Establishing health technology assessment (HTA) in middle-income countries: a comparative analysis of the path towards institutionalisation in Thailand and the Philippines

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Thesis submitted in accordance with the requirements for the degree of

Doctor of Philosophy
of the
University of London

NOVEMBER 2019

Department of Health Services Research and Policy

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LONDON SCHOOL OF HYGIENE & TROPICAL MEDICINE

Funded by the Economic and Social Research Council

Declaration of originality

I Ioana Vlad, confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

Signed Date

Abstract

This thesis examines the process of establishing HTA in two middle-income countries, Thailand and the Philippines. It conceptualises HTA establishment as involving decisions in relation to creating HTA organisations, developing processes and the methods used for analysing and appraising evidence, and embedding HTA in existing decision-making and governance structures. These elements make up the path towards institutionalisation.

A comparative case study design with a pragmatic constructivist approach was chosen to allow for a rich description of the process of institutionalisation. The two case countries were selected based on their similarity with regard to their early interest in HTA, but differences regarding the degree to which HTA has been institutionalised at the time of the study. The analysis of the process of institutionalisation was informed by interviews with key policy actors and documentary review. The conceptual perspectives chosen for the analysis of HTA institutionalisation focus on ideas, interests and institutions.

This study found that HTA advocates organised in policy networks, of which senior civil servants were important members, were key to initiating the process of establishing HTA. The rules of the administrative systems, which provide civil servants with varying degrees of independence, determined the way in which HTA organisations were established. The development of HTA processes was largely influenced by the existing rules for making coverage decisions. HTA processes and methods were not directly copied from other countries but were developed in each country and adjusted over time. The interests of some policy actors opposed to HTA seemed to undermine institutionalisation at different points in time. However, this thesis also found examples in which opposition to the results of HTA strengthened its development in the long term. How HTA processes operated was influenced by other aspects of health systems governance, especially mechanisms for procurement and reimbursement, as well as the long-term evolution of the heath system, which explained and structured power struggles between policy actors.

Acknowledgements

I would like to thank my supervisor, Stefanie Ettelt, for her steady guidance through the process of writing this PhD thesis. I am grateful both for her patience and meticulousness – without which this process would have been impossible. I would also like to thank my supervisor, Justin Parkhurst, who supported my introduction to the PhD process and asked the important questions throughout this process. I am also grateful to Professor David Gough for his guidance in the early days of this PhD.

I am grateful to my advisor, Kalipso Chalkidou, and the International Decisions Support Initiative (IDSI) for their support in the delivery of this thesis. I am also grateful for the financial support received as part of the IDSI, which allowed me to focus on this project. I would also like to thank the participants of this study for being so generous with their time and wisdom, as well as welcoming me to their countries. I particularly like to thank the entire HITAP organisation for hosting me for three months as I was carrying out the interviews for this thesis. It was an invaluable experience, for which I will always be grateful. I am equally thankful to the team at Epimetrics for their kindness and eagerness to share ideas.

Finally, I am grateful for the moments I shared with my all my PhD friends – each are wonderful people. Special thanks go to Donna Alabdulbaqi for holding my hand when I needed it the most. Thank you to Laskmi Govindasamy and Mathilde Mailfert for their constant friendship throughout these years. Thank you to my friends all over the world – Germany, Sweden, Romania – for staying close.

To Iriana Gil Paz, thank you for making hard days better and good days wonderful. Thanks to my sister, Mihaela, for her incredibly steady support and love. To my nephews, Octave and Théophile – it is a joy to watch you grow.

I dedicate this thesis to my parents: my mom, Gina Vlad, who showed me how to steadily get things done, day in and day out; and to my dad, Mihăiță Vlad, who showed me how to say ‘we’ll figure it out’ and mean it. Both are invaluable lessons.

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Table of Abbreviations

AIHO	Alliance for Improving Health Outcomes Research
AHTAPol	Agency for Health Technology Assessment in Poland
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
CEO	Chief Executive Officer
CT	computerised tomography
CUA	Cost-utility analysis
EBM	Evidence-based Medicine
ERG	Evidence Review Group
DALY	disability-adjusted life years
DMS	Department of Medical Services
DoH	Department of Health
FDA	Food and Drug Administration
FEC	Formulary Executive Council
GHBP	guaranteed health benefit package
ICER	incremental cost-effectiveness ratio
IHPF	International Health Programme Foundation
IHPP	International Health Policy Programme
IMRTA	Institute of Medical Research and Technology Assessment
INAHTA	International Network for Agencies in Health Technology Assessment
INCLEN	International Clinical Epidemiology Network

IQWiG	Institute for Quality and Efficiency in Health Care
HAS	Haute Autorité de Santé
HPPD	Health Policy Development and Planning Bureau
HITAP	Health Intervention and Technology Assessment Programme
HMOs	health maintenance organisations
HPV	Human Papillomavirus
HSRI	Health Systems Research Institute
HTA	health technology assessment
HTAi	Health Technology Assessment International
LGU	local government unit
LSHTM	London School of Hygiene and Tropical Medicine
MCDA	multi-criteria decision analysis
MoPH	Ministry of Public Health
MRI	magnetic resonance imaging
NCPAM	National Center for Pharmaceutical Access and Management
NEBT	National Epidemiology Board of Thailand
NHSO	National Health Security Office
NICE	National Institute for Health and Care Excellence
NIP	National Immunization Programme
NLEM	National List of Essential Medicines
NHIP	National Health Insurance Program
PCV	pneumococcal conjugate vaccines
PET	positron emission tomography
PIDS	Philippine Institute for Development Studies

PhilHealth	Philippine Health Insurance Corporation
PNDF	Philippine National Drug Formulary
QALY	quality-adjusted life year
RCTs	Randomised Controlled Trials
RDS	Rural Doctors' Society
TASSIT	Technological Assessment and Social Security in Thailand
ThaiHealth	Thai Health Foundation
SBU	Swedish Council on Technology Assessment
SPICE	Setting Priorities Using Information on Cost-Effectiveness
SDBP	Subcommittee for the Development of the Benefits Package and Service Delivery (SDBP)
UHC	universal health coverage
UCS	Universal Coverage Scheme
USA	United States of America
USAID	United States Agency for International Development
UK	United Kingdom
WHO	World Health Organisation
WHO/TDR	WHO Special Programme for Research and Training in Tropical Diseases
YLL	years of life lost

1. Introduction

Many governments across the world have adopted health technology assessment (HTA) as part of their approach to governing their healthcare systems, specifically to assist decision-making on which health services to cover and which to exclude from publicly funded health care. The argument for institutionalising HTA relies on the belief that, if used well, HTA can lead to an equitable distribution of scarce healthcare resources, by making coverage decision-making more systematic and transparent, reducing their exposure to the influence of vested interests, and increasing their legitimacy (Glassman and Chalkidou, 2012). However, the process by which HTA becomes part of countries' health systems governance is not yet fully understood. It is clear that HTA takes different forms in different countries, but what explains these different organisational arrangements, procedures for decision-making or even the types of technologies being assessed is not equally clear. This thesis aims to understand the process of establishing HTA organisations and processes – often termed institutionalisation of HTA – in the context of two middle-income countries, the Philippines and Thailand. It is important to expand our understanding of how HTA institutionalisation has taken place because countries at various levels of economic development continue setting goals to institutionalise HTA (Augustovski, Alcaraz, Caporale, García, *et al.*, 2015; Downey *et al.*, 2017; Wild, Stricka and Patera, 2017).

To date, there have not been many studies of HTA institutionalisation, which means we are not able to explain why there are major differences in the resulting HTA arrangements between countries. For example, agencies and other organisations mandated with conducting HTA differ widely with regards to their organisational structures or their overall role in health system governance. Many HTA organisations have some degree of independence from government, either as institutes at arm's length from government, such as the National Institute for Health and Care Excellence (NICE) in the United Kingdom (UK), or as independent public institutes, such as the Haute Autorité de Santé (HAS) in France or the Agency for Health Technology Assessment in Poland (AHTAPol). Some of these bodies act in

an advisory role to the Ministers of Health (or other decision-makers), such as AHTAPol, whereas others are mandated with decision-making, as is the case for NICE (Oortwijn *et al.*, 2017). Emerging literature from high-income countries focuses on such aspects of HTA establishment in order to explain what influences observed differences (Löblová *et al.*, 2019). Some authors have linked the choice of organisational arrangements to existing characteristics of the regulatory system that give market approval for new technologies (Allen *et al.*, 2013; Barron *et al.*, 2015) while others explain the divergence based on the administrative traditions that characterise the political system of a country (Torbica, Tarricone and Drummond, 2018). Further, value for money considerations are given more or less importance in different countries, which has been hypothesised to be due to differences between preferred social values among the general population (Landwehr and Klinnert, 2014). However, focusing on such specific elements of HTA establishment is insufficient to explain how the entire process of institutionalisation takes place.

Even less is known about the development of HTA organisations to inform coverage decisions in middle-income countries (Augustovski, Alcaraz, Caporale, García Martí, *et al.*, 2015), despite the fact that some middle-income countries have long histories of engagement with HTA and of attempts to establish HTA bodies. Specifically, starting in the 1990s, a number of middle-income countries initiated processes of HTA institutionalisation, including Malaysia (1995), Brazil (1999) and the Philippines (1999), followed in the 2000s by countries such as Thailand (2007) and Colombia (2011). Other examples are Poland and Hungary, two countries that started their HTA projects as middle-income countries, in 2005 and 2007 respectively, but have since been classified in the high-income group (Chootipongchaivat *et al.*, 2016; Löblová, 2016; Castro, 2017).

There is an increasing body of work that is dedicated to advising middle-income countries – many of which aim to develop universal health coverage (UHC) - on how to determine the type of services covered by publicly funded health systems and on the likely challenges to making such coverage decisions (Chalkidou *et al.*, 2013; Voorhoeve *et al.*, 2017). This advice includes HTA, but also other attempts to define services, such as essential medicines lists or essential benefit packages, often

referred to as ‘priority-setting’. This advice, and the criteria suggested for decision-making, are developed building on the cumulative experience of high-income countries (Daniels, Porteny and Urritia, 2015). However, in middle-income countries, HTA and other tools for priority-setting will respond to policy problems specific to this context. In high-income countries, HTA became associated with coverage decisions for innovative technologies, often made by comparing alternative technologies based on criteria of value for money. Middle-income countries encounter additional challenges with regards to coverage of health services. These challenges include fast adoption of innovative health services, in parallel with increases in health budgets as these countries’ economies grow. In this context, decision-makers in these countries are likely to face tough questions on what to fund first, as well as how best to allocate health budgets to achieve competing UHC goals, often in the context of fast-growing private healthcare provision. As middle-income countries expand public coverage to innovative services, they may also need to ensure access to services considered essential and well-established, and may therefore experience pressure to ensure essential services and set harder limits to their benefit packages (Glassman *et al.*, 2016). This specific context of middle-income countries is likely to influence procedural, methodological or organisational choices on the path towards HTA institutionalisation.

Therefore, to understand the process of HTA institutionalisation, it is necessary to understand differences in context, such as the ideas, interests and institutions that shape the development of health system governance in each country; whether and how these differences influence how HTA bodies become established; and how these bodies function. It is reasonable to expect controversies about the use of HTA for coverage and resource allocation decisions in middle-income countries, as experienced in high-income countries. In the latter, such contestation has influenced specific arrangements for HTA - for example, the establishment of mechanisms for public participation - or has even ended the process of institutionalisation (Hassenteufel *et al.*, 2017). Debates that are likely to emerge in middle-income countries on whether value for money is a reasonable criterion for decision-making, whether HTA processes lead to more public involvement and transparency of decision-making, or whether they actually depoliticise decisions that are inherently

political (Baltussen *et al.*, 2016). However, debates in middle-income countries are likely to be shaped first and foremost by the specific problems policy-makers in these contexts encounter, which are different than the ones in high-income countries, as explained above. In addition, in high-income countries, HTA institutionalisation as a tool for informing coverage decisions and for distributing healthcare resources attracted controversy both among academics, as well as among politicians, officials, industry representatives, members of civil society and the wider public. Therefore, these categories of actors and their interests should be understood in middle-income countries as well.

Existing literature, albeit scarce, indicates that there is likely to be a degree of policy transfer of HTA from high-income countries, whereby countries learn from, or even copy models of HTA approaches established by high-income countries. HTA is an idea that crossed borders, with some academics and HTA approaches from specific countries, such as the UK, being particularly influential (Benoit and Gorry, 2017). However, policy transfer is insufficient to explain institutionalisation, in the absence of an understanding of how institutional characteristics, such as administrative traditions or health system arrangements, may influence the process of establishing HTA (Landwehr and Böhm, 2014; Hassenteufel *et al.*, 2017; Torbica, Tarricone and Drummond, 2018). Since such arrangements will from high-income countries and between differ in middle-income countries and from country to country, therefore they need to be understood in each country context in order to explain HTA institutionalisation.

To conclude, this thesis aims to understand better how HTA has been established to inform coverage decisions of publicly funded health services in middle-income countries, by analysing the ideas, interests and institutions involved in shaping the development of HTA bodies mandated with this task in Thailand and the Philippines. Specifically, this thesis examines how policy actors conceptualised the problems they wanted HTA to address and their expectations towards HTA providing a solution to these problems; the interest pursued by different groups of policy actors in supporting, or opposing, the development of HTA; the choices policy actors made in relation to the principles and methods underpinning HTA; and how they

established organisations and developed rules and processes to conduct HTA and to use the evidence generated by HTA to inform coverage decisions. Using the multiple lenses of ideas, interests and institutions, this thesis aims to unpack the process of institutionalising HTA as experienced in Thailand and the Philippines, to understand better the challenges policy-makers in middle-income countries face when working towards universal health coverage and introducing HTA to inform coverage decisions.

This thesis is structured as follows. Chapter 2 presents the review of the literature with a view to define the concepts used in this analysis. Chapter 3 introduces the aims and objectives, clarifies the theoretical approach taken by this thesis and describes the methods used in this thesis. Chapter 4 provides a historical account of the development of HTA in Thailand and the Philippines to provide information about the cases selected for this study. Chapters 5 to 8 present the comparative analysis, including the ideas shaping how and why HTA was developed (Chapter 5), how HTA organisations were established (Chapter 6), how the rules and processes underpinning HTA were developed (Chapter 7), and what were the barriers and opportunities encountered during HTA institutionalisation (Chapter 8). The final chapter discusses the key findings in the light of the literature on HTA institutionalisation in middle-income countries, and their implications for policy and research.

2. Establishing HTA: a literature review

Organisations that promote the use of HTA, such as the International Network for Agencies in Health Technology Assessment (INAHTA), Health Technology Assessment International (HTAi) and the World Health Organisation (WHO) have produced different definitions of HTA. These definitions can refer to HTA as a type of *research* (e.g., WHO), or as a *process* of using evidence to inform decisions on including or excluding a health technology (e.g., HTAi, 2019). Reference to 'HTA' might include all these elements or prioritise one specific element, which has led to a significant degree of complexity in the literature on HTA. More generally, the concept of HTA tends to include at least three core elements: a) the methods of scientific enquiry on the impacts of health technology ('assessment'); b) the critical appraisal of the evidence generated by this enquiry and the deliberative process of reaching a recommendation on the adoption of the technology ('appraisal'); and c) the organisations that conduct and/or coordinate the assessment and appraisal (Velasco Garrido *et al.*, 2008; Drummond *et al.*, 2012). HTA institutionalisation necessarily includes all of the above elements.

This chapter will review the literature on the distinct elements of HTA. Specifically, it will clarify the nature of the policy decisions that HTA can inform discussed by scholars of HTA, the methods used as part of HTA processes, the means whereby HTA processes link evidence generation to decision-making, the role of HTA organisations in this process, and, finally, it will propose an operationalisation for HTA institutionalisation.

The role of HTA in policy-making

Governments use HTA to inform coverage decisions about the types of healthcare services that are available to patients through public funding schemes, such as publicly funded health insurance. Such decisions can be made in many different ways and the organisational arrangements developed for the purpose of making such decisions take different forms in different countries. Generally, some form of legislation typically provides the general framework, whose components are then

implemented at different levels of the health system. Taken together, they define the health benefits package. Coverage decisions can be more or less *explicit*, on a spectrum from services that are *implicitly* included or excluded via resource allocation decisions or organisational arrangements to an *explicitly* defined health benefit package that is continuously updated through a list of inclusions or exclusion (Velasco Garrido *et al.*, 2008).

Starting in the 1980s, governments in Europe and the United States of America (USA) showed increasing interest in making coverage decisions more explicit and directive. To that end, they developed specific processes and methods to make decision-making more transparent and rational (Schreyögg *et al.*, 2005; Sabik and Lie, 2008). One of the most commonly invoked explanations for this willingness of policy-makers to be more explicit about coverage decisions– as well as the use of HTA for that purpose – was the need to limit or control rising health expenditures (Banta, 2003; Syrett, 2007b). Concerns arose specifically about new, costly health technologies, which were believed to drive the observed increase in health care expenditure. Studies confirm that changes in medical technology contribute to raising health expenditures, although estimates on the size of that contribution vary considerably[1] (Fan and Savedoff, 2014). The desire to make coverage decisions more transparent was also informed by the evidence-based medicine (EBM) movement, whose main goal was to ensure that treatment decisions were made based on the best available evidence about the safety and efficacy of interventions (Sackett *et al.*, 1996). However, efforts to make coverage decisions more explicit have always attracted criticism of rationing in healthcare, on the grounds that they exclude patients with certain conditions from receiving treatments judged as insufficiently effective or too expensive (Smith, 1996; Ubel and Goold, 1998a; Maynard, 1999).

The rationing debates have driven the development of an extensive branch of normative literature focusing on justice in health and healthcare. Theories of distributive justice were particularly important in framing the early debates about

[1] Depending on assumptions about technical innovation being an independent factor or being determined by factors such as increased demand and insurance.

priority-setting or rationing in healthcare. These theories proposed a series of core principles as to what is being distributed – e.g. utilities, welfare or primary goods. Economists and medical ethicists then defined and operationalised these principles as relevant criteria for the distribution of healthcare (Olsen, 1997). These underlying definitions and their operationalisations matter because they inform, directly or indirectly, health policies and medical practice. One of the most used criteria for distributing health care is *need*, which is defined in relation to what constitutes ill-health, a controversial topic. On its face, this concept can easily be understood as clinical need, which indicates that need should be judged by physicians. According to Cookson and Dolan (2000), this principle was one of the more palatable for physicians in the United Kingdom (UK). However, most attempts to define need agree that any definition of need should indicate what is meant by ill-health, which can mean the degree of ill-health; immediate pain and suffering as well as threat to life; lifetime ill-health; and considerations about the potential to benefit from health care based on the initial state of ill-health (Cookson and Dolan, 2000). Finally, need has also been used in relation to effectiveness – specifically in relation to what needs can be met by available interventions (Culyer, 1995).

Another important principle in distributional justice is about *maximising the consequences of healthcare*. As in the case of need principles, the definition of what these 'consequences' are has been widely debated and multiple proposals exist (Cookson and Dolan, 2000). One proposed maximising principle is that health and distribution of health care should maximise population health. However, difficulties in measuring (i.e. comparing and ranking) all possible health states is both practically and conceptually challenging, if not impossible. An alternative was proposed under the name of 'wellbeing', which is a term that indicates attempts to value health instead of measuring it. These valuations can be subjective, i.e., preference based, or objective, that is, derived by valuing opportunities and capabilities (Hausman, 2008). In practice, preference-based valuations have been used the most widely.

Lastly, *equalitarian* principles of distributional justice focus on reducing inequalities in health. In general, equalitarian principles have not been proposed as a main

criterion, instead they have been considered in addition of one of the other principles. Some of these proposals were developed in relation to tools of maximising wellbeing, subjectively valued (e.g. fair innings) (Kelleher, 2014). These will be discussed in the following section, on HTA methods.

These answers to the question of how health care should be distributed in a fair manner outlined above are important foundational principles that underlie the rationale for establishing HTA. These core principles were applied through the tools that were developed to measure or evaluate health in order to meet goals of distributive justice, which were extensively used in HTA processes. While alternatives to what is viewed as just in the distribution of health care exist - for example, rights-based approaches - distributive justice theories were the lens through which rationing problems were approached most often (Dolan and Olsen, 2002).

Because there is no consensus on what substantive moral principles should guide distribution of resources for health care, scholars focused on procedural justice principles instead, while continuing to attempt to combine the core principles and guide decision-making (Cookson and Dolan, 2000). In particular, the accountability for reasonableness framework has proven particularly influential in the development of HTA processes (Daniels and Sabin, 1997). Daniels and Sabin (1997) propose four conditions that need to be satisfied for coverage decisions (which are about distribution of health care) to be fair: publicity, relevance, appeals and enforcement. The *publicity condition* refers to a requirement that two types of information are publicly and transparently accessible: a) the actual decisions about a service being covered or excluded; and b) the reasons for these decisions. The *relevance condition* focuses more closely on these reasons. A reasonable basis for decision-making is one that is accepted by the actors who want to find a solution for coverage decisions and that is justifiable and co-operative, knowing that agreement on substantive principles will be elusive. The *appeals condition* refers to establishing a mechanism to review decisions that are challenged or that should be re-considered based on emerging evidence. Finally, the *enforcement condition* refers to establishing voluntary or

public regulation to make sure that the previous three conditions are met (Daniels and Sabin, 1997).

Daniels does not attempt to solve the problem of which ethical principles should be applied to reach distributional fairness, which continues to be unsolved (Daniels, 2000; Daniels, Porteny and Urritia, 2015). In fact, Cookson and Dolan (2000) noted that the most consistent engagement in attempting to combine existing principles came from health economists. Some of these attempts were tested when governments established policy process of making explicit coverage decisions for their health systems. The earliest cases of explicit priority-setting took place in Norway (1987), the USA state of Oregon (1989), the Netherlands (1992), Sweden (1993), and New Zealand (1993). These first attempts at explicit priority-setting generally stopped short of making binding decisions. Rather, they worked on identifying principles that should guide selection, as well as working on more public involvement and transparency in decision-making (Sabik and Lie, 2008). The notable exception is the Oregon experience, which became notorious as an experiment in which the use of a sole health measure to prioritise treatments and conditions, drawing heavily from health economics methods, was met with strong resistance from the local community, in particular disability rights groups. Their criticism highlighted that the way in which quality of life was measured would lead to discrimination against people living with disabilities (Fox and Leichter, 1993; Smith, 1996). Such criticism linked to methods for valuing quality of life will be discussed further in the following section, on scientific methods for HTA. Some other countries used HTA agencies to provide a partial answer to this question (e.g. UK), whereas other countries established separate processes for clarifying the health benefits packages and for assessing new technologies (e.g. Sweden) (Sabik and Lie, 2008).

These and other attempts to make coverage decisions more explicit were accompanied by fierce debates. The term rationing in particular attracted much of that contestation. As a response, many researchers and policy-makers preferred to use the more palatable concept of priority-setting instead. In the UK, the term of 'rationing' was banned from usage at the Department of Health (DoH) for a while, to be replaced with 'priority-setting' (Klein, 1998). As Syrett (2007b) points out,

'priority-setting' emphasises a more 'rational' process of applying a systematic process to find the best courses of action. Of course, the difference is one of form (discourse) rather than essence (Syrett, 2007b). Some scholars, aware that the different term would not remove the likely contestation and the need for hard choices to exclude certain services that individuals might demand, argued against this shift in language as another way of concealing hard choices (Ubel and Goold, 1998). Interestingly, Ubel (2015) revised this position years later, agreeing that the term rationing was polarising to the point of impeding debate and progress.

Still, the shift in discourse seems to have taken hold to a certain extent. Currently, the term priority-setting is used widely to refer to any government attempt to clarify its reasons for inclusion of services. In theory, HTA is part of priority-setting, if the latter is understood as making coverage decisions explicitly. However, there seems to be a separation between the two. First, HTA is most often associated with limits – exclusions rather than inclusions. Second, HTA does not consider priorities across conditions, traditionally, but rather single technologies. As will be shown later, this distinction is being blurred in middle-income countries.

Scientific methods used for HTA

Many different criteria can be applied in HTA to inform coverage decisions. These criteria are generally about the health technology being assessed: its clinical benefit (safety, efficacy, effectiveness), its efficiency/value for money (cost-effectiveness, cost), or the ethical implications of a positive or negative coverage decision. Other considerations are emerging, depending on the technology, such as socioeconomic impact (loss of productivity) or innovation (Stephens, Handke and Doshi, 2012; Angelis, Lange and Kanavos, 2018). The conditions for which the treatment is indicated also raise relevant criteria, specifically disease severity and unmet need (i.e. burden of disease). The selection of criteria will depend on policy goals, defined by policy-makers. However, each comes with associated operationalisations which consists - often but not always - of scientific methods that are used for evidence generation in HTA processes. They also come with specific links with the theories of distributional justice outlined above.

The following section discusses the most common methods used to generate evidence that speak to these criteria. Note that some of these methods will be more established and more frequently used than others. Specifically, most countries use a comparative assessment of benefits at well as economic evaluations. However, 'additional' criteria such as the ones outlined above are increasingly used. Angelis and colleagues (2018) have assessed how the additional criteria that go beyond clinical benefit and efficiency are applied for new medicines and found that the relative importance of these criteria is often unknown, which they suggest may be a reason for differences in coverage recommendations for the same technology between countries at similar income levels.

Methods to assess safety, efficacy and effectiveness of technologies

Clinical studies of safety and efficacy of health technology typically form the core of HTA. They use statistical analyses to produce 'mathematical estimates of the risk of benefit and harm, derived from high-quality research on population samples' (Greenhalgh, 2014, p. 2). There has been much debate about appropriate study designs and relevant outcome measures, which can only be outlined in general terms below.

Proponents of EBM have successfully advocated for a hierarchy of evidence to establish a scientific standard for evidence of safety and efficacy of clinical interventions, with systematic reviews and/or meta-analyses of randomised controlled trials (RCTs) seen as the most robust type of evidence. However, the reliance on RCTs in the quest of identifying the best way of practicing medicine has also been criticised (Jones and Podolsky, 2015). Some clinicians have argued that the use of RCTs is unnecessary, for example where interventions have large effects that can be established through the use of other measures, such as treatment outcome over expected prognosis (Glasziou *et al.*, 2007). RCTs are also limited with regard to generalisability as they purposefully exclude the context of an intervention (Deaton and Cartwright, 2018).

Health professionals also feared that a 'religious' adherence to RCTs would limit their professional freedom (Sackett *et al.*, 1996). They argued that clinical decision-making cannot be solely based on RCT evidence and that it should equally draw on patient characteristics and preferences, as well as the experience of the health professionals themselves. Lastly, they pointed out that there were many cases when an RCT would not be ethical or feasible (Lambert, 2006). In contrast, proponents of the hierarchy of evidence did not dispute the importance of such factors, or that there will be cases in which conducting an RCT is not ethical or feasible, but believed that RCTs, when available, provided the best evidence of treatment efficacy, that health professionals should be able to appraise such evidence and apply it effectively, alongside their professional judgement (Sackett *et al.*, 1996). In an anthropological enquiry of the EBM movement, Lambert (2006) notes that, throughout the history of EBM, its proponents tended to absorb criticism by expanding the remit of EBM to include a broader evidence base.

If safety and efficacy are at the core of assessing health technologies, measuring the effectiveness of health technologies is the most prominent criterion used by HTA (Stephens, Handke and Doshi, 2012). Evidence on clinical effectiveness, i.e. the effects of an intervention under 'real world' conditions, can draw on a variety of study designs, and responds to some of the limitations of RCTs. Evidence of effectiveness can be generated by observational or pragmatic experimental studies. To establish evidence of effectiveness, pragmatic clinical trials can be conducted that relax some of the more stringent design requirements of RCTs, but increase the external validity of their findings (generalisability). Pragmatic clinical trials can also be less intrusive, for example by measuring rates of adherence (as opposed to enforcing adherence) and by selecting end points that are relevant for patients. On this later point, final health outcomes are more relevant for patients than surrogate outcomes (typical example: cholesterol levels), which are frequently used for RCTs. Finally, in many cases, it is only feasible or ethically permissible to collect effectiveness data by using routine data collected in registries and other administrative databases. There is increasing acknowledgement that other types of studies, including from other disciplines, can contribute to our knowledge of the effectiveness of health technologies in real-life settings (Lambert, 2006).

The choice of any of these methods for HTA should be understood in relation to the philosophical debates about the fair distribution of health and healthcare. As we have seen, a satisfactory answer is elusive, which explains why proponents of specific methods and processes - such as HTA or EBM - encountered considerable resistance. For example, EBM has been criticised for over-managerialising healthcare (introducing an 'audit culture') and working in the service of 'cost-cutters' (Sackett *et al.*, 1996, p. 71). Sackett explained that such criticism was due to a misunderstanding of the role of EBM and of its consequences, which was to 'identify and apply the most efficacious interventions to maximise the quality and quantity of life for individual patients' and by this it 'may raise rather than lower the cost of their care' (Sackett *et al.*, 1996, p. 72). Maynard (1996) argued that it would in fact be unethical from a societal perspective to provide the treatment that is most effective, irrespective of its costs, because it will mean an inefficient use of scarce resources (Maynard, 1996, p. 170). In contrast, based on an individual equity judgement, the most efficacious and effective treatments should be the ones provided.

These different views exemplify how ethical principles are codified in the methods used for HTA and why methodological choices are both important and a source of debate. For example, the underlying reasoning for using RCTs and systematic reviews or meta-analyses of RCTs is about establishing safety and efficacy of treatments for the average patient, using statistical analysis. The analysis of effectiveness tends to be less standardised than evidence of efficacy, because it responds to a wider range of the questions; it can therefore draw on different types of studies such as clinical trials (including pragmatic trials), observational studies and clinical case series. However, the space between the average patient and the needs of individual patients remain at the forefront of the concerns of many clinicians. As effectiveness evidence is sometimes unavailable, expert opinion, based on clinicians' experience, is also used in HTA processes. When that happens, the deliberative process is about negotiating principles and priorities in the committee room. HTA processes, with their rules and standards, are designed to equalise one perspective receiving disproportionate weight compared to other, competing perspectives.

Methods used for economic evaluation of health interventions

As explained above, introducing clinical innovation does not only raise questions of safety and effectiveness. In addition, innovation in healthcare has often been linked to the increasing costs of health care and raised questions about efficiency (Cookson, Griffin and Nord, 2014). Thus, at health system level, a relevant question is not only whether the medical services provided are effective, but also whether they are efficient.

Economic evaluation is used in HTA processes to apply the criterion of efficiency (or value for money) to coverage decisions. Economic evaluations can be conducted in many different ways for the purpose of HTA, although some have become more widely used than others. Some of these approaches can be used to promote technical efficiency, i.e., how best to produce services, or allocative efficiency, i.e. which services to produce. The degree to which both goals can be achieved by specific types of economic evaluation has been a source of debate among health economists (see Oliver, Healey and Donaldson, 2002).

Cost-benefit analysis (CBA), as the most established method for comparing the overall costs and benefits (valued in monetary terms) of alternative courses of action, developed to inform investment in different areas of public policy, can inform allocative efficiency, including in healthcare. However, due to criticism about assigning monetary value to health benefits, as well as the impractical data requirements, health economists migrated towards applying cost-effectiveness analysis (CEA) instead (Meltzer and Smith, 2011). If CBA can compare the overall benefits and costs of a technology, CEA compares the marginal health benefits attributed to a new technology with the benefits attributed to alternative treatment. The result, an incremental cost-effectiveness ratio (ICER), expresses the cost per extra unit of health gain achieved by the new technology. However, because CEAs can only compare alternative courses of actions with similar benefits, it can only inform decision-making by reference to an incremental cost-effectiveness threshold.

The use of cost-effectiveness thresholds is one of the most controversial aspect to applying CEA to inform coverage decisions. A cost-effectiveness threshold must be

applied to the incremental cost per benefit ratios in order to determine whether an intervention offers good value for money and therefore should be funded. In principle, such a threshold can be empirically calculated based on the available health budgets (Culyer *et al.*, 2007; Culyer, 2015). However, HTA agencies that used a cost-effectiveness threshold, such as NICE, did not establish a clearly defined and transparently communicated threshold at first and did not generate these thresholds by calculating them empirically. This has been a source of criticism to the use of CEA to inform coverage decisions (Harris, 2005).

As acceptability for the idea of a threshold grew, more research about the appropriate manner of estimating such a threshold was undertaken. Thokala et al. (2018) reviewed the methods that can be applied to determine cost-effectiveness thresholds empirically, distinguishing supply-side and demand-side approaches. Health economists who prefer supply-side approaches take as a starting point the existence of fixed budgets, which cannot be changed, at least not in the short-term (Vallejo-Torres *et al.*, 2016). In other words, at any given time, the threshold is implied by the existing budgets. In contrast, proponents of demand-side approaches aim to derive a cost-effectiveness threshold by estimating societal willingness to pay. Discussing the advantages and disadvantages of both perspectives, Thokola and colleagues (2018) note that threshold set by using supply-side reasoning tend to be higher than those supported by demand-side arguments. As a result, they argue that the two approaches could be complementary and that the approach to setting cost-effectiveness thresholds should be selected based on the problem the analysis is aimed to address (Thokala *et al.*, 2018).

Another type of economic evaluation often used in HTA, cost-utility analysis (CUA) is a type of analysis that uses a multi-dimensional health outcome measure, such as quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs). As a composite measure of health benefits, QALYs were first developed as a way of capturing the benefits of interventions that were not related to life years gained, but to quality of life (Klarman, 1982). Economists began to use QALYs as part of early applications of cost-effectiveness analysis to health, which highlighted the need to reflect differences in the quality of the extra life years gained from an intervention.

There have been extensive debates about and criticism directed at the methods used to elicit QALYs and the resulting estimates. These debates are either about the valuation of health states, or the underlying assumptions used in order to apply a unitary method of health gain. Measurement issues refer to the health state classification tools (including the domains of health) or the samples to which these are applied (general population or a relevant subgroup). Methods to value health states have also been contested. The health states are valued through preference derivation methods[2] (e.g., standard gamble, time trade-off or rating scales), but it is relevant which sample[3] these techniques are applied to. The existing systems of health state classification, description and preference derivation result in values that differ systematically across different samples, which reveals measurement problems. Consequently, the resulting QALY calculations (and eventually, cost-effectiveness ratios) will be different depending on the tools used to describe health states and to derive preferences for health states (Nord, 2014).

These limitations notwithstanding, QALYs have become extensively used in HTA processes. Because of their widespread use, Lipscomb *et al.* (2009) argue for improving the estimates underpinning QALYs incrementally, rather than abandoning QALYs altogether. Nord (2014) agrees that discussions about the use of QALYs in HTA should be separated from concerns about the accuracy of measures used in QALY calculations. He suggests that QALY values should be seen as an indicator of the size of health gain rather than the actual utility resulting from a health intervention (Nord, 2014). The overall goal of a measure of health gain would thus remain unchanged, i.e. to provide a quantitative estimate of value of health improvements.

The second type of concerns about the use of QALYs are the simplifying assumptions that underpin QALY calculations, which are more difficult to dismiss.

[2] Preference measurement tools have been developed based on expected utility theory (first developed in 1944). Despite criticism and existing alternatives, it dominates normative decision theory.

[3] Experience utility, i.e. patient samples, is preferred by health economists because it is seen as more accurate. In practice, most valuations have used samples of general population, also known as decision utility analysis.

These refer to the impact of the use of QALYs on distributional fairness based on its assumptions about patient characteristics or time spent in different health states (for a detailed analysis, see Lipscomb *et al.*, 2009). Put simply, QALY maximisation approaches disadvantage people who have lower capacity to benefit because of the nature of their disease, age or comorbidity (Nord, 2014).

There is considerable literature on the ways in which such equity concerns can be incorporated in economic evaluation models (Williams, 1997; Nord *et al.*, 1999; Farrant, 2009; Cookson, Griffin and Nord, 2014). For the purpose of this work, it is sufficient to mention that there are two main ways in which equity principles, beyond the ones implied by utilitarian theories that informed much of the economic evaluation tools, can be considered as part of HTA. The first approach is to incorporate them in economic evaluation. A second option is to consider equity concerns separately and include such principles in the deliberative mechanisms incorporated in HTA processes.

The degree to which each of these methods is used in HTA processes varies considerably and has important implications for decision-making. In particular, many HTA agencies explicitly state that cost-effectiveness is not an over-riding criterion (e.g. Germany). In other cases, for example, in England or France, cost-effectiveness is used as a minimum criterion, which also includes the analysis of evidence of efficacy and effectiveness. Further, many HTA agencies do not take into account affordability issues as a criterion or they consider it only in special cases, often by a separate organisation (e.g. NICE) (Cairns, 2016).

To deal with increasing variety in criteria for decision-making, as well as specific methodological limitation like the ones regarding QALYs, HTA agencies in different countries have started producing methods and process manuals. These guidelines are useful because standardising evidence requirements minimise the measurement problems mentioned above by limiting variability. Further, they provide transparency to the process of decision-making, which is in line with the principles of procedural justice that have been adopted as part of HTA.

The principles of HTA processes

This section examines the principles and debates around HTA processes, which can be generally described as the overall pathway from identifying a policy problem (usually a technology to assess) to decision-making on whether that technology should be covered and under what conditions. Typically, HTA processes are conceptualised as including distinct steps for assessment (evidence generation and/or synthesis) and for using its findings to inform the political process of decision-making (appraisal). These steps have been developed based on the experiences of high-income countries. However, existing structuring tools for the HTA processes tend to vary.

For example, Drummond and colleagues (2008) reviewed existing literature of practices of HTA and recommended a series of principles for the good process of HTA, structured by four proposed elements of HTA: structure of HTA programs, methods of HTA, processes for conducting HTA and use of HTA for decision-making. Other ways in which HTA processes are structured start from the idea that a technology is under assessment and propose the following structure: identification of technologies for assessment; prioritisation among technologies; carrying out the assessment; appraisal for assessment results, which can include recommendations for exclusion, inclusions, or further evidence review; dissemination of results; and implementation of decisions (Oortwijn *et al.*, 2013). Others go further and speak about systems of market authorisation, HTA and coverage decision-making, each with their own processes (Allen *et al.*, 2013).

The variety in how HTA processes are conceptualised can partly be explained by the diversity of HTA arrangements, as well as rapid changed to these arrangements, as proposed by Drummond (2008). Another influence could be the purpose of these conceptualisations. For example, they can be used to compare HTA processes in different countries, necessary since there is such diversity in how HTA processes operate. In some countries, an HTA agency may be charged with multiple parts of the process, while in other countries, these steps are undertaken by different organisations. In France, for example, the Haute Autorité de Santé (HAS) carries out the evidence review and develops policy recommendations. Other countries, such as

England and Wales, commission HTA reports from independent research bodies such as academic departments (Stevens and Milne, 2004). Velasco Garrido et al (2008) notes that the term appraisal is used in some countries to indicate deliberations on the results of the assessment, whereas in others it might include decision-making. This is due to the specific arrangements for HTA that NICE coordinates, which has codified this step of a HTA process in relation to the role of NICE as decision-maker.

The way HTA processes are conceptualised also matters because a series of normative principles have been developed for 'good practice' of HTA. These principles are important because they go back to a foundational principle of HTA, which is procedural justice. Procedural justice, in particular the accountability for reasonableness framework, plays an important role in how good practice for HTA is viewed. Good practices for HTA processes refer to inclusiveness - engaging all relevant actors as well as all relevant evidence- and transparency -a clearly defined link between evidence and decision-making, that is communicated appropriately, and possibility to appeal decisions (Drummond *et al.*, 2008). In recent year, more sophisticated frameworks for HTA processes were developed, in order to account for increasing criteria used in decision-making and ensure their transparency (Oortwijn *et al.*, 2017; Angelis, Lange and Kanavos, 2018).

Organisations mandated with HTA

A final element of HTA refers to organisations that coordinate HTA processes, often referred to as HTA agencies. This thesis focuses on government organisations that are mandated with coordinating HTA processes. Other types of HTA organisations exist, for example organisations that are commissioned with conducting HTA, but are not involved in coordinating appraisal or decision-making processes. These types of organisations fall outside the direct scope of this study, which is concerned with the reasons why governments adopt HTA for the purpose of informing coverage decisions. HTA organisations are usually established by being integrated into existing governance structures, for example as a government department, or by creating a distinct organisation with some degree of self-governance (e.g. at 'arm's length') (Sorenson, Drummond and Kanavos, 2008). Broadly speaking, HTA

organisations usually fall into two categories: a) organisations that produce and disseminate assessments; or b) organisations that serve either a regulatory function (by making binding decisions) or advisory function (by providing recommendations to be considered by a separate decision-maker charged with coverage decisions). Landwehr and Böhm (2011) argue that the degree of independence of HTA organisations is not only a function of their relationship with ministries of health, but also depends on their link with bodies mandated with the implementation of the decisions, especially payers, service providers, and manufacturers (Landwehr and Böhm, 2014). Thus, it is important to consider how HTA organisation relate to decision-makers in government, as well as how they 'sit' within the existing structure of the health system and its governance arrangements.

The development of HTA organisations are greatly context-specific, and although some differences between organisations seem small, they tend to have substantial consequences. Two characteristics are particularly relevant for this analysis: the degree of independence from policy-makers experienced by HTA organisations (i.e., whether policy-makers can influence their agendas); and whether the organisation is mandated with decision-making or has an advisory role only.

Government-based HTA organisations are often called HTA agencies. However, in practice, few HTA organisations actually have a 'agency' status which would imply being a government organisation with a degree of independence and decision-making power (Barron *et al.*, 2015). Many HTA organisations are institutes at arm's length from government, but most of them have no decision-making power. Others are departments of Ministries of Health or part of the administration of a public payer. NICE is often seen as an example of HTA agency. However, its position is unusual amongst HTA organisations internationally, mostly because it makes coverage decisions independently from the Department of Health and Social Care. Allen and colleagues (2013) compared HTA systems in 33 European countries and developed two taxonomies for HTA organisations: the first establishes whether regulatory functions, HTA processes and coverage decisions are undertaken within the same organisation; the second looks at the timing and coordination between the assessment of safety and efficacy, the economic analysis (i.e. the assessment of cost-

effectiveness) and the appraisal as part of the decision-making process. In Europe, Allen et al (2013) identify ten 'archetypes' of HTA organisations resulting from combining the two categories. While observing this substantial degree of variation, the authors do not attempt to explain how this variation has come about or what has motivated policy-makers in different systems to make the choices they have made when establishing their approach to HTA-informed coverage decisions.

Policy scholars recognised the weakness in comparative analyses of HTA bodies that did not try to explain the reasons why certain procedural and organisational choices were made in some places but not in others. Landwehr and Böhm (2011) compared HTA organisations in Austria, Germany, Norway, New Zealand, Sweden and the UK based on a series of pre-defined characteristics of the health system - the existence of 'positive' (inclusion) or 'negative' (exclusion) lists for health benefits - and of the organisation – degree of delegation and independence; inclusiveness, transparency and publicity. Their study shows that both the elements of HTA (in particular process elements) and the characteristics of the health system are relevant to understand why certain HTA organisations arrive at specific design characteristics. Landwehr and Böhm conclude that governments have the option to engage in 'strategic institutional design' (Landwehr and Böhm, 2014) according to political realities and the definition of the policy problem. However, they also concede that the ability to design HTA organisations is constrained by existing institutions, such as existing practices of defining the health benefit package.

Some other scholars have attempted to identify how certain institutional traditions and cultural values influence the establishment of HTA organisations. For example, Torbica and colleagues (2018) compare the influence of public administrative traditions in England, Germany and France on the development of HTA. They find that the organisation of NICE is highly compatible with the tradition of British government administration, which delegates specialised tasks to arm's length organisations with a high degree of independence. By comparison, in France, the government delegates specialised tasks, but continues to be in control of decision-making, by giving the organisation a lower degree of independence. Further, the German Federal Government delegates a substantial number of specialist tasks, but

the independence of organisations is typically rated as low. This is mirrored by the recommendations by the Institute for Quality and Efficiency in Health Care (IQWiG) not being binding to the decision-maker, the Federal Joint Committee (known as G-BA). Countries such as France and Germany, which fund health care largely through social health insurance, give lower priority to efficiency concerns than, for example, England, which operates tighter budget control (Torbica, Tarricone and Drummond, 2018).

Such differences in country context have also informed the choice of procedures and methods of HTA, by embedding certain policy values within health systems and therefore influencing the policy goals that are likely to be set. The use of cost-effectiveness is a pertinent example. Several authors suggest that methods of economic evaluation applied by HTA organisations are tightly linked with social values prevalent in their country context. In the UK, arguably, the principle of fairness of distribution is equally expressed in the foundational values of the National Health Service and in the use of QALY gains valued equally (although some exceptions are made for end-of-life treatment). In contrast, in the German social health insurance system, meeting the individual needs of patients is given more weight than distributional fairness (Torbica, Tarricone and Drummond, 2018). This finding is also confirmed by Landwehr and Böhm (2014), who link social values prevalent in a country's administration with the characteristics of the HTA organisation and their preference of decision-making criteria (Landwehr and Klinnert, 2014).

Other authors have underlined the political nature of decisions informed by HTA and the political context of HTA organisations. Wood and Flinders (2014) have shown that by delegating decision-making to arm's length bodies, policy-makers engage in a process of de-politicising decisions that are inherently political insofar as they affect the interests of different actors (Wood and Flinders, 2014). Wood (2014) noted that NICE in the England has successfully resisted pressures from politicians to change their decisions because its formalised procedures and scientific authority provided a degree of 'insulation' against political influences. Ferlie and Mcgivern

(2013) also argue that NICE's decisions have been accepted largely because of its ability to embed expert knowledge in its organisational structure and procedures.

Political scientists have theorised 'de-politicization' at governmental level as: a) a way of delegating decision-making to enhance the legitimacy of the decision; b) a way to limit the control of politicians with the aim to increase efficiency and leading to good governance); and c) a way to shifts blame and blur accountability lines by professionalising decision-making, thus de-politicizing essentially political decisions (Wood and Flinders, 2014). For instance, in Norway, positive and negative decisions regarding coverage of new technologies are split between two levels of governance: Parliament retains power for positive coverage decisions, while exclusions from coverage are delegated to an independent regulatory body (Landwehr & Böhm, 2011). Selectively delegating negative coverage decisions to the HTA body provides an institutional configuration that creates a distance between the political apparatus and a decision that is likely to be unpopular with manufacturers and patient organisations. In England, coverage recommendations by NICE, made at national level, are binding on the NHS, with local NHS commissioners being mandated to pay for drugs that have received a positive decision. Since NICE does not have a budget for the implementation of its decisions, it is removed from resource allocation and implementation, which take place at local level (Williams, 2013). Thus, it has been argued that NICE contributes to the de-politicization of a controversial mandate – the explicit rationing of health care - at central level, while *de facto* prioritization and the management of scarce resources is delegated to the local level, and thus more implicit (Landwehr and Böhm, 2011; Williams, 2013; Hammond et al., 2019). These local commissioning organisations have experienced a series of repeated restructuring reforms in recent years, but local priority-setting has been retained; at the same time, NICE's mandate and size have gradually expanded since its creation (Boyle, 2011; Bevan *et al.*, 2014; Checkland et al, 2018).

A final segment of the policy studies literature sees HTA organisations as an illustration of a wider trend of agencification, i.e., the proliferation of bodies that are at arm's length from their respective ministries and perform a public function (Pollitt *et al.*, 2001). This body of literature views politicians delegating decision-making to

government organisations – agencies - as a way of improving quality of their services, restoring trust to citizens and containing levels of expenditures. The most common argument given for agencification is that decentralising hierarchical structures of public bureaucracies will lead to increased performance, i.e. improved efficiency and better outcomes. Thatcher analyses the diffusion of HTA agencies across Europe, and compares their characteristics to the characteristics of agencies in other policy fields (Thatcher, 2010). He argues that HTA agencies have been promoted by governments for the same reasons as agencies in other public sectors.

An important characteristic of the phenomenon of agencification is that it transcends international boundaries. Moynihan (2006) reviews the literature on agencification and draws three important conclusions. First, there is evidence of policy convergence across countries towards delegating decision-making to agencies at arm's length to government. Second, national context has influenced the organisational structure of agencies considerably. Lastly, national contextual differences are supported by the ambiguity of the initial policy idea which allows governments to apply the same idea in different ways. The literature on 'agencification' thus highlights the difficulties in comparing agencies in different contexts, which follows from the difficulty of defining the nature of agencies (Pollitt *et al.*, 2001). For example, variation in public law in different countries can explain whether agencies have to fit into an overall legislative framework or the legislative framework is specified for each body. Comparison is also hindered by the fact that countries have developed divergent terminology for agencies, which is adapted to context – the 'arm's length' term used in the UK government being a good example. This makes it then difficult to capture nuances in translation. Even agencies that seem similar in terms of their legal status, often operate differently and interact differently with the institutions and actors of the political system in which they are embedded.

HTA has also been studied as a case of policy transfer. In particular, the model of NICE is seen as being particularly influential in informing emerging HTA organisations, including in other high-income countries. For example, Hassenteufel and colleagues (2017) show that NICE was an important inspiration for the early attempts to establish HTA in Germany. However, opposition from politicians

towards this model of HTA led to the development of a German-specific approach, which gives less priority to economic analysis. In contrast, the development of HTA organisation in France were less influenced originally by the English model, but evolved to be similar to NICE than to the HTA processes and bodies in Germany. The authors conclude that it is important to understand both the degree to which models of HTA were inspired by models from abroad, as well as to identify the limits of such transfer and their causes and explanations.

In sum, to understand how HTA organisations are established, it is necessary to clarify the policy goals or the policy problems which HTA organisations aims to address, the methods underpinning HTA, the procedures of conducting HTA and of using HTA to inform coverage decisions, and the role of the HTA organisation conducting or coordinating these processes.

Establishing HTA in middle-income countries

This section will discuss the existing literature on establishing HTA organisations in middle-income countries and consider its contribution to our understanding of the role of HTA in policy-making, the methods of HTA, the processes developed and the organisations created to conduct HTA and inform coverage decisions. Taken together, these elements make up the path towards institutionalisation.

The role of HTA in policy-making: HTA and universal health coverage

In middle-income countries, health policy debates in recent years have been dominated by the concept of universal health coverage (UHC), which includes three distinct policy goals: expanding health coverage to wider segments of the population; improving financial risk protection; and expanding the types of health services people receive, while ensuring that basic services are covered (World Health Organization, 2010). To be able to achieve this aim, governments and public payers have to find a method to determine the coverage of health services that goes beyond existing approaches, such as developing and applying essential medicines lists. There is an increasing body of work that is dedicated to advising low- and middle-income countries moving towards UHC on how to determine the type of services covered by

publicly funded health systems and on the likely challenges of making coverage decisions (Chalkidou *et al.*, 2013; Voorhoeve *et al.*, 2017). Such advice often presents HTA as a tool for priority-setting, one that is useful to governments as 'a robust process and evidence in order to ensure that the health benefits package [i.e. coverage] decisions are systematic, transparent and acceptable to all stakeholders' (Teerawattananon and Luz, 2016, p. 1). The term priority-setting is used widely in relation to countries' move towards universal health coverage (Teerawattananon *et al.*, 2016)

Such advice on how to make coverage decisions, in the context of advocacy for UHC, is often produced by international organisations such as the WHO (World Health Organisation, 2014). In particular, the WHO convened a consultative group on equity and UHC, in which key actors debated approaches to ensuring distributional fairness when moving towards UHC. In 2014, the Consultative Group published the report 'Making Fair Choices on the Path to Universal Health Coverage'. The premise of the report is that priority-setting, i.e., having a mechanism to determine which service are funded and which are not funded, is unavoidable on the road towards UHC. The report also posits that, in practice, moving towards UHC often happens in ways that are unfair and involves unacceptable trade-offs (Norheim, 2015). It then proposes a framework for 'making critical choices about expanding service coverage, including more people, and shifting to prepayment and pooling of funds' (Voorhoeve *et al.*, 2016, p. 13). The Consultative Group propose a three steps strategy for moving towards UHC. First, it proposes to categorise existing services as high, medium and low priority according to their cost-effectiveness, the likelihood they affect the worse-off and financial risk protection. Second, it recommends expanding coverage to high-priority services first and covering these in full. Third, it advises countries to weigh the effects of any policy on the worse-off (World Health Organisation, 2014).

Other commentators look more closely at specific decisions that governments need to take as part of the three steps outlined above. For example, Smith and Chalkidou (2017) argue that policy options for the expansion of coverage and for reducing catastrophic health expenditures are limited in number, unlikely to vary much across

jurisdictions, and relatively uncontroversial among experts. In contrast, prioritising among services to cover would raise specific problems depending on governments' policy goals and are often contested. Based on this rationale, a large part of the focus of the advice given to middle-income countries includes developing or adapting specific priority-setting tools, such as guides on how to establish an essential benefit package (Glassman *et al.*, 2016).

Other authors, however, have emphasised the enduring tensions between approaches to priority-setting and the right to health. In particular, commentators have questioned whether considerations of cost-effectiveness of services and their affordability to public payers used to define health benefits packages compromises the right to health (Ooms *et al.*, 2014; Forman *et al.*, 2016). In response, Rumbold and colleagues (2017) have argued that countries can pursue policies aiming to reach both goals without these policies undermining each other, if certain conditions are met. The first condition is that the right to health should be understood as requiring progressive realisation and depends on resource availability. The second condition is that decisions on coverage of health services should be made in a manner that does not exclusively use principles of utilitarian maximisation of population health, to the detriment of other ethical principles, such as meeting the needs of individuals or ensuring equal access to healthcare. In order for these conditions to be met, the authors advise countries moving towards UHC to clarify the ethical principles that should guide their coverage decisions, to institutionalise deliberative processes that apply these principles and to revise health budgets in ways that can reasonably ensure the realisation of the right to health. Rumbold and colleagues (2017) also propose several options for 'institutionalisation' of processes of priority-setting. One option is to establish organisations to assess single interventions, a role that is reminiscent of HTA agencies in high-income countries. Other options are to establish processes to debate the best allocation of health budgets more generally, by identifying all types of services that should be covered if services are expanded and/or by deliberating on the criteria that should be used to inform priority-setting between available health services.

In sum, middle-income countries are, perhaps paradoxically, confronted with more criteria for decision-making, more sophisticated tools for decision-making and a more comprehensive menu of available policy solutions. These tools build on the experience of high-income countries. The social values that guide priority-setting in healthcare have been given a great importance, in particular with regards to UHC. As explained earlier, however, there is no consensus on which ethical criteria should primarily guide coverage decisions. As a result, these tools can arguably inform a transparent, participative, evidence-informed – thus procedurally fair – process, but do not replace the need for creating consensus in-country. Further, rights-based approaches appear more frequently among commentators of middle-income countries' road to UHC compared to scholarly debates on high-income countries' coverage policies, where theories of distributive justice have been at the forefront.

Scientific methods used for HTA in middle-income countries

The need to generate appropriate research evidence and the need for resources to support HTA processes is an important concern for middle-income countries wanting to establish HTA. As outlined previously, this research evidence includes epidemiological studies on burden of disease, efficacy and effectiveness studies of health services, as well as routine data to monitor, for example, utilisation rates of specific services, the quality of these services or their costs (Gutierrez *et al.*, 2015). In particular, the production of economic evaluation and other types of research is expected to be lower in countries with more restricted budgets (Vassall *et al.*, 2016), in part because there are fewer people trained in health economics at postgraduate level and therefore less capacity to conduct research. It has also been observed that smaller countries can struggle to afford and staff such research activities irrespective of income level (Pitt, Goodman and Hanson, 2016).

Furthermore, many middle-income countries do not have strong health information systems, which means that data on burden of disease and health sector data are unlikely to be available or of insufficient quality. In principle, the absence of such data could be overcome through mathematical modelling and extrapolations from

similar settings; however, this again requires expertise and funding. Information on effectiveness and burden of disease can sometimes be inferred from studies carried out in high income countries. Alternatively, global estimates can be used if available. However, data that are known to play an important role in estimates of incremental cost-effectiveness ratios (costs of both alternatives, effectiveness of comparator) are often imprecise – particularly if they based on global rather than national studies – and introduce substantial uncertainty (Walker *et al.*, 2010). Therefore, there are limits to using extrapolations based on global data in HTA processes.

Despite the challenges outlined above, middle-income countries are advised to make use of the data and research that is already available in order to inform coverage decisions that would be otherwise made implicitly. One example is the global effort to estimate the burden of disease, which is taken as a starting point for priority-setting in many middle-income countries. Other examples are the Disease Control Priorities project, now in its third edition (Jamison *et al.*, 2018), which identifies interventions for priority conditions, and the WHO-CHOICE project, which aims to support the use of cost-effectiveness by low and middle-income countries (World Health Organisation, 2019).

These global studies used often use a single measure valuing health states known as disability-adjusted life-years (DALYs). DALYs are readily available and easier to use in low- and middle-income countries because they are used in global estimates of disease and thus do not require researchers to conduct surveys to elicit preference valuation of health outcomes (used to develop QALYs). International donors will favour the application of DALYs, while most guidelines in high-income countries suggest the utilisation of QALYs. Consequently, some health economics journals have different methodological requirements for economic evaluations from low- and middle-income countries, on one side, and high-income countries, on the other. International and regional collaborations seem to provide an answer to this problem as well as to the issues of health economics capacity, potentially supporting development of methods and theory around transferability of economic evaluations (Pitt, Goodman and Hanson, 2016).

In sum, burden of disease studies have become particularly relevant for informing priority-setting at national and international level (the latter, for countries which receive development assistance). However, using Global Burden of Disease estimates that use DALYs are contested for reasons similar to QALY contestation. One aspect of the contestation refers to the validity of the tool. A second aspect refers to the ethical principles that underlie it. For example, by not accounting separately for severity of disease, DALY-based burden of disease can give a higher importance to diseases with high prevalence and low severity (Voigt and King, 2017). Further, Voigt and King (2017) also criticise the argument that budget allocation, be it by governments or international donors, should use burden of disease as a primary criterion for prioritising spending.

Finally, as was the case in high-income countries, applying the criterion of value for money requires establishing a cost-effectiveness threshold. A widespread practice is for studies to quote a threshold range of 1 to 3 times the country's Gross Domestic Product (GDP) per capita. This range was first applied to low- and middle-income countries by the WHO-CHOICE project to support the use of cost-effectiveness analysis with the aim to inform resource allocation in low-and middle-income countries (Thokala *et al.*, 2018). However, analyses of the appropriateness of this threshold shows that the proposed range is likely to be too high to be affordable for many countries. Empirically derived cost-effectiveness thresholds based on available budgets (via supply-side methods) have indeed been shown to be at the low end of this range (Woods *et al.*, 2016; Robinson *et al.*, 2017). In contrast, cost-effectiveness thresholds derived by estimating willingness-to-pay tend to result in estimates that are the higher end of the 1-3 times GDP per capita. In this context, value for money considerations could easily conflict with affordability concerns. As explained previously, policy-makers in high-income countries often do not tackle the challenge of affordability explicitly as part of coverage decisions, or they do so only for specific decisions (Cairns, 2016). In sum, despite an increasing evidence base for *how to* establish cost-effectiveness thresholds empirically, balancing value-for-money and affordability in the context of defining a basic benefit package, as advised for middle-income countries, is a difficult political undertaking that is not routinely attempted by high-income countries as part of HTA processes.

Processes for priority-setting

The literature on HTA processes in middle-income countries distinguishes itself by debates on whether the existing principles usually associated with HTA in high-income countries will suffice in debates over priority-setting in middle-income countries. For example, Daniels and colleagues (2015) confirm the usefulness of HTA for countries at all income levels, but worry about HTA being limited in the criteria that it applies (safety, efficacy, cost-effectiveness). They suggest that expanding its remit to include criteria such as budget impact, equity and financial risk protection might be too broad for this single tool (Daniels, Porteny and Urritia, 2015). In a response, Culyer (2016) argues that much of the criticism directed at HTA is based on the methods that it uses but that critics ignore the deliberative aspects of HTA. He further argues that HTA should not be replaced by its methods and that the ethical principles already underpinning HTA should be recognised, as well as its capacity to adapt to the objectives of the policy, as defined by policy-makers.

Other commentators have argued that multi-criteria decision analysis (MCDA) is a better fit for middle-income countries, as an addition to HTA or as a replacement to it (Youngkong, Tromp and Chitama, 2011; Castro, Moreno-Mattar and Rivillas, 2018). MCDA is a tool that was developed for use in low- and middle-income countries by Baltussen and Niessen (2006). MCDA is a response to the fact that the existing tools that aim to integrate evidence in coverage decisions, such as HTA, only focus on single criteria. In practice, policy-makers have to consider a variety of criteria when making decisions, which may include scientific evidence, as well as equity considerations or political aspects. MCDA aims to incorporate a larger number of criteria into a single process, which is in line with HTA processes in high-income countries as well.

HTA organisations & the overall process of institutionalisation in middle-income countries

Middle-income countries have been advised to 'institutionalise HTA', including by establishing bodies charged with HTA at government level (Glassman and

Chalkidou, 2012). Analyses of how lower resource settings should institutionalise HTA offer roadmaps based on policy learning from high-income countries. These roadmaps take into account configurations of the elements of HTA - policy problem, method, process and organisations- as they have developed in high-income countries (Chootipongchaivat *et al.*, 2016; Kaló *et al.*, 2016; Wild, Stricka and Patera, 2017). As explained previously, however, the question of how high-income countries institutionalised HTA and what explains specific configurations of HTA elements is only now being explored (e.g., Torbica, Tarricone and Drummond, 2018).

With regards to establishing HTA organisations in middle-income countries, some authors suggest an evolutionary process of HTA organisations, from HTA committees for appraisal processes to a 'public HTA organisation' or agency (Kaló *et al.*, 2016). However, as noted by social scientists who study the phenomenon of 'agencification,' the term 'agency' lacks analytical clarity. Moynihan (2006) argues that two public organisations in two different countries referred to as agencies can be different in form and process if they are governed by a different set of rules.

For this reason, this study will analyse organisations and HTA processes separately. The existing literature often treats the two together, which makes drawing out the specific institutional characteristics difficult. This gap in knowledge might explain why the existing literature has not reached a conclusion with regards to the question of the degree to which bureaucratic traditions influence HTA development (Landwehr and Böhm, 2014; Löblová *et al.*, 2019).

In sum, the establishment of HTA organisations is the most obvious sign of institutionalisation and is seen as a desirable step that would ensure a degree of rationality to coverage decisions. However, establishing organisations, or HTA agencies, is not the full extent of institutionalisation. This thesis will explore the question of institutionalisation of HTA, which includes the goals of policy-making (i.e., the role of HTA in policy-making) and these goals' underlying principles; the methods used in HTA processes, as well as the organisational structures that coordinate these processes.

The following chapter will outline the aims and objective of this thesis, as well as the theoretical approach and methods utilised to achieve them.

3. Aims, concepts and methods

Aims and objectives

This thesis aims to understand how HTA was established in two middle-income countries, Thailand and the Philippines. To understand how HTA was established, this thesis will analyse comparatively the methods applied for HTA, the principles underpinning the selection of methods, the approach to using HTA evidence to make coverage decisions for publicly funded health services, and the types of organisations that were created by the two governments to commission or conduct HTA. However, none of these elements by themselves explain how HTA becomes institutionalised. Understanding *what* decisions are made with regards to the elements of HTA will not explain institutionalisation in the absence of an account of *how and why* such decisions are made. Specifically, one might ask about ideas that have shaped governments' interest in HTA, the actors promoting, or opposed to, HTA being used, and whose interests are reflected in its application; and how existing structures of health system governance have influenced how HTA organisations were established and how they function. This thesis therefore considers the creation of HTA as a process of policy change, which will be analysed through three analytical lenses: ideas, interests and institutions.

This understanding of HTA institutionalisation applies equally to middle- and high-income settings. However, the analysis of this process in middle-income countries has a number of additional dimensions. First, while high-income countries also experience constraints to their health budgets, government budgets for health in middle-income countries are usually even tighter. Second, the interest in establishing a mechanism of HTA to inform decisions coincides with, or is embedded in, efforts to move towards UHC. As a result, countries are likely to define the policy problems to which HTA responds in different ways. For example, a single reimbursement decision will pose a different decision-making problem than defining an essential benefit package in its entirety. Third, most methods used in HTA have been developed in high-income countries, which has implications if these methods are

then being applied to address challenges that are different from those that they were developed to address. It is therefore important to appreciate the context of the development of HTA organisations, processes and methods in middle-income countries.

Aiming to understand how HTA was established in Thailand and the Philippines as a process of policy change, this thesis has the following specific objectives:

- To examine how actors conceptualised the policy problem that HTA was aimed to solve and whether existing institutions influenced the definition of the policy problem;
- To investigate the role of existing institutions in shaping the options for establishing an HTA organisation, as well as actor strategies used for organisational establishment;
- To explain how choices with regards to HTA processes were made, and how actors and existing institutions influenced these choices;
- To compare and contrast the influence of ideas, interests and institutions on the development of HTA in both countries, and to derive insights into the opportunities and challenges associated with developing HTA in middle-income countries.

Conceptual framework

Scholars of policy studies have proposed a series of variables to explain the drivers of policy change. The starting point is that individuals drive social action, but that there are constraints to their behaviours stemming from external factors. However, there is enormous variation in how scholars explain which of these variables is the primary driver of policy change. Depending on the school of thought, the individual actor, the social groups to which they pertain or the sources of constraints on individuals' behaviour are proposed as the primary explanatory variables of policy change. Scholars who propose one of these factors as the primary variable have developed theories trying to explain the mechanisms by which policy change occurs. These theories often include an account of the interaction between one primary driver of policy change and all or some of the other elements.

Actors' interests – whose interests are reflected in HTA institutionalisation?

Scholars who propose individual actors as the primary drivers of policy change tend to conceptualise them as rational actors with clear preferences for a given policy based on self-interest. Actors form coalitions based on shared interests and use their resources to exercise power in order to change policy accordingly (John, 2013c). Interests have traditionally been defined as material interests, often stemming from socio-economic positions of actors (e.g. as representatives of an industry or of the workforce) (Hall, 1996). This traditional view stems from the assumption that policy actors are individuals who aim to attain maximum benefit, given their specific preference (that can be exogenously defined), and that this benefit is achieved by strategically weighing all possible courses of actions (Hall and Taylor, 1996). While many policy scholars have relaxed these assumptions, the fact that actors' policy preferences are determined by interests (whether perceived or independently determined) remains relevant for the study of policy change (Hall and Taylor, 1996; Béland, 2010).

In the case of HTA, accounts of actors' interests as drivers of political behaviour are important because the use of HTA to make coverage decisions has frequently generated opposition from certain categories of actors. These actors' policy preferences have often been in line with interests that are relatively straightforward to identify (Banta, 2003; Hauck and Smith, 2015). Relevant actors include policy-makers (civil servants and politicians); manufacturers of technologies such as pharmaceuticals or medical devices (who have an interest to sell their products to the most people, at the highest price); physicians (whose clinical practice is likely to be influenced by HTA decision-making, which in some cases might also influence provider revenues) (Mills and Hsu, 2014); patients (who might oppose HTA when it leads to negative coverage decisions which limit the types of health services they receive); civil society advocates (who advocate on behalf of specific categories of patients and might disagree with coverage decisions that affect these groups); and the general public (who receives information on coverage decisions based on HTA processes through mass and social media and might react negatively to the idea that access to health care is being limited). Furthermore, while often ignored, researchers such as health economists or clinical epidemiologists are likely to have an interest in producing – and being compensated for - the evidence that is to be used in HTA processes (Banta, 2003).

The interests of policy-makers have been the topic of extensive study (John, 2013c; Flinders and Wood, 2014). With regards to HTA, it is often assumed that policy-makers might be particularly responsive to value for money or cost-containment considerations (Banta, 2003). They may also avoid unpopular coverage decisions based on strategic considerations about electoral support or a desire to maintain power and access to resources (Hauck and Smith, 2015). In addition, policy studies scholars have extensively explored the question of why policy-makers are willing to delegate, and therefore relinquish, decision-making power to independent expert bodies, or agencies. The proliferation of expert bodies has been described as 'agencification' (Pollitt *et al.*, 2001). One explanation comes from the literature of depoliticization (Wood and Flinders, 2014), which suggests that the benefits of relinquishing responsibility for unpopular decisions comes with political gains by avoiding blame, among other reasons. However, there are important accounts of

agencification which argue that interests cannot satisfactorily explain the increase in the number of these government organisations. Instead, these accounts focus on the changing nature of government and on the importance of ideas of expertise, efficiency or regulation (e.g., Majone, 1998; Hoppe, 2009).

Interest-based explanations can explain specific policy preferences, but there are limits to their explanatory power. As discussed in the previous chapter, establishing HTA is likely to be the result of a sequence of decisions made at different points in time. The policy preferences of individuals involved in these decisions will likely be impossible to disentangle at each stage. In addition, it seems likely that some policy preferences will be caused by reasons other than self-interest (John, 2013c). For example, some actors such as patients' groups or physicians might argue that coverage decisions based solely on cost-effectiveness are discriminatory. These actors will have identifiable interests, but might equally have a deeply held belief that care should not be denied in any circumstances. As shown in the previous chapter, tensions between different principles will not be resolved by more evidence because these disagreements stem from different ethical positions on what principles should guide coverage decisions.

A perhaps more informative approach to understanding how actors influence policy-making comes from studies of policy networks (Rhodes and Marsh, 1992; Shearer *et al.*, 2016). Scholars adopting this approach have shown that policy networks are particularly influential when advocating for, as well as resisting, policy change. These patterns of influence are particularly visible in specific policy fields, such as health policy.

Rhodes and Marsh (1992) suggested that types of policy network can be identified based on the nature of relationships between its members and developed a typology of policy networks placed on a continuum from 'policy community' to 'issue network' (Rhodes and Marsh, 1992). While there is increasingly sophisticated work on the role of policy networks in policy change, including some application to health policy in low and middle-income countries (Jessani, Boulay and Bennett, 2016; Foli, Béland and Fenwick, 2018), policy networks seem to be mediating rather than

primary factors in policy change (Shearer *et al.*, 2016). As suggested by Shearer and colleagues, policy networks can 'help visualise how interests, embedded in nodes, are structured in the policy process and how network structure changed as actors form and dissolve relationships' (Shearer *et al.*, 2016, p. 1202).

In sum, considering the interests of policy actors when exploring HTA institutionalisation is necessary, but not sufficient. It is important to clarify who are the actors that have an interest in the establishment of HTA (and whether that results in a position of advocacy, opposition or neutrality). Further, identifying policy networks will be relevant for this analysis, because when present, they structure the way actors express interests during the process of policy change.

However, other reasons exist to support or oppose HTA beyond actors' interests and the manner in which policy networks structure these interests. First, actors will have deeply held beliefs about policy improvement and the actions that they think will produce this outcome. Second, interest-based accounts do not seem to cover the complexity resulting from the fact that the actions of policy actors are not only determined by their interests, but also by the rules that shape how government operates. How governments go about establishing HTA remains unclear. The fact that policy-makers might benefit from delegating tough decisions and avoiding blame that might engender loss of power is relevant, but what guides the specific limits put on HTA decision-making? Why are some HTA bodies more independent than others? What guides the specific placement of HTA bodies within heath system governance? These questions will be explored in the following sections, focusing on accounts that centre ideas and institutions, respectively, as primary explanatory variables for policy change.

Ideas – what is being institutionalised?

Policy change is often seen as an attempt to improve policy and policy outcomes. To argue for improvement, actors have to express what problems they are trying to solve and what they propose as a solution to the problem. Actors will also develop causal accounts of the origins of the problem, and how it can be solved (John, 2013a). In

policy studies, these accounts are collectively referred to as ideas. Importantly, whereas policy problems are at times treated as independent from the policy process, or externally determined, policy scholars such as Bacchi and Goodwin (2016) suggest that causal accounts of problems and their solution reflect deeply held beliefs about how the world works, the values at the core of individual and collective action. These ideas are selectively used when representing the problem (Bacchi and Goodwin, 2016).

Scholars have argued that advocacy for specific ideas, which is often undertaken by policy networks, can explain policy change. For example, Haas (1992) has developed the concept of epistemic communities to refer to groups of professionals, often within multi-disciplinary networks, that produce policy-relevant knowledge about complex policy problems. Members of these epistemic communities share normative beliefs, beliefs about causality and scientific knowledge, as well as a set of practices proposed for policy improvement (Haas, 1992). Epistemic communities are particularly relevant for ideas that cross borders and are adapted in different contexts. Thus, ideas (and not only interests) can be the reason why certain types of coalitions are formed. Further, policy networks have been shown to influence the adoption of specific health policy solutions in the health sector of low-and middle-income countries (Shearer *et al.*, 2016; Béland, Howlett and Mukherjee, 2018), including as part of global health initiatives (Hanefeld and Walt, 2015).

Studies of policy transfer have explored how actors from different policy sectors engage in policy learning (Dolowitz and Marsh, 2000). Such work has discussed how and why policy transfer happens, and the key role of policy networks in this process. However, questions about the extent of policy transfer remain, as policy rarely stays in the same shape as transferred, and is likely to evolve once in place (Benson and Jordan, 2011). It is sometimes expected that policy transfer will lead to convergence between countries. However, such findings tend to reflect developments at a certain point in time and the selective interpretation of the analyst. Radaelli (2005) noted that the limits of convergence are still insufficiently explored.

Some scholars have argued that, as cognitive processes, ideas are not externally determined but have a life of their own. This means that debate and advocacy are variables that determine policy change independently (e.g., Majone, 1998). Such a perspective has a bearing on empirical research, because empirical findings are based on a set of ideas about what is and how what is can be known. If these are challenged, such accounts necessarily step into the realm of philosophy (John, 2013a). Taken to its logical conclusion, this view suggests that rational judgements about causality, efficacy – which are at the basis of scientific evidence - are merely part of the discourse that constitutes political life. However, for the purpose of this study, ideas are conceptually useful if a narrower operationalisation is used.

We operationalise ideas as actors' ability to formulate policy problems, find policy solutions and act within policy paradigms, as proposed by Smith (2013). Specifically, policy actors identify problems to which they believe HTA is able to provide a solution. This operationalisation of ideas allows to identify causal and normative beliefs underpinning the policy solution (in this case, HTA), to do the same for policy problems to which the solution responds, and to identify whether either the problem or the solution can be linked to ideological and moral claims expressed by actors involved in establishing HTA in their country. For example, economic evaluation that may be used as part of HTA methods is underpinned by a social ethics of maximising population health. When they inform decision-making, economic evaluation findings are likely to have to be balanced against the individual ethics of non-discrimination or meeting the needs of individuals. The manner in which such trade-offs are done as part of HTA processes is often based on procedural ethics, which some argue can ensure fair decision-making and increase legitimacy of HTA. Further, it is particularly important to understand how the policy problem came about and what kind of assumptions are made about its origins, as well as the kind of facets of the problem that are given less representation (Bacchi and Goodwin, 2016). For example, if HTA emerges as part of a country's attempts to establish UHC, the specific problem to which HTA responds will emerge as part of a political process of selecting certain policy problems over others and framing these problems in politically favourable ways (Fox and Reich, 2015).

There is therefore conceptual overlap between interests and ideas. Actors will express policy preferences and argue for the usefulness of the solution by expressing ideas. Thus, the study of interests is equally relevant for the identification of ideas. The two variables often have a symbiotic relationship which has proven difficult to unravel (John, 2013a). An important distinction can be made between ideas that are used to forward actors' interests and ideas that are based on core normative beliefs, which highlights the role of ideas, independently from interests. As an explanatory variable, ideas are particularly useful to investigate how policy agendas are set and why actors advocate for certain policy solutions, such as HTA.

As was the case with interests, a focus on ideas is not sufficient to explain how HTA becomes established, even if this perspective is combined with an analysis of interests. In particular, the concept of ideas is not as useful in explaining the limits to policy implementation and the directions in which HTA developed over time in different country settings. To understand how HTA becomes embedded in a system requires an additional layer of analysis, to explain why and how the same idea of HTA has resulted in different choices for organisations, processes and methods in different jurisdictions.

Institutions – how does HTA get institutionalised?

Institutions are defined as the 'formal and informal procedures, routines, norms and conventions embedded in the organizational structure of the polity or political economy' (Hall and Taylor, 1996, p. 96). Political systems operate by these rules and procedures which are most often expressed in the operation of formal organisations. Institutionalists study how these rules and procedures determine how policy-making happens. Historical institutionalists in particular are interested in understanding how past ideas and decisions structure current policy-making. This often involves creating and formalising the system of rules in constitutions, organisations and procedures.

Other, less formalised rules create political norms that also influence how policy decisions are being made and which actors are involved in the process (Tuohy, 1999; Tsebelis, 2000; Béland, 2010). New institutionalists have different propositions for the manner in which institutions influence policy change. For example, some institutionalists have suggested that institutions influence individuals' behaviour by shaping 'values, norms, identities and beliefs' (March and Olsen, 1984) or 'identities, resources, values, norms, and rules' (March and Olsen, 1998). As such, institutions would also include belief systems and habits of decision-making through which new policies are filtered and interpreted. This 'logic of appropriateness', coined by March and Olsen (March and Olsen, 1998), encourages certain patterns of behaviours and discourage others. Institutions influence how ideas are taken up and affect the ability of actors to access and influence policy-making (John, 2013b). In other words, actors internalise ideas embedded in institutions, and this is the mechanism through which institutions influence actors' behaviours.

There is agreement among institutionalists that institutions constrain the behaviours of policy actors. This study adopts this understanding and operationalises institutions as formal and informal rules and practices that actors identify as 'the way of doing things', as opposed to merely an individual's choice of behaviour, irrespective of the consistency of this behaviour. This operationalisation is informed by Hall and Taylor's concept of standards operating procedures (Hall and Taylor, 1996), which refers to specific rules of behaviours that are agreed upon and generally followed by individuals. When formal and informal rules of behaviour are broken, this is where actors' interests or ideas can be identified as more dominant in determining behaviour (Lowndes and Roberts, 2013b).

In the case of HTA, institutions are important in two ways. First, the concept of institutions helps analyse the process of institutionalisation as the establishment of rules and procedures that reflect the ideas associated with HTA (e.g. ideas about distributional justice, legitimate decision-making, and the choice of scientific methods and the principles underpinning them, such as value for money). Furthermore, using institutions as an analytical lens can explain why core concepts included in HTA manifest themselves in different institutional forms in the

jurisdiction in which they are applied. There are therefore different types of institutions that will be relevant for the study of HTA institutionalisation. First, this study is interested in analysing the institutions associated with HTA as a tool (e.g. rules and procedures established as part of HTA). Second, institutions such as the rules and procedures of Ministries of Health and health insurers are also expected to inform how actors conceptualise the policy problems. Distinguishing between the two can help separate between the ideas embedded in HTA as the solution to a policy problem and the ideas embedded in existing institutions in the context in which HTA is being established. Thus, institutions can help explain how a country's institutional context influences the creation of HTA organisations and processes - and thus the institutionalisation of HTA.

The 3Is – ideas, interests and institutions

Figure 3.1 outlines the operationalisation of ideas, interests and institutions and their associations with each of the specific objectives of this study: explain how HTA emerged on the policy agenda, how organisations and processes were developed and how the organisations and processes operate in practice.

The conceptual framework outlines how the three core concepts were operationalised for the specific objectives of this research. With regards to ideas, the analysis will identify the manner in which policy problems associated with HTA are defined, as well as the exact characteristics of HTA as the policy solution proposed or put in place. Institutions are operationalised in three ways: a) existing institutions that might be relevant for the definition of the policy problem, specifically who the decision-makers are and what standard procedures they follow; b) the existing decision-makers or procedures that influence strategies and options for the establishment of organisations; and c) existing decision-makers and procedures that are developed as part of HTA establishment. Interests are operationalised as advocates and reactive actors to HTA, as well as the strategies through which these actors purse their interests. It is expected that these concepts will interact with each other in relation to each of the specific objectives of this study. For example, institutions and interests will be useful in defining policy problems by analysing

which actors put the problem on the agenda and had an interest in the manner the problem was defined, as well as indicating the decision-makers or the procedures employed to make decisions regarding the specific problem.

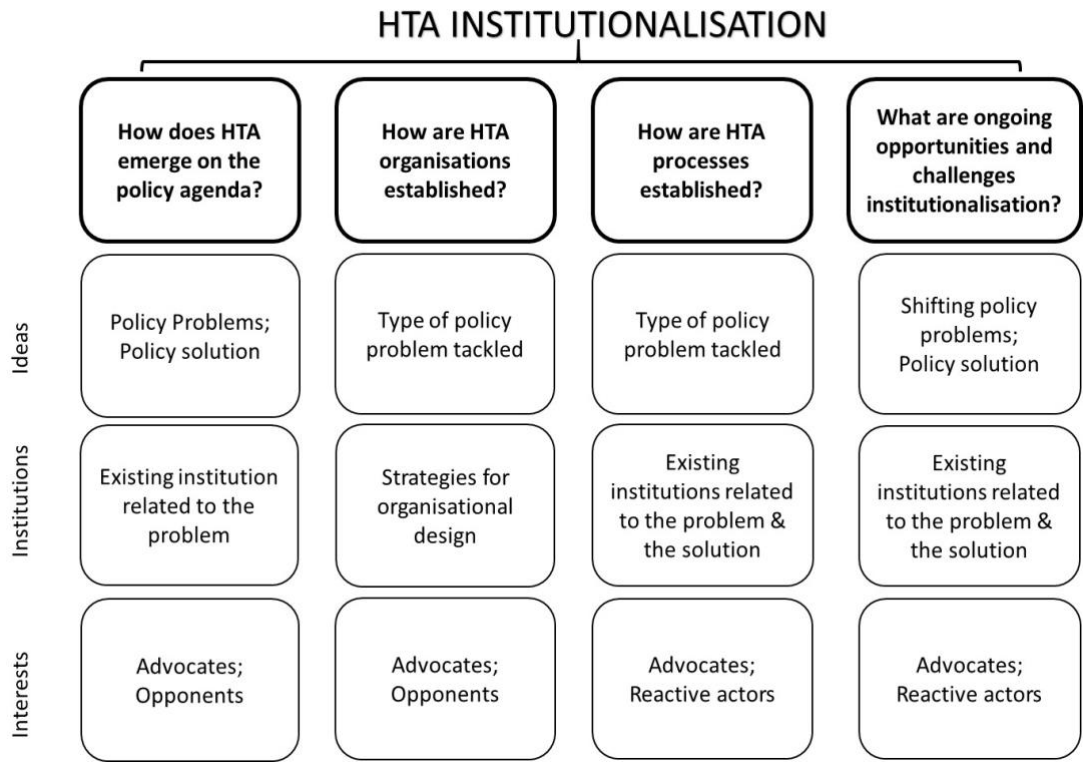

Figure 3.1. Institutionalisation of HTA: conceptual framework. Source: own figure.

The following sections explore how this conceptual framework informed and guided the study design and the methods used for data collection and analysis.

Methods

This study uses a comparative case study design to understand the process of establishing HTA in two middle-income countries, Thailand and the Philippines. Case studies are particularly suited for the 'comprehensive, holistic, and in-depth investigation of a complex issue (phenomena, event, situation, organization, program individual or group) in context, where the boundary between the context and issue is unclear and contains many variables' (Harrison *et al.*, 2017). It is for this reason that case studies are well suited to analyse the establishment of HTA, which is a complex

process of policy-making that is emergent, situational and changing over time. However, case studies are defined differently depending on the epistemological position of the researcher, with some authors disputing case studies as a study design entirely, and instead seeing case study analysis either as a method or a phenomenon to be studied (Creswell *et al.*, 2007). Harrison et al. (2017) argue that the first step in identifying the appropriate approach to case study analysis should be clarifying the researchers' epistemological position, as well as the nature of the phenomenon and the research questions that the research aims to answer.

This study takes a pragmatic constructivist view, as proposed by Merriam (2010). This perspective sees reality as being constructed intersubjectively, as a result of experiences and understandings that are social, but posits that this results in a shared reality that can be studied. The pragmatic constructivist approach suggests that the selection of cases should reflect their potential to illustrate the phenomenon of interest effectively. For this study, case selection was done with a view of expanding our understanding of the process of institutionalising HTA, defined as embedding HTA in health system governance, in middle-income counties. Two country cases, the Philippines and Thailand, were identified on the basis that they began using HTA relatively early compared to other middle-income countries. This study examines the development of HTA in both countries over a period of approximately 20 years, from the early 1990s - when researchers and policy-makers first became interested in HTA - to 2016, the year in which the interviews were conducted. The appropriate duration to effectively study a policy cycle was first proposed by Sabatier (1988) as a time span of a decade or more, and was subsequently confirmed by empirical research (Weible *et al.,* 2012).

The comparative design allows a detailed examination of the complex drivers of HTA establishment and how the factors identified as relevant play out in different settings. Both countries are middle-income countries, as defined by the World Bank, that have a long history of engaging with the idea of HTA. Policy actors in Thailand discussed a proposal for HTA in as early as 1997, whereas in the Philippines, the legal mandate for HTA dates back to 1995. In addition, both countries were exposed to similar sources of policy transfer of the idea from abroad.

However, case selection was also informed by the differences between the two countries. The first set of differences was about the outcomes of attempts to establish HTA. Thailand is widely seen as a success story for HTA in Southeast Asia and beyond (Culyer, Podhisita and Santatiwongchai, 2016). In contrast, as of 2016, efforts to establish HTA in the Philippines were perceived as not having achieved a comparable level of success with no HTA organisation established.

The two countries also differ with regards their economic development, political systems and cultures. At the time when HTA emerged, both countries were classified by the World Bank in the lower middle-income group (using 1995 as a reference point). However, Thailand's economic development progressed faster than the Philippines'. In 2016, Thailand had been re-classified as upper middle-income, whereas the Philippines continued to be classified as a lower middle-income country. In terms of political systems, Thailand is a constitutional monarchy, with a parliamentary system. Between 2014 and 2019, Thailand was ruled by a military-appointed National Council for Peace and Order (NCPO) which also nominated the Prime Minister. The NCPO replaced the role of the Cabinet, which had previously been appointed by an elected Prime Minister. A National Assembly was also appointed by the military after the elected Parliament was dissolved in 2014. The Philippines, in contrast, has a presidential system of government, in which the President is elected every six years as the head of the executive branch, while the bicameral legislature - the Senate and the House of Representatives - are elected separately every three years. The two countries are also different with regards to their cultures, as well as the manner in which they were affected by European colonial powers. The Philippines was a Spanish colony between the 16th to19th century, followed by becoming a colony of the USA, before achieving independence in 1946. The colonial influence can be seen in the dominance of the Catholic religion in the country, as well as its system of government reminiscent of the political system in the USA. In contrast, Thailand was the only Southeast Asian country that has never been colonised by a European power and has always remained an independent kingdom. The Buddhist religion is an important part of Thai identity, as is reverence for the monarchy.

The two countries have also developed different health system structures with different approaches to health system governance. In Thailand, three public health insurance schemes (two tax-based and one social health insurance scheme) account for the majority of health care expenditure in the country, with private health insurance and out-of-pocket expenditure contributing 4.7% and 11.6% of total health expenditures (2012 figures), respectively (Table 3.1) (Tangcharoensathien, 2015). In the Philippines, out-of-pocket spending is significantly higher (55.8% of total health expenditure in 2014), as is private health insurance (8.6% of total health expenditure in 2014). Social health insurance accounts for 14.2% of total health expenditure (in 2104 figures), while other government spending reached 17.4% of total health expenditure (Dayrit *et al.*, 2018). In Thailand, more that 80% of health facilities are owned by the government, of which 70% are under the administration of the Ministry of Public Health (MoPH) (Tangcharoensathien, 2015). By comparison, health facilities in the Philippines are approximately equally split between the public and private sector (Dayrit *et al.*, 2018).

Table 3.1. Key health system indicators. Source: Tangcharoensathien, 2015; Dayrit *et al.*, 2018.

	Thailand	**Philippines**
Government general expenditure (% out of total health expenditure)	68.4	17.4
Social Health Insurance (% out of total health expenditure)	7.3	14.2
Private insurance (% out of total heath expenditure)	4.7	8.6
Out-of-pocket payments (% out of total heath expenditure)	11.6	55.8
Other (e.g., employer benefits, development assistance; % out of total heath expenditure)	8	4

Governments of both countries have expressed as a policy goal achieving UHC; however, their progress towards this goal varies. Thailand is often mentioned as a

success story in moving towards UHC, having achieved near universal population coverage to services in 2002. Initially, the Universal Coverage Scheme (UCS) was designed to include a co-payment of 30 Bhat, which was removed in 2006, but re-instated on 2012. As a result, the UCS is also known by the name of the '30-baht scheme' (Thaiprayoon and Wibulpolprasert, 2017; Tangcharoensathien *et al.*, 2018). Some commentators have argued that the success of this Thai policy reform has contributed to the raising prominence of UHC as a policy aim and it becoming a global policy movement (Harris, 2015). In contrast, the Philippines have moved towards UHC more slowly. The country took a different approach compared to Thailand. Specifically, the Philippines used its social health insurance scheme, the National Health Insurance Program (NHIP), established in 1995, to gradually expand population coverage. In parallel, it gradually expanded services offered through this social health insurance programme (Obermann, Jowett and Kwon, 2018). By 2016, the Philippines government claimed that 92% of the population had access to publicly funded health services. However, more detailed analysis indicates that the level of out-of-pocket spending has continued to remain high, suggesting that the high population coverage masks a deficit in service coverage which may undermine the financial risk protection role of the NHIP (Dayrit *et al.*, 2018). However, UHC has remained an important part of the policy agenda (Obermann, Jowett and Kwon, 2018), and culminated in a UHC bill passed in 2018 and signed into law in 2019.

This study will compare the process of HTA institutionalisation in the Philippines and Thailand, two middle-income countries that were early adopters of HTA in their region, but that contrasted with regards to their progress of establishing HTA and the economic, political and cultural context in which HTA became established. The value of comparing the two countries is twofold. First, the comparison allows for an analysis of the factors that have influenced the establishment of HTA that derive from their differences in context. Second, processes of HTA establishment were selected based on having led to different outcomes, as opposed to selecting cases where HTA was considered successfully established. The rationale for doing so was that this would offer a richer understanding of what are the opportunities and challenges to institutionalising HTA.

Data collection methods

Data collection for this study was done through two methods: document review and key-informant interviews. Document review was used to gather background information on both countries' health systems and procedural knowledge on HTA. Interviews were used to identify how decisions that have led to the establishment of HTA organisations and processes were made.

Document review

In this study, documents were used extensively and for a variety of purposes. These were:

a) To collect background information about the health system of each country and the overall context in which interviewees' accounts should be understood;
b) To collect data describing the development of HTA and of the procedural aspects of HTA;
c) To identify supplementary questions to be explored in interviews;
d) To substantiate interview data.

Documents were identified at the stage of case study selection, through recommendations from advisors to this study, through being mentioned in key reports, as well as through Google Scholar searches. Other documents were recommended by interviewees. Unpublished documents, such as meeting minutes, were provided by interviewees and consent to use these documents was obtained. Reports or journal articles that provided background on the health system contexts were identified through Google searches, as well as by searching local databases, for example the HSRI Knowledge Library (Thailand) or Philippine Institute for Development Studies (PIDS) publications (the Philippines).

A variety of types of documents were identified and used to guide data collection and analysis. These included:

- Journal articles;
- Books;
- Research reports (e.g., published by independent organisations);
- PhD dissertations and master theses;
- Project reports (e.g., of research projects that were relevant for HTA development);
- Annual reports of key government organisations (e.g. payers);
- Administrative documents (e.g. administrative orders, meeting minutes, memoranda);
- Government websites/databases (e.g. FDA registration information);
- Legislation (passed or drafted).

A list of the documents that were used in data analysis is provided in Appendix 1.

For Thailand, documents identified were limited to those published in English. The language barrier was offset by the fact that there was extensive literature published in English, both about the overall health system context and about the development of HTA. These research articles and reports were used in lieu of official documents published in Thai, which were not accessible to the researcher. In the Philippines, all policy documents were available in English. As HTA in the Philippines has not yet been studied as frequently as in Thailand, there were fewer research articles available about the development of HTA in the Philippines.

Documents were scanned and those considered highly relevant were read in their totality. Those considered less or only partially relevant (e.g., legislation, wide ranging reports, PhD theses on broader health system topics) were searched for relevant passages using keyword searches. The authorship of the documents was noted, including individual authors and organisations, in order to understand the origins of the document and the context of its production. For example, policy documents were treated as a primary source of data that could be analysed in similar ways as interview data. In contrast, secondary sources such as published articles

about the establishment of HTA were more directive, and their analytical findings were considered in the context of alternative explanations emerging from this study.

Document were analysed in four steps. First, documents were used to compile an initial overview of the case study countries, particularly with regard to the description of the development of HTA, and how this was linked to other major policy developments, to provide background knowledge (e.g. step-wise descriptions of HTA processes in Thailand). This first overview informed the development of the topic guide for interviews and the conceptual framework.

Second, documents provided background information about individual interviewees, such as information about the research interests and expertise of researchers involved in HTA. Further, documents helped identify supplemental questions for specific interviewees. In addition, information from documents was used to allow the interviewer to focus on specific questions during interviews, instead of asking for information that could have been obtained elsewhere.

Third, information that explained specific points about why and how HTA was established was analysed alongside the interview data. Specifically, relevant passages in documents were coded and then assigned to the analytical themes used for the analysis of the interviews. However, most information collected from documents was descriptive and had to be supplemented by interview data as the information was not specific enough.

In a fourth step, documents were used to verify and contextualise interview data. Some specific information, such as dates, was checked in documents to minimise the risk of recall bias in interviews. In addition, documents were a rich source of information about specific episodes of policy-making that interviewees mentioned as relevant. A number of debates on specific pieces of legislation and important episodes in which coverage decisions were contested, had already been examined in the published literature, which was used in contextualising interview information.

Interviews

The second method of data collection consisted of used semi-structured interviews with policy actors involved in the process of establishing HTA in both countries. Interviews were used because of their usefulness in drawing out 'detail, depth and an insider's perspective' (Leech, 2002, p. 665), while also allowing for some degree of control and replicability of data collection, which is particularly useful in this type of comparative research.

HTA as a tool to inform coverage decisions typically involves actors in senior policy decisions, including at the highest level of government. This is mirrored by the seniority of business, academic and professional actors and representatives of civil society movements who have an interest in how health coverage decisions are made. Interviews for this study can therefore be regarded as 'elite' interviews, as most interviewees were in positions of seniority and elevated social status (Harvey, 2010).

The interviewees were identified based on their involvement in, and knowledge of, the development of HTA in Thailand and the Philippines. As the literature indicated, the main actor categories are broad and include policy-makers (such as politicians and civil servants), researchers (including in government or academia), physician professional groups, and civil society groups such as patient advocacy groups. A final relevant actor category included representatives of international organisations active in global health which had an influence on policy-making in each country, although this only relates to the Philippines. No representative of an international organisation was interviewed in Thailand, as international organisations were not seen as relevant at the time of the interviews. International organisations and experts had been relevant in earlier initiatives, but these actors were difficult to access at the time when the interviews for this study were conducted. Nonetheless, the most relevant actors for the establishment of HTA in Thailand were national actors. The number of actors interviewed in each category is listed in table 3.2.

Influenced by these considerations and the conceptual framework for this study, interviewees were selected primarily based on their involvement in and knowledge

about the decisions that led to HTA becoming embedded in both countries. Interviewees were selected based on two criteria: a) the overall categories or relevant actors, and b) participation in different stages of HTA establishment. However, the interviewees' position was also assessed to understand their likely status and normative power, which went beyond the power stemming from their knowledge and capacity to explain phenomena (Littig, 2009).

Table 3.2. Distribution of interviewees per actor category.

Actor category	**Thailand**	**Philippines**	**Total**
Policy-makers	5	4	9
Civil service	6	5	10
Academia	6	5	11
Pharmaceutical industry	3	3	6
Physicians	1	2	3
Civil society	2	2	4
International	0	1	1
Total	23	22	55

In both countries, there was a preponderance of policy-makers such as members of the civil service, which was due to the fact that these were the players that were most directly involved in advocating for and establishing HTA. However, a diversity of perspectives was sought, encompassing both proponents and opponents of HTA. During this process, conflicting perspectives were identified based on the likely interests of different categories of actors. For example, in Thailand, opposition to the universal coverage reforms from policy-makers or civil servants was often, although not always, a good indicator of opposition to HTA.

The interviewer's access to key actors in both countries was facilitated by the fact that one of the advisors for this research project was the director of the former international branch of NICE, the most prominent HTA agency in the UK. NICE International had existing collaborations with key actors involved in establishing HTA in both countries. As the international arm of NICE at the time, this

organisation offered technical advice to low- and middle-income countries attempting to establish HTA. Some of the same activities are now carried out independently from NICE, through the International Decisions Support Initiative (iDSI). These links allowed for a preliminary identification of two to three interviewees in each country and provided the interviewer with a point of contact during fieldwork. The interviewer spent three months in each country, February-April 2016 in Thailand, and April-July 2016 in the Philippines. During the time spent in Thailand, the researcher was hosted by HITAP, the Thai HTA organisation. This was helpful as it enabled informal conversations, and provided an opportunity to observe meetings and the day-to-day operation of the organisation. However, the interviewer was independent during this time and advice on interviewees was gratefully received and used, but it did not determine who was contacted for an interview or why. In contrast, while key contacts were available in the Philippines, the interviewer had no permanent base during the time spent in the country.

As indicated, access to interviewees was enabled by existing contacts, in the first instance. This initial introduction to potential interviewees was subsequently expanded both in terms of actor category covered and the perspectives on HTA that interviewees were able to contribute. Each interviewee was asked at the end of the interview to recommend other individuals for interview, which had a snowballing effect on identifying and recruiting additional interviewees.

Most interviewees were contacted via email, which included an information sheet and a consent form (see details on obtaining informed consent in the section on ethical considerations). In some cases, the interviewees were approached via personal introductions by contacts in the country. Some interviewees asked to see the list of questions before agreeing to the interviews, in particular pharmaceutical industry representatives, who in some cases reviewed the questions with help with their legal departments. Three interviewees declined to be interviewed in Thailand, and one in the Philippines. They were representatives of groups who likely had their interests affected by the use of HTA to inform coverage decisions. In Thailand, convincing physicians to participate in an interview proved to be difficult, and only one interview with a physician was conducted. In the Philippines, the representative

of a pharmaceutical company refused to be interviewed. However, it was possible to carry out three interviews with industry representatives in each country.

In total, 55 interviews were conducted, of which 22 were carried out in the Philippines, and 23 in Thailand. Interviews lasted between 35 and 140 minutes, with 75 minutes being the average duration. This resulted in 56 hours of interviews in total, which were professionally transcribed.

Conducting interviews

A topic guide was developed based on the literature reviewed for this study and the conceptual perspectives chosen for analysis, focusing on ideas, interests and institutions. The topic guide is presented in Appendix 2. A flexible approach was taken, whereby the topic guide was adapted for each interviewee. Further, the interviewer used the topic guide as a structuring tool rather than a blueprint. This enabled the interviewer freedom in the progression of the interview, with the goal being to examine the roles, interests and subjective perceptions of the process of HTA establishment rather than impose certain assumptions of what happened.

Interviewing elites raises a series of methodological issues, which include difficulty in access to relevant actors, as well as power and knowledge imbalance between the interviewer and interviewees (Harvey, 2011; Mikecz, 2012). Some social scientists have challenged the term ‘elite’ and its implication of higher status, as well as the definition of what separates elites from non-elites (Cochrane, 1998; Desmond, 2004; Smith, 2006). For example, Smith (2006) argues that the difficulty of access to information gathered in interviews with members of an ‘elite’ is not confined to powerful or high-status groups, but can also be associated with individuals that belong to marginalised groups. In addition, the terms ‘elites’ and ‘experts’ are sometimes used interchangeably, although this may differ in different research traditions (Littig, 2009). There is a lack of conceptual clarity about the definition of

elites and whether they are defined with regards to their status, their position (in the organisation they represent) or the knowledge they possess.

Pre-interview preparation involved considering the interviewee's knowledge of the process or their position and adjusting the topic guide accordingly. To adjust the topic guide, the involvement of each interviewee in the process of establishing HTA was assessed before making contact, based on documents, reading papers by or about the interviewee or existing professional histories or accounts from other interviewees, if they were recommended. The professional role of the interviewees at the time of data collection was relevant, but its informative value was not without limits because interviewees' positions changed over time, with some actors moving to new professional roles, including those that this study would classify as a different 'actor category' (e.g. an industry representative taking on a job as a government official). Knowing about these changes informed the assessment of the interviewee's status and degree of influence over the development of HTA, and the position they took with regards to HTA. For example, the move of an industry official to a government position was kept in mind as a potential case of conflicts of interest.

During the interview, the researcher sought clarification on statements that seemed unclear or that contradicted information collected earlier. Contradictions in interviewee accounts were explored in subsequent interviews and informed the ongoing development of topic guides. As mentioned earlier, questions were adjusted to each interviewee to maximise the information that she or he would be able to contribute, given their different experiences of the process of HTA becoming established. For example, interviews with less senior civil servants were particularly helpful in questioning an already established narrative, which younger civil servants tended to do.

Researcher positionality in elite interviews is important, as it speaks to the relationship between interviewer and interviewee (Mikecz, 2012). The interviews for this study confirmed that this positionality is not fixed, which has been identified as a common characteristic in elite interviews. With the researcher being a student, interviewees tended to be in more powerful positions. However, it was found that

coming from a reputable organisation such as London School of Hygiene and Tropical Medicine (LSHTM), and the association with NICE International, enhanced the status of the researcher.

It is also likely that most interviewees perceived the interviewer as an outsider. On the one hand, this outsider perspective was advantageous, as it allowed the researcher to conduct interviews in a manner that was not influenced by existing preconceptions. On the other hand, it is also likely that the researcher has a more limited understanding of context; however, meticulous preparation was aimed to mitigate this shortcoming.

All interviews were conducted in English. In the Philippines, English is an official language of the government. In Thailand, most interviewees were experienced in communicating in English due to their professional requirements. The fact that the interviewer was able to have exposure to the Thai language as well as English spoken by Thai speakers helped with any difficulties in understanding, including differences in pronunciation. One interviewee asked to have a Thai speaker present although they were able to communicate in English.

There was also an element of cultural learning involved in conducting the interviews. In Thailand, the interviewer had to appreciate some cultural norms such as respect for seniority and the reluctance of interviewees to refuse to meet. The latter required some adjustment, in particularly with interviewees who agreed to be interviewed but were slow in scheduling an appointment. Belatedly, it became clear that some interviewees were unwilling to be interviewed but did not want to decline the invitation outright. It was more difficult to schedule interviews in Thailand than in the Philippines; however, in the end, a sufficient number of relevant individuals were interviewed in both countries.

Data analysis

The data collected for this study was analysed thematically, which is a method for ‘identifying, analysing and reporting patterns (themes) within data’ (Braun and

Clarke, 2008, p. 79). These patterns of meaning were identified as part of an iterative process that started during data collection, when some emerging themes were pursued either by investigating them in documents or during interviews. Similarly, data analysis and writing were also not strictly separated, rather there was an alternation between analysis and writing. Existing guidance, particularly Braun and Clarke's (2008) step-wise conceptualisation of thematic analysis and more general overviews of the qualitative data analysis process (Ritchie, Spencer and O'Connor, 2014a; Spencer, Ritchie and O'Connor, 2014b), informed the steps of the analysis, but did not provide a strict pathway for the analysis.

Interviews were read for familiarisation with the data and re-read for deeper analysis and coding. Because the interviewees in Thailand were not native speakers of English, the transcriptions had to be checked with the audio recordings. An analytical framework was developed based on this initial reading of the data, as well as being informed by the conceptual framework for this study. This analytical framework was developed via a hybrid, instead of a purely deductive/inductive, approach. Specifically, the conceptual framework and the research questions determined the broad categories of the analytical framework (e.g., emergence of HTA as a policy idea; establishing organisations; developing HTA processes). However, emerging themes were also refined during the reading of the data, instead of being purely determined by the conceptual framework.

Data management involved the use of NVIVO version 10, a computer-assisted qualitative data analysis software, which was used because of the large quantity of interview data. Because of the complexity of the data, coding was carried out at two levels of abstraction. This approach is in line with the separation between indexing (and sorting) and categorisation (or coding) proposed by Spencer et al. (2014), whereby indexing refers to signalling where to find specific 'topics', and categorising refers to assigning labels to signal the range of what was said in relation to a particular 'topic'. The first level of abstraction consisted of sorting data based on the analytical framework and checking whether the framework needed revision.

As a second step of categorisation, all text coded under one topic was reviewed and categorised in themes and sub-themes. The topics for which this level of categorisation was done were selected based on relevance to the research aims and specific objectives. This step involved the analysis moving from description to interpretation, as it also included identification of overarching themes. The interpretative work also included a re-reading of the interviews to check understanding and interpretations with alternative explanations, including by returning to documents. If there were discrepancies, more documentary data or clarifications from interviewees were sought.

This analysis was done by splitting data in two datasets covering the Thailand and Philippines cases, respectively. The identification of themes and sub-themes were done for each country separately, followed by an analysis of each theme in comparison. During the earlier stages of analysis, written accounts of the two country case studies were produced, which examined how each theme contributed to HTA institutionalisation in each country. However, it was found that writing comparative sections on specific elements of the process of institutionalisation, informed by the research objectives, was more amenable to comparing the themes that were produced for each of the two cases.

Ethical considerations

Ethical approval was granted by the LSHTM Research Ethics Committee (reference number 10472, 21 December 2015), the Institute for the Development of Human Research Protections (IHRP) in Thailand (granted February 23, 2016), and the Research Institute for Health Sciences Ethics Review Committee in the Philippines (reference number 273/E/O/16/15).

The most important ethical concern with regards to this study was to ensure anonymity and confidentiality of interviewees. Before each interview, interviewees were sent a consent form that allowed them to choose the level of anonymity with which they were comfortable (see Appendix 3). The existing choices ranged from the ability to use the data for analysis, but not allowing the researcher to use

verbatim quotes, to allowing the researcher to fully disclose the identity of the interviewees. Additional information and an opportunity for discussion was provided before the start of the interviews. Some interviewees asked to sign at the end or decided to return the consent form after further consideration. They were also reminded that they were free to indicate if they did not wish for any specific information to be quoted.

Among the 55 interviewees, there was a variety in choices with regards to the level of anonymity they preferred. In general, senior officials were more likely to indicate that they could be identified by name. Interviewees who were less senior were more likely to prefer higher levels of anonymity. Because of the variation of choices and acknowledging the difficulty of maintaining anonymity of interviewees, a choice was made to anonymise quotes by using a country identifier, the number of the interview and the actor category (e.g., I3TH_civil service). These identifiers are used in this thesis when quotes are reproduced verbatim.

Maintaining anonymity of other interviewees was found to be difficult during the interviews themselves. Interviewees often asked about those who had already been interviewed. In those cases, only those interviewees who had agreed to be named would be mentioned, in other cases the researcher only referred to the organisational affiliations.

4. Description of cases

This chapter presents an overview of the decades-long processes of HTA establishment in Thailand and the Philippines. It indicates the main policy developments to which HTA was linked, as well as the key organisations and processes that were established over the period under consideration. Their development will be analysed in detail in subsequent chapters.

Thailand

HTA rose to prominence in the context of two major policy developments that punctuated a long-term movement for health system reform. The first was the introduction of the Social Security Scheme in 1990, and the second was the establishment of a Universal Coverage Scheme (UCS) in 2001. Both reforms resulted in a new configuration of health system governance, which included new arrangements on how funds were allocated, what services were included in the benefits package and how these services were provided and regulated. These new governance arrangements also played a key role in how HTA developed.

The emergence of HTA as a policy idea among Thai health policy-makers can be traced back to at least 1987. Previous studies of the historical evolution of HTA in Thailand outline a complex, incremental process (Tantivess, Teerawattananon and Mills, 2009; Teerawattananon *et al.*, 2009; Culyer, Podhisita and Santatiwongchai, 2016). A brief account of the development of HTA in Thailand is presented below, which draws on these studies and the interviews conducted for this thesis.

The establishment of HTA in Thailand can be described in three main stages. The *first stage* involved a number of small research projects that either referred specifically to HTA or generated evidence that can be used for HTA, such as economic evaluation and epidemiological research on priority conditions. This preparatory stage is characterised by research projects that were jointly coordinated and funded by Thai government organisations and international funding agencies. The earliest ‘distinct programme to have a title related to HTA’ in Thailand

(I1TH_civil service), was the Technological Assessment and Social Security in Thailand (TASSIT) project. TASSIT was established in 1993 as a collaboration between Karolinska Institutet, Sweden, and a Thai independent public organisation, the Health System Research Institute (HSRI)[4]. It was co-financed by the HSRI and the Swedish International Development Agency and was discontinued in 1999. The programme was aimed at generating evidence to inform the management of the newly established Social Security Scheme, a social health insurance programme for employees in the private sector. It included a series of related projects, such as a proposal for a national HTA mechanism, technical assistance for cost analyses in hospital management, a health financing and equity study, and an international training programme for Thai researchers (Tomson and Sundbom, 1999b).

This first stage of establishment also included research programmes that generated evidence associated with HTA without advocating specifically for HTA establishment. In 2000, the first Thai burden of disease estimates were produced under the coordination of the Thai Working Group on Burden of Disease. This working group was co-financed by the WHO Country Office and the Australian Agency for International Development and received technical support from academic bodies in Australia. In Thailand, it was housed by the International Health Policy Programme (IHPP), a research office of the Thai Ministry of Public Health (MoPH) (Bundhamcharoen *et al.*, 2016). As a result of the success of the first study, the Wellcome Trust in the UK and the University of Queensland in Australia co-financed a research programme on Setting Priorities Using Information on Cost-Effectiveness (SPICE), established in 2004. This research programme contributed to the second Thai Burden of Disease study. It also carried out a series of economic evaluations and epidemiological research on disease priorities and associated interventions in Thailand (e.g. anti-retroviral treatment, rotavirus vaccinations, mental health interventions, cardiovascular disease and diabetes, road traffic injuries prevention).

[4] The HSRI was established through royal decree in 1992 as an autonomous research management organisation.

A *second stage* in the development of HTA was characterised by the creation of research bodies within the structures of the MoPH, with no identifiable international involvement in terms of funding or initiative. In 2002, a Health Technology Assessment Unit was established in the Department of Medical Services (DMS) in the MoPH. Its activities were focused on standards of care and quality improvement in the country's top hospitals. In 2007, the unit was strengthened, and became the Institute of Medical Research and Technology Assessment (IMRTA). The IMRTA specialised in the development of clinical practice guidelines, including by using elements of economic evaluation. Also in 2007, the Health Intervention and Technology Assessment Programme (HITAP) was established as a 3-year research programme funded by the Thai Health Promotion Foundation[5] (ThaiHealth). Over time, HITAP developed into a de-facto HTA agency in Thailand. However, there have been few direct links or cooperation between IMRTA and HITAP, despite the fact that both bodies are mandated to carry out HTA – albeit with different focuses.

A *third stage* of HTA establishment included the development of two distinct decision-making processes for HTA. These two processes support a) coverage and pricing decisions for essential medicines, and b) new inclusions to the benefits package for the largest public insurance scheme in Thailand, the UCS HITAP played a major role in the development of these two processes. In 2008, it published the first Thai economic evaluation guidelines, which were endorsed by the committee in charge of the development of the country's National Essential Medicines List (NLEM) (Wibulpolprasert and Subcommittee for Development of the National List of Essential Drugs, 2008). In 2009, a similar endorsement was given by the Subcommittee for the Development of the Benefits Package and Service Delivery (SDBP) under the Universal Coverage Scheme. Since then, HITAP has provided the secretariat for these two HTA processes and has been involved in subsequent changes to their procedures. For example, a second edition of the Thai economic evaluation guidelines was published in 2013, for which HITAP carried out work on estimating willingness-to-pay (i.e. cost-effectiveness) thresholds for

[5] Also known as Thai Health, the Foundation was created in 2001 and was charged with allocating revenue from excise taxes. These revenues are earmarked for health promotion.

publicly funded services and the development of methodological approaches for economic evaluation of health promotion interventions in Thailand. Such developments were ongoing in 2016, when the interviews for this study were conducted.

The Philippines

There are comparatively fewer existing accounts of the development of HTA in the Philippines. A notable exception is the work of De Rosas-Valera (2009), which informs the brief description below, alongside the interviews for this study.

As in Thailand, the emergence of HTA was part of health system reforms which significantly re-organised the governance of the Philippines health system. The National Health Insurance Act of 1995, and its revisions in 2004 and 2013, directly contributed to the establishment of HTA as part of system governance, as did a UHC Act promulgated in 2019. The 1995 Act mandated the establishment of the NHIP, a social health insurance scheme that was envisioned to gradually expand towards reaching universal health coverage. The UHC Act of 2019 built on this goal and directly mandated the creation of a HTA Council that would guide coverage decisions for the NHIP, as well as the Department of Health (DoH).

As was the case in Thailand, before the concept of HTA emerged, a number of international organisations promoted the use of economic evaluation in informing decisions on specific health programmes and evaluating their performance. For example, the WHO Special Programme for Research and Training in Tropical Diseases (WHO/TDR), in collaboration with the World Bank and the United States Agency for International Development (USAID), supported the use of health economics in studies on disease control, particularly on malaria (Herrin and Rosenfield, 1988). Other WHO units and programmes supported the same tools of economic evaluation for the prioritisation of investment in key development areas, such as nutrition (Popkin *et al.*, 1980; Fowler, 1982). In addition, the World Bank and USAID supported the wider development of health economics, but with a focus on health financing and demand-side economics research. For example, the USAID financed a major health financing research programme, the Health Finance

Development Project, which informed the design of the 1995 Act that established the NHIP.

The beginnings of HTA in the Philippines date back to the 1990s and, similar to Thailand, can be analysed in three stages. However, in contrast to Thailand, the earliest stages of HTA development already included establishing HTA processes at national government level.

The *first* stage linked HTA establishment with the National Health Insurance Act passed by Congress in 1995. The Act set out the details of the NHIP, with the goal of gradually increasing coverage to 'constitute one universal health insurance program for the entire population' (National Health Insurance Act of 1995 - Republic Act No. 7875). This act stated that 'health care providers shall take part in programs of quality assurance, utilization review, and technology assessment', thus announcing the government's intention to establish HTA (National Health Insurance Act of 1995 - Republic Act No. 7875). The provision to develop HTA was put into practice in 1999 when a HTA Committee was created within the Philippines Health Insurance Corporation (PhilHealth), a government corporation created to implement and govern the NHIP. This HTA committee was in place from 1999 until it was disbanded in 2009 following Presidential elections and a change of administration, which also replaced the leadership of PhilHealth.

A *second* stage of HTA development includes establishing a HTA process under the DoH that focused on new medicines included in the country's essential medicines list, the Philippine National Drug Formulary (PNDF). Again, this process was established alongside landmark legislation that was wider than HTA. Specifically, in 2008, the Philippines Congress passed the Cheaper Medicines Act, which empowered the government to regulate the price of medicines. In 2010, the Secretary of Health established a new advisory body to the DoH, the National Center for Pharmaceutical Access and Management (NCPAM), mandated with the implementation of the Cheaper Medicines Act. NCPAM's tasks included coordinating the PNDF and the inclusion of new medicines in this list. In this role, NCPAM gradually developed new evidence requirements for the PNDF that

included cost-effectiveness, as well associated procedures for the generation and appraisal of this evidence.

A *third* stage of establishing HTA was marked by parallel efforts to develop HTA processes at the DoH and PhilHealth. At the DoH, these efforts consisted in changes to the existing process to include new medicines into the PNDF, including by commissioning a methodological manual for economic evaluation and repeated process revisions (e.g., changes to submission timelines, clearer prioritisation and decision-making criteria). At PhilHealth, the interest in HTA focused on applying its principles to the development of condition-specific health benefits packages. In 2016, a Subcommittee for Benefits Package Development endorsed a plan for developing a guaranteed benefits package of publicly funded health services for PhilHealth. This plan included epidemiological analyses to map the burden of diseases in the Philippines and cost-effectiveness studies to identify the interventions that offered the most value for money for priority conditions. These parallel efforts were linked to efforts to ensure UHC. In October 2018, the Philippine Congress passed UHC Bill that mandated the establishment of a HTA Council to make coverage decisions for medicines and health services. The Philippine President signed into law the ensuing UHC Act in 2019.

Structure of analysis

The outline of HTA development in the two countries identifies the main types of initiatives related to HTA. However, these descriptive overviews do not reveal the reasons for establishing HTA or how decisions were made in favour or against options to build the organisational structures coordinating HTA or the processes of HTA. Similarly, the outline of the initiatives related to HTA do not provide insights about the actors involved in initiating and sustaining the process of HTA institutionalisation. The next chapter explores, comparatively, the role of the actors involved in establishing HTA and their interests, as well as the ideas that formed and transformed during this process. Chapter 6 will analyse the establishment of HTA organisations, while process development will be explored in chapter 7. Finally, chapter 8 will analyse challenges to the institutionalisation of HTA.

5. Emergence of HTA in Thailand and the Philippines

The process of establishing HTA in Thailand and the Philippines spanned over twenty years and involved multiple setbacks and advances. It also included an evolutionary process of what was understood to be HTA. This chapter will present an overview of this evolutionary process, by following the policy problems for which HTA was presented as a solution. Following the ideas, or what gets institutionalised, enables a look at what elements get transferred from other settings, how ideas are influenced by country institutions, as well as what actors are relevant for the emergence of HTA on the policy agenda.

This chapter is structured in three parts: the first two parts present the country analyses of the evolution of the policy problems to which HTA was aimed to respond in Thailand and the Philippines. The third part includes a comparison of these analysis between the two countries. Subsequent chapters will examine the design of HTA. Specifically, chapter 6 focuses on establishing organisations mandated with conducting HTA; chapter 7 analyses the process of conducting HTA. Chapter 8 will identify ongoing challenges to institutionalisation.

The development of HTA as a policy idea in Thailand

Interviewees placed the emergence of HTA as a policy solution in the context of wider efforts to strengthen the country's health research system and the use of evidence in health policy-making, dating back to the 1980s. While efforts to strengthen the use of evidence in policy-making provided a context and some of the paths through which HTA emerged, interviewees also highlighted specific policy problems that HTA responded to: high cost technology; medicines reimbursement; and coverage decisions on all services, in the context of pressure on the UHC scheme (UCS) to include more services.

Interviewees also identified the key actors that pursued these efforts as a network of academics and civil servants, known as the Rural Doctors' Society (RDS). The RDS collaborated with national and international actors and were effective in accessing national and international funding to support their priorities. The members of the initial RDS, founded in the 1978, were medical doctors educated in the country's top medical universities who chose to practice in remote rural areas of Thailand instead of pursuing careers in urban medical centres. Many of them were involved in student political activism in the 1970s and founded a first version of the RDS named the Rural Doctor's Federation in 1976. This network took shape around the recognition of the problem of inequitable access to health service in Thailand, with urban centres being favoured to the detriment of rural facilities. The latter served a much larger and more vulnerable population. In time, many of these doctors, who were employed in government hospitals and therefore were part of the civil service took up positions within the bureaucracy of the MoPH.

Key-informants described the members of this network as 'reformists', 'technocrats' or 'technocrats-activists', being 'outside the MoPH and still inside it', and 'wearing many hats' as both members of the bureaucracy and of civil society (I1TH_civil service, I3TH_civil service, I4TH_academia). Other scholars of health reform in Thailand described them as 'reformist bureaucrats' (Harris, 2015) or 'health reformists' (Pitayarangsarit, 2004; Naidoo, Nhavoto and Reddi, 2005). As a policy network, the Rural Doctor's Society is small in comparison to the bureaucratic apparatus of the MoPH. However, it can be treated as a category of actors with considerable influence and power. In fact, some accounts of the Thai health system reform effort separate the entire MoPH bureaucracy in two categories: the 'reformists' and the 'conservatives' (Health Insurance System Research Office, 2012).

The emergence of HTA was also initially associated with international actors supporting evidence generation that is useful in HTA processes. Multilateral organisations active in global health, particularly the WHO and the World Bank, supported the generation of evidence and some supported the development of in-country research capacity. This included research capacity-building for disciplines

that would become relevant for HTA, namely clinical epidemiology and health economics. For example, organisations such as WHO and World Bank played an important role in producing economic evaluations to make the case for more investment in disease control or to evaluate the implementation of internationally funded programmes (Mills, 2014). As a case in point, the first economic evaluation study in Thailand was carried out with support from the WHO/TDR programme and aimed to 'apply economic concepts and tools to the monitoring and evaluation' of malaria control programmes in Thailand (Kaewsonthi et al., 1983: v). Continuing support from the WHO/TDR programme led to the establishment of a Centre for Health Economics at the Faculty of Economics of the Chulalongkorn University in 1990. In addition, WHO/TDR financed 50 scholarships for researchers in tropical disease control at Mahidol University and Chulalongkorn University. In parallel, the Rockefeller Foundation supported the development of clinical epidemiology groups that they envisioned would create a bridge between clinical medicine and public health as part of an International Clinical Epidemiology Network (INCLEN) initiative. Another USA-based foundation, the Pew Charitable Trust, made investments a programme named the International Health Policy Program. Both INCLEN and the International Health Policy Program were initiatives that worked by building in-country research teams that carried out studies on high priority health issues and that could respond to policy needs.

The RDS preferred a more country-driven approach to prioritising evidence generation. In the late 1980s, some RDS members were involved in discussions with the WHO Country Office and the Rockefeller Foundation – the more influential international actors - about associating funding for research from these organisations with a prioritisation of policy problems. The rationale for these discussions was to ensure that the country budget of these organisations funded research on Thai priorities and was informed by the country context, as opposed to being informed by international priorities. Some national actors who believed that the WHO country budget did not correspond to in-country priorities proposed to develop, in collaboration with the WHO Country Office, a better aligned funding structure. Plans included the establishment of teams of civil servants and university researchers (named Programme Implementation Co-ordinating Teams) that would have

*'*significant control over how the WHO country budget was allocated*'* (Sitthi-Amorn et al., 1997: 12). Although this effort was short-lived, the WHO Country Office provided funding for a Thai Health Assembly, organised in 1987 and modelled after the World Health Assembly. Part of these funds were used to commission reviews on a series of priority policy problems and associated policy solutions, one of which was HTA. Furthermore, the idea of a Thai Health Assembly will continue to be supported by RDS members and will inform the establishment of a public organisation named the National Health Commission Office, in 2008. Despite being short-lived, these initiatives show the capacity of policy actors, including the RDS, to establish links with international organisations in order to achieve their goals. In the case of the RDS, these goals included local generation of evidence relevant for health policy-making.

The interest in evidence use in policy by the RDS was also manifested in a desire to establish national funding for health research. They expressed this preference in discussions with the Rockefeller Foundation about the establishment of a 'country advisory board which creates conditions for undertaking high priority public health research' (Sitthi-Amorn, Chunharas, & Chooprapawan, 1997: 14). The resulting National Epidemiology Board of Thailand (NEBT) was established as part of the MoPH but received its funding from the Rockefeller Foundation. In line with the desire to prioritise the most pressing research needs, one of the first activities of the NEBT was to conduct a prioritisation of health problems in Thailand, with the aim of commissioning research on these priorities and subsequently enabling the implementation of the resulting recommendations. This was an early lesson for Thai civil servants who supported evidence-informed policy-making about the difficulties of such a process, as well as of the key role of policy researchers in linking evidence and policy-makers.

> During the time of the National Epidemiology Board of Thailand, we used to try to interview policy-makers - like civil servants, the Permanent Secretary - for priority health research, but no one had the wisdom to tell you what should be priority health research. So, we learned that research prioritisation through asking the policy-makers doesn't work. That's why we need another group of people we call policy advocates, or policy elites, who understand the technical part of the evidence, at the same time they understand the political part of policy making, and they can link the two together. It doesn't mean

> that these policy advocates or these policy elites do not do research. They themselves are sometimes involved in doing research, but research is not their main interest. They are not pure researchers. (I10TH_civil service)

However, the NEBT was also short-lived and was terminated in 1990 by an incoming Minister of Health, following a political crisis that led to a change in government.

> Then later on, this NEBT was abolished due to a political conflict. There was a political conflict back in early 1990. Some people, young people [in the] NEBT used the facilities to support this political movement. Then, a new minister [...] came in and he felt that this is ... He didn't like it, so he abolished the NEBT, and that was one of the pushes for the seniors to establish two things at the same time, in parallel. One is an non-governmental organisation called the National Health Foundation, and the other is an independent public agency, which is the Health System Research Institute. (I10_civil service)

The RDS was effective in mobilising national funds as well, particularly as some of its members had links with or became senior MoPH officials. These connections between key RDS members and senior health officials led to the establishment of the HSRI in 1990. The HSRI was endowed with core national funding for health research and took over some of the initiatives of the NEBT, whereas the Rockefeller Foundation re-directed some of the funds of the NEBT to the National Health Foundation, a new non-governmental organisation established by members of the RDS, still functioning in 2016. These early examples of civil servants attempting to establish research bodies within the bureaucracy will be mirrored at the establishment of HITAP (2007).

The HSRI took over efforts to increase the capacity to produce policy-relevant health research, including by strengthening the country's health information system as well as providing in-country support for health policy and system research. One of the HSRI's first projects was another attempt at informing policy priorities based on burden of disease.

> At that time, I think they used only YLL [years of life lost] or something, not DALY or anything, at that time. There was a report coming out, maybe in 1994, if my memory is correct, […], about the prioritisation of health programmes in Thailand. There's some epidemiological evidence there. (I10TH_civil service)

The HSRI became an important actor that invested in research 'capacity', a role which heretofore had been occupied mostly by international organisations. Interviewees suggested that a key aspect of this support from HRSI a scholarship programme co-financed by HSRI, other Thai government agencies and the WHO Country Office, with specific focus on health systems and policy research (e.g., health financing, health economics). The award recipients were often civil servants and were required to return and work within Thai the civil service or academia. The two future founding leaders of HITAP benefitted from this programme, having completed their PhDs at the LSHTM and the University of East Anglia.

These efforts towards strengthening the country's research system provided the background for the establishment of HTA. These early initiatives are important because many of the actors presented here became HTA advocates and are part of efforts to establish HTA.

The transfer of HTA as a policy solution with broad potential applications

The HSRI leadership strongly supported the idea of HTA and used its role as a research funder to finance HTA-related projects, showing support for HTA as a policy solution with broad potential applications. Between 1992 and 1999, the HSRI's support for HTA included both national and regional or international activities. First, the HSRI participated in an internationally-funded project, TASSIT, which ran from 1993 to 2002. TASSIT was initially a Swedish initiative aimed at generating evidence on health financing and care provision for the Social Security Scheme, but also had a specific focus on HTA. Second, in the mid-1990s, the HSRI organised and/or participated in a series of workshops and regional meetings on HTA, with the aim to promote the idea of HTA among policy-makers in Thailand, and to establish a regional network for HTA in South-East Asia. Third, the HSRI established a technical committee and associated research and development programme on HTA in Thailand. Between 1997 and 2002, this committee coordinated a five-year development plan with four priorities.

The four priorities of the HTA committee (i.e., the characteristics of the policy solution) were:

(1) Establishing an information centre and international linkages on HTA;
(2) Assessment of priorities (i.e., both prioritisation of technologies and assessment of individual technologies identified as priority), establishment of a mechanism for hospital accreditation, and a national mechanism for HTA;
(3) Develop evidence-based medicine and clinical practice guidelines (seen as a separate activity that should be carried out by actors who were interested in clinical decision-making, e.g., Royal College of Physicians);
(4) The rational use of medicines, specifically the generation of pharmaco-economics evidence (Tomson and Sundbom, 1999b).

Some of these would not typically be associated with HTA directly, but they were likely influenced by HSRI priorities. For example, the hospital accreditation mechanism was born out of a project on quality improvement that HSRI established. This project was the basis for the subsequently creation of an independent public institute to coordinate quality assurance and hospital accreditation. The rationale for the creation of this body was to remove a conflict of interest from the MoPH, which both owned public hospitals and accredited them, as well as enabling the participation of private hospital in public insurance schemes. Thus, HSRI saw both HTA and hospital accreditation as specialised tasks that would be carried out by independent bodies.

The HRSI HTA committee consisted of two part-time staff and a wider network of relevant actors, such as researchers, civil servants from the Bureau of Policy and Planning, the MoPH, including the DMS and the Thai Food and Drug Administration (FDA), and physicians working in public tertiary hospitals under MoPH administration.

The HSRI HTA committee used a broad definition of HTA, as seen by its four areas of work. This broad areas of work also reflected the interests of the early advocates for HTA - civil servants and academics many of whom were members of RDS. Some of these early advocates who were members of the RDS took an approach to HTA that was about investment in medical equipment and budget allocation. Others

took an understanding of HTA as a policy solution that focused in effectiveness evidence, clinical practice guidelines and the quality of health services. This is reflected in two failed attempts at regulating investment in expensive medical technology, and a second, comparatively successful, establishment of a HTA institute under the MoPH whose main approach to HTA includes effectiveness evidence and the development of clinical practice guidelines. These initiatives will be explored in chapters 6 (organisations) and 7 (processes).

Investment in medical equipment

Among RDS members, the initial policy problem that was associated with the emergence of HTA, named as such, was the uncontrolled diffusion of novel, high-cost technologies among urban health providers, particularly private hospitals. The diffusion and perceived irrational use of innovative medical equipment was of importance to these civil servants because of a lack of effective means for the MoPH to keep track of the fast growth of private hospitals, brought about by the economic boom in the 1980s and early 1990s. Expectedly, actors who were involved in these early discussions about the usefulness of HTA in Thailand highlighted the conflict of interests that physicians and providers had of using innovative technologies as a source of revenue (TH_I11_physician).

This initial policy problem mirrors the emergence of HTA in other contexts. However, there was a specificity to how the policy problem was defined in the Thai context. This specificity was linked to the establishment of the Social Security Scheme, its governance arrangements and the lessons learned from its first decade. The 1990s saw a fast increase in the volume of services provided in private hospitals partly due to the expansion of coverage to the employed sector after the establishment of the Social Security Scheme (1990), as well as partly because of increased demand in affluent urban centres. The Social Security Scheme commissioned a benefits package including inpatient care and some outpatient services (provided in ambulatory clinics linked with large hospitals). Interviewees

indicated that the benefit package was not defined further because policy priorities at the time were focused on expanding population coverage

> So at that time we focused on policy, focused on expanding [health] protection schemes to the population. Not much [focus] on creating a benefits package, or its cost-effectiveness. So, [we wanted to] get things done, expand population coverage in 1990s. (I12TH_civil service)

While the health benefit package was not given more attention, policy-makers considered it important to design a mechanism for cost-containment (Nitayarumphong, 2006). As a result, the choice of payment mechanism was designed to incentivise providers to contain their costs. Specifically, the Scheme paid private providers through a capitation budget allocated per registered member.

The Social Security Scheme attracted attention of health systems researchers, who conducted a series of studies about its functioning (Tangcharoensathien, Supachutikul and Lertiendumrong, 1999; Mills *et al.*, 2000). Evaluations of the scheme indicated that the cost-containment incentives had been effective in maintaining the financial health of the scheme, but there was also evidence of hospitals providing lower quality of care to Social Security patients compared to patients who paid privately at the same facilities (Tangcharoensathien, Supachutikul, & Lertiendumrong, 1999), overall low utilisation rates and evidence of directing complicated cases to public facilities (Mills *et al.*, 2000). These studies also highlighted an 'immense' growth in high-cost medical equipment in these private hospitals (Tangcharoensathien *et al.*, 2000). Specifically with regards to medical equipment, the Scheme incentivised providers, alongside existing tax incentives for import of medical equipment, to invest in more innovative and costly medical equipment. Further, chains of private hospitals that catered to Social Security patients were established in already well served urban settings. These chains invested in well-equipped ambulatory departments which further attracted patients to private care (Tangcharoensathien et al., 1999). Researchers concluded that revenues from the Social Security Scheme were re-invested in high-cost, technology-intensive equipment (Tangcharoensathien, Supachutikul and Lertiendumrong, 1999). Studies also questioned the cost-effectiveness of the services prioritised by the existing

health insurance scheme (inpatient care compared to health promotion) and within these services. For example, health promotion through 'physical check-ups' in a hospital setting were described as the 'least cost-effective' means of preventative care, and yet these services were prioritised by the Social Security Scheme (Tangcharoensathien, Supachutikul and Lertiendumrong, 1999, p. 921).

The inefficient use of resources was a problem both in the public and the private sector of the health system. Members of the RDS consistently carried out research that showed disparities between allocation of MoPH health budgets to urban and rural areas, and between more developed and less developed provinces in the country (Nitayarumphong, 2006). Other evidence generated by health systems researchers who were HTA advocates highlighted the uneven geographical distribution of high-cost medical equipment - such as magnetic resonance imaging (MRI), computerised tomography (CT) and positron emission tomography (PET) scanners. An example often cited at the time and remembered by key informants refers to a Thai study indicating that there were more CT scanners in Bangkok than in the entirety of the UK (TH_I10_civil service) (Tomson and Sundbom, 1999b).

The RDS had a longstanding interest in budget allocation for the health sector (I20TH_NGO). In 1998, the RDS publicly drew attention to irregularities in the procurement of medical equipment and medicines at provincial levels. Specifically, the MoPH leadership (Minister and Deputy Minister) put pressure on Provincial Chief Medical Officers to procure medical equipment and medicines from pre-selected suppliers (Nitayarumphong, 2006). These Officers had considerable freedom of budget allocation due to previous efforts at decentralisation. However, decision-making by the Provincial Chief Medical Officer and MoPH remained in the hands of individuals - civil servants and political appointees (Pungprawat, 2009). At central levels, the MoPH negotiated its budget allocation with the Bureau of Budget in the Ministry of Finance every year. Next, the Office of the Permanent Secretary of the MoPH allocated funds centrally for the Bangkok area and transferred funds for provinces to Provincial Chief Medical Officers. Behind the scenes, a member of the RDS described how they lobbied the Bureau of Budget to apply more equitable formulas for budget allocation to the MoPH. This led to conflicts with the Permanent

Secretary of the MoPH, who favoured the existing historical patterns of budget allocation that concentrated investment in urban, more developed areas (Nitayarumphong, 2006).

As a result of this accumulation of knowledge and links within the civil service, particularly among the members of the RDS and the health system reform movement[6], there was a growing recognition that the Social Security Scheme was an important source of revenue for private and urban government hospitals which had created incentives for even more investment in profit-making high-cost technologies. The proliferation of high-cost technology in urban centres was criticised as an example of the inequitable distribution of health system resources and used as an argument for the need of health system reform. The diffusion of high-cost technologies was highlighted as a major cause of waste of resources in the health system and an indicator of inefficient resource allocation. RDS members contrasted the large investments in expensive medical technologies with the underinvestment and lack of access to basic health services in rural areas. They argued that this concentration of medical equipment in already well-served urban settings was an inefficient use of resources and was inequitable as it disadvantaged rural populations.

HTA and universal health coverage

The policy problem evolved considerably after 2000, as a result of the policy agenda becoming dominated by the universal health coverage reforms and the institutional changes brought about by the establishment of the UCS. The evolution of the policy problem had two facets. On one hand, it consisted of continued interest in budget allocation for high-cost specialised care, which included investment in medical equipment. On the other, a new policy problem emerged, specifically making explicit coverage decisions for the newly established scheme. Both these problems

[6] The health system reform movement who were the most influential in policy-making– and were also member of the RDS – are sometimes referred to as the Rose Garden group, by the name of the hotel where members would meet regularly. For more details, see Nitayarumphong (2006).

are best understood in the context of new institutional arrangements brought about by the UCS reforms, and the power struggles their establishment engendered.

The quality of service provision included in the UCS as well as the budget allocation for these services emerged as a policy problem during the discussions about the UCS and became associated with HTA. In particular, medical professionals criticised the UCS scheme as providing 'second class', low-quality services to people on low incomes (Nitayarumphong, 2006: 107). For its advocates, HTA was seen as a response to making decisions about which innovative medical technologies and services should be provided in these hospitals.

However, a deeper fault line hidden behind such debates was about budget allocations for these top public hospitals and for the entire newly established scheme (Hughes & Leethongdee, 2007; Hughes, Leethongdee, and Osiri, 2010). In the first years of its existence, the UCS budget was administered by the MoPH and there were attempts by MoPH actors to influence how much of the budget would be pooled at central level, under the authority of the MoPH. The MoPH wanted to allocate budgets for high-cost, specialised care and capital investments for its large network of public facilities. In 2005, after protracted negotiations on this issue, the UCS budget was transferred to the newly-created National Health Security Fund, to be administered by a National Health Security Office (NHSO). Consequently, the MoPH's budget allocation power decreased substantially (Pitayarangsarit, Limwattananon, Tantivess, Kharamanond, & Tangcharoensathien, 2008).

Civil servants interviewed for this study suggest that this reduction in its budget allocation power was the cause of consistent dissatisfaction among the MoPH leadership and civil service that were opposed to UCS reforms, as well as physicians in specialised public hospitals (I8TH_civil service; I10TH_civil service). In particular, officials at the MoPH were unhappy with the budgets for capital investment and infrastructure development it received from the NHSO (Tangcharoensathien, 2015). According to interviewees, the relationship between the MoPH and the NHSO with regards to both budget allocation and the alignment of policy goals continued to be a problem in the decades to come. An interviewee from

the academia summarises the ensuing relationship between the NSHO and MoPH, suggesting that the loss in financial power did not mean equal loss in political power.

> NHSO is the manager of Universal Health Coverage, and normally, they have only money, not authority. So, for healthcare providers - many healthcare providers are under Ministry of Public Health – they have authority, but they don't have money. (I6TH_academia)

Besides the MoPH civil servants that were opposed to UCS, sometimes referred to as the 'conservatives' within the bureaucracy, there was opposition to the reforms coming from physicians. Specifically, the Thai Medical Council, the leading physicians' association in Thailand, showed strong opposition to universal coverage reforms. Interviewees made a distinction between rural physicians, including the RDS and their network of 'reformists', which were supportive of the UCS, and physicians working in urban areas, allied with the 'conservatives' in the bureaucracy, which were in opposition to the reform proposal. The Thai Medical Council was often presented as in competition and direct conflict with the RDS as a result of the UCS debates in the early 2000s. The RDS, whose key members had a high social profile, had also been voted into the leadership of the Council during the 1980s, but gradually lost this influence in the decade that followed.

> Political pressure within that group, also, has to be important, but we can say that, okay, the Medical Council in Thailand used to be [...]The members that elected the Medical Council [leadership], used to be the people who worked in rural areas, we call them the Rural Doctors' Society. But at this time, most of the people who are elected are the people who work in big cities, and have a really negative idea toward the universal [coverage] policy. (I8_civil service)

Urban physicians also opposed the newly introduced purchaser-provider split that reduced the revenues of government-owned hospitals in urban areas (Pitayarangsarit, 2004). Some physicians actively resisted the implementation of the scheme, for example when they refused to complete the paperwork required by the NHSO (Pitayarangsarit, 2004).

The second version of the policy problem that HTA could solve, namely how to make explicit coverage decisions for the UCS, was slower to emerge. In fact, HTA was not part of the debates for UCS initially. As had been the case with the Social Security Scheme, the design of the benefits package was not debated. Actors

supporting the UCS reforms, including the Rural Doctor's Society, preferred not to raise the problem of determining an evidence-based benefits package, even though there had been previous discussions about the importance of investing in cost-effective interventions (as seen above, in the case of the Social Security Scheme). One key informant involved in the design of the UCS indicated that this was a strategic decision, so as to not add a likely controversial question to what were already difficult negotiations.

> So I don't think that it [HTA] was a relevant question to raise, […] don't ask this question when there is a moment of political window [for UHC] open briefly. So the benefits package initially was not guided by HTA evidence. (I12TH_civil service)

The initial UCS benefits package was modelled on the existing benefits package of the Social Security Scheme, with the long-term goal of harmonising the differences between the UCS, the Social Security Scheme and the Civil Servants Medical Benefits Scheme[7]. In addition, the UCS ensured that all Thai citizens had access to medicines listed on the NLEM[8].

The difficulty of defining a benefits package of health services became apparent during a series of controversies linked to high-profile inclusion and exclusion decisions. For example, renal replacement therapy for patients with end stage kidney disease was initially (in 2001) excluded because of its substantial budget impact, but was re-evaluated and included in the UCS budget in 2006. There was also sustained pressure from manufacturers and physician groups to open reimbursement to medicines and other services that were not included in either the NLEM or the existing UCS benefits package. Interviewees described a growing pressure on the UCS to name clearer criteria to justify decisions about the inclusion or exclusion of services, especially to manufacturers and patients. In this context, HTA was seen as

[7] The Civil Servants Medical Benefits Scheme was the first publicly financed health insurance scheme in Thailand. It covers the covers the cost of health care for civil servants and their dependants as well as civil service pensioners and their dependants.

[8] The NLEM had been first used as a reimbursement list in 1998.

both providing a mechanism to develop such criteria and a process to manage these emerging conflicts.

> In the context of universal health coverage, the demand for new health technologies increased - very new technologies, usually expensive. Policymakers have very limited resources. They need someone to help them and [HITAP] helped them with evidence, helped them with a participatory, transparent process. (I1TH_civil service)

HTA developed as a tool that offered procedural clarity in coverage decisions for high-cost medicines in the NLEM and for the expansion of the UCS benefits package. Put differently, HTA emerged as a way to expand access to 'technologies', while also enforcing limits to the expansion of the reimbursement lists. After its establishment in 2006, HITAP provided the technical secretariat for two decision making processes: on inclusions to the NLEM and on the development of UCS benefits package.

By 2016, these decision-making processes faced increasingly complex prioritisation and decision-making problems, particularly with regards to setting priorities for between conditions, the methods for assessing these priorities, as well as the implementation of the interventions recommended by HTA processes. Consequently, the idea of HTA as part of the processes for benefit decisions expanded to include comparing interventions that offered the best value for money across different conditions, as well as the effective implementation of new services added in the benefits package. The need for evidence also became broader.

> For example, now we evaluate a programme that's already implemented, so it's actually programme evaluation. But I said this is HTA as well. Why? I think the implementation of policy comes from ex-ante evaluation. We said, ok, it would be good for the country to do this and decision-makers decided to implement. So after implementation, it has become programme evaluation. And HTA researchers are the best people to do the ex-post evaluation. Because they are the ones who were involved in advising about the programme, at policy agenda-setting and policy implementation [levels]. And it's also good for them to learn, as well, [whether] what they predict at the beginning - 80% acceptance of screening for Down Syndrome - will be real when implemented. Because that 80% comes from research on small groups [sample], and now we implemented it for a large group. (TH_I3_ civil service)

In summary, the policy problems that HTA was seen to be able to solve evolved considerably. Important HTA advocates included researchers and civil servants that were members of a policy network whose goal was to advance health system reform. These advocates started from a broad understanding on HTA as a solution to numerous policy problems. In time, these policy problems were refined in the context of country institutions, particularly the governance structures of the UCS.

Subsequent chapters will explain how these problems were taken up by HTA bodies (chapter 6) and how HTA processes associated with these problems were established – or not (chapter 7).

The development of HTA as a policy idea in the Philippines

As in Thailand, HTA emerged as a policy idea in the context of wider policy problems expressed by actors who first advocated for HTA. In the Philippines, this wider context was about improving the efficiency of government as a steward of health policy. HTA advocates acted in this context, with the initial push in establishing HTA coming from within the civil service, which also benefited from links with researchers.

All interviewees mentioned the same civil servant as the key figure in advocating for HTA in the Philippines, Dr Madeleine Valera, 'the mother of HTA' (I3PH_academia, I8PH_civil service). Valera was a career executive civil servant[9] who held several senior positions at the Philippine DoH (1988-1998), PhilHealth (1998-2010) and again at DoH (2012-2013). As a civil servant, she was involved in the legislative process that led to two landmark pieces of legislation: the Generics Act (1988) and the National Health Insurance Act (1995). Furthermore, key informants suggested that her early leadership on HTA led to the development of a policy network for HTA advocacy that included civil servants and researchers as main members.

[9] The Philippines civil service includes two broad categories: career and non-career service. The highest grade for the career service is the career executive service officer (CESO), as Dr Valera. The non-career executive service officers are often named through Presidential appointment.

It is important to look closely at the development of the Generics Act and the National Health Insurance Act, not only because they speak Dr Valera's advocacy for HTA, but because they were major pieces of legislation that constituted important institutional pillars of health policy in the Philippines and of the development of HTA. The Generics Act of 1988 was a major win for its initiators - the Secretary of Health and a group of top level executives at DoH -, which was aided by a political climate favourable to reforms, after the ouster of President Ferdinand Marcos. The Generics Act was important for the development of HTA because it was the basis for establishing a process to develop an essential medicines list. Subsequent to the Generics Act, Madeleine Valera became part of the National Drug Policy Committee secretariat and as such supported the development of regulations to limit procurement of medicines to the essential medicines list (known as the National Formulary)[10].

The NHIP, which was established by the National Health Insurance Act, reformed the existing public insurance scheme, the Medicare Program[11], for government workers (Medicare I) and employees in the private sector (Medicare II). As a result of the negotiation process for the National Health Insurance Act, the final NHIP structure included many concessions to providers and employers, particularly with regards to the type of health benefits includes - inpatient care- and the payment mechanisms - fee-for-service, whereby PhilHealth would reimburse facilities up to fixed amount. The NHIP also adopted a first-dollar policy, whereby financial risk was placed on patients and not on PhilHealth or the providers, and .

In this context, a proposal to include HTA in the legislative text was taken up by a private insurance group that also 'understood the importance of HTA' with regards to cost-containment (I16PH_civil service). However, key-informants credit Dr

[10] Despite the implementation of a Devolution Act (1992), which shifted responsibility for 'personal health care' to local government units, medicines policy remained under the remit of the DoH, together with other public health responsibilities.

[11] At the time, the Medicare Program was the healthcare component of two larger social security programmes: the Government Service Insurance System for civil servants and the Social Security System for workers in the private sector. The Medicare programme reimbursed physicians through a fee-for-service mechanism for inpatient care.

Valera[12] with the fact the HTA is explicitly mentioned in the National Health Insurance Act of 1995. At the time, the existing commercial insurers and health maintenance organisations (HMOs) provided coverage for services not included in the existing public schemes (Solon *et al.*, 1995). Private insurers were involved in NHIP negotiations as they were seen as an important source of health financing that was likely to grow in the future[13].

HTA advocates – including Dr Valera – describe learning about HTA from international research literature, as well as from initial HTA programmes established in the region, particularly a HTA programme developed by the Malaysian government (De Rosas-Valera, 2009). Further, the establishment of the NHIP included extensive input from health economists, as a result of USAID allocating a large investment for the 'Baseline Studies on Health Care Financing Reforms'. Health economists at the University of the Philippines and the PIDS[14] collaborated on these studies, but the major push was the large investment from the USAID. One of the USAID-funded studies informing the reforms tackled the problem of diffusion of medical technologies as an important, if overlooked, aspect of the health system reforms (Picazo, 1995).

The first iteration of HTA, named as such, in the Philippines responded to this problem of investment in expensive, technology-intensive medical equipment and its likely inflationary effect on health expenditures. Researchers and civil servants involved in informing the plans for the NHIP identified this problem of funding expensive equipment, but considered it important for the future development of the Program, rather than a current problem faced by the health system. At NHIP's inception in 1995, policy-makers envisioned that it would achieve universal coverage by 2015, therefore its long-term evolution was important. However, given

[12] DoH civil servants were often assigned as liaisons to key legislators and other negotiators, keeping track of their position and any changes in these positions. This was also done in the case of the Generics Act (Kintanar and Romualdez, 1989).

[13] Contrary to these expectations, the growth of private insurance in the Philippines remained slow until 2013, when it accelerated (Dayrit *et al.*, 2018).

[14] The PIDS is a government-owned corporation with a mandate to produce research for government planning.

the low levels of expenditure in the country prior to the NHIP establishment, the problem of overinvestment in expensive medical equipment had not yet emerged. The Medicare Program, did not cover high-cost procedures, and offered low levels of financial protection for its members. Thus, the USAID funded study did not find that Medicare's payments for expensive medical equipment were excessive (Picazo, 1995).

The study suggested that the risk of overinvestment in medical equipment only existed in a few affluent urban areas (Picazo, 1995). Like in Thailand, private hospitals at every level of care, including large corporate hospitals in urban conglomerations and small diagnostic or ambulatory clinics made their own decisions about acquiring medical equipment. These acquisitions were often informed by physicians' participation in professional conferences or through direct contact with suppliers (Picazo, 1995). In contrast, in the public sector the more acute problem was under-investment in medical equipment and infrastructure, particularly outside urban conglomerations. The procurement of medical equipment was largely the responsibility of the DoH, through central budgeting, for a limited number of general medical centres and regional hospitals, some specialist hospitals and one university hospital. Other 600 provincial, district and municipal hospitals had been devolved from the DoH to becoming the responsibility of local government units (LGUs) after 1992, which likely accelerated the problem of underinvestment.

Regardless, the National Health Insurance Act mandated the creation of a technology assessment programme to tackle the problem of investment in medical equipment ensuring that 'the acquisition and use of scarce and expensive medical technologies and equipment are consistent with actual needs and standards of medical practice' (National Health Insurance Act, Republic Act No. 7875 of 1995) (see chapter 6 for more details on alternative proposals for HTA establishment). This legal mandate provided an opportunity for civil servants and researchers who advocated for HTA to build a policy network that became involved in the development of HTA procedures, once PhilHealth was established.

Despite a narrowly defined focus on HTA associated with the text of the 1995 National Health Insurance Act (on acquisition and use of expensive medical

equipment), the HTA committee under PhilHealth significantly shifted its remit once it became established. HTA advocates realised that there was a mismatch between the problem indicated in the NHIP Act, and the actual role of PhilHealth. Simply put, PhilHealth did not have the authority to influence providers' investment in medical equipment, except indirectly through the services for which it authorised reimbursement. The overall policy problem facing PhilHealth in its first years was how to define reimbursable services and how to pay providers for these service, as well as checking that providers' claims reflected real clinical practice. PhilHealth also encountered the problem of providers started claiming reimbursement for medicines that were not included in the country's essential medicines list (PNDF), which was against PhilHealth reimbursement policies.

> But, if I remember it right, what was written in the law, the first initial law, was that it focuses on big ticket equipment and other devices. […] But that's what I remember, more often the devices were adequate. But what happened to us - our questions were very basic in terms of drugs, laboratory, ordinary laboratory tests. In the law, it was more focused on big-ticket items. Now, […] I think, the concept of health technology back then was about big-ticket items, but actually health technology is not only about big equipment, but actually it's anything that has to do with delivering health services. (I6PH_civil service)

HTA advocates thus developed a series of procedures to help PhilHealth decide what services were to be reimbursed, i.e., what were the appropriate services for the diagnoses that were reimbursable. This was done through reviewing clinical practice guidelines and by developing a positive list for medicines, which supplemented the PNDF. The development of this HTA process at PhilHealth, as well as the reasons for abandoning these early initiatives are analysed in detail in chapter 7.

While the positive list allowed for reimbursement of more medicines, albeit temporarily, it also served to highlight the inadequacy of the PNDF published by the DoH as the reimbursement list for PhilHealth. The PNDF's list initial role was to ensure availability of key medicines as well as to rationalise procurement of medicines by the DoH (for its vertical programmes and the few DoH-retained hospitals), by the LGUs for the majority of public facilities, and by large hospitals that also engaged in procuring medicines. The further development of HTA was tightly linked with the specific problem of establishing the PNDF as an appropriate

reimbursement list for PhilHealth. The DoH and PhilHealth collaborated to develop a HTA process for that purpose. However, a HTA process split between DoH and PhilHealth was not successfully implemented due to disagreements between DoH and PhilHealth with regards to each of their roles and responsibilities (see chapter 7 for more details).

The new policy problem: pricing and reimbursement of essential medicines

Pharmaceutical policy took an prominent place in policy debates from the early 2000s. It was increasingly recognised that Filipinos paid the highest prices for medicines, both in the region and among middle-income countries across the world. From 2006, the problem of medicines prices was also discussed in Congress, when a first draft of what would become the Universally Accessible and Quality Medicines Act (also known as the Cheaper Medicines Act) of 2008 was presented. The Act strengthened regulation with regards to price monitoring and introduced a legal basis for direct regulation of medicines prices. The evolution of HTA become linked to this important policy changes both with regards to organisational and process development, although indirectly.

As the institutional framework with regards to essential medicines changed, HTA advocates adapted to the new conditions to develop HTA processes. After the Cheaper Medicines Act was passed and the focus of pharmaceutical policy shifted to the issue of appropriate pricing, NCAPM, a newly created body under the DoH, was mandated with conducting HTAs to support the development of a new edition of the PNDF, that would also include price negotiations. In 2012, cost-effectiveness became a full criterion for decisions between alternative medicines to be included in the Formulary. As of 2016, a formal price negotiation process had not been created, but the process associated with Formulary inclusions had evolved towards a fully developed HTA process.

Defining a guaranteed benefits package

After 2010, the continuous expansion of services reimbursed by PhilHealth and appropriateness of decision-making for benefit expansion emerged as a policy problem. Ongoing additions to the benefits package happened alongside an expansion of population coverage and a number of associated policies aimed at increasing financial risk protection for members. Thus, the first iteration of this policy problem that led to the re-emergence of HTA as a major concern at PhilHealth was about the incremental and piecemeal additions to PhilHealth health benefits package.

As explained previously, PhilHealth had been established with a mandate to expand its benefits package. Since 1998, its benefits had been under a process of continuous revisions through Circulars approved by the PhilHealth Board. These inclusions have been described as appearing to be 'the product of lobbying, sometimes with the support of professional medical organizations, but occasionally resulting from the private interest of a single congressman or senator' (Obermann *et al.*, 2006, p. 3181).

A similar description could characterise the process in place for coverage decisions at the time of the interviews for this research. Benefit requests could reach the President and Chief Executive Officer (CEO) or other decision-makers (e.g., members of the PhilHealth Board), who then referred the intervention to the Departments responsible with benefit development. However, despite receiving orders for benefits packages from higher hierarchical levels, which were often political appointees, civil servants indicated that some benefit development became delayed within the PhilHealth civil service. This was because any new benefit requires a specific definition, clinical guidelines or pathways, a payment mechanism and implementation by a local PhilHealth office.

> A lobby group will approach somebody, an insider for example, who is part of decision making and that person will approach the President and CEO and then that person will write marginal notes and route that document […] saying it is approved in principle, make a benefit out of that. (I3PH_civil service)

HTA advocates criticised these informal procedures and argued that the expansion in

services was done in an unstructured, irrational manner (I1PH_civil society). The proposed solution was to develop a basic 'guaranteed' benefits package using cost-effectiveness criteria across and within conditions and an associated decision-making process for further inclusions.

More generally, interviewees from within the civil service, as well as academia, suggested that opposing interests were at play when making coverage decisions both at PhilHealth and the DoH. For example, pharmaceutical companies, patient organisations and other civil society groups lobbied for specific additions to PhilHealth benefits or DoH programmes reflecting their particular concerns. These benefits could be targeted at services for which there was unanimous agreement that they should be prioritised (e.g., maternal and child health), but led to fragmented programmes. Other actors questioned whether the services included in benefit packages were appropriate or offered the best value for money, even when they were for priority conditions.

> We have 46 health care programs, we have […] kangaroo mother care, and we have new-born care. They are the same right, and we have infant, and there are three separate programs because there's people lobbying for each of these. We have women's health, and sick motherhood, and family planning, and they are all fragmented, and then we need to give that, run that to 81 provinces, 144 cities, 1,491 municipalities, 42,000 *barangays* and [central government] are not in control of that. They can only recommend to the LGU. The local government unit health care workers are not hired by the Department of Health. So they [central government] can say TB is important but that doesn't mean anything to them [LGUs]. To them that's a suggestion, and we may or may not use it. (I15PH_academia)

Actors with an interest in specific services being reimbursable questioned whether the types of conditions being prioritised were appropriate. For example, outpatient benefits, including primary care, had been discussed by PhilHealth and actors funding vertical programmes (e.g., UNICEF Philippines). A primary care benefit was developed, but its implementation was delayed due to its high budget impact.

In sum, interviewees expressed that PhilHealth benefit expansion did not employ a transparent or rational process. In parallel with benefit expansion at PhilHealth, DoH vertical programmes continued to grow, which was seen as contributing to

fragmentation of care provision and funding. International donors generally were seen as lobbying DoH primarily.

> These funders and donors and advocates target DOH and they say okay, we have this much money and we have a TB program. Of course, DOH always accept that money and tries to integrate into their present set up, but at the frontlines there are very few people who will be able to handle that. So (…) okay we have a schistosomiasis program, it all goes there, but they [frontline workers] have to report to different [programmes], so there's so much paperwork because of this fragmented [setup] - okay I'm going to report to the TB program, the HIV [programme], malaria [programme], all those things. So, they become so overworked that they can't even see patients. That's the kind of system that we have. (I15PH_academia)

A third iteration of the policy problem was linked to insufficient capacity to spend incoming funds. While the idea of scarcity of resources was discussed by interviewees, the more acute problem was the allocation of the available budget, which had significantly increased in early 2010[15]. Both at PhilHealth and at the DoH, incoming budgets for capital investments had been consistently underspent starting 2013. At PhilHealth, interviewees explained low utilisation rates as the result of its Board's reluctance to implement benefit packages with high-budget impact (the most important of which was the primary care benefit) because of a desire to ensure appropriate reserves. Traditionally, PhilHealth leadership had taken a conservative approach prioritised reserves over expanding service coverage (I8Ph_PhilHealth).

> The question always was, how much does the Actuary Department allocate for each benefit, because it's always a question of how much? They [Actuary Department] don't even care about the effectiveness of the interventions, it's always budget. (I7PH_civil service)

A guaranteed benefit package was proposed in 2016 to solve this multi-faceted problem. Its development will be analysed in chapter 7.

In summary, HTA advocates who were civil servants and researchers defined the policy problems HTA could solve in an continuously evolving manner. The initial policy problem focused on investment in medical equipment, only to change when

[15] The source of the incoming revenues was the Sin Tax Law passed in 2012. Most of the funds were earmarked for the NHIP.

PhilHealth officials were met with the more pressing problem of defining reimbursable services. Among these services, medicines were particularly important, and eventually provided the impetus for developing other HTA processes at the DoH. Finally, the fragmented evolution of service coverage in the country led HTA advocates to develop a proposal for a guaranteed benefit package which included include a HTA mechanism.

Chapters 6 and 7 will analyse the organisational structures that developed these HTA processes and how HTA processes were developed for each of these policy problems.

Comparative analysis of the emergence of HTA

Comparing the evolution of HTA as a policy idea in the two countries identified several stages of development in Thailand and the Philippines, during which advocates redefined what they saw as the policy problems that HTA was expected to help solve, while also reconsidering how HTA could provide the solution to these problems.

The development of the ideas about HTA in Thailand and the Philippines shows clear similarities between the policy problems HTA was expected to solve. First, HTA was associated with problems about the investment in expensive medical equipment. Second, HTA was applied to the complex problems raised by coverage of medicines. Lastly, as both countries moved towards UHC, HTA became associated with increasing demands for expansion of publicly funded services. On its surface, the most likely explanation for this uniform pattern of change may be the transfer of the policy idea across borders. As discussed in Chapter 2, the same evolution of HTA was shown at global level: from comparing alternative technologies to comparing services for different conditions, to applying diverse criteria for prioritising health services.

Indeed, HTA advocates in both countries reported links with global health institutions promoting HTA or global HTA experts. However, a closer look at policy problems shows that they were defined in specific ways in each country.

Specifically, HTA advocates re-defined the policy problems with reference to existing or new country institutions. For example, the problems related to innovative medical equipment in Thailand should be understood both in reference to the Social Security Scheme and the UCS reforms and in the context of how these policy reforms changed to procedures for budget allocation. In contrast, in the Philippines, the same problem of overinvestment in innovative medical equipment was defined prior to the establishment of a new payer, PhilHealth. This caused a mismatch between the problem defined in the National Health Insurance Act and the actual problems faced by PhilHealth. The latter were about establishing what routine services were appropriate for reimbursable diagnoses, rather than investment in high-cost medical equipment.

HTA advocates in both countries responded differently to pressures to include new interventions among publicly funded services. In Thailand, HTA advocates decided against the developing a clearly defined benefits package because they saw this as a potential to risk to their health system reform efforts. In contrast, in the Philippines, the idea of a guaranteed benefit package was taken up by HTA advocates while debates about UHC were ongoing. Again, this suggests that in order to understand how HTA became established, the problems it aimed to solve need to be understood in context, where context means existing country institutions related to the policy problem, as well as how these institutions influence the positions of relevant policy actors.

Comparing HTA establishment in the two counties shows an important similarity, specifically the role of civil servants at middle to high levels of the bureaucracy as HTA advocates. In both countries, the main thrust for HTA advocacy across the three stages of establishment came from within the bureaucracy of ministries of health or payers. These actors developed formal and informal links with researchers in national universities and international organisations present in the country. The linkages between national policy actors, specifically civil servants and researchers, and global policy actors – e.g., global HTA experts, members of the international global health bureaucracy -, were key in the emergence of HTA - and of economic evaluations as one of its preferred tools - in each country.

However, the characteristics of the links between these actors that advocated for HTA were specific to each country. In Thailand, HTA advocates were part of an established network of civil servants, academics and members of civil society, the RDS. This network had a longstanding involvement in a movement for health system reforms that included consistent support for the development of health system and policy research. In the Philippines, a network of advocates that were civil servants and researchers developed around the idea of HTA. This network was formed around HTA advocacy, as opposed to the idea being taken up by an existing network, as was the case of Thailand.

Identifying the HTA advocates, as well as the policy problems for which they advocated HTA was a solution is the first step in analysing the establishment of HTA organisation and processes. Subsequent chapters will explain how these problems were taken up by HTA bodies (chapter 6) and whether and how HTA processes associated with these problems were established (chapter 7).

6. Creating HTA organisations in Thailand and the Philippines

Having previously analysed the role of actors and ideas in establishing HTA, the following chapter analyses the organisations that were created to coordinate HTA. Institutionalising HTA processes often means establishing: a) a new organisation within a country's health system governance; and b) processes of decision-making, typically consisting of procedures for evidence generation and appraisal, as well as procedures for participation and consultation in decision-making, in compliance with ethical principles of fairness. Yet a HTA process might be established that does not bring about the creation of a new organisation; likewise, a new organisation might be created that subsequently moves away from using HTA. The following two chapters will examine these two aspects of HTA design – the organisation and the processes – separately. In this chapter, the organisations mandated with HTA will be analysed in terms of whether and why new bodies were established, and why particular organisations – and not others – were put in charge with coordinating HTA.

The creation of an organisational structure also interacts with established arrangements of health system governance[16], and is in turn influenced by these arrangements. Existing approaches to health system governance to some extent determine which policy problems are most relevant to be addressed by HTA or how existing decision-making processes might be amenable to include HTA procedures. For example, health system reforms towards universal health coverage, which increasingly occupy health policy debates in middle-income countries such as Thailand and the Philippines, were likely to cause changes to the configuration of reimbursable services and the purchasing of these health services, to which HTA is often applied. Such reforms might also influence the use of HTA by focusing

[16] Health system governance is used here in its meaning of governance of the health system (Kickbusch and Gleicher, 2012) and refers to a set of state/government institutions that constrain state and non-state actors' behaviours and interactions (Pyone, Smith and van den Broek, 2017).

attention on specific policy goals, such as the efficiency, equity or the quality of service provision in each country.

The chapter consists of an analysis of HTA organisational design in Thailand and the Philippines as defined above, followed by a section comparing both countries. Two aspects of creating HTA organisations will be examined specifically: 1) the governance arrangements relevant to HTA, as they relate to health system reform; 2) the creation of organisations coordinating HTA.

Establishing HTA organisations in Thailand

As outlined in Chapter 5, HTA was established in Thailand as part of a process that spanned over three decades and that still continued as of 2016. As can be expected, major shifts in health system governance have taken place during these decades, including substantial health system reforms in 1990 and 2000. Major political events, including three military coups in 1991, 2006 and 2014 and a severe financial crisis in 1997, also changed the country's political and economic outlook significantly.

This section consists of an in-depth analysis of the creation of organisations mandated with coordinating HTA, which is explained in the context of major changes to health systems governance that are relevant for the development of HTA.

Organisational design for HTA

Interviewees linked the establishment of both organisations with the work done to support HTA by the HSRI, which they identified as central in the development of HTA. The role of the HSRI and its link with the RDS in promoting HTA in Thailand was examined in Chapter 5. In short, the HSRI leadership strongly supported the idea of HTA and used its role as a research funder to finance HTA-related projects. Between 1992 and 1999, the HSRI's support for HTA included both national and regional/international activities. As part of this support, the HSRI established a technical committee and associated research and development programme on HTA in Thailand. The HTA committee or working group considered the options for both the organisational design and the processes of using HTA. Specifically, the committee considered two options for establishing an HTA organisation.

The *first* option for establishing HTA was identifying any existing organisations with similar responsibilities and either widen their mandate to include HTA or create an HTA unit within these organisations. The Food and Drug Administration's Office of Medical Devices was discussed as an obvious choice, given its role in regulating market access for medical equipment. However, actors suggested that the HTA mechanism would require the generation of evidence on effectiveness and cost-effectiveness, and could not rely solely on international evidence of safety and efficacy, necessary for market authorisation. Committee members also believed that the organisation should take a broader perspective on HTA that encompassed pharmaceuticals and other technologies, and not just medical devices (Tomson and Sundbom, 1999b).

The *second* option discussed by committee members was to establish a new independent body for HTA, for which they considered the model of agencies created in other countries that generated and compiled HTA-related evidence and/or had a regulatory role. The TASSIT project, as a Thai-Swedish partnership, enabled direct learning from the Swedish Council on Technology Assessment (SBU), established as a Swedish government agency in 1992. The Director of the SBU at the time, Egon Jonsson, who was an early advocate for HTA globally, was commissioned, together with Dr Monchai Chalaprawat, professor at Chulalungkorn University, to develop a proposal for an independent national HTA body. Prepared in 1997, their report proposed the establishment of an independent 'national council, committee or board' on HTA, composed of various actors relevant for the governance of medical technology, but excluding manufacturers due to their vested interest in HTA. The council would be mandated with 'providing scientific facts and conclusions about the appropriate diffusions and use of health care technology in Thailand' (Tomson and Sundbom, 1999a, p. 17). The proposal detailed what kind of evidence this council would use, specifically reviews of the published literature on safety and efficacy, research on cost-effectiveness for selected medical equipment and evidence on the existing diffusion and use of technology in the country. There was an understanding that it was important to ensure a degree of independence between the council and the MoPH, but that government funds could be used to set up the organisation.

> It was elaborated [by a MoPH representative] that a national mechanism could be created by some fund partly financed by the government, since it would seem possible for the government to support a non-profit organization dealing with HTA (Tomson and Sundbom, 1999a, p. 10).

However, the proposal for a Thailand Council on Technology Assessment was never implemented. Studies suggest that this was due to a lack of human resources at HSRI. In particular, the HSRI committee lacked full-time staff and functioned as a 'a loose network of academics interested in HTA' that were only 'meeting part-time' (Teerawattananon *et al.*, 2009, p. 244). It was also suggested that the proposal was not implemented due to a lack of infrastructure for 'health economics appraisal,' (i.e., decision-making based on economic evaluation). These factors led to a failure to scale up TASSIT activities, including the council, as financing ended at the end of the 1990s (Tantivess, Teerawattananon and Mills, 2009, p. 934). In addition, as one civil servant suggested, the lack of follow-up of TASSIT proposals may have also been caused by insufficient ownership of the project, which was seen in Thailand as a Swedish initiative (I10TH_civil service).

However, the strong previous support for HTA from the HSRI, mentioned by several interviewees, makes these assertions puzzling. In fact, the TASSIT programme was an ambitious project in this respect (Culyer, Podhisita and Santatiwongchai, 2016). In 1999, a TASSIT project report described the establishment of a Working Committee on Thai-Swedish Co-operation[17] that included HTA activities (Tomson and Sundbom, 1999a). Further, in February 1999, three civil servants visited the SBU offices in Sweden, and plans were made to organise a similar study tour during 2000/2001, at the suggestion of the Swedish partners. These civil servants were affiliated with the MoPH's DMS, specifically its Bureau of Medical Technical (Technological) Development. In 2002, one of these civil servants became the Director of the newly established HTA unit (later named IMRTA), in the same Department. It is notable that the individuals who participated to the study visit were also involved in the first attempt to establish a body mandated with HTA in Thailand. However, interviews did not identify a direct link between the

[17] As part of the MoPH Committee on International Health Cooperation.

establishment of this unit and the activities of TASSIT, while indicating a link between HSRI support and the establishment of IMRTA (I8TH_civil service).

Another explanation for the lack of continuity of TASSIT proposals could be that a change in leadership at HSRI led to a change in priorities. Indeed, starting in 1998, the strategy of HSRI and its activities supporting HTA changed in focus. The new HSRI leadership supported a slightly different understanding of HTA that focused on standard setting and efficiency of technology use in tertiary hospitals, particularly through accreditation mechanisms, rather than on the broader activities first outlined by the committee. HSRI pursued this focus by establishing a collaboration between HSRI, the DMS at the MoPH and major private and public hospitals. This collaboration was established as part of a project on hospital quality improvement and accreditation[18] (Poolsukh, 2002). Notably, the civil servants who would later establish IMRTA also collaborated with the HSRI during this quality improvement project (I23TH_civil service).

Beyond its strategy to support HTA, the HSRI, alongside the RDS, had a strategy of financially supporting the establishment of a series of organisations within the Thai health system governance structure. The RDS were known to pursue policy change through creating new organisations that became part of health system governance, but were independent from the existing bureaucracy.

> We have four principal organisations. I don't think we can afford to have the fifth, the sixth, the seventh, but we have some significant things to do, some specialised things to do like technology assessment. So instead of creating a new organisation that needs national legislation, it's easier to branch out from the principal ones. (I19TH_civil society)

Many of these organisations were initially supported by funding from the HSRI and were known as the 'networks of HSRI' (I8TH_civil service) or 'daughter institutes' (I10TH_civil service). Particularly after 1998, HSRI supported the establishment of small projects with technical or research purposes (e.g. accreditation, health information systems, health financing reform, ethics in human research) within the

[18] Between 1997-2001, 35 hospitals joined the programme voluntarily, with 7 hospitals undertaking accreditation by the end of 2000.

existing administration or under the HSRI. Civil servants and members of the Rural Doctors Society (or mentees of the RDS) were put in charge of small research or technical programmes focusing on the priorities of the HSRI Director General and/or Board.

These small projects were funded by the HSRI initially, but were encouraged to pursue independence from both HSRI and their line managers in the MoPH. This resulted in some organisations becoming independent such as the Institute of Healthcare Accreditation, a public organisation, and the Health Insurance System Research Office, which is currently an independent public organisation. The organisations that became independent did so through three main legislative pathways: a special act regulating a wider policy (e.g. the Health Insurance System Research Office, through the National Health Insurance Act that set up the UCS) or a royal decree under the Public Agency and Institute Act (e.g., the HSRI, the Health Accreditation Institute) (I10TH_civil service). However, there are also examples of failure to achieve independence from the administration as some of these research programmes stayed dependent of HSRI funding or remained strictly under the auspices of the MoPH (I8TH_civil service).

Interviewees understood the establishment of IMRTA as part of this wider strategy of establishing organisations that should aim to become independent. IMRTA was established in 2002 with the support of the Deputy Director of the DMS at the time, who also supported the idea that this unit should eventually become independent (I21TH_MoPH). The HTA unit was to work in collaboration with a hospital accreditation institute, which was an idea that was developed in discussions among the contributors to TASSIT. To this end, the unit was expected to generate evidence on the effectiveness of medical technologies and encourage hospitals under its administration to conduct more research that would then influence clinical practice. Over time, this unit expanded its remit to include the development of clinical practice guidelines or standard treatment guidelines, in addition to assessing the effectiveness (less frequently, the cost-effectiveness) of new technologies to be adopted as standard of care in tertiary hospitals.

However, interviewees described IMRTA as a less successful example of the organisational design strategy of the HSRI, particularly with regards to its independence from the MoPH. The HTA unit remained closely embedded within the Department of Medical Services (as it became an institute in the Department in 2007).

> We tried, as HSRI, tried to invest in many people, to try to establish a unit to work as Dr Yot [the director of HITAP] is at this moment. But, it failed. For example, HSRI used to invest in a number of people in the Department of Medical Services, and tried to support them to do HTA in general, but […] the mission was not a success. (I8TH_civil service)

Reasons given for the lack of success were the level of commitment of its staff, lack of support from the management of the DMS, IMRTA's embeddedness in the bureaucracy, therefore its lack of autonomy, as well as the novelty of HTA in the country (I8TH_civil service, I21TH_civil service). Some scholars suggested that IMRTA did not have sufficient capacity and funding to conduct research or to influence decision-making on investment in medical technology (Teerawattananon *et al.*, 2009; Culyer, Podhisita and Santatiwongchai, 2016). These accounts are contradicted by the fact that the unit was strengthened in 2007, when it became an institute under the DMS. However, the Department was also the centre of debates on budget allocation for specialised care during the UCS design. In general, as part of a government ministry, the DMS, as other MoPH departments, was highly centralised and exposed to government politics, e.g. when recruiting its Director General, especially during the phase when the UCS was planned. When the new UCS governance structure was established in 2005, the reformist bureaucrats had won the argument at the cost of the officials who favoured more conservative approaches (I10TH_MoPH). However, the latter maintained leadership within the DMS after the establishment of the NHSO.

The establishment of HITAP in 2006 was also linked to the HSRI and informed by its approach to influence policy through building organisational networks, although it developed in a different way. The network strategy of the HSRI was adapted in the face of belief by some actors that it might not be effective in leading to independence. However, the goal of establishing organisations for specialised tasks

was maintained as worthy among reformists. As such, the development of HITAP followed an adjusted path, but still inspired by the HSRI's strategy for organisational creation, as outlined above.

Specifically, HTAP's establishment grew out of the IHPP, created in 2002. The IHPP originated from the work of the Thailand Research Fund's Senior Researcher Scholar programme in health economics and financing, that had produced studies to inform plans for health system reform at the beginning of the 2000s. The main contributions of the programme were: 'cost studies, the estimation of budget requirements for the universal coverage scheme in its implementation phase and a manual for analysis of hospital financial status and performance' (Pitayarangsarit and Tangcharoensathien, 2009, p. 72). IHPP also produced a number of influential economic evaluations (e.g., national programme to prevent mother-to-child HIV transmission, use of micronutrient supplements in HIV treatment, proton radiation therapy) (Tantivess, Teerawattananon and Mills, 2009).

In 2001, the IHPP was established via a formal agreement in the form of a memorandum of understanding (MoU) between the HSRI and the MoPH, specifically its Bureau of Policy and Strategy, under the Office of the Permanent Secretary.

> The IHPP is not the daughter institute, no, because it was established based on the MoU [Memorandum of Understanding]. The daughter institutes were established based on Health System Research Institute's own creation, not partnership with any organisation. It is their internal creation. And, they are in an interim process; the Health System Research Institute expected that these agencies would soon be independent; that they would move out of the Health System Research Institute to either having their own Royal Decree or law to establish an independent institute, or spin out into a private foundation. (I10TH_civil service)

Interviewees mentioned discussions between the signatories of the initial Memorandum on whether IHPP should stay within the MoPH or sever its ties completely, to achieve the independence preferred by the HSRI. A compromise was reached in the form of a status of 'semi-autonomy' (I10TH_civil service; I12TH_civil service) that meant that the IHPP remained under the authority of the MoPH, with one of its administrators being a civil servant employed by this office.

In addition, a foundation attached to the IHPP was established, the International Health Programme Foundation (IHPF), which allowed IHPP flexibility as to its sources of funding and use of these funds. Through its foundation, IHPP could receive funding from organisations other than government sources, including from international organisation (Pitayarangsarit and Tangcharoensathien, 2009). This resulted in the IHPP having both strong links with government and a degree of independence, though its 'foundation' status.

> Of course, through personal contact, and through […] civil servant status, it is linked to the Ministry of Health. […] So, IHPP has two hats. One hat, it's like a programme, a group, research group, within Bureau of Health Policy and Strategy. The other hat is an NGO, the IHPF, the foundation. (I10TH_civil service)

HITAP was established due to the growing interest in generating economic evaluation among leadership and staff at IHPP. In the first instance, two IHPP researchers undertook PhD research on the use of cost-effectiveness analysis in the development of HIV/AIDS policy (Tantivess, 2006), and the feasibility of using economic evaluation in reimbursement decisions relating to health services in Thailand (Teerawattananon, 2006). This was followed by the two researchers being asked to develop a proposal for a research programme in economic evaluation of health services, initially, which was later broadened to include HTA.

Initially, IHPP sought international funding for this proposal, which was unsuccessful. Eventually, the ThaiHealth made the equivalent of US$1 million (or 30 million Baht) available the proposed programme over three years. HITAP would later secure a second tranche of funding from the same organisation, the maximum time that ThaiHealth can support one programme. According to one academic, the connection of IHPP with senior civil servants and politicians, and the RDS, secured its financial support.

> Some technocrats in the Ministry of Public Health sold this idea about establishing HITAP in the country, and many of their partners thought, oh, it's a good thing; it's a good start, to have some organisations like HITAP, just to conduct or generate the evidence to support policy decision-making, especially in this area: first, economic evaluation, and then, broader, HTA. Yes, they thought that this was quite important to start in Thailand. So, they had a small group, like a dinner meeting, together with a big boss, with big

> people, big policy-makers, and they talked, and they said, okay, we should find some funds to support HITAP. And, yes, they got funds from ThaiHealth. (I6TH_academia)

In turn, the IHPP organisational model influenced the establishment of HITAP. One interviewee referred to IHPP as HITAP's 'mother organisation' (I4TH_civil service). The directors of both programmes were civil servants accountable to the Bureau of Policy and Strategy, which meant that both organisations reported to the same part of the Ministry of Public Health. As IHPP had done, HITAP created an associated foundation to provide it with more financial flexibility by being able to attract funding from other national and international sources of funding, reducing its dependence on government sources such as ThaiHealth and the HSRI.

Both IHPP and HITAP were therefore only loosely connected with the Ministry of Public Health. HITAP has remained a semi-autonomous research organisation within the MoPH, despite formally still being part of the MoPH. However, reflecting the idiosyncrasy of the two programmes in the Thai health system governance structures, the semi-autonomous status is defined by practice, not by formal rules.

> When they have - like a MoPH structure, they have six departments, they have this dependent organisation, ... and then suddenly they have included IHPP and HITAP. I don't know why. And after that, people never questioned it and then they continued that. So it became - I don't know how or when - it became official. (I4TH_civil service)

However, maintaining independence from the MoPH was an aim from the start of HITAP, unlike in the case of IHPP. As HITAP grew, its leadership showed a desire to secure its independence and to clearly define its status within the Thai structure of health system governance. In 2015, the HITAP leadership advocated for and drafted a bill that would have made HITAP an autonomous public organisation. However, this initiative was unsuccessful, because after the military coup of 2014, the Cabinet (i.e. the executive) had begun to reign in the creation of new public organisations and increased the supervision of existing ones[19].

[19] The Thai Health Promotion Foundation, the major initial funder of HITAP, was a prominent target of this movement, branded as anti-corruption.

> Public organisations are quite independent, still under the Ministry but not just small programmes like this [HITAP]. But it [establishing HTA as a public organisation] failed because the government tried to freeze the number of public organisations. This is not only HITAP, but many organisations under other ministries as well that tried to become public organisation. (I1TH_civil service)

The development of the processes of using HTA established under the coordination of HITAP will be analysed in chapter 7.

Summary

This section examined the establishment of two organisations mandated with HTA in Thailand, IMRTA and HITAP. Each of these two organisations has a distinct focus, with IMRTA concerned with improving clinical effectiveness and clinical practice in tertiary hospitals and HITAP focusing on economic evaluation for coverage decisions of the UCS.

The difference in focus reflected changes in the understanding of the idea, starting from a broad conceptualisation of HTA that included prioritisation of medical technologies and standard setting in tertiary hospitals, and clinical practice guidelines and pharmacoeconomics. The creation of IMRTA was guided by an interest in using HTA to developed standards of care for specialised services, which were likely to require expensive investments in medical technology. In contrast, HITAP was established with a focus on developing the prominence of economic evaluation to inform coverage of health services.

These two organisations emerged from discussions among key advocates for HTA who considered the options for establishing an HTA organisation, convened with support from the HSRI. The preferred option, inspired by the SBU, was to create an independent body that would assess medical equipment needs for the entire health system and individual technologies, when necessary. However, as this was not immediately feasible, an incremental approach was chosen, with small programmes established within existing bureaucratic structures initially, using government funding and civil servant support, but with a view of achieving independence at a later stage. The HSRI financially supported this strategy, which resulted in the

IMRTA being established as part of the MoPH/DMS. The establishment of HITAP and its mother organisation, IHPP, also aimed for autonomy, but this time, initiators were able to use an opportunity to place the new programme outside of the MoPH. This resulted in HITAP being seen 'semi-autonomous': overseen by the MoPH but with a substantial degree of autonomy.

Organisational design for HTA must be explained in the context of a wider understanding of organisational design in the country's health governance. In Thailand, organisational design strategies included:

- Health reformists' and HSRIs' organisational design strategy of establishing independent bodies through incremental steps.
- The interest of high-level civil servants who had alliances with the RDS and the HSRI.
- The use of the legal framework that guided organisational creation: the use of Royal Decrees or special legislation.
- Wider politics of the executive that supported or sought to limit the creation of independent bodies.

Establishing HTA organisations in the Philippines

As outlined in Chapter 5, the establishment of HTA in the Philippines started in the early 1990s and was ongoing as of 2016. During this time, the Philippine health system underwent major changes: devolution of health service provision from central to local governments (in 1992), the establishment of a social health insurance programme (1995), major efforts for expansion of coverage (early 2000s), medicines pricing regulations (late 2000s), as well as accelerated moves towards universal coverage (since 2010). New health policy programmes and changing priorities for health system reform can be identified with each change in government. For example, Gloria Arroyo, Philippine President between 2001 and 2010, focused on reducing prices for, and improving access to, essential medicines, as well as increasing membership to the country's social insurance programme. Her successor, Benigno Aquino, President from 2010 to 2016 led major reforms towards UHC, which included increased financing and coverage of the country's NHIP, major

improvements in health facilities infrastructure, as well as increased efforts to achieve the health-related Millennium Development Goals.

The following section will analyse development of HTA organisations in the Philippines in the context of changes to health system governance that were relevant for HTA development.

Organisational design for HTA

As of 2016, several government bodies, either under the DoH or under PhilHealth, were coordinating HTA-associated tasks. NCPAM, under the DoH, provided the secretariat of a Philippine National Drug Formulary System, which used HTA principles in making decisions on inclusions to the country's National Formulary – or PNDF-, acting as an essential medicines list and a reimbursement list for PhilHealth[20]. At PhilHealth, the Department of Health Benefit Development used HTA principles in the design of some of its benefits packages and supported the development of a priority-setting project using HTA principles as part of a proposal for an overhaul of its benefit development system. However, as of 2016, there were no organisations in the Philippine health system governance that were solely charged with HTA, despite the fact that proposals for the establishment of such an organisation were gaining ground.

The history of HTA in the country (1994-ongoing) shows that there were multiple attempts to establish organisations to coordinate HTA. The first such attempt could be traced back to 1994. At that time, a number of researchers and civil servants became increasingly interested in HTA as an important tool to inform investment decisions on medical technologies, particularly in the context of the announced establishment of the NHIP. These early advocates entertained two main options for

[20] However, PhilHealth was bundling payment for medicines as part of its case rates.

HTA organisational design: a) the establishment an independent body mandated with HTA; and b) the inclusion of HTA within the mandate of larger organisations.

The *first option* was proposed during the negotiations for the country's National Health Insurance Act of 1995. Specifically, a proposal that an independent, public-private council be established and charged with HTA was included in one of the drafts of the bill. This council, tentatively named the Provider Practice and Payment Commission (PPPC), would be tasked to advise the newly established payer on innovative medical equipment for which the new NHIP should pay (Picazo, 1995).

This proposal emerged from a USAID-financed project[21] commissioned to inform the creation of the NHIP. Picazo (1995) analysed existing options for advising on appropriate diffusion and use of medical equipment by considering the models of organisations in charge with HTA internationally. For example, the model of the Office for Health Technology Assessment of the USA Congress suggested that the Philippines Congress could take over some oversight of a potential HTA process. The researchers dismissed this model as 'dangerous, given the Legislature's penchant to politicize' (Picazo, 1995: 52). An executive branch model, also stemming from the USA[22], was dismissed for the same reasons. The author suggested that the government should not be the sole owner of a HTA body. Preferable alternatives were independent 'professional/trade associations; academic/research entities; or consortia' (Picazo, 1995: 52). In line with this last preference, the proposal made for inclusion in the National Health Insurance Act outlined that the HTA council would be a public-private partnership. However, this first specific organisational design proposal did not receive sufficient support. Providers successfully argued that, in order to identify appropriate medical devices for reimbursement, it was sufficient to have providers (physicians and hospitals) represented in the PhilHealth Board. HTA advocates rightly identified this point of view as a conflict of interest (Picazo, 1995).

[21] A series of research studies produced as part of the Baseline Studies for Health Care Financing Reforms project.

[22] After the model of the Agency for Health Care Policy and Research, which is under the US Department of Health and Human Services. The Agency receives government funding for health services research and has specialised in measuring and improving quality of care.

As a compromise, the initial proposal was replaced by a more generic reference that health technology assessment should be included under the quality assurance programme of the NHIP. In other words, the *second option* for organisational design was eventually used, by embedding HTA-related functions in PhilHealth. Specifically, HTA was taken up by the Department of Quality Assurance as part of its responsibilities to develop policies for health service delivery and reimbursement. The Vice-President (VP) for Quality Assurance established a HTA committee to guide the Department in the development of such policies. Other activities of the Quality Assurance department were: the development of accreditation procedures for PhilHealth providers; management and analysis of PhilHealth data (on burden of disease, disease classification, as well as data on utilisation and performance review); and complaints and/or other technical issues regarding claims. At the time, the Department was also running a Peer Review committee that would convene expert clinicians to make decisions on disputes on claims reimbursement. As such, the HTA committee was only one of the two committees charged with supporting the activities of the department and was directly linked with the department.

According to key-informants, the HTA committee was established because the VP for Quality Assurance, Madeleine Valera, was a strong supporter of HTA. However, the HTA committee did not receive equal backing from higher levels in the PhilHealth governance, such as the Board of Directors or the PhilHealth President and CEO. Consequently, its role in the PhilHealth governance were determined by the limits of the Quality Assurance Department's mandate and the influence of the VP for Quality Assurance in the organisations.

> [I]t was seen within PhilHealth as just a specific function of her office [the Quality Assurance Office]. That means you still have the prove to everybody else within the organisation that your decision is right. Just like in any other office. So it never had, I don't think, sort of legitimacy that this is a corporation output, or the legitimacy that this is a health system output. So that was the problem. […] Had it been higher, not at the office of [Quality assurance]. Let's say it was made a committee reporting to the Board - different start. (I9PH_PhilHealth)

In other words, HTA activities were embedded in the structures of PhilHealth. This implied being removed from decision-making happening at the level of the President

and of the Board (I4PH_civil service). Consequently, the activities of the HTA committee were easily curtailed in 2006, and completely stopped once the VP for Quality Assurance was replaced and left the organisation, in 2009. The development of the procedures associated with the work of this committee, as well as what led to its discontinuation, will be explained in chapter 7, on process design.

In sum, this first attempt to establish HTA within the structures of PhilHealth had three characteristics. First, it was linked to major legislation (the National Health Insurance Act of 1995) that directly mandated the use of HTA. Second, HTA was attached to the mandate of a larger organisation within health system governance. Third, organisational design was dependent on the authority and resources of civil servants, as well as the limits imposed to the freedom of civil servants by other institutional rules within the larger organisation. These three characteristics are representative of the subsequent development of organisations charged with HTA, as will be shown below.

A subsequent episode of HTA design, the development of HTA procedures for determining inclusions in the country's National Formulary, was also preceded by a major legislative episode: the passing of the Universally Accessible, Cheaper and Quality Medicines Act of 2008 (also known as the Cheaper Medicines Act of 2008). The Act was a complex and controversial piece of legislation. In particular, the imposition of maximum retail prices for selected medicines drew strong criticism towards the Philippine government, nationally and internationally. Between 2008-2010 its implementation was led by the Secretary of Health, with support of an ad-hoc group at DoH and an Advisory Council including industry and civil society.

In 2010, the Secretary of Health created a new body charged with the implementation of the new law, the NCPAM. NCPAM's mandate included managing medicines access programme established during the negotiations for the Cheaper Medicines Act, strengthening efforts for rational use of medicines (encouraging generics prescribing and utilisation) and the coordination of decision-making processes for the National Formulary, as well as the Advisory Council, which became permanent. NCPAM coordinated the development of a HTA process as part of its responsibility to strengthen the procedures of the National Formulary

(or PNDF). In 2012, it drafted new regulations for medicines selection to the PNDF that included cost-effectiveness as a criterion. As had been the case at the PhilHealth, the development of this process was coordinated and supported by middle- and high-level civil servants (the NCPAM Director and an Assistant Secretary of Health[23], respectively). The procedural changes associated with this episode will be analysed in chapter 7, on the use of HTA for inclusions in the National Formulary.

After 2010, the incoming administration of President Aquino took up wide policy reforms towards universal health coverage, which were supported by a series of key legislative proposals[24]. In 2013, Congress passed a revision of the NHIP Act of 1995, which had been particularly relevant for HTA establishment. The new act contained a re-definition of the usefulness of HTA[25] by moving away from standards of care and indicating that cost-effectiveness should be the basis of benefit expansion. As was the case in 1995, legislation did not indicate any direct organisational design aspects around HTA. It did, however, indicate that both the DoH and PhilHealth would be entitled to make coverage decisions for health services based on their cost-effectiveness. As such, the Act indirectly created a mandate for HTA both within the DoH and PhilHealth.

During 2013-2016, the design of HTA continued the pattern of attaching HTA processes to existing organisations. In the case of DoH, NCPAM continued an ongoing development of HTA principles and associated procedures for the National Formulary, while also administering its other tasks. At PhilHealth, civil servants that had supported the now defunct HTA committee used HTA principles for the

[23] And former VP for Quality Assurance at PhilHealth during 1999-2009.

[24] These bills referred to a so-called Sin Tax Law, a Reproductive Health bill, a revision of the National Health Insurance Act of 1995 and an Act strengthening of the Bureau of Food and Drug Administration.

[25] The 2004 revision of the 1995 Act did not bring about changes with regards to HTA. However, it indicated that 'The Corporation shall assess the advantage and appropriateness of health technology consistent with actual needs and current standards of medical practice and ethics and with national health objectives. In this regard, the Corporation may require specific types of health care providers to upgrade their facilities, equipment and manpower complement as a prerequisite to accreditation.' In other words, the problem was under-diffusion of health technologies and/or lack of compliance with accreditation requirements.

development of selected benefits packages. For example, the NCPAM and PhilHealth collaborated in the design and implementation of a primary care benefits package including outpatient medicines[26] and a benefits package for catastrophic conditions - z-benefit- developed with technical assistance from NICE International. In addition, consistent support for the revival of HTA from among the civil service at PhilHealth, alongside increasing demands on benefit development, led to an initiative of a priority-setting process for all benefit development work. The process built on the existing departments/functions of PhilHealth and attached them to HTA-related responsibilities. Two existing departments, i.e., the Departments of Benefits Development and Department of the Actuary, would design benefits according to recommendations of an appraisal committee responding to the Board. The details of the design of this process will be analysed in Chapter 7, on process design.

Organisational design of HTA through adding on HTA functions to the mandates of existing bodies matters because existing rules and practices of the organisations interact with decisions made through HTA processes. For example, the HTA committee within PhilHealth was simply stopped once the PhilHealth Executive Committee and Board decided to discontinue the honorary payment of the HTA committee members, once the Committee also lost the support of the PhilHealth President and CEO and the VP overseeing the Quality Assurance Group, a supporter of HTA, left the organisation. At the DoH, NCAPM had their direct accountability lines changed several times, based on decisions by the Secretary of Health. As a policy body, the NCPAM should have been placed in the Health Policy and System Development Team. However, as it managed procurement of medicines for managed access programs, NCPAM was moved under the direct supervision of the Secretary of Health, and later under the Office of Health Regulation (a step removed from the Secretary of Health). Finally, in 2016, the NCPAM was downgraded to a policy body, renamed the Pharmaceutical Division, and placed under the DoH Health Policy and Planning Bureau for a short time. After a change in administration, the

[26] Two versions of the primary care benefits package were designed (2012, 2015). The expanded benefits package (2015) had its implementation halted. Most accounts suggest this was due to its budget impact once it included medicines for non-communicable disease (i.e., hypertension, diabetes, ischaemic heart disease).

body remained under the Office of Health Regulations. These changes will be further explained in Chapter 7, in relation to the HTA processes NCPAM was coordinating.

With both DoH and PhilHealth housing HTA activities, the question of what would be the best or most appropriate placement for HTA began to gain ground. The option of establishing an independent organisation to coordinate HTA became increasingly salient. Table 6.1 outlines the options for organisational design that advocates were considering in 2016. Establishing an independent body for HTA was by far the preferred option among HTA advocates. There were a series of interim solutions that HTA advocates believe would help organisational design for HTA move towards the target of an independent body. For example, actors who supported the design of the priority-setting process for PhilHealth benefit development treated it as a prototype, expressing different plans for HTA in the short term and in the medium and long term. Thus, while it was acceptable for a HTA process to be housed at PhilHealth in the short-term, it was indicated that it would be preferable to move all HTA activities under the coordination of the DoH in the long term (I7PH_academia; I12PH_civil service).

Another proposal was that the DoH would create a mirror committee to the one charged with decision-making for the National Formulary. The newly created committee would be tasked with decision-making on health benefits and would follow the existing procedures used by the National Formulary Committee. However, moving benefit decision-making at DoH would have entailed that PhilHealth is stripped of its decision-making power on benefits development. Thus, debates around the organisational design of HTA in 2016 should be understood in the context of ongoing purchasing reform plans. Actors who supported strategic purchasing reforms believed that there was no circumstance in which HTA should be carried out at PhilHealth, and that it was the remit of the DoH. The underlying meaning here is not so much that a payer should not make decisions based on HTA, but that DoH should not be involved in purchasing services. In fact, in order to effectively use its strategic purchasing power, PhilHealth would have to be present or inform negotiations and decisions taken during any HTA process.

> Okay, this is my position. That should not be PhilHealth, but the process, let's just make PhilHealth do it, then in the next administration, we'll tell the Minister of Health to say it should be done for the whole … for everything. Not just what PhilHealth pays for. (I12_civil service)

Even among the supporters of HTA, there were different points of view with regards to the best placement of HTA within health governance. The preferred options depended on the informant's main interest. Actors whose main advocacy referred to HTA supported the use of the tool either at PhilHealth or the DoH. However, PhilHealth housing HTA for benefit development also had its supporters, including those that were against stripping PhilHealth of its power to make coverage decisions. Actors whose main interest was the establishment of strategic purchasing by PhilHealth advocated for: a) an independent council or several HTA committees housed by the DoH; and b) a clearer split between functions of the DoH and PhilHealth – the DOH would become responsible for quality assurance, accreditation and benefit development and PhilHealth would manage contracts with providers and strategic purchasing (negotiating payments, pooled procurement).

> If we realign our roles and DOH views PhilHealth as its purchaser, then we have to work very closely with them and they have to understand that in a way they have to give up some of their powers and listen to DoH. But if the new Secretary of Health feels like we'll just do the public health part, let them do whatever they want, and then it's a totally different thing even if I insist on certain things with them I wouldn't get the buy-in. (I8PH_civil service)

The further development of HTA was seen as dependant of the outcomes of these debates on DoH and PhilHealth roles. The 2018 UHC Bill, signed into law in 2019, established a new configuration of health system governance and prominently mandated the establishment of a HTA advisory body. Unlike the National Health Insurance Act of 1995 which failed to specify details on organisational design, the final version of the UHC Act states that the HTA Council should be housed by the DOH, as per the preference of HTA advocates. Further, it states that the HTA Council must transition in a separate entity of the DoH within five years of its effective operation. The Act envisions that the Council would be attached to the Department of Science and Technology instead, which would also provide training grants for policy systems experts. These are all design details that are reminiscent of the Thai model (Republic Act 11223 of 2018, approved Feb 2019). The links

between HTA advocates in the Philippines and HITAP and NICE International will be explained in Chapters 7 and 8.

Table 6.1. Design as a process of 'placement' and of development of an appropriate organisational form (June 2016-March 2019). Source: interviews & document review.

Date	Options for organisational design	Policy basis	Placement
June 2016	HTA for medicines – DOH HTA for benefits - PhilHealth	Generics Act of 1988 Cheaper Medicines Act of 2008 – indirectly Board Resolution 2016 - directly	Department of Health PhilHealth
June 2016	Parallel HTA committees at DoH (essential medicines; benefits)	N/A	DoH – Health Policy Development and Planning Bureau (HPPD), and/or Office of Health Regulations
Sept 2017	National HTA Program – expands PNDF guidelines to services beyond medicines.	Draft DoH administrative order (Sept 2017)	DoH - HPDD
Sept 2017	HTA Council	UHC Bill Draft	Coordinated by PHIC
March 2019	HTA Unit	UHC Act 2019	Independent, secretariat by an HTA office under the HPDD

Summary

This section has analysed the nature of organisational design for HTA in the Philippines, between 1994-2016. During this time, several existing organisations coordinated HTA processes. These processes had a varied focus: a) the development of quality standards and reimbursement policies (at PhilHealth); b) coverage

decisions on essential medicines (at the DoH); and c) coverage decisions and priority-setting for health benefits package development (at PhilHealth). Despite this, there were no organisations solely mandated with HTA in the country until the UHC Act of 2019 mandated the creation of a HTA Council linked the structures of the DoH, but with a mandate to become independent in five years since its establishment. The change in focus is associated with changes to the idea of HTA, but also with changes to health governance structures.

Advocates for HTA applied a strategy for organisational design that had three facets. *First,* it linked HTA establishment with major legislative episode. As a consequence, there is a legal mandate for HTA in the Philippines starting with the National Health Insurance Act of 1995. This legal mandate has been consistently updated with all subsequent revisions of the National Health Insurance Program (in 2004, 2013 and 2018). An exception was the Cheaper Medicines Act of 2008, which did not make direct reference to HTA. However, it mandated a strengthening of National Formulary decision-making. *Second*, except for 2019, organisational design details were not specified in legislation. In consequence, HTA activities were attached to existing governance structures, specifically: the Quality Assurance Department of PhilHealth, the NCPAM at DoH, and the Departments of Benefits Development and of the Actuary, at PhilHealth. *Third*, the establishment and development of associated HTA processes were substantially influenced by the institutional power and its limits exercised by middle- and high-level civil servants who were HTA advocates.

An alternative organisational design option, that of establishing a body solely mandated with HTA, was considered by advocates as early as 1994. However, despite the existence of legal mandates, no such organisations had been established as of 2016. In the context of a movement for clearly defining purchasing roles between PhilHealth and the DoH, the necessity of a body solely mandated with HTA re-emerged. Advocacy for such a body is best understood in the context of debates for clearly delineating purchasing roles in the country, which fed into the design of the UHC Act of 2019.

Comparative analysis of organisational design for HTA

Having analysed the processes of organisational design for HTA in each of the two countries, both similarities and differences emerge, as well as some case-specific characteristics.

Major similarities are the options considered for organisational design and the role of HTA advocates. In both countries, the available options for building an organisation were limited between: attaching HTA tasks to existing organisations; or establishing an independent body mandated with conducting HTA. In addition, a variation of the first option was considered in Thailand, which was the establishment of a HTA-specific unit as part of existing structures with associated mandates. As found in Chapter 5, the existence of HTA advocates organised in networks was also decisive in both countries. Within these networks, civil servants seemed to have had some degree of freedom in establishing organisations for HTA. It is perhaps unwise to assume that 'political will' coming from the highest levels of health governance is not important. However, the Thai and Philippine cases suggest that the role of middle to high ranking civil servants should not be overlooked when defining 'political will' for establishing HTA.

While the options available for organisational design were limited to two main choices, the strategies used by advocates were different for each country. In Thailand, the core of the strategy was to establish small programmes financially supported by research funding allocated by the HSRI, with the goal that these programmes should pursue independence from the government bureaucracy. Importantly, this strategy was not solely applied to HTA, but was more broadly used in Thai health system governance. HITAP's establishment, along with its 'mother organisation' IHPP's, followed a modified version of this core strategy, whereby the research funders entered an agreement with other offices of the MoPH. Consequently, HITAP has a special status within the Thai MoPH, known as 'semi-autonomy'. In the Philippines, the strategy for organisational design required a legal mandate for HTA that was then used by civil servants to develop HTA activities within existing structures of PhilHealth and the DoH. Despite the existence of the

legal mandate, between 2004 and 2006, none of these structures was solely mandated with HTA. This choice of organisational design again suggests, the importance of the civil service for explaining the uptake of HTA in both countries, while also showing that a legal mandate on its own did not lead to HTA becoming institutionalised.

This analysis suggests that the differences in strategies for establishing HTA can in part be explained by factors relating to the main advocates for HTA, which were civil servants. Compared to the Philippines, civil servants in Thailand benefitted from a wider degree of freedom, especially as they also created links through the network of the RDS. In the Philippines, civil servants were less autonomous in their decisions regarding the approach to establishing HTA. As a consequence, the HTA processes that were developed were attached to existing organisations. The development of these processes will be explained in detail in the subsequent chapter.

The available country-specific strategies for organisational design also translated in the degree of independence of the organisation that coordinated HTA. In both countries, advocates for HTA indicated a preference for a HTA organisation that was independent. In Thailand, there were clear pathways to achieve independence for a newly created organisation. This could be done by special legislation or by a single Royal Decree, under the Public Agency and Institute Act. HITAP attempted to use this institutional mechanism to achieve the status of an independent public organisation in 2015, but this was prevented by the executive branch which limited the creation of independent public bodies. However, HITAP had been able to maintain a degree of autonomy by establishing an associated foundation. In contrast, in the Philippine, HTA advocates were not able to identify alternative pathways towards independence that did not require legislation. However, the legal mandate did not lead to a body dedicated to HTA being established. The exception was the UHC Act of 2019, which became law after years of debates about purchasing health services, which also included debates about establishing an HTA organisation. As a consequence, the Act included specific organisational and process details that HTA advocates hoped would facilitate the development of a HTA organisation.

In sum, the comparative analysis above showed that the options for organisational design considered were broadly similar across contexts. In both countries, HTA

advocates and their networks, worked from within the civil service to build HTA organisations. However, they did so within existing institutional constraints which shaped the opportunities for creating HTA organisations in the context of new health governance structures in each country.

7. Developing HTA processes in Thailand and the Philippines

This chapter will analyse the development of HTA processes, taking as a starting point the policy problems that HTA was expected to address. As outlined in Chapter 5, these policy problems evolved over time in both countries, but following a pattern that was similar. In short, these policy problems were linked to: a) investments in high-cost medical equipment; b) coverage decisions for medicines; and c) setting priorities for the further definition and expansion of the benefit package. Each country case study will explore the development of HTA processes responding to these three policy problems. It will analyse how HTA processes evolved under the influence of how policy problems were defined, of changing institutional contexts and of policy actors' interests.

This chapter will analyse the processes functioning as of 2016, as well as other attempts at process development that were either not implemented or were less durable. It first analyses the development of HTA process in Thailand and in the Philippines separately, followed by comparing the HTA process development in both countries. Successful proposals will be discussed in more detail than those proposals that failed to be implemented.

The development of HTA processes in Thailand

The first full-fledged proposal for a HTA process in Thailand dates back to 1997 and aimed to establish a national mechanism to inform investment decisions on innovative medical equipment. This proposal emerged from the TASSIT project under the name of the National Council on Health Technology Assessment. The plans for this Council drew heavily on the model of the SBU[27] (see more details on why in Chapter 6). The proposal details a process that consisted of several structures

[27] The Director of the Swedish Council on HTA, Egon Jonsson, acted as the consultant of the project.

with distinct roles: a HTA Council; a Standing Scientific Committee and several ad-hoc scientific committees as required by the technology assessed; and a Secretariat (Jonsson and Chalaprawat, 1997).

Initially, the proposal stated that the Council would not decide whether technologies should be covered, but it would present recommendations based on evidence synthesis and primary research on the cost-effectiveness of individual technologies. It would also generate evidence on the diffusion and use of health technology already in place (Jonsson and Chalaprawat, 1997). However, by 1999, TASSIT project documents suggested that HTA advocates were arguing that a HTA council should have a regulatory role, and not merely an advisory one (Tomson and Sundbom, 1999b).

These plans for a national HTA council never came to fruition. Causes for this can be found in the governance of the TASSIT project (the project ended when its funding ended), as well as the influence of key actors (such as a change in focus of HSRI leadership) (see more details in chapter 6). A more convincing explanation refers to the fact that the policy problem, as it was defined, would affect multiple decision-making points as well as broad policies: budget allocation to and by the MoPH (the Bureau of Budget approved budget proposals from the MoPH); Social Security Scheme payment mechanisms; and the existing tax incentives for the import of medical equipment which further incentivised investment in innovative equipment. In other words, there was no existing decision-making structure committed to linking evidence on the diffusion, uptake and cost-effectiveness of medical technology with resource allocation decisions (see a more detailed analysis of how the problem was defined in chapter 5).

Despite the failure of this first proposal, policy actors who supported HTA continued to be preoccupied with this problem and the proposed solution of establishing a national mechanism to assess appropriateness of investment in medical equipment. HTA advocates continued to look into the link between budget allocation procedures and investment in medical technologies across the health sector. However, the difficulty of the task was highlighted by another failed attempt to establish a national mechanism to assess newly introduced and expensive medical equipment. This

second proposal for a similar mechanism was part of a legislative initiative to strengthen the regulatory environment for medical devices. Passed in 2008, the Medical Device Act included wide regulatory provisions regarding medical devices registration, advertisements, and authorisations for sale and distribution.

With regards to HTA, the Act included provisions for the establishment of a Medical Device Board that would, among other tasks, identify medical equipment that should undergo HTA in order to ensure 'that the use of such medical devices are [sic] suitable and corresponds to the health problems of the public and the economic and social conditions of the country' (Medical Device Act, B.E. 2551/2008 – unofficial translation). The proposed membership of the Board largely derived from the MoPH (ten members from various MoPH departments) which was to be balanced by nine to eleven 'qualified members' (experts), one of which would be an expert in HTA. According to HTA advocates, the HTA process aimed to assess the appropriateness of innovative and costly medical equipment before market authorization.

Similarly to the TASSIT proposal, the Medical Device Board would have represented a significant change in governance arrangements. However, HTA-specific plans, as well as the wider Act, had not been implemented by 2016, as the MoPH omitted to develop secondary legislation for the implementation of this Act (Tangcharoensathien, 2015). This was due to the fact that the general provisions of the new Act went against the interests of manufacturers, suppliers and users of medical equipment in private and some public hospitals, which opposed regulation to what had so far been a growing, but unregulated market for the medical equipment industry. Medical device regulation is difficult across the board and HTA being applied to it is still in its infancy, including in high-income countries.

In addition, the provisions of the new Act also exposed conflicting policy priorities within the MoPH, which were linked to a planned known as the Medical Hub Policy. This plan aimed to attract foreign patients to well-equipped private facilities and present Thailand as a model destination for medical tourism. The Medical Hub policy was supported by the Ministry of Finance, which designed incentives for large private hospitals to attract foreign patients with hotel-like facilities disposing of state-of-the-art technology (Pitakdumrongkit, 2017). The Ministry of Finance also

had economic development priorities which included stimulating the local medical device manufacturing market. The Bureau of Investment aimed to grow local manufacturing of basic medical devices and of and advanced equipment (and therefore has put in place tax incentives for the import of basic materials for manufacturing such equipment) (Pitakdumrongkit, 2017). The intention was that the revenues generated as a result of this plan would be re-invested in the public health system (UCS), as one of the worries for the sustainability of the scheme was maintaining appropriate levels of funding.

However, some UCS supporters believed that the focus on medical tourism would have a detrimental effect on the UCS in two ways. First, they believed that health professionals would be disincentivised to practice within the public health system. Second, they mistrusted that revenues from the Medical Hub Policy would in fact be re-invested in the UCS. In interviews, HTA advocates expressed mistrust that the MoPH would use such funds to invest in under-favoured areas rather than in already rich and developed urban hospitals (I8TH_civil service). These latter worries were confirmed by budget allocations from the Ministry of Finance in subsequent years. For example, it was reported that the Bureau of Budget 'intentionally misinterpreted' the capital replacement and depreciation costs included in the estimates of the capitation budget of the UCS as a standard for capital investment and therefore did not allocate sufficient funds to the MoPH for investment in its large network of public facilities (Tangcharoensathien, 2015).

The ongoing evolution of the Medical Hub Policy, the halted implementation of the Medical Device Act (including its HTA process) shows a behind-closed-doors process of negotiation and lobbying. Over the next decade, capital investment budget did not keep pace with the growth of the UCS budget and was recently identified as one of the major problems threatening the sustainability of the UCS (Tangcharoensathien *et al.*, 2018). Because the UCS budget is allocated annually, it is sensitive to political decision-making by the Cabinet and the Bureau of Budget. The budget allocation negotiations are opaque, and it was hard to find the specific reason for this. However, in the context of strained relationships between the MoPH and the NHSO, it is likely that the cause for such variability to lie with MoPH actors

lobbying to either receive more of a say in NHSO governance or undermine it altogether and re-establish a separate funding stream towards the MoPH.

It is notable that HTA advocates, informed by the nature of the institutional context regarding investment in medical equipment in the country, attempted to establish an ambitious HTA process that would have been part of the regulatory framework for medical equipment. Even though the Medical Device Act had not been implemented as of 2016, there were signs that its implementation would be attempted again in 2018. This topic is likely to be a subject of further development in the following years.

A third attempt to establish a HTA process took a different focus because it came at a time of changing the definition of the policy problem. The introduction of HTA in the DMS in 2002 was important because the department coordinates high-cost care provided in the largest and most specialised public hospitals, specifically 32 hospitals and institutes, most of which are located in the Bangkok and Greater Bangkok Area. In 2002, budgets for high-cost care and capital investments were still under the administration of the MoPH, which indicated that a HTA process could inform investment in medical equipment for these hospitals. However, the MoPH was stripped of this power in 2005.

The definition of the problem changed as existing governance arrangements changed. Specifically, it was defined less as a budget allocation problem and more as a problem of identifying which high-cost, specialised services should be provided in tertiary hospitals. According to an interviewee from the civil service, the status of HTA processes at the DMS was raised by the creation of the IMRTA in 2007. This move by the DMS leadership was a reaction to a particular study, carried out by the IHPP, on the appropriateness of investing in proton radiation therapy for cancer treatment, compared with existing radiation therapy. This study indicated that public investment on such expensive medical technology was not advisable as replacement to alternative radiation therapy. The study recommended that innovative technology should not be prioritised over investment in more basic infrastructure, even though the technology would likely be more efficacious (although not as effective in real-world conditions if basic infrastructure is not available).

> Lack of basic instruments of radiation therapy and essential health personnel, especially radiation therapists and medical physicists, should be the first priority of the government investment before attempting to invest in expensive medical technology. (Prakongsai, Tantivess and Tangcharoensathien, 2007)

This position was controversial because many health professionals were naturally inclined to want to apply the most efficacious treatments. As a response to these controversies, the Department leadership moved to strengthen the existing HTA process to establish authority over recommendations on adoption of medical technologies (I10TH_civil service). After this episode, the HTA process at the DMS was defined as intending to set 'the standard of medical technology in Thailand', beyond the specialised hospitals under its administration (I21TH_civil service). It was a move to establish authority and legitimacy on making recommendations on the use of innovative technologies in tertiary care under the DMS, and not under the IHPP.

To do so, the IMRTA maintained a focus on generating evidence on clinical effectiveness for specialised tertiary care and evolved as a research body generating evidence in support of the development of clinical practice guidelines for high-cost, specialised services (I2TH_academia). The evidence IMRTA advocates for and generates includes epidemiological research, systematic reviews of efficacy and effectiveness (informed by Cochrane methodology) and other clinical effectiveness research, such as standard practice surveys. However, a discrepancy between the aims of the process and its operation could be seen, or, as indicated by one interviewee, the IMRTA was too embedded in the MOPH/DMS line of command to be able to set its own priorities or make independent recommendation (I21TH_civil service). Because of this, interviewees suggested that the IMRTA process was a failed initiative of HTA advocates as it had had initial links with TASSIT and HSRI, which were subsequently lost (see Chapter 6 for more details).

In summary, a narrow definition of the purpose of HTA, namely to inform decisions on the introduction of expensive medical equipment in tertiary hospitals, led to three options for process design being developed by HTA advocates. The initial framing of the policy problem led to failed proposals for a HTA process. The failure could be explained by the proposal not fitting with the existing institutional context (i.e., what

other decision-making procedures there were tackling the same problem) or by their fit with actors' interests or conflicting institutional developments (the Medical Hub Policy). The IMRTA was a hybrid in that it was created to establish legitimacy over technology-related investment with the MoPH. After the change in institutional context in 2005, it adjusted the focus of the HTA process to one of indirectly influencing providers by generating evidence on clinical effectiveness research.

Coverage decisions for medicines

The establishment of the UCS in 2001 also raised the question of how to ensure cost-containment with regards to medicines expenditure, while also making decisions about the coverage of high-cost medicines that were deemed essential. The existing processes to make coverage decisions for medicines, up to that point, had been the country's essential medicines list, the NLEM. After the establishment of the NHSO in 2003 and especially after the full transfer of UCS funds to the National Health Security Fund in 2005, there was sustained pressure from medical professionals and manufacturers to open a reimbursement path through NHSO decision-making. For example, as early as 2003, multinational pharmaceutical company Novartis established the Glivec International Patient Assistance Program to facilitate access to imatinib (a cancer medicine with the brand name Glivec), to eligible patients within the UCS. Decision-making on eligibility would have been made by the USA- based Max Foundation. The rationale for this process was that it would ensure independence of decisions on treatment (Sruamsiri *et al.*, 2015).

Initially, this policy problem was taken up at other levels of governance than the NLEM, specifically the Permanent Secretary of the MoPH, the leadership of the FDA and the Secretary General of the NHSO. In 2005, the head of the FDA and a new Permanent Secretary initiated direct price negotiations with manufacturers of key innovative medicines (among which was imatinib) which were deemed unaffordable for the UCS. The Minister of Public Health created an ad-hoc Working Group for Price Negotiation of Patented Essential Medicines. By links with these decision- makers through IHPP, HITAP researchers carried out key research projects

that fed into these negotiations. However, the negotiations broke down: manufacturers did not agree to lower prices, which led the policy-makers mentioned above to support compulsory licences for the medicines under consideration. Cheaper alternatives were to be produced by the Government Pharmaceutical Organisation, a publicly owned pharmaceutical manufacturer.

The events surrounding the issue of compulsory licensing in Thailand have been analysed in detail in published literature (Wibulpolprasert *et al.*, 2011; Mohara, Yamabhai, *et al.*, 2012). They are important for the development of HTA processes because they exemplify the pressure on the Thai government to develop a reimbursement pathway for innovative medicines. For example, imatinib was included in the compulsory license programme initially, but no compulsory license was necessary as the manufacturer eventually offered, in January 2008, to expand its patient access programme and grant universal access for Thai cancer patients. The drug was subsequently included in Thailand's NLEM in 2008, within a special category for high-cost medicines (Jor2 or E2 sub-list). Specific procurement and reimbursement procedures were developed alongside this new category of the NLEM. Specifically, in addition to the capitation budget of the UCS, hospitals could be reimbursed for E2 medicines under a separate reimbursement stream (Yoongthong et al., 2012). The payers implemented this programme over time, which allowed subsequent negotiations between payers and manufacturers. The NHSO initiated implementation of the E2 programme in 2009. In 2013, the Social Security Scheme transferred its budget for medicines procurement in the E2 programme to the NHSO, to participate in pooled procurement through the NHSO.

The HTA process developed incrementally over that same decade, in parallel with the events described above. The developed of a HTA process for medicines coverage took the existing NLEM procedures as a starting point. Figure 7.1 provides a chronological overview of the addition of the main elements of the HTA processes to the existing procedures of the NLEM. Their evolution will be analysed below. The first step in the development of the HTA process consisted of a change to the role of the NLEM in the Thai health system. From 2004, the new NLEM was described as an optimum medicines list for Thailand. In other words, the NLEM evolved from

being a minimum list of basic, essential medicines utilised solely for procurement by public hospitals to becoming a reimbursement list for all three public insurance schemes. This happened gradually (in 1999 for the Civil Servants Medical Benefits Scheme; in 2004 for the UCS).

The second set of changes to the NLEM were procedural changes related to the specialities represented in the Clinical Working groups, on the one hand, and evidence requirements, on the other hand. To support the use of pharmaco-economics for NLEM selection, the membership of the Clinical Working Groups was altered to include one health economist in each of the Clinical Working Groups. Furthermore, starting in 2004, clinical effectiveness became an additional criterion for assessment, alongside safety and efficacy. The NLEM Subcommittee and Secretariat developed a scoring system (ISafE) combining the above criteria. This scoring system was used to support prioritisation of medicines to be included in the NLEM for each therapeutic class (Chongtrakul, Sumpradit and Yoongthong, 2005).

The ISafE score has been described as a 'threshold of quality' (Wibulpolprasert, 2008), whereby medicines that score below the 50th percentile for each therapeutic category were excluded from the NLEM based on clinical effectiveness criteria. In addition, the ISafE score was applied alongside some consideration for cost. Specifically, those medicines that passed the 'threshold of quality' were subsequently assessed through a secondary step of dividing medicines costs by their ISafE score. An academic researcher who was involved in the first application of the new procedures described the new inclusion process as a form of rudimentary economic evaluation. An Essential Medical Cost Index (EMCI) was used to that end, multiplying WHO recommended Defined Daily Doses by the cost derived from the list price at the Ministry of Commerce.

> They developed something called [ISafE score] […] to incorporate evidence-based medicine [in NLEM], and as part of that they kind of calculated some sort of a simple economic evaluation process, by having the cost divided by outcomes, and that is the system that every Working Group needs to use. […] ISafE is more like the effectiveness part, and EMIC is an ICER [incremental cost-effectiveness ratio] kind of part. (I2TH_academia)

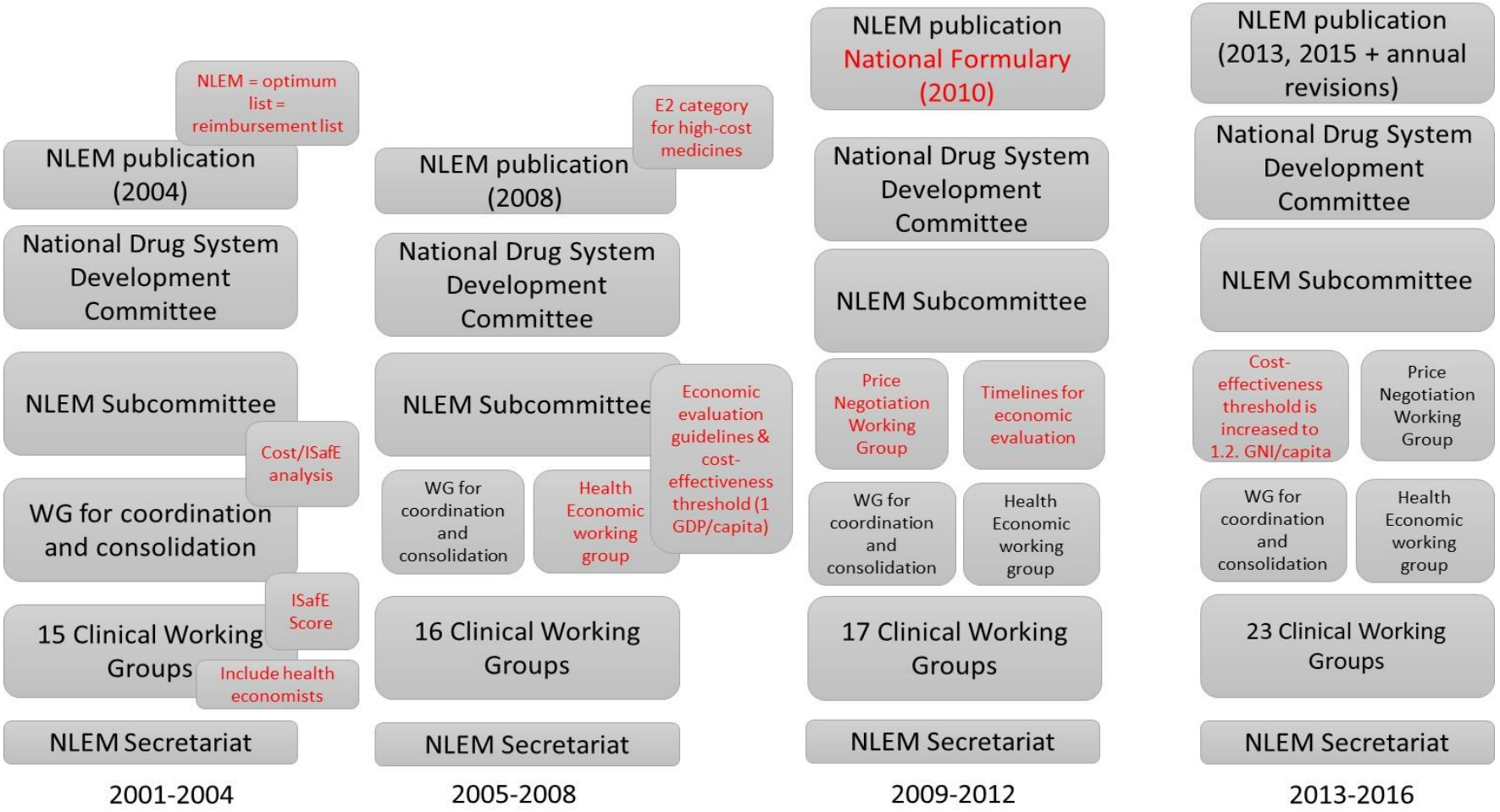

Figure 7.1. Evolution of the procedures for the selection of essential medicines (2004-2016). Source: own analysis, based on key-informant interviews and Chongtrakul, Sumpradit, & Yoongthong, 2005; Teerawattananon, Tritasavit, Suchonwanich, & Kingkaew, 2014.

The 2008 edition of the NLEM established the methodological foundations for a full-fledged HTA process. Interviewees indicated that the 2008 edition of the NLEM played a key role in the development of HTA in the country (I12TH_civil service). In parallel with generating economic evaluation evidence for NLEM informally, HITAP's key activity for the first year after its establishment in 2007 was to develop methodological standards for HTA. For that purpose, HITAP organised a consultative process for the development of economic evaluation guidelines, and commissioned the development of a Thai national database of economic evaluation studies. The first steps towards the development of Thai guidelines had been undertaken even earlier as part of the PhD research of the HITAP director (or leader, in HITAP terminology), which explored the feasibility of using economic evaluations for reimbursement of health services in Thailand[28] (Teerawattananon, 2006).

The guideline development process included convening a larger group of national experts in economic evaluation, who then carried out reviews of the state of the art of methods for HTA and economic evaluation and made recommendations as to the appropriate choices for Thai HTA standards. The guidelines were based on an extensive assessment of existing HTA processes in other countries: Australia, Canada, Denmark, Norway, Hungary, England and Wales (Teerawattananon & Chaikledkaew, 2008). One interviewee described this process as one that included multiple consultative meetings and debates. Debates were often settled by consensus facilitated by the HTA expertise of the HITAP director (ITH6_civil service). The NLEM Subcommittee endorsed the guidelines in 2007, which then became the methodological standards for economic evaluation to inform the Subcommittee.

[28] The PhD was obtained from East Anglia University, United Kingdom, in October 2006.

> The idea came from […] having seen [from abroad] that a national guideline is so important, so that Thai pharmaceutical industry can conduct HTA themselves, but based on the guidelines and assumptions [included there]. So this guideline will harmonise different partners and different contributions in a more transcribed way, and if the pharmaceutical industry conducts this in line with the guidelines and they have an external peer review, and it is in line with the guidelines, the result is reliable. So this prevents potential distortion that pharmaceutical industry produces competing and conflicting findings. So this is a powerful normative work that contributed to the long-term development of HTA. (I12TH_civil service)

The economic evaluation guidelines did not make any reference to a cost-effectiveness threshold, and instead suggested how incremental cost-effectiveness analyses should be presented in order to judge comparative value for money. The NLEM Subcommittee made a separate decision on the cost-effectiveness threshold, which referenced the WHO's Commission of Macroeconomics in Health (World Health Organization, 2001) recommendation of a threshold of 1-3 times GDP per capita (I12TH_civil service).

It is notable that economic evaluations carried out by HITAP researchers in support of policy decisions prior to this threshold decision used the highest point of this range. For example, in 2001, the Prime Minister announced universal access to HIV/AIDS medicines, mere months after the newly established UCS had excluded this treatment from its benefit package. IHPP researchers, including an official who would become part of HITAP leadership, had a close involvement in carrying out research, including economic evaluations, on how to ensure universal access to anti-retroviral therapy. Two economic evaluations carried out before and after 2001 both indicated that anti-retroviral therapy was cost-effective at a threshold of 3 times the GDP per capita. However, extensive analyses of this policy process (see Tantivess, 2006; Tantivess & Walt, 2006) showed that evidence on cost-effectiveness was not decisive in the 2001 decision of ensuring universal access. In fact, the decision to reverse course and grant universal access to anti-retroviral therapy was influenced by

a combination of factors which included a well-organised civil society advocacy, with links to a growing global advocacy, reductions in medicines prices, as well as the change in political leadership which led to higher prominence of the RDS in early 2000s (Tantivess & Walt, 2006). However, the economic evaluation results that the treatment to be cost-effective highlighted to HTA advocates a tension between cost-effectiveness and affordability. Many policy-makers believed the treatment to be unaffordable for the newly established UCS, even if it provided good value for money. As a result, HTA advocates learned that economic evaluation can inform the process of decision-making, but does not determine decision-making (I3TH_researcher). They also saw that, in practice, a threshold of 3 times the GDP per capita was too high and that affordability was an important consideration. As a result, in December 2007, the Subcommittee decided to use the lower point value as a threshold (1GDP/capita).

HITAP and IHPP learned from this experience on the use of economic evaluation in policy-making, which added to their growing expertise in economic evaluation. As such, HITAP became the co-secretariat of the Health Economic Working Group, as the coordinator of the development of the economic evaluation guidelines. Prior to this change, the secretariat of the NLEM had been coordinated solely by the FDA, whose focus was on safety and efficacy of drugs. Consequently, the Health Economic Working Group was established and HITAP became its co-secretary. Importantly, the Health Economics Working Group was placed at coordination level, which in effect created an additional step or filter in the selection process: prioritisation of submissions that should undergo economic evaluation.

For the 2008 revision of the NLEM, price negotiations for the most contested medicines were carried out by an ad-hoc price negotiation working group. However, for subsequent revisions, a permanent Committee for Price Negotiation of Patented Essential Drugs was created. The Price Negotiation Working Group was established to negotiate with pharmaceutical companies on high-cost medicines that would also

undergo economic evaluation. Since then, the process has worked as follows: the pharmaceutical manufacturer submits a price which is used as the basis for the economic analysis. The analysis presents results and indicates the price at which the medicine is cost-effective. These tables are then used to inform the negotiation of the price between the NLEM Subcommittee and the manufacturer.

All these procedural changes were made directly by the NLEM Subcommittee. Interviewees suggested that there was consistent support for HTA from three subsequent chairs of the Subcommittee starting in 2001 and this view continued to be represented in the NLEM committee through the decade that followed. In particular, key members of the progressive faction of the bureaucracy (often members of the RDS) either had links with the chairperson of the subcommittee or took up the position themselves (I2TH_academia; I6TH_academia; I10TH_civil service). The skills of the chairperson were seen as particularly important, as decision-making was done through consensus, not voting (I8TH_MoPH). Further, the chairperson was able to name key individuals for newly created positions (such as the Health Economic Working Group). The NLEM Subcommittee chair supported these procedural changes based on the advocacy of a HTA supporter (I10TH_civil service). Given this antecedent, it is likely that such incremental changes of the HTA process will continue. According to key-informants, a complete overhaul of the system is unlikely from one chair to another, but small procedural changes such as the ones that affect HTA processes are at the discretion of the chairperson of the NLEM Subcommittee (ITH7_pharma; I3TH_MoPH).

In summary, the development of the HTA process for reimbursement of medicines was influenced by the manner in which related policy problems were defined, as well as the existing institutions associated with the problem. Medicines reimbursement was important from two angles: essential medicines and cost-containment, and how to reimburse innovative, expensive medicines that were deemed essential. The NLEM selection process, alongside procurement requirements, were the processes

associated with the first version of the policy problem. The problem of funding innovative medicines was addressed by developing alternative institutional mechanisms, including negotiations with manufacturers and issuing compulsory licenses/pricing and reimbursement. Between 2004 and 2012, a decision-making process that combined elements of the two was developed, with some high-cost medicines becoming part of the NLEM and the latter being re-named into an optimal list to be used for reimbursement. Methods for these economic evaluations, as well as the economic evaluation guidelines produced in 2007, drew heavily on the experience from other countries. Debates on methodology were agreed on amongst national experts who were involved in consultations. The development of the HTA process also included carrying out economic evaluations for decision-making on NLEM and for innovative medicines, such as antiretroviral and oncology drugs.

Defining the benefit package: setting priorities and choosing between alternatives

After the UCS was established in 2001, policy questions about the definition of the benefit package provided by the scheme became increasingly urgent. As examined in Chapter 5, many HTA advocates were also supporters of the UCS reform. However, while some health reformists understood the usefulness of HTA for coverage decisions, they felt that the question of benefit package design should not be raised at the first stages of the UCS, so as not to risk the progress of health system reform. They perceived the problem as too difficult to solve and likely to draw even more criticism to the UCS. As a result, a major point of focus during creation of the UCS was the development of payment mechanisms for health services and associated budget allocation responsibilities, with less attention given to the composition of the benefit package. Consequently, the UCS benefit package was modelled on the benefit packages of existing schemes, in particular the Social Security Scheme and

the Voluntary Health Card Scheme, a tax-financed scheme ran by the MoPH (Pitayarangsarit, 2004).

However, the NHSO Board was soon forced to tackle the design of the health benefits package. A major exclusion from the UCS benefit package was renal replacement therapy for end-stage kidney disease, which drew considerable criticism. Civil society groups, alongside the Royal Society of Nephrology and some health reformists did not agree with the exclusion, which was made based on cost-effectiveness grounds, but ignored equity aspects. The NHSO commissioned a series of studies by HITAP and IHPP, with a view of identifying the best possible pathway for inclusion (Tantivess, Werayingyong, Chuengsaman, & Terrawattananon, 2013). The ensuing policy became known under the name of Peritoneal Dialysis First and was informed by an economic evaluation that compared haemodialysis and peritoneal dialysis with current treatment i.e. palliative care (Teerawattananon, Mugford, & Tangcharoensathien, 2007). Neither of these options were deemed cost-effective, but 'peritoneal dialysis was found to provide better value for money' compared to haemodialysis (Tantivess et al., 2013). Policy change was not immediate, with costs being a consistent concern and nephrologists opposing adoption of peritoneal dialysis instead of haemodialysis, which they preferred. However, physicians eventually conceded that haemodialysis would not be available to patients in isolated communities due to lack of equipment or difficulties in accessing health facilities. As demands from civil society continued in the face of the fact that the other publicly financed schemes were providing these services, universal access to peritoneal dialysis was announced in January 2008, whereas haemodialysis remained available with a co-payment. The policy was

continued to be monitored closely, as one of five budget subcategories of the NHSO[29] (NHSO Annual Report, 2013).

Based on this example of evidence generation that informed both coverage decisions and the subsequent design of reimbursement arrangements, the NHSO Board created a NSHO Subcommittee for the Development of Benefit Package and Service Delivery (SBPD). The SBPD commissioned the IHPP and HITAP to develop a process for prioritisation of services requested for inclusion in the UCS benefit package.

The prioritisation process was developed between 2009 and 2010 and was coordinated by a research team (the IHPP and HITAP) and a project team (which also included officials of the NHSO, thus creating a direct link with policy-makers throughout the development process). The research team was responsible for reviewing international experience on explicit priority-setting for interventions considered for public reimbursement and propose criteria and procedures for prioritisation. The research team presented a consultation panel with the six most commonly used criteria for priority-setting, identified based on their review of experiences of HTA agencies in England and Wales, Canada, Spain, Germany, Netherlands, Sweden, and the United States. The research team then convened a consultation panel on prioritisation criteria, which deliberated on the adoption of these six selected criteria in Thailand. This consultation panel included academicians who deliberated on the types of evidence that would need to be gathered for each criterion. They also decided that all criteria should be given equal weight with the option to make additional adjustments in the future (Youngkong *et al.*, 2012).

[29] Alongside general capitation, HIV/AIDS programme, chronic diseases package and a psychosis package. High-cost care is administered under general capitation, as are other vertical programmes.

The project team was responsible for organising consultative meetings to agree on the procedures for the nomination of interventions and their prioritisation for assessment. As such, the project team also put together a consultation panel that included participants selected for 'their expertise and […] purposively to cover stakeholders who play an important role in the Thai health insurance system' (Youngkong *et al.*, 2012). The goal of this panel was to agree on the number and type of actors involved in the decision-making process and the criteria for prioritisation.

Figure 7.2 presents an outline of the resulting process for the prioritisation and assessment of proposed health services to be reimbursed by the UCS.As a first step, technology proposals are sent in to HITAP and IHPP as part of a nomination process. This step was inspired by the topic selection process that IHPP and HITAP had previously used to enable them to carry out research that policy-relevant. This strategy was also reminiscent of the idea of policy-relevant research that led to the establishment of the HSRI (see Chapter 5 for more details). The Nomination Working Group membership included:

- Decision-makers from the Bureau of Policy and Strategy, Ministry of Public Health, and the administrators of the three health insurance schemes (4 members);
- Health professionals, i.e., representatives of the Royal Colleges of Physicians and the Royal College of Dentists (4 members);
- Academics from faculties of public health, nursing, pharmacy and health economics. The faculties of Medicine and Dentistry were covered under the category of health professionals, through the Royal Colleges (4 members).

- Civil society, i.e., representatives from civil society groups registered as a legal entity (e.g., foundation) and represented in the National Health Commission[30] (13 organisations) (4 members).
- Patient groups, as listed by the National Health Commission Office (4 members).
- Industry, i.e., representatives of the Thai Pharmaceutical Industry Association (TPMA), the Pharmaceutical Research and Development Association (PReMA), the Thai Medical Device Technology Association (3 members).
- Lay people, i.e., provincial networks of the National Health Assembly, 15 randomly selected provincial networks (4 members).

Notably, this Nomination Working Group included representatives of all insurance schemes in the country. Interviewees suggested that this was due to the long-term plan of 'harmonising' the benefit packages of all health insurance, with the CSMBS having the more generous plan.

The two research organisations, HITAP and IHPP, would be tasked to synthesise evidence on the prioritisation criteria for each of the prioritised interventions. Group The evidence on prioritisation criteria would be subsequently presented to a Topic Selection Working Group that would also be established as a part of the process. The Topic Selection Working Group included the same members as the Nomination Working Group, except for industry and lay people representatives. Industry representatives were excluded due to potential conflict of interest, whereas lay people representatives were deemed difficult to identify for the purpose of topic

[30] The National Health Commission is an autonomous government agency aiming at providing input to heath policy based on wider public participation. For example, they organise an annual Thai Health Assembly.

selection (they usually convene once a year for the Thai Health Assembly) and to also being represented by the civil society category (Youngkong *et al.*, 2012).

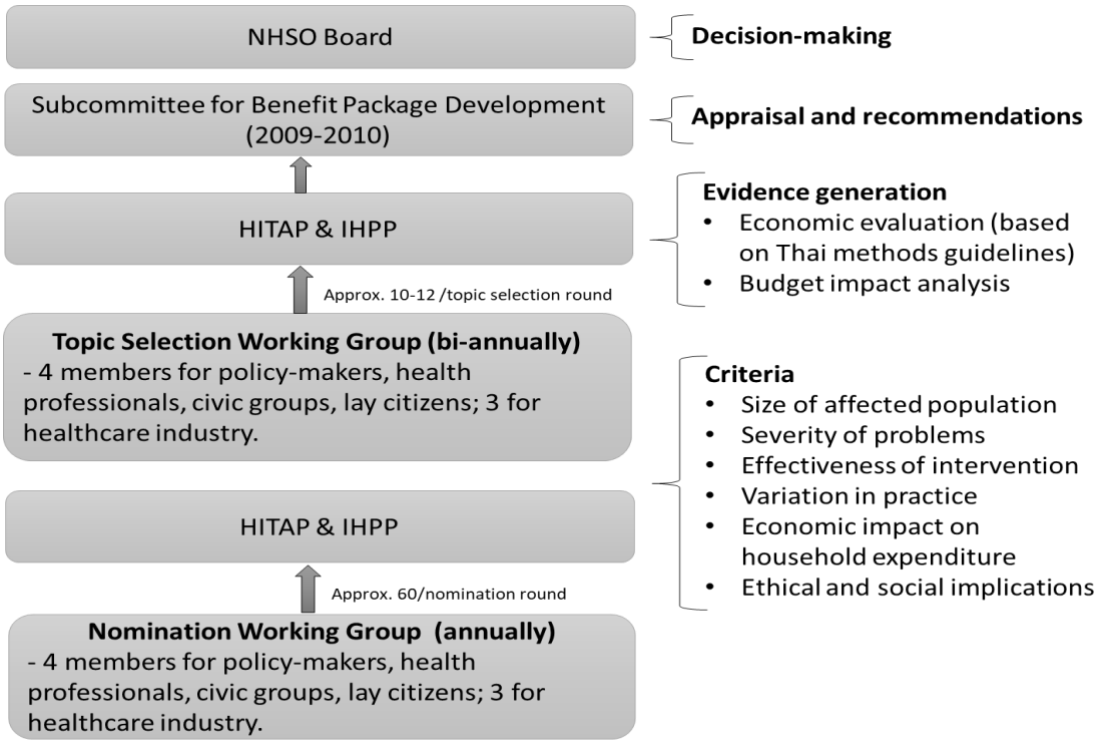

Figure 7.2. Prioritisation and decision-making for inclusions in the Universal Coverage Benefit Package. Source: Mohara et al., 2012; Youngkong et al., 2012.

Notably, the procedures for the Nomination Working Group built on the existence of the National Health Commission Office (NHCO), established in 2007 as part of the National Heath Act, with the goal to enable wider participation in health policy-making for the entire Thai health system (not just UCS). One of the key activities of the Commission is the yearly Thai Health Assembly. As explained in Chapter 5, the idea for the Thai Health Assembly first emerged amongst the RDS in the late 1980s. This is why a national nomination process was proposed to be organised every

January, when the Thai Health Assembly generally happens. According to interviewees, sixty to eighty proposals were typically received as part of a yearly nomination process and were subsequently presented to the Topic Selection Working Group, alongside evidence on prioritisation criteria prepared by HITAP or IHPP.

According to interviewees, six to seven interventions were typically selected per round of prioritisation, two times a year, out of all the requests received in January, with HITAP and IHPP having capacity to conduct ten to twelve assessments per year (Mohara, Youngkong, *et al.*, 2012). In 2009-2010, twelve interventions were selected for assessment, of which five resulted in a recommendation for inclusion in the UCS benefit package. The procedures state that the SCBP appraises evidence and makes recommendations to the Board. The NHSO Board is therefore the ultimate decision-maker. However, interviewees highlighted the importance of the Secretary General of the NHSO in organising deliberations within the Board and, ultimately, making decisions. As is the case in the NLEM Subcommittee, decision-making is generally made through consensus, not through voting. In case consensus is not reached, it is the chair, usually the Secretary General, who makes the decision (I8TH_civil service).

Support from the Secretary General also meant the NHSO Board agreed to earmark funding for the research necessary for this HTA process and transfer these funds to the HSRI. HITAP and IHPP have to justify their research proposals to the HSRI and the funding did not go directly to them. A civil servant interviewed for this study suggested that a key factor that allowed research bodies such as HITAP and IHPP to be involved in evidence generation for NHSO was that the NHSO did not develop any in-house capacity to conduct research in support of these tasks (I3TH_ civil service).

In summary, the development of a HTA process for defining the health benefit package of the UCS was due to the responses and difficulties arising from the greater

variety of technologies being considered, in an institutional context where there were increasing demands from a newly established payer, namely the NHSO. As was the case for the NLEM, HTA process development was initiated in response to complex policy problems with regards to coverage of health services. Their solution was initially informed by evidence outside any formal processes of HTA. Researchers at HITAP and IHPP were then tasked with developing a HTA process to formalise their input in policy-making. Importantly, the incremental development process for HTA processes built on existing institutions. Specifically, the governance mechanisms of the NHSO were built into the associated processes. Furthermore, other institutions, such as the participatory infrastructure promoted by the RDS and set up after the passing of the National Health Act of 2007 (i.e., NHCO), also influenced specific procedural steps as part of the HTA process housed by the NHSO.

Summary

The development of HTA processes in Thailand responded to different policy problems that required decision-making, namely decisions on investment in expensive medical equipment; coverage decisions on medicines; and setting priorities for assessment of requests for inclusion in the UCS benefit package. Different HTA processes were developed to address these tasks, some of which were never fully implemented or were amended (as on medical equipment). HITAP played an important role in the development of HTA processes for medicines and UCS benefit packages.

In the case of medical equipment, changing power structures regarding investment in medical equipment brought about by universal coverage reforms explain the focus of two proposals (1997, 2008) for HTA processes at national level: assessing expensive medical equipment and make recommendation about its use during market authorization. In addition, a changing institutional context also influenced the strengthening of the HTA unit within the MoPH (IMRTA). This happened as a

response to IHPP-generated evidence contesting the appropriateness of investing in expensive radiation technology which they compared with the low priority that was given to providing access to basic equipment and appropriately trained personnel. In this context, the DMS attempted to establish authority over evidence generation on standards of practice for medical equipment. However, changing institutional roles and diminished budget allocation power for the MoPH led to limited impact of this initiative.

The problem of developing reimbursement procedures for innovative medicines was equally influenced by existing institutions. Initially, policy development for reimbursement of innovative medicines (e.g., oncology and antiretroviral therapy) was carried out independently from existing procedures for designing the country's essential medicines list. Evidence from economic evaluations and policy research provided by IHPP and HITAP researchers was used, independently from a HTA process, to inform policy development for innovative medicines and decision about inclusion in the NLEM. Consequently, the NLEM transitioned from an essential medicines list used for public procurement, to an optimum list and a de-facto reimbursement list used to inform centralised procurement of high-cost medicines by the NHSO. The procedural adjustments to accommodate this change were developed incrementally and built on existing procedures. With support from subsequent NLEM Subcommittee chairs, HITAP played an important role in both evidence generation and incremental changes to the procedures of the NLEM, thus becoming the coordinators and legitimate experts on HTA in the country.

The third policy problem, regarding new inclusions to the UCS benefit package, was addressed by developing a process of prioritisation and of assessing appropriateness of available interventions. The process was developed through a direct commission from the NSHO SBPD. It was informed by a review of existing priority-setting criteria internationally, which were the adapted using multi-criteria decision analysis principles through several rounds of consultations with Thai decision-makers and

academics. The development of the HTA process was decisively informed by existing country institutions, specifically the NHSO governance arrangements and the participatory mechanisms coordinated by the NHCO.

Specific challenges to the existing HTA processes in the country will be further analysed in Chapter 8.

The development of HTA processes in the Philippines

As in Thailand, the Philippines developed distinct HTA processes that evolved in response to different policy problems: a) investments in innovative medical equipment; b) coverage of medicines and c) setting priorities for the expansion of publicly funded health services. The section analyses what influenced the development of several HTA processes associated with these policy problems in the Philippines.

As explained in chapter 5, the Health Insurance Act of 1995 established a legal mandate for HTA. This act indicated that HTA would be used to assess the use of expensive medical equipment by providers offering care to PhilHealth members. This Act also linked HTA with other tools for regulating provider behaviour, specifically quality assurance, utilisation review and accreditation of health care providers.

In 1998, one of the early advocates of HTA became Vice President of the Accreditation and Quality Assurance Group at PhilHealth and proceeded to implement this HTA mandate. The development of a HTA process was coordinated by the Quality Assurance Group within PhilHealth, and happened incrementally, building on the reimbursement procedures of the newly-established payer. In 1999, the Quality Assurance Group established a Technical Working Group, eventually referred to as the ‘HTA committee’, that was tasked with conducting ‘appropriate

research and validation studies to assist the Corporation formulate reasonable policies on reimbursement of providers' services' (PhilHealth Special Order No. 23, 1999). Thus, the stated goal of the HTA committee was to develop reimbursement policies within the confines of the already established payment mechanism, fee-for-service, and its procedures of reimbursement. These procedures included continuously updating the health benefit package through PhilHealth circulars, which the HTA committee was mandated to assist in drafting (PhilHealth Special Order No. 23, 1999).

The PhilHealth leadership set priorities for expansion of coverage for example on grounds of health planning priorities (e.g., Millennium Development Goals conditions) and other considerations, including lobbying from various actors (I12PH_civil service). Further, the Quality Assurance Group's other responsibilities contributed to identifying services in need of assessment based on its utilisation and claims review processes.

> The problem was that the claims and the review decision differed and it was based on the perspective of the reviewer. I mean different across the country, based on the perspective of the reviewer. And it's hard to say what is right and wrong if you don't have a basis for it. So that's why we were looking for something, a standard, at that time. Basically, it's the subjectivity of the review process. We don't have clinical practice guidelines at that time, or treatment [guidelines] that were being used by PhilHealth at that time. (I6PH_PhilHealth)

The interest in finding a mechanism to aid decision-making was therefore driven both by the difficulty of making decisions where peer reviewers disagreed and a large number of claims that could not be reimbursed according to existing rules, but were submitted by providers nonetheless. In the context of PhilHealth actively having to define services that were reimbursable, the HTA committee took up that role.

The basic structure of the HTA committee was informed by principles of HTA conveyed through direct advice from an international HTA expert, David Banta (I6TH_PhilHealth). This advice influenced the multi-disciplinary composition of the committee, and its role as peer-reviewers of HTA assessment reports (also referred to as HTAs) produced by the Secretariat (i.e. PhilHealth staff). Furthermore, the evidence principles that guided the generation of such reports followed the hierarchy of evidence which placed randomised controlled trails (RCTs), systematic reviews and meta-analyses at the top, as well as procedures for quality review of evidence through established checklists. If the evidence was particularly weak or contested, the committee members would carry out the evidence review and international experts working as external consultants carried out peer-review.

The HTA committee brought together experts on: methods for HTA (clinical epidemiology, health policy and economics), the top services PhilHealth reimbursed (surgery, internal medicine, including clinical immunology and obstetrics and gynaecology), and technology-related topics (medical devices and rational use of medicines, pharmacology and toxicology) (I6TH_civil service).

The HTA process did not seek to limit reimbursement. Its main role was to issue procedures associated to expanding coverage. However, it did have a view of standardising medical care. For instance, new benefits prioritised by PhilHealth management were issued alongside clinical pathways and quality standards based on appraisals of clinical practice guidelines. For this purpose, the HTA committee secretariat sought guidelines that were first assessed for quality and selected so that they respected the hierarchy of evidence (I16PH_civil service).

> Back then, when we were doing HTA, I think we adopted standards. We don't have to reinvent the wheel. If the healthcare providers themselves, their medical societies, developed the standards, we just looked at each standard and if they followed the process of evidence-based development of guidelines. If they did, then we adopted them. If not, we went further into looking at

> international standards that then we adopted. It's not really us developing them, we adopted them and saw if they follow the correct methods. And we did that with health technology assessment. (I8PH_PhilHealth)

One key reimbursement regulation that directed the focus of the HTA processes was that reimbursement for medicines was permissible only for generic medicines included in the country's essential medicines list (PNDF). Providers, particularly private hospitals, complained to the PhilHealth about their reimbursement claims being refused. Physicians also believed that more innovative procedures and medicines should be reimbursed and claimed these for reimbursement. The problem was exacerbated because the PNDF at the DoH was not being updated regularly.

The HTA process for medicines developed incrementally. First, since medicines represented the largest share of claims that could not be reimbursed to providers, and pressure to expand the reimbursement list was growing, the HTA committee and Quality Assurance staff attempted to collaborate with the PNDF committee, with the aim of supporting PNDF to take up HTA for inclusions in the essential medicine list and associated Formulary (I16PH_civil service). The PNDF committee did not take up HTA at that time, but responded to the pressure form PhilHealth by issuing a new PNDF edition. As a second step, the Quality Assurance Group proposed that PhilHealth issuing a circular to providers announcing the newly reimbursable medicines, according to the PNDF. As a third step, the HTA committee proposed that, in order to avoid delays in the future, the HTA committee assess medicines and announce new inclusion through circulars, upon approval from the PhilHealth Board. These circulars would expire after a year or when the medicines would be included in the PNDF.

The positive list was introduced in May 2000[31] and meant that PhilHealth could pay claims for 'medicines not yet listed in the PNDF, but which are approved by the Bureau of Food and Drugs and the National Drug Council [responsible with the PNDF] or the Health Technology Assessment Committee' (PhilHealth Board Resolution no 338, s. 2000). Finally, in August 2000, another Board resolution stated that approval from the PNDF committee approval was no longer necessary and that reimbursement for medicines not yet listed in the PNDF could be granted solely with approval from the HTA committee, for medicines that had received market authorisation from the Bureau of Food and Drug Administration. The positive list was updated each year until 2006, when an episode of contestation led to a complete re-organisation of technology assessment for medicines.

As was the case for the other activities of the HTA committee and the Quality Assurance Group, the development of the positive list aimed to expand reimbursement of medicines. As expressed in meeting minutes of the HTA committee from 2003, '[t]he committee stressed that the purpose of the positive list is to look at the drugs that might really be more effective than existing PNDF drugs' (HTA Committee Meeting Minutes, October 2003). As such they were therapeutic equivalents, which meant that the main sources of evidence required for this process was from studies of efficacy and effectiveness. This evidence was retrieved from RCTs, clinical practice guidelines, systematic reviews or meta-analyses, often from other countries. The articles retrieved based on set search criteria would then be assessed for quality and included as sources of evidence in an evidence table developed by PhilHealth staff for that purpose.

[31] In November 1999, the Board had already approved a series of medicines, recommended by the National Drug Committee but not yet included in the PNDF.

Key-informants explained that the analysis of cost of the medicines under considerations were warranted only when a) any new medicine was considered as being sufficiently supported by evidence of safety and efficacy; and b) the new medicine was more expensive than its therapeutic equivalent already included in the PNDF. However, these analyses of cost were not full economic evaluations. Instead, judgements on cost-effectiveness were made by assessing and comparing costs between a technology of interest and comparators, as well as the strength of evidence of efficacy. In other words, assessment of evidence of efficacy was structured, whereas 'cost-effectiveness' judgements were made based expert judgement (I3PH_civil service).

Much of the data used for these HTA reports came from other countries and published in scientific databases which were unavailable to PhilHealth staff. The HTA committee debated whether requests for evidence should be made directly to manufacturers, many of whom were multinational companies (I3PH_civil service). This move was questioned by some members who believed that only studies published in peer-reviewed journals constituted acceptable evidence. In contrast, the chair of the committee believed that asking manufacturers to provide evidence was an acceptable solution as long as evidence requirements were specified and papers were subsequently evaluated for quality (I16PH_civil service). However, there was some downsides to this procedural change, specifically that the manufacturers would often criticise the delay in producing assessments and including medicines under evaluation in the positive list.

> We told them, well, we'll give you the parameter, show us the evidence, so we, sort of, put the burden on them, to look for those. And, the drug companies normally could find that literature, and come back to us for us to use that literature for assessment. I mean, in an ideal world, we shouldn't be doing that, we should have been having our own resources, so that we could use them, but that's how we did it at the time. We basically threw the burden back at the applicant, and said, well, produce this literature or we don't do anything with it. And, it took us months to evaluate, we got criticised for being too slow.

> But it was because we were not a full-time committee, we were a part time committee, drawn from different sources. So, there were those inefficiencies. (I17PH_civil service)

Criticism of the functioning of the HTA committee reached a peak when it was decided to assess atorvastatin (brand name Lipitor), developed by the multinational pharmaceutical company Pfizer. The assessment was initiated based on the utilisation review of PhilHealth, which highlighted that the medicine was increasingly being prescribed by physicians.

> So, we said that, okay, let's take a look at it, even though nobody applied for it. There was no application from the industry, or from a health professional, but they were being used heavily by many of the healthcare providers accredited by PhilHealth. And, we said, no, we'll have to put a stop to this, seeing that if they use it, the patient now has to pay out of pocket, even though in the formulary there's a cheaper version, called simvastatin and it is effective. (I17PH_civil service)

The HTA assessment concluded that the existing evidence did not prove that the medicine was efficacious as the available evidence used on surrogate markers (in this case, lower cholesterol and blood lipids). The HTA committee concluded that providers would not be reimbursed when prescribing atorvastatin based on the view that its efficacy was not proven and that it was more expensive than existing treatment (I17TH_civil service).

In response, the manufacturer's country representative confronted the chairperson of the HTA committee and the VP of Quality Assurance Group, and threatened the President and CEO of PhilHealth with litigation (I3PH_civil service; I11PH_pharma). The manufacturer's representatives argued that the HTA committee did not use the most up-to-date data, as it did not ask the company to submit evidence.

> They managed to exclude the most recent evidence on the product. So the assessment was done a year or two before, but by the time they published it

> there are new data already so I was criticising them that if you're coming up with an HTA such as this that will have an impact on the product [sales], then you should have all available data. I don't care if you need to revise it but it needs to be updated at the time that you came up with that assessment. (I11PH_pharma).

The HTA committee, in contrast, argued that the surrogate marker was not an appropriate outcome measure and that, in the absence of data on relevant outcomes, such as cardiac events avoided, the evidence of safety and effectiveness of the drug was insufficient for a positive decision.

> No government in their right mind, with limited resources, is going to ask people to buy that product, and expect it to be reimbursed, if it's that kind of a cost benefit ratio, I mean, two out of 1,000 with positive beneficial effect. But, the argument seems to be, well, because the cholesterol went down. Yes, but that surrogate marker, you haven't verified this outcome. Secondly, we told Pfizer, well, your own data in their own website said so… it's a warning, it's on the website, that says that we cannot guarantee that the drug will cause the prevention of primary or secondary cardiac conditions, and it is not used for the treatment of cardiac [events]. The website said so itself, so we went to Pfizer in the Philippines and said, your website says so. They said, well, did you see the fine print at the bottom? What? For US citizens only. The website was created for US residents, and it shouldn't be used for the rest of the world, or ROW. Can you imagine the arrogance of industry at that time? (I17PH_DoH)

In response to the complaints of the manufacturers, the HTA committee agreed to publish a letter-to-the-editor of the HTA newsletter from Pfizer, and to conduct the evaluation with the data provided by Pfizer in the future. However, after the atorvastatin episode, the leadership of PhilHealth indicated that the HTA committee should end assessments of medicines, arguing that this was the responsibility of the DoH, through the PNDF committee. However, it supported the stance that the HTA committee could contribute evidence in support of the activities of the PNDF. Thus, the HTA committee was involved in drawing new regulations for the PNDF that used the procedures developed for PhilHealth (see following section for a detailed analysis). These plans were not implemented, and the activities of the HTA

committee with regards to assessment of individual technologies were curtailed. Instead, the HTA committee focused on appraisal of CPGs and the development of standards for reimbursement, but was no longer involved in assessing specific technologies. The committee continued to convene until a change in administration, when the incoming PhilHealth President ceased to approve the honoraria for the HTA committee members (I3PH_PhilHealth).

In sum, the initial policy problem to which HTA responded referred to likely overinvestment associated with expensive medical equipment. This understanding of HTA was given a legal basis as part of the National Health Insurance Act of 1995. A committee was formed to implement this mandate when one of its architects became a high-ranking official at PhilHealth, the newly created payer organisation. The design of the process for HTA was influenced by two factors: a) the payer's problems and priorities with regards to defining benefits for assessment; and b) by learning about HTA from international experts. Based on these institutional rules and procedures at PhilHealth, not only the perception of the problem which HTA was supposed to address changed, but also the specific procedures of the HTA process. PhilHealth priorities and procedures also directly influenced the establishment of the positive list for medicines reimbursement.

Coverage decisions for medicines

As explained above, the first changes to the Formulary selection procedures that signalled a move towards HTA were made in 2002. At the time, HTA advocates at PhilHealth attempted to persuade the Formulary committee of the importance of HTA. In fact, new procedures for the Formulary Committee published in 2002 indicated that cost-effectiveness evidence might be used for selection of medicines. However, the National Formulary Committee was slow to implement the new

procedures in practice. According to a former member of the HTA committee, this was because the membership of the committee included experts who were not likely to consider cost-effectiveness as a criterion for decision-making. The use of pharmaco-economics and HTA was an innovative development, which had not been established among the more conservative advisers that were part of the National Formulary Committee (I16PH_civil service).

As discussed above, criticism directed towards the slowness of the PNDF resulted in a debate over appropriate reimbursement policies for PhilHealth and their alignment with PNDF selection. The consensus that emerged amongst HTA advocates and DoH and PhilHealth officials was that the legitimate place for HTA activities was decision-making for PNDF inclusions at DoH.

Procedures for selection of essential medicines and listing/delisting in the Philippine National Drug Formulary (PNDF) were re-designed to include input from the PhilHealth HTA committee. In 2006, a joint DoH/PhilHealth administrative order was written that combined elements of the two existing processes (HTA committee at PhilHealth and PNDF procedures) and represented a complete reorganisation of the process for inclusion of medicines at DoH. First, the membership of the National Formulary Committee - now renamed the Formulary Executive Council (FEC) - was reduced to ten members, who represented multiple disciplines, including health economics and clinical epidemiology. The FEC and its secretariat continued to be hosted by the DoH. The HTA committee at PhilHealth was tasked to form two other committees responsible for the prioritisation of medicines to be assessed and to bring together the evidence in their support: the Epidemiology Committees (consisting of two sub-committees for Clinical Epidemiology and Public Health) and the Pharmacology Committee, respectively.

The Epidemiology Committee and its two subcommittees would have to undertake a process whereby they would identify conditions for which new medicines need to be

included in the Formulary, to be used either for clinics and hospitals (Clinical Epidemiology sub-committee) or for public health programmes run by the DoH (Public Health Sub-committee). The subcommittees would also need to prioritise requests from the DoH, PhilHealth or other relevant individuals and organisations including manufacturers, non-government organisations, health professionals' organisations, and members of the public. The Epidemiology committees were charged with prioritising proposals by reviewing 'the most cost-effective clinical or public health practice guidelines' (AO 2006/018), as well as applying a series of criteria for prioritisation. Specifically, prioritisation of medicines was done based on burden of disease, efficacy and safety (expressed as a benefit/risk ratio), pharmaco-economics analysis (based on 'quality' economic evaluations), appropriateness to health provision structures in the country (e.g., level of expertise required for prescribing or administering etc.). The Pharmacology Committee was mandated with evidence generation to support comparative assessment of medicines, specifically by calculating the benefit/risk ratio for medicines in the same therapeutic class.

To guide decision-making by the FEC at DoH, evidence synthesis and generation rules were transferred from the HTA committee at PhilHealth. Cost-effectiveness was more clearly defined as a criterion for deletion of medicines from the PNDF (i.e., if there were more cost-effective medicines), but its use depended on the Committee deciding to assess cost-effectiveness. As had been the case since 2002, the new regulations stated that the FEC may choose to perform a cost-effectiveness analysis, not that it is mandated to do so. In general, cost-effectiveness was often quoted in the regulations in different versions, such as economic dominance, defining medicines as more or less cost-effective). However, the procedures associated with regard to methodological guidance were not developed in detail.

The DoH and PhilHealth also negotiated that PhilHealth paid for the activities of the clinical epidemiology and pharmacology committees (i.e. the honoraria of committee

members). PhilHealth would also ensure the secretariat of these two committees. Lastly, PhilHealth committed to cover the cost of the publication and distribution of the Formulary. However, a change in leadership at PhilHealth resulted in a loss of support for these plans, and increased pressure from PhilHealth to ensure the payer maintained decision-making power for coverage decisions. This pressure was expressed in another amendment of the PNDF regulations in 2008, which granted PhilHealth increased decision-making power. Based on the new regulations, decisions by the FEC would have to be approved by the PhilHealth President, as well as Secretary of Health. However, these new provisions will change again in 2010, after another change in leadership at PhilHealth.

In parallel, the overall medicines policy was re-configured in 2008, as part of the Cheaper Medicines Act, which included amendments of patent protection laws to allow local manufacturers to produce and register medicines reaching the end of their patent protection, to disallow patents for newly discovered uses of known medicines, legal protection for parallel imports, and, importantly, the power to directly set ceiling prices by the President and a mandate for DoH to establish a system for price regulation and monitoring (Picazo, 2011, p. 17). It also led to the establishment of the Food and Drug Administration as a regulatory agency and a strengthening of its regulatory powers.

During the negotiations regarding the implementation of the Act, the existing routine procedures for PNDF selection were interrupted and the PNDF was not updated between 2008-2011. According to one DoH civil servant, several options were considered for the re-constitution of the Formulary, including having the PNDF secretariat housed by the FDA (newly established as a regulatory agency and not a Bureau of the DoH) or PhilHealth. However, neither of these organisations accepted the tasks, it was implied, because the new Formulary would likely involve price negotiations with industry (I18PH_civil service). Furthermore, PhilHealth was

resistant in immediately widening its role in medicines financing and allowing for outpatient medicines reimbursement, due to the likely budget impact. As a third option, the Secretary of Health created a new policy body within the DoH, the NCPAM, just before a change in administration.

> 'Because [the NCPAM was] running the formulary [...] because there was really a very ... there is really a very powerful industry in the Philippines and you have to present them with that [HTA]. You sit down with them and you have to argue with them on the basis of evidence, that ... they're very powerful in the Philippines.' (I5PH_civil service)

The experience of the Cheaper Medicines Act had highlighted the uncomfortable position that civil servants found themselves in when negotiating with the industry. Interviewees from the civil service indicated that, at different times, civil servants and even Secretaries of Health had been 'fearful' (I17PH_civil service), felt 'bullied' by the industry (I22PH_civil service) or had engaged in 'battling with these various interest groups' (I5PH_civil service). The official appointed to lead the newly created body was supported by the DoH leadership to take on a masters' degree in HTA at the University of Birmingham in the UK (2011-2012) to mitigate the strength of the industry with expertise in HTA. Further, the main supporter of HTA in the Philippines who had initiated HTA at PhilHealth was appointed Undersecretary of Health at the DoH, under the new administration, and continued to support HTA as a policy solution for pharmaceutical selection, procurement and reimbursement.

> HTA is not very new to the Philippines, […] Undersecretary Madeleine Valera - so she introduced HTA back in 1999 in PhilHealth. They were already doing it, except that here [in the Philippines] reforms are personality based, so she left PhilHealth and PhilHealth dropped HTA. (I5PH_Civil service)

NCAPM issued new procedural rules for PNDF inclusion soon thereafter. The new rules, collectively referred to as the Philippines National Formulary System (PNFS),

included substantial revisions to the membership of the committee, submission procedures and prioritisation of submissions, as well as procedures for evidence synthesis and generation, and rules for transparency, such as declaration of conflicts of interest, and public sharing of PNDF materials). Cost-effectiveness was added as a criterion for inclusion, alongside the detailed procedures to be used. In addition, more stringent criteria were attached to decision-making on exemptions to procurement requested by government bodies (e.g., DoH programmes or public hospitals).

The FEC could ask for further evidence gathering to be carried out by so-called evidence review groups (ERG). The ERGs would be charged with preparing evidence summaries on the PNFS' inclusion criteria: benefit/risk assessment; cost-effectiveness; budgetary impact and health system consideration. The evidence summaries would be based systematic reviews and other sources such as clinical practice guidelines and post-marketing surveillance data. Criteria for forwarding submissions to the ERGs would be 'deliberated on by the FEC' (AO 0018/2012). In practice, the ensuing process for ERG submissions was a not very systematic, lacking a score or checklist (I3PH_academia). Decision-making was described by one member of the FEC as being based on whether the evidence was deemed *'*sound and believable', but not associated procedures were clarified (I13PH_academia). Besides FEC members, specialities representatives could be called for deliberations if necessary. Consequently, key informants spoke about prioritisation and even decision-making in some cases being reached depending on who was present at the meeting (I3PH_academia), particularly since 2015, membership was lowered from eleven to seven members due to difficulties in achieving quorum (I18PH_civil service).

Submissions to the ERG happened only in two cases: if evidence was contested among FEC members, submissions were prioritised and submitted for ERG review;

if evidence was believable, but no decision-making could be reached (high degree of uncertainty), submission to the ERG would also be warranted. However, formal economic evaluations by the ERG were rare. Most decisions are made based on efficacy/effectiveness data or expert opinion and a comparison with prices on the successful price bid list or the Drug Price Reference Index (DPRI) for essential medicines.

> So I don't know if there are other people in the country who can do that. So because of that many of the decisions that are made in the HTA I would say about 80 percent do not include a cost-effectiveness evaluation or economic models. Many times it was down to either cost minimisation type of analysis or even a cost consequence analysis. (I13PH_academia)

Although cost-effectiveness evaluations were rare, the FEC secretariat and the NCPAM continued to make incremental moves to support their use by the FEC. In 2012, the Undersecretary of Health established links with NICE International in order to learn from the process of NICE. In 2012-2013, the FEC secretariat received support from NICE International and HITAP in carrying out three economic evaluations for priority topics in the country. As a result of these partnerships, the Formulary Secretariat commissioned the development of a methods manual by a leading health economist in the country. The aim of this manual was to standardise the evaluation process, ensure methodological quality and a transparent process based on HTA principles. Further, a cost-effectiveness threshold of 1 GDP per capita was adopted by the FEC, as recommended by the WHO Commission of Macroeconomics in Health.

According to FEC members, dissent over a FEC decision within the committee was rare. However, some high-profile cases of contestation were linked to a limited number of cost-effective analyses on innovative vaccines, conducted starting in 2013 (I2PH_academia). These episodes of dissent will be discussed in chapter 8.

In summary, HTA processes for medicines coverage developed incrementally based on the existing procedures at the PNDF, as well as being informed by the HTA processes of PhilHealth. Initially, HTA advocates tried to complement the procedures for inclusion in the Formulary and reimbursement at PhilHealth. However, the collaboration between PhilHealth and the DoH on assessing medicines was short-lived. PhilHealth leaders challenged regulations indicating that PhilHealth could pay for evidence generation experts and that DoH would maintain decision-making power. PhilHealth believed it should be able to make decisions over the coverage of medicines, not only their reimbursement. As will be seen in chapter 8, the lack of clarity in roles between the DoH and PhilHealth continued to be a challenge to the sustainability of PNDF processes.

The expansion of services covered by PhilHealth

In January 2016, a Subcommittee for Benefits was established under the PhilHealth Board for the first time and was charged with clarifying decision-making on benefit expansion by PhilHealth (see chapter 5 for a more in-depth analysis of this policy problem). In short, the process of developing benefits by PhilHealth became of interest for policy action in the context of perceived irrational prioritisation of benefits as well as delays in the implementation of primary care benefits or other benefits under consideration by the PhilHealth Board (I16PH_civil service; I7PH_reseracher). Interviewees explained that the Subcommittee was formed at the advice of researchers and civil servants that had a wider interest in health care reforms and advancing towards UHC. This advice was given directly to a member of the PhilHealth Board (I16PH_civil service).

The members of the Benefits Subcommittee are representatives for: the employers sector (chair), informal economy sector (vice-chair), elected local chief executives,

Department of Finance, health care providers sector, formal economy sector, Filipino Overseas Worker sector, Department of Social Welfare and Development, and an expert member of the Monetary Board (members). Civil servants of the PhilHealth Department for Benefit Development and representatives of the commissioner (UNICEF Philippines) also sat on Subcommittee meetings. The Subcommittee met approximately five times during December 2015 – June 2016.

In parallel, the UNCEF Philippines, which had an interest in benefit package development and was awaiting the implementation of a benefit package for premature births, as well as one for children with disabilities, commissioned a study to provide answers to the question of what conditions should be prioritised for the expansion of benefit packages. Two private research organisations established by Filipino academics, Epimetrics, Inc. and the Alliance for Improving Health Outcomes Research (AIHO), carried out this study. The research group was invited to present its work to the Subcommittee on Benefits in January 2016.

The research group utilised Global Burden of Disease and Census Population Projections (2015-2035) to produce a 'list of the most burdensome disease causes' (Wong *et al.*, 2018). The research group presented the findings of the initial study by comparing the top burden of disease (measured in DALYs) to the main claims paid by the PhilHealth in 2014. They used the Pareto principle as an arbitrary point to identify the diseases responsible with the largest share of the disease burden, i.e., 80% of DALYs lost. In general, the research group showed a mismatch between the burden of health problems and current spending, as well as very few of these priority problems being allocated a large share of the spending because costly interventions were prioritised over less costly and often less technology intense interventions (e.g., pre-term birth complications interventions: paying for routine obstetric care and caesarean sections separately) (Wong *et al.*, 2018). The Pareto principle was used in presentations to the Subcommittee members, who easily understood the general

principle that a small number of conditions would cause the majority of DALYs lost. Based on its findings, the research team suggested that PhilHealth should be developing its benefit packages by using criteria of burden of disease, cost-effectiveness and relevant ethical criteria (particularly priority to the worse off).

> But then when [PhilHealth]got the list … okay, ischemic heart disease, we already have a package for this or COPD. We already have this. I don't know what others, diabetes, other common ones. So the question was, what do we do now? What do we do with this list? What are the interventions that we should cover, because they're so used to expanding by intervention/interest group? Like, it's a very niche population, like children with disabilities, premature new-borns, other packages. Kidney transplants, breast cancer … they were so used to disease/intervention [pairs], that they weren't sure what to do with the list of the high burden diseases. 'Okay, you gave this to us. What do we do with it?' […] 'What do you propose? Maybe you need a benefit package. Maybe you need a priority-setting process' and then they said, 'Oh, maybe, yes. That's a good idea. We can do that,' […] So deliverables kept on changing along the way, because we just had to respond to what PhilHealth … what we thought PhilHealth needed and basically our assessment of how they could benefit from our work.' (I7PH_civil service)

In light of these findings, the Subcommittee agreed to expand the remit of the initial project. Initially researchers considered developing distinct benefit packages for the 48 conditions that they identified as causing 80% of DALYs lost (I7PH_researcher). However, the research team realised that the task was beyond their capacity, partly because it required data that was unavailable (e.g., on the costs of the proposed benefits). There was an ongoing process of consultation and decision-making between researchers, civil servants and commissioners to decide on the best proposal for the Committee. Eventually, a new goal was set that was to produce: 1) a proposal for a priority-setting process, 2) a prototype for the development of benefit packages, and 3) a list of interventions to undergo economic evaluation.

The prototype for the development of the benefit package was renamed the guaranteed health benefit package (GHBP). The prototype uses the tool developed by the WHO-CHOICE initiative for generalised cost-effectiveness analysis: the

OneHealth Tool (OHT) software. These tools were useful in localizing foreign cost-effectiveness studies (by inputting global disease burden estimates, as well as adapting outcomes and costs to the Philippine population). In the short term, researchers proposed that the process would have to be supported by such localisation of global data. In the long term, however, they outlined the need for systematic data collection, epidemiological data, more information on intervention inputs and costs, and health utility data elicited from a Philippine sample. Such pre-requisites for economic evaluation were lacking in the country at the time.

The development process for the GHBP included a first step of reviewing literature on priority-setting principles. Interviewees indicated that the research group was informed by two main sources from the international literature: the report by Glassman and Chalkidou (2012) that reviews the experience of priority-setting institutions, with a focus of making recommendations for low and middle-income countries; second, the accountability for reasonableness framework (Daniels, 2000), which has informed many established HTA processes. Furthermore, researchers reviewed the published experiences of HTA processes in other settings, such as Australia, Chile, Thailand, and England and Wales. Based on these sources, researchers identified twenty procedural and substantive criteria that they then prioritised in focus group discussions with selected actors. The research group identified participants based on their expertise in public health, evidence-based medicines, ethics, quality of care, health policy, health economics, epidemiology and law. The focus group discussions were aimed at debating and re-classifying criteria, in order to identify which criteria should or should not be used for priority-setting by PhilHealth.

The development of this process highlights the difficulties of translating existing criteria and process steps from other settings. As expected, consultations on the relevant priority-setting criteria were relevant for consensus building, rather than

achieving agreement (I2PH_academia). Interviewees involved in the consultations highlighted that some results were unexpected, in particular the lower value received by equity considerations. Participants did not value equity and fairness highly because there was a perception that it would lead to exclusion of parts of the population that are comparatively better off, thus undermining the goals of UHC. Furthermore, participants also valued 'expressed stakeholder demand' negatively due to being associated with undue influence and lobbying for specific benefit packages.

Roundtable discussions used the outputs from focus group discussions to refine the list of process and priority-setting criteria. Some experts argued that over-emphasis on magnitude did not sufficiently take into account the difference between life-saving interventions and lower-impact treatments. Furthermore, some experts, particularly clinicians, disagreed with prioritising high-burden diseases over rare conditions. Ultimately, it was research group members who made decisions on how many criteria to select, and many of these criteria were adopted through direct emulation of existing HTA processes. For example, cost-effectiveness was relatively low on the list, below equity and fairness, but it was added as a criterion for priority-setting anyway. Overall, the research team added cost-effectiveness as a criterion to be included after three main priority-setting criteria were applied to shortlist interventions: magnitude and severity with an equity component, effectiveness and household impact.

Researchers themselves indicated that there were some barriers to the direct emulation of criteria and practices used in other settings. First, there was little guidance on how decisions on criteria were made in other countries, which raised a question about the out-of-context character of existing advice. In particular, the research team wondered why and how certain decisions were taken with regards to HTA process steps. There were also questions about why certain processes were

carried out in specific parts of the bureaucracy and what was the link with other parts of the civil service. Consequently, researchers tried to use of existing structures of PhilHealth for the different functions of the process. Interestingly, the creation of a jury pool for shortlisting and appraisal panels was based on the example of Thailand's nomination and prioritisation panels. As explained in the case study of Thailand, the participatory mechanisms used by the NHSO drew on pre-existing structures of public engagement, namely the Thai National Health Assembly. Following this model, the research group recommended that PhilHealth assemble a three-year jury pool of 'experts, advocates and sectoral representatives, willing to declare conflicts of interest and ensuring that the members would be geographically representative' (Timola, 2018), but that would mean establishing these mechanisms for this specific process.

The proposal outlined above was approved by the Benefits Subcommittee and the PhilHealth Board in May 2016. However, this approval came just before a change in administration which led to new appointments at the DoH and the leadership of PhilHeath. Clearly, the implementation of the priority-setting process depended on the incoming leadership. In addition, civil servants and HTA advocates indicated that the influence of the civil service, whose members were involved in the process development, could also lead to the implementation of the proposal, as was the continuing support from the research team. Consultants describe aiding civil servants in the implementation of their output, including by preparing policy documents, such as circulars, for implementation.

> Once they're okay with it, now that their board has approved of it [the priority-setting process], then our work is not yet done. It's still in our commitment to do the circulars with them. Because if we expect them to take it on after we give them a full technical report then maybe it's one year after, two years after, it still not yet done. The strategy for us, for fast massive uptake, will have to be: okay, now that it's approved, you give it back to us, what are the main issues? Okay, we take this into account; we draft it for you, you [route] it in

> the office, and if you need any more changes tell us, we will help you edit it. It's really an added arm and leg for them [civil servants]. (I12PH_ researcher)

As explained in chapter 6, however, some HTA advocates believed that HTA processes should be housed by the DoH. In effect, subsequent developments led to focus being concentrated on DoH activities, with plans for a HTA council housed by the DoH to consider coverage decisions for health services, as well as medicines.

In sum, the development of the priority-setting process for PhilHealth was prompted by increasing debates on the appropriateness of the benefits being provided. These debates focused equally on the types of services being provided and the conditions that were being prioritised via existing benefit packages. A research project commissioned by UNICEF Philippines attempted to respond to both these aspects of the policy problem. It reviewed existing procedures for priority-setting from other countries to identify criteria for prioritisation and review these through a consultative process. The research team also produced analyses that associated priority conditions by burden of disease with cost-effective interventions. Based on these analyses, the team produced a proposal for priority-setting to PhilHealth which was adopted by PhilHealth Subcommittee on Benefits. Decision-making and implementation of the process remained the decision of the PhilHealth Board.

Summary

The development of HTA processes in the Philippines was organised around three policy problems that policy-makers needed to address. They were very similar to the problems to which HTA was expected to respond in Thailand and resulted in attempts to develop HTA processes to: inform decisions on investment in medical equipment (which evolved into defining reimbursable services for PhilHealth); inform decisions of inclusion in the country's essential medicines list; and develop a mechanism of setting priorities for the expansion of PhilHealth's benefit package.

In chronological order, the first HTA process was developed even though the problem of overinvestment in medical equipment was anticipated rather than identified as a major trend in the Philippine health sector. Further, the existing institutional arrangements for social health insurance did not provide many levers for tackling the problem of investment in medical equipment. Consequently, once a HTA process was established, it contributed to refining the policy problem in accordance with the institutional context - specifically, the reimbursement of medicines and of routine medical services used in reimbursable inpatient procedures. However, the new focus, particularly on medicines, attracted opposition from manufacturers. One episode of confrontation between manufacturers and PhilHealth over the assessment of atorvastatin (Lipitor) that involved a recommendation to not reimburse the medicine had important consequences to limiting the activities of the HTA committee and, ultimately, its discontinuation. The conflict over atorvastatin directly led to PhilHealth giving up HTA of medicines. However, HTA processes for medicines were not completely abandoned. They were moved to the DoH, which policy-makers believed had the authority to carry out such assessments for inclusion in the essential medicines list and associated National Formulary.

The HTA process developed for the National Formulary resulted in task sharing between the DoH and PhilHealth and built on the procedures that had been developed by the HTA committee. However, the new process was never implemented due to disagreements between DoH and the PhilHealth leadership. In parallel, direct, ad-hoc negotiations with manufacturers as a result of the Cheaper Medicines Act suspended regular procedures for medicine selection in the Formulary. The re-constitution of the Formulary Committee brought about the development of new procedures for the Formulary and the inclusion of cost-effectiveness as a formal criterion for medicine selection and that could inform price negotiations (2012). However, the associated procedures were slow to be developed and economic evaluations rarely informed the deliberations for inclusions.

A third HTA process was developed as an answer to the opaque process of benefit development by the payer, PhilHealth. The UNICEF country office, which had collaborated with PhilHealth on the development of selected benefits, funded a study on identifying priority conditions that should be tackled by PhilHealth. The results were presented to a PhilHealth Subcommittee on Benefits, although there were no formal links between PhilHealth and the commissioning of the study. The policy problem was refined in collaboration with this Subcommittee and PhilHealth civil servants. Specifically, PhilHealth already provided benefits targeting high-burden conditions, although not consistently. The focus of the study became to identify best available interventions for 48 conditions that caused 80% of disease burden. While the task of using generalised cost-effectiveness analysis to achieve this goal proved to be beyond the capacity of the research team given available resources, the project resulted in a proposal for a process to develop a guaranteed benefit package for the PhilHealth and to assess any new interventions being considered by PhilHealth. The process was developed by reviewing international experience in priority-setting and by consultative meetings to adapt international criteria and principles to the Philippine context. Both proposals were approved by PhilHealth Board just before a change in administration. The implementation of the two proposals was likely to depend both by incoming PhilHealth leadership and wider debates over purchasing responsibilities in the Philippine health system.

The debates over purchasing and further contestation to the functioning of HTA in the Philippines will be analysed in Chapter 8. The following section will compare and contrast the development of HTA processes in the two countries.

Comparative analysis of the development of HTA processes

The analysis of HTA process development in the two countries highlighted the multiple attempts at establishing HTA processes. The policy problems that were tackled by HTA processes were remarkably similar across the two countries. The

fact that HTA was initially seen as a tool to inform investment in medical equipment seems like a clear sign of policy transfer, as was the problem of high-cost medicines. The same cannot be said about defining a minimum benefit package. High-income countries have only rarely set out to clearly define their health benefit packages. Instead, they use HTA and other means to define aspects of the health benefit package. For middle-income countries, in line with development towards UHC, the complex question of how to cover the basic services emerges, in addition to increasing demand for innovative services.

Unsurprisingly, then, the first policy problem raised by HTA advocates in both countries was investment in expensive medical equipment. Differences between the two countries came from the degree to which HTA advocates defined the policy problem through the lens of the existing country institutions that were mandated with finding solutions to the problem or needed to be reformed to do so. For example, in the case of Thailand, HTA advocates concentrated on the existing decision-making arrangements for investment in medical equipment. Specifically, government involvement in medical equipment was considerable, at different levels of government: the MoPH central and provincial leadership, as well as the Bureau of Budget under the Ministry of Finance. As a consequence, all these decision-making points needed to be informed by a proposed HTA process. HTA advocates also believed that investment in medical equipment by private providers was to the detriment of the public health system, in the absence of a uniform policy that supported private provision alongside public provision. Seen only briefly in the 1990s in association to HTA, the problem re-emerged as the Thai government unveiled the Thai Medical Hub policy designed to encourage medical tourism to Thailand. Initially, the growth of the medical tourism industry was seen as an opportunity to increase financing of the publicly financed UCS. However, these coordination plans did not receive sufficient support. As a consequence, the ambitious proposal for a Medical Device Board also encountered in-government

opposition. Furthermore, the plans were ambitious given that the application of HTA to medical equipment is notoriously difficult due to the generally lower levels of regulation applied to medical devices. As such, opposition also came from outside government.

In contrast, in the Philippines, there was little role for government when it came to investing in expensive medical equipment. As such, the first iteration of HTA was implemented independently from the institutional arrangements for investment in medical equipment. In other words, the idea of HTA - as a tool for cost-containment associated with innovative medical equipment - was transferred in an institutional context where there were no clear decision-making structures for the problem. Thus, the Philippine case at this stage seems to be a pure case of policy transfer. However, the lack of power structures - that could be infringed upon by a HTA process with regards to medical equipment - allowed the process to be modelled by the payers' other needs or policy problems. Once implemented, the focus of HTA processes further changed based on the priorities and role of the payer under which it functioned. Neither of these included direct influence on investment in medical equipment. Rather, the focus of HTA processes shifted towards basic services and treatments, which represented the bulk of reimbursable claims by PhilHealth. The focus of the HTA processes evolved as a response to PhilHealth's institutional roles. Specifically, PhilHealth could influence provider behaviour indirectly, based on: a) limiting reimbursement of medicines to those included in the National Formulary; b) developing procedures to judge reimbursable claims from providers; c) developing evidence-based guidance for providing newly introduced services; and d) developing accreditation procedures for providers.

One particular factor that distinguished the two cases was the degree to which domestic research and evidence generation influenced the establishment of HTA processes. In Thailand, evidence generated by IHPP on specific equipment directly

drove the MoPH to attempt to establish authority over generating such evidence and associated recommendations for appropriate investment in medical equipment. In contrast, in the Philippines, evidence generation, appraisal and coverage decisions seemed to be brought about by HTA processes, once established. Because both countries had domestic research teams that developed policy proposals for priority-setting, we posit that the contrast was due to weaker institutional pathways for research to inform policy-making in the Philippines rather than a lack of capacity from researchers. This hypothesis is supported by the lack of pre-requisites for economic evaluations – such as burden of disease studies based on basic national statistics or costing data – in the Philippines. By comparison, key-informants in Thailand highlighted the importance of this basic evidence 'infrastructure'.

In both countries, the placement of the authority for coverage decisions was a significant institutional influence on the design of HTA processes. Different views over who should coordinate HTA processes led to interruptions in the case of the Philippines, and parallel organisations aiming to coordinate HTA processes in Thailand. For example, in the Philippines, once the policy problem to which HTA procedures at PhilHealth responded was re-defined to be the lack of reimbursement of newer medicines, HTA advocates agreed that the authority for such decision-making lay with the DoH, which was already hosting a committee for inclusion in the essential medicines list and associated Formulary. In response to the contested exclusion of Lipitor from PhilHealth reimbursement and the opposition from manufacturers linked to this decision, HTA of pharmaceuticals was moved to the DoH.

As the two countries expanded their publicly-provided services, they needed to consider the role of the essential medicines list and develop procedures for reimbursement and procurement of medicines. In Thailand, HTA processes focused particularly on reimbursement, whereas the role of the essential medicines list for

medicines procurement was particularly important for the Philippines. This difference is due to the institutional context in each country. In Thailand, the newly created UCS added a third layer of reimbursement procedures, in parallel with reinforcing the rule that each scheme was to use the NLEM list as a reimbursement list. This was done with soft regulation, rather than a clear decision as part of the UCS reforms. In contrast, the essential medicines list in the Philippines was mainly used for procurement of medicines by the DoH. The same limitation for reimbursement of essential medicines only by the PhilHealth existed. However, in practice, the benefit packages developed by the PhilHealth had not way of tracking which medicines were actually used. Providers were reimbursed for a specific kind of service, not the medicines they used to provide that service.

In both countries, HTA processes were developed as part of adjustments to existing selection procedures for their respective essential medicines list. Both countries had rules that limited reimbursement by public insurance schemes to medicines in the essential medicines list. Eventually, both countries moved to include patented, innovative and expensive medicines in their essential medicines lists. For example, in Thailand, the essential medicines list was re-branded as an optimal list once it included high-cost medicines. In Thailand, the NLEM has been referred to as an optimal list, perhaps to respond to criticism that the UCS will not be able to provide the newest medicines demanded by patients. However, the institutional place of the NLEM stayed the same, with new procedures being added, including economic evaluation for expensive medicines and price negotiations in collaboration with the NHSO. A new sub-list was also created, specifically for these expensive medicines. In contrast, in the Philippines, both the procedures and the institutional placement of the PNDF process were repeatedly changed, starting in 2006, due to changes in legislation.

There was considerable difference between the extent to which economic evaluation were conducted to inform decisions on which drugs to include and played a role in policy development for reimbursement or procurement. As seen in the Philippine case, regulations clearly stated that cost-effectiveness should be a criterion for decision-making employed by the committee. However, very few economic evaluations were carried out to support PNDF inclusion. Three such studies, starting with 2012, informed deliberations over exemption requests to procure innovative vaccines. In Thailand, the move towards HTA included informal generation of economic evaluation and other research to inform policy development of high-cost medicines before cost-effectiveness became an official criterion for NLEM inclusion. Associated procedures were developed incrementally and consisted of the creation of a Health Economic Working Group under the NLEM that could identify the type of problems of the NLEM that were amenable for economic evaluation.

Comparing the two processes also highlights the role of economic evaluation guidelines. In Thailand, interviewees suggested that the guidelines played a key role in developing and establishing HTA. They were based on PhD research of the official who later became the HITAP director. The process of guideline development included commissioning topics to researchers from universities who reviewed the state of the art and assessed the most appropriate rule based on the Thai capacity. It also guided ‘infrastructure’ needs such as preference valuation for health-related quality of life from a Thai sample, and built on an already strong health information system. The process of guideline development was settled based on authority and expertise. In the Philippines, having more than one economist in the Formulary Executive Committee highlighted differences and debates between what were considered acceptable assumptions for economic evaluations. As such, guidelines that could provide a common frame of reference and limit variability in methodology were under development as of 2016.

Economic evaluation guidelines are important because different health economists could carry out research to answer a specific question in different ways. Uniformity would ensure that the same analysis could be carried out by different researcher, and not negotiate choices that are unlikely to be evidence-informed. The importance of the guidelines can be seen in the Philippines, where there was a limited number of heath economists, who would not only argue for the appropriateness if the analysis, but also the specific methodological choices made. Methodological guidelines minimise both such disagreements and variability in methods used.

The similarity in policy problem that HTA was expected to address continues for the third type of HTA processes developed in each country. Again, the definition of the policy problem was influenced by in-country institutions. In Thailand, there was sustained pressure on the NSHO to expand the health benefit package, often by adding services on its high-cost list, which was explicitly defined. In the Philippines, PhilHealth continuously expanded its benefit packages and was, by all accounts, responsive to lobbying and advocacy from various sources. The definition of the policy problem highlighted the need to prioritise among conditions as well as judging the value for money of interventions tackling specific diseases. In the Philippines, the researchers who developed the priority-setting and associated HTA process addressed the first part of the problem more clearly. In Thailand, the priority-setting process approached prioritising between conditions indirectly, by prioritising proposals for consideration, not by comparing interventions across conditions.

In both countries, the priority-setting processes was directly commissioned by the payer (Thailand) or a development partner collaborating with the payer (Philippines). The development process included reviewing international experiences and organising consultative meetings to debate appropriateness of principles and criteria for priority-setting with in-country actors. Notably, the Philippine researchers drew

heavily on the priority-setting process developed in Thailand. Decision-making on appropriateness of criteria was debated in groups of experts and policy-makers, but were ultimately decided by researchers and a limited numbers of policy experts.

Conclusion

This chapter analysed the process of developed of several HTA processes in Thailand and the Philippines. These processes responded to policy problems that were similar in both countries, but that were defined in detail through their association with existing institutions. These existing institutions, specifically existing decision-making procedures for the three policy problems, were modified incrementally by adding the distinct elements of HTA. The processes that failed tended to attempt to establish completely new decision-making processes. The common frame provided by HTA as a policy solution, particularly its associated methods, was an important tool that, while debated, tended to be settled among a limited number of experts. Once settled, it enabled collaboration amongst experts that shared a common frame of reference.

Existing institutions were not only relevant for the development of HTA processes, but also for their ongoing functioning and sustainability. This issue will be explored in chapter 8.

8. Ongoing functioning of HTA processes in Thailand and the Philippines

Having explained how HTA was established, both in terms of organisation and process elements, the current chapter looks at how HTA processes and organisations operated in an ongoing process of institutionalisation. First, it will explore how the interest of actors who are generally associated with opposition to HTA emerge with regards to specific decisions. Second, it will analyse the nature of the debates that emerge when decisions are contested. Finally, it will explore the link between HTA and other parts of health system governance, specifically the interaction between HTA organisations and processes and MoPH/DoH or payers.

This chapter will start by analysing these three elements for each of the two countries, followed by a comparison of the characteristics of the ongoing process of institutionalisation in both countries.

Ongoing functioning of HTA processes in Thailand

As of 2016, the three HTA processes functioning in Thailand – the NLEM process, the SCBP process and the IMRTA process - had reached different levels of establishment. Specifically, one interviewee referred to the NLEM process as having been successful in collecting the 'low-hanging fruit' (I3TH_civil service) of applying economic evaluation to high-cost medicines and contributing to lowering prices of such medicines. They described the usefulness of producing evidence for decision-making for high-profile medicines and indicated that the contestation was particularly useful to the establishment of the NLEM HTA process (I3TH_civil service). In particular, HITAP carried out research related to high-cost medicines that were directly tackled by the Thai government through compulsory licenses

before the establishment of HTA processes. Interviewees from HITAP suggested that such research contributed to establishing both the authority of HITAP within the bureaucracy, and the legitimacy of using cost-effectiveness to inform inclusion of high-cost medicines (I2TH_civil service).

In contrast, the use of HTA at the NHSO appeared less established. In 2011, as part of the NHSO priority-setting, HITAP and IHPP argued that the decision-making process should focus on developing a "population-based screening package" for the UCS. Eleven interventions were suggested for inclusion into this screening package, presented to the Subcommittee in 2013 (Teerawattananon et al., 2016). Compared to medicines and other curative services, health promotion interventions were quick to attract contestation. First, actors in the NHSO Board opined that value for money was not a relevant consideration for this screening benefit package because 'health promotion is always good' (I7TH_academia). Second, HTA researchers also noted that these debates were o caused by the lack of high quality studies of the effectiveness of health promotion interventions. There was also debate on how to measure the effectiveness of health promotion interventions, for example with regard to measuring health outcomes (Greco, Lorgelly and Yamabhai, 2016). As a result of these two factors, the evidence generated to support the development of the population-based screening package often did not include economic evaluation. Interviewees suggested that, opposition to value for money as a criterion notwithstanding, the lack of clear judgment on the value for money for these interventions led to HTA processes encountering more contestation and questioning.

> But sometimes research is like art. […] Most of the time, we cannot do economic evaluation for every health promotion intervention, as we cannot find good evidence to support the effectiveness of this kind of intervention. So, when you review the best [effectiveness] evidence you have in hand, and you summarise everything for every intervention, the existing interventions in Thailand now, and you show them to policy-makers, it seems like, hmm, difficult to judge, because we don't have economic evaluation results to support making the decision that this is worth to invest in, for example. So, it's

> difficult; it's more difficult than treatment interventions, when you use an economic evaluation study. (I6TH_academia)

Some of the methodological problems outlined above were addressed by a second edition of the Thai HTA guidelines, which included more guidance for generating evidence of effectiveness. Further, considerations with regards to other criteria, such as social and ethical implications of coverage decisions were given increased attention (Chaikledkaew and Kittrongsiri, 2014). Another area of improvement was on the cost-effectiveness threshold, which had not been included in the first edition. In 2013, HITAP conducted a study that estimated a cost-effectiveness threshold for the Thai population based on willingness to pay (i.e. using a demand-side method). The results showed a range between 0.4 -2 times GDP/capita, which was lower, but 'in line with the range of 1-3 times the GDP per capita that the Commission on Macroeconomics and Health recommends' (Thavorncharoensap *et al.*, 2013, p. 34). The findings were considered to be 'consistent with the past allocation decisions of the NLEM, which set a ceiling threshold of 1 GDP/QALY' (Thavorncharoensap *et al.*, 2013). The study also indicated that there should be more than one threshold, depending on the conditions under consideration and the size of health improvement they produce.

Furthermore, as stated by an official of HITAP, the work of the SCBP process at NHSO also resulted in several other questions to which answers were required regarding the implementation of selected interventions. These were not covered in existing guidelines, because they were not normally part of HTA processes. Such questions required different types of evidence to be answered, such as evaluations of programmes and implementation research. For example, HITAP embarked on the development of quality standards to ensure appropriate implementation of interventions that had been recommended and included in the UCS benefit package. This particular task was carried out with support from the international branch of NICE, with which HITAP had developed close working relationships. Some

interviewees from Thailand indicated that this new direction of HITAP was not desirable or appropriate and that HITAP should continue to focus on assessing value for money and informing decisions to fund health services (I5TH_civil service; I10TH_civil service).

However, some of the debates around health promotion interventions, even when expressed in methodological terms, were not about strength of evidence, but about opposition to HITAP acquiring more power (I23TH_academia). The same actors who disagreed with HTA processes assessing health promotion interventions also suggested that the MoPH should not have more than one HTA body and indicated that IMRTA should be maintained and strengthened (I23TH_academia). This was explained by the fact that HITAP staff were predominantly pharmacists, therefore not qualified to assess medical interventions. The IMRTA was not seen as having the same problem, as it was part of the DMS, which managed the country's top speciality hospitals.

A key factor to the sustainability of HTA processes was the support from the NHSO. For example, the high-cost medicines included in the NLEM were then procured centrally by the NHSO. As one key-informant suggested, the balance of power in the NHSO Board was vital for the adherence to either of the HTA processes coordinated by HITAP, and not reverting to decision-making via informal pathways. As suggested at the start of this section, both the NHSO membership and the NHSO Secretary General were important in what direction the procedures set up during 2009-2010 would take. As one civil servant interviewed in 2016 warned:

> And then if the Benefit Package Subcommittee does not use evidence and if the NHSO is lobbied successfully [by the pharmaceutical industry], then HITAP is not used by policy-makers. So if the [industry] is clever enough, [they] don't fight with [HITAP] but try to drive the policy-makers in NHSO. So far they couldn't, but at the upcoming change of administration in the NHSO, perhaps they can. So – if there is no demand for HTA evidence, you

> don’t have to fight the suppliers of evidence, which are HITAP and IHPP. (I12TH_civil service)

An example of the importance of this link with the NHSO were developments emerging in 2016 with regards to the coverage of Human Papillomavirus (HPV) vaccines. The two HPV vaccines available on the market in 2016 were Gardasil quadrivalent - which protects against Human Papillomavirus Types 6, 11, 16, and 18 -, produced by MSD Sanofi, and Cervarix, produced by GlaxoSmithKline (GSK). The two vaccines were introduced in the Thai market in 2007. Soon thereafter, HITAP and IHPP, with funding from the World Bank, undertook a study to identify appropriate policy options for cervical cancer prevention and concluded that HPV vaccination was unlikely to be cost-effective at given prices. Instead, it found that cervical cancer screening through VIA or Pap smear provided better value for money (Tangcharoensathien et al. 2008). The vaccines were also submitted for inclusion in the NLEM several times at lower prices, but they were again found not to provide sufficient value for money and were therefore not included in the reimbursement list.

The repeated attempts to include HPV vaccines in the NLEM were driven by the National Vaccines Institute, an institute under the MoPH. The leadership of the Institute disagreed with the NLEM decisions and attempted to re-initiate the process of NLEM assessment several times, unsuccessfully. Until 2016, the NHSO resisted requests to procure medicines that had not been included in the NLEM. However, in 2016, a budget line for HPV at the NHSO was published for the 2017 NHSO budget line. In the context of pressure from the National Vaccines Institute to re-initiate the NLEM process, it was seen as possible that a second strategy had been to negotiate directly with the NHSO Board.

This example shows the importance of NHSO decision-makers and their power of allocating NHSO budgets, including its central procurement power. The appointment of the NHSO Secretary General had been consistently criticised starting in 2012. It is

likely that these changes were linked with the conflictual position between different factions of the MoPH which dated back to the UCS establishment.

> Normally, the people who are inside the Ministry, and also the people from the big hospitals, they prefer the previous system that the budget, all the budget go through the Ministry of Public Health, that they have the power […]. But, in the system of the NHSO, all have to be in the committee, and the committee is comprised of the people from outside also, such as civil society groups. So, they [the former group] are not happy [at this], because they have to [convince the outsiders]. (I8TH_civil service)

After the end of the interviews for this study, the NHSO was in fact stripped of its procurement power, through a decision of the Cabinet. Procurement for medicines was moved under the administration of Siriraj Hospital, a Bangkok-based teaching hospital. This decision would likely have an impact on the sustainability of HTA processes (both NLEM and NHSO) for two reasons. First, as indicated by one interviewee, the demand for HTA evidence could be removed if it lost the support from the NHSO leadership. Second, even if HTA processes would still function as outlined in Chapter 7, the loss of linkages with procurement processes, or the removal of the NLEM as a reimbursement list, would likely make these processes less effective in practice.

In summary, the functioning of HTA processes in Thailand showed ongoing debates that focused on three angles. The first type of debates that emerged were about the appropriateness of value for money criteria for services other than high-cost medicines. The second type of debates expressed disagreements caused by specific interests and fights for power. For example, advocates for offering HPV vaccines under the UCS scheme challenged the NLEM HTA process and eventually argued that NHSO should procure vaccines despite none being included in the reimbursement list. Further, some actors expressed that HTA processes should be coordinated by IMRTA instead. This view aligned with long-term conflicts between UCS supporters and opponents. Lastly, the sustainability of HTA processes emerged

as being linked to NHSO's procurement power. Interviewees indicated that attempts to influence the NHSO Board had been unsuccessful as of 2016. However, in 2018, the NHSO was stripped of its procurement power by the Cabinet. This change in governance arrangements was likely to influence the sustainability of HTA processes at NLEM and NHSO.

Ongoing functioning of HTA processes in the Philippines

In the Philippines, the PNDF process was the only HTA process operating as of 2016. As explained in chapter 7, the PNDF did not commission economic evaluations often. However, faced with requests for inclusion of several new generation vaccines, three economic evaluations were undertaken to assess the inclusion in the PNDF of HPV vaccines, pneumococcal conjugate vaccines (PCV) and dengue vaccine.

The economic evaluations for HPV and PCV vaccines were carried out in March 2013, with technical assistance from HITAP and NICE international. The study found that a national HPV vaccination programme was cost-effective, under favourable assumptions of lifelong immunity (Guerrero, 2015). However, the vaccine was not included in the PNDF until 2015. In parallel, the DoH launched a pilot programme for school-based vaccination of 10 000 girls, in two provinces. The manufacturers of Gardasil, MSD, donated 20 000 doses out of the 30 000 needed for three doses for each girl. In order to procure the remaining 10 000 doses, the Secretary of Health approved a one-year exemption from PNDF inclusion, which allowed public bodies to procure specific medicines that are not included in the PNDF.

The pilot programme and the results of the economic evaluation were contested in the public space. The debate focused on the choice of the vaccine procured by the DoH for the pilot programme. The choice of the vaccine was contested both by

critics and supporters of the inclusion of the vaccine in the PNDF and it becoming part of the National Immunization Programme (NIP). Among supporters of the inclusion of the vaccine in the NIP, it was suggested that HPV bivalent should have been procured simply because it was cheaper and, in the absence of epidemiological data that supported the types of strains more prevalent in the Philippines, the cheaper vaccine should be chosen. As the results of the economic evaluation carried out by the PNDF were leaked to researchers and then to the press, the debate focused on the results of these studies, which were critiqued on methodological grounds. Among opponents of including HPV vaccines in the NIP, the argument was that the existing evidence only supported the conclusion that Gardasil offered value for money only under favourable assumptions of lifelong immunity. Further, the decision to procure Gardasil could only be supported if the protection against genital warts was accepted as an outcome. Again, the lack of epidemiological data contributed to this line of contestation, alongside the critique of the assumptions for the economic evaluation.

Thus, debates about the pilot programme were expressed in 'technical terms' about epidemiology, effectiveness or value for money. However, one interviewee suggested this debate had been engendered by the belief that the funds for the HPV vaccines were coming from Sin Tax revenues. This was not the case, but it was effective in attracting attention. Specifically, for opponents of the programme, it highlighted the issue of opportunity cost, which prompted the DoH to argue that the funds were extra-budgetary (I7PH_academia). For vaccine advocates, it appeared that these critics were encroaching on the territory of vaccines specialists. In particular, some paediatricians criticised the PNDF decision-making process as not appropriate for vaccines, particularly because of a perception of FEC members as experts in pharmacology, not epidemiology or burden of disease (I19PH_academia). As a more appropriate alternative, the Philippine Foundation for Vaccines had recommended the creation of a National Immunisation Technical Advisory Group.

Again, while the debates appeared to be about expertise, they were in fact caused by who was perceived as having the correct expertise for decision-making.

In 2014, there was a similar episode of contestation brought about by another vaccine programme, this time on PCV. This episode led to the removal of the Secretary of Health who had approved procurement. In 2012, the DoH authorised the procurement of one million doses of PCV 10 vaccine (at the price of $15.40 per unit), manufactured by GlaxoSmithKline under the brand name Synflorix. The main alternative to PCV 10 was PCV 13 (Prevenar), manufactured by Pfizer. According to interviewees, the decision was informed by a WHO-commissioned economic evaluation to assess the value for money of the two vaccines in the Philippines. Researchers from the LSHTM were commissioned to carry out the research, together with an academic from the University of Philippines, Manila, who joined the team 'because they wanted a Filipino to be part of this WHO team that would do the evaluation' (I13PH_academia). The prices used for the study were below market prices, as they were negotiation through a UNICEF tender. According to a interviewee, the difference in price between the two vaccines was the equivalent of US$ 1 (I6PH_civil service). The economic evaluation indicated that PCV 13 represented better value for money compared to PCV 10, at the given price. However, despite the results of the economic evaluation, the Assistant Secretary responsible with the Expanded Immunization Program approved the procurement of PCV 10. Because the vaccine had not been considered for inclusion in the Formulary, a certificate of exemption was needed to allow legal procurement. The Secretary of Health approved this certificate, which was administered through the PNDF, in 2012.

However, the competitor company, Pfizer, contested the decision, one argument being the results of the economic evaluation which indicated that PCV 13 represented better value for money. Furthermore, the economic model was also

criticised based on the degree to which cross-protection to other conditions beyond pneumonia were considered when evaluating the effectiveness of each vaccine. Faced with this situation, the Secretary of Health decided to embargo the economic evaluation and commission another study, this time in collaboration with the PNDF and with support from NICE International and HITAP. The study used an economic model developed by HITAP researchers and confirmed the findings of the initial study (Haasis *et al.*, 2015). However, GSK also contested the new study based on the fact that it had excluded cross-protection for otitis media. Actors such as Philippine Vaccine Foundation, however, argued that there was insufficient local data on serotypes to be able to assess cost-effectiveness, therefore the decision to procure PCV 10 was justified (as the cheaper vaccine).

The decision was publicly criticised by the Secretary of Justice, specifically on the grounds that the Secretary disregarded FEC recommendations about the cost-effectiveness of the two alternative vaccines. Despite the fact that the FEC only issued recommendations, with the Secretary of Health being the ultimate decision-maker, not respecting the FEC recommendation in the case of a vaccine (PCV) led to accusation of corruption and the removal of the Secretary of Health. Interviewees suggested that the outcome of these episodes of contestation had the effect of strengthening the procedures of the PNDF and disincentivised subsequent Secretaries of Health to disregard PNDF recommendations.

> Pragmatically speaking because we have been the instrument in the downfall of people and in making sure somebody doesn't get kicked out. We're more than just recommendatory now. (I13PH_academia)

This point was proven by another similar debate over vaccine procurement that took place in 2016, this time with regards to the decision, by a subsequent Secretary of Health, to establish a programme for vaccination against dengue fever, the only vaccine available being Dengvaxia, developed by Sanofi Pasteur. In early 2016, the FEC assessed the evidence of safety and efficacy of this vaccine to decide on its

inclusion in the PNDF. One member of the committee reviewed the evidence on the effectiveness of the new vaccine and concluded that the vaccine could be approved. However, other FEC members believed that, in the absence of epidemiological data from the Philippines, the safety of the vaccine was uncertain. If the vaccine did not protect against serotypes present in the Philippines, it raised safety concerns for children who might be exposed to a second infection, which is generally more dangerous (I2PH_academia).

During this process, the PNDF FEC and its secretariat were put in an adversarial position with the Secretary of Health (I3PH_academia; I5PH_civil service). Interviewees reported that the PNDF committee was pressured to make a decision on the vaccine even before market authorization had been granted, which was also eventually sped up (I3PH_academia). Further, interviewees indicated that the new Secretary of Health did not want to go against the FEC recommendation, since the announcement of the provision of the vaccine had already been made publicly by the DoH before the FEC reached a conclusion. Consequently, the Secretary of Health put pressure on the FEC to grant a positive recommendation for the procurement of a dengue vaccine. Eventually, the FEC recommended an annually renewable exemption, despite disagreements between FEC members.

As the vaccine started being administered to children, emerging evidence was confirming that the vaccine might not be effective or even increase severe cases of dengue fever (World Health Organisation, 2016). Thus, in 2018, even though the mandate of the Secretary of Health had been changed after the 2016 change in administration, the Philippine Congress organised hearings reviewing the basis for the decision to approve the vaccine programme, to which the former Secretary of Health was cited. In the aftermath, the regulations for granting exemption requests were tightened in 2018, via new administrative orders outlining the PNDF process rules.

Like in Thailand, the operation of HTA processes was determined by these links between decision-making for procurement, as well as reimbursement by the payer. As explained in previous chapters, the UCS Act of 2019 will attempt to establish clearer roles for both the DoH and PhilHealth. The further developments in this area are likely to influence the ongoing institutionalisation of HTA.

Comparative analysis on the ongoing functioning of HTA processes

In both countries, generating evidence on the most controversial topics related to pharmaceutical policy led to important challenges from a variety of actor categories. The most important such category referred to specialised clinicians who outlined arguments for adoption of innovative medicines, particularly new generation vaccines. However, even among health professionals, there was no universal support for the inclusion of such innovative medicines in either of the countries' essential medicines list. In both countries, these actors' criticism was often expressed in terminology that referred to quality of evidence. However, these criticisms were often about fights for power and legitimacy over decision-making. As seen in the Philippines, it was argued that the FEC committee did not have the necessary expertise to make coverage decisions on vaccines. In Thailand, similarly, there were repeated attempts to advocate for procurement of HPV vaccines directly by the NHSO, despite the NLEM not having granted their inclusion.

Surprisingly, episodes of contestations such as the ones outlined above for both Thailand and the Philippines seem to have led to a strengthening of authority and procedures of HTA processes in both countries. However, this was only the case when HTA processes were supported by other institutional rules or decision-making points that were not strictly part of HTA processes. For example, in both countries, episodes of challenges to the use of HTA highlighted the link between HTA processes and procedures associated with other goals that went beyond HTA. These procedures referred to arrangements for reimbursement; procurement; and setting

priorities for budget planning and resource allocation. Overall, these goals can be collectively referred as purchasing, for which roles were being challenged and contested. Specifically, HTA could inform coverage decisions, but if it were to influence purchasing activities, it needed to influence a series of powerful and diverse existing decision-making points, as well as becoming involved in aspects beyond value for money (specifically, issues of affordability were often raised, as well as issues regarding implementation).

In contrast, the sustainability of HTA processes depended on the changing role of the payer. In Thailand, the role of the Board and the Secretary General of the NHSO was tenuous but had resulted in a strong role of the payer in central planning of services and procurement of high-cost medicines. As of 2016, the role of the NHSO in procurement (particularly of high-cost medicines and medical equipment) was being contested by the MoPH. In the Philippines, ongoing debates over health system reform focused precisely on whether the payer should be responsible with defining the health benefit package or whether the purchasing and coverage decisions should be separated between PhilHealth and DoH, respectively. Both bodies would have to give up considerable power to establish a separation between these roles. In this context, interviewees indicated that HTA advocates believed that HTA activities should be hosted by the body responsible with policy direction, but there was a split between those who thought DoH or PhilHealth should be that body.

Having analysed the emergence of the idea of HTA (chapter 5), the development of HTA organisations (chapter 6) and processes (chapter 7), as well as challenges to the ongoing functioning of HTA (chapter 8) in Thailand and the Philippines, the following chapter with bring together the findings of this analysis and discuss the path towards institutionalisation of HTA in these two middle-income countries.

9. Discussion

Summary of findings

This thesis has compared the path towards institutionalisation of HTA in two middle-income countries. To do so, it analysed the emergence of HTA as a policy idea, examined how and why organisations, processes and methods of HTA were established, and identified opportunities and challenges to the continued functioning of HTA. For this purpose, the analysis used three theoretical perspectives, examining the interests of policy actors, policy ideas and the existing and emerging institutions.

At the time of data collection, the two countries had reached different levels of development of HTA. The HTA processes in Thailand being widely seen as more established and as a successful model for HTA among middle-income countries and in South-East Asia. The main organisation coordinating HTA in Thailand, HITAP was seen as a source of authoritative expertise both in the country and abroad. However, in 2016, the role of HTAP under the MoPH, and the existence of another HTA body, IMRTA, which was seen as less successful, continued to be debated in Thailand. In addition, HITAP was criticised for dominating the HTA process, by being both a producer of evidence and involved in its appraisal and use in decision-making. In contrast, HTA processes in the Philippines were presented in interviews as emergent and still under development. In 2016, HTA advocates were debating the appropriate placement of an HTA organisation, specifically whether the DoH or the payer should coordinate HTA processes. At the time of writing, two alternative HTA processes were developed for these two options.

Establishing the elements of HTA

During the 20-year period examined in this study, there was remarkable similarity between how policy actors in Thailand and the Philippines perceived policy problems that were associated with the *emergence and development of HTA as a policy idea*. Over the years, the definition of the policy problems HTA was expected to solve changed considerably, but the pattern of change was almost identical in the two countries. In both countries HTA emerged following its transfer from abroad through a range of activities from international organisations and bi-lateral initiatives. Specifically, HTA advocates in both countries grappled with the same problems as part of their initial attempts to establish HTA (dating back to the early 1990s): the impact of high-cost medical equipment on healthcare expenditure. Over the following stages of HTA establishment, the problem of containing the costs of expensive medical equipment was replaced by problems related to public provision of expensive medicines and, finally, by questions regarding the coverage of other types of health services. In order to meaningfully compare the development of HTA in the two countries, it was necessary to explore policy problems in relation to existing institutions (i.e. how resource allocation and coverage decisions were made before HTA was introduced), because these institutions guided attempts to establish HTA processes and organisations. This study found that actors in the two countries defined the policy problems that HTA meant to address in different ways reflecting differences in institutions that shaped decision-making.

The emergence of HTA as a solution to these problems also depended on the roles and interests of the actors who became *HTA advocates*. In both countries, the principal advocates for HTA were civil servants and researchers, who were organised in policy networks. This broad similarity masked differences with regards to the purpose of these networks, which were important for the development of HTA. In Thailand, HTA advocates were part of a network formed around a

movement for health system reform with the overarching goal to improve access to care for underserved rural populations. Their advocacy for HTA took place in the context of wider efforts to increase the use of evidence in health policy-making. These efforts went beyond the use of HTA. In the Philippines, in contrast, researchers and civil servants formed a network that advocated for HTA specifically. However, their advocacy for HTA also emerged in the context of health system reform, specifically, the establishment of the social health insurance programme, the NHIP, for which HTA was seen as useful.

The choices for establishing *organisations* mandated with coordinating HTA appear to be similar when comparing the two countries. In both Thailand and the Philippines, a number of options were considered, including integrating HTA in existing bureaucratic structures (e.g. establishing an HTA committee coordinated by an existing office), establishing HTA-specific structures within the bureaucracy (e.g. an HTA unit or programme) or establishing independent public organisations (e.g. an institute). HTA advocates in both countries stated that the latter was both the most desirable and most difficult to achieve option as it signified a loss of power for current decision-makers. Also, in both countries, advocates for HTA, who were strongly represented in the civil service, used the tools of their position, such as their ability to use budgets and decision-making power at senior levels of the civil service, to establish organisations mandated with HTA. They also drew on network resources, such as access to international actors, support and mentorship to younger civil servants and links to political appointees, for that purpose.

These two factors, networks among HTA advocates and the tools of the civil service, informed the strategies used to establish organisations to coordinate HTA. Yet while the options for establishing HTA organisations were seen as similar among actors in both countries, different organisational structures emerged in each country. In Thailand, the strategy of HTA advocates was to establish HTA programmes within different departments of the MoPH. In interviews, HTA advocates spoke about their

desire to ensure the independence of any program established within the bureaucracy, but they also mentioned that they had experienced difficulties in achieving this aim. The two existing bodies mandated with HTA in Thailand, HITAP and IMRTA, differed in their degree of independence from the bureaucracy. HITAP's status was one of semi-independence, due to it being established without a direct line of accountability to the government bureaucracy. It was subsequently integrated into the MoPH, although it maintained its financial independence. IMRTA was established as an HTA unit within a department of the MoPH, the DMS, and was directly overseen by this department even after changing its status to being an 'institute'.

In the Philippines, HTA advocates who were senior civil servants used the social health insurance debates to provide a legislative mandate for HTA, as part of the operations of the newly established payer, PhilHealth. However, the authority of civil servants was not sufficient to establish new offices or organisations for the purpose of coordinating HTA. Instead, civil servants who supported HTA developed HTA procedures embedded in existing departments of PhilHealth. These procedures were carried out by HTA committees that were supported by funds allocated within the existing bureaucracy. While policy actors in the Philippines also regarded organisational independence as desirable, this required a change in legislation, thus independence was only possible after an act of Congress was passed. After 2016, plans for a UHC bill included details about establishing an HTA Council, which represented a departure from previous efforts that had not been specific about the organisational structure for HTA.

In both countries, the *development of HTA processes* consisted of making incremental changes to the status quo related to the specific policy problems. These changes were guided by existing institutions needed to change in order to establish HTA processes that were able to address these problems. In both countries, policy actors tended to reject proposals for HTA processes that were entirely new and

would have required substantial changes to the existing decision-making apparatus leading to such options being discarded. Proposals for HTA processes all drew inspiration from international models of HTA informed decision-making, reflecting the origins and policy transfer of HTA from high-income settings. However, policy transfer cannot explain why some of these suggestions were embraced while others failed. By comparing differences in decision-making structures in the two countries, the study demonstrates that HTA processes that built on the existing rules for decision-making tended to be more successful that suggestions that would have required an entirely new approach.

Existing structures and processes for decision-making thus shaped the choices for the development of HTA processes, with the latter building on the former, but not replacing existing processes entirely. For example, both countries developed HTA processes focused on determining the essential medicines list. These processes built on pre-existing rules for decision-making about the type of medicines included in the essential medicines lists. Both countries had already been developing an essential medicines list to which public procurement and reimbursement were limited. In Thailand, the NLEM was developed by the NLEM Subcommittee, under the authority of the Prime-Minister's Office. An HTA process was added to the existing NLEM decision-making procedures to determine the inclusion of high-cost medicines. As a result, a comprehensive health benefit package that was originally build around the concept of a negative list evolved to include a list of high-cost medicines that were centrally procured and distributed by the payer, the NHSO. In the Philippines, the PNDF was developed under the authority of the DoH. Again, HTA principles were introduced to develop and clarify the PNDF procedures. Other coverage decisions were made by the payer, PhilHealth, which took a positive list principle, meaning that new benefits were continuously added and specified as part of condition-specific benefit packages (e.g. childhood pneumonia). However, this

analysis shows that the PNDF decision-making process and the benefit development by PhilHealth were not always well aligned.

As ideas about the purpose of HTA evolved, governments in both countries faced the challenge of having to reconcile growing public expectations to provide more expensive medical services with the aim of delivering UHC, thus requiring decisions about the boundaries of publicly funded health services to become more explicit. As a consequence, Thailand broadened its use of HTA developing a process applied to all reimbursement decisions by the payer, NHSO, whereas policy actors in the Philippines embarked on debating the development of a similar process for the PhilHealth. These processes built on the decision-making and governance structures of the payers and were separate from essential medicines list decisions. However, this study was unable to fully compare their development as, at the time of writing, the process in the Philippines was still at proposal stage. However, these processes tended to go beyond HTA being limited to individual technologies compared to their alternatives and attempted to prioritise conditions and identify the interventions that provided the most value for money.

The two countries contrasted in the *degree in which evidence generation was used to inform coverage decisions before HTA was established*. The government in Thailand had already used research evidence to inform high-profile coverage decisions relating to antiretroviral treatment and renal replacement therapy before HITAP was established in 2007. These decisions were informed by policy analyses, including economic evaluations, commissioned by the NHSO for this purpose. Interviewees suggested that the use of evidence in these coverage decisions provided a model for establishing two HTA mechanisms for high-cost medicines and for other coverage decisions made by the NHSO. In contrast, in the Philippines, respondents mentioned specific studies that directly informed coverage decisions only in relation to existing HTA processes. The controversy following the decision on the exclusion of certain statins showed how the recommendations resulting from HTA were challenged by

manufacturers, which made it difficult for decision-makers to follow the recommendations of the HTA committee. However, the analysis suggests that over time such challenges strengthened the argument for the use of HTA in decision-making in the Philippines. For example, two consecutive Secretaries of Health were strongly criticised for the decision to fund several new generation vaccines (i.e. pneumococcal, HPV and dengue vaccination) against recommendations by the PNDF committee, which were informed by economic evaluations. Interviewees indicated that, due to such criticism, Secretaries of Health became less inclined to ignore PNDF recommendations. In parallel, PNDF regulations gradually limited the discretion of the Secretary of Health to follow PNDF recommendations.

The *choice of methods* used in HTA highlighted a major difference between the two countries: the development and use of country-specific methodological guidelines for conducting HTA in Thailand, in contrast to a lack of such guidelines in the Philippines. Methodological guidelines provided a common ground for debates among actors involved in, or affected by, individual decisions in Thailand. However, in the Philippines, interviewees suggested that, in the absence of guidelines, the debates on criteria for decision-making or specific methodological choices were more likely to derail the decision-making process. In Thailand, methodological guidelines for HTA were developed at the beginning of the development of the HTA process for high-cost medicines. These guidelines were then adopted by the committee mandated with determining the list of essential medicines (NLEM) and were added to the evidence and process rules already in use. The development process included a review of existing methodological guidelines used in other middle- and high-income countries, the commissioning of a series of reviews of existing methodological choices and an assessment of their appropriateness in the context of Thailand, and lastly, a consultation process among researchers and other relevant actors. In contrast, in the Philippines, guidelines for the use of HTA in coverage decisions were still being developed in 2016, despite the fact that cost-

effectiveness had been a criterion for decision-making since 2012. Methodological choices in this case depended on the expertise of the PNDF committee members. In the absence of methodological guidelines, some researchers expressed in interviews some reluctance to undertake analyses for fear of criticism from other researchers and manufacturers, especially relating to economic evaluations. Notably, the guideline development process in the Philippines, which began in 2016, took a similar approach to the one used in Thailand and included learning from the Thai guidelines.

As can be expected, establishing HTA processes was met with *resistance from different groups of actors*, including some policy-makers, civil servants and HTA advocates, as well as manufacturers and physicians. In both countries, decisions on specific technologies, most often medicines, attracted controversies which focused on a number of issues including procedural characteristics such as transparency and the timeliness of the decision, and the nature and validity of the evidence, including challenges of the appropriateness of evidence of effectiveness and on the validity of economic models. These debates could be characterised as 'technical' in the sense that they focused on procedures and research methods. However, to the focus on technical issues tended to mask 'political' reasons, stemming from a) actors' interests, or b) different 'ideas' about the moral acceptability of criteria to guide coverage decisions.

Actors' interests were more readily identified when specific decisions were made. For example, both countries considered introducing HPV vaccination (Thailand, 2009; the Philippines, 2013), with essential medicines list committees in both countries assessing the evidence for inclusion. Interviewees agreed that cost-effectiveness was a relevant criterion in both countries. In Thailand, the committee reached a negative verdict, while in the Philippines the decision was positive. In both countries, physicians advocating for the adoption of the vaccines criticised how the evidence was appraised and used to inform the recommendation for or against

inclusion. The analysis of these discussions suggests that power struggles were at the root of criticisms of the use of evidence, specifically as they relate to differences in views as to who should be tasked with conducting evidence appraisals (i.e. whether the 'right' experts were included), and who had the authority to make the decision (i.e. other bodies within the bureaucracy were seen as more legitimate).

Actors also disagreed on the criteria for decision-making. The analysis suggests that such debates tended to be driven both by differences in actor interests and in their uptake of ideas. For example, manufacturers tended to argue that excluding certain types of medicines violated principles of equity. In Thailand, representatives of the pharmaceutical industry wondered, in interviews, whether the country should follow the example of the Cancer Drug Fund established in the UK to fund oncological treatment. In the Philippines, some researchers and civil servants also worried that cost-effectiveness would weigh more than equity considerations as a criterion for coverage decisions. They argued that the criterion of cost-effectiveness was not particularly helpful to determine whether interventions should be funded that offered small to moderate benefits to individuals, but that were deemed cost-effective because of the high prevalence of the condition in the population (e.g. high blood pressure), especially when compared with medicines for orphan conditions that would not be cost-effective under normal condition, but offer important improvements in the quality of life of a small number of patients. Even though these concerns were discussed in 'methodological' terms, they expressed a moral stance that prioritised health gains for the individual over health gains for the population, or at least one that showed awareness of the conflict between these two principles.

In Thailand, as HTA started being applied to complex health promotion interventions, some actors challenged the appropriateness of doing so, but for different reasons. Some believed health promotion interventions were always a good investment, whereas others argued that the effectiveness of such complex interventions was difficult to prove during the assessment process and to maintain

during implementation (as the more complex the interventions, the less certain its effectiveness is). As one interviewee suggested, even though HTA processes for high-cost medicines were seen as successful, these were the 'low-hanging fruit' of using HTA (I3TH_civil service), while other, emerging questions about the best use of the available budgets were much more complex and challenged the established approach to HTA.

The path towards institutionalisation

The path towards institutionalisation of HTA in both countries involved many decisions, including in relation to creating HTA organisations, developing processes and the methods used for analysing and appraising evidence, and embedding HTA in existing decision-making and governance structures. The emergence of the idea of HTA and the development of HTA organisations and processes were analysed separately for each country in order to understand how institutions, interests and ideas, individually and in combination, determined each element of HTA. Figure 9.1 shows how these findings relate to the aims and objectives of the study and how ideas, interests and institutions, that constitute the elements of the analytical framework, interact with one another in this analysis.

This study found that interests, more specifically, HTA advocates organised in policy networks, were key to initiating the process of establishing HTA in both Thailand and the Philippines. In both countries, senior civil servants were important members of these networks and were able to utilise the resources of the civil service to establish organisations that coordinate HTA. The rules of the administrative systems, which allowed civil servants varying degrees of independence, determined the way in which HTA organisations were established, and the form taken by these organisations.

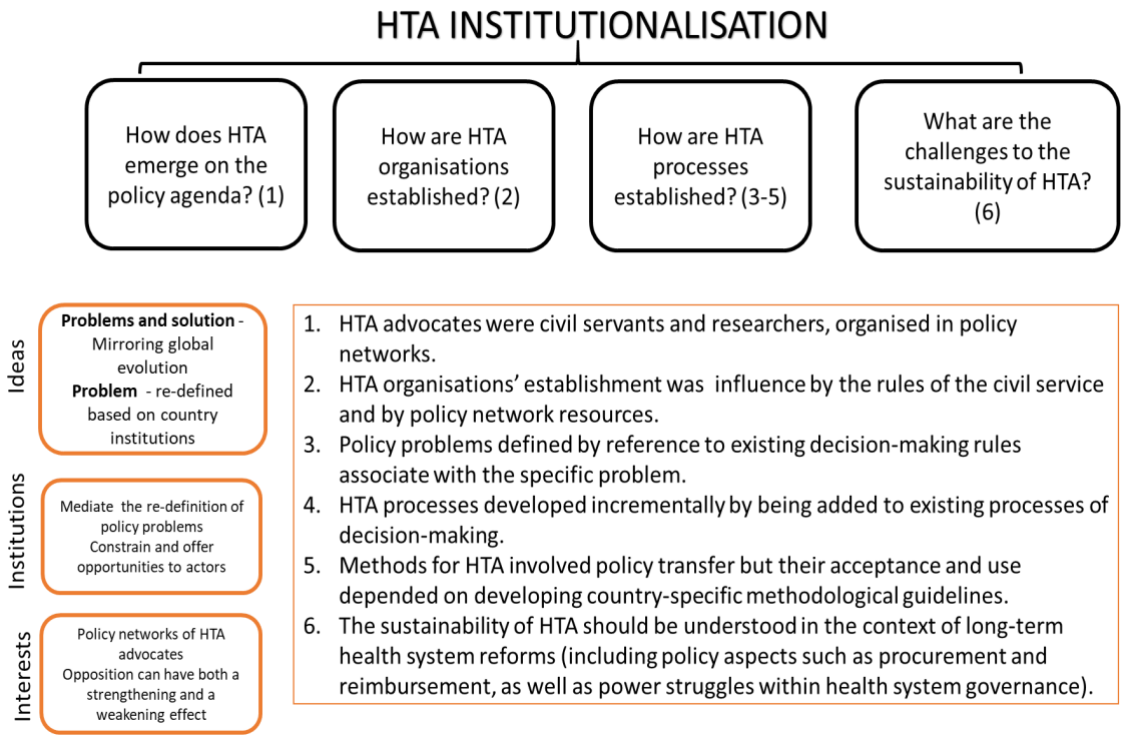

Figure 9.1. The influence of the 3Is on HTA institutionalisation. Source: own analysis.

The establishment of HTA processes, in contrast, was largely influenced by existing institutions, especially the existing rules for making coverage decisions in which emerging HTA processes were integrated. The idea of HTA as a solution to problems associated with making coverage decisions may be directly transferred from other countries together with a generic understanding of the policy problem, but the definition of the specific problems that HTA were expected to 'solve' reflected factors associated with existing institutions. This interaction of factors explains the observation that HTA processes and methods were not directly copied from other countries, but were developed in each country and adjusted over time. Attempts to copy approaches directly from other countries did not result in successful implementation. Therefore, this thesis has shown that the (re)-definition

of the policy problem to reflect these existing institutions was an important first step towards institutionalising HTA.

The interests of some policy actors such as pharmaceutical manufacturers appeared to be a barrier to the development of HTA processes at different times and seemed to undermine institutionalisation. However, perhaps paradoxically, this thesis also found examples in which opposition to HTA and the results of HTA strengthened the development and acceptance of HTA in the long term. In addition, the functioning of HTA processes was influenced by other aspects of health systems governance, especially the processes that followed coverage decisions made by HTA organisations, relating to the procurement of medicines and the mechanisms of reimbursing providers for health services they delivered. The long-term evolution of the heath system also had a bearing on the sustainability of HTA in both countries because it explained and structured some power relations and struggles between policy actors, as well as influencing what policy problems were likely to became more prominent.

This study confirms findings from research on HTA establishment in other middle-income countries, which highlights the importance of HTA advocates and their ability to form policy networks (Góméz-Dantés and Frenk, 2009; Ozieranski, McKee and King, 2012; Löblová, 2018a). Policy networks have also been found influential in the transfer of policy ideas between countries (Rhodes and Marsh, 1992; Dolowitz and Marsh, 2000; Benson and Jordan, 2011), and even an emerging type of governance as more non-state actors became involved in policy-making (Marsh and Smith, 2000). In studies of the role of networks in establishing HTA, epistemic communities have been found to be particularly relevant to explain why certain countries have embraced the use of HTA while others have not (Löblová, 2018a). Epistemic communities refer to a specific type of policy network consisted of professionals with a variety of backgrounds and from different disciplines, but *'with recognised expertise and competence in a particular domain and an authoritative*

claim to policy relevant knowledge within that domain or issue-area' (Haas, 1992, p. 3). Löblová (2016) noted that international networks were important in explaining the transfer of HTA to between countries, in addition to domestic networks. Benoit and Gorry (2017) traced the links between different members of a large global network for HTA whose members worked towards promoting HTA both in their own countries and internationally. This thesis confirms their assessment, as findings show that proponents of HTA in both Thailand and the Philippines had direct contact with experts who were active within global HTA networks. When Thailand became a model of HTA in Southeast Asia, the HTA proponents in the Philippines also sought advice from experts in Thailand. The influence of international policy networks also resonates with the observation that the actors in both countries shared the same conception of the policy problems to which HTA was considered the solution initially.

In both countries, however, the influence of advocates and policy networks was mediated (through constraints and opportunities) by existing rules of behaviour for civil servants, hinting at the influence of institutions. Civil servants used the resources of the bureaucracy, in addition to the resources of the policy network, to mobilise support for HTA. This finding is in line with other studies of policy change which suggest that policy networks can drive policy change, but that these changes usually follow a pattern shaped by institutions (Tuohy, 1999; Béland, 2010; Shearer *et al.*, 2016). Indeed, studies of policy networks formed around shared knowledge (i.e. epistemic communities) also suggested that the mere absence or presence of this type of policy network is insufficient to explain the establishment of HTA. Löblová (2018b) studied the mechanism by which epistemic communities influenced adoption of HTA in Poland and the Czech Republic. She found that the non-adoption of HTA in the Czech Republic was caused by a loss of interests from policy-makers, which undercut the ability of policy networks to achieve their preferred policy solution and institutionalise it through the bureaucracy. Löblová (2018b) showed

that bureaucratic power was an integral part of the establishment of HTA in the two countries of her study, unlike earlier conceptual work on policy networks, which considered the bureaucracy as less important for networks to achieve policy change (Haas, 1992).

Some studies from high-income countries also suggest that formal institutions, specifically the civil service system and the administrative traditions in which health systems operate have an impact on the type of organisations that are created to conduct or coordinate HTA. For example, Torbica *et al.* (2018) found that administrative systems in Britain and the US (also known as Anglo-American systems) were more likely to establish independent agencies than Napoleonic systems (for example the administrative system in France or Spain). Torbica and colleagues reason that the former systems tend to offer a higher degree of independence to civil servants than the latter systems, and are more likely to delegate specialised tasks to subordinate authorities. They (2018) conclude that these characteristics explain the organisational structures that coordinate HTA. They give the example of NICE, an independent HTA agency with decision-making power in England and Wales, and contrast it with the HTA agency in France, which is tasked with making coverage decisions, but remains under closer control of the government (Torbica, Tarricone and Drummond, 2018).

However, there are some limits to making the same connection for the administrative systems in middle-income countries and HTA organisations. First, these categorisations of administrative systems might not effectively explain how civil service systems in middle-income countries operate, even though the latter often followed the example of high-income countries, either as a consequence of being imposed during colonisation, or by policy learning from existing examples (Haque, 2007). Supporting this view, this study found that the two countries took different approaches to the establishment of HTA organisations, although they both fall into the Anglo-American model of administrative systems (as a parliamentary system in

Thailand; and a presidential system in the Philippines). It therefore concludes that studies of administrative systems in high income countries do not sufficiently explain the development of HTA organisations in middle-income countries.

Tsebelis (2000) offers an alternative explanation for the degree of independence within the civil service in different political and administrative traditions. He argues that veto players - defined as 'individual or collective decision makers whose agreement is required for the change of the status quo' (Tsebelis, 2000, p. 442) - can explain the degree of independence within the bureaucracy better than the administrative traditions or the overall political system. His veto points theory hypothesises that the more veto points exist in a system, the higher the independence of the bureaucracy, because the latter can use veto players against each other (Tsebelis, 2000). Bump and Chang (2017) also suggest that veto player theory can be useful to help analyse differences in approaches to priority-setting in health systems, of which HTA is a part. They also acknowledge that veto points are relevant in shaping the opportunities of interest groups to advance their agendas, as proposed by Immergut (1992).

In both countries, the degree of independence of the bureaucracy, which underpinned the actions of civil servants, played a decisive role in how HTA organisations were established. In Thailand, this study found that the administrative system allowed some degree of independence to civil servants, which contributed to shaping the organisations created to conduct HTA. Interviewees described a pattern within the bureaucracy of establishing organisations that enjoyed various degrees of independence from the ministries to which they were formally subordinate. This pattern was confirmed by existing literature and included establishing 'network organisations' that would be tasked with specialised mandates. These network organisations often also included foundations, which increased their financial independence (Lorsuwannarat, 2014). An alternative explanation for this ability could be offered by the role of the policy network that advocated for HTA as part of

its wider efforts for health system reforms. Harris studied the progressive policy network that also advocated for HTA to advance the goal of universal coverage reform through the 'developmental capture' of the state (Harris, 2015). This study suggests that, while the policy network of health reformists was important, the administrative system in Thailand made a key contribution to the type of organisation created for the purpose of HTA. Interviewees suggested that the HSRI initially attempted to establish an HTA body within the DMS (which eventually became IMRTA) by following the example of network organisations. The establishment of HITAP also followed this strategy to some extent, as some of its governance structures were reminiscent on 'network' organisations (e.g. establishing an attached foundation to a body that is technically part of the MoPH bureaucracy). HITAP's establishment also benefitted from the resources – financial, links with top policy-makers - of the network, which explains its special 'semi-autonomous' status because HITAP was not directly part of the structure of any MoPH department.

The importance of the administrative system becomes even clearer when comparing the two country case studies. In contrast to Thailand, civil servants in the Philippines had less discretion when creating organisations mandated with new tasks. The administrative system in the Philippines has been characterised as one of 'hyper-presidentialism' (Rose-Ackerman, Desierto and Volosin, 2011) where the President of the Philippines can take charge of public agencies – often through naming political appointees rather than career civil servants at the helm of these agencies (Monsod, 2017). According to these analyses, the power to establish specialised bodies was therefore concentrated at the highest levels of the executive branch unless Congress passed legislation that curtails the power of the executive. These rules could be seen in operation when organisations that were mandated with HTA were established. For most of its development, HTA was attached as a specialised task of existing bodies and had little independence. This changed in 2018, when debates over the UHC Bill included more details about establishing a separate HTA body,

referred to as a HTA board, as well as details about its placement and organisational structures.

As mentioned previously, the establishment of HTA processes followed different mechanisms than the establishment of HTA organisations. HTA processes were developed incrementally by building on existing institutions, specifically existing decision-making processes associated with coverage decisions (e.g. the essential medicines lists and reimbursement policies of payers). Similar observations were made by other authors who suggest that HTA and other mechanisms for priority-setting in middle-income countries are always fitted into an existing context and never start entirely from scratch (Goddard, Hauck and Smith, 2006; Baltussen *et al.*, 2016; Lauer, Rajan and Bertram, 2017). However, the literature on how exactly these institutions influence HTA establishment remains scarce.

This study brings specificity to the relevance of existing processes for the development of HTA processes. The analysis shows that the old and new institutions co-existed, and that any attempts to establish new processes to make coverage decisions had to deal with the processes already in place. This confirms an element of path dependency, whereby specific choices, once made, limit the options available in the future (Béland, 2010), which is well established in institutional and policy studies. It also demonstrates that the process of policy-making was incremental, whereby policy-makers made smaller adjustments, which could be reversed or modified if, for example, there were unexpected consequences, as well as being easier to establish in the first place (Lindblom, 1959).

Lowndes and Roberts (2013a) try to explain why building new institutions is consistently seen as a worthy pursuit, even though most attempts to 'institutionalise' end in failure. They argue that institutionalisation is desirable because the role of institutions is to 'stabilize and regularize political behaviour' and 'prescribe and proscribe certain forms of behaviour' (Lowndes and Roberts, 2013a, p. 188). If

stability is what makes institutionalisation desirable, incrementalism, which means continuous change (Lindblom, 1959), complicates the nature of institutionalisation. Lowndes and Roberts (2013a) argue that institutionalisation has two main elements, which they term 'robustness' and 'revisability'. Robustness, they argue, refers to the degree to which values embedded in institutions are clear and how newly established institutions are enforced (i.e. whether they influence the behaviour of policy actors). Revisability refers to whether institutions are flexible enough to adapt to contestation and have a degree of variability (i.e. whether they allow for different design variations to adjust to new circumstances) (Lowndes and Roberts, 2013a). Each characteristic of institutionalisation is reflected below in the two processes of institutionalisation that were analysed in this study.

The *values* that become institutionalised through HTA processes, sometimes referred to as social values, are the existing principles of distributional justice that have been proposed for priority-setting in both high-income and middle-income countries (Littlejohns *et al.,* 2012). Empirical studies suggest that some of these principles are given more importance in some countries than in others due to the values and cultures embedded in their health systems (Torbica, Tarricone and Drummond, 2018), and depending on whether the former are in congruence with societal values, which can be measured by public preference surveys (Landwehr and Klinnert, 2014). Others suggest that some principles, in particular maximising population coverage based on evidence of cost-effectiveness, are implicitly and unduly given too much weight as part of HTA processes (Baltussen *et al.*, 2016).

This study showed that the importance of values starts from the level of how policy problems were defined. Certain values are already embedded in existing institutions as well as being added through the newly developed HTA processes. Specifically, in both countries, HTA was established in the context of long - term movements towards health system reform, as part of the development of UHC. However, health system reform towards UHC expressed different goals from among the ones

available under the umbrella-term of UHC. In Thailand, policy actors noted that establishing limits to the health benefit package was avoided in the design of the UCS. The reasons for this was twofold. First, health reformers believed that identifying the interventions the UCS would offer could be controversial and risk delaying or stopping the reform process, for example by supporting criticism of the UCS system as a second class system. They also feared that discussing the values underpinning coverage decisions would deflect from the principal goal and values of the policy reform, which was to expand access to health care by increasing population coverage and offering financial protection, rather than by establishing the appropriate services to cover (Pitayarangsarit, 2004). Coverage decisions became important only after the UCS had been established and functioning.

In the Philippines, it was found that the values embedded in existing institutions were clashing and in turn influenced the definition of the policy problems. The initial thrust of social health insurance scheme (NHIP) was to gradually increase population coverage and reach UHC. However, the NHIP had not set a clear goal with regards to financial risk protection (Obermann, Jowett and Kwon, 2018). Consequently, the NHIP approached increasing population coverage by adding certain services (through condition specific benefit packages) alongside new categories of membership (which were offered different levels of coverage). This resulted in lower importance given to ensuring financial risk protection. As more financing sources became available, the problem of consolidating coverage decisions became prominent (Picazo *et al.*, 2014). The proposed solution was in line with the existing practice of defining covered services first, by defining a basic guaranteed benefit package for the most common conditions, in addition to an HTA process to determines the inclusion of new services into the benefit package.

This view of HTA processes as institutions that require *enforcement* also helps explain the importance of methodological guidelines and process clarity which contributed to HTA processes being more established in Thailand than in the

Philippines. In March and Olsen's terminology (1998), guidelines establish a 'logic of appropriateness' which leads to actors' acting according to 'rules and practices that are socially constructed, publicly known, anticipated and accepted' (March and Olsen, 1998, p. 952). This logic of appropriateness is particularly important for decisions which are likely to be contested, of which coverage decisions in health care are a classic example. Applying the logic of appropriateness to this field does not mean that the presence of guidelines prevents contestation. However, this thesis finds that contestation of coverage decisions in the presence of guidelines led to debates being framed within the existing agreement provided by the guidelines – certain values were therefore institutionalised and enforced through guidelines. Further, decisions were challenged within the confines of the guidelines, but were not challenging the approach to decision-making itself. The contestation became focused on methodologies, and not values. In the absence of guidelines, actors such as researchers, even if their academic credentials were respected, found involvement in generating or appraising evidence difficult precisely because the lack of clarity about the rules for evidence generation and appraisal increased their risk of being seen at fault.

The degree to which proposed HTA processes were enforced in both countries also depended on whether and how these processes were compatible with other aspects of health system governance. This compatibility with existing institutions was not only an important part of HTA process design, but shaped its way of working. Most studies of HTA processes focus on how the coverage decisions are made and whether procedural aspects influence the outcome of the decision (Allen *et al.*, 2013). However, emerging literature on HTA processes in high income countries looks at the implementation of these decisions by other actors involved in health system governance. (Williams, 2013; Smith and Chalkidou, 2017). For example, an often overlooked aspect of decision-making by NICE in England and Wales is that purchasing decisions made by local NHS organisations, such as Clinical

Commissioning Groups, might mean that services approved by NICE may not be available to their patients based on resource allocation decisions. Williams (2016) described this phenomenon as an example of 'implicit priority-setting' within a system of explicit decision-making.

In both case study countries, the degree to which coverage decisions were implemented through procurement or reimbursement mechanisms emerged as an important factor to both the development and operation of HTA processes. This was most obvious when HTA was not well aligned with other parts of the system associated with resource allocation, such as rules relating to procurement and reimbursement. The HTA processes that were integrated into existing procurement and reimbursement mechanisms had more chances reach their expressed goal, in the sense that the covered medicines were bought at the agreed price and made available to patients. In Thailand, HTA was successfully used in decisions about high-cost medicines because coverage decisions were directly linked to procurement. A Price Negotiation Working Group that included representatives of the NHSO (payer) negotiated prices of high-cost medicines, which were then centrally procured by the NHSO, which implemented a high-cost procurement programme designed to provide these medicines as part of the UCS. In the Philippines, coverage decisions for medicines were made in parallel with coverage decisions made by the payer. The latter undermined PNDF decision-making because some health benefit packages reimbursed services without specifying which medicines were being used. This practice went against an existing rule that the payer, PhilHealth, could only reimburse medicines that were already included in the PNDF. Respondents indicated that this practice constituted an important challenge to the HTA process relating to medicines.

Lowndes and Roberts (2013) argue that institutions need to be *revisable* in order to be sustainable in the face of contestation from powerful interests and actors jostling for power. They also suggest that institutionalisation is an ongoing process. In both

countries, ideas, interests, and institutions continued to interact and influence the process of institutionalising HTA. Both power struggles and shifting interests led to actors trying to shift the agenda towards including new policy problems and launching new solutions, thus attempting to establish new 'rules of the game'. Such new ideas did not always relate directly to HTA, but often impacted on the existing institutions that interacted with HTA, which shaped the process of institutionalisation.

In both countries, HTA processes and organisations developed and operated in the context of power struggles between governmental payer organisations (NHSO in Thailand, PhilHealth in the Philippines) and the MoPH or DoH. Such struggles for dominance could be observed in both countries, yet they manifested themselves in different forms.

In Thailand, conflicts between the MoPH and the NHSO, identified by interviewees, foreshadowed important changes to the purchasing infrastructure which came into effect after the end of this study. After 2016, the Cabinet, decided to strip the NHSO of its power to procure medicines and other devices centrally, and shift the budget and authority for procurement to a large Bangkok-based hospital, under the administration of the DMS. Simultaneously, the existence of HITAP was questioned by some actors who argued that HTA processes should be consolidated under the authority of the MoPH, suggesting that activities of either IMRTA or HITAP should be terminated. If policy-makers would decide to suspend HITAP as the Thai HTA agency, HTA would be firmly placed under the control of MoPH.

In the Philippines, the DoH and the payer (PhilHealth) are engaged in a similar conflict. Some interviewees participating in this study believed that there should be a 'strategic alignment' between the DoH and PhilHealth whereby the DoH would be charged with making coverage decisions informed by HTA, while PhilHealth focused on purchasing services. This was seen as potentially reducing the

fragmentation of governance and improve the coverage and provision of services in the country. Other actors, however, believed that PhilHealth should maintain its role in making coverage decisions and organising the reimbursement of these services, but it should strive to bring together its various health benefits package into one single basic benefits package. In 2018, Congress passed a UHC Bill which will have the likely effect that HTA will become a responsibility of the DoH, while PhilHealth maintained some coverage responsibilities. In other words, neither of the two positions won out.

To conclude, the two countries followed similar patterns of policy development, starting from establishing social health insurance programme in the early 1990s, deciding to move towards UHC and managing the implementation of their UHC programmes. In both countries, HTA was initially promoted by advocates, among whom senior civil servants were able to make a decisive contribution to shaping the agenda and who adapted the idea of HTA to policy problems defined by reference to the specific context of each country. These findings highlight the importance of considering the influence of actor interests together with the presence of ideas, in this case the idea of HTA as a solution to policy problems associated with the need to more clearly specify the type of service available under UHC.

This thesis also highlighted the importance of considering the role of institutions, both as they relate to the operations of government administration, and the opportunities and challenges arising from these practices, and the rules and practices already in existence for making coverage decisions. Over time, HTA organisations and processes in Thailand and the Philippines developed in different directions as a result of two institutional factors: a) the degree to which civil servants were able to use their discretion to create semi-autonomous organisations, and b) the approaches and rules of government applied to the procurement and reimbursement of health service. In addition, this study also identified the role of power struggles between government organisation as a factor that influenced the institutionalisation of HTA in

both countries. Such power struggles are not unusual in many countries, which mean that they should be considered as a relevant factor potentially influencing that institutionalisation of HTA in any country irrespective of its classification as high or middle-income.

Contributions to knowledge

This thesis contributes to the literature on how HTA becomes established in middle-income countries by analysing the long-term process of HTA development in two countries that have institutionalised HTA to different degrees. Establishing institutions to undertake coverage decisions in an evidence-informed, transparent manner is expressed by many experts and organisations as a desirable goal for low and middle-income countries (World Health Organization, 2001; Glassman and Chalkidou, 2012; Augustovski *et al.*, 2015; Downey *et al.*, 2017; Wild, Stricka and Patera, 2017). As a consequence, there is substantial interest in the mechanisms of transfer of HTA to low and middle-income countries. Existing guidance looks at the key elements of HTA or normative principles for HTA processes (Chootipongchaivat *et al.*, 2016; Wild, Stricka and Patera, 2017). The literature that explains what determines specific configurations of HTA in a comparative country context is scarce, although there are a few exceptions from high-income countries (Landwehr and Böhm, 2014; Hassenteufel *et al.*, 2017). Only a few studies specifically focus on HTA in middle-income countries. However, they focus their analyses the early stages of the institutionalisation process (Castro, 2017; Löblová, 2018b).

This study also provides insights into the path towards institutionalisation in Thailand and the Philippines specifically. In particular, Thailand is often seen as successful in using HTA and has become a model for other middle-income countries (Culyer, Podhisita and Santatiwongchai, 2016). This study highlights the importance of policy networks and the role of the wider health system reform movement for

understanding the development of HTA in Thailand. It also hints at continuous power struggles within the health system, which are likely to influence the future evolution of HTA in Thailand. This study also adds insights into the difficulties of establishing HTA in the Philippines, including the dominance of political actors over the bureaucracy, as well as less overall development of evidence use in policy-making, for purposes outside of HTA. These findings are not about the level of capacity to generate evidence in the Philippines, but rather about a lack of a 'logic of appropriateness' recognised by actors with regards to evidence informing policy-making.

Finally, this study confirms earlier observations that the making of coverage decisions should be seen in a wider systems perspective (Hanson *et al.*, 2019), especially with regard to the interaction of HTA with procurement and reimbursement processes, which together determine whether the use of HTA is sustainable.

Limitations of this study

This section describes the limitations of this study, as they relate to the study design, the methods of data collection and the analysis of country case studies.

Country cases selected

This study examined two cases of HTA being established in middle-income countries, using interviews with policy actors and document reviews as methods of data collection. The two cases provide substantial detail about a long-term process of HTA development.

The cases were not selected with a view of establishing causality and ensuring predictive value to the findings, for example by using cases that are most similar or most different (Yin, 2014). While such an approach would have allowed to identify

causal links between contextual characteristics and HTA establishment, the case selection and the approach taken to the analysis allows for generalisation in two ways.

First, the factors that have been found relevant in these two countries may be relevant in other places, although they may operate differently. Based on the findings of this study, some of these characteristics are: independence of the bureaucracy, existing processes to make coverage decisions, as well as the overall power struggles in health system governance. The cases are described in their context, in sufficient detail to allow the reader to draw their own conclusions about whether the findings of this study may be transferable to other countries. This will depend on context and needs to be carefully considered. In order to do that, it is necessary for readers to both have sufficient detail of the context in which these findings apply, and to understand whether such context characteristics are relevant for other middle-income countries.

Second, the comparison of the two cases allowed for broader conclusions about the establishment of HTA in middle-income countries. As other authors have suggested, emerging economies often share similar challenges, especially as many of these countries aspire to move towards UHC and expand access to publicly funded health care services. As shown by this study, however, comparing cases that involve policy transfer necessitates an in-depth look at the context within the country. The conceptual framework used for this study suggests a structured manner in which to analyse context.

Document analysis

The document analysis was particularly important in corroborating interview data and ensuring reliability of the findings. However, the long-term perspective taken in this analysis, made it difficult to substantiate all factual information required to

describe the process accurately and uniformly over 20 years. Consequently, some periods in the process of establishing HTA are presented with more details than others.

Furthermore, some types of documents (e.g. administrative documents, meeting minutes) were not available for the case study on Thailand as documents tended to be published in Thai only. However, this lack of documents was offset by secondary sources such as reports and journal articles published in English (and some documents published in both Thai and English). As a result, policy documents were an important primary source of data for the analysis of HTA in the Philippines, but less so for the analysis of Thailand, while there were more studies available as secondary sources on Thailand than the Philippines.

However, the documents identified were used in systematically for both case studies. Specifically, documents were reviewed to prepare interviews, to corroborate specific information from the interviews and to collect data describing the development of HTA and of the procedural aspects of HTA. In both cases, the authors/source of the documents were reviewed to analyse the position of the author(s) of the document in the process of establishing HTA. This was done systematically for all documents, including reports or journal articles.

Interviews

It was not always possible to interview the same number of actors in each actor categories in both countries. More specifically, policy-makers including members of the civil service tend to outweigh actors in other categories significantly. However, special efforts were made to interview both advocates and critics of HTA from within the same actor category (e.g. civil service) in both countries to be able to include as holistic a view as possible.

It was particularly difficult to convince physicians who were likely to have reservations about the use of HTA to agree to be interviewed. Actors who were identified as opponents of HTA were particularly cautious in the way they expressed their views. In one case, one interviewee seemed offended when one particular topic was explored in more detail – specifically, they had expressed support for using cost-effectiveness analysis, but disagreed with how it was applied as a principle by a specific organisation. In such interviews, careful consideration of non-verbal cues was important, as well as needing more interviewing skills to draw out what was of interest for the research question but was expressed in an indirect manner and what was irrelevant. In some circumstances, interviewees would also not be available for further clarifying questions following the interview. In these cases, as well as when interviewees had difficulties recalling certain details, relying documentary review became particularly important. Data collected through such interviews had to be contextualised with particular care during data analysis, when it was necessary to do extensive documentary review in order to corroborate information and to draw conclusions with confidence.

Data analysis

Data analysis for this study was guided by an analytical framework that was informed by the two bodies of literature: studies relating to establishing HTA and studies relating to the analysis of interests, ideas and institutions.

Two factors influenced the degree of detail that could be provided for the country cases. *First,* the long-term perspective on the process of establishing HTA added to the already difficult task of piecing together complex policy processes. For instance, there was variation as to how much detail interviewees could recall, and how many documents were available and accessible for earlier stages of development. Furthermore, because the two countries were at different stages of development, certain elements were discussed by interviewees in more detail in one country than

the other. *Second,* the conceptual framework provided an incentive for analysing cases in as much detail as possible, because it covers broad concepts that will be relevant in any policy development process. Therefore, a balance needed to be found between the length of the process analysed and the level of detail analysed for each episode and theme. At times the complexity and level of detail of each case were almost overwhelming. However, when it was possible to make a meaningful comparison between each aspect of HTA establishment between the two countries, it was deemed that a sufficient amount of detail has been reached.

Conclusions

This study examined the process of HTA institutionalisation in two countries over 20 years, which includes how HTA was transferred and how the policy problem was perceived to which HTA was seen to bring the solution. Middle-income countries are likely to share the same problems concerning coverage decisions (Voorhoeve, Tan-Torres Edejer, Kapiriri, Norheim, Snowden, Basenya, Bayarsaikhan, Chentaf, Eyal, Folsom, Halina Tun Hussein, *et al.*, 2017), especially since many of them have adopted the overarching goal of moving towards UHC. Further, it also confirms earlier observations that changes to the mechanism of making coverage decisions rarely start 'from a blank slate' (Hauck, Thomas and Smith, 2016), while adding specificity to how institutions needed to be adjusted to encompass HTA. These findings also confirm the value of a longer term perspective of the policy process (Hassenteufel *et al.,* 2017).

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Appendices

Appendix 1. List of documents

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Appendix 2. Topic Guide

Name:

Organization:

Date:

History of HTA: policy decision for establishment

- Can you tell me about the history of HTA in your country?
  - How did HTA appear on the policy agenda?
- What were key actors' positions regarding the establishment of HTA?
  - Did the position of the actors change?

Process and organisational establishment

- Can you tell me about the creation of the institutional structure of HTA?
  - What were the differences between what the body was set up to do and what it ended up doing in practice?
  - How did the body change throughout the years? Has its mandate get expanded or limited, formally or informally?
- Can you tell me about the establishment of HTA processes?
  - What were the challenges and opportunities for HTA process establishment?

Reflections about the current state of HTA

- Can you tell me about the current status of HTA in your country?
- Can you tell me about how you would improve HTA in your country?

Identification of controversial episodes • What would you say was a key episode of the use of HTA in your country?   - Are there any written documents on this episode?
Identification of other informants and of relevant documents • Who else would you recommend I speak to for this study? • What do you feel are the most relevant published reports and materials about HTA in your country?
Closing • What would you like to add? • Do you have any questions for me?

Appendix 3. Consent Form

CONSENT FORM

Title of Project: *The establishment and functioning of health technology assessment (HTA) agencies in Thailand and the Philippines*

Investigator: Ioana Vlad, MSc, PhD candidate

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My questions concerning this study have been answered by:

I have read the information sheet concerning this research and I understand what is involved in the interview proposed. I understand that at any time I may withdraw from the interview. This interview will be recorded unless I request otherwise.

If you agree to take part, please tick (only) one box as appropriate:

[ ] I agree to take part in this interview, and for quotes and other material arising from my participation to be used and attributed by name.
(Note, individual statements can still be requested to remain anonymous during the interview)

[ ] I agree that material from my interview may be quoted, but I would like my name to be anonymised.

[ ] I agree that material from my interview may be quoted, but I would like my name to be anonymised as well as any other information that might be used to identify me, including the organisation that employs me and my position within it.

[ ] I do not agree that any material from my interview may be quoted, but the researchers may use information from my interview to inform their analysis.

Name of Participant	Date	Signature
Investigator	Date	Signature