

# The Emergence of Health Technology Assessment Organizations

Lessons from five countries

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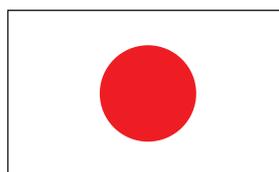
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**THE ACCESS AND  
DELIVERY PARTNERSHIP**

*New Health Technologies for TB, Malaria and NTDs*



From the People of Japan

**The Access and Delivery Partnership (ADP)**, which aims at assisting low- and middle-income countries (LMICs) enhance their capacity to access, deliver, and introduce new health technologies for TB, malaria, and neglected tropical diseases (NTDs). The ADP is a five-year project, running from April 2013 until March 2018.

Led and coordinated by the United Nations Development Programme (UNDP), the ADP is a unique collaboration between UNDP, TDR (the Special Programme for Research and Training in Tropical Diseases, which is hosted at the World Health Organization) and PATH. Working together, the project partners will leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs. The ADP emphasizes consultation, collaboration, and implementation with partner-country governments and stakeholders, working to develop the capacities of LMICs to access and introduce new technologies.

New health technologies are broadly defined as drugs, diagnostic tools, and vaccines that are relevant for the prevention, treatment, or cure of TB, malaria, and NTDs but are not yet available for market introduction or have not been introduced in LMICs. The introduction of new health technologies can place burdens on existing health systems, including new requirements for drug regulation, supply and distribution, and health personnel training. Accordingly, the ADP will focus on providing LMIC stakeholders with the necessary skills to develop the systems and processes required to effectively access new health technologies, and introduce them to populations in need.



## THE ACCESS AND DELIVERY PARTNERSHIP

*New Health Technologies for TB, Malaria and NTDs*

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## ACRONYMS AND ABBREVIATIONS

BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)
BMG	Bundesministerium für Gesundheit (Federal Ministry of Health)
CADTH	Canadian Agency for Drugs and Technology in Health
CDR	Common Drug Review
DAHTA	Deutsche Agentur für Health Technology Assessment (German Agency for Health Technology Assessment)
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information (German Institute of Medical Documentation and Information)
DH	Department of Health
G-BA	Gemeinsamer Bundesausschuss (Federal Joint Committee)
HIC	high-income country
HTA	health technology assessment
ICER	incremental cost-effectiveness ratio
INAHTA	International Network of Agencies for HTA
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
LIC	low-income country
L-MIC	lower middle-income country
LMIC	low- and middle-income country
MBS	Medicare Benefits Schedule
MSAC	Medical Services Advisory Committee
NICE	National Institute for Health and Care Excellence
NHMRC	National Health and Medical Research Council
NHS	National Health Service
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
QALY	quality-adjusted life year
R&D	research and development
SHI	social health insurance
ZonMW	Netherlands Organization for Health Research and Development

## INTRODUCTION

Health policymakers in low- and lower middle-income countries (LICs, L-MICs) are presented with an ever-expanding selection of products and services promising to address the health needs of their populations. Along with these interventions comes increased availability of evidence surrounding the efficacy, effectiveness, and costs. While resources for health are finite, demand for available services is unlimited, and policymakers (including government ministries, donors, and other stakeholders) have to make difficult decisions around which interventions to prioritize and how to allocate resources. In many settings, formal mechanisms to assist policymakers in sifting through available evidence to make informed decisions are weak; as a result, health resources are often directed toward relatively ineffective interventions, while more deserving products and services remain underutilized. Consequently, there is widespread acknowledgement of the need to improve evidence-informed policymaking, and growing momentum toward establishing and strengthening transparent priority-setting processes in LICs and L-MICs.<sup>1</sup> Many L-MICs have already made impressive progress in establishing formal processes and institutions around priority setting, while others are still in the nascent stages of developing such institutions and require guidance and support.

Much of the existing literature on priority setting in health focuses on the need for better priority-setting processes and the appropriate design of such institutions. However, to date, there has been little systematic investigation of the drivers of successful institutionalization of such mechanisms for health in LICs. We propose to address this gap by investigating the broader political economy of institutionalizing priority setting—specifically, health technology assessment (HTA)—in five high-income countries (HICs) with relatively well-established institutions. By doing so, we identify lessons for stakeholders interested in establishing such institutions in low-resource settings.

## BACKGROUND

Calls for more formal and explicit processes to guide priority setting in health are increasing in low- and middle-income countries (LMICs), especially in the context of efforts to attain universal health coverage. Priority-setting mechanisms include rules, processes, and dedicated institutions. HTA agencies represent an important type of priority-setting mechanism.

HTA examines the consequences of the application of health technologies and is closely related to evidence-based medicine. Both HTA and evidence-based medicine are aimed at better informing decision-makers. As such, HTA has become an issue of great interest, although it has also attracted controversy. Advocates of HTA argue that it helps to promote efficiency of resource allocation, whilst critics state that HTA is simply a means to restrict access to new and costly technologies.<sup>2</sup>

HTA dates from the late 1970s, when the expansion of technology and health care costs began to capture the attention of decision-makers.<sup>3</sup> The introduction and subsequent growth of HTA within Europe runs alongside health policies that place greater emphasis on measurement, accountability, value for money, and evidence-based policies and practices. Moreover, the advent of randomized controlled trials and the subsequent availability of data, growth in medical research and information technology, and increased decentralization of health system decision-making all contributed to an increased need for HTA activities.<sup>4</sup>

The first formal HTA agency was established in 1975 in the United States with the Office of Technology Assessment, which published its first report in 1976.<sup>5</sup> HTA started to flourish outside the United States in the 1980s. In Europe, the first institutions or organizational bodies dedicated to the evaluation of health care technologies were established in France and Spain in the early 1980s and in Sweden in 1987.<sup>6</sup>

Over the following decade, HTA programs were established in almost all European countries, either in new agencies or institutes or in established academic, governmental, or nongovernmental units. Broadly speaking, such bodies fall into two categories:

- independent (arms-length) review bodies that produce and disseminate assessment reports on a breadth of topics, including health technologies and interventions; and
- entities under government mandates (e.g., from health ministries) with responsibilities for decision-making and priority setting, typically pertaining to the reimbursement and pricing of health technologies.

The latter serve an advisory or a regulatory function. This spread has been facilitated by international organizations such as the World Bank and, more recently, the World Health Organization (WHO).<sup>7</sup> Also of importance are the HTA membership associations, notably the International Society of Technology Assessment in Health Care and its successor organization Health Technology Assessment International, and the International Network of Agencies for HTA (INAHTA). The *International Journal of Technology*

*Assessment in Health Care* has played a particularly crucial role in communicating the principles and outcomes of HTA.

In 1999, the United Kingdom introduced the National Institute for Clinical Excellence, renamed later as the National Institute for Health and Clinical Excellence, and more recently as the National Institute for Health and Care Excellence (NICE). NICE remains one of the best-known HTA organizations in the world. HTA agencies have gained space in taxation-based and social health insurance (SHI) systems, evidenced by the development of these agencies in different settings. For example, in 2004, the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen—IQWiG) was established in Germany. In the United States, the Patient-Centered Outcomes Research Institute was established in 2011. In fact, most HICs utilize some form of HTA process or agency to facilitate decision-making and priority setting within their health systems.<sup>8</sup>

More recently, a number of HTA agencies have formed in LMICs. For example, the National Agency for Health Surveillance and the Department of Science and Technology have been conducting HTA in Brazil since the mid-2000s; the Health Intervention and Technology Assessment Program was created in Thailand in 2007; and the Health Technology Assessment Institute of Colombia was established by law in 2012. According to INAHTA, there are around 52 HTA agencies that support health system decision-making, ultimately affecting over 1 billion people in 32 countries around the globe.<sup>9</sup>

## METHODS

This research set out to answer what drives the institutionalization of HTA in HICs? To answer this question, we conducted a desk review of literature related to the establishment of HTA agencies in five HICs. Cases were selected based on the institutional maturity of HTA and to ensure a mix of centralized and decentralized health systems. The five cases selected include Australia, Canada, England and Wales, Germany, and the Netherlands. All five areas have HTA agencies or processes that are broadly considered to be functioning well and sufficiently established. This allows a better understanding of the bigger forces that act on agencies or processes and their effect on national policy.

To understand the factors driving the institutionalization of HTA in these countries, we examined the following questions:

- What were the problems HTA solved or aimed to solve?
- How does the health system function?
- How do HTA activities relate to decision-making?
- Who are the main HTA stakeholders?
- How is HTA funded?
- What is the institutional arrangement?

# FINDINGS

## Australia

HTA in Australia has a relatively long history, dating back to recommendations from the Committee on Applications and Costs of Modern Technology in Medical Practice, also known as the Sax Committee.

Due to sustained pressure for health care policymakers to provide explicit justification for their resource allocation decisions, prioritization processes are now based on HTA. This has resulted in a movement toward the use of HTA, including economic evaluation, to inform such decision-making, particularly concerning whether or not a technology should be publicly subsidized. In Australia, the process of HTA for pharmaceuticals is particularly well established. In 1991, Australia became the first country to introduce a mandatory requirement for cost-effectiveness evaluations of new pharmaceuticals. However, the introduction of formal HTA processes for other medical technologies, such as procedures and devices, is a more recent development.

### **Problem**

In the 1970s, in response to growing concerns about the rising costs of health care in Australia, the Sax Committee was created. Policymakers were especially concerned about the growing costs of technology and diagnostics. The Sax Committee identified technology assessment as a promising mechanism to help control costs, and in 1982, the National Health Technology Advisory Panel was established.<sup>10</sup>

### **Health system context**

The health system offers universal access to health care regardless of ability to pay through the government health insurance system, Medicare, which is financed through general taxation and an earmarked Medicare tax levy. Most taxpayers pay a Medicare levy of 1.5 percent of their taxable income. There are co-payments for certain services and population groups. Medicare provides a safety net for out-of-pocket payments, and, above certain thresholds, it can cover 80 percent or more of co-payments.

Australian states are also involved in funding and providing health care. There is a degree of devolution, as states pay for acute care. There is also private health insurance which is cross-subsidized through a tax rebate of 30 percent of the premium. The Medicare Benefits Schedule (MBS) lists the eligible medical services and technologies for which subsidies are provided. Essential pharmaceuticals are subsidized. Subsidies are limited to items included on the respective medical and pharmaceutical benefits schedule. The Pharmaceutical Benefits Scheme (PBS) subsidizes the purchase of pharmaceuticals on its approved list for two groups: general beneficiaries and concessional beneficiaries (holders of pensioner and other entitlement cards). Concessional cardholders, mainly pensioners, have lower co-payments than the general public. The main hallmarks of the Australian health care system include: the preservation of a universal tax-funded system; the use of supply-side controls to contain costs; equity of access; maintaining a high-performance sustainable health system that provides cost-effective health services;

and complementarity between the public and private sectors. The health system strives to be equitable, effective, appropriate, efficient, responsive, accessible, safe, and sustainable.

The Department of Health and Ageing is the principal national agency in health care and is responsible for policy formulation. The Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC), both independent committees, serve as advisory technical bodies that provide recommendations in regard to which drugs and services should be listed and subsidized with public resources. They are supported by secretariats within the Ministry and do not form agencies in themselves, in contrast to NICE in the United Kingdom and IQWiG in Germany. The states are autonomous in administering health services at the regional level and vary somewhat among jurisdictions, especially in resource distribution and organizational structures. The government controls the supply and cost of drugs through the PBS. State health departments are also important players.

Although voluntary, most large hospitals seek accreditation, and several states now require their public-sector hospitals to do so. There are financial incentives, since private insurers pay higher reimbursement rates to accredited facilities.

### **Institutional arrangement**

HTA assessments in Australia are undertaken by a variety of agencies and committees at the national, state, and hospital level, and in the private sector. Private health insurers are increasingly utilizing HTA processes in decision-making regarding the introduction of new medical technologies. Clinical and cost-effectiveness are used to include drugs in the PBS. In 2005, a report by the Australian Productivity Commission expressed concern that the fragmented nature of HTA was raising costs and reducing the efficiency of the process.<sup>10</sup>

There are two key HTA bodies at the national level: the PBAC and the MSAC. The PBAC is an independent statutory body established in 1953 to make recommendations to the Minister for Health and Ageing on drugs and medicinal preparations that should be made available as pharmaceutical benefits. It is also responsible for determining which vaccines are made available through the National Immunization Program. The PBAC makes recommendations to the Minister in relation to products that should be available for subsidy under the PBS. The Minister cannot list a product on the PBS without a positive recommendation from the PBAC, but s/he may decline to list it even if s/he receives a positive recommendation, which has only occurred twice (once for Viagra®).

The membership of the PBAC includes medical practitioners, pharmacists, consumer representatives, and health economists. Currently, there are 18 members, including the Chair. The PBAC is relatively immune to political interference because it is an independent statutory committee (not a government agency or public body). The Pharmaceutical Evaluation Branch within the Ministry of Health is charged with acting as the secretariat in supporting the PBAC. It has nearly 80 staff, but only about half are directly involved in PBAC processes. There are four external evaluation groups based in universities.

The PBAC may establish sub-committees, consisting of members with appropriate expertise, to assist in performing its functions. There are presently two sub-committees: the Drug Utilization Sub-Committee monitors the patterns and trends of drug use and makes such utilization data available publicly, while the Economics Sub-Committee advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to the PBAC.

Even though the PBAC uses HTA to inform its decisions, the PBS is an uncapped appropriation program that has been very successful in controlling overall growth rates in health care expenditure.

Some evaluations are performed by PBAC house staff, but the majority are outsourced and are not independent. All external groups are academic and are selected on the basis of a tender process. The evaluation is performed on behalf of the Department of Health and Ageing, and the final product is presented as the Department's evaluation of the submission. The avoidance of conflicts of interest is paramount, and a group cannot also undertake any type of work for industry.

Submissions requesting the inclusion of a pharmaceutical product or vaccine on the PBS or in the National Immunization Program are generally prepared by the manufacturer of the product, which holds the data required to assess the effectiveness, safety, and cost-effectiveness of the product. Submissions from medical bodies, health professionals, and private individuals and their representatives are also considered. The PBAC has published comprehensive guidelines to guide the preparation of submissions.<sup>11</sup>

The MSAC, established in 1998 to 'strengthen the sustainability of the health system', makes recommendations to the Minister on whether a new procedure, test, or device should receive public funding.<sup>12</sup> MSAC advice is also utilized by the states in relation to new technologies in public hospitals. The MSAC is supported by two sub-committees: the Evaluation Sub-Committee and the PICO Advisory Sub-Committee.

The MSAC advises the Minister on covering new medical technologies and procedures and the indications for which these should be covered by the MBS. In terms of priority setting, the PBAC process is passive, as the order and timing of evaluation are determined by the receipt of a submission from a sponsor, which does not have to be the drug's manufacturer. The receipt of a submission by a specified deadline guarantees its consideration at the next meeting of the PBAC, which happens three times per year. The MSAC has much longer processes and more limited capacity; therefore, it must employ prioritization processes.

The MSAC's size and composition is determined by the Minister for Health and Ageing. The MSAC Executive consists of the Chair, Deputy Chair, chairs of any MSAC sub-committees, and the Chief Medical Officer (or proxy). The MSAC's composition is drawn from a wide range of experts. It meets up to four times per year, whereas sub-committees and working groups may meet more frequently. Assessments produced by independent contractors (evaluators), in consultation with an Advisory Panel chaired by a member of the MSAC, provide expert input into the assessment process and ensure that the contractor's assessment is clinically relevant. Given the number of applications the MSAC receives for

assessment, it can prioritize consideration of assessments based on clinical need, cost, likely benefit, and other factors determined by the MSAC, such as access and equity.

Both the PBAC and the MSAC publish their recommendations online, though there is no explicit communications strategy as such. The listing of new medicines on the PBS is heavily publicized, and the media are frequently interested in what the PBAC is doing. Nongovernmental organizations and patient and provider groups will frequently comment on outcomes. The MSAC publishes evaluation reports, while the PBAC publishes summaries. In addition, the National Prescribing Service publishes RADAR to provide health professionals with evidence and information on new technologies, and timely updates on changes to benefits schemes.<sup>13</sup>

Decision analysis is conducted using randomized controlled trials and other types of evidence depending on the clinical question being addressed. Formal evaluation of uncertainty around point estimates reflects the quality of the evidence used and offers the committee additional information on whether to accept or reject the technology. The PBAC applies a reference case/methods guide for its evaluations. Cost-effectiveness is a mandatory criterion for PBS listing. Though no explicit threshold exists, various analyses of PBAC recommendations have noted that positive recommendations become less likely above \$50,000 per quality-adjusted life year (QALY). Issues of uncertainty, however, may preclude listing at much lower incremental cost-effectiveness ratios (ICERs); conversely, higher ICERs have been accepted where significant clinical benefit and need have been demonstrated.

### **HTA decision-making link**

HTA decisions from the two main HTA agencies, the PBAC and the MSAC, are binding, not merely advisory. In the case of a positive recommendation, the Minister may choose not to comply, but this rarely happens. The PBAC is organically linked to the health care system of Australia. Its positive recommendations, subject to ministerial and—for high-budget impact items—Cabinet approval, result in the drugs being listed in the PBS. As a result, there is no need for any specific implementation strategy, or financial or regulatory incentives. The situation is similar with the MSAC's recommendations and the MBS. There is a degree of devolution, with hospitals and states making their own decisions for inpatient drugs and procedures, but decisions made at the national level are hardwired into the system and implemented through the PBS and the MBS.

In both cases, PBAC and MSAC recommendations are translated directly into inclusion or rejection for listing in the respective Medicare schemes. During the early years of the PBAC, only clinical need was considered for listing drugs. Following amendments to the National Health Act 1953 in the late 1980s, the PBAC is now required to consider the effectiveness and cost of a drug proposed for PBS listing compared to other therapies or no therapy. The introduction of formal HTA processes for other medical technologies, such as procedures and devices, is more recent, and vaccines were added to the PBAC's remit in 2006.

While appeals against PBAC recommendations are not allowed, appeals regarding the PBAC process are permitted under the Administrative Decisions Act but rarely occur. Technology sponsors may request an independent review, but only in those cases where the PBAC rejects a technology outright. This option has only been used twice since it was introduced in 2005.

The PBAC Drug Utilization Sub-Committee monitors utilization and uptake and compares observed vs. expected rates. Because PBAC decisions are binding, they are implemented across the country. The utilization of new technology by clinicians is limited by government policy. For example, the availability of subsidized private-sector magnetic resonance imaging services is restricted, although there is no limit to unsubsidized use, and there are regulations and guidelines for doctors prescribing subsidized medicines listed under the PBS.

Over recent years, there has been a move toward centralization of decision-making with respect to the adoption of technologies in hospitals. Centralization of processes could eliminate much of the duplicative efforts by individual hospitals in determining whether a drug or technology should be made available, resulting in more equitable access to health care resources across the country. There have now been many calls for transparency in regulatory and reimbursement decisions in Australia and internationally with an expected impact on MSAC and PBAC processes. The MSAC is enacting a number of reforms to improve the efficiency, transparency, accountability, and consistency of its processes.<sup>14, 12</sup>

## **Stakeholders**

PBAC stakeholders frequently consult with professional groups and consumer organizations, and will convene ad hoc roundtables where issues of contention warrant broader input and discourse. The frequency of PBAC meetings was reduced from quarterly to three times a year in 2004 to permit greater feedback to sponsors through the process. Major consumer groups in Australia are the Australian Consumers' Association and the Consumers' Health Forum. Consumer groups are most active in relation to specific chronic illnesses, such as the Stroke, Heart, Cancer and Diabetes Foundations, and HIV/AIDS, mental health, and reproductive rights groups.

While appeals against PBAC recommendations are not allowed, appeals about the PBAC process are permitted under the Administrative Decisions Act of 1977.<sup>15</sup> Such appeals must allege lack of and/or inadequate procedural fairness or due process, and are rare. A case in point is when the PBAC was sued by Pfizer in the late 1990s over its decision not to recommend listing Viagra®, in part over concerns about potential leakage and hence overall cost to government. Pfizer asserted that the PBAC had no right to consider total cost, that it was an irrelevant consideration and outside its legislative remit. The Federal Court found that not only was the PBAC reasonable in considering total cost to government, it was obliged to do so. Additionally, an independent review mechanism for PBAC recommendations was introduced in 2005 as a provision of the Free Trade Agreement with the United States. Independent reviews have only been requested by technology sponsors twice.

Pharmaceutical companies and manufacturers of some other health technologies have been reluctant to have their submissions to the PBAC and the MSAC released in the public domain because they contain commercially sensitive information. Sponsors requesting registration or subsidy of health technologies through these agencies are permitted to provide information on a commercial-in-confidence basis as part of their submissions. Generally, the PBAC releases a clinical summary. The clinical and economic information released in the Public Summary Documents is quite detailed; only three things are not disclosed, with the intention of protecting researchers' opportunity to publish: the actual ICER (expressed as falling within a range), the drug price proposed by the company (though this is in the public domain once the drug is listed), and any details of unpublished data relied on by the PBAC. The MSAC publishes two sets of guidelines: one for medical services and the other for diagnostic services. The MSAC, on the other hand, releases its complete evaluation report, censoring information deemed commercial-in-confidence.

## **Budget**

Australia spends an estimated 2.3 percent of the national health budget on research, and substantial health research and development (R&D) funding comes from public funds.<sup>16</sup> The National Health and Medical Research Council (NHMRC), a statutory authority, is a major funding body for health and medical research. The NHMRC consolidates the functions of research funding and development of advice within a single national organization. It brings together and draws upon the resources of all components of the health system, including governments, medical practitioners, nurses and allied health professionals, researchers, teaching and research institutions, public and private program managers, service administrators, community health organizations, social health researchers, and consumers.

The Australian Research Council was established as an independent body, under the Minister for Education, Science, and Training, and is the primary source of advice to the government on investment in the national research effort. Its mission is to advance Australia's capacity to undertake quality research that brings economic, social, and cultural benefit to the Australian community. The Australian Research Council funds research and research training in science, the social sciences, and the humanities. Its funding increased by AUD736 million, doubling the funds for research by 2006. The Council funds research on health issues but not clinically oriented research, which comes under the NHMRC.

The total cost of running the PBS secretariat and processes, excluding the subsidies themselves, was about AUD14.4 million in 2007 (just 0.01 percent of the Australian health care budget). Estimated costs are about AUD60,000 to AUD80,000 per report. PBAC processes are also now partly cost-recovered, as the remainder is funded by government.<sup>17</sup>

## Canada

Canada is considered an early adopter of formal HTA. Canada's first HTA agency, Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS, renamed Institut national d'excellence en santé et en services sociaux—INESSS—in 2011), was established in Quebec in 1988 to support the Minister of Health and Social Services by producing assessments of health technologies, and by disseminating results to key constituencies in the health care system. Alberta and British Columbia followed suit. Saskatchewan, Manitoba, Newfoundland, and Ontario have research groups that conduct HTA-relevant assessments. In 1990, the first national HTA agency, the Canadian Agency for Drugs and Technology in Health (CADTH, formerly known as the Canadian Coordinating Office for Health Technology Assessment), was formed to 'encourage the appropriate use of health technology by influencing decision-makers through the collection, creation, and dissemination of HTA of new medical technologies and pharmaceutical therapies'.<sup>18</sup> It was initially given a three-year mandate, but following a favorable independent evaluation in 1993, it became a permanent body. It commissions original HTA studies in areas not covered by provincial HTA agencies and coordinates the dissemination of studies more broadly. In 2003, the CADTH launched the Common Drug Review (CDR) as a single national drug review process on which to base formulary recommendations.

HTA in Canada was supported by a favorable enabling environment, including the positive predisposition of clinicians, patients, and managers toward health sciences, and the lack of Canada-based developers and producers of health technologies.<sup>19</sup> As such, HTA was perceived as a tool to inform evidence-based policymaking, rather than one to serve as a mediation mechanism between technology promoters and those expected to pay their costs.<sup>19</sup> HTA has been used to inform decisions on the procurement and withdrawal of health technologies, on insurance plan coverage, on referral of patients for treatment in other jurisdictions, on clinical practice for older technologies, and on the development of specific programs. The Canadian health system is quite decentralized; therefore, HTA entities exist in many provinces. However, there has been movement toward greater standardization of methods and inter-province harmonization.

### **Problem**

Following a series of studies of technology diffusion, demand began to grow for HTA programs in the 1980s, with academic and health care stakeholders calling for a more systematic and structured approach to assessment, beyond the regulatory function provided by the federal government.<sup>19,20</sup> This demand coincided with a period of rapid increase in public expenditure, which in the 1990s grew faster than the economy or other public expenditure areas, triggering concern about the financial sustainability of the Canadian health system.<sup>21</sup> Up to that point, provinces had relied on global budgeting mechanisms to guide decisions about the introduction of health technologies, but there was recognition of the bluntness of this approach.<sup>19</sup>

## **Health system context**

The Canadian health system is characterized by five principles: public administration, comprehensiveness, universality, portability, and accessibility. Health services are highly decentralized, with provincial and territorial governments responsible for overseeing the organization and delivery of health services. As a result, according to Battista, ‘the Canadian “system” consists of thirteen slightly different “systems”’.<sup>19</sup> The federal government regulates pharmaceuticals and devices, is responsible for the financing and administration of health services for First Nation and Inuit people, and provides public health insurance for members of the armed forces, veterans, federal prison inmates, and refugees.

Marchildon identifies three primary reasons for the highly decentralized structure:

- Provincial and territorial governments bear the responsibility for funding and delivering most services.
- Physicians in the Canadian health system function as independent contractors.
- Many organizations, including regional health authorities and privately governed hospitals, operate at “arm’s length” from provincial governments.<sup>18</sup>

Approximately 70 percent of health-sector financing comes from public sources, generated through general tax revenues by federal, provincial, and territorial governments. The system is supported through publically funded health insurance plans that are administered on a provincial and/or territorial basis within guidelines set by the federal government. Provinces also receive around 25 percent of their financing through the Canada Health Transfer, an annual cash transfer from the federal government. This transfer also serves as an accountability mechanism through which the federal government ensures that provinces are aligned with the provisions of the Canada Health Act. Most of the health funding goes toward universal hospital and Medicare plans, in addition to prescription drug coverage and long-term care.

Private health care in Canada is financed through private health insurance plans—mostly linked to employment-based insurance for non-Medicare services, such as prescription drugs, dental, and vision care—and out-of-pocket payments.

## **Institutional arrangement**

Most HTA in Canada is conducted by government-funded agencies with permanent evaluation staff.<sup>21</sup> At the national level, the CADTH is mandated ‘to provide evidence-based evaluations of new health technologies including prescription drugs and medical devices, procedures, and systems to all participating governments’.<sup>18</sup> Furthermore, several provincial agencies exist (see Table 1). Government-funded agencies at the federal and provincial level regularly fund academic and research institutes to conduct assessments. HTA activities also exist at a more local level; for example, McGill University Health Centre established its own HTA agency to provide advice on decisions surrounding resource allocation.<sup>21</sup> Canada’s provincial and federal HTA agencies participate as members in the International Network of Agencies for Health Technology Assessment, representing 23 countries, and the CADTH

assumes responsibility for broader “horizon scanning” for information on technologies not widely used in Canada.

According to a review conducted by Menon, most assessments focus on therapeutic technologies used to treat disease (66 percent of all reports), followed by diagnostics (21 percent), screening (13 percent), preventative (7 percent), and other technologies (5 percent).<sup>20</sup> The most commonly studied health area was cardiovascular disease (23 percent). Most studies relied upon literature review, followed by cost analysis or economic evaluation.<sup>20</sup> While economic considerations are also important for decision-makers, only about 25 percent of HTAs in Canada include economic evaluation; the rest only address clinical effectiveness.<sup>18</sup>

The CDR was formed to streamline the process for reviewing and making recommendations about adding new pharmaceuticals to provincial formularies. The CDR includes:

- a systematic review of clinical evidence and pharmaco-economic data;
- the CADTH’s drug advisory committee, the Canadian Expert Drug Advisory Committee, which makes recommendations about formulary listing; and
- provincial and territorial health ministries that make formulary and benefit coverage decisions based on the recommendations of their own committees, considering political pressures.<sup>18</sup>

In general, assessment of pharmaceuticals, though more recent, is more developed than other health technologies, at least in part because “pharma” is as an industry better understood and better organized than the more diffuse health technology industry.<sup>19</sup>

While concerns exist about duplication of efforts between the different layers of HTA in Canada, a review of the national and provincial programs found very little redundancy.<sup>20</sup> In cases where different agencies reviewed the same technology, there was variation in the focus of the assessment, or a clear justification for updating the assessment.<sup>20, 21</sup> In 2004, to improve coordination, health ministers approved a national strategy for the management of health technologies, which included provisions for improved information exchange between HTA agencies, and communication with policymakers. The strategy includes a policy-sharing forum on health technology and a health technology analysis exchange, both coordinated by the CADTH.<sup>21</sup>

In general, HTA has been well received by relevant stakeholders. While assessing the future of Medicare, Federal Commissions recommend increasing resources for assessments. The quasi-governmental model is most common in Canada; while most funding comes from government sources, agencies maintain an important degree of autonomy. Furthermore, further evidence of the institutionalization of HTA in Canada can be seen in the emergence of assessment agencies in hospitals. Overall, HTA has evolved and matured gradually in Canada, without radical shifts in approach. One of the effects of this approach has been a “managed diffusion” of health technologies, and through what is widely perceived by policymakers and the public as a “politically acceptable” delay to the introduction of new technologies. The Canadian system also likely benefits from lower costs available to later adopters and some risk

mitigation. This more evidence-based approach is becoming increasingly more ingrained in the culture of decision-making in Canada. However, while HTA agencies are important influencers on the diffusion of expensive technologies, physicians remain influential with regard to lower-cost technologies.<sup>19</sup>

### **HTA decision-making link**

HTA recommendations are considered advisory, not binding, and governments (and other stakeholders, such as hospital administrators) ultimately determine whether to introduce new technologies or prescription drugs within their respective health systems. However, the culture of HTA is becoming more and more ingrained as an essential component of rational, evidence-based decision-making, so there is increased pressure to justify decisions in accordance with HTA recommendations.

### **Stakeholders**

In general, HTA in Canada has benefited from a favorable enabling environment characterized by strong public support for the health sciences. Furthermore, because Canada does not invest heavily in R&D of health technologies, the role of HTA has been viewed as relatively uncontentious, unlike other contexts where similar agencies are required to settle disputes between promoters of technologies and those who pay for them.

The primary clients for HTA outputs in Canada are government decision-makers; however, other health care institutions, providers, and patient associations are also commonly identified as target audiences, particularly for smaller, hospital-based initiatives (see Table 1).<sup>19, 20, 21</sup>

### **Budget**

The CADTH is funded by Health Canada, and by provinces and territories (with the exception of Quebec) in proportion to population.<sup>18</sup> The CADTH has an annual operating budget of CAD24.2 million.<sup>22</sup> From that funding, the CDR receives CAD2 million per year. Funding for provincial-level HTA is more variable, as there are numerous HTA entities operating at the subnational level, but most funding comes from government sources.

## England and Wales

The National Institute of Health and Care Excellence (NICE) is probably the best-known HTA-based decision-making model worldwide, although it is actually an appraisal institution and not an HTA body. HTA emerged as a priority in the United Kingdom in response to concerns about the rising costs of health technologies. Woolf and Henshall estimate that new technologies were contributing to a 0.5 percent to 1 percent increase in costs to the National Health Service (NHS) per year.<sup>23</sup> HTA was viewed as a mechanism to improve evidence-informed decision-making around technologies and interventions and to achieve better value for money.

### **Problem**

Over the course of the 1970s and 1980s, concern mounted in the United Kingdom about the growing cost of health services without strong supporting evidence on effectiveness and efficiency. Archie Cochrane found that the demands of patients and doctors overrode such considerations, and studies commissioned by the Health Committee of the House of Commons estimated that 5 percent to 20 percent of surgical procedures were unnecessary or conducted for inappropriate indications.<sup>24</sup>

In response to these concerns, a growing number of entities, including the Medical Research Council and the Department of Health (DH), began conducting HTA. However, these efforts were criticized for a lack of coordination. In 1988, the House of Lords Select Committee on Science and Technology highlighted a need for more funding for research to inform more efficient and effective resource allocation within the NHS. In 1991, the government appointed a Director of R&D for the DH and the NHS, and HTA was identified as the primary activity for the new program. According to Drummond and Banta, ‘the launch of the R&D Programme marked a shift in emphasis away from the NHS as a passive recipient of new technology to a knowledge-based health service with a strong research infrastructure and competence in critically reviewing its own needs’.<sup>24</sup>

Although the R&D program produced a significant amount of evidence, its impact on policymaking and clinical practice was minimal. As a result, new technologies were available in some locations and not others, leading to inequitable access, often referred to as “post-code rationing” or the “post-code lottery”. In addition, there was a lack of independently produced professional standards and a slow uptake of innovative new technologies. This led to the establishment of NICE in 1999 to provide guidance on health technologies and practice with the aim of maximizing health gains within budget constraints.<sup>24</sup>

NICE currently produces technology appraisals, clinical guidelines, and interventional procedures. In 2005, it also began evaluating public health interventions. NICE guidance for public health focuses solely on England, whereas guidance on health technologies and clinical practice covers England and Wales, and guidance on interventional procedures covers England, Wales, and Scotland.

## Health system context

While the United Kingdom comprises England, Scotland, Wales, and Northern Ireland, this case study is limited to England and Wales, corresponding to the jurisdiction of NICE.

The NHS, founded in 1948, is viewed as a ‘remarkable experiment in health care’ in that it offers free comprehensive health care (with some exceptions, such as dental services and eye care) at the point of service.<sup>25</sup> The DH, overseen by the Secretary of State for Health, manages the NHS and sets health policy more broadly. The NHS is financed through general taxation, with some contribution from national insurance. Remarkably, only roughly 11 percent of the population has supplementary private health insurance.<sup>23</sup>

The NHS is guided by seven core principles:

- The NHS provides a comprehensive service available to all.
- Access to NHS services is based on clinical need, not an individual’s ability to pay.
- The NHS aspires to the highest standards of excellence and professionalism.
- The NHS aspires to put patients at the heart of everything it does.
- The NHS works across organizational boundaries and in partnership with other organizations in the interests of patients, local communities, and the wider population.
- The NHS is committed to providing best value for taxpayers’ money and the most effective, fair, and sustainable use of finite resources.
- The NHS is accountable to the public, communities, and patients that it serves.

In 2013, the most significant reforms to the NHS since it was founded came into effect with passage of the Health and Social Care Act 2012. Among the most significant changes include:

- The NHS England and Clinical Commissioning Groups were granted statutory responsibility for commissioning health services.
- Local authorities were given expanded responsibility for public health duties.
- Local Healthwatch organizations were created.
- Strategic health authorities and primary care trusts were abolished.
- Health Education England and the Health Research Authority were established as statutory non-departmental bodies.
- A sector regulator’s role was established for health care in England.<sup>26, 27</sup>

## **Institutional arrangement**

NICE was founded in 1999 and designated a special health authority to ‘reduce variation in the availability and quality of NHS treatments and care’. In 2013, NICE became a Non-departmental Public Body as part of broader reforms enacted through the Health and Social Care Act 2012. According to its framework agreement with the DH, NICE’s role is ‘to provide guidance and support to providers and commissioners to help them improve outcomes for people using the NHS public health and social care services. NICE supports the health and care system by defining quality in the NHS, public health, and social care sectors and helps promote the integration of health and social care’.<sup>28</sup>

To this end, NICE evaluates health technologies; provides guidance on clinical care, public health, social care, and interventional procedures; develops quality standards; provides guidance on safe staffing; sets out indicators for the General Practice Quality and Outcomes Framework and for the Clinical Commissioning Group Outcomes Indicator set; provides evidence on value for money for high-cost, low-volume drugs and treatments; and assesses the value of new medicines under value-based pricing.<sup>27</sup>

NICE provides guidance across four main areas:

- the use of health technologies, including pharmaceuticals, devices, diagnostics, surgical and other procedures, and health promotion tools through technical appraisals;
- appropriate treatment and care for patients with specific diseases and conditions through clinical guidelines;
- safety and efficacy of interventional procedures (i.e., any surgery, test, or treatment that involves entering the body through skin, muscle, vein, artery, or body cavity); and
- activities to promote healthy living and prevent poor health through public health efforts.<sup>29</sup>

As a result of the 2013 reforms, NICE also now provides guidance in the area of social care. In developing guidance, NICE considers effectiveness (how well an intervention works) and cost-effectiveness (how well an intervention works in relation to how much it costs). In some cases, it also considers efficacy (how well an intervention works under ideal conditions). Because in many instances the available evidence is insufficient, NICE is also guided by a set of social principles.<sup>28, 29</sup>

NICE is governed by a board, with the Chair and Deputy Chair appointed by the Secretary of State for Health. A Chief Executive is appointed by the board, subject to approval by the Secretary of State. According to its framework agreement, NICE works closely with the following bodies: NHS England, Public Health England, the Department for Education, the Health and Social Care Information Centre, the Care Quality Commission, Monitor, the Medicines and Health Care Products Regulatory Agency, Health Education England, local NHS bodies, local authorities, devolved administrations, other government departments, and other public and patient representatives.<sup>28</sup>

NICE produces three different versions of technology appraisals: full appraisals, quick reference guides, and information for the public. Each version targets different stakeholder groups, from the NHS and

health professionals (full appraisals and quick reference guides), to patient groups and a lay audience (information for the public).

NICE does not apply a fixed willingness-to-pay threshold, but bases decisions primarily on the cost-effectiveness estimate for ICERs below GBP20,000 per QALY.<sup>30</sup> Typically, NICE requires additional justification for ratios over GBP25,000 per QALY. Particular considerations would include the degree of uncertainty surrounding the estimate, equity and public health impacts, and the innovative nature of the technology. Such data would typically include new trial data, new analysis, or modification of the economic model and changes in the licensed indications of the technology.

There are three processes for technology appraisal: single-technology appraisal, multiple-technology appraisal, and fast-track appraisal. Single-technology appraisal is used primarily for new pharmaceuticals and/or to grant extensions to licenses for existing products. Multiple-technology appraisal is used in cases where several technologies need to be appraised to address a condition, and when a topic is especially complex. In 2017, a fast-track appraisal was introduced for technologies viewed as offering ‘exceptional value for money’ to facilitate more timely introduction and patient access. Technologies that have an ICER (as determined by the manufacturer) of less than GBP10,000 per QALY gained, and it is likely that the ICER is less than GBP20,000, or when cost comparison show that it is likely to show similar or better health benefits for a reduced cost than already recommended technologies. According to the NHS constitution, technologies that receive a positive recommendation through the single- or multiple-technology appraisal process should be made available within three months; technologies that receive a positive recommendation through fast-track appraisal should be made available within 30 days.

### **HTA decision-making link**

NICE guidance serves a quasi-legal function—with the exception of technology appraisals, which are legally binding.<sup>31</sup> As noted above, technologies that receive a positive recommendation must be made available within three months (or 30 days in the case of fast-track appraisals).

### **Stakeholders**

NICE is governed by a board with various sub-committees, and partner and citizen councils. The Citizen’s Council is comprised of approximately 30 individuals who reflect the demographic characteristics of the United Kingdom and represent the public in advising NICE on overarching moral and ethical issues. They do not produce or provide input into NICE guidance. Other stakeholders provide input into NICE guidance development through various consultations, including on the scope or topic, and by providing comments on draft guidance.

NICE also coordinates with other HTA bodies in the United Kingdom, such as the National Coordinating Centre for HTA, part of the National Institute of Health Research, which manages, supports, and develops the NHS HTA program on behalf of the DH R&D Division. The NHS HTA program provides information on the costs, effectiveness, and broader impacts of health technologies specifically for those who use, manage, and provide care in the NHS. Additionally, it supports NICE by managing technology

assessment report contracts, contributing to single-technology appraisals, and by commissioning Evidence Review Group reports, which appraise manufacturers' submissions. Other HTA groups in the United Kingdom include academia, the Medical Research Council, the National Horizon Scanning Centre, the United Kingdom Cochrane Centre, the Committee on the Safety of Medicines, the Joint Committee on Vaccination and Immunization, and other commercial and charitable groups.

NICE's engagement with a broad representation of stakeholders, from multiple sectors and disciplines, introduces a variety of perspectives into the appraisal and decision-making process. This is particularly helpful when reaching consensus on conflicting evidence or recommendations that require knowledge of both scientific literature and the realities of clinical practice. Moreover, given the paucity of scientific evidence about patient treatment preferences and viewpoints on issues such as equity and fairness in health care, it is important to elicit such perspectives from a variety of stakeholders. At implementation, a high level of stakeholder involvement increases public and professional ownership of the guidance, thereby enhancing the likelihood that it will guide effective decision-making and clinical practice.

## **Budget**

NICE is a public organization and receives most of its funding from government (specifically the DH) but is independent of government in the way it operates. As the NHS is funded by taxation, it was considered appropriate to create NICE as a public-sector/NHS body with public funds. To ensure its independence, it has broad stakeholder representation and a strict conflict of interest policy. The budget allocated to NICE is currently around GBP60 million, the equivalent of 0.06 percent of the NHS annual budget.<sup>32</sup>

The outsourcing costs of HTAs are approximately GBP200,000 per guideline and GBP60,000 for a review of a manufacturer's submission (through a single-technology appraisal) to GBP150,000 for a new systematic review and economic model for HTAs. This figure does not include the cost of NICE staff or additional expenses to cover the committees' travel and accommodation costs. NICE spends approximately 4 percent of its total budget on its communications program responsible for providing editorial services, dealing with the press and media, publishing and disseminating NICE guidance, and maintaining the NICE website and intranet.

## Germany

HTA came relatively late to Germany, and the German model differs significantly from that of other countries in our review. HTA is used in Germany primarily to inform price negotiations, not for decisions about coverage and the inclusion of certain technologies or interventions in the benefits package. Discussion around HTA began in the 1990s as part of a broader shift toward evidence-based medicine. HTA was first formally established in 2000 in the context of the German Health Care Reform 2000. The most prominent HTA bodies in Germany are the Federal Joint Committee (Gemeinsamer Bundesausschuss—G-BA), which determines the social health insurance (SHI) benefits package; the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen—IQWiG), established by the G-BA to assess the effectiveness, quality, and efficiency of technologies; and the German Institute for Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information—DIMDI) which housed the first formal HTA unit (Deutsche Agentur für Health Technology Assessment—DAHTA).<sup>33</sup>

### **Problem**

Increased awareness among decision-makers (primarily the government and self-governing bodies) about the need for HTA to support decision-making at different levels of health care and to enhance networking on a European level and various health care reforms has served to strengthen and institutionalize HTA in Germany. According to Sorenson:

*Prior to the early 2000s, coverage decisions and the management of health technology use and diffusion in Germany showed considerable inconsistency between different health care sectors. For instance, the ambulatory sector was notably more regulated than the hospital sector, where explicit coverage decisions were virtually non-existent. The difference(s) between sectors constituted a barrier to regulation and to HTA's role as an effective mechanism for informed decision-making and priority setting.*<sup>34</sup>

### **Health system context**

Germany pioneered the Bismarckian model of health care and operates an insurance-based system, financed largely through contributions from employees and employers. SHI schemes cover about 85 percent of the population and are made up of sickness funds and not-for profit insurance schemes. A further 11 percent of the population is covered by substitutive private health insurance, including certain professional groups (e.g., civil servants).<sup>35</sup>

Coverage includes preventative services, hospital care, physician services, mental health care, dental care, optometry, physical therapy, prescription drugs, medical aids, rehabilitation, hospice and palliative care, and compensation for sick leave. In total, out-of-pocket spending accounts for about 13.6 percent of health spending. Children are exempt from out-of-pocket contributions, and spending for adults cannot exceed 2 percent of household income.<sup>36</sup>

Decision-making in the German health system is shared between the states, the federal government (specifically the Federal Assembly, the Federal Council, and the Federal Ministry of Health), and civil society organizations (including payers and providers). The German health care system is based on decentralized decision-making, and actors/stakeholders in the system operate on the basis of self-governance. The paramount decision-making body in this framework is the Federal Joint Committee (G-BA). Representatives of stakeholders in the system (namely the SHI funds, office-based physicians, and the national association of hospitals) are included on the G-BA committee. Patients' representatives are members of the G-BA, but they do not have the right to vote on whether a service should be reimbursed or not.

The G-BA has been institutionalized as a legal entity under public law. It has wide-ranging regulatory powers which are laid down in Volume Five of the Social Code Book that governs statutory health insurance. The G-BA has a central responsibility in the field of medical service provision for those with statutory health insurance. This does not concern the question of licensing pharmaceuticals for the German market, which is the task of the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte—BfArM) and furthermore of the European Medicines Agency, since most drugs are now licensed at the European level.

The G-BA regulates reimbursement exclusions and restrictions in the provision of drugs through directives based on the efficiency requirement. All directives issued by the G-BA are subject to approval by the Federal Ministry of Health (Bundesministerium für Gesundheit—BMG). The BMG responds within two months if it has any objections.

### **Institutional arrangement**

The DIMDI sits in the BMG and supports the dissemination of evidence on the clinical and cost-effectiveness of technologies and other medical technologies. The primary mechanism for dissemination is the DAHTA, a searchable database of HTA reports commissioned by the DIMDI and other German and international HTA entities.

When commissioning assessments, the DIMDI has a set process and standard operating procedures by which it prioritizes topics for assessment according to set methods, starting with a public identification of topics, through to prioritization and selection by the board (who apply Delphi methods) through to publication of results.

Reports come in three forms: full, methods-focused, or brief rapid review. Assessments are carried out by contractors (until late 2016, DIMDI staff conducted some assessments), and results are reviewed internally and externally. The internal review is conducted by DAHTA and DIMDI staff to verify the content and structure of the report, as well as alignment with the set methodology. The external review assesses the content and methods and is conducted by experts from scientific and academic institutions.<sup>34</sup> Once the report is finalized, it is made available on the DIMDI website.<sup>33</sup> The DIMDI is supported by two

boards: the HTA Board of Trustees, responsible for topic selection, and the scientific advisory board, which provides input into methods.<sup>34</sup>

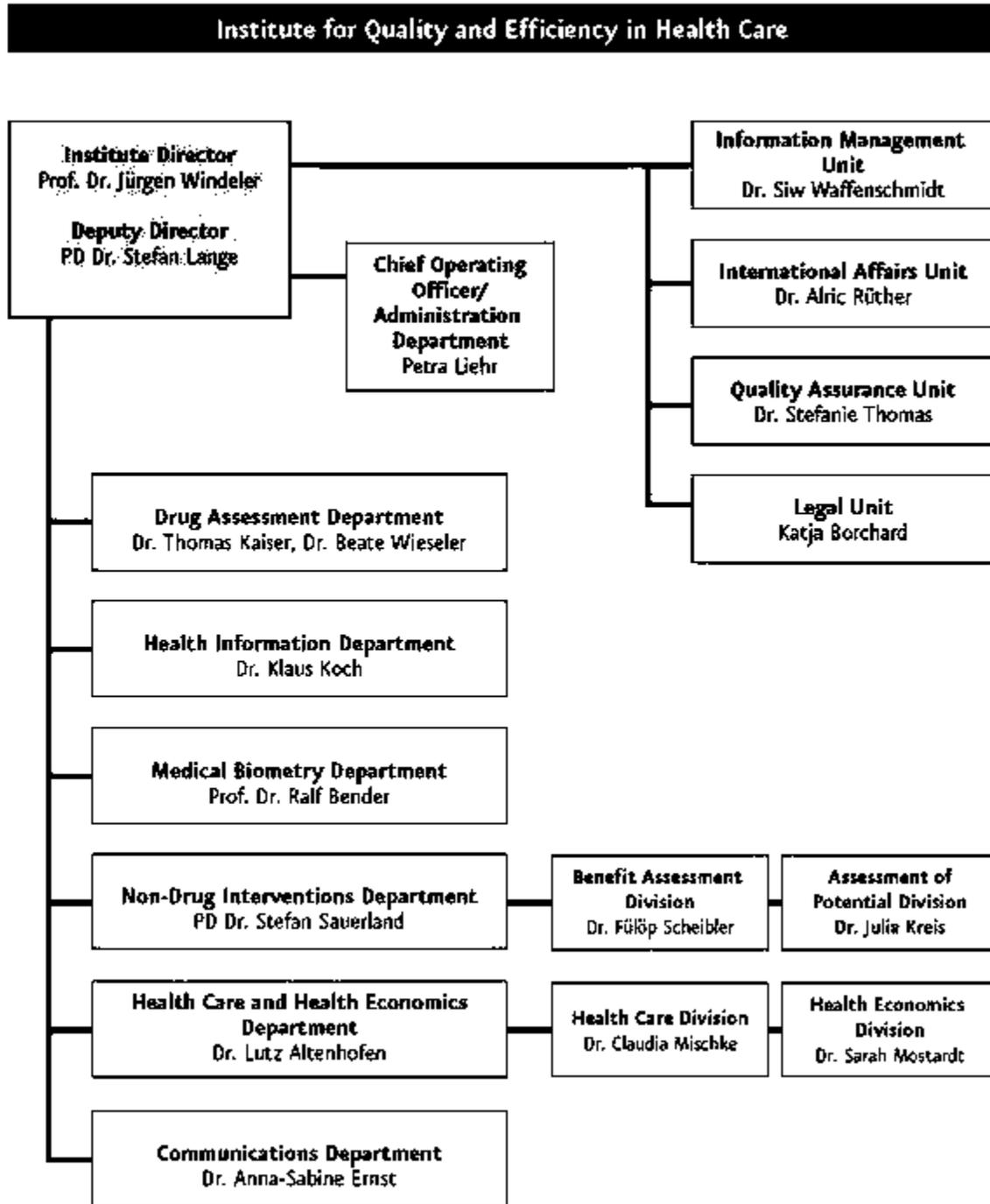
The DIMDI closely collaborates with other institutes of the BMG, other federal and state authorities, as well as national and international organizations. For example, the BfArM is involved in the authorization of medicinal products and in the approval of clinical investigations/performance evaluations of medical devices and in vitro diagnostic agents in Germany. It also supplies the DIMDI with data concerning incidents involving medical devices in Germany.

In general, submissions and data from manufacturers and other stakeholders are accepted but have to be published and made available in the public domain. Since 2011, manufacturers have had to present reports of the additional benefit of new drugs before market entry. The G-BA decides which additional benefit a new drug has and under which circumstances it might be reimbursed. For drugs without an additional benefit a fixed price will be established. If this is not possible due to a lack of pharmaceutical comparators, a price will be negotiated between the health insurance scheme and the manufacturer. This price may not exceed the costs of an existing treatment standard. If no treatment standard exists, or an additional benefit has been established, the price of the new medicine will be negotiated between the Federal Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the drug company. This procedure is constituted in the Law on Realignment of the Pharmaceutical Market in Germany (*Arzneimittelmarkt-Neuordnungsgesetz—AMNOG*). According to the Law, manufacturers have to submit their dossier in a template.

In the development of HTA reports, key stakeholders are invited from the DAHTA at the DIMDI to submit, review, and comment on the evidence the committee used to reach its decision. This can be written or oral evidence, commentary, analysis, or primary research.

The IQWiG became a formal entity in June 2004 as part of the SHI Modernization Act. In November 2004, it began developing its first consumer health information briefing on the painkiller Vioxx® and cholesterol drug Sortis®.<sup>37</sup> In March 2005, it issued its first draft report on rapid-acting insulin analogues for diabetes treatment. The structure of the IQWiG is illustrated in Figure 1. Technologies evaluated by the IQWiG include drugs, medical devices, surgical procedures, diagnostic and screening tests, clinical practice guidelines, and disease management programs. The IQWiG evaluates the evidence in relation to the nature and severity of disease, the magnitude of therapeutic effect, the availability of treatment alternatives, and side effect profile and risk of adverse events.<sup>34</sup> Assessments are commissioned by the G-BA or the BMG.<sup>38</sup> The IQWiG can also identify topics for assessment through a process known as general commission. Assessments conducted and commissioned by the IQWiG are also required to adhere to set methods. Draft results are reviewed internally and through hearings.

Figure 1. Organizational structure of the Institute for Quality and Efficiency in Health Care (IQWiG)<sup>39</sup>



Other entities engaged in HTA in Germany include: the Office of Technology Assessment at the German Parliament, the Institute for Technology Assessment and Systems Analysis, the Institute for Medical Outcomes Research, the Potsdam Institute of Pharmaco-epidemiology and Technology Assessment, the

German Scientific Working Group of Technology Assessment in Health Care, and the German Network for Evidence Based Medicine HTA Division.

### **HTA decision-making link**

The IQWiG provides reports on the costs and benefits of technologies. Evidence provided by the IQWiG is reviewed by the G-BA to inform decisions about the composition of the benefits package for SHI funding schemes. In reports commissioned by the G-BA, the IQWiG provides recommendations, but the G-BA is not legally bound to follow those recommendations.<sup>40</sup> If the G-BA chooses to ignore IQWiG recommendations, it needs to provide suitable justification. Patients and manufacturers have the right to launch appeals against G-BA decisions; however, up until now courts have mostly sided with the G-BA.

### **Stakeholders**

Key HTA stakeholders include the Federal Assembly, the Federal Council, and the BMG at the federal and state levels. Provider associations are represented at the state level, and patient associations and private health insurance companies also contribute to decision-making.

### **Budget**

The IQWiG is financed through levies on inpatient and outpatient medical treatment. The G-BA determines the overall amount each year.<sup>40</sup> The Foundation Council set a budget of about EUR8 million in 2005 for the IQWiG, and by 2010 this had reached some EUR13 million, representing 0.0076 percent of the SHI expenditure. In 2011, the budget was set at EUR15 million. The budget covers not only staff salaries and running costs, but also expenditure on external experts. The average cost for IQWiG reports differs depending on the kind of report, time, and effort; costs are between EUR50,000 and EUR500,000. EUR13 million was available in 2010 for a total of nine completed commissions and eight preliminary benefit assessments. Report plans were prepared for a total of 39 commissions. In addition, the G-BA awarded nine new commissions. The DAHTA may commission about 15 reports per year, and the costs average out at EUR50,000 per report. This figure does not include the cost of DAHTA staff or additional expenses to cover the committees' travel and accommodation costs.

HTA activities at the DAHTA are sponsored by national health insurance contributions. The levels are decided by the government in consultation. The DIMDI is also allowed to work on external assignments, which are financed through third-party funds. Since 2000, about EUR750,000 has been available each year for the HTA program at the DAHTA. Currently, this is equivalent to less than 0.01 percent of the total annual budget for the statutory health insurance in Germany.

## The Netherlands

The Dutch health system is based on principles of social health insurance. It is very fragmented, with a complex mix of institutions, providers, and payers. There are many entities funding and conducting HTA activities, and the link between recommendations and decision-making surrounding coverage and payment is opaque.

### **Problem**

The 1980s were characterized by rising health care costs due to increased availability of new health technologies, high insurance premiums, growing administrative costs, and an expanded range of services.<sup>41</sup> As a result, there was heightened demand from policymakers and politician for recommendations based on systematic evaluation to support evidence-based policymaking. HTA was perceived as a mechanism to provide policymakers with the information they needed. Expanding the use of HTA was also perceived as providing an opportunity for better coordination of assessment activities in the Netherlands.<sup>42</sup>

Up until that point, there was no single formal process for regulating health technologies. The Dutch government first began regulating health technologies in the 1960s and 1970s in response to steadily rising health care costs, largely attributed to the widespread construction of hospitals and care facilities, through Article 18 of the Hospital Provision Act. Initially, the diffusion of health technologies was controlled by limiting the number of facilities and procedures through Article 18. Increasingly, the government began to use the tool as a planning instrument to ensure equitable geographic distribution. Gradually, Article 18 was used not just to control the purchase of equipment, but to regulate the use of specialized services.<sup>43</sup> Article 18 regulated the use of established technologies, but not new, innovative technologies.

In 1982, patients who traveled abroad for heart and liver transplantations began to demand reimbursement, prompting a national debate about whether the procedures were established or experimental. The procedures were ultimately excluded from the benefits packages pending formal evaluation. This debate paved the way for a new policy in 1983 which required that all new major medical technologies be assessed for efficacy and cost-effectiveness. The results of these assessments would prioritize products for inclusion in the benefits package.<sup>41</sup>

The first major evaluations began in 1985 (studying in vitro fertilization and heart and liver transplants), funded by the Health Insurance Council and implemented by academic institutions. The results of these studies informed coverage decisions with defined conditions of use. Other major evaluations were conducted around breast cancer screening pilots, which were deemed cost-effective, and a national screening program commenced in 1989.

Acknowledging a lack of experience with HTA, the Steering Committee for Future Healthcare Scenarios was asked to advise on policy options. The committee developed a report on the future of health technology and, notably, how HTA should be integrated with decision-making processes. The report

acknowledged a number of issues to be addressed—specifically, funding, institutional base, coordination, and HTA expertise. In 1988, another key policy document, *Limits to Care*, was developed by the Health Insurance Council, the National Council for Public Health, and the Health Council, in response to the Steering Committee’s report. This report sought to establish boundaries between effective and ineffective, affordable and unaffordable care, and expressed consensus that HTA should inform decision-making.<sup>41</sup>

Following these reports, a National Fund for Investigative Medicine was created in 1988 by the Health Insurance Council, the Ministry of Health, and the Ministry of Education and Science, with a budget of *f*36 million per year.<sup>43</sup> The Fund served as the national HTA program, but has been more recently replaced by the Netherlands Organization for Health Research and Development (ZonMw), a merger of the Netherlands Organization for Scientific Research and the Netherlands Organization for Health Research and Development.

### **Health system context**

The Dutch health system, based on social health insurance, is characterized by ‘an elaborate mix of institutions and regulations’, resulting in ‘an interdependent mix of public and private initiatives under the umbrella of central government’, according to Sorenson.<sup>42</sup> Every citizen is entitled to health care under the Dutch Constitution. Public health care, infectious disease control, environmental protection, and the regulation of health care professionals are the responsibility of central government—specifically, the Ministry of Health, Welfare and Sport. Service delivery is carried out by independent practitioners and nonprofit organizations.<sup>43</sup>

The Dutch system has undergone significant transition in the last decade. Until 2006, compulsory national health insurance was implemented through the Sickness Fund Act of 1996. About 60 percent of the population was covered by social security, while the rest were insured through social insurance schemes provided to government employees, or other private plans. However, in 2006 the basic health care insurance policy was introduced, a landmark structural reform to the health system, covering the entire population with a single national health insurance scheme. Prior to this reform, there were 22 different sickness funds. This reform effectively did away with the dual system of public and private insurance; instead, insurers compete, and patients now choose the provider and national insurance policy that best fits their needs. The primary role of government has changed from one of ‘steering the system to safeguarding the system at a distance’ by regulating quality, accessibility, and affordability. The package covers all acute care provided by hospitals, general practitioners and specialists; all drug and appliance costs; and transportation.

### **Institutional arrangement**

There is no single HTA entity in the Netherlands; many constituents work together to support priority setting and national policy development in the face of differing research agendas. Table 2 lists the most influential HTA bodies in the Netherlands. Beyond this list, there are a number of smaller organizations

that conduct HTA. There is a widely acknowledged need for more effective coordination and harmonization between these different entities.

Because resources for HTA are not sufficient to evaluate all new and existing technologies, there is an increased focus on priority setting for HTA. Early on, there was little consideration of the areas of greatest concern, and evaluations did not examine the social, ethical, and legal implications of health technology. In the 1990s, a more explicit and rational process was implemented to justify technologies or areas requiring assessment whereby the technologies were ranked according to degree of uncertainty concerning efficacy and effectiveness; frequency of use; costs; impact on morbidity, mortality, and quality of life; and rate of use.<sup>34</sup> Sometimes topics are generated outside of this formal process, based on requests from ministries and parliament, and based on horizon-scanning activities conducted by the Health Council.

Assessments usually involve systematic literature review and meta-analysis. HTA results are used to ‘address knowledge gaps and disseminate results to stakeholders; to decide on coverage or reimbursement of technologies in the benefits package; to define or redefine a technology’s established indications in order to promote appropriate use; to establish guidelines for use in order to reduce significant and/or unexplained practice variations; and to underpin planning and regulation for priority-setting or estimating future need for a health technology.’<sup>34</sup>

### **HTA decision-making link**

While demand for HTA is growing, and assessments are sometimes linked directly to national policy and decision-making processes, the overall impact is acknowledged to still be limited. According to Sorenson, ‘Decisions regarding payment or non-payment for medical treatment are only based to a limited degree on “hard” factors, such as cost-effectiveness and much more on less transparent considerations, as a result of pressure by lobby groups, media, etc.’<sup>34</sup> Therefore, reimbursement limits are being set randomly, with the potential for inefficient resource allocation.

This is attributed in part to the uncoordinated nature of the system in the Netherlands, with many different entities, and a lack of capacity, resources, and incentives, which often undermines attempts to improve the use of evidence in policymaking.

### **Stakeholders**

A number of policy reports made the case for the institutionalization of HTA. The Council for Health Research published a report in 1988 titled *Advice on Medical Technology Assessment*, which provided advice on how to institutionalize HTA in the Netherlands and laid out a framework on priority setting for HTA. In 1991, the Health Insurance Council published a report titled *Limits to the Growth of the Benefit Package: Third Report*, which argued that the current basis for deciding inclusion in the benefits package was insufficient, and advised on how to define the basic benefits package with four screens:

- Is the care necessary to ensure normal function or protect life?

- Is the intervention proven to be clinically effective?
- Is the care cost-effective?
- Can the care be left up to individual responsibility?<sup>41</sup>

While there is no formal and defined role in HTA for stakeholder participation and consultation, there are many stakeholder groups interested in HTA (see Table 3).

### **Budget**

Given the fragmented nature of HTA activities in the Netherlands, funding comes from a number of public and private sources, but most of the available funds are public. For instance, HTA in the Netherlands was funded through the National Fund for Investigative Medicine, created in the early 1990s to support systematic evaluations of new medical technologies. In 1999, the Fund was replaced by the Efficiency Studies Program, part of the ZonMW, which has an annual budget of \$14.3 million.<sup>44</sup> The Health Council of the Netherlands is funded by the government, with contributions from various ministries. Additionally, the government funds some primary research, but without a direct link to decisions surrounding inclusion in the benefits package.

## DISCUSSION

Although there are important variations in context, there are a number of lessons that can be drawn from the process of establishing and institutionalizing HTA in these five regions which may inform other countries, including LMICs, interested in doing the same.

The movement toward priority setting—and, ultimately, HTA—in the five cases described here was motivated by a number of factors (see Table 4). All countries were experiencing resource constraints which were especially pronounced given the rapid expansion in the availability of health technologies. Other factors, such as variability in available services and technologies according to geographic location, also contributed, but the root cause was found to be the need for a more rational process to enable policymakers to make the most of scarce resources.

In all of the cases reviewed here, the process of institutionalizing priority-setting mechanisms was protracted, and the HTA agencies themselves continue to evolve today. While the need for better priority setting to guide decisions to adopt new technologies and interventions was in many cases identified back in the 1970s, in most cases, formal HTA agencies did not form until the 1990s and have evolved substantially since that time. This is important to note because LMICs and indeed any other country interested in establishing such mechanisms may require support in not just establishing formal priority-setting entities. Before establishing HTA agencies, much work was done to build a demand for and a culture of priority setting and evidence-informed policymaking in the cases we reviewed. Even after such agencies were created, there has been significant incremental change to the mandate and design of such institutions. These processes are still ongoing, and LMICs will likely require longer-term support for this.

The need for better coordination of HTA activities, within case countries and between countries, was commonly identified. However, challenges associated with coordination appear most pronounced in countries with more decentralized health systems, where many agencies conduct HTA, and where decision-making occurs at many levels. In the case of the Netherlands, HTA recommendations are considered advisory, and there is an acknowledged need for better coordination of activities and recommendations to improve efficiency and lead to better uptake of evidence in policy. In the United Kingdom, where recommendations from NICE are binding, and there are relatively fewer HTA entities, the link to decision-making is more straightforward. The pros and cons of these different models, particularly in the context of health systems in countries interested in introducing HTA, should be considered carefully before making choices about institutional design.

## CONCLUSION

Our review of five HIC and region cases shows that while countries were facing common challenges when demands for priority-setting mechanisms began, in practice, HYA takes different forms across different countries. This is unsurprising given the differences across health systems, and the complex mix of historical, cultural, and normative forces which underpin those systems. With growing demand in LMICs for priority-setting mechanisms such as HTA, policymakers, donors, and technical partners should resist the temptation to adopt a one-size-fits-all approach to establishing such entities, as the political economy surrounding health systems is just as diverse as in our case countries. Furthermore, institutionalization does not end with the formal establishment of entities that conduct or use HTA, but takes time and repeated iteration to build not just demand for improved priority setting, but to ensure the use of recommendations.

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## APPENDIX

### A.1 HTA agencies in Canada

Table 1: HTA agencies in Canada<sup>19</sup>

Province	HTA producer	Year	Technology assessed
Alberta	HTA program/Institute of Health Economics (IHE)	1995	Drugs, treatment and devices, complex modes of intervention, practices, policies
	Capital Health Office for Health Innovation	2005	Treatment and devices, complex modes of intervention
	Alberta Health Technology Assessment Coalition (AHTAC)	2005	Drugs, treatment and devices, complex modes of intervention, practices
	University of Alberta/Capital Health Evidence-Based Practice Center (EPC)	2002	Drugs, treatment and devices, complex modes of intervention, practices
	University of Calgary/The Institute for Advanced Policy Research	2004	Policy
	Calgary Health Region/Foothills Medical Center/Department of Surgery	2005	Surgical technologies (equipment or procedure; new, replacement or upgrade)
British Columbia	Therapeutics Initiative	1994	Drugs
	Innovation in Health Technology	2006	Innovation
Manitoba	Manitoba Centre for Health Policy (MCHP)	1991	Complex interventions, practices, policy
New Brunswick	None		
Newfoundland and Labrador	Newfoundland and Labrador Center for Applied Health Research	1999	Drugs, treatment and devices, complex (modes) of intervention, practices, policies
Nova Scotia	Capital Health Drug Evaluation Unit/Drug Evaluation Alliance of Nova Scotia (DEANS)/Dalhousie University	1998	Drugs, practices, policy
Ontario	Ontario Health Technology Advisory Committee (OHTAC) and Medical Advisory Secretariat (MAS)	2003	Drugs, treatment and devices, complex modes of intervention, practices, policies
	Institute for Clinical Evaluative Sciences	1992	Drugs, treatment and devices, complex modes of intervention, practices, policies
	London Health Sciences Center/High Impact Technology Evaluation (HiTec)	2004	Drugs, treatment and devices, complex modes of intervention, practices, policies

	Evidence-based Practice Center/University of Ottawa	2002	Drugs, treatment and devices
	Evidence-based Practice Center McMaster University	1997	Drugs, treatment and devices, complex modes of intervention, practices, policies
	Program for Assessment of Technology in Health (PATH)/McMaster University	2003	Drugs, treatment and devices, complex modes of intervention, practices, policies
	Toronto Health Economics and Technology Assessment Collaborative (THETA)/University of Toronto	2007	Drugs, treatments
	Technology Assessment at Sick Kids (TASK)/Toronto Sick Kids Hospital	2007	Drugs, treatments and devices, complex modes of intervention, policies
Prince Edward Island	None		
Quebec	Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS)	1988	Drugs, treatment and devices, complex modes of interventions, practices, policies
	Conseil du médicament	1988	Drugs
	Technology Assessment Unit (TAU) McGill University Health Center (MUHC)	2002	Drugs, treatment and devices, practices
	Unité d'évaluation des technologies et des modes d'intervention en santé (UETMIS)/Centre hospitalier	2005	Treatment and devices, practices
	Direction de l'évaluation des technologies et des modes d'intervention en santé/Centre hospitalier universitaire de l'université de Montréal (CHUM)	2005	Treatment and devices, practices
	UETMIS/Centre hospitalier universitaire de Québec (CHUQ)	2005	Treatment and devices, practices
Saskatchewan	Health Quality Council (HQC)	2002	Treatment, practices, drugs, complex interventions
National	Canadian Agency for Drugs and Technologies in Health (CADTH) HTA Drugs and Devices Common Drug Review Canadian Optimal Medication Prescribing and Utilization Service (COMPUS)	1989	Drugs, treatment and devices, complex modes of intervention; Drugs, policies; Drugs, practice
	Applied Research and Analysis Directorate (ARAD)/Health Canada	1999/ 2000	Drug policy

## A.2 HTA providers in the Netherlands

Table 2: HTA providers in the Netherlands<sup>34</sup>

<b>HTA provider</b>	<b>Brief description of scope</b>
Netherlands Organization for Health Research and Development (ZonMw, formerly the National Fund for Investigative Medicine)	National health council appointed by the Ministry of Health and the NWO to promote quality and innovation in health; responsible for programming, priority setting and allocation of government funds; the ZonMw Health Care Efficiency research program supports cost-effectiveness studies and implementation research
Netherlands Organization for Scientific Research (NWO)	Statutory body with the goal of improving the quality of health research in the Netherlands; has supported HTA assessments and initiatives
Council for Public Health and Health Care (RVZ)	Independent government advisory body, created in 1995; issues advisory reports on health policy, including prevention, health protection, general health, and social care
National Institute for Public Health and the Environment (RIVM)	Evaluates and monitors vaccines and medical devices, among other technology assessment activities
Netherlands Institute of Primary Health Care	Independent, nonprofit research body involved in health service research, including technology assessment
Netherlands Organization for Applied Scientific Research (TNO)	Most influential biomedical technology institute; evaluates medical devices and coordinates European Union-wide HTA activities; does not conduct much technology assessment itself
Dutch Institute for Healthcare Improvement (CBO)	Conducts quality assurance and HTA
Academic institutions	Erasmus University, Institute for Medical Technology Assessment

### A.3 Stakeholders interested in HTA in the Netherlands

Table 3. Stakeholders interested in HTA in the Netherlands<sup>41</sup>

Stakeholder	Involvement in HTA
Government (Ministries of Health and of Education, Culture and Science)	Involved with the Fund for Investigative Medicine and also sometimes funds other priority assessments; historically government allowed other organizations to take leadership with regard to HTA; however, there are now more active promoters of HTA
Parliament	Helped to create an environment conducive to HTA by asking questions and holding hearings
Independent research institutes, think tanks and academia (Rathenau Institute, Netherlands Institute of Primary Healthcare, Erasmus University)	Advise government on institutionalizing HTA and conduct assessments
Netherlands Organization for Scientific Research (NWO)	Statutory organization tasked with improving the quality of research in the Netherlands; the Stimulation Program for Health Research, part of NWO, includes HTA; also evaluates the scientific merit of proposals submitted to the National Fund for Investigative Medicine
Netherlands Organization for Health Research and Development (ZonMw)	Advises government on policy issues regarding research—namely, identifying priorities for research; determines priorities according to importance for public health and scientific interest
Health Council of the Netherlands	Statutory body advising government on best practice and evidence related to medicine, health care, public health and environmental protection; reported on health technologies before HTA institutionalization by convening experts to evaluate the effectiveness, efficiency, safety, and availability of health technologies, including any proposal for mass population screening; currently, uses HTA results for priority setting and guideline production; presents all reports, complete with implementation recommendations, to the Minister of Health; disseminates results through journals, websites, and other means
Health Insurance Council (CVZ)	Includes approximately 35 members representing major health care interests; funded early HTA studies and is one of three founding members of the National Fund for Investigative Medicine; funds its own evaluations
Council for Health Care	Includes providers, insurers, and consumers; provides policy guidance to government; uses HTA results to inform reimbursement and pricing decisions
National Institute for Public Health and the Environment (RIVM)	Produces data and information that informs priority setting for HTA (e.g., health of the population and financing of the health system)
Dutch Health Research and Development Council	Created in 1996 to promote the efficient allocation of government resources to health research projects; responsible for priority setting and allocation of funds

Netherlands Organization for Applied Scientific Research (TNO)	Medical technology section evaluates the safe, effective, and reliable use of medical devices; small but well established
National Organization for Quality Assurance in Hospitals (CBO)	Involved in quality assurance and technology assessment; its primary focus is the safety, effectiveness, appropriate use, and physical acceptance of established medical practice
Netherlands Institute of Mental Health and Addiction	Interest in evaluation of mental health services

## A.4 Health system problems and HTA solutions

Table 4. Health system problems and related HTA solutions

<b>Problem</b>	<b>HTA theory</b>	<b>HTA solution</b>
Rising costs	HTA considers the potential economic implications of health technologies and bears in mind budget constraints. HTA promotes cost-effectiveness and can help control costs by informing better decisions.	HTA agencies negotiate better prices by using the results of comparative safety and efficacy.
Rising number of available technologies	HTA allows the assessment of added benefit of competing health technologies aimed at promoting a more efficient allocation of resources. HTA potentially has the ability to reduce costs by appraising the value of innovation.	Since 1991, Australia (AHTA) has used HTA to choose among many available technologies to define the public benefits package. In 2003, Canada (CADTH) launched the Common Drug Review as a single national process on which to base formulary recommendations.
Quality disparity	HTA is able to inform health technology implementation and reduce the variability of health care.	The United Kingdom established HTA in 1999 (NICE) to provide evidence and guidelines to standardize access and quality across geographies.
Accountability and legitimacy issues	HTA allows for systematic and transparent decision-making and allows decision-makers to be held accountable for the evidence and the reasoning behind their decisions, ensuring legitimacy and “buy-in” from relevant stakeholders.	In the United Kingdom (NICE), the appraisal committee ensures due process—by ensuring that any vested interests are declared—independence, and broad stakeholder engagement.
Need for coordination of assessment	Having centralized or less fragmented HTA processes allows for economies of scale and scope, and potentially for more influential health policy decision-making.	In Canada (CADTH), health ministers approved a national strategy for the management of health technologies in 2004, including provisions for improved information exchange between HTA agencies, and communication with policymakers. In the Netherlands, the HTA system remains fragmented, which undermines its ability to inform decision-making.