



POLICY BRIEF

Factors conducive to the development of health technology assessment in Asia

IMPACTS AND POLICY OPTIONS







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Sarocha CHOOTIPONGCHAIVAT Nattha TRITASAVIT Alia LUZ Yot TEERAWATTANANON Sripen TANTIVESS



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Factors conducive to the development of health technology assessment in Asia: impacts and policy options

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Contents

Aut	chorship and acknowledgments	iv
List	t of abbreviations	v
I.	Policy Brief	1
II.	Working Paper	6
	Introduction	6
	Health systems context	8
	Historical development and current practice of HTA agencies in study settings	10
	Policy impact of HTA	13
	Characteristics of successful HTA agencies	16
	Factors conducive to the setting up of HTA agencies	18
	Constraints to the use of HTA policy decisions	20
	Recommendations for institutionalizing HTA	22
	Step-by-step practical guide and achievement indicators	25
AN	NEX I. Milestones	28
AN	NEX II. Guide for developing the site working paper	30
	Introduction	30
	Objectives	31
	Methods	32
	Results	33
	Discussion	37
AN	NEX III. Country background papers	38
	Health systems context in China	38
	Health systems context in Indonesia	41
	Health systems context in the Republic of Korea	43
	Health systems context in Malaysia	46
	Health systems context in Thailand	49
	Health systems context in Viet Nam	51
Ref	erences	53

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List of abbreviations

CHPETA Center for Health Policy and Evaluation and Technology

Assessment

CNHDRC China National Health Development Research Center

DSAP Discipline of Social and Administrative Pharmacy

GAVI The Global Alliance for Vaccines and Immunizations

GDP gross domestic product

GHB government health budget

HIRA Health Insurance Review and Assessment Services

HITAP Health Intervention and Technology Assessment Program

H-SIGHT Horizon Scanning Service of Innovative Global Health

Technology

HSPI Health Strategy and Policy Institute

HTA health technology assessment

HTAi Health Technology Assessment international

iDSI international Development Support Initiative

INAHTA International Network of Agencies for Health Technology

Assessment

ISPOR International Society for Pharmacoeconomics and Outcomes

Research

LMIC low- and middle-income countries

MaHTAS Malaysian Health Technology Assessment Section

MICs middle-income countries

MOH Ministry of Health

MOHW Ministry of Health and Welfare

MoPH Ministry of Public Health

NCDs noncommunicable diseases

NECA National Evidence-based Healthcare Collaboration Agency

NHI National Health Insurance

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 Institution of Health Technology Assessment

NLEM National List of Essential Medicines

OECD Organisation for Economic Co-operation and Development

00P out-of-pocket payments

PSD Pharmaceutical Services Division

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

UHC Universal Health Coverage

UNICEF United Nations Children's Fund

USM Universiti Sains Malaysia

WHO World Health Organization

WHO-CHOICE World Health Organization Choosing Interventions that are

Cost-Effective



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 investment 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 six settings – China, 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 evidence 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 covers a variety of factors ranging from a shortage of skilled HTA researchers to limited information technology infrastructure and low political support. As a result, benefits packages can become too broad, ill-defined and/or unreasonable, which results in difficulties in linking payments to the benefits package. Consequently, inefficient delivery of health services becomes the norm, thus increasing out-of-pocket payments (OOPs) for patients. On the other hand, 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 use of resources. As OOPs for patients increase, access to essential health services becomes inequitable. For instance, patients who can afford high-cost technology become the only ones with access to it while vulnerable groups such as 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 countries faces several impediments, especially in linking evidence with policy and practice. Barriers to the development of HTA systems at country level include:

- Silo-based decision-making processes, referring to a process whereby decisions are made without transparency and the participation of relevant stakeholders;
- Policy makers without adequate decision-making capacity, meaning that policy considerations do not focus on long-term outcomes, equitable distribution, or make explicit cost-benefit links;
- Countries with strict controls on research dissemination, meaning that outcomes that are unfavourable to decision makers tend not to be used in policy-making;
- Respect for expert (senior) opinions or authorities means that they are valued more than evidence-based research. This commonly forms the last barrier to the use of HTA in policy decisions.

Evidence

Lessons drawn from experience in the study settings where HTA has long been developed illustrate six contextual factors that frequently exist in health systems. It is clear that these factors are conducive to both the demand and supply of quality HTA studies, that is, the establishment of HTA agencies and their contribution to evidence-informed coverage policies.

- A high proportion of public investment and strategic purchasing in health care compared to private health expenditure is a strong incentive for countries to ensure investment in cost-effective interventions with good clinical outcomes.
- Political will, leadership and legislation push 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 the need for more and better quality HTA.
- A good health information technology infrastructure encourages HTA use. HTA is a highly analytical and multidisciplinary process which requires a wide breadth of information. A well-developed information technology infrastructure allows for economic analyses that require large and complete datasets.
- Local training on HTA-related disciplines strengthens and builds on existing or new capacity. Postgraduate training in HTA, locally and internationally, ensures a critical mass of HTA researchers to conduct studies and meet the growing demand for HTA.

- Effective collaboration between HTA agencies or programmes and local stakeholders strengthens the link between research and policy. Good working relationships between HTA agencies or programmes and policy-makers as well as multiple stakeholders can lead to wellaccepted HTA results and greater legitimacy for use in policy.
- A country's independence from external support or international aid forces them to budget scarce resources effectively. There are fewer tendencies to rely on external groups for analyses and allocative decisions, or to make allowances for inefficient or unwise decisions.

Recommendations

The recommendations comprise five factors conducive to HTA development and a practical step-by-step guide, including a checklist to monitor the progress of the introduction and development of HTA. 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 in decision-making bodies and other relevant stakeholders that are using HTA.
- 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 the policy decision-making mechanism.** The appropriate mechanism for linking HTA to decision-making will vary depending 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 programmes, high-cost medical device package and public health programmes.
- 4. **HTA legislation**. The existence of legislation may help sustain the 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 focusing on technical issues.
- 5. **International collaboration**. International technical support is very useful, especially in the formative stages, for financial and technical

capacity-building. However, in-country development of 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 summarized in Table 1 provides information on 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, 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 being used on a routine basis by decision-makers; however, HTA systems are dynamic and continually develop over time even in well-developed settings. The following practices are recommended for each phase of HTA development. During these phases, four components – human resources, money, materials and management – must be taken into account in order to establish a functioning HTA system.

Table 1. Components needed to establish a functioning HTA system

	Early developmental phase	Moderately-developed phase
Human resources	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 of moving towards full-time HTA staff.	Clear demand for HTA by decision-makers and interest in HTA by academics. Availability of local short- term training courses as well as postgraduate training 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. Data is available locally.

Table 1. Components needed to establish a functioning HTA system (cont.)

	Early developmental phase	Moderately-developed phase
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 HTA methods and processes, coordinate HTA agencies and liaise between HTA agencies and decision-making bodies.

Source: Authors

In order to monitor the progress in implementing this practical step-by-step guide, the list in Box 1 brings together the 10 most important achievement indicators for settings where HTA is nascent. These indicators act as a checklist for settings to determine the level of maturity of their HTA development and inform those people responsible for HTA development about potential improvements. The indicators do not determine the phase of HTA development, but rather indicate areas where progress is required; they do not need to be made in any particular order.

Box 1. Checklist of achievement indicators to monitor progress of HTA development Formal mechanism to link HTA unit and policy-makers Full-time group of HTA researchers Use of HTA results in policy implementation HTA process guidelines HTA method guidelines Appointment of HTA focal point agency Collaboration of domestic stakeholders in carrying out HTA research Domestic HTA training Allocation of annual budget to HTA activities by government Policy statement on the willingness to use HTA in policy decision-making



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 investment 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 priority-setting, especially in the UHC context.(1) To date, only a few LMICs have managed to accomplish the establishment of an HTA system. However, Asia Pacific is one region where HTA institutions and networks are operating successfully in Organisation for Economic Co-operation and Development (OECD) countries and a few of the middle-income countries (MICs).(2) However, many of the LMICs in the region have HTA systems that are still at a very early stage of development.

Employing desk reviews and qualitative research techniques, this Policy Brief and Working Paper draws lessons from the introduction of HTA in selected Asia Pacific countries – China, Indonesia, the Republic of Korea, Malaysia, Thailand and Viet Nam. It describes the historical development and current practice of 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 the quality of life.(3)
- **Health technology assessment** is the systematic evaluation of the 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 about health technologies. (4)
- Health benefits package is defined as those services, activities and
 goods reimbursed or directly provided by publicly-funded statutory or
 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, assessment 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 programmes, 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 the health benefits package) by authorities tasked with this responsibility including the health ministry and public insurance offices.

Health systems context

Health-care systems in the Asia Pacific region must address the needs of 4.2 billion people, accounting 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 to private-dominated health-care systems. This diversity in settings is due to the variety of administrations and economic systems. In order to understand HTA systems in this area, it is essential to first gain an understanding of the health systems context. By understanding the health systems context, it will become easier to transfer the lessons learnt to other countries with a similar context.

This Working Paper draws on the experiences of HTA systems in HTAsiaLink¹ members that voluntarily participated in this project. These include China, Indonesia, the Republic of Korea, Malaysia, Thailand and Viet Nam. Table 2 describes key characteristics of health-care systems in the study countries. It shows that these countries have had varying degrees of success in terms of improving public health using life expectancy at birth and infant mortality rate as proxies. The Republic of Korea has the longest life expectancy at birth and the lowest infant mortality rate while, in contrast, Indonesia has almost 10 years less life expectancy and an infant mortality rate at least five times higher. Three countries – the Republic of Korea, Malaysia and Thailand – have already achieved more than 90% health coverage via publicly-funded health insurance; the other three countries have made a strong commitment to UHC and aim to achieve it within the next five years. At least two countries currently

¹ HTAsiaLink is a regional network of not-for-profit HTA agencies to foster research collaboration between countries and build the capacity of individuals and organizations. At the moment the network consists of 13 organizations from Bhutan, China, 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.

spend 6% or more of their gross domestic product on health while the other countries still have relatively modest health spending as a percentage of gross domestic product. The Governments of Thailand and China may be under the highest pressure to set health-care priorities as they already spend 14% and 12%, respectively, of the government budget on health, which means that there is not much fiscal space left to expand public health services. On the other hand, the Republic of Korea and Malaysia do not have high government budgets for health; nevertheless, these governments encounter pressure to meet the needs and demands of the public, which shoulders the high financial burden of financing health care through premiums. The other 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

Countries	Population (million)	Life expectancy at birth(6)	Infant mortality rate (per 1000 live births)(7)	% health insurance coverage	Year of achieving UHC	THE as % of GDP	GHB as % of Government budget(8)
China	1360	75	11	70-90	2020	5.4	12.5
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(9)	4.75	5.8
Thailand	67	74	11	100	2002	4.5	14.2
Viet Nam	90	76	19	70	2020	6.0	9.5

Note 1: UHC = universal health coverage; THE = total health expenditure; GDP = gross domestic product; GHB = 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).

Historical development and current practice of HTA agencies in study settings

As discussed previously, the need for health-care priority-setting is recognized in each study setting. This 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 the HTA agencies 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 evidence generated by NICE is 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) is recognized as the first HTA agency established in the region in 1995, followed by the Health Intervention and Technology Assessment Program (HITAP) in Thailand in 2007. The National Evidence-based Healthcare Collaboration Agency (NECA) in the Republic of Korea and the China National Health Development Research Center (CNHDRC) soon followed in 2008. The Health Strategy and Policy Institute (HSPI/HSPI-HITA) in Viet Nam was established in 2013 and the HTA Committee in Indonesia in 2014. To date, all study sites have at least one HTA focal point including the HTA Committee in Indonesia and HSPI in Viet Nam. However, only two sites, the Republic of Korea and Indonesia, have formally appointed an HTA body through legislation.

NECA and HITAP are well-established not only in terms of human resources and the range of technologies assessed but also with regard to the significant role they play in evidence-informed policy development in national health authorities and public insurance schemes and in the price negotiation

Table 3. Characteristics of HTA institutes involved in this project

	Te	chnologie	Technologies assessed	Jo o'll	Number of	Annual		
Institute (site, year of establishment)	Medi- cines	Devices	Public health interventions	HTA in pricing	research (full-time)/ admin. staff	budget (million US\$)	Number of HTA projects	HTA legislation (year of issuing)
CHPETA (China, 2008)	>	>	>	>	10/0	1.6	5–8 topics per year/at least 5 HTA reports annually	N/A
NECA (Republic of Korea, 2008)	>	>	>	>	80/40	10	90 (59 at Center for nHTA)	National Health Insurance Act 2006
MaHTAS (Malaysia, 1995)	>	>	>		27/4	- (MOH operational budget)	20 technology reviews/5 HTA reports/5 clinical practice guidelines	N/A
HITAP (Thailand, 2007)	>	>	>	>	34/17	2	20	N/A
HSPI/HSPI-HTA (Viet Nam, 1998/2013)	>	>	>	>			N/A	N/A
HTA Committee (Indonesia, 2014)	>	>	>		12 (total, PT)	0.1	5-6	Presidential Regulation 12/2013

Note. CHPETA = Health Policy Evaluation and Technology Assessment; NECA = National Evidence-based Healthcare Collaborating Agency; MaHTAS = Malaysian Health Technology Assessment Section; NIHTA = National Institution of Health Technology Assessment; HITAP = Health Intervention and Technology Assessment Program; HSPI = Health Strategy and Policy Institute; nHTA = new HTA, and PT = Part Time

Source: Based on information collected by the country study authors

of health technologies in the case of NECA and HITAP. These two 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 of political pressure. They have also contributed to local capacity-building for both academics and decision-makers.

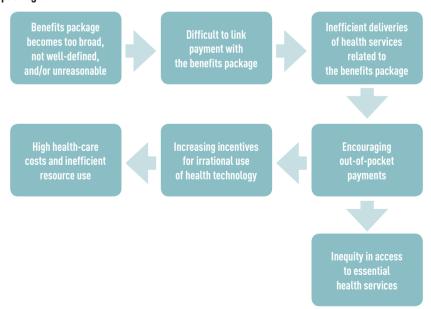
CNHDRC and MaHTAS have made relatively good progress in conducting HTA research and connecting research findings with national policies. CNHDRC usually selects HTA topics at the request of the central government and the results are distributed only to the government and selected academics. Peculiarly,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

Policy impact of HTA

Based on the experiences of 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 cases, such as in 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

Figure 1. Potential impact of not using HTA in the development of health benefits backages



Source: Authors

addressed extensively in Europe and North America.(10–12) 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 to the impact of not using HTA in LMICs. Fig. 1 illustrates the negative consequences found from not using evidence-based priority-setting in the development of health benefits packages in selected Asian countries.

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 development of benefits packages will 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 unreasonable². For example, suppose the benefits package defines the coverage of breast cancer treatment but does not include a detailed description of treatment regimens, such as whether the drug trastuzumab is included, or for which cancer stages, or what indication3. Due to these problems, it will be difficult to link payments with the benefits package; for example, 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 payments 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.

If the benefits package and payments are not linked, then providers do not benefit from cost-recovery or lack incentives to provide services and it is difficult to introduce efficient service procurement, such as central purchasing or payer-provider contracts. This can create inefficient service delivery and result in the introduction of OOPs. This situation occurs in Indonesia, Viet Nam and the Philippines where providers will ask patients to pay for essential services.

When OOP is customary, this encourages the irrational use of health technology; providers will aim for profit or act in their own best interests. As a result, patients will pay for and receive more services than are necessary.

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

³ In Viet Nam and the Philippines, trastuzumab has been included in the benefits package without any clear indications on stages, while in Thailand the drug is reimbursed only for the early stage. In Indonesia, there is no mention about drugs for breast cancer treatment.

Due to limited health resources and infrastructure, health expenditure will subsequently increase and inefficiencies in the health system will be exacerbated. Additionally, due to high health-care costs and OOPs, there will be inequity in access to essential health services, especially for the poor and vulnerable groups who are most in need of proper health care.

Characteristics of successful HTA agencies

Learning from HTA agencies in the study settings, this chapter presents various characteristics of successful HTA agencies in the region that have applied HTA and kept decision-makers informed on policy developments. The seven features of 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 (Box 2).

- Independence. Independence means that there is no political pressure
 that can influence the process and outcome of HTA. This characteristic is
 found in many successful HTA agencies that are entirely autonomous or
 semi-autonomous such as NECA and HITAP.
- 2. **Financial sustainability.** Financial sustainability means that a consistent financial flow is ensured for the HTA agency. Many HTA agencies in the Asia Pacific countries tend to rely heavily on research grants. This means that there is no sustainable or predictable financial support, which could jeopardize the existence of a successful HTA agency. In contrast, NECA and MaHTAS have annual budgets that are allocated by the government.
- Management of conflicts of interest. HTA agencies regularly face challenges in dealing with different interests in the health-care sector. This can be seen in the relationship between HTA agencies and the pharmaceutical industry, health professionals, politicians, civil society,

Box 2. Seven features of a successful HTA agency

- 1. Independence
- 2. Financial sustainability
- 3. Management of conflicts of interest
- 4. Full-time multidisciplinary staff
- 5. Extensive networks
- 6. Good systematic process
- 7. High-quality research with a quality assurance mechanism

- patient groups, etc. In order to maintain the impartiality of the HTA agency, good management of conflicts of interest is needed. For instance, NECA and HITAP collaborate with private companies and industry without receiving financial support from them in order to maintain their neutrality.
- 4. **Full-time multidisciplinary staff**. HTA involves many fields including drugs, medical devices, clinical practice, health promotion, disease prevention and health policy. Having multidisciplinary teams working on and developing their skills 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 the experience of NECA and HITAP, HTA teams benefits from a critical mass of multidisciplinary staff and to ensure impact; for instance, NECA, MaHTAS and HITAP have 80, 27 and 34 full-time academic staff, respectively.
- 5. Extensive networks. HITAP, for example, works with medical consortiums, all levels of public and private hospitals, universities and royal colleges, civil society, etc. In addition, in 2013 HITAP established an international unit which works extensively with international partners such as HTAsiaLink, the international Development Support Initiative (iDSI), the World Health Organization (WHO) and NICE. NECA actively participates in professional societies in the Republic of Korea with strong academic competency in traditional economic analysis, as well as in international and regional networks such as HTAsiaLink, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and HTA international (HTAi), in order to support methodological development and to share experiences.
- 6. Good systematic process. An HTA agency needs a systematic process to identify policy-relevant topics for assessment. To illustrate this, NECA has established the Horizon Scanning Service of Innovative Global Health Technology (H-SIGHT). This centre aims to identify new health technologies including pharmaceuticals, medical devices and procedures and health interventions. Once technologies are selected, their potential impact is analysed based on available scientific evidence and provided to stakeholders such as policy-makers, health-care providers and industries. Another example is MaHTAS, which has also recently initiated horizon scanning activities.
- 7. **High-quality research with a quality assurance mechanism**. HITAP's research projects, for example, have preliminary reviews by stakeholders followed by external reviews and are published in high-quality academic journals. Similarly, research conducted by NECA is also published in the journal literature. This procedure can be considered as a quality assurance mechanism for the research results produced by these HTA agencies.

Factors conducive to the setting up of HTA agencies

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

Political will, leadership and legislation push HTA development forward. As shown in the summary table, countries such as Indonesia and the Republic of Korea have legislated HTA in policy-making. 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.

A good health information infrastructure encourages HTA use. HTA is a highly analytical and multidisciplinary process which requires a wide breadth of information. The cost of conducting HTA in countries with insufficient information technology infrastructure will be very high, and may even make it unaffordable for the government. Information technology infrastructure allows economic analyses to be conducted that require large and complete datasets. 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.

Local training on HTA-related disciplines strengthens and builds on existing or new capacity. The Republic of Korea, Malaysia and Thailand all had postgraduate training in pharmacoeconomics, health economics and related HTA disciplines before establishing formal HTA agencies. In Thailand, for example, there are Social and Administrative Pharmacy (SAP) units in university schools and faculties of pharmacy; Malaysia has the Discipline of Social and Administrative Pharmacy (DSAP) in the Universiti Sains Malaysia (USM) that corresponds in function to SAP. The Republic of Korea, Malaysia and Thailand send strong candidates for HTA researcher positions for local and international training.

Effective collaboration between HTA agencies or programmes and stakeholders strengthens the link between research and policy. NECA and HITAP, for instance, have good working relationships not only with political stakeholders but also with health professional associations, civil society and industry. These stakeholders are engaged in the HTA process beginning with the 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 use in policy.

Independence from external support or international aid forces countries 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 for 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 to Fight AIDS, Tuberculosis and Malaria (Global Fund), resulting in the need to set priorities on programmes that the fund will no longer support.

Constraints to the use of HTA policy decisions

One of the main goals of HTA is to support decision-makers in developing policy. However, many issues exist that prevent HTA from being used. This chapter discusses the most common constraints identified by HTA agencies in the Asia Pacific region. The most prevalent constraints are silo-based decision-making processes, low-quality decision-making criteria, tight control of research dissemination, and respect for expert or senior opinion leaders. These constraints are discussed below.

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

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

At the same time, some countries may have strict control on research dissemination. Research outcomes that are unfavourable to decision-makers tend not to be used in policy-making. In other words, HTA studies that have findings contradictory to policy cannot easily be disseminated to stakeholders. This is a complete reversal of the concept of evidence-based

policy and is called policy-based evidence – it presents a major constraint to effective policy that benefits society.

The fact that respect for expert (senior) opinion or authorities is held in higher regard than evidence-based research forms the last common constraint to the use of HTA in policy decisions. Typically, in Asian culture, respect for senior or authority figures is often of paramount importance. In this situation, other findings will be placed lower on the evidence hierarchy. Moreover, the nature of HTA topic selection is such that researchers are more likely to select issues that are not in line with expert opinion and existing evidence. Despite this process, expert opinion can still go unopposed and eventually may grow to become a larger problem. Therefore, using strong HTA results in policymaking is often challenging in such contexts.

Recommendations for institutionalizing HTA

The following recommendations are aimed at readers working at sites that are at an early stage of HTA capacity development. Although this study focuses on the use of HTA to inform coverage decisions under UHC, these recommendations comprise the basic components for HTA systems and 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 developed in HTA research organizations as well as in decision-making bodies and other relevant stakeholder groups using HTA. In the Republic of Korea, Malaysia and Thailand, strong academic programmes exist that enable capacity development prior to the establishment of HTA agencies. These programmes offer a wide range of training, including short-term workshops and master's and doctoral programmes. Overseas training often cannot replace local capacity-development programmes. Therefore, the availability of HTA training programmes 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, making it essential to create an HTA focal point or agency to coordinate HTA activities and liaise with partners. This focal point 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 should be independent of 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 staff because conducting HTA is very technical and time-consuming. Although the number of full-time staff depends on the scope and responsibility of the core team or HTA institute, the focal point needs to have a 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 depending on the context and design of the health system. Nonetheless, a key point from this study is that the link between HTA for coverage decisions and UHC includes the pharmaceutical reimbursement list/essential medicines list/formulary list, immunization programmes, high-cost medical devices packages, and public health programmes. The assessment of drugs and vaccines is quite straightforward and commonly available in the literature while the assessment of medical devices is more complex in terms of the lack of data on quality and standardization of safety, longterm efficacy and effectiveness. For instance, the effectiveness of medical devices depends on the skills and expertise of those health professionals who use the devices. Also, different settings may allow different types of health professionals to use 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 programmes 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 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 of the HTA process rather than focusing on technical issues.
- 5. International collaboration. Each HTA agency in this study has 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. Today, resources are widely available at the international level through international agencies such as WHO-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 developing the capacity of local researchers and are rarely adaptable to address local-specific policy questions. As a result, a gap remains with in-country technical support, which involves hands-on supervision and working closely on local studies.

Once some 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 country can be influential in the context of another country, especially in places that have a similar economic and health infrastructure. Therefore, regional networking, such as HTAsiaLink and the HTA Network of the Americas (RedETSA), is as important as international or global networking, which is widely available in many forms such as HTAi, ISPOR, the International Network of Agencies for Health Technology Assessment (INAHTA), and the 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 overseas development assistance. As such, one of the recommendations to global donors, such as the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund, is to provide support for the country to set its own priorities instead of responding to the donor's own agenda. This may not be in line with the country's goals and may lead to unsustainability of the country's health development. Eventually, HTA capacity development should be part of GAVI's and Global Fund's packages for graduating countries.

Step-by-step practical guide and achievement indicators

This step-by-step practical guide provides information on 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 four components – human resources, money, materials and management – need to be taken into account in order to establish a functioning HTA system.

Early phase

During the early phase it may not be possible to identify a national HTA agency or to provide a clearly established HTA focal point, so HTA can be initiated in academic units, Ministry of Health units, or even in hospital units. The important factor is the 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 towards working full-time. Additionally, the group can begin small with the aim of expanding capacity to a multidisciplinary team to reach a critical mass. In this study, it has been 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 development. 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, and so on. 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 details such as quality of life measures based on local values because data from other settings with similar contexts can be used in the analysis. For example, HTA work in Indonesia, the Philippines and Viet Nam borrows utility data from Thailand.

From a management perspective, sites in the early stages should move from informal to formal mechanisms to manage 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 makes the system inefficient and counterproductive. It is also very important to have local short-term 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 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. (13)

In moderately-developed HTA settings, the HTA focal point provides and sets methodological and process guidelines to standardize HTA research. Methods for measuring the 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 HTA methods and processes, and to liaise among HTA agencies and between HTA agencies and decision-making bodies. For example, in the Republic of Korea and Thailand, HTA units exist in public and private sectors as well as in 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 impact of HTA on policy.

In order to monitor progress in following the step-by-step practical guide, Box 3 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 those people 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 I for a full list).

Box 3. Checklist of achievement indicators for progression of HTA development | Formal mechanism to link HTA unit and policy-makers | Full-time group of HTA researchers | Use of HTA results in policy implementation | HTA process guidelines | HTA method guidelines | Appointment of HTA focal point agency | Collaboration of domestic stakeholders in carrying out HTA research | Domestic HTA training workshop | Allocation of annual budget to HTA activities by government | Policy statement on the willingness to use HTA in policy decision-making

Source: Authors



Table 4 shows milestones indicating the achievements of a national HTA system. These milestones were rated by the six authors of the country studies on a four-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

Table 4. Ranked milestones indicating the achievements of a national HTA system

Items rating (1 = least important, 4 = most important)	China	Indonesia	Korea, Republic of	Malaysia	Thailand	Viet Nam	Total score	Average score
Formal mechanism to link HTA unit and policymakers (1)	4	4	4	4	4	4	24	4
Full-time group of HTA researchers (2)	4	4	4	2.7	4	4	22.7	3.8
Use of HTA results in policy implementation (3)	4	4	3	3.3	4	4	22.3	3.7
HTA process guidelines (4)	4	4	3	4	4	3	22	3.7
HTA method guidelines (5)	4	4	3	4	4	4	23	3.8
Appointment of HTA focal point agency (6)	4	4	2	4	4	4	22	3.7
Collaboration of domestic stakeholders in doing HTA research (7)	4	4	3	4	4	4	23	3.8
Domestic HTA training workshop (8)	3	4	1	3.3	4	4	19.3	3.2

Table 4. Ranked milestones indicating the achievements of a national HTA system (cont.)

Items rating (1 = least important, 4 = most important)	China	Indonesia	Korea, Republic of	Malaysia	Thailand	Viet Nam	Total score	Average score
Allocation of annual budget to HTA activities by government (9)	4	4	2	3	3	3	19	3.2
Policy statement on the willingness to use HTA in policy decision-making(10)	4	4	2	3.3	2	4	19.3	3.2
National HTA database of HTA reports	4	3	2	3.7	2	4	18.7	3.1
HTA legislation	4	2	4	2.3	1	4	17.3	2.8
Membership of domestic HTA agency in international networks	4	2	3	2.3	3	3	17.3	2.8
Postgraduate training on HTA-related disciplines	3	2	2	3	3.5	2	15.5	2.6
Data registry for clinical and economics data for use in HTA	3	3	2	3.3	2	3	16.3	2.7
International journal publications on HTA made by local researchers	2	3	2	2	3.5	3	15.5	2.6
National HTA conference	2	2	1	3	2.5	3	13.5	2.2
HTA as part of undergraduate curricula for health fields	2	1	2	2.7	3	2	12.7	2.2
Full-time dedicated clinical experts*			4				4	4
HTA method manuals in local language**			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 II. Guide for developing the site Working Paper Introduction

Since UHC is high on the global health agenda, governments of LMICs have pledged to increase health investment in order to offer universal access to essential health services. HTA has been recognized as a necessary tool for setting priorities(1) but so far only a few LMICs have managed to accomplish the establishment of HTA systems. Asia Pacific is a region where HTA institutions and networks have been operating successfully in OECD countries and a few MICs.(14) However, many of the LMICs in the region have HTA systems that are still in the very early stages of development.(2)

Decision-makers and scholars in low-income countries in other parts of the world are increasingly interested to learn about and build on the success of HTA systems in the Asia Pacific region. In particular, there is a need for increased understanding of policies – on both a macro- and meso-level – that are conducive to the development and sustainability of HTA systems. (15) Therefore, collaboration between the WHO's Asia Pacific Observatory (APO) and the Prince Mahidol Award Foundation was established in order to address this need. To draw lessons learnt from the experience of HTA agencies in Asia and to synthesize information on factors conducive to success, indicators for a qualitative study were developed to be used as a guide for other countries to assess the development of HTA in their own setting.

The development of indicators for the qualitative study aims to guide the chapter authors to develop site papers that were presented in the face-to-face authors' meeting on 24 November 2014 . At this meeting, authors discussed with other experts and drew lessons learnt from cross-country studies for the APO Policy Brief.



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



Literature reviews were performed on established databases such as PubMed and Embase, and by manual searching of relevant websites such as those of HTA agencies or HTA associations/networks including HTAsiaLink, ISPOR, HTAi and 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.



Five dimensions were identified as important for the development and sustainability of HTA (Table 5). These indicators provide an outline for the authors of each country chapter to determine these factors in their own settings, which will then be used in the development of each chapter of the Working Paper. 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: noncommunicable diseases (NCDs), ageing 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 government. This may involve the establishment of a national tax-based insurance scheme, especially in UHC. Other situations associated with the perceived benefits of HTA include rapidly-growing health expenditure, a notable decrease in the country's fiscal capabilities and economic downturn. In some settings, policy-makers foresee substantial escalation in health spending in the future as a consequence of the burden of NCDs and health problems among the elderly.

Table 5. Indicators for identifying supportive factors in developing and sustaining HTA (cont.)

Content	Indicators	Rationale
		Inefficient use of health resources including irrational use of health technology and its underpinning factors such as the rigorous marketing approaches of the health technology industry and demands for costly technology among health professionals, patient groups, NGOs and the public are driving forces on government to adopt HTA and evidence-informed decisions.
Health systems context in study settings	 Political commitment to UHC and HTA National health, trade and industry policy Health systems reforms Influence of development partners and international organizations Social norms and values for access to health services/technology Technical cooperation programmes, regional and international 	Contextual factors of the health systems may have considerable effects on the introduction of HTA 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 industrial sector; influence of donors and international governmental organizations; and reforms in 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 countries where health policy research and HTA capacity is lacking, technical support through international collaboration is important in making HTA evidence generation feasible.

Table 5. Indicators for identifying supportive factors in developing and sustaining HTA (cont.)

Content	Indicators	Rationale
Historical develop- ment of HTA	Change in the following elements over time: Health policy and systems research HTA advocacy HTA champions Pilot HTA programme and scaling up efforts Resource mobilization for HTA Capacity-building programmes Development of HTA infrastructure HTA-informed policy decisions Key contextual elements	In many countries, the introduction of HTA takes a long time. Regardless of successes and failures, useful lessons can be learnt through the narrative assessment of key actors, their efforts, features of HTA development processes, available resources, and context, all of which are likely to change over time. Learning from the historical development of HTA agencies and systems in each country 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 (organizations responsible, guidelines, evidence generation, use of HTA in policymaking, 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, equipment, management system Guidelines, national, methods and process HTA projects and reports Local and international collaboration	Characteristics of present HTA systems, with or without HTA institutions, and current experience in each health system provide valuable information to inspire and guide HTA development in other settings. Learning about the availability and ways in which HTA guidelines and tools are developed and used can help inform the potential success and sustainability of HTA systems.

Table 5. Indicators for identifying supportive factors in developing and sustaining HTA (cont.)

Content	Indicators	Rationale
Policy impact	 Monitoring and 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 has a policy impact. Policy impact of ad hoc HTA studies can be a factor conducive 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 the supportive factors and impediments to HTA having a policy impact.

Source: (1, 2, 14-22)



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 factors conducive to HTA development in Asia. However, other dimensions or indicators may emerge during the development of the country chapters or discussions during the face-to-face meeting. To the best of our knowledge, this is the first effort that aims to synthesize factors conducive to HTA development in LMICs and this work can be very helpful for decision-makers and other stakeholders in LMICs.

These indicators are not independent of 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:

- 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.

ANNEX III. Country background 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 can be 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 nature 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 to increase profits, resulting in the 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 ageing population due to increased life expectancy. Over the past few decades, life expectancy at birth in China has increased from 35 years in 1949 to 75 years in 2010.(23) This improvement has contributed to population ageing; in 2010, about 9% of China's total population was over the age of 65.(24) In addition to the ageing population, a more sedentary lifestyle due to rapid socioeconomic development over the past few decades has dramatically increased people's risk of chronic disease. Both the increase in ageing and in NCD patients will burden the national health budget. High marketization and openness also contributes to the rapid adoption 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 gross domestic product ratio increased by 6.9% and the total health expenditure (THE) to gross domestic product ratio increased by 28.8%; TPE accounted for almost half of THE. (25) To avoid unreasonable increases in THE

as economic development slows down in the future, HTA is needed so that the most cost-effective health technologies are prioritized.

To cope with the growing 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, the urban resident basic medical insurance, and a reformed version of the rural cooperative medical system. (26) Since the early 2000s, coverage of medical insurance schemes continued to expand. Individual OOP payments fell from almost 60% in 2002 to 34.9% in 2011. However, the ultimate goal of sustainable UHC has not yet been achieved, and thus there is a need for the efficient use of health-care resources. If this does not occur, excess health spending will eventually become an enormous financial burden 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 the development of HTA in China.

In 1991, the NHFPC established a research institute to conduct policy research and recommendations and in 2008, the 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 programmes 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 CNHDRC projects 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 institution that has close links with the decision-making process and obtains projects from government organizations.

Policy impact

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 adopted by the MOH, preventing a massive purchase of machines in hospitals. Through HTA, the adoption of inefficient and expensive high-tech equipment 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, CNHDRC was commissioned by the Policy and Regulation Department of NHFPC to carry out the Chinese Health Policy Prioritization Project supported by 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 to determine 10 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 the most pressing and promise the most impact for the cost.

CHPETA, under CNHDRC, has supported policy-makers and stakeholders in many other projects involving health economic evaluation and analysis. The centre 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. Ultimately, these projects allow policy-makers and stakeholders to make informed decisions and provide guidance for further direction. 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 Indonesia

Since 2001, Indonesia has been one of the few countries in Southeast Asia that has seriously introduced extensive government decentralization, resulting in a shift in responsibility for health-care services to 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 widely across the country.

In 2014, the Government of Indonesia introduced 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 (NHI). In addition, to strengthening HTA in the MOH, the Ministerial decree 71/2013 concerning health services in NHI stated the need for HTA to develop the use of technology in health-care provision to improve quality and efficiency as well as additional benefits for health insurance. HTA is based on the proposal of the association of health facilities, health professional organizations and Badan Penyelenggara Jaminan Sosial Kesehatan Health (Health Care and Social Security Agency).

Need for HTA in setting health priorities

Indonesia is facing challenges in terms of meeting the need for health-care services for NCDs; however, NCDs are still a low priority for the government. Results from the WHO report in 2011 on NCD country profiles show the rapid increase in morbidity and mortality from cardiovascular disease, diabetes, chronic lung disease and cancer – accounting for 64% of overall mortality in 2010.(27) 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 gross domestic product per capita is above US\$ 3500, it is now considered as a GAVI and Global Fund graduating country. (28) 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

In 2004, HTA was formally delegated to the HTA Committee which consists of 13 key experts from public health authorities and academia with support from the Secretariat Pusat Pembiayaan Jaminan Kesehatan (Center for Health Insurance). Although the HTA Committee has plans to institutionalize HTA for policy use in order to sustain UHC, its current work is focused on evidence-based medicine – conducting evidence syntheses or safety and efficacy studies for the development of clinical practice guidelines⁴. There are no full-time researchers or an established HTA organization in Indonesia, reflecting inadequate capacity and technical expertise; however, there has been interest in establishing hospital-based HTA in tertiary hospitals although there are some difficulties with 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 these 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 programmes⁵.

- 4 Sastroasmoro S. (Evidence-based) health technology assessment: Indonesian experience and future direction. [presentation]. HTA Training Workshop, Pullman Jakarta, Indonesia. 23 June 2014.
- 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 NHI provides health care in the Republic of Korea. Nearly all citizens are beneficiaries of the programme. The Ministry of Health and Welfare (MOHW) supervises the operation of the NHI programme and decides overall policy. 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 of operating the NHI including managing the enrolment of the insured and their dependents, collecting insurance contribution on a monthly basis, contracting medical fee schedules with health-care providers, and reimbursing health insurance benefits. As the single player 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 diseases. The Health Insurance Review and Assessment Services (HIRA) processes and evaluates medical claims and the 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. 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 for nHTA, which makes decisions based on the HTA reports produced by NECA.

Need for HTA in setting health priorities

The Republic of Korea is facing rising health-care expenditure and the rapid growth of its elderly population. Expanding the current NHI 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. HTA becomes more important than ever in providing answers to these 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 system or electronic cigarettes (e-cigarettes), which were introduced in 2008. E-cigarettes have been widely advertised as an 'incredible smoking cessation device' on the market. However, NECA's research found that none of the e-cigarettes sold on the market contained any information for users about the actual ingredients of the nicotine cartridges and surprisingly, formaldehyde, a carcinogen, was detected in all the products tested. Therefore, there was not enough evidence showing that e-cigarettes were a safe and effective tool for quitting smoking. Based on these 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 on the market.

Current practice

HIRA, which is a reimbursement claims reviewing agency for the NHI, initially started HTA activities in the Republic of Korea: the Evidence-Based Medicine Team and the Center for nHTA. However, when NECA was established in December 2008 to specialize in HTA research, the Center for nHTA 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 the Center for nHTA, for example, H-SIGHT has been established in NECA to provide early awareness and alerting systems for new and emerging health technologies. This centre aims to identify emerging health technologies including pharmaceuticals, medical devices and procedures and health interventions. The potential impact of selected technologies potential are analysed based on scientific evidence and provided to various stakeholders such as policy-makers, health-care providers and the industrial sector.

Among technologies approved by the Ministry of Food and Drug Safety, a new medical device or diagnostic, combined with a new procedural technique, has to go through the nHTA process before determining national coverage. The MOHW's Committee for nHTA, 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 Center for nHTA at NECA. Non-medicine technologies with little or no supporting evidence are classified into different levels for a Limited Approval process set up 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 Center for nHTA under NECA. There have been several case-studies of the successful use of HTA to inform on medications, medical devices and other health-related products such as the e-cigarettes mentioned previously. 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 UHC and its public health system provides broad-based health services to all Malaysian citizens. (29) 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 centre. (30) The government, mostly through general taxation, heavily finances health services at public facilities. While the system has worked relatively well for many years, the rising cost of health care is putting increased strain on government financing, resulting in increased pressure for major financial and policy reform for health care. (30)

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 (MaHTAS) agency was established in 1995 under the Medical Programme, MOH Malaysia, in keeping with the Ministry's policy of ensuring that safe, effective, and cost-effective technology is being used in MOH 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 NCDs due to its ageing 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 OOP with costs that only a minority of the population can afford.

Currently, Malaysia spends 4.75% of its gross domestic product on health care. In the 2012 budget, the government dedicated US\$ 5.4 billion to public health care. (29, 30) 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 centres. Consequently, public health-care facilities suffer from problems of overcrowding, understaffing and long waiting times.

A change in the health-care financing system has been discussed for a number of years in order to overcome these limitations. (30, 31) To this end, several major health reform plans were mooted to unify the system and provide a more sustainable financing mechanism. (29, 32) 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.

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 that are found to provide good health benefits and are cost-effective at the same time) are on the rise.

Current practice

Since 1995, 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 MOH facilities. Subsequently, in 2001, the use of an evidence-based approach led to the development and implementation of evidence-based clinical practice guidelines being put under 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 technologies assessed were mainly programmes, procedures and medical devices.

As for the listing of pharmaceuticals in the MOH formulary, the PSD has conducted limited HTA in their drug review process to ensure a comprehensive, evidence-based and updated list of medicines is available for use in the MOH. The process to introduce a newly 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 evaluations and initiating horizon scanning activities.

There is also an established academic unit in the USM called the DSAP that has prominent HTA capacity and a regional reputation. The unit is actively involved in the formulation and monitoring of the National Medicine Policy, 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 used in the formulation of national and MOH health technology policies, providing the basis for the development of clinical practice guidelines and decisions for clinical practice and purchasing or procurement decisions, for initiating programmes and procedures, and to a certain extent for reimbursement decisions.

Pricing recommendations are also not provided for in the decision-making process. However, it is expected that HTA will become 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 item 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. A 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 from 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 but the country faced challenges for more than 14 years before HTA was operationalized in policy decision-making.

Need for HTA in setting health priorities

Over the past two decades, life expectancy in Thailand has increased significantly, resulting in an ageing population and an increasing burden of NCDs while its economic growth has lagged. The increased burden of NCDs requires long-term treatment and high-cost health investment, contrasting markedly with the ability to pay for health care. In recognition of the public's growing health needs, the Thai Government introduced 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) and the UHC health benefits package. (36, 37) 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 makes 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 Ministry of Public Health (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. The NLEM, although it accepts HTA produced by the private sector, 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 funded by potential users such as the MoPH and NHSO. Of these, HITAP conducts about 10–12 HTA studies 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

Governance of the health-care system in Viet Nam is centralized. The 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 of achieving 100% of the total population of 90 million by 2020.

Need for HTA in setting health priorities

Viet Nam is facing a rapid increase in health expenditure – spending 7% of gross domestic product on health in 2011 – owing to a rising disease burden and health problems such as NCDs and an ageing 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 on the market are covered by the benefits package. Decisions on investment and population coverage, even for a single drug or vaccine, can take up to two years. The MOH establishes 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-forservice 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 undermine efficient delivery of services and contribute to rising OOPs.

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 has in the past resulted in collaboration with international organizations such as the University of Queensland and Atlantic Philanthropies. As such, HTA has largely been conducted as part of academic activities until only recently. In 2014, the Health Minister appointed an HTA focal point 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: prioritization of topics, assessment of topics and dissemination of results 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.



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