HTAi 2019 Latin America Policy Forum
Background Paper

The Link Between Health Technology Assessment and Decision Making for Resource Allocation

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Introduction

Today, health systems worldwide are forced to operate under increasingly complex political, economic and technical conditions: rapid changes in technology; strong pressure to include new preventive, diagnostic, therapeutic and rehabilitation interventions; population ageing; and health budgets that, year after year, take up a larger share of countries' gross domestic product (GDP).

During the last decades, Latin American and Caribbean (LA) countries have shown substantial health improvements and the entire region has made considerable progress towards universal health coverage (UHC). LA, however, faces the same difficulties as other health systems worldwide, which are aggravated by the inequality, inefficiency and suboptimal health outcomes that still prevail across LA countries (Dmytraczenko 2015; Cotlear et al. 2015; Atun et al. 2015).

Health Technology Assessment (HTA) is a process to assess the potential impact and value of a technology, for example, when analyzing whether or not to include it in a benefits package (INHATA 2018).

Health Technology Assessment (HTA)

Health technologies have become an essential component of every health system. During the last decades, their use has increased significantly. In general, the implementation of new technologies has brought substantial benefits in prevention, safety, health, quality of life and lower rates of adverse events. In settings with limited resources, however, the correct and widespread implementation of technology poses a difficult challenge and, sometimes, a serious problem.

The rapid development of new technologies and the huge volume of available evidence pose a new challenge for health systems. Providing healthcare services means making decisions about the type of interventions that will be offered, the organization of the health system, who will pay for the interventions, who will offer them and how. The challenge is to use available resources to achieve adequate health outcomes, while considering population's expectations and demands.

Many countries have made a firm commitment to reaching universal health coverage (UHC) for their populations. UHC is one of the main objectives of the World Health Organization (WHO). Therefore, prioritizing interventions is a basic strategy. According to WHO documents, social values should be at the center of all deliberative processes.[1,2] In this context, health decision makers have a growing need for more reliable and detailed information to make better and more transparent decisions. They need to maximize benefits and set priorities to overcome budget limitations. HTA's growth and development reflects this need for sound and transparent information to inform decisions on the development, inclusion and use of health technologies.[3] The history of HTA can be traced back to the '70s and is closely linked to this growing concern about the emergence of expensive technologies and health systems' limited capacity to fund their use. Since the '70s, HTA has evolved to become a multi-disciplinary field. The objective of HTA is to gather available evidence to help decision makers, healthcare practitioners and patients understand the relative value of technologies. There is no single definition of HTA. According to one definition, HTA as a multi-disciplinary field of policy analysis that studies the medical, social, ethical and economic implications of the development, diffusion and use of health technology.[1,2]

During the last 15 years, the development of HTA has been remarkable. Today, HTA is an essential part of health systems in many countries. LA countries have undertaken several HTA initiatives. Argentina, Brazil, Colombia, Chile, Mexico and Uruguay have their own HTA agencies—and are INAHTA members. At present, there are many LA countries that use HTA (to different extents) in their decision-making processes to allocate health resources. Most LA initiatives take place under the Health Technology Assessment Network for the Americas (RedETSA), which is coordinated by the Pan American Health Organization (PAHO).

HTA has the potential to be an extremely useful tool for decision makers. However, an inadequate use of HTA may result in inefficient resource allocation, coverage of interventions that offer minimum benefits (if any), delays in patients' access to useful health technologies, unnecessary risks for patients, and sending wrong messages to technology manufacturers and developers, among others.[4] In addition to this, HTA is not a purely technical process. Decision-making processes must consider broad dimensions. HTA decisions have the potential to affect a large number of people and organizations. Therefore, to be fairer and more transparent, HTA processes must be based on a series of basic principles. These principles include transparency, involving all key stakeholders, having a clear system for setting priorities and a clear link between HTA findings and the decision-making process.[5–8]

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HTA is frequently described as a mediating mechanism between research and policy domains. However, to work properly, those involved in HTA need to understand decision makers' needs, values and systems. In turn, decision makers need to know and trust HTA processes (Velasco et al. 2008). Therefore, an effective link between HTA and decision making depends on the structure of the relationship between these two domains.

Agreeing on what makes a good assessment is relatively easy. Defining the components of a good decision, however, is more difficult. This is why establishing a clear link between HTA findings and decision making is internationally acknowledged as a good practice (Pichon-Riviere et al. 2018.; Drummond et al. 2008). The consensus is that the link between HTA and decision making must be clearly established and transparent.

The main objective of the 2019 Latin America Policy Forum, which is in its fourth year, is to explore and discuss:

- different models used in the region and worldwide that link HTA and decision making for the allocation of health resources;
- the advantages and disadvantages and the barriers to and facilitators of said models; and
- the potential applicability of international experiences in Latin America.

The objective of this document is to stimulate the discussions that will take place during the 2019 HTAi Latin American Policy Forum. This document outlines the basic aspects of the link between HTA and health resource allocation decision making and presents a series of examples and experiences from different health systems.

The information presented was obtained from a literature search and the websites of HTA agencies and health systems.

Background

HTAi created the Policy Forum as a neutral venue to hold strategic discussions about the present state of HTA, its development and implications for health care systems, the industry, patients and other stakeholders. HTAi's Policy Forums are attended by representatives of three main groups: (1) decision makers involved in health system decisions about coverage/pricing/reimbursement of drugs and devices; (2) organizations that carry out HTA to inform said decisions; and (3) biomedical companies and manufacturers of medical technology. The Policy Forum has been held for 14 years in Europe and the United States and for five years in Asia. In 2016, HTAi held its first Latin America Policy Forum, making this the fourth Latin America Policy Forum.

The Forum's approach, agenda and logistics were defined by an Organizing Committee made up of representatives of participating institutions (three representatives of the public sector and three representatives of technology manufacturers). Argentina's Institute of Clinical Effectiveness and Health Policy (IECS, www.iecs.org.ar) is serving as the Scientific Secretariat for this Latin America Policy Forum.

The following process is used to select the Forum's central topic:

1. preparation of a list of potential topics using different sources of information;
2. selection the five topics regarded as most relevant (these topics were chosen by Forum organizers and the Scientific Secretariat after consultation with potential Forum participants);
3. a shortlist is sent to participants and topics are ranked using their feedback; and
4. the topic is finalized by the Organizing Committee.

The topic selected for this Forum was "The Link Between Health Technology Assessment and Decision Making to Set Resource Allocation Priorities."

To prepare this background paper, the Scientific Secretariat reviewed the literature and the resources on websites of several organizations involved in HTA and policy making. The purpose of this document is to review the links between HTA and decision making in the allocation of health resources. This is not an exhaustive review; the main objective of this document is to spread basic knowledge and stimulate discussions during the 2019 Policy Forum.

This Policy Forum is closely linked to the three previous Forums. The first Latin America Policy Forum, which was held in Costa Rica in 2016, dealt with "Good Practices in the Application of Health Technology Assessment for Decision Making in Latin America" (Pichon-Riviere 2018 A). This Forum prioritized the following principles as the most relevant to promote HTA in LA countries:

- HTA processes must be transparent and HTA findings must be adequately communicated;
- HTA processes must involve all relevant stakeholders;
- appeals: there must be a mechanism to challenge decisions;
- there must be a clear system for setting priorities; and
- the link between HTA and decision making must be clear.

The second Latin America Policy Forum, which was held in Lima in 2017, focused on the inclusion of different stakeholders in HTA processes (Pichon-Riviere et al. 2018 B). The third Policy Forum was held in Montevideo in 2018 and discussed the value frameworks in HTA (Policy Forum 2018, Background paper: Defining the value of health technology in Latin America: developments in value frameworks to inform the allocation of healthcare resources).

What are the lessons that Latin America could learn from these international experiences? Is it possible to extrapolate these experiences to our region? What is the present state of development of HTA and

its link to decision making in Latin America? These questions will be discussed during the 2019 Latin America Policy Forum to be held in Buenos Aires.

Assessment and decision making

Even though the role of HTA as an important link between research and policy is widely accepted, putting theory into practice is harder than it seems. One of the main barriers derives from the fact that research and policy speak different languages, have different motivations, values, education backgrounds and institutional mechanisms (Velasco et al. 2008). Decision makers have specific information needs and need context-specific data. They need to get the right information within a specific period of time (time frames depend on the decision to be made). Information must be reliable, to the point and written in easily comprehensible language. On the other hand, research tends to produce more general (non-context specific) information. In fact, research results are usually obtained under ideal conditions, which do not reflect the real world, and derive from rigorous methods, usually not compatible with decision-making time frames. This is why the underlying structure of the relationship between HTA and decision making is key to ensure greater coordination between them.

From an organizational point of view, a health system can be divided into macro, meso and micro levels. HTA and its relationship with decision making can be analyzed from the perspective of these three levels. The macro level refers to stakeholders and institutions involved in decision-making processes for the entire health system and public health interventions. The meso level refers to intermediate units, such as hospitals and primary care centers. Finally, the micro level refers to the interaction between individual patients and healthcare professionals. Even though HTA can play an important role in any such level, this document focuses on HTA's role at the macro level. Particularly, we will analyze the role of HTA in informing technology coverage and inclusion decisions (Glassman 2017).

To decide which technologies will be included in a health insurance package, at what price and under which conditions, many countries have clearly defined processes for each stage that go from setting priorities among technologies to be assessed to the final decision.

The process usually starts when a technology is nominated for its potential inclusion in a benefits package. The parties entitled to initiate this process vary between countries and may include the Department of Health or other payers, healthcare service providers, technology manufacturers, patients or users. Even though the first step is to nominate a technology—a step that can be taken by different stakeholders in different countries—not all applications or requests will be necessarily considered. This step calls for **prioritization** to decide which technologies will be assessed and considered for potential inclusion in a benefits package.

The next step in the process is the **assessment**. Here, it is necessary to the define the **scope** of the HTA document, the questions that will be addressed and their relationship to decision makers' information needs. At this point, it is also necessary to define the dimensions that will be analyzed in the HTA report and the stakeholders that will take part in the process. These important decisions will shape the entire HTA process.

The step following the assessment is the one that enables a health system to reach a **decision**. Here, we must refer to two words commonly used to describe this process: *assessment* and *appraisal*. An *assessment* process is the analytical process (both scientific and technical) of gathering and summarizing relevant information about the candidate health technology. Usually, it includes systematic identification of concrete evidence on effectiveness and cost-effectiveness and, in many cases, it may be necessary to obtain new evidence. An assessment process must employ well-defined methods and be potentially replicable in other contexts.

An *appraisal* process is the political process of making a decision or a recommendation about health technologies, taking into account assessment information but also other factors (Stevens & Milne

2004). The English word assessment is usually translated into Spanish as "*evaluación*." However, finding a Spanish equivalent for *appraisal* is harder because sometimes—though, not always—the word is used in the sense of *recommendation* and other times in the sense of *decision making*. This involves weighing the applicability of evidence (e.g. cost-effectiveness threshold), social values and other considerations.

In some health systems (e.g. the United Kingdom's National Health Service), the link between both processes can be clearly perceived as an assessment-appraisal tandem. Ideally, they are expected to be in close collaboration with each other; however, HTA and decision making are two separate processes. HTA informs policy decisions, but is not binding and, therefore, an assessment is not equivalent to a decision. This difference between *assessment* and *appraisal* implies that these processes may be conducted by different agencies or bodies and, particularly, that *assessment* and *appraisal* are qualitatively different processes that must, therefore, be kept separate.

Usually, the assessment process is carried out or commissioned by an entity (usually an HTA agency), while coverage decisions are then made by a committee or a body organized for that purpose. Sometimes, the boundaries between these two entities (i.e. the HTA agency or the entity in charge of the assessment, on one hand, and the entity in charge of making the decision, on the other hand) are not clear or are structured in different ways. For example, both entities may be under the umbrella of the department of health (e.g. HAS in France) or there might be an entity or committee responsible for making decisions that commissions an academic institution to conduct the assessment because there is no agency specifically in charge of assessments (e.g. Brazil and Chile). In other countries, there are several entities in charge of making decisions about vaccines, drugs, devices, etc. Many countries have decided to organize federal HTA agencies that centralize most assessments (e.g. United Kingdom, France, Germany). Other countries have several regional HTA agencies that may or may not be coordinated by a single central agency (e.g. Spain). In some countries, HTA is delegated to upstream units within the department of health, while other countries have created federal committees that coordinate different institutions or bodies to make decisions (e.g. Brazil and Chile).

Finally, the way in which the results of HTA and decision making are implemented and monitored also varies between countries. In some cases, decisions have a strong financial component. In these cases, a health technology will be accessible and covered only for the indication, the patient population and the clinical condition specified by the HTA and the decision, but it will not be available at all upon a non-coverage decision. In many cases, HTA findings are closely related to pricing and may be conclusive when determining how much the health system will pay for a health technology (Maniadakis et al. n.d.; Glassman 2017). In other cases, the results of HTA and appraisal are published as clinical practice guidelines, which may be followed to a greater or lesser extent. In this last case, the link is weaker.

In short, we can summarize the stages of the process as follows: (1) an initial stage to set priorities among the health technologies to be assessed followed by assessment, (2) recommendation, (3) decision making, and (4) implementation. The procedures used to move through these stages, the institutional framework and the entities in charge of the different processes will shape the final relationship between HTA and decision making.

DIAGRAM

Characteristics of the link between HTA and decision making

Each health system is different and, therefore, has a unique HTA structure and establishes a different relationship between HTA and decision-making processes.

On one hand, we have health systems with a very weak link (if any) between HTA and decision making. In these cases, decision makers are not required to get an HTA report to inform their decisions. Therefore, the HTA entity (or HTA agency, if any) might select technologies to be assessed according to their academic interest, for example, without considering decision makers' information needs. These assessments do not necessarily consider dimensions important to decision makers and may not involve all relevant stakeholders (i.e. are not context-specific). These HTAs do not consider decision makers' time frames and their language and content may be very different from what a decision maker can understand or needs. Once the HTA report is ready, it may be published (e.g. in a website) and the responsibility for finding and using it rests with decision makers. The only way of knowing if the HTA report was used or not to inform a decision (and to what extent) is to ask decision makers or to analyze the degree of consistency between HTA findings and the decision. In this example, implementation and monitoring of HTA decisions is very poor as well. HTA may be used to draft clinical practice guidelines (CPG). However, since the implementation of CPGs is not mandatory, adherence is not monitored, and reimbursement or payment decisions will not depend on the correct use of health technologies or interventions as defined in HTA recommendations.

Of course, these are extreme examples of a weak link between HTA and decision making. In Latin America, however, many HTA processes have a lot in common with the above examples—especially during initial stages. There are small HTA offices or agencies and there are no distinct institutions to link their findings with decision-making processes. As a result, HTA agencies do not take an active part in decision-making processes and have minimal or no impact on the health system. Consequently, HTA agencies tend to lack the necessary (human or financial) resources and are caught in a vicious circle: since HTA seems irrelevant to the health system, it does not obtain enough funding and therefore, cannot produce relevant information and exert a greater influence on decision-making processes.

On the other hand, we might think of an example where HTA and decision making are closely and strongly linked. Under this scenario, a country or health system could rely on HTA to inform all their decisions. Sometimes the link can be a statutory requirement, whereby the law prescribes the type of assessment needed in each case or the type of information to be gathered before adding a health technology to a benefits package (e.g. the United Kingdom, France, Brazil and Mexico in LA).

Therefore, when there is a strong link between decision making and HTA, HTA takes a specific policy question as the starting point. The process starts by identifying decision makers' information needs and understanding the problem they face in order to frame a question compatible with HTA research

methods. Since decision makers are required to inform their decisions with HTA findings, they will be keen to take part in the process of framing the question and defining the characteristics of the HTA process. The assessment process will consider dimensions that are relevant for decision makers (e.g. cost-effectiveness or budget impact, if applicable). In addition to this, the process will consider the perspective of all relevant stakeholders (i.e. it will be context-specific). Finally, recommendations issued will be strongly based on HTA findings, which will be a determining factor in decision making. Decisions are implemented and closely monitored—for example, through CPGs applied nationwide—and there are administrative mechanisms that subject all coverage, payments or reimbursements of medicine, technologies or practices to the conditions set forth in the HTA and the decision made.

The previous examples describe two very different types of link between HTA and decision making.

Specifically, when making decisions, the values and criteria applied by decision-making committees—as well as their roles and members—vary significantly among countries. As for decision criteria, some agencies only analyze costs after the effectiveness of a technology is duly proven—for example, if the technology is not proven to be more effective than the existing alternative, the agency does not move forward with the process and the cost analysis (e.g. the IQWiG/G-BA in Germany or HAS in France). Alternatively, some agencies asses health technologies' effectiveness and cost simultaneously and base their decision on cost-effectiveness (e.g. the United Kingdom, Canada, Sweden). During appraisal, some countries also consider other ethical, strategic and legal criteria (e.g. alignment with national health policies, degree of innovation, impact on the economy, etc.). During the 2018 HTAi Latin America Policy Forum held in Montevideo, participants identified a series of essential criteria to decide whetherto cover a new technology: disease burden and severity, effectiveness and safety of the technology, quality of evidence, cost-effectiveness and budget impact (Policy Forum 2018).

Decision-making committees may be made up of government/payer representatives, patients/caregivers/users, healthcare providers, technology manufacturers, and clinical or methodology experts. Some of them have voting rights, while others act only as consultants, as is usually the case with representatives of technology manufacturers and patients. The kind of output produced by these committees also varies between health systems. In some countries, committee recommendations are legally binding and have decision-making authority within the health system (e.g. NICE in UK or G-BA in Germany). In these cases, recommendation and decision making are part of the same step (i.e. appraisal). In other cases, committees issue recommendations that, depending on the country, might have a greater or lesser influence on decision-making processes. In these cases, recommendation and decision making are two separate steps that are, more or less, connected. For example, in many countries, even though the final decision rests with the Secretary of Health, committee recommendations are considered as preliminary decisions and it is rare for final decisions to depart from these recommendations. In other cases, however, decisions may be entirely independent from committee recommendations, and HTA or the consideration of committee recommendations may not be specifically required. In these cases, the link between HTA and decision making is weaker and even if the process has five well-defined steps (prioritization of technologies to be assessed, assessment, recommendation, decision and implementation), these steps may be disconnected.

Finally, legal frameworks and the level of institutionalization of all these mechanisms also varies between countries and health systems, as well as other important characteristics of assessment and decision-making processes, such as transparency and the existence of mechanisms to appeal decisions.

The next section includes a description of the link between HTA and decision making in seven countries. These descriptions take into account all the aspects described above.

International Experiences

In this section, we offer a brief description of the health systems of seven countries, focusing on the link between HTA and decision making according to the following outline:

A) Brief description of health system

B) Analysis of the link between HTA and decision making considering the following stages:

1) Prioritization of assessments

a) Parties entitled to apply for HTA (for a specific topic) and application criteria

b) Link between applications and decision makers' needs

c) Stakeholders involved in prioritization

d) Parties entitled to prioritize topics and prioritization criteria

2) Assessment

a) Institutions responsible for the assessment process

b) Link between decision makers and assessment processes

c) Dimensions considered during assessment and link with decision makers' needs

d) Stakeholders involved in the assessment process and link with decision makers' needs

3) Appraisal

a) Institutions responsible for the appraisal process

b) Dimensions considered to issue a recommendation and/or make decision beyond those included in the HTA report

c) Stakeholders involved in the appraisal process and their role

d) Mechanisms used to issue a recommendation and/or make a decision

e) Link between assessment (HTA report) and appraisal

f) Link between recommendation and decision making (if handled as separate processes)

g) Appeals/revisions

4) Implementation

a) Implementation and monitoring of coverage decisions (i.e. are decisions implemented through administrative mechanisms or as clinical practice guidelines?)

5) Institutionalization

a) Regulatory framework for HTA and its link to decision making

Australia

With a population of 24 million, Australia has a universal health system, funded by taxpayers, that provides free healthcare services to its citizens through its national system known as Medicare. The private sector accounts for approximately 10 per cent of total health-care expenditure. Health policy and the provision of healthcare services are regulated by the Australian Department of Health through its Pharmaceutical Benefits Scheme (PBS), which regulates the provision of medicines to the population; the Medicare Benefits Scheme (MBS), which regulates the provision of other health technologies; and the National Immunization Program (NIP), which regulates the supply and administration of vaccines. Australia has two government agencies that conduct HTA for services provided under the Australian public health system: the Pharmaceutical Benefit Advisory Committee (PBAC), which conducts HTA for medicines to be included in the PBS, and the Medical Services Advisory Committee (MSAC), which conducts HTA for technologies to be included in the MBS. Both agencies give the Department of Health advice on the effectiveness and cost-effectiveness of the technologies to be included in PBS, MBS and NIP benefits. These agencies, that meet three times a year, are made up of physicians, healthcare professionals, economists, patient representatives and the general population. The Australian health system does not fund technologies unless previously assessed by PBAC or MSAC for potential inclusion in Medicare.

1) Prioritization of technologies to be assessed

The PBAC receives HTA applications from technology producers, while the MSAC receives HTA applications both from technology producers and the government. At present, there is no specific prioritization process and assessments are largely based on the requests received.

2) Assessment

The PBAC conducts assessments requested by technology producers. For this purpose, in general, they commission Australian organizations that also gather additional information. The MSAC usually prepares their own reports and also works with other Australian organizations. Both agencies assess effectiveness, cost-effectiveness and disease burden to inform their recommendations to the Department of Health.

3) Appraisal

Both agencies issue recommendations either to use or not use a technology, or to use it just for a subgroup of patients.

PBAC recommendations to the Department of Health are based on the following criteria:

- effectiveness;
- cost-effectiveness and budget impact;
- disease burden;
- alternative treatments;
- uncertainty about clinical benefits and cost-effectiveness; and
- equity.

In addition to these criteria, there is a 'Rule of Rescue', which includes:

- lack of alternative treatments in Australia;
- severe and progressive medical conditions expected to lead to premature death; and
- very low prevalence and incidence of the medical condition.

4) Implementation and Monitoring

Recommendations are available to the general public on websites of the agencies conducting the assessments. The HTA process also includes surveillance of the use of health technologies approved for

inclusion in Medicare.

5) Institutionalization

In Australia, HTA is clearly established as one of the mechanisms used to make public funding decisions. A drug or a health technology cannot be used in the Australian public health system unless a recommendation for use has been previously issued by PBAC or MSAC.

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Brazil

Brazil has approximately 210 million inhabitants. There is a single tax-financed public health system (SUS, for its Portuguese acronym) that covers the entire population, including social security. SUS has a clearly defined benefits package that includes primary care, community care, hospital services, basic medicines, highly complex medication, high-cost medicines, high-complexity procedures, prosthesis, implantable medical devices, diagnostic imaging and diagnostic tests, among others. There is a federal agency that uses formal HTA analysis to make decisions about health services funded with government funds. In 2011, Brazil created the National Committee for Health Technology Incorporation (CONITEC), which issues recommendations to the Department of Health for the inclusion or exclusion of health technologies and regarding other changes to be made in SUS.

Below, we analyze the process used to include new technologies in Brazil's SUS.

1) Prioritization of technologies to be assessed

Anyone can submit an HTA applications. There is a specific mechanism and form for internal applications (i.e. filed by SUS agencies and bodies) and one for external applications (i.e. filed by the industry, patient groups, scientific societies, etc.). Applicants must also submit information to back the request, including (1) description of relevant medical condition, (2) description of the health technology, (3) description of scientific evidence through a systematic review or a scientific-technical report, (4) economic evaluation from a SUS perspective, and (5) budget impact analysis. Information referring to items 3, 4, and 5 must stick to specific methodological guidelines.

There is no official system to set priorities among topics. Once an application is filed, the law prescribes a 180-day term (extendable for 90 days) to make a decision.

2) Assessment

CONITEC analyzes the information attached to the inclusion request and determines whether it is necessary to obtain additional information. Additional information may refer to the medical

condition, the assessed technology, scientific evidence supporting its use, cost-effectiveness from SUS perspective, and potential budget impact. Additional assessments needed, if any, are conducted by the Executive Secretariat of CONITEC (DGITS) or, alternatively, commissioned to external entities. Stakeholders have another opportunity to make contributions during public consultation, which takes place in all cases after the evaluation of all available information by CONITEC and their preliminary conclusions. Occasionally, users (patients) are actively invited to submit information for the selection of the technologies to be assessed, comment on the assessment approach, send data to be considered when preparing the report, and comment on the first or draft version of the report.

3) Appraisal

The body responsible for producing recommendations is CONITEC's Plenary Meeting, which is made up of 13 members that represent each of the following groups.

a) Representatives of the seven secretariats of the Ministry of Health: the Secretariat of Science, Technology and Strategic Supplies; the Executive Secretariat; the Special Secretariat for Indigenous Health; the Secretariat for Health Care; the Secretariat of Health Surveillance; the Secretariat of Strategic and Participatory Management; and the Secretariat of Labor and Education Management in Health
b) National Health Council (CNS)
c) National Agency of Supplementary Health (ANS)
d) National Health Surveillance Agency (ANVISA)
e) National Council of Health Secretaries (CONASS)
f) National Council of Municipal Health Secretaries (CONASEMS)
g) Federal Medical Council (CFM)

The Plenary Meeting analyzes available information and makes a preliminary recommendation for the inclusion or exclusion of the health technology. CONITEC uses this information to initiate a 20-day public consultation process where all stakeholders (i.e. industry, patients, users, scientific societies, etc.) can comment on available information and preliminary conclusions or submit additional information. After analyzing this new information, the Plenary Meeting ratifies or rectifies its original recommendation. Recommendations are then sent to the Secretariat of Science, Technology, and Strategic Supplies (SCTIE), which makes the final decision. The SCTIE decides on the need to hold a public hearing before making a decision based on CONITEC's recommendations. When held, public hearings are called and carried out by CONITEC.

There are no specific inclusion criteria (e.g. cost-effectiveness threshold). However, according to the laws governing CONITEC's activities, CONITEC is responsible for incorporating new technologies according to *"rational criteria and efficacy and effectiveness parameters relevant to the health needs of citizens and the health system on the basis of cost-effectiveness."* Under these laws, assessment and appraisal processes must consider the health needs of the population, scientific evidence on effectiveness and safety for the health technology, organizational impact, cost-effectiveness, and budget impact.

4) Implementation and monitoring

SCTIE's decisions on inclusion, exclusion or change of covered technologies are implemented in SUS effective benefits package. Only technologies included in the package after CONITEC's HTA can be funded with public funds. CONITEC is also responsible for preparing clinical practice guidelines and national protocols that are also used to support coverage decisions.

5) Institutionalization

In Brazil, legislation clearly defines the role of HTA in decision making. CONITEC was created by Federal Law No. 12,401, passed on April 28, 2011. Under this law, any technology included in the benefits

package must go through an HTA process. CONITEC recommendations are not legally binding; the final decision is made by the Department of Health through its SCTIE Secretariat. However, most SCTIE decisions are consistent with CONITEC's recommendations. On the other hand, SCTIE's decisions are legally binding and define the characteristics of the benefits package to be funded with public funds.

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Canada

Canada's publicly funded health system is financed with general revenue raised through federal, provincial and territorial taxation. Roles and responsibilities are divided between these levels of government. Each province is responsible for administering and offering health care according to national standards.

The five principles of the Canada Health Act are:

1. the health insurance plan must be administered by a public authority;
2. access to medically necessary hospital, physician and dentistry services;
3. universality;
4. accessibility; and
5. portability: coverage must be maintained when an insured person moves or travels within Canada or travels outside the country. There is a wide network of primary and secondary-hospital care.

The national regulatory agency is Health Canada.

There is a main independent, non-for-profit HTA agency known as the Canadian Agency for Drugs and Technologies in Health (CADTH) and some provinces have their own agencies (Health Quality Ontario; INESS in Quebec, etc.).

Our analysis of the link between HTA and decision making refers particularly to CADTH, since this is the most important agency in Canada and plays a prominent role in decision-making processes to include new technologies.

1) Prioritization

There is no prioritization process because all new drugs and indications approved by the regulatory agency are assessed. The industry sends dossiers that are assessed on a first come, first served basis. There is a six-month period between the date the dossier is submitted and the date the recommendation is issued. Companies may opt to submit a clinical and economic dossier simultaneously. In these cases, if the drug is not approved, the HTA report is not published. In the case of medical devices, diagnostic procedures, medical procedures, programs and other interventions, there is a selection or prioritization process because not all of them are evaluated. Some provincial agencies

work on this together with the pan-Canadian Collaborative to centralize optimal identification and prioritization of topics across Canada.

HTA applications can be submitted by technology manufacturers and producers through the corresponding CADTH body. In the case of drugs, applications are sent to the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review Process (pCODR). Other stakeholders may also file HTA applications for drugs, such as support groups for cancer patients, which can ask pCODR to consider a specific technology. The CADTH can also initiate HTA processes when considered relevant for the entire population—though criteria used to make these requests are not explicit. DCR in-house and external experts, for example, assess requests received and interact with the industry. Those assessments are then sent to the Canadian Expert Drug Advisory Committee (CEDAC). CEDAC holds monthly meetings and issues recommendations. Any public healthcare worker—clinician or decision maker—can request a Rapid Assessment of a topic.

2) Assessment

There are different types of processes, ranging from full HTA reports to intermediate reports and rapid assessments. These processes are conducted internally by CADTH or "reliable" contractors (i.e. individuals, academic groups and small companies). In the case of Quebec there are two entities, INESS and Conseil du Médicament. Basic criteria used includes clinical effectiveness, cost-effectiveness and budget impact. Depending on the type of drug to be assessed, CADTH calls and coordinates different stakeholders. The CDR works with a clinical-economic expert panel and pCODR with a Clinical Guidance Panel. These panels conduct the clinical review and consider the opinions of other stakeholders. An Economic Guidance Panel conducts the economic review and considers the opinions of several stakeholders, including members of the Clinical Guidance Panel. There is also a consultation process with the applicant, the manufacturer (if different), pre-registered patient groups and the Provincial Advisory Group. Decision makers are also involved in this process in several ways: the board includes several senior government officials and advisory committees with representatives of provincial and territorial government officials, who also help set priorities. All provinces and territories have a CADTH Liaison Officer to have direct access to decision makers. All decision makers can observe expert panel discussions and make recommendations. Decision makers can also submit an official Request for Advice to ask for clarifications of expert committee recommendations and take part in recommendation committees (e.g. CEDEC or pERC).

Finally, these experts check all the information submitted and reach a conclusion using a deliberative framework. After that, they issue an initial recommendation.

3) Appraisal

There are three expert committees that issue and support recommendations. All recommendations are public and subject to public consultation.

The three committees are:

- the Pan-Canadian Oncology Drug Review Expert Review Committee (pERC) for oncology drugs;
- the Canadian Drug Expert Committee (CDEC) for all other drugs; and
- the Health Technology Expert Review Panel (HTERP) for medical devices and diagnostic tests, procedures, programs and other interventions.

What's unique about Canada is that there are specific assessments and recommendations depending on the type of health technology. In general terms, despite the differences between committees, their discussions consider patient outcomes, evidence on safety, efficacy, effectiveness, therapeutic advantages and disadvantages, cost and cost-effectiveness as compared to existing treatments, alignment with patients' values, and feasibility of implementation within the health system, among others. These committees produce recommendations for the provinces. Later, provinces make a decentralized coverage decision. There is no official appeals process; stakeholders have different opportunities to engage in dialogue and express their views before the final recommendation. There

is even an 'embargoed recommendation", which is sent confidentially to stakeholders 10 business days before the CDEC's meeting making the final recommendation for them to voice their opinions.

4) Implementation

Committee recommendations are published in the formulary listing recommendations for all types of drug coverage plans. Coverage decisions are implemented by each territory by publishing the effective list of drugs.

5) Institutionalization

HTA reports are one of the key tools used by committees (e.g. CDEC and pERC) to produce recommendations. Final recommendations are not binding on decision makers but are acknowledged as extremely valuable information to inform final decisions. In addition to this, HTA reports are frequently used to negotiate prices with manufacturers at a federal, provincial and territorial level (confidential negotiations). HTA is highly institutionalized in the decision-making process. The characteristics and processes of HTA are defined by CADTH in their Bylaws.

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England

The National Health Service (NHS) provides comprehensive public health care. The NHS is funded mainly from general taxation and, to a lesser extent, by national insurance contributions. Most services are offered free of charge, while some drugs, dentistry and ophthalmology care require minor copayments. Only a few services are financed privately. Most hospitals belong to the NHS. The upper levels of this hierarchical system are responsible for coordinating and framing health policy, while lower levels run and administer health care services.

1) Prioritization of technologies to be assessed

In order to set priorities among health technologies, the National Horizon Scanning Centre (NHSC) provides the Department of Health and Social Care, national policymakers and the NHS with advance notice of new and emerging health technologies that might require urgent evaluation, consideration of clinical and cost impacts, or modification of clinical guidance. There is a national program in charge of setting HTA priorities that receives support from expert advisory panels made up of technicians and clinicians. Criteria used to set priorities are based on the following questions.

- Which are the benefits in terms of reducing uncertainty? This may refer to:
  - patient outcomes;
  - cost-effectiveness (population-based) for NHS;
  - targeted services; and
  - methodological improvements through HTA.
- How much sooner can benefits be obtained, considering the time needed to conduct the assessment and implement changes in current practices?
- Value for money
- Importance of an early assessment
- Other factors (e.g. policy considerations, prevalence of condition, and social/ethical concerns)

2) Assessment

NICE is responsible for HTA through their NICE-HTA program. HTA reports are prepared by experts or academic centers. The Department of Health and Social Care of the UK has set forth a series of directions that NICE must take into account during HTA: balance of clinical benefits and costs (i.e. cost-effectiveness); degree of clinical need of patients with the disease under consideration; NHS' clinical priorities; effective use of resources and promotion of innovation; and any other direction from the Secretary of State. Decisions should reflect social values obtained through social value judgements.

From an operating perspective, the following dimensions are considered.

- Disease burden: severity (mainly from the perspective of end-of-life care), treatment availability (unmet needs) and prevalence.
- Therapeutic and safety impact: efficacy, safety, clinically meaningful outcomes (preferred), intermediate (surrogate) outcomes, health-related quality of life, dealing with uncertainty explicitly (quality of evidence), implicitly (preference for RCTs), and indirectly (rejection if not backed by scientifically robust evidence).
- Level of innovation
- Cost-effectiveness and budget impact analysis
- Alignment with NHS' health priorities
- Ethical considerations
- Resource impact (cost impact on the NHS or the public sector)

- Clinical and policy importance (if the matter falls within a priority area for the government)
- Presence of inappropriate variation in practice
- Potential factors affecting the timelines for the guidance to be produced (degree of urgency, relevancy of guideline at the expected date of delivery)
- Likelihood of guidance having an impact on public health and quality of life, the reduction in health inequalities, or the delivery of quality programs or interventions.

During HTA, the involvement of other stakeholders is also considered. At the beginning of this stage, there is an initial meeting with those who took part in the appraisal committee. During assessment, technology manufacturers may be requested to send additional or supplementary information.

3) Appraisal

NICE HTA recommendations are prepared by an independent entity known as the Technology Appraisal Committee (TAC). TAC members serve for three-year terms and include NHS members, representatives of caregivers and patient organizations, scholars and industry representatives. Usually, no other factors are considered when producing a recommendation because the assessment process already includes multiple, broad and deep evaluations.

For the process of formulating recommendations, different stakeholders are called (consultees and commentators). These stakeholders can play different roles.

Consultees include:

- national groups representing patients and caregivers,
- health professional bodies,
- manufacturers of the technology under review,
- the Department of Health,
- the Welsh Assembly government,
- specialized commissioning groups, and
- primary care trusts and local health boards.

Consultees may submit evidence during appraisal, comment on appraisal documents and file appeals against final recommendations issued by the Appraisal Committee. In addition to this, consultees other than manufacturers are required to appoint experts in patient care or clinical experts.

Commentators include:

- manufacturers of comparator technologies,
- NHS Quality Improvement Scotland,
- any relevant National Collaborating Center (groups commissioned by NICE to develop clinical guidelines, if relevant,
- related research groups, and
- other groups (such as the NHS Confederation, the NHS Purchasing and Supplies Agency, the British National Form, the Scottish Medicines Consortium, the Medicines and Healthcare Products Regulatory Agency, the Department of Health, Social Services, and Public Safety for Northern Ireland, and patient or professional organizations that only cover Wales).

These organizations are invited by NICE to take part in the appraisal process and issue comments on the documents prepared during the process. Commentators cannot appeal final decisions.

TAC makes the recommendation during the final meeting. They gather in a face-to-face meeting (usually there are two of these meetings) and engage in a thorough discussion of all aspects assessed. They try to reach a consensus and disagreements are settled by a simple majority vote. Final

recommendation decisions are made by the chair of the committee. The decision-making process is strongly linked with the assessment process. There is early interaction between the assessing team and the appraisal team through an initial meeting to approach the technology and another one to present results and address additional changes to the HTA report. Both assessment and appraisal are used to inform coverage and reimbursement recommendations about health technologies and fix selling prices; though, in general, price decisions are made after a posterior negotiation process.

4) Implementation and monitoring

The decision is implemented through clinical prescription guidelines and drug forms. NHS is legally bound to implement guidelines and all coverage recommendations within a term of three months as from the date the recommendation is put forward. NICE has developed a program to support implementation of HTA and guidelines, and also follows up the implementation of their guidelines by related NHS divisions.

5) Institutionalization

NICE was originally set up in 1999. However, their current role only dates back to 2013, when they were established in legislation as a Non-Departmental Public Body. Before 2013, NICE's current responsibilities rested with the Department of Health and Social Care, NICE's main funding source. Operationally, however, NICE is independent from the government. The NICE Board sets their strategic priorities and policies, but day-to-day decision making is the responsibility of their Senior Management Team.

Officially, their guidance is England-only. However, they have agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland. Decisions on how their guidance applies in these countries are made by the devolved administrations, who are often involved and consulted with in the development of NICE guidance.

NICE's role is to improve outcomes for people using the NHS and other public health and social care services. Therefore, HTA is only one of the many things they do. In addition to that they produce evidence-based guidance and advice for health, public health and social care practitioners; develop quality standards and performance metrics for those providing and commissioning health, public health and social care services; and provide a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

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Germany

The German health system is a hybrid public-private system where the public sector takes up the larger share. The German public health system was shaped during the industrial revolution of the late 19th Century and was among the first public health systems in Europe. Today, Germany has a Statutory Health Insurance System (SHI), in which the entire population is required to maintain health insurance. SHI is based on medical care funds. Funding comes from statutory financial contributions from employers and employees (based on workers' income). The children of beneficiaries receive coverage and retirees are charged a percentage of their retirement annuity. The unemployed have access to medical care through the government, which undertakes the share otherwise payable by the employer. People with higher levels of income may opt for private health insurance, but their employers are only required to contribute the amount applicable to public insurance. State health insurance providers are self-governing bodies called GKV (Statutory Health Insurance Funds, for its German acronym). The state establishes a regulatory framework and plays an oversight role. Each Fund has a direct contractual relationship with their healthcare service providers. Under the German system, patients are free to choose their practitioners (both primary care physicians and specialists). The federal government is responsible for overseeing the contractual relationship between insurance companies and healthcare providers, defining the benefits package and guaranteeing care to chronic patients. According to data from 2013, 99.8 per cent of the population had some type of health insurance.

The Federal Joint Committee (G-BA, for its German acronym) decides which medical services will be covered by SHI. G-BA decisions are binding across the entire country. G-BA is made up of the National Associations of Statutory Health Insurance Physicians and Dentists, the German Hospital Federation, and the National Association of Statutory Health Insurance Funds. The G-BA has broad regulatory powers to decide on the coverage of innovative diagnostic and therapeutic services, quality of outpatient and inpatient care, and drug regulation (except for marketing approvals). The Institute for Quality and Efficiency in Health Care (IQWiG, for its German acronym) is responsible for preparing HTA reports on drugs, devices, interventions and diagnostic methods. Their recommendations are strong, but not binding, on the G-BA. The Federal Institute for Drugs and Medical Devices (BfArM, for its German acronym) makes decisions concerning the approval of pharmaceuticals. BfArM evaluates safety, efficacy and quality. Diagnostic methods are assessed as medical devices and must meet European Community requirements. In Germany, except for a few exceptions, drugs approved by EMA (European Medicines Agency) or BfArM are covered by SHI. The German Institute of Medical Documentation and Information (DIMDI, for its German acronym) works jointly with the Department of Health in HTAs, but with a different approach. Their reports are designed to inform health policies but are not primarily aimed at defining the benefits package. IQWiG can commission DIMDI to conduct HTA, but IQWiG's assessments of benefits differ from those produced by DIMDI.

We will analyze the link between HTA and decision making in Germany across the different stages, focusing on the relationship between IQWiG and G-BA with regard to the benefits package under SHI.

1) Prioritization of technologies to be assessed

HTA applications may be submitted by those insured by SHI and other stakeholders through a website. Applications may request the assessment of drugs for specific indications, diagnostic tests, medical treatments, and quality and efficiency aspects. Most reports commissioned by G-BA are aimed to inform coverage decisions. Prioritization is carried out by a first IQWiG committee, made up of representatives of patient organizations, self-help groups for people with disabilities and patients with chronic illness, representatives of the Federal Government Commissioner for Patients' Affairs, a representative of chronic care, and members of the general public. The committee selects 15 topics and frames HTA research questions. A second committee, an extended Expert Committee, analyzes this initial short list of candidate topics. This second committee is made up of representatives of the Foundation for Quality and Efficiency in Health Care (IQWiG's governing body) and a representative of the Department of Health. Together, both committees select up to five topics. According to IQWiG,

in addition to the scientific perspective, the inclusion of these stakeholders guarantees that general public's and patients' perspectives, preferences and values will be considered for prioritization purposes. Committee decisions are aimed at identifying the most relevant topics, considering the following factors, among others:

- number of people affected;
- disease burden or severity of the condition;
- complexity of evidence available to answer research questions;
- existence of previous HTA reports on the same topic in Germany; and
- intervention-related cost.

2) Assessment

IQWiG commissions one of their suppliers to conduct HTA according to explicit rules. IQWiG requires the following principles to be applied during the assessment.

- Independence: the contents of reports cannot be influenced by industry, health insurance funds or public authorities. All parties involved in IQWiG reports must disclose all potential conflicts of interest.
- Evidence-based: reports must be based on evidence (proof), rather than personal opinions.
- Patient-oriented: benefits are assessed considering patients' preferences and needs.
- Transparency: in addition to publishing the final results of an assessment, all intermediate stages of a report are published, including draft and preliminary reports. Patients, the pharmaceutical industry, insurance companies and other stakeholders can submit comments on these intermediate stages, which are considered by the IQWiG in meetings specifically held for this purpose. These meetings can influence the final version and, exceptionally, an additional oral discussion is held. Preliminary versions are sent to external observers and efforts are made to involve all relevant stakeholders in the process. Assessments consider efficiency, quality and safety, as well as economic and financial aspects. For financial justification purposes, special focus is placed on the existence or lack of additional benefits as compared to other available technologies. Sometimes, experts and patient associations are asked to express their opinion to assess benefits from users or beneficiaries' perspective. Patients' opinions and experiences are recorded using qualitative research tools. IQWiG interviews patients and/or patients' representatives during the assessment phase. The G-BA, in turn, is a member of the advisory group PREFER, which focuses on when and how to include patients' preferences in decision-making processes. This is the only way in which the G-BA takes part in the assessment process.

3) Appraisal

Final coverage and reimbursement decisions are made by the G-BA. In addition to the criteria used during the assessment, the G-BA considers the level of additional perceived benefits offered by the health technology. In order to fix reimbursement and sale prices, the G-BA classifies benefits as being:

- major: healing, significant improvement in survival, long-lasting absence of serious symptoms or adverse events;
- significant: attenuation of serious symptoms, moderate improvement in survival;
- marginal: Reduction of mild symptoms;
- not quantifiable; or
- no additional benefits offered: benefits offered are less than those offered by comparator.

The G-BA may also request a revision or issue comments on the document delivered by IQWiG. In addition to this, if evidence about an assessed technology changes over time, it is possible to apply for an update on the topic.

4) Implementation and monitoring

In Germany, in most cases, drugs approved by BfArM or EMA are covered by health insurance. Once the level of benefit is determined, the G-BA makes pricing and reimbursement decisions. Before that, prices are fixed by technology manufacturers.

5) Institutionalization

Even though the conclusions of IQWiG's HTA reports are closely related to the final decision, the report is not legally binding on the G-BA. IQWiG reports are public and, therefore, can be used by private health insurance companies, patient associations, and the general public.

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Scotland

The population of Scotland stands at about five million. Life expectancy in Scotland is lower than that of the United Kingdom and the rest of Europe, with the three leading causes of death being cardiovascular disease, cancer and chronic respiratory disease. Scotland has a universal health system, financed through taxation, that provides free health care to the entire population. The private sector is very small. Scotland's Ministry of Public Health, Sport, and Wellbeing is responsible for health policy and the provision of healthcare services. The Ministry delegates these responsibilities to 14 regional NHS boards. The provision of health care services is administered regionally, except for some services managed at national level, such as ambulances, medical records, education, training and quality improvement initiatives. Approximatively 85 per cent of total health expenditure comes from public sources, while the remaining 15 per cent is private and usually relates to dentistry and ophthalmology. Approximately 90 per cent of healthcare services are provided by general practitioners who work in multidisciplinary teams made up of nurses, obstetricians, social workers and administrative workers.

Scotland has two government agencies that conduct HTA: the Scottish Health Technologies Group (SHTG), which is in charge of assessing non-drug technologies, and the Scottish Medicines Consortium (SMC), which conducts HTA for drugs. Both agencies give effectiveness and cost-effectiveness advice to Scottish NHS regional boards. The SMC meets on a monthly basis, while the SHTG meets every three months. These meetings are open to the public and can be attended with advance registration. Both agencies are made up of clinicians and representatives of the industry, health districts, patients and the general public. No drug can be used in Scotland unless previously assessed by the SMC.

1) Prioritization of technologies to be assessed

In the case of the SHTG, any person can submit an HTA application by filling a specific form. Forms are prioritized using pre-defined criteria. If a decision is made to move forward with the assessment

process, the applicant is invited to submit information to SHTG's Evidence Review Committee (ERC). The final decision to move forward with the assessment rests with ERC.

In the case of the SMC, HTA application are filed by the pharmaceutical industry and are assessed by SMC's New Drugs Committee (NDC).

2) Assessment

In the case of non-drug technologies, if a decision is made to assess the technology, Evidence Notes (EN) are prepared. EN range from rapid reviews (which do not include systematic reviews) of approximately 10-15 pages prepared in a one to six-month period (depending on the amount of information available and the question to be answered) to full systematic reviews that may take between six and 18 months.

In the case of drugs, SMC's NDC issues a preliminary recommendation based on interactions with technology manufacturers and assessment findings, which is independent from available evidence. Later, expert recommendations, and general public and patients' opinions are included to produce a final recommendation to the NHS regional boards.

The SMC evaluates and makes recommendations considering effectiveness, disease burden, existing treatments and cost-effectiveness. The process, from application to final recommendation, takes approximately 18 weeks.

3) Appraisal

Both agencies make recommendations to either to use or not to use the technology, or to use it only for a subgroup of patients. The most frequent reasons why the SMC may recommend not to include a drug are: (1) the comparator is not adequate in the Scottish context, (2) the new drug is not better than a cheaper drug, (3) not cost-effective, or (4) HTA application not submitted by manufacturers.

4) Implementation and Monitoring

In 2013, the government analyzed access to new technologies and implemented some changes that are now in full force and effect (e.g. meetings of both agencies involved in HTA are now open to the public). On the other hand, in 2016, another review was made to evaluate access to technologies aimed at treating orphan diseases and end-of-life care.

5) Institutionalization

Technologies with a recommendation to use must be covered in all health system regions. In the case of technologies with a recommendation not to use, the region may submit an Individual Patient Treatment Request. All regions failing to observe a recommendation, shall justify any such decision.

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Thailand

Thailand has offered universal coverage since 2001 through three public health insurance programs. A person can be affiliated only to one of these public programs depending on their employment status. The Civil Servant Medical Benefit Scheme (CSMBS) covers both active and retired government employees and their families; the Social Security Scheme (SSS) covers active private sector employees; and the rest of the population not covered by SSS and CSMBS is covered by the Universal Coverage Scheme (UCS). In 2014, out of Thailand's 66 million inhabitants, 97 per cent had access to a health plan: 48 million were covered by UCS, 11 million (17 per cent) by SSS, and seven million (seven per cent) by CSMBS. There are also some private health insurance programs that account for a small percentage of beneficiaries.

Each subsector has its own package with specific coverage, funding and provider payment methods. Medicine expenses are reimbursed in all three programs according to the national list of essential medicines. High-cost medicines for all public health care providers are purchased centrally to increase the government's bargaining power. The UCS is funded from general taxation. The UCS beneficiaries are referred to specialists by primary care physicians through a system of capitation payments. The National Health Security Office (NHSO), an autonomous organization chaired by the Secretary of Health, decides the content of the UCS package through the Subcommittee for the Development of the Benefit Package and Service Delivery. The SSS is financed with contributions made by employees (calculated according to wage), employers and the government. The SSS has agreements with hospitals for the provision of health care services and uses a capitation system. This sector is managed by the Social Security Office of the Ministry of Labor, which oversees defining the benefits package for the SSS. Finally, the CSMBS is funded through general taxation and beneficiaries can seek care in any public or private hospital contracted by CSMBS. The payment methods are capitation (for services or interventions provided) and fixed rates for some diagnostic-related groups. This program is run by the Comptroller General's Department of the Ministry of Finance, which acts as payer but does not decide the content of the benefits package.

Bellow, we analyze the process followed in Thailand to include new technologies in the benefits package of the UCS.

1) Prioritization of technologies to be assessed

The list of candidate topics can be prepared by representatives of different stakeholders: coverage policymakers, scholars, healthcare practitioners, patient groups, civil society groups and representatives of the healthcare industry. Only a fixed number of topics can be submitted, twice a year, to the Health Intervention and Technology Assessment Program (HITAP), an institute that conducts research into health policy, sponsored by the Ministry of Public Health. In addition to this this agency sends an invitation to said representatives every year asking them to send their suggestions. Apart from suggesting a topic, applicants must provide information to support and establish the relevance of their request. Possible topics include drugs, devices, disease prevention programs and health promotion programs. Decision makers may also request that a specific topic be assessed. The resulting list is revised by HITAP researchers, who exclude topics already assessed during the last five-year period, technologies already proven effective, topics not directly related to health, and other topics which, at their discretion, should be assessed by other agencies. A short list is prepared and priorities are set by a panel made up of representatives from four groups of stakeholders (healthcare practitioners, scholars, patients and civil society groups that did not take part in group in charge of preparing the list) using six criteria: size of affected population, disease burden, effectiveness of interventions, practice variations, economic impact on household spending, and ethical and social implications. HITAP's research staff facilitates topic selection by offering additional information. Each selection criterion has been identified through an explicit approach based on well-defined parameters and thresholds using multiple-criteria decision analysis. Proposed interventions are classified using this system and ordered through a process conducted by HITAP jointly with other stakeholders

invited to take part in the discussions. The resulting list is then submitted to the Subcommittee for the Development of the Benefit Package and Service Delivery for final selection.

2) Assessment

Topics approved by this subcommittee are assessed in an HTA report, prepared either by HITAP or the International Health Policy Program (IHPP). HTA methods defined by Thailand are closely followed and the process is carried out in collaboration with external experts. Thai guidelines recommend quantifying incremental costs and health outcomes, expressed as quality-adjusted life year (QALY), for the new interventions versus standard practices through the incremental cost-effectiveness ratio (ICER). In addition to this, a budget impact analysis is performed. Relevant stakeholders take part in defining research questions, validating results, and preparing the preliminary recommendations to be included at the end of the HTA report.

3) Appraisal

These reports and preliminary recommendations are submitted to the SCBP, which will issue an opinion and a final recommendation to be considered by final decision makers. Though not explicitly defined, the criteria used may also include HTA findings, feasibility and social values judgements. With regard to cost-effectiveness, SCBP considers a threshold of per capital GDP per QALY gained. SCBP's final recommendation is submitted to NHSO's board of members, who make the final inclusion or exclusion decision. The main criteria used by NHSO are value for money invested in health and budget impact.

4) Implementation and monitoring

NHSO decisions are implemented in the benefits package of UCS. There is no explicit system of appeals to challenge NHSO inclusion decisions.

5) Institutionalization

Recommendations from HTA reports are not legally binding; the use of HTA reports by decision makers is voluntary. HITAP has no legal authority; rather, it serves as a technical agency for all public health authorities across Thailand. HTA reports are available for free in HITAP's website. In addition to this, to enhance the usefulness of HTA, HITAP has developed a system to communicate research results and recommendations to the main stakeholders, including policymakers who make decisions on coverage, healthcare workers, patients, the healthcare industry, and the general public. HITAP communicates with stakeholders through policy forums, formal presentations, technical discussions, articles published in national and international journals, and public media like websites, bulletins, books, newspapers, radio and television. At present, HTA is applied mainly to pharmaceuticals and medical devices, and includes an assessment of regulatory frameworks, coverage policies and the information actually demanded by real HTA users. Development in the fields of health promotion and prevention, public health and other social initiatives is not as extensive because these areas are not regulated in Thailand.

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Conclusions

A close link between HTA and decision-making processes is a major principle of good HTA practices. A weak link may render all HTA efforts useless. However, just as agreeing on what makes a good assessment is relatively easy, determining how HTA should be linked to the decision-making process is harder.

This difficulty stems partly from the differences between health systems worldwide, their institutions and their broad range of links and mechanisms. However, the analysis of different international experiences shows that there are common elements. A successful link between HTA and decision making can only take place if those preparing and working on HTA consider the needs, values and mechanisms used by decision makers. A correct institutionalization of HTA structures, transparency and a formal link between HTA and decision making are also needed. Institutions, mechanisms and processes must adapt to the characteristics and needs of each health system; it is not possible to find a one-size fits all solution or to extrapolate successful experiences to all health systems. However, we could define a benchmark of successful strategies that can then be adapted to each specific health system and context.

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