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Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

Sarocha Chootipongchaivat
Nattha Tritasavit
Alia Luz
Yot Teerawattananon
Sripen Tantivess

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POLICY BRIEF AND WORKING PAPER
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Health Intervention and Technology Assessment Program (HITAP)
6th Floor, 6th Building, Department of Health,
Ministry of Public Health, Tiwanon Road,
Muang, Nonthaburi 11000, Thailand
Tel: (66) 2590-4549 or (66) 2590-4374-5
E-mail: info@hitap.net
www.hitap.net

CONTENTS

AUTHORSHIP AND ACKNOWLEDGMENTS

Sarocha Chootipongchaivat, Nattha Tritasavit, Alia Luz, Dr. Yot Teerawattananon, and Dr. Sripen Tantivess from the Health Intervention and Technology Assessment Program (HITAP), Thailand, authored this policy brief. The authors gratefully acknowledge funding support from the Asia Pacific Observatory on Health Systems and Policies and the Prince Mahidol Award Foundation under the Royal Patronage.

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2015
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LIST OF ABBREVIATIONS

BPJS	Badan Penyelenggara Jaminan Sosial Kesehatan
CDC	Center for Disease Control
CDE	Center for Drug Evaluation
CHNRI	Child Health and Nutrition Research Initiative
CHPETA	Center for Health Policy Evaluation and Technology Assessment
CNHDRC	China National Health Development Research Center
CNHTA	Center for New Health Technology Assessment
DBC	Drug Benefit Committee
DSAP	Discipline of Social and Administrative Pharmacy
EBM	Evidence-Based Medicine
ELSI	Ethical, Legal and Social Implications
ENDS	Electronic Nicotine Delivery Systems
GAVI	Global Alliance for Vaccines and Immunization
GDP	Gross Domestic Product
GHB	Government Health Budget
HIRA	Health Insurance Review and Assessment Service

HITAP	Health Intervention and Technology Assessment Program
H-SIGHT	Horizon Scanning Service of Innovative Global Health Technology
HPSR	Health Policy and Systems Research
HSPI	Health Strategy and Policy Institute
HTA	Health Technology Assessment
HTAi	Health Technology Assessment international
iDSI	international Decision Support Initiative
INAHTA	International Network of Agencies for Health Technology Assessment
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
LMICs	Low- and Middle-Income Countries
MaHTAS	Malaysian Health Technology Assessment Section
MFDS	Ministry of Food and Drug Safety
MOH	Ministry of Health
MOHW	Ministry of Health and Welfare
MoPH	Ministry of Public Health

NCDs	Non-Communicable Diseases
NECA	National Evidence-based Healthcare Collaborating Agency
NGO	Non-Governmental Organization
NHI	National Health Insurance
NHIA	National Health Insurance Administration
NHFPC	National Health and Family Planning Commission
NHIS	National Health Insurance Service
NHSO	National Health Security Office
nHTA	new Health Technology Assessment
NICE	National Institute for Health and Care Excellence
NIHTA	National Institute of Health Technology Assessment
NLEM	National List of Essential Medicines
OECD	Organisation for Economic Co-operation and Development
OOP	Out-of-Pocket Payment
P2JK	Pusat Pembiayaan Jaminan Kesehatan
PMAC	Prince Mahidol Award Conference

PSD	Pharmaceutical Services Division
RCMS	Rural Cooperative Medical System
RedETSA	HTA Network of the Americas
SAP	Social and Administrative Pharmacy
SMDM	Society for Medical Decision Making
THE	Total Health Expenditure
TPE	Total Pharmaceutical Expenditure
UEBMI	Urban Employee Basic Medical Insurance
UHC	Universal Health Coverage
UNICEF	United Nations Children's Fund
USM	Universiti Sains Malaysia
WHO	World Health Organization
WHO-CHOICE	World Health Organization's Choosing Interventions that are Cost-Effective

1 POLICY BRIEF

Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT

OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

I. POLICY BRIEF

With Universal Health Coverage (UHC) high on the global health agenda, governments of many low- and middle-income countries (LMICs) have pledged to increase health investments in the scale-up of essential health services to meet the needs of their people. This has led to the recognition of health technology assessment (HTA) as a necessary tool for setting priorities especially in the UHC context (1). This policy brief was developed based on experiences from seven settings, including China, Chinese Taipei, Indonesia, the Republic of Korea, Malaysia, Thailand, and Viet Nam, which represent approximately one-sixth of the world's population. The policy brief highlights the problems and evidences concerning HTA development in the Asia-Pacific region and makes recommendations that may be potentially applicable to settings in other regions.

Problems

In settings where HTA is well-established, evidence supports coverage decisions, including the design of health service delivery. However, in settings with limited HTA capacity, the use of evidence in identifying appropriate UHC interventions is lacking. Limited HTA capacity includes a variety of factors ranging from a shortage of skilled HTA researchers to limited information infrastructure and low political support. As a result, the benefits package can become too broad, ill-defined and/or unreasonable, which results in difficulties in linking the payment with the benefits package. Consequently, inefficient deliveries of health services will increasingly become the norm, thus increasing the out-of-pocket payments (OOPs) for patients. On the other end, providers have increased incentives for the irrational use of health

technology as uninformed patients are likely to pay for these services with the outcome being higher health care costs and inefficient resource use. As OOPs for patients increase, access to essential health services becomes inequitable. For instance, patients who can afford high-cost technology are the only ones with access to it while vulnerable groups such as the low-income communities are unable to gain access.

Governments in the region have recognized the need for HTA to support UHC; nevertheless, HTA institutionalization in some settings faces several impediments, especially in linking evidence with policy and practice. The set of barriers to the development of HTA systems involves the following:

- **Silo-based decision-making process** refers to a process wherein decisions are made without transparency and participation of relevant stakeholders.
- Policy makers have **low quality decision-making criteria** when allocating resources, meaning that policy considerations do not focus on long-term outcomes, distributive effects (equity), or making explicit links between cost and outcome.
- Some settings may have **strict control on research dissemination,** meaning that research outcomes that are unfavorable to decision-makers tend to not be used in policy making.
- The fact that **respect for expert (senior) opinions or authorities** is held in higher than evidence-based research forms the last common barrier for using HTA in policy decisions.

Evidence

Lessons drawn on the experiences of the study settings where HTA has long been developed illustrate six contextual factors that commonly exist in the health systems. It is evident that these factors are conducive for both the demand and supply of quality HTA studies, i.e. the establishment of HTA agencies and their contributions to evidence-informed coverage policies.

- **A high proportion of public investment and strategic purchasing mechanism** in health care compared to private health expenditure is a strong incentive for settings to try to ensure investment in cost-effective interventions with good clinical outcomes.
- **Political will, leadership, and legislation** pushes HTA development forward. HTA is therefore legitimized in the decision-making process and backed by high-level policy, which means it will be linked directly with public health resource allocation. This generates demand and need for more and better quality HTA.
- **A good health information infrastructure** encourages HTA use. HTA is a highly analytical and multidisciplinary process which requires a wide breadth of information. A well-developed information infrastructure allows for economic analyses that require large and complete data sets.
- **Local training on HTA-related disciplines** strengthens and builds on existing or new capacity. Postgraduate training on HTA, locally and internationally, ensures reaching a critical mass of HTA researchers to conduct studies and meet the growing demand of HTA.
- **Effective collaboration between HTA agencies/programs and local stakeholders** builds up the link between research and policy. Good working relationships between HTA agencies/programs and policy makers as well as multiple stakeholders can lead to well-accepted HTA results and greater legitimacy for policy use.
- **Settings' independence from external support or international aid** forces them to budget scarce resources effectively. There are fewer tendencies to make allowances on inefficient or unwise decisions and policy making is more focused.

Recommendations

The recommendations provided comprise five factors for HTA development and a practical step-by-step guide, including a checklist to monitor the progress of HTA introduction and development. Although this policy brief focuses on the use of HTA to inform coverage decisions under UHC, these recommendations include the basic components of HTA systems which can also be applied for the use of HTA in general resource allocation. The five recommendations are as follows:

1. **Human resource development:** It is very important that sufficient human resource capacity is built into HTA research organizations as well as decision-making bodies and other relevant stakeholders that are using HTA.
2. **Core team or HTA institutes:** The HTA process involves multiple stakeholders, which makes it essential to have an HTA focal point or agency to coordinate HTA activities and cooperate with partners. This group must be committed to HTA work and be responsible for gaining the trust of all stakeholders.
3. **Linking HTA to policy decision-making mechanisms:** The appropriate mechanism for linking HTA to decision-making will vary based on the context and design of the health system. The link between HTA for coverage decisions and UHC includes the pharmaceutical reimbursement list/essential drug list/formulary list, immunization programs, high-cost medical devices package, and public health programs.
4. **HTA legislation:** The existence of legislation may help sustain long-term and successful use of HTA. HTA legislation should ensure the presence of key factors such as participation, transparency, and systematic application in the HTA process rather than focus on technical issues.
5. **International collaboration:** International technical support is very useful, especially in the formative stages, in terms of financial and technical capacity building support. However, in-country development in these areas should take priority so that reliance on international support diminishes over time. Eventually, international collaboration should be sustained in terms of information and knowledge exchange across agencies.

The practical step-by-step guide in Table 1 provides information on the HTA systems development, which can be divided into two phases. The early phase of HTA development is defined as the period when HTAs are not conducted locally, are conducted without links to policy making, or are used on an ad hoc basis. The moderately developed phase is defined as a period when HTA is being used on a routine basis by decision-makers; however, HTA systems are dynamic and continually develop over time. The following practices are recommended for each phase of HTA development. During these phases, considerations need to be made for four components, namely manpower, money, materials, and management, in order to establish a functioning HTA system. These components are summarized in the table below.

TABLE 1

Components needed to establish a functioning HTA system

Components	Early Developmental Phase	Moderate Developmental Phase
 Manpower	No clearly established HTA focal point, but a clear commitment by HTA units with part-time staff to acquire and further develop knowledge and skills in HTA with the aim to move towards full-time HTA staff.	Clear demand for HTA by decision-makers and interest in HTA by academics and availability of local short course trainings as well as postgraduate trainings to increase capacity.
 Money	Financial resources from national and international funding sources made available for HTA research and capacity building.	Flexible and sustainable government resources for HTA.
 Materials	No requirement for specific materials. Data can be borrowed from other settings with similar contexts.	The HTA focal point provides methodological and process guidelines for standardizing HTA research. Availability of local data.
 Management	Informal and formal mechanisms to ensure management of potential conflicts of interest and development of methodological HTA guidelines.	More than one HTA agency producing policy relevant HTA reports and a clear HTA focal point to set standards for the HTA methods and processes, coordinate among HTA agencies and between HTA agencies and decision-making bodies.

Source: Authors

In order to monitor the progress of following the practical step-by-step guide, the figure below brings together the 10 most important achievement indicators for settings where HTA is nascent. The achievement indicators act as a checklist for settings to determine the level of maturity of their HTA development and inform people who are responsible for HTA development about potential improvements. The indicators do not determine the phase of HTA development, but rather indicate the progress made, the indicators do not need to be made in sequence or any particular order.

FIGURE 1

Checklist of achievement indicators for progression of HTA development

2

WORKING PAPER

Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT

OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

II. WORKING PAPER

1. Introduction

Background

With Universal Health Coverage (UHC) high on the global health agenda, governments of many low- and middle-income countries (LMICs) have pledged to increase health investments in the scale-up of essential health services to meet the needs of their people. This has led to the recognition of health technology assessment (HTA), a necessary tool for setting priorities, especially in the UHC context (1). To date, only a few LMICs have accomplished the establishment of HTA systems. The Asia-Pacific is one region where HTA institutions and networks have been operating successfully in Organisation for Economic Co-operation and Development (OECD) countries and a few of the middle-income settings (2). However, many of the LMICs in the region have HTA systems that are still very early in development.

Employing qualitative research techniques, this policy brief and working papers draw lessons from HTA introduction in selected Asia-Pacific areas comprising China, Chinese Taipei, Indonesia, the Republic of Korea, Malaysia, Thailand, and Viet Nam. It describes the historical development and current practice of the HTA systems and identifies supportive policies and operational practices that were conducive to the introduction and maturation of HTA in these settings. Additionally, the brief provides practical recommendations on how to effectively develop HTA systems in LMICs.

Definitions

In this paper, the terms "health technology", "health technology assessment", and "health benefits package" are defined as follows:

- **Health technology** refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve health problems and improve quality of lives (3).
- **Health technology assessment (HTA)** is the systematic evaluation of properties and effects of health technology, addressing the direct and intended effects of this technology as well as its indirect and unintended consequences; it is aimed mainly at informing decision-makers regarding health technologies (4).
- **Health benefits package** is defined as services, activities, and goods reimbursed or directly provided by publicly funded statutory/mandatory insurance schemes or by national health services (5). It is a type of policy instrument used to set priorities for public spending on health care.

Scope

Taking into account the time dimension, which relates to the context in which HTA research is conducted, assessments of health technologies can be categorized as ex-ante and ex-post. Ex-ante HTA, usually known as "assessment for policy", determines the effects and consequences of a technology before its introduction into a health system. This perspective aims to inform policy decisions including health programs, pharmaceutical formulary, benefits coverage, quality standards, and clinical guidelines. On the other hand, ex-post HTA refers to the "after launch" or retrospective evaluation of technologies and policies after implementation. This policy brief and working paper's focus is on the ex-ante type as it reviews the features of HTA institutes and mechanisms at the national level; these generate evidence for coverage decisions (development of health benefits package) by authorities tasked with this responsibility including the health ministry and public insurance offices.

2. Health systems context

Health care systems in the Asia-Pacific region must address the needs of 4.2 billion people, which accounts for more than 60% of the world's population. As a result, the health systems for each study setting are quite diverse, ranging from areas that have public-dominated health care systems such as China to private-dominated health care systems such as Chinese Taipei. The diversity among the settings is due to the variety in administrations and economic systems. In order to understand the HTA systems in areas of study, it is essential to have a better understanding of the health system context first. By understanding the health system context, it will become easier to transfer the lessons learned to other settings with a similar context.

This working paper draws on the experiences of HTA systems in HTAsiaLink[1] members that voluntarily participated in this project. These include China, Chinese Taipei, Indonesia, the Republic of Korea, Malaysia, Thailand, and Viet Nam. Table 2 describes

[1] *HTAsiaLink is a regional network of not-for-profit HTA agencies to foster research collaborations between settings and build capacity of individuals and organizations. At the moment the network consists of 13 organizations from 10 settings, including Bhutan, China, Chinese Taipei, Japan, the Republic of Korea, Malaysia, the Philippines, Singapore, Thailand, and Viet Nam plus two associate members (HealthPACT from Australia and NICE International from the UK). See http://htasialink.org/ for more information and http://www.hitap.net/en/activities-network/htasialink for HTAsiaLink bi-annual newsletters.*

key characteristics of health care systems in the study settings. It shows that these sites have had varying degrees of success in terms of improving population health using life expectancy at birth and infant mortality rate as proxies. The Republic of Korea and Chinese Taipei have the longest life expectancy at birth and the lowest infant mortality rate while, in contrast, Indonesia has almost 10 years less life expectancy and at least five times higher infant mortality rate. Four settings, namely the Republic of Korea, Malaysia, Chinese Taipei, and Thailand, have already achieved more than 90% health coverage via publicly-funded health insurance; the remaining three countries have made a strong commitment to UHC and aim to achieve it within the next five years. At least three sites currently spend 6% or more of their gross domestic product (GDP) on health while other sites still have relatively modest health spending as a percentage of GDP. The governments of Thailand and China may be under the highest pressure to set health care priorities compared to others as they already spend 14% and 12% of the government budget on health, respectively, which means that there is not much fiscal space left to expand public health services. On the other hand, Chinese Taipei, the Republic of Korea, and Malaysia do not have high government budgets on health; nevertheless, these governments encounter pressure to meet the needs and demands of the public, which shoulders high financial burden of financing health care through premiums. The remaining countries that have committed to UHC — Indonesia and Viet Nam — are also pressured by the need to consider the resource demands of health care coverage for 248 million and 90 million people, respectively.

TABLE 2

Context of the study HTA systems

Sites	Population (million)	Life expectancy at birth[6]	Infant mortality rate (per 1,000 live births)[7]	% health insurance coverage	Year of achieving UHC	THE as % of GDP	GHB as % of government budget[8]
China	1,360	75	11	70–90	2020	5.4	12.5
Chinese Taipei	23	80[9]	4[9]	100	1995	6.9	19.8
Indonesia	248	71	25	60	2019	3.44	6.9
Republic of Korea	50	81	3	100	1988	6.8	13.6
Malaysia	28	75	7	100	1980s[10]	4.75	5.8
Thailand	67	74	11	100	2002v	4.5	14.2
Viet Nam	90	76	19	70	2020	6.0	9.5

Note 1: *UHC stands for universal health coverage; THE for total health expenditure; GDP for gross domestic product; GHB for government health budget.*

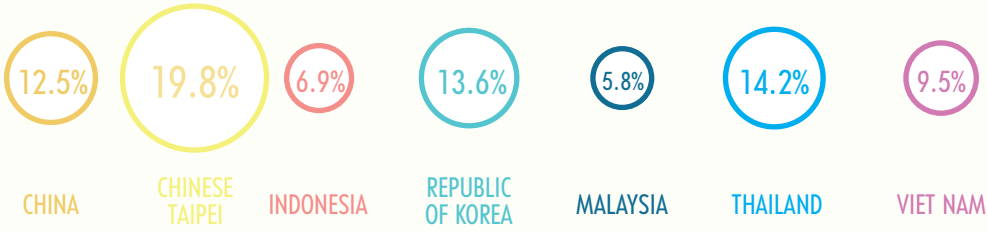
Note 2: *Unreferenced statistics were based on information given by the area authors.*

Note 3: *For sites that have not yet achieved UHC, the year presented is set by the government.*

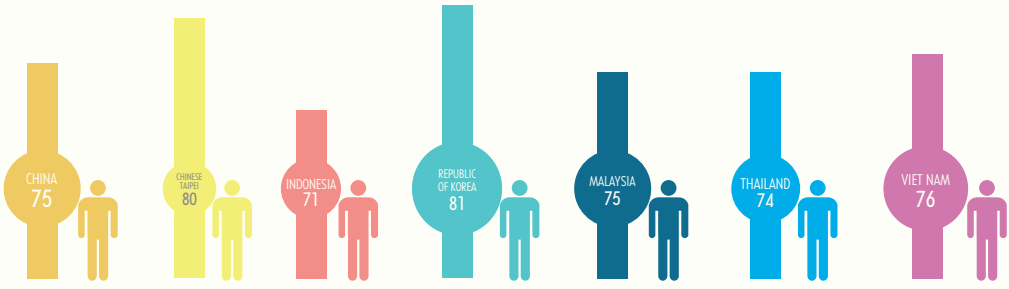
Sources: World Bank (2015); WHO (2015); Savedoff WD, Smith AL (2011); National Statistics Republic of China (2014).

Sites

GHB as % of government budget



Life expectancy at birth



3. Historical development and current practice of HTA agencies in study settings

As discussed previously, the need for setting health care priorities is recognized in each study setting. Health priority setting can be conducted in a formal or informal manner, with or without HTA agencies; however, this section focuses on the historical development of organizations dedicated to formal HTA. It is noteworthy that there is a separation between HTA evidence producers and decision-making bodies. All HTA agencies in the region included in this study have no decision-making power, but rather provide evidence to support policy decision-making. This is unlike some European organizations such as the National Institute for Health and Care Excellence (NICE) of the UK, which is perhaps regarded as the most famous HTA agency. NICE is responsible for making coverage decisions for the National Health Service and most of the evidences generated by NICE are from independent groups and academic institutions in the UK, and private industry submissions. As a result, the focus of the HTA agencies mentioned in this report is on organizations that generate HTA evidence to support other decision-making agencies.

Historically, the Malaysian Health Technology Assessment Section (MaHTAS; Malaysia) is recognized as the first HTA agency established in the region in 1995, followed by the establishment of Health Intervention and Technology Assessment Program (HITAP; Thailand), and the Center for Drug Evaluation/ Health Technology Assessment (CDE/HTA; Chinese Taipei) in 2007. The National Evidence-based Healthcare Collaborating Agency (NECA; the Republic of Korea) and the China National Health Development Research Center (CNHDRC; China) soon followed in 2008. The Health Strategy and Policy Institute (HSPI/HSPI-HITA; Viet Nam) was established in 2013 and the HTA committee (Indonesia) was set up in 2014. To date, all study sites have at least one HTA focal point including the HTA Committee in Indonesia and Health Strategy and Policy Institute (HSPI) in Viet Nam. However, only three sites, namely Chinese Taipei, the Republic of Korea, and Indonesia have formally appointed an HTA body through legislation.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NECA, CDE/HTA, and HITAP are well-established not only in terms of human resources and range of assessed technologies but also with regard to the significant role they play in evidence-informed policy development in national health authorities and public insurance schemes as well as in price negotiation of health technologies in the case of NECA and HITAP. These three agencies have distinguished, transparent, participatory HTA processes, including stakeholder involvement in the selection of HTA topics and the dissemination of results not only to decision-makers but also to a wide range of stakeholders. In addition, these HTA bodies are autonomous and highly independent from political pressure. They have also contributed to local capacity building for both academics and decision-makers.

CNHDRC and MaHTAS have made relatively good progress in conducting HTA research and connecting research findings with national policies. The CNHDRC usually obtains HTA topics at the request of the central government and the results are distributed only to the government and selected academics. Peculiarly, MaHTAS — although under the realm of the Ministry of Health — makes recommendations that are neither politically influenced nor befitting with prevailing government views.

While there is high political awareness and support for HTA as part of UHC development in Indonesia and Viet Nam, the HTA Committee and HSPI are at an early stage of development and are undergoing capacity strengthening with support from international partners. With the objective of linking HTA to policy, HTA studies are currently being undertaken as demonstration projects and results are expected to be available by the end of 2015. Table 3 summarizes the characteristics of the agencies considered in this report.

TABLE 3

Characteristics of HTA institutes involved in this project

Institute (site, year of establishment)	Assessed technologies			Use of HTA in pricing
	Medicines	Devices	Public health interventions	
CHPETA (China, 2008)	✓	✓	✓	✓
CDEHTA/NIHTA (Chinese Taipei, 2007/2013)	✓	✓	✓	
HTA committee (Indonesia, 2014)	✓	✓	✓	
NECA (Republic of Korea, 2008)	✓	✓	✓	✓
MaHTAS (Malaysia, 1995)	✓	✓	✓	
HITAP (Thailand, 2007)	✓	✓	✓	✓
HSPI/HSPI-HTA (Viet Nam, 1998/2013)	✓	✓	✓	✓

Number of researchers (Full Time)/ admin. staff	Annual budget (million USD)	Number of HTA projects	HTA legislation (year of issuing)
10 (FT)/0	1.6	5 – 8 topics per year / at least 5 HTA reports annually	N/A
22/3	2	60 (50 new drugs & devices / 10 public health)	National Health Insurance Act 2013
12 (Total, PT)	0.1	5 – 6	Presidential Regulation 12/2013
80/40	10	90 (59 for Committee of new HTA)	National Health Insurance Act 2006
27/4	– (MOH operational budget)	20 technology reviews / 5 HTA reports / 5 clinical practice guidelines	N/A
34 (FT)/17	2	20	N/A
		N/A	N/A

Note: *CHPETA stands for Center for Health Policy Evaluation and Technology Assessment; NECA for National Evidence-based Healthcare Collaborating Agency; MaHTAS for Malaysian Health Technology Assessment Section; NIHTA for National Institute of Health Technology Assessment; HITAP for Health Intervention and Technology Assessment Program; and HSPI for Health Strategy and Policy Institute;*

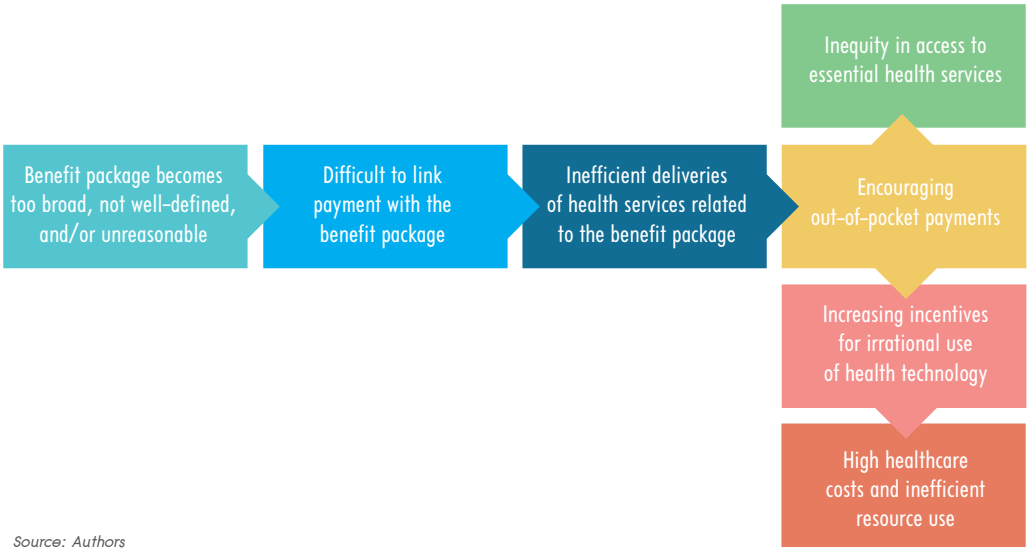
Source: Based on information from the setting authors

4. Policy impact of HTA

Taking into account the experiences from Chinese Taipei, the Republic of Korea, and Thailand as well as some selected cases in China and Malaysia, HTA is a useful tool for assisting in allocating resources, especially when the systems are ready to synergize with coverage decisions, health financing, and procurement of health technologies. In some sites such as the Republic of Korea and Thailand, HTA is also used as a means for improving efficiency through price negotiation with industry. Sites that have implemented HTA are not necessarily able to use it for cost containment because the budget requirement for the introduction of new technologies increases over time. The application of HTA in resource allocation, infrastructure, and human resource development has been addressed extensively in Europe and North America (11–13). However, rarely has the impact of not using HTA been addressed, particularly in LMICs. As such, this working paper provides an opportunity to dedicate a section on the impact of not using HTA in LMICs. Figure 2 illustrates the negative consequences found from not using evidence-based priority setting in health benefits package development in selected Asian settings.

FIGURE 2

Potential impact of not using HTA in health benefits package development



Source: Authors

It is likely that the long-term negative consequences of disregarding evidence-based health care priority setting (which can be in the form of HTA) in the benefits package development would result in inefficient and inequitable health care systems, which are opposite to the goals of UHC. Without comprehensive and reliable evidence in making coverage decisions, the benefits package can become too broad, not well-defined, and/or unreasonable[2]. For example, the benefits package defines

[2] *The decision cannot be defended appropriately, for example, due to inconsistent decision-making, to stakeholders.*

the coverage of breast cancer treatment without a detailed description of the treatment regimens, e.g. whether the drug trastuzumab is included or for which cancer staging or what indication[3]. Due to these problems, it is difficult to link payment with the benefits package, e.g. it is not possible to determine unit costs given that the benefits package is too broad or it is financially not feasible to fund the package. This can result in payment agencies deciding not to link provider payment directly, which is in contrast to what is defined in the benefits package. This situation is common in some settings and occasionally occurs in many other settings in situations where some parts of the benefits package, such as long-term care, do not have clearly defined interventions.

[3] *In Viet Nam, trastuzumab has been included in the benefits packages without clear indications on staging while, in Thailand, the drug is reimbursed for only the early stage. In Indonesia, there is no mention about drugs for breast cancer treatment.*

If the benefits package and payment are not linked, then providers do not have the cost-recovery or incentives of providing services and it is difficult to introduce efficient service procurement such as central purchasing or payer-provider contract. This can create inefficient deliveries of services and result in the introduction of OOPs. This is obvious in Indonesia and Viet Nam where providers will ask patients to pay for essential services.

When OOP is customary, this encourages irrational use of health technology; providers will aim for profit or act in their best interests. As a result, patients will pay for and receive more services than are necessary. Due to limited health resources and infrastructure, health expenditures will subsequently increase and inefficiencies in the health system will be exacerbated. Additionally, due to high health care costs and OOP, there will be inequity in access to essential health services, especially for the poor and vulnerable groups most in need of proper health care.

5. Characteristics of successful HTA agencies

Learning from the HTA agencies in the study settings, this chapter introduces different features of successful HTA agencies in the region that have applied HTA and informed decision-makers on policy developments. The seven features for a successful HTA agency are: independence; financial sustainability; management of conflicts of interest; full-time multidisciplinary staff; extensive networks; good systematic process; and high quality research with a quality assurance mechanism. Each of these characteristics is explained hereafter.

The first characteristic of a successful HTA agency is **independence.** Independence means that there should be no political pressure that can influence the process and outcome of HTA. This characteristic has been found in many successful HTA agencies that are entirely autonomous or semi-autonomous such as NECA, CDE/HTA, and HITAP.

The second feature is **financial sustainability.** Financial sustainability refers to the ability of an HTA agency to have a consistent financial flow. For instance, many HTA agencies in the Asia-Pacific settings tend to rely heavily on research grants. This means that there is no sustainable financial support, which could jeopardize the existence of a successful HTA agency when no grants are made available or obtained. In contrast, NECA, CDE/HTA and MaHTAS have annual budgets that are allocated by the government.

The third factor that contributes to a successful HTA agency is **good management of potential conflict of interest.** HTA agencies regularly face challenges in dealing with different interests in the health care sector. This can be exemplified by the relationship between HTA agencies and the pharmaceutical industry, health professionals, politicians, civil society, patient groups, etc. In order to maintain the impartiality of the HTA agency, good management of conflict of interest is needed. For instance, NECA, HITAP, and CDE/HTA collaborate with private companies and industry without receiving financial support from them in order to maintain neutrality.

The fourth characteristic that creates a strong HTA agency is having **full-time research staff** working on and developing their skills. HTA is a concept that applies to many domains including drugs, medical devices, clinical practice, health promotions, disease prevention and health policy. Having multidisciplinary teams is therefore an asset when performing HTA. The skills to be developed are not only technical but also include interpersonal skills for working with stakeholders and communications skills to transfer messages to non-technical partners. Based on experiences from NECA, CDE/HTA, and HITAP, HTA teams benefit from multidisciplinary staff and critical mass to ensure impact; for instance, NECA, CDE/HTA, MaHTAS and HITAP have 80, 22, 27 and 34 full-time academic staff, respectively.

The fifth characteristic is to have an **extensive network** with local and international partners. For example, HITAP works with medical consortiums, all levels of public and private hospitals, universities and royal colleges, civil society, etc. Additionally, HITAP established an international unit in 2013 which works extensively with international partners such as HTAsiaLink, international Decision Support Initiative (iDSI), World Health Organization (WHO), and NICE. Meanwhile, NECA and CDE/HTA actively participate in professional societies in Chinese Taipei and the Republic of Korea with strong academic competency in traditional economic analysis as well as international and regional networks such as HTAsiaLink, International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and Health Technology Assessment international (HTAi) in order to support methodological development and to share experiences.

The sixth characteristic of successful HTA agencies is to have **a systematic process** to identify policy-relevant topics for assessment. To illustrate this, NECA has established a center named Horizon Scanning Service of Innovative Global Health Technology (H-SIGHT). This center aims to identify new health technologies including pharmaceuticals, medical device and procedures, and health interventions. Once technologies are selected, their potential impact is analyzed based on scientific evidence and provided to various stakeholders such as policy makers, health care providers and industries. Another example is MaHTAS, which has recently initiated Horizon Scanning Activities.

The last characteristic is to produce **high quality research with a quality assurance mechanism.** For instance, HITAP's research projects have preliminary reviews by stakeholders as well as external reviews and are published in high quality academic journals. Similarly, research conducted by NECA and CDE/HTA are also being published by journals. This can be considered as a quality assurance mechanism for the research results that are produced by these HTA agencies.

FIGURE 3

Seven features of a successful HTA agency

6. Conducive factors for setting up HTA agencies

This chapter provides an overview of factors that influence the establishment of HTA agencies. First, **a high proportion of public investment and strategic purchasing mechanism in health care compared to private health expenditure** is a strong incentive for settings to try to ensure investment in cost-effective interventions with good clinical outcomes. Generally, settings with UHC are more likely to have HTA systems established compared to settings that rely heavily on private contributions or external support. Sites with comprehensive benefits packages such as Chinese Taipei, the Republic of Korea, and Thailand have well-established HTA systems. Malaysia has also established a relatively good HTA system, while China has the foundation and workings of an HTA system but is not yet fully developed. Viet Nam and Indonesia currently do not have well-established systems.

A high proportion of public investment and strategic purchasing mechanism in health care compared to private health expenditure

Political will, leadership, and legislation

Second, **political will, leadership, and legislation** pushes HTA development forward. As described in the summary table, sites such as Chinese Taipei, Indonesia, and the Republic of Korea have legislated HTA in policy making. In these areas, HTA is therefore legitimized in the decision-making process and backed by high level policy, which means it will be linked directly with public health resource allocation. This in turn generates demand and the need for more and better quality HTA.

Third, **a good health information infrastructure** encourages HTA use. HTA is a highly analytical and multidisciplinary process which requires a wide breadth of information. Sites with insufficient information infrastructure will have a high cost of conducting HTA which may even make it unaffordable for the government. Information infrastructure allows for the conduction of economic analyses that require large and complete data sets. One example is NECA's budget impact analysis for changing the reimbursement criteria for osteoporosis drug therapy conducted in the Republic of Korea. NECA conducted a clinical study that followed up patient T-scores for six months. Another case study was conducted through CDE in Chinese Taipei for the application of the da Vinci Surgical System for 21 surgeries including radical prostatectomy, radical proctectomy, lobectomy, valvular and/or annuloplasty, etc.; the surgical system was assessed regarding its clinical effectiveness, cost-effectiveness, and budget impact.

A good health information infrastructure

Fourth, **local training on HTA-related disciplines** strengthens and builds on existing or new capacity. Chinese Taipei, the Republic of Korea, Malaysia, and Thailand all had postgraduate training on pharmacoeconomics, health economics, and other related HTA disciplines before establishing formal HTA agencies. In Thailand, for example, there are Social and Administrative Pharmacy (SAP) units in Schools/Faculties of Pharmacy in universities; Malaysia has the Discipline of Social and Administrative Pharmacy (DSAP) in the Universiti Sains Malaysia (USM) that corresponds in function with SAP. Chinese Taipei, the Republic of Korea, Malaysia, and Thailand send strong candidates to be HTA researchers for local and international trainings.

Local training on HTA-related disciplines

Effective collaboration between HTA agencies/programs and stakeholders

Fifth, **effective collaboration between HTA agencies/programs and stakeholders** builds up the link between research and policy. NECA, HITAP, and CDE, for instance, have good working relationships with not only political stakeholders but also with health professional associations, civil society, and industry. These stakeholders are engaged in the HTA process beginning from selection of topics for assessment to fine-tuning the final report and recommendations. These relationships lead to well-accepted HTA results and greater legitimacy for policy use.

Sixth, **settings' independence from external support or international aid** forces them to budget their scarce resources more effectively. For example, Thailand is not eligible for international aid and is therefore not reliant on support. In this case, there is less of a tendency to make allowances on inefficient or unwise decisions so policy making is more focused. Thailand is now concerned that it will be ineligible for funding from external sources such as the Global Fund, resulting in the need to set priorities on programs that will no longer be supported by the Global Fund.

Settings' independence from external support or international aid

7. Barriers of using HTA policy decisions

One of the main goals of HTA is to support decision-makers in their policy development. However, many issues exist that prevent HTA from being used. This chapter discusses the most common barriers that have been raised by HTA agencies in the Asia-Pacific region. The most prevailing barriers are silo-based decision-making process, low quality decision-making criteria, tight control of research dissemination, and respect for expert/senior opinions. These barriers are discussed below.

A silo-based decision-making process refers to a process wherein decisions are made without transparency and participation of other relevant stakeholders. The nature of the process prevents HTA use in policies. For instance, some Asian settings have shown that the chair of the decision-making body often influences other committee members more than HTA reports in making policy decisions while other settings have shown that HTA results are not being used due to silo-based processes both within and between government departments. Another possible factor for not incorporating HTA results into the decision-making process is the lack of understanding regarding the importance of research evidence.

A silo-based decision-making process

Another barrier that prevents HTA from being used in policy decisions is that **policy makers have poor decision-making criteria when allocating resources.** For instance, policy considerations focus mainly on unit costs of introducing health technologies or safety and short-term outcomes separately. In this case, the policy considerations do not focus on long-term outcomes, distributive effects (equity), or creating explicit links between cost and outcome.

Policy makers have poor decision-making criteria when allocating resources

At the same time, some settings may have **strict control on research dissemination.** Research outcomes that are unfavorable to decision-makers tend to not be used in policy making. In other words, HTA studies that have contradictory findings to policy cannot be easily disseminated to stakeholders. This is a complete reversal from the concept of evidence-based policy and is called policy-based evidence; this presents a major barrier for preventing effective policy that benefits society.

Strict control on research dissemination

The fact that **respect for expert (senior) opinions or authorities is held in higher than evidence-based research** forms the last common barrier for using HTA in policy decisions. Typically, in Asian culture, the respect for seniors or authority figures is often of paramount importance. In this case, other types of justification will be lower on the evidence hierarchy, whereas in more modern evidence hierarchy is the reverse. Moreover, the nature of HTA topic selection is that researchers are more likely to select issues that are not in line with expert opinions and existing evidence. Despite this process, expert opinions can still go unchallenged and eventually may become a larger problem. Therefore, using strong HTA results in policy making may likely be challenging.

Respect for expert (senior) opinions or authorities is held in higher than evidence-based research

8. Recommendations for HTA institutionalization

The following recommendations target readers who are working in sites that are at the early stages of developing HTA capacity. Although this study focuses on the use of HTA to inform coverage decisions under UHC, these recommendations comprise the basic components of HTA systems, which can also be applied to the use of HTA in general resource allocation. The five recommendations are as follows:

1. Human resource development

It is very important that HTA capacity is built in HTA research organizations as well as decision-making bodies and other relevant stakeholders that are using HTA. In Chinese Taipei, the Republic of Korea, Malaysia, and Thailand, strong academic programs exist to provide capacity building activities prior to the establishment of HTA agencies. The programs offer a wide range of training, including short-course HTA workshops and Master's and doctoral programs. Overseas training is unlikely to substitute local capacity building programs. Therefore, the availability of HTA training programs at local academic institutions is one of the most significant factors that should be considered as part of HTA institutionalization.

2. Core team or HTA institutes

The HTA process involves multiple stakeholders, which makes it essential to have an HTA focal point or agency to coordinate the HTA activities and cooperate with partners. This focal point organization must not only be committed to HTA work but should also be responsible for gaining the trust of all stakeholders. As such, the focal point organization should be independent from the government, refuse financial support from private sources, and have a clear or explicit code of conduct to deal with conflicts of interest.

Most importantly, the focal point should have full-time academic staff because conducting HTA is very technical and time-consuming. Although the number of full-time staff relies on the scope and responsibility of the core team or HTA institute, the focal point needs to have critical mass and the ability to retain staff in order to make a significant impact.

3. Linking HTA to policy decision-making mechanisms

As HTA is a type of policy research, it is inevitably linked to policy-making decisions. The appropriate mechanism for linking HTA to decision-making will vary based on the context and design of the health system. Nonetheless, a key point taken from this study is that the link between HTA for coverage decisions and UHC includes the pharmaceutical reimbursement list/essential drug list/formulary list, immunization programs, high-cost medical device packages, and public health programs. The assessments of drugs and vaccines are quite straightforward and commonly available in literature while the assessment of medical devices is more complex in terms of the lack of data on quality and generalizability of safety, long-term efficacy and effectiveness. For instance, effectiveness of medical devices depends on the skills and expertises of health professionals who use the devices. Also, different settings may allow different types of health professionals to utilize the medical devices and sometimes the application of medical devices is linked to different medical procedures. Public health interventions are the most challenging because they require a mature HTA agency to incorporate them into HTA programs as these assessments are resource-consuming, require a multidisciplinary approach, and need advanced assessment approaches for complex interventions.

4. HTA legislation

HTA legislation is not a prerequisite for a well-functioning HTA system — with Thailand being an example — and at the same time, HTA legislation does not necessarily guarantee the successful use of HTA. Nevertheless, the existence of legislation may help sustain the long-term and successful use of HTA. HTA legislation should ensure the presence of key components such as participation, transparency, and systematic application in the HTA process rather than focus on technical issues.

5. International collaboration

Each HTA agency in this study received international support in terms of South-South or North-South partnerships and formal overseas training for staff. International technical support is very useful, especially in the formative stages. To date, resources are widely available at the international level through international agencies including World Health Organization's Choosing Interventions that are Cost-Effective (WHO-CHOICE) and the World Bank flagship program as well as academic networks including the Disease Control Priorities Network. However, these resources offer policy advice rather than build capacity of local researchers and are rarely adaptable to address local-specific policy questions. As a result, a gap in international support remains with in-country technical support, which involves hands-on supervision and working closely on local studies.

Once moderate progress has been made, international support to enhance policy awareness of the usefulness of HTA becomes more important. The experience of using HTA in policy decisions in one setting can be influential in the context of another setting,

especially in places that have similar economic and health infrastructure. Therefore, regional networking, such as HTAsiaLink and HTA Network of the Americas (RedETSA), is equally important compared to international or global networking, which is widely available in many forms such as the HTAi, ISPOR, International Network of Agencies for Health Technology Assessment (INAHTA), and Society for Medical Decision Making (SMDM).

As experience from lower-middle income countries indicates, it is important to note that low-income and lower-middle income countries have health budgets that sometimes rely heavily on international aid. As such, one of the recommendations to global donors, such as the Global Alliance for Vaccines and Immunization (GAVI) or the Global Fund, is to provide support for the country to set its own priorities instead of pushing the donor's own agenda, which may not be in line with the country's goals and lead to unsustainability of the country's health development. Eventually, HTA capacity building should be part of GAVI and Global Fund's packages for graduating countries.

9. Step-by-step practical guide and achievement indicators

The step-by-step practical guide will provide information on the HTA systems development, which can be divided into two phases. The early phase of HTA development is defined as the period when HTAs are not conducted locally, are conducted without links to policy making, or are used on an ad hoc basis. The moderately developed phase is defined as the period when HTA is used on a routine basis by decision-makers; however, HTA systems are dynamic and continually develop over time. The following practices are recommended for each phase of HTA development. During these phases, considerations need to be made for four components, namely manpower, money, materials, and management, in order to establish a functioning HTA system.

Early phase

In the early phase, it may not be possible to identify a national HTA agency or have a clearly established HTA focal point so HTA can be initiated in university academic units, Ministry of Health units, or even in hospital units. The important factor is commitment by those responsible for HTA to acquire and further develop knowledge and skills. They can start HTA work on a part-time basis but should move toward working on a full-time basis. Additionally, the group can begin small with the aim of expanding capacity to a multidisciplinary team in order to obtain critical mass. Based on the study settings, it was found that pharmacists are a good group of health professionals to be groomed for HTA work.

Financial resources should be made available for HTA research and capacity building. It is very difficult to estimate the budget needed because it depends on many variables such as the number of people, the context of the setting, etc. Based on experiences in the study settings, the budget allocated for the early phase is much smaller than the budget available for health systems research and policy in LMICs. The budget is generally supplemented by international donors that currently support low- and lower-middle income settings.

Unlike basic and clinical research, HTA does not necessarily require specific materials such as quality of life measures based on local values because data from other settings with similar contexts can be applied to the analysis. For example, HTA work in Indonesia and Viet Nam borrow utility data from Thailand.

From a management perspective, sites in early stages should develop informal or formal mechanisms to ensure management of potential conflicts of interest among researchers. It is also necessary to involve all relevant stakeholders in the process in order to have a participatory HTA process. To ensure the quality of studies, methodological HTA guidelines should also be developed.

Moderately developed phase

During this phase, there is a clear demand for HTA by decision-makers and interest in HTA by academics. Postgraduate training is useful for satisfying the increasing demand for HTA staff. With a shortage of postgraduates, it is likely that the limited number of HTA researchers will increase competition for HTA staff in different fields. This will result in high turnover rates of HTA staff which make the system inefficient and counterproductive. It is also very important to have local short course training for decision-makers, health care professionals, and other relevant stakeholders who wish to learn about and understand HTA.

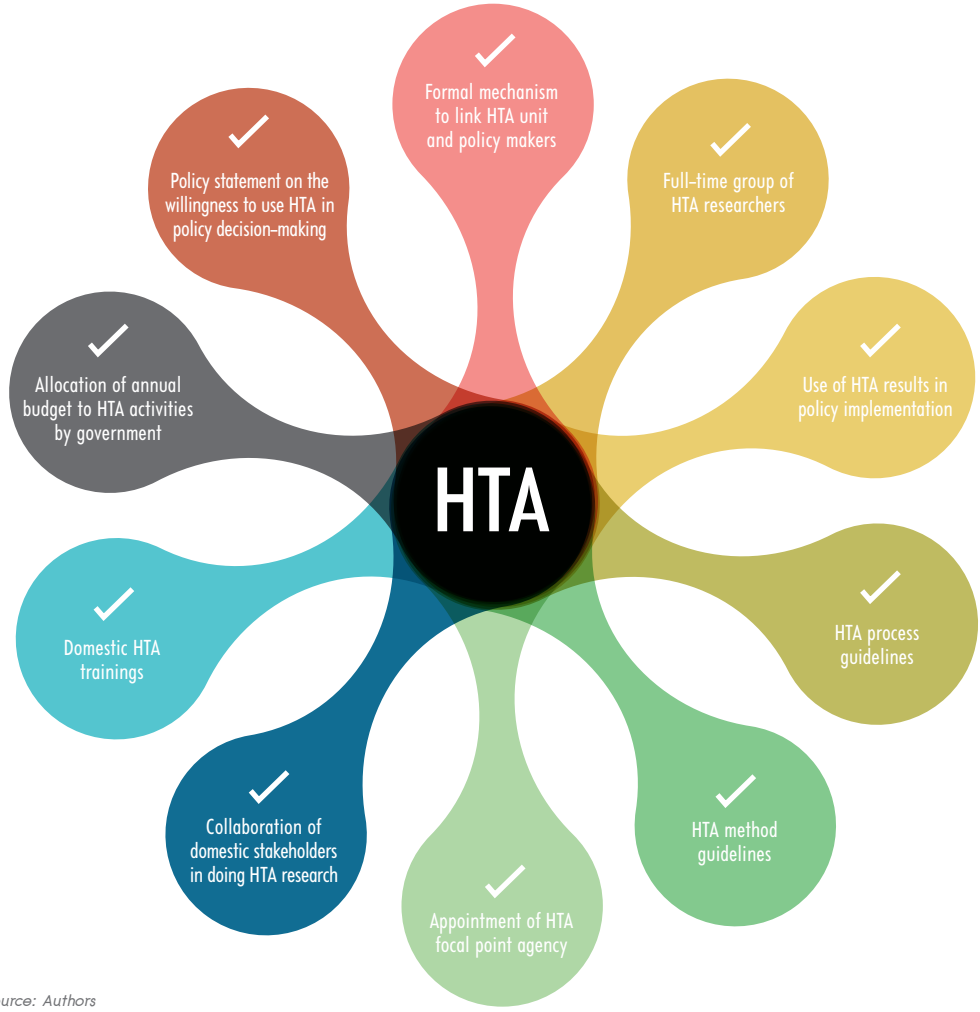
The government should make financial resources available in order to support HTA research so that HTA researchers do not have to rely on industry support. This budget should be more flexible and sustainable than other budget items because HTA research may extend beyond a fiscal year. Experiences from HTA systems in Europe and North America show that the total budget for HTA in a setting that uses HTA on a routine basis is still less than 0.1% of the total health budget (14).

In moderately developed HTA settings, the HTA focal point provides and sets methodological and process guidelines for standardizing HTA research. Materials for measuring health-related quality of life based on local values should be available for use. In some settings, there are HTA databases that compile all available HTA-related studies to support national and local decision-makers. In Thailand, a costing menu (a list of direct medical, direct non-medical, and indirect costs that represent the costs for different types of health facilities and households) has been developed for efficiency purposes so that researchers do not need to collect the same kind of cost data and to ensure comparability across studies.

There is usually more than one HTA agency that produces policy relevant HTA reports so it is necessary to have an HTA focal point to set standards for the HTA methods and processes, and to coordinate among HTA agencies and between HTA agencies and decision-making bodies. For example, in Chinese Taipei, the Republic of Korea, and Thailand, HTA units exist in public and private sectors as well as universities. Although it would be advantageous for HTA systems to have legislation in support of HTA, it was not deemed necessary. At this stage, it is essential to make HTA results accessible to all relevant stakeholders so that they can understand the HTA impact on policy.

In order to monitor the progress of following the step-by-step practical guide, the list on the right page succinctly summarizes the 10 most important achievement indicators for settings in which HTA is nascent. The achievement indicators act as a checklist for settings to determine the level of maturity of HTA development and inform people who are responsible for HTA development about potential improvements. However, the indicators do not determine the phase of HTA development, but rather indicate the progress made. The achievement indicators were selected from a list of 20 items through a rating scale (see Annex 1 for a full list).

Checklist of achievement indicators for progression of HTA development



Source: Authors

ANNEX 1

MILESTONES

Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT

OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

ANNEX 1 MILESTONES

TABLE 4

Ranked milestones indicating achievements of national HTA systems

Items Rating (1 = least important, 4 = most important)	China	Chinese Taipei
Formal mechanism to link HTA unit and policy makers (1)	4	4
Full-time group of HTA researchers (2)	4	4
Use of HTA results in policy implementation (3)	4	4
HTA process guidelines (4)	4	4
HTA method guidelines (5)	4	2
Appointment of HTA focal point agency (6)	4	3
Collaboration of domestic stakeholders in doing HTA research (7)	4	2
Domestic HTA trainings (8)	3	4
Allocation of annual budget to HTA activities by government (9)	4	4
Policy statement on the willingness to use HTA in policy decision-making (10)	4	3
National HTA database of HTA reports	4	2
HTA legislation	4	3
Membership of domestic HTA agency in international networks	4	3
Postgraduate training on HTA related disciplines	3	4
Data registry for clinical and economics data for use in HTA	3	2
International journal publications on HTA made by local researchers	2	2
National HTA conference	2	3
HTA as part of undergraduate curricula for health fields	2	3
Full-time dedicated clinical experts*		
HTA method manuals in local language**		

Table 4 shows milestones indicating achievements of national HTA systems. These milestones were rated by seven authors from different settings on a 4-point scale. The top ten milestones were selected based on the ten highest average scores and represent the achievement indicators. Two additional items were suggested by the Republic of Korea but these were not included in the final milestones selection.

Indonesia	Republic of Korea	Malaysia	Viet Nam	Thailand	Total score	Average score
4	4	4	4	4	**28**	**4**
4	4	2.7	4	4	**26.7**	**3.8**
4	3	3.3	4	4	**26.3**	**3.8**
4	3	4	3	4	**26**	**3.7**
4	3	4	4	4	**25**	**3.6**
4	2	4	4	4	**25**	**3.6**
4	3	4	4	4	**25**	**3.6**
4	1	3.3	4	4	**23.3**	**3.3**
4	2	3	3	3	**23**	**3.3**
4	2	3.3	4	2	**22.3**	**3.2**
3	2	3.7	4	2	**20.7**	**3.0**
2	4	2.3	4	1	**20.3**	**2.9**
2	3	2.3	3	3	**20.3**	**2.9**
2	2	3	2	3.5	**19.5**	**2.8**
3	2	3.3	3	2	**18.3**	**2.6**
3	2	2	3	3.5	**17.5**	**2.5**
2	1	3	3	2.5	**16.5**	**2.4**
1	2	2.7	2	3	**15.7**	**2.2**
	4				**4**	**4**
	2				**2**	**2**

Note: **The item "Full-time dedicated clinical experts" was not included because of its overlap with "Full-time group of HTA researchers".*
***The item "HTA method manuals in local language" was not included because the standard languages for HTA method manuals are always local languages.*

Source: Authors

ANNEX 2

GUIDE FOR DEVELOPING THE SITE WORKING PAPER

Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT

OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

ANNEX 2
GUIDE FOR DEVELOPING THE SITE WORKING PAPER

Introduction

Since Universal Health Coverage (UHC) is high on the global health agenda, governments of many low- and middle-income countries (LMICs) have pledged to increase health investments in order to offer universal access of essential health services. Health technology assessment (HTA) has been recognized as a necessary tool for setting priorities (1) but only a few LMICs have accomplished the establishment of HTA systems so far. Asia-Pacific is a region where HTA institutions and networks have been operating successfully in Organisation for Economic Co-operation and Development (OECD) countries and a few of the middle-income settings (15). However, many of the LMICs in the region have HTA systems that are still in very early development (2).

Decision-makers and scholars in low-income countries (LICs) in other parts of the world are increasingly interested to learn about and build upon the successful HTA systems of the Asia-Pacific region. In particular, there is a need for increased understanding of policies — on both macro- and meso-level — that are conducive to the development and sustainability of HTA systems (16). Therefore, a collaboration between the Asia-Pacific Observatory (APO), World Health Organization (WHO), and the Prince Mahidol Award Foundation was established in order to address this need. To draw lessons learned from the experiences of HTA agencies in Asia and to synthesize the information on factors conducive for success, indicators for a qualitative study were developed to be used as a guide for other settings to assess the development of HTA in their settings.

The development of the indicators for the qualitative study aims to guide the chapter authors to develop site papers that will be presented in the face-to-face authors' meeting on November 24, 2014. In this meeting, authors will discuss with other experts to draw lessons learned from cross-setting studies for the APO policy brief.

Objectives

1. To provide the chapter authors with a table of indicators to consider and use when documenting each respective site paper.
2. To provide a framework for data analysis in order to develop the APO policy brief.

Methods

Literature reviews were performed on established databases such as PubMed and Embase, and by manual searching from relevant websites such as of HTA agencies or HTA associations/networks including HTAsiaLink, International Society for Pharmacoeconomics and Outcomes Research (ISPOR), Health Technology Assessment international (HTAi), and International Network of Agencies for Health Technology Assessment (INAHTA). The review focused on essential components based on the five dimensions outlined in the proposal which were related to the establishment of HTA agencies and the use of HTA in health resource allocation in resource-limited settings.

Results

Five dimensions were identified as important for the development and sustainability of HTA (Table 5). These indicators serve as an outline for the authors of each setting to determine these factors in their settings, which will be used in the development of the site working papers. Some of the indicators may become generalizable; however, other indicators are dynamic and may occur after the development of HTA.

TABLE 5

Indicators for identifying supportive factors in developing and sustaining HTA

Content	Indicators	Rationale
Need for HTA in setting health priorities	• Rapid increase in health expenditure • Burden of disease and health problems: Non-communicable diseases (NCDs), aging population • Irrational use of health technology • Economic recession • Public sector dominated health care delivery • Establishment of government-financed insurance scheme • Development of benefits package and national formularies • Strong marketing campaigns of industry • Demands for high-cost technology	Although HTA is essential for decision-making in all circumstances, several factors encourage the need for the introduction of this policy-oriented research. In particular, HTA is required when health care provision and finance are mainly the responsibility of the government. This may involve the establishment of national tax-based insurance scheme, especially UHC. Other situations associated with the perceived benefits of HTA include rapidly growing health expenditure, notable decrease in the setting's fiscal capabilities, and economic downturn. In some settings, policy makers foresee substantial escalation in health spending in the future as a consequence of burden of NCDs and health problems among the elderly. Inefficient use of health resources including irrational use of health technology and its underpinning factors such as rigorous marketing approaches of health technology industry and demands for costly technology among health professionals, patient groups, non-governmental organizations (NGOs) and the public are driving forces on governments to adopt HTA and make evidence-informed decisions.

Content	Indicators	Rationale
Health systems context in study settings	• Political commitment for UHC and HTA • National health, trade and industry policy • Health system reforms • Influence from development partners and international organizations • Social norms and values for access to health services/technologies • Technical cooperation programs, regional and international	Contextual factors of the health systems may have considerable effects on HTA introduction in a particular setting. Political and policy context including strong commitment towards UHC and evidence-based health policy; conflicts between the goals and strategy of policies in the health, trade, and industry sector; influences from donors and international governmental organizations; and reforms in the health systems usually have a crucial role in national policy development including the use of scientific evidence. Social norms and values concerning human rights, access to health care and rationing of resources are crucial in (democratic, open) societies. In such settings, policy makers recognize norms and values possessed by their constituencies and may require HTA as a tool to address the social and ethical consequences of health technology-related policies. In settings where health policy research and HTA capacity are lacking, technical support through international collaboration is important in making HTA evidence generation feasible.

TABLE 5 (CONTINUED)

Indicators for identifying supportive factors in developing and sustaining HTA

Content	Indicators	Rationale
Historical development of HTA	Change in the following elements over time: • Health Policy and Systems Research (HPSR) • HTA advocacy • HTA champions • Pilot HTA program and scaling up efforts • Resource mobilization for HTA • Capacity building programs • Development of HTA infrastructure • HTA-informed policy decisions • Key contextual elements	In many settings, HTA introduction takes a long time. Regardless of successes and failures, useful lessons can be learned through the narrative assessment of key actors, their efforts, features of HTA development processes, available resources, and contexts, all of which are likely to change over time. Learning from the historical development of HTA agencies and systems in each setting will result in a better understanding of different characteristics of HTA in the present day (mentioned below) and may be useful for considering future sustainability.
Current practice (responsible organization, guidelines, evidence generation, use of HTA in policy making, local networks)	• Governance for health resource allocation: authority, policy strategy, coordination across organizations and sectors • Responsible organization, focal point • HTA institutes • Resources: researchers, research grants, equipments, management system • Guidelines (national, methods and process) • HTA projects and reports • Local and international collaborations	Characteristics of present HTA systems, with or without HTA institutions, and current experiences in each health system are valuable information to inspire and guide HTA development in other settings. Learning about the availability and the way in which HTA guidelines and tools are developed and used can help inform the potential success and sustainability of HTA systems.

Content	Indicators	Rationale
Policy impact	• Monitoring & evaluation: HTA institute, research, impact, and feedback mechanism • Acceptance of HTA process and evidence among policy makers • Discussion on HTA findings in decision-making processes • Policy justification provided, either for or against HTA-based recommendations • Supportive factors and impediments	HTA is a part of health systems and policy research and it can be meaningful only if it makes policy impact. Policy impact of ad hoc HTA studies can be a conducive factor to the establishment of HTA organizations or systems. Moreover, policy impact of HTA is also a crucial element for the sustainability of HTA. Availability of monitoring and evaluation of HTA contributions in policy is the first step to recognizing policy impact. HTA is in fact used as a guide for decision-making but the HTA itself does not make the decision. Acceptance of HTA processes and the consideration of evidence in policy decision-making are necessary to ensure policy impact. Lastly, it is necessary to understand supportive factors and impediments of making policy impact of HTA.

Source: (1, 2, 15 - 23)

Discussion

This is an early development of indicators that will be used to guide the development of site papers and analysis of the APO policy brief on conducive factors to HTA development in Asia. However, other dimensions or indicators may emerge during the development of the site chapters or discussions during the face-to-face meeting. To our best knowledge, this is the first effort that aims to synthesize conducive factors for HTA development in LMICs and this work can be very helpful for decision-makers and other stakeholders in LMICs.

These indicators are not independent from each other and many of them are interrelated. In addition, some factors may have a synergic effect, for example, while the high burden of NCDs and the commitment to establish UHC both encourage HTA adoption, the presence of both factors in a setting will result in increased impact on the demand for HTA.

The indicators shown in Table 5 can be categorized into three groups:

Almost impossible to change in the short- and intermediate-term

Changeable within a short period of time

Changeable but with significant effort

The indicators shown in Table 5 can be categorized into three groups:

1. Almost impossible to change in the short- and intermediate-term, such as the level of health care spending and its financial sources.
2. Changeable within a short period of time, such as availability of HTA champions and/or guidelines.
3. Changeable but with significant effort, such as health systems and policy research capacity.

It will be very interesting to see whether this framework can be useful at the global, national, or sub-national levels given that particular key components are almost impossible to change, such as the level of health care spending and the financial resources within a setting. Although these indicators may not change at the national level or the sub-national level (such as in the case of countries that have low levels of overall health care spending and suddenly obtain significant financial support for particular areas, e.g. the Global Fund for AIDS, TB, and malaria or GAVI for vaccination programs), it may reveal supportive factors or indicators that are conducive to HTA development. Therefore, these indicators should not be used for simple interpretation.

ANNEX 3

WORKING PAPERS

Policy Brief and Working Paper

CONDUCIVE FACTORS TO THE DEVELOPMENT

OF HEALTH TECHNOLOGY ASSESSMENT IN ASIA

ANNEX 3
WORKING PAPERS

Health systems context in China

China is a unique country with a population of 1.4 billion and strong economic development which has attracted interest from transnational industries. Therefore, it is expected that China will become one of the largest health product manufacturers. One of the main features of the health care system in China is its decentralized system with strong provincial level administration. This shift from a centralized to a decentralized system has been caused by various political, economic, and social reforms made in response to the changing demographics and needs of the country. Decentralization and privatization has led to health service providers increasing their prices for more profit gain, resulting in unaffordability of health care. Within China's health system, both traditional and modern medicines play an important role.

Need for HTA in setting health priorities

China is faced with major challenges in implementing successful universal coverage health insurance. One of the challenges is the aging population due to increased

HTA is needed so that the most cost-effective health technologies are prioritized.

life expectancy. Over the past few decades, the life expectancy at birth in China increased from 35 years in 1949 to 75 years in 2010 (24). This improvement has contributed to population aging; in 2010, about 9% of China's total population was over the age of 65 (25). In addition to the aging population, a more sedentary lifestyle due to rapid socio-economic development in the past few decades has dramatically increased people's risk of chronic diseases. Both the increase in aging and NCD patients will burden the national health budget. High marketization and openness also contributes to a fast adaptation of expensive medications and health technologies from overseas, resulting in high medication costs. A study showed that from 1990 to 2009, the total pharmaceutical expenditure (TPE) to GDP ratio increased by 6.9% and the total health expenditure to GDP ratio increased by 28.8%; TPE accounted for almost half of the total health expenditure spending (26). To avoid unreasonable increases in total health expenditure as economic development slows down in the future, health technology assessment is needed so that the most cost-effective health technologies are prioritized.

To cope with the growing out-of-pocket payments (OOPs) and health needs, China's Social Insurance Law was formally enacted in July 2011 and formed three basic medical insurance schemes: the urban employee basic medical insurance (UEBMI), the urban resident basic medical insurance (URBMI), and a reformed version of the rural cooperative medical system (RCMS) (27). Since the early 2000s, the coverage of the medical insurance systems continued to expand. Individual OOP payments fell from almost 60% in 2002 to 34.9% in 2011. However, the ultimate goal of sustainable Universal Health Care (UHC) has not yet been achieved, and thus there is a need for efficient use of health care resources. Without doing so, excess health spending will eventually cause enormous financial burdens to the general public, health care providers, and the government.

Current practice

China has five HTA institutes, four of which are at universities and one falls under the former Ministry of Health (now called the National Health and Family Planning Commission, or NHFPC). The four HTA institutes that are located at universities formed the original framework in developing HTA in China.

In 1991, the NHFPC established a research institute to conduct policy research and recommendations and in 2008, the China National Health Development Research Center (CNHDRC) established the Center for Health Policy Evaluation and Technology Assessment (CHPETA). Its main functions are to conduct health policy evaluation research and provide relevant scientific evidence for policy makers; to carry out HTA and provide guidance for appropriate health technology decisions; to evaluate public health programs and provide valid evidence of project implementation results for stakeholders; and to carry out technical evaluation, training, and advice for health policy makers.

Initially, the CHPETA supported projects of the CNHDRC in health economics evaluation. In 2009, after the discovery of the first H1N1 case in China, the CNHDRC was commissioned by the Ministry of Health (MOH) to evaluate the actual cost of H1N1 case treatment, prevention, and control measures. The CHPETA was responsible for the cost-effectiveness analysis and provided accurate and timely results to support influenza prevention and control decisions. This led to a widespread recognition of the value of HTA, and CHPETA began to expand its function to many other areas. CNHDRC is the only institute that has a close link with decision-making process and obtains topics from government organizations.

Policy impact

The CHPETA has conducted several HTAs that have impacted health policies. For instance, the report on the da Vinci surgical system suggested insufficient evidence to support the use of the system in China due to potential overuse, inequality, ethical and financial problems. Results were adapted by the MOH, preventing

a massive purchase of machines in hospitals. Through HTA, the adoption of inefficient and expensive high-tech was avoided preventing an unnecessary burden on the country's health care system. Similar impacts have been shown in other cases of HTA.

On a larger scale, the CNHDRC was commissioned by the Policy and Regulation Department of NHFPC to carry out the Chinese Health Policy Prioritization Project in support of UNICEF. The project, focusing on the main issues of China's current health reform, uses a tool developed by the Child Health and Nutrition Research Initiative (CHNRI) to determine ten key issues and priority areas of health policy. This project emphasizes evidence-based decision-making and provides valuable information to policy makers and stakeholders so that they can utilize their time and resources on policies that are most pressing and promises the most impact for the cost.

The CHPETA, under the CNHDRC, has been supporting policy makers and stakeholders in many other projects involving health economic evaluation and analysis. The center has made further impacts through other projects including the "Establishing and improving the National Health Care System Rehabilitation Pilot Assessment Project," the "National Standardized Treatment of Acute Myocardial Infarction Project," and "China's Western Region Maternal and Child Health Priority Identification Project," among others. Ultimately, these projects allow policy makers and stakeholders to make informed decisions and provide guidance for further directions. However, there are concerns about whether a central level HTA is appropriate in China or whether each provincial government should have its own HTA unit.

Health systems context in Chinese Taipei

Chinese Taipei is one of the few Asian sites with strong and sustainable economic development, high budget reserves, high human development index (35), and successful universal health coverage (UHC). The Chinese Taipei National Health Insurance (NHI), which covers both general western medicine and traditional Chinese medicine, was launched in1995 and covers approximately 99.9% of the population, including prison inmates. Chinese Taipei's NHI system has now become a role model of a single-payer social insurance and has earned praise in the international society, thus realizing the ideals of UHC.

Need for HTA in setting health priorities

The need for HTA in Chinese Taipei is being driven by a rapid increase in health expenditure. Other factors that contribute to the growing health expenditure are the increase in non-communicable diseases (NCDs) and an aging population (36). Also, the strong marketing campaigns of industry and the demand for high-cost technology impact financial health resources. As health care delivery is dominated by the public sector, the National Health Insurance Administration (NHIA) considers the need to choose interventions judiciously and effectively manages technologies that are to be adopted within Chinese Taipei's NHI for the purpose of a sustainable universal coverage and to ensure provision of affordable services to the population.

Chinese Taipei is now establishing an independent nationwide HTA agency.

CHINESE TAIPEI

With the introduction of a global budgeting system — which sets annual spending caps on broad health care sectors — the NHIA must ensure that health care quality in Chinese Taipei will not be compromised due to resource constraints. The NHIA has not only consistently worked together with the medical institutions to provide quality care that often goes beyond the call of duty to better satisfy the needs of the insured but has also been devoted to developing health technology assessment (HTA) systems to evaluate properties, effects and/or impacts of health technologies, and interventions for supporting reimbursement decisions of the NHIA, in pursuit of its commitment to improvement.

Current practice

The Center for Drug Evaluation (CDE), which is responsible for technical reviews on drugs, medical devices and other related services, previously worked on HTA as an informal HTA working group. Initially, this HTA working group only consisted of six members and started to produce HTA brief reports since 2007. The HTA reports were employed as references to support the Drug Benefit Committee (DBC) on decisions of drug reimbursement and were gradually accepted by decision-makers and stakeholders. At the end of 2007, the CDE Board of Directors and Ministry of Health and Welfare (MOHW) passed the proposal of establishing the "Division of Health Technology Assessment" and the division was officially formed on 1 April, 2008. From then on until 2012, the DBC decided the listing of new drugs in the NHI based on both the manufacturers' dossiers and the HTA reports written by the CDE/HTA Division.

With the launch of the 2nd generation NHI Act in 2013, the MOHW planned to establish an independent nationwide HTA agency, termed the National Institute of Health Technology Assessment (NIHTA), and is now under preparation towards becoming a medical non-profit corporation independent from governmental agencies and manufacturers. This HTA institute will focus on drugs, medical devices, and public health programs.

Policy impact

During 2007 – 2013, the CDE/HTA assisted the NHIA in carrying out HTA assessments for 204 new drugs and 38 breakthrough drugs, eight medical devices, as well as providing 108 consultations to manufacturers. To prevent delays in the reimbursement process, the CDE/HTA utilized a fast-track channel to generate an HTA report for new drugs within 42 calendar days. The number of annual completed cases was increased from the initial 59 to the current 68. The aspects of assessment consisted of comparative effectiveness, cost-effectiveness, budget impact, and Ethical, Legal and Social Implications (ELSI) issues.

The CDE is also working with and for other public health agencies including the CDC, Health Promotion Administration, and the Chinese Taipei Blood Services Foundation in conducting HTA for vaccines and other public health policies. This reflects the real success of the CDE in implementing HTA as a useful tool for policy development. Furthermore, the CDE has become an international actor, sharing its HTA experience in other LMICs through ISPOR, HTAi, INAHTA and HTAsiaLink.

Health systems context in Indonesia

Since 2001, Indonesia is one of the few countries in Southeast Asia that has seriously introduced extensive government decentralization, resulting in a shift in responsibilities of health care services to the local authorities. Given that Indonesia has over 17,000 islands, this type of policy may be appropriate; however, implementation and coordination remain very challenging. Having faced a decade of transitional government decentralization, health infrastructure and human resources for health vary largely across the geographical areas.

A Presidential decree stating that HTA is considered important to achieving quality health care efficiently.

INDONESIA

In 2014, the government of Indonesia introduced Universal Health Coverage (UHC) to ensure equity in access to health care and provide financial protection. The UHC scheme aims to gradually increase coverage and reach universal access by 2019 with resources committed from tax revenues. With a UHC policy, politicians recognized the need for HTA as a tool for health prioritization and issued a Presidential decree (Presidential Regulation number 111/2013) stating that Health Technology Assessment is considered important to achieving quality health care efficiently as an implementation of the national health insurance system. In addition, to strengthen HTA in the Ministry of Health, the Ministerial decree 71/2013 regarding health services in NHI stated the needs of HTA in order to develop the use of technology in the provision of health care to improve quality and efficiency as well as additional benefits of health insurance. HTA shall be based on the proposal of the association of health facilities, health professional organizations, and Badan Penyelenggara Jaminan Sosial Kesehatan (BPJS) Health.

Need for HTA in setting health priorities

Indonesia is facing challenges in terms of meeting the need of health care services for non-communicable diseases (NCDs); however, NCDs are still low priority for the government. The results from the WHO report in 2011 on NCD country profiles show the rapid increase of morbidity and mortality from cardiovascular disease, diabetes, chronic lung disease, and cancer —accounting for 64% of overall mortality in 2010 (28). This is a major challenge for the newly established UHC scheme because NCDs are high-cost and require long-term care. As a result, the benefits package that was developed when UHC was first introduced includes many NCD interventions. However, there are some concerns regarding the future development of the benefits package to ensure that new or currently excluded technologies can be used as part of UHC. This raises the need for evidence-based and continual benefits package development.

Since Indonesia's GDP per capita is above USD 3,500 (29), it is now considered as a Global Alliance for Vaccines and Immunization (GAVI) and Global Fund graduating country. This will affect the procurement of some essential vaccines and support for HIV, tuberculosis, and malaria prevention and control which are not currently part of the UHC benefits package. Eventually, the government of Indonesia will need to prioritize these health services that are currently financed by international donors.

Current practice

HTA was formally appointed in 2014 to the HTA Committee which consists of 13 key senior experts in public health authorities and academia with support from the Secretariat Pusat Pembiayaan Jaminan Kesehatan (P2JK). Although the HTA Committee has a plan to institutionalize HTA for policy use in order to sustain UHC, its current work is focused on evidence-based medicine — conducting evidence synthesis or safety and efficacy studies for the development of clinical practice guidelines[4]. There are no full-time researchers or an established HTA organization in Indonesia, reflecting inadequate capacity and technical expertise; however, there has been interest to establish hospital-based HTA in tertiary hospitals although there are some difficulties on technical expertise and financial and non-financial support. The methodological guidelines for evidence synthesis have been issued by the HTA Committee but there are no methodological and process guidelines for HTA that incorporate economic analysis.

Policy impact

Based on the above lessons, HTA has not yet made a policy impact in Indonesia. There are currently several ongoing activities to improve capacity and conduct HTA case studies including the use of HTA to evaluate medicines, renal dialysis, and NCD prevention and control programs[5].

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[4] *Sastroasmoro, Sudigdo. "(Evidence-based) Health Technology Assessment: Indonesian experience and future direction". HTA Training Workshop. Pullman Jakarta, Jalan M.H. Thamrin No. 59, Jakarta Pusat, DKI Jakarta 10350, Indonesia. 23 June 2014. Presentation.*

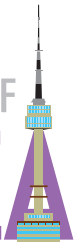
[5] *HITAP. 2015. Mission report on HTA workshop (January 2015) in Indonesia and the mission report on workshop (January 2015) on the WHO PEN disease interventions economic evaluation in Indonesia.*

Health systems context in the Republic of Korea

A compulsory National Health Insurance (NHI) provides health care in the Republic of Korea. Nearly all the citizens are beneficiaries of the program. The Ministry of Health and Welfare (MOHW) supervises the operation of the NHI program and decides overall policies. As a non-profit institution, the National Health Insurance Service (NHIS) is the single insurer providing health insurance based on solidarity to all citizens living in the Republic of Korea.

The NHIS has the responsibility for operating the NHI including managing the enrollment of the insured and their dependents, collecting insurance contribution on a monthly basis, contracting medical fee schedules with the health care providers, and reimbursing health insurance benefits. As a single payer in the Republic of Korea, the NHIS is responsible for promoting public health and improving social security by providing insurance benefits to prevent, diagnose, treat, and rehabilitate people's diseases. The Health Insurance Review and Assessment Service (HIRA) processes and evaluates the medical claims and adequacy of medical services while the National Evidence-based Healthcare Collaborating Agency (NECA) is the main agency for HTA including drugs, medical devices, diagnostics, and procedures. Particularly, when a new medical procedure or a diagnostic method is introduced in the Republic of Korea, it must undergo an assessment of safety and effectiveness by the Committee of new HTA, which makes decisions based on the HTA reports produced by NECA.

THE REPUBLIC OF KOREA



HTA in the Republic of Korea is already legislated and carried out regularly through a national HTA agency.

Need for HTA in setting health priorities

The Republic of Korea is facing an increasing trend of health care expenditures and rapid growth of its elderly population. Expanding the current national health insurance coverage (about 62% in 2010) is a big issue in the political arena. In addition, there are growing concerns over the irrational use of high-cost technologies which are not covered by the national insurance. Health technology assessment becomes more important than ever to answer all the aforementioned challenges. In addition to this, the country has a faster rate of adoption of advanced health technologies and has evidence of overutilization of health products and services. One example is the electronic nicotine delivery systems (ENDS) or electronic cigarettes (referred to as e-cigarettes hereafter), which were introduced in 2008. E-cigarettes have been widely advertised as an "incredible smoking cessation device" in the market. However, NECA's research found that every e-cigarette which was sold in the market did not contain any information about the actual ingredients of nicotine cartridges for its users and surprisingly, formaldehyde, a carcinogen, was detected in every tested product. Therefore, there was not enough evidence showing that e-cigarettes were a safe and effective tool for quitting smoking. Based on the research findings, NECA suggested that e-cigarettes should be regulated as a tobacco product and that further research was needed on the detailed analysis of the ingredients of all e-cigarettes in the market.

Current practice

The Health Insurance Review and Assessment Service (HIRA), which is a reimbursement claims reviewing agency for the National Health Insurance, initially started HTA activities in the Republic of Korea: Evidence Based Medicine (EBM) Team and the Center for New Health Technology Assessment (CNHTA). However, when NECA was established in December 2008 to specialize in HTA research, CNHTA support was transferred from HIRA in 2010.

NECA has a comprehensive mandate to promote the use of HTA for decision-making at various levels including coverage decisions and clinical practice. Well-developed HTA guidelines are already in place and HTA capacity is available in several academic units. In addition to CNHTA, for example, the Horizon Scanning Service of Innovative Global Health Technology (H-SIGHT) has been established in NECA for early awareness and alert systems for new and emerging health technology. This center aims to identify emerging health technologies including pharmaceuticals,

medical device and procedures, and health interventions. Selected technologies' potential impacts are analyzed based on scientific evidence and provided to various stakeholders such as policy makers, health care providers, industries, and so forth.

Among technologies approved by the Ministry of Food and Drug Safety (MFDS), a new medical device or diagnostic, combined with a new procedural technique, has to go through the nHTA (new HTA) process before national coverage determinations. The nHTA committee of the MOHW, comprising 20 experts from various health and medical fields, assesses the safety and effectiveness of new health technologies based on systematic reviews provided by the CNHTA at NECA. Non-medicine technologies with little/no supporting evidence are classified into different levels for a "Limited Approval" process instituted in the health care system for nHTA. NECA is tasked with the rigorous supervision of the clinical and economic analyses of these technologies.

Stakeholders, particularly health professionals, have been involved in the HTA process including the prioritization of HTA topics. As described above, a clear governance structure and process on the use of HTA to support policy decision-making has been established for new drugs, devices, medical procedures, and diagnostic methods.

Policy impact

The Republic of Korea's HTA development is advanced, particularly with HTA already legislated under the Health and Medical Service Technology Act of 2008 and carried out regularly through a national HTA agency. There is a well-developed system for the introduction of new health interventions in the government's health care system, with HTA used frequently to inform policy decisions on new technologies via the CNHTA under NECA. There have been several case studies of successful use of HTA to inform on medications, medical devices, and other health-related products such as the aforesaid e-cigarettes. Despite the successful conduct of several economic analyses, however, pricing recommendations are made on a case-by-case basis.

Health systems context in Malaysia

Malaysia is transitioning from a middle-income to a high-income country, with fast and sustainable growth over many decades. The country has already achieved universal health coverage and its public health system provides broad-based health services to all Malaysian citizens (30). Their benefits package covers basic primary services such as immunization to complex tertiary health care such as heart and kidney transplants that are available through public hospitals and clinics. A private health care system exists in parallel, giving Malaysians the choice of receiving care at either a public or private center (31). The government, mostly through general taxation, heavily finances health services at public facilities. While the system worked relatively well for many years, the rising costs of health care for government financing have resulted in increasing pressure for major financial and policy reform for health care (31).

HTA will be a pertinent agenda in the Malaysian health care system.

In terms of these reforms, the outlook for evidence-based change and policy making is optimistic as the importance of HTA has already been recognized with the formation of the oldest HTA agency in the region. The Malaysian Health Technology Assessment Section (MaHTAS) agency was established in 1995 under the Medical Programme, Ministry of Health (MOH) Malaysia, in keeping with the Ministry's policy of ensuring that safe, effective, and cost-effective technology is being used in the Ministry of Health facilities in Malaysia. Another agency that uses the HTA process is the Formulary and Pharmacoeconomic Unit in the Pharmaceutical Services Division (PSD).

Need for HTA in setting health priorities

As with many countries, Malaysia has a growing burden of disease and health problems, particularly non-communicable diseases (NCDs) due to its aging population and the population's unhealthy lifestyles. Demand for health care services is met primarily through public health care and private hospital expenditure is still paid chiefly from out-of-pocket payment with costs that a minority of the population can afford.

Currently, Malaysia spends 4.75% of its GDP on health care. In the 2012 budget, the government health care dedicated USD 5.4 billion to public health care (30, 31). The duality of the system has given rise to several challenges to public health care providers such as a perpetual drain of government doctors to the private sector and a lack of expenditure controls in private centers. Consequently, the public health care facilities suffer from problems of being overcrowded, understaffed, and long waiting times.

A change in the health care financing system has been discussed for a number of years in order to overcome the limitations (31, 32). To this end, several major health reform plans were mooted to unify the system and provide a more sustainable financing mechanism (30, 33). The implementation of a new system, however, will require a significant amount of political and administrative will, particularly in the face of intense public interest[6,7,8].

Significant overhaul of the health care system will mean a higher need for focused and prioritized decision-making, particularly in terms of efficient resource allocation. Coupled with strong marketing campaigns of various industries and demands for high-cost technology, the demand and need for HTA (drugs, devices, procedures, and other health care technologies found to have good health benefits and are cost-effective at the same time) are on the rise.

Current practice

MaHTAS has been given the mandate to conduct HTA in keeping with the Ministry's policy of ensuring that safe, effective, and cost-effective technology is being used in the MOH facilities since 1995. Subsequently, in 2001, the use of evidence-based approach led to the development and implementation of evidence-based clinical practice guidelines being put under the MaHTAS purview. HTA conducted by MaHTAS assessed a wide range of health technologies including medical devices, medical procedures, programmes, regenerative medicine, biologics, drugs, and organizational and support systems for the delivery of health care — particularly new technologies. From 1997 to 2014, the assessed technologies were mainly programmes, procedures, and medical devices.

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[6] *Too early to talk about 1Care, says ministry, in The Star. 2012: Malaysia.*
[7] *1Care proposal draws contrasting opinions at forum, in The Star. 2012.*
[8] *1Care plan not a blueprint. Report was only a suggestion, says Liow, in The Star. 2012.*

As for the listing of pharmaceuticals in the MOH formulary, the PSD conducted limited HTA in their drug review process to ensure a comprehensive, evidence-based, and updated list of medicines available for use in the MOH. The process to introduce a new registered drug, add or alter specifications for its use, and to remove listed drugs is coordinated by the Formulary and Pharmacoeconomic Unit in the PSD (34).

MaHTAS's governance structure for involving HTA stakeholders from the selection of topics for HTA to the decision-making process is well-founded. Safety, comparative effectiveness, and cost are major concerns when conducting HTA. Currently, MaHTAS is embarking on local economic evaluation and initiating Horizon Scanning activities.

There is also an established academic unit in the Universiti Sains Malaysia (USM) called the Discipline of Social and Administrative Pharmacy (DSAP) that has prominent HTA capacity and regional reputation. The unit is actively involved in the formulation and monitoring of the Malaysian National Medicines Policy (MNMP), with members as part of the steering committee.

Policy impact

In Malaysia, the impact of HTA can be seen when recommendations derived from HTA studies are being used in the formulation of national and Ministry of Health health technology policies, providing the basis for CPG development and decision for clinical practice, purchasing/procurement decision, initiating programs and procedures, and to a certain extent on reimbursement decisions.

Pricing recommendations are also not provided for the decision-making process. However, it is expected that HTA will be a major component of the current health reform in order to ensure quality and cost containment.

With rising health care costs and the need to balance and optimize resource allocation for the sustainability of health care delivery services in Malaysia, it is expected that HTA will be a pertinent agenda in the Malaysian health care system.

Health systems context in Thailand

In 1997, the right to health was written into the Thai constitution by public representatives and passed by a public referendum, which provided a platform to support social movement in the development of public health policy. Strong civil society commonly makes public policy decisions transparent and participatory; thus, evidence has become a means for different stakeholders to reach a consensus. Additionally, the Thai health sector is influenced by practices in Western countries where evidence is used in policy decision-making. It is common for decision-makers and technical advisers to study in and graduate from Western countries; therefore, newly introduced practices and information in Western countries are transferred to Thailand in a relatively short time. HTA has been discussed in policy since the establishment of the Health Systems Research Institute (HSRI) but the country faced challenges for more than 14 years before HTA was operationalized in policy decision-making.

HTA in Thailand is seen by stakeholders as a way for all to be engaged in policy development in a very transparent way.

Need for HTA in setting health priorities

Over the past two decades, the life expectancy in Thailand has increased significantly, resulting in an aging population and an increasing burden of non-communicable diseases (NCDs) while its economic growth has lagged. The increased burden of NCDs requires long-term treatments and high-cost health investments which is in contrast with the ability to pay for health care. In recognition of the public's growing health needs, the Thai government introduced Universal Health Coverage (UHC) in 2002 which covers minor health problems with relatively low costs of care to serious health problems with high costs and potentially catastrophic expenditure. As a result, there is pressure from industry, health professionals, and patient representatives to cover a range of treatments, some of which might not offer good value for money. Currently, evidence such as value for money is used in the development of Thailand's benefits package as well as the National List of Essential Medicines.

Current practice

After widespread recognition of the value of HTA, decision-makers have accepted HTA as an integral part of the decision-making process, particularly in the development of the National List of Essential Medicines (NLEM) (37) and the UHC health benefits package (38). The use of HTA in these two policy processes have similar features in terms of participatory and systematic selection of HTA topics, conducting HTA using standardized methodological recommendations derived from the National HTA Guidelines — involving a wide range of stakeholders in HTA appraisal, and disseminating HTA results in the public domain.

The current HTA system in Thailand has a clear distinction between decision-making bodies (HTA users) and HTA units in the public sector including universities, health systems and policy research institutes, and MoPH departments, whereas the private sector has HTA units in transnational pharmaceutical companies. HTA users established mechanisms to ensure the quality of HTA evidence by indicating certain criteria for HTA units to generate evidence. For example, the National Health Security Office (NHSO) does not accept HTA evidence generated by individuals,

for-profit organizations, or the private sector, and requests that HTA units have a proven academic record. For the NLEM, although HTA produced by the private sector is accepted, it needs to follow the national HTA methodological and process guidelines and work under the close supervision of the Health Economic Working Group, consisting of government officers and established academics.

Policy impact

Twenty to thirty policy-relevant HTA researches are conducted annually which are funded by potential users such as the MoPH and NHSO. Of these, HITAP conducts about 10 – 12 HTA researches for the development of the UHC benefits package and the NLEM. HITAP engages in a participatory, rigorous HTA policy process by involving multiple partners in the selection of appropriate topics. This process empowers all stakeholders involved, creating a better understanding of HTA. Thus, HTA in Thailand is seen by stakeholders as a way for all to be engaged in policy development in a very transparent way.

Health systems context in Viet Nam

The governance of the health care system in Viet Nam is centralized. The Ministry of Health (MOH) plays an important role in planning and implementing health plans. Both macro- and micro-level decisions are made by very high-level officers in around 20 departments, resulting in most decisions being made individually. The Viet Nam Social Security, which is the only public health scheme in Viet Nam, is independent and autonomous under the government of Viet Nam, and is responsible for financing health insurance and working with the MOH to determine the benefits package. The current coverage of public insurance is at 69% with the aim to achieve 100% of the total 90 million by 2020.

HTA and other priority setting tools are relatively new disciplines in Viet Nam, there is some good individual HTA capacity.

Need for HTA in setting health priorities

Viet Nam is facing a rapid increase in health expenditure — spending 7% of gross domestic product (GDP) on health in 2011 — owing to rising disease burden and health problems such as non-communicable diseases (NCDs) and an aging population. In addition, the priority setting process is not well-established, leading to the irrational use of health technologies. There are no clear requests from decision-makers for evidence in the policy making process and most technologies that are available in the market are covered by the benefits package. The decisions on investment and population coverage, even for a single drug or vaccine, can take up to two years. The MOH established the benefits package and is responsible for revising the current package; however, the definition of the benefits package is not based on cost-effectiveness, affordability, or other technical criteria. In recent years, the benefits package has been expanded to meet the requirements of suppliers who have invested in advanced technologies and to keep pace with a fast-growing pharmaceutical market.

Hospital autonomy combined with the lack of effective control of fee-for-service mechanisms encourages hospitals to increase high-cost services. Balance billing, although not permitted, remains widespread. The payment system does not promote cost containment and has put in place a set of perverse incentives that undermines efficient delivery of services and contributes to rising out-of-pocket payments.

Current practice

HTA and other priority setting tools are relatively new disciplines in Viet Nam, although there is some good individual HTA capacity in universities which have resulted in past collaborations with international organizations such as the University of Queensland

and Atlantic Philanthropies. As such, HTA has been conducted as part of academic activities until only recently. In 2014, the Health Minister appointed an HTA focal point agency within the MOH to collaborate with other stakeholders and conduct policy relevant HTA in support of government policy. Currently, the HTA focal point is working in collaboration with other local units to conduct three policy relevant HTA studies with support from international organizations. The HTA studies comprise three phases: topics prioritization, topics assessment, and results dissemination as well as the development of HTA process guidelines.

Policy impact

It is expected that the first round of policy-relevant HTA studies will be completed and considered by the government and other relevant stakeholders by mid-2015. Whether it will be accepted and used routinely remains to be seen.

NOTE

NOTE

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Health Intervention and Technology Assessment Program (HITAP)
6th Floor, 6th Building, Department of Health,
Ministry of Public Health, Tiwanon Road,
Muang, Nonthaburi 11000, Thailand
Tel: (66) 2590-4549 or (66) 2590-4374-5
E-mail: info@hitap.net
www.hitap.net