HTAi 2020 Latin America Policy Forum on Health Technology Assessment

Background Document

Identification and selection of health technologies in need for HTA for reimbursement decisions

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Contents:

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Introduction

Health technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system (O'Rourke 2020). This assessment can address both direct and expected as well as indirect and unexpected consequences. Its main objective is to inform on health care decision making and it is issued by multidisciplinary groups using explicit analytical frameworks based on assorted methods. This

information is then used by health systems for decision-making that particularly affects the allocation of health resources, as is the case, for example, the decision to incorporate or not a specific health technology to the benefits package.

HTA has an ever-growing importance in the world and Latin America (LA). Globally, efforts are focused on strengthening the correct use of HTA; on promoting convergence of different tools and existing value frameworks, on encouraging the creation of the necessary technical resource and on improving participation and involvement of the different actors (van der Wilt, Rüther and Trowman, 2019). However, there are still gaps and differences regarding the way HTA is related to the allocation of health resources. In general and unlike low-income countries, high income countries have a bigger use of HTA in questions related to the reimbursement or decision on what to include in the benefits package (World Health Organization, 2015). Further, HTA stage of implementation is quite heterogeneous in Latin America, there being countries in the early stages of adoption and others in decision-making stage. Therefore, the unquestionable willingness to promote the strengthening of good practices and the generation of informed and deliberative decision-making processes is both a reality and a challenge. (Lessa *et al.*, 2017; Pichon-Riviere *et al.*, 2018)

Health Technology Assessment (HTA)

Health technologies are an essential constitutive part of any health system as has been shown by its increased use in the last decades. The introduction of new technologies has resulted in significant benefits in terms of prevention, safety, health improvement, quality of life or reduction in adverse effects. However, in a current context of limited resources, the accurate incorporation and promotion of technologies have become a challenge and in some cases, even a problem.

The fast emergence of technologies and increased volume of available evidence have become a challenge that health systems must face. To provide health service implies making decisions about which interventions must be offered (and which implicitly or explicitly should not), the way the health system will be organized, who will pay for these interventions as well as how and who must provide them. The challenge then lies on how to obtain adequate health results with available resources considering, in so doing, the social values, expectations and demands of the population.

Currently, many countries have agreed on attaining universal health coverage (UHC) for their population, being one of the prioritized objectives by the World Health Organization (WHO). Regarding UHC, the prioritization of intervention is a central strategy and the documents elaborated by this organism highlights the importance of performing this prioritization considering the best available evidence and social values. [1,2]

In this challenging context then, health decision makers must count on the availability of detailed and reliable information with which to make transparent and legitimate decisions in order to define priorities leading to attaining the highest benefit with limited budgets. HTA growth and development is a clear evidence of the demand for solid and transparent information to ground decisions about development, incorporation and promotion of health technologies. [3]

Precisely, HTA has its origins in this growing preoccupation for the spreading of new and costly health technologies in the 1970s and the limitations of the health systems to sponsor their use. As a discipline, it has experienced an

evolution since the 70s to become a multidisciplinary specialty with the purpose to gather and synthesize available evidence to help health decision makers, health professionals and patients have a clear understanding of the relative value of technologies. HTA can then be defined as the systematic assessment of the properties and effects of a health technology, considering both direct and indirect consequences to be able to inform decision-making. [1,2]

HTA development has been particularly notorious in the last 15 years and has become an indispensable component of the health systems in many countries. There are several initiatives in Latin America and the Caribbean (LA). Argentina, Brazil, Colombia, Chile, Mexico and Uruguay have HTA agencies and members of the International Network of Agencies for Health Technology Assessment (INAHTA). Further, many Latin American countries are currently implementing HTA, each at its own pace, for resource allocation decisions. Most regional initiatives are grouped in Network for Health Technology Assessment in Latin America (http://redetsa.org/), coordinated by the Pan-American Health Organization (PAHO).

HTA is undoubtedly a great tool for decision makers, however, if it is not adequately used , it could lead to deciding on an inefficient resource allocation, approving the inclusion of a low or cero impact benefit or intervention to coverage, hindering or delaying patients' access to useful health technologies, exposing patients to unnecessary risks and sending wrong messages to technology producers, among others [4] Similarly, since HTA is not a purely technical exercise, since HTA-based decisions have the potential to affect a big number of people and institutions and since HTA decision-making process needs to be more and more legitimate, a series of basic principles have been proposed. These aspects define the nature of the principles: transparency in HTA implementation processes, involvement of relevant actors, clear priority-setting mechanisms for HTA, and strong link between assessment and decision-making. [5–8]

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Decision-making depends on having appropriate information when needed; yet, not even the richest countries have been able to get all resources and skills to incorporate or even assess all potentially effective technologies (Henshall 1997). Therefore, it is always crucial to set priorities about which issues or technologies to assess, particularly in low and middle-income countries which usually have fewer resources to carry out HTA processes. Having a clear system to define HTA priorities in the agencies is

regarded as one of the fundamental principles of good practices both at international and regional level (Drummond et al 2008, Pichon-Riviere et al 2018)

Identification and priority allocation of health resources are two key HTA elements with which to make decisions on which intervention and technology include in a benefit package, for example. However, this document and the 5th Latin American Policy Forum on Health Technology Assessment will not deal with these more systemic aspects, rather, they will be treated in the way HTA agencies identify and prioritize interventions and technologies to be assessed. Further, prioritization of technologies to be assessed for disinvestment decisions or for exclusion from benefit package is a very important component of prioritization processes and despite the existence of mechanisms and principles for decisions on technology disinvestment, this document will not address them in a specific way.

The main objectives of the 5th Latin American Policy Forum on Health Technology Assessment will be:

- To explore different mechanisms used in the world for the identification and prioritization of health technologies to be assessed.
- To explore the positive and negative aspects of the mechanisms currently used in Latin America for the identification and prioritization of technologies to be assessed.
- To assess feasibility of implementation of the different models used in the world in the Latin American health systems as well as to explore main barriers and facilitators for an improvement process.
- To identify relevant criteria that Latin American HTA agencies should consider when deciding on the prioritization of technologies to be assessed

The main objective of this document is to provide relevant discussion information for the 2020 Latin American Policy Forum on HTAi that will take place on-line, on October 19th-21th . This document will provide basic concepts on how technologies to be assessed are identified, defined and prioritized and will also present a selection of international experiences.

The information presented in this document is the result of an exhaustive literature search and webpage visits of different health systems and HTA agencies.

Background

The Policy Forum on Health Technology Assessment (Policy Forum) is an activity organized by HTAi (Health Technology Assessment International). The main purpose for its creation in 2004 was to provide a neutral space for a strategic discussion on HTA state of affairs, its development and implications for the health systems, industry, patients and other concerned parties. This forum convenes agents from three main institutions: 1) decision-makers on coverage and reimbursement/ on pricing for pharmaceuticals and medical devices in the health systems, 2) organisms that organize HTA to support such decisions, 3) biomedical companies that produce technologies. This Forum has been held for over a period of 15 years in Europe and USA, 8 years in Asia and 5 years in Latin America, this being the 5th Forum in the region.

The focus, agenda and logistic details have been developed by an organizing committee made up of the Forum President and participating agents from different institutions (3 representing the public sector and 3 representing companies that produce technology). The Institute for Clinical Effectiveness and Health Policy (IECS www.iecs.org.ar -by its Spanish acronym) acted as the Scientific Secretariat.

The topic selection process for this Forum started in the 4th Forum, which included the following steps:

1) Creation of a list of potentially relevant topics from Forum members ´proposals and other sources
2) The list was sent to the participants and their responses were received to develop a ranking of the topics of greatest interest and importance.
3) Selection of the two most relevant topics to be presented to the Forum participants. This selection was made by the organizers and the scientific secretariat after consulting potential participants
4) Selection of final forum topic through a deliberative process by the Organizing Committee

This process yielded the following topic for the upcoming 5th Forum: “Mechanisms for identification and prioritization of health technologies to be assessed by HTA agencies”

This fifth edition of the Latin American Policy Forum is the result of the 4 previous ones. The first LA Policy Forum was held in Costa Rica in 2016. The topic was “Good Practice Principles for the Implementation of Health Technology Assessment in Decision-Making in Latin America” (Pichon-Riviere *et al.*, 2018). The most relevant prioritized principles to promote HTA implementation in LA were:

- Transparency in HTA process implementation and communication of results
- Involvement of relevant actors in HTA process
- Existence of appeal mechanisms
- Existence of clear mechanisms for HTA priority setting
- Existence of clear link between assessment and decision-making

The second forum took place in Lima in 2017 and dealt with the topic of involvement of different stakeholders in HTA process; the third Forum was held in Montevideo in 2018 and offered discussion space for the topic of value frameworks for HTA . Buenos Aires was the chosen place for the fourth Forum where debates centered on the relation between HTA and decision making. (Pichon-Riviere et al 2018a, 2018b, 2019)

As has been mentioned, the existence of clear mechanisms for HTA priority setting was highlighted during the Policy Forum in 2016 as a key good practice principle to be implemented and strengthened in LA. Similarly, controversial aspects were discussed during that Forum related to the identification and definition of technologies as well as the prioritization of technologies to be assessed by the agencies. For example, there was a debate about the mechanism used by some countries that allows some stakeholdres, even the industry, to define technologies to be assessed (Australia, Brazil and Mexico in LA). Immediately, controversy arose around the feasibility to make technology assessment, some countries finding it impossible to carry it out due to restricted resource availability and having to limit the requests for assessment to the internal order of the public organisms. Further, some participants mentioned the importance of having clearly defined priorities that allow them to manage their assessment agenda according to what is important for the country rather to the needs of other stakeholders (such as technology industry or sponsors) or to politics-related needs. Conversely, some other participants considered that it could be more convenient not to have a fixed priority-setting process since this mechanism could restrict HTA decision-making. In this line, some participants expressed their concern that this fixed priority-setting process could quickly become infeasible due to the inevitable need for the agenda to be modified in light of different contingencies, like the need to update the benefits plan or politics-related issues (Pichon-Riviere A 2018)

Despite these controversies, the importance of how agencies identified and prioritized topics and its influence on the agency and health systems´ processes and results had already been agreed upon during the 2016 Forum. Since then, the region has shown greater awareness and bigger efforts to make HTA processes more transparent and participative. In this sense, the discussion on how agencies identify and prioritize which technologies they will assess has become a need identified by the members of this Forum.

Mechanisms and Prioritization Criteria for Nomination and Selection of Technologies to be Assessed by HTA Agencies

No country or HTA agency has the necessary resources to assess all possible technologies at the time they might be required. Therefore, it is necessary for health systems and HTA agencies to establish a clear process to identify, prioritize and select the topics to be evaluated. In situations where not all technologies will be evaluated (which is common for all HTA agencies in the world), the selection of which ones will be finally evaluated and considered for coverage and / or inclusion in benefit packages could cause serious distortions in the decision on how health resources are used if there are no clear and explicit mechanisms that guide this process of prioritization (Drummond et al., 2008). Choosing which technologies to assess or not could become more influential than the result of the assessment itself. Therefore, the need to set priorities about which technologies to asses is not a new topic for the HTA community. Moreover, there is a clear interest in making an efficient use of resources by the agencies, which has turned the process of identification of assessments with the highest potential to offer the best benefit in relation to their implementation cost the most important concern for them. This efficient identification process will certainly permit to maximize the benefits derived from HTA investment resources and therefore should involve all assessment decision makers in the agencies (Henshall *et al.*, 1997). Cost -effectiveness should then guide all HTA resources decisions as is the case with other health resources. (Drummond *et al.*, 2008)

Clearly, there is then sufficient argumentative ground to justify the importance of making an appropriate prioritization of assessments (Poblete-Vargas and Castillo-Laborde, 2014) considering, on the one hand, the obvious limited resource availability with which to make all possible assessments in some countries and, on the other hand, the need to make efficient use of those limited resources. Because of these factors, the prioritization mechanism becomes of utmost importance to align the assessment with the objectives defined by the health system. The information generated by the technology assessments then will be more relevant for decision makers. Once again, the effort invested in the assessment (in terms of human resources, time and cost) is highly justified in light of the "benefits" that this assessment will produce (answers to relevant health needs and health care; improved decisions, more efficient use of resources, etc,..) . Finally, an adequate prioritization process, if communicated in timely manner, is a key element to improve transparency and health system account reporting in general and the HTA agencies in particular.

Prioritization involves different elements: identification of the relevant problems for decision makers, identification of technologies that could respond to the needs or problems identified by health authorities, identification of possible evaluations that could help decision makers to achieve their objectives, judgment on the potential benefits and costs of possible evaluations to determine priorities, to communicate this prioritization to those responsible for conducting the evaluations and to all parties with an interest in these technologies and constant monitoring of proper process implementation (Henshall *et al.*, 1997).

Despite these relatively common elements in the prioritization process, not two countries or agencies or health systems in the world implement it in the same way or use the same criterion for decision-making (Henshall *et al.*, 1997; Specchia *et al.*, 2015; Frutos Pérez-Surio *et al.*, 2019). A review of criteria used by 11 agencies when deciding which technology to assess yielded 51 different criteria for the prioritization process (Noorani *et al.*, 2007). A systematic review of literature with focus on used prioritization processes yielded 56 different criteria used by agencies (Frutos Pérez-Surio *et al.*, 2019). In the review by Noorani et al., it was found that the agencies used a median of five criteria (with a range of three to ten), the most frequent criteria being clinical impact, economic impact, disease burden and level of available evidence.

An exhaustive review of the literature and the web pages of the main HTA agencies published by Varela-Lema and collaborators in 2017, aimed to identify and analyze the criteria, processes and conceptual frameworks used for the prioritization of health interventions. Their main finding was that no universal criteria or standard procedures for prioritization were identified, although most of the agencies analyzed seem to take into account eight critical domains: 1) need for intervention; 2) health outcomes; 3) type of intervention benefit; 4) economic consequences; 5) existing knowledge about the intervention / quality and uncertainty of the evidence; 6) implementation and complexity of the intervention / feasibility; 7) priority, justice and ethics; and 8) global context (Varela-Lema et al 2017)

Specchia and collaborators conducted a systematic review of the literature and websites of all European HTA agencies members of INAHTA. (Specchia et al., 2015). They found that the most frequently cited criteria for prioritizing were the potential benefits of technology, the costs and cost-effectiveness associated with the introduction of technology, and the burden of disease. Of the 30 HTA agencies evaluated, 14 made the criteria used for prioritization explicit and 5 agencies also explicitly described the process by which prioritization was carried out (GÖG: Gesundheit Österreich GmbH, Austria; LBI-HTA: Ludwig Boltzmann Institute for Health Technology Assessments, Austria; AETS: Health Technology Assessment Agency, Spain; AVALIA-T: Health Technology Assessment Branch of Galicia, Spain; OSTEBA: Euskal Herriko Osasun Saileko-Osasun Teknologien Ebaluazioko Zerbitzua, Spain). Further, 12 out of the 14 agencies that mentioned the criteria used considered the criterion of economic impact and costs, 11 the impact on ethical, social, cultural and / or legal aspects; 9 the frequency of the disease, 8 the burden of disease, and 7 the impact on clinical practice.

However, many HTA programs and agencies today do not have clear mechanisms or processes to define assessment priorities. Therefore, neither the criteria used to select interventions and technologies to be assessed nor the stakeholders participating in these processes or mechanisms for technologies prioritization are known.

Considering that no country can assure that it evaluates all technologies , this situation, as previously mentioned, can lead to a distortion in the decision-making process ; which renders the whole process less transparent and less legitimate in the decisions.

Stages of Prioritization Process

A. Identification of the technologies to be assessed

The first stage is the identification of potential assessment topics so that they can then be prioritized at a later stage. Three mechanisms that can be used by agencies for this process of identifying possible assessments are described below.

Consultation of experts and decision-makers

Decision-makers can be consulted when having to define which assessments are necessary for specific areas in light of the decisions they should make. However, feedback from these stakeholders could be biased if they emphasized their particular areas, as might very well be the case with costly technologies or topics of current interest for the public, not necessarily related to the country health priorities. (Henshall *et al.*, 1997). So, this consultation to experts can be complemented by analyzing health statistics or by searching other experts' opinion to identify a wider and more complete range of problems to which technology assessment could contribute valuable information for decision making. In other cases, assessment request can come to the HTA agency directly from Ministry of Health, hospitals or other national or subnational institutions. Yet, agencies in general count on the existence of more formal mechanisms for the identification of assessment topics, as will be described below.

Systematized Mechanisms for Identifying Technologies to Be Evaluated

One mechanism to identify assessment topics used mainly in high-income countries is the "horizon scanning" (HS). Its main objective is to identify new and emerging technologies that could have a significant impact on the health system, even before they obtain regulatory approval. This allows them to get ahead to be evaluated by the regulatory agency and the HTA agency. In general, a technology is defined as emerging when "... has not yet been adopted by the health system; drugs in Phase II / III in clinical trials or before launch, devices before their launch in the market, or in the first six months of entry, or devices that are already in the market but with a diffusion of less than 10% or are only available in a few centers ». A new technology can be defined as "a technology in the adoption phase, available for clinical use for a short time, usually in the period of launch or newly released in the market (*Agencia de Evaluación de Tecnologías Sanitarias (AETS) Instituto de Salud Carlos III - Ministerio de Sanidad y Consumo. Sistemas de Detección de Tecnologías Sanitarias Nuevas y Emergentes. Proyecto "Sintesis-Nuevas Tecnologías"*, 2003)

According to the HTAi/INAHTA/EuroScan glossary, horizon scanning (HS) is: "The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society.. Among its advantages, it is worth noticing that it allows early dialogue with the producers of technology even before this information becomes public as well as it promotes the articulation of new technologies with the health programs. Therefore, it is common for the health systems to design systems and exploration programs for heath care horizons, also known as first alert systems or early alert systems for the appropriate identification of these emerging technologies (Chalkidou and Fontana, 2017; EunetHTA, 2018).

These HS advantages can be less relevant in low and middle income countries since they are not innovation producers and their challenges in HTA are not only new technologies. This might account for the fact that HS activities in Latin America are still very limited and no HTA agency in the region has yet developed and kept long term HS important activities or in case they have produced these activities, they have not acquired a clear differentiation from other HS activities and functions performed by the agency (save some exceptions like Brazil). This lack of methodologies or specific processes to predict the arrival of new technologies makes their assessment take place in a reactive way, generally after they have been introduced in the market and be under pressure from different interested parts (Pichon-Riviere 2012)

However, it can be necessary for these low and middle income countries, like the ones in LA, to be able to make active searches for technologies and interventions focused by HTA in order to identify promising, potentially effective and cost effective interventions that are not being widely used or promoted because of lack of a specific "sponsor "that claims for their coverage or inclusion in a benefit package. Examples of such interventions could be: a colon cancer screening program; primary or secondary prevention interventions for cardiovascular disease, guidelines or protocols like pre-surgical evaluation to prevent unnecessary use of resources. This active methodology for identifying technologies and interventions of value for the health system can be a mechanism to better align the HTA agency work to the national health priorities which, in our region, are not only related to new technologies . Further, this methodology guarantees that the list of candidate technologies to be assessed- which later will need to be prioritized- includes interventions and technologies of high impact and high potential social value (Oortwijn W, Jansen M, 2019); the latter being a key component of decision making when issuing the list of candidate technologies to be assessed. Then, during the prioritization process, the added value of HTA will be taken into account in the decision-making process, selecting for evaluation those technologies in which HTA can provide more relevant or influential information at the time of the decision-making process. However, this prioritization process is valid only if the original list from which it is made is actually constituted by interventions and technologies of value to society and, in turn, if those interventions and technologies of value for the society have not been left out of this list.

<u>Nomination mechanisms /and formal request of technologies to be assessed</u>

Another source of identification of technologies to be assessed is the formal mechanisms for nomination of technologies by different stakeholders. In many cases, this nomination mechanism is actually a nomination or request for technologies to be incorporated into the benefit package. But because this also implies a need for evaluation to inform the decision of incorporation to the benefits package, it is considered here as one of the mechanisms for identifying technologies to be evaluated.

This nomination process, both for evaluation or for incorporation of technologies in the benefits package, can be closed, i.e exclusive to members of the Ministry or the public health system, or open to other stakeholders, such as scientific societies, industry, patients or users of the health system in general. In LA there are several countries that have open nomination processes for the evaluation and incorporation of technologies in benefits packages, such as in Argentina, Brazil, Mexico or Uruguay. The

way in which this nomination process is carried out, and the stakeholders that will be involved in it, will have a great influence on the subsequent work of the HTA agency.

A situation could occur, especially in countries with open nomination processes, that part of the work involved in the evaluation should be shared with those who make the nomination. For example, there are countries requiring that certain applicants (typically the industry) present relatively detailed information (dossiers) to justify the request. This information usually includes technology-specific data, analysis of evidence about its effectiveness and safety, in addition to economic information about cost-effectiveness and budgetary impact in the country. In these cases, countries usually develop methodological guidelines to assist applicants when carrying out searches and synthesis of information as well as analysis and results presentations. Beyond the information presented by the interested parties during the nomination process, the agencies themselves also make an analysis and evaluation of the information presented and might even take their own independent evaluations. Further, these regulations usually establish the time and manner in which the HTA agency should respond to these requests. In some countries, regulations force agencies to respond to all presented requests at specific times, leaving no time or space for the prioritization process. Brazil and Mexico follow this policy .

However, in some other countries, nomination does not imply that the technology will be evaluated. Rather, some mechanisms are established to prioritize which technologies will be selected for assessment out of a list of nominated technologies. At the same time, countries and health systems can also search for mechanisms to align this nomination process with their health priorities. For example, instead of establishing completely open mechanisms for nomination of all kinds of technologies and system´s stakeholders, they can set up more restricted mechanisms aimed at certain types of technologies or areas of higher priority (for example, for certain type of health problem, certain type of technology , interventions aimed at certain type of populations, etc,..)

As has been stated before, these are some alternatives that can help countries and health systems guarantee that the list of candidate technologies and interventions to be assessed will be made up by those technologies and interventions of potentially high social impact. In this way, the prioritization process could then be focused on determining in which technologies HTA can make the best contribution.

Many of the criteria used by the agencies, identified in the revisions and mentioned before are aimed at evaluating the potential social impact that these technologies can have.

Finally, there is a very important component in the elaboration of the list of candidate technologies to be assessed: the stakeholders involved in the process of identification and nomination of technologies. This list will certainly vary according to whether it is issued considering only the requests by the producing industry or by the sponsors. Therefore, having an active participation and involvement of a wide range of stakeholders can guarantee that the list will include technologies and interventions of high impact and relevance for the society.

B. Prioritization

Once the list of nominated technologies or topics have been completed, another complex stage of the prioritization process starts, mainly how to prioritize technology assessment in light of the benefits and costs involved in the assessment process. This means identifying which are the expected benefits resulting from the assessment which not necessarily will coincide with those resulting from the technology at issue. (Henshall 1997).

Countries can use quantitative, deliberative prioritization systems or a combination of both. Those who use more quantitative systems establish scores according to both the dimensions considered and the expected or preliminary performance (before the formal evaluation) of the technology in each of these predefined dimensions. For example , a country can use as criteria the population affected by the use of technology, the potential impact on the disease, the potential impact on health services and policies, social / judicial demand and economic impact. Each of these criteria may have a specific score (and eventually a weighting), which will not necessarily be the same for everyone. For example, it could be that the potential impact on the disease has a greater weight (for example 5 points maximum), than the potential impact on health services (3 points maximum). In turn, the performance of each technology in these criteria will influence the final score to be obtained in each criterion. In this way, the final score will be determined by taking into account the relative score of each dimension and then the performance of the technology in each of these dimensions. Those technologies with the highest scores will be those prioritized to be evaluated earlier, or even technologies with very low scores could be directly discarded from the evaluation process.

Additionally, health systems can use mechanisms specifically designed to align the selection of technologies with the priorities of the health system. For example, in Argentina the Ministry of Health and Social Development has defined, based on the operational capacity of those who make HTA reports in each period of time, a quota system to be able to face evaluations of different types of technologies for different populations. Those technologies selected to be assessed are finally placed in one of the following categories: technologies that favor equity and / or have a favorable impact on public health, technologies for infrequent diseases, technologies with high economic impact, technologies selected for disinvestment (obsolete technologies or with new technologies with better results or cost-effectiveness ratio), technologies with the possibility of using recent reports already made by members of National Commission for Health Technology Assessment (CONETEC, by its Spanish acronym). The quota is that, in that evaluation cycle, only one of the technologies corresponding to each category will be evaluated in the determined period of time (in total five initial technologies are evaluated) (Ministry of Health - Argentina, 2019)

In this process of prioritization, it is usual to take into account both criteria that make the potential social impact of technologies and the benefits expected by the HTA process. The ideal final objective is to prioritize for its evaluation interventions and technologies with a high potential value for society and

in which the HTA can provide relevant information for decision-making in order to justify the efforts and resources that will be invested in the process of evaluation.

The way in which different health systems carry out these processes is very varied and they adjust to the characteristics of their health systems. The following section will describe the processes of prioritization of a selected series of countries

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International Experiences

This section briefly describes health systems and mechanisms for HTA prioritization in four countries.

The following guideline has been chosen for this description:

A) Short description of health system

B) Prioritization of the technologies to be assessed :
   a) Which mechanisms are used for identifying technologies to be assessed:
      a. Horizon scanning
      b. Nomination (who can request evaluation topics, mechanisms)
   b) Prioritization: which criteria and mechanisms are used , who participates in the process

Germany

Germany has a universal multi-payer health system; funded by social security (Gesetzliche Krankenversicherung) and by private health insurance (PrivateKrankenversicherung). The public sector was established during the industrial revolution at the end of the 19th century, being a pioneer in Europe. It is mandatory for every citizen to have health insurance (Statutory Health Insurance System, SHI by its English acronym), and the coverage is around 90% of the population. The vast majority of the population, therefore, is in the public insurance system. The SHI is a mutual system where the state guarantees health care access through mandatory financial contributions related to the level of income of each worker, where a proportion is also assumed by the employer. The children of the beneficiaries are covered and the retirees contribute part of their income. Those who are unemployed access through the state, which assumes the proportion corresponding to the employer. In the case of private insurance, the group of inhabitants who receive the highest income may choose to hire one, and their employer will make the contribution that would correspond if they chose state coverage. Private insurance has autonomy in its management. The state provides the regulatory framework and plays a supervisory role. Each Fund establishes a direct contract relationship with its health providers. In the German health system, the patient has freedom to choose his or her doctor, either first level or specialist doctor. The federal government is responsible for overseeing the contractual relationship between insurers and providers, defining the content of benefit packages and ensuring assistance in chronic care of the sick patient. The health system is regulated by the Joint Federal Committee (Gemeinsamer Bundesausschuss or G-BA), a public health organization authorized to make binding regulations that arise from the health reform bills passed by lawmakers, along with routine decisions about medical care in Germany. This committee is the one who defines the coverage of the insured under the SHI regime and their decisions are binding for the members of the health system. The G-BA consists of 13 members, who have the right to vote on these binding regulations. Members are made up of legal representatives from public health insurance, hospitals, doctors and dentists and three impartial members. In addition, there are five patient representatives with an advisory function, without the right

to vote. One of the most important tasks is deciding what treatments and benefits the insurance companies have to pay by law. The principle underlying these decisions is that each treatment and performance must be required, in addition to being economical, sufficient and appropriate. It has broad regulatory powers that comprise the coverage of innovative diagnostic and therapeutic services, quality assurance of outpatient and hospital treatment and medication regulation (except marketing licenses). There are differences between medications and medical devices; and also between hospital and outpatient use of technologies.

The Institute for Quality and Efficiency in Health Care (IQWiG, by its acronym in German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), is responsible for conducting HTAs on drugs, devices, interventions and diagnostic methods, and although their recommendations are important for the G-BA, they are not binding. The authorization to market drugs is carried out by the Federal Institute of Medicines and Medical Devices (BfArM, by its acronym in German Bundesinstitut für Arzneimittel und Medizinische Produkte), which evaluates its safety, efficacy and quality. Diagnostic methods are evaluated as a medical device and must meet the requirements established by the European Community. In Germany, with exceptions, the approval of a drug by BfArM or EMA (European Medicines Agency) implies coverage by the SHI. The German Institute of Documentation and Medical Information (DIMDI, by its acronym in German Deutsches Institut für medizinische Dokumentation und Information) is an agency associated with the Ministry of Health which also conducts HTA, although differently from IQWIG. The documents are designed to inform the drafting of health policies and not primarily to issue the benefits package. However, IQWiG may commission DIMDI to conduct HTA but the evaluation of the benefit made by IQWiG differs from that carried out by DIMDI.

In 2017, health spending in Germany amounted to 375.6 billion euros, or 4,544 euros per capita. This represented an increase of 4.7, compared to the previous year. Expenditure represented 11.5% of gross domestic product. Of this total expenditure, about three quarters is public; and the remaining fourth private part. According to the Euro index of health consumers, which placed it in seventh position in its 2015 survey, Germany has long had the most free-of-restrictions and consumer-oriented healthcare system in Europe. In 2016, out-of-pocket expenses represented just over 12% of total health spending. After the reforms of the health system (in 2004, the Law of Modernization of Legal Medical Insurance (SHI) and in 2007 the Law of Strengthening of the Competition of Legal Medical Insurance (GKV-WSG), drug copayments were increased, with a minimum of € 5 per prescription and a maximum of € 10, plus costs above a reference price.

Several regulations were also designed to protect certain people from significant expenses, such as those under 18, low-income groups and people with chronic diseases. Some limits were also set on pocket payments: for people without chronic conditions, co-payment cap is 2% of the annual gross household income; and for people with chronic diseases, this cap is 1%.

Prioritization of Technologies to Be Evaluated

Selection of Topics and Identification of Information Needs:

The General Health Law (German Social Code Book V) specifies that IQWIG must provide general information about the quality and efficiency of health technologies,(including medicines, diagnostic tests, devices, procedures) about health problems that have a substantial epidemiological relevance and that is easy to understand by citizens. Since 2006, the IQWIG must also monitor and evaluate continuously (horizon scan) important developments in medicine and report on them.

Fort the above exposed, these are the reasons for the IQWIG to evaluate a topic:

Comply with its statutory responsibility to provide consumers with health information, as well as on its own initiative within the framework of the G-BA general commission

- Due to direct commission received from GBA or the Ministry of Health

- In response to other commissions given to the Institute and its related information

Most of the IQWIG reports are commissioned by the G-BA for coverage decisions of the beneficiaries of the health system. The G-BA starts the selection of the topic in the case of drugs, and IQWIG then specifies the focus and the PICO question (population, intervention, comparison, and outcome).

For all new medications or indications approved by the regulatory authority for marketing, the production industry submits a dossier and within three months the G-BA evaluates the degree of additional benefit that this medication provides (this is known as AMNOG process, -Arzneimittelmarkt-Neuordnungsgesetz or pharmaceutical market reform law-). For all technologies that are not drugs, there are two different processes of prioritization: the official in G-BA, and the “public”, called “Themen-CheckMedizin” that is done through IQWIG. The one carried out through the G-BA does not involve a formal process of prioritization. The different actors in Berlin select the topics to be evaluated on the basis of which are most promising and urgent, to be then commissioned to IQWIG. In the public process, the topics are nominated by citizens and then prioritized.

Since 2016, anyone can send a request at any time for IQWIG to make an HTA. IQWIG collects the proposals and through a two-step process selects up to 5 topics per year to evaluate. To do this, once a year, IQWIG conducts a two-step process: the Selection Committee, whose members provide the perspective of the patient and the citizen as well as the scientific perspective; preselect 15 initial topics. After this, the Institute selects 5 topics of those 15 to begin the production of HTA reports. Proposals for topics for HTA reports can be submitted by insured persons in the SHI and other interested persons through a website. They can propose drug evaluations for a given indication, diagnostic tests, medical treatments, quality and efficiency issues. In this way, the consumer public and patients are given the chance to suggest topics relevant to them. The first step is carried out by the IQWiG selection committee, which is made up of representatives of patient organizations, self-help groups of patients with chronic and disabled diseases, representatives of the Federal Government Commissioner for Patient Affairs and a chronic patient care delegate and members of the general public. A second committee (Extended Committee of Experts) deliberates on this first selection of nominated topics. It is

made up of representatives of the organizations that form the board of the governing body of the IQWiG, which is the Foundation for Quality and Efficiency in health care, as well as a representative of the Ministry of Health. Together with the previous committee, they select up to 5 topics to be evaluated (and those reports are not binding). The approximately 10 issues that have not been prioritized in that year remain on the list to be considered in this process the following year. Those that did not enter the list of the 15 most prioritized in the first phase are removed from the list and are not considered again.

According to IQWIG, these actors ensure that the perspectives of both the general public and the patients, regarding their preferences and values, as well as the scientific perspective are considered in this process of prioritization. These two committees select the topics based on identifying those that are particularly relevant to the health care of patients considering, among other things:

- How big is the number of affected people?
- How big is the burden or seriousness of the disease
- How complete is the available evidence about the investigation question?
- Has the investigation question been already investigated in the current HTA reports in Germany?
- Which costs are related to the intervention?

Since there is no universally accepted definition of what are "diseases of substantial epidemiological importance", one of the parameters is their frequency (incidence-prevalence). In this case, diseases that affect at least 1% of the population at a given time (prevalence) or develop in a year (incidence) are prioritized. This threshold applies to different subgroups of the population based on age and sex (0 to 17 years; 18 to 59; 60 and over) to more adequately reflect the particularities of each age group and sex.

There is a catalog (updated every two years) that contains information about the prevalence and hospitalization rates of the 1,500 most common health problems (coded based on the 3 digits of the ICD33-10 code). This catalog may be amended based on the topics commissioned to IQWIG, for example, to include medical problems whose significance and disease burden cannot be satisfactorily reflected by their prevalence or incidence.

The results of that process along with an IQWIG comment are published on a “Topic check medicine” website. In January 2019, the first preliminary report of the topics suggested by the public was published: that of music therapy in cancer patients. IQWIG can also initiate evaluations of non-pharmaceutical products on its own.

The European Union is working on a new regulation for medical devises, while Germany is defining a new law on digitalization (“Apps”). Until these changes are implemented, G-BA members prioritize medical device issues primarily based on epidemiological criteria and prospects for clinical success of the new device.

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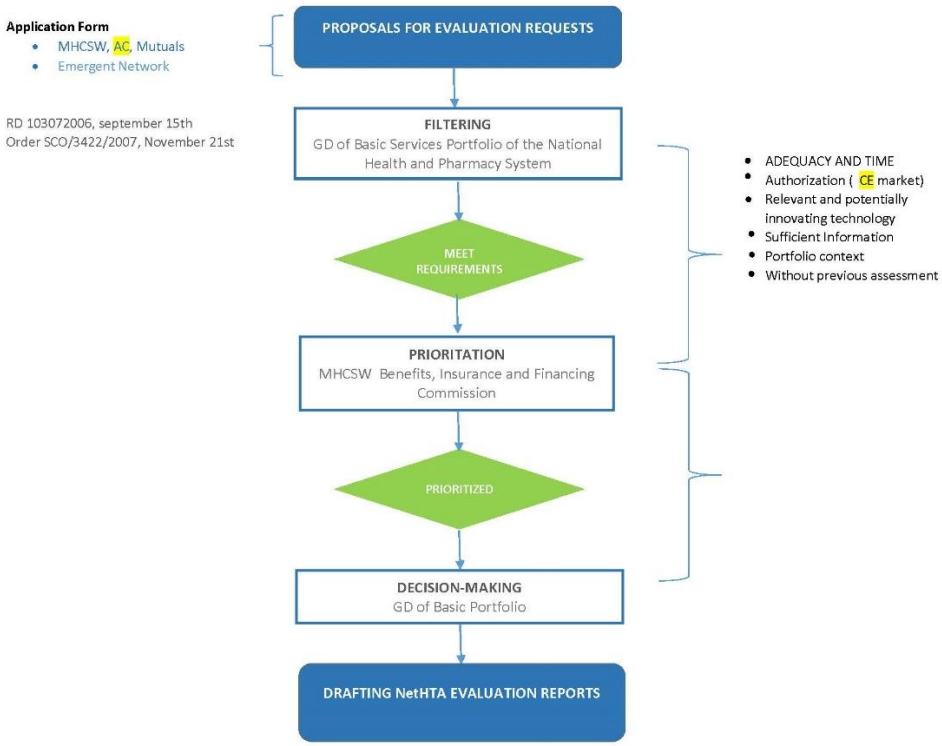
Spain

The National Health System in Spain is decentralized in the Autonomous Communities (equivalent to Regions). The Interterritorial Council of the National Health System (SNS, by its Spanish acronym)) is the permanent coordinating body among the Autonomous Health Services. It is made up of, among others, the Health Councelors of all the autonomous communities and chaired by the Minister of Health. There is a basic service portfolio determined by the General Directorate of Basic Services Portfolio of the National Health and Pharmacy System, reporting to the central level. The autonomous communities may approve their respective service portfolios, which will include, at least, the portfolio of common services of the National Health System, which must be guaranteed to all users.

The Interterritorial Council in 2012 formally creates the Spanish Network of Health Technology and Benefits Assessment Agencies of the SNS (RedETS, by its Spanish acronym)). Applications for technology

evaluation are collected every year to be incorporated into the basic service portfolio. These can be carried out by the Ministry of Health, Consumption and Social Welfare, by the Autonomous Communities as well as by the Emerging Technologies Identification Network formed by a subgroup of the Spanish Technology Assessment Agencies.

The collection of applications and their initial filtering to select those that will be prioritized depends on the General Directorate of Basic Portfolio of Services of the National Health and Pharmacy System. These requests are made in a specific form in which different aspects are considered, mainly: frequency and severity of the pathology, risks and safety of technology, efficiency and effectiveness, expected budgetary impact and expected introduction and dissemination. Once the potential technologies to be evaluated have been filtered, the final prioritization process is carried out by the Benefits, Insurance and Financing Commission.



(Reproducida de Leonor Varela-Lema-Priorizacion de los criterios en los informes de evaluación)

In 2015, the Benefits, Insurance and Financing Commission asked RedETS to develop a tool that would make the prioritization process more explicit. To this end, the PriTec tool that had been developed by one of the RedETS HTA Agency in 2008 was adapted. It was used to define the final list of technologies to be evaluated by RedETS, after the prioritization process in 2017 by the Benefits, Insurance and Financing Commission. For its adaptation, the participation of directors and / or representatives of the different agencies / units belonging to the RedETS and the General Directorate of Basic Portfolio of

Services of the SNS and Pharmacy was required. A group of representatives from the health administrations of the Autonomous Communities that make up the Benefits, Insurance and Financing Commission were also part of the adaptation process. The tool consists of 5 domains with different criteria within each one. In turn, the necessary information and score scale are defined in different categories for each of the criteria.

The amount of technologies to be evaluated and therefore reports to be made depends on the budget allocated by the Ministry to the RedETS for the preparation of evaluation reports and clinical practice guidelines as well as on the availability of work of the RedETS Agencies themselves; which translates, in practical terms, into an absolute number of reports.

Therefore, all health technologies whose score has exceeded that cut-off point will be selected. These technologies are distributed among the RedETS Agencies so that, within eight or ten months, they carry out the evaluation report.

Once the reports are available, the final proposal of the candidate technologies for inclusion in the common service portfolio of the SNS, is made by the Commission on benefits, insurance and financing and submitted to the Interterritorial Council of the National Health System for final approval .

With respect to those technologies that were not prioritized for obtaining a score lower than the cut-off point used, different situations may occur. If the request for evaluation arose from an HTA Agency of any of the autonomous communities, the same Agency could decide to take the evaluation anyway to respond to the need for local information that the request generated, but this decision will not affect the portfolio of services nationwide. When it comes to technologies that are proposed by the portfolio of services for inclusion, they can be discussed again in specific commissions and eventually re-included as requests for evaluation in subsequent years (or simply considered in these technical commissions).

The following chart describes the domains included in the tool with their corresponding criteria and weighted weight for each of them.

Domain	Criteria	Explanation
Disease or clinical condition (weight 33%)	Seriousness of pathology or clinical condition	Can the pahology/ies or clinical condition requiring the intervention lead to serious health consequences for the patients , family members or caregivers?
	Unmet needs	Are there important unmet needs related to the pahology/ies or clinical condition requiring the intervention?
	Frequency of pathology/ies or clinical condition	Are the pathology/ies or clinical condition requiring intervention very frequent?
	Vulnerability condition	Is the intervention aimed at people with rare diseases and groups in situations of dependency or at risk of social exclusion?

Compared Results/Outcomes (Weight 25.5%)	Safety	Is it expected or estimated that the technology (s) under evaluation contribute to improving safety compared to the usual clinical practice?
	Effectiveness	Is it expected or estimated that the technology (s) contribute to improving clinical results compared to usual clinical practice?
	Risk for health workers or the environment	Is it expected or estimated that the technology (s) under evaluation contribute tp improving the risk for health care workers, public health or the environment as compared to usual clinical practice?
Economic Impact (weight 20.5%)	Health costs derived from consumption of material resources	Is it expected or estimated that the technology (s) lead to an increase or decrease of costs from consumption of material resources as compared to existing alternatives in usual clinical practice? (infrastructure, equipment, and consumables)
	Additional health costs derived from health care	Is it expected or estimated that the technology (s) lead to an increase or decrease in health care costs as compared to existing alternatives?
	Non-healthcare costs	Is it expected or estimated that the technology (s) lead to an increase or decrease of non health costs as compared to existing alternatives?
Implementation impact (weight 10.5%)	Organizational/structural impact	Is it expected or estimated that the adoption of the technology (s) could have an important organizational/ structural impact ?
	Budgetary impact	Is it expected that the financing of the technology (s) at the SNS level might require a huge investment by the health system that could compromise the viability of the system?
	Ethical, social, cultural or legal impact	Is it expected or estimated that the adoption of the technology (s) could have important ethical, social, cultural or legal implications ?
Aspects related to dissemination (weight 10.5%)	Benefits for health care/ efficiency	Is it expected that the technology (s) contribute to improving the quality of health care and / or efficiency in the provision of services?
	Improvement of profesional practice	Is it expected that the technology (s) contribute to improving professional practice?
	Interest/ socila, political or profesional demand	Is there an important social, profesional or political interest/ demand for the technology (s)?

	Degree of adoption	Is the technology/ Are the technologies new or is it/are they widely disseminated in routine clinical practice?

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United Kingdom

The National Health Service (NHS, by its English acronym) is a comprehensive public health system, mainly funded through central government taxes and national insurance contributions. Most services are free. For some medications, dental services and vision care, modest copayments are required. Only some care is funded privately. The vast majority of hospitals are owned by the NHS. The upper levels in the hierarchical system are responsible for the coordination and formulation of policies while the lower levels are in charge of the health services management.

The National Institute of Health and Care of Excellence of the United Kingdom (NICE, by its English acronym) is responsible for the evaluation of health technologies through the “NICE technology evaluation program". Both the evaluation and appraisal of the results are used as a tool to inform coverage recommendations related to the state of reimbursement of the relevant technologies, as well as to determine the price at which the technology will be commercialized, although usually the final price is the result of a subsequent negotiation process.

The process of prioritizing the technologies to be evaluated for eventual inclusion within the NHS benefits is explicit. NICE establishes the following aspects as general characteristics of the selection process:

- The topics should be relevant for the patients, caregivers, health care professionals, providers and the public health
- The assessment should contribute to making a better use of the health system resources
- The selection of topics to be evaluated should follow a standardized process

- The process of topics selection should be the fastest possible to minimize the uncertainty period
- The activities for selection of topics should be inclusive , open, transparent and consistently implemented
- All stages of the process should be duly documented , with clear operating procedures and responsibilities and with a clear monitoring of progress that in turn should be open to all considered topics
- There should be appropriate governance structures and agreements among all relevant involved parties.

Regarding the prioritization process itself, NICE considers for its evaluation all new medications and indications it considers relevant. The health technologies that can enter the NICE Technology Evaluation Program are medicinal products, medical devices, diagnostic techniques, surgical procedures or other therapeutic techniques and care and screening systems. NICE manages this process on behalf of the Department of Health and Social Assistance and can only begin to evaluate a technology when it has been formally referred to it by the Secretary of State for Health

The identification of new and emerging health technologies that could be suitable for evaluation is carried out by the Innovation Observatory of the National Institute for Health Research of the University of Newcastle (independent research team). This center notifies NICE of new medicines in development, about 20 months before the marketing authorization and, in the case of new indications, about 15 months before the marketing authorization. These deadlines were defined by NICE for considering them appropriate to guarantee publication of guidelines the closest possible to the products launch. Regarding the horizon scanning process carried out by this observatory, they use advanced data systems that scan open and confidential data sources. These are complemented by interactions with companies to verify and confirm this information. Data sources include trial records, as well as secondary sources such as scientific literature, regulatory agencies (including the Food and Drug Administration (FDA), European Medicines Agency (EMA), Medicines and Health Products Regulatory Agency (MHRA)) , clinical experts, patients or patient organizations, media and tertiary sources (other horizon scanning organizations for example). Public and patient consultation is a critical element of the observatory's work. It hosts a national public and patient forum called “Valuing Our Intellectual Capacity and Experience (VOICE, by its acronym in English).This forum can be used to help prioritize, get queries on an innovation topic (by companies and horizon exploration organizations), or educate committee members about a topic.

In addition to these issues that the observatory routinely nominates for evaluation by NICE, health professionals, researchers and patients can also suggest potential technologies for NICE to evaluate by contacting the Innovation Observatory of the National Research Institute in health. If the production company is the one wanting to propose a new drug for the evaluation of the technology (which has not yet received a marketing authorization), it can do so through the UKPharmaScan platform. This is a secure horizon scan database that contains information on new drugs under development up to three years before its launch in the United Kingdom or the start of phase III of clinical development. It also

depends on NICE. In turn, the government or the NHS may request the review of a particular technology or disease that is of particular interest.

The selection decisions of the nominated topics come from considering each potential issue against the so-called “elimination criteria” and “prioritization criteria”.

The elimination criteria identify inappropriate topics for the Technology Assessment Program, mainly:

- If the technology has not received a marketing authorization (or equivalent) or if there are no plans to receive it
- If it is identical to a topic for which there is a published or NICE guide in progress, or a topic that has been considered and removed from the topic selection process, or that has been considered in the last 3 years and has not been prioritized.
- If it is a topic widely accepted and implemented based on the existing published guides of the Department of Health and Social Assistance, or other government departments

Finally, topics such as vaccines or drugs for the treatment of the human immunodeficiency virus are evaluated by other entities and therefore are eliminated from this process unless, by way of exception, NICE is requested to evaluate

Prioritization criteria to select which technologies will be evaluated (issuing summaries of evidence for medications), include the following aspects:

Clinical Impact:

- There is high potential that the medication (if effective) will significantly improve the quality of life or life expectancy
- The potentially affected population is large
- The natural course of the disease to which the treatment is directed is towards aggravation
- There are few therapeutic options
- There are potential safety problems with treatment

Variation in clinical practice :

- Wide variation in practice
- Very divergent clinical opinions
- Reports on the difficulty accessing treatment or its “off label” use

Need for Information:

- There is considerable uncertainty about the relation risk/benefit of the treatment
- There is high volume of of requests for information to the health system about this treatment

Impact on Resources:

- High potential impact on the use of resources because of this treatment

When deciding on the preparation of HTA reports, the following items are considered:

- Which are the benefits in terms of reducing uncertainties?
- How earlier can benefits be obtained considering the time needed to perform an assessment and the possibility to achieve a change in practice?
- Would the assessment offer value in exchange for money?
- How important is an early assessment?
- Is it possible for the technology to have a significant impact on government policies related to health?
- Is it possible for the technology to have a significant impact on NHS resources if it is administered to all patients for whom it is indicated?
- Is there a significant inappropriate variation in the use of technology across the country?
- Which other factors include political considerations, disease prevalence and social / ethical concerns?

This elimination process and the prioritization of the nominated topics are carried out by a NICE topic selection team advised by a clinical consulting group. Its task involves seeking the opinion of experts and interacting with other relevant stakeholders (including technology producers) when appropriate. Recommendations derived from this process are considered by an internal group at NICE and by the NHS. The steps of this process are in turn public through the NICE website where decisions on nominated technologies are explained.

Finally, the list of possible topics is delivered to the evaluation team to generate the drafts of the scope (approach) of the technological evaluation to be developed for that technology. On these drafts are defined the issues that will be submitted to the ministry to formally request the evaluation of the technology

As a special consideration, and as part of the arrangements for administering the Cancer Medicines Fund, as of 2016, all new medications and new indications (for medications that are already licensed) against cancer are automatically referred to NICE for its evaluation Therefore, prioritization times are shortened and drafts of the approach to evaluations of these technologies are received before.

Medicines marketed in England that do not meet the criteria for referral to the technology assessment program can be considered for another program called “Highly specialized technologies program”, to

obtain a summary of the evidence that helps inform decision making at the local level . This program was designed for the evaluation of drugs oriented to the treatment of rare or ultra-rare diseases.

It is not explicitly defined if those technologies not selected for evaluation can be sent again for consideration

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Thailand

Thailand provides universal coverage since 2001 through three public health insurance plans. A person can be a member of only one of these public plans according to their employment. The Public Servants' Medical Benefits Plan (CSMBS) covers active and retired public employees and their families, the Social Security Plan (SSS) for private sector employees in activity, and a third for all other citizens called the Universal Coverage Scheme (UCS). In 2014 of the total 66 million inhabitants of the country, 97% had access to a health plan; 48 million through the UCS, 11 million (17%) through SSS, and 7 million (7%) through the CSMBS.

The National Health Security Office (NHSO), an autonomous entity chaired by the Minister of Health, determines the CUS benefit package through the Subcommittee on the Development of the Benefit Package and Service Delivery

There is a process for the incorporation of new technologies into the benefits package of the universal coverage system in Thailand.

Twice a year, a fixed number of topics can be nominated for evaluation to the Health Intervention and Technology Assessment Program (HITAP), a health policy research institute sponsored by the Ministry of Public Health of Thailand. This nomination can be made by representatives of different groups of actors: coverage policy developers, academics, health professionals, patient associations, civic and citizen

groups and representatives of the health industry. HITAP sends an invitation to these representatives to send their proposed topics.

The topics must be accompanied by information that supports their nomination regarding their importance and justification for the presentation. Medications, devices, disease prevention and health promotion programs can be nominated. It may be the case that decision makers also request a technology that they believe is necessary to evaluate. This list is reviewed by HITAP researchers who exclude topics:

- that have been previously evaluated over a period of five years
- whose effectiveness is widely proven
- that are not directly related to health
- that they consider should be evaluated by another institutional organization

A “short list” is created whose prioritization is carried out by a panel made up of representatives of four stakeholder groups: health professionals, academics, patients and civic groups that have not been part of the stakeholder group that nominated the issues.

The prioritization of topics for this short list should be done according to six established criteria:

- Size of the affected population
- Desease burden
- Effectiveness of the interventions
- Variation in practice
- Economic impact on household spending
- Ethical and social implication.

The selection of topics is facilitated by the additional information provided by HITAP research staff. Each of these selection criteria has been identified through an explicit scoring approach with well-defined parameters and thresholds performed using the multi-criteria decision analysis method. Based on this system, the proposed interventions are classified and their order is adjusted through a process carried out by HITAP, in conjunction with other stakeholders convened for this purpose, ensuring the deliberative and inclusive nature of this step.

The resulting list is submitted to the Subcommittee for the Development of the Benefit Package and Service Delivery subcommittee and Service Delivery (SCBP, by its English acronym) for the final selection.

It is not explicit which path a technology that has not been selected for evaluation can take, in terms of the possibility of being resubmitted for selection or if it is permanently excluded from this process or if it can be nominated by another agency different from the one that proposed it initially.

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