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### HEALTH TECHNOLOGY ASSESSMENT AND INCORPORATION INTO HEALTH SYSTEMS: FINAL REPORT

#### **Background**

1. In 2012, the 28th Pan American Sanitary Conference approved Document CSP28/11 (1), adopting Resolution CSP28.R9 (2) on Health Technology Assessment and Incorporation into Health Systems. This resolution urges the Member States to promote the adoption of decision-making processes based on health technology assessment (HTA) for the incorporation of these technologies into health systems. To accomplish this, it is necessary to strengthen institutions and human resources, and review and strengthen institutional frameworks for the incorporation of health technologies by promoting the creation of transparent processes. Moreover, in the resolution, the countries recognized the successes and progress of the Health Technology Assessment Network of the Americas (RedETSA), especially in the production and sharing of HTA information and results at the national and regional level.

2. In 2014 and 2015, a mapping was performed to determine the status of HTA implementation as a tool to support decision-making in the Region of the Americas. The results of this work were published in the Pan American Journal of Public Health (3) and in the progress report presented to the 54th Directing Council of the Pan American Health Organization (PAHO) (Document CD54/INF/5) (4), with emphasis on the need to expand RedETSA, prepare a continuous training strategy and develop tools for employing HTA in decision-making, support the production and availability of HTA reports, and strengthen the link between HTA and decision-making. This new report to the PAHO Governing Bodies describes the progress made in the Region since the adoption of Resolution CSP28.R9 and reports in greater detail on the results obtained in the final part of the period.

#### **Analysis of Progress Achieved**

##### ***Establishment of an Institutional Framework for HTA-based Decision-making***

3. Institutionalization of HTA in the Region has been continuously strengthened since the adoption of Resolution CSP28.R9, both nationally and regionally, as reflected in the

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new mapping performed between 2019 and 2021 in 21 countries in the Region.<sup>1</sup> Among the countries that have made the greatest progress, the following achievements are worth mentioning, in chronological order: *a*) Chile, with the creation of the Priority Recommendation Commission in 2015, specifically for the high-cost technology program, and the Department of Health Technology Assessment and Evidence-based Health in 2017, coordinating HTA teams with practice guidelines, in line with the integrated approach recommended by PAHO and described further on in this report; *b*) Mexico, where the National Center for Health Technology Excellence (known as CENETEC) has gradually expanded the scope of the technologies assessed in its reports to support decision-making by the General Health Council on the incorporation of technologies ranging from medical equipment (2015) and medicines (2017) to *in vitro* diagnostic medical equipment (2019); *c*) Argentina, with the creation in 2018 of the National Commission for Health Technology Assessment (known as CONETEC), which issues recommendations for the Compulsory Medical Program and serves as a reference for the entire health system, and the consolidation of the Argentine Network of Public Institutions for Health Technology Assessment (known as RedARETS); *d*) Peru, with the creation in 2020 of a National Network for Health Technology Assessment (known as RENETSA)<sup>2</sup> to coordinate the three main public agencies that conduct HTA in the country; *e*) Colombia, with the determination in 2020 of the cost-effectiveness threshold for the country and the consolidation of its national agency, the Institute for Health Technology Assessment (known as IETS), which marks 10 years of operation in 2022; *f*) Brazil, with the strengthening of the National Committee for the Incorporation of Health Technology in the Unified Health System (known as CONITEC), which in 2021 marked 10 years since its creation, having issued more than 650 HTA reports, held 608 public consultations, and provided more than 353,000 contributions (5), in addition to the expansion of the National Network for Health Technology Assessment (known as REBRATS), comprised of more than 120 institutions; and *g*) Uruguay, with the creation of the National Health Technologies Assessment Division in 2021, through a law passed by the National Congress.

4. Other countries that have made significant progress in the institutionalization and development of HTA should also be noted: El Salvador, with the creation of the Directorate of Health Technology, which has a Health Technology Assessment Unit (2015); Bermuda, with the creation of the HTA area in the Bermuda Health Council (2016) and the passage of legislation (2020) to create a drug formulary using HTA with cost-effectiveness criteria; Ecuador, with the development of the HTA area in the Ministry of Health Directorate of Health Intelligence (2017); Guatemala, with the formalization and implementation of an HTA procedure in the Guatemalan Social Security Institute (2018); and Costa Rica, with the creation of the Directorate of Health Technology Assessment in the Costa Rican Social Security Fund (2019) to include the assessment of medical devices in addition to medicines.

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<sup>1</sup> Survey on development and implementation of an integrated approach, which also included technology management, rational use of medicines, and practice guidelines, employing an integrated approach to health technology that includes regulation, assessment, selection, incorporation, and rational use.

<sup>2</sup> Created by ministerial resolution in April 2020 and consisting of the National Institute of Public Health (known as INS), through the National Center for Public Health; the General Directorate of Medicines, Supplies, and Drugs (known as DIGEMID); and Social Health Insurance (known as ESSALUD), through the Institute for Health Technology Assessment and Research (known as IETSI).

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5. Since the 2015 progress report, the number of countries in the Region with HTA units, commissions, agencies, or bodies has risen from 12 to 18, and the number of countries with regulations that require some use of HTA in decision-making has also risen, increasing from 7 to 14, according to the updated mapping (2021). Nonetheless, actual linkage between decision-making and HTA conclusions is still limited: only in Brazil and Canada must all decision-making on technology coverage consider the conclusions of HTA reports, while in Chile this is only applicable to high-cost technologies.<sup>3</sup> The rest of the countries have indicated different frequencies in the use of HTA to support decision-making.

### ***Promotion of Network Collaboration***

6. One example of the progress made in these years is the consolidation of RedETSA, whose scope has significantly expanded since its creation in 2011. The initial 20 institutions and 12 countries rose to 26 institutions and 14 countries in 2015 and 40 institutions and 20 countries in 2022 (with Bermuda, Bolivia, the Dominican Republic, Guatemala, Honduras, and Panama joining in this latter period). RedETSA's achievements include holding 11 in-person meetings of members to exchange information on good practices and discuss topics such as the role of HTA in price regulation; judicialization of coverage; and integration of HTA with other elements of the integrated health technology cycle, such as regulation, practice guidelines, and health technology management. The result of these meetings was the creation of working groups to study different topics and develop tools; two of these groups (one on the adaptation of HTA reports and the other on HTA for medical devices) have, respectively, produced a work tool and a systematic review.

### ***Human Resources Development for HTA***

7. The Region has also made progress in its HTA capacities. Document production has increased, particularly in Argentina, Brazil, Canada, Chile, Colombia, and Peru, and the complexity and standardization of reporting formats have substantially increased.<sup>4</sup> An analysis of the mapping data reveals widespread use of methodological guidelines for the production of HTA reports in RedETSA countries. The aspects considered when conducting an HTA have also been broadened, especially with the incorporation of ethics and equity as explicit criteria in decision-making.

8. At the regional level, the main challenges and constraints identified in the mapping to strengthen the use of HTA as a tool for decision-making on coverage are the lack of qualified human resources, lack of knowledge and promotion of HTA as a decision-making tool, a need for greater institutionalization of HTA, limited availability of epidemiological information, and the cost of technology at the national level.

9. RedETSA has also been key in efforts to coordinate human resources training in the Region. More than 120 scholarships have been awarded to members from 15 countries to participate in basic and advanced HTA courses taught by two member institutions in

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<sup>3</sup> Financial Protection System for High-Cost Diagnostics and Treatments, Ricarte Soto Law, 2015.

<sup>4</sup> According to the more than 2,500 HTA reports published in the Regional Database of Health Technology Assessment Reports of the Americas (known as BRISA).

Argentina, the Institute for Clinical Effectiveness and Health Policy (known as IECS) and RedARETS. Through a technical exchange program, 32 professionals from 12 countries attended in-person training sessions at CONITEC (Brazil), IETS (Colombia), the National Institute for Excellence in Health and Social Services (known as INESSS), and the Canadian Agency for Drugs and Technologies in Health (known as CADTH) (Canada). Another initiative that had a significant impact in this area were the courses developed and offered at PAHO's Virtual Campus for Public Health, in which 662 participants from 33 countries participated, with the support of several PAHO Collaborating Centers in the Region.<sup>5</sup>

10. Other capacity building activities carried out include a webinar series on topics related to HTA and decision-making, which has now been offered 32 times. An HTA toolbox for emerging countries was also created, containing useful theoretical tools and case studies for reference. In 2021, a cooperation project was launched for capacity building for the management of medical devices in Caribbean countries, consisting of a series of webinars, individual workshops that addressed the specific needs and challenges of each Member State, and the creation of a community of practice for sharing information and disseminating good practices.

#### ***Promotion of the Production of Evidence and Dissemination of Information***

11. In response to the challenge of ensuring the accessibility and visibility of HTA reports, in 2017 the Regional Database of Health Technology Assessment Reports of the Americas (known as BRISA) was created. This database, a compilation of the reports produced by RedETSA members, contains over 2,500 reports in Spanish, French, English, and Portuguese. Developed with the support of the Latin American and Caribbean Center on Health Sciences Information (known as BIREME), it permits searches with Boolean criteria and filters, and searches across other bibliographic databases, such as LILACS and MEDLINE. During the COVID-19 pandemic, a special section on COVID-19 technology reports was created that already contains more than 400 reports. The impact on the visibility of the reports can be seen in the increase in the number of visits, which has risen from 3,055 users annually in 2018 to over 220 000 in 2021. BRISA's digital library has become an undeniable source of reference for the preparation of HTA reports and has been included in the methodological manuals for RedETSA members.

#### ***Adoption of an Integrated Approach for the Assessment, Selection, Incorporation, and Rational Use of Health Technologies***

12. Since HTA was first conceived as a decision-making tool that can be used at any time in the life cycle of a health technology, progress has been made in the adoption of an integrated approach involving the assessment, selection, incorporation, and rational use of health technologies. For example, a course in Spanish and English that includes these components was designed at PAHO's Virtual Campus for Public Health, the most recent

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<sup>5</sup> Institute for Clinical Effectiveness and Health Policy (IECS) and the University of La Plata University Pharmacology Center, in Argentina; and the University of Vermont in the United States.

version of which (2020–2021) also covers the context of the COVID-19 pandemic.<sup>6</sup> Likewise, the mapping also incorporated information on the rational use and implementation of practice guidelines in the countries. Based on this mapping, a profile was constructed that describes HTA and health coverage decision-making processes for each country in the Region, integrating the entire life cycle of health technologies. Some examples of HTA units from countries that adopted an integrated approach are Mexico's CENETEC, which integrates HTA, practice guidelines, and the management of medical equipment for rational and efficient use; El Salvador's Directorate of Health Technologies, with technical units for HTA, rational use, quality assurance, and pharmacovigilance; and Chile's Department of Health Technology Assessment and Evidence-based Health, which in addition to producing HTA reports to support decision-making, is also responsible for spearheading and coordinating the development of the country's practice guidelines.

### **Lessons Learned**

13. As evidenced in this report, health technology assessment has made substantial progress in the Region since the resolution was adopted. However, several of the health system needs and challenges that motivated it have persisted or worsened, such as rising costs and the availability of technologies with little added benefit. Work is still needed for countries to develop HTA-based processes for the incorporation of health technologies.

14. HTA institutionalization and capacity building are incremental processes that are part of strengthening technology assessment as a tool for decision-making. It is therefore essential to work through networks and capitalize on the experience and output of other countries and institutions, through actions such as adapting HTA reports from other agencies, developing mechanisms for utilizing the decisions of other jurisdictions (reliance), and standardizing and complexifying the structure of HTA reports – practices in which RedETSA has played an important role.

15. There are different types of institutional frameworks and structures among the organizations in the Region that carry out HTA process in decision-making (institutions, agencies, commissions, ministry units, national networks). While there is no single successful strategy, it has been noted that the countries that have made the greatest progress are those that follow key guidelines such as transparency, coordination of activities among the different actors, independence, and social participation in HTA and decision-making processes.

16. While the main contribution of HTA is usually to support decision-making on the incorporation of health technologies into benefit plans, it has also been shown to improve equity, the quality of care, and efficiency in other areas of the health system. Thus, HTA can play a key role when coupled with other processes aimed at directly tackling the rising cost of technology, such as price regulation and joint procurement mechanisms.

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<sup>6</sup> Virtual course: "Assessment, selection, rational use, and management of health technologies," with support from the following PAHO/WHO Collaborating Centers: Institute for Clinical Effectiveness and Health Policy (IECS) and the University of La Plata University Pharmacology Center (Argentina) and the University of Vermont (United States).

**Action Needed to Improve the Situation**

17. Considering the progress made and the challenges described in this report, the following actions are recommended to continue strengthening HTA to support decision making in the countries of the Region and promoting the development of equitable, efficient, and high-quality health systems:

- a) *Formalize and consolidate the links between HTA and decision-making processes.* Since the impact of HTA depends on its link with decision-making, it is essential to advance in the formalization of that link by setting standards in countries where they do not yet exist and strengthening the role of HTA in countries where the existing standards still allow decisions to be made without considering the conclusions of HTA reports.
- b) *Analyze and strengthen institutional frameworks.* Support the Member States in building sound institutional frameworks around key guidelines, such as transparency, coordination of activities among actors, independence, and social participation in HTA and decision-making processes.
- c) *Support the Caribbean countries in strengthening HTA.* While HTA institutionalization and capacity in the Region have substantially improved over the past decade, the progress has been mixed, reaching the Caribbean subregion to a lesser degree. Potential opportunities for meeting this objective include RedETSA membership for countries in this subregion, together with the utilization of existing capacities by the committees that select products for essential medicines lists, and of capacities created through cooperation activities for the management of medical devices in recent years.
- d) *Increase the availability of local data.* Improving the quality and impact of HTA will require increasing the availability of local data, such as epidemiological or unit cost information, to produce more accurate and valid HTA reports for local contexts.
- e) *Continue improving the quality and standardization of HTA reports.* Although the publication of HTA reports produced by RedETSA members in the BRISA digital library facilitated standardization and improvement of their quality, it is necessary to actively advance in the implementation of standards that will result in reports with a standardized methodology and the highest technical quality.

**Action by the Executive Committee**

18. The Executive Committee is invited to take note of this report and provide any comments it deems pertinent.

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