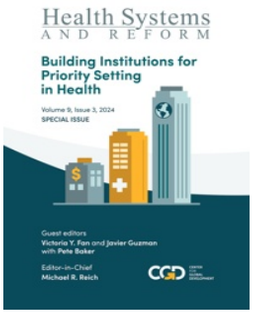

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COMMENTARY

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Harnessing Health Technology Assessment in Latin America and the Caribbean: Keeping the Region on Course

Ursula Giedion[a,b], Manuel Antonio Espinoza[c,d], Pamela Góngora-Salazar[b,e], Abha Mehndiratta[f], and Dan Ollendorff[a,g]

[a]Center for Global Development, Washington, DC, USA; [b]Social Protection and Health Division, Inter-American Development Bank, Washington, DC, USA; [c]Department of Public Health, Pontificia Universidad Católica de Chile, Santiago, Chile; [d]Faculty of Medicine, Center for Cancer Prevention and Control, Santiago, Chile; [e]Nuffield Department of Population Health, University of Oxford, Oxford, UK; [f]Center for Global Development, London, UK; [g]Center for the Evaluation of Value and Risk in Health, Tufts Medical Center, Boston, MA, USA

ABSTRACT

Latin America and the Caribbean has made significant progress toward universal health coverage (UHC), but health spending efficiency, equity, and sustainability remain major challenges—and progress is hindered by the difficult macroeconomic context. Health technology assessment (HTA) can make resource allocation more efficient and equitable when systematically used to inform coverage decisions. We highlight five considerations that need to be taken into account to realize the full potential of HTA in the LAC region: i) explicitly link HTA to decision-making and anchor it in legal frameworks, ii) systematically incorporate the opportunity cost as a core principle into HTA activities informing coverage decisions, iii) make the internationally available evidence more fit for purpose for low- and middle-income countries (LMICs), iv) incorporate pragmatism as a key principle of HTA activities in the region, and v) institutionalize the monitoring of HTA processes and results.

KEYWORDS

Health technology assessment; Latin America and the Caribbean; low- and middle-income countries; priority-setting; universal health coverage

Introduction

Latin America and the Caribbean (LAC) has moved significantly closer to UHC, but challenges remain. Out-of-pocket expenditure is still above 30%.[1] Inequalities in access to health care persist within urban and rural areas and between the rich and the poor.[2–5] For example, in a sample of 11 countries in LAC, the under-five mortality rate is up to 6.5 times higher in the lowest as compared to the richest quintile.[4,6] Access to essential services as measured by the UHC service coverage index in LAC (73.9) is significantly below that observed in high-income countries (83) and large gaps exist between formal and material health care coverage.[7] At the same time, access to high cost technologies is often granted through different types of judicial mechanisms.[2,8] LAC countries could improve life expectancy at birth by about 5 years on average, at current levels of public spending, if they followed best practices.[9,10] Pressure on health spending, combined with a bleak and uncertain fiscal outlook, paints a complicated picture for policymakers in LAC.[11,12] Therefore, the need to systematically assess the value of health technologies, and incorporate efficiency considerations in coverage decisions, is more important than ever.

Health technology assessment (HTA), understood as a systematic policy-based process aimed at optimizing the allocation of scarce health resources and improving both the efficiency and equity of health systems, can play a key role in this context.[13,14] Explicit priority setting, inevitably creates "winners" and "losers."[15,16] Therefore, HTA must be implemented as part of a fair and legitimate decision-making process.[17–19] HTA contributes to this legitimacy with content and procedures —content being the robust and reliable evidence which will be used for informed decision-making, whereas procedures relate with the principles of good governance that ultimately build trust.

Legitimacy conferred through HTA is particularly relevant in LAC. First, citizens are increasingly using rights-based litigation to challenge coverage decisions in the judiciary and to request technologies that are not being publicly financed.[18] Second, frequent changes in leadership might put policies that lack legitimacy at risk.[18–22] Lastly, the context of growing distrust of governments and high levels of corruption underscore the importance of transparent, coherent, and participatory processes.[23–27]

CONTACT Ursula Giedion ugiedion@healthglobal.ch Social Protection and Health Division, Inter-American Development Bank, Washington, DC

Institutionalizing HTA for Coverage Decision-Making Processes in LAC: Progress to Date

Despite the fact that the institutionalization of HTA has been on the policy agendas of an increasing number of LAC countries,[24] it is not systematically used to inform coverage decision-making. Furthermore, technical capacities as well as deliberative processes are still at an early stage.[25,26]

The level of institutionalization of HTA varies substantially across the region. On one end of the spectrum is Brazil and its Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde—CONITEC. CONITEC has adopted (and gradually improved) a systematic HTA process, culminating in a deliberative decision-making process with broad public participation, whose final recommendation determines the health system's decision.[27] On the other end of the spectrum are countries such as Nicaragua, Bolivia, or Haiti, where HTA is not yet part of the policy agenda.

In between, there are countries at different stages of what can be considered partial institutionalization of HTA for coverage decision-making. Colombia, for example, has established an independent national HTA agency with strong technical capacity—the Instituto de Evaluacion de Tecnologías en Salud (IETS) but HTA is not systematically being used to inform coverage decisions in this country. Mexico has a consolidated HTA body called CENETEC which generates HTA reports and clinical guidelines, but these are recommendations only.[28] In Chile, HTA has been used to inform high-cost coverage decisions (Ley Ricarte Soto (LRS), 2015), but it has not been institutionalized to update the Universal Health Benefits Plan (GES/AUGE).[29]

Five Recommendations to Tap the Potential of HTA in LAC

Barriers to the systematic use of HTA for coverage decision-making in LAC have been identified elsewhere and include lack of skilled human resources at the national level, insufficient financial support, and the reluctance of politicians to delegate decision-making to more independent bodies.[30–32] In this commentary, we underscore five issues that health systems in the region ought to address to realize the full potential of HTA for coverage decision-making as a means toward smarter resource allocation decisions in the region.[33]

Make The Link Between HTA and Coverage Decisions Explicit And Anchor It in the Legal and Normative Framework

Institutionalization is not only, nor primarily, about creating new institutions.[34] First and foremost, it means establishing transparent, consistent, and participatory processes and, importantly, a clear and explicit role for HTA in the decision-making process that is anchored in the normative framework.[35]

In Brazil, the use of HTA to support coverage decisions is enshrined in law and is mandatory for its National Health System (Sistema Unico de Saude), whereas in Chile it is only mandatory for high-cost treatments related to the LRS.[34] In some countries, the use of HTA is mentioned in the existing normative frameworks but its consideration is not mandatory in decision-making. In most countries, this explicit and institutionalized linkage is still missing and HTAs are carried out sporadically and on a "per demand" basis.[30,36] For example, in Costa Rica[34] and Colombia, the consideration of HTA recommendations is neither mandatory nor systematic.[37]

Establishing the link between HTA and decision-making, and anchoring it in a legal normative framework, guarantees that it truly informs coverage decisions—a *sine qua non*—to unlock its potential for decision-making in the region.

Systematically Incorporate the Opportunity Cost as a Core Principle into HTA analysis Informing Coverage Decisions

HTAs conducted in the region focus primarily on comparative efficacy/effectiveness, and, to a lesser extent, on budget impact and affordability. Efficiency and equity, both key objectives of health systems, are not systematically addressed.

With the exception of Brazil,[38] economic evaluations are not standard practice for HTAs informing coverage decisions in LAC. This is particularly relevant in the context of the evaluation of high-cost medicines, as they constrain the allocation of limited resources to other pressing areas that demand public investment,[39] such as closing coverage gaps for essential services.[7] Although there are valid reasons for funding non-cost-effective interventions, policy makers need to recognize the trade-offs carefully. A recent study by the Inter-American Development Bank illustrates the point: about 88,000 QALYs are lost in Colombia by allocating public funds to finance 10 high-cost drugs instead of investing them in the health system in general.[40]

According to the current director of IETS, in Colombia, "Individual rights trump collective rights."[41] Ignoring opportunity costs in decision-making is particularly worrying given the severe fiscal constraints in the LAC region.[33] As shown by other studies, the fewer resources available, the greater the health benefits of employing a priority-setting process based on cost-effectiveness and the higher the opportunity cost of neglecting this approach.[42]

The scarcity of data and the lack of skilled human resources may, at least in part, explain the limited use of cost-effectiveness considerations in the region. Some countries also limit cost-effectiveness evaluations in coverage decisions by law and mandate coverage for specific patients and technologies, irrespective of their cost-effectiveness. Also, stakeholders with conflicting agendas or interests may resist the implementation of cost-effectiveness analysis. Whatever the reason for this situation, countries should at least begin to calculate and present the opportunity costs of their coverage decisions in terms of population health, and include this information in their deliberative processes.[25]

While both efficiency and equity are important goals for health systems, prioritizing the systematic consideration of opportunity cost in coverage decision-making should be the top priority for the region as it moves toward UHC. As technical capacity and data availability increase, countries should then gradually incorporate an equity dimension into their analysis. Even in high-income countries, the systematic use of sophisticated CEA analysis often coexists with much less advanced equity analysis when conducting HTA to inform decision-making, partly because of the complexity of the analysis and its intensive data requirements.

Make Internationally Available Evidence More Fit for Purpose for LMICs

Many countries in LAC—and LMICs more broadly—are not just concerned about the marginal decision of whether to cover a new treatment option for a specific condition, but also about revising and refining an entire health benefits package or portfolio of interventions. This requires understanding the trade-offs between investing in new technologies and closing coverage gaps for effective interventions already included in the benefits package. Data on incremental cost-effectiveness are of limited use in this context as it offers comparisons at the margin only, and comparators may not be locally relevant. Instead, information on the clinical effectiveness and safety of the interventions of interest is needed, both in absolute and relative terms, compared to locally relevant alternatives. This data can then be combined with local information on cost to understand how cost-effectiveness compares across a broad set of interventions.

Studies on the health effects of interventions may be conducted in a variety of settings and be multinational in nature. However, the majority of these studies concentrate on high-cost interventions, with few targeting the main disease burden in LMICs.[43] There is also a pronounced gap in the type of evidence that can be used in LMICs, such as real-world evaluations of intervention effects and studies of the implementation of health interventions in given settings. Even if the level of LAC and general LMIC representation in clinical studies, and the types of studies conducted were to improve, there remains the problem of identifying, curating, and adjusting data on health effects for local use.

Unfortunately, information on effectiveness is not readily available in a single location. Relevant information would need to be systematically identified in the literature, abstracted, and presented in a standardized fashion. A somewhat less intensive approach would be to use the disability-adjusted life year (DALY) calculator developed by the Center for the Evaluation of Value and Risk in Health (CEVR),[44] which converts health outcomes expressed in non-DALY metrics (e.g., deaths averted) into DALYs based on local data on typical age of disease onset and gender-specific life expectancy. In either case, these efforts are time-consuming and require significant resources. Developing an open-access, international database of intervention effects, with enough detailed information for analysts and policymakers to apply to the local setting, would go some way to addressing this shortcoming. Repositories such as clinicaltrials.gov,[45] the EU Clinical Trials Register,[46] and the WHO NCD portal[47] could form the basis of such a database, providing data easily accessible and usable, as well as tools to adapt the information to make it locally relevant.

Employ Pragmatism When Carrying Out HTA

More pragmatism is needed in the production of HTA results in LAC to counter financial and human resource constraints.[48] A recent regional survey found that only 10% of respondents felt they had sufficient public funding for HTA.[31] For example, in early 2023, Argentina was in the throes of designing a universal health benefits package, with hundreds of candidates for inclusion awaiting HTA, but had to rely on a HTA body with very scarce financial support and human resources to carry out this task.[49]

In jurisdictions with limited capacities for HTA, adaptive HTA (aHTA) could be used to obtain

information that may be sufficient for the decision-context.[50] Although aHTA is often viewed as a simplification that lacks the good practices of a comprehensive HTA process, it can constitute an improvement over the current decision-process insofar as is embedded in a systematic priority-setting process anchored in principles of good governance. To our knowledge, there is no country in Latin-America that has formally adopted the aHTA approach, which can be partially explained because it is a very recent strategy still under development.

Focusing HTA efforts on technologies with reasonable doubt about their cost-effectiveness could be more efficient than evaluating all technologies, including those highly unlikely to be cost-effective. This approach allows for a pragmatic use of limited resources. Pichon-Riviere et al. (2021) proposed estimating a technology's likelihood of being cost-effective in the absence of local economic assessments, which reflects similar considerations.[51]

LAC countries could also discuss whether to request and critically review evaluations provided by interested parties rather than only focusing on full HTAs in-house. This approach is pragmatic but controversial because evaluations might be biased, and it risks prioritizing interventions on a first-come, first-served basis. On the other hand, most HTA bodies in the region will not have the capacity to develop studies for a full HTA process on a large scale. In this context, countries should strengthen their capacity to critically assess evidence at the request of the health authority.

Although pragmatism may decrease the degree of precision, it helps to set up a HTA-based approach that fits the purpose, contributing to improve coverage decision-making in the region.

More Monitoring of HTA Processes and Results

Securing commitment from policymakers to systematically incorporate HTA into decision-making depends on successfully convincing them that HTA delivers on its promises in concrete and measurable ways. Unfortunately, information such as whether HTA has improved allocative efficiency, or how much has been saved and reinvested elsewhere, is virtually nonexistent in LAC.[52] Other jurisdictions have used indicators that describe the performance of HTA processes, such as the number of technologies that have been evaluated or the influence of HTA recommendations on actual decision-making.[53–56] For example, India has estimated an overall return on investment of HTA of 9 units of benefits per unit cost.[57] Some studies have also evaluated whether HTA bodies' processes are aligned with their mandate or whether they fulfill basic procedural principles (for example, transparency, participation, consistency, revisability). One such study in Chile has demonstrated significant improvements compared to previous processes, but also identified inconsistencies between official evaluation reports and decisions as well as lack of accountability, especially to those patients who demanded technologies that were not chosen.[29] Whatever the approach, countries in the region need to make a better case for HTA-based coverage decisions by beginning to monitor their processes and outcomes.

Concluding Remarks

Progress toward UHC in the LAC region is threatened by the difficult macroeconomic and fiscal context and the lack of institutional capacity to respond to the pressure of new health technologies. Realizing the full potential of HTA requires a clear and explicit role for HTA in decision-making and institutionalized processes that are perceived to be legitimate and fair. The HTA value dimensions must be in synergy with the key goals of LAC health systems and their commitment to UHC. To achieve this, countries must start by placing cost-effectiveness and, gradually, equity criteria at the heart of coverage decisions. Prioritizing HTA efforts with pragmatism is necessary given the sheer number of technologies to be assessed and the scarcity of available resources. Finally, monitoring of HTA processes and their results will build evidence for further advocacy and investment in priority-setting systems for UHC.

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ORCID

Manuel Antonio Espinoza http://orcid.org/0000-0001-9564-9512
Pamela Góngora-Salazar http://orcid.org/0000-0002-3160-7097

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