NEWS FROM THE REGION

Latin America Policy Makers Grapple With Health Technology Assessment and Health Policy

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ISPOR held its Latin America Regional Health Policy Summit on September 11, 2019, in Bogotá, Colombia. With policy makers, payers, industry, and patient representatives from Argentina, Brazil, Colombia, Chile, Mexico, Peru, and Uruguay, as well as guests from Asia, Europe, and the United States, the summit addressed how to translate outcomes research into policy decisions. Policy makers from the region discussed health technology assessment (HTA) as a tool for prioritizing health resources, assessing the value of novel and innovative technologies versus disruptive innovators, and the implementation of managed entry agreements in Latin American countries. Keynote presenters included Hector Castro MD, MSc, PhD, Management Sciences for Health, Washington, DC, USA; Manuel A. Espinoza, MD, MSc, PhD, Pontificia Universidad Católica, Santiago, Chile; Ramiro Gilardino, MD, MHS, MSc, ISPOR, Lawrenceville, NJ; and Jan Weinreich, PhD, Roche Pharma, Basel, Switzerland

Current Stage of Universal Health Coverage and the Role of HTA in Designing Health Benefit Packages

Universal health coverage (UHC) aims to provide access to qualified health services and financial protection from catastrophic health expenditures. The discussion, led by Dr. Ramiro Gilardino, pointed out that while UHC is on the agenda of most countries in Latin America, and many have improved healthcare coverage through primary healthcare implementation and healthcare systems modifications, many countries are struggling to find a mechanism to expand the service coverage to people with unmet needs and to increase measures to guarantee financial protection for catastrophic expenditures.

Prioritized health services baskets, also called "health benefits packages," have been shown to be a cost-effective method to improve the UHC index through increasing the delivery of services (eg, pharmaceutical products, medical devices, diagnostics tests, and diagnostic/therapeutic procedures), while reducing costs that could impoverish patients.[1] In the discussion, participants shared that some countries in Latin America have explored this strategy as an efficient alternative that can strengthen the healthcare system.

HTA could be employed as a decision support tool to review and summarize the comparative evidence of healthcare interventions, although the lack of technical capabilities and limited experience in low- and middle-incomes countries have limited progress.[2] Recognizing that HTA is in different levels of development in Latin America, the participants said HTA has a promising role in informing what new technologies to incorporate in the health benefits packages, as well as those that are outdated and should be removed

from the benefits packages. The use of HTA for disinvestment was said to be important, but it was stated that none of the countries represented at the Summit currently use HTA regularly for this purpose.

Mimicking the ongoing European Union HTA harmonization process, a joint comparative clinical efficacy assessment is something that could be replicated in Latin American countries. But participants noted that the development of joint initiatives (ie, joint purchasing) would require the support from global organizations such as the Pan American Health Organization/REDETSA (the Health Technology Assessment Network of the Americas). Finally, the discussion also brought to light that the lack of defined and uniform decision-making rules (eg, thresholds or explicit prioritization) is a challenge for the assessment and appraisal of high-cost drugs, especially for ultra-rare diseases and those that might be a disruptive innovator.

Value in Health Coverage Decision Making

In the first part of this session, Manuel A. Espinoza described different approaches to measure value in health, emphasizing the challenges and opportunities for local healthcare systems to implement a systematic decision-making process for coverage and reimbursement. This presentation highlighted that in Latin America, significant efforts have been made to build capacities to characterize health benefits and reveal the value of these technologies, mostly anchored on the principles of evidence-based medicine.

Other health systems have taken a step forward, considering the opportunity cost of an alternative use of limited resources. This consideration of health benefits forgone elsewhere in the health system is revealed through cost-effectiveness analysis, a type of study that is increasingly being taken into account in Latin America.

More recently, some countries have paid attention to alternative approaches to reveal value, including general methods such as multicriteria decision analysis and evidence to decision framework,[3] as well as specific instruments such as value assessment frameworks developed by scientific societies or healthcare institutions.[4]

Assessing the Value of Novel and Innovative Health Technologies

As part of the second session, Jan Weinreich described that the broader understanding of all value components will, in turn, foster understanding of the societal benefits of healthcare investment resulting in increased access to medicines. This "proposed" value framework will capture a comprehensive perspective on the value of medicines for society and lay the foundation for stakeholder engagement with the ultimate objective of patients and society benefiting from the advances in science.

There is a general belief that countries in Latin America are not yet prepared to adopt innovative technologies. Additionally, external models for incorporation might not apply in the regional context; however, much of the data presented in the session, which was based on surveys of participants, demonstrated otherwise.

> In countries where health services are generally accessible and affordable, governments are struggling to respond to rising healthcare costs and the growing health needs of their populations.

According to discussion participants, the elements of value for innovation should include cost-effectiveness and budget impact analysis as well as the societal perspective, which considers how much health the patient gains and what is the cost of that gain. For patients with cancer, the assessment of their health status requires strong outcomes measures like overall survival or progression-free survival; however, this could be difficult to obtain in patients with some types of rare cancers. Additionally, discussion participants said there is a need to standardize how the innovative technologies will be incorporated to avoid inequities and inequalities in access to health services. Acknowledging that the valuation of innovation should follow the established HTA process, harmonization between the different HTA agencies might increase knowledge and improve the capacity to perform this kind of assessment.

When innovation provides clear value for the population, but funding constraints challenge its adoption, a value-based approach, with the support of the health benefits packages, could be implemented.

Additionally, when fragmentation and multiple financial mechanisms exist for a certain disease, prioritizing and harmonizing them into a single policy could improve the allocative efficiency and increase patient access. Surveys of the participants noted that personalized medicine would benefit a small portion of the population, roughly less than 10%. There were also mixed perceptions about how these technologies should be incorporated and funded, specifically, when the participants were surveyed to assess their thoughts on how these novel technologies should be financed, the majority of them responded "partially" when asked if the funding should come from public resources.

Price Negotiation and Management of Entry Agreements

The discussion led by Hector Castro explored the opportunities and challenges for implementing price negotiations and managed entry agreements in Latin American countries. Barriers to and facilitators for were explored throughout the session in order to promote a policy dialogue among participants. According to Dr Castro, while unfinished agendas for infectious diseases like HIV, tuberculosis, or malaria are still existing in many low- and middle-income countries, the burden of noncommunicable chronic conditions has substantially climbed to the top as one of the most pressuring concerns in these settings.

Policymakers in many low- and-middle-income countries are >

interested in combining a mixture of policy interventions in order to reach sustainable UHC, mostly by improving their levels of allocative and technical efficiency. Decision makers in low- and-middle-income countries are considering a number of policy ammunition tactics for this purpose, including price negotiation of healthcare commodities and managed entry agreements. Managed entry agreements represent a potential opportunity for granting early access to innovation; however, as in the case of price negotiation, they also come with caveats including heavier transaction costs for the healthcare system.

According to the participants, financial agreements followed by hybrid schemes were the most common type of managed entry agreements seen in the region. Also, there was consensus that managed entry agreements should be a joint effort initiated by the payer (either public or private) and the technology producer. Participants stated that they believe that the challenges to the future development of managed entry agreements include lack of financial incentives (eg, pay for performance), lack of administrative and clinical data collection or strong set of data, and internal government legal barriers that would prevent timely implementation. Some participants said the fragmentation of the health systems in their countries would allow manufacturers to make different managed entry agreements, without the other sectors of the health system knowing about them. Additionally, there are manufacturer monopolies for certain drugs that would make negotiations difficult, especially in small countries. To move forward, participants said the factors needed are: (1) alignment between stakeholders and political will to commit (and trust among the stakeholders involved); (2) adequate regulatory and legal frameworks that ensure transparency of the process, including the outcomes assessment; and (3) mechanisms that favor countries that may be disadvantaged during the price negotiations (eg, consolidated purchasing).

Participants said they believe that when the regulatory and reimbursement agencies, the technology producers, the HTA, and the healthcare providers join efforts and align, a fast-track process for the access of high-cost drugs to the patient can be achieved. Cited as an example was how Colombia handled the assessment of, and negotiations for, hepatitis C drugs.

Ultimately, according to participants, a successful agreement would need to be built on a comprehensive process that includes the patient selection, the treatment protocol, and the data collection and analysis.

ISPOR President-Elect Jens Grueger, PhD pointed out that access to innovation is a complex area and requires the expertise and collaboration of industry, health authorities, providers and society, and, of course, patients. We need to create transparency and trust so that we can build a sustainable approach.

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References

1. Watkins DA, Jamison DT, Mills A, et al. Universal health coverage and essential packages of care. In: *Disease Control Priorities: Improving Health and Reducing Poverty* (3rd ed). Washington, DC: The International Bank for Reconstruction and Development/The World Bank, 2017.

2. Chalkidou K, Glassman A, Marten R, et al. Priority-setting for achieving universal health coverage. *Bull World Health Organ.* 2016;94(6):462-467. doi:10.2471/BLT.15.155721.

3. Thokala P, Devlin N, Marsh K, et al. Multiple criteria decision analysis for health care decision making—an introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force. *Value Health.* 2016;19(1):1-13. doi:10.1016/j.jval.2015.12.003.

4. Willke RJ, Chapman RH, Seidman JJ, Schnipper LE, Gleason PP. Current value frameworks—what's new? *Value Health.* 2019;22(6):S7-S11.