลยี ด้านสุขภาพมีได้หลายมิติ และในแต่ละมิติอาจได้ข้อสรุปที่ไม่ตรงกัน ดังนั้นผู้กำหนดนโยบายควรพิจารณาปัจจัยต่าง ๆ เหล่านี้ร่วมกันอย่างเป็นระบบในการประเมินเทคโนโลยีด้านสุขภาพ ปัจจุบันได้มีความพยายามในการนำการวิเคราะห์ การตัดสินใจโดยใช้เกณฑ์ที่หลากหลายร่วมกันมาใช้ในขั้นตอนต่าง ๆ ของการประเมินเทคโนโลยีด้านสุขภาพ เพื่อสนับสนุนการตัดสินใจเชิงนโยบายในประเทศไทย ได้แก่ กระบวนการคัดเลือกหัวข้อเทคโนโลยีด้านสุขภาพ ที่ควรทำการประเมินและกระบวนการประเมินเทคโนโลยีหรือมาตรการด้านสุขภาพเพื่อพิจารณาบรรจุ เข้าสู่ชุดสิทธิประโยชน์ทั้งนี้เป็นการเพิ่มความชอบธรรมของการตัดสินใจผ่านกระบวนการที่โปร่งใสเป็นระบบ และพิจารณาอย่างรอบคอบ