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A STAR IN THE EAST

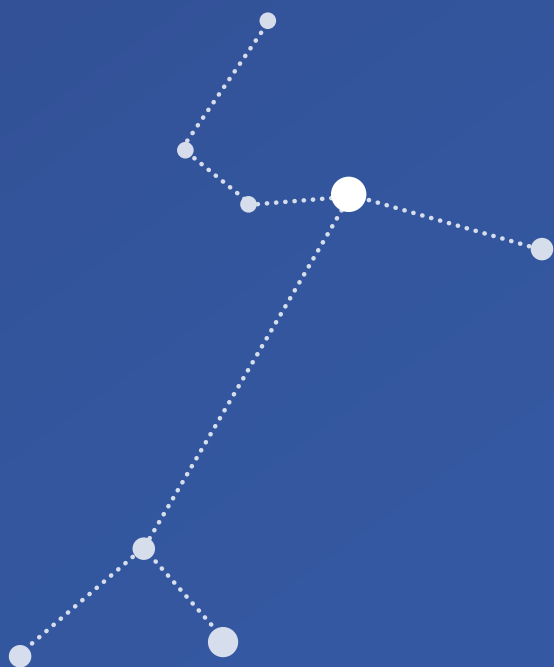
A SHORT HISTORY OF HITAP



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PREFACE AND ACKNOWLEDGEMENTS

The initial plan for the history of Health Intervention and Technology Assessment Program (HITAP) was drawn up by Dr Tony, together with guidelines for the selection of key informants and the conduct of the interviews. Dr Tony also drew up the basic structure of the book. The work on collecting data and writing up the text took place over August – November 2015. The key sources of information came from interviews with key informants. These interviews were supplemented by reviews of relevant English and Thai language documents, including academic and other publications by HITAP and its collaborators, publicity material prepared by HITAP and NICE for general purposes, and from relevant websites. The three authors corresponded throughout the period and Dr Tony spent three weeks in Thailand working face to face on a daily basis with the two local authors. All interviews were recorded with the permission of the informants, and were subsequently transcribed, summarised and translated by members of HITAP staff. The interviews were conducted by at least two of the authors; only occasionally were all three present. Wherever possible, accounts of events from more than one informant were cross-checked and, where necessary, followed up with a supplementary conversation. The typescript was drafted in sections by one of the authors, then shared with the other two, corrected and edited. The final typescript was edited from start to finish by Dr Tony and shared with the other two authors for a final check before submission to the publishers.

We would like to record our thanks to the Prince Mahidol Award Foundation for funding support and for launching the book at the 2016 Prince Mahidol Award Conference in Bangkok. We owe a great of gratitude to Dr Yot Teerawattananon, HITAP's "Program Leader", who gave unreservedly of his time as we struggled to unravel this history of HITAP. We have benefitted greatly from the insightful comments of Dr Kalipso Chalkidou, on whose encyclopaedic knowledge of NICE International and its partners we have drawn very extensively. Drs Viroj Tangcharoensathien and Suwit Wibulpolprasert had a vital role to play in the creation of HITAP and were crucial informants concerning the period prior

to HITAP's creation and its early days. Dr Somkid Kaewsonthi, the "mother" of Thai health economics graciously gave us a day of her time and provided much valuable information about the early days of HTA in Thailand. The tireless work of our translators and transcribers is thankfully noted. They were Ms Prateep Naiyana, Ms Anongwadee Danpan, Mr Aran Kaweerattanaphon, Ms Chalarntorn Yothasmutra and Ms Suteenoot Tangsathitkulchai. Our thanks also to Nick Timmins and Tommy Wilkinson for their critical reading of parts of the book. Finally, the accuracy of an oral history is entirely dependent on the powers of recall and the integrity of the informants. Our informants, to whom we express our heartfelt thanks, were: Dr Somkid Kaewsonthi, Ms Busakorn Lerswatanasivalee, Ms Amporn Charoensomsak (Pharmaceutical Research and Manufacturers Association), Dr Chitr Sitthi-Amorn (Saint Louis Hospital), Dr Jasmine Raoh-Fang Pwu (Center for Drug Evaluation, Taiwan), Dr Jeonghoon Ahn (National Evidence-based Healthcare Collaborating Agency, South Korea), Dr Kitima Yuthavong (Freelance academician), Dr Kulkanya Chokephaibulkit (Faculty of Medicine Siriraj Hospital, Mahidol University), Dr Samrit Srithamrongsawat (Deputy Secretary General, National Health Security Office), Dr Siriwat Tiptaradol (Consultant, National Health Commission Office of Thailand), Dr Somsak Chunharas (National Health Foundation), Dr Sripen Tantivess (HITAP Senior Researcher), Dr Suwit Wibulpolprasert (Senior Advisor, International Health Policy Program), Dr Tawee Chotpitayasunondh (Queen Sirikit National Institute of Child Health), Dr Viroj Tangcharoensathien (Senior Advisor, International Health and Policy Program), Dr Visanu Thamlikitkul (Faculty of Medicine Siriraj Hospital, Mahidol University and Chairman, Subcommittee for Development of the National List of Essential Medicines), Dr Kalipso Chalkidou (NICE International, UK), Dr Sayomporn Sirinavin (Faculty of Medicine Ramathibodi Hospital, Mahidol University), Dr Vicharn Panich (President Mahidol University Council and Chair of HITAP Foundation) and Dr Yot Teerawattananon (HITAP Program Leader and Senior Researcher).

GLOSSARY OF TERMS

Adverse Selection

A process through which there is an increasing tendency for high risk patients to dominate the clientele of insurers, leading to rising premiums which further intensifies the domination.

Capitation

A method of paying doctors or other health care providers a fixed fee per period per patient registered (sometimes differentiated according to age or sex of patient) regardless of the amount of service provided.

Community Rating

Insurance premiums set according to the average or expected use of a class of insured persons.

Comparator

One or more alternative technologies with which another is compared in cost-effectiveness analyses and health technology appraisals.

Co-payment

A sum of money paid by an insured person at the point of use of care — often a percentage of the fees due.

Cost-Effectiveness Analysis

In its most general sense, cost-effectiveness is the attainment of a given rate of output or outcome at the lowest possible opportunity cost. Cost-effectiveness analysis is method of comparing the opportunity costs of various alternative courses of action having the same benefit or in terms of a common unit of output, outcome, or other measure of accomplishment. This procedure is used when benefits are difficult to value monetarily, when those that are measurable are not commensurable, or when the objectives are set in terms of health itself.

Cost Function

A mathematical relationship in which cost is the dependent variable and rate or volume of output, throughput or outcome the independent variable. Strictly, the cost in question is the lowest cost at which each rate of output can be produced.

Deductible

An arrangement under which an insured person makes a limited contribution when health care is used and the insurer pays all other expenses.

Disability-Adjusted Life Years

Roughly speaking, the reciprocal of Quality-Adjusted Life Years.

Effectiveness

A measure similar to efficacy except that it refers to the potential effect of a particular medical technology or procedure on outcomes (commonly the health of patients) when used in actual practice.

Efficacy

The maximum potential effect of a particular medical action in altering the natural history of a particular disease for the better. Typically measured by the impact of the action under highly controlled circumstances, such as those of a clinical trial.

Elasticity

The per cent change in a variable (like the rate of use of health care) divided by the per cent change in a determinant (like personal income).

EuroQol

A name for the EQ-5D version of the QALY has five dimensions: mobility, self-care, usual activity, pain/discomfort, and anxiety/depression. The traditional EQ-5D instrument described each dimension in terms of three levels: 1 – no problem, 2 – some problem, 3 – extreme problem.

Experience Rating

Insurance premiums set according to the record of claims by an insured person.

External Validity

The extent to which the results of a study can be generalised beyond the setting in which they were derived without being misleading. Cf. effectiveness.

Gross Domestic Product

The total expenditure by residents and foreigners on domestically produced goods and services in a year.

Health Technology Assessment

Similar to cost-effectiveness analysis. HTA usually addresses the following questions: does the technology in question work? For whom does it work? How well does it work? At what cost does it work? How does it compare with other technologies deemed to be suitable comparators? It generally uses insights from economics, epidemiology, biostatistics and bioethics.

Hypothecation

A tax whose proceeds are devoted to a specific purpose only.

Internal Validity

The reliability and accuracy of a trial's results after the removal of bias. Cf. efficacy.

Markov Model

A model in which the progress of a disease with and without interventions is modelled in a sequence of time periods, each being associated with a particular measure of health, and each having a probability of moving from it to the next state.

Maximand

The entity being maximised. Commonly in HTA either health or utility.

Meta-analysis

Using statistical techniques to synthesise the results from separate but related studies in order to obtain an overall estimate of the effect of a treatment.

Moral Hazard

This is of two main types. Ex ante moral hazard refers to the effect that being insured has on behaviour, generally increasing the probability that the event insured against, such as an accident or disease brought about by lifestyle choices, will occur. Ex post moral hazard derives from the price-elasticity of demand: being insured reduces the patient's price of care and hence leads to an increase in demand by insured persons. There is nothing particularly moral or immoral about either.

Multicriteria Decision Analysis

A technique akin to cost-effectiveness analysis for helping decision-makers to take decisions. It explicitly helps decision-makers to consider factors beyond standard welfare or health maximisation models which are often treated in a somewhat ad hoc manner. Care is needed to ensure that the many potential "criteria" do not overlap and give rise to double-counting.

Narrative Review

The traditional way in which literature reviews have been done, in which the selection of items reviewed, the quality assessments, the data extraction and the conclusions and the extent to which different studies come to the same conclusion are all subjective.

Opportunity Cost

The value of a resource in its most highly valued alternative use. In cost-effectiveness and related studies (like health technology assessment) the value is usually taken in terms of the health forgone as resources are used for one health-promoting purpose rather than another.

Presenteeism

Reduced productivity at work through sickness or accidents.

Primary Research

Research that generates the data it uses.

Purchasing Power Parity

More reliable exchange rates for making international comparisons (for example of health care expenditures) than market determined exchange rates. PPPs are based on comparing the cost of a standard bundle of goods and services in each country being compared.

Quality-Adjusted Life Years

A generic measure of health-related quality of life that takes into account both the quantity and the quality of life generated by interventions. The invention and further development of the QALY was a response to the treatment of health outcomes solely in terms of survival without any weight being given to the quality of the additional years of life. It is designed for self-completion by respondents and is suited for use in postal surveys, clinics and face-to-face interviews. See EuroQol.

Secondary Research

Research that uses data (for example, administrative data) collected for purposes other than those to hand. It includes reviews of research results such as meta-analysis and systematic reviews.

Societal Perspective

Describes a wide scope of costs and effects from an intervention in order to judge whether on balance it is the general community's interest to provide it at public expense. Cost-effectiveness studies often adopt this perspective (or at least claim to) but a cost-effectiveness study can be done from any of a wide range of perspectives, some narrow and some broad, depending on the interest of the commissioner of such a study.

Systematic Review

A comprehensive and relatively unbiased synthesis of the research evidence. Essential features include the prior specification and explicit identification and scoping of research questions, the use of explicit methods for searching the literature, explicit criteria for including or excluding material, explicit criteria for appraising quality and reliability, and a systematic analysis/synthesis of research findings.

Threshold

A test cost-effectiveness ratio that sets the upper bound for health care technologies to be deemed cost-effective.

ACRONYMS

BPS	Bureau of Policy and Strategy
CGD	Center for Global Development
DALY	Disability-Adjusted Life Year
DRG	Diagnosis Related Group
EBM	Evidence-Based Medicine
FDA	Food and Drug Administration
GDP	Gross Domestic Product
HITAP	Health Intervention and Technology Assessment Program
HIU	HITAP International Unit
HPV	Human Papillomavirus
HSRI	Health Systems Research Institute
HTA	Health Technology Assessment
iDSI	International Decision Support Initiative
IHPP	International Health Policy Program
MCDA	Multi-Criteria Decision Analysis
MCHVS	Maternal and Child Health Voucher Scheme

MOPH	Ministry of Public Health
NICE	National Institute for Health and Care Excellence
NLEM	National List of Essential Medicines
NHS	National Health Service
ODI	Overseas Development Institute
PATH	Program for Appropriate Technology in Health
PCV	Pneumococcal Conjugate Virus
PEN	The World Health Organization Package of Essential Non-Communicable Disease Interventions
PPP	Purchasing Power Parity
PRICELESS SA	Priority Cost Effective Lessons for System Strengthening South Africa
QALY	Quality-Adjusted Life Year
UHC	Universal Health Coverage
WHO	World Health Organization

CHAPTER 1

A STAR IN THE EAST
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HEALTH TECHNOLOGY ASSESSMENT

The devil's business?

"A physician who changes his or her way of practising medicine because of cost rather than purely medical considerations has indeed embarked on the 'slippery slope' of compromised ethics and waffled priorities." (Loewy 1980)

"Thousands of women with advanced breast cancer are set to be denied 'last chance' medication that can give them extra months, if not years, with their loved ones." (Daily Mail 2015)

"Six breast cancer drugs are to be banned from use by NHS patients, according to the Daily Mail. How's that for 'war on women'?" (Joondeph 2015)

"The National Institute for Health and Clinical Excellence (NICE) has proposed that drugs for the treatment of dementia be banned to National Health Service (NHS) patients on the grounds that their cost is too high . . . despite NICE's admission that these drugs are effective in the treatment of Alzheimer's disease and despite NICE having approved even more expensive treatments. The effect is that thousands of Alzheimer's patients will be denied the only treatment available. It is difficult to think of this as anything but wickedness or folly or more likely both." (Harris 2005)

Fortunately no one yet has thought of hurling such charges at HITAP — Thailand's Health Intervention and Technology Assessment Program — though the time will surely come when it happens — and in public. At that time, it will be of evident importance that a proper understanding of HITAP and its work, both its current and its possible future work, be had by everyone, from the most senior ministers in government, through the chief executive officers of major private companies supplying the health care services of the country, to professionals of all kinds, especially clinicians and managers, and of course patients and the public — the clients of health care and their families and informal carers.

What is Health Technology Assessment?

In this chapter, we explore the meaning of Health Technology Assessment (HTA) and describe what we believe to be the best guide to its proper practice. It is neither a textbook nor a "how-to-do-it" guide. It is, instead, an introduction to a way of making policy whose basics should be made familiar to all. Put at its simplest, HTA is a systematic way of considering the pros and cons of alternative courses of action but, especially in the context of health care, a context that is both complicated in the sense that both "health" and "health care" are many faceted so that lots of considerations (academic, professional, political,...) need to be borne in mind simultaneously, and complex in that woven into these varied considerations are questions of medical science, economics, politics, ethics (values), and aspiration. The quantitative is intrinsically interwoven with the qualitative. The context is one in which *we have to choose*. There is no easy escape route — for example, by doubling the budget or assuming that everyone agrees, or leaving things to the "experts". The theory is tough, the science is hard, the economics difficult, and the statistics advanced. The unavoidable trade-offs are often agonising, much is uncertain, reputations are at stake, and getting things wrong costs lives.

A newcomer to the field of HTA is apt to be bewildered by its terminology and its many associated acronyms. Commonly encountered terms (near synonyms) include: behavioural cost analysis (BCA), benefit-cost analysis (BCA again), budget-impact analysis (BIA), comparative effectiveness research (CER), cost-benefit analysis (CBA), cost-consequences analysis (CCA), cost-effectiveness analysis (CEA), cost-efficiency analysis (CEA again), cost-minimization analysis (CMA), cost-per-QALY analysis (CQA), cost-value analysis (CVA), distributional cost-effectiveness analysis (DCEA), extended cost-effectiveness analysis (ECEA), generalised cost-effectiveness analysis (GCEA), health technology assessment (HTA), intervention cost-effectiveness analysis (ICEA), relative effectiveness assessment (REA), sectoral cost-effectiveness analysis (SCEA). To these, the World Health Organization (WHO) in its wisdom has added a nineteenth, "Health Intervention and Technology Assessment (HITA)" as though here was some possibility of doubt that the technologies in question are interventions, or that the term "technology" might not embrace as wide a range of interventions as one may choose to subject to analysis¹.

Another source of confusion is "technology", which conjures up pictures of machinery, tubes, wires and computers: so-called "hi-tech" medicine. Some health care interventions are of course like that but "technology" is simply a "way of doing something" and, in HTA, any procedure, piece of equipment, drug or organisational form is a technology and so capable, at least in principle, of being assessed as such (in practice things may get tricky — as we shall shortly see). More confusion can arise from the enormous variability in the quality of studies that identify themselves as being HTA (or kindred approaches). Yet another source of confusion is that the simple inclusion or omission of a particular cost or consequence seems capable of transforming a study from being one type into being another.

¹ The most cynical of us three authors awaits eagerly the advent of CEAC (CEA for childhood), or CEARD (CEA for rare diseases), or GCEAE (Grand CEA of everything)!

Definitions also abound. The WHO leads the way with HTA is "the systematic evaluation of properties, effects, and/or impacts of health technology. It is a multidisciplinary process to evaluate the social, economic, organisational and ethical issues of a health intervention or health technology. The main purpose of conducting an assessment is to inform a policy decision-making. Considering the definition of health technology, as the application of organised knowledge and skills in the form of medicines, medical devices, vaccines, procedures and systems developed to solve a health problem and improve quality of life." The suggestion appears to be that other ways of assessing interventions are not systematic (a proposition likely to have moral philosophers, among others, on the warpath!) and that part of the *definition* is (a) a description of the disciplines required in its execution (the WHO list oddly omits clinical disciplines) and (b) a partial list of the purposes for which it may be used. HTA is indeed all of these things, but it is also more, and the WHO definition fails to convey the *essential* character of HTA altogether.

To cut through all this nonsense, it is best to keep things simple. The simplest definition is that HTA and kindred procedures are means of evaluating the worthwhileness of interventions of any kind (from drugs to the design of new delivery systems) in terms of their opportunity costs and their outcomes. Put a little more technically, it seeks to help decision-makers get the best possible combination of relevant outcomes at the lowest opportunity cost and as much of them as the budget will allow. Simple perhaps, but great complexity lurks beneath this benign definition. Relevant outcomes need to be chosen (they are not given). They include short term, intermediate and long term effects. They may include the characteristics of the processes used to determine and deliver services as well as their more ultimate outcomes. The link between intervention and outcome needs to be understood — qualitatively and preferably quantitatively.

Many issues of measurement will arise. Issues of value will arise, both in the narrow sense of "willingness to pay" and the broader ones involved in making judgements, for example, about what is meant by "more or less health", or how one ought to weight health benefits and costs that fall on different people (children, people near death, first nations people, the chronically sick...), or in determining the social priority to be accorded to the financial protection that a new public insurance scheme (a very grand "intervention"!) might give. From these complexities arise the multi-disciplinary nature of HTA, though not all disciplines will be required for every study. "Cost" will for most purposes be ultimately found to be "health forgone" as resources that could be used for a particular technology or group of the population are actually used for another (presumably more fruitful) purpose. Deciding what is to receive priority necessitates either direct comparisons between alternative interventions or their comparison with some standard "threshold" ratio of expected gain to expected cost, deciding which is akin to a constitutional question, closely tied in with determining the overall public budget for health care, that needs determination outside the context of the assessment of a specific technology.

Medical interventions, and other kinds too, have benefits which can be huge (but are never 100 % guaranteed), they carry risks like unintended side-effects which can be catastrophic (but are not inevitable) and they have costs. In deciding matters like which interventions to cover in a public health insurance scheme, all three elements need to be balanced. Sometimes the choice is easy, as when one intervention is more effective than the other, has fewer probable side-effects and other risks, and is cheaper. Often, however, the choice is harder, as when the more effective interventions is also less risky but also much more costly. In such cases, it is illuminating to see the "cost" side in terms of "opportunity costs" rather than in monetary terms. If a particular intervention is estimated to cost

a given amount in monetary terms, then committing to its provision out of a given health budget means that there can only be less spent on other procedures with (assuming them to be effective) an associated loss of health. It is not always easy to make hard estimates of this "health" cost but its existence is inevitable. So cost is important since spending unwisely will reduce the impact of what is spent on the nation's health.



An elderly patient being examined for macular degeneration

HITAP and an Example of an HTA

Here is an example of the sort of work HITAP does.

Age-related macular degeneration is a common eye condition and a leading cause of vision loss among people age 50 and older. It causes damage to the macula, a small spot near the middle of the retina and the part of the eye needed for sharp, central vision for objects that are straight ahead. It can be treated with drugs by either ranibizumab or bevacizumab. Bevacizumab was originally a cancer drug but it can also be used to treat the problem and had been so used by ophthalmologists for many years in Thailand "off-label" — that is, it was not among those treatments officially allowed by the national safety regulators. On the other hand, ranibizumab, which is manufactured by the same company,

had the same active ingredient and was registered for the use in eye disorder. Its price, however, was fifty times that of bevacizumab. The Subcommittee for Development of a Thai National List of Essential Medicines asked HITAP to evaluate the two products. This was a relatively straightforward HTA — but it was also a pioneering one. HITAP's study found that bevacizumab's effectiveness was equivalent to ranibizumab's but its cost was much lower, and bevacizumab was subsequently recommended to be included in the national list as a result. Thanks to HITAP, Thailand was the first country to support the use of bevacizumab for age-related macular degeneration. The World Health Organization (WHO) also later supported the use of the drug for treating this condition². This pioneering work by HITAP is fully described in Anothaisintawee et al. (2012).

HITAP exists to help decision-makers in government, the health professions, health care management, the health products industry, the media, and patients and the general public, to take better decisions and, no less important, to enable them to understand why decisions, which may sometimes be deeply unpopular and counter-intuitive, may nonetheless be the right ones under the circumstances.

HITAP is the product of two great movements that have dramatically changed the practice of modern medicine throughout the world and increasingly among low- and middle-income countries that aspire to Universal Health Coverage: universal coverage in terms both of the persons covered by the schemes (ultimately every citizen or resident) on affordable terms of access for all, and the services to which they are entitled (ultimately all that are cost-effective). One of these movements has become known as "Evidence-Based Medicine" (EBM); the other is "Health Technology Assessment" (HTA).

Evidence-Based Medicine

EBM is the practice of medicine informed by the best available evidence of effectiveness and other empirically amenable aspects of the clinical management of a patient. Evidence alone is never sufficient to decide on the best course of action, whether for an individual or for an entire social insurance scheme, because

² The safety of using bevacizumab for macular diseases remains questionable, so HITAP is now following-up on the safety aspects of the two drugs.

many other factors than evidence come into play — factors like the meaning of "health", opinions about the appropriate scope of costs and benefits, acceptability of different levels and consequences of risk, tolerable levels of uncertainty. Consequently, many prefer the term "Evidence-*Informed* Medicine". We shall use the traditional name but we shall mean it also in this second slightly nuanced sense — of evidence being important but not being the only important thing. There is a lot of argument as to what constitutes evidence, the weight to put upon different kinds (for example, evidence from randomised controlled trials or from observational studies) and how best to handle differences of opinion among experts. There is remarkably little evidence that evidence-based medicine leads to better health outcomes for patients, though this is absence of (good) evidence rather than (good) evidence of absence of effect. An important precursor of evidence-based medicine was Cochrane (1972) but the term was coined by Guyatt (1991), Guyatt et al. (1992) and Eddy (2005). As is only to be expected, the early days of evidence-based medicine were accompanied by an excess of enthusiasm, so it is useful to have an antidote against the mindless idolatry of evidence-based medicine (see, for an amusing example, Gordon et al. 2003).

Those who attempt conscientiously to use evidence in their decision-making commonly need to confront the following issues: the frequent absence of scientific research (clinical, economic, social) on an important aspect of the matter to hand; research that is of poor quality (by being poorly designed, poorly executed, or poorly reported); a too narrow interpretation of "scientific" (for example, by excluding economic and social evidence of a statistical kind); the irrelevance in part or whole of such research as may exist; the need for interpretational skills that they do not have (especially with multidisciplinary material or evidence from disciplines not represented among the decision-making group); research that may be out of date; research (even high-quality research) whose outcomes are ambiguous and conditional on unknown factors; research that is controversial and contested by expert researchers in the field; research of high quality when judged by a criterion such as internal validity (with highly controlled conditions

and expert clinicians) but poor when judged by another such as external validity (in the real world with many unknown imperfections and average clinicians); research that is of one level in respect of its clinical or epidemiological quality or completeness but of another in respect of its economic or social character; the need to supplement research evidence by the practical experience of clinicians and other professionals either to fill gaps in knowledge or to form judgements about the quality and relevance of such research as exists; non-technical issues as to whether a technology is *sufficiently* effective to warrant recommendation/use; non-technical issues as to whether a technology's probable benefits justify the costs that can be attributed to its introduction and use and the associated risks attached to its use; non-technical issues as to how much uncertainty to accept and how best to hedge against risks; how best to explain to stakeholders how all such factors have been balanced.

All of which is really to say (again) that evidence alone is never enough; but at least it points one in the right direction by focusing attention on the question "how well and at what cost does a particular intervention work?". It also forces one to think carefully about how to decide (as an individual or collective) when the evidence is poor, contested, or absent.

Health Technology Assessment

HTA builds on evidence-based medicine by asking similar questions: does the technology in question work, for whom does it work, how well does it work? It also goes further by examining questions like: at what cost does it work, and how well does it perform compared with other technologies deemed to be suitable comparators? It generally uses insights from economics, epidemiology and biostatistics.

HTA is, as we have seen, one of several closely related methods for analysing decision choices. The usual context for using HTA or any of its rough equivalents can be described as high level "prioritisation". Classic examples of such prioritisation

issues include choosing the bundle of services to be included in a set of insured benefits, or deciding which interventions to add to the bundle, or which to remove from it. The insurance could be either public or private: in both cases decisions as to entitlement need to be taken given expectations about the public funding to be made available, or the premium revenue expected over a given period of time, the degree of coinsurance (the contribution, if any, made by beneficiaries in the form of a premium or pre-payment), and co-payments (the amount, if any, payable each time a service is used). HTA is not a form of analysis for application only in decisions about public expenditure, though that is its most common arena of application.

HITAP supports a model of best practice for decision-making called the Reference Case. This is a set of principles endorsed by NICE International (the international unit of the National Institute for Health and Care Excellence in England and Wales), the Global Fund, and the Bill and Melinda Gates Foundation. It includes broad categories of desired features that effectively define the commitment that HITAP makes to the quality of its research and evidence-informed advice. The extent to which any particular decision-making process falls short in any one or more of these desired qualities identifies a weakness in the procedure and increases the probability that a poor decision will be made. Effectively, then, the Reference Case specifies the characteristics of a "good" decision or at any rate of a "good" decision process. It also sets the standard by which HITAP chooses to be judged.

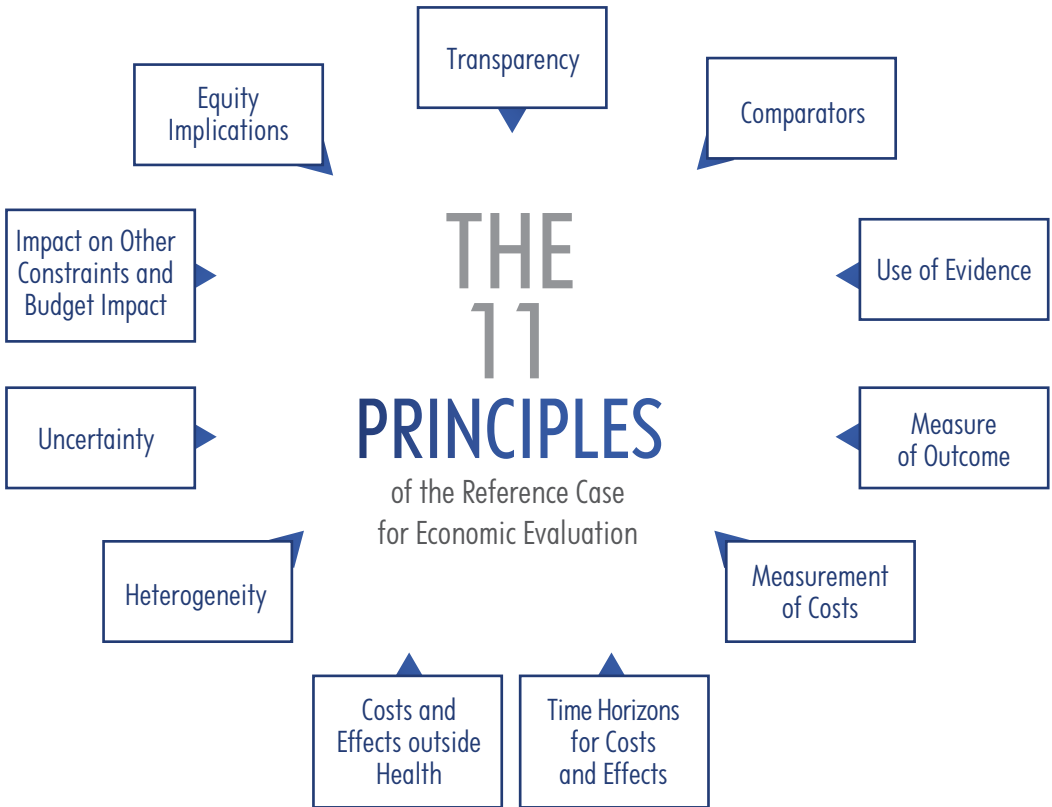
HTA is intended to be an aid to thought, not a substitute for it. At the most basic level, it is a list of elements about a decision that merit detailed consideration. Each element needs to be considered bearing in mind the context (local, historical, financial, social, capacity to deliver, etc.) in which it is being used. Different countries may have different conventions about the meaning of "health"; about the "burden" of disease; about the objectives of the (public or private) health care systems; about the proper role of the public and private sectors; about the budget to be made available; about local price, wage, salary and other cost structures;

about equity and fairness in the distribution of health and health services; about the fairness of the financial contribution required of individuals, families and employers; and about the processes through which decisions are taken, differences of opinion settled and participation by experts and non-experts allowed. At the most fundamental level, a decision has to be made about the perspective from which a decision is to be made. A common view in HTA is that the perspective ought to be "societal", that is, broadly encompassing all gains and losses to whomsoever they accrue. Alternative perspectives include one from the purview of a specific government department (for example, the Ministry of Public Health, Ministry of Finance), or a private insurer, or a perspective designed to identify the ways in which costs and benefits fall for specific "players" in the system (like employers and organised labour in the case of interventions for health in the workplace).

The Reference Case

The Bill and Melinda Gates Foundation is one of the largest investors in research into the value of health care interventions in low- and middle-income countries. In 2013, a novel collaboration known as the Methods for Economic Evaluation Project was established by the Foundation to improve the quality and transparency of this research and to guide researchers in undertaking and reporting well-conducted and robust analyses. The methods project was a collaboration led by NICE International in the UK with partners from institutions including HITAP in Thailand, the University of York's Centre for Health Economics, the London School of Hygiene and Tropical Medicine, and the University of Glasgow. An important stage was a workshop held at the Bill and Melinda Gates Foundation headquarters in Seattle in June 2013 that was attended by researchers, policymakers, methodologists and donors. A key output was what was then called the Gates Reference Case (Bill and Melinda Gates Foundation 2014). It was drafted by Karl Claxton, Paul Revill and Mark Sculpher (University of York), Tommy Wilkinson (NICE International), John Cairns (London School of Hygiene and Tropical Medicine) and Andrew Briggs (University of Glasgow).

FIGURE 1.1 The 11 Principles of the Reference Case for Economic Evaluation



The Reference Case was built on some basic principles of good HTA practice on *which the next* section draws heavily. Some readers may want to focus just on the principles (*italicised*) together with what is called the "base case analysis" outlining the most basic ingredients of the principle in question. Each principle is also followed by a more detailed elaboration to enable the reader to form

a judgement of the degree of sophistication to which HTA aspires as well as the pragmatic difficulties that are often confronted and how they may best be met. HTA is not a counsel of perfection but it is important to be reminded of the real-world limitations that may constrain one's ability to approximate to excellence in decision-making — and therefore how also to qualify and implement recommendations in health policy wisely and credibly.

In all cases, the effective application of these principles will require deliberation, discussion, participation of many with a reasonable claim to have their voices heard, and a careful weighing of pros and cons.

1. Transparency Principle: An HTA should be communicated clearly and transparently to allow the decision-maker(s) to interpret the methods and results, and all stakeholder groups to gain access to the evidence and the reasoning used in making recommendations and taking decisions.

Base Case Analysis:

- State decision problem using Problem–Intervention–Comparison–Outcomes format and describe context of decision.
- Outline limitations of analysis in informing health policy.
- Declare interests of study authors and source of funding.

Even the most methodologically robust HTA will not be informative if the methods and results are not reported clearly and transparently. Clarity and transparency also enhance the overall transparency of the decision it is used to inform, thereby improving the accountability of the decision-maker to stakeholders and the overall credibility of decisions and the institutions that support them. Clear and transparent reporting also improves people's ability to decide whether research undertaken in one context may be used to support decision-making in another. A fundamental element of good scientific practice is that results are reproducible. Clear and transparent reporting enhances the capacity of other researchers to reproduce the results of the analysis.

2. Comparators Principle: The comparators against which costs and effects are measured should accurately reflect the decision problem.

Base Case Analysis:

- Current practice in context of decision problem to serve as base case comparator
- A "do nothing" comparator should also be explored.

It is always and everywhere unpersuasive to argue for the adoption of an intervention simply on the grounds that it may do good. Lots of interventions do good but they do not do *enough* good to warrant their cost and they may do a lot less good than other affordable alternatives. Suitable alternatives must therefore be identified.

Methods for determining relevant comparators include:

- those interventions currently available to the population
- "do nothing" — for example by comparing the new intervention to "best supportive care"
- current "best practice"
- the treatment or practice most likely to be replaced if the new intervention is adopted.

Comparative analysis of interventions in routine use should form the base case, with additional analysis exploring "do nothing" as a minimum requirement. The most appropriate comparator is not always immediately obvious. Comparators may not always be alternative interventions but may be different ways of

administering the same intervention. Nor may the comparator always be in the same area of medicine, for example a drug might be compared with a surgical procedure.

3. Use of Evidence Principle: An HTA should consider all available evidence relevant to the decision problem.

Base Case Analysis:

Apply systematic and transparent approach to obtaining and using evidence. Evidence refers to any information to be used to inform (qualitatively or quantitatively) the design, results and conclusions of an HTA, including the unbiased estimate of clinical effectiveness and the costs and resource use associated with the interventions being compared.

Failure to draw on all relevant and available evidence can introduce biases of unknown direction. Some judgement may be necessary as to what constitutes "all relevant and available evidence". The judgement should be made in a systematic and transparent way and without bias. While it is important to make a systematic review of the literature to obtain estimates of the clinical effects of the intervention and its comparator(s), for some elements the collection and synthesis of all information may be prohibitively expensive or time-consuming. In these instances, a judgement should be made transparently about the likely implications of missing information in the HTA. Researchers should clearly state when the evidence is weak or unavailable and offer any helpful comments to aid decision-makers' interpretation, for example by indicating whether the conclusions are likely to be sensitive to plausible estimates of what is missing.

4. Measure of Outcome Principle: The measure of health outcome should be appropriate to the decision problem, should capture positive and negative effects on length of life and quality of life, and should be generalisable across disease states.

Base Case Analysis:

Generic (such as the QALY or DALY) health outcome measure

The measure of health outcome ought to be broad enough to capture all socially valued aspects of health or avoidable ill health and be applicable across types of intervention and disease states. Using a generic outcome measure allows consideration of opportunity costs for the entire health sector and facilitates comparisons between interventions. A disease-specific measure makes it hard for the decision-maker to make reasoned trade-offs between competing interventions for different diseases and can undermine comparability and consistency in decision-making. Disability-Adjusted Life Years (DALYs) averted are the metric most frequently used in HTAs for low- and middle-income countries while Quality-Adjusted Life Years (QALYs) are frequently used in HTAs for high-income countries. Reasons for using one or the other should be made clear and a preference for one over the other will aid consistency across different decisions by the same group of decision-makers.

5. Measurement of Costs Principle: All differences between the intervention and the comparator in expected resource use and costs of delivery to the target population(s) should be incorporated into the HTA.

Base Case Analysis:

All relevant direct resource use and costs of implementing intervention to be identified, included donated resources and out of pocket payments (see principle 7)

Decision-makers need to know the resource use and costs associated with different options because more costly options will result in more benefits (and health) forgone. This is a point often missed by those who think that consideration of "cost" introduces an unwarranted commercial element into a humanitarian choice. The monetary cost of a new intervention, however, together with a given health care budget, means that the equivalent sum is no longer available to provide other health benefits. The loss of these is the humanitarian "opportunity cost" of a decision³. Where data are available, costs of resource inputs used to deliver interventions should also be reported to help determine what drives the differences in costs. In addition to reporting costs, quantities of resources used should be reported separately from their unit costs/prices. All relevant resource items involved in the direct delivery of health interventions should be captured as there will always be associated opportunity costs, even if these fall in other jurisdictions (as when a country attracts international funding for the delivery of an intervention). In some cases, decision-makers will also be specifically concerned about the sources of funds and, for example, whether they come with strings attached. The average unit cost of an intervention depends upon its rate of use, the volume of its use, the scale at which it is used, the timing of its introduction and the range of other interventions delivered alongside it. For instance, the cost of each visit to a clinic nurse may differ with overall patient throughput (rate per

³ If the health budget is increased to accommodate a new intervention, then the opportunity cost is felt elsewhere – in education, say, public housing, or defence. If the cost is met from outside the public sector budget, then the opportunity cost is private consumption.

month, etc.), the capacity of the clinic (scale), the number of patients present at any time (volume) as well as whether and how other interventions are delivered from the same "platform" (scope). Economies of scale and scope may be important and should be incorporated when feasible, particularly when alternatives are likely to differ in their scale and scope of implementation. Caution should be used when applying cost functions if these cannot be supported with reliable local evidence, or when other non-health effects may also have social value. Primacy should be placed on the transparency, reasonableness and reproducibility of cost estimates, so that different decision-makers can assess whether results are generalisable to their jurisdictions.

Key considerations:

- Costs should be estimated so that they reflect the resource use and unit costs/ prices that are anticipated when interventions are rolled out in real health care settings. Protocol-driven costs in clinical trials should be excluded. Conversely, any costs not incurred in clinical trial settings but anticipated in real health care settings, should be incorporated.
- Overall costs of interventions should be reported as well as costs of resource inputs. In addition, whenever possible, it is useful to report quantities of resources separately from their unit costs/prices.
- Capital and fixed costs can be annualised over the period of implementation, but decision-makers should also consider when costs are likely to be incurred (see also budget impact).

- Where possible cost estimates should be corroborated against costs incurred when implementing the intervention(s) being evaluated (or other similar interventions) in real health care settings, for example using data from feasibility studies or pragmatic trials.
- All resource items involved in the direct delivery of health interventions that are expected to differ between alternatives should be costed. This includes donated inputs. While any resource items that do not differ across alternatives can be excluded, care should be taken to ensure that there are truly no significant differences before doing so.
- Economies of scale and scope that are expected with the delivery of interventions should be estimated and incorporated (when feasible). However, these must be based on reliable data from the jurisdiction of concern.
- The means of delivering interventions is not exogenously set — different delivery mechanisms are usually feasible and the choice of delivery mechanism should meet the overall objectives of health systems. Researchers should consider heterogeneity among recipients, impacts on non-health budgets, and equity considerations when using cost functions to evaluate alternative delivery mechanisms.
- Costs should be reported in both US dollars (to enable international comparison) and local currency, and any costs that are estimated in other currencies should be converted to US dollars and local currency. The date and source of the exchange rate used should be reported in addition to whether the exchange rate is unadjusted (real) or adjusted for purchasing power parity (PPP).

6. Time Horizons for Costs and Effects Principle: The time horizon used in an HTA should be of sufficient length to capture all costs and effects relevant to the decision problem; an appropriate discount rate should be used to discount cost and effects to present value.

Base Case Analysis:

- Lifetime time horizon (or sufficient to capture all relevant cost and effects)
- Discount rate of x per cent for both costs and effects (the "x" may be a specific required rate)

An HTA should use a time horizon long enough to capture all costs and effects relevant to a decision problem. The nature of the interventions and comparators in the decision problem will largely define the appropriate time horizon. The time horizon will often be "lifetime" — that is, the natural average length of life in the population cohort for which the analysis is undertaken. The time horizon should never be determined by the length of time for which evidence is available. Where data are not available to inform an appropriate time period, some projection of costs and effects into the future will be needed.

When projecting costs and effects into the future, the costs and effects should be discounted to reflect their value at the time the decision is being made. This ensures that the time preferences of the population that will be affected by the decision (or the decision-makers) are taken into account. Opinions differ as to the appropriate discount rate(s) to be used in HTAs and different constituencies will vary in their time preferences with respect to health and wealth. In some jurisdictions, there may be common required discounting procedures for all public investment decisions. For comparability and to test sensitivity, alternative rates may be used. In any event the rationale for a preferred rate ought always to be given.

7. Costs and Effects outside Health Principle: Non-health effects and costs associated with gaining or providing access to health interventions that don't accrue to the health budget should be identified where relevant to the decision problem. All costs and effects should be disaggregated, either by sector of the economy or to whom they accrue.

Base Case Analysis:

- Reflect direct costs to the health budget and direct health outcomes to patients.
- Include costs incurred by external funders or individual out-of-pocket payments where it substitutes for costs that would otherwise accrue to the health budget.
- All relevant non-health effects and costs that fall outside health budget to be identified

In addition to health outcomes and direct costs falling on the health budget, other costs and consequences of interventions may also be relevant. These include wider impacts on families, communities, and other sectors of the economy. They may also include other (direct and indirect) costs such as the cost of accessing health care (travel, out-of-pocket and care costs, and so on), indirect time costs (such as those relating to the productivity of individuals and informal carers) and costs falling on other ministries' budgets. Some alternative interventions may deliver important non-health effects that have social value. They should therefore be included in the analysis with a justification for the selection of the included non-health effects and an explanation of how they may be valued. By presenting non-health effects separately, decision-makers can draw their own conclusions about the relative merits of the different effects. In health systems where a significant proportion of interventions is funded through out-of-pocket payments, there may be good reasons to adopt a perspective other than that of the health care provider. Similarly, direct health intervention costs may impose

different opportunity costs according to who funds a particular intervention. In many low- and middle-income country contexts, health interventions rely upon direct funding from different sources (for instance national ministries of health may fund recurrent costs; whereas international donors may fund drugs or specific technologies). In these instances donor funds (including the direct provision of drugs and health care materials) may form a significant proportion of the budget available for health. It would be inappropriate for an analysis to disregard the direct impact of an intervention of donor funds, but it is also important that recognition is made of different sources of funding. For these reasons, it is recommended that direct costs, health effects, non-health effects and costs that fall outside the health sector are disaggregated so that it is clear who are the beneficiaries and the funders of interventions. This facilitates exploration of health system constraints, budget impacts and opportunity costs, and equity issues. It also allows decision-makers to make judgements on the relative importance of each in their own jurisdictions.

Key considerations:

- The base case analysis, suitable when one is seeking to establish what is the best decision for the whole of society, should reflect direct health care costs and health outcomes, and should in most cases adopt a disaggregated societal perspective so that the funders and beneficiaries of health interventions can be clearly identified.
- Direct costs incurred by funders where these would otherwise fall on government health budgets should be included in the base case.

- Out of pocket costs falling on individuals can be included if these are costs that would otherwise fall on the health budget, however the impact of excluding them should be included in a sensitivity analysis.
- Where there are believed to be important non-health effects and costs falling outside of the health budget, these should be included in an analysis but reported separately, with a clear justification for their selection and a thorough exploration of the ways they can be valued. Any non-health effects and costs that fall outside of the health budget that potentially conflict with other social objectives should be highlighted and discussed. For example, a particular intervention may be expected to have productivity benefits but its adoption may result in adverse equity consequences.
- Decision-makers should be made aware that interventions with positive incremental direct health costs are also likely to impose non-health opportunity costs associated with health interventions that are forgone, insofar as interventions forgone have non-health effects. For example, an intervention for HIV/AIDS may have non-health effects but if adopted these may displace interventions for maternal health that have equal or even greater claims to generating additional elements of positive social value.
- Care should be taken to ensure that non-health effects and costs are not double counted. Double counting can occur where a particular effect (or cost) of an intervention relative to a comparator is attributed to more than one outcome measure.
- Direct health costs should be disaggregated by funder. Both health and non-health effects should be disaggregated by characteristics of recipients and beneficiaries and, in the case of non-health effects, the sector or area in which these are incurred.

8. Heterogeneity Principle: The cost and effects of the intervention on subpopulations within the decision problem should be explored and the implications appropriately characterised.

Base Case Analysis:

- Explore and identify significant population subgroups.
- Report separate subgroup analysis where heterogeneity relevant to the decision problem exists.

It is important to distinguish between uncertainty, variability, and heterogeneity. Uncertainty refers to the fact that we do not always know what the exact costs and effects of an intervention will be in a particular population of individuals. Variability refers to the fact that responses to an intervention will differ within the population or even within a subpopulation of individuals or patients with the same observed characteristics. Heterogeneity refers to those differences in response that can be associated with differences in observed characteristics, where sources of natural variability can be identified and understood. As more becomes known about the sources of variability, patient populations can be partitioned into subpopulations or subgroups, each with a different estimate of the expected effect and cost of the intervention, with an associated uncertainty. An exploration of heterogeneity enables decision-makers to consider whether an intervention should be made available to groups of individuals with greater capacity to benefit. Since any observed characteristics that affect the health benefits and costs of an intervention are relevant in principle, the exploration of heterogeneity should include subgroups where there is good evidence that the relative effect of the intervention differs. It should also include exploring characteristics that influence absolute health effects, even where the relative effect is similar, such as differences in baseline risk of an event or incidence and

prevalence of a condition. There may also be characteristics that are unrelated to clinical effects but influence the costs of providing care such as geographical location. The question of which sets of observed characteristics to explore should be informed by 1) the evidence base regarding differences in relative effect, baseline risk or other relevant characteristics, and 2) whether any differences are likely to have important influences on costs and effects.

9. Uncertainty Principle: The uncertainty associated with an HTA should be appropriately characterised.

Base Case Analysis:

- Explore all relevant structural, parameter source, and parameter precision uncertainty.
- Probabilistic sensitivity analysis is preferred but not explicitly required.

All decisions carry a risk that a better course of action could have been selected. All HTAs reflect a degree of uncertainty, so it is important that all types of uncertainty are appropriately presented to the decision-maker. These include uncertainty about the source of parameters used in the HTA, the precision of the parameters, and whether models accurately simulate the cost and effects of the intervention and comparators. Characterising uncertainty will facilitate decision-makers' deliberation and help them minimise some uncertainty. For example, they might delay implementation to allow for more evidence to be gained. In this situation, appropriately characterising uncertainty will allow the decision-maker to make an informed trade-off of the value of new information, the implications of potentially delaying treatment to patients or individuals, and irrecoverable costs that are associated with implementing funding for an intervention.

There are three types of uncertainty to consider:

- Structural uncertainty — for example in relation to the categorisation of different states of health and the representation of different pathways of care. These structural assumptions should be clearly documented and the evidence and rationale to support them provided. The impact of structural uncertainty on estimates of cost effectiveness should be explored by separate analyses of a range of plausible scenarios.
- Source of values to inform parameter estimates — the implications of different estimates of key parameters (such as estimates of relative effectiveness) should be reflected in sensitivity analyses (for example, through the inclusion of alternative sources of parameter estimates). Inputs should be fully justified, and uncertainty explored through sensitivity analyses using alternative input values.
- Parameter precision — uncertainty around the mean health and cost inputs in the model. To characterise parameter uncertainty, probabilistic sensitivity analysis (PSA) is preferred, as this enables the uncertainty associated with parameters to be simultaneously reflected in the results of the model.

10. Impact on Other Constraints and Budget Impact Principle: The impact of implementing the intervention on health budgets and other constraints should be identified clearly and separately.

Base Case Analysis:

Report expected budget impact of implementing the intervention on all relevant budgets in the context for the population identified in the decision problem.

It is important to determine the net total costs involved in the deployment of a health intervention on a particular scale, as this is also a measure of the value of what must be forgone. The costs of an intervention (even when capital investment is not required) are unlikely to be evenly spread over time. There will often be high initial costs offset by later health benefits and at times, cost savings. In addition to expenditure constraints, decision-makers may be subject to other infrastructural or resource limitations such as limited laboratory capacity or insufficient skilled workers. Since non-health benefits and costs do not have an impact on health budgets or other constraints on health care, they should be assessed separately. The budget impact should be disaggregated and reflect the costs to all parties as a result of implementation of the intervention (cost outputs). This includes (but is not limited to) impact on government and social insurance budgets, households and direct out-of-pocket expenses, third-party payers, and external donors.

11. Equity Implications Principle: An HTA should explore the equity implications of implementing the intervention.

Base Case Analysis:

Equity implications of implementing the intervention for the populations described in the decision problem should be reported, however the reporting method is at discretion of researcher or the needs of the decision-maker.

Resource allocation decisions in health frequently reflect considerations other than efficiency, for example, there may be equity implications of deploying an intervention. Important equity considerations may include issues such as whether equal access is given to those in equal need, whether resources are distributed fairly to those with different levels of need, or recognition that interventions such as smoking cessation programmes may simultaneously

improve population health but increase health inequalities, or that different degrees of financial protection from unanticipated and heavy expenditures may be among the consequences. Limiting an HTA to a determination of average cost-effectiveness in a population as a whole may ignore differences in capacity to benefit and/or in access to care, and may prevent the decision-maker from appropriately considering the differential impacts of a decision on different subgroups within the population. Such judgements are all more or less political or ethical and in such matters the usual "experts" have no particular authority (other than as members of the community from which they come). The chief role for an analyst here is to find ways of eliciting the value judgements of decision-makers (or stakeholders) and embodying them in the analysis.

Exploration of equity is a principle that should be addressed in its own right in a robust HTA. There are many dimensions to assessing the equity implications of a proposed intervention. Methods employed may be qualitative, or may involve the quantitative assessment of distributive impact and expected trade-offs. At the most basic level, an exploration of equity impacts may involve a description of particular groups within the constituency that may be disproportionately affected (positively or negatively) by a decision. Adherence to the equity principle is not, however, simply a matter for reporting of results. Equity implications should be considered at all stages of an HTA, including the design, analysis and reporting stages.

Our Approach

This book is not an evaluation of HITAP. If it were, the foregoing might provide a useful framework for evaluating its methods, processes and their outcomes. Our purpose in outlining what we believe to be the core elements of HTA is to inform the reader an insight into what a well-conducted HTA may involve, to indicate that

addressing these issues is HITAP's core technical skill, and to provide a general backdrop to the descriptions that follow. The foregoing summarises the intellectual framework that underpins HITAP's approach to high level health technology decision-making and prioritisation. One thing should be apparent. Although the methods of HTA are sophisticated and its practitioners require years of training (theoretical and practical), its fundamentals are rooted in humane values to do with using resources to the best effect in enhancing a people's health, promoting fairer (according to the values of decision-makers) distributions of resources and outcomes, and doing so through procedures that are open, reasonable and accountable — and therefore credible and acceptable.

The practitioners of HTA are driven folks. They believe in what they do with a passion. They really do want to make the world a better place.

THE THAI HEALTH SYSTEM AND HTA IN THAILAND

"Finding true north is important for accurate navigation to embarking on the right path. While there may be many paths to making policy decisions, the ultimate goal is to end up with a decision that has been well-informed by evidence. Evidence-based policy decisions result in more transparent and effective outcomes that are defensible to the public." (Dr Yot Teerawattananon and Nattha Tritasavit)

Health Care in Thailand

Prior to the arrival of modern Western medicine, health care in Thailand was characterised by traditional medicine, which was holistic, simple and not evidence-based. Traditional healers relied on their five senses and experience, diagnosing through interrogation, observation, auscultation and olfaction. Herbal medicines and massage were the main treatments. There were no formal health care facilities. Many Buddhist temples acted as clinical centres and sometimes even as medical schools, since temples were places of intellect and learned discourse (Teerawattananon et al. 2009). Clinical knowledge had grown through observation, trial and error, and relied on traditional beliefs which sometimes could mislead. One belief in traditional medicine had it, for example, that a woman who had just delivered a baby was "wet" and needed to be dehydrated. This was not a good procedure for one likely already to be dehydrated due to blood loss. Principles in traditional medicine were not clear, not systematically documented, and were rarely subjected to well-designed tests for efficacy or effectiveness (Chokewiwat 2002).

All this began to change from about the middle of the nineteenth century as kings and other leaders of Thailand began to travel abroad and brought back innovations from western countries⁴. In 1888, during the reign of King Chulalongkorn, the fifth king of Chakri Dynasty, the first formal hospital in Thailand, Siriraj Hospital, was established. The first medical school, the Phaetthayakorn School, teaching both Western and traditional medicine, was established in the following year. The first non-profit private health facility in Thailand, the Bangkok Nursing Home, was founded in 1898, with the support of the king, by British residents for the benefit of expatriates. Public policy for health and sanitation were the responsibilities of the Ministries of the Interior and Urban Affairs (Nakhon Ban) until the Public Health Department was established under the Ministry of the Interior in 1918. The Department was later promoted to the status of Ministry of Public Health (MOPH)

⁴ For an early history, see Charuluxananana and Chentanez (2007).

in 1942, overseeing health-related issues throughout the country and managing all public health facilities (Ekachampaka and Wattanamano 2011).

Since then, the system has evolved in leaps and somewhat unpredictable bounds arising from political instability and a tenacious pursuit by senior civil servants and other influential people to introduce universal health coverage. Thailand has, somewhat remarkably, now achieved universal health coverage for all of its population and the principles of evidence-based practice in both medicine and health policy in general are gaining ground.

A key factor in making universal coverage possible and making what was possible sustainable lay in making it affordable. That task has fallen largely to the application of health technology assessment (HTA) and Thailand's success in deploying the tools and methods of HTA is largely due in turn to the work of HITAP.

Overview of Health Insurance in Thailand

Prior to universal coverage in Thailand, there were five main categories of health insurance. These have been well summarised in Damrongplasit and Melnick (2009). In 1975, a Low-Income Card scheme was introduced. This was a publicly subsidised programme, initially for the poor, which was gradually extended to cover other groups: the elderly, young children, community leaders and health volunteers. In 1960, a Civil Servant Medical Benefit Scheme was inaugurated as a fringe benefit for government employees, their dependents and retired civil servants. In 1983, a Voluntary Health Card scheme was established — initially as a maternal and child health fund and then expanded like the Low-Income Card scheme. It became a government-subsidised health insurance scheme aimed at people in the informal employment sector who were ineligible for other types of health insurance. This scheme was funded by equal payments between households and

the Ministry of Public Health. Each family could purchase a health card at a price of 500 baht (about US\$20 back then) per year, and the government would contribute the same amount to the fund. A Workmen's Compensation Fund had existed since 1972. In 1990, this was expanded into a compulsory Social Security Scheme for employees in the formal private employment sector, funded from contributions by employees, employers, and the government. There was also a small private health insurance market catering mainly to expatriates, visitors and relatively well-off Thais.

Despite this patchwork of schemes, there remained something like 18 million people without ready access to basic health care (Limwattananon and Sakulpanich 2012). In 2001, Prime Minister Thaksin Shinawatra had a landslide victory for his Thai Rak Thai (Thais love Thais) Party on a platform including a universal coverage scheme marketed as the "30 baht treat all diseases" scheme for universal coverage. This followed a long "struggle" by many practical idealists, like Dr Sanguan Nitayarumphong, the first secretary general of the National Health Security Office, who had tirelessly been working for universal coverage behind the scenes (Nitayarumphong 2006). Under the scheme, people pay 30 baht US\$0.86 for each visit or admission. The plan had been to merge the existing schemes into one universal coverage scheme, thereby removing overlaps in coverage, gaps, and improving equity of access. This, however, was resisted by the three ministries operating the existing schemes and by the civil servants and trade unionists benefitting from the two employment based schemes. The government therefore decided to fund the 30 baht scheme by pooling the Ministry of Public Health budgets for public hospitals, other health facilities, and the low income and voluntary health card schemes and providing some additional money. This could be done without legislation, enabling progress to be made while legislation was prepared and debated (Towse et al. 2004).

The National Health Security Act was passed by the Thai parliament in November 2002. It created new institutions for regulating the quality and financial elements of the scheme. If it proves politically acceptable in the future, all the benefit entitlements for the public employee and social security schemes' members were to be preserved but the management of their financing would be transferred to the National Health Security Office, which runs the universal scheme. This single act greatly expanded government-funded coverage to the uninsured and effectively assured 100 per cent coverage of the population. Especially costly procedures like organ transplantation and renal dialysis were not in the insured bundle but much was. Each person registers with a public health unit for primary services and these units act as gatekeepers to secondary and tertiary care through a system of referral. No one was to pay more than 30 baht per visit for either outpatient or inpatient care, including drugs.

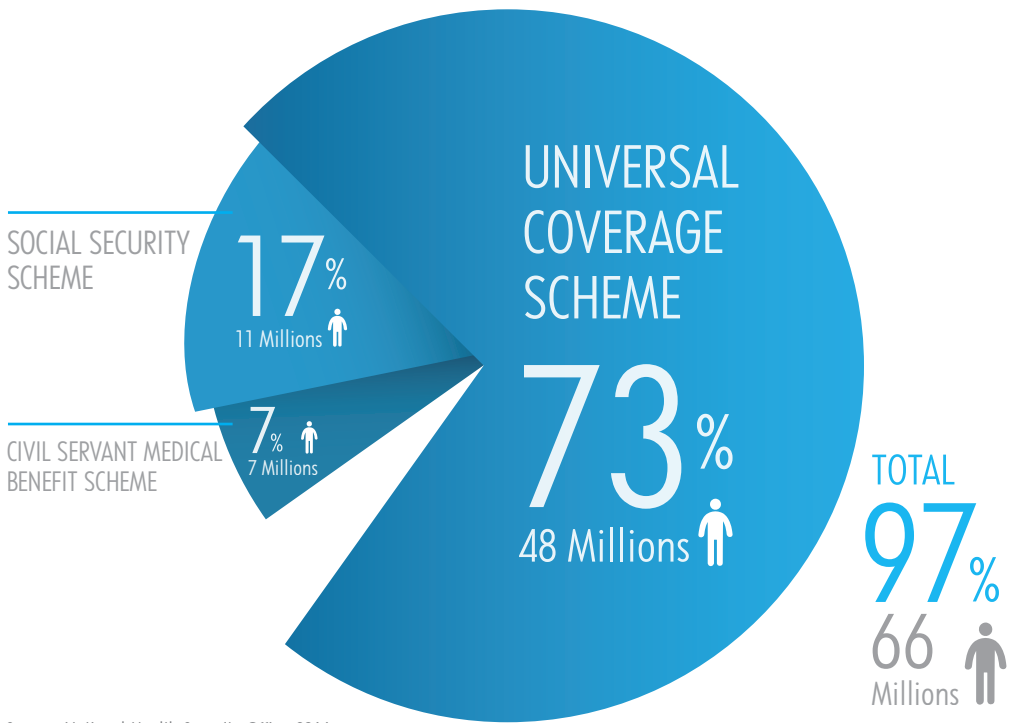
The new scheme covered 47 million people, or three quarters of the population, including 18 million people who had previously been uninsured. The other quarter were the public sector workers, the retired public sector people and their dependants, and private sector employees, who all remained in their previous schemes. It improved access to health services, improved the equity of service utilisation and banished impoverishment through medical bills. The whole thing was remarkable not only for the speed of its implementation, but also because it was pursued in the aftermath of the 1997 Asian financial crisis, when Gross Domestic Product (GDP) per capita was low, against the advice of external Cassandras who believed the scheme was financially unviable (Health Insurance System Research Office 2012).

The position as it stands today is that Thailand has three public health insurance schemes and a number of private health insurance plans. An individual may be a member of only one of these public plans according to their employment

status. Two schemes remain from the former arrangements: the compulsory Social Security Scheme for employees in the formal private sector and the Civil Servant Medical Benefit Scheme for government employees. From 2001, there is also the Universal Coverage Scheme (the "30 baht treat all diseases" scheme) for those who are not employed in a formal sector (like the self-employed, those in the "black economy" and the unemployed). Among the three schemes, the Universal Coverage Scheme has the highest population coverage rate (Figure 2.1).

FIGURE 2.1

Thai population registered in the three public insurance schemes (2014)



Source: National Health Security Office 2014

All three schemes rely on the National List of Essential Medicines for pharmaceutical reimbursement. In principle, each public scheme, the National List, and the private insurance sector, are potential customers for evidence-based information about the effectiveness and cost-effectiveness of the procedures to be made available to their eligible memberships. In practice, the demand for HITAP's services come mainly from the managers of the universal scheme and the National List. This is hardly surprising since these are the main pressure points for public expenditure control in the health sector.

Key Public Players in Thai Health Systems

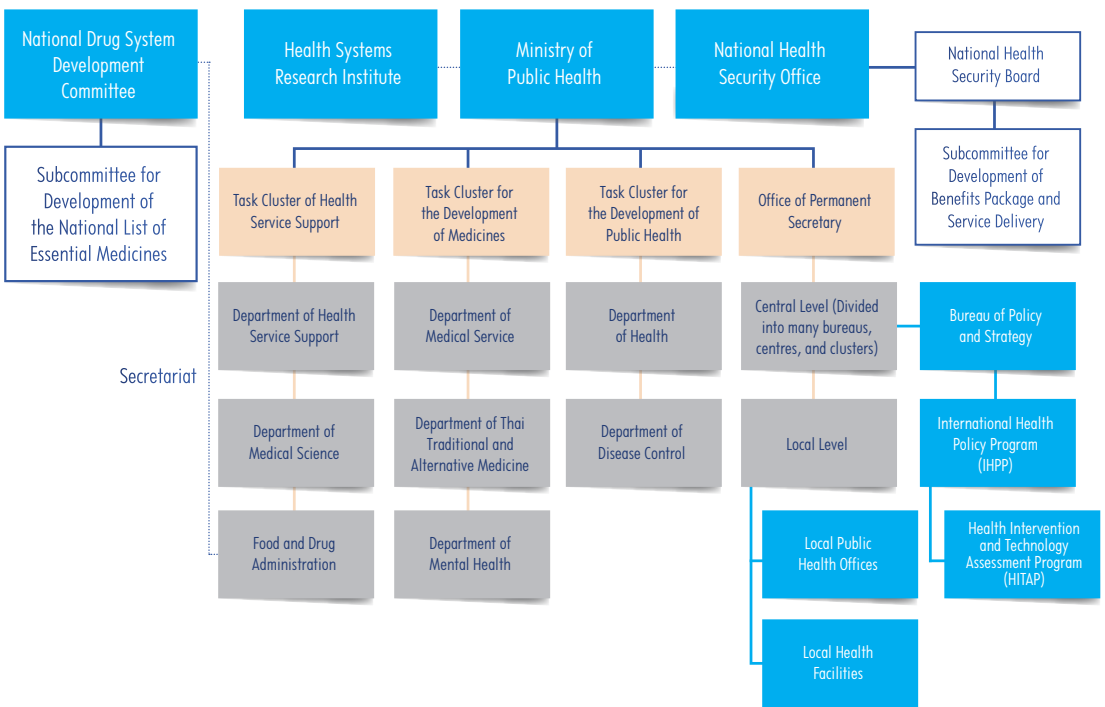
There are three categories of key government player in the health system: health care providers, health system research and development bodies, and health care purchasers.

The Office of the Permanent Secretary of the Ministry of Public Health has a central and a local level. The health care providers outside the major urban centres of population are mostly health facilities under the Office's local level agencies. The central level of the Office is concerned with drafting and developing policy and strategies. Accordingly, the central Office has within it the Bureau for Policy and Strategy, which is the umbrella organisation for the International Health Policy Program (IHPP) and HITAP. Both are research bodies for health system development: HITAP's main focus is on health technology assessment; the International Program's main focus is overall health system and policy. Another major developmental agency is the Health Systems Research Institute, a public organisation for generating and managing improvements for Thai health system. Departments in the Ministry contribute to the health system through the development of new medicines, public health, and health service support. Health system support includes the work of the Food and Drug Administration (FDA) in maintaining and developing Thai drug

formularies. Under the direct supervision by the Prime Minister (or assigned Deputy Prime Minister) is the National Drug System Development Committee, with responsibility for national drug policy and strategy. The Subcommittee for Development of the National List of Essential Medicines, which maintains the essential drug list, with the Food and Drug Administration as the secretariat, is under this Committee (Figure 2.2).

Since the three insurance schemes in Thailand target different populations and have different histories, no single ministry is responsible for all schemes. Management of the Universal Coverage Scheme is the responsibility of the National Health Security

FIGURE 2.2
Structure of the Ministry of Public Health and related bodies



Adapted from: Ministry of Public Health 2015

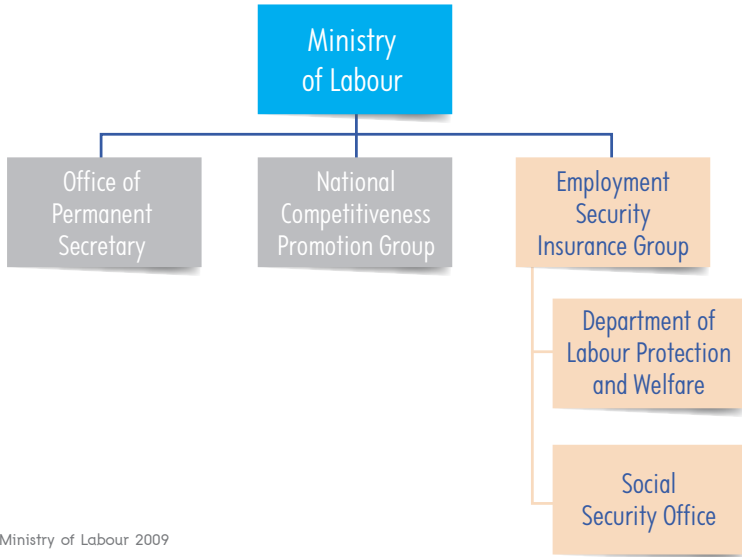
Office, outside the Ministry of Public Health but chaired by the Health Minister. Its main board, the National Health Security Board, determines the scope and oversees the operation of the Scheme. The Subcommittee for the Development of the Benefits Package and Service Delivery was established under the Board to improve the benefits provided to the members. The Social Security Scheme, targeting working individuals, is the responsibility of the Ministry of Labour's Social Security Office. The Civil Servant Medical Benefit Scheme is the responsibility of the Ministry of Finance's Comptroller General's Department (Figure 2.3).

The Social Security Scheme

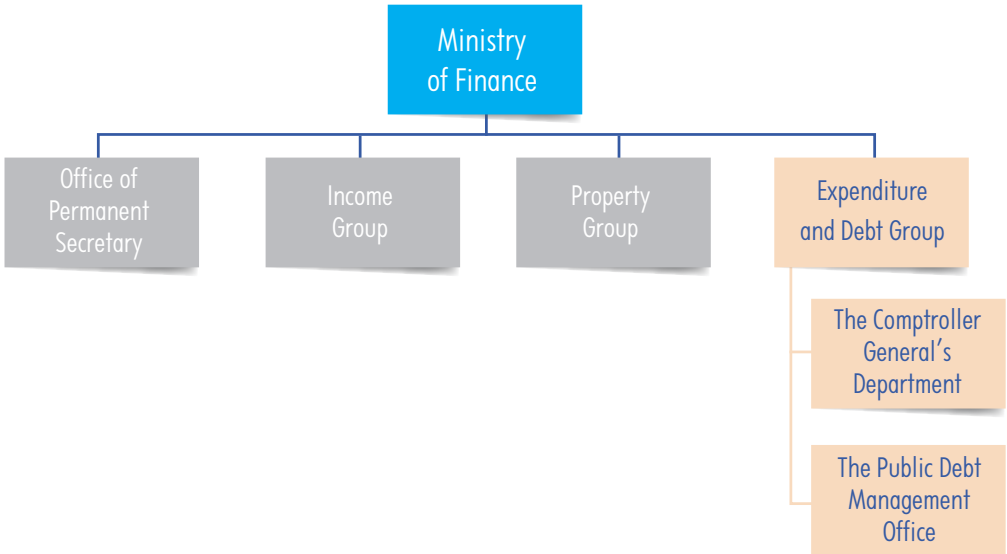
This scheme began life as the Workmen's Compensation Fund in 1972. It covered private sector employees and paid for treatments only for workplace-related illnesses. It was funded wholly by private sector employers, with experience-rated insurance premiums. The scope of the insurance was enlarged to cover all-cause conditions in 1990 when the Social Security Act was enacted. The Social Security Office was established in the Ministry of Labour, and the Workmen's Compensation fund, previously a part of Ministry of Interior, was moved there. The Social Security Scheme is now funded by contributions from employees, employers, and government with employees' contributions based on each individual's salary. Insurance cover under the Scheme differs from that under the other two public health insurance schemes by including not only health expenditure but also compensation for financial loss for absenteeism due to sickness and work-related disability. Members of the Scheme are registered with a local health care provider (usually a hospital).

Since the establishment of the 1990 Scheme, the Social Security Office purchases services from hospitals according to fee schedules for inpatient and outpatient services: there is prospective capitation payment for outpatient departments. Thai Diagnosis Related Groups (DRGs), assigning a fixed reimbursement rate for each health condition, are used as the basis for funding inpatient departments. Treatment under the Scheme is free of user charge provided the member is treated at his or her registered care provider. Free care at other providers is available only in emergency situations (Thongchuenchit and Preechachart 2012).

FIGURE 2.3
 Players in the Ministries of Labour and Finance



Adapted from: Ministry of Labour 2009



Adapted from: Ministry of Finance 2011

The Civil Servant Medical Benefit Scheme

This scheme covers the smallest number of people of the three public schemes, yet is the most generous. As a workplace based welfare scheme, medical benefits for civil servants, including former employee pensioners, were provided and funded from general taxation. There were no premiums or co-payments. A difference between the Civil Servants' Scheme and the other two schemes is that it is the only one to cover dependents as well. Moreover, while the managers of the other two schemes determined the benefit entitlements of members of the schemes, the Comptroller General's Department was only the payer and did not have full power over the benefits packages.

Significant changes to the payment system were made by the revised Decree of 2010. Up to that date the Comptroller General's Department reimbursed hospitals by workload payments for inpatient and outpatient services. After 2010, while reimbursement for outpatient services remained the same, inpatient departments were mainly reimbursed according to Thai DRGs. Prior to 2010, hospitals were reimbursed for direct services only. After 2010, there was also reimbursement for health promotion and disease prevention. The inpatient arrangements also apply to those private hospitals that register with the scheme (formerly they were reimbursed only for emergency admissions). Insured persons under this Scheme are not obliged to go to a specific health care facility, as with the Social Security Scheme and the Universal Coverage Scheme, but are able to go to any hospital registered with the Scheme.

Universal Coverage

The National Health Security Office was established by the National Health Security Act 2002 to act as the manager and purchaser for the Universal Coverage Scheme. The Office is an arm's-length autonomous public organisation under the Minister of Health. Its main governance body, the National Health Security Board, comprises the Minister of Health and representatives of other government divisions, regional administrative units, non-profit organisations, health professionals and senior advisers. The tasks of the Board also include specifying the benefits package under the scheme. A "negative list" was and still is used by which all diseases and interventions were covered except those explicitly excluded. The benefits were comprehensive and there was no financial ceiling for any intervention. Initially, high-cost interventions, like anti-retroviral therapy drugs for the treatment of HIV/AIDS or renal replacement therapy, were excluded and the benefits package under universal coverage was virtually the same as under its predecessor, the Low-Income Scheme.

Subsequently, the benefits package was updated and HIV/AIDS drugs and renal replacement therapy were included in the package (in 2003 and 2008 respectively). The Scheme was funded out of general taxation. Initially, there was a co-payment of 30 baht for each hospital visit (hence the Scheme's popular name) but this was terminated in 2006. There is now no payment at the point of service. The National Health Security Office purchases health care services from a Contracted Unit for Primary Care and its network of primary care units, which can be based in either hospitals or health centres, using a fee schedule: again, prospective capitation for outpatient services and Thai DRGs for inpatient services (paid in arrears). Patients are reimbursed only if they utilise the health facility at which they are registered (Thammathacharee and Patcharanaruemol 2012).

The comprehensive benefits package was intended to cover every intervention not included on the negative list. However, as new high-cost interventions arrived, providers were reluctant to offer them since (so they claimed) the new interventions' high costs were not taken into account in setting the reimbursement rate. To deal with this, the National Health Security Board established the Subcommittee for the Development of the Benefits Package and Service Delivery to determine which new interventions would be covered in the benefits package and also improve access to services. There were, however, no systematic criteria for selection (or rejection) and the interventions were evaluated on an ad hoc basis until cost-effectiveness and budget impact were adopted as criteria in 2009. The benefits package is now updated continually, expanding both service coverage and the access.

Remaining Arbitrary Differences

By 2012, virtually the entire Thai population was protected by one of the three main public insurance schemes. However, the differences between the schemes meant that there were inequities in the receipt of services, in the sense that equal needs had unequal treatments. Expenditures per member also differed — but not according to need. For example, health spending per capita in the civil servants' scheme was much higher than in the other two schemes, their use of surgical procedures was substantially higher, they were more likely to have access to branded medicines and to medicines that were not on the essential medicines list, and their lengths of hospital inpatient stay were longer. Moreover, the reimbursement methods provided different incentives for providers from one scheme to another, some encouraging and some discouraging particular patterns of care (Limwattananon et al. 2004, 2009).

The National List of Essential Medicines and Medicine Pricing

The National List has been maintained since 1983 by the Subcommittee for the Development of the National List of Essential Medicines, currently under the National Drug System Development Committee, chaired by the Prime Minister or a Deputy Prime Minister. It is responsible for formulating overall national drug policy and strategy. The list was initially a minimum list, including only basic medicines. In 2004, it was expanded and became an "optimum" list which was intended to enable the treatment of a wide range of diseases as well as preventive care and public health interventions. In 2008, the significant step of introducing cost-effectiveness and budget impact as criteria for inclusion was taken. These were additional to the traditional criteria of effectiveness, safety and quality.

Medicines are included in the National List according to their generic rather than their brand name and, if there is more than one product that is clinically equivalent in a therapeutic group, only one product will be listed. Low-cost medicines in the list are procured locally. High-cost medicines for all public health providers, however, are centrally procured in order to increase government negotiating power through bulk purchase. For high cost medicines, specific tenders are invited and only one product per generic name, specification and delivery method will be chosen. Each contracted high-cost medicine supplier is given a contract for 1 - 5 years during which the National Health Security Office will purchase at the agreed price solely from that contracted supplier and for all public three insurance schemes.

There has been no direct mechanism for controlling medicine prices in Thailand, though a ceiling price is applied for medicines purchasing by public health providers. Until 2013, ceiling prices based on the median prices of samples taken across all Thailand were set for locally purchased (low cost) medicines and other health products on the National List. After 2013, ceiling prices were set for all

medicines, including those on the National List. Five methods of setting ceiling prices are used: cost-plus pricing, profit-ceiling pricing, comparative pricing (including median method based on Thai and international prices) and direct price negotiation normally in conjunction with other methods. Cost-effectiveness evidence was considered only as supplementary evidence since the evidential base was too poor for its use as a major tool.

With the introduction of the cost-effectiveness criterion for benefit specification and pharmaceutical prices, however, the stage was set for the emergence of agencies able to deliver the necessary technical and empirical support for decision-making.

HTA was in demand!

HTA before HITAP

HTA in Thailand can be traced back to at least 1979, when the first health economics book in Thai was published by Dr Somkid Kaewsonthi, then a lecturer at the Faculty of Economics at Chulalongkorn University and Thailand's pioneering health economist (Kaewsonthi 1979). Health economics teaching and research at Chulalongkorn was continually developed, sometimes with support from international agencies like the Special Programme for Research and Training in Tropical Disease⁵. In 1990, a Center for Health Economics was created. Its focus was not, however, on HTA or cost-effectiveness. Most of the development in economic evaluation of health and HTA took place in faculties of pharmacy, beginning in 1991 with the establishment of the Social Administration Pharmacy Unit in the Faculty of Pharmacy at Mahidol University. It was not until the advent of HITAP, however, that effective links began to be made between the research community and the needs of policymakers in the Ministries with health care responsibilities.

⁵ This is a global programme of scientific collaboration (commonly referred to as TDR) that helps facilitate, support and influence efforts to combat diseases of poverty. It is hosted by the World Health Organization and is sponsored by the United Nations Children's Fund, the United Nations Development Programme, the World Bank and the WHO.

In 1987, a study by US researchers pointed out what seemed to be an unsustainably high rate of growth of health expenditures compared to Gross Domestic Product (Meyers and Causino 1985). This might have stimulated Thai economists to take an interest in what was happening. It was a factor that led to HTA being raised as a major discussion topic at the First Thai Public Health Assembly in 1988. This is a forum for the public and private sectors to share experience, discuss health-related issues and raise awareness of health problems. It is hosted by the Ministry of Public Health. The structure of the forum follows that of the World Health Assembly. A background paper on HTA (in Thai) was commissioned from Dr Chitr Sitthi-Amorn, a distinguished clinical epidemiologist (note: not an economist) in the Faculty of Medicine at Chulalongkorn University. The paper (Sitthi-Amorn 1988) was a comprehensive survey of the field and reviewed the experiences of other countries. This was the first Thai paper to focus on HTA. But it had little in the way of consequences either for policy or for the research interests of health economists.

That is not altogether true, for the Health Systems Research Institute — an autonomous agency initiated in 1992 by the Ministry of Public Health — produced some empirical studies that informed policy. One was a cost-effectiveness study of proton radiation therapy (Prakongsai et al. 2001). However, there was no systematic process for including HTA evidence in policy decision-making. After the Public Health Assembly, there were attempts, both local and international, to establish HTA and institutions in which it might flourish, but they all failed (see chapter 3). What is more, as is clear from Teerawattananon (2007), the number of economic evaluation studies in each disease and field in Thailand prior to the birth of HITAP bore no relation at all to the burden of disease. Major health problems were not a criterion for the choice of research topic. This might be thought fair enough, considering that the research topics were mostly generated

by individual interests and private investments, but researchers could then scarcely complain if their work had little policy impact — it did not tell the policymakers what they wanted to know.

What really eventually caused HTA in Thailand to take off was Universal Health Coverage. Getting that into being was a huge achievement and one not easily accomplished. Because of its enormous implications for public expenditure an active policy demand for HTA-informed evidence was its inevitable consequence as a means of controlling the content of the insured bundle and for price negotiations with suppliers of pharmaceuticals and other medical supplies. What HITAP had to offer at its beginning was simple: expertise in health technology assessment and a willingness to contribute to the policy-making process.

CHAPTER 3

A STAR IN THE EAST
A SHORT HISTORY OF HITAP

HITAP IS BORN

"(Having seen what others did) I came to a conclusion that if you just talk only – if you just have intellectual debates about it without bringing it down to action in ways that it has a policy link, no work of national significance will be realised, therefore, you have no place in the policy world." (Dr Viroj Tangcharoensathien, Former Director, International Health Policy Program)

"A small body of determined spirits fired by an unquenchable faith in their mission can alter the course of history." (Mahatma Gandhi)

Nearly a decade ago, a small programme of health technology assessment (HTA) in Thailand was created. There had been few, if any, successful attempts at such a thing in low-income settings so this was a truly pioneering effort. This chapter tells the story of that programme, Thailand's Health Intervention and Technology Assessment Program (HITAP). We begin with a review of some previous attempts to establish an HTA organisation in Thailand. Then the focus is on a handful of key players who shared a big idea of what HTA might do for Thailand, whose vision, determination and political skills brought HITAP about. The final section looks inside HITAP, at its structure and organisation.

Early rehearsals

As has been seen in chapter 2, an interest in health technology assessment existed in Thailand at least two decades ago, and possibly further back than that. Apart from universities and research institutions that carried out basic research mainly for academic purposes, there were but few units within a handful of public organisations conducting health technology appraisal in ways that would support public policy-making. Three early attempts are worthy of note: Technological Assessment and Social Security in Thailand (TASSIT); the Institute of Medical Research and Technology Assessment (IMRTA); and Setting Priorities Using Information on Cost-Effectiveness (SPICE). However, with limited expertise available in health economics, inadequate institutional support capacity and a lack of any long-term commitment among those who were involved, these programmes had only limited influence on policy decisions. With the exception of IMRTA, the other two programmes faded and died.

Increasing public expenditures following the introduction of new public health insurance schemes had raised financial and managerial concerns at the national level and regional levels in Thailand, and these concerns persisted even though the initial attempts at using health economics and HTA fell by the wayside.

The Civil Servant Medical Benefit Scheme had been in existence since 1960. The new publicly supported insurance schemes included Social Health Insurance, initiated in 1990 under the Social Security Office, and the Universal Health Coverage Scheme, initiated in 2002 under the National Health Security Office. Over this period, health managers, especially those within the overarching Ministry of Public Health, continued to see HTA as a prime instrument for cost control despite the then poor infrastructure of HTA in Thailand (Teerawattananon et al. 2009).

Technological Assessment and Social Security in Thailand (TASSIT)

TASSIT was the first and probably most ambitious attempt to do HTA work in Thailand in the 1990s. It was launched in 1993 by a group of epidemiological and clinical experts as a project of the Health Systems Research Institute (HSRI), an autonomous agency initiated in 1992 by the Ministry of Public Health to sponsor research to support the strategic planning of the country's health systems. TASSIT was a collaboration between the Institute in Thailand and the Karolinska Institute and the Swedish Planning and Rationalization Institute (SPRI), both in Stockholm, Sweden. The collaboration was intended to transfer knowledge and know-how, together with institutional strengthening for health development. One of TASSIT's activities centred on health technology assessment (Tomson and Sundbom 1999).

As a part of the plan for capacity development in its initial phase, the project arranged exchange visits for study purposes from both sides, which included training for Thai professionals in Sweden. The training programme included courses on health technology assessment and drug utilisation at the Swedish Council on Technology Assessment in Health Care (SBU). SBU is one of the earliest formally established HTA agencies in the world. It was founded in 1987 and tasked by the government to assess health care interventions broadly – from medical, economic, ethical and social perspectives. Its research was mainly secondary, in the form of systematic reviews.

In 1997, a contract for a further five years was signed. TASSIT had identified several issues to be addressed, including the assessment and rational use of health care technologies, resource allocation, financial management, quality management, health manpower development, and a research programme on social security. Matters of the rational use of health technologies and resource allocation lay at the core of policy interest at that time as they are, of course, also at the heart of HTA.

TASSIT was not intended as a merely a short term collaboration. In 1997, the collaborators developed a proposal for the *Development of a National Mechanism for Health Care Technology Assessment in Thailand*. According to this proposal (Tomson and Sundbom 1999), a mechanism was to be set up in the form of an independent National Council that would command the trust of government, be dependable and have authority. It would be financed by the government. It was also proposed that a National Council committee for HTA be established, made up of individuals selected from various parts of the public and private health care systems. This committee would reach evidence-based conclusions and make recommendations but would not have any regulatory function. The day-to-day activities of HTA would be run by a secretariat unit within the National Council. The secretariat would be responsible for commissioning and assisting in HTA research and would carry out other administrative activities, including training and communication with other organisations. This meant that most of the actual HTA research would be commissioned or outsourced to experts outside the Council. The proposal anticipated that:

"HTA will grow into a movement and an attitude of sound critical views on the diffusion and use of technology, instead of investment in and diffusion of technology in [an] uncontrolled fashion. The HTA should collaborate with the Ministry of Public Health, the National Economic and Social Development Bureau [Board], the Royal Colleges of Medicine, and hospitals at the operational level. International collaboration will also be emphasised." (Tomson and Sundbom 1999, Annex 7).

In the event, and despite its ambitious start, TASSIT failed to scale up and eventually faded out in the late 1990s. The ambitious proposal for the development of a national mechanism for health care technology assessment went with it. The reason for this failure was mainly that there were insufficient human resources at the Thai end and that they had no long-term commitment to doing HTA work, with little in the way of a health economics or an HTA infrastructure to support it (Tantivess et al. 2009).

Institute of Medical Research and Technology Assessment (IMRTA)

In 2002, research on the assessment of medical technology began in the Department of Medical Services (DMS), a division of the Ministry of Public Health. Initially it was located within the DMS's Technological Support and Development Unit. Later (2007) it was transformed into the Institute of Medical Research and Technology Assessment. The Institute's activities are grouped in four clusters, one of which is medical technology assessment. However, the medical technology assessment in question was done mainly to support medical services delivered by health facilities under the DMS, which are mostly tertiary hospitals. Assessments actually using economic analysis were few and the research capacity to do them, as we have seen, barely existed. Moreover, the Institute relied solely on support from the general budget of the Ministry of Public Health and had no clear plan for building research capacity for HTA. Its ability to inform decision-making for investment in health technology and policy practice was limited (Teerawattananon et al. 2009).

Setting Priorities Using Information on Cost-Effectiveness (SPICE)

SPICE was a project introduced in 2004 as an international collaboration between the Ministry of Public Health and the University of Queensland in Australia. Funded by the Wellcome Trust and the Australian's National Health and Medical Research Council, SPICE aimed to assess health care interventions in the fields of HIV/AIDS, cardiovascular disease, stroke, diabetes, cancer, road traffic injuries and

mental health. HTA for medical devices and surgical procedures was developed and managed by the medical technology assessment group in the Ministry of Public Health's Department of Medical Services. SPICE ended in 2009 because, again, there was no long-term commitment to it and little research capacity had been created, the leadership was overseas and by its nature not able easily to become involved closely in Thai policy-making. Nor had the creation of local leaders in Thailand been a priority (Tantivess, Teerawattananon and Mills 2009). Although SPICE supported three or four PhD students (in Australia), they did not contribute to HTA capacity in Thailand.

A Retrospect

Although the Institute of Medical Research and Technology Assessment survives today, its role in technology assessment is not for the improvement of benefits packages in any health insurance plan; rather, it is to support good practice in the health facilities under the Ministry of Public Health in general and those under the Department of Medical Services in particular. Its role is naturally limited by the core business and overall objectives of the DMS. The Institute, along with the other early initiatives, suffered from insufficient research capacity to meet the new demands arising from Social Health Insurance and the Universal Health Coverage Scheme. There was also a lack of long term commitment. A professional HTA programme of policy-relevant research requires not only highly capable research staff, and in sufficient numbers, but also their organisation in a mutually supportive and collegial environment, in which proper career planning can take place and suitable links established with universities and other centres of research and advanced training. One of the reasons why TASSIT and SPICE had such short lives is that they also had poor, if any, relations with the governmental decision-making machinery. TASSIT was essentially run by and for the senior external members from Sweden. SPICE had a lot of full-time researchers and research assistants but none of them were involved in policy processes. The topics for assessment were set by the team without proper stakeholder consultation. Those who formed these

early teams often had prior commitments elsewhere. Dr Viroj Tangcharoensathien, a key player in the early days and one of our key informants, who served as the director of the International Health Policy Program for nearly ten years, views the success of research programmes in general, and those under the International Program in particular, as depending very much on what he calls "core principles," namely, *generating evidence, influencing policy, and capacity building*. In his vivid analogy, these core principles are "the three rivers that flow to merge and form the large one". None of these early precursors had the right mix. HITAP, by contrast, was to have them, as we shall see.

The Key Players and their Big Idea

Building an organisation is like constructing a building. Just as the construction of a building needs a clear idea about how it should look, how it will be used, and who will use it, so does creating an organisation such as HITAP. HITAP did indeed begin with a clear idea about the goals it would set itself, the functions it would perform and the human capacity it would need to carry them out. Although many people contributed to the making of HITAP, the most important players were a quartet of remarkable people: Dr Suwit Wibulpolprasert, Dr Viroj Tangcharoensathien, Dr Yot Teerawattananon and Dr Sripen Tantivess.



Dr Suwit Wibulpolprasert

Dr Viroj Tangcharoensathien

Dr Yot Teerawattananon

Dr Sripen Tantivess

The first three of these key players are medical doctors. Dr Sripen's first degree is in pharmaceutical science and her PhD is in public policy. Drs Viroj, Yot and Sripen all had PhD degree training from well-known institutions in the United Kingdom. After graduation from the medical school in Thailand, the three medical doctors worked as practitioners and directors at rural district hospitals in poor, under-served Thai provinces: Dr Suwit in the North and Northeast, Dr Viroj in the Northeast, Dr Yot in the North. After rural service for some years, they moved to the Ministry of Public Health in Bangkok. Dr Sripen had more than ten years of experience at the Food and Drug Administration before engaging full-time in research with the International Health Policy Program in the late 1990s.

Dr Viroj seems to have acquired an interest in health economics during his years at the rural district hospital in Ubon Ratchathani Province in the Northeast. Some evidence for this is the methodological work on the costing of hospital services which he developed for his rural district hospital and a provincial hospital (Chokewiwat 2011). This was admired by his senior colleague, Dr Suwit, at that time the head of the budgeting section of the Health Planning Division of the Ministry of Public Health. After ten years in the rural district hospital, Dr Viroj won a Rockefeller Foundation scholarship to do a PhD in health economics and health care financing at the London School of Hygiene and Tropical Medicine. Dr Suwit, on the other hand, brought with him eight years of experience in providing rural health services and administration when he came to work at the central Ministry. There he played a significant role supporting health development in both administration and academic affairs. His progressive vision and understanding of the health system are well respected inside Thailand as well as internationally. The two men, Drs Suwit and Viroj, complemented each other well, rather as an architect does an engineer.

Back from London in the early 1990s, Dr Viroj was affiliated with the Planning Division of the Ministry of Public Health (now the Bureau of Policy and Strategy). He was actively involved in designing the payment system for Thailand's Social Health Insurance, which had been created to supplement the civil servants' insurance plan by providing for workers in the private sector. He estimated the 700 baht capitation rate and successfully convinced the first secretary general of the Social Security Office, Amphon Singhagowin, to adopt capitation as closed end payment method for contracting providers. In 2001, he was involved again in similar work for the Universal Health Coverage scheme that was set up for the many Thai people who remained uncovered by other health insurance plans (over 47 million of them). Most of them were low-income people living in rural areas. Dr Viroj worked with Dr Sanguan Nitayarumphong, the first secretary general of the National Health Security Office, who had spent many years in his advocacy of universal coverage for Thailand, and who was much admired by, among others, Dr Yot (Nitayarumphong 2006)⁶. All these experiences led Dr Viroj to realise how much Thailand needed competent professionals who could carry out economic analysis of health interventions, technologies and programmes, advise on system design, and thereby help the planners to prioritise technologies systematically, with clear and humane criteria, using all the available evidence about effectiveness and cost-effectiveness, and within an organisational structure for the health services that gave appropriate incentives to both providers and users.

In 1997, Thailand was plunged into an economic crisis attributed by many to poor management in the financial sector, over-investment by private companies, and inadequate supervision of foreign currency exchange by the Bank of Thailand. The crisis had a huge impact on the entire economy at both the macro- and micro-levels. There was significant inflation and a marked contraction in household real income with a consequential fall in most people's ability to pay for health care

⁶ Great events, such as Thailand's introduction of universal health coverage, are usually the product of complex forces — including strong personalities, smart tacticians and serendipity. One important contributor to universal coverage in Thailand was probably the persistent work of a small group of highly intelligent public service oriented doctors-cum-civil servants, who were members of the so-called Rural Doctors' Society, created in 1978. Some of the key players in preparing the way for HITAP were members. For an account of the probable role of these "bureaucrats", see Harris (2015).

(Tangcharoensathien et al. 2000). The crisis put pressure on the government to increase its support of the public health system. The combination of the rise in public health spending and the growth in service utilisation of public health facilities was already present before the crisis. Now the issue of cost containment was to assume major proportions. As one of the few trained health economists at that time, Dr Viroj perceived an urgent need to build the country's capacity to invent evidence-based policies to manage the situation with maximum efficiency.

Leadership and Inspiration

It was the International Health Policy Program that gave birth to HITAP in 2007. Dr Suwit was at that time the Senior Adviser on Disease Control at the Ministry of Public Health. Earlier, he had been the first Director of the International Health Policy Program (later succeeded by Dr Viroj). This Program had been first established in 1998 as a research project on health financing and economics in the Health Systems Research Institute. The project was supported by the Senior Research Scholar grant awarded to Dr Viroj by the Thailand Research Fund.

A few years after his graduation from the London School, Dr Viroj was seconded by the Bureau of Policy and Strategy to the Health Systems Research Institute. The aim was to allow him to do more policy-linked health systems researches, rather than spending time with the bureaucratic requirements of the Bureau. His performance and publications while at the Institute had won him a Senior Research Scholar's award from the Thailand Research Fund in 1998, with the support of its director, Dr Vicharn Panich. The Fund is an autonomous research funding agency, founded under the Office of the Prime Minister in 1992. Dr Viroj was awarded the scholarship twice, each time for three years. The grant is to support outstanding senior research scholars in conducting high quality research

which also provides vehicles for the training of a new generation of researchers. The awards required him to build capacity in health policy and health financing and economics. With the grant money at his disposal, Dr Viroj accordingly began to recruit promising young scholars to do research with him. These included, for example, Dr Piya Hanvoravongchai, now a lecturer at the Chulalongkorn Medical School and Dr Siriwan Pitayarangsarit, the current director of the International Health Policy Program. In early 2000, the Thailand Research Fund requested Dr Tada Yipinsoi together with Dr Suwit, to assess Dr Viroj's Senior Research Scholar project, as a result of which it was strongly recommended that the achievements to date should be put on a more permanent footing. This recommendation was realised in 2001 by the creation of the International Health Policy Program as a unit under the Health Systems Research Institute. The founding of the Program was built on a three-year memorandum of understanding between the Ministry of Public Health and the Health Systems Research Institute, initiated by Dr Suwit in his capacity as the Deputy Permanent Secretary in the Ministry.

The International Health Policy Program was thus effectively the joint creation of Drs Suwit and Viroj. Its aim was to strengthen and use the capacity of Thai researchers through conducting policy-relevant research on health care financing, economic evaluation, public health insurance and health policy analysis. Later, this aim was enlarged to include improving the national health care system through generating knowledge and reliable evidence for policy decision-making and improving system design. This was different from other such programmes within the Ministry at that time. The Program regarded human capacity building in and around health economics as of critically high significance for generating relevant and reliable evidence for policy. Dr Suwit became the Program's first Director followed after two years by Dr Viroj.

When the Program was launched, Dr Viroj had already been at the Health Systems Research Institute for seven years on secondment from the Bureau of Policy and Strategy. However, when the three year memorandum of understanding came to an end, he decided to make the Program a research unit under the Ministry's Bureau of Policy and Strategy in order to give it an arm's length relationship with the decision-making processes of the Ministry. Furthermore, for greater financial flexibility, the Program was re-established as a private non-profit foundation. So while it still had the legal status of a governmental unit within the Ministry, it had considerable discretion as non-profit foundation. This semi-autonomous status gave it sufficient independence and flexibility in carrying out research while being neither too close to the Ministry to be dominated nor too distant to be policy irrelevant. This clever strategy was also adopted by the HITAP a few years later.

During his years at the Health Systems Research Institute, Dr Viroj learned much about the strengths and weaknesses of the research programmes located there. One was TASSIT. It was designed to include HTA among its activities but, as we have seen, failed to scale up sufficiently to become an effective programme. That experience gave him a clear idea about what was needed to create an effective and sustainable research programme that could influence policy. In his view, the most crucial elements were his "three rivers": of evidence generation, policy relevance and capacity building. These principles later became core principles in HITAP's own strategic development.

Another important talent that helped Dr Viroj fulfil his ambition of creating effective research programmes, like the International Program and HITAP, was his ability to mobilise funds for research and capacity building. In 1998, when he received the Senior Research Scholar grant from the Thailand Research Fund, he was able to supplement the funding with further money mobilised from international

sources. In this way, he was able to support the training of half a dozen or so young researchers at a PhD level in Thai universities and abroad. Many of these young researchers were also trained in health economics and policy research. They included two of our key players: Drs Yot and Sripen, who were already working in the International Program soon after the start of the new millennium, and who each received PhD fellowships from the WHO South East Asia Regional Office.

Before joining the International Program, Dr Yot had had three years of experience as the director of and practitioner in the community hospital of Pong, a district of Phayao Province in the upper North of Thailand. He moved (on secondment) to work in Bangkok in 2000. He initially received an offer to be a faculty member at the Department of Community Medicine in the Medical School at Chulalongkorn University. He declined it, however, and took up instead the offer of a research fellowship in the International Program, a decision inspired partly by Dr Viroj's reputation in health economics and partly by his own wish to do good research in the same area. Dr Yot was thus in the Program and worked under Dr Viroj's supervision for a little over two years. In 2002, he won a WHO fellowship to study for a PhD in the UK — the same year that Dr Sripen also went to England.

For his PhD study, Dr Yot decided to do health economics at the University of East Anglia, focusing his thesis on economic analysis for health technology assessment. His decision was hugely influenced by his experience at the International Health Policy Program, especially his research there on preventing HIV transmission from infected pregnant mother to child. Specifically, that earlier research had addressed the question of whether treatment by giving Nevirapine in addition to the usual treatment with Zidovudine alone could enhance the reduction of HIV transmission from mother to child. The result proved to be significantly positive. He did this study before he knew much about health economics. His main

source of knowledge then was a book by an epidemiologist physician, Dr Phirom Kamolratanakul of Chulalongkorn University's Medical School. Although Dr Yot's published research (Teerawattananon et al. 2005) did not have direct influence on any policy decision — by the time his research was finished the policymakers had already recommended this treatment — the experience was important for Dr Yot's choice of the field for his PhD thesis.

With her background in pharmaceutical sciences and public health and having worked at the Thai Food and Drug Administration for more than ten years, Dr Sripen Tantivess had become deeply interested in full-time research. She moved to the International Program in late 1999 and was assigned to the health financing project. Like Dr Yot and many other research fellows in the Program's team, Dr Sripen was trained under Dr Viroj's supervision. When she got her WHO fellowship to do a PhD at the London School of Hygiene and Tropical Medicine, she chose the field of public policy and focused her thesis research on the politics of universal access to antiretroviral therapy in Thailand. Some highly complementary skills were being developed in these two bright young students.

The ideas leading to the creation of HITAP probably evolved over several years. The policy trigger arose from the health and economic circumstances in Thailand after the early 1990s. Particularly important among these was the emergence of the two public health insurance plans and the economic crisis of 1997. They affected both the demand for and the supply of economic evaluation in health: the demand because of the need to find financially manageable means of delivering two major new programmes of care under conditions of financial instability, and the supply because the intellectual challenge of creating acceptable procedures for making difficult choices appealed strongly to these two young analysts, Drs Yot and Sripen, who had the backing of two now senior health policy "mandarins" (Drs Viroj and Suwit).

The Organisation is Born

Considering that its mission was to produce scientific evidence for policy decisions, the International Health Policy Program must have had a keen interest in HTA from its early years. Indeed, from 2000 to 2003 some studies by researchers in the Program had already applied cost-effectiveness methods to assess health interventions. Examples of such studies include studies on interferon- α , a national programme to prevent mother-child HIV transmission, the use of micronutrient supplements in HIV treatment, and proton radiation therapy (Tantivess, Teerawattananon and Mills 2009). Nonetheless, the International Program was still not ready formally to set up an HTA unit. It simply had insufficient research capacity at its disposal.

Although Drs Yot and Sripen never admitted that they were expected to start an HTA programme up, evidence seems to suggest that this was the case. In 2005, while they were not yet done with their studies, the International Program asked the two of them to prepare a grant proposal for an HTA research programme. The proposal was submitted to Harvard University in the United States. Although it was not successful, the aim of the proposal was to initiate a national programme for HTA that would assist decision-making in the provision and utilisation of pharmaceuticals, medical devices, procedures, and health prevention and promotion in Thailand.

When Drs Yot and Sripen returned in 2006, an initiative for HTA research programme had already got under way. Dr Yot at the International Health Policy Program revised the unsuccessful Harvard proposal for submission to four other funding sources: the Thai Health Promotion Foundation (ThaiHealth), the Health Systems Research Institute (HSRI), the National Health Security Office, and the Bureau of Policy and Strategy (BPS) in the Ministry of Public Health. The proposal was submitted in December 2006 and was approved in January the following year.

Approximately 30 million baht was made available, mostly from the Thai Health Promotion Fund, for running the first three years of what was now to become HITAP. This then, after a long period of gestation, marked the birth of the organisation. The Health Intervention and Technology Assessment Program had at last arrived.

Its title and acronym emerged from a brainstorming session of the staff and was suggested by Dr Sripen.

HITAP: Goal, Vision, Missions and Strategies

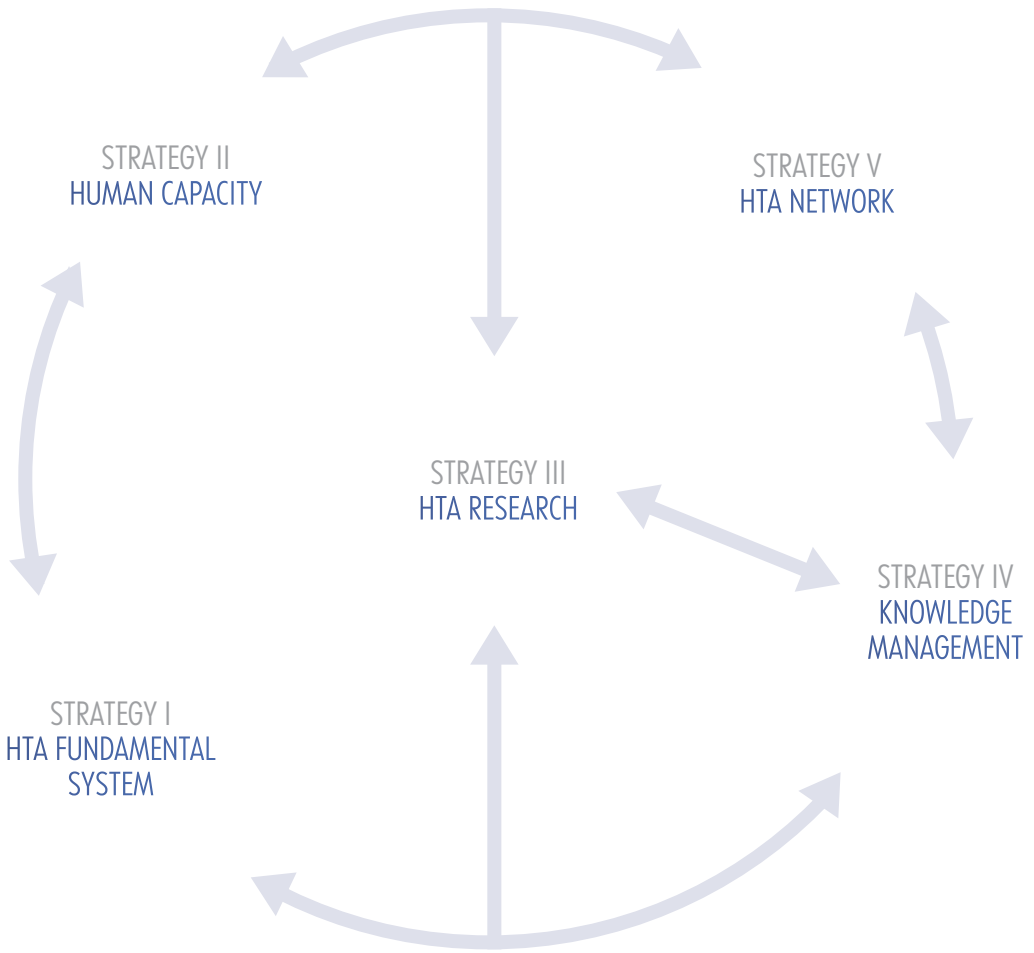
The ultimate goal of HITAP is to provide policymakers, health professionals, health providers and the public with scientific evidence about the costs and benefits of introducing of health products, procedures and programmes. Behind this goal, HITAP's vision is a state of the world in which the only health interventions and technologies available at public expense are all demonstrably effective and available for all in Thailand. This is translated into the following specific missions: to appraise efficiently, using transparent processes, health interventions and technologies by using methodologies of a high international standard; to develop systems and mechanisms that will promote the optimal selection, procurement and management of health technologies and contribute to the effective policy design of the health care system; and to disseminate research findings and elevate public understanding to enable the best use of the results of health interventions and technology assessment (HITAP Annual Report 2010).

At the operational level, these missions are further translated into strategies defining activities required to achieve the goal. During the first phase (2007–2009) of HITAP, four strategies were identified. Later a fifth strategy was added. The five are as follows.

Strategy 1: Basic research and development for health technology assessment

This strategy addresses the need to improve the infrastructure for health interventions and technology assessment by developing a body of knowledge and methods meeting the highest international standards while recognising the resource and non-budgetary constraints current in Thailand. Work already accomplished under this strategy includes development of methodological guidelines, a database of HTA studies in Thailand, tools and quality of life measures for cost–utility analysis, and a social value–based threshold ceiling.

FIGURE 3.1
HITAP's strategies



The methodological guidelines for health technology assessment are an outstanding achievement. These were the first Thai guidelines developed by experts from various agencies to lay out the required economic principles governing the conduct of HTA in Thailand (Tangcharoensathien and Kamolratanakul 2008). The guidelines were published in the Journal of the Medical Association of Thailand, the first version in 2008 and the second in 2014. The guidelines were endorsed by the Subcommittee for Development of the National List of Essential Medicines and the Subcommittee for Development of Benefits Package of the National Health Security Office. All studies follow the same guidelines, regardless of the client agency for whom the assessments are being done.

Strategy 2: Capacity strengthening for HTA at individual, institutional and system levels

This strategy addresses two important problems: the numerical insufficiency of health economists competent to conduct HTA, and inadequate understanding and appreciation of the potential of HTA among potential users of research. Human capacity building and effective education programmes were plainly needed. Since 2007, HITAP and HITAP partners can claim to have nurtured eight completed PhDs (five from overseas and three from domestic universities) and four master students (three from overseas universities and one domestic). Seven PhD students (four of whom have already graduated) and more than 17 master students (twelve already graduated) have been supervised by HITAP staff. HITAP provides its staff with both on-the-job and formal training in Thailand and abroad. Since research constitutes the major task of HITAP, strengthening and maintaining the technical competency of researchers is crucial. HITAP has a capacity strengthening scheme. There are explicit procedures and criteria for the financial support of research staff giving presentations at domestic and international forums. Scholarships are made available for short-term and advanced postgraduate training within Thailand and abroad. Moreover, HITAP's collaborations with HTA

and academic institutes in a widely diverse set of countries at different levels of development (for example, the UK, Korea, Taiwan, Japan, Indonesia and Vietnam) enable their prime purpose to be supplemented by developing staff competencies through on-the-job practical experience in a variety of contexts.

Between September 2012 and September 2015, Dr Yot held a Senior Research Scholarship grant from the Thailand Research Fund to support research and capacity building. This grant, together with funding from other sources, enabled fifteen young researchers to receive on-the-job training, and eight to receive postgraduate training in health economics, social sciences, epidemiology and pharmaceutical science (three in Thailand and five in the UK). In all, 46 research studies related to health intervention and technology assessment were completed; of these, 35 were used to support policy decisions and 22 were published as scientific papers in domestic and international journals.

In addition, training courses are organised annually for physicians, pharmacists, public health administrators and many others with an interest in HTA. These include training sessions on economic evaluation for HTA and meta-analysis of HTA research, and workshops and forums on HTA. So far these training courses have been well received among stakeholders, policymakers, health planners and researchers from both public and private institutes. Over 1,000 participants have benefitted from these courses to date.

Strategy 3: Assess health technologies and methods for setting priorities in health and health care

This strategy addresses the growing needs for HTA, particularly for cost-effectiveness and budget-impact appraisal in Thailand. The main focus is to carry out HTA studies and these are regarded as HITAP's core business.

In addition to providing advice based on scientific evidence for stakeholders and decision-makers, the research processes on which the advice is based provide a means of on-the-job hands-on training for HITAP researchers and their external collaborators. Two further related activities in strategy 3 are the prioritisation and selection of technologies for appraisal and research, and the development of research procedures that embody transparency and accountability.

Strategy 4: Dissemination of research results to policymakers, medical practitioners and the general public

Knowledge management, translation and integration of research findings into policy and practice are the core elements of this strategy. HITAP actively encourages stakeholder participation in the process of prioritising and selecting research topics. Policymakers and stakeholders are actively engaged in reviewing research results and in formulating appropriate policy recommendations. The dissemination of research results to respective stakeholders is done through a variety of channels – meetings, seminars, press releases and other social media including emails, blogs, Twitter and Facebook. The intention is to create two-way communication between researchers and research users (including patients and the general public). HITAP's websites are frequently updated with regard to both structure and content and HITAP employs media communication specialists to ensure that its websites are truly effective. This attention by a research organisation to public communication is probably unique in Thailand.

Strategy 5: Development of HITAP's own management and of connections between HITAP and academics and other HTA bodies at national and international levels

This strategy aims to develop HITAP's internal management so that it is recognisably an organisation with good governance. HITAP's collaborations

operate at the regional, national and international levels and include academic institutes, health professional consortia and associations, and health providers. Some take the form of networks. Two notable networks are the HTAsiaLink consisting of more than 20 HTA institutes throughout Asia, and the International Decision Support Initiative (iDSI) of NICE International, funded by the Bill and Melinda Gates Foundation, the Department for International Development in London and the Rockefeller Foundation.

Some characteristics stand out. HITAP's strategies, especially the first four, plainly reflect Dr Viroj's "three rivers": generating evidence, influencing policy and capacity building. Networking has become an increasingly important part of HITAP's work (and of its Program Leader's activity). Networking is viewed not only as a means of promoting HITAP's image but also as a means of capacity strengthening and staff development, and as a method for expanding sources of HTA information and funding support. This too reflects the views of the HITAP's key mentors, Drs Suwit and Viroj, who early on saw the important role that networking can play in capacity building for individuals, in creating nodes of activity (like institutes) and in networking and environment building for creating a context in which HTA and evidence-based practice can flourish. Although each of the five strategies is important in its own right, strategy 3 on HTA and policy analysis is plainly to be seen as HITAP's truly core business. This is well-reflected in the fact that the largest group of the HITAP staff is devoted to research in applying HTA methods to specific health care interventions.

Funding HITAP

A fundamental principle of HITAP's funding arrangements is that no contracts or financial support of any kind is accepted from for-profit sources. Unlike other organisations within the Ministry of Public Health, HITAP does not depend on direct

financial support from the government's annual budget either. In this respect, HITAP is similarly placed to the International Health Policy Program. HITAP's status is semi-autonomous by which it has to seek funding support from other sources, governmental or non-governmental, domestic or international. Insofar as HITAP receives funding from the public budget, it is via other government funded organisations, including the Ministry of Public Health, via specific research or other consultancy contracts. In the first three years of its existence, about 80 per cent of HITAP's funding came from four sources. the Thai Health Promotion Foundation, the Health Systems Research Institute, the National Health Security Office, and the Bureau of Policy and Strategy. Only the Bureau of Policy and Strategy was an organisation in the Ministry of Public Health. Relatively little support came from international sources. Over the years, the number and variety of funding sources has increased. Table 3.1 lists the funders during the period 2007 - 2014 according as they were domestic non-MOPH, domestic MOPH, or international.

From its beginning in 2007 to 2014, the amount of annual funding that HITAP has received has grown substantially from just over 17 million baht per year to well over 40 million baht (Figure 3.2). Most striking is the large share of funding taken up by international sources in the more recent years, reflecting both HITAP's effectiveness as an international networking organisation and its growing reputation and international standing. These matters receive further attention in chapters 5 and 6.

The chart indicates two broad periods. The first covers the first three years of HITAP's existence, peaking in the second year at a little under 24m baht but averaging about 20m baht per year. The second period, 2010 - 2014, sees the average doubled at 40m baht per year but no evident subsequent upward trend. Within the totals, however, there appear to be trends, with income from domestic non-MOPH sources falling and income from international sources rising markedly. Annual income from the domestic MOPH sources ranged between 2m and 7m over the entire period of eight years. The obvious question arises:

TABLE 3.1
Sources of funding support to HITAP, 2007 – 2014

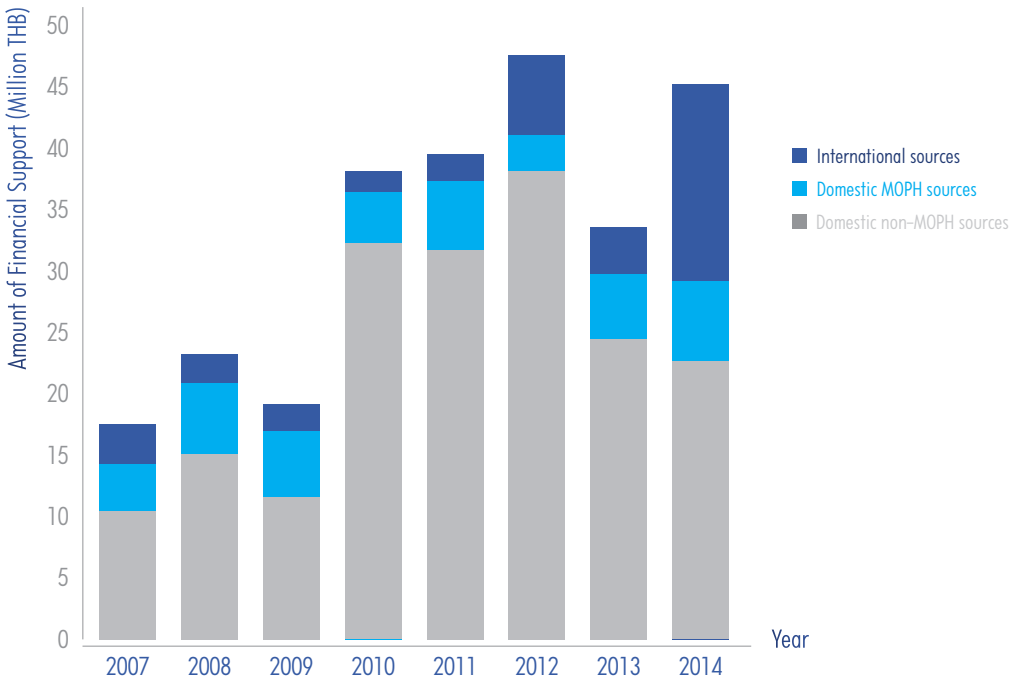
<i>DOMESTIC, NON-MOPH SOURCES</i>	<i>DOMESTIC, MOPH SOURCES</i>	<i>INTERNATIONAL SOURCES</i>
<ul style="list-style-type: none"> • Center for Alcohol Studies • National Health Commission Office • National Health Security Office • National Institute for Child and Family Development • Thai Health Promotion Foundation • ThaiHealth Global Link Initiative Program • Thailand Research Fund • Thailand Convention and Exhibition Bureau • National Science Technology and Innovation Policy Office 	<ul style="list-style-type: none"> • Bureau of Policy and Strategy • Department of Disease Control • Department of Health • Department of Mental Health • Government Pharmaceutical Organization • Health Systems Research Institute* • Institute of Health Promotion for People with Disability* • Health Insurance System Research Office* • National Health Care Financing Development Office* • Institute of Dermatology • International Health Policy Program 	<ul style="list-style-type: none"> • Asia Pacific Observatory on Health Systems and Policies • EuroQoL • Global Development Network • International Decision Support Initiative • Program for Appropriate Technology in Health • The Rockefeller Foundation • Thai MOPH-US CDC Collaboration • Tufts University • United Nations Population Fund • World Health Organization

Source: HITAP

Note: * These are autonomous organisations that are not in the structure of the Ministry of Public Health but receive financial support through it.

what happened in 2009/10 to cause the step jump in funding, substantial part of which came from international sources. The answer seems to be that HITAP was able to establish, in addition to its national standing, a remarkable regional, even global, reputation in a short space of time, of which more in chapter 6.

FIGURE 3.2
 HITAP's income 2007 – 2014



Independence

Like IHPP, HITAP was designed from the start to be a non-profit arm's-length organisation. As such, it faces in two directions: one governmental and the other non-governmental. As a governmental programme, it has a formal, official link with the Ministry of Public Health through the International Health Policy Program and the Bureau of Policy and Strategy. Its reporting to the Bureau usually goes via the International Program. In this direction, then, HITAP is an official agency of the Ministry of Public Health with formal accountability. However, it also has other accountabilities and income sources and so depends neither directly nor solely on the Ministry for financial support. Any Ministry income coming HITAP's way comes as specific commissions or from other agencies which the Ministry funds. Consequently HITAP has considerable flexibility in both personnel and financial administration. As a non-governmental research programme with a mandate to provide usable scientific evidence for stakeholders and policymakers, HITAP also enjoys considerable freedom in programme management and administration. It keeps some distance between it and the decision-makers and their advisers, and this, together with the visible involvement of other researchers and stakeholders means that it is largely immunised from political and commercial pressures to produce results "to order". HITAP is both a part of, and not a part of, the Ministry of Public Health.

Function

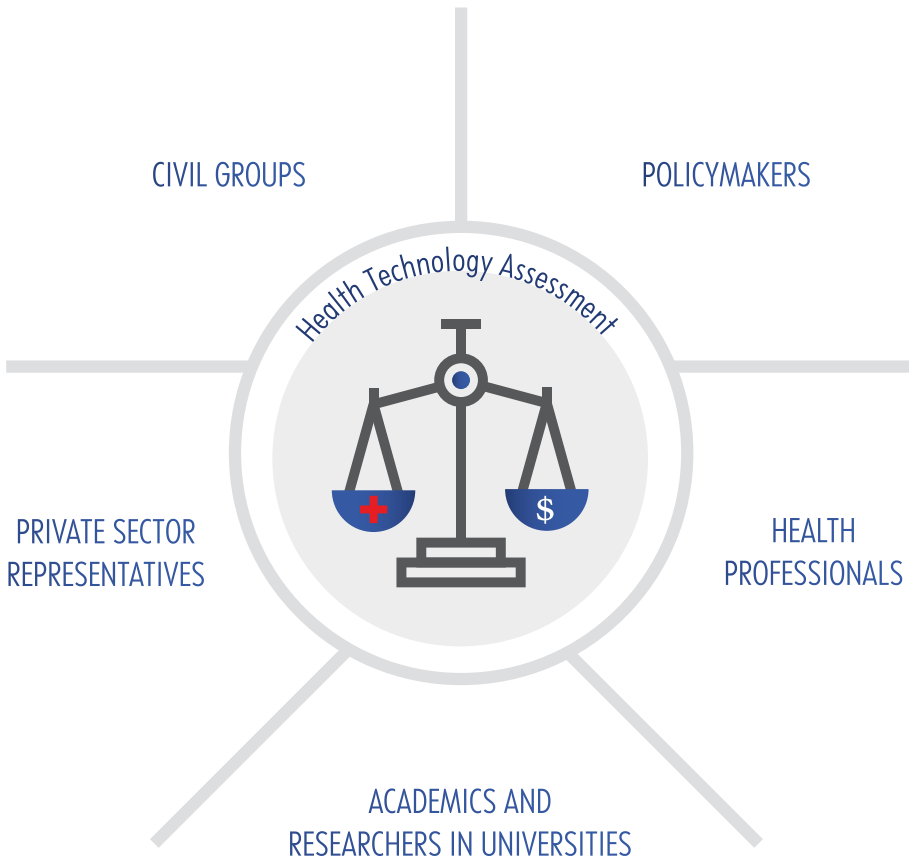
HITAP was created to provide rigorous scientific evidence through professional assessment of evidence in support of public decision-making including system design, the selection of technologies for assessment, and the actual assessment of those selected and agreed by relevant government agencies. In this capacity, HITAP assumes the role of adviser — never decision-maker and never regulator. This clearly defined but circumscribed role is strongly defended in HITAP and

it has political advantages since it does not put HITAP directly in any line of fire — other than being exposed to potential criticism on academic grounds by academic critics. It also grants HITAP an important immunity against potential conflict of interest. Up to the present, HITAP has successfully stuck to this advisory role, providing only evidence and recommendations but leaving the decision-making in the hands of policy authorities like the National Health Security Office and the Subcommittee for Development of the National List of Essential Medicines. This does not entirely insulate HITAP from criticism, as when its recommendations run against the interests of particular stakeholders, but so long as its recommendations do not exceed the boundaries of what the evidence will bear, it has the benefit of scientific objectivity — other kinds of judgement will have been exercised by others.

Stakeholders and Accountability

The processes of health technology assessment involve — or should involve — stakeholders. The "stake" is an outward symbol of a right to be consulted (at a minimum) by virtue of having a material interest in the assessment, for example as a person who might want to prescribe the treatment's use, or a person involved in its manufacture, or as a person or carer of a person who might be a candidate for receiving the treatment in question. There are weaker forms of involvement as when one may comment, which is not quite the same as being consulted, or stronger forms, as when one may sit at the table and participate in deliberations about the treatment. Yet more complete an involvement is when one actually has voting rights at decision time. There are many further intermediate points. They all need to be balanced against conflicts of interest so as to eliminate so far as possible self-interested bias from the process. This includes, of course, bias coming from groups of patients or patient advocates with particular interests in a product, for the decision-makers have to balance the interests of such patients against the interests of all the many patients not at the table who may suffer if resources are channelled to those who happen to be present.

FIGURE 3.3
Five groups of stakeholders in HTA process



Stakeholders fall mainly into five groups:

- Policymakers -- such as the National Health Security Office, the Subcommittee for Development of the National List of Essential Medicines, and departments/organisations in the Ministry of Public Health
- Health professionals -- such as clinical experts in the diseases or technologies in question, the Royal Colleges, Medical Associations, medical schools, and health care providers including managers
- Academics and researchers in universities -- such as faculty of pharmacy of different universities (Mahidol, Chulalongkorn, Chiang Mai, Khon Kaen, and Naresuan), health economists, biostatisticians, epidemiologists and bio-ethicists
- Private sector representatives -- such as manufacturers like the Pharmaceutical Research and Manufacturers Association, the Thai Medical Device Technology Industry Association and the Thai Pharmaceutical Manufacturers Association. This group might also include private health insurers
- Civil groups including civic societies, charities, and patient groups.

Each of these groups has a particular interest in HTA. Depending on their interests and special skills, they are invited to participate in HITAP's meetings and workshops at different phases of the HTA process. At HITAP, involving stakeholders at all stages of HTA is one of the key strategies that enhance the quality, transparency and accountability of the health technology assessment. This is also reflected in HITAP management strategies.

Organisational Structure

HITAP was and is a relatively small organisation. According to the first Annual Report for 2007, it began the year with 12 staff and ended it with 31. At least half of the research staff had a pharmacy background. Most were research staff, including research assistants and postgraduate students. The same is true today, with a staff of 55 (42 full-time) employed by the Foundation apart from four on secondment from the Ministry of Public Health. Seven are working for postgraduate degrees.

HITAP has a flat organisational structure. Activities are organised into 4 clusters: research (by far the largest), communications, international capacity building, and administration. All clusters are under supervision of the Program Leader so every member of staff has an easy and direct link to Dr Yot. This is the simplest organisational form and seems to have served HITAP well. Whether it would be sustainable with substantial growth is another question, of course.

Management

HITAP developed its management approach by drawing upon the experience of other organisations in Thailand as well as that of some in developed countries. The aim was to focus operations on delivering the ultimate goal of embodying HTA research and other forms of economic evaluation in health policy decision-making. Integrating research into policy and practice is complex. It involves many stakeholders coming from different professional and disciplinary cultures who may not fully grasp either the techniques of HTA or the general philosophy from which it comes. Context matters too. For example, context determines the perspective from which a research question might be addressed – one designed to answer a question about the admissibility of a specific drug to the essential list will have a different perspective from one designed to identify the gainers and losers from a workplace intervention and estimate the distribution of the gains and losses. HITAP has strategies to address such issues. Five important ones are:

- effective communication between HITAP and key stakeholders;
- enhancing the public image of the HITAP;
- ensuring the validity and reliability of research;
- ensuring the policy relevance of HTA topics and research results;
- ensuring good programme management (Tantivess et al. 2009: 937).

These strategies were translated into a statement of practical good practice for the HITAP administrators and researchers as summarised in Table 3.2.

FIGURE 3.4
HITAP organisation chart

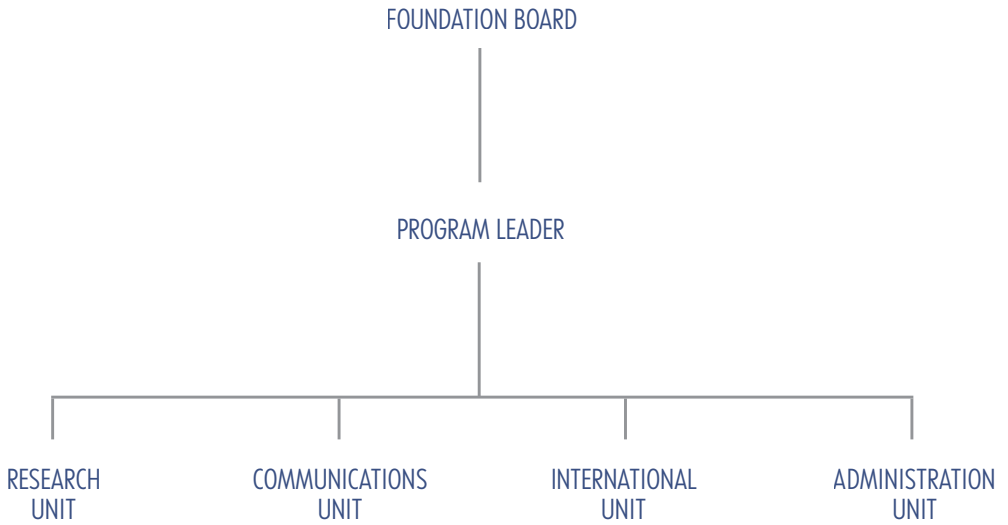


TABLE 3.2

HITAP management strategies and the practices they imply

MANAGEMENT STRATEGIES	GOOD PRACTICES
<p>1. Promoting effective communication</p>	<ul style="list-style-type: none"> • Sincere dialogue with all parties, including general public, to pursue understanding and collaboration • Tailor-made information and messages to suit particular target groups • Two-way communication
<p>2. Enhancing HITAP's image</p>	<ul style="list-style-type: none"> • Transparency; stakeholder participation; avoiding conflict of interest • Strengthening technical capacity of researchers • Good manners and discipline of staff • Accountability for granting agencies while pursuing public interest
<p>3. Ensuring validity and reliability of research</p>	<ul style="list-style-type: none"> • Strengthening technical capability of researchers • Exchanging experience and knowledge with scientists in Thailand and other countries through various channels
<p>4. Ensuring policy relevance of HTA topics and research</p>	<ul style="list-style-type: none"> • Constructive engagement with policymakers and key stakeholders • Keeping open minds, listening to all parties, keeping up with development of social phenomena and taking policy-related elements into account
<p>5. Ensuring appropriate programme management</p>	<ul style="list-style-type: none"> • Institutional lesson learning; monitoring and evaluation; research and development

Source: Tantivess et al. (2009)

Small is beautiful – but is it sustainable?

One is struck by several features that characterised HITAP's earliest days and that have remained largely as they then were – entirely fit for purpose in a small organisation having a highly focused concept of its core business. There is great attention to detail. The atmosphere is informal and contact between colleagues is easy. The Program Leader is accessible. The spirit is collegial. The working environment is attractive. Individuals have opportunities to shine – and to shine in public. The obvious question remains – could all these good things survive the departure of the Program Leader? Are they inherently the product of a singular personality with a singular leadership style? Could they survive further expansion of *existing* activity? Could they survive expansions in the *variety* types and purposes of research? Does HITAP's future success hang particularly on the continuing patronage (in the best sense of the word) of Drs Suwit and Viroj? We shall return to these daunting questions in the final chapter.

HITAP AS A RESEARCH ORGANISATION

“The assumption that good quality knowledge that has been properly packaged will be sought out and requested by decision-makers is an outdated and simplistic linear model of translation.” (Somsak Chunharas 2006)

“Chalarntorn just helped me summarising our works so far. She informed me that there are 162 studies done by HITAP during the past 8 years. Fifteen studies (9%) are related to methodological development, (HTA and cost) databases and guidelines. Nineteen studies (12%) are about KTE and capacity development. Four studies (2%) are about HTA governance and HTA network. There are 124 technology assessment projects (77%) per se (i.e. 26 HTAs on drugs, 8 on medical devices, 4 medical procedures, 38 on disease prevention and health promotion measures, 26 on packages of care—mixing screening and treatments, 22 on other public health policies such as evaluation of the Thai’s government compulsory license policy.” (Dr Yot Teerawattananon)

HTA agencies take many forms. One way of figuring out the character of such an agency is to imagine a scale of its possible organisational status — for example embedded within an academic organisation like a university; embedded within the health care provider system like a national health care service; embedded within a ministry of health; at arm's length from the foregoing organisations with independent or partial independence status; independent or partially independent with networking into academic research centres on the one hand and into client "users", usually governmental, on the other; a "social enterprise"⁷; a registered charity. Corresponding to these various types may be the nature of the ownership of the agency: publicly owned, privately owned or owned by a charitable (or equivalent) trust. Related to that will be the lines of accountability: governmental (regional or national) departments or regulatory agencies, private owners as in partnerships or shareholders as in limited liability companies, a regulatory commission for non-profit charities and organisations. A hierarchy of income sources is also often observable: completely public funding usually from a relevant ministry (health, labour or finance), complete private funding (from sponsoring manufacturers and others with an interest in having particular interventions evaluated), mixed funding from government (regional or national) as a general subsidy with or without supplementary payments for specific evaluations or other products, with additional fees for services charged to manufacturers and other sponsors of evaluations. In principle also one might see a range of motivations: for-profit, non-profit or combinations as when a for-profit organisation owns a not-for-profit subsidiary organisation. Where does HITAP fit into this scheme of things?

HITAP describes itself, as we saw in chapter 3, as a "semi-autonomous" non-profit organisation with public funding from four main sponsors: the Thai Health Promotion Foundation, the Health Systems Research Institute, the National Health Security Office and the Bureau of Policy and Strategy —

⁷ A social enterprise is a UK arrangement having the following characteristics: a clear social and/or environmental mission set out in their governing documents, generating the majority of its income through trade, reinvesting the majority of its profits, autonomy from the state, majority controlled in the interests of the social mission, being accountable and transparent.

(Table 3.1). In addition, as we have again seen, HITAP receives funding from various non-profit international organisations, some governmental, like the World Bank and the World Health Organization, and some non-governmental, like the Center for Alcohol Studies, the Global Development Network and the Bill and Melinda Gates Foundation, and is accountable to them through the various research contracts that it holds. Over time, HITAP has come to rely less on Ministry of Public Health contracts and international sources have increased enormously (Figure 3.2). HITAP is "semi-autonomous" partly by virtue of having this diversified portfolio of funding, partly by virtue of its arm's length relationship with the Ministry of Public Health and partly because of a third factor: the creation of the Health Intervention and Technology Assessment Foundation in 2010.

The HITAP Foundation

The Foundation acts to support the HITAP's operation in all of its missions and strategies. The Foundation is the custodian of HITAP's goal, vision and missions and thus acts in much the same way, and with the same responsibilities, as the board of any non-profit organisation, ensuring as best it may that senior staff conduct HITAP's affairs in ways that are consistent with the values embodied in its statements of principle. It is also there to make sure that there is good governance in all HITAP's business. The Foundation is not directly involved in day-to-day financial and personnel management, but it seeks to ensure that these are conducted with due process and, should the need arise, it can call the Program Leader to account. The HITAP Foundation is HITAP's effective internal managing body. It manages the domestic and international grants and deals with staff hiring, budgets, and administrative considerations. Nearly 90 per cent of HITAP staff (fifty-five people as of October 2015) are employed by the Foundation; the rest are on either full-time or part-time secondment from other government organisations, including Ministry departments, and universities. HITAP's Program Leader is accountable to

the Board but also, as a government employee, to a Deputy Permanent Secretary with the task of overseeing HITAP. In this respect, HITAP does not differ markedly from other similar agencies (NICE is one) in which there is political accountability of varying degrees of directness as well as accountability to an independent board.

HITAP's Principles of Good Governance

In 2012, HITAP developed seven principles of good governance (HITAP 2012). They are: transparency, inclusiveness, accountability, quality, timeliness, consistency and contestability. These governance principles are recommended for every stage of the major processes of health technology assessment, ranging from initial technology/topic selection through the actual conduct of research, to appraisal of results and dissemination of findings and recommendations. For example, there are five HITAP stages in research: a background review, the definition and scoping of the research question(s), the elaboration of the protocol, doing the research, formulation of recommendations/disseminating of results, and the preparation of a final report. The seven governance principles apply in equal measure at each stage.

In addition, to avoid conflicts of interest among researchers and for the Program as a whole, there is a personal and institutional code of conduct. According to this code, neither the Program as a whole nor any individual researchers may take any benefits such as research grants, sponsorship to attend conferences and training courses, or other direct and indirect benefits from private, for-profit companies or health-related agencies. In common with other similar organisations, staff must complete an annual form in which any potential conflicts of interest are recorded. These may, depending on their nature, preclude that member of staff from particular types of work.

External Academic Relations

Unlike some other HTA agencies (for example, NICE in England and Wales or the Pharmaceutical Benefits Advisory Committee in Australia), HITAP's research is mostly conducted in-house rather than being dependent on contracted evaluations performed by university-based research groups. In England and Wales, for example, NICE has established Evidence Review Groups, which are external academic organisations independent of NICE, which produce reviews of the evidence submitted and may conduct original literature reviews and modelling exercises in order to advise NICE committees. HITAP is, by contrast, a research organisation that actually does research as well as assessing the research evidence adduced by others in support of particular interventions. Nonetheless, some of the research topics assigned to HITAP are conducted principally in external research bodies like Mahidol and Silpakorn Universities, with HITAP acting as supervisor.

NICE describes its main analytical work as "appraisal" rather than "assessment". Assessment involves the actual conduct of HTA — assessing technologies — whereas appraisal is a secondary activity, concerned with appraising the assessments of others. In practice, HITAP does both, engaging in original research and HTAs and reviewing and appraising the research of others, particularly, of course, that of manufacturers and other sponsors of interventions who are seeking to have them available for the Thai population at public expense. As HTA skills have developed in the universities, there is more collaboration between them and HITAP than was hitherto possible.

NICE is very explicitly a part of the UK National Health Service. From its inception, it was concerned to be seen by service providers as an ally and team member, not a governmental regulatory agency under the thumb of the ministry (the Department of Health). It considers the evidence and makes a judgement on whether or not the intervention should be recommended as a clinically and cost-effective use of

NHS resources, or whether it should only be recommended for specific subgroups of patients. HITAP sets a high value on complete independence: being on no one's "side" as it were. Both, however, are independent organisations responsible for providing national guidance on promoting good health and preventing and treating ill health.

Styles of Research

Both HITAP and NICE — and indeed all HTA agencies — are concerned with specific types of research, whether conducted within the agency or contracted for others to provide. To set their style in context, consider the various types of research in which researchers engage. The highest academic accolades invariably go — it does not matter which discipline — to the "high priests" who engage in "fundamental" research. This can take three forms: the theoretical, which is often abstract and context-free, speculative, sometimes axiomatic, postulating hypotheses, usually addressed to answering questions that are internal to the discipline or concerned with building general models of systems (from the structure of the universe to the design of health care systems); the applied, in which what is applied is the theory just outlined, sometimes with a view to testing the theory as part of a science-oriented project, sometimes with a view to having an impact on the practical world of industry, social policy and so on, and sometimes simply out of researchers' curiosity; and the descriptive, which is less analytical, often tentative, pre-paradigmatic and qualitative. Descriptive research is done with a view of exploring "data" in search of a better understanding and, perhaps, eventual formalisation in hypotheses and empirical estimates of important "determinants" and parameters of models designed to explain observations or predict what is expected to happen if some intervention or disturbance occurs.

There is evidently a kind of hierarchy here, from the most general "blue skies" research, whose immediate practical value may not be discernible, to the most

practical work designed to answer specific practical questions that are of immediate use beyond the "houses of intellect"⁸. HTA work inclines generally to the latter end of these spectrums. At its most theoretical, it is inevitably blue skies and often motivated purely by scientific curiosity. But the most fundamental questions in HTA are also abstract questions and require fairly abstract, even mathematical or philosophical, consideration: concepts like "efficiency" and "equity", quasi-political ideas like "accountability" or "reasonableness", frameworks like causative epidemiological or econometric "models". The sorts of fundamental questions that arise in HTA usually, however, have their origin in attempts actually to answer more practical questions, when one frequently finds that one cannot progress very far because the necessary tools have not yet been designed, or that satisfactory and widely agreed concepts have not been defined. The natural home for research of this kind is the universities, not because the people in them are in any sense brighter or more inventive than others but because only in the universities can one usually find people in sufficient numbers, and across an appropriate range of academic disciplines, on whom to draw — people, moreover, whose research funding can be internal and not subject to any need for short-term justification to an outside organisation in terms of practical usefulness. Agencies such as HITAP belong to the applied end of the spectrum, their purpose and justification lying in their ability to come up with practical answers to important practical questions. HTA agencies must face in two directions: one face towards the end-users of research in government, industry, the health professions, and the wider public of patients, informal carers and future patients and carers; the other towards the rest of the research community, feeding difficult issues that applied researchers have not been able to resolve back to the specialists and to guide those at the more abstract end of the spectrum to focus on issues that are likely to have practical consequences, even if one cannot at that stage be confident about what those consequences might be.

⁸ Jacques Barzun's marvellous name for universities (Barzun 1978).

HITAP Must, in a Single Word, Network

Related to these distinctions is that between primary and secondary research. Primary research is research that generates the data it uses. It does not use (or mainly use) data such as administrative data, collected for purposes other than the research purpose at hand. Secondary research, by contrast, is research that uses data collected for purposes other than those immediately to hand. In the field of health care evaluation, examples of primary research include clinical trials (of any kind), the empirical modelling of health outcomes not directly measured in trials, and the original analysis of already collected primary data. Examples of secondary research include systematic and narrative reviews and meta-analyses, where the research uses the research outputs of others, typically in the form of research publications and reports, rather than the primary data used in such studies.

What, then, characterises HITAP's research? How does it select the topics for its research? How does HITAP manage the networking? What links does it have with academic research centres? What contribution does it make to the HTA research capacity of Thailand? How does it communicate its conclusions about effectiveness and cost-effectiveness to its end-users?

Topic Selection

The quest for research topics began at HITAP's birth. Some (mainly academic) research organisations generate, as we have seen, research topics according to researchers' curiosity and interest (curiosity-driven research). By the time it was born, however, HITAP's leadership had already realised that this could not be the right path for HITAP to follow. As we saw in chapter 2, the topics chosen for economic evaluation prior to HITAP, in terms of disease burden or type of intervention, did not match the situation on the ground in Thailand. In other

words, major health problems were not a major focal point of research interest. Not surprisingly, this meant that few economic evaluations had any policy impact or influence on professional practice in Thailand prior to HITAP. They did not tell policymakers what they wanted to know — let alone what they *needed* to know⁹!

Should HITAP carry on in the same way? Plainly not. HITAP aimed to inform policy decisions for better health in Thai society, so the research had to be relevant to policy and where better to get a sense of relevance than from the policy decision-makers themselves? But who were the policy decision-makers? Each of the obvious groups, like those managing the essential medicines list or the universal health care budget policymakers had their own, perhaps competitive, missions, as did the manufacturers, the external aid donors, the private sector, and so on. HITAP decided to initiate a participatory and transparent process of topic selection. After various trials and errors, with much feedback from the various stakeholder groups (ministerial policymakers, academics, health professionals, civil societies, patient groups, the general population and industry), the process was established that continues today in much the same form, but increasingly systematic, transparent and participatory with the passage of time.

HITAP-initiated Annual Topic Selection

Prior to 2012, there were three main components to the process of topic selection: nomination, selection and review. Nomination was by stakeholders and prioritisation by researchers. A provisional list of topics was then presented to stakeholders for final comment.

As a new-born research organisation with scarcely any reputation in either academic or policy circles, HITAP had no idea of what to expect when it arranged the first topic selection in 2007. It knew that its clients were concerned with

⁹ What they need to know depends, of course, on what they are trying to achieve. For example, if they wanted to maximise the impact of the health budget on population health, then they would need understanding of the productivity of various types of intervention, or platforms like clinics and hospitals to support interventions, in terms of impact on population health. But they may not realise this — and therefore not want it.

coverage choices and that they were health insurance schemes and policy sections in various divisions of the Ministry of Public Health (Department of Health, Department of Disease Control, Thai Food and Drug Administration, etc.). At the end of 2006, a first set of prioritisation criteria had been developed (Table 4.1) and a binary scoring system proposed (using only 0 and 1), but at this point in time only policymakers were included in the first stage.



HITAP's annual topic selection process (December 2011)

TABLE 4.1
Criteria for topic selection in 2007

CRITERIA	SCORING
Likely policy relevance	High: 1, Low: 0
Size of health problems to be addressed by the intervention	Large: 1, Small: 0
Financial cost of the intervention	High: 1, Low: 0
Contribution of the research to the literature	Positive: 1, Negative: 0
Variation in clinical practice	High: 1, Low: 0
Feasibility of altering clinical practice	Feasible: 1, Not feasible: 0

Each criterion had an equal weight.

So as to enhance policy relevance of the research at this early stage, only health policy-making bodies were invited to nominate topics and join the subsequent topic prioritisation workshop. The list of agencies invited for the first HITAP topic selection is in Table 4.2. They were included on the basis that they were all potential users of HTA results. They included health care payers for the three public insurance schemes, all departments in the Ministry of Public Health at that time, and organisations funding HITAP.

At the end of December 2006, letters were sent to relevant policy-making organisations inviting them to nominate topics, by the following mid-January. They were told that the HTA information would be provided free of any charge. Of the fifteen organisations invited, twelve responded positively. The non-responders were the Department of Thai Traditional Medicines, the Thai Health Promotion

TABLE 4.2

Early participants in topic selection and prioritisation

TYPE OF ORGANISATION	INVITEES
Health care payers	<ul style="list-style-type: none"> • National Health Security Office • Ministry of Finance's Department of General Comptroller • Social Security Office
Health care programme managers at national level (Ministry of Public Health departments)	<ul style="list-style-type: none"> • Department of Medical Services • Department of Disease Control • Department of Health • Department of Mental Health • Department of Health Service Delivery Support • Department of Medical Sciences • Department of Thai Traditional Medicines • Bureau of Policy and Strategy • Food and Drug Administration including the Subcommittee for Development of the National List of Essential Medicines
HITAP funding organisations	<ul style="list-style-type: none"> • Thai Health Promotion Foundation • Health Systems Research Institute

Foundation, and the Social Security Office. Fifty-two topics were nominated. After exclusion of those judged to be irrelevant, not appropriate for HTA or about which there was already ample information, twenty-nine topics were long-listed. These were then prioritised by HITAP researchers against the criteria and presented to the stakeholders in a specially convened workshop during early February 2007. They were presented with information on the topics that HITAP research had discovered and a ranking of the topics that HITAP constructed as a guide. In the event, HITAP's scoring plan was rejected on the grounds that it was too prone to bias since each of the organisations would weight their own interest higher than others' interests, that the score was subjective, that they were not sufficiently familiar with the topics and that, anyway, they were given too little time for a proper consultation. Instead they chose their top ten priority topics without scoring or ranking. HITAP then took the lists of topics chosen by each agency and ranked interventions by the frequency with which they had been chosen. The final shortlist (Table 4.3) of ten included five that were among the top twenty major health problems in Thailand at that time as determined by burden of disease (Lertpitakpong et al. 2008).

Future rounds were conducted in a similar fashion in subsequent years. The letters asking for topic nominations are sent out at the end of each year (September - December), and the topic prioritisation workshops are held a few months after topic nomination. Numbers of topics in the long listing have been reduced since there were complaints from the first round that discussion time for each topic was too short. Stakeholder representation was enlarged to include the royal colleges of medicine, hospital associations, academics from teaching hospitals, faculties of pharmacy, faculties of public health and faculties of economics, and industry (in form of a representative from the Pharmaceutical Research and Manufacturers Association), civil societies, patients and general population.

TABLE 4.3

The final short list of ten HITAP research projects for 2007

RANKS	TOPICS	NOMINATED BY
1	PET scanner	<ul style="list-style-type: none"> • Ministry of Finance's Department of General Comptroller • Health Systems Research Institute • Department of Health Service Delivery Support • Department of Medical Sciences • Food and Drug Administration
2	Medical management of osteoporosis	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines • National Health Security Office
3	Advanced management of Hepatitis B and C infection	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines
4	Medical management for Dementia/ Alzheimer's disease	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines
4	Bone marrow transplantation in acute myeloid leukemia	<ul style="list-style-type: none"> • National Health Security Office
6	Lipid lowering medications	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines
6	Erythropoietin for treatment of advanced cancer	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines
6	Cochlear implantation	<ul style="list-style-type: none"> • National Health Security Office
6	HIV oral fluid testing for HIV diagnosis	<ul style="list-style-type: none"> • Food and Drug Administration
6	Insulin analogues	<ul style="list-style-type: none"> • Subcommittee for Development of the National List of Essential Medicines

Adapted from: Lertpitakpong et al.

By year three manufacturers were invited to nominate topics though they had only observer status in the selection workshop. Civil societies were added in year four and patients and general populations in year five. There were adjustments to the criteria but the scoring system continued to (Pilasant and Teerawattananon 2010). From the second year, the scoring was also used for prioritisation. And so things continued up to 2012.

At this point (2012), HITAP decided to change the procedure. It was not because the process was unsuccessful nor because the research on the prioritised topics was of no use for policy decisions. It turned out that most of the research results were used to inform policy decisions for the National List of Essential Medicines and the contents of the benefits package managed by the Subcommittee for the Development of the Benefits Package and Service Delivery in the National Health Security Office. The interests of other stakeholder groups were not well represented in these outcomes and some, like manufacturers, had anyway had only observer status. Although the selection process had a high profile and ensured that a wide range of people, including the general public, knew about HITAP and what it did, the organising of the process and the large number of invitations offering full expenses was judged to be not worthwhile. From now on the process was to be focused more precisely on the interests of the two Subcommittees.

Topic Selection in the Subcommittee for Development of the National List of Essential Medicines

As we have seen, the National List of Essential Medicines (NLEM) was first created in 1981, and the Subcommittee for Development of the National List of Essential Medicines had been working since 1983 with the Thai Food and Drug Administration as the secretariat. In 2004, the Subcommittee's main function shifted from that of maintaining an essential list to one of maintaining an *optimal* list. Up to 2004, the criteria for selection were cost, safety, efficacy and effectiveness of drugs, and



The Subcommittee for Development of the NLEM meeting (March 2011)

evidence was sought on each of them. The evidence generated by this process was used not only to determine what went on the list but also to inform price negotiations between NLEM and manufacturers (a task undertaken by one of NLEM's twenty-eight specialist working groups). There was increasing realisation that evidence of cost-effectiveness was required for optimal coverage decisions and cost-effectiveness was accordingly included as a fifth criterion for the coverage in 2008 in addition to cost, safety, efficacy and effectiveness.

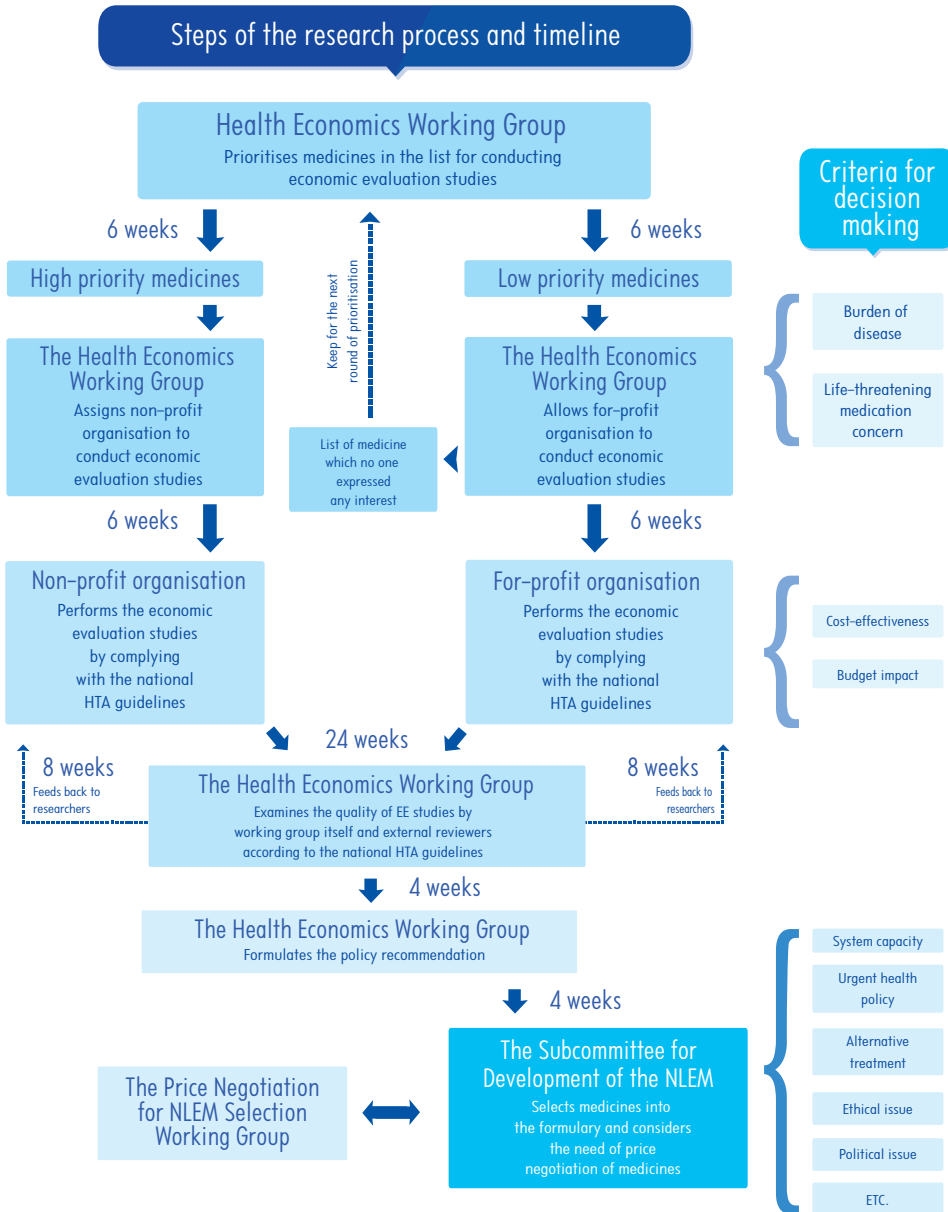
The establishment of a Health Economics Working Group (HEWG) under the Subcommittee followed in 2009. The HEWG's membership then comprised health economists, representatives from the Subcommittee, academics, and representatives from the three health insurance schemes and the working group secretariat. Its secretariat was provided by HITAP and the Food and Drug Administration. The working group was responsible for developing procedures

and for generating and assuring the quality of the economic evidence. After 2009, the HEWG introduced a framework for incorporating economic evaluation evidence in the NLEM decision process and this was endorsed by its Subcommittee in 2010. Under this framework, National Expert Working Groups were set up comprising health professionals and academics, to assess cost, safety and clinical effectiveness. They then proposed medicines to another group (the Working Group for the Coordination and Consolidation on NLEM) through which the topics passed to the Subcommittee. Requests for economic evaluation went to the HEWG only when the Subcommittee deemed it necessary. The HEWG then prioritised the requests based on burden of disease, the risk to life and financial burden on households posed by the condition and social consideration and commissioned the actual cost-effectiveness research from non-profit agencies (like HITAP).

The HEWG is not equipped to conduct research itself. It generally commissions about ten high-priority studies a year. If economic analyses are to be done for non-priority interventions, an open call for unfunded research is made to which any interested research team can respond, whether or not they are non-profit. Pharmaceutical industries may also volunteer for low-priority topics but are strictly excluded from bidding for any high-priority ones. Studies for the low-priority medicines are not supported financially by HEWG from public funds and so are effectively left for industry to fund as and when it decides it is worth their while. The conclusions of all commissioned studies are validated by the HEWG before being presented to the Subcommittee. The unfunded call allows industry to contribute to the process and also allows firms to produce evidence of their technologies for the HEWG and the Subcommittee.

Twenty weeks are allowed for the research team to produce a full assessment for each commission. The results are then presented to the HEWG, which provides

FIGURE 4.1
The NLEM review process



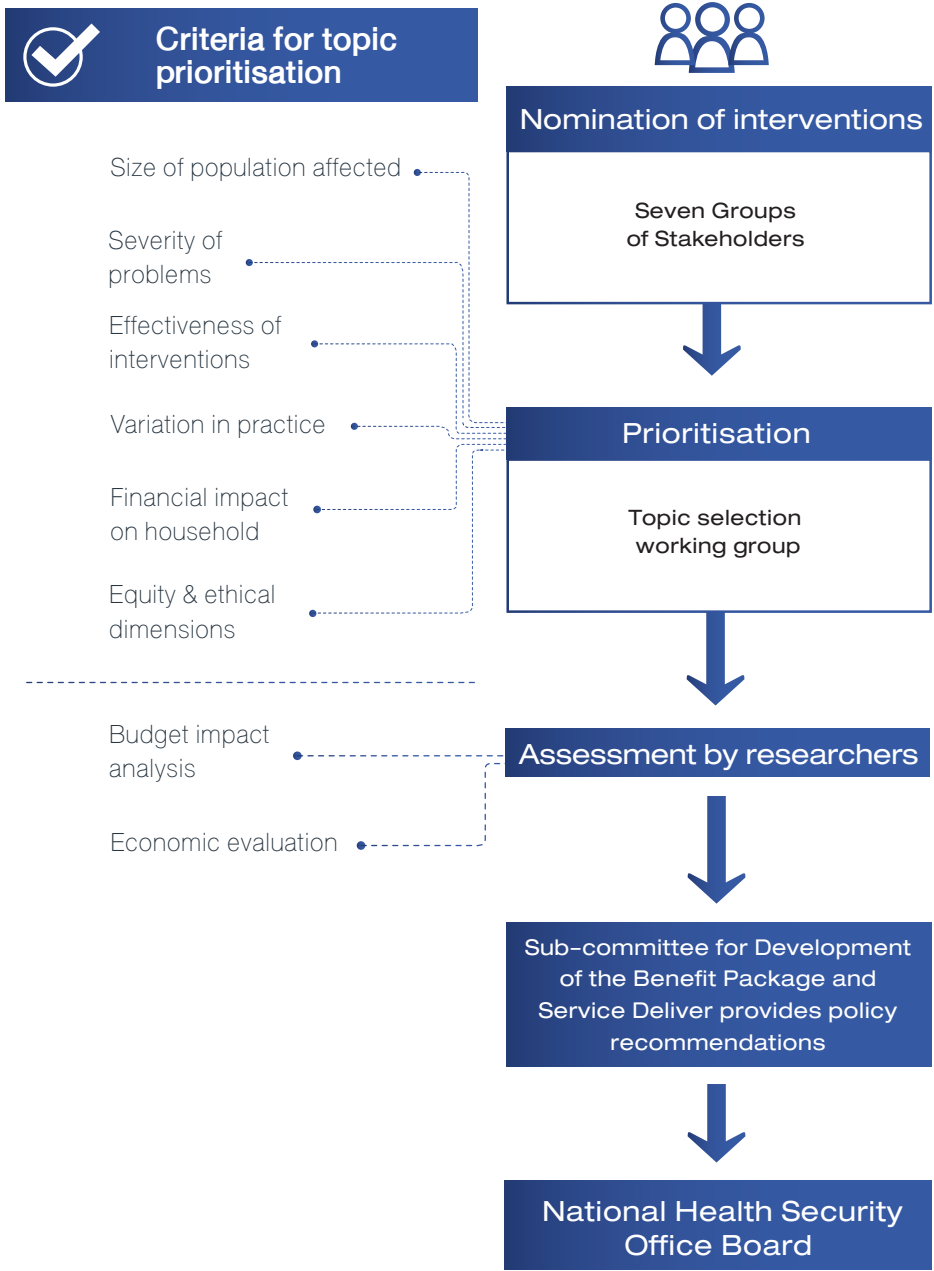
feedback to the researchers after internal and external review to ensure that studies meet the requirement in the HTA methodological guidelines developed by HITAP. These guidelines had been endorsed by the Subcommittee. The HEWG then makes recommendations to the Subcommittee. If the Subcommittee judges the price of a drug to be too high, the Price Negotiation Working Group is asked to negotiate with the manufacturer. The process is outlined in Figure 4.1.

HITAP fits into this picture in two ways — as a member of the HEWG and as a non-profit organisation that can be commissioned to do the research. HITAP, working together with the representatives from the Food and Drug Administration, also serves as the secretariat of the HEWG. Each year to date, HITAP has been commissioned to perform five or six such economic evaluations for the NLEM.

Topic Selection for the Benefits Package

The Subcommittee for Development of the Benefits Package and Service Delivery in the National Health Security Office is responsible for selecting interventions for inclusion in the Benefits Package for universal coverage. It was established in 2007 but had no systematic guidance on or process for making coverage decisions. In order to improve matters, the Universal Health Coverage Benefits Package project (UCBP) was initiated. The process of prioritisation was an enhanced version of HITAP's own annual topic selection process. This is unsurprising since it was HITAP, together with its mother organisation, the International Health Policy Program, which proposed it. The International Program and HITAP provided the secretariat of the Project. The duties of the secretariat are to facilitate the process for HTA topic nomination, to prioritise the nominated topics against a set of criteria, to conduct the assessment on the topic and to present their conclusions and recommendations to the Subcommittees. The outline of the process and the criteria for topic prioritisation is as shown in Figure 4.2.

FIGURE 4.2
 Topic selection process for the Benefits Package



Seven stakeholder groups nominate interventions, including patients' representatives and representatives of the general public, who were not included in HITAP's earlier procedure. The list of stakeholders was identified through the interests revealed in literature reviews and stakeholder consultation. The stakeholders involved now included health professionals, academics, patient groups, selected health charities, policymakers, manufacturers, and the general public. The nomination process operates via a website twice a year. In each round, an approved group may nominate a maximum of three topics with a maximum overall for the groups of twenty-one for the secretariat to prioritise. Only the first four groups in the list, however, may participate in the Stakeholders' Working Group. Once the Stakeholders' Working Group has agreed the priority topics, the chosen topics are assigned to either the International Program or HITAP for a full assessment. The results of the assessment are then presented to the Subcommittee. Initially, HITAP committed itself to conducting two or three assessments per round or five a year. The Subcommittee is planning to expand the flow of decisions, which will probably require additional research teams as well as HITAP to manage the increased flow of assessments.

A key difference between the two processes is that topics for NLEM are exclusively medical while those for the benefits package cover a broad range: medicines, medical devices, disease prevention and health promotion. Only health professionals and policymakers are allowed to nominate topics for NLEM consideration, for reasons that are not very clear (as though the other stakeholders groups had no interest or competence in thinking about "priorities"). The benefits package procedure gains from the engagement of a wider set of stakeholders who can come up with ideas or prioritisation that have not occurred to clinicians. For example, the provision of adult diapers to elderly and disabled people was one proposed independently by patient groups. The fact that they were not in the end

included in the insured bundle had nothing to do with the source of the proposal but was on account of budgetary impact. There were also some environmental concerns that reflected the influence of further non-clinical considerations.

There are other routes through which HITAP gets its research ideas. Health promotion and disease prevention is a long-term stream of work funded by the National Health Security Office since 2011. The main aim of the project is to create a health promotion and prevention package for different sections of the population defined, for example, by demography. HITAP also responds to ad hoc requests from other policy bodies and this has posed a difficult choice for HITAP: how best to achieve a reasonable and politically acceptable balance. The internal procedure is essentially that Dr Yot as Program Leader consults with senior staff in HITAP and presents the issues involved at one of HITAP's monthly staff meetings.

Finally, HITAP itself is a source of ideas and has undertaken research in the theory and practice of HTA from the beginning. Tools for the Thai quality of life calculator, standardised costings list, HTA methodological guidelines, and Thailand's cost-effectiveness threshold for cost-effectiveness, and their periodic updating are examples.

HITAP Training

Dr Yot was already offering training before he became the Program Leader. Soon after HITAP was established, two-day HTA workshops at a basic level directed at policymakers and other non-specialists were arranged. Later, a more advanced workshop programme in economic evaluation was additionally provided in the form of three-day technical workshop mainly for researchers. The economic evaluation workshops have taken place annually since HITAP's inception. The HTA workshop was introduced only in 2013, to introduce people to HTA without going



The 11th Health Economic Evaluation Training (July 2015)

into technical details. Both types of workshop are open to anyone with an interest in the subject. Participants have included policymakers, health professionals (medical doctors, pharmacists and nurses), public health personnel, people from industry, and postgraduate students.

The economic evaluation workshop has been held eleven times up to 2015. The HTA workshop has taken place three times. HTA workshops not only help to build HTA capacity in Thailand — they increase both the demand for HTA studies and HITAP's ability to recruit staff with the right competencies to meet future demands. The workshops are also opportunities to disseminate HITAP publications and for linking people more permanently to HITAP as a source of professional support and, for HITAP, a source of occasional research collaboration.

Although HTA has existed in Thailand for many years, we have seen that it has only recently begun to be formally applied in policy decision-making and many policymakers and their advisers are not, as a result, familiar with it. The two-day workshops for policymakers (and other non-technical clients) cover basic knowledge enabling its clients to be able to develop informed opinions about the uses of HTA, to participate in research prioritisation procedures, to commission HTA research and to be able to interrogate HTA experts and their products in appraising the quality of their work. There are also less formal methods of capacity development for these groups. For example, every year HITAP receives requests from the Hospital Administration School, Faculty of Medicine Ramathibodi Hospital, Mahidol University to deliver a basic (three-hour) course on HTA to hospital executive officers. There is also a recent initiative in the Ministry of Public Health to develop capacities internally for future decision-making leaders, including wanting HITAP's experience and expertise to be shared with these trainees.

HITAP provides an introduction to HTA and the interpretation of HTA results specifically for members of the Subcommittee for Development of NLEM and the Coverage Subcommittee, being direct users of economic evaluation and other HTA studies. This takes place for all new members and is a form of on-the-job training since they acquire their HTA skills in real-life situations.

The Wider Training Situation

There appears to be no undergraduate training in HTA anywhere in Thailand, though Chulalongkorn University offers an undergraduate option in health economics. Thammasat University has an undergraduate course in health economics but neither economic evaluation nor HTA appear to feature in it. The MPH curriculum in the Faculty of Public Health at Thammasat has a course called Introduction to Health Economics but again no mention of economic evaluation in any form.

HTA is more readily available at the graduate level, though on a limited scale. The first attempts to establish research groups which might have had sufficient skills and experience to offer advanced training in HTA in Thailand were in

1990 when the Center for Health Economics was founded in the Faculty of Economics in Chulalongkorn University and, just a little later, in 1991 when the Social Administration Pharmacy Unit was started in the Faculty of Pharmacy, Mahidol University. The MSc in Health Economics and Health Care Management at Chulalongkorn University offers modules in Economic Analysis and Evaluation of Health Care Services, and Epidemiology and Health Care Priorities, but with limited multidisciplinary content. The Mahidol programme offers courses in health outcome assessment, cost analysis in health care, cost-effectiveness modelling in health, and cost-effectiveness analysis alongside clinical trials and observational studies, which are probably the closest thing to an HTA programme in Thailand.

The Faculty of Economics at Chulalongkorn University has steadily developed expertise in Health Economics since 1979 through research, staff development and teaching. The Faculty has provided an undergraduate course in Health Economics to its own students, some short courses for other institutions and for the Ministry of Public Health. There are several four-week short courses including one on economic evaluation that explores the nature, purpose and limitations of economic analysis and evaluation; public and private perspectives; measurement and valuation; and analysis of costs, performance and effectiveness; evaluation of cost-effectiveness, inequality and equity. Several international workshops are provided in cooperation with the World Bank and World Health Organization. Research activities initially focused on economic aspects of malaria control, health care financing and disease patterns in Thailand. An International Programme in Health Economics was begun in 1993 and in 1998 a Master Degree Programme in Economics with specialisation in Health Economics commenced with the first enrolment of 20 students.

As a small research unit in a context in which the demand for HTA research is increasing, HITAP is faced with real capacity constraints. It consequently outsources some of its training activity from partners — mostly lecturers from university faculties of pharmacy but very few from departments of economics. While some of the pharmacy academic staff have had formal training in HTA, others have

not, and few are fully conversant with the techniques of cost-benefit and cost-effectiveness analysis that underpin important aspects of HTA. In this HITAP differs from NICE with its strong links to health economics research groups across the country. Of all HITAP's academic partners, the Faculty of Pharmacy at Mahidol University is probably the strongest in terms of academic staff with formal training in pharmacoeconomics and related subjects. Adjunct staff from Mahidol University have worked closely with HITAP as part-time project consultants since HITAP's inception. Their capability has strengthened over time, and currently Mahidol University is planning to establish a separate HTA research unit, independent of both HITAP and the Faculty of Pharmacy. The unit, titled Health Policy and Technology Assessment (HePTA), is financially supported by the Bill and Melinda Gates Foundation and Mahidol University itself.

Other significant partners are the Faculties of Pharmacy at Naresuan, Chiang Mai, Khon Kaen, and Silpakorn Universities. All of them have been commissioned by the HEWG to conduct economic evaluations to inform NLEM development. While the staff at Naresuan University have been formally trained, those at Chiang Mai and Silpakorn Universities have never been formally trained in HTA. However, thanks to on-the-job training with HITAP, they are now able to act as training consultants, and those at Silpakorn University has been used as such in Vietnam. Postgraduate students from the partner research units who are studying HTA-related subjects also get a chance of conducting an economic evaluation as a part of their thesis and receive supervision both from their faculty supervisor and from HITAP staff.

Communicating and the Use of HITAP's Recommendations

Although HITAP is intimately involved in various policy process and is even located in the structure of the Ministry of Public Health, it sees itself, as we have previously seen, very firmly as "advisory only" and by no means a decision-making body. HITAP's recommendations are not legally binding. The evidence users

Study blasts overzealous health tests

CHECK-UPS UNNECESSARY: REPORT

Far from improving quality of life, health-examination packages provided in Thailand often unnecessary, and frequently carry side effects that can harm people's health and even lead to death, a recent study has found. **14A1**

HEALTH

4 drugs join low-cost scheme

PARITTA WANGKIJAT

Four expensive medicines for breast cancer, hepatitis C and leukemia have been added to the national drug lists.

The decision will improve access to the drugs by universal healthcare scheme members, especially low-income patients.

The National Health Security Office (NHISO) board, chaired by Chuan Thirakulpong yesterday approved the inclusion on the list of Trastuzumab for treatment of the early stages of breast cancer, and Peginterferon for hepatitis C treatment in HIV-infected people. Nilotinib and Dasatinib for leukemia treatment were

also approved. The board's approval was based on a recommendation from the Health Intervention and

Technology Assessment Programme (Hitap), which found that adding the drugs to the essential medicine lists will reduce government spending over time compared with having patients in long-term care on other drugs.

The drugs could also help extend patients' lives. Trastuzumab can extend the life of a breast cancer patient from 9.11 years to 11.12 years, while Peginterferon for patients infected with HIV and hepatitis C can cut treatment costs by up to 317 million baht within five years, according to Hitap.

The NHISO's sub-committee for drug list development approved the drugs on March 28 and forwarded the decision to the NHISO board for approval but the board could not hold the meeting for two months, due to political turmoil.

HITAP's media coverage in national press

decide for themselves whether to follow HITAP's recommendations. HITAP is not an advocate for any policy, which its leadership is content to leave to those with accountability for it.

However, communication with policymakers and others affected by decisions and the evidence provided by HITAP is another matter. A great deal needs to be done to make stakeholders understand HTA and its products better. HITAP has consequently created a dedicated communications team working on presenting information to suit each group of stakeholder. The primary product from each of HITAP's projects is a research report, complemented by policy briefs for policymakers and others who are interested, whether or not they are from the health sector. HITAP's policy briefs are short, four-page, briefings designed to inform policymakers and non-technical readerships. The communication team also publishes HITAP newsletters, which include updates on HITAP work and other HTA trivia in plain language every 3 - 4 months. Hard copies of newsletters and policy briefs are circulated to subscribers, and electronic versions are uploaded to the website. The full range of communication products and target audiences also includes press releases, fact sheets, infographics and, of course, articles in technical and academic journals.

HITAP PRODUCTS AND THEIR IMPACT

“The greatest merit that HITAP has on health care practices and the national health system is that it acts as a key mechanism to facilitate justifiable and evidence-based allocation of the limited public resources, in preference to the practice of arbitrary budget allocation (by some authority) or in favour of certain advocacy groups. HITAP, whose analysis provides information to guide evidence-based decisions, is part of the success factors of the Universal Health Coverage scheme in Thailand.”
(Vicharn Panich)

"Products" seems an unglamorous term for works of the intellect, works designed not just to influence policy but to influence the ways in which people think — and think specifically about policy. Economic evaluations are often subtle works, tailored to carefully perceived contexts of their application. They are also scientific in the fundamental sense of developing and testing hypotheses and predicting consequences. They are humane in another fundamental sense that the motive of improving the health of humans is never lost sight of, together with the idea that this is to be achieved both through generating better outcomes of health care and through better processes of decision-making about health care. "Products" they are, nonetheless, in the jargon of our times, and perhaps no diminishing harm is done if we allow also that songs, symphonies, still lifes and ziggurats are "products". We therefore approached HITAP's products in anticipation of discovering things thoughtful, new and useful. We have not been disappointed.

HITAP's products are all research or research-related. They form a foundation for evidence-based policy and clinical practice in Thailand. Some have the character of being direct evidence, for example, as regards whether a particular intervention "works", how well, for whom and at what cost. Some are interpretive and judgemental, as when trade-offs need to be made and public decision-makers in the departments of ministries that value assistance in quantifying what can be quantified and need help in evaluating the quality of what evidence there is. Some is supportive, for example, technical and other kinds of training (Teerawattananon et al. 2014).

In chapter 4, we described three broad types of research: the theoretical, the applied, and the descriptive. The same typology may be applied to products. HITAP's products are to be found in each category, though chiefly in the first two. A notable example of the third is Thavorncharoensap et al. (2010). The negative

consequences of alcohol consumption impose a well-recognised and substantial economic burden on societies worldwide. More controversial is the question of whether the negative effects are compensated by tax payments and lower costs of care for the elderly due to shortened life expectancy. The data that are currently available are, however, invariably for rich countries in the West and there are next to no well-designed estimates of the economic costs of alcohol consumption in low- and middle-income countries. Because alcohol habits vary widely from one country to another and because the consequences are very dependent upon other social characteristics such as driving habits and traffic regulation, patterns of criminal behaviour and youth fashions, it is dangerous to suppose that the effects estimated for the rich countries can be readily transferred to low- and middle-income countries. This descriptive HITAP study was a prevalence-based, cost-of-illness study. The estimated costs in this study included both direct and indirect costs. Direct costs included health care costs, costs of law enforcement, and costs of property damage due to road-traffic accidents. Indirect costs included costs of productivity loss due to premature mortality, and costs of reduced productivity due to absenteeism and presenteeism. The total economic cost of alcohol consumption in Thailand in 2006 was estimated at US\$9,627 million (PPP) or about 2% of the total GDP. Productivity loss due to premature mortality and costs of reduced productivity due to reduced on-the-job productivity (presenteeism) outweighed direct costs, representing 96% of the total. This essentially descriptive research identified several policy options that were clearly worth exploring. It was used to support the passing of the Alcohol Control Act in 2008, which introduced tighter controls over the availability of alcohol products and increased excise duties on alcohol. At the time, the government was split over the virtues of such a policy — the Ministry of Finance was opposed to tighter controls and was afraid that the government would actually lose revenue through the higher excise tax¹⁰. In the event, this study was used to support the argument that any excise tax

¹⁰ Technically, this would occur if the elasticity of demand for alcohol in general was greater than 1.0.

loss would be offset by a fall in the social costs of alcohol consumption. HITAP's estimates (the only ones available for Thailand) are still used in public campaigns against alcohol abuse. Descriptive studies can be — as this one was — both analytical and useful. Indeed, the National Authority on Tobacco and Alcohol in Sri Lanka is currently conducting a similar study with support from HITAP.

Contributions to Policy Debate

Not all of HITAP's HTA research products appear as formal publications in academic outlets. A good example of HITAP's contribution to a current debate and of the value of bias-free analysis arose in the context of the expansion of antiretroviral therapy (ART) for HIV/AIDS in Thailand. ART uses a combination of medicines which, when taken in combination, prevent the growth of the virus.

Thai universal health care coverage excluded ART for HIV/AIDS when it was introduced in 2002. The following year, however, it became included for all eligible patients after a public commitment by the Prime Minister during the World AIDS Conference in Bangkok to do so. The announcement was clearly not the result of a careful prioritisation assessment, but it was considered a victory by advocates for HIV care and was used to inspire other low- and middle-income countries to follow the trail Thailand had blazed.

Up to March 2014, almost 300,000 HIV-infected persons were receiving ART. The ART guidelines indicated that HIV-infected persons with CD4 lower than 350 cells/mm³ were eligible. CD4 cells (T-helper cells) are a type of white blood cell that fights infection. The number present in a blood sample is indicative of the effectiveness of a person's immune system. The previous threshold had been 250 cells/mm³ but many eligible patients were not accessing treatment. The change came about as the outcome of a controversy between two opposing sides,

one opposed to the change because of inaccessibility, the other supporting the change because scientific evidence suggested this would provide a greater health benefit for HIV patients. The central theme of the debate was whether Thailand should devote its limited resources to those patients most likely to benefit or to all patients regardless of their prospective benefit.

Then, on 31 July 2013, the national AIDS committee approved an "end AIDS" policy, with the ultimate goal of zero mother-to-child HIV transmissions, reducing new HIV infections to fewer than 1,000 persons/year and providing ART to all patients known to be infected: that is, to provide ART regardless of CD4 levels. Although there is no evidence to support the benefit of ART for HIV patients at CD4 above 500 cells/mm³ (a study in Africa had shown that early ART can reduce HIV transmission).

The national AIDS committee produced a report indicating that the policy was based on economic evidence, produced by overseas AIDS experts. The evidence suggested that expanding or scaling up ART to all HIV-infected individuals would offer a good economic return to the country: spending US\$95 million over 10 years would result in a return of investment amounting to over US\$300 million, a benefit/cost ratio of 3.2.

HITAP was requested by the National Health Security Office to assess the feasibility of this policy because the Office was to be responsible for financing most of the "end AIDS" policy under universal health coverage. HITAP duly examined the evidence. Two anomalies arose. First, the report provided an optimistic estimate of the effectiveness of HIV screening, suggesting that one new HIV case would be detected for every 26 screened. This contrasted with the empirical evidence in Thailand, which showed that scaling up HIV screening would significantly

increase the number of screenings needed to identify a new HIV case from 26 to more than 200 (economists call this "diminishing marginal returns"). Second, the US\$95 million cost estimated by economists from USAID was the discounted present value of the cost stream over ten years. This was mistakenly understood by the AIDS committee as the *undiscounted* total over ten years and used as an undiscounted sum, implying that the policy would need US\$100 million of investments over 10 years or an addition of only US\$10 million per annum on top of the current HIV budget. HITAP's estimate, however, was that the actual total cash flows over the period were US\$380 million or an average of US\$38 million per annum rather than US\$10 million.

The review results were presented in a stakeholder consultation meeting in October 2015 and created debate about the financial sustainability of this policy and feasibility of devoting human resources for HIV screening and early ART.

It remains to be seen how the National Health Security Office will decide on this case, but one thing is certain: the story illustrates the benefits both of having evidence-based policy decisions and of having at least elementary economic literacy. Decision-makers and other stakeholders need to be empowered to access and *appropriately interpret* the available evidence if they are to claim that policy decisions are well-informed by evidence.

Pharmaceutical Price Negotiations

HITAP has supported the National Health Security Office in pharmaceutical price negotiations for many years. In 2007, two companies were applying for human papillomavirus (HPV) vaccine licensing in Thailand. The Thai government knew that the vaccine was effective in reducing the burden of cervical cancer. HITAP was requested to conduct an economic evaluation and budget impact analysis (Teerawattananon and Tritasavit 2015).



Dr Yot Teerawattananon presented an economic evaluation and budget impact analysis on HPV vaccine to the Deputy Minister, Ministry of Public Health (June 2012)

The findings were revealed in 2009, showing that at the price of US\$450 per course (three doses), HPV did not represent good value for money for public investment. The price of the vaccine needed to be reduced by approximately 60 per cent in order for the vaccine to become cost-effective at the WHO recommended threshold of value of GDP per capita per Quality-Adjusted Life Year. The results were made publicly available and the government decided not to include the vaccine, preferring prevention through screening. The two companies examined the report and agreed with the findings. Three months later, they reduced the price of the vaccine in line with the report's recommendations. Although the government had not included the vaccine in the universal programme as of 2014 on account of its heavy budget impact, non-poor Thai households still benefitted from the significant price reduction in the private market, from US\$450 to US\$200 per course.

In 2010, the reimbursement rate for a rigid intraocular lens was 3,000 baht and the flexible lens rate was 4,500 baht or more. HITAP did some background research and informed the National Health Security Office that prices of 1,000 baht or less and 1,500 baht might be achievable. The outcome of an open tender process the following year produced just such relative prices, with a saving of more than 400 million baht per year for the Thai government.

There are many other such examples (see also Teerawattananon et al. 2014).

Publications

Most of HITAP's research publications are too recent to have acquired substantial citation, which is a common basis for assessing the impact of research on fellow researchers — the main consumers of journal articles. Nonetheless, several have reached scores in the low 20s. That indicator of impact is therefore not currently reliably available. A well-cited item (Youngkong et al. 2012) is a methodological piece on Multicriteria Decision Analysis, which is discussed a little later. This was published online in late 2012 and had been cited a respectable 21 times, according to Google Scholar at the time of writing. Although it is far from the purpose of this book to evaluate¹¹, as distinct from describe, HITAP's effectiveness and impact, this is certainly evidence of impact on the world of academe. HITAP's main function is, however, to have impact on policy. Having impact on the research community is undoubtedly useful — it ensures that HITAP researchers think about what they are doing and it provides evidence of its academic credibility for the non-academic world. It is probably even necessary if HITAP's advice is to be regarded as authoritative, though never as the sole or principal rationale for research topic selection. More telling evidence of HITAP's impact on the academic community is provided by a recent comparison between

¹¹ External evaluations of HITAP are discussed in chapter 6.

the quality of economic evaluations in Thailand before and after the publication of the HITAP Methodological Guidelines (Journal of the Medical Association of Thailand 2008, 2014). The importance of this Guidelines work by HITAP is further discussed later. On every criterion, there was a marked improvement as is revealed in Table 5.1.

TABLE 5.1

Comparison of compliance with best reporting practices in Thai economic evaluations before and after publication of the first Thai HTA Guidelines by HITAP in 2008

GOOD PRACTICE	BEFORE (%)	AFTER (%)
Perspective specified	59	88
Comparators described	90	100
Discounting used	50	88
ICER reported	52	97
Uncertainty analysis performed	47	79
Of which, probabilistic sensitivity	43	70
Funding source disclosed	69	75

Source: Kittrongsiri and Chaikledkaew (2015)

In many cases, the link between HITAP research and its policy consequences has been very evident. Of the 162 studies published over the past eight years, HITAP's own estimate of policy impact is that around one third have resulted directly in policy action while at least 70% have generated public discussion. The range of the work is wide and includes systematic reviews (for example on preparedness for a flu pandemic), theoretical and methodological studies (for example the comprehensive guide for conducting economic evaluations), formal economic evaluations (for example on seasonal influenza vaccination and cervical cancer prevention and control), randomised controlled trials (for example on provider-initiated HIV/AIDS counselling and testing in Thailand), other clinical studies (for example screening of refractive error among students by teachers, and on the effectiveness of diapers for the chronically incontinent in Thailand), impact of the government use of license in seven medicines, and the development of benefits package for population-based screening for the Thai population.

What follows is an attempt to give the reader a more substantial review of both the range and the flavour of HITAP's products. We cannot hope to go into technical detail — which is, of course, to be found in the publications themselves — but we shall try to provide sufficient detail to convey the general competence, indeed exemplary nature, of the work and perhaps to whet the appetite sufficiently for some readers to want to dig into the actual products themselves.

Systematic Reviewing

A systematic review differs from other types of literature review in that it is a comprehensive and relatively unbiased synthesis of the research evidence. Essential features for minimising bias include the prior specification and explicit identification and scoping of research questions, the use of explicit methods for searching the literature, explicit criteria for including or excluding material,

explicit criteria for appraising quality and reliability, and a systematic analysis/synthesis of research findings. An earlier systematic review (Teerawattananon et al. 2007) had identified the poor quality of many studies both in respect of their methods and the quality of the data available. A later systematic review (Velasco et al. 2012) investigated the lack of good-quality evidence for estimating the probability of a pandemic of flu, its duration and the expected mortality reduction from antivirals. The use of higher-quality evidence resulted (Teerawattananon et al. 2007) in better precision of estimated values compared to methods that used lower quality sources. Careful evaluation of evidence was emphasised as being necessary to identify appropriate parameters in models used in evaluations and this topic should, the authors said, be included in methodological guidelines. Critical knowledge gaps were identified and needed urgent addressing. Where new evidence could not be obtained in a timely fashion consensus among experts should be sought to ensure consistency in the use of whatever assumptions were being made.

A more recent piece of research included a review of literature, economic modelling, and qualitative research (Teerawattananon et al. 2015) and addressed issues in prioritising screening services under universal health coverage in Thailand to identify major disease areas and health problems where screening could play a role in mitigating the burden of ill health. A consultation process was conducted with forty-one stakeholders in a one-day workshop. Twelve diseases/health problems were identified during the discussion. Subsequently, health technology assessments, including systematic reviews and meta-analyses of health outcomes, economic evaluations and budget impact analyses were completed. Several health screening programmes with evidence of low impact were excluded in the process. There was strong evidence against prostate cancer screening, which was also removed from the list of priorities; chest x-rays

of the general population were excluded, there being no proven effectiveness. Screening for hepatitis C in the general population was also excluded on the grounds that its prevalence in the general population was very low. The introduction of eleven new population-based health screening programmes was recommended, including cervical cancer, HIV, chronic hepatitis B and cardiovascular disease. The results of this study were presented to the National Health Security Office and the proposed screening package was accepted. The programme will start in 2016.

Effectiveness Research

A (quasi-experimental) study of effectiveness (Teerawattananon et al. 2015) led to serious consideration of the inclusion of disposable diapers for the chronically incontinent in the universal health benefits package. The purpose of this study was to assess the effect of diapers for health-related quality of life and the ability to perform independent activities of daily living of adults with urinary or faecal incontinence. Diapers reduce wetness and odour from incontinence, so patients can continue with their normal activities and avoid the stigma of incontinence. They are therefore used along with anti-incontinence therapy in the care of incontinent people, especially those with chronic and untreatable incontinence. However, there are disadvantages with using absorbent products. Long-term use may introduce urinary tract infection or dermatitis due to skin contact with stool, and urine and some people (especially men) are reluctant to use diapers because of their connotations with babies or female sanitary wear. Oddly, although absorbent products have been widely available and used in both rich and poor countries, their effectiveness in terms of improving quality of life and increasing independent living had not been studied. The study confirmed that both the health and the social effects were beneficial, however, it was not a cost-effectiveness study — though possibly a useful preparatory study for future research. It was predicted that 360,000 Thai people are in need of adult diapers,



HITAP researcher interviewed patient for a research project on Economic evaluation of absorbent products for urinary and faecal incontinence among disabled and elderly people in Thailand (July 2010)

which would cost US\$650 million per year, corresponding to 13% of the total Universal Health Coverage Scheme budget. Not surprisingly, the service was deemed unaffordable under universal health coverage by the National Health Security Office.

Methodological Research

The outstanding methodological HITAP products are undoubtedly the two versions of Guidelines for Health Technology Assessment in Thailand (Journal of the Medical Association of Thailand 2008, 2014) which were referred to earlier and which have had substantial impact on research design and research reporting in Thailand. Drs Viroj and Suwit, whose early importance we have seen in the creation of HITAP, were two of the three Chief Editors of the journal. The initiative came about following the review previously mentioned (Teerawattananon et al. 2007)

that had revealed many flaws in the then Thai literature on HTA. There was also a feeling that Thailand ought to have its own set of principles rather than relying or adapting on an ad hoc basis those from other countries. As the authors put it: "...guidelines will increase the transparency of studies by allowing readers or users to assess precisely what the analysts have done and whether the method was appropriate. These guidelines will also help to ensure standards that enable comparisons across health care interventions because the difference in, for example, a cost-effectiveness ratio is likely to reflect true differences between the interventions being evaluated rather than differences in study methodologies." (p. S12).

The first edition was an able and detailed suite of guidance advice that reflected international best practice as advocated by Drummond et al. (2005). This was adopted within official circles in Thailand — at the National List of Essential Medicines (NLEM) for the essential medicines list and at the National Health Security Office for use in determining the benefits package available under universal health coverage. In both 2008 and 2014 dissemination was done through taking up an entire special edition of the *Journal of the Medical Association of Thailand*. This had the great advantage not only of giving it an attractive publication format but of making it clear that HTA was going to be an essential component of Thai health policy-making. In each case, furthermore, the specific contents of the guidance were assigned to different authors each of whom took responsibility for a particular topic. Thus, the sections in the 2008 edition covered, among other topics, an account of the procedures used in developing the guidelines, the scope of HTAs, types of economic evaluation, measurement of costs, measurement of clinical effects, use of utilities, methods for discounting, treatment of uncertainty, and presentation. There was a chapter discussing other issues such as feasibility, legal constraints and matters of equity and societal fairness.

In both editions, a narrow interpretation of the adjective "economic" was taken, effectively equating it to "financial" or at any rate to an approach that assumed that the sole purpose of social activity in the health territory is the maximisation of health. This is a pity, since economic theory knows no such boundaries. As a result, important evaluative dimensions like financial protection, equitable funding of health care, equitable distribution of health outcomes, or the contribution of better health to cultural and other dimensions of the quality of life became regarded as "outside" economics. Multicriteria Decision Analysis is a tool (discussed below) that seeks also to compensate for an unduly narrow focus of some cost-effectiveness studies.

At any rate, the prime purpose of the second edition was seen as remedying the neglect of at least some of these other considerations in the first edition, so as to present decision-makers with a more comprehensive empirical — quantitative and qualitative — set of information and ideas. Whether the second edition is thereby best seen as supplementing the economic principles of the first or as completing them is perhaps too moot a point to concern us here. The second edition covers the same ground as the first, with each topic often written by the same authors who wrote the first edition, though in greater detail, with a closer tying of principles to the underlying theory and new topics added: methods of high quality systematic reviews and meta-analysis, budget impact analysis, social and ethical analysis, dynamic analysis for HTA of infectious diseases, screening, extending HTA to cover medical devices, whole disease modelling (as patients move through the various stages of some diseases), and standardised costs for general use.

Another methodological piece concerned the Multicriteria Decision Analysis (MCDA) to which we referred above (Youngkong et al. 2014). MCDA differs from cost-effectiveness analysis by explicitly helping decision-makers to consider factors

beyond the narrow perspective of standard welfare or health maximisation and which thus has some affinity with the aspirations of HITAP's second edition of the guidelines. HITAP's preferred definition of MCDA is by Devlin and Sussex (2011): "a set of methods and approaches to aid decision-making, where decisions are based on more than one criterion, which make explicit the impact of all the criteria applied and the relative importance attached to them."

This was to be pioneering work since, as the authors explained: "this is the first time in a low- or middle-income country that MCDA is practically used including a deliberative process and multiple stakeholders' involvement to guide national-level priority setting in health care coverage decisions. The experience of Thailand, and therefore this article, also holds relevance for other countries, as it may inform them on the options and limitations of MCDA for setting priorities in health" (p. 962).

Four basic steps in the priority-setting process were identified: nomination of interventions for assessment, selection of interventions for assessment, technology assessment of interventions, and appraisal of interventions. A panel representative of stakeholders was set up to address the first two of these steps. In the early phases of the work, the following six criteria emerged from extensive consultation and deliberation among researchers and stakeholders:

6 CRITERIA EMERGED

from extensive consultation and deliberation among
researchers and stakeholders

1

Size of population
affected by disease

2

Severity
of disease

3

Effectiveness
of the intervention

4

Variation
in practice

5

Economic impact of
household expenditure

6

Equity/ethical and
social implication

- **Size of population affected by disease:** As an indicator, the panel agreed to use the prevalence of the disease and scaled the prevalence on various levels.
- **Severity of disease:** As an indicator, the panel used health state valuations, with a range from 0 (worst health status) to 1 (best health status), and defined five dimensions (mobility, self-care, usual activity, pain/discomfort, anxiety/depression).
- **Effectiveness of the intervention:** For this, the panel created a separate scoring system for three categories of interventions: treatment/rehabilitation (giving higher priority to interventions that cure a disease than only improve quality of life), screening/diagnostic (giving higher priority to interventions with high accuracy), and preventive (giving higher priority to interventions that can effectively prevent a disease).
- **Variation in practice:** Because there are three separate public health insurance systems for Thai citizens, there is concern about differentials in entitlement under the plans. The panel therefore developed different scales to reflect variations in practice.
- **Economic impact of household expenditure:** One of the objectives of universal coverage is to protect household income from catastrophic health expenditure defined as household spending on health in excess of ten percent of total expenditure.
- **Equity/ethical and social implication:** The panel considered patients who were poor and with rare diseases were deemed to be more deserving of health care than are others and so priority was given to diseases that are more frequent among the poor.

With these basic ground rules, the research then went on to test the consistency of applying them to an actual prioritisation process over nine interventions with the "accountability for reasonableness" criteria developed by Daniels and Sabin (2002) and Daniels (2008): transparency about the grounds of decisions, appeals to rationales that everyone can accept as relevant and fair, procedures for revising decisions in the light of challenges to them and the presence of mechanisms to ensure that the first three requirements are met.

It is difficult to do justice to a complex process and, in the event, the panel did not reach definitive conclusions on the actual prioritisation, but the following conclusions seem to have had significance: the merits of MCDA became especially clear when the experimental process was compared with the situation before, where priority setting was said to be ad hoc and driven by interests of stakeholder groups. Deliberation was an important element. The consideration of the further criteria, which could not be quantified or were for other reasons missing in the conventional appraisal, was captured in the process of deliberation. As an example, one of the interventions considered was "absorbent products for urinary and faecal incontinence among disabled and elderly people". This was prioritised, even though its conventional score was not in the top rank, because of the weight given to criteria such as "vulnerability," "a more cost-effective alternative," and "feasibility of implementation", all of which had been argued during the deliberation process in when selecting interventions for assessment — step two.

Economic Evaluations

Among HITAP's original economic evaluations is one that enlisted the help of school teachers (Teerawattananon et al. 2014). Refractive error is a major cause of visual impairment and, when untreated, is the second most common cause of blindness in the world. Refractive error is a failure of the optical



School children with their glasses in the research development of the system for screening of refractive errors and providing spectacles among pre-primary and primary school children in Thailand

surfaces of the eye to focus images clearly. A refractive error is correctable with spectacles, contact lenses or laser surgery; spectacles are the most available and least expensive method. However, screening using professional ophthalmologists or ophthalmological nurses is prohibitively costly in Thailand. This study therefore sought to compare the effectiveness of using teachers to do the screening, having received prior specialist training. The study found that the prevalence of refractive error among Thai school children was 6.6%, which is similar to other Asian countries, though lower than in Singapore and China, and demonstrated that refractive error screening by teachers is reasonably accurate and feasible in Thailand. Like all screening tests there are two main issues relating to effectiveness: the frequency with which diseased eyes are diagnosed as not diseased (false negative) and the frequency with which healthy eyes are diagnosed as diseased (false positive). Both kinds of error were present but were not deemed to be

sufficient to make screening undesirable. The teachers were very willing to participate (without extra pay) and in general found that children with corrected eyesight behaved better in class.

As a feasibility study, this was not a complete HTA, lacking a detailed costing element. However, it was well-received by the National Health Security Office, so they expanded the pilot provinces from 4 in the study to 10. The Office now plans to implement a national refractive error programme covering all 76 Thai provinces. Further, HITAP was asked to develop a policy and plan for this nationwide scaling up and a plan was presented to the Office in September 2015. The recommendations were worked out in close consultation with relevant stakeholders including the Royal College of Ophthalmology, the Ministry of Public Health, and the Ministry of Education. The proposed programme differs somewhat from the trial programme. On grounds of feasibility, it was decided that the nationwide screening programme would be feasible only if it were restricted to pupils in their first year of pre-primary school and primary school, covering around 1.5 million students per year rather than embracing all students in pre-primary and primary levels, though all other protocols are intended to stay the same.

A technical piece on cervical cancer which has been well cited was Praditsitthikorn et al. (2011). Patients with cervical cancer in Thailand had experienced increasing morbidity and mortality and there was dissatisfaction with the performance of cervical screening programmes. The purpose of screening is to detect preinvasive cancers. A standard method has been cytology (the "Pap smear" is one kind), involving the taking of small tissue samples which are then examined in a laboratory for abnormal cell changes. This method had been used in Thailand for many years but with little impact on cervical cancer rates. It is costly, takes time and many women are lost to follow-up for reasons that are not clear. About 70 per cent

of cases of cervical cancer worldwide are caused by genotypes 16 and 18 of human papillomavirus (HPV), which is sexually transmitted, and the use of a vaccine for the prevention of human papillomavirus (HPV) infection is an alternative, or complementary preventive procedure. Another screening method, which is much cheaper is visual inspection of the cervix (VIA), using acetic acid (VIA), to view possible lesions with the naked eye. This shifts the identification of precancerous lesions from the laboratory to the clinic. It also eliminates the need for laboratories and the transport of specimens, it requires very little equipment and provides women with test results immediately. A range of medical professionals, including nurses and midwives, can perform the procedure, provided they receive adequate training and supervision. The question therefore was: what is the optimum mix of interventions that are cost effective for the prevention and control of cervical cancer in Thailand?

Praditsithikorn et al. (2011) developed a computer-based Markov model of the natural history of cervical cancer was used to simulate an age-stratified cohort of women in Thailand. A Markov model is one in which the progress of a disease with and without interventions is modelled in a sequence of time periods, each being associated with a particular measure of health, and each having a probability of moving from it to the next state. The interventions in this study were the three candidates just described. Each method showed a decrease in the number of women developing cervical cancer compared with "no intervention" and the most cost-effective strategy from a broad societal perspective¹² was the combination of VIA and sequential Pap smear (that is, VIA every 5 years for women aged 30 - 45 years, followed by Pap smear every 5 years for women aged 50 - 60 years). The results suggest that controlling cervical cancer in Thailand is best done by increasing the numbers of women having routine VIA and Pap smear screening (Yothasamut et al. 2010). Currently, screening coverage for cervical cancer has

¹² See chapter 1.

reached 70%, which is the highest since the programme was introduced a long time ago. The WHO World Report (2013, p.8) reports that HITAP attributes its success to several factors:

- the strong research environment in Thailand which, for instance, provides staff for HITAP and supports peer review of their recommendations;
- collegiate relationships with similar institutions in other countries, such as NICE in England and Wales;
- working with peers (HITAP meets with other Asian HTA institutions, and has formed an association with Japan, Malaysia and South Korea);
- transparency in research methods, so that difficult or unpopular decisions can be understood;
- a code of conduct (HITAP adheres to a strict code of behaviour which, for instance, precludes acceptance of gifts or money from pharmaceutical companies);
- political support from government, fostered by opening doors to, and discussing methods with, decision-makers;
- popular support, generated by lectures at universities and dissemination of recommendations to the general public;
- external review.

A recent study by Guerrero et al. (2015) used the Markov methodology in an application in the Philippines. Cervical cancer is the second leading cause of cancer deaths among Filipina women and there is poor access to screening and treatment services. This study aimed once again to evaluate the health and economic benefits of HPV vaccination and its combination with different

screening strategies to find an optimal preventive strategy in the Philippines. The screening scenarios examined were Pap smear and VIA which could be undertaken alone, in combination, or in combination with HPV vaccination with various possible coverages of the female population. The analysis used country-specific epidemiological, cost and clinical data and was conducted from a health system perspective. VIA again turned out to be a dominant cost-effective strategy with a predicted reduction in cervical cancer cases and deaths of 25%. Pap smear screening was not cost-effective due to its high laboratory cost in the Philippines. Adding HPV vaccination at a cost of US\$54 per vaccinated girl on top of VIA screening was found to be potentially cost-effective using favourable assumptions about the long term value of vaccination and a threshold of GDP per capita. The highest incremental QALY gain was achieved with 80 per cent coverage and a combination of VIA for 35-45 year old women done every five years following vaccination for 11 year olds. This strategy was predicted also to result in a two-thirds reduction in the prevalence of cervical cancer. HPV vaccination was not cost-effective if vaccine protection lasted for fewer than 20 years. The study thus concluded that high VIA coverage targeting women aged 35 - 45 years old at five-year intervals is the most efficient and cost-saving strategy in reducing cervical cancer burden in the Philippines. Adding a vaccination programme at high coverage among 11-year-old girls is potentially cost-effective in the Philippines assuming a life-long duration of vaccine efficacy.

HITAP's Own Views on the Use of HTA in Policy

In Yothasamut et al. (2009), we find a clear exposition of how the senior scholars at HITAP view the role of HTA in public policy decision-making. They make specific recommendations to "facilitate" the use of economic evaluation in decision-making, of which the following is an edited account:

Standardisation: To improve the quality of economic evaluations for decision-making, there is a need for methodological guidance that standardises best practice. A common method allows readers to assess what the analysts have done and whether their methods were appropriate. Consistent methods also enable better comparisons of value for money across health interventions by eliminating variations in cost-effectiveness ratios that result from methodological variations.

Timeliness: Economic evaluations should be planned and used routinely, even required by law, rather than being done ad hoc or at the whim of a particular decision-maker. In addition, the development of an economic evaluation database is crucial in assisting its users to gain faster access to reliable information for competing health technologies. Although there are several international databases of the economic evaluation literature, they usually include only evaluations published in academic journals and in English. Many useful studies are thereby missed, many of which are applications in low- and middle-income countries appearing only in "grey" literature such as MSc and PhD theses and research reports, and often using local languages.

Prioritisation: Prioritisation according to disease burden alone takes no account of either the effectiveness or the cost of interventions. A useful checklist of initial criteria to bear in mind in selecting interventions for more detailed evaluation is:

- interventions requiring a significant increase in health expenditure, or a significant budgetary burden, or a poor return on investments, or interventions that will drain a high level of resources from other interventions;
- interventions likely to offer significant improvement in health outcomes but that are not in common use;
- interventions likely to have significant adverse effects in terms of health outcomes, ethical implications or organisational impact;
- interventions likely to have a socially undesirable redistributive impacts either on people's financial circumstances or health.

Training: Economic evaluation is likely to be used well only when the users have the capacity to understand, use and explain it to others. One therefore needs appropriate levels of training for policy decision-makers, professionals and key stakeholders like manufacturers and patient advocacy groups. Only some of these may need the ability to manage or conduct studies, but all need to be able to understand the products that the researchers generate, to commission them when that is their role, and to be able to distinguish good and bad workmanship.

Educating the Public: Since decision-makers are sensitive to the interests of the public, the public itself needs to understand both the need for selection and choice and the specific criteria that are used in their jurisdiction. They need this also in order to be well-informed critics and intelligent participants in any public consultation and deliberation. Most fundamentally, they need such an understanding if they are to trust the prioritisation processes in their jurisdictions.

Transparency and Participation: Stakeholders should be involved from the beginning, that is, in horizon scanning and in setting and fine-tuning the research questions. During the study, stakeholders can also be involved as input experts to inform and verify information used in the study, such as the validity of the chosen outcome indicators.

The maximand: QALY maximisation, as assumed in much economic evaluation, is not the only goal in health care resource allocation. Equity, urgency and necessity (severity of disease), social solidarity, and protection against heavy, let alone catastrophic, expenditure also matter.

There seems little doubt that concerns such as these suffuse all of HITAP's research products.

Research Training

Although HITAP is primarily a research organisation, it requires a stream of able researchers to support an expanding portfolio. By virtue of its core work, it is also an agency that can provide work experience and on-the-job training probably better than any in Thailand.

In the early days of HITAP, there was little training in HTA available and a lot of reliance was placed on sending scholars aboard (Dr Yot himself was one such). The situation today has become much improved. The current picture is discussed in chapter 4. From its beginning, HITAP has engaged in capacity building for research skills and capacity building is one of HITAP's five "strategies". HITAP runs

internal training workshops both for those needing an introduction to HTA methods and for more advanced students. There is much "on-the-job" training, coupled with mentoring, lots of participative activity, a journal club, and internal and external seminar presentations and staff discussions. Trainees participate in overseas work. Relatively junior staff are encouraged to become team leaders and advisers on projects, thereby building research management skills as well as purely technical ones. These programmes were applauded in HITAP's second external review, albeit with recommendations that a great deal more could be done both in recruiting and retention policies.

There is now more training and research capacity for HTA in Thai universities than existed when HITAP was set up. In the early days, it was HITAP that provided training for university academics, a balance that is now pretty well reversed. Many universities now provided scholarships for their staff to study HTA abroad. Several have also established HTA units which work closely with the Subcommittee for the Development of the National List of Essential Medicines, researching products in both low and high priority categories (see chapter 4) and sometimes working with private companies to evaluate their own products. At least four HITAP staff have left the office to join private companies so far, which has been a bone of contention for HITAP. Dr Yot reports occasions when he had direct conversations with one big company after several of his staff had been "poached", and was told that it was his own fault — if it were not for Dr Yot and HITAP, the companies would not need to learn the language and skills of HTA and that was why the poaching took place mainly in Thailand — where both the need was greatest (from the companies' point of view) and the skills most available to be poached! This is a common phenomenon elsewhere too, by which individuals trained in the public sector for public service are recruited into industry. It may be painful

in the short run, but in the long run it greatly improves the ability of industry to present its case in line with the standards the regulators expect.

All in all, it seems that HITAP's approach as here outlined is productive in building infrastructure, collaborations, lasting commitment and in delivering valuable research — of all three kinds. It has succeeded precisely where its antecedents so badly failed.

HITAP INTERNATIONAL

"... to take responsibility for appraising a wide range of health technologies and programmes, including pharmaceuticals, medical devices, interventions, individual and community health promotion and disease prevention as well as social health policy. Since 2013, the HITAP International Unit (HIU) has supported low- and middle-income country governments and international organisations for country capacity building and Health Technology Assessment (HTA). HITAP and HIU also focus on building networks and partnerships, such as with the regional HTA network HTAsiaLink, as well as international research collaborations."[From the website of the International Decision Support Initiative (iDSI)]

Foreign connections bring many benefits both to HITAP itself and to those whom it serves. International activity gains HITAP high regard as a regional and global HTA agency. When travelling abroad, HITAP leaders receive very positive appreciation which builds confidence in HITAP's selection of topics and methods of working. Research collaboration with colleagues in other countries is invigorating for HITAP staff, it strengthens their capacity to apply HTA skills in different settings and builds confidence, reputations and careers. Working with other countries is also a source of income. At present, HITAP receives up to US\$1 million annually from abroad, which builds financial security by reducing dependence on domestic sources and, by diversifying funding, also enhances intellectual independence. HITAP's extensive international connections are also sources on which it can depend for support, advice and information. It ensures that HITAP is fully connected to what goes on elsewhere and that there are few significant loops, if any, of which HITAP is not a member. It also enhances HITAP's ability to respond quickly and authoritatively to internal enquiries concerning what goes on elsewhere. For example, there have been times when health administrators in Thailand have asked HITAP to provide a quick briefing on HTA or health policy in other countries and HITAP has been able to provide it within 48 hours either from its own knowledge or by putting them in direct contact with colleagues overseas.

HITAP's reputation at the international level stems from its domestic performance and a capacity for sharing experience gained from its domestic work, including its relations with policy-making groups. In 2013, HITAP began receiving a markedly larger number of requests for experience sharing and technical support from the South East Asia region. There was much internal discussion as to whether a dedicated unit for international work was warranted — either as a separate body from HITAP with its own support services and research capacity, or as a unit within HITAP. In the event, the internal solution was adopted: the HITAP International

Unit (HIU). The unit is serviced by HITAP's researchers and administrative staff. But increasingly much of the international work fell to the Program Leader himself, Dr Yot, with invitations to join commissions, boards, working groups, and so on, all of which added greatly to HITAP's international reputation and influence.

The HITAP International Unit

HITAP established this international unit in 2013, drawing on its experiences locally and internationally to work at the global level with overseas development aid, international organisations, non-profit organisations, and overseas governments to build capacity for health technology assessment. This was a natural consequence of HITAP's already strong international profile. So it is scarcely surprising that HITAP has moved resolutions at Thailand's National Health Assembly, a WHO SE Asia Regional Committee and at the World Health Assembly or that HITAP, together with several international partners, convened the 2016 Prince Mahidol Conference on priority setting for universal health coverage. While HITAP hired a full-time staff member in late 2013 to manage international work, the Unit itself was not officially founded until late 2014, when it acquired a name, governance, vision and mission.



The Unit created its own arrangements because HITAP's vision, mission, and goals all had their focus on Thailand and Thai society, whereas HIU's main goal is to collaborate with international partners and networks to improve HTA and priority-setting capacity through research and capacity building activity, particularly in low- and middle-income countries. The Unit has three broad lines of accountability. It is naturally bound to be accountable to the HITAP Foundation board. It also created an International Advisory Committee to review and provide advice on HIU's international work, offer guidance on HIU's overall direction, and provide some mentoring for staff. HIU is also accountable to its delivery partners and funders in Thailand and abroad to meet the deliverables set out under each contract.

A "Working Model" of the HITAP International Unit (HIU) has the following components.

Vision: Building HTA capacity for a better society

Goal: Supporting effective and sustainable priority setting in developing countries

Mission: To foster collaborations with international/regional organisations, HTA units and other respective institutes in other countries; build HTA capacity in developing countries; coordinate technical and policy support from relevant institutes in Thailand including in HITAP

Structure: Three workstreams comprising: International Relations, HTA Capacity Building, and Collaborative Research

Strategies:

International Relations

- Collaborate with WHO and other institutes, local and international, to facilitate the implementation of HITA resolution and other activities.
- Provide support to programmes and activities under the HTAsiaLink.
- Convene international meetings/conferences such as PMAC and its side event.

HTA Capacity Building

- Organise HTA trainings, internship programmes, and study visits for policymakers, technical officers and researchers in developing countries.
- Convene policy forums on HTA institutionalisation in target countries.

Collaborative Research

Coordinate joint HTA studies and research in different areas as part of HITAP's international capacity building programmes.

FIGURE 6.1

Working Model of the HITAP International Unit (HIU)



Research Conducted with Other HTAsiaLink Members

HIU's staffing is international. Currently there are two Thais, one Filipina, and one Indian ODI Fellow¹³. Some HIU jobs are purely coordinating/administration while others entail a combination of coordination and research duties. Although HIU is not aiming to build an independent research capacity, three staff have a background in economics and participate either partially or fully in research activities. The unit arranges internships at HITAP for international students and researchers who would like to spend time at HITAP. They have included one intern and one fellow from US universities who work on both domestic and international work.

All HIU activities are self-funded through mostly international grants and contracts. In line with HITAP's principles, HIU does not accept for-profit projects.

Three other international aspects of HITAP are of particular interest. One is that HITAP as a whole has been subject to two external reviews which were both essentially conducted by overseas experts. These reviews are an excellent opportunity to have a relatively objective appraisal of the quality of what HITAP does and the way in which it does it. The second is the story of HTAsiaLink, whose founding was critically thanks to HITAP's sponsorship and whose subsequent history has been hugely supported by HITAP. The third is the character of HITAP's relations with individual countries, mostly but not exclusively, in South East Asia.

¹³ The UK Overseas Development Institute's 2-year fellowship programme

The External Reviews

There have been two international reviews of HITAP (HITAP 2009, 2011). The first review took place in 2009, two years after its foundation. The review was prepared by four external evaluators: Dr John Cairns, Dr Kalipso Chalkidou, Dr Paibul Suriyawongpaisal, and Dr Jirawat Panpiemras. Cairns is a professor of health economics at the London School of Hygiene and Tropical Medicine and was previously Director of the Health Economics Research Unit at University of Aberdeen in Scotland. He served for many years on NICE's Appraisals Committee. Chalkidou is the founding Director of NICE International in London, England. Suriyawongpaisal is a professor in the Community Medicine Center at Mahidol University, Thailand, and Panpiemras is a research fellow at the Thailand Development Research Institute in Bangkok. Drs Mark Sculpher and Karl Claxton, from the University of York in England, wrote a commentary on the appraisal. The entire review, the internal HITAP reaction it generated, and the commentary were deemed to have public value in that lessons may lie in them for other low- and middle-income countries. They were published as a three-part report entitled *First Step*, clearly signalling that HITAP was both eager to learn and here to stay.

The review focused on HITAP's own quadruple (at that time) strategy, comprising research and development of fundamental knowledge and infrastructure for HTA, human capacity strengthening, the actual assessment of health care technologies and interventions, and HTA management and processes in undertaking HTA. HITAP's own guidelines and adoption of the "Reference Case" were used as an analytical framework for much of the review since they reflected both the best international standards and had also been explicitly subscribed to by HITAP.

The findings were highly supportive. "HITAP has made significant progress with respect to all four strategies. Since its establishment in early 2007, there have been significant improvements in the infrastructure for undertaking HTA in Thailand... and also in the way HTA evidence feeds into policy." "HITAP's impact has been national and international, with formal agreements with agencies in Korea... and the UK... as well as international academic institutions. HITAP can serve as an international model for other low- and middle-income countries interested in setting up HTA agencies." Praise indeed!

But not entirely unqualified. Suggestions were made for more explicit methods of selecting and involving stakeholders, scheduling updates for past evaluations, a possible need for an appeals mechanism even though HITAP is only an advisory agency, and for creating some means of embodying equity into evaluations. The tension between providing on-the-job training for HITAP staff, most of whom were young and, at that time, quite inexperienced as researchers, was noted. There was some concern that timeliness of products may have been slipping. HITAP was urged to use the Advisory Board more effectively in strategic planning regarding such things as staff training, succession planning and external funding.

The two York commentators thought that "the evaluation was thorough, balanced, insightful and entirely helpful" and made a number of further helpful suggestions based on their experiences at NICE and the Centre for Health Economics at York: for example, that some pressure on staff and further multidisciplinary intellectual strengthening could be achieved by forging links with the academic research community — links that seemed to be strangely lacking.

The second review took place in 2011. This was conducted by the same team with the addition of Dr Jeonghoon Ahn, a research fellow and senior director at the National Evidence-based Healthcare Collaborating Agency in Seoul, South Korea.

Two further external commentators were Dr David Hailey from the School of Information Systems and Technology at the University of Wollongong, Australia, and Dr Ruth Lopert from the Department of Health Policy and Management at the George Washington University in the USA. In a previous role, she had established and directed the Pharmaceutical Policy Taskforce in the Australian Department of Health and Ageing.

A fifth strategic aim had been added to the previous four: development of organisational management and building relationships with national and international HTA agencies. This review complimented HITAP again on its achievements and its responses to the first review. It also identified some intractable issues with which HITAP was still wrestling, especially the diversity of topics with which HITAP is presented, requiring a multidisciplinary span that is hard to maintain given HITAP's then size, and the issue of timely delivery which arose from having too few senior supervisory research staff. Succession planning was again identified as an issue that the Board ought to address.

The main recommendations from this review related to a concern about a lack of overall strategic direction, the need for key performance indicators for each of the five strategic aims, and addressing the issue of scale and scope of the research staff required to cope with an expanding workload — a load that had every prospect of growing further in the future. Further diversification of the funding base and cementing relationships at home and abroad with similar agencies and evidence users were seen as important ways of giving HITAP a more certain and sustainable future. This review, like the first, did not seem to spend much effort in assessing the technical quality of a sample of HITAP's publications, relying instead on the facts of publication in peer-reviewed journals and client satisfaction as sufficient sources of evidence of quality.

We take up the main issues raised in these reviews in the final chapter of this history. For the moment we note the encouraging nature of the two international reviews which plainly exposed HITAP as exemplary in a world context. A note of caution, however. At the root of HITAP's success, and therefore at the root of a strategy for its future, lies the meeting of clients' needs, that is moulding and satisfying the information needs of decision-makers in Thailand and overseas. That has to be the principal driver of its portfolio of topics and all else is derivative from it: the originality and academic quality of the research, staff development, the size and scope of the organisation and its funding, and its management and governance structure. HITAP is not an academic department — but its research needs to meet the highest academic standards. HITAP does not engage in blue-skies research — but it needs to have good connections with those in the universities who do. HITAP is not a teaching organisation — but it needs to continue to provide on-the-job training and to work closely with Thai and overseas centres of higher education. All of these features have implications for HITAP's general strategy but especially for its international strategy. This has been hugely fruitful up to this point in HITAP's history and the momentum needs to be maintained, with every prospect of HITAP in its more mature years becoming a centre whose prestige and influence regionally and globally will continue to be second to none.

HTAsiaLink

HTAsiaLink is a network founded in January 2011, with the objective of supporting collaboration between Asian HTA agencies. The founding organisational members were the Taiwan Center for Drug Evaluation, the National Evidence-based Healthcare Collaborating Agency of South Korea, and HITAP. The network's editorial office was established at HITAP and HITAP issued its first newsletter in June 2011. The newsletter is currently distributed two times a year. The need for a website was apparent from the beginning and, in 2012, the Korean agency agreed to create and maintain an HTAsiaLink website.

In addition to the three founding institutional members, membership now includes twenty-one other agencies. (Table 6.1)

TABLE 6.1
List of HTAsiaLink Members (as of November 2015)

ORGANISATIONS	COUNTRIES
Academic Medicine Research Institute (AMRI)	Singapore
Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, (ASERNIP-S)	Australia
Division of Health Policy Evaluation and Technology Assessment, China National Health Development Research Center (CNHDRC)	China
Division of HTA, Center for Drug Evaluation (CDE)	Taiwan
Eastern Health Alliance Health Services Research Unit	Singapore
Essential Medicines and Technology Division (EMTD), Department of Medical Services, Ministry of Health	Bhutan
Health Data Research Center, National Taiwan University	Taiwan
Health Intervention and Technology Assessment Program (HITAP)	Thailand
Health Policy Advisory Committee on Technology (HealthPACT)	Australia & New Zealand
Health Strategy and Policy Institute (HSPI)	Vietnam
International Health Policy Program (IHPP)	Thailand
Leading Researchers	Mongolia
Malaysia Health Technology Assessment Section (MaHTAS), Ministry of Health	Malaysia
Ministry of Health	Singapore
National Center for Pharmaceutical Access and Management Department of Health (NCPAM)	Philippines
National Evidence-based Healthcare Collaborating Agency (NECA)	South Korea
National Health Committee (NHC)	New Zealand
National Institute of Public Health (NIPH)	Japan
NICE International	UK
Pharmaceutical Services Division (PSD), Ministry of Health	Malaysia
School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM)	Malaysia
Sub Division of Allied Pharmaceutical & Medicine Technology	Indonesia
Tianjin International Joint Academy of Biotechnology and Medicine (TJAB)	China
University of Sydney	Australia

The network is supported as the leading group of HTA organisations in Asia by various international bodies including the World Health Organization, The International Network of Agencies for Health Technology Assessment, Health Technology Assessment international, and the International Society for Pharmacoeconomics and Outcomes Research.

From 2012, HTAsiaLink has held an annual conference in one of its member countries, the first taking place in Thailand. A characteristic of this young organisation is that its members are also mostly young and HTAsiaLink has sought from the beginning to support young researchers, to give them opportunities to share their work with others and to expose them to the wider world of HTA. HTAsiaLink's conferences are typically occasions at which young Asian health researchers can meet major international research and policy figures and have them critique their work in a relaxed and friendly but thoroughly professional way. Prizes are awarded for presentations judged to be the best. This is in addition to the usual fare of such conferences, like plenary sessions, panels and training workshops.

To date, HTAsiaLink has published seven newsletters. Each typically reports on research that is likely to be of interest to members but that has not yet been completed or published. The most recent report highlights progress towards universal health coverage in the region and the role that HTA can play. The HTAsiaLink network has proved valuable as a means of conducting rapid reviews. In 2011, China's Central Ministry of Health was developing its twelfth five-year plan. An issue arose as to how best to budget for advanced health care technologies like Da Vinci and Tomotherapy. The Da Vinci system is a form of laparoscopic minimally invasive surgery consisting of a surgeon's console and a patient operating table with three or four interactive robotic arms controlled from the console. Three arms

are for holding objects like scalpels. The surgeon uses the console's master controls to manipulate the robotic arms. The instruments' jointed-wrist design exceeds the natural range of motion of the human hand and fine movements without tremors are enabled. Tomotherapy combines in a single machine 3-D imaging from computerised tomography with radiation therapy and enables physicians to identify the size, shape and location of hard-to-reach tumours with reduced side effects. Dr Zhao Kun, Director of the China National Health Development Research Center contacted HTAsiaLink members requesting information on the safety, efficacy, cost, effectiveness, cost-effectiveness and practical experience of use in each country of these and similar hi-tech interventions. Within a week, she had replies from most members sufficient for her to make firm recommendations to the Chinese Minister of Health. HTAsiaLink works!

It is as yet too early to assess the contribution of HTAsiaLink to research or research capacity development in the South East Asia region, though the approach adopted seems to be highly promising. An early HTAsiaLink research collaboration between Japan, Korea, Malaysia and Thailand was on the social value of the QALY in different Asian settings. Using the EuroQol version of the QALY measure of health outcome, a pilot test of willingness to pay in each country was performed in 2011/12 to explore the feasibility of the instrument/methods used and to examine the value of a QALY associated with improving quality of life in mild, moderate and severe health conditions, and with extending life during terminal illness (Lim et al. 2013).

As for the contribution of HITAP to HTAsiaLink, that seems clear: it is remarkable.

Relations with Countries and International Networks

HITAP International Unit and NICE International

"NICE International was set up to respond to requests from around the world for help to improve evidence-based decisions about resource allocation in healthcare by improving systems, capacity and information-gathering. We do not attempt to replicate the UK model of healthcare or to transplant NICE into other countries' healthcare systems. Instead, we offer our advice and support on a not-for-profit basis to help countries deliver clinical and cost-effective healthcare to the people who live there." (NICE 2011)



Memorandum of Understanding Signing Ceremony between the Ministry of Public Health Thailand and the the National Institute for Health and Care Excellence (September 2010)

NICE International was established in 2008 in response to the increasing demand from researchers, non-governmental organisations, health insurance funds and ministries of health and finance across the globe for more information about the National Institute for Health and Care Excellence (NICE) itself, its creation, and the way in which it has become a part of the policy and practice architecture of the National Health Service in England and Wales. NICE International delivers hands-on advice on technical projects in many low- and middle-income countries, helping them to build capacity, adapt guidelines, develop clinical pathways, establish performance standards, carry out economic evaluations of interventions and technologies, and boost governance and transparency in decision-making. It also engages policymakers and forms partnerships with them and works closely with the Bill and Melinda Gates Foundation, the Rockefeller Foundation and the UK Department for International Development.

November 2013 saw the launch of a new network of partners, led by NICE International, in the form of an international Decision Support Initiative (iDSI), bringing together the Center for Global Development, NICE International, HITAP, several major UK universities (University of Glasgow, Imperial College London, London School of Hygiene and Tropical Medicine, University of Strathclyde, University of York), the US-based Johns Hopkins University, the Office of Health Economics, Meteos, and Priority Cost Effective Lessons for System Strengthening South Africa (PRICELESS SA). The common purpose was to strengthen capacity in low- and middle-income partner countries for evidence gathering and use in priority setting, including the explicit respecting of local circumstances, traditions and values in health care. iDSI's mission is "to guide decision-makers to effective and efficient resource allocation strategies for improving people's health". Like the other core members, HITAP came to iDSI, as we have seen, with an already well-established set of relationships with countries, especially ones in South East Asia.

An early achievement of the new network was its adoption with minor adjustments of the Reference Case described in Chapter One. This had been developed by the York group at the Centre for Health Economics under Mark Sculpher's leadership at the behest of the Bill and Melinda Gates Foundation. Damian Walker, Senior Program Officer at the Foundation, said of the Reference Case:

"Getting more health for the money is a principle that guides our grant making at the Bill and Melinda Gates Foundation. However, our ability to discern which programs provide the best value for money has been compromised by a lack of standard methods. In partnership with NICE International, 2014 saw the successful launch of the reference case for the conduct and reporting of economic evaluation sponsored by the foundation. In the future, I expect the Reference Case to be a requirement for all foundation-sponsored economic evaluations, significantly improving our ability to identify the best buys in global health." (NICE 2014a)

An aspiration of the iDSI network is for the Reference Case to become the gold standard for all economic evaluation work throughout the world especially among countries striving to realise Universal Health Coverage. As Amanda Glassman, Director of Global Health Policy at Center for Global Development (CGD), has said:

"People who decide how to spend health budgets hold the lives of many others in their hands. With hope, the iDSI will better equip these decisions-makers with fair, evidence-based recommendations on how to help as many people as possible with the resources available." (in NICE 2014b)

HITAP's networking experience made it a natural partner for iDSI. Networks are an important means of sharing information efficiently and, in the process,

of strengthening capacity among members to undertake and use evidence in policy-making. Networks can also encourage collaborative and mutually beneficial research, thus avoiding unnecessary — and potentially costly — duplicated activity. What is more, networks can network with other networks — as has proved to be the case with iDSI — thus widening shared experience even further and potentially reaping economies of scale and scope.

HITAP in Myanmar

Myanmar, formerly called Burma, has a woefully inadequate system of health care. It does not have its own NICE or HITAP, nor is it planning to have one. They do, however, have some resources for HTA, they have access to external research funders, and they have had the smart idea of seeking the expert help



The first mission in Myanmar for a feasibility study of the Community Health Initiative for Maternal and Child Health in Myanmar (May 2010)

of a group from abroad — HITAP with the support of the South East Asia regional office of the WHO. As part of their commitment to providing primary health care, Myanmar began preparations in 2008 for implementing a programme of health system strengthening. This is defined by the World Health Organization as a process of identifying and implementing an array of initiatives and strategies to improve the functioning of the health system. The problem was: where should one begin?

HITAP's advice was to develop and enhance accessibility to antenatal care for pregnant women, specifically by using skilled birth attendants for poor mothers and their children. At the time, hospital-based antenatal care was prohibitively costly for the vast majority of women and both maternal and neonatal mortality rates were among the highest in the ASEAN region. HITAP, in collaboration with the WHO, provided technical support to Myanmar's Ministry of Health for a feasibility study of a voucher scheme. The scheme would eliminate provider fees and other household money costs of access. Pregnant women had the choice of using the vouchers at any health facility. A capacity building programme covering research methods, data collection and analysis, evidence-based policy decisions, as well as public communication to facilitate the services uptake, was organised by HITAP for local partners. The programme was to be called the Maternal and Child Health Voucher Scheme and, of course, like all health programmes it has its own acronym: MCHVS.

The study was conducted in three townships in Myanmar from May 2010 to March 2011. A first mission in May 2010 developed a protocol for MCHVS which was technically and financially feasible, acceptable to stakeholders and acceptable in cultural terms. A second mission was conducted in August 2010 to assess and to provide training for the local partners in conducting a costing study. The last mission, conducted during March 2011, estimated the potential cost and health

outcomes from the future implementation of the scheme and devised a monitoring and evaluation process.

The study demonstrated that the MCHVS was feasible and had a good chance of being implemented in Myanmar and of increasing the accessibility of antenatal care, especially by poor households. After the study, guidelines for the management of the Scheme were developed jointly by HITAP and the Ministry of Health in Myanmar. The responsibility for the future management of the Scheme was handed over to the Ministry. The guidelines covered voucher distribution, financial management, communication, and monitoring and evaluation. The pilot programme was initiated in one of the townships on 11 May 2013 and, following a review six months later, was judged to be a great success, with utilisation rising from 73 per cent to 93 per cent, and has been extended to other townships¹⁴.

The Myanmar work was HITAP's first international work. It was a great demonstration project and HITAP received requests to provide support in other countries. It demonstrated many of the best characteristics of successful programmes: it came at the request of the client government rather than that of an outside agency, it was sensitive to the local culture, it involved local stakeholders, and it was competently conducted using sound methods. HITAP is now providing support to Vietnam, Indonesia, the Philippines, Sri Lanka, Bhutan, Nepal, as well as Myanmar.

HITAP in Indonesia

Following a scoping visit by HITAP to Jakarta in June 2014 and an explicit request by the Indonesian authorities, Indonesia was selected for iDSI practical support. This work aims to provide policymakers with coordinated support in priority setting as a means of achieving universal health coverage. An initial workshop in June 2014 was jointly organised by the Seattle-based Program for Appropriate Technology

¹⁴ Technical aspects of the cost-utility analysis that was the core of the analysis are in Kingkaew et al. (2015).



A field visit in Indonesia by HITAP (September 2015)

in Health (PATH)¹⁵, HITAP and the Republic of Korea's National Evidence-based Healthcare Collaborating Agency. It introduced concepts of HTA and evidence-informed priority setting to Indonesian health officers and key stakeholders, and explored the need, demand and capacity for HTA research in Indonesia. The workshop was followed by a further visit by HITAP in September to gain better understanding of possible roles of HTA in Indonesia and where specific practical support might best be located. A further visit by NICE International took place in November. In early 2015, HITAP organised training programmes for two key groups: the Indonesian national HTA Committee and the WHO Package of Essential Noncommunicable (PEN) disease interventions evaluation team. This was followed later in the year by a stakeholder meeting to discuss the findings of the PEN evaluation study and explore the role of HTA in supporting Indonesian progress towards universal health coverage. Study tours for senior Indonesian officials to

¹⁵ PATH is a US-based research institute having multiple research programmes in economic evaluation and health technology assessment. It has affiliates in Canada. This is an example of inter-network collaboration.

both NICE International and HITAP are planned and there is a commitment to further support as and when requested by the host country.

A further collaboration between HITAP, iDSI, and Indonesia is now under way to develop the methodology of the iDSI Reference Case in that context.

HITAP in the Philippines

The HITAP team has also been working with the Philippine Department of Health's National Center for Pharmaceutical Access and Management, who wanted to know whether the Human Papillomavirus (HPV) and the Pneumococcal Conjugate virus (PCV) vaccines should be included in the care package offered under the Philippine health care system. The National Center and HITAP jointly conducted the two vaccine economic evaluations having also run a workshop to prepare the Philippine partners who would be doing the analysis.

These vaccines are especially important in the Philippines because of a high incidence of cervical cancer and HPV in women, and of *Streptococcus pneumoniae*-related diseases, such as pneumonia, meningitis and other respiratory tract diseases in children. The studies identified cost-effective vaccines (if they were administered under comprehensive universal health coverage) as well as strategies for the consideration of policymakers. A major finding was that HPV vaccination could reduce the burden of cervical cancer by 50%. The primary recommendations were an expansion of screening to 80% of women aged 35–45 years at five-year intervals, the inclusion of the HPV vaccine in primary care for 11-year-old girls and the implementation of universal PCV vaccination for children.

HITAP included capacity development for their Philippine partners but the more recent methodological work has uses well beyond the country. In addition to the workshops already conducted, short- and long-term capacity building activities

were implemented and planned. An internship at HITAP for National Center staff will soon be realised, as well as formal postgraduate training at the Faculty of Pharmacy, Mahidol University in Thailand, for two National Center staff. The two teams plan to select HTA topics in the Philippines and involve various stakeholders in the process. To quality assure future HTA, a Philippines Methods Manual on Drug Evaluation will shortly be completed following completion of the joint methodological work.

To crown all this activity, a memorandum of understanding between the Department of Health in the Philippines and the Ministry of Public Health in Thailand concerning future collaborations in HTA is in the process of being drafted and is planned for signing in January 2016.

HITAP in South Africa

The first meeting of iDSI in Africa took place in March 2015 and focused on the South African environment for priority-setting and health technology assessment.

South Africa is among the most unequal countries in the world as far as access to health care is concerned, despite its being an upper-middle income country and having some secondary care institutions of the highest world quality. Such is the inheritance of apartheid. PRICELESS SA (Priority Cost Effective Lessons for System Strengthening South Africa) at the University of the Witwatersrand convened a two-day meeting with more than seventy stakeholders to identify ways of scaling up practical support for evidence-informed priority setting in achieving equitable health care for all South Africans. The group comprised senior SA government officials from Health Ministries and the Treasury, including the Director General of the National Department of Health, Ms Precious Matsoso, WHO staff, the Bill and Melinda Gates Foundation, the private sector (health insurance and pharmaceutical sectors), and researchers and leaders in priority-setting from the UK, Thailand and Zambia.

Policymakers from South Africa were extremely positive about the initiative and encouraged by the potential. A presentation by Dr Mpuma Kamanga from the Zambian Ministry of Health also gave the attendees a glimpse into the work which is taking place in that country to enable the development of a social health insurance scheme for underpinning universal access to quality health care. Some key areas for iDSI support were identified, including support for decision-making in the essential medicines programme and public health insurance benefits package designs, and technical collaboration for training and capacity building. The idea is that iDSI will assist PRICELESS SA and other South African academic centres in becoming an HTA support hub for central and provincial governments in South Africa — or possibly for a larger area of Sub-Saharan Africa.

HITAP in Vietnam

iDSI has helped the Ministry of Health in Vietnam to develop the first set of evidence-informed clinical quality standards. They form part of wider efforts by the Ministry to improve hospital care quality as Vietnam moves towards universal health coverage.

Stroke is the leading cause of death in Vietnam, with 230,000 cases annually accounting for 110,000 deaths and 1,748 Disability-Adjusted Life Years lost per 100,000 population (Institute for Health Metrics and Evaluation 2013). Stroke is estimated to cost the Vietnamese health system US\$48 million per year. Many complications are preventable using simple, inexpensive interventions, but many hospitals lack access to evidence-based standards of care due to workforce and capacity constraints. The MOH and the Vietnam Health Economics Association requested iDSI practical support to develop widely accepted and locally feasible and acceptable standards of care, based on robust evidence and worked out through a nationally-owned process. The Rockefeller Foundation provided funding support for the work.



a two-day review on a process manual of selection criteria by HITAP (June 2014)

NICE International enlisted the collaborative help of the Royal College of Physicians of London and NHS England for their expertise in developing clinical quality indicators and delivering stroke service improvement not only in the UK but in low- and middle-income countries worldwide. A multi-stakeholder committee was convened, comprising Vietnamese Ministry and provincial policymakers, stroke clinicians and hospital administrators from across the country. In three successive workshops in Hanoi, the committee managed to prioritise the clinical areas with greatest potential for impact in Vietnam, identify relevant clinical recommendations from UK evidence-based guidelines and adapted these into quality statements with measurable indicators, suited to the Vietnamese context. The standards emphasise low cost, high impact interventions, including prevention, joint working between the clinical disciplines needed in stroke units, early diagnosis, and early rehabilitation (mobilisation and swallowing checks).

The quality standards exercise brought together Vietnamese policymakers and stroke clinicians for the first time in a deliberative, evidence-informed process. And it had direct policy impact. The Ministry now includes the quality standards in its hospital quality accreditation criteria, and is funding pilot implementation of the quality standards for stroke in several provinces. Full implementation in all 1,050 acute hospitals could lead to estimated net savings of US\$2.8 million per year, primarily resulting from better care and referral processes, with associated reductions in lengths of stay. There is a good prospect that quality standards will also be set in other clinical areas. But for that to happen, Vietnam needs to develop its institutional capacity.

A beginning was made in 2013 in the Health Strategy and Policy Institute charged with developing research-informed policy advice over a broad range of policy and evaluative topics. With the support of the Rockefeller Foundation, the Institute and HITAP decided to build a detailed two-year plan as a first step to institutionalising HTA research for policy-making in Vietnam. The Ministry entrusted the main tasks to its new Institute. In April 2014, NICE International, HITAP, the Institute and other stakeholders and policymakers met to map out the rough framework of the plan, beginning with the preliminary selection of topics relevant to Vietnam's immediate circumstances. At the initial meeting in April 2014, HITAP researchers developed a guidance document for the technical teams at Health Strategy and Policy Institute (HSPI), the Hanoi Medical University, the Hanoi School of Public Health, and the Vietnam Health Economics Association. HITAP researchers had further direct discussions in May with HSPI staff during the HTAsiaLink conference in Beijing to discuss the primary set of criteria for topic selection developed from literature reviews and their uses, and shared HITAP's experience with Thailand's procedures for topic selection. Subsequently, the Vietnam team sent their first draft of the selection criteria to HITAP for comment and suggestions. Following that and further exchanges, a process manual

of selection criteria was completed in November 2014. This had been preceded by a two-day review by HITAP in June at which methodological issues were settled and specific priorities were identified. These included the use of PEG-interferon for treating chronic hepatitis C; using trastuzumab for treating HER-2+ breast cancer; and using MRI for non-specific diagnosis.

In addition to this battery of support activity, HITAP has chaperoned Vietnamese colleagues through the international world of HTA by making the Institute a member of HTAsiaLink, supporting continuous involvement in regional HTA meetings, such as the Asia Pacific Observatory meetings and the Prince Mahidol Award Conferences, as well as opening up access to still wider international iDSI meetings and events.

HITAP in Bhutan

A collaboration between HITAP and Bhutan's Ministry of Health began in 2013 with support from the Regional Office for South East Asia of the World Health Organization. Most of the HTA capacity building activities by HITAP in Bhutan to date had been through training and workshops. No hands-on experience for the entire HTA process had been started.

In 2009, thanks to the extremely high prevalence of Bhutanese with non-communicable disease risk factors, the Bhutanese Ministry of Health implemented interventions for hypertension and diabetes in primary care settings as a part of the World Health Organization's PEN in two pilot areas. Four years later, the World Health Organization and the Ministry of Health itself wanted to know what impact the programme had had and adopted HTA as its tool for the purpose. HITAP was invited to visit Bhutan to provide lectures and workshops tailored for the evaluation and to help in the analysis of the data. The results were presented to high-level decision-makers in the Ministry.

HTA capacity in Bhutan was further built through a secondment programme whereby research staff from the Essential Medicines and Technology Division of the Bhutan's Ministry of Health, with a fellowship from Health Technology Assessment international (a global scientific and professional society), came to train at HITAP for a month in 2014. The fellowship offered the staff basic training in HTA and economic evaluation and an opportunity to review and appraise HTA evidence with close supervision from HITAP's staff. A year later, HITAP visited Bhutan again to provide a workshop on selecting topics for further HTA research, participated in by representatives from various departments in Bhutan's Ministry of Health. This relationship with Bhutan is still a "work in progress".



HITAP staff provided a workshop on selecting topics for further HTA research to representatives from Bhutan's Ministry of Health (September 2015)

HITAP and the Wider International Stage

HITAP is behind the scenes in much international diplomacy. Some notable examples are through the role it plays in providing the Thai government with evidence-based materials, and the whole region with exemplary procedures and an effective track record. WHO resolutions raise decision-makers' awareness of the potential HTA has in low- and middle-income countries and encourages the WHO and international donors to work actively in HTA development and to support progress towards universal health coverage (UHC).

Thus, the Regional WHO Committee adopted Resolution SEA/RC66/R71 on effective management of medicines at the initiative of the Thai government. This resolution urged member states:

"to invest in all areas of medicines management and implement, as appropriate, the recommendations with regard to medicines regulation, policy and coordination, supply, selection and use as agreed at the Regional Consultation on Effective Management of Medicines 23 - 26 April 2013 in Bangkok".

Countries were urged to speed up implementation of recommendations in Resolution SEA/RC64/R52 on National Essential Drug Policy and the rational use of medicines, and to undertake a situational analysis of medicines in health care delivery for monitoring and planning purposes at least every four years and to publish such reports.

A 2015 Briefing Note from the regional office of the WHO uses Thailand as a case study of the use of HTA and identifies the critically important role of HITAP. The Note is effectively an introduction to the "how to do it" of HTA with HITAP as exemplar. Some of the high points of this Note are:

"All countries, rich and poor alike, face resource constraints within which policy choices must be made... HITA have been used effectively to inform UHC-related policy decisions in Thailand. Three particular areas have been requested for replication by other SEAR countries and form the basis of WHO support for country case studies in collaboration with Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health (MOPH), Government of Thailand: cost-effectiveness of essential lists of medicines to inform strategies for affordable access to medicines, including price negotiations; assessment of current and alternative clinical options for a particular intervention to inform a multi-sectoral approach to addressing non-communicable diseases that balances prevention and curative services; and, assessing the multi-dimensional impact of alcohol/tobacco use and other health risks. Relevant illustrations from Thailand are presented here along with the process of institutionalisation for sustained use of HITA for policy support. ...Notably, this exercise led to a substantial reduction in the price of medicines where the coverage decision recommended was 'no' or 'price reduction' – e.g. within months of sharing the results, the price of oxaliplatin was reduced by 70 per cent, making access affordable for patients on the one hand, and a budgetary impact of 150 million Baht per year less. Budget impact analysis of lifetime health care cost of using alternative regimens for prevention of mother-to-child HIV transmission as developed for Thailand allowed the government to make an informed discussion on effective resource allocation including balancing prevention and curative interventions."

On institutionalising HTA processes:

"The process of HITA in Thailand... involves 5 key steps: 1. Submission of health topics by a range of stakeholders. 2. Prioritisation of health topics by a working group and proposed to the policy-making agency (National Health Security Office

— NHSO) for final selection. 3. Technology assessment carried out by the technical unit (the Health Intervention and Technology Assessment Program — HITAP) and submitted to NHSO. 4. Appraisal of the assessment findings/report by NHSO. 5. Decision for benefit package development by NHSO. Since its inception in 2009, HITAP has considered 120 topics nominated by stakeholders for prioritisation and selected more than 50 for further assessment; and, informed by this process, 20 new interventions were included in the benefit package based on value for money, budget impact, feasibility and for their impact on equity.

"Overall, the HITA process has been found to support the legitimacy of policy decisions by increasing the transparency, inclusiveness and accountability of the process. However, within this, different stakeholders have different capacities and interests in participating in the process — which requires constant strengthening of capacities as well as advocacy. ...Resolution SEA/RC66/R4 calls for Regional and international support for comprehensive capacity development — training of researchers and providing capacity development to policymakers and other relevant stakeholders instrumental in linking research to policy for effective institutionalisation of HITA."

Crowning these influential public endorsements was the May 2014 World Health Assembly resolution whereby the Assembly urged member states:

"(1) to consider establishing national systems of health intervention and technology assessment, ...in support of universal health coverage to inform policy decisions, including priority-setting, selection, procurement supply system management and use of health interventions and/or technologies, as well as the formulation of sustainable financing benefit packages...

(2) to strengthen the link between health technology assessment and regulation and management...

(3) to consider... developing national methodological and process guidelines and monitoring systems for health intervention and technology assessment in order to ensure the transparency, quality and policy relevance of related assessments...

(4) to further consolidate and promote health intervention and technology assessment within national frameworks, such as those for health system research, health professional education, health system strengthening and universal health coverage

(5) to consider strengthening national capacity for regional and international networking, developing national know-how, avoiding duplication of efforts and achieving better use of resources;

(6) to consider also collaborating with other Member States' health organisations, academic institutions, professional associations and other key stakeholders in the country or region in order to collect and share information and lessons learnt...

(7) to identify gaps with regard to promoting and implementing evidence-based health policy, as well as improving related information systems and research capacity...

(8) to develop and improve the collection of data on health intervention and technology assessment, training relevant professionals, as appropriate, so as to improve assessment capacity".

The Assembly also directed the Director-General:

- 1. "to assess the status of health intervention and technology assessment in Member States in terms of methodology, human resources and institutional capacity, governance, linkage between health intervention and technology assessment units and/or networks with policy authorities, utilisation of assessment results, and interest in and impediments to strengthening capacity;*

2. *to raise awareness, foster knowledge and encourage the practice of health intervention and technology assessment and its uses in evidence-based decision-making among national policymakers and other stakeholders, by drawing best practices from the operation, performance and contribution of competent research institutes and health intervention and technology assessment agencies and programmes...*
3. *to integrate health intervention and technology assessment concepts and principles into the relevant strategies and areas of work of WHO, including, but not limited to, those on universal health coverage...*
4. *to provide technical support to Member States, especially low-income countries, relevant intergovernmental organisations and global health partners, in order to strengthen capacity for health intervention and technology assessment, including, when appropriate, the development and use of global guidance on methods and processes based on internationally agreed practices;*
5. *to ensure adequate capacity at all levels of WHO...*
6. *to support the exchange of information, sharing of experiences and capacity-building in health intervention and technology assessment through collaborative mechanisms and networks...*
7. *to report on progress in the implementation of this resolution to the Sixty-ninth World Health Assembly."*

HITAP as the model for all to follow evidently lurks between the lines of both these injunctions from the World Health Assembly.

In conclusion

Characterising all these initiatives and the international perception of HITAP's standing are not only the competences required in reviewing epidemiological, clinical, statistical and economic and other highly technical literatures, or conducting original primary research, but also the very conspicuous attention given to process. Identifying and involving critically important stakeholders including government — but not government alone — not only ensures access to local knowledge and experience but builds local ownership of outcomes and local credibility in the processes for making decisions for the populace at large. These are the selfsame characteristics that underlie HITAP's processes within Thailand. Their absence underlay the failure of HITAP's predecessors in Thailand and they are one of the distinctive features of HTAsiaLink's and iDSI's approaches to helping countries on their roads to universal health coverage.

HITAP AND THE FUTURE: OBVIOUS AND LESS OBVIOUS POSSIBILITIES

"Trying to predict the future is like trying to drive down a country road at night with no lights while looking out the back window."

"Follow effective action with quiet reflection. From the quiet reflection will come even more effective action." (Peter Drucker)

Futurology is no science. In truth, the future is essentially unknowable, let alone forecastable. But it is certainly discussable and possible futures can be anticipated, so that one is better prepared for them if and when some recognisable form of them comes about. In this chapter, we consider some possibilities and their implications for HITAP now and for its planning in the very near future. We consider some questions to which we do not know the answers but which we think the bright minds in HITAP could usefully address. We hope this chapter provides fodder for in-house brainstorming sessions for HITAP and its friends.

The Price of Success

HITAP is an extraordinary success. One of the characteristics of successful organisations is that they tend to expand, not only because the value of what they ordinarily do is increasingly appreciated and demanded, but because being successful at something generally leads people to expect one to be successful at other things as well. In this way, the portfolio of what they "ordinarily" do over time grows and becomes more varied and complex. This was true of NICE. From a staff of 10 and a turnover of £600,000 in 1999/2000, it grew to employ directly more than 600 people with a core government grant in 2014/15 of just under £65 million and a total turnover of around £71 million. It now has dozens of committees while the growth in health technology assessment means it now has four appraisal committees rather than the one it started out with. Its original remit was to support the National Health Service in England and Wales by conducting economic appraisals of technologies and to write authoritative clinical guidelines which (for the first time anywhere) included considerations of cost-effectiveness. To these were added economic evaluations of public health interventions; then guidance on medical technologies and diagnostics guidance; then what they termed "Interventional procedures" (guidance for procedures like laser treatments for eye problems or deep brain stimulation for chronic pain); then

the management of the National Confidential Enquiries into deaths of people undergoing medical care (subsequently taken on by another agency). Social care followed public health. NICE then acquired the British National Formulary and the British National Formulary for Children. More recently, it now sets standards for clinical practice, social care and public health in the National Health Service and issues guidance to manufacturers on the standards expected for making claims of cost-effectiveness and for embodying economic elements in clinical trials (Timmins et al. 2015).

HITAP might well experience something similar. It would begin with a narrower range of work than NICE did (no clinical guidelines) and only indirect relations with the health care system since it does not make decisions, but only advises the government departments that do make decisions. But several factors suggest that HITAP might come under pressure to extend and expand. The first and most important is that it has set itself standards of excellence (rigour of analysis and sound empirical methods) that are hard to beat. The second and third are political. Incomes rise and fall as a result of HITAP recommendations that are adopted and HITAP has proved resistant to the obvious corrupting influences that can arise. It can be trusted. Third, many of the decisions that need making about the technologies to be publicly funded are difficult to explain and defend — and especially to the general public and to patient advocacy groups. What could be more convenient for politicians if they were able to delegate them to a truly authoritative and independent agency that bore in mind all the evidence and all the clinical, scientific, economic and ethical issues that arise in each case? In short, an agency that is authoritative, credible, incorruptible and fair-minded.

Only time will tell. But meanwhile, what sorts of extension or expansion might HITAP firmly set its face against or, alternatively, embrace?

The Price of Technologies

Chapter 5 described one of the ways in which HITAP has already played a role in price negotiations in Thailand. This role may readily be extended, for two main reasons. First, as the envelope of coverage increases over time, and with it the health care budget, the average cost of additions to the publicly insured bundle of services will tend to rise. This will make it increasingly important for decision-makers to have cost-effectiveness information. Second, if — as is to be expected — HTA methods are applied increasingly to health care interventions that go well beyond pharmaceuticals, the quality of the clinical data relating to efficacy and effectiveness is likely to fall, with fewer clinical trials and even fewer well-executed trials, limited economic information, many more claims made on behalf of the interventions than are supported by evidence, and many more cases in which expert opinion is divided. Reliance on systematic and other secondary research will be less helpful. Decision-makers and HITAP will require more primary research, and require also the development of new interpretation skills with "fuzzy" and largely qualitative data, and methods for obtaining reliable and consensual opinions from experts that will be credible to all stakeholders.

An estimate of the incremental cost-effectiveness ratio effectively sets the maximum price that ought — given the value assumptions embodied in the analysis — to be paid. It represents the community's willingness to pay for the product. Whether it is *necessary* to pay such a sum is unlikely. While decision-makers may welcome having reasonable estimates of the *maximum willingness to pay*, the critical piece of missing information is the *minimum willingness to accept* of the manufacturers. Attempts to measure this will then come on to the research agenda, and the negotiations between buyers and sellers is in essence an attempt to find an agreed price lying between the maximum willingness to pay and minimum willingness to accept. Knowing only the maximum boundary of willingness to pay is dangerous if it becomes a unique point of departure for a negotiation, probably inherently biasing the outcome upwards.

One can therefore envisage a scenario in which HITAP enlarges its advisory function to embrace these elements. It might even become a player — for example an "honest broker" — in the field of negotiation. That would be a major departure for HITAP and one that could be inherently political and controversial. HITAP has, up to the present, carefully distanced itself from any role in actual decision-making. This is in contrast to the role played by NICE, which essentially enables politicians to distance themselves from difficult decisions by taking these decisions out of the political arena and into the world of evidence-based assessment and explicit social value criteria.

There is such a role to be played but whether it is played by HITAP or not, HITAP will doubtless be expected to gear up to support the role, whoever does play it.

HITAP the Role Model

As we saw in chapter 6, HITAP has been hugely influential outside Thailand and especially in South East Asia, both through HTAsiaLink and through one-to-one relationships with other governments and agencies. Even tentative steps to establish processes of the sort that characterise HITAP (and even more so, NICE) take most people well outside their comfort zones. To create a HITAP-type agency requires special people skills and people competencies as well as merely technical skills. The people in organisations like HITAP are usually driven by a passion (especially one for universal health coverage and better access to health care). They are not in it for the money. They expect and usually command academic and scientific respect. They are credible. They are trusted. They have developed processes that expose their work to external gaze and to ensure satisfying career development for their staff.

HITAP can accordingly expect to see its international work to grow and to face increasing demands from outside as to "how to do it". This is less likely to refer to the technicalities of Health Technology Assessment. It is much more likely to relate to organisational matters and the management of relationships between the agency and those for whom its work has consequences — the health professions, clinical and managerial; the senior civil service; the government; industry; patients, informal carers; the general public. In short, assuring political sustainability.

Being a role model of this sort brings in its train visitors, some of whom may want to stay a while and probe quite deeply. Students of technology assessment will be naturally drawn to HITAP for work experience and internships. The same goes for manufacturers who will want to ensure that their presentations, together with the evidence and the analysis on which they are based, are every bit as professional as those of HITAP. HITAP already entertains academic thesis writers. That may be expected to increase, with associated deepening relationships with universities in Thailand as well as elsewhere. HTAsiaLink and NICE International may not remain the main networking bridges between HITAP and the outside world.

HIITAP the Regional Hub

An alternative future scenario, not incompatible with HITAP being a role model to be adapted and adopted, is HITAP the regional hub. There are many countries whose current position in terms of capacity to conduct HTA, even of a rudimentary sort, is so limited, or so untrustworthy, as to make the idea of subscribing to a regional hub an interesting proposition: a hub that has the technical capacity and the political integrity, including an ability to listen to and absorb the specifics of another country's history, values and on-the-ground reality. HITAP is uniquely well-placed to develop its HITAP International Unit into a quasi-permanent agency for other countries' HTA. HITAP would need to develop further its reviewing skills

to make shrewd judgements about the applicability of research results obtained elsewhere to a client country and its judgemental skills in assessing the acceptability of new technologies, or the dropping of old ones, as the client pursued its own agenda for universal coverage.

The advantages of having a regional hub capable of meeting the HTA needs of several subscribing member states would raise some challenging questions of governance and accountability, as well as creating opportunities for developing a new science of the generalisability of research. The ultimate decisions would, of course, have to remain with the client country's own authorities but the hub could be a relatively cost-effective means to them for acquiring a knowledge and information base which they could then use in their own decision-making on the road to universal health coverage. For HITAP, there could be economies of scale and scope, and the potential for building an unrivalled database and archive of methods and evidence in health technology assessment.

HITAP and the Manufacturers

Given the inevitable importance of manufacturers' evidence about the effectiveness and cost-effectiveness of their technologies, the quality of that evidence should be as high as may reasonably be expected. This requires in-house competencies in HTA skills which in turn require initial investments in training and subsequent maintenance of skills. We have already seen HITAP working with universities in providing basic and more advanced training courses in HTA and related topics. The training needs in industry are likely to present an expanding demand, especially as the range of activity progresses well beyond the economic evaluation of pharmaceuticals, the meeting of which might well fall at least in part to HITAP. This does not represent an inherent compromise over HITAP's intellectual and commercial independence provided it is managed carefully, but it will help to

ensure a good understanding of what is required from industry, what constitutes high quality work, and what is needed in terms of presentation skills. All of these will make HITAP's work for its governmental clients so much the easier.

At another level, manufacturers are themselves a potential source of funding for HITAP HTA. Canada has already introduced a system of charging manufacturers fees when their products are reviewed by the Canadian Agency for Drugs and Technologies in Health which, like HITAP, is a purely advisory agency — advising the Canadian provincial ministries of health. The Canadian agency now generates a sizeable fraction of its income from such fees, which has enabled it to speed up its processes, thereby substantially sweetening what would otherwise have been a bitter pill for industry to swallow. Any such future moves in Thailand would involve a further development of HITAP's professional working with the manufacturing sector at home and abroad.

Independence

Should HITAP acquire greater influence still, or even some decision-making authority within Thailand, then the pressure on its independence will increase. It will have to learn to live with greater external scrutiny of its procedures and decisions and not all of this will be friendly or motivated by high principle. Judicial reviews may be demanded when the stakes are high and HITAP will need to be assiduous in assuring due process and that it sticks to doing as it says it will do and doing it as it says it will do it. Identifying conflicts of interest and dealing with them fairly and reasonably will become ever more important. Anticipating and learning how to handle commercial attempts to acquire improper influence, many of which are far subtler than banknotes proffered in brown paper envelopes, will need to form a part of everyone's training.

It will not be enough (indeed, it is already not enough) to be scrupulously honest. HITAP has to be seen to be scrupulously honest. Transparency and accountability will be the keys to maintaining HITAP's future independence.

HITAP is proudly independent and insistent on its strictly advisory role. The questions arise: would departures from the purely advisory role prejudice HITAP's independence and autonomy, and would a greater integration with another organisation (say into the Ministry of Public Health) necessarily prejudice the quality of its advice? The answers to these questions are not self-evident and we think them worth serious consideration and deliberation by HITAP and its friends. We saw earlier (chapter 4) that HITAP thinks of itself as "semi-autonomous" through its funding diversity, the establishment of the Foundation as well as its accountability, through the Program Leader to a Deputy Permanent Secretary. This arrangement strikes us as slightly untidy — which itself may help to guarantee HITAP's independence — but which may suffice so long as HITAP's role is no more than advisory and the advice continues to be based on HTA and related analytical tools. Were its role to become broader, or it was to become more intimately engaged in actual policy-making, a tighter line of accountability would almost certainly be required. For example, a broadening of the advisory only role, might warrant the protection of a university and the internal accountability that would attach to a research unit such as HITAP being located in a university; greater integration with policy, say in the Ministry of Public Health, would probably warrant very different arrangements that would entail much less openness and ability to share knowledge and internal workings. The specifics need to be modelled and thought through, together with the identification of specific measures to protect the values that HITAP plainly cherishes. For example, were HITAP to become more closely engaged as a policy decision-maker, the particular sections so involved

might have separate status from other divisions in a new HITAP that bound one section to appropriate rules of procedure and confidentiality while not applying it to other sections.

We have no firm opinions on these matters, other than we think them worth considering. Indeed, we think it necessary to consider them, for the continuing expansion of HITAP that we think is bound to happen will itself force consideration of new governance structures on to HITAP. It ought to be possible for HITAP to increase its usefulness, clarify and enhance its accountability, and do both without unacceptable loss of independence and integrity. It is certainly worth trying!

Funding Diversity

One of the attractions of a larger portfolio of work, whether or not it is also a wider portfolio in terms of the range of types of intervention subjected to HTA, is that it often enables a greater diversification of funding sources. Although HITAP is not dependent upon a single funder, a large number of funders of reasonable magnitude and from a variety of economic and political environments, makes for greater overall financial stability. It also requires skilful planning and management. It should continue to be worked at.

Changing Policies in Thailand

Changing domestic policies are plainly matters to be anticipated wherever possible. The more obvious of these include the impact of changing policies over public expenditure controls. This can work in two contrary directions. On the one hand, the use of HTA as currently funded is a claim, directly and indirectly, on public expenditure¹⁶ and savings might therefore be demanded of — or forced on — HITAP. On the other hand, HTA can be used as an instrument of public expenditure control — especially through lowering the implicit or explicit cost-effectiveness threshold, and so HITAP becomes an important agency in controlling health care costs while maintaining, at least in principle, quality standards.

¹⁶ Moving to a fee-based system for funding HTAs could obviously reduce this dependence significantly.

Less obvious possibilities in the future might arise as universal health coverage expands the range of interventions that are publicly insured. One question that is almost inevitably bound to arise relates to terms of access. The wider the population scope of universal coverage and the more complete its range of included interventions, the higher the cost per capita and in total. Specific question arises: should there be an earmarked health care "tax-cum-premium" managed perhaps by a quasi-independent health commission through which all universal health care was funded? Should premiums be experience- or community-rated? How would adverse selection be controlled? Should there be deductibles and co-payments (with or without the hypothecated tax) and, if so, set at what rates, with what exemptions and for what services? Answering such questions would require a new research agenda that is part empirical (for example, to estimate income and price elasticities of demand or various services and population groups) and part ethical and political (for example, discovering through surveys and other investigations what public attitudes are held about the relevant issues). These are standard topics in health economics but lie outside HTA and so any new role for HITAP in addressing them would represent challenges — and tough ones for those in HITAP (doubtless the majority) whose basic disciplinary training lies in medicine, pharmacology, epidemiology or biostatistics rather than economics.

Other policy shifts might occur in terms of political favouring of private insurance over public, with consequential needs for new regulatory arrangements and possibly with private insurers using HTA in determining their own range of insured products, the associated premiums and, again, co-payments, and asking HITAP to provide the necessary evidence base.

Threshold research is currently much favoured in some countries and may come to the core as a researchable topic in HITAP. It could be coupled (though they are not necessarily linked) with willingness-to-pay studies drawing on social surveys or experimental economics skills.

Then there is the impact of policy that is institutionally directed at HITAP itself: For example a wish to absorb it more completely into government or —a move in the other direction, to distance it further by giving it delegated decision-making powers more like those of NICE. Either type of change is likely to be resisted by the HITAP we know, but some changes may nonetheless be irresistible. It would be prudent to plan for them, if only in a rudimentary way.

To Outsource or Not to Outsource

If there is to be expansion, the question will arise as to how best to arrange it. Two obvious alternatives are to keep everything under the same umbrella and in the same place, whether within a Ministry building as now, or elsewhere, or to create a distributed model by which HITAP staff are located in different sites and hosted (probably) by other organisations (one might imagine them to be universities). This could take at least two of many forms. One would be a loose association of research units, possibly commissioned (outsourced) by HITAP; the other would be a more federal solution. The distributed model was a natural one for NICE to adopt since NICE itself was not a research organisation. The research commissioning processes in England and Wales do not require strict coordination between the various sites that support NICE's work in clinical guidelines, technology appraisals, and so on. Competition among universities and Royal Colleges of Medicine for NICE-related research contracts seemed a natural way of proceeding. That, of course, might be a possibility for Thailand too, under which HITAP would become just one of a number of research centres bidding for research resources to serve the commissioners in the relevant sections of the Ministry of Public Health and other relevant ministries. However, in Thailand a single organisation (HITAP) with institutionally and geographically distributed staff might have the advantages of closer links with the pools of external multi-disciplinary expertise, shared staff appointments, greater access to health economists, and the like. But there would

be disadvantages too and too much distributed responsibility might make for an administratively cumbersome new HITAP. Once again, we have no firm views. There are potential gains and disadvantages of each option. The issues are surely, however, well worth discussion.

Does HITAP Have an Optimal Size?

How large ought HITAP to be? The answer is unlikely to be found by considering only the demand for its work, for that could be met, in the event of markedly increasing demand, by the establishment of new "HITAPs" — competitor organisations. The answer most probably lies in considering softer issues: issues like the idea of "critical mass" and "collegiality". Both require qualitative discussion and closer analysis of their likely impacts on the quality and timeliness of HITAP's work.

Critical mass generally refers to a minimum number of people having particular subject skills or fields of responsibility. A research community in which every single researcher has at least one or two others with whom to exchange views and share technical problems is more likely to be creative and successful than if each was in a personal silo. The maximum is harder to define but will almost have been exceeded if communications were becoming impossible or the sheer size of the organisation forced artificial spatial constraints on it.

Optimal size will depend also on the staffing structure and its ability to support an appropriate number of principal investigators, mentors and research managers with, at its head, probably no longer a single charismatic leader but a senior management team — mostly comprising researchers.

Issues of critical mass and organisational size are excellent topics for staff away-days and brainstormings.

HITAP as a Model for Low- and Middle-income Countries

HITAP's manifest success at home and its ever-increasing influence abroad brings in its train a difficult question: how should it play its international role as exemplary and a model for other low- and middle-income countries to follow? One way of answering this question would be simply for it to carry on as it has been working over the past few years. But that may be neither possible nor desirable. Not possible because the scale of the role would need more than the current arrangements, including HITAP International, are capable of delivering. The most important respect in which this is true concerns the key role of Dr Yot in international work. It would take only a very small increase in HITAP's international commitments or him (or his successor) to be totally overwhelmed. Not desirable because it would put at risk the most important element in the story of HITAP's success, that is its extreme sensitivity to the local and specific in demography, history, economic standing, culture, infrastructure (human and physical) and political sophistication. The "model" that HITAP represents is not something that can be, as it were, lifted off the shelf and slotted into another country's system. Nor is the essence of the model having skills in cost-effectiveness and related techniques of analysis (though having, or acquiring, such skills is undoubtedly essential). Rather, the model that others should follow is one of self-determination with learnings from those (like the Thais) who have found ways of building prioritising processes into the machinery of government and simultaneously engaged the research community in significant ways to provide the required evidential support — a support that far transcends the simply clinical (though the clinical is rarely "simple!").

The full exercise of HITAP's role as model needs specific attention and an organisational response that is commensurate. It might be a response that builds on the HIU; it will certainly be a response that ensures the full and active participation of HITAP's leadership, with appropriate support.

Perhaps, of all the brainstorming topics we have suggested, this is the most challenging. In facing it, HITAP will almost certainly need the support and enabling power of the government.

Securing the Future: Succession Planning

From its birth, HITAP has been led by the inspirational figure of its "Program Leader", Dr Yot Teerawattananon: Dr Yot as he is universally and affectionately known. His self-adopted title says much. He is not the "Director", "Chair", "Head of Department" or "Chief Executive Officer". The title echoes a modest but self-confident personality. The inspirational role betrays a conviction and a passion for what HITAP does and the ways in which it does them. There can be no doubt that the achievements of HITAP are at root the achievements of Dr Yot, which implies no minimisation of the brilliant supporting role played by his senior colleagues and, in particular, by Dr Sripen Tantivess.

Belbin's (2010) well-known categorisation of team roles played in successful organisations identifies nine roles in three groups: action-oriented, people-oriented, and thought-oriented. Each role has characteristic strengths and weaknesses:

Action-oriented

- *Shapers: challenge the team to improve. Obstacles are challenges to be overcome. They may be argumentative and offensive.*
- *Implementers: create practical actions and plans. They may be inflexible and conservative, resistant to change.*
- *Completer-Finishers: see projects through, attend to detail, meet deadlines. They may be too perfectionist, worriers and poor delegators.*

People-oriented

- *Coordinators: team leaders, chairs, good listeners and delegators. They may over-delegate and be manipulative.*
- *Team Workers: help ensure people within work together effectively good negotiators. They may be indecisive.*
- *Resource Investigators: innovative, curious, network builders. They may not sustain their interest and may be over-optimistic.*

Thought-oriented

- *The Plant: creative innovator. They may be impractical and solitary and not great at communicating their ideas.*
- *Monitor-Evaluators: critically analyse and evaluate, think strategically. They may appear cold, detached and unable to motivate others.*
- *Specialists: have specialised knowledge. They may be preoccupied with minutiae and miss the wood for the trees.*

Dr Yot possesses many of these characteristics himself, apparently with few of the weaknesses. In a small organisation, it may well be a condition for success that the inspirational figure is indeed such an all-rounder. The downside comes when the organisation grows sufficiently to need serious delegation of roles or when the time comes for the inspirational leader to move on, or retire. HITAP is probably moving to such a stage as Dr Yot has indicated that he will probably move on in perhaps three years' time. It is therefore time for succession planning. The successor will be — and ought to be — a very different personality, having different skills for the task will be a different one. The issues need brainstorming now. The search for Dr Yot's successor needs to begin soon.

A Star in the East

Sirius, the Dog Star, is the brightest star system in the night sky. It is a star group that rises and sets and has for time immemorial (its name, for example, is derived from Sanskrit) been an object of awe and inspiration. It may be too fanciful a conceit to compare HITAP with Sirius¹⁷ but, like all conceits, it shocks us into an awareness that there is something special about the thing being compared, for which conventional metaphors may not serve. And HITAP is certainly special. We have tried through this short history to convey what the many facets of HITAP are that make it so special. It is unique in the way it has not only put HTA at the service of the government of Thailand but also at the service of other governments in the region. It has the admiration of kindred researchers. Its integrity is unimpeachable. It is a model for advice-giving bodies. It listens and engages. It has a spring in its step: with a youthful Program Leader and staff who are young (their average age is currently about 33). It has accomplished much in its eight short years and punched well above its weight domestically and internationally. It produces good science, does first rate primary and secondary research, is politically astute, makes sound judgements, and deserves every ounce of the respect it has earned at home and abroad.

A star in the East indeed!

¹⁷ Indeed, it is probably unwise, because Sirius is known as the "Robber Star" in Thailand!

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