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Research Paper

Health technology assessment in low- and middle-income countries: a landscape assessment

Joseph B. Babigumira[a,b], Alisa M. Jenny[a], Rebecca Bartlein[c], Andy Stergachis[a,b] and Louis P. Garrison Jr.[a,b]

[a]Global Medicines Program, Department of Global Health, University of Washington, [b]Pharmaceutical Outcomes Research and Policy Program, Department of Pharmacy, University of Washington, and [c]Bill and Melinda Gates Foundation, Seattle, WA, USA

Abstract

Objectives Health technology assessment (HTA) for a wide range of healthcare technologies is an essential component of well-functioning health systems. Knowledge of the use of HTA in low- and middle-income countries (LMICs) is limited.

Methods We performed a survey of HTA in selected LMICs. We interviewed key stakeholders on the use, conduct and challenges of performing HTA in their countries. We performed mixed-methods analyses to identify, characterize and describe HTA and how it relates to gross domestic product and government effectiveness.

Key findings Of the 19 countries selected for participation, stakeholders in 12 (63%) countries responded to the survey – Afghanistan, Bangladesh, Democratic Republic of Congo (DR Congo), Dominican Republic, Ethiopia, Jordan, Kenya, Namibia, Rwanda, South Africa, Swaziland and Vietnam. Eight countries surveyed have some form of informal HTA activity conducted by stakeholders including academia, industry, government and the World Health Organization. There is evidence of knowledge sharing with five countries using HTAs from their neighbouring countries or from more developed countries. We found no evidence of formal HTA performed through dedicated, independent bodies in the LMICs surveyed. There was some evidence that HTA was moderately related to GDP per capita and strongly related to degree of centralization (government effectiveness). Respondents identified resources, both financial and human, as challenges to conducting HTA.

Conclusions Formal HTA appears to be non-existent or limited in the LMICs surveyed but some evidence of informal HTA exists. Efforts to formalize HTA and to use existing HTA evidence will improve the quality of regulatory, coverage, formulary and reimbursement decisions, and individual and public health.

Keywords decision-making; health expenditures; health policy; internationality; technology assessment, biomedical/economics

Background

Health technology assessment (HTA) is the structured analysis of healthcare technologies performed for providing input into regulatory, coverage/formulary and reimbursement policy decisions.[1] HTA itself can be considered a health technology in the form of a process technology for making certain types of resource allocation decisions and can exist in more and less sophisticated versions.[1] With regard to its breadth and scope, HTA can be divided into 'micro' HTA which focuses on technologies such as drugs and devices that are considered to be incremental to the health system or 'macro' HTA which focuses on elements of the architecture or framework of health system in general, such as the number, types and mix of healthcare facilities and health workers in the system.[2]

Low- and middle-income countries (LMICs) have limited healthcare budgets and often struggle to prioritize healthcare needs and direct their investments in health technologies.[3] HTA is as an essential component of well-functioning health systems and is critical to the successful progression towards universal health coverage.[4] In the coming years, HTA will also be critical in LMICs in view of the global health pipeline of new medicines and vaccines that are intended for direct introduction into these countries.[5]

Correspondence: Alisa M. Jenny, Global Medicines Program, Department of Global Health, University of Washington, Harris Hydraulics Building, Room 321, 1705 NE Pacific Street, Box 357965, Seattle, WA 98195-7965, USA.
E-mail: ajenny@uw.edu

Increasing institutional and human resource capacity for HTA can form the foundation for the product development partnerships that will be needed for successful evaluation and adoption of these new products in LMICs.[6]

The main challenges to HTA in low-income countries are lack of local data, limited technical expertise, and weak or non-existent local institutions with the capacity to conduct HTA.[3] But there is a growing interest in HTA in LMICs with varying levels of institutional development and limited application to making regulatory, coverage/formulary and reimbursement decisions.[7–17] The existing HTA occurs predominantly in middle-income countries; the limited evidence available points to the historical and ongoing lack of HTA in low-income countries, despite having a great need.[1,3,18,19]

Conceptual framework

Towse *et al.* developed a conceptual framework of HTA as it relates the healthcare system.[2] The framework identified two key drivers of the focus and breadth of HTA: the 'level of spend', and the 'degree of centralization' (Figure 1).

The level of spend refers to the amount of resources available within a country.[2] Low-income countries will focus HTA on identifying basic services and interventions of high public health priority, to address the most serious causes of death, and to maximize the benefit of foreign aid. As countries gain wealth, the focus may shift from endemic infectious diseases to chronic diseases, clinical practice guidelines and assessment of new healthcare technologies.[2] HTA will increasingly be used to compare multiple treatment options and as an entry hurdle for high cost imported technologies. High-income countries with increasing numbers of substitute technologies will consider both new and existing technologies, including identification of areas of disinvestment. The overriding focus of HTA in wealthy countries is cost-effectiveness.[2]

The degree of centralization refers to the decision-maker(s) responsible for healthcare spending.[2] With out-of-pocket spending, decisions lie with individual patients and doctors, and HTA is performed only to meet whatever regulatory barriers exist to market entry, such as efficacy and safety. As third-party payment systems develop, payers use HTA to ensure that claims are justified, focusing on the highest cost interventions, and using comparative effectiveness to manage demand for services. When healthcare plans are large or national health systems exist, decision-making becomes more centralized with a greater emphasis on efficiency. All healthcare technologies, including broader societal objectives for the system, become candidates for HTA.

Utilizing this framework as a guide for design and interpretation, we conducted a landscape assessment of HTA in selected LMICs with an emphasis on low-income countries. The aim of the assessment was to identify, characterize and describe HTA in these settings.

Methods

We conducted a landscape survey in selected LMICs in 2012, to assess the status and use of HTA. The 22-item survey was distributed by email and postal mail to a key informant in each of the following 19 countries: Afghanistan, Angola, Bangladesh, Democratic Republic of the Congo, Dominican Republic, Ethiopia, Guatemala, Jordan, Kenya, Liberia, Lesotho, Mali, Mozambique, Namibia, Rwanda, South Sudan, South Africa, Swaziland and Vietnam. We selected these countries for participation in the study based on the local presence of a Management Sciences for Health (MSH) office. MSH is a private, non-profit international organization working to strengthen healthcare management and improve access to pharmaceutical and other healthcare services in LMICs. MSH is active in many diverse countries around the world and had knowledge of who the key informants and stakeholders in HTA were in the selected countries. The key informants were predominantly government employees but also included academics and employees of non-governmental organizations involved in the pharmaceutical sector.

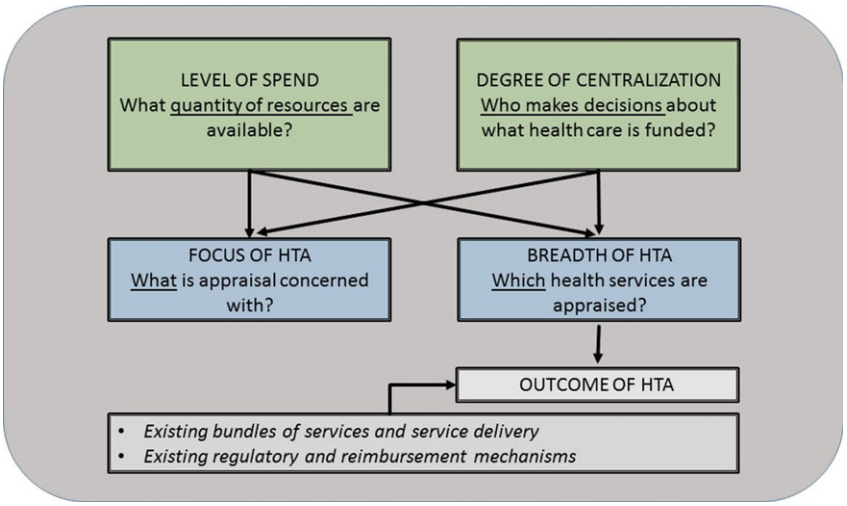

Figure 1 Conceptual framework of healthcare systems and HTA.

The survey items were organized under three themes: (1) HTA as it relates to the healthcare system, (2) conduct of HTA in the country and (3) challenges to conducting HTA in the country. We used structured survey questions for themes 1 and 2 and open-ended questions for theme 3. For the first and second themes, we calculated the distribution of responses to structured questions and analysed HTA attributes by country. For the third theme, we analysed the qualitative responses based on key concepts and opinions expressed in the open-ended responses. For non-English-speaking countries, the survey was translated from English into Spanish or French, and was mailed and emailed to key contacts in each of the selected countries.

We also performed an analysis of the relationship between the performance of HTA and country income (as a proxy of level of spend),[20] and HTA and government effectiveness using the World Bank world governance indicator index (as a proxy of degree of centralization).[21]

Results

Of the 19 countries selected for participation in the survey, key informants in 12 (63%) countries submitted responses.

HTA use in the healthcare system

Survey responses are shown in Table 1. Two countries, Rwanda and South Africa, responded that HTA is used for the range of regulatory, coverage/formulary and reimbursement activities. Ethiopia and Namibia reported use of HTA for both regulatory and coverage/formulary but not for reimbursement, while Afghanistan reported use of HTA for regulatory and reimbursement purposes. Bangladesh, DR Congo, Dominican Republic, Jordan and Kenya reported that HTA is not used in any capacity in the healthcare system. Vietnam stated there is some use of HTA but not in a formal capacity.

There were a wide range of stakeholders identified in the each country's HTA processes. Half of the respondents reported that academic institutions are stakeholders in the HTA process – Afghanistan, DRC, Ethiopia, Jordan, Rwanda and Vietnam, and all of those countries, with the exception of Jordan, reported that clinical professional organizations are also stakeholders in HTA. The Ministry of Health (MOH) was identified as a key stakeholder in four countries – Dominican Republic, Jordan, Namibia and Rwanda, with it being the only stakeholder in the country for the Dominican Republic. Other reported HTA stakeholders are the World Health Organization (Afghanistan, DR Congo, Jordan and Rwanda) and product manufacturers (Afghanistan, DR Congo, Namibia and South Africa). Respondents in all countries but Jordan and Swaziland reported that the MOH is responsible for using current evidence to assess and reorganize the healthcare system.

Respondents in five countries (Afghanistan, Ethiopia, Namibia, Rwanda and South Africa) reported that economic considerations influence regulatory, formulary or reimbursement decisions. Respondents in two countries (Dominican

Table 1 Results of the landscape survey

Attribute	*N* (%)	Countries*
HTA use in the healthcare system		
Role of HTA in the healthcare system†		
Regulatory	5 (42)	AF, ET, NA, RW, ZA
Coverage/formulary	4 (33)	ET, NA, RW, ZA
Reimbursement	3 (25)	AF, RW, ZA
None of the above	5 (42)	BD, DO, CD, JO, KE
Unknown	1 (8)	SZ
Other	1 (8)	VN
Stakeholders in current HTA process†		
Product manufacturers	4 (33)	AF, CD, NA, ZA
WHO	4 (33)	AF, CD, JO, RW
Patient organizations	1 (8)	ET
Private insurers	2 (17)	RW, ZA
Academic institutions	6 (50)	AF, CD, ET, JO, RW, VN
Clinical professional organizations	5 (42)	AF, CD, ET, RW, VN
Ministry of Health	4 (33)	DO, JO, NA, RW
No HTA	1 (8)	KE
Agency that reviews health system based on published evidence		
Ministry of Health	10 (83)	AF, BD, CD, DO, ET, KE, NA, RW, ZA, VN
Other	2 (17)	JO, SZ
Presence of agency utilizing HTA for regulatory decisions		
Yes	5 (42)	AF, ET, NA, RW, ZA
No	5 (42)	DO, CD, JO, KE, VN
Unknown	2 (17)	BD, SZ
Presence of agency utilizing HTA for reimbursement decisions		
Yes	3 (25)	AF, RW, ZA
No	6 (50)	DO, CD, ET, JO, KE VN
Unknown	3 (25)	BD, NA, SZ
Extent of use of HTAs from other countries or regions		
Never	2 (17)	DO, CD
Sometimes	3 (25)	ET, JO, KE
Frequently	1 (8)	RW
Always	1 (8)	ZA
Unknown	5 (42)	AF, BD, NA, SZ, VN
Use published HTAs from other LMICs		
Yes	3 (25)	ET, JO, RW
No	6 (50)	AF, DO, CD, KE, ZA, VN
Unknown	3 (25)	BD, NA, SZ
Use published HTAs from high-income countries		
Yes	5 (42)	ET, JO, RW, ZA, VN
No	4 (33)	AF, DO, CD, KE
Unknown	3 (25)	BD, NA, SZ
Other countries use your country's published HTAs		
Yes	1 (8)	RW
No	5 (42)	AF, DO, KE, NA, ZA
Unknown	6 (50)	BD, CD, ET, JO, SZ, VN
HTA functions for which economics is a consideration†		
Regulatory	3 (25)	AF, ET, RW
Coverage/formulary	4 (33)	ET, NA, RW, ZA
Reimbursement	3 (25)	AF, RW, ZA
None or the above	2 (17)	JO, KE
Unknown	5 (42)	BD, CD, DO, SZ, VN
Conduct of HTA in the country		
Written guideline or established HTA process		
Yes	4 (33)	ET, NA, RW, ZA
No	8 (67)	AF, BD, CD, DO, JO, KE, SZ, VN

Table 1 (continued)

Attribute	*N* (%)	Countries*
Form of current HTA guidance		
Advisory	3 (25)	AF, ET, ZA
Unknown/not sure	5 (42)	BD, CD, NA, SZ, VN
None	4 (33)	DO, JO, KE
Agency responsible for conducting HTA		
Ministry of Health	4 (33)	ET, NA, RW, ZA
Other formal entity	2 (17)	AF, JO
None identified	6 (50)	BD, DO, CD, KE, SZ, VN
Formal process for identifying technologies for HTA review		
Yes	3 (25)	ET, NA, RW
No	6 (50)	AF, DO, CD, JO, KE, ZA
Unknown	3 (25)	BD, SZ, VN
Active discussion on HTA performance in the country		
Yes	6 (50)	AF, JO, NA, RW, ZA, VN
No/Unknown	6 (50)	BD, DO, CD, ET, KE, SZ

HTA, health technology assessment.
*International Organization for Standardization country code.
†Percentages do not add up to 100 due to multiple selections.

Republic and DRC) reported that they never use HTAs from other countries or regions, while respondents in three countries (Ethiopia, Jordan and Kenya) reported that they use HTAs from other countries some of the time. Only South Africa responded that they always use HTAs conducted in other countries, while Rwanda responded that they frequently did. Respondents in the countries of Ethiopia, Jordan and Rwanda reported using published HTAs from both other developing and developed countries. South Africa and Vietnam use published HTAs only from high-income countries. South Africa was the only country to report that other countries use their published HTAs.

Conduct of HTA in the country

Data on the conduct of HTA in different countries are also shown in Table 1. Respondents in Ethiopia, Namibia, Rwanda and South Africa reported that written guidelines or established processes exist for HTA in their countries. Respondents in Afghanistan, Ethiopia and South Africa reported that current HTA guidance is advisory, but none of the respondents reported that HTA guidance is mandatory in their countries.

Respondents in half of the countries (Bangladesh, Dominican Republic, DR Congo, Kenya, Swaziland and Vietnam) reported that there is currently no specific agency responsible for HTA in the country, while respondents in Ethiopia, Namibia, Rwanda and South Africa reported that the MOH is responsible. Respondents in Afghanistan and Jordan reported that the entity responsible for HTA in their countries, are the General Directorate of Pharmaceutical Affairs and the High Health Council respectively.

Rwanda was the only country that reported economic considerations, such as budget impact or cost-effectiveness analysis, influence HTA functions with regard to regulatory decisions, coverage/formulary decisions and reimbursement decisions. However, Afghanistan, Ethiopia, Namibia and South Africa all reported that economic considerations influence at least some aspect of HTA function. Ethiopia, Namibia and Rwanda reported that there is a formal process for identifying technologies for HTA. The remaining nine countries reported there was no formal process or that they do not know if any exists.

Challenges of conducting HTA in the country

Respondents in five countries – Afghanistan, Jordan, Namibia, South Africa and Vietnam – reported that there is active discussion or debate about HTA, though the extent and depth of the discussions varied. South Africa reported active implementation of HTA as part of their National Health Insurance, while Jordan reported the formation of a national committee but limited progress due to a lack of financial support. In Afghanistan, Namibia and Vietnam, HTA has yet to be elevated to the national agenda.

Training and capacity building were both frequently cited as needed to establish an effective and efficient HTA process. Respondents reported that there is limited knowledge about how to go about initiating HTA that is significantly contributing to delays and reluctance about how to move forward. Additionally, many respondents indicated that they are looking to their national government to provide the laws and enact specific policy that formalizes HTA. The main challenges cited were resources, both financial and human, to conduct HTA in the countries surveyed. Other challenges identified include the need for consensus building among stakeholders, the need to raise awareness about the value of HTA, and the development and enforcement of HTA policies and guidelines.

Relationship between HTA, national income and government effectiveness

We used two survey variables as proxies for presence of HTA in a country – presence of written guidelines for HTA and formal identification of technologies for HTA. Of the countries surveyed, respondents in South Africa, Namibia and Rwanda reported that they had written guidelines for HTA and a process of formal identification of technologies for HTA (Table 2). These three also had the highest scores on the government effectiveness index (Table 2). South Africa and Namibia also have high levels of GDP per capita. Rwanda is an outlier with HTA in this regard, with a relatively low GDP per capita. Jordan, the Dominican Republic and Vietnam have a relatively high GDP per capita but respondents in these countries reported no written guidelines for HTA or formal identification of HTA

Discussion

Several themes emerged from our landscape assessment of HTA in LMICs. Most countries reported having some HTA activity but only a few use HTA to inform regulatory, coverage/formulary and reimbursement decisions. HTA is of interest, in most countries, to a wide variety of stakeholders including academics, industry, government and the World

Table 2 Presence of health technology assessment (HTA), population and gross domestic product (GDP) in order of government effectiveness

Country	Population (2013, millions)	Written HTA guideline	Formal ID of technologies for HTA	GDP per capita (2013, US dollars)	Government effectiveness rank* (2013, percentile)
South Africa†	53.0	Yes	Yes	6618	66.51
Namibia†	2.3	Yes	Yes	5462	60.29
Rwanda‡	11.8	Yes	Yes	633	55.50
Jordan†	6.5	No	No	5214	49.76
Vietnam†	89.7	No	Unknown	1910	44.02
Swaziland†	1.3	No	Unknown	3034	39.71
Kenya†	44.4	No	No	994	36.84
Dominican Republic†	10.4	No	No	5826	36.36
Ethiopia‡	94.1	Yes	Yes	498	35.89
Bangladesh†	156.6	No	Unknown	829	22.49
Afghanistan‡	30.6	No	No	678	7.18
DR Congo‡	67.5	No	No	454	1.44

*Percentile rank among all countries (ranges from 0 (lowest) to 100 (highest) rank). Source: Worldwide Governance Indicators, World Bank http://info.worldbank.org/governance/wgi/index.aspx#home
The World Bank Group (http://data.worldbank.org/about/country-and-lending-groups) †Middle Income; ‡Low Income.

Health Organization (WHO). There is some evidence of knowledge sharing with some countries using HTAs from their neighbours or from more developed countries.

There is no evidence to suggest that formal micro- or macro-HTA is performed by a dedicated independent body in any of the countries; in the few countries with HTA activity, it occurs in ministries of health. A few countries have established processes for HTA but the results of HTA are only used in an advisory role. The lack of independent bodies dedicated to HTA is not ideal; some analysts have argued that some degree of independence will be important in having a sustainable HTA process.[22]

There was some evidence to suggest that HTA may be moderately related to the level of spend (GDP per capita) and strongly related to degree of centralization (government effectiveness). Although there is limited formal HTA and no dedicated, independent HTA bodies, these data from LMICs appear to support the conceptual model of Towse *et al.* However, the HTA activity and the health systems do not support a complete analysis of all the different aspects of the conceptual model in this setting. For instance, the data allow us to assess the relationship between the level of spend and the presence of HTA but not whether use of HTA supports interventions of high public health priority as suggested by the conceptual model. We are also unable to assess the relationship between government effectiveness (degree of centralization) and the distribution and types of payers for health care, which inhibits our ability to draw conclusions.

Assessments that qualify as HTA, though limited, are increasing in low-income countries.[23–27] However, these studies are often not used systematically to inform national-level decision-making and are often conducted based on the interests of specific groups and not the government or the health system per se. Thus, when HTA does occur, it is not performed to enhance macro-level public policy goals such as universal health coverage.

Our findings are consistent with emerging evidence in the field to suggest that HTA in LMICs, while limited, particularly in low-income countries, is increasing.[7,12,14,15] Momentum is building, particularly in the areas of capacity building and research tool development.[28] The WHO is emerging as a leader in the development of HTA in LMICs, particularly as it relates to universal health coverage.[29]

One limitation of our study is that the sample of countries as well as survey respondents was a convenience sample. We are only able to make inferences about the surveyed countries based on respondents' knowledge and perceptions of the status of HTA in their countries, which do not represent all LMICs. An additional limitation is that we did not validate the translation of the survey from English to Spanish and French. This may have influenced the interpretation of the survey responses. Despite these limitations, we believe that our survey adds to the knowledge on the status of, or lack thereof, formal HTA in LMICs, particularly in sub-Saharan Africa.

While respondents in half of the countries reported that there was some level of active discussion on implementing HTA, few currently have formal HTA bodies. It is also important to distinguish which functions of HTA should be conducted in countries individually, and when countries can potentially share resources and findings so that excessive time and resources are not spent to recreate the same information. For example, centralized or regional resources that house published and unpublished HTAs from low-, middle- and high-income countries may be useful as it would help various government bodies access the available information from other countries that are in similar situations. Knowledge sharing across regions or continents, organized through some sort of pan-African HTA body, for example, is recommended. Where countries have context-specific problems, they can perform their own HTA studies. However, we contend that the vast majority of microlevel health technologies and health policy questions can be addressed with a few well-designed studies that are generalizable to other settings: information about effectiveness and cost-effectiveness are global public goods that can benefit decision-makers in mul-

tiple jurisdictions. We recommend that countries make efforts to formalize HTA and its role in decision-making to inform health policy. We also recommend that a first step when conducting a HTA be to start by reviewing the large number of HTA studies performed by academics and others so as to maximize use of existing knowledge.

In conclusion, while formal HTA appears to be non-existent or limited in most LMICs, informal HTA exists in these settings. Efforts to formalize both micro- and macro-HTA and to use existing HTA evidence should improve the quality of regulatory, coverage, formulary and reimbursement decisions, and improve individual and public health.

Declarations

Conflict of interest

The Author(s) declare(s) that they have no conflict of interest to disclose.

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Authors' contributions

LG, JBB and AS conceived and designed the study. JBB and RB developed survey instrument and collected data. JBB, RB, and AJ analyzed the data. AJ produced the first version of the manuscript. JB drafted the final version of the manuscript. All authors read and approved the final version of the manuscript.

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