

# Adopting Health Technology Assessment

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A report on the socio-cultural, political, and legal influences on health technology assessment adoption

Four case studies: England and Wales, Japan, Poland & Thailand

WORKING PAPER  
Version 1

Rebecca Dittrich • OCTOBER 2016 • Elisabeth Asifiri



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## ABBREVIATIONS

AOTM	Agenja Oceny Technologii Medycznych Health Technology Assessment Agency, Poland 2004-2015
AOTMiT	Agenja Oceny Technologii Medycznych i Taryfikacji Health Technology Assessment and Tariffs Agency, Poland 2015
BBP	Basic Benefits Package
CHUIKYO	Central Social Insurance Medical Council
EBM	Evidence-Based Medicine
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
HITAP	Health Intervention and Technology Assessment Program
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
IHPP	International Health Policy Program
INAHTA	International Network of Agencies for Health Technology Assesment
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
JA	Joint Action
JCQHC	Japan Council for Quality Health Care
JMA	Japan Medical Association
JPMA	Japanese Pharmaceuticals Manufacturers Association
MHLW	Ministry of Health, Labour and Welfare
MOPH	Ministry of Public Health
MOH	Ministry of Health
NCQA	National Center for Quality Assessment in Health Care
NHF	National Health (Insurance) Funds
NHS	National Health Service
NHSO	National Health Security Office
NLEM	National List of Essential Medicines
NICE	National Institute for Health and Care Excellence
PE	Pharmacoeconomics
RCT	Randomized-Controlled Trial
SCBP	Subcommittee for Development of Benefits Package and Service Delivery
TC	Transparency Council
UC	Universal Health Coverage Scheme
WB	World Bank

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## FOREWORD

Demand for international action on health systems strengthening to ensure countries achieve universal health coverage and better health results is growing rapidly. The introduction of Health Technology Assessment (HTA) is one of the approaches adopted by some middle and high countries to prioritize health benefits in a systematic and transparent way. But, the adoption of HTA often involves significant challenges from political and legal perspectives.

Identifying these challenges and finding solutions to address them remains valuable information for many countries seeking to expand health coverage in a cost-effective and sustainable manner. The Global Health and Development Group based within the Institute of Global Health Innovation at Imperial College London (previously NICE International) and the World Bank agreed to collaborate on a joint study to compare the experiences from select middle- and high-income countries in adopting and implementing HTA, and to extract lessons about the key influences and potential benefits and costs of adopting HTA. Those countries studied include: England, Japan, Poland, and Thailand.

Japan hosted the annual conference of HTA International (HTAi) for the first time in Tokyo in May 2016. This study provided the background for presentation and discussion at the HTAi meeting. To undertake this task, The Global Health and Development Group based within the Institute of Global Health Innovation at Imperial College London (previously NICE International) and the World Bank brought together a health policy specialist with knowledge and experience in the Polish healthcare system and a dual-degree Juris Doctorate and Masters of Public Health Candidate. The draft report synthesizes the case studies into a working paper.

## INTRODUCTION

Health Technology Assessment (HTA) creates a bridge between evidence and policymaking to inform evidence-based decisions on efficiently allocating resources. It accounts for the clinical and cost effectiveness of technologies (where technologies range from pharmaceuticals and devices to medical interventions) as compared to treatment alternatives (Taylor & Taylor, 2009), as well as social values, ethics, and other important considerations. With changing population demographics and rising healthcare expenditures, countries have increasingly turned to the utilization of HTA to decide how to disperse resources and control costs while offering the highest quality healthcare. HTA can become especially important where the government supports a universal healthcare coverage scheme that is quickly becoming unaffordable.

Many countries have decades of experience with HTA (whether through small agencies, independent research institutions, etc.) before the government officially integrates HTA into its respective price setting, reimbursement, or healthcare funding scheme. Yet, few studies have examined comprehensively various political, socio-cultural, medical and scientific, and legal influences that bring governments to their “tipping points” where they decide to formally incorporate HTA into their decision making process.

In order to determine those influences, this report offers four case studies on the governance mechanisms connecting HTA structures or Agencies to the healthcare decision-making body, and it presents the major driving forces and important barriers that came together to create that mechanism. The political and social structures of England and Wales, Thailand, Japan, and Poland vary greatly, as do the forces that influenced their respective adoption and the manner in which HTA was officially integrated. England and Wales officially adopted HTA when NICE was established as a mechanism for explicit—rather than implicit—rationing of healthcare services to reduce regional disparities in health services. Thailand has a long history with HTA; however, HTA was formally adopted when the government appointed the HTA Agency, HITAP, to a gate-keeping secretarial role in addition to its role conducting technology assessments. AOTM (now AOTMiT), the Polish Health Technology Assessment Agency, was formally established in 2005. Japan has not yet officially adopted HTA, but it is currently actively preparing to integrate one component of HTA—pharmacoeconomic evaluation—into its national fee-schedule for pricing reimbursement of pharmaceuticals.

Each country under study has a history of experience experimenting with HTA—often small and inconsequential to the healthcare system. Following that long history, they have each adopted (or, in the case of Japan, are on their way to

adopting) HTA in some fashion (whether to produce guidelines and recommendations or to integrate pharmacoeconomics into price-setting), making HTA an integral part of the healthcare system. Understanding the various forces that have contributed to this adoption decision offers valuable insight into adoption processes other countries may face. The individual conceptual framework developed for each country may provide guidance to countries with similar political and socio-cultural structures. The synthesis of these individual frameworks offers a guide for other countries to consider when preparing to integrate HTA into the broader health system.

## **OPERATIONALLY DEFINING “HTA ADOPTION”**

For the purposes of this report, “HTA Adoption” has been operationally defined as the point in time at which the country government came to rely on and integrate HTA—or a principle of HTA (such as pharmacoeconomic evidence)—as a key resource for healthcare benefit priority setting and decision-making. While many countries have long and detailed histories with HTA that are used to explain what brought each country to formal adoption, HTA is not considered adopted until it is consistently used by the government to make coverage decisions.



# 1. ENGLAND & WALES

By: Rebecca Dittrich

## 1.1 The Healthcare System

England offers universal coverage to country residents, nonresidents with a European Health Insurance Card, and emergency care to non-European visitors or illegal immigrants. The 2012 Health and Social Care Act places the daily responsibility of running the National Health Service (NHS) in the hands of a then-new governmental organization—the NHS Commissioning Board, later renamed NHS England. NHS England manages the healthcare budget, oversees the 211 Clinical Commissioning Groups responsible for care in their districts, and ensures that the directives of the Secretary of State for Health are realized. The volume and comprehensiveness of services covered by NHS vary according to the decisions of each Clinical Commissioning Group (Thorlby & Arora, 2015).

NHS Wales also provides healthcare free at the point of access, but free choice under the NHS Wales structure is much smaller than that under NHS England. Welsh patients are not offered the same variety of choice when seeking secondary care services. Three NHS specialist trusts oversee seven local health boards (LHBs), which plan and provide healthcare services to all Welsh residents (Longley, Riley, Davies & Hernandez-Quevedo, 2012).

The National Institute for Health and Care Excellence (NICE) was established in 1999 as an NHS special health authority to promote good health and prevent and treat poor health (Taylor & Taylor, 2009). NICE functions to (National Institute for Health and Care Excellent, 2015):

1. Produce evidence-based guidelines and advice for use by health, public health, and social care practitioners
2. Develop quality standards and performance standards for those offering and contracting healthcare services
3. Provide a broad array of informational materials

NICE offers guidance on medical technologies, diagnostics, interventional procedures, disease prevention and management, and the provision of social care. General NICE guidelines offer evidence-based recommendations on a variety of topics and promote integrated care. Medical technology and diagnostic guidance ensures that the NHS may quickly and appropriately adopt the most clinical and cost-effective technologies. Interventional procedures guidance evaluates whether certain interventional procedures are sufficiently safe and effective to be adopted by the NHS (National Institute for Health and Care Excellence, 2015).

NICE also conducts technology appraisals on the clinical and cost effectiveness of pharmaceutical drugs, biopharmaceutical products, devices, diagnostic agents and other health technologies (National Institute for Health and Care Excellence, 2015). The English Clinical Commissioning Groups and Welsh Local Health Boards are legally obligated to implement NICE recommendations—by making a medication available— within three months following a technology appraisal (Casey, 2014). Not all technologies are appraised by NICE—appraisal of a technology requires a formal referral from the Secretary of State for Health (Naidoo, 2013). NICE only appraises approximately 40% of new medicines, prioritizing those that might impose a significant cost on NHS or that would offer a significant health benefit to patients.

Wales also has a second body for offering HTA guidance—the All Wales Medicines Strategy Group (AWMSG). In 2002, the AWMSG was established to advise the Welsh Assembly on integrating new drugs, to apprise the Welsh Assembly on the implications on the NHS if such drugs were made available, and to offer guidance on prescribing strategies. Many of these tasks overlap with NICE. However, the AWMSG will not appraise a technology if NICE intends to produce a recommendation within 18 months (Taylor & Taylor, 2009). AWMSG guidance always defers to NICE guidance (International Society for Pharmacoeconomics and Outcomes Research, 2008). Because the AWMSG was created after NICE, and it is deferential to NICE, the implementation of NICE will be considered the point at which England & Wales adopted HTA.<sup>1</sup>

With the creation of NICE, HTA was officially adopted. It took the decisions about healthcare services funding out of the hands of the political system and placed it in the control of an HTA agency (Chalkidou, 2015). As one of the first major HTA agencies, NICE also played a key role in motivating pharmaceutical companies to begin conducting their own economic evaluation to prove the drug's clinical and cost effectiveness. As NICE gained power and reputation, its negative appraisal of a drug incentivized countries without a relationship to NICE to be wary of and impose restrictions on a product (Ikegami, Drummond, Fukuhara, Nishimura, Torrance & Schubert, 2002). The pharmaceutical industry needed to find solutions to avoid a negative NICE appraisal that could make a technology obsolete.

NICE offers a unique story in HTA adoption. Its origins take root much earlier than those of many other HTA agencies. NICE is an HTA agency deeply integrated into the legal framework guiding the healthcare system, where many other countries either have not legally integrated an agency or have not formally

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<sup>1</sup> The AWMSG will not be further discussed as a part of this project.

established an agency at all. It offers insight into the process of creating a highly developed HTA agency—something that other countries may one day strive to attain as health services resource allocation becomes more and more critical.<sup>2</sup>

## 1.2 The Path Towards HTA Adoption

When the NHS was established in 1948, it launched with the intention “to meet *all* need for advice, treatment, and care” (emphasis added) (Stevens & Milne, p. 12, 2004). But, the NHS has been pressured by the need to contain health services costs since as early as its creation (Stevens & Milne, 2004), and it struggled with healthcare variations, skepticism of healthcare technologies, and changing population demographics.

Research in the United Kingdom (UK) on healthcare variation originates in the 1930s on a study of the variation in tonsillectomy incidence, and the UK has experienced distrust in the presumed universal effectiveness of a healthcare technology since the 1960s. In 1958, thalidomide, the pregnancy anti-nausea medication, was licensed for use in the UK. Only two years later in 1961, Dr. William McBride wrote to the *Lancet* to express concern about the increase in deformed babies correlating with pregnant mothers who had taken thalidomide. The drug was pulled from the market that same year (Press Association, 2012). However, the fear instilled and the doubt created from the thalidomide scandal was long lasting, and it led to the establishment of the drug licensing system that still exists today. In the 1960s, the UK developed the Medicines Control Agency to license pharmaceuticals for their safety, efficacy, and quality (Stevens & Milne, 2004). The creation of the Medicines Control Agency marked an important step in the history of HTA in the UK (Stevens & Milne, 2004). It introduced the notion of regulating health technologies (rooted in mistrust, and expressing an interest in greater oversight) very early.

Available technologies continued to grow exponentially from the 1950s. Where there were once only a handful of new chemical entities introduced each year, over 50 new entities were introduced each year by 2004. The complexity of the healthcare industry also continued to increase, as new methods in diagnostics, pharmaceuticals, and treatment settings became available. New technologies also increased the number of treatable patients and strained the system. Both the increasing quantity and increasing complexity of products available in the healthcare industry burdened the NHS as a universal coverage provider (Stevens & Milne, 2004).

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<sup>2</sup> This report focuses on England and Wales; however, broader influences on the United Kingdom in general are strongly relevant and will be greatly discussed.

Between 1961 and 2001, the percentage of persons over 65 grew from 9% to 13% (Stevens & Milne, 2004), per capita GDP in the UK doubled, and the increase in individual wealth coincided with an increase in expectations of the healthcare system (Stevens & Milne, 2004). Together, these changes in population dynamics demanded greater quantity and higher quality healthcare services; the NHS would need to ration resources appropriately if it was going to be able to meet these demands.

The Royal Commission on the National Health Service, responsible for promoting the best use of the NHS's financial and human resources, recognized the unfeasibility of meeting all healthcare user expectations in 1979. It subsequently modified the rhetoric of its objective to “satisfy the reasonable expectations” of NHS consumers (Socialist Health Association, 2015). Chapter 2, Section 14 of the Commission newly read:

“It is important for any health service to carry its users with it, given that it can never satisfy the demands made upon it. It is misleading to pretend that the NHS can meet all expectations. Hard choices have to be made. It is a primary duty of those concerned in the provision of health care to make it clear to the rest of us what we can reasonably expect” (Socialist Health Association, 2015).

Health economics has been an established area of academia in the UK since the 1960s (Stevens & Bilne, 2004). Between the 1970s and 80s, an increasing number of organizations engaged in HTA. The studies were mainly uncoordinated efforts conducted by charitable organizations, universities, and medical centers. The studies conducted by the Medical Research Council in Britain focused on quality clinical trials for research, not policy making or healthcare quality improvement (Drummond & Banta, 2009).

The Department of Health commissioned a study on heart transplantation effectiveness and cost-effectiveness in the early 1980s. The study was well regarded and utilized to determine whether or not to expand the NHS heart transplantation program, but it also identified concerns with technology evaluations. The practical problems identified as a result of the study came to be known as “Buxton’s Law”—that “it is always too early to assess a new technology, until suddenly it’s too late” (Drummond & Banta, 2009).

The focus on economic evaluation did lead to a quickly developing literature base on healthcare cost effectiveness, but it was often poorly linked to the growing interest in evidence-based medicine (EBM) or HTA.

In 1988, the House of Lords Committee on Science and Technology produced a report on Priorities in Medical Research. It offered key findings on the need for cost-effectiveness research and initiated the push towards economic evaluation and HTA integration. The Report read, in part:

“Some setting of priorities and some emphasis on problem led research is essential. There appears to be no effective means of setting priorities. Filling gaps in national research effort is not a responsibility which governments should leave to charity...

“The NHS should be brought into the mainstream of medical research. It should articulate its research needs; and it should ensure that the fruits of research are systematically transferred into service” (House of Lords Select Committee on Science and Technology, 1988).

The House of Lords Report identified a substantial gap in funding that would be critical for conducting the applied research necessary for promoting NHS efficiency and effectiveness. The results of the Report culminated in the 1991 creation of the Research and Development Programme, which led to the establishment of NICE (Drummond & Banta, 2009).

Following the Report, the government appointed Professor Michael Peckham as first Director of Research and Development for the NHS and the Department of Health in January of 1991 (Drummond & Banta, 2009). Peckham took on his role with a personal focus on evaluative research, launching both the Cochrane Collaboration and R&D Programme (or Strategy)—created half a year after he took on his position—to realize this goal (Rawlins, 2015; Adam, 1991). The Programme was intended to address three key problems within the NHS (Adam, 1991):

- (1) Weak health services and public health research, creating a lack of support for many NHS decisions;
- (2) Ineffective (at best, non-existent at worst) relationship between research and practice; and
- (3) Tendency to conduct research on a narrow range of NHS activity.

Under the R&D Programme, the NHS converted from a passive recipient of healthcare technology into an active research-based health service. The Programme staunchly supported evidence-based practice, guidelines—and especially original clinical trials—to better oversee the NHS. While the R&D Programme did not conduct its own HTA studies, the HTA program implemented as part of the R&D Programme in 1993 purchased high-quality HTA research where the NHS required it most (Drummond & Banta, 2009; Stevens & Milne, 2004). This HTA program was established after the Department of Health

Advisory Group on Health Technology Assessment released its report *Assessing the effects of health technologies: Principles, practice, and proposals* (Raftery & Powell, 2013). The report emphasized the need for systematic reviews of existing evidence and the importance of studies on effectiveness not efficacy, pragmatism not explanation. In 1996, a National Screening Committee was established, boasting the HTA program as its research arm (Raftery & Powell, 2013). Politicians remained in control of funding decisions at this time (Chalkidou, 2015).

In 1997, the Labour Party (under Tony Blaire) reclaimed power from the 20-year hold of the Conservative Party (BBC). Out of concern for the variability in healthcare offered by the NHS, the Labour Party supported national standards in healthcare and created a significant amount of HTA-related guidance (Rawlins, 2015; Oliver, Mossialos & Robinson, 2004). Of most significant concern, the ability of NHS hospitals to make decisions on the technologies that would or would not be offered—especially when it came to expensive new medications—created a “post-code lottery.” Apart from the unequal access to care that can result from healthcare management or service-provider inefficiencies, NHS hospitals were at liberty to decide which services they would or would not offer. Some hospitals elected not to provide new, expensive technologies. This created national variations in access to healthcare based on “post-codes,” despite the universal coverage model (Rawlins, 2015; Sorenson & Chalkidou, 2012). The public—and media—were frustrated about the lack of equality across the system (Rawlins, 2015).

The Blaire government was also facing a political (and financial) problem. It had run on the promise of maintaining the spending plans of the previous government, and it would not be able to offer additional resources to the NHS in order to improve its quality (Rawlins, 2015). As an initial consideration to address this growing problem, Baroness Margaret Jay summoned the then-Chairman of the Committee on Safety of Medicine to inquire as to whether the Committee had the capacity and willingness to include cost-effectiveness in its quality-based assessments. Concerned that quality problems would consistently be used to justify denial of a medication as opposed to cost-effectiveness to deny coverage of a medication, Rawlins advised that cost-effectiveness should not be incorporated into the Committee’s responsibilities (Rawlins, 2015).

In December of 1997, the government announced its intention to create an independent entity for cost-effectiveness decisions—NICE (then the National Institute for Clinical Excellence)—to advise the NHS on the use of individual or competing technologies and to create quality of care guidelines for healthcare professionals. Efforts were to account for both clinical and cost-effectiveness (Rawlins, 2015).



Prior to the creation of NICE and the creation of a centralized system for producing and promoting guidelines, the Royal Colleges created guidelines on clinical practice. However, the Department of Health funded the Colleges with little organization, and the method for disseminating and incorporating the guidelines was unclear. The need for a more sophisticated and organized method for creating guidelines became increasingly important (Rawlins, 2015).

The Blair government followed through on its commitment to create NICE over the next two years. In 1998, a consultation document on issues of quality within the NHS included the proposal for NICE. NICE was established subject to legislation in 1999.

In 1999, Sir Michael Rawlins, the founding chairman of NICE, welcomed the Institute's establishment by stressing its importance:

“Of course resources do not stretch to satisfying the demands placed on them by everyone. No healthcare system in the world begins to meet, and match, the aspirations of all those who work in it or use it. All public services would like more money...

“More money for health is a political issue and not a matter for the Institute, but we do have a role to play. It is our job to contribute to the management of the NHS by providing a rationale for the use of its resources. In the areas that we will be called to evaluate products and therapies, it is our task to consider them against the background of providing the greatest good for the greatest number; and evaluating their worth in the whole context of health, health gain and a return to fitness. By making national recommendations about the use of products we will be able to play our part in getting patients their best value for money” (National Institute for Health and Care Excellence, 2015).

NICE was established as a part of the NHS in England and Wales subject to Statutory Instruments 220, 260, and 2219 in 1999. Instrument 220—The National Institute for Clinical Excellence (Establishment and Constitution) Order 1999—established NICE as a Special Health Authority and placed the Institute under the direction and control of the Secretary of State. This order was amended with Instrument 2219 to include excluded phrasing and miswordings. Instrument 260—The National Institute for Clinical Excellence Regulations 1999—created the governance structure for NICE and terms for the appointment, disqualification, termination, and suspension of chairmen, officers, and committees.

### 1.3 Major Barriers to HTA Adoption

The public responded to the idea of explicit rationing of healthcare services unfavorably. Traditionally, the NHS had engaged in implicit rationing. Of course, in a universal healthcare system, all services cannot be funded. Before the Internal Market Reform (see key tipping points), providers engaged in implicit rationing by making individualized decisions about what technologies to adopt or services to perform. Implicit rationing was a political process, and much of the public did not even know that rationing occurred (Jackson, 2013).

NICE would alter healthcare decision making from implicit to explicit rationing. The utilization of a standardized model would reduce the post-code lottery, but would introduce its own problems unpalatable by the larger population. NICE would need to distinguish between social value and scientific judgments, and it did not have the Citizens Council to help it to make social value judgments until 2002 (Rawlins, 2013). Despite public frustration with the post-code lottery, the public was more comfortable accepting rationing decisions from healthcare providers than policymakers or politicians (Hunter, 1995).

The NHS has historically avoided directly discussing the use of rationing in healthcare decision-making (King & Maynard, 1999). Prior to the legal establishment of NICE in 1999, Chairman Sir Michael Rawlins avoided using the term “rationing”, instead emphasizing the term “prioritization” (Rawlins, 2015). The public reaction to what it felt avoided the truth of rationing was even more negative than to the concept of rationing itself. As a result, both the public and the pharmaceutical industry offered NICE a “lukewarm” welcome upon its establishment (Rawlins, 2015).

In actuality, concerns over the use of the term rationing frivolously affected the implementation of NICE. The government had traditionally played a heavy-handed role in making healthcare decisions, and it had been committed to the incorporation of cost-effectiveness research into healthcare decision making for a significant amount of time. Sir Michael Rawlins held meetings with patient groups prior to NICE’s creation and listened to the concerns of the pharmaceutical industry in order to assuage fears or explain methods (Rawlins, 2015).

### 1.4 Key Tipping Points for HTA Adoption

The 1991 NHS Internal Market Reforms that connected healthcare purchasers and providers through contractual financial relationships placed HTA policy



prominently on the agenda (Stevens & Milne, 2004). In a 1985 report to the Nuffield Provincial Hospitals Trust, Alain Enthoven wrote about the NHS:

“The National Health Service...is obviously the democratic choice of the overwhelming majority of the British people...And it produces a great deal of care for the money spent...But the NHS is under increasing economic pressure. The prospects for real growth in the resources devoted to the NHS appear to be very limited...So the NHS will need to find ways to produce even more value for money if it is to make effective new medical technology available to all who can benefit from it at the standards enjoyed in all other industrialized democracies” (Enthoven, 1991, citing Enthoven, 1985, *Reflections on the Management of the National Health Service*)

The Internal Market Reform did away with the monopolistic control that District Health Authorities (DHAs) had over the people in their district by acting as service suppliers. Under that model, the NHS was provider, not patient, dominated. DHAs were therefore driven by the needs of the provider, and the structure offered no incentives for providers to utilize resources effectively and prioritize patient needs. The Reform created a purchasing agency (demand side) distinct from the suppliers (supply side). DHAs (then Primary Care Trusts, and now Clinical Commissioning Groups) were recast as purchasers of services for their district members, and hospitals, general practitioners, and others were recast as suppliers of healthcare services to DHAs. DHAs then were choosing from competing suppliers (Enthoven, 1991). The new Model placed in the DHAs responsibility for ensuring value for money in patient care and launched a newfound emphasis on cost-effectiveness (Stevens & Milne, 2004). If providers wanted to buy new technologies or continue with traditional practices, they would need to convince the DHAs to purchase those services (Klein, 1994).

As previously addressed, the creation of the R&D Programme—and incorporation of the HTA program—laid the foundation for the creation of NICE. Although it did not create a mechanism whereby HTA guidance would be utilized for making funding decisions, it set HTA at center stage of the government’s new push to strengthen research and better convert research into practice.

The Blair Government drove the momentum for an HTA Agency to incorporate HTA research into practical funding application. The Administration’s commitment to maintaining previous spending on the NHS but improving the quality of the system forced it to get creative—especially if incorporating cost-effectiveness into the role of the Committee on Safety of Medicine was not an option; implementing an HTA agency for healthcare funding decision-making allowed the new government to achieve this balance.

The centralized financial structure of the NHS allows the UK Treasury to have control over healthcare expenditure that is greater than many other countries. The government has always actively engaged in creating policy solutions to promote cost savings and solve quality problems within the NHS.

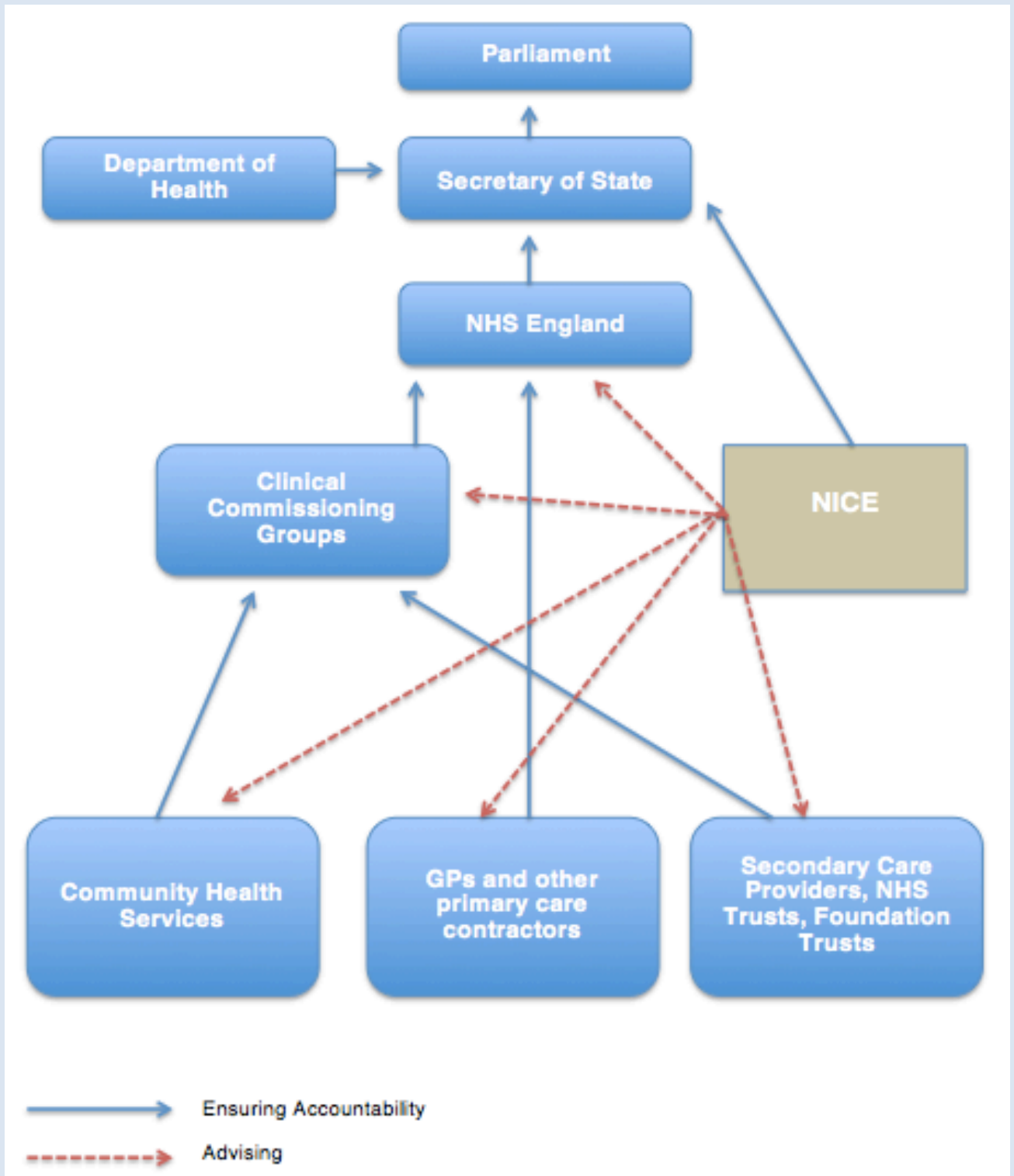
The establishment of an HTA Agency that would make funding decisions would also help solve the critical problem of the post-code lottery. So long as clinical providers made decisions about service provision—and that decision was made based on government budgetary constraints—care would continue to vary substantially (Klein, 1994). The NHS required reforms to address systematic challenges in healthcare delivery, access to and quality of care, as well as standardized coverage—which an HTA Agency would help provide.

### 1.5 HTA Governing Structure

NICE is accountable to the Secretary of State for Health (in England) and the National Assembly for Wales (in Wales), and reports directly to the NHS (not the Department of Health) (Akehurst, 2010; National Institute for Health and Care Excellence, 1999). In Wales, NICE Guidance is incorporated into the healthcare system through the funding Direction for LHBs and NHS Trusts to fund positively appraised technologies. Wales is not involved in the process of deciding which technologies will be appraised or on what grounds guidelines will be created.

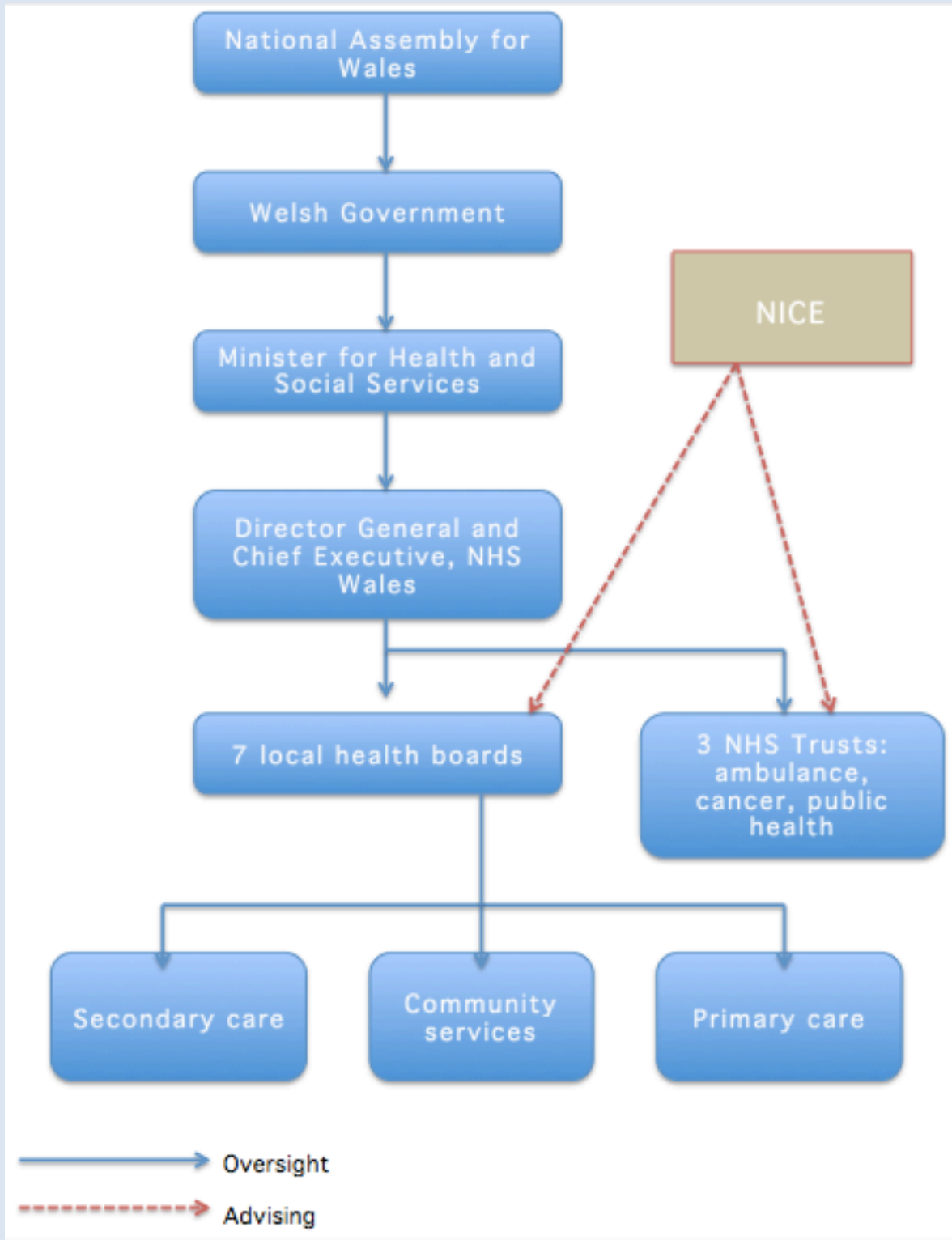
The Health Technology Assessment (HTA) Programme of the NHS R&D Strategy commissions technology assessments from a short list of academic centers; these assessments, among others, are used by NICE to conduct appraisals (Woods, 2002).

**FIGURE A: NICE Guidance and NHS England**  
(Adapted from Thorlby & Arora, 2014)



**FIGURE B: NICE Guidance and NHS Wales**

(Adapted from Longley, Riley, Davies & Hernandez-Quevedo, 2009)



## England

Parliament, the Secretary of State for Health, and the Department of Health in England are jointly responsible for health-based legislation and policy. According to the 2006 Health Act, the Secretary of State is legally obligated to provide health services free of charge and promote comprehensive health coverage.

NICE itself is included in the Health and Social Care Act of 2012 and the NHS Constitution. Together, they place requirements on the healthcare system to incorporate NICE and grant a positive right to utilizers of the system to benefit from NICE guidance. When England introduced the Health and Social Care Act in 2012, the establishment of the duties of NICE and the Institute's functions played a prominent role. The Act outlines the general duties of NICE, requirements in its roles of producing quality standards, advice, and guidance, etc. (Health and Social Care Act, 2012). Through the Act, the functionality of NICE is intricately woven into the legal structure of the English healthcare system.

England's NHS Constitution also secures the function of NICE within the healthcare system. The provision on nationally approved treatments, drugs and programs reads that those utilizing the English healthcare system "have the right to drugs and treatments that have been recommended by NICE for use in NHS, if [their] doctor says they are clinically appropriate for [them]" (National Health Service, 2015). As a result, the NHS is legally obligated to fund technologies that have been appraised and recommended. The NHS is required to review clinical management after the publication of related NICE guidelines (Taylor & Taylor, 2009).

## Wales

When NICE was originally created in 1999, it was established as a Special Health Authority in England and Wales. In 2004, following an Arms Length Bodies review, NICE merged with what was previously the English Health Development Agency and was reincorporated as a Special Health Authority in England only (Welsh Assembly Government, 2009; NHS Wales, 2013). Wales subsequently implemented an agreement to utilize NICE's clinical recommendations. (In 2003, NICE was reestablished as a Non-Departmental Public Body). In 2003, the Welsh Assembly Government's Minister for Health and Social Services issued a funding Direction for NICE's technology appraisals. As a result of the Direction, Local Health Boards and NHS Trusts became legally required to fund and make available technologies appraised and recommended by NICE within three months (unless a longer implementation period is specifically in order) (Welsh Assembly Government, 2009; The National Assembly for Wales, 2003). The NHS is also required to review its clinical management in a certain area once relevant NICE guidelines have been released (Taylor & Taylor, 2009).

“It will be for LHBs to ensure that satisfactory arrangements are in place for patients to receive treatment within the terms of NICE Guidance. Generally, this will mean the introduction of robust strategies within service agreements with NHS Trusts for the implementation of all appraisal guidance” (The National Assembly for Wales, 2003).

More recently, the Welsh government agreed to a new Service Level Agreement which includes not only the incorporation of NICE technology appraisals, but also clinical guidelines, interventional procedure guidance, public health and social care guidance, NICE Quality Standards, Clinical Pathways and NHS Evidence (NHS Wales, 2013).

### **Process for Appeal**

The ability to appeal a NICE recommendation is first stated in the Health and Social Care Act. Provision 238 mandates that regulations under the section on advice, guidance, information and recommendations may also create the opportunity to appeal the recommendations made by NICE. Specifically, the provision reads that rules for appeal may include (Health and Social Care Act, 2012):

1. The types of recommendations against which an appeal can be brought;
2. The individual(s) who can bring an appeal;
3. The grounds upon which an appeal can be brought; and
4. The persons who should be responsible for hearing an appeal.

In 2014, NICE published its current appeals guidelines, including the rules for appeal as they are mandated in the Health and Social Care Act. The guidelines grant the opportunity for a consultee involved in a technology appraisal or the creation of guidance on a highly specialized technology (HST) can appeal the final recommendations within 15 days of when the final draft guidance is issued to commentators and consultees (National Institute for Health and Care Excellence, 2014). (Note: other types of guidance have options for contestability that are less formalized (Rawlins, 2015).

The Appeal Panel does not rehear the evidence already submitted during the appraisal process for the purposes of reevaluating the same information. Appeals can only be filed on the two grounds (National Institute for Health and Care Excellence, 2014, 2014):

Ground 1(a): NICE failed to act fairly.

This is not to say that appellants may argue that it is “unfair” not to cover a certain medication, but that NICE was unfair during the appraisal or HST guidance processes.

Ground 1(b): NICE has exceeded its powers.

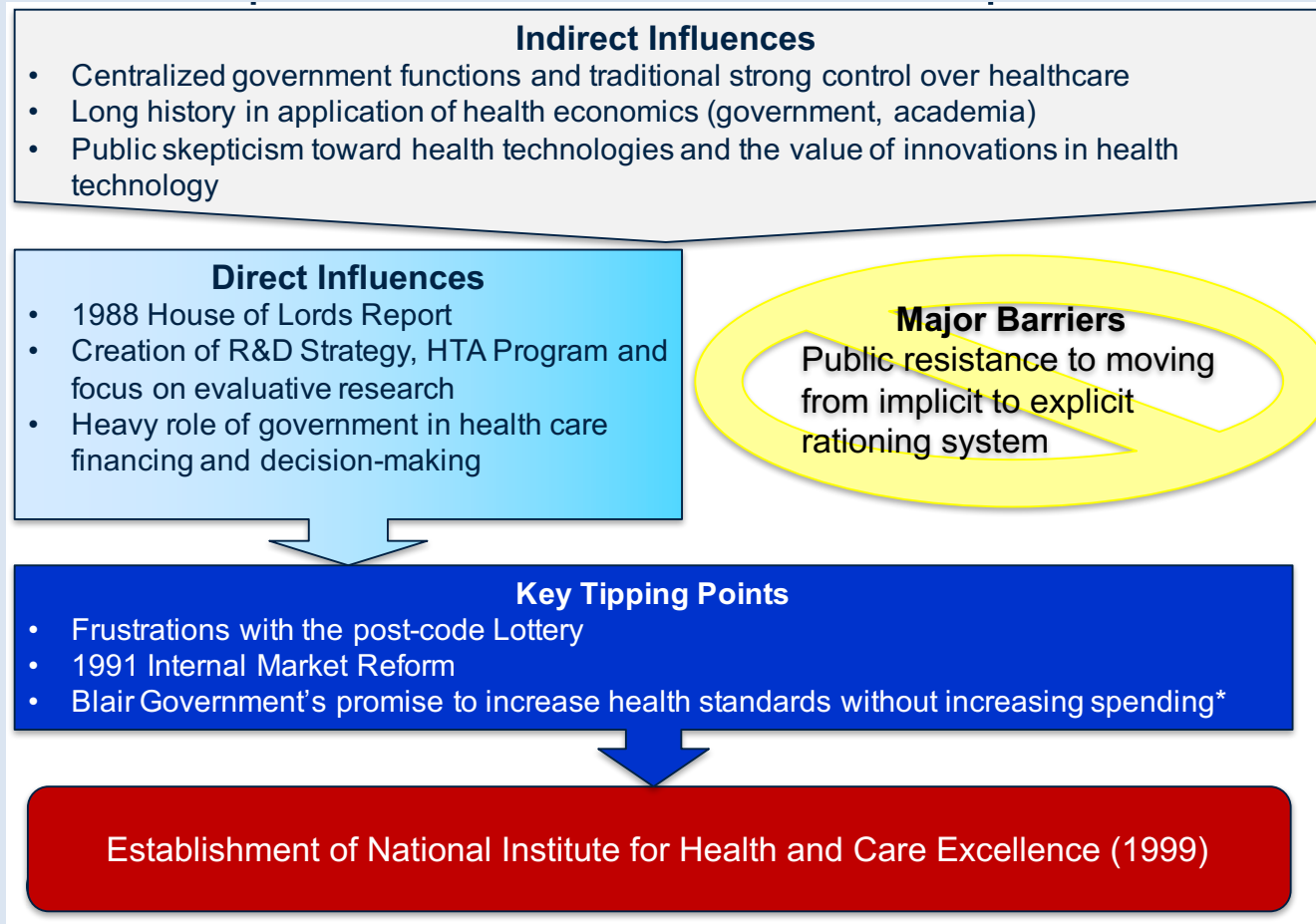
As NICE is a public body statutorily established under the Secretary of State for Health, the Appeal Panel will hear claims that NICE acted beyond its scope of powers.

Ground 2: In light of the evidence heard by NICE, the recommendation is unreasonable.

The Appeal Panel will hear a case on the assertion that the decision made by NICE could not be reasonably justified in light of the evidence submitted.

If the appellant loses and still has cause for contestability, he or she may seek judicial review through the Administrative Court. To prevail, the contesting party would need to prove that either (1) the NICE process has not been reasonably followed, or (2) the guidance given is so inaccurate that a reasonable person could not have given it. While guidance can be overturned by judicial review, most often the court directs NICE to reassess certain information and reevaluate its guidance. NICE has been brought under judicial review four times (Rawlins Interview, 2015).

## 1.6 Conceptual Framework: Factors Influencing HTA Adoption





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## 2. THAILAND

By: Rebecca Dittrich

### 2.1 The Healthcare System

The Thai Healthcare System is divided into three publicly financed health insurance plans: (1) Universal Health Coverage Scheme (UC), (2) Social Security Scheme (SS), and (3) Civil Servant Medical Benefit Scheme (CSMBS) (Ngorsuraches, Meng, & Kulsomboon, 2012). The plans cover 45 million, 10 million, and 4 million people, respectively, and together they offer healthcare coverage to 99% of the Thai population (Tantivess, 2015; Tantivess, Teerawattananon & Mills, 2009). Resources devoted to healthcare in Thailand have increased dramatically in the past three decades. Total health expenditure has increased at a greater rate than GDP—where health expenditure was 3.5% of GDP in 1979, it was 6.09% of GDP in 2000 (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

The UC scheme covers those ineligible for CSMBS or SS; it is funded mainly from general tax revenue and is managed by the National Health Security Office (NHSO) (Ngorsuraches, Meng, & Kulsomboon, 2012). The Ministry of Public Health (MoPH) is the primary agency in charge of promoting, organizing, and supporting the health services activities offered throughout the country at hospitals and health centers. The Thai Food and Drug Administration (FDA) controls market authorization for pharmaceuticals and devices. Market authorization requires safety, efficacy, and quality product information from the promoting manufacturer. The Ministry of Commerce controls drug prices and mandates price labeling on over-the-counter (OTC) drugs—this price is set according to cost structures and international pricing schemes submitted by pharmaceutical companies. The Medicine Price Ceiling controls the price of non-OTC drugs by setting a maximum chargeable price. The Committee for Development of the Medicine Price List, within the Ministry of Commerce, sets the Ceiling. The price of medical devices has no ceiling and is driven by market demand. The National List of Essential Medicines (NLEM) (or National List of Essential Drugs (NLED)) includes drugs, vaccines, etc. necessary to control major health problems. The MoPH is mandated to produce the NLEM, and public health facilities are required to offer all items on the NLEM. Only those medications listed on the NLEM will be covered by the public health insurance plans – the list is consulted for pharmaceutical reimbursement (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

Health care coverage was drastically expanded when Thailand integrated UC in 2001 (Mohara, Youngkong, Velasco, Werayingyong, Pachanee, Prakongsai,

Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk, & Teerawattananon, 2012). Thailand has a long history of support for health technology assessment and evidence-based policy research on healthcare coverage. This history helped build the momentum for health technology assessment that led to the eventual creation of the Health Intervention and Technology Assessment Program (HITAP) in 2007. HTA was not officially adopted in Thailand until the Subcommittee for the Development of the Benefit Package and Service Delivery (SCBP) ventured to create an explicit mechanism for UC benefit package inclusion decisions in 2009 (Tantivess, 2015). At that time, the SCBP, a subcommittee of the NHSO, appointed HITAP and the International Health Policy Program (IHPP) to the position of secretary and tasked them with creating a methodological process for determining the UC benefits package. To do so, HITAP and IHPP adhered closely to the principles of HTA. By utilizing HTA principles to make formalized decisions about the UC benefits package, HTA became an integral feature of the healthcare system.

What led the NHSO to solicit the assistance of HITAP and IHPP and formally integrate HTA into a structured mechanism for UC benefits package decision making included a long and complex history of increasing HTA support in Thailand.

## 2.2 The Path Towards HTA Adoption

Thai support for economic evaluation in the healthcare arena traces back to the 1980s. Officers would leave Thailand to study evidence-based policy before returning to Thailand to work as researchers or technical officers in economic evaluation (Tantivess, 2015). The culture of using evidence to inform policy decisions continued to grow in Thailand. In 1982, the country published its first economic evaluation and incorporated health economics into pharmacy school training in 1991. The country has supported health policy and systems research (HPSR) for the past three decades, making it primed for the correct cost-effectiveness analysis (CEA) scheme to take hold (Tantivess, Teerawattananon & Mills, 2009).

Before the advent of UC, Thailand turned to HTA to influence the Social Health Insurance Scheme developed in 1991. An HTA Unit, Technology Assessment for Social Security in Thailand (TASSIT) was established in 1993 to help regulate coverage under the social security scheme (Tantivess, 2015; Tantivess, 2013). TASSIT was terminated in 1996, due not to a lack of support for HTA, but to (1) a lack of human resources and trained researchers to conduct economic evaluation, and (2) the expiration of the three-year Wellcome Trust grant that provided funding for TASSIT (Tantivess, 2015).

The government tried again to establish an HTA unit in 2002 under the MoPH. The Thai economic crisis beginning in mid-1997 led to a decline in individual ability to support health care costs. It placed pressure on the Thai government to increase support of the public health system. The crisis led more people to fall into poverty and qualify for coverage under the public health plan (before UC) and strained the financial budget. With increased pressure and demand for health services, health managers, especially within the MoPH, recognized the necessity of cost containment, especially with HTA methods. The MoPH's Department of Medical Services created an HTA unit in response, but the division's limited research capacity only developed 12 studies. The unit relied on limited support from the MoPH budget. Though the unit still exists, without a plan to expand capacity, it has had little practical role in informing health technology coverage decision-making, despite its overlapping timeline with the introduction of UC (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

When UC was introduced in 2001, it merged the pre-existing Voluntary Health Card for rural population coverage and the Medical Welfare scheme for poor and indigent coverage. It dramatically expanded health insurance coverage for the Thai population, but struggled with issues such as maintaining allocative efficiency, identifying cost-effective benefits, and providing evidence-based care. From the start, HTA was considered an important policy to maintain UC (Yang, 2009). The failure of TASSIT in 1996 due to a lack of capacity and lack of funding had taught the government about the importance of gaining support for HTA. As a result, building capacity and fostering communication with policy makers, the public, and key stakeholders about the importance of HTA was considered essential (Tantivess, 2015).

The World Bank and other international experts were vocal about their concerns that the UC scheme, as it had been developed, would not be sustainable for the then lower-middle income economic status of the country. The calculation of Thai researchers to project UC coverage came to similar conclusions; it demonstrated the importance of identifying cost-containing strategies while maintaining the mission of universal coverage to offer access to essential benefits. Cost assessment and cost effectiveness analyses were recognized by the NHSO as important to making the scheme sustainable (Tantivess, 2015).

The introduction of universal coverage raised awareness among the public and policymakers about the necessity of resource allocation and the importance of rationing tools in healthcare decision-making (Tantivess, Teerawattananon & Mills, 2009). Previously, policymakers and practitioners sometimes viewed cost-effectiveness research or pharmacoeconomics as pseudoscience—from an outside perspective, they felt it grounded in complex calculations, random assumptions,



and arbitrary perspectives, philosophies, and concepts. Health workers expressed disagreement with the population-level focus of HTA as compared to the patient-level focus of medical practice (Tantivess, 2008). But, stakeholders across the board recognized that the increased pressure on limited resources initiated by UC would make priority-setting essential. National policymakers, hospital directors and health professionals all agreed that services would need to be rationed. While recognizing the necessity of resource allocation, policymakers also voiced a need for more transparency in decision-making (Teerawattananon & Russell, 2008).

Without a methodological system for determining the UC benefits package, UC benefits would be determined because of the advocacy of health professionals, activists, or industry. As a result, concerns arose about what essential benefits were being missed under the coverage scheme, and whether the most important benefits were covered. The “losing” stakeholders demanded that the government adopt a more systematic, transparent approach for determining coverage (Tantivess, Velasco, Yothasamut, Mohara, Limprayoonpong & Teerawattananon, 2012).

As was the case in many countries, the proliferation of available technologies, and the increasing cost of technologies, amplified the demand for expensive health interventions (Teerawattananon & Russell, 2008). The government was forced to find solutions to ration access to and availability of expensive technologies that realistically could not be offered to everyone.

The decision making process for the inclusion of services in the UC benefit package before HTA utilization was problematic for two reasons. First, many interventions were considered without the necessary supporting evidence. Second, there was no systematic process for determining the technologies to be covered (Kingkaew, 2013). If UC was going to equitably and efficiently allocate limited resources, it needed a process for prioritizing essential benefits that would reach the entire population. HTA offered such a scheme. As a result, Thailand had become fertile ground for a national HTA unit. Concerns from the medical community about economic evaluation’s threat to innovation, clinical freedom, or its intrusion into physician autonomy did not appear to significantly impact general HTA acceptance (Tantivess, 2008; Teerawattananon & Russell, 2008).

The capacity for HTA that existed in Thailand before HITAP was small. No institution or organization had the ability to conduct larger-scale HTA on

surgical procedures or public health programs (Tantivess, 2015).<sup>3</sup> Larger ticket items had a higher potential to drain the healthcare system's limited resources. Thus, after the implementation of UC and before the establishment of HITAP, NHSO requested technical support from universities or independent research institutes to conduct HTA on an intervention-to-intervention basis (Tantivess, 2015).

Since it was established in the late 1990s, the International Health Policy Program (IHPP) has been conducting studies on issues such as healthcare financing, workforce, and system performance. However, between 2000 and 2003, it became clear that the capacity that IHPP had to conduct cost-effectiveness analysis could not meet the demands of policymakers, the Subcommittee for the National List of Essential Medicines (NLEM) Development, the UC, SS, and CSMBS, and Ministry of Public Health (MoPH) departments. The IHPP had an eye on capacity building in health systems and policy research, and as a result it was given long-term scholarships by WHO and other national and international institutions to send research fellows to post-graduate courses in Australia, Europe and the US. Those researchers who studied health financing abroad were expected to return to play a prominent role in evidence generation for health resource allocation (Tantivess, Teerawattananon & Mills, 2009).

By 2006, the limitations on the government budget to support all health technologies were well recognized across the national and hospital levels. Different citizens groups, supported by civil society organizations and patient groups, claimed their right to early access to new and expensive medical and public health interventions, and demanded more participatory decision making with greater transparency (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

With the increasing demand for cost-effectiveness analyses, a proposal to establish an HTA unit within IHPP was submitted to Thailand Health Promotion Foundation (ThaiHealth), the Health Systems Research Institute (HSRI, an anonymous state agency), and the MoPH's Bureau of Policy and Strategy—institutions known to be receptive to health policy and systems research (Kamae, 2010).

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<sup>3</sup> For example, in 2004, the Ministry of Public Health (MoPH) and University of Queensland, Brisbane, QLD, Australia introduced the research project "Setting Priorities using Information on Cost-Effectiveness (SPICE)". The project was funded by the Wellcome Trust but involved no long-term commitment, and it expired in 2009 (Tantivess, Teerawattananon & Mills, 2009).



While awaiting the official approval of this HTA unit in July 2006, IHPP and other institutions began drafting strategic and management plans for the organization. According to the plans, the first task of HITAP would be to prepare standard guidelines on economic evaluation. With the introduction of HITAP came the opportunity to create national guidelines for HTA and to coordinate with the previously consulted experts to establish a more unified HTA front (Tantivess, 2015). This set of guidelines went on to be adopted by the NLEM Subcommittee in December 2007, and set the stage as the first edition of national health economic appraisal guidelines (Tantivess, Teerawattananon & Mills, 2009).

When approved, HITAP was officially launched as a three-year initiative aimed at becoming a national HTA institute (Tantivess, Teerawattananon & Mills, 2009). It was formally established in 2007 under the Bureau of Policy and Strategy within the Ministry of Public Health (HITAP, 2014).

HITAP aims to equip health professionals, policy makers, and the public alike with scientific evidence on the costs and benefits of healthcare products, programs, and procedures. To do so, HITAP set three aims (Tantivess, Teerawattananon & Mills, 2009):

1. To appraise health interventions and technologies efficiently and transparently, utilizing international, standardized methods
2. To develop schemes and mechanisms to secure optimal selection, attainment, and management of health technology along with appropriate policy determination
3. To educate the public and disseminate findings in order to maximize the use of appropriate health interventions and HTA results

HITAP utilized four strategies to achieve these aims, to overcome past obstacles in promoting HTA in Thailand, and to introduce the concept of knowledge management to enhance the value of the HTA research (Tantivess, Teerawattananon & Mills, 2009):

Strategy I: Improve infrastructure for economic assessment by identifying and developing a unit to support HTA studies. Activities to achieve this goal included developing a database on Thai HTA studies, designing methodological guidelines, and determining a value-based ceiling threshold. This standardization was essential to increasing the accuracy, integrity, and utilization of research results (Tangcharoensathien & Kamolratanakul, 2008).

Strategy II: Increase health economist capacity and enhance knowledge and understanding of HTA amongst potential research users. Activities to achieve this goal included education enhancement through annual training programs on basic and advanced health economics. Stakeholders, policymakers, healthcare planners, health professionals, and researchers from public and private institutions utilize these programs. HITAP staff offers technical support to attendees of the programs even after the programs end.

Strategy III: Address the growing demand for HTA vis-à-vis cost-effectiveness and budget-impact appraisals. To do so, research was conducted on the relevant topic areas to expose research fellows to relevant research questions and to offer fellows on-the-job training on HTA conduction.

Strategy IV: Integrate research findings into policy and practice, and improve HTA management. HITAP assessed HTA management in developed and developing countries, as well as the past experience with HTA in Thailand itself. Other activities to achieve this goal included evaluating HITAP's own performance, and focusing on public relations and international relationships. HITAP offered technical and information support to relevant NGOs, government agencies, professional organizations, and the media—all those active in relevant policy fields.

Through 2008, HITAP played prominent roles in the promotion of HTA and the utilization of economic evaluation. In its first three years, it was well funded by ThaiHealth and HSRI (among others). It did not struggle with the financial insecurity of HTA units in the past. It also applied for external grant funding, which accounted for 30% of its total budget between 2007 and 2008. It supported the development of a quality of life measurement tool, and, in collaboration with Mahidol University, it developed a healthcare services standard cost list to equip academia, researchers, and other interested parties with necessary data on cost items.

In 2009, the SCBP within the NHSO appointed IHPP and HITAP to the position of secretary to the SCBP. They were tasked with the responsibility of producing methodologically sound research to inform decision-making in the development of the UC benefit package. HITAP (along with other HTA experts) designed methodological guidelines for conducting HTA in Thailand in 2009. The Subcommittee for Development of NLEM endorsed these guidelines as a Thai

standard methodology for conducting such national studies (Health Intervention and Technology Assessment Program, 2014).

HTA was first officially incorporated into health coverage decisions as part of the NLEM development. The development of the NLEM in 2004 utilized two cost and efficiency criteria: the “ISafe score (Information, Safety, and ease of use and Efficacy)” and the “Essential Medical Cost Index (EMCI)” to determine the inclusions on the list. After the 2004 revision of the NLEM, the ISafe Score and EMCI were continually incorporated in the determination of benefits. In 2007, the Subcommittee for Development of the NLEM appointed the Health Economic Working Group—a group of academics and MoPH researchers—to assist in the utilization of pharmacoeconomic studies to determine the inclusion of new and expensive pharmaceuticals in the NLEM (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009). Following the Working Group, the 2008 revision of the NLEM marked the first time that pharmacoeconomic evidence played a role in determining the reimbursement list for medications (Wibulpolprasert, 2008). The working group began consulting HITAP to conduct pharmacoeconomic assessments on potential drug inclusions, and the results of HITAP’s studies were included in the Subcommittee’s NLEM inclusion/exclusion determinations (Jirawattanapisal, Kingkaew, Lee & Yang, 2009). In 2009, “cost-effectiveness” was added as a necessary criterion when determining inclusion/exclusion on the NLEM (Health Intervention and Technology Assessment Program, 2014).

As a strong but non-binding legal instrument, HITAP’s methodological guidelines for pharmacoeconomic evaluation had a great impact on the utilization of HTA for decisions about the NLEM and UC benefit package. The guidelines have been approved and adopted by both the Subcommittee on the NLEM and the SCBP and therefore set as the Thai National HTA Guidelines. Both subcommittees also critically included HTA in the determination of benefits by setting a “benchmark” of cost-effectiveness. Any technology with a cost-per-QALY lesser than the average GDP came to be considered includable on the NLEM (Jirawattanapisal, Kingkaew, Lee & Yang, 2009).

While there is no ceiling on the cost of medical devices, oversight of devices through economic and social evaluation was introduced in 2008. The revised Medical Device Act B.E.2551 (2008) requires that devices costing upward of 100 million Baht (\$3.3 million USD) be assessed on their social, economic, and ethical value prior to achieving market authorization (Tantivess, Teerawattananon & Mills, 2009; Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

“Registrant who wishes to produce or import medical device...shall submit an application to the licensor for the assessment that such medical device has efficiency, quality, standard and safety for use including assessment of its effect and feasibility in economic and social aspects to implement the use of the medical device in appropriateness widely and fairly and after the licensor has issues the assessment certificate it may produce or import.” (Medical Device Act B.E.2551 (2008), Section 22)

Cost-effectiveness is expected to take an even more prominent legal role in the future. The Drug Act, B.E.2530 (1987) is currently being revised to include express permissions for the Thai FDA to refuse market authorization if pharmacoeconomic evidence does not prove the drug to be cost-effective (Adcock, Pornwiriyangkura & Rungpry, 2015). Whether or not Thailand has the capacity for such regulatory control, and whether or not it is appropriate to include value for money in market approval, remains to be debated (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).<sup>4</sup>

### 2.3 Major Barriers to HTA Adoption

Once HITAP was created, it still struggled to prove that it would not follow the same unsustainable trends as prior HTA units. Many of these insufficiencies were tackled with HITAP’s 4-part strategic plan. However, before it was appointed as secretary to the SCBP, it needed to strengthen its health economics research capacity, as there were few well-trained scientists in cost-effectiveness analysis and the HTA work environment was not conducive to high-quality appraisals. The lack of national methodological standards for conducting HTA research was problematic, and there was insufficient infrastructure to support the necessary amount of economic evaluation (Tantivess, Teerawattananon & Mills, 2009). As a result, upon HITAP’s creation, it set out to build its research capacity by creating and strengthening a network of international partners and researchers. It also aimed to strengthen its local network capacity by reaching internally to engage PhD students in universities, physicians with the capacity to conduct HTA research and utilize their work in hospital settings, and others interested in HTA research (Tantivess, 2015).

### 2.4 Key Tipping Points for HTA Adoption

IHPP acted as a launching point for HITAP, introducing HITAP as a successful, sustainable HTA unit. National HTA efforts had tried and failed in the past.

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<sup>4</sup> Market approval offers availability in Thailand, separate from whether or not the drug will be covered under the NLEM

IHPP, however, offered its organizational expertise in conducting cost-effectiveness analyses. IHPP was able to offer its experience developing research staff and its extensive network of domestic and international organizations in HSPR—both of which critically supported HITAP as a newly developed institute (Tantivess, Teerawattananon & Mills, 2009). IHPP was grounded as a legitimate, semi-autonomous research arm of the Bureau of Policy and Strategy within the MoPH. Not only did it hold expertise in cost-effectiveness analysis, but also in health outcomes research and qualitative policy analysis—both important to HTA study. The HTA studies that IHPP conducted in the past were well developed and well promoted, having been utilized by national policymakers. IHPP had built a strong reputation for itself of having been exposed to the relevant policy questions, having maintained political neutrality, and having become well connected to the important policy circles (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

HITAP built capacity by forging a network of health economists, universities, institutions, eventually leading to its secretarial appointment. Insufficient capacity of TASSIT and other HTA units led to their eventual demise. By building capacity, HITAP proved that it could handle the responsibility of playing an intimate role in the NHSO's UC benefit package decision-making process. HITAP utilized three approaches to increase competence and capacity in the short and long term. It focused on an apprenticeship system to select highly qualified PhD graduates committed to HITAP; it transferred knowledge and experience to these apprentices through mentoring. HITAP also recruited young individuals to work with mentors to acquire on-the-job training. Finally, it supported apprentices who showed capability and commitment to HITAP by supporting PhD study, both locally and abroad, in areas of health economics, epidemiology, evidence synthesis, health ethics, and allocation of resources (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009).

NHSO officers recognized that a systematic process for determining the UC benefit package was essential to maintaining relationships with medical device and pharmaceutical companies while denying incorporation of a specific technology into the benefit package. By offering cost-effectiveness analyses, the NHSO could support its (politically unpalatable) denial of coverage with evidence-based research. Economic evaluation helped to remove the political pressure and create a systematic method for determining the UC benefit package. It offered policymakers a rational means by which to explain their decisions and to gain acceptance from stakeholders and the public (Teerawattananon & Russell, 2008).

Teerawattananon & Russell (2008) interviewed professionals within the Thai healthcare system between December 2004 and May 2005. Respondents included

senior administrators at the Ministry of Public Health and NHSO, hospital directors responsible for allocating resources within their respective institutions, health professionals responsible for resource allocation at the patient level, and academics who produce or use economic evaluation. When asked what factors influence their decision to include or exclude interventions in the UC benefits package, policymakers listed the following:

- The number of patients requiring treatment;
- The severity of the disease that would be treated;
- The cost and affordability of the intervention;
- Equity of access to the intervention;
- Whether SS or CSMBS cover similar services;
- The budgetary impact of the intervention (which policymakers stated was of particular interest); and
- Political pressure (which policymakers claimed played a particularly prominent role)

One policymaker offered the example that the inclusion of anti-retroviral therapy (ART) for HIV/AIDS was due to political pressure and influence:

“At that time, the government had just appointed an expert committee to consider it (the inclusion of ART), but the committee had not reached their conclusion when the government announced publicly the inclusion of ART on “World AIDS Day” in 2002.” (Teerawattananon & Russell, 2008).

## 2.5 HTA Governing Structure

The SCBP makes recommendations to the National Health Security Office (NHSO), which manages and oversees the UC (McManus, 2012; Mohara, Youngkong, Velasco, Werayingyong, Pachanee, Prakongsai, Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk & Teerawattananon, 2012). The NHSO is an autonomous entity established by the National Health Security Act in 2002. An NHSO Board within the NHSO is chaired by the Minister of Public Health and makes final decisions on copayments, benefits package, standards guidelines, etc. (McManus, 2012). The NHSO Board selects members for the SCBP (Mohara, Youngkong, Velasco, Werayingyong, Pachanee, Prakongsai, Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk & Teerawattananon, 2012).

In venturing to create such an explicit mechanism for decision-making, the SCBP solicited the assistance of HITAP and the International Health Policy Program (IHPP) to devise a system based on the principles of HTA to determine what will and will not be included in the UC benefit package (Mohara, Youngkong, Velasco,



Werayingyong, Pachanee, Prakongsai, Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk & Teerawattananon, 2012).

In collaboration in 2009, HITAP and IHPP developed formal methodological guidelines to offer an explicit system for making coverage decisions (Mohara, Youngkong, Velasco, Werayingyong, Pachanee, Prakongsai, Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk & Teerawattananon, 2012). They then produced methodological guidelines that were adopted by the NHSO (McManus, 2012). In 2011, HITAP produced its own process guidelines for conducting HTA. The system is based on the seven international HTA agency guidelines reviewed for the 2009 development of methodological guidelines. It includes (Mohara, Youngkong, Velasco, Werayingyong, Pachanee, Prakongsai, Tantivess, Tangcharoensathien, Lertiendumrong, Jongudomsuk & Teerawattananon, 2012):

1. Nomination of health topics: representatives of stakeholder groups may propose six topics to HITAP and IHPP annually. Though the topics can include a wide range of technologies and programs, most assessments are requested by the NLEM subcommittee (Tantivess, Teerawattananon & Mills, 2009)
2. Prioritization of health topics: a panel of stakeholder groups selects at least ten topics for assessment according to pre-determined prioritization criteria
3. Technology Assessment: HITAP and IHPP conduct economic evaluation and budget impact analysis on the selected topics which have been approved by the SCBP
4. Appraisal: HITAP and IHPP submit their findings and recommendations to SCBP for appraisal.
5. Decision-making: the NHSO Board makes final coverage decisions. While the Board is not required to follow the SCBP's recommendation on the inclusion or exclusion of assessed interventions, it does in practice.

Notably, the SCBP may, and sometimes does, request feasibility studies, societal-impact studies, etc. from other institutions aside from HITAP and IHPP during the Appraisal stage. HITAP provides only cost-effectiveness and budget-impact information, but the NHSO also accounts for matters such as the influence of the technology on society. NHSO can choose to rely on research from other institutions (aside from HITAP and IHPP), but HITAP has the largest capacity for economic evaluation. It is the only HTA unit in Thailand to assess

pharmaceutical drugs, medical devices, and healthcare policies (Wilsdon, Fiz & Haderi, 2013).

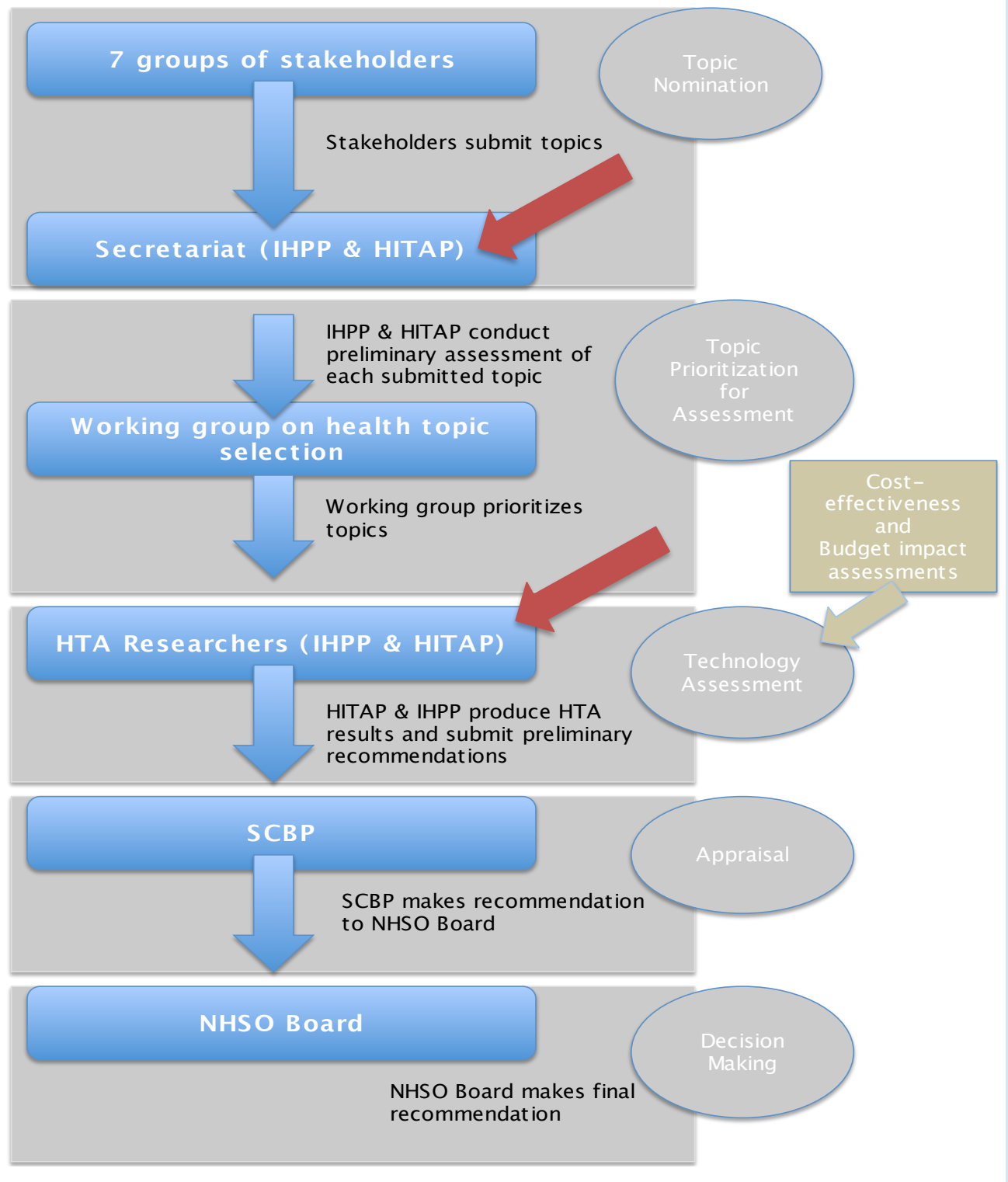
In 2007, the Subcommittee for Development created the Health Economic Working Group to help incorporate pharmacoeconomic evidence into the determination of inclusion/exclusion on the NLEM (Teerawattananon, Tantivess, Yothasamut, Kingkaew & Chaisiri, 2009). The Working Group consults HITAP on pharmacoeconomic study; HITAP has acted as an official member of the Working Group since 2009. In 2009, the Subcommittee for Development also adopted HITAP's HTA methodological guidelines as standard methodology for conducting pharmacoeconomic studies (Health Intervention and Technology Assessment Program, 2014).

There is no legal mandate for HTA's role in determining the UC benefit package (Tantivess, 2013). The NHSO has no legal mandate to follow the recommendations that HITAP and IHPP make to SCBP. However, through HITAP's roles as secretary and technology assessor to offer preliminary recommendations, HTA plays a role in the governing structure of the UC Scheme. The SCBP sometimes relies more heavily on the feasibility studies or social studies of potential technology adoption presented by institutions with less focus on cost-effectiveness and budget impact. Further, there are no rules or legal mandates controlling the characteristics of technologies that will or will not be adopted (Tantivess, 2015). Thus, there is no legal connection between HTA recommendations and the decisions of the NHSO board (Tantivess, 2015).

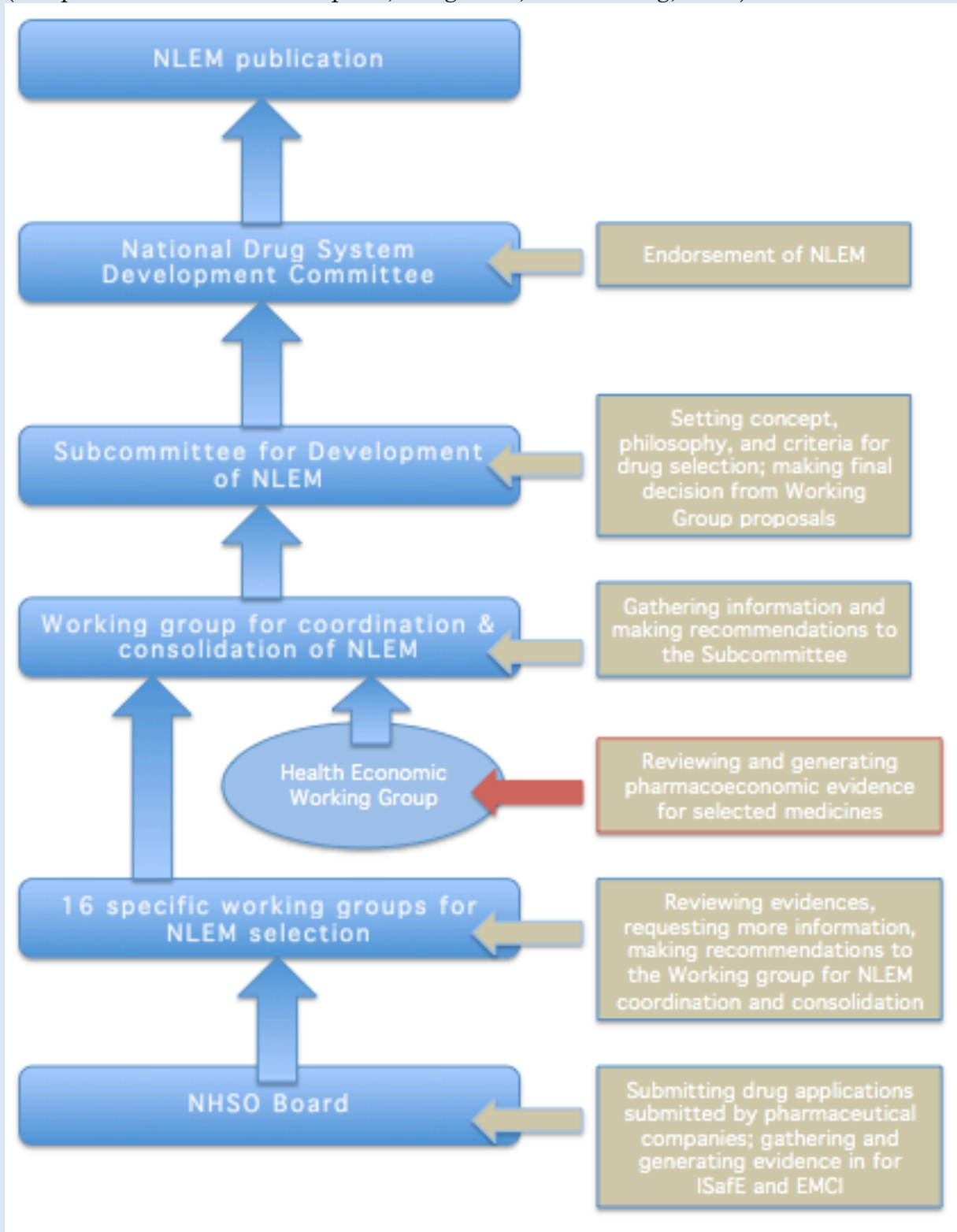
HTA also plays a critical role in the determination of the NLEM, but has no legal connection to the drug-coverage determination scheme. In 2009, cost-effectiveness was included in the criteria for determining drug coverage under the NLEM. Since then, HITAP has acted as a member of the Health Economic Working Group under the Subcommittee for Development of the NLEM. While the Working Group has no legal mandate to consult HITAP, the inclusion of cost-effectiveness as part of the NLEM's inclusion/exclusion criteria requires some form of pharmacoeconomic study to be conducted.



**FIGURE C: NHSO, SCBP, and the utilization of HTA**  
 (Adapted from Kingkaew, 2013)



**FIGURE D: Subcommittee for Development, NLEM, and HTA utilization**  
 (Adapted from: Jirawattanapisal, Kingkaew, Lee & Yang, 2009)



## Process for Appeal

At this time, the HTA process guidelines include a process for appeal of topic selection, but not for petitioning for coverage of a technology that has been denied. When HITAP set out to develop its current process guidelines in 2011, it convened several staff and stakeholder meetings. Among other topic areas, stakeholders placed special emphasis on the need to establish a formal mechanism for appeal throughout the HTA process.

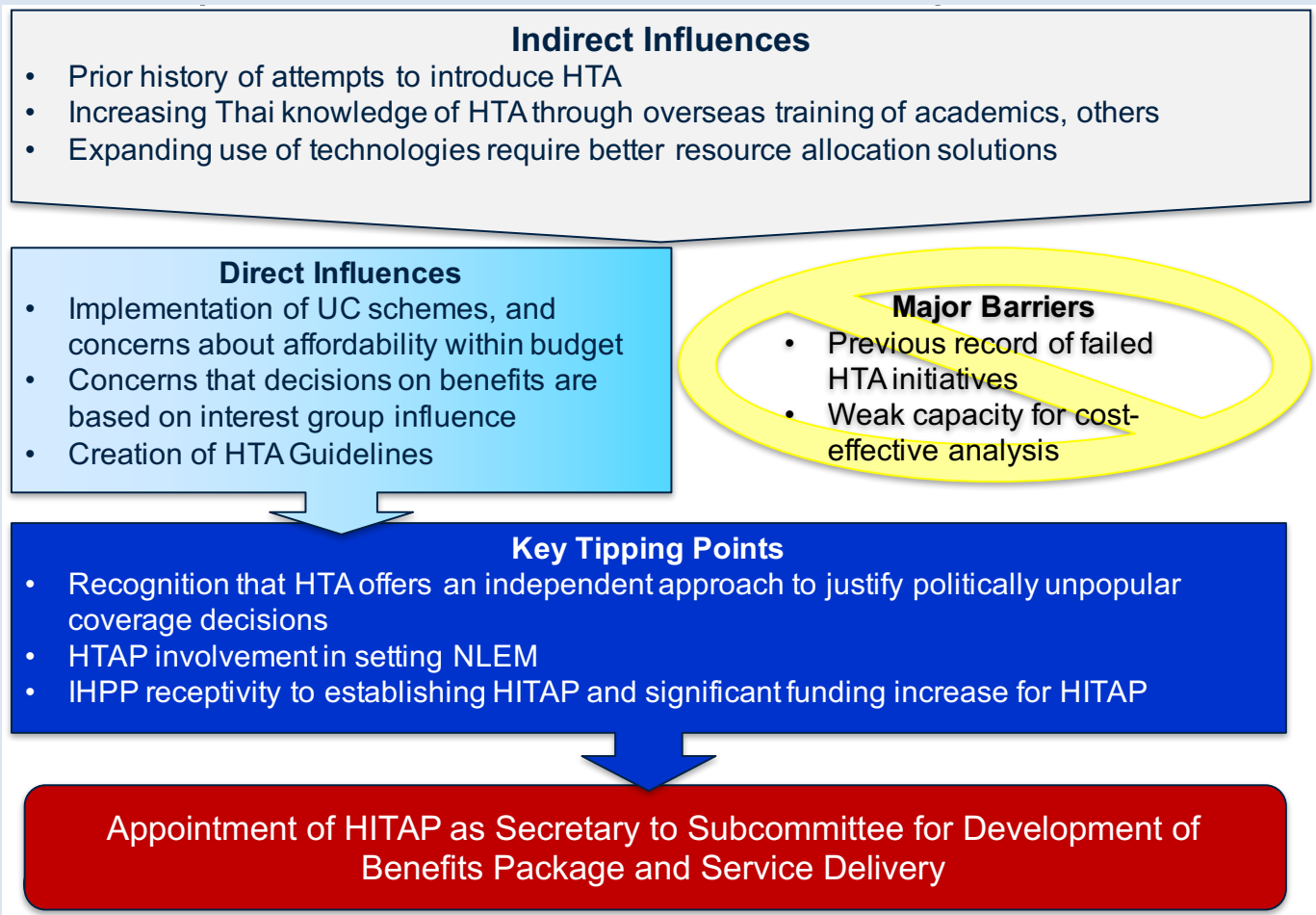
In the current guidelines, contestability is highlighted as a key aspect of topic selection. The guidelines state (Health Intervention and Technology Assessment Program, 2012):

“Stakeholders should be able to appeal decisions based on emerging issues or arguments. Revisions should be made explicit in the pertinent report.”  
(Health Intervention and Technology Assessment Program, 2012)

There is no structured mechanism for administering this appeals process over topic selection. No method for appeal has been actualized at any other stage of the HTA process at this time.

Under the CSMBS scheme, three attending physicians can approve and grant access to a medication that has not been included on the NLEM (Jirawattanapisal, Kingkaew, Lee & Yang, 2009).

## 2.6 Conceptual Framework: Factors Influencing HTA Adoption



\*Note: Despite promises about spending, the Blair government increased spending by more than any other administration before or since. The money was primarily used by NICE for growth.

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### **3. Poland**

By: Elisabeth Asifiri

#### **3.1 Healthcare System and HTA Background**

The Polish health care system is based on a single insurance fund and the decisions on what the fund covers are made by the Minister of Health and by the President of the National Health Fund (NHF).

Since 1989, as a result of the fall of Soviet rule, the Polish health care system has been undergoing major reforms. Under the communist rule, Poland's health care system was organized along the ideology established by Nikolai Aleksandrovich Semashko, in which health services and entire health system was based on a publicly owned and state controlled system where each citizen had a right to free and equal health care services. By 1989, the Polish health care system suffered from years of inadequate resources and degradation, and the strains were visible throughout the entire health care system. It was characterized by: low doctor's salaries, primary care based on multispecialty groups, inadequate and unsuitable hospital infrastructure and unofficial (informal or envelope) payments by patients.

Rebuilding the health care system became a top necessity immediately following the establishment of the new government in 1989. Under the new democratic system, people expected to have immediate access to high quality services on an instant basis. But it also became apparent that little funding was available to support the health care system. The need to provide health services to the public at an affordable price while maintaining quality standards, without breaking an already small and stretched budget influenced the work undertaken by a group of few passionate experts, who quickly gained support from the Ministry to design and implement the necessary reforms. Politicians and other decision makers understood the value of such reforms, given the growing demands of the public expectations in health care sector. Building a lean new system and improving the current performance became the top priority for the Ministry of Health, which sought ways to improve access to and quality of health services while containing costs, and they looked to its Western neighbors for solutions (Nizankowski & Wilk 2009). These conditions provided a favorable environment for the development of the Health Technology Assessment (HTA) in Poland.

The new health system structure is based on a series of laws which were passed beginning in late 1990's. One of the foundational legislation was the Law on the Universal Health Insurance which went into effect on January 1999 created seventeen National Health Funds (NHF) (initially called Sickness Funds, from



2002 known as NHF) throughout the entire country. Currently, sixteen NHFs provide access to health services to people who have insurance in that region, and one central Fund which is responsible for the overall access to health services, policy and general management (NFZ, 2015).

The main responsibility of the regional NHFs is to contract health services in the region to ensure access to health services for its regional population. A system to facilitate contracting between NHF and various health care providers was needed which would supply information and values on medicines, treatments and technologies to be considered (TNO Report, 2002). As part of positive competition, each NHF is expected to compete against other NHFs by offering the best health packages to their patients to attract patients. The basic benefits package (BBP) would work in line with NHF by identifying what would generally be offered to patients and be reimbursed through the NHF.

In an ongoing effort to improve the performance of its health care system, Poland has undergone a long process to restructure its governance and organization. Questions regarding costing of health services, what kind of services could be accessible and also how to maintain the quality standards of care led to Health Technology Assessment becoming a key topic, especially during the parallel development of the BBP.

Poland turned to international experience for solutions, new tools and methods, including how to structure the new health care system, based on socialized insurance and universal access to health services (Nizankowski & Wilk 2009). Initial international contacts and collaborations were focused on accreditation and medical technology assessment needs. The aim was to maintain the quality of health services through the introduction of an accreditation system, while the medical technology assessment process were to be classified into a measurable system of performance. Medical technology assessment soon developed into the more comprehensive *health technologies assessment (HTA)*. As a tool for decision-making which combines cost effectiveness, clinical efficacy, and ethical considerations in evaluating the overall value of health technologies, covering a wide array of health services, medicines and technologies, HTA emerged as a favored approach to measuring value for money on publicly reimbursed health services (Nizankowski, 2015).

### 3.2 The Path Towards HTA Adoption

The first discussions towards developing HTA in Poland occurred at the Drug Information Association Annual Meeting in San Francisco in 1992, when the then Director of the Department of Science and Education from the Ministry of Health in Poland, Professor Rafal Nizankowski presented a vision of

improvements needed in health system based on HTA ideas not yet known and utilized in the country (Nizankowski & Wilk, 2009). Professor Nizankowski identified the need to develop new activities in three interrelated areas: Health Technology Assessment, Clinical Epidemiology and Quality Assurance (Nizankowski & Wilk, 2009). With the support of the Minister of Health, two years after the conference in San Francisco, Professor Nizankowski left the Ministry and returned to his hometown Krakow to develop the National Center for Quality Assessment in Health Care (NCQA), whose objectives were to identify and support activities aimed at improving effectiveness, safety and other aspects of quality of healthcare services provided within the Polish healthcare system (Nizankowski & Wilk 2009). Professor Nizankowski was fully supported by the Minister of Health to participate in international conferences, exchange information and bring international expertise to Poland.

The meeting of the International Society for Quality Assurance in Health Care in 1998 in Budapest on Quality Assurance was one of the key moments in the development of the HTA in Poland, when selected staff from the NCQA, were invited to participate at a pre-conference workshop on Health Technology Assessment and for the first time, they met and heard from the top experts on the topic, including David Banta and Egon Johnson, and learned the importance and the impact technology assessment can have on the healthcare sector (Nizankowski & Wilk 2009). Following the workshop Professor Nizankowski, formed two new units within the Standardization Department: one to focus on accreditation and the other on health technology assessment. According to the Director of NCQA, both departments were considered foundation blocks to the development of and preparation of the first elaborated HTA reports, which quickly followed and according to some marked the beginning of HTA in Poland (Nizankowski & Wilk 2009).

During the initial development stages of HTA, a review was undertaken by a group of Polish experts of selected comparator countries with established HTA systems, and the Canadian system was selected as having a system closest to the Polish health care system. This led to close collaboration between Canada and Poland, including the new staff at NCQA receiving their initial training in evidence based medicine (EBM) from McMaster University in Canada (Nizankowski & Wilk 2009). While the Canadian cooperation continued over time, the National Institute for Health and Care Excellence (NICE) in England as well as French National Authority for Health (Haute Autorité de Santé, HAS) also joined and influenced the development of the AOTM through their exchange of knowledge, information and training of new staff.

The NCQA continued to develop accreditation standards and assessments on health technologies. Being the sole source providing trainings to the recipients of

the HTA reports, the group trained on reports performed for the Ministry of Health, National Health Fund and the pharmaceutical industry (Nizankowski & Wilk 2009). Ministerial support continued to be strong and senior staff of NCQA participated in the Ministerial working groups organized by the Ministry to move health technology assessment forward in Poland.

HTA adoption was influenced by Prof. Rafal Nizankowski, whose leadership and early involvement set the direction of the future Agency. Very early he understood the opportunity HTA provided and the need it would fill within health care system during the restructuring process. During an interview with Professor Nizankowski, the passion and sentiment towards HTA could not be overlooked and considering more than 10 years passed since his work began, he passionately spoke about lessons learned during the interview. Although the political influence has decreased considerably since the Agency became independent, he continues to feel that the political influences remain still too strong. In addition, while he oversaw the guideline development process and worked on the structure, functions and job descriptions of the staff including the director of the Agency, he did not foresee that the person coming into the position would do such a major sweep of essential staff, letting them go and in addition close the Krakow branch with the explanation to consolidate issues all under one office in Warsaw (Nizankowski, 2015).

Professor Nizankowski welcomed the support from the Ministry especially giving him the opportunity to establish NCQA in Krakow, as he strongly believed that HTA should be kept at a distance from politics as well as from the incoming international pharmaceutical companies, entering the newly opened Polish market and at that time establishing themselves in Warsaw. Locating NCQA in Krakow minimized the political influence, at least to a degree, giving the new team space to diligently work on some of the key areas like Evidence Based Medicine, Medical Technologies Assessment and Quality of Care. The relationship with the Ministry remained strong for many years, up until there was a wave of political changes and instabilities leading to several changes in Ministers of Health, which trickled down as far as the center and eventually did affect NCQA.

Influenced by the effective work coming out of NCQA, and seen as the next step, reliable clinical and economic assessment of new and existing interventions gained interests by a few outside of NCQA, who established their own small groups focusing on economic analysis. By 1999, interest in pharmacoeconomics sprang up in Krakow and Warsaw almost simultaneously. Professor Nizankowski collaborated with the Medical School University in Krakow, who later as the first offered pharmacoeconomics as part of an undergraduate curriculum (Nizankowski & Wilk 2009). Pharmacoeconomic analysis was soon initiated at

the National Drug Institute (Nizankowski & Wilk 2009). The integration of pharmacoeconomics with medical practices did take longer though, as the medical society was not too keen in accepting pharmacoeconomics into their circles.

Outside of Poland, there was close collaboration with some of the neighbors, who were considering HTA adoption and who were experiencing similar changes following the fall of the communist rule. Hungary being a close neighbor became a good partner in the exchange of information and development of HTA. Similarly, the contacts with Czech scientists led to close collaborations and included the participation of both the Czech and Hungarian counterparts at the first conference of HTAi in 2004 in Krakow (Nizankowski & Wilk 2009).

USA, being the pioneer in HTA, as it was originally developed by Blue Cross and Blue Shield and Kaiser Permanente, was of interest to Poland and collaboration begun early on the HTA development process. Specifically from the medical standpoint, there were plans among some to privatize the system and they wanted to learn how Kaiser Permanente (KP) used HTA, especially in the private sector. James Brevis from KP was closely collaborating with the Polish team and participated at a number of meetings and conferences including one held and organized in Poland in early 2000.

For two years, from 2002 -2004, HTA existed only within the private sector, working mainly with pharmaceutical sector until the change of Minister in 2004 brought the HTA back as a government priority and Professor Nizankowski was asked to join the Ministry as a Deputy Minister of Health, which he accepted. Minister of Health Balicki made HTA one of his administrations priorities and delegated Deputy Minister Nizankowski to take the lead and to establish a national HTA agency by 2005 (Nizankowski, 2015). The political environment became amiable and as part of the plan to set up an HTA agency in Warsaw, a Working Group was established under Deputy Minister Nizankowski's leadership, to prepare background documents for the new institution, including guidelines, the first ones issued in 2007. The kick off of the Agency was arranged to coincide with the first HTAi Conference held in Krakow in 2004 under the auspices of the Minister of Health, who himself attended the conference and awarded President Walesa an Order of Achievement, thus raising the status and importance of HTA's visibility in the country (Nizankowski & Wilk 2009).

During both the time of NCQA and the creation of Agency, the general mood remained cautious but friendly, allowing for the development of ideas and shaping the direction needed for HTA in Poland.

With external experts, stakeholders, representatives from Ministry of Health, policy makers, the medical community and the pharma community, the structure of the future Agency was deeply debated over an extended period. Heated discussions came down to the model of the future Agency, setting the structure and foundation: should it have a heavy or light model of functioning. Both, limited budget available for the Agency and a strong lobby from the pharma community influenced the debate towards the light model, which would leave the Agency to strictly perform an administrative function of checking documentation and preparing for assessment meetings. The overall budget of the Agency did not permit a heavy model, which would involve staff preparing all the documentation for submission by companies and a middle ground tone was preferred, arguing for a mixed model, in hope to avoid the Agency becoming simply another bureaucratic structure easily to be influenced by the outside pressures (Nizankowski & Wilk 2009). The aim was for staff to be involved on at least some of the preparation of the documentation for submission to the Ministry which would give them the opportunity to have a deeper understanding and feel of the process and at the same time raise and maintain their expertise level (Nizankowski 2015). Although, in the end it seemed like the mixed model won, the reality within the Agency resulted yet in the other outcome and the work performed was mainly of administrative functions.

The Polish Agency for Health Technology Assessment (Agency - since 2015 it is known as AOTMiT) was formally established in September 2005 as an advisory body to the Minister, following the passing of the *decree* by the Minister of Health. Initially, the Agency was established as part of the Ministry and its budget, thus strongly tied to Minister's influence, both politically and financially, unable to work independently.

The Agency started its work officially in February 2006, primarily on activities described in the Act, to include Drug Reimbursement List (according to the Transparency Directive), non-drug technologies, health programs and international collaboration with institutions such as HTAi, INAHTA, ISPOR, EUnetHTA. The main goals of the Agency were to educate, inform and to build up internal capacities (Lipska, 2010).

The Transparency Directive (89/105/EEC) was a big hurdle for Poland; being a requirement stemming from Poland joining the European Union and it needed to be integrated into the Polish system. For the large part the TD concerns open and disclosed financial system as referred to companies, stocks and securities; however, this does include setting and negotiating prices and medicines through a clearly defined and regulated, transparent system. The Transparency Directive required 90/180 days to make an aggregate decision both on reimbursement and price, objective and verifiable criteria and the possibility of an appeal regarding



the list of reimbursed drugs which is announced through an ordinance by the Minister of Health. Poland and a few other countries joining the EU had an issue with the TD and a grace period until 2006 was given.

For the EU it was important that the pricing and reimbursement of drugs is transparent as is the list of reimbursed drugs, which is a general list of drugs reimbursed from public funding. In support of that, Poland received EU funding to assist with the implementation of Transparency Directive. A 2 million Euro EU twinning project signed between Poland and France to run from October 2006 to April 2008 included 2 components: institution building and trainings (Lipska, 2015). During the project period 68 experts from all over EU came to help establish transparent and clear decision making process (Lipska, 2015). The project was installed within the AOTM as it included a clearly defined pricing of medicines mechanism as well as an HTA component.

Currently in Poland, pharmaceuticals are financed with public funds through two ways: the list of reimbursed drugs managed by the Minister of Health and the therapeutic drugs managed by the President of the NHF (Nizankowski & Wilk 2009). Before pharmaceuticals are placed on one of the two lists for reimbursement, AOTMiT's role is to provide recommendation to Minister of Health (AOTMiT, 2015).

Following its establishment in 2005, the Agency was invited to work together and coordinate another politically sensitive project, which was the formulation of the BBP. BBP is a required tool used in enabling agreements between regional health insurance funds and providers, and constitutes a mechanism for monitoring and ensuring quality standards by the government (TNO Report, 2002). A defined benefit package would ensure a more effective, safe and efficiently managed health care system and thus went hand in hand with HTA development. Both BBP and HTA go together, one providing a list or package of services that will be paid for from public funds, while the other will measure the impact and supplies information whether it should be provided with public funds (TNO Report, 2002). The development of BBP became a sensitive area of development and it attracted a lot of the public attention. It was thanks to public attention focusing on the issues related to BBP that the development of HTA Agency and the preparatory work were able to continue quietly and unnoticed. (Nizankowski & Wilk, 2009). It provided a quiet and calm environment around the implementation of the health technology assessment process of reaching decisions on financing health technologies with public funds (Nizankowski & Wilk, 2009).

Dr. Med. Wojciech Jerzy Matuszewicz became the acting director of the Agency in April 23, 2008 and was responsible for the preparation and shaping of the

documentation prepared to legalize the Agency as an independent institution. In 2009, the Bill was passed establishing the Agency as an independent legal entity with its own budget, operating at the national level under the supervision of the Ministry of Health. Dr. Med. Matuszewicz became then the director of the Agency for a 5 year term. Prior to becoming the acting director, Dr. Med Matuszewicz was placed for some time working at the NHF, to have a closer insight into the payer process and structure.

An independent HTA, with an independent Director and its own budget came into force on 12 August 2009, following the passing of the Bill and since then it has given recommendations on 516 drugs and 27 non-drug medical technologies. The Bill further changed the name of the Consultative Council to Transparency Council and increased the number of experts. This independent group consists of high level experts chosen by Minister of Health and President of the National Health Fund to provide their expertise. They are expected to meet regularly to review and assess the technologies submitted and together with the Director of the Agency issue a recommendation to the Minister of Health.

The Agency's scope was widened to include tariffs and the name was changed to The Agency for Health Technology Assessment and Tariffs (AOTMiT) in January 2015. Additionally, the Agency received a new duty, it became responsible for evaluating and providing opinions on projects related to all national public health programs (ATOMiT, 2015). Along with adding Tariffs, the same Bill increased the number of deputy's to two, a Deputy Director on Health Technology Assessment and one Deputy Director on Tariffs.

Since March 2015, the Agency announced an 'open call' for clinics and hospitals to join their pilot program to price the different procedures with motivation that based on the amount of data provided by each, they will be paid for participating in this pilot. The pilot started with Mental Disease, which has just been finished. A schedule for 2015 and 2016 of the upcoming specialties has been published on the Agency's website.

Similar to the HTA component, AOTMiT prepares the documentation, based on the data and feedback received, for the Tariffs Council, scheduled to meet quite often (since the start of the Teriffs component, there have been 8 total meetings of the Tariffs council in 10 months) to make a decision, which is then submitted to the Minister of Health for approval. The Ministry then submits the decision to the National Health Fund for pricing of procedures and for contracting of procedures with providers.



### 3.3 Major Barriers to HTA Adoption

The medical community in Poland was invited to participate in the HTA development process from its initial proposal, through concept building and implementation stage. Represented by the Chamber of Physicians, there was careful hesitation during various stages of the HTA development and set the tone regarding the support of Ministry's goals and ideas. During the expert Working Group meeting at the Ministry of Health in 1999 on how to utilize the newly acquired knowledge on HTA and create an Agency, the strongest opposition came from medical community who, as doctors, saw the risk of HTA being used as a tool to limit access to health services to the public, and limit the right to citizens to have access to free healthcare.

In addition, the medical community did not agree with someone or some 'Body' to oversee their standards, evaluate their procedures and monitor their approach with patients which they felt was totally up to their knowledge and expertise level to decide which form of treatment would be used. It should at least remain within their peer community to make such decisions.

The fact that the Polish Constitution stipulates that each citizen has a right to health services provided by the Government afforded challenges for the Ministry, but also strengthen arguments that a system needs to be put in place which will secure citizens basic access to health services, and this is where the Basic Benefits Package (BBP) came in (TNO Report, 2002). Without BBP and HTA used as tools together, fears were that the health care system would not sustain itself for long.

The delays during the Working Group meetings at the Ministry of Health continued for an extended time with little hope of a compromise and as a result the Minister of Health sought outside advice in the form of World Bank (the Bank) funding support from a WB lending program already ongoing in Poland (World Bank, 2000). The Bank projects that were agreed upon in 2000 consisted of two parts, the development of the basic benefits package and establishment of HTA (World Bank, 2000). The Dutch TNO Prevention and Health was awarded the tender and produced together with local medical and expert community, among other things, 7 technical papers related to the development of the Basic Benefits Package and Health Technology Assessment. A series of publications on public health issues, including clinical effectiveness and economic analyses were published together with TNO and the Ministry (Nizankowski and Wilk, 2009). There was considerable Polish medical expertise involved in all the work TNO performed in Poland to push the issue forward and progress was slowly being made.

Initial attempts in 1999 to bring together experts from pharmacoeconomics and technology assessment to discuss HTA failed. Pharmacoeconomics was still a fairly new area and knowledge was not only new but limited and fragmented. Doctors were approaching this specialization with caution, feeling that pharmacoeconomists were deciding on financing without having the realistic hands-on medical understanding on medical procedures and the day to day medical issues they experience. Questioning doctors' ethics in treating patients to their best ability and being limited by someone who does not have their background was not well received by the medical community, who didn't even welcome peer evaluations warmly. In 2006, under the AOTM auspices, it was finally possible for the national experts in HTA and pharmacoeconomics to come together and meet to review the available models of HTA in consideration of moving forward to the next phase of HTA development and in preparation to set up an independent Agency.

The political disruptions strained the HTA development in 2002, when the new Minister of Health Lapinski did not see the benefit of the institution based out of Krakow, in addition to not seeing in general the benefits of HTA. He cut off all the funding to the Standardization Bureau at the NCQA, causing the unit to dissolve within a short period of time and leaving scores of experts without a job. During this time, the existing expertise was either lost or was transferred to the private sector as many of the highly experienced staff started private companies and begun working with the industry or supported government in other areas, yet they all remained local. They provided all the services that the Standardization Bureau provided before and worked closely with private companies, especially pharmaceutical companies. HTA disintegrated and lay dormant until the change of Minister in 2004 brought the HTA development back on the table. The new Minister of Health was interested in developing evidence based medicine further and set a goal to establish a national HTA agency as one of the priorities in 2004 and by 2005 they begun to realize that goal.

HTA had its beginnings in Krakow, a somewhat rival city to Warsaw, and the first HTA reports were similarly produced first in Krakow. After HTA work was moved to Warsaw, few locals were interested to move to Warsaw, instead they opted in setting up their own private HTA companies in Krakow and continued with developing their expertise in this area. Years later the noticeable lack of experts in Warsaw led to the Agency opening a branch in Krakow to support the work.

Compensation was another challenge that the developing Agency had to manage. Given the small AOTM budget, recruiting experts on competitive salaries equivalent to Warsaw city trends was nearly impossible. Thus the Agency needed to focus on potential staff in Warsaw, willing to work for low pay, but getting a

great opportunity to experience a dynamic and very high powered environment. Developing an expertise in a quite prestigious area with international opportunities in training and program exchange with other HTA agencies in other countries resonates with a younger and inexperienced generation. Building on this dream is how staff recruitment was approached. Staff was provided training opportunities in France, Denmark, UK and Spain, as part of the priorities of the early years of the agency and with EU funding and it goes without saying that the international exchanges and internships brought back new knowledge and skills. The average age of staff was very young at 31 years, compared to other agencies.

Budget within the Agency was a major barrier towards the adoption of a well-running and efficient HTA. The work of the Agency, including the work of the Transparency Council, remained strained and was regularly criticized when the process tended to take longer than planned in part due to slow actions and response of the TC members at each step. The slow response was in part due to the low incentive in the form of remuneration (which accounted to about US\$80 equivalent in Polish currency per meeting) for each meeting thus not emphasizing this work as a priority issue. Similarly, low salaries of the staff, risked a high turnover of staff just trained and it made them susceptible to influences from industry.

In 2012 Minister of Health Arlukowicz did try to dissolve the AOTM and to integrate the functions of the Agency within the National Health Insurance Fund, the payer of the services and thus in many experts' opinions would be too close to the source. The idea died rather quickly as it was met with strong criticism and other more pressing issues became a priority.

### **3.4 Key Tipping Points for HTA Adoption**

Following the independence and the creation of the new government after 1989, Poland was left with severe budgetary problems throughout all the sectors and reached out to IMF and the World Bank for assistance to rebuild its economy. Some of the first HTA related background and technical papers were financed from the World Bank loan (WB loan number 3466-POL) at the request of the Minister of Health. World Bank's involvement, and the Dutch consultancy, TNO Prevention and Health, who prepared 7 key reports analyzing the current situation in Poland and suggesting solutions in such areas as purchasing of health services and the creation of Health Technology Assessment led the process and moved the development of HTA forward without interruptions.

During the concept building stage, the debate of the location of the future Agency was strongly argued. On one side external experts argued of locating it in

Warsaw giving the opportunity to secure skilled employees as higher wages would have to be offered, but the budget did not allow for that. The counter argument came from Deputy Minister Nizankowski, who argued that having the agency in Warsaw would lead to too much politics influencing the Agency's work, which the Agency should be distanced from as much as possible. He often used the example of Joint Commission being based out of Chicago, away from the Capital and its politics. Deputy Minister lost the argument, and the plans were to establish the Agency in Warsaw. Once the Agency was up and running, however; the lack of experienced expertise in HTA in Warsaw did in the end lead to Agency opening a branch in Krakow, thus accessing some of the local key experts based there. The Krakow branch performed assessment preparations for submission to the Ministry, while the Warsaw branch kept on doing, for the most part, the administrative function. Krakow branch existed up until the Agency became an independent body and the new director of the AOTM Agency, Dr. Matuszewicz liquidated the Krakow branch and consolidated it back in Warsaw.

The budget constraints Poland found itself in, further validated the need to look at rationalization of health spending through utilization of HTA together with the development of a Basic Benefit Package. Not just BBP, but the timing of BBP can be considered a Tipping Point as the passing of the decree creating the Agency was in large part due to the Basic Benefits Package being developed at the same time and causing such a big media frenzy, that HTA's guidelines preparation and the preparation of the decree was able to continue almost unnoticed and pass (Nizankowski & Wilk 2009).

### 3.5 HTA Governing Structure

AOTMiT is an independent government agency which is a legal entity overseen by the Minister of Health (AOTMiT, 2015). The agency's function is consultative-advisory to the Minister of Health. The Agency is to develop recommendations on financing of health care services from public funds for the Ministry of Health and on medical technologies (drug and non-drug), which is then to share and disseminate the information on the evaluations of the medical technologies in the country as well as in other countries (AOTMiT, 2015). In some occasions it can themselves develop health technology assessments or verify them, strongly emphasizing the technologies financed from public funds (Guidelines, 2007).

The Agency's work is based on the initially developed Guidelines, which give the majority of the power to Minister of Health, as the final decision maker on the technologies to be financed from public funds. (Concept Guidelines of AOTM, 2005) According to the Guidelines, the Minister shall not positively include a technology without a positive recommendation from AOTMiT, however, a positive recommendation does not oblige the Minister to finance a technology from public

funds (Guidelines 2007). As the Minister see fit, she/he may request additional analysis of a certain technology based on available funding. The Minister's actions have been contested based on these mentioned guidelines. This happened on many occasions, for example, when the Minister chose not to include a medication on the reimbursement list which received a positive recommendation from AOTMiT. Similarly, criticized was Minister's action when a technology on the reimbursement list was included which did receive a negative review from AOTMiT.

Regional and local governments may organize public health programs and sometimes they are counter to the decision provided by AOTMiT. In 2010 the Lubelski Region local government decided to continue providing the HPV vaccination to their local population despite not receiving a positive opinion from AOTMiT. They voted on it in their local government and continued without waiting (Gazeta Wyborcza, 2010).

In 2008 an insulin for children received a positive recommendation from AOTMiT, yet the Minister of Health decided not to include it in the updated reimbursement list. One of the regional children's association wrote a letter to the Minister asking to include it in the already issued list charging discrimination since no new insulin was present in the reimbursement list, while this insulin did receive a positive recommendation. The Ministry's spokesman explained that despite AOTMiT issuing a positive recommendation it did not show that the insulin had above average effectiveness (Gazeta Wyborcza, 2011). Eventually, the insulin did make it to the reimbursement list.

Nexavar, used in Oncology brought controversy for AOTMiT, who did not provide it with a positive recommendation, making Poland the only EU country not paying for this therapy. The remaining EU countries issued a positive recommendation and it is being reimbursed (AOTM, 2015).

The Chamber of Pharmaceutical items in Poland (IGFP), representing many producers whose medications did not make it on the reimbursement list, requested a meeting with the Minister in 2012. Given that AOTMiT did issue positive opinions confirming clinical effectiveness, cost-effectiveness and acceptable impact on the budget of the payer, yet despite this, the procedures or medications did not make it to the reimbursement list, thus the Association wanted to meet with the Minister and for him to explain what criteria does the Minister of Health use when deciding.

The latest Guidelines state:

“It is recommended to perform the analysis from the societal perspective”.  
(AOTM 2010)

It is justified because (ATOM 2010):

1. Health outcomes of given technology can concern not only the patients, but also other members of the society (family, caregivers);
2. The desired aim of economic analysis is the optimal allocation of resources at the societal level;
3. Broad societal perspective minimizes the risk of avoiding aspects, which could be important for decision makers.

The governing structure of AOTMiT consists of the President, who leads and oversees all AOTMiT activities. The Transparency Council (TC) - an advisory, independent body of 20 highly qualified members appointed by Minister of Health, prepares together with the President appraisals. Before each planned meeting a ten member team is picked by lottery, but in such a way that at least one member is present from all the representative categories (AOTMiT, 2015). The calendar is set way in advance to ensure transparency and the work regulations are agreed upon by the Council in advance and approved by the Director of the Agency (AOTMiT, 2015).

The assessment and recommendation include (Gulacsi, 2014):

- All medical technologies, drugs, devices, and other services (i.e. screenings or other health orientated programs funded through local authorities' budgets) claiming funding,
- It covers assessment reports including scoping, systematic review of clinical findings, economic evaluation and budget impact analysis.
- The cost-effectiveness threshold chosen is 3 x GDP per capita/QALY (quality-adjusted life-year)



## Elements of the HTA report according to „old” and „new” guidelines



Polish HTA guidelines 2007



Polish HTA guidelines 2009



Presentation: Iga Lipska Dec 2010

The Minister of Health's role does influence the assessment process. After an assessment and opinion is issued by Agency, it is submitted to the Minister for his/her consideration. As it is not a binding opinion, the Minister can use it as he/she sees it fit: can accept it or ignore it as shown above. Despite many criticism directed to this area, this has not lead to changing of the guidelines.

Recommendations, statements and opinions issued by AOTMiT are based on officially published data, experts opinions, Manufacturer's submission and polish public payer (National Health Fund) evaluation. Its role in decision making process is connected with assessment and appraisal and is coherent with international standards regarding HTA. The assessment is provided by an Analytic Team, within the AOTMiT, using Polish HTA guidelines (first issue 2007).

Based on previous reviews, up until 2011, it seems that clinical efficacy and safety are found to contribute most to the final recommendations issued. Although cost effectiveness was the underlying factor, being sensitive and politically correct whether documented or not was of higher importance. Thus



although it may not have been cost effective, other arguments were provided. (Gulacsi, 2014). Following the passing of the Reimbursement Act of 2011, this changed, as clinical effectiveness, efficacy, efficiency, safety and pricing and economics have been included in one of the Article, clearly identified in the Bill as part of the criteria to be used, with clinical effectiveness being the most important. This brings a major balance to patients, especially with very rare diseases where the medical costs tend to be quite high.

The Regulation by the Minister of Health of 18 December 2013, on the procedure and preparation of analysis of verification procedures of Agency of Health Technology Assessment has been added later on to ensure that a spot check system exists for possible review and analysis to ensure quality and consistency of the HTA reports being issued is maintained. The other is a Regulation from Minister of Health dated 22 October 2009 clearly defining the manner and procedure for carrying out audit at Agency for Health Technology Assessment.

The level of transparency and the low involvement of the members of Transparency Council's in their work was criticized and in 2009, with the new Bill, the number of Council members increased from 8 to 20 member to increase productivity and time effectiveness. With the Bill the name of the Council was changed from Consultative to Transparency Council (Puls Medycyny, 25 June 2008).

Legally, there are two institutions able to influence the work of the Agency, the National Health Insurance and the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Registration). The individual roles and responsibilities remain unclear in many areas and have not been clearly described in their respective documents, thus leaving some issues without clarity as to whose jurisdiction it falls under. It happens that Regulations developed by AOTMiT can often be issued with conflicting information to regulations from NHF or the Registration office or be counterproductive, leaving doctors confused on what to do. Fears of fines by doctors often lead to them ignoring a new regulation issued by AOTMiT and maintaining the status quo.

There were numerous Bills related to HTA with a Bill or a decree issued almost every year since 2004, starting with a bill in 2004 creating the Agency and the last one passing on 15 January 2015 bringing Tariffs under the Agency. The Bill establishing an independent HTA, with an independent director and its own budget came into force on 12 August 2009.

In principle, there are no EU laws regulating health technology assessment in Poland; however, there is a directive, which brings Poland into a network of HTA collaborating EU member states. The European HTA Network was established in 2013 by Directive 2011/24/EU on cross-border health care. The HTA Network

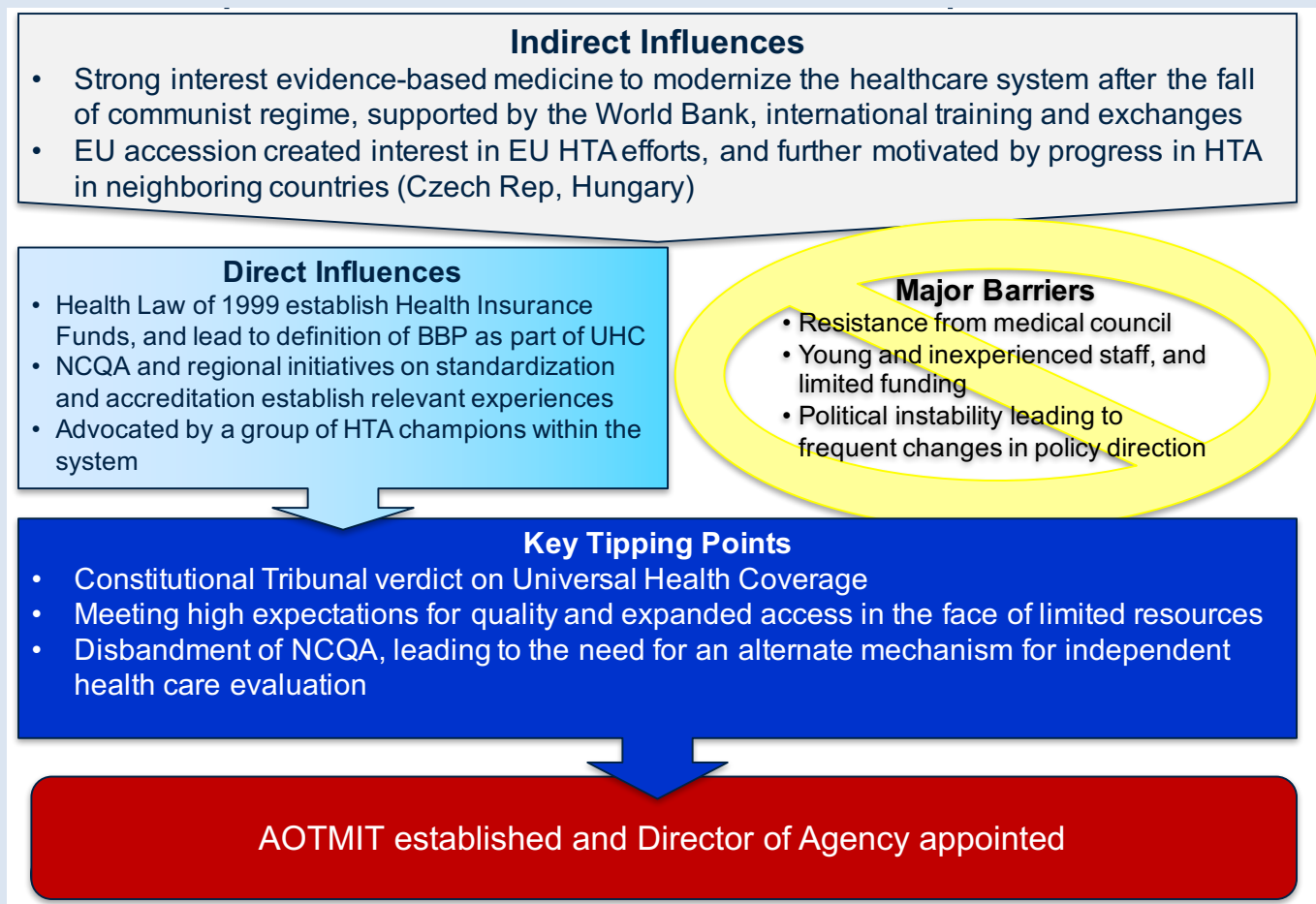
(The Network) aims at supporting cooperation between national authorities or bodies responsible for Health Technology Assessments. It is a voluntary network, gathering all EU Member States, Norway and Iceland. All of the support under this Directive and Treaty of EU shall not interfere with Member States' competence in deciding on the implementation of HTA conclusions and shall not harmonize national laws or regulations of the members States. Poland, as an individual member is free to decide the level at which it is willing to participate in cooperation efforts and may choose which joint work it will involve itself in. Further Art 15(7) of Directive 2011/24, and article 168 of the Treaty of the EU, provide measures to implement the HTA network Multiannual Work Programme (MWP).

### **Process for Appeal**

Today, the reimbursement process begins with a submission from the manufacturer to the Ministry of Health, to include an HTA report. Following an internal review by the Ministry, the submission then goes to AOTM. AOTM assesses the submission before it presents it to the Transparency (Consultative before 2009) Council which is the chosen committee to work on this assessment and the Director of the Agency is part of the Transparency Council. Following the assessment, the views of the council are then shared with the Drug Management within the Ministry who are responsible for price negotiations and the Minister of Health makes the final recommendation. To maintain a transparent process, all of the recommendations from Transparency Council (TC) are published on the Agency's website.

As the Minister can choose to accept the assessment or decline to use the assessment, there is no Appeals process. However, over time and given the access to internet, the stakeholders have learned to openly influence the process through their commentaries and critical analysis of the submitted HTA materials (Nizankowski & Wilk 2009).

### 3.6 Conceptual Framework: Factors Influencing HTA Adoption



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## 4. JAPAN

By: Rebecca Dittrich

### 4.1 The Healthcare System

The Japanese government regulates the majority of Japan's universal health coverage insurance system. Japanese citizens are required to enroll with one of over 3,400 public insurers according to their employment status and/or residential locale. All of these plans cover the same basic benefits package, and citizens may purchase supplemental private coverage if desired (Matsuda, 2015). The Japanese healthcare system has historically been characterized by the following primary factors (Hisashige, 2009):

1. Overutilization of drugs;
2. High accessibility to services and technologies;
3. Low levels of staff and human resources;
4. A discontinuous, non-standardized offering of services;
5. Healthy lifestyles maintained by most citizens;
6. A preference towards high-priced medical technologies; and
7. Poor attention to the quality of healthcare services being delivered

Japan's national health insurance system utilizes a fee-schedule for controlling the introduction of healthcare technologies and creating a financial mechanism for determining reimbursement. The fee-schedule set for a drug is based on a comparison with similar drugs. High prices are set for non-innovative drugs that offer multiple similar comparators (and, thus, the introduction of the new drug might not be prudent). The pricing formula does not account for efficiency, effectiveness, or cost. The fee-schedule is revised every two years to reflect the market price of drugs, but at no point are changes in efficacy or cost-effectiveness considered (Hisashige, 2009).

In the health system's current state, the government does not require pharmacoeconomic evaluation for the consideration or approval of a drug. The regulatory system for medical devices can be characterized by a lack of transparency, insufficient staff capacity for reviewing devices, excess delays in approval, complicated requirements for approval, and great expense. The medical device industry is also controlled only through fee scheduling, so there is no control over healthcare providers promoting diffuse utilization of expensive technologies (Hisashige, 2009).

While Japan has not yet formally adopted HTA, it has begun to seriously consider the inclusion of pharmacoeconomic evidence in pharmaceutical price setting. As pharmacoeconomic evaluation is one component of HTA, Japan's

experience thus far offers a lesson to other countries currently working through challenges of adopting some or all features of health technology assessment.

## 4.2 The Path Towards HTA Adoption

In the 1970s, the concept of technology assessment in Japan was first mentioned in a government white paper; it was proposed with the intention of addressing problems of accountability and transparency, among others. However, in 1973, when an economic recession hit, industry expressed concern over the strict regulations that would accompany HTA, and subsequently lost interest. The Council for Science and Technology had gone so far as to create a law to support HTA, but the law failed. Into the 1980s, some small HTA projects continued but never left the ground past their pilot stage. In 1985, the Japanese Association of Medical Technology Assessment—containing health economists, bioethicists, physicians, health researchers, etc.—undertook promotional activities to educate on and disseminate information about HTA. At that time, only a few institutions were conducting HTA research, including members of the Association of Medical Decision Making and the Association of Clinical Economics.

By 1988, the Ministry of Health and Welfare (MHW, now Ministry of Health, Labor, and Welfare) began paying increasing attention to HTA, although they made no formal movement towards actual policy change. By 1990, funding for HTA began for diagnostic imaging and testing, expanding to preventive and information technology in 1990. However, by 2000, HTA funding remained .2 USD million from the government budget.

Another economic recession hit Japan in 1991 with the collapse of the bubble economy, and healthcare expenditure began to surpass economic growth. In 1993, the MHW funded the establishment of the Institute for Health Economics and Policy, intending to survey and collect research on the state of health economics in Japan to support the development of health services and policy (Doherty, Kamae, Lee, H. Li, S. Li, Liu, Tarn & Yang, 2004). In 1996, the MHW created the Advisory Committee on the Application of HTA, with the goal of utilizing HTA to improve healthcare quality while providing care efficiently. The Committee published a report in 1997, but without an action plan, financial support for realizing the aims listed within the report, or delegation of responsibility, it never progressed.

The MHW tried again in 1998, organizing the Advisory Committee of Promotion of Health Technology assessment to examine evidence-based medicine (EBM) and to apply HTA in clinical practice. However, the focus quickly shifted away from HTA towards EBM (Hisashige, 2009). The MHW produced a second report in



1999, with a focus on the need to develop clinical guidelines and to promote projects focusing on EBM (Takeo & Budgell, 2003).

Economic evaluation was incorporated into academic training in Japan in 2000 when the University of Tokyo established the first ever Division of Pharmacoeconomics in Japan (Doherty, Kamae, Lee, H. Li, S. Li, Liu, Tarn & Yang, 2004).

In 2000, a structured process for incorporating HTA in the health system was introduced in Japan when the MHLW proposed to follow the example of NICE and establish an evidence-based medical center at the National Institute of Public Health. Researchers and policy makers were slowly softening to the philosophy of HTA, and the Medical Information Network Services was created to form and distribute clinical practice guidelines (Tatara & Okamoto, 2009).<sup>5</sup> In the same year, efforts to establish a national EBM database at the National Institute of Public Health (NIPH) were suspended, after the Liberal Democratic Party (backed by the Japanese Medical Association, whose influence is discussed later) opposed the effort. While the JMA was willing to support EBM and the public dissemination of such information, it disapproved of the NIPH as the project lead. It felt that to preserve professional autonomy and the progression of medicine, a government institution would not be preferable for creating and administering clinical practice guidelines (Takeo & Budgell, 2003).

In a political compromise, the EBM database project was placed under the Japan Council for Quality Health Care (JCQHC), an independent organization for hospital accreditation (Takeo & Budgell, 2003). By 2004, the work of JCQHC was established and fully operational, but its impact is small (Tatara & Okamoto, 2009). At present, it creates guidelines and offers them for sale to interested healthcare professional networks (Kamae, 2015). Despite these numerous efforts to introduce HTA into the Japanese healthcare system, its recognition and incorporation has ebbed and flowed, always remaining small (if at all), until recently.

With cultural emphasis on the autonomy of the healthcare industry, medical professionals with a traditionally paternalistic mindset have typically controlled economic evaluation in Japan (Oliver, 2003; Ikegami, Drummond, Fukuhara, Nishimura, Torrance & Schubert, 2002). The Japanese translation of the term “guideline” holds a binding connotation, creating concern amongst clinicians about the potential threat to their autonomy (Takeo & Budgell, 2003). Public health researchers, and pharmaceutical researchers and scientists were often

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<sup>5</sup> The contribution that these guidelines have made to clinical decision-making is negligible (Tatara & Okamoto, 2009).

excluded from studies (Doherty, Kamae, Lee, H. Li, S. Li, Liu, Tarn & Yang, 2004). Because medical professionals were hesitant to consider external influences in their decision-making, medical studies focused mainly on the clinical consequences of the intervention, with cost-effectiveness data as an afterthought (Oliver, 2003). Without the proper training in pharmacoeconomics or understanding of the principles of economic evaluation, medical professionals would often conduct subpar evaluations (Oliver, 2003).

Evaluation was also often based out of leading universities, whose conservative environment made adapting to new challenges and opportunities in pharmacoeconomics problematic (Doherty, Kamae, Lee, H. Li, S. Li, Liu, Tarn & Yang, 2004). Japanese universities infrequently focus on interdisciplinary studies, restricting topics like pharmacoeconomics that can be required to be taught in an interdisciplinary program like public health. The capability of university-based information systems to conduct economic evaluation was poor, producing studies with insufficient reliability (Doherty, Kamae, Lee, H. Li, S. Li, Liu, Tarn & Yang, 2004). Finally, university-based physicians would often conduct research aligning with personal interests rather than those of the broader population (Oliver, 2003). The government's recent decision to consider pharmacoeconomic evidence in pricing reimbursement will likely lead to strengthening economic evaluation capacity at institutional levels and the expansion and availability of trained professionals to undertake the necessary interdisciplinary evaluation.

The existing fee-schedule scheme has also created a culture of expectation for drug coverage. As almost all drugs and devices are covered by insurance (Fukuda, 2016), Japanese healthcare seekers are adapted to being able to utilize any technology desired, regardless of its quality or cost-effectiveness. As a result, any incorporation of pharmacoeconomic evidence is probably not likely to exclude drugs, but only change pricing (Fukuda & Shirowa, 2015). Japan has one of the fastest drug reimbursement systems, and HTA would threaten that speed (Grainger, 2009). Also, the “new is best” mentality encourages a preference for the newer, more expensive technologies (regardless of their efficacy or cost-effectiveness)<sup>6</sup> (Hisashige, 2009). In order to overcome these cultural and professional expectations within the healthcare system, it will likely require both the internal governmental push and the external international pull for HTA to be adopted.

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<sup>6</sup> Most Japanese residents pay 30% copay for medical goods and services (children under 3 years old and persons aged 70-74 with lower incomes —20%; persons 75 and older with lower incomes—10%) (Matsuda, 2015).

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) held its first Asia-Pacific Conference in Japan in 2003; it subsequently established an ISPOR-Japan chapter in 2005. The influence of HTA in Japan became a topic of international discussion at the 2012 annual ISPOR meeting in DC. The meeting featured a session on HTA from the perspectives of the U.S., Europe, and Japan (Blanchard, 2012). HTA had been rapidly developing in the Asian-Pacific region over the past decade (Tokuyama & Gericke, 2014), placing pressure on the Japanese authorities to seriously consider its adoption (Fukuda & Shiroiwa, 2015).

Responding to growing pressure to join the international trend towards HTA, as well as the unaffordability of the Japanese healthcare system as population dynamics change, the MHLW announced its intention to seriously consider utilizing cost-effectiveness information to determine pricing for medical technologies in 2011 (Kamae, 2014). The MHLW created a Subcommittee on Cost-Effectiveness to begin to consider how pharmacoeconomic evidence could be utilized to determine pricing and slow healthcare costs. The path of the new Subcommittee would follow three distinct stages:

1. Finalizing the goal of the Subcommittee;
2. Identifying examples that would shed light on the Subcommittee's goals; and
3. Determining how to incorporate lessons learned from the examples, and identifying and challenges moving forward.

However, the Subcommittee suffers from an extremely limited knowledge of economic evaluation and pharmacoeconomic capacity in Japan. Composed mainly of medical officers, the Subcommittee members do not have the training or skillset to necessarily understand how pharmacoeconomics could best be incorporated (Kamae, 2015).

After listening to a University lecture by Dr. Takashi Fukuda, Senior Chief Researcher at the Institute of Public Health, the Subcommittee wanted to better understand how pharmacoeconomic studies could feasibly be applied in Japan. As a result, the Committee requested case studies from the pharmaceutical industry to review and consider (Kamae, 2015). This "pilot program" would review the pharmacoeconomic evaluation on 5 pharmaceutical products and 3 medical devices submitted by participating companies (Kamae, 2015; Fukuda & Shiroiwa, 2015; Quintiles, 2015). A special review team evaluated the economic evidence submitted by companies in order to report on the quality and feasibility of pharmacoeconomic studies in Japan (Kamae, 2015). The results of the pilot are intended to evaluate the capacity of companies to comply with requirement to submit pharmacoeconomic evidence (Fukuda & Shiroiwa, 2015). The results of this study will not be made publicly accessible, but lessons from the study are to

be used to offer guidance on the possible introduction of pharmacoeconomic evidence in Japan in April 2016 (Fukuda & Shiroya, 2015; The Canon Institute for Global Studies, 2015; Quintiles, 2015). Japan expected to pilot the introduction of pharmacoeconomic methods in 2014, but the pilot introduction has since been postponed to 2016 (Kennedy-Martin, Mitchell, Boye, Chen, Curtis, Flynn, Ikeda, Liu, Tarn, Yang & Papadimitropoulos, 2014; Isao, 2014). It appears that the MHLW is still on track to launch piloted guidelines in April of 2016 (Kamae, 2015).

Initial results show that company submission of pharmacoeconomic evidence is probably feasible, and companies may require one year to submit data and the government approximately a half year to review it (Fukuda & Shiroya, 2015). The Subcommittee has moved into the third stage of determining next steps and identifying challenges. It is possible that the Subcommittee will adapt and utilize guidelines on incorporating pharmacoeconomic evidence in the Japanese pricing scheme that Dr. Fukuda published three years ago (Kamae, 2015).

The Central Insurance Medical Council (Chuikyo) is currently considering the integration of HTA into Japan's drug pricing and reimbursement scheme, anticipating the 2016 piloted introduction of the guidelines (Kennedy-Martin, Mitchell, Boye, Chen, Curtis, Flynn, Ikeda, Liu, Tarn, Yang & Papadimitropoulos, 2014). It is also discussing the Key Performance Indicators that might be used as evaluation criteria. While QALYs are likely to be considered as one of the elements for quantifying and evaluating health outcomes, Chuikyo remains sensitive to the fact that such objectification of health would might the Japanese cultural belief that the priceless value of life cannot be measured (Quintiles, 2015).

In December 2012, Japanese Prime Minister Shinzo Abe took office. Soon after, he announced his intention to implement a host of policies to stimulate the country's stagnant, deflated economy—known as “Abenomics” (McBride & Xu, 2015). The plan offered a three-pronged approach (Prime Minister of Japan and His Cabinet, 2013):

1. To dispel the deflation mindset by implementing aggressive monetary policy;
2. To rejuvenate the dampened economy by introducing flexible fiscal policy; and
3. To convert “expectation” into “action” and restore the faith of companies and people by implementing a new growth strategy—the “Japan Revitalization Strategy”

The Revitalization Strategy has been key to placing HTA prominently on the list of priorities for the Japanese healthcare system. While the Subcommittee on

Cost-Effectiveness was already established when Abe took office, it only represents the commitment to HTA of one Subcommittee within one Ministry. Abe's Revitalization Strategy sat higher in priority and prominence than a Ministry Subcommittee, placing the goal of pharmacoeconomic incorporation more centrally on the national agenda (Kamae, 2015).

As part of the goal for creating and developing an industry fostering good health and longevity, the plan proposed the creation of a Japanese NIH with the intention to:

“Push forward the development of practical applications of Japan's outstanding innovative medical technologies, establish control tower functions [through the Japanese version of NIH] which will create arrangements to ensure integrated research management, the linking of research and clinical practice, and high quality clinical research and clinical trials that meet international standards” (Japan Revitalization Strategy, p. 20, 2013).

While the original 2013 Revitalization Strategy stressed the importance of connecting research to clinical practice, it was not until 2014 that Abe's Revised Revitalization Strategy specifically mandated the introduction of HTA. As part of the goal to consolidate and consider the score of healthcare services subject to insurance coverage, the plan required the introduction of cost-benefit analyses to assess whether or not insurance should cover innovative technologies (Japan Revitalization Strategy: Revised in 2014, 2014):

“To simultaneously satisfy patients needs to enjoy the benefits of medical innovations and the requirement to ensure the sustainability of health insurance, the Government will trial cost-benefit analysis in the assessment of innovative medical technologies for insurance coverage by FY2016. The Government will also consider a mechanism for offering ongoing access to a system combining insured and uninsured healthcare services for use in the case of medical technologies assessed as less cost-effective. Regarding the combination of insured and uninsured healthcare services, the Government will consider how to deal with medical technologies that are assessed as effective but are unlikely to be covered by insurance due to a failure of clinical trials to progress, as a result of difficulties in recovering development costs.”

The pharmaceutical industry in Japan has been traditionally insular (Maeda, 2015). As a result, the lack of clinical epidemiology studied in the country and its weak contribution to evidence-based medicine worldwide was not particularly problematic on an international level (Tatara & Okomoto, 2009). Additionally,

the pharmaceutical industry and Japanese government have had traditionally close ties, making it difficult to introduce regulations on an industry that has historically had little oversight. However, in 2012, the Japanese Chapter of the European Federation of Pharmaceutical Industries and Associations published a statement announcing qualified support for HTA, marking an important step for the potential of HTA in Japan. The statement read:

HTA presents opportunity for better evaluation of the merits of certain therapies and for a reflection on the reallocation of healthcare related resources—debate should not be limited to the drugs component only. HTA used in a selective, judicious way with the right methodology and expectations could add value to the patients and should not only be introduced as a new price control mechanism (European Federation of Pharmaceutical Industries and Associations, 2015).

The above position statement added a caution that the introduction of HTA in Australia, Canada, and the United Kingdom had been used strictly for setting prices and restricting access to innovative medications. It advised that any modifications to Japan’s current system first be trialed with pilot programs (European Federation of Pharmaceutical Industries and Associations, 2015).

Furthermore, the statement qualified its support for HTA with the following conditions (European Federation of Pharmaceutical Industries and Associations, 2015):

1. It should not be used universally
2. It should not create a delay in processing drug approval
3. It should not create an additional financial burden to society
4. It should be transparent and a clearly-defined mechanism for drug pricing.

In conjunction with the Revitalization Strategy, the Cabinet approved and launched a Healthcare Policy in 2013. This original Healthcare Policy was introduced to:

1. Establish “control tower” oversight in medical research and development, through establishing a “Promotion Headquarters” and administrative agency for research management;
2. Manage global outreach of the medical market;
3. Create services aimed at extending healthy life expectancy; and
4. Promote the use of information and communications technology

Responding to the first task of the Healthcare Policy, the Cabinet approved the Headquarters for Healthcare Policy in August of 2013 (subsequently legally established in June 2014) (The Healthcare Policy and the New System of Medical R&D, 2015). The Act on Promotion of Healthcare Policy (the Promotion Act) and



the Act on the Independent Administrative Agency of Japan Agency for Medical Research and Development (the AMED Act) were subsequently enacted in May of 2014. Article 17(1) of the Promotion Act mandates that the government create a new Healthcare Policy in keeping with two basic principles (outlined in Article 2):

“1. Provide medical care using the cutting-edge technologies

To provide people with the top level of medical care in the world by promoting integrated medical R&D activities, from basic R&D to practical applications R&D, and by smoothly putting the research outcomes into practical application

2. Contribute to economic growth

To contribute to Japan’s economic growth while helping to improve the quality of medical care abroad by promoting the creation and overseas expansion of industries that contribute to the establishment of a society in which people enjoy long and healthy lives.”

The 2013 Healthcare Policy extends for five years after FY2014. While it does not explicitly discuss the introduction of cost-benefit analyses for determining drug reimbursement prices (as addressed in the Revised Revitalization Strategy), it emphasizes improved clinical trials and dissemination of R&D information on the quality and effectiveness of drugs. Increased R&D oversight and information dissemination will hopefully address the trend in Japan to perceive newer or more high tech innovations as necessarily greater (Oliver, 2003).

The Policy also places strong emphasis on Japan’s pursuit of overseas expansion of drug and medical device, service, and technology. It emphasizes the need to protect IP rights when expanding globally, but also a desire to utilize HTA to promote positive market environments (The Healthcare Policy, 2014).

“In pursuing the overseas expansion of drugs, medical devices, etc., medical technology and medical services originating in Japan, the government will work with relevant countries to encourage the protection of IP rights, to achieve environmental improvements that will ensure that IP rights in regard to such products are properly secured and appropriate prices for them are set. In addition, it will promote improvements in market environments in these countries, conducting a study of systems for determining prices, including health technology assessments (HTA) for each country” (The Healthcare Policy, 2014).

As of the beginning of 2014, a policy on cost-effectiveness methodology has not yet been determined, and only a summary agreement in the government committee suggested utilizing a NICE-type methodology (Kamae, 2014). Yet, the



2015 Basic Policy on Economic and Fiscal Management and Reform addresses the general intention to revise pharmaceutical pricing as part of its reforms relating to drug dispensation and cost compensation:

“The government will optimize the national health insurance reimbursement prices of drugs in light of prevailing market prices and will consider the most appropriate method and frequency of revising those reimbursement prices...while also considering the relationship between drug prices and fees for medical services” (Basic Policy on Economic and Fiscal Management and Reform, 2015).

In January of 2014, the WHO Executive Board published the Secretariat Report on Health Intervention and Technology Assessment in Support of Universal Coverage, referenced above. The report stated:

“Because of the scientific complexities, the ever increasing number of interventions and technologies to be evaluated and the resource implications, many countries will not be able to build full capacity for health technology assessment themselves. In spite of these constraints, all countries will need to develop ways to determine priorities for assessing interventions and technologies. Networking among countries and institutions, with information exchange, joint assessments and the adaptation of findings from other countries, will increasingly be the approach taken in order to make the best use of limited resources and to yield robust scientific outcomes” (World Health Organization, 2014).

The WHO Secretariat Report reflects the growing importance of HTA across the globe, and its publication impacted Japanese policymakers—especially as the government aims to expand Japan’s medical device and pharmaceutical market overseas. While the MHLW and members of the Subcommittee on Cost-Effectiveness, do not have a strong connection to the pulse of international law, other parts of the government have been strongly impacted by WHO regulations. As a result, the Report played an important role in influencing Japan to make HTA a priority (Kamae, 2015).

The incorporation of pharmacoeconomic evidence into the Japanese healthcare system will require a fundamental revision to the pharmaceutical price determination and reimbursement scheme. The changes will likely occur gradually in phases. According to the latest information on Pharmaceutical Administration and Regulations, the fee-schedule for determining pricing still applies, and the inclusion of pharmacoeconomic studies when seeking admission to the NHI is not required (Japanese Pharmaceutical Manufacturers Association, 2014).

### 4.3 Major Barriers to HTA Adoption

Medical societies, pharmaceutical and health insurance companies and health professionals have worried that HTA would threaten the mechanisms of consensus building for healthcare decisions that they have typically relied on. This consensus building also favors incremental change and not the large-scale reform that the inclusion of pharmacoeconomic evaluation in fee-schedule pricing would entail (Hisashige, 2009). The Ministry of Health, Labour, and Welfare, too, traditionally relied on smaller-scale consensus building. The Japanese Medical Association (JMA), which represents primary care physicians treating older populations typically with traditional medicine—has been particularly skeptical of HTA (Hisashige, 2009).

As noted above, despite efforts to promote HTA in Japan in the past, the uptake of economic evaluation has been stifled. Comprehensive evaluation of medical technologies through an organized HTA process would highlight past failures in implemented healthcare policies (Hisashige, 2009).

While some pharmaceutical associations have embraced the concept of HTA in Japan, the Japan Pharmaceutical Manufacturers Association has spoken out against its adoption. In 2012, the JPMA released a position statement on the potential adoption of HTA. It expressed concerns about the introduction of cost-effectiveness standards to regulate coverage in the Japanese healthcare system, and cautioned about the use of HTA in other countries. It purported that HTA in other countries has been used practically to restrict patient access to pharmaceuticals by limiting reimbursement under the national or social insurance health system. It also cautioned that HTA focuses primarily on cutting prices in order to contain costs, ultimately limiting the availability of drugs for patients when and where they are required. The JPMA advises that the lack of epidemiological data or healthcare cost databases in Japan limit the country's ability to perform objective, scientific economic evaluations. It warns that in order to accommodate the required cost-effectiveness data, pharmaceutical companies would be required to change the design of their clinical trials (Japanese Pharmaceutical Manufacturers Association, 2012).

Importantly, however, the JPMA has not always disputed HTA. In 2007, JPMA started funding a research and education project on pharmacoeconomics, and subsequently proposed a new pricing system—a severely modified version of which was adopted by the MHLW in 2010 (Kamae, 2010). The JPMA instead worries over the cost-effectiveness analysis in HTA and its unfavorable practical application (Japanese Pharmaceutical Manufacturers Association, 2012).

In fact, pharmaceutical companies have progressively *lost* interest in pharmacoeconomic studies. Because of the fee-schedule format for pricing reimbursement, the pharmaceutical industry has little to no incentive to conduct pharmacoeconomic studies (Kamae, 2010). The structures for approval and pricing offer no room for negotiating higher prices if pharmacoeconomic evidence proves good value for money of a technology (Kamae, 2010). New technologies will be reimbursed according to the prices offered for their comparators, and those prices will be reduced every two years, despite the effectiveness or value for money of the product (Oliver, 2003).

As a result of the automatic reduction in reimbursement price every two years, the pharmaceutical industry is incentivized not to focus on the cost effectiveness of one product, but to introduce the greatest number of new technologies; they will be reimbursed at a slightly greater rate than their existing comparators. The return on investment in these so-called “me too” drugs is strong. Manufacturers are able to develop and produce such a drug at low cost with little difference in chemical compound and little additional therapeutic benefit. Yet, by marketing the drug as a major innovation against any comparator in its therapeutic category, the industry can continue to turn a profit. Where the pricing reimbursement scheme is standardized, industry has little motivation to prove the worth of a product (Tatara & Okamoto, 2009; Oliver, 2003).

The opinions of the pharmaceutical industry or the public will not practically prevent pharmacoeconomic evidence integration, however. While the Japanese government is careful to communicate with external parties during the decision making process, the government’s final decisions are absolute orders. The pharmaceutical companies are not allowed to communicate with or attempt to influence committee members, by order of police. The public or companies may express their opinions to the government through the media or statements such as that of the JPMA but may not communicate with government offices directly (Kamae, 2015).

Further, as it was originally structured, the Japanese social insurance system was not built to make data available for use in pharmacoeconomic studies. Even where data do exist, access to data has been limited. Lack of consensus on how and where pharmacoeconomic evidence will be utilized remains an obstacle in the way of adoption (Kamae, 2015).

#### 4.4 Key Tipping Points for HTA Adoption

While Japan has committed to pilot HTA guidelines in 2016, it remains to be seen whether or not this commitment comes to fruition. However, it is closer to including HTA in healthcare coverage decision-making through

pharmacoeconomic evaluation than it has ever been in the past. In previous efforts, aspects of HTA have been launched, where offshoot Committees of the MHLW have produced reports on HTA or offered weakly received guidelines. For the first time, however, Japan has begun battling with the question of how to formally incorporate cost-effectiveness into its reimbursement system (Kamae, 2010).

Domestic concerns have driven the move toward HTA. One of the primary motivations has come from the changing demographic landscape. The rapidly aging population is straining the healthcare budget from both the revenue and expenditure side and is contributing to an “over-indebted healthcare state” (The Economist, 2013). Historically, Japan has been able to maintain long life expectancy and low infant mortality at a relatively low cost to the system. However, with population aging, costs of medical technologies increasing, and economic growth rates slowing, Japan has needed to rethink the necessity of HTA regulations (Tokuyama & Gericke, 2014). By 2060, over 40% of the Japanese population will be over 65 years of age. Healthcare expenditure on the social healthcare system continues to outpace economic growth. The rapidly changing population dynamics will require a health system that caters to the needs of a primarily elderly population (Tatara & Okamoto, 2009). As a result of the aging Japanese population, the NHI scheme for the employed is becoming financially strained as elderly shift away from the Employer Health Insurance scheme towards the Citizen’s Health Insurance scheme for unemployed individuals (Kamae, 2010).

Currently, Japan spends greater than 8.3% of its GDP on healthcare (Fukuda, 2016). Japan hosts the second largest pharmaceutical market in the world (Blanchard, 2012). The expense and dominance of the pharmaceutical industry will be an increasing financial burden as it accommodates the health needs of an aging population. A culture valuing investment in the latest technology without evidence of economic benefits and health gains is no longer tenable. Costs of care have gone up and become unsustainable, as opportunities to collect insurance premiums and taxes have gone down (Oliver, 2003).

The MHLW’s 2011 announcement to introduce cost-effectiveness strategies in pricing decisions instigated the creation of the Subcommittee on Cost-Effectiveness and motivated informed decision-making through economic evaluation. Prime Minister Abe continued the momentum towards HTA adoption with his Revitalization Strategy in 2012 and Revised Strategy in 2013. While the 2012 Strategy emphasized the importance of good clinical research that links research to practice, the 2013 Strategy explicitly called for the use of cost-benefit analysis to assess innovative medical technologies. The strengthening of clinical research is key for HTA to be realizable in Japan. Poor attention has been paid to

the quality of healthcare services in the past, and few RCTs are conducted in Japan—though they are the gold standard for determining the effectiveness of a service (Hisashige, 2009). While pharmaceuticals are better regulated and evaluated with RCTs, the quality of RCTs in Japan has traditionally been weak (Hisashige, 2009). HTA requires high-quality trials, but high-quality trials have not traditionally been a focus of the Japanese healthcare industry—until the Revitalization Strategy and Healthcare Policy required them.

The creation of the Subcommittee on Cost-Effectiveness to consider how pharmacoeconomic evidence could be incorporated was critical to bringing attention to HTA. With the creation of the Subcommittee, the limited internal knowledge of economic evaluation became increasingly clear, and Subcommittee members relied on knowledge of academic experts external to the government for training and guidance.

#### 4.5 HTA Governing Structure

Until the utilization of pharmacoeconomic evidence is formally integrated into the healthcare system, the structure governing its relationship with the system remains to be determined.

Based on an analysis of the current health system's governance structure, a scheme (or agency) for pharmacoeconomic evaluation will probably be placed under the Ministry of Health, Labour, and Welfare (MHLW), and the Central Social Insurance Medical Council (Chuikyo) will control how pharmacoeconomic evaluation will be incorporated into the pricing and reimbursement structure. The current Subcommittee on Cost-Effectiveness within the MHLW could become a decision-making body for pharmacoeconomic evaluation (Kamae, 2015)

However, incorporating HTA principles into the pricing reimbursement mechanism will need to accommodate the 60-day, at most 90-day, decision period on drug coverage currently present in Japan, after approval (Fukuda, 2016). Japan is the second largest pharmaceutical market, 99% of drugs are covered under the national insurance program, but, only 5% of companies attach pharmacoeconomic information with requests for coverage (Blanchard, 2012). In general, according to Ataru Igashiri of the University of Tokyo, the question of what aspects of healthcare and at what levels of the health system should be subject to pharmacoeconomic evaluation has been a leading issue in recent years (Blanchard, 2012).

Because pharmacoeconomic evidence has not yet been integrated (or, HTA adopted), and the governing structure to relate HTA to the healthcare system has not yet been determined, it is impossible to identify the legal influences on that

structure. Yet, it will either need to adjust its coverage laws or accommodate the current three-month decision period for drug coverage while utilizing HTA processes.

To do this, Japan may begin by using pharmaco-economic evidence for re-pricing already-approved drugs only (Kamae, 2015; Fukuda & Shiroiwa, 2015). The scope of drugs that will be reviewed according to HTA principles is still under review (Quintiles Japan, 2015). The following selection criteria may be used to evaluate existing drugs (Fukuda, 2016):

- Drugs listed for fiscal years 2012 to 2015 for which the price was determined by a similar drug, and:
  - The premium rate is the highest;
  - The expected peak sales are highest amongst drugs with a premium at or above 10%.
- Drugs listed for fiscal years 2012 to 2015 for which the price was determined by a costing method (no similar drug), and:
  - The profit premium rate is the highest;
  - The expected peak sales are highest among drugs with a premium at or above 10%.

The use of pharmaco-economic evidence for decision-making on new drugs may be incorporated further in the future (Kamae, 2015). New drug evaluation will not be able to accommodate the 60-day decision period requirements, and so these results will not be included in the pilot program (Fukuda, 2016). New drugs may be evaluated according to the following criteria (Fukuda, 2016):

- For drugs priced according to the similar drug method:
  - The manufacturer requests a premium rate of 10% or more; and
  - The expected sales will be over 50 billion yen.
- For drugs priced according to the costing method (where no similar drug exists):
  - The manufacturer requests a profit premium of 10% or more; and
  - The expected sales will exceed 10 billion yen.

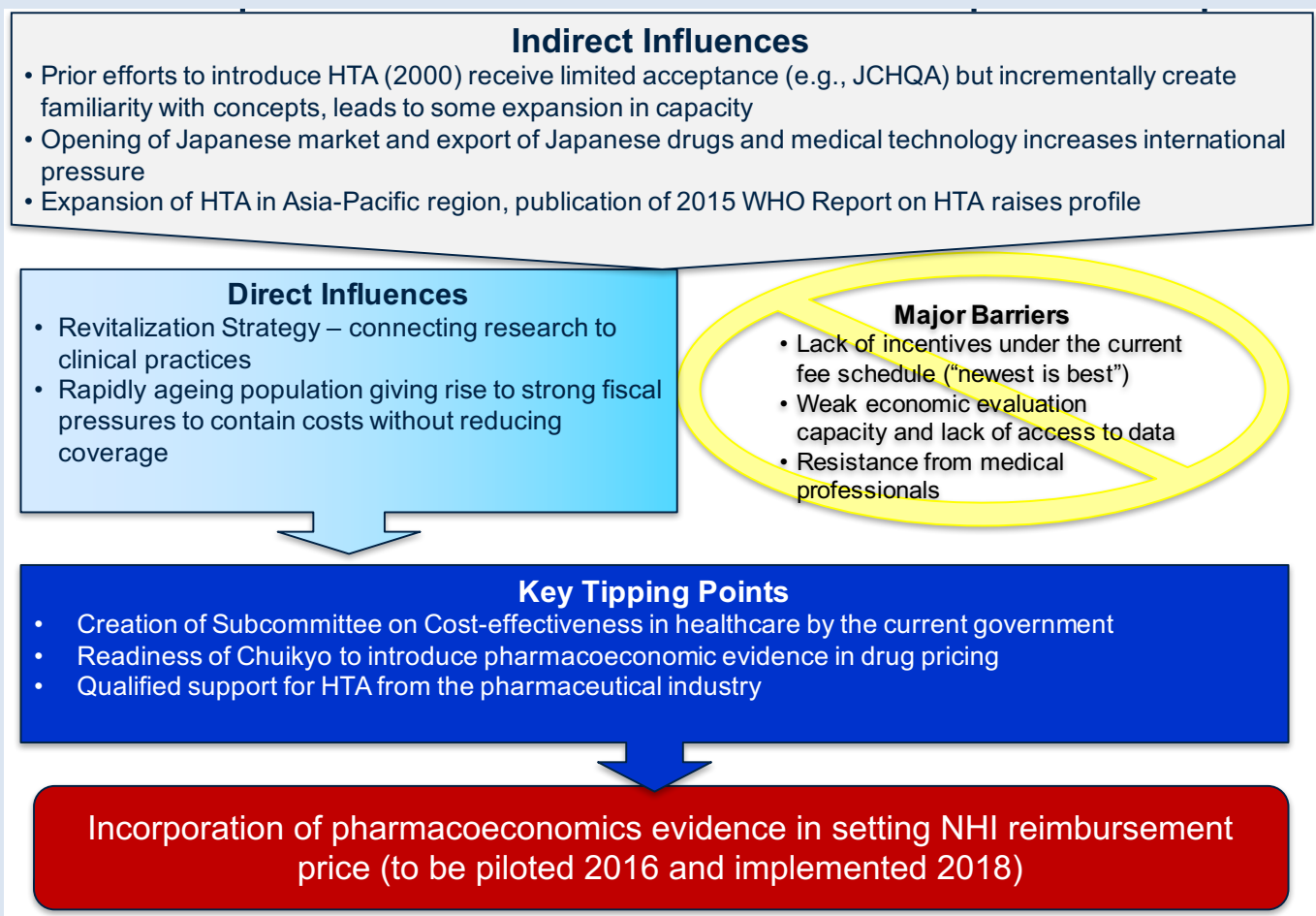
The process for cost effectiveness evaluation is expected to follow a three-part path: data submission, review and re-analyses, and appraisal (Fukuda, 2016). The Marketing Authorization Holder will first perform an analysis based on guidelines, and submit data; preliminary consultation about the framework of the analysis will be held before the analysis itself is initiated. The submitted data will then be reviewed by a neutral independent organization in collaboration with external specialists. Finally, as a meeting of the Special Organization for Cost-Effectiveness, results will be appraised and a draft evaluation will be prepared. The Marketing Approval Holder will have the opportunity to attend the meeting and express its views (Fukuda, 2016).



## Process for Appeal

As HTA has not been formally adopted and integrated into the Japanese healthcare system at this time, the opportunity to appeal and process for doing so remains to be determined.

### 4.6 Conceptual Framework: Factors Influencing HTA Adoption





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## DISCUSSION

England and Wales, Japan, Poland, and Thailand represent a broad array of political and healthcare systems. As a result, their experiences incorporating HTA principles into the pricing, reimbursement, or coverage decisions under their respective universal coverage schemes vary greatly. However, their experiences offer lessons for the future about the challenges countries in the early stages of HTA adoption may face. Where their experiences are different, other countries looking for guidance may find it in a country with a similar political and socio-cultural framework. Where they are similar, the lessons that the countries learned and steps they took to overcome barriers to HTA adoption offer critical lessons to other countries in the future.

The experiences of England and Wales, Thailand, Poland and Japan fall on a spectrum of government involvement. While England wrestled with the questions of how HTA principles would be incorporated, the heavy-handed role of the government in creating NICE meant that there was little opportunity for public pushback. Japan, on the opposite end of the spectrum, has struggled with HTA adoption as it balances the interests of pharmaceutical companies, the medical profession, and the government. While strong government influence may make adoption easier, is it not always best in the long term. AOTMiT has struggled to distance itself from Polish government control and fulfill its functions as an independent body. The Minister of Health ultimately decides whether a recommendation from AOTMiT will be incorporated into the public payer system.

Scarce resources motivated the implementation of HTA principles within the healthcare system in all four countries under study. The need to find an effective way to allocate scarce resources led England and Wales, Thailand, and Poland—and is leading Japan—to search for a standardized method of coverage decision making. In England and Wales, this need grew out of the realization that limited resources were being used with great variability across the country. The health system could not offer everything to everybody, but was unfairly offering varying access to all. In Thailand, the advent of universal health coverage created a need to introduce rationing tools into healthcare decision making in order to fund the plan with limited resources. In Poland, the post-Communist era brought a need to balance the population's demand for greater access to medical services with the need to control the number of services offered with the limited funds of a newly forming government. In Japan, the rapidly aging population has made funding nearly all health technologies unaffordable. It has caused the government to search new solutions to manage scarce healthcare resources.

Demographic changes and proliferating technologies creating a need to allocate scarce resources is not a problem unique to Japan. While the Japanese

population is facing one of the more severe examples of an aging population that requires more output and inputs less funding, Thailand and England and Wales faced similar challenges. Changing demographics and growing technological possibilities often led to greater demands for quality and quantity out of the healthcare system. Only in the mid-2000s did the aging population become a spoken topic within the Polish government, making slow headway.

The introduction of universal health coverage and the strain that it places on healthcare resources is similarly not unique to Thailand. As Poland considered the development of a basic benefit package, it focused on the question of managing the costs of health services within that package. The implementation of a universal health coverage scheme can lead policymakers and stakeholders to recognize the importance of resource allocations through priority setting to maintain affordability. As a result, the adoption of HTA can coincide well with the advent of UC. HTA solves two key problems facing a government when it considers universal coverage: (1) how will a technology's value be determined, and (2) what process will be used to decide what technologies will be covered. In 2015, Poland added tariffs to AOTMiT and began collecting data on the costs of specialties within various hospital systems.

It follows then that one major challenge countries face is how to incorporate HTA into the current healthcare system if it is not coinciding with the major overhaul of UC implementation. The manner in which reimbursement, drug coverage, or price setting was handled in the past affects the ease with which HTA can be adopted. For example, the fee-schedule process of drug reimbursement has posed particular challenges in Japan, as the government must consider (1) how to devise a new scheme or incorporate pharmacoeconomic evidence into the fee schedule, and (2) how to take away drugs found not to be cost-effective but that are currently covered.

A country's historical familiarity with health economics and other HTA principles (such as economic evaluation, pharmacoeconomics, etc.) is critical to the ease with which HTA can be adopted. It can also affect the role that interest groups play. Countries with long histories experimenting with HTA and health economics are more comfortable with the concept of economic evaluation. Thailand's government, for example, had tried on multiple occasions to utilize HTA principles in its healthcare coverage scheme. While efforts failed multiple times before the eventual success of HITAP, the familiarity with HTA helped with fluid integration and acceptance later on. Similarly, health economics had been an established area of academia under study in the UK since the 1960s, and in-country experts were well equipped to prepare for a large-scale health economics project such as HTA.

Where a country has a shorter history experimenting with HTA and few in-country experts, building internal knowledge and relying on external experts is key.<sup>7</sup> Poland relied on international cooperation and training from external experts to gain the knowledge it needed to adopt HTA. The Polish effort to adopt HTA was strongly supported by a number of countries, including Canada, France, and England—they trained future HTA employees, especially on how to prepare HTA reports, and hosted 6-week visiting internships. Where countries may have expertise internal to the country but not to the government, relying on the assistance of academics, researchers, and other support systems is crucial. Building momentum for HTA adoption in Japan required relying on experts external to the government, where the Subcommittee on Cost-Effectiveness suffered from a critical shortage of pharmacoeconomic evaluation knowledge. When medical paternalism challenges the government's efforts to engage in explicit priority setting, building relationships between medical professionals, policymakers, and health economists is key to a successful conversation about HTA adoption.

Equally important to building knowledge about economic evaluation is building the capacity for the work and challenges involved. Successfully integrating HTA into the pricing, reimbursement, or coverage scheme requires the capacity to conduct economic evaluation, review data and research, and make decisions about coverage. Human resources are essential. This is especially true where a country undertakes to create an HTA agency. HITAP's appointment to its Secretariat role only occurred once it had built sufficient capacity to perform the necessary work. One of Japan's first steps in its journey to consider pharmacoeconomic evidence incorporation has been to solicit pharmacoeconomic evidence from pharmaceutical companies and ensure they have the capacity to develop such data.

## Limitations

The information reflected in the case studies reviews the available literature and documents interviews with HTA experts, policy makers, and/or government officials involved in the HTA adoption process. However, the results may reflect a limited perspective on the adoption process where a restricted number and type (for example, representatives from government, academia, or the private sector) of interviews were obtained. While the case studies aim to provide an objective,

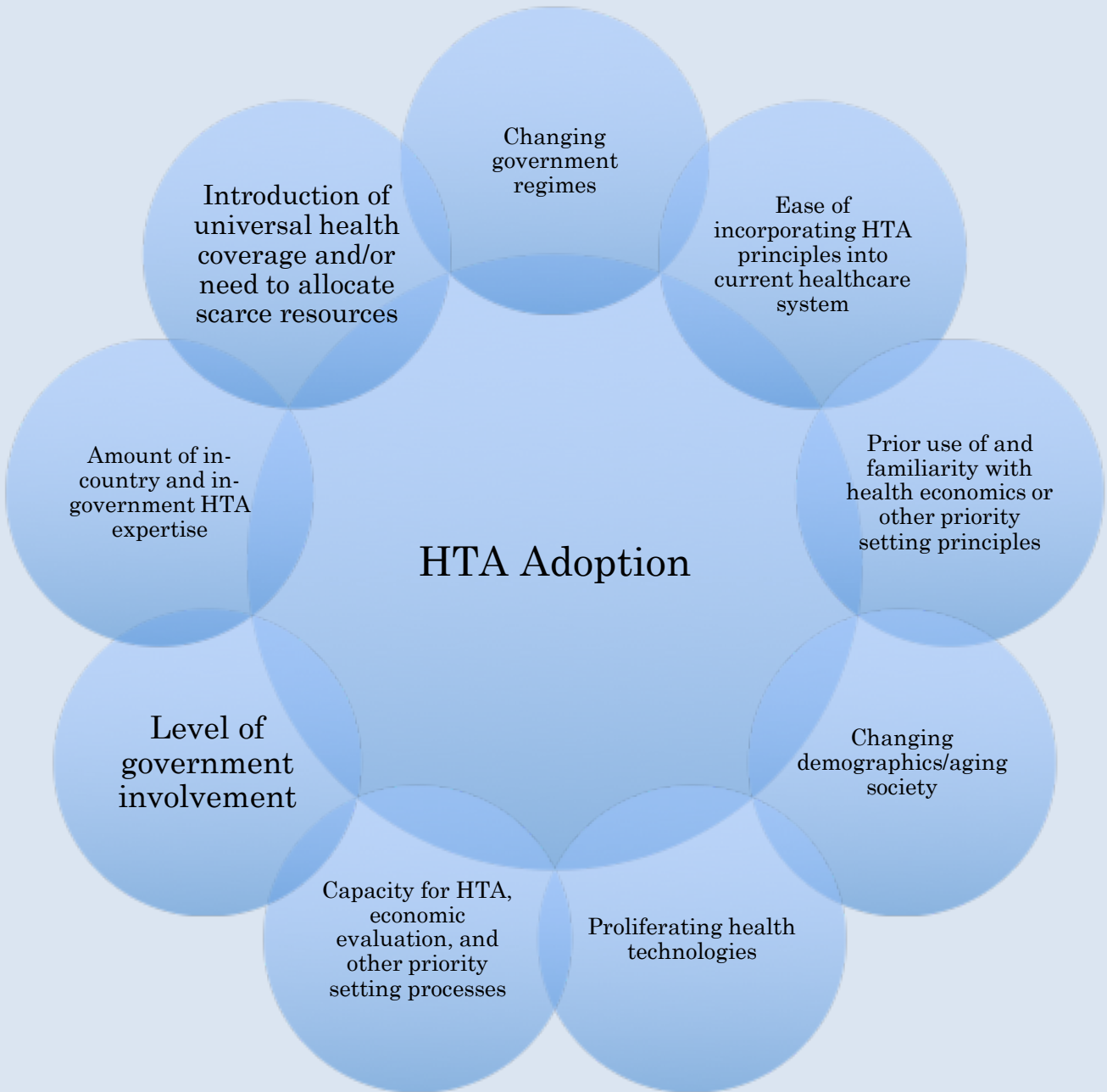
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<sup>7</sup> While building expertise in the area of health economics is key for any country considering HTA adoption (consider Thailand's experience sending health officers abroad to learn about economic evaluation), it is particularly critical where in-country expertise is low.



comprehensive view of the issue, they oftentimes reflect the perspectives of those involved in the HTA adoption process. Others involved in the adoption process but not interviewed may have different, undocumented perspectives on the process.

### Comprehensive Conceptual Framework for HTA Adoption





## **CONCLUSION**

The experiences of England and Wales, Thailand, Poland, and Japan adopting or considering the adoption of HTA principles vary greatly. While England and Wales, Thailand, and Poland have created HTA agencies, not every country utilizing HTA principles has established such an agency. However, the common socio-cultural, legal, and political influences across countries adopting HTA can offer valuable lessons.

Where the lesson universally applied to all four countries under study, it could help other countries prepare as they consider HTA adoption. Where lessons were regional or country-specific, they can offer learning tools for countries preparing for HTA adoption with similar social and political structure.

It is the authors' hope that elucidating these common influences will help countries preparing to adopt HTA to remain apprised of the barriers that they might face and the influences motivating adoption that they could prepare for.