IX Latin America Health Technology Assessment Policy Forum 2024 (HTAi LATAM Policy Forum)

Navigating the Future: Horizon Scanning and Early Dialogue in HTA

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Overview of the 2024 Latam Policy

This document focuses on horizon scanning and early dialogue as two phases within the broader HTA process that occur early in the technology lifecycle. The goal is to prepare the healthcare system for the introduction of new technologies, align interests among different actors (pharmaceutical industry, payers, patients and regulatory bodies), and optimize technology adoption processes.

Horizon Scanning can be defined as the process of identifying potential trends, opportunities, new technologies, or threats that could impact an area of interest. Early dialogue refers to a structured and collaborative process between healthcare technology producers, regulatory and HTA agencies during the initial stages of technology development. Its aim is to facilitate communication and information exchange to optimize technology development, regulatory approval and wider access.

Exploring regional implementation possibilities of these practices involves researching international experiences, studying implementation manuals, and reviewing protocols to facilitate the introduction of these practices in Latin America.

Sometimes differences in the definitions and scope of these practices need some conversations to plan and implement them. These debates will involve various stakeholders, their responsibilities, scopes, and limitations, as well as the consensus or differing perspectives that need consideration, particularly in low- and middle-income countries (LMICs) and the Latin American region.

Glossary

- **Budget Impact Analysis (BIA)**: An evaluation of the financial impact of the introduction of a technology or service on the capital and operating budgets of a government or agency.
- **Emerging technology:** Health technology that has not yet been adopted within the healthcare system.
- **Health Technologies:** All methods used by healthcare professionals to promote health, prevent and treat diseases, and improve rehabilitation and long-term care. These technologies include pharmaceuticals, devices, diagnostics, procedures (and technologies used as part of a procedure), programs, healthcare settings, and public health activities.
- **Health Technologies Assessment (HTA):** 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.
- **Horizon Scanning (HS)**: 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.
- **Stakeholders:** These are individuals or groups with an interest in a particular technology. This may include policymakers and regulators within the Ministry of Health, the Medical Device Authority, universities and research institutes, health agencies, other ministries, clinical professionals, etc.
- **Technology Stages:**
  -New: A technology in the adoption phase that has only been available for clinical use for a short time, typically in the launch or early post-marketing stages.
  -Emerging: A technology not yet adopted by the healthcare system. For pharmaceuticals, this usually refers to Phase II or Phase III clinical trials or perhaps pre-launch. For medical devices, it could be pre-marketing, within the first 6 months of marketing, or marketed with less than 10% diffusion or localized to a few centers.
- **Topic:** An innovative medicine and its intended use (indication).

Introduction

Vision and Goal: HTAi Policy Forum Series

Since 2003, HTAi Policy Forum Series has been a key gathering for senior international experts, fostering dialogue among public and private stakeholders, advancing HTA science and policy, and encouraging genuine exchange. Promoted by Health Technology Assessment International (HTAi), the Forum offers a neutral space for strategic discussions on the development and current state of health technology and its implications for health systems, industry, patients, and other stakeholders.

The Forum brings together representatives from three main groups:

- Decision-makers responsible for coverage, reimbursement, and pricing of drugs and devices used in the health system.
- Organizations that conduct HTA to support these decisions.
- Biomedical companies that produce these technologies.

The main Policy Forum has been operating for 21 years with a focus on Europe and the United States, and for the past 11 years, a Policy Forum has been operating in Asia. In 2016, the Policy Forum started in Latin America. An Organizing Committee composed of the Forum Chair and representatives from participating institutions -three representatives from the public sector and three from technology manufacturers- developed the theme, agenda, and logistical details of the Forum. The Institute for Clinical Effectiveness and Health Policy in Argentina (IECS – www.iecs.org.ar) served as the Scientific Secretariat.

Regarding the Latam Policy Forum, the first Forum was held in Costa Rica in 2016, where the principles of good practices in applying HTA to decision-making in Latin America were discussed. During this Forum, the most relevant principles to promote the application of HTA in the Latin American region were prioritized, which were[1]:

- Transparency in HTA processes and communication of HTA results
- Stakeholder engagement in the HTA process
- Existence of appeal mechanisms
- Clear mechanisms for setting HTA priorities
- A clear link between HTA and decision-making

The Latam Policy Forum 2017 was held in Lima, with the central theme of stakeholder engagement in the HTA process, identified as a priority topic during the 2016 Forum. In 2018, the Forum took place in Montevideo, where HTA value frameworks were discussed. In 2019, the Forum moved to Buenos Aires, focusing on the relationship between HTA and decision-making. During the Covid-19 pandemic years, the Forum was held online, and in 2020 the Forum examined mechanisms used by HTA agencies to prioritize evaluation topics, and in 2021 the role of deliberative processes in HTA was discussed. In

[1] Pichon-Riviere A, Soto NC, Augustovski FA, García Martí S, Sampietro-Colom L. Health Technology Assessment for decision making In Latin America: good practice principles. International Journal of Technology Assessment in Health Care. 2018;34(3):241-247.

2022, the Forum returned to an in-person format and was held in Brasilia, focusing on the use of real-world evidence in the HTA process. The results of the discussions held during the five most recent Latam Policy Forums are available in a series of publications: Pichon-Riviere et al. 2018-2022[2,3,4,5,6,7]. In 2023, the Latam Policy Forum was held in Santiago, Chile, where discussions centered around Managed Entry Agreements (MEAs). The forum featured participation from patients and international speakers, fostering rich dialogue and exchange of ideas on this critical topic.

As for this year´s forum, the Forum will be held on August 12 and 13 in Cartagena, Colombia. The process for selecting the topic began during the previous year's event and included the following steps: A list of topics was prepared based on suggestions from the members of the Latam Policy Forum, and a vote was conducted during the closing of the 2023 Forum to identify the highest priority topics. The prioritized topics were sent to the Organizing Committee for their comments/suggestions. The final theme was selected through a deliberative process by the Organizing Committee. As a result of this process, the theme selected for the Latam Policy Forum was: "Navigating the Future: Horizon Scanning and Early Dialogue in HTA."

The main objectives of the ninth Latam Policy Forum are to:

- Define what is meant by Horizon Scanning and Early Dialogue, both in general and specifically in the context of our region.
- Characterize the specific objectives and aspects in which these processes could differ worldwide and in our region.
- Facilitate interaction among different stakeholders to evaluate the current state of these processes in the region and discuss potential future actions.

[2] Stakeholder involvement in the Health Technology Assessment process in Latin America. Pichon-Riviere A, Soto N, Augustovski F, Sampietro-Colom L. Int J Technol Assess Health Care. 2018 Jan;34(3):248-253.

[3] Defining the Value of Health Technologies in Latin America: Developments in Value Frameworks to Inform the Allocation of Healthcare Resources. Pichon-Riviere A, Garcia-Marti S, Oortwijn W, Augustovski F, Sampietro-Colom L. Int J Technol Assess Health Care. 2019 Jan;35(1):64-68.

[4] The link between health technology assessment and decision making for the allocation of health resources in Latin America. Pichon-Riviere A, Augustovski F, García Martí S, Alfie V, Sampietro-Colom L. Int J Technol Assess Health Care. 2020 Apr;36(2):173-178.

[5] Identification and selection of health technologies for assessment by agencies in support of reimbursement decisions in Latin America. Pichon-Riviere A, Augustovski F, García Martí S, Alcaraz A, Alfie V, Sampietro-Colom L. Int J Technol Assess Health Care. 2021 Aug 16;37(1):e80.

[6] Deliberative processes in decision making informed by health technology assessment in Latin America. Alcaraz A, Pichon-Riviere A, García-Martí S, Alfie V, Augustovski F, Castro H. Int J Technol Assess Health Care. 2022 Dec 16;38(1):e86.

[7] Real-world evidence: experiences and challenges for decision making in Latin America. García Martí S, Pichón-Riviere A, Augustovski F, Espinoza M. Int J Technol Assess Health Care. 2023 Dec 18;39(1):e73.

Background Paper 2024: Renewed Format for Better Preparation and Dialogue

In each edition of the HTAi LATAM Policy Forum, the objective of this background document is to provide information as a starting point for the discussions at the meeting. For 2024, new formats have been introduced to allow better preparation and participation of all forum attendees. This edition includes updated and enhanced base material for the debates, with a new format designed to improve circulation and rapid dissemination. The goal is to foster greater understanding and engagement from stakeholders and attendees by renewing the approach and offering a comprehensive perspective on this year's selected topics.

To ensure quick reading and easy access, we will have available not only this base document, but also video and podcast materials, improving accessibility and understanding before the event.

- **Written Document:** It compiles concepts and definitions about the topic and also explores different countries' implementation experiences that can be taken as references.
- **Video:** Wija Oortwijn and Laura Sampietro, authors of the paper "How can health systems prepare for new and emerging health technologies? The role of horizon scanning revisited"[8] discuss the concept of Horizon Scanning, its application in their home countries, and some recommendations for countries that have not yet implemented it.
- **Podcast:** With Iñaki Gutiérrez-Ibarluzea, discussing key issues of horizon scanning and its impact on health systems.

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Commented [2]: Enlace a podcast

[8] How can Health Systems prepare for new and emerging Health Technologies? The role of Horizon Scanning revisited. Oortwijn W, Sampietro-Colom L, Habens F, Trowman R. Int J Technol Assess Health Care. 2018 Jan;34(3):254-259.

Life Cycle of Health Technologies and the Role of Horizon Scanning and Early Dialogue Within It

The life cycle of health technologies encompasses various phases, from conception and initial research and development to evaluation, implementation, widespread adoption, and eventually decline or replacement. **Horizon scanning (HS) and early dialogue (ED) may play crucial roles throughout this cycle**. Traditionally, these two processes are positioned in the early stages like research and development, although some conceptualizations of early dialogue can occur in the phase of evaluation.

However, **they can play a role throughout the entire cycle**. **During the conception and initial development phase**, HS identifies new technologies and emerging trends to prepare the health systems, while ED facilitates collaboration between developers and HTA agencies to ensure the generation of relevant and high-quality knowledge and data aligned with HTA methods. **In the evaluation and testing phase**, HS continues to monitor technological advancements, and early dialogue provides ongoing advice to address uncertainties and adjust clinical and economic studies as needed. I**n the implementation and adoption phase**, HS surveys the adoption and impact of the technology in clinical practice and the health system, and ED may continue to ensure that implementation meets expectations and addresses any emerging issues. **In the maintenance and review phase**, horizon scanning identifies alternative technologies or improvements for potential replacement or updates, and early dialogue may be necessary for new iterations or updates of the existing technology. Finally, in the **decline or replacement phase**, HS detects emerging technologies that could replace current ones, and ED focuses on transitioning to these new technologies.

Early dialogue and horizon scanning are two interrelated processes that contribute to a more informed and efficient evaluation and adoption of new technologies. **HS** is primarily conducted for **health system planning and preparation**, whereas **ED aims to provide information to guide the development and dissemination of medicines at various stages of their life cycle**[9]

The Role of Horizon Scanning in Healthcare Systems

Horizon Scanning is employed in various fields such as health, science and technology, economics, politics, environment, and education to identify and evaluate new opportunities, challenges, and emerging trends. This capability allows organizations and governments to **anticipate future changes, adapt proactively, and make informed decisions, thereby enhancing strategic planning** in a dynamic and complex world.

Horizon Scanning becomes crucial within HTA, as it focuses on **identifying technologies in their early stages**. By doing so, it enables the anticipation of emerging technologies and **trends that can shape the future landscape of healthcare**. This process helps health systems prepare for changes, prioritize

[9]Parsons J, Milverton J, Ellery B, Tamblyn D, Merlin T. Horizon scanning and early assessment. Health Technology Assessment Policy and Methods Review. Canberra, ACT: Australian Department of Health and Aged Care, 2023.

research, and plan financially and operationally. It can also facilitate early access to new technologies and suggest excluding obsolete ones.

This proactive approach serves as the initial stage of HTA, providing a foundation for more comprehensive assessments as these technologies develop and become integrated into clinical practice, as will be later illustrated by international examples. HS is a part within health technology assessment that **helps health systems prepare for new technologies likely to have a significant impact on patients and/or healthcare systems.** In essence, HS helps health systems stay alert and prepare for new technologies, typically one to three years before they are approved by regulatory agencies.[1] It takes place before (or just as) the technology reaches the market and receives regulatory approval. In this sense, the difference between horizon scanning and health technology assessment once the technology is available is that the latter focuses on technologies once they obtained regulatory commercial approval oriented to evaluate its potential coverage, whereas horizon scanning is oriented to prepare the health system in other kind of decisions not related to coverage because it occurs earlier in the process when the technology is not yet available.

Horizon Scanning scope and Activities

HS involves **analyzing information** to **identify, monitor and evaluate emerging health technologies that may pose risks or offer opportunities**. It includes a series of efforts to **determine new technologies' potential value and impact** on clinical care, the health system, patient outcomes, and costs. Each healthcare system can develop its own HS process, with particular variations.

According to Parsons et al. (2023), the scope of HS includes several key aspects. It involves **identifying and evaluating medical technologies** based on criteria such as **high cost, high effectiveness, disruptive potential, and addressing high unmet needs, particularly for rare diseases or special populations**. Other specific criteria, such as **clinical or policy needs**, are also considered.

HS typically involves **determining the future time frame for the impact of the decisions taken with the information of the HS**. Organizations follow a structured process that includes identifying relevant topics from multiple sources, filtering them using specific criteria, prioritizing technologies for evaluation, developing comprehensive reports, and disseminating the results. This systematic approach ensures a thorough assessment of emerging technologies and their potential impact on healthcare. Visual tools like flowcharts are often used to clearly and concisely represent the HS process, with examples provided by the Agency for Care Effectiveness (ACE) in Singapore and the Innovation Observatory of the National Institute for Health Research (NIHR-IO) in England. **The scope of HS for medications varies significantly across countries[1], reflecting their differing priorities and health system needs.** Austria and Canada both prioritize high-cost and high-impact technologies, with a possible focus on disruptive innovations, while Brazil emphasizes high-cost technologies but not high-impact or disruptive innovations, only partially addressing unmet needs and rare diseases. In contrast, Denmark and Italy have not specified their priorities clearly across any of these criteria. Norway, similar to Austria and Canada, values high-impact technologies with a possible focus on disruptive innovations but does not specify other criteria. **This comparison underscores the diverse approaches countries take in prioritizing medical technologies for HS.**

Hines et al[10], organize HS into the following list of steps or activities:

1. **Identify and detect** emerging technologies/diagnostics/treatments/clinical programs.
2. **Filter** and **prioritize** technologies based on methods and criteria.
3. **Assess** potential impacts.
4. **Update and disseminate information**; clearly communicate potential health and healthcare system impacts resulting from the adoption of these technologies.
5. **Monitor and follow up** on supplied information (including feedback from stakeholders or involved parties) and evaluate the process.

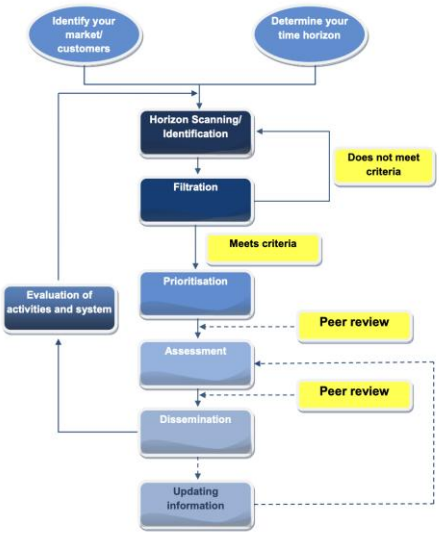


Figure 1. Source: Based on EuroScan (2014)[11]

Some experiences around the world: useful insights for reference and insight

Below, we present a number of **relevant precedents**, highlighting aspects that **could serve as a reference for replicating similar experiences in other countries.** As noted in the previous section, for most agencies HS follows a process of topic identification, filtration of topics, and selection (prioritization) of topics for further attention. Methods for stakeholder involvement including patient engagement are primarily included in the largest and most established HS organizations (i-HTS, CADTH and NICE)[12](2023:11).

[10] Hines P, Hiu Yu L, Guy RH, et al. Scanning the horizon: a systematic literature review of methodologies. BMJ Open 2019;9:e026764. doi:10.1136/ bmjopen-2018-026764

[11] EuroScan International Network. A toolkit for the identification and assessment of new and emerging health technologies. Birmingham: EuroScan International Network, October 2014. Available via: https://www.euroscan.org/assets/Uploads/EuroScan-Methods-Toolkit-October-2014-FINAL-CC-added.pdf.

[12] Parsons J, Milverton J, Ellery B, Tamblyn D, Merlin T. Horizon scanning and early assessment. Health Technology Assessment Policy and Methods Review. Canberra, ACT: Australian Department of Health and Aged Care, 2024.

Experience 1. COLOMBIA. Institute of Health Technology Assessment - IETS: Methodological Manual for Defining the Category of Therapeutic Value under Article 72 of Law 1753/2015[13]

In 2018, in Colombia, Decree 433 partially regulated Article 72 of Law 1753, **establishing criteria for evaluation by the Institute of Health Technology Assessment (IETS)**[14]. This includes classifying the therapeutic value of new drugs, conducting economic evaluations (EE), and budget impact analyses (BIA). The decree mandates that IETS **classifies new drugs based on safety and comparative efficacy or effectiveness, and assess the uncertainty level of these evaluations** considering at least the quality of evidence and the magnitude of outcomes evaluated.

Thus, the IETS manual provides a guide for evaluating HTA in a **rigorous, transparent, and participatory manner** to estimate the **additional clinical benefit of medicines in terms of safety and effectiveness**. It develops a specific methodology that allows for the assignment of a category to new medicines and health technologies, incorporating their economic evaluation and a budget impact analysis. The result is an **objective and systematic assessment of the therapeutic value of medicines, especially new ones**, to ensure their appropriate use in the Colombian health system. The manual defines HS as a systematic verification activity designed to identify opportunities, challenges, risks, issues, or threats related to non-commercialized health technologies. Its objective is to obtain relevant information that facilitates decision-making about the future use of these technologies.

Identification

The text does not provide details regarding how this aspect of the process unfolds.

Filtration and Prioritization

The manual provides **a methodology to determine the therapeutic value** of a health technology by weighing various parameters: **effectiveness, safety and certainty of evidence** (which corresponds to the dimension of effectiveness). The value categories established by this decree are as follows:

Category*	Effectiveness	Safety	Certainty of evidence
1	Higher	Higher or with minor difference	High
2	Considerable	Higher or with minor difference	High or moderate
3	Higher	Higher or with minor difference	Moderate
	Minor	Higher or with minor difference	High or moderate
	No difference	Higher or with minor difference	High or moderate
4	Non-inferiority	No difference	High or moderate

[13] Instituto de Evaluación Tecnológica en Salud (IETS). Manual metodológico para la definición de la categoría de valor terapéutico en el marco del artículo 72 de la Ley 1753/2015. Bogotá, D.C: Instituto de Evaluación Tecnológica en Salud (IETS) y Ministerio de Salud y Protección Social (MSPS); 2023.

[14] IETS is a government agency that evaluates health technologies to ensure they are safe, effective, and cost-efficient, guiding healthcare decision-making

	No difference	No difference	High or moderate
	Higher of considerable	Minor risk increase	High or moderate
		Minor risk increase	High or moderate
5	Any	Greater or considerable risk increase	High or moderate
	Minor	Minor risk increase	
	Comparator with minor, considerable, or major superiority	Any	
6	Non definable	Any	Any
	Any	Non definable	
	Any	Any	Low or very low

**Note: This table is a revised adaptation of the one proposed in the manual*

The manual provides a breakdown of the **types of outcomes for assessing efficacy and effectiveness, along with how they should be measured**. For instance, **safety is a significant factor**, evaluating potential serious adverse events and additional studies. Outcomes are analyzed using validated clinical instruments for aspects such as quality of life. Composite and surrogate outcomes are accepted under certain conditions, classified by relevance and validation.

Key criteria for defining therapeutic value and supporting informed healthcare decisions include clinical outcomes like **efficacy, safety, health-related quality of life, and other significant patient indicators**. This assessment relies on **high-quality scientific evidence, prioritizing randomized clinical trials and meta-analyses.** Phase 4 studies and global health alerts are included to ensure safety, with non-randomized evidence considered only in exceptional cases, such as ultra-rare diseases.

Therapeutic comparators are selected based on their demonstrated **superiority in effectiveness and safety**, aligned with the best available evidence and updated Clinical Practice Guidelines. Decree 433 of 2018 defines the comparator as the best option based on scientific and clinical criteria. Clear guidelines are provided for using multiple comparators, mixed evidence, and **evaluating evidence certainty with methodologies like GRADE**.

These criteria are vital for the systematic evaluation of the therapeutic value of medications, especially new ones, ensuring their appropriate use within the Colombian healthcare system. They help **classify health technologies into six categories of therapeutic value**, guiding the estimation of their additional clinical benefit compared to existing alternatives and **supporting informed healthcare decisions.**

Early Dialogue activities mentioned in IETS Manual

In Colombia, Decrees 433 and 710 of 2018, regulate the execution of ED as part of the IETS assessment process. Early Dialogues facilitate **early interaction between drug developers and evaluating entities like IETS**. These interactions are **crucial for exchanging relevant information, discussing the evaluation scope, and aligning expectations** before the formal evaluation process begins. The objectives are to **enhance decision-making capabilities at early stages** of a health technology's life

cycle and to promote timely adjustments in research study designs. In Colombia, developers can initiate these dialogues either through a horizon scan requested by INVIMA or IETS or by directly requesting an ED with IETS. This process, which spans **35 to 42 days**, involves the submission of a request form, signing confidentiality agreements, providing detailed drug information, ongoing exchanges of queries, and a feedback phase.

The methodology encourages **active stakeholder participation**, ensuring that all parties contribute meaningfully to the evaluation process. Emphasizing transparency and confidentiality, the ED process ensures that evaluations are conducted openly and fairly while protecting sensitive information.

The IETS manual defines ED, or scientific consultations, as structured processes where drug developers provide scientific evidence about a technology to a Health Technology Assessment (HTA) agency. These guidelines aim to improve the quality and efficiency of health technology assessments, ensuring that new medications meet necessary standards for registration and use in Colombia's healthcare system.

Experience 2. BRAZIL. National Committee for Health Technology Incorporation (CONITEC)[15]

In Brazil, the National Committee for Health Technology Incorporation (CONITEC) is responsible for evaluating the incorporation of new technologies into the public health system. CONITEC conducts cost-effectiveness analyses, **reviews scientific evidence, and consults experts to make informed decisions about including technologies in the Brazilian health system.** This committee plays a crucial role in ensuring that medical technologies are accessible and effective for the population served by the Unified Health System (SUS) in Brazil.

CONITEC is instrumental in evaluating the incorporation, exclusion, and modification of technologies within the Unified Health System (SUS), one of the largest health systems in the world. CONITEC supports health technology assessments (HTA) at the federal level and also **develops horizon scanning (HS) activities that generate outputs to be used by the Brazilian Ministry of Health.** CONITEC is part of EuroScan, the largest international collaboration network for new and emerging health technologies.

CONITEC's HS system **has developed several outputs to address different information needs within SUS**. These include **internal reports, alert reports, briefs, and HS sections in recommendation reports.**

Internal reports are designed to support the Ministry of Health (MH) in legal defenses, assist in defining medicines for Productive Development Partnerships (PDP), provide information to patients, managers, and policymakers, and support the development of Brazilian Clinical Guidelines (PCDT). These reports come in **two types: short reports, which are four to six pages long and cover a single technology, and extensive reports, which provide in-depth reviews of one or several technologies for a given clinical indication.**

[15] Gomes PTC, Mata VE, Borges TC, Galato D. Horizon scanning in Brazil: outputs and repercussions. Rev Saude Publica. 2019;53:111.

Alert reports aim to predict the impact of new and emerging technologies that might be legally demanded or brought to court in the future. These reports are written in simple language and are brief, making them accessible to judges, patients, health professionals, and managers. Each alert report typically includes information on a technology for a specific therapeutic indication.

CONITEC's recommendation reports are official documents that include scientific evidence, economic evaluations, and budget impact assessments of health technologies submitted for analysis for incorporation into SUS. The HS sections of these reports present potential competing drugs, either by new routes of administration or by representing new therapeutic classes, to support CONITEC's discussions.

Through these activities, CONITEC ensures that medical technologies are accessible and effective for the Brazilian population. By participating in international collaborations like EuroScan, CONITEC enhances its capacity to evaluate and predict the impact of new health technologies, thereby improving decision-making processes within SUS.

Experience 3. CANADA. Canada's Drug Agency (CDA, formerly CADTH)

Canada's Drug Agency (CDA, formerly CADTH) is the Canadian HTA agency. CDA is a non-profit organization that operates independently and receives funding from Canada's federal, provincial, and territorial governments. Its mission is to provide Canada's healthcare leaders and decision-makers with dependable, timely, and unbiased evidence-based information and advice through a range of tailored products and services[16]. They define[17] **HS as a high-level summary of a new or emerging health technology likely to have a significant impact on the delivery of health care in Canada**. CDA is interested in health technologies – devices, procedures, diagnostics, and other health interventions – that are within one to three years from being licensed in Canada or in the early days of use in Canada. This indicates that these technologies have not yet been approved for use in Canada, are not widely accessible, or are not part of routine clinical practice. **Technologies awaiting approval** typically receive Health Canada's authorization within **six to 18 months.**

The purpose of the HS for decision-makers, is to support planning and priority setting by increasing awareness of new and emerging health technologies. **It helps them assess the evidence on these technologies** to better meet existing health care challenges. HS products are also intended to **assist in prioritizing and allocating resources**, as well as to **inform decision makers** of the possible implications of introducing new and emerging health technologies. **Health care providers** and decision-makers can use HS products to facilitate the **appropriate adoption and use** of new and emerging health technologies, and to understand their potential risks and benefits. **Patients and caregivers may also use these publications to learn about new and emerging health technologies** that might affect their treatment. HS products do not make recommendations for or against a particular new or emerging health technology. Readers are cautioned that a lack of good quality evidence does not necessarily mean a lack of effectiveness or harm. This is particularly the case for

[16] About Horizon Scanning. n.d. Accessed July 3, 2024. https://www.cadth.ca/horizon-scanning

[17] CADTH Health Technology Management Program. Horizon Scanning Products and Services Processes. September 2017. https://www.cadth.ca/sites/default/files/pdf/HS_Consolidated_Process_Final.pdf

new and emerging health technologies for which little information may yet be available, but which may in the future be supported by additional evidence once clinical development is completed. The HS products are public and freely available.

The **process has different phases**: Topic Identification and Prioritization, Research and Development, Review and Approval and Publication and Dissemination.

Identification and prioritization

Potential new or emerging technologies evaluated for HS products are identified through a range of sources, including:

- Medical and technology media services
- Health care associations, networks, and conferences
- Major medical journals
- Popular press and CDA media monitoring
- Regulatory agency news
- Other health technology assessment and HS networks and agency websites
- CDA Rapid Response, Health Technology Assessment, or Optimal Use service queries.

Canadian health care decision-makers, CDA staff, board and advisory committee members, industry, patients, and clinicians can also suggest topics to the Product Development team.

Proposed technologies are **filtered for further evaluation by CDA's Product Development team**. They meet **three or more times annually to short list technologies** that are collected during the ongoing scanning process. Potential health technologies are prioritized to be either monitored or considered for assessment, following these **criteria: Burden of disease, prevalence of the condition, or potential population impact of this technology in Canada.** If the technology is within CDA's HS time horizon, if it is a **new or innovative technology** and if it has the potential to have a **significant impact on patient outcomes or health care resources** or if it will have an **impact on health disparities**. Technologies that meet the initial filtering criteria are entered into the appropriate HS database for further investigation. The database is a repository that can be used to track and monitor new and emerging technologies and can be filtered for specific technologies, diseases, or priority areas.

The **primary goal of priority setting** is to **choose technologies for more detailed evaluation based** on their anticipated **interest and relevance to CDA stakeholders.** Pan-Canadian committees and networks represent stakeholder interests at federal, provincial, and territorial levels to prioritize drug evaluation topics. For devices, an internal multicriteria process is used to prioritize topics.

The Product Development team then creates comprehensive summaries of selected technologies, including descriptions, regulatory statuses, target populations, intended usage settings, and recent clinical trial data. For drugs, the team assesses the clinical development stage based on published phase II and/or phase III data. After technologies have been approved for further evaluation, they may be included in one of the following CDA HS Service products. The reason for selecting each of these alternatives is not explicitly stated in CDA's methods.

- **Issues in Emerging Health Technologies (IEHT) Bulletins**: These concise reviews describe drug and device technologies not yet approved or widely available for clinical use in Canada. The IEHT process involves project initiation through industry and external peer review engagement, comprehensive literature searches, screening and retrieval of relevant articles, drafting concise bulletins with detailed technology descriptions and evidence summaries, followed by rigorous internal and external review, and final approval before publication. They include technology descriptions, regulatory status or availability, potential patient populations, costs, implementation challenges, and summaries of available evidence.
- **Health Technology Update (HTU) Newsletter**: Each issue typically features five articles on new and emerging healthcare technologies, covering a range of devices, procedures, diagnostics, and interventions unless it is a themed issue. A kick-off meeting initiates the project. Industry engagement occurs when applicable, contacting manufacturers for article review and additional information. External clinical experts may also review articles. A comprehensive literature search is conducted by RIS using key databases and grey literature sources, focusing on recent English-language publications. Information not found in published sources is gathered through expert input, with short detailed articles. A Mini-Roundup lists recent HS Reports, and is included at the end of the newsletter. Internal and external reviews ensure accuracy and completeness, with revisions made accordingly.
- **Horizon Scan Roundup**: CDA's HS Service monitors national and international health information sources, compiling titles from CDA and other recognized HS agencies and health organizations known for identifying innovative medical technologies. Each report summary should describe the technology, its purpose, and other relevant high level information, and capture why the technology might be important (i.e., benefits over existing technologies, if possible). Each report summary is no more than three sentences long. The Roundup focuses on medical devices, laboratory tests, biomarkers, programs, and procedures, published biannually in full and included as a Mini-Roundup within the HTU Newsletter.

Experience 4. MALAYSIA. Malaysian Health Technology Assessment Section (MaHTAS) Medical Development Division Ministry of Health Malaysia

The Malaysian Health Technology Assessment Section (MaHTAS) is the Health Technology Assessment and Policy Agency of the Ministry of Health of Malaysia. This agency evaluates health technologies, including medical devices, medications, medical procedures, and health systems, with the aim of providing evidence-based information to support decision-making in health policies and clinical practices. The **Ministry of Health's Horizon Scanning Manual (2022)**[18] illustrates this process, following **specific guidelines to identify, monitor, and assess new technologies and innovations in healthcare**. It classifies health technology innovations into:

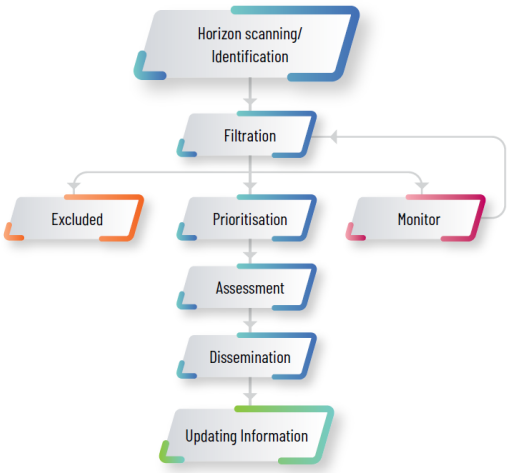
- New technologies (e.g., new chemical entities, devices, procedures).
- Existing technologies used in new patient groups or for new indications.

[18] Manual on Horizon Scanning of Health Technologies 2022. https://www.moh.gov.my/moh/resources/Penerbitan/MAHTAS/EBOOK_Manual_On_Horizon_Scanning_Of_Health_Technologies_(2nd_Edition).pdf

- Significant changes in existing technologies affecting clinical outcomes, healthcare resources, or human resource allocation.

MaHTAS's horizon scanning system **predicts the future impact of a technology, allowing funders and investors to set priorities** despite the challenges of evaluating developing technologies due to the uncertainty of available evidence. The HTA and Clinical Practice Guidelines Council leads the process, supported by the Technical Advisory Committee for Horizon Scanning (TAC HS), which includes policymakers, clinicians, researchers, and representatives from health innovation agencies.

Implementation. The following chart illustrates how horizon scanning progresses and operates according to this manual. We can appreciate that the phases are aligned with the ones generally proposed for HS activities.



Identification

The first step in the horizon scanning process is to **detect emerging technologies that will impact clinical practice, health outcomes, health systems, costs, disease burden, and inter-institutional collaboration.** This identification is **proactively carried out by MaHTAS staff** through medical databases, commercial websites, scientific journals, clinical trial registries, and patent applications, and reactively through requests from commercial developers, researchers, or experts.

Disinvestment in obsolete or low-value health technologies is crucial for the sustainability of the health system, allowing for reinvestment in more effective technologies. An obsolete technology is defined as one that has been replaced by other technologies or proven to be ineffective, harmful, or useless. **The identification of obsolete technologies** is conducted through reviews of clinical guideline reports and technology assessments, consultations with national experts and TAC HS members, regulatory agencies, and searches in international networks, databases, and publications. **Innovative and emerging technologies are prioritized, focusing on diseases with a high burden in Malaysia.** The **sources for identification** include information from research institutes, universities, manufacturers,

clinical trial registries, and patent applications (primary sources), as well as information mediated by commercial agents, physicians, regulatory authorities, experts, or scientific journals (secondary sources), and by other HTA organizations (tertiary sources). The **frequency of scanning** varies depending on the type of source, ranging from **daily to weekly or monthly.**

Filtration

MaHTAS staff conduct the identification of emerging technologies, prioritizing **patient protection** against untested technologies that may have **negative economic and/or clinical effects**. This process follows a series of predetermined steps, including the use of a specific form that is completed and discussed internally to make prioritization decisions.

Technologies can be **monitored** -if they are in very early stages of development-, **excluded** -e.g., if they are already approved or have a low disease burden-, or sent for **prioritization**. During the filtering process, obsolete technologies are also eliminated.

The **filtering criteria** include: the novelty or **innovation of the technology** (completely new, with a new indication for use, or with a significant modification), with **priority given to local innovations**; the evaluation **timeframe**, which is framed within 24 months prior to commercialization, patenting, or expected launch; and the **burden or importance of the disease**, prioritizing technologies for diseases with a high burden in Malaysia or diseases that, although not highly prevalent, are important due to their **high mortality or high treatment cost**, such as rare diseases.

Graphically, the process is as follows:

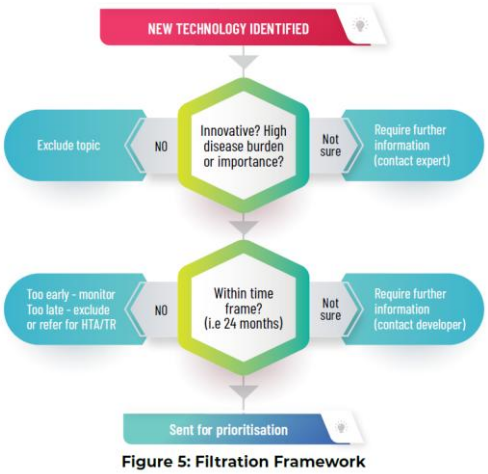


Figure 5: Filtration Framework

Adapted from: EuroScan International Network. A Toolkit for the Identification and Assessment of the New and Emerging Health Technologies. Birmingham: Euroscan International Network; 2014

Prioritization

At this stage, a **detailed evaluation** is conducted to determine if the filtered technologies have a significant clinical or financial impact that justifies further assessment. The prioritization criteria include the disease burden and the number of people affected, **giving higher priority to diseases with a greater burden**. It is considered whether **current treatments exist** or if the technology is a **new therapy that replaces or complements existing treatments**, with priority given to **innovative technologies**. **Local innovations** are also prioritized. These criteria ensure that the technologies selected for further evaluation align with health needs and the impact on the health system. Also obsolete technologies are under a process of prioritization.

Both MaHTAS staff and the Technical Advisory Committee for Horizon Scanning (TAC HS) can present technologies for prioritization. **Committee members score based on these criteria, and technologies are prioritized according to their ranking and discussion**. This process uses a specific form and excludes members from the industry or developers with potential conflicts of interest.

Assessment

The evaluation of a technology and the prediction of its potential impact determine if it will be disseminated in the health system, considering the interests and needs of stakeholders and its impact on the system, clinical practice, outcomes, and costs. **MaHTAS provides three types of assessments**, ranging from a **4-week, 5-10 page rapid evaluation** that includes a summary of technology, effectiveness, safety, and cost, to a **4-6 month detailed HS report often exceeding 40 pages**. In between, they offer a **10-20 page brief taking 4-6 weeks**, covering technology background, operation, disease burden, comparators, safety and effectiveness data, costs, and social, ethical, and legal concerns. Sources for these assessments include databases of ongoing clinical trials, commercial databases of pharmaceutical products and medical devices, registration and licensing sites, scientific conferences, and bibliographic databases.

The manual includes advisory models with fields related to technology, patients, evidence and policies, and expected impacts.

Dissemination

The **MaHTAS system informs various stakeholders**, including policymakers and implementers from the Ministry of Health, drug authorities, universities and research institutes, and other agencies such as the Ministry of Science, Technology, and Innovation, Bioeconomy Corp, and the Malaysian Investment Development Authority (MIDA). It also involves healthcare providers and professionals.

The manual emphasizes **the importance of an effective dissemination strategy to ensure that the information reaches those who can utilize it**. MaHTAS staff distribute the full report via **email** to stakeholders and make it available on the Ministry of Health Malaysia's **website**. Additionally, the *myMaHTAS 2.0* **mobile app** and website provide access to the reports. Other dissemination methods include collaboration with similar programs, **newsletters**, **peer-reviewed publications, conference presentations**, and the use of **social media.**

Information update

The manual acknowledges that early assessment reports may contain incomplete and evolving information, which can be modified or expanded before the full implementation of the technology. Therefore, it is necessary to update and communicate this information, encourage stakeholder feedback, and consider reevaluation to include new data. Additionally, it recommends involving experts and industry members, and includes reference documents on confidentiality and ethical aspects.

Experience 4. United Kingdom. NICE (National Institute for Health and Care Excellence)

In the United Kingdom, NICE (National Institute for Health and Care Excellence) is an independent public body that provides evidence-based guidance and recommendations on the most effective ways to prevent, diagnose, and treat medical conditions. NICE evaluates the effectiveness and cost-effectiveness of medical technologies and treatments to inform healthcare professionals and decision-makers within the British healthcare system. NICE itself doesn't directly conduct horizon scanning for its Technology Appraisal program. HS for health technology appraisal involves notifying the NICE of topics through technology briefings. National Institute for Health and Care Research (NIHR) Innovation Observatory (IO), acts as an **early warning system**[19]. They describe themselves as a horizon scanning facility, funded by the NIHR and based at Newcastle University in the UK. The NIHR Innovation Observatory utilizes a scanning system to detect these potential topics including the use of artificial intelligence and other tools that they design and develop[20]. These tools search, identify, and extract data across various open data sources to help derive knowledge and insights. They follow the development of new and repurposed medicines from at least two years before estimated UK license to provide a timely notification to NICE. This early notification triggers the NICE Technology Appraisal process and allows NICE to provide new guidelines as close to the license date as possible.
Subsequently, topics proposed by the IO are filtered against the established NICE topic selection criteria to assess the relevance and priority of the notified topics. This criteria considers factors like the size of the affected population, the severity of the disease being addressed, the potential impact on healthcare resources and the claimed therapeutic benefit of the medicine. Based on these selection criteria, NICE prioritizes the most impactful topics for formal technology appraisal. These are then referred for further evaluation within the HTA process.

Horizon Scanning: Opportunities for Improvement

Some authors mention that **HS for HTA is a complex and time-consuming process**[21]**.** The timelines and progress through HTA are challenging due to the increasing number of innovative drugs,

[19] "About This Guide | NICE Health Technology Evaluation Topic Selection: The Manual | Guidance | NICE" Accessed July 3, 2024. https://www.nice.org.uk/process/pmg37/chapter/about-this-guide

[20] "NIHR - Innovation Observatory." n.d. Accessed July 3, 2024. https://www.io.nihr.ac.uk/

[21] Khan SK, Gonzalez-Moral SG, Lanyi K, Ogunbayo D, Craig D. Closing the loop between horizon scanning and health technology assessment – an overview of topics submitted for appraisal in England. International Journal of Technology Assessment in Health Care. 2023;39(1):e64.

significant uncertainties, and limited transparency in clinical developments and regulatory pathways. **A better understanding of clinical trials and regulatory requirements could help reduce some of this uncertainty and improve the timeliness of HTA**. **HS systems have not yet reached their full potential in preparing health systems**[22]. Often, horizon scanning occurs too late in the development stage of a new technology, resulting in lost years of life, financial resources, and access to health. **Earlier engagement in the horizon scanning process is a need.**
As stated by Oortwjin et al, a clear definition of the end user, the time horizon, and the scope of HS can improve the process and usefulness.[23]

Increased collaboration between HS organizations and the pharmaceutical industry is necessary to establish effective methods of engagement and information sharing. Understanding the clinical areas of interest to stakeholders is crucial for improving horizon scanning processes and ensuring the timely capture of developing technologies in those clinical areas.
There are several reasons for collaboration in HS, with one of the primary motivations being the sharing of resources, as the HS process can be resource-intensive[24]. Some countries address this resource intensity by limiting the scope of their HS programs. **Successful collaboration requires alignment between participating jurisdictions regarding the goals or purposes of HS.** Although differences may exist in the targeted populations and technologies, time horizons (short, medium, long term), and overall objectives **international collaboration in HS** is highlighted[25] as a significant opportunity to improve the identification of new technologies and their potential impact on healthcare. Forming alliances with other countries or HTA agencies could enrich the HS process, offering a more global perspective on emerging health trends. By leveraging international expertise and data, the process can be more comprehensive and effective, ultimately leading to better-informed decisions and more robust health technology assessments.

Transparency is a critical factor for all stakeholders involved in the HS and health technology assessment (HTA) processes. For patients, understanding the reasons behind the approval or rejection of a drug is essential. Providing clear and detailed explanations can help patients comprehend the decision-making process and its outcomes, fostering trust in the healthcare system.

The **importance of involving patients in the HS process** is emphasized to incorporate their experiences and needs in identifying new health technologies. Active patient participation could enrich the identification process by ensuring that it is more attuned to the needs and preferences of end users. This patient-centered approach can lead to the identification of more relevant technologies and promote the development of solutions that truly address the concerns and expectations of those who will ultimately benefit from them.

[22] Oortwijn W, Sampietro-Colom L, Habens F, Trowman R. How can Health Systems prepare for new and emerging Health Technologies? The Role of Horizon Scanning revisited. Int J Technol Assess Health Care. 2018 Jan;34(3):254-259. doi: 10.1017/S0266462318000363. Epub 2018 Jun 11.
[23] Oortwijn W, Sampietro-Colom L, Habens F, Trowman R. How can health systems prepare for new and emerging health technologies? The role of horizon scanning revisited. Int J Technol Assess Health Care. 2018 Jan;34(3):254-9.
[24] Vogler S. "Ready for the future?" - Status of national and cross-country horizon scanning systems for medicines in European countries. Ger Med Sci. 2022 Mar 31;20:Doc05.
[25] Parsons J, Milverton J, Ellery B, Tamblyn D, Merlin T. Horizon scanning and early assessment. Health Technology Assessment Policy and Methods Review. Canberra, ACT: Australian Department of Health and Aged Care, 2024.

Early dialogue? What activities are included under this term

The nomenclature and **definitions of Early Dialogue varied widely** in the literature[25].

We are defining Early Dialogue (ED) as the activities **aimed to provide information to inform and optimize technologies research, development and incorporation** at different stages of the life cycle of the technology, while HS is primarily undertaken for health system planning and preparedness to emerging and new technologies.

Health technologies have a **lifecycle** from the start of research to their subsequent use to improve the quality of life of beneficiaries within a health system.

Early Dialogue can include various **activities and objectives, t**heir common feature is the **timing**, as their name suggests: in the initial or early stages of a technology's lifecycle, from prototype stage to coverage evaluation going through regulatory approval.

Early dialogue can be divided into **different types with different objectives and stakeholders involved**[25]. The timeline is flexible, and activities can happen at different stages of the technology life cycle. Figure E1 from the previous referenced work shows the approximate timing of these types of technology assessments throughout the product development cycle.

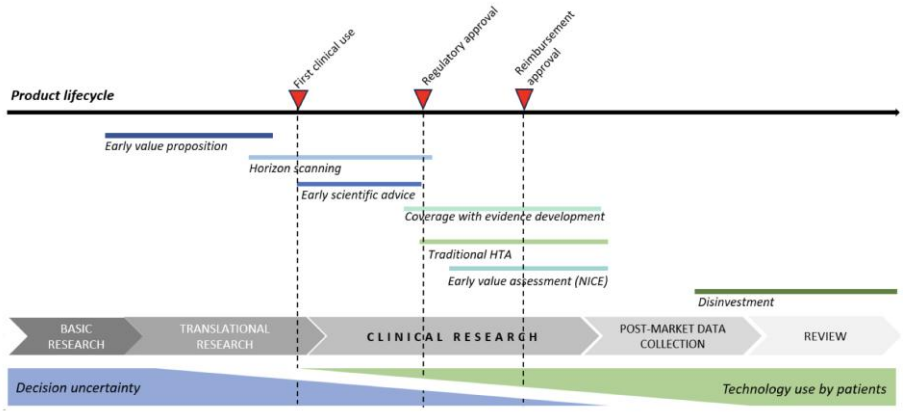


Figure E1 Types and timing of assessment and research in the technology lifecycle

1) Early Value Proposition (EVP)

It consists mainly of **economic forecast analyses** and occurs **much earlier in the product life cycle** because it **guides product development for the company**. Although traditionally associated with early economic analysis within the technology lifecycle, other criteria such as **stakeholder preferences** have recently been included to determine value in these early analyses. The objective of these studies is to inform investment and product development decisions for the technology company. However, they typically **do not inform decision-making by policymakers, meaning they do not promote an equitable, efficient, and high-quality health system**, and therefore do not align with the accepted

definition of HTA. The intelligence provided by this type of analysis is largely **useful only to the company.**

2) Early scientific advice (ESA)

Once the technology is chosen to be developed, **regulatory agencies and HTA bodies provide advice early in this stage of research**. Sometimes, they do this jointly with drug developers in many jurisdictions and countries. The goal is to advise the company before the start of a key clinical trial (phase III) on aspects of trial design and on the population, intervention, comparator, and outcomes (PICO) that are relevant for the healthcare system and HTA decision-making. This process can permit patient participation to align evidence production with patient preferences.

3) Coverage with evidence development evaluation

This instance can occur either **before or after the market authorization of a health technology**. An **example** of a post-market evaluation is **Early Value Assessment (EVA)**, a process recently initiated by **NICE in the UK[26]**. This process takes in general 6 months and has the following objectives:

• identify the evidence that is available on the technologies
• explore if technologies have the potential to address the identified unmet need
• identify important evidence gaps to help direct evidence generation
• determine if technologies should be used while further evidence is generated.

This scheme provides an access pathway for medical technologies, focusing on clinical needs and broader health system priorities. While its applicability to medicines in Australia is limited, particularly to rare diseases, elements of this process could be relevant to the HTA of other medical technologies, such as highly specialized technologies like cell and gene therapies.
Assessment for coverage with evidence development occurs just before or during traditional HTA.

From the perspective of HTA, these activities can be exemplified as follows:

Pre-Market:

- R&D Industry: Including basic and clinical research (Potential Early Dialogue to outline research directions)
- Horizon Scanning activities as previously described occur in this phase

REGULATORY APPROVAL:

- Potential Early Dialogue between producers and regulatory agencies to align pivotal study design and submissions with agency requirements

Post-Market:

- Early Dialogue activities between HTA Agencies and Technology Producers to adapt submissions for HTA evaluations and avoid duplicating efforts with regulatory agencies.
- Potential Horizon Scanning to prepare health systems, especially in LMICs, taking into account approvals in HICs.

[26] Early value assessment interim statement. NICE process and methods [PMG39] Published: 15 December 2022.

Optimizing Utilization

- One action that can sometimes be considered as Early Dialogue can include the early conversations after the incorporation of a technology to develop Managed Entry Agreements to facilitate the adoption.

Why is ED important for Health Systems?

Early Dialogue activities can have the potential to enhance evaluation and assessment processes by making the evidence generated more useful for decision-making and reducing uncertainty.

In the document developed by Parsons et al[27] they describe different implications of the implementation of this kind of processes, some of the concepts included are developed in this section. Although limited, evidence suggests that **early advice helps reduce uncertainty**, which can **accelerate the lifecycle of health technologies**, thereby **improving access to medicines and benefiting patients.** This advice can be **advantageous for the company** and also incorporate the possibility for **patients to participate** in the trial design and outcomes, ensuring that the study design is meaningful to them. There is not enough evidence to indicate that early advice provides additional value to the HTA process (through a reduction in uncertainty).

Early Value Assessments (EVA) and Early Scientific Advice (ESA) have the potential to enhance evaluation and assessment processes by making the evidence generated more useful for decision-making and reducing uncertainty. However, the current evidence base lacks sufficient information on the benefits of ESA or EVA for stakeholders. The implementation of EVA varies, and there is no guidance on best practices. ESA could benefit drug sponsors by improving marketing applications and reducing time to market access, but it is unclear if the service is cost-effective for the advising agencies. Although the benefits for the healthcare system from ESA and EVA in developing evidence that addresses key health priorities remain hypothetical, they are considered an opportunity for meaningful patient involvement, allowing trial design and PICO aspects to better reflect patient experience and preferences.

It would be premature to conclude that the Early Value Assessment, as implemented by NICE, is an effective way to address health system priorities and enable earlier access to effective technologies. However, coverage with evidence development is likely beneficial when there are high-priority diseases with significant unmet clinical need, where a technology shows promise but limited evidence is available to demonstrate it, and where the magnitude of clinical benefit and cost-effectiveness are uncertain.

Since the next year 2025, the European Union will be implementing a new joint assessment regulation regarding Health Technology Assessment that will include activities like horizon scanning and clinical assessments of health technologies[28], previously voluntary under initiatives like EUnetHTA. Member States' HTA bodies are required to conduct Joint Clinical Assessments (JCAs) for new medicines and high-risk medical devices. They will also participate in Joint Scientific Consultations (JSCs) to advise manufacturers on clinical study designs. EU-level horizon scanning exercises will identify promising health technologies early to assist Member States' health systems in preparation.

[27] Parsons J, Milverton J, Ellery B, Tamblyn D, Merlin T. Horizon scanning and early assessment. Health Technology Assessment Policy and Methods Review. Canberra, ACT: Australian Department of Health and Aged Care, 2023.

[28] Drummond, M., Tarricone, R. & Torbica, A. European union regulation of health technology assessment: what is required for it to succeed?. Eur J Health Econ 23, 913–915 (2022).

A prioritization process targeting drugs in high-priority disease areas would be crucial for the success of any such program. Moreover, there should be clear expectations regarding evidence development and potential benefit relative to the drug's promise, with a variety of stakeholders involved to advise and collaborate with the industry on how data should be collected and interpreted.

Early Dialogue: Opportunities for Improvement

In reviewing the **current scenario of ED, several opportunities for improvement have been identified.**

Provision of ESA by regulatory and HTA agencies occurs on an *ad hoc* basis. **Generally, the sponsor seeks guidance, rather than the regulatory or HTA agency providing or requiring it proactively**, which is an opportunity for improvement. **Enhancing stakeholder engagement** is crucial, as it ensures that **all relevant parties** can contribute meaningfully to the evaluation process. **Increasing transparency and communication** throughout the ED process would foster greater **trust and collaboration between developers and evaluators**. Additionally, **refining the methods for measuring outcomes** and ensuring they are **consistently applied** would improve the **reliability and validity of assessments**[29]. Implementing these improvements would not only **streamline the ED process** but also **enhance the overall quality and efficiency** of HTA, ultimately benefiting the healthcare system by ensuring that **new medications are evaluated more thoroughly and accurately.**

Advancing procedures to ensure that emerging technologies are ready for **swift evaluation upon arrival is another significant opportunity**. **Agility** should be seen as a virtue in the ED process, allowing for **faster integration of new technologies into the healthcare system**. By anticipating and preparing for the evaluation of these technologies in advance, the ED process can become more efficient, **reducing delays and improving the timely availability of innovative treatments.** For **patients**, this not only means **quicker access to new therapies** but also assurance that **these treatments are genuinely effective**. This dual focus on speed and efficacy is essential for meeting patient needs and improving health outcomes.

Discussion

Horizon Scanning and Early Dialogue hold significant potential in preparing the health system for new medicines, vaccines, and highly specialized technologies and also have the potential of **streamline the process of evidence generation to optimize it and align the interest of all the stakeholders including producers, funders and patients**. However, the precise purpose, timing, and scope of these activities require careful consideration, along with **strategies to enhance efficiencies in the HTA process.**

Despite the efforts through pricing and reimbursement policies to ensure equitable patient access to affordable and effective medicines, challenges remain. High prices of new medicines have resulted in catastrophic household spending, prompting the exploration of new policy options. The interest in HS and ED systems reflects a proactive approach to gain early insights into emerging health technologies, enabling policymakers to make evidence-based strategic decisions and prioritize resources effectively.

[29] Ibargoyen-Roteta N, Galnares-Cordero L, Benguria-Arrate G, Chacón-Acevedo KR, Gutiérrez-Sepulveda MP, Low-Padilla E, De La Hoz-Siegler IH, Guevara-Pérez CI, Del Pozo-Pérez Á, Suárez M, Dauben HP, Otte M, Gutiérrez-Ibarluzea I. A systematic review of the early dialogue frameworks used within health technology assessment and their actual adoption from HTA agencies. Front Public Health. 2022 Oct 6;10:942230.

The WHO publication identified five prerequisites that were considered key elements to successful cross-country collaborations in activities such as HTA or HS[30]. These include strong support and commitment of political leaders; a functioning governance and working structure; and provision of adequate resources, because collaborative action is time- and resource-intensive.

Early Dialogue with its two general objectives of shaping the research and development of technologies aligning the interest of different stakeholders and also optimizing the process of evidence generation and incorporation (regulatory and HTA phases) has a great potential to increase the efficiency of evidence generation and enhance patient impact.

It facilitates communication and collaboration among key stakeholders, including regulatory agencies, healthcare providers, industry representatives, and patient groups. By engaging stakeholders in the initial stages of technology development, early dialogue helps to align expectations, address uncertainties, and guide the design of clinical studies to generate relevant and robust evidence. This collaborative approach not only enhances the quality and relevance of HTA but also accelerates the adoption of effective technologies, ultimately benefiting patients and health systems.

Adapting international experiences and best practices in Horizon Scanning and Early Dialogue to the unique needs and contexts of Latin American countries is essential for ensuring the relevance and effectiveness of these processes. While global experiences offer valuable insights and methodologies, the socioeconomic and healthcare infrastructure variations across Latin America necessitate a tailored approach. Factors such as healthcare access, economic disparities, disease prevalence, and healthcare system organization differ significantly within the region, and these differences must be considered.. Customizing international best practices to address these regional specificities will enhance the applicability and impact of HS y ED in Latin American countries.

Sustainable HS and ED activities require funding, institutional support, and a commitment to maintaining high standards of evidence generation and analysis. Governments play a pivotal role in providing the necessary financial resources and creating a stable policy environment that supports these activities. By establishing dedicated funding streams, it can be ensured that these processes are consistently resourced and capable of delivering high-quality and useful assessments over time.

While horizon scanning can provide critical early information to prepare health systems for future changes, its successful implementation depends on well-defined objectives, appropriate timing, and a clear scope.

Implementing these processes in Latin America presents a range of challenges, including limited resources, varying levels of HTA maturity, and political and economic instability. Additionally, the diversity in healthcare systems and regulatory environments across Latin American countries adds complexity to this topic.

[30] World Health Organization. Regional Office for Europe. (2020). Cross-country collaborations to improve access to medicines and vaccines in the WHO European Region. World Health Organization. Regional Office for Europe. https://iris.who.int/handle/10665/332933. License: CC BY-NC-SA 3.0 IGO

Regional networks, international collaborations, and partnerships with more established HTA systems can provide valuable insights and technical expertise to develop effective horizon scanning (HS) and early dialogue (ED) processes in the region.

This will ensure regional health systems to be well-prepared for future advancements and technologies, ultimately contributing to more sustainable and equitable access to healthcare.

ANNEX

This annex summarizes the organizations, resources, and networks involved in HS and Health Technology Assessment (HTA), including their year of establishment and objectives. The information is based on two key sources:

- Parsons J et al. (2023). Horizon Scanning and Early Assessment. Health Technology Assessment Policy and Methods Review. Canberra, ACT: Australian Department of Health and Aged Care.
- Vogler, Sabine. ""Ready for the future?" – Status of national and cross-country horizon scanning systems for medicines in European countries." GMS German Medical Science 20 (2022)

1989

Agency for Healthcare Research and Quality (AHRQ):

- Country: United States
- Affiliation: U.S. Department of Health and Human Services
- Objective: Improve quality, safety, efficiency, and effectiveness of the healthcare system. National Healthcare Horizon Scanning System for identifying novel interventions and high-impact technologies.
- Functions: Conduct research, Generate evidence, Promote evidence-based practices, Enhance health decision-making
- Role in Horizon Scanning:
    - Collaborates with organizations like the Economic Cycle Research Institute (ECRI) to develop horizon scanning systems
    - Identifies and monitors novel interventions and new uses of existing interventions
    - Evaluates and improves existing horizon scanning systems and protocols
    - Develops transparent processes to identify impactful healthcare interventions

1998

National Institute for Health Research (NIHR):

- Organization: The NIHR is a biomedical and health research organization in the United Kingdom.
- Objectives: To provide advance notice of new and emerging health technologies and interventions likely to have a significant impact on the National Health Service (NHS) and patients within the next two to three years.
- Purpose: Funds research to improve health and healthcare.
    - Horizon Scanning Research and Intelligence Centre (HSRIC): was established as an independent research entity at the University of Birmingham in 1998 and became part of the National Institute for Health Research (NIHR) in England in 2006.
        - Previous Name: Formerly known as the National Horizon Scanning Centre (NHSC).
        - Responsibilities: Conducts horizon scanning to identify new and emerging health technologies.
        - Impact: Focuses on technologies likely to have a significant impact on the National Health Service (NHS) and patients within the next two to three years.

1999

EuroScan (International HealthTechScan - i-HTS)

- Formerly Known As: EuroScan.
- Countries Involved: Iceland, Italy, Netherlands, Norway, Sweden, UK, Spain, Canada, USA, Taiwan, Singapore, Malaysia, Ireland, among others.
- Objectives: To conduct proactive Horizon Scanning, share reports, and collaborate on the identification of new health technologies using systematic tools for proactive topic selection and prioritization.
- Focus: Horizon scanning of emerging health technologies.
- Resources: Includes courses and advice on methods.
- Capacity Building: Focuses on developing capacity in horizon scanning.
- Collaboration: Promotes collaboration among European countries and Canada.
- Information Sharing: Crucial for sharing information and insights on new and emerging health technologies.
- Impact: Enhances preparation and assessment of technologies across different health systems.

2015

Beneluxa Initiative

- Transnational Collaboration: Involves five European countries: Belgium, the Netherlands, Luxembourg, Austria, and Ireland.
- Independent Participation: Started as an initiative independent of Beneluxa membership.
- Objectives: Collaborate on horizon scanning to identify new innovative medicines.
- Membership: Countries involved are Belgium, the Netherlands, Luxembourg, Austria, and Ireland.
- Main Function: Collaborate on horizon scanning and share information among member countries.
- Objectives: Collaborative Horizon Scanning and pricing negotiations for innovative medicines. Improve patient access to otherwise hard-to-access medicines, and to support joint negotiations for pricing[31]
- Countries Involved: Belgium, Netherlands, Luxembourg, Austria, Ireland.

2015

Nordic Pharmaceutical Forum (NPF)[32]

- Countries Involved: Finland, Iceland, Norway, Sweden and Denmark.
- Objectives: To collaborate on identifying new opportunities in hospital medicines, joint procurement, logistics, and ensuring the supply of medications.

2017

[31] World Health Organization. Cross-country collaborations to improve access to medicines and vaccines in the WHO European Region. Copenhagen: World Health Organization; 2020.

[32] Vogler S. "Ready for the future?" - Status of national and cross-country horizon scanning systems for medicines in European countries. Ger Med Sci. 2022;20:1-13.

Valletta Declaration (VD)[33]:

- Established in 2017 to collaborate on horizon scanning.
- Member Countries: Italy, Croacia, Cyprus, Greece, Malta, Romania, Slovenia, Spain, Portugal.
- Main Function: Collaborate on horizon scanning to identify new innovative medicines and work together in this area. Improve patient access to otherwise hard-to-access medicines, and to support joint negotiations for pricing[34]

2019

International Horizon Scanning Initiative (IHSI)

- Origin: Initiated by the Beneluxa collaboration.
- Purpose: Aimed at performing joint HS across multiple countries.
- Advanced Undertaking: Considered the most advanced in cross-country horizon scanning efforts.
- Integration: Participating countries integrate HS outcomes into their systems for managing new medicines.
- Decision-Making: Outcomes are used to inform whether to conduct HTA and start price negotiations.
- Countries Involved: Belgium, the Netherlands, Denmark, Ireland, Norway, Portugal, Sweden, Switzerland, and further countries expressed interest.
- Objectives: To provide outcomes such as fair pharmaceutical prices and mitigate the impact of disruptive technologies. It includes creating a joint Horizon Scanning database for data collection and sharing.

Pharmaceutical Pricing and Reimbursement Information (PPRI) Network:[35]

- Countries Involved: 47 countries including EU member states, other European countries, Canada, South Africa, South Korea.
- Objectives: Addresses drug pricing and reimbursement policies. Competent authorities collaborate on pharmaceutical pricing and reimbursement.
- Network Composition: Consists of representatives from competent authorities for drug pricing and reimbursement in various European countries.
- Activities: Conducts surveys to study horizon scanning systems for medicines in member countries.

European Network for Health Technology Assessment (EUnetHTA)[36]

- Objectives: To support collaboration among HTA bodies in Europe.
- Country-Specific HS Approaches

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Austrian Institute for Health Technology Assessment, Health Services Organization[37]

- Approach: Reactive.
- Involved Organizations: Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

CONITEC Brazil[38]

- Approach: Reactive.
- Involved Organizations:
- Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

Canada CADTH[39]

- Approach: Proactive and reactive.
- Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

DACEHTA[40]

- Country: Denmark
- Approach: Proactive and reactive.
- Involved Organizations: Government, industry, consumers.
- Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

Norway[41]

- Approach: Proactive and reactive.
- Involved Organizations: NIPHNO.
- Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

Italy[42]

- Approach: Proactive and reactive.
- Involved Organizations: Government, industry, consumers.
- Funding: Government.
- Additional Participants: Consumers, clinicians, industry.

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Swedish Early Awareness Alert (EAA) system[43]

- Country: Sweden
- Objective: Identify, filter, and prioritize new and emerging health technologies and new uses of existing interventions
- Purpose: Evaluate or predict the impact of these technologies on health, healthcare services, and society
- Function: Disseminate timely information
- Status: Currently operational for monitoring and anticipating the impact of health technologies in Sweden

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