

HTAi

Background Paper

HTA and Decision Making in Asia:
How can the available resources be used most
effectively to deliver high quality HTA that can be
used by health system decision makers?

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1. Introduction

This note sets out background information on the three related main topics to be considered in the meeting, as follows:

- What information do decision makers need?
- How can HTA best meet these information needs?
- How can HTA and decision making best be linked?

In addition, short appendices provide information on:

- Definitions of health technology and health technology assessment
- An overview of the use of HTA in each of the health systems of the participants in the meeting.
- A characterisation of the elements of HTA systems

The note begins (Part A) by looking at the context: namely, the increasing interest in the use of HTA, how HTA has evolved, where HTA has got to in Asia. Part B sets out a distinction between assessment, appraisal and decision making and then addresses the three questions for the meeting.

Part A: The Context

2. Increasing interest in HTA

There are a number of global trends in health care that are affecting the ability of countries to ensure their citizens have access to health care. These include:

- aging populations and a growth in the disease burden – particularly from chronic disease;
- an increased range of potential health technologies that could be made available;
- economic pressures, with recent and projected economic growth rates in many countries below historical levels;
- more countries seeking to achieve one or more of (i) universal coverage of a minimum benefit package for their citizens, (ii) adding to existing coverage by increasing the numbers of services included in the benefit package (for example by including outpatient services including drugs), and (iii) reducing the amount of co-payment faced by patients on services that are included in the benefit package (World Health Report 2010).

As a result, countries are focusing on cost control and improving efficiency to enable health care spending to provide better value in terms of the health outcomes achieved for money spent. HTA has been widely recognized as one means of improving health system efficiency. For example, the World Health Report of 2010 sees one policy solution to inefficiencies in health care systems as

"Regular evaluation and incorporation of evidence on the costs and impact of interventions, technologies, medicines, and policy options."

We should note, however, that it is only *one* tool to improve health system performance and when considering how to use and improve the use of HTA, this needs to be put in the context of other tools and of the strengths and weaknesses of the health care system (Towse et al. 2011). The broad HTAi definition of HTA includes the efficiency of the organizational systems or the architecture of the health care system within which individual technologies are used (see Annex 1). For the purposes of this paper, we focus on the use of HTA to inform decisions about the use of individual technologies, notably about inclusion in a benefit package. It is important, however, that the context is borne in mind, or efficient HTA for individual technologies may not result in optimal use of those technologies within the health care system because of problems elsewhere in the system. We can also note the separate remits of regulatory agencies and HTA processes (i.e. that efficacy, safety and quality are essentially the regulatory remit, while effectiveness and value are the HTA remit – both can be concerned with the benefit-risk balance but from different perspectives).

3. The evolution of HTA

It is helpful to note the ways in which HTA has evolved in different health care systems around the world. Battista and Hodge (2009) conclude from analysing a number of country's experiences with implementation and operation of HTA that HTA goes through three different phases of development. These are summarised in Table 1 below and are the 'emergence', 'consolidation' and 'expansion' of HTA. Under each phase, one needs to answer the following questions:

- the rationale for HTA (Why is it being done?);
- the definition of the scope and breadth of HTA (What products, services or systems is the HTA covering?) This covers issues such as HTA topic selection;
- the methods and organizational models of HTA (How is HTA conducted?) This covers issues around governance and organisation, evidence requirements and assessment methods;
- the knowledge transmission strategies (Then what happens?). This covers issues relating to HTA dissemination and implementation.

Table 1: The 'natural' history of HTA development

	Emergence	Consolidation	Expansion
Why?	<ul style="list-style-type: none"> • Convergence of needs, demands, and supply • Key individuals are "champions" of HTA • Receptive policy/political environment 	<ul style="list-style-type: none"> • Early successes attract interest of more decision makers • Expansion of demand for HTA products • Formalized priority settings process 	<ul style="list-style-type: none"> • HTA as part of official political discourse • Increased demand for diversified products
What?	<ul style="list-style-type: none"> • Narrow interpretation of health technology • Focus on high intensity technology (e.g., imaging) • Exclusion of pharmaceuticals 	<ul style="list-style-type: none"> • Broadening of scope of HTA • Possible addition of pharmaceuticals • Shift from specific technologies to care processes for the management of health conditions 	<ul style="list-style-type: none"> • Further broadening of scope of HTA (pharmaceuticals, public health, delivery models, social services) • Existing practices and new interventions
How?	<ul style="list-style-type: none"> • Modest resources, at times project or deliverables specific • Minimal scientific capacity 	<ul style="list-style-type: none"> • Expansion of scientific team • Modest addition of resources • Research partnerships sought 	<ul style="list-style-type: none"> • Significant increase in resources • Expansion of scientific team and partnerships • Diversification of products • Clinical practice guidelines
And, Then What?	<ul style="list-style-type: none"> • Knowledge translation minimal • Efforts directed to policy makers, often by means of personal communication 	<ul style="list-style-type: none"> • Progression of knowledge translation efforts • Broadening of targets audiences 	<ul style="list-style-type: none"> • Consolidation of multiple target audiences • Specialization of KT instruments • Increased proportion of resources to KT

Source: Battista and Hodge (2009)

However, such a history has also to be linked to the evolution of health care systems (Towse et al. 2011). Where health care is predominantly paid for out of pocket, which health care services and products are funded is a product of the decisions made by individual patients and their doctors. There is little incentive for collective decision making about health care technologies, other than in relation to questions as to whether services such as vaccination are provided by the public sector. Whilst, in principle, there would be a role for HTA in a self-pay market in providing evidence to doctors and patients about "what works," opportunities for dissemination may be limited, and it is not clear who would fund such an exercise.

As public insurance funding develops, it is in governments' interests to ensure that claims on those funds are justified. However, it is often some time before government-sponsored insurers begin to actively manage health care providers. Initially, they may simply pay bills on a "fee-for-service" basis. The initial focus of HTA may be on those services which are highest cost. Over time, however, more active purchasing is likely to evolve. Where health care funding is predominantly collective (for example, in a fully taxpayer funded system) decisions about health care may become increasingly taken at the level of the payer, rather than the provider. Governments and other third party payers will argue it is in the interests of all members of society as enrollees or taxpayers that funds are used efficiently. Ultimately, all services will be seen as candidates for HTA and key aspects of system architecture such as payment mechanisms and incentives will also come under scrutiny (see Annex 1).

4. The evolution of HTA systems in Asia

Brief factual summaries of the status of HTA and relevant parts of the health systems of the participants in the meeting are set out in Annex 2. It is difficult to summarise a complex picture, but we can identify the following:

- There is a trend towards increased coverage of health care services including pharmaceuticals. Even in the case of Singapore, which places a strong emphasis on personal responsibility, government schemes to provide support for citizens are expanding.
- Most health care coverage is provided by publicly funded payers (including social insurance) with few private insurers; hospitals are both public and privately owned (most hospitals are publicly owned); primary care is both publicly and privately provided (most primary care services are privately provided – but paid for by public payers).
- Use of, and interest in use of, HTA has been increasing, albeit at very different rates – in part reflecting differences in health care systems and the state of evolution of these systems;
- Several participants are using HTA to assess medical equipment purchases, and a number are also using HTA to inform the development of clinical practice guidelines.
- There are important differences in how pharmaceutical reimbursement decisions are taken. Some participants have both an "essential" list and a broader list of drugs made available by payers. Whilst all apply listing criteria, formal HTA is used by some participants but not others. HTA in some cases includes the use of cost-effectiveness analysis but in others focuses on clinical benefits with pricing addressed separately.
- In most, but not all, cases there is a clear decision maker for whom the HTA assessment report is for. The length of process varies, with at least one participant (Malaysia) having a separate "rapid" assessment process which differs from the longer routine process.
- Where formal HTA is used in decisions about listing of pharmaceuticals, the links to pharmaceutical pricing differ. In some cases pricing and listing is integrated; in others, it appears to be separate.
- Often, it is not at all clear what happens after decisions using HTA are made, i.e., whether that leads to optimal use of a drug, device or clinical practice guideline within the health care system.

Part B: Topics for the Meeting

5. Separating decision making, assessment and appraisal

In order to make sense of the three questions the meeting is addressing it is helpful to make an important distinction between decision making, assessment, and appraisal. These can be defined as follows:

- **Assessment:** the technical assessment of technologies or care options to develop or synthesize evidence on benefit, need, impact, cost, context etc. Assessments are undertaken by HTA experts.
- **Appraisal:** the appraisal (consideration - formal or informal) of evidence from **assessments**, alongside other relevant information (e.g. availability of financial and other resources, political or system priorities) to develop recommendations for a
- **Formal decision** about what technologies/care to offer/provide. Decisions are made by those with relevant responsibility/authority in the health care system.

The appraisal of assessments and other relevant evidence can be complex. Decision makers may undertake appraisal themselves, or (particularly when decisions are likely to come under public scrutiny) may seek help from expert advisors and/or formal structures such as an expert committee or external body with representation or input from relevant stakeholders (patients, clinicians, and the life sciences industry.)

It is helpful to separate these individual activities from the division of responsibility between HTA bodies and payers and/or the Ministry of Health. This is because HTA bodies may be responsible for some or all of the following:

- Selecting topics, time lines, and the questions for analysis
- Undertaking HTA assessment in-house;
- Commissioning HTA assessment from others – e.g. universities, research institutes;
- Appraising evidence from HTA (internal or external) to provide advice or recommendations to decision makers (individuals or bodies/committees);
- Making decisions;
- Dissemination and implementation.

For example, in the context of individual technologies:

- In Australia the MSAC appraises technologies and services to go on the Medical Benefit Scheme, making recommendations to the Minister, and the PBAC appraises drugs to go on the Pharmaceutical Benefit Scheme. Assessments are subcontracted to academic groups. However, the PBAC process operates to a tight timetable and is driven by a manufacturer's submission. The MSAC process can take much longer, and referrals are made from several bodies.
- NICE in the UK subcontracts the assessment of evidence to academic groups. It manages the topic selection process on behalf of the Department of Health, but Ministers make the final decision on NICE's programme. NICE has Appraisal Committees who make recommendations and NICE issues formal guidance to the health system. NICE also develops clinical practice standards and provides evidence reviews which can be accessed by local decision makers. It also has an increasing focus on dissemination and implementation.
- In Germany, IQWiG assesses the evidence on new drugs and other technologies in-house and appraises the evidence also, making a recommendation to the Federal Joint Committee (G-BA) of health insurers. However, the G-BA reappraises the evidence assessment of IQWiG and may reach a different decision. Topics are referred to IQWiG but it can also initiate assessments itself.

A characterization of elements of HTA systems from Sorenson et al (2008) is included as Annex 3.

6. What information do decision makers need?

Decision makers require information which is:

- **Timely.** As noted by Drummond et al. (2008) there are several aspects to this. Firstly, when new technologies are available, clinicians and patients expect quick decisions as to whether they can have access to them. Secondly, HTA is not a “one-shot” activity and decisions need to be reviewed from time to time in the light of new evidence or treatments. However, this requires transparency in regard to optimal timing of such reviews and preferably criteria that might trigger a review, whether initiated by the manufacturer or the decision maker. Thirdly, decision makers may themselves request evidence to review a health technology, for example, if budget expectations have been exceeded or if there is a safety concern.
- **Relevant.** Information has to address the particular issue that the decision maker is, or should be, concerned about. This means that the technologies reviewed and the aspects of their performance considered (e.g., clinical and wider benefits, price, overall cost, cost-effectiveness, etc.) have to be of importance to the decision maker. Similarly, in the case of a particular technology, if the review is too broad, then an HTA body may spend time looking at evidence that is not relevant to the particular question of concern to the decision maker. There may be very limited evidence for the issue of concern. However, a full assessment of this evidence is most important.
- **From appropriate methods, well applied.** The methods for identifying, analysing and assessing the evidence must be thorough and scientifically appropriate, given the nature of the decision.
- **Using appropriate processes.** In addition, the process of conducting the assessment must be robust, and stand up to scrutiny.
- **Useable.** The assessment must be reported to the decision maker in a way that enables the decision maker to understand and act on the findings.

7. How can HTA best meet these requirements of decision makers?

We can look at the four elements we have identified as being of importance to the decision maker.

- **The issue of timeliness** can be approached in several ways:
 - Knowing how many health technologies with significant potential health and / or budget impact are on the horizon. Such “horizon scanning” exercises can help HTA bodies plan their capacity for review and also alert decision makers and budget holders as to the potential impact on the health care system.
 - Having different types of HTA processes and timeline – for example a “rapid” assessment and a “full” assessment. The former can be designed to ensure timeliness of response, while the latter could lead to a later review.
 - One issue to be addressed is the extent of the transferability of evidence from other jurisdictions. Local context for evidence can be important, but it is not realistic to expect health technology providers to collect evidence in every jurisdiction. Evidence from elsewhere, if relevant, can reduce timelines.
 - Increasing use of “managed entry agreements” in response to increasing pressures on health care systems to manage costs while allowing patients access to promising and/or expensive new treatments.
 - Having a standard review period (e.g., two years) when an HTA body looks at whether there is any relevant new evidence. If a standard review period is to be considered, then additional criteria related to the selection of technologies for review should be included. It is not practical or reasonable for decision-makers or manufacturers to assume all technologies would be subject to a full reassessment at a set time period.
 - Having a “trigger” process whereby the decision maker, or the HTA body, or key stakeholders in the health care system, or the health technology provider can request a review if, for example, significant new evidence becomes available.
- **The relevance issue** can be addressed by:

- A priority setting process for selecting topics to be reviewed. As Drummond et al (2008) put it, “as with all other healthcare resources, the resources used in HTA should themselves be used in a cost-effective manner.” In the case of pharmaceuticals, many jurisdictions require the assessment of all new drugs and formulations. Even here the nature of the HTA review may differ. More generally, priority setting criteria need to be agreed with decision makers, so that the resulting reviews are deemed of importance. Stakeholders in the healthcare system can be involved in the process of applying the criteria, i.e. “given what matters to decision makers, which technologies we are using or are thinking of using meet these criteria?” The most effective use of HTA might be when technologies are one or more of (i) expected or claimed to have the potential to have a major health impact for individual patients, (ii) likely to have a major budget impact either because of the price of the technology or because of the numbers of patients who could use the technology, (iii) subject to a lot of uncertainty as to their benefit, and (iv) where the results of the HTA may be expected to impact on clinical practice.
- A scoping exercise for each technology reviewed, in which the HTA body and the decision maker agree on the exact questions that the decision maker wants answered. In some cases, the questions are self-evident as they are defined by the remit of the decision maker. For example, there may be a binary yes/no question as to whether a drug is reimbursed for all of its licensed indications, and the criteria on which judgment is to be made may be unambiguous. However, in most cases, there are a number of different decisions that can be made and the focus of effort needs to be set out in advance. The HTA body may have the detailed knowledge to set out the scope in response to the decision makers concerns, but the decision maker may be expected to “sign off” on the scope before the HTA review begins. In a number of jurisdictions where “scoping” is used, the technology suppliers and other interested stakeholders are also given the opportunity to comment on the HTA body’s proposed scope.
- **Using appropriate methods well applied.** This covers sources of evidence, how it is analysed, and how it is assessed.
 - There are a number of internationally recognized guides to good practice in these areas. Most HTA bodies adapt one or more of these to reflect local preferences on decision maker perspective, methods, and available resources.
 - There is a general issue of proportionality. The resources expended by reviewers and providers of a technology in an assessment process needs to be realistic given the size of the likely spend on the technology and other priorities for health system reform. An over-engineered HTA system can manifest in the form of delayed decision making as well via excessive costs. This is especially important in systems with limited capability and capacity. Applying sophisticated HTA processes to all new technologies may not make sense.
 - One important aspect of proportionality is the requirements for evidence. Where possible it makes sense to use evidence generated elsewhere if it is transferable. We can note the growing investment in some parts of Asia in disease registries. While the resulting data may not always have the necessary rigour and quality for use in all HTA processes, there may be opportunities to aid decision-making where such data is used to make better decisions on the overall treatment of specific conditions.
 - Correct methods need people with the abilities (and responsibility/accountability) to apply them credibly. This typically requires an academic infrastructure to support the work of an HTA agency, including training and developing its staff.
- **Using appropriate processes.** Assessment processes differ, for example, as to whether the technology supplier is required to make a submission of relevant evidence, which drives the assessment process, or whether an independent review of all evidence is initiated to which the technology supplier can contribute. The opportunity for other interested stakeholders to submit evidence or comment on a draft assessment before it is sent to the decision maker also varies.
- **The need for the assessment to be useable.** We discuss in the next section the nature of the link between HTA and decision making.

8. How can HTA and decision making best be linked?

We can think of HTA and decision making as an issue of supply and demand. HTA assessments are supplied to decision makers who are the customers for the HTA "product". In the absence of an interested decision maker, HTA becomes a product without a customer, and therefore has little immediate practical value. The nature of the engagement between decision maker and the HTA assessment is crucial.

Drummond et al. (2008) set out as one of their 15 key principles: The link between HTA findings and decision-making processes needs to be transparent and clearly defined. They add:

"A clear distinction needs to be made between the HTA itself and the resulting decisions. The link between the assessment and the decision will be different in various settings, but in all cases it should be transparent."

We can note that, in a review of 14 HTA organisations around the world, Neumann et al. (2010) found that this principle was one that was observed in only half of the bodies they reviewed.

We thus have two key elements to an effective link between HTA and decision-making:

- (i) *An alignment of requirements (i.e., of "supply" and "demand")*. Clearly, we might expect the ability of the HTA body to meet decision maker requirements for timely, relevant, robust and useable information to be a key part of achieving this alignment. However, there may well be situations in which the HTA body does not have a single decision making body to engage with. Even when the Ministry of Health is the decision maker, approval of a technology may not mean that it is used optimally in the health care system. The decision makers on use of the product (for example clinicians, or the committee of a hospital) may have other concerns that were not addressed by the HTA review. Issues that could be explored include:
 - a. How to "sell" HTA recommendations to decision makers?
 - b. How to make all relevant decision makers a part of the HTA process?
- (ii) *Clarity about "who does what?" and the need for the link to not only be effective but be seen to be effective*. We can expect that as the HTA system and its goals evolve, decision makers move from requiring only technology assessment to needing assistance with the appraisal of evidence and with criteria for decision making. However, "who does what?" should remain clear. For example, the criteria used by decision makers will evolve, but the role of the HTA element of the process will be to assess and report evidence relevant to these criteria. The opportunity to include stakeholders in the process could increase – for example, inviting comment on draft appraisals before final decisions are made.

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- Annex 1: Definition of health technology and of HTA

Annex 1: Definition of health technology and of HTA

A health technology is defined by HTAi as

An intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation. Health technologies include pharmaceuticals, devices, procedures and organizational systems used in health care.

Health Technology Assessment (HTA) is defined in the HTAi mission as

a scientifically based and multidisciplinary means of informing decision making regarding the introduction of effective innovations and the efficient use of resources in health care.

We can categorise HTA into three types (Towse et al., 2011):

- HTA aimed at **appraisal of individual technologies**, or groups of closely related technologies
- HTA aimed at developing **clinical practice guidelines** or the way in which individual technologies are combined with and within a delivery system to manage patient clinical pathways efficiently
- HTA which is about the **efficiency of the organizational systems or architecture of the health care system**

The focus of HTA on individual technologies can be on safety and efficacy (we noted the separate remit of regulatory agencies in this area), or for HTA bodies, on effectiveness and relative effectiveness or added therapeutic value, on cost-effectiveness for the health system, or on a broader societal view of added value or cost-effectiveness. Technologies can be inside or outside of the health system. Examples of technologies at different levels are illustrated below:

Specific technology (tool)	Area	Type
Aspirin, lipid-lowering drugs, ACE inhibitors	Intervention provided in health-care services	Drug
Stent/stenting Coronary artery bypass grafting (CABG)	Intervention provided in health-care services	Device/procedure
Rehabilitation programme Educational interventions	Intervention provided in health-care services	Multifaceted intervention
Disease management programme for CVD	Intervention applied to the health-care system (organization of service provision)	Multifaceted intervention
Pay for performance (e.g. targeting higher prescription of aspirin for CVD)	Intervention applied to the health-care system (payment of providers)	Policy
Smoking ban	Intervention outside health-care system	Policy

Source: Garrido et al. 2008

Annex 2: Short summary of HTA arrangements of the eight participants

This Annex provides a brief summary for each country covering:

- The extent of health care coverage for most citizens
- The formal arrangements for listing and/or pricing of drugs and devices
- The nature of any formal arrangements for HTA, including the listing or pricing of drugs and devices, clinical guidelines, and procurement by hospitals

China

China has achieved health care coverage above 95% of the population through three major schemes, the Rural Co-operative Medical Scheme run by the Ministry of Health (MoH), and two urban schemes for urban workers and urban residents which are both administered by the Ministry of Social Security. There are substantial co-payments particularly for treatment outside of hospitals.

Listing decisions for pharmaceuticals are made at the national level (for both the Insurance List and the Essential Drugs List), at the Provincial level (the Provinces can add to the national list) and at tertiary level hospitals (where a subset of the available drugs are usually included in the formulary). Hospitals at the grass-roots level (first and secondary level) such as community care centres and township health centres can't add extra drugs outside of the Essential Drug List onto the formulary. There is no requirement for any use of HTA in these listing decisions. However, some pharmaco-economic studies are conducted by companies and by academic groups, and some HTAs are required by the MoH for treatment procedures and high-tech devices. Academics have published two sets of pharmaco-economic guidelines.

There is an HTA body which is part of the MoH, called the China National Health Development Research Center (CNHDRC). It has been collaborating with NICE International on issues relating to clinical practice guidelines and payments for clinical pathways.

Japan

Universal coverage health insurance scheme was established in 1961, with Employees Health Insurance and National Health Insurance for non-employees. Co-payment by the patient is 30% for both inpatient and outpatient care for the general public, and 10% for the advanced elderly (75 years old and over).

Reimbursement price of new technologies including drugs and devices which are covered by the insurance scheme is determined by the Ministry of Health, Labour and Welfare (MHLVV) upon the consultation with the Central Social Insurance Medical Council (Chuilvo). For example, the price of a new drug is determined on the basis of comparison with existing drug from the same category, with some premiums for innovation, usefulness and market size. If there are no existing drugs in the category, the price is determined based on the costing data submitted by the manufacturer. In both cases foreign price adjustment is applied under certain conditions. Drug prices are revised biennially based on the wholesale price survey.

In the early 90's, the Ministry allowed the manufacturers to submit economic evaluation data for drugs on a voluntary basis. However, they were not necessarily used for pricing decision. In April 2012, the Ministry created a new committee named "Cost-Effectiveness Evaluation Committee" under Chuikyo. In the committee, some issues around health technology assessment have been discussed, such as selection criteria of technologies to be evaluated, evaluation methods, and use of evaluation results.

The Committee agreed to a principle that technologies which fulfil a number of categories would be subject to assessment. These include: the existence of alternative treatments; a potential large budget impact; and established safety and efficacy. Drugs and devices for rare diseases are excluded. The health economic assessment is only to be one part of the health technology assessment, and not the sole basis for deciding on listing or reimbursement price. Additionally, the judgment of the health economic assessment should allow certain flexibility, and rigid application should be avoided.

Korea

Korea has universal coverage managed by a single insurer: the National Health Insurance Program (NHI). This is divided into (i) the Ministry of Health, Welfare, and Family Affairs (MIHWAF), responsible for the regulation and policy, (ii) the National Health Insurance Service (NHIS), which manages enrolment in the NHI, (iii) the Health Insurance Review and Assessment Service (HIRA), in charge of reviewing insurance claims and assessing the quality of healthcare, and (iv) the healthcare providers. Insured individuals pay a portion of the health cost which differs according to the level and type of medical care.

Every new health technology should be assessed in terms of its safety and efficacy. Therefore, any new drug or other technology goes through several steps before inclusion on the reimbursement list. First, the Korean Food and Drug Administration (KFDA), in the case of drugs, or the Committee for New Health Technology Assessment (CNHTA), in the case of other new technologies, analyses the product and gives approval to enter into the market. Second, HIRA reviews the relevant information (e.g. safety, effectiveness and cost effectiveness) for drugs and makes a recommendation. Since 2007 all new pharmaceuticals submitted to be included in the positive list are required to submit a cost-effectiveness analysis using the Guidelines for Economic Evaluation of Pharmaceuticals in Korea (KPEG), prepared by HIRA. In 2008 the Health Care Technology Enhancing Act created a new independent agency: the National Evidence-based Healthcare Collaborating Agency (NECA). This agency reports on medical devices, diagnostics, procedures and some drugs. An external expert review committee selects NECA's study topics. The final decision on listing is made by the MIHWAF. Additionally, in the case of drugs, a price negotiation is undertaken by the NHIS.

Malaysia

Malaysia has dichotomous health care system, public and private. The public healthcare system in Malaysia is funded by the government principally through the Ministry of Health (MOH). Healthcare expenditure has been escalating over the years which is partly contributed by medicines expenditure increasing by an average of 15% annually.

In Malaysia, the principal regulatory authority responsible for regulating pharmaceuticals is the Drug Control Authority (DCA). All medicines to be marketed and used in Malaysia must be registered with the DCA. A registered drug must be listed on the MOH Drug Formulary before it can be used within the MOH facilities. The MOH Drug Formulary is a comprehensive list of medicines which have been selected and approved for use by the MOH Drug List Review Panel. Currently (as at April 2013) there are 1591 items in the MOH Drug Formulary. All applications for formulary listing are submitted to the Pharmaceutical Services Division which acts as the Secretariat for the MOH Drug List Review Panel. The applications for formulary listing are subjected to evidence-based evaluation which takes into account the safety, efficacy, and cost analysis of the medicine. Whenever available cost-effectiveness analysis will also be done.

Pharmacoeconomic evidence is the key element considered for formulary listing. However, in view of the limitations in obtaining relevant pharmacoeconomic evidence, the MOH is encouraging pharmacoeconomic research in Malaysia. In line with this, the Pharmacoeconomic Guideline for Malaysia was launched on 31st March 2012.

The MOH also provides a mechanism to use medicines not listed in the MOH Drug Formulary. Special Drug Approval requests need to be submitted to the Director General of Health Malaysia to obtain permission to use these medicines. However approval is limited to life-saving medicines which are needed due to failure to treatment with all alternatives available in the formulary.

HTA has a role in the health care system in Malaysia. The Health Technology Assessment Section (MaHTAS) produces two types of reports: HTA Reports and Technology Review (TR) Reports. The HTA reports take between 8 and 16 months to prepare and are reviewed by external experts. Between 1997 and 2012 the HTA unit produced 56 of these reports. 14 per cent were related to the use of drugs, the majority (37%) are on public health programs.

In response to urgent health technology information requests (mainly from the government healthcare providers), the HTA also prepares a second type of report, the TR. These reports need a maximum of 2-4 months and are sometimes not reviewed by external experts. The section (MaHTAS) wrote 232 TR reports between 2001 and 2012 out of which 8% were related to drugs, but the majority of reports were on medical devices (33%) and procedures (29%). The demand for TR reports is in part a response to the MoH requirement for an HTA unit recommendation before approving purchase of medical devices costing more than RM500,000 (US\$165,000). The spirit of this circular is to have an HTA done on "expensive &/or big volumes(quantity)" medical devices that are to be tendered for purchase by MoH).

From 1995 onwards MaHTAS is mandated to do HTA on new health technologies to be adopted or procured by MoH. Since 2001 the MaHTAS also has the responsibility to develop and implement national evidence-based Clinical Practice Guidelines.

HTA recommendations take into consideration factors such as evidence of safety and efficacy/effectiveness mainly but sometimes evidence of cost/cost-effectiveness from other countries are included in the review. Results of HTA analysis from other HTA agencies in other countries (when available) are also included in the HTA/TR reports.

These HTA and TR reports are endorsed by the Council of HTA-CPG in the MoH in which the chairman of this council is the Director-general of Health Malaysia. The members include Deans of Government Medical Universities, the Master of the Academy of Medicine Malaysia, President of the Association of Private Hospitals, President of Malaysian Medical Association and all Deputy Directors-General of Health as well as Directors of various divisions in the MoH.

Philippines

The health sector is principally financed by private sources. Out-of-pocket expenditures correspond to 53 per cent of the health expenditure.

The government is aiming to achieve "universal coverage" focussing on increasing the number of poor families covered by the Philippine Health Insurance Corporation (PhilHealth). This agency is financed by premium contributions or prepayment from households and budget appropriations from government. By 2008 73 per cent of the population was covered.

The Food and Drug Administration (FDA) regulates pharmaceutical products. The FDA also identifies a list of essential drugs which is reviewed and approved by the National Formulary Committee. This list is called Philippine National Drug Formulary (PNDF) and is used by the PhilHealth for reimbursement of expenses on drugs. The ceiling price for reimbursement is based on the Drug Price Reference Index, which is a publication of the range of prices of a selected group of drugs. In order to reduce out-of-pocket expenditures, maximum prices of selected drugs are set by a price advisory council tasked for this.

In 1999 a committee of health technology assessment (HTA) was established by PhilHealth. The objective was to include the cost-effectiveness analysis of tests and treatments in the development of reimbursement policies. The most important influence of the committee is on drug reimbursement policy. The drugs which are recommended by the HTA committee are included in the PhilHealth positive list. These are drugs that are not in the PNDP list, but are reimbursed by PhilHealth. After a year these drugs are excluded from the positive list while waiting for the National Formulary Committee analysis to be incorporated in the PNDP.

Additionally, the HTA committee is also responsible for the appraisal and dissemination of clinical practice guidelines as well as for the evaluation of the effectiveness and safety of medical and surgical procedures.

Singapore

The health care system in Singapore is based on the idea of promoting shared responsibility through a co-payment system while at the same time the government seeks to provide affordable healthcare to all Singaporeans.

Universal health coverage is provided by tax-financed government subsidies available to all citizens at public hospitals and government polyclinics. Co-payments are differentiated by income as well as choice of wards with different physical amenities. The second level of protection takes the form of Medisave, a compulsory medical savings account scheme for each Singaporean which can be drawn on to pay for their share of medical treatment. Medisave also serves to allow families to save up for their future healthcare needs, a large portion of which will materialise in post-retirement years. The third tier of support is provided by the national basic insurance schemes, MediShield and ElderShield. MediShield risk-pools premiums paid by Singaporeans to provide protection for large medical bills, while ElderShield protects against long-term care expenditures in old age. Finally, there is also an endowment fund, Medifund, which provides the ultimate safety net to ensure that no Singaporean is denied basic healthcare because of an inability to pay. Medifund covers not just the lower-income but also those who earn more but face large bills relative to their income.

These multiple tiers of financing ensure a progressive healthcare financing system where government subsidies go to the most needy in society. Our financing system acknowledges that there is no free healthcare, and there is a need to co-share the burden of financing across individuals, employers, government and non-profits in an equitable yet sustainable way. This has allowed us to achieve outstanding results in delivering good quality and affordable basic healthcare to all Singaporeans.

To guide coverage decisions, the Ministry of Health has an expert panel Drug Advisory Committee responsible for recommendations of which drugs should be included in the Standard Drug List 1 and 2. These correspond to the lists of drugs subsidized in the public sector. The patient must pay a small fixed amount for those medicaments in the list 1 and 50 per cent of the price of the medicaments in the list 2. The committee takes into consideration relevance and the cost-effectiveness of the medicament in its recommendations. The Ministry of Health makes the final decision including other considerations such as budget impact, clinical value and policy priorities.

Within the Ministry of Health, the Health Technology Assessment (HTA) branch carries out HTA to support decision-making and policy development. The branch also administers the MOH Clinical Practice Guidelines programme, which develops evidence-based clinical guidance for doctors in Singapore. The Pharmacoeconomics and Drug Utilisation Unit (PEDU) provides secretariat assistance to the Drug Advisory Committee, including HTA functions. The Policy Research and Economics Office carries out economic evaluations and undertakes policy research which facilitates and supports the development of robust, forward-looking healthcare policies, and healthcare programmes which support the needs of the population.

Taiwan

Taiwan has a centralized National Health Insurance plan covering virtually all of the population. Providers are paid on a fee-for-service basis, but are subject to global budget caps that can be used to reduce fee levels across the board. Reimbursement levels for drugs are established by the Bureau of National Health Insurance (BNHI) based on the degree of "clinical improvement" and in relation to the median of 10 reference countries or to comparable drugs (if no or minimal improvements). HTA applied to drugs was first established in 2008 as a pilot project. The Centre for Drug Evaluation (CDE) HTA team complete the assessment report, then this report goes to the Drug Benefit Committee (DBC) in BNHI for their decision making on listing or not and for price determination. Beginning in 2013, as part of Second Generation National Health Insurance reform, the pilot project is being replaced by a new agency unit for HTA. In addition to the original process whereby DBC appraise the HTA report and make recommendations, the recommendations are now required to be approved by a new committee, the 'Joint Meeting of Pharmaceutical Benefit and Reimbursement Schedule.' A team in the ministry is currently putting together a proposal for the new National Institute for Health Technology Assessment (NIHTA). It is expected that the overall process will become more transparent and engage stakeholders more actively.

HTA in Taiwan is currently operating in the drug and medical device reimbursement areas.

Thailand

Thailand achieves universal coverage through three main Health insurance schemes — one covering government employees and their families — the Civil Servant Medical Benefit Scheme (CSMBS), one covering private sector employees — the Social Security Scheme (SSS), and a third covering all other citizens - Universal Coverage (UC). All three schemes have their own health service benefit packages and also have their own payment systems.

The Thai Food and Drug Administration develops the National List of Essential Medicines (NLEM). NLEM works as a reimbursement list for all three schemes. HTA, including economic evaluation, budget impact analysis, is an input into decision making. It is mostly undertaken by the Health Intervention and Technology Assessment Program (HITAP). There is a National guideline for HTA and a Guideline for HTA process intended to achieve good governance. Cost-utility analysis (CUA) is recommended to be the method of choice when data and resources are available. Otherwise, cost-effectiveness analysis (CEA) is acceptable. HITAP also undertakes HTA on non-drug interventions.

Due to the fee-for-service payment, the CSMBS beneficiaries tend to have more access to the drugs unlisted on the NLEM. UC and SSS have both a disincentive to provide drugs unlisted on the NLEM and a disincentive to provide costly drugs listed on the NLEM as they have budget caps.

Annex 3: A characterization of the elements of HTA systems

HTA governance and organization	<ul style="list-style-type: none"> • Institutions/committees • Entities responsible for reviewing HTA evidence for priority setting and decision-making • HTA agenda-setting body • Reimbursement requirements and limitations • Stakeholder involvement • International collaboration
HTA topic selection and analytical design	<ul style="list-style-type: none"> • Governance of topic selection • Criteria for topic selection • Criteria for assessment • Criteria outlined or publicly available • Analysis perspective • Duration required to conduct assessments
Evidence requirements and assessment methods	<ul style="list-style-type: none"> • Documents required from manufacturer • Systematic literature review and synthesis • Unpublished data/grey literature • Preferred clinical study type/evidence • Type of economic assessment preferred or required • Availability of guidelines outlining methodological requirements • Methodological requirements covering issues such as choice of comparator, specification of (preferred) outcome variable, subgroup analyses, type of costs (direct or indirect), incremental analysis required, time horizon, equity issues, discounting, modelling, sensitivity analyses, CE or WTP threshold, sensitivity analyses, missing or complete data and support for methodological development
HTA dissemination and implementation	<ul style="list-style-type: none"> • Channels for HTA dissemination • Use of HTA results • Evidence considered in decision-making • Any reported obstacles to effective implementation such as legal proceedings, etc. • Formal processes to measure impact • Process for re-evaluation or appeals • Accountability for stakeholder input • Transparent/public decision-making process

Source: Sorenson et al. (2008)



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