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Impact of health technology assessment implementation with a special focus on middle-income countries

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ABSTRACT

Objectives: Building an efficient health technology assessment (HTA) system requires significant effort and political commitment, in addition to human and financial resources. Expectations of what HTA can offer to middle-income countries (MICs) are continuously rising, which drives health policymakers to raise the question of whether HTA could help secure the financial sustainability needed to implement universal health coverage. In this study, we explored the impact HTA adoption may have on the countries and its impact on health system objectives, as well as transferability of benefits and drawbacks observed in higher-income to middle-income countries.

Methods: We utilized secondary data from a systematic literature review and primary data by disseminating a survey among local stakeholders in three MICs across three continents to capture their perspective on the impact of HTA implementation from a local context.

Results: It was evident from the results of both the literature review and survey that the positive impacts of HTA implementation outweigh the negative impacts. Most of the reviewed literature discussed the impact of HTA on the intermediate objectives of the health finance policy in relation to the broad health system goals. According to the survey respondents, the most evident benefit of HTA implementation is improving the transparency and accountability of healthcare decisions.

Conclusions: Overall, HTA implementation can introduce a myriad of benefits to healthcare systems in MICs as well. Our findings show that while HTA implementation may have the potential to generate cost savings in specific areas, there is no guarantee that HTA can generate savings at the macro level.

Public Interest Summary: Health technologies (medicines, devices, and interventions) are rapidly increasing in complexity and cost. Health Technology Assessment (HTA) guides healthcare decision-makers in choosing the most suitable, effective, affordable, and acceptable health technology to invest limited healthcare resources. However, healthcare decision-makers in middle-income countries (MICS) are still uncertain about whether adopting HTA would help them achieve the financial sustainability needed to achieve universal health coverage.

Therefore: we sought to gather evidence on how HTA has affected the health systems of countries that have already adopted it by reviewing published research reports. In addition, healthcare decision-makers from three MICs were questioned about their perception of how HTA implementation will affect their country's health system.

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We found that the positive effects of HTA implementation outweigh the negative ones; specifically, the transparency and accountability of decisions are improved. However, although HTA implementation may generate cost savings in specific areas, it may not significantly contribute to overall financial sustainability.

Background

The welfare of patients has always been the core and essence of healthcare. Accordingly, choosing what is best for patients remains the ultimate recurring dilemma of those responsible for healthcare decisions. In the era of evidence-based decisions, the continuous advancement of health technologies coupled with limited budgets allocated for healthcare has led to the development of health technology assessment (HTA). HTA is defined as the systematic evaluation of the properties and effects of a health technology while addressing its direct and intended effects, as well as its indirect and unintended consequences, and it is aimed mainly at informing decision-making regarding health technologies [1]. HTA is a tool that captures the multifaceted nature of healthcare to present it to stakeholders (those involved in funding, planning, purchasing, and investing in healthcare) to guide them in making the most suitable, clinically effective, affordable, acceptable, efficient, and scientifically sound decisions by maximizing the allocative efficiency of available resources [2].

The novelty of HTA is that it is defined by its purpose and not by a specific method; it is able to encompass different areas affected by the introduction of a new specific health technology. These areas are grouped into four main sections: the technology, the patient, the organization, and the economy; they are connected by common and overlapping factors such as ethics [3].

Significant effort, political commitment, and human and financial resources are needed to build an efficient HTA system [4]. This is the reason healthcare policymakers in middle-income countries (MICs) often question the benefits HTA offers in exchange for investment. It is commonly argued in health policy debates whether HTA can generate cost-savings for healthcare systems, which is much needed to secure the financial sustainability of universal health coverage. However, the impact of HTA on MICs has not been thoroughly researched, partly because MICs are behind high-income countries (HICs) in HTA implementation. Therefore, conducting a review to explore the available evidence on the benefits of HTA is crucial to support the HTA method of decision-making, bearing in mind that it can be quite challenging owing to the absence of formal HTA agencies in most MICs [5].

The current study aims to explore the impact of HTA adoption in MICs on health systems and health system goals, and to assess the transferability of the benefits and drawbacks of HTA experienced in HICs to MICs through local stakeholders.

Methods

First, a literature review was conducted to identify studies that describe the impact of HTA implementation. This was followed by a survey to capture the views of a convenience sample of experts in the healthcare field on the expected benefits of HTA in three MICs.

Literature review

A literature search was conducted on Scopus in January 2020. Search terms were constructed using a combination of domains related to "health technology assessment" and "impact" (see Appendix 1). Scopus was selected because it covers both EMBASE and MEDLINE databases, in addition to other journals.

The titles and abstracts of all articles were screened using predefined exclusion criteria: (1) without an abstract, (2) written in languages other than English, (3) not related to the impact of HTA implementation, and (4) those published before 2013. Title-abstract screening was conducted

by two independent reviewers using EndNote and Zotero, and any disagreements were resolved by a senior researcher.

The complete text of articles meeting the screening criteria was reviewed to check eligibility for data extraction. A standardized data extraction sheet was developed and assessed for fitness for the purpose through a pilot data extraction round, and it was circulated among reviewers. The extraction sheet was then finalized according to the reviewers' comments and feedback. Screened papers were excluded if: (1) the full-text version was not accessible; (2) it was duplicated; (3) it was a book chapter. All extracted data were double-checked by another researcher. The result of this process formed the basis of the qualitative evidence synthesis.

The data extraction process focused on the following research domains: the methodology used in data collection (whether the paper reported primary or secondary data such as the conclusions of papers reported elsewhere), the purpose of undertaking HTA (reimbursement, pricing, planning, budgeting, and clinical guidelines), and the impact of HTA, including both benefits and drawbacks. Then at a later stage, HTA impacts were categorized according to the broad or intermediary health system objectives determined by the World Health Organization [6].

World Bank income categorization was used to classify the economic status of each country [7]. This was followed by the quality assessment of all the papers included in the analysis. The Standards for Reporting Qualitative Research (SRQR) were used to assess the reporting quality of the included studies [8] (see Appendix 2).

HTA impact survey in MICs

To explore the relevance of the literature review findings for MICs, an online survey using Google forms was distributed among a group of MIC experts in the healthcare field. The survey participants were recruited through the personal network of the primary investigators. The survey comprised four major sections (Appendix 3). Section one was about the respondents' demographics, section two asked about the current status of HTA implementation in their respective countries and the current or expected impacts of HTA implementation, and section three evaluated the expected or perceived impact of HTA implementation on the broad health system goals as well as the intermediate objectives of health finance policies [6]. Section four captured the respondents' feedback on the transferability of the findings of the systematic literature review. Consent for using the survey data was also incorporated as a question in the survey.

To ensure reasonable generalizability, the survey was distributed in three countries belonging to three different geographic regions: Egypt, Indonesia, and Ukraine. The stakeholders that were surveyed represented public, private, and academic sectors as well as non-governmental organizations, and the ratio of respondents representing different stakeholders was given due consideration.

The survey consisted of 12 questions (including consent). It was designed by the research team based on the information extracted from the literature review, and it was reviewed by two HTA experts (academic professors) before it was sent to the respondents. The survey was written primarily in English, as most respondents were fluent in English. However, to avoid potential selection bias arising from selecting only English speakers, the survey was translated into Ukrainian for some respondents from Ukraine as they faced difficulty with answering the survey in English. The translation was performed by a certified translator and then reviewed by the research team to proofread the Ukrainian version of the survey.

Results

General systematic literature review (SLR) results

A total of 1440 papers were identified in the primary database after the removal of duplicates. Fig. 1 illustrates the literature selection process. For the full-text review, 113 papers were assessed for eligibility, and 44 were included in the analysis.

The included papers revealed that HICs were analyzed 100 times, upper middle-income countries were analyzed 17 times, and low and lower middle-income countries together were analyzed only four times, as shown in Fig. 2. It should be noted that there has been a substantial increase in the number of publications across all economic statuses, indicating a rise in interest in exploring the impact of HTA. This phenomenon is generally more plausible in middle-income countries.

European and Central Asian regions dominated the publication field by generating the greatest number of assessments ($n = 82$), and they were followed by East Asia and the Pacific ($n = 20$). North America's number of publications ($n = 9$) on the topic exceeded that of Latin America and the Caribbean ($n = 6$).

Other regions, such as the Middle East and North Africa ($n = 2$) (9, 10), South Asia ($n = 1$) [11], and the Sub-Saharan region ($n = 1$) [12], are still taking their first steps in the field.

Among the 44 publications included in the review, several papers

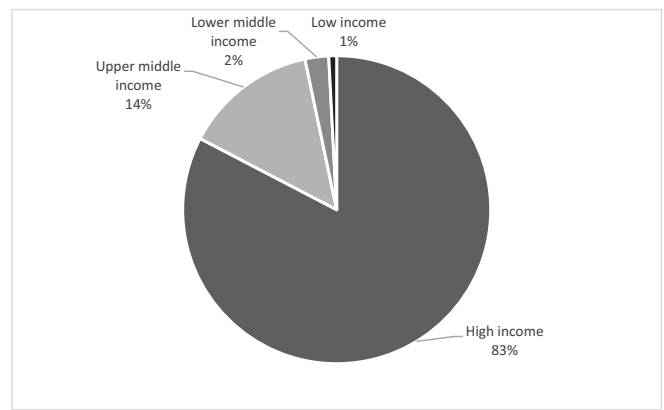


Fig. 2. Proportion of countries included in the study by income group.

utilized more than one research method; 16 (37%) publications used literature review in their methodology, three conducted systematic literature reviews, nine (20%) collected data through surveys, and five (11%) through case studies. Eight (18%) publications used editorial reports/expert commentary. Ten (23%) publications depended on the analysis of administrative data, and the rest did not clarify the

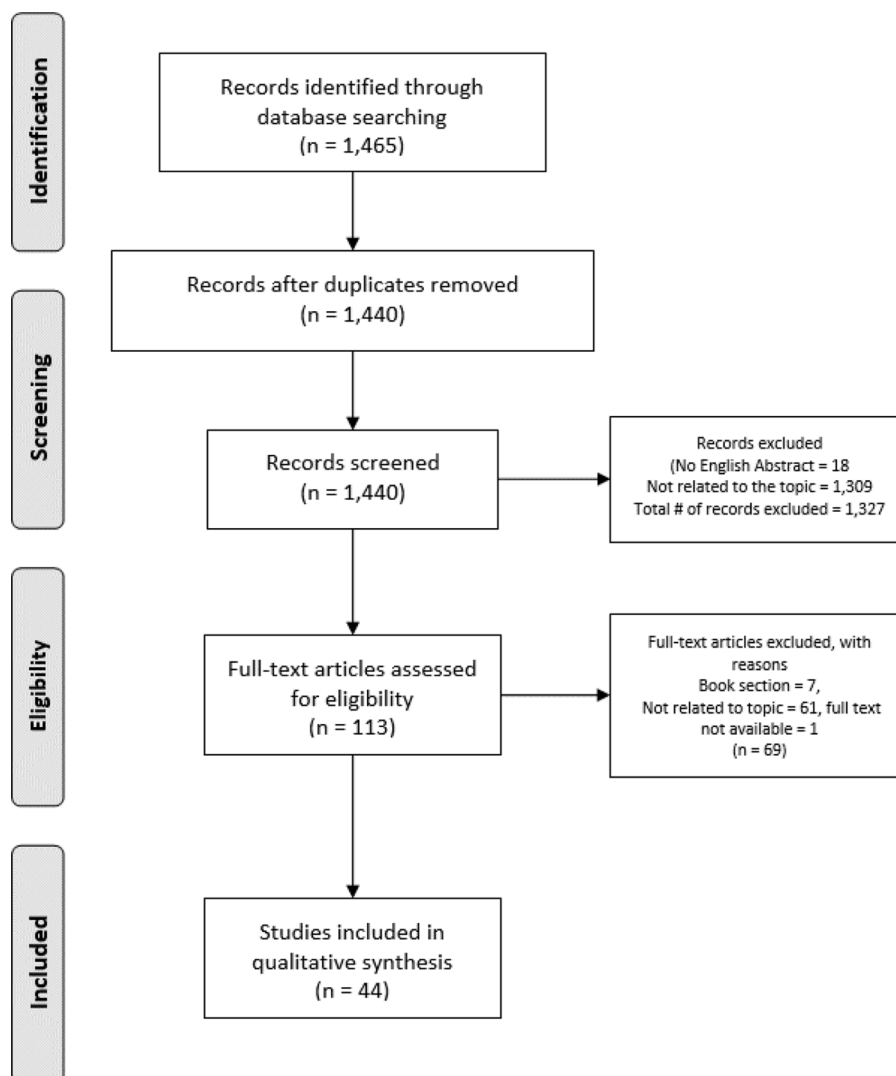


Fig. 1. Prisma flow diagram of the systematic literature review.

Table 1
HTA impact summary from the literature.

Health system objectives	Positive impact	Negative impact
Health gain	<ul style="list-style-type: none"> • HTA increases health benefits of patients along with moderate improvement in clinical efficacy. (14, 15) 	
Equity in health	<ul style="list-style-type: none"> • Enables the achievement of greater equity through increasing availability and improving access to innovative health technologies by taming financial barriers such as requiring co-payment at point of access. (10, 28, 36, 40–42) 	<ul style="list-style-type: none"> • Generates restrictions in accessibility by applying reimbursement for sub-populations or sub-indications. (17)
Financial protection	<ul style="list-style-type: none"> • Protection of households from catastrophic health spending through different methods such as waiving co-payment of essential drugs. (10, 28) 	
Equity in finance	<ul style="list-style-type: none"> • Ensuring the accessibility of drugs on the positive list regardless of financial status. (10) 	
Responsiveness	<ul style="list-style-type: none"> • HTA (including hospital based HTA) accelerates the acceptance of new treatments. This in turn improves patient access to new technologies, providing an array of new choices which cater for diverse patient needs, at the individual and the population levels. (14, 15, 34, 35, 38, 40, 41, 43) • Providing scientifically sound evidence and facilitating the conduction of multidisciplinary research. (44) • The greatest benefit of a managed entry scheme is probably that it offers access to innovative technologies which otherwise would not happen (46). • Adoption of evidence-based health policies and hence the adoption of more positively effective resilient health policies. (29) 	<ul style="list-style-type: none"> • HTA lacks the ability to incorporate societal values into the decision-making process. HTA tends to slow down decisions due to restrictions generated by the appraisal, which in addition to negative reimbursement decisions hinder patients' access to health technologies, especially noted in cases of orphan drugs. (9, 10, 16, 33, 45) • Negative reimbursement decision led to a strong resistance from clinicians. (13)
Transparency and accountability	<ul style="list-style-type: none"> • HTA improves transparency and fairness. (12, 17, 24, 38, 39, 44, 47–51) • Litigation of high-cost drugs produced more positive verdicts (51) and decreased knowledge gaps through development of a competent database. (44) • Hospital-based HTA improves workflow and communication between the medical staff and hospital management. (43) 	<ul style="list-style-type: none"> • Despite the fact that transparency is one of the founding principles of HTA, in real practice it may show the opposite, such as insufficient consultation with experts, manufacturers and patient organizations. (52) • Managed Entry Schemes may lead to a lack of transparency (46).
Quality and efficiency in service delivery	<ul style="list-style-type: none"> • HTA enables regional decision makers to design more efficient service delivery models by eliminating any uncertainties about clinical effectiveness (53, 54). • Hospital-based HTA improves the quality of medical service through improving clinical practice while integrating patient needs and medical staff capabilities, which ultimately lead to the reduction of patients' length of stay. (13, 36, 43, 50) • Hospital-based HTA improves efficiency by reducing the probability of purchasing expensive drugs and restricting over-using drugs prescription. (42, 43) 	
Fiscal sustainability & administrative efficiency	<ul style="list-style-type: none"> • HTA induces unit price reduction. It generates cost saving through informing reimbursement and disinvestment decisions, which in the long-term improves technical, and allocative efficiency, as well as strategic pricing. HTA can contribute to budget control to ensure fiscal sustainability. (9, 11–15, 17, 24, 27, 28, 33, 36–38, 40–43, 45–47, 49, 55–59) • HTA improves pharmaceutical pricing, specially it ensures better value for money of orphan drugs. (25–26, 40, 53, 60) • HTA reports help control the demand on novel technologies. (9) • It improves the organizational structure through the establishment of database that documents the administrative processes. (24) • De-facto HTA could be used to delist ineffective product, set products' prices, and facilitate price volume agreement/risk sharing scheme. Its implementation results in price cuts and cost shifting. (20) 	<ul style="list-style-type: none"> • Centralized HTA is associated with higher prices for the least expensive product. (42) • When reviewing already reimbursed technologies HTA may lead to increase in prices based on value for money. (45) • In Japan HTA resulted in increased drug price four times that of the current price. (56) • De-facto HTA implementation might trigger parallel export as a result of dramatic price cuts. (20)

methodology used.

Most of the studies (70%) researched used HTA to advise reimbursement decisions or to formulate benefit packages, while 45% limited analysis to its role in pricing health technologies. Only a few studies considered using HTA for other purposes, such as planning and budgeting (20%), formulating clinical practice guidelines and protocols (23%), and other uses (18%).

In general, 75% of the included papers discussed only the positive impact of HTA on their respective health systems, whereas seven percent reported only drawbacks. The remaining 18% reported a mixture of both.

Impact of HTA relating to healthcare system objectives

The broader aim of HTA is to improve health systems; two studies [11,13] support this assumption. Hence, we assessed the direct influence of HTA on health systems using the broad health system goals published by the WHO [6] as a guide: health gain, equity in health, financial

protection, equity in finance, and responsiveness. In addition, we adopted three other financing policy objectives and requirements that serve as intermediate objectives for the broad health system goals: transparency and accountability, quality and efficiency in service delivery, and fiscal sustainability and administrative efficiency.

The largest impact of HTA was observed on the intermediate objectives of health finance policies in relation to broad health system goals; 31 (70%) articles reported impacts related to this category. This is driven by the positive effect of HTA on the financial sustainability and administrative efficiency of the healthcare system, as well as its effects on transparency and accountability. Regarding HTA's direct effect on the broad health system goals, it was mainly dominated by its impact on the responsiveness of health systems to patients' needs (48%) and equity in health (45%), while its impact on other objectives such as direct health gain (27%) and financial protection of households (14%) was less evident. The least affected health system objective was equity in finance, discussed in only four (9%) articles.

HTA enables the health gain of populations by improving patient

outcomes [14,15]. However, severe restrictions on drug utilization generated from HTA can be a barrier that leads to disease progression [10,16,17], which in turn, has a negative impact on health gain.

The benefits of HTA implementation include improving equity in health and improving access to drugs, which broadens patients' choices. However, negative reimbursement decisions might lead to more restrictions on patient access; therefore, it is suggested that policymakers consider "accountability for reasonableness" to improve access to orphan drugs [18]. Moreover, in a comprehensive HTA appraisal, policymakers should consider equity in the methodological document to improve equity in health [19]. It was reported in Romania that potential parallel exports might harm equity in health. Hence, the government should reevaluate its external reference pricing system [20].

Since HTA strengthens the confidence of payers by improving transparency and accountability, payers in some countries excluded the cost-sharing system for the drugs from the positive list [10], which may impact equity in finance. Nevertheless, an increase in drug prices (e.g., in Japan) with high co-payment rates can harm financial equity [21]. In MICs with high budget restrictions where cost sharing is applied, HTA is expected to aid in selecting the effective treatment and influencing the pricing negotiation process.

Aside from broadening patients' choices, HTA reduces knowledge gaps and supports responsiveness, which is directly related to improving knowledge. Accordingly, the HTA team should disseminate clinical guidelines that are easy to use, acceptable to both patients and physicians [22], and address the needs of the population; hence, it is preferable that HTA use real-world data [23].

In addition to the adapted WHO Health system goals mentioned in Table 1, a few more HTA consequences were observed in the reviewed papers, such as increasing independent research and enhancing its quality [24]. This has led to improving guidelines [14,15,25,26], filling research gaps [9,14,15], and informing decisions related to the inclusion of drugs into the National List of Essential Medicines (NLEM) [25]. It has also increased the private sector's share of spending by activating alternative financing methods, offering service provision, and identifying additional sources of revenue [27].

HTA impact in MICs

MIC literature

The implications of HTA specifically in MICs were discussed in 15 of the 44 papers [9-11, 15,20,25,26,28-35], which reported that HTA enabled better decisions. In Argentina, HTA was reported to generate cost savings [11], Myanmar reported the successful use of HTA for resource allocation [28], and Vietnam managed to utilize HTA to maximize the benefits of both old and new technologies in a short time to meet public demands [25]. In conclusion, most of the studies agreed that HTA could help achieve better health financing decisions [11,29].

Survey in MICs

The survey conducted in the study included 58 participants in three countries (Egypt, $N = 28$; Ukraine, $N = 21$; Indonesia, $N = 9$), who represent academia (36%), the governmental sector (34%), the private sector (33%), and the non-governmental sector (12%). It should be noted that the selection of more than one affiliation was allowed.

HTA progression status in participant countries

The introduction of HTA in lower MICs is still in its inceptive stages, which was evident in the respondents' answers regarding HTA utilization in their countries: two-thirds (66%) reported partial HTA implementation in their country, while (29%) reported no HTA implementation. In contrast, three percent reported complete HTA implementation, while two percent were unaware of the HTA implementation status in their country.

Respondents who reported that HTA implementation was

progressing in some way in their countries were asked to choose the main areas in which HTA was being implemented from four different sets of options. These options include (1) supporting benefit package/reimbursement decisions, (2) supporting decisions in pharmaceuticals/medical devices, (3) improving clinical practice guidelines/financing protocols, (4) supporting national, regional, or institutional planning/budgeting, or others to be mentioned by the respondent.

The majority of respondents (75%) reported the use of HTA to inform decisions related to basic benefit packages and/or reimbursement decisions, while half the respondents (50%) reported using HTA to inform health program planning and budgeting. A few respondents (20%) reported that HTA is being used for planning and budgeting on national, regional, or institutional level; a similar proportion (20%) reported the utilization of HTA in improving their clinical practice guidelines and/or financing protocols. The utilization of HTA to formulate the essential national drug list was only reported by five percent of the respondents, whereas three percent reported the absence of a defined area for HTA implementation, as elaborated in Fig. 3.

When respondents were asked about positive HTA implications, most answers revolved around the role of HTA in improving drug availability and accessibility by revising the list of drugs included in the basic benefit package in each country. Furthermore, other implications included improving the performance of the healthcare system through the proper allocation of financial resources, enhancing budgeting and planning decisions, and supporting decision making, particularly for the national health insurance benefit package. There were no negative implications of HTA mentioned, other than doubts regarding the cost and time needed to have qualified HTA experts implement it within the healthcare system.

Respondents who reported that HTA has not yet been implemented or was premature in their country were asked about their point of view regarding areas that should be prioritized for HTA implementation by choosing from five previously set choices, and with an option to write an opinion of their own.

The highest priority according to the respondents' answers was the reimbursement list/basic benefit package (44%), followed by the formulation of clinical practice guidelines and protocols, and the pricing of health products (both were 17%). Planning and budgeting of health programs was selected by (11%), while those who opted for other options (11%) noted that HTA would enable better access to more advanced technologies and improve the transparency of medicine reimbursement decisions and procurement decisions, facilitating a more economically feasible health cost allocation process, as shown in Fig. 4.

The group representing non-HTA implementing countries was asked about their opinion regarding how HTA implementation can positively affect the healthcare system in their country. There was consensus that HTA implementation would generally have a positive influence, mostly owing to the rationalizing of spending and managing cost of technologies, which enables the achievement of a more efficient equitable health service. "If done properly", the HTA should secure reimbursement of medicinal products for vulnerable patient groups, including patients with rare diseases."

Regarding their perception of the negative effects of HTA implementation, most respondents were apprehensive not of HTA itself, but rather of the time required for HTA implementation and its integration in the healthcare system, which can be considerably lengthy, and consequently, might delay the accessibility to new health technologies in the transition period. Some respondents were concerned that the time consumed by the assessment process for every technology with similar implications may delay patient access. Others mentioned that if HTA entities were private, they could be manipulated by the pharma industry.

Perceived HTA impact on health system objectives

Respondents were asked about their perception of HTA

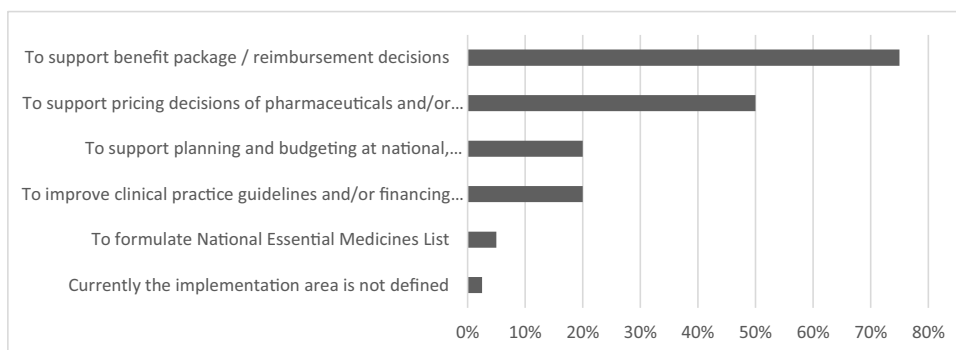


Fig. 3. Uses of HTA reported in HTA implementing countries.

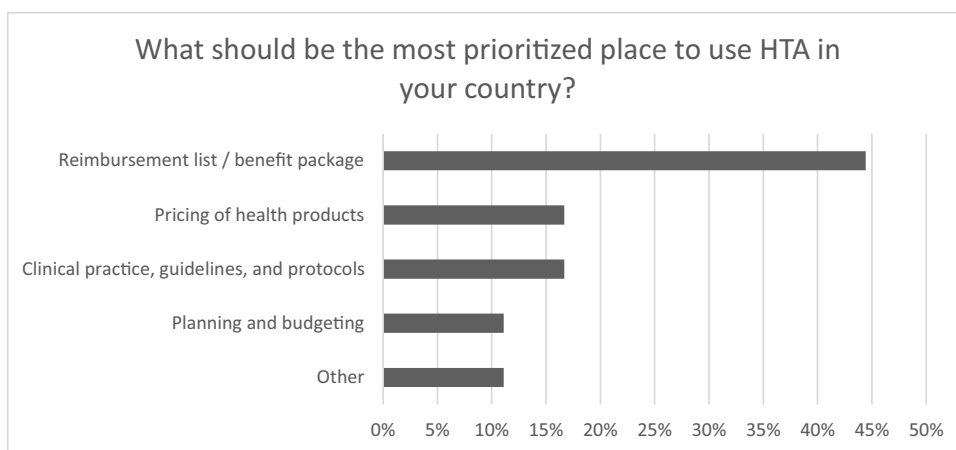


Fig. 4. Opinion of experts from non-HTA implementing countries on top priorities for using HTA.

implementation regarding its effect on the ability of their respective health systems to achieve their goals. The possible answers were positive influence, negative influence, no influence, and not sure/do not know, as shown in Table 2. Respondents reported that HTA implementation would have the most positive influence on transparency and accountability in healthcare decisions (97%). This was followed by maximizing health gains of the population (84%), quality and efficiency in service delivery (81%), and improving the responsiveness of the healthcare system to patients' needs (72%).

Interestingly, survey respondents were less convinced about HTA implications on financial objectives; 40 respondents (69%) reported that HTA positively influences fiscal sustainability and administrative efficiency, financial protection of patients, and equity in finance.

In general, most respondents expected HTA to have a positive impact rather than a negative one, as only a maximum of three percent thought it would negatively affect the health system goals in four of the seven domains.

In the last section of the survey, we inquired about the respondents' expectations concerning the main findings from the systematic literature review regarding the implementation of HTA in their respective countries. The results were aggregated into 15 main domains presented in Table 3, and the possible answers were yes, no, or maybe. The majority of the respondents believed that HTA would improve the formulation of clinical guidelines (76%) and clinical practice (72%). A considerable proportion (67%) disagreed that HTA implementation would lead to an increase in prices of the selected technologies. Around half of the participants were uncertain about some domains, such as increased patient co-payment, decreased selected health technology prices, and reduced hospital stay (52%, 48%, and 48%, respectively).

Table 2
Perceived impact of HTA on healthcare system goals.

Healthcare system goal	Positively influence	Does not influence	I do not know/I am not sure	Negatively influence
Health gain	84%	3%	12%	0%
Equity in health	76%	14%	7%	3%
Financial protection of patients	66%	19%	12%	3%
Equity in finance	64%	22%	14%	0%
Responsiveness to patient needs	72%	10%	16%	2%
Transparency and accountability of health care decisions	97%	2%	2%	0%
Quality and efficiency in service delivery	81%	10%	9%	0%
Fiscal sustainability & administrative efficiency	69%	9%	21%	2%

Discussion

In the current study, we explored the impact of HTA adoption on health systems and health system goals, and assessed the transferability, consequent benefits, and drawbacks of HTA in MICs from the perspective of local stakeholders. This was done through the utilization of secondary data derived from a systematic literature review, as well as primary data generated from a survey conducted among local stakeholders.

Based on published literature, MICs were lagging behind HICs

Table 3
Perceived results of HTA implementation.

HTA impact	Yes	Maybe	No
Improved health outcomes	71%	29%	0%
Reduced health expenditure	45%	38%	17%
Cost-savings in selected diseases	67%	31%	2%
Increased prices of selected health technologies (such as drugs or medical devices)	5%	28%	67%
Decreased prices of selected health technologies (such as drugs or medical devices)	45%	48%	7%
Implementation of increased patient copayment	22%	52%	26%
Restricted access to drugs due to slower regulatory and reimbursement process	24%	43%	33%
Restricted access to the expensive (orphan and cancer drug) health technologies due to negative reimbursement decisions	36%	43%	21%
Improved access to drugs by reducing opportunity cost of inappropriate utilization	71%	22%	7%
Reduced access to drugs due to parallel exports from countries with lower pharmaceutical prices to countries with higher prices	5%	41%	53%
Reduced knowledge gap among stakeholders	60%	28%	12%
Improved communication between medical staff and hospital management	62%	31%	7%
Improved clinical guidelines	76%	21%	3%
Improved clinical practice	72%	24%	3%
Reduced length of hospital stays	41%	48%	10%

considerably in their HTA adoption status, and accordingly, in their assessment of the implications that may be caused by HTA implementation. Nevertheless, there has been a clear rise in HTA activity recently, which is evident from the increased number of related publications. However, Europe and Central Asia dominate the global publication arena by generating the highest number of articles on the impact of HTA implementation. However, it is worth mentioning that only a few papers are based on the analysis of administrative data, when compared to other methods (23%).

It was quite evident from the results of both the literature review and accompanying survey that the positive impacts of HTA implementation outweigh the negative impacts. The majority of papers included (almost 75%) in the literature review discussed only the positive impact of HTA on their respective health systems, while only seven percent discussed only drawbacks. Most papers focused on HTA's favorable impact on fiscal sustainability and administrative efficiency, while the impact on direct health gain and financial protection was discussed to a lesser extent. According to the survey respondents, the most expected positive effect of HTA implementation was transparency and accountability of healthcare decisions, followed by maximizing health gains of the population and improving the responsiveness of the healthcare system to patients' needs. As MICs, in comparison with HICs, have limited experience in making transparent and accountable public policy decisions, the health status of their population is worse, and their healthcare systems are less patient-centric, which is highly important and may already justify the necessary investment to build an HTA system.

According to scientific literature, HTA can support the control of the healthcare budget; however, there is no clear evidence of whether it can generate savings at the healthcare system level. Consequently, we cannot determine whether countries that are advanced in HTA implementation could reduce healthcare expenditure or could have better budget control than other countries that are lagging in HTA implementation. Even if future studies can provide an answer based on the experiences in HICs, it is uncertain whether such evidence is transferable to MICs, whose healthcare systems are relatively underfinanced. It was noticeable that few survey respondents from MICs expected that HTA could contribute to the financial goals of healthcare systems in comparison with other benefits. In general, there is no evidence that HTA implementation can generate cost savings in MICs at the healthcare system level.

The introduction of HTA in Egypt, Ukraine, and Indonesia is still in

its incipient stage, and the focus is limited to utilizing HTA to inform decisions related to basic benefit packages and/or reimbursement decisions. However, in general, most respondents expect HTA to have a positive impact rather than a negative one; only three percent thought it would have a negative impact on health system goals in four out of seven domains.

HTA is gradually spreading in MICs; for example, the recent HTA regulation in Ukraine [30–32] established an independent HTA agency with detailed HTA procedures for medicines and mandates for conducting HTA for medical devices starting in 2022. However, progress should be gauged by continuous assessment of HTA impact according to the health system objectives, rather than by relying on data from more developed countries.

The study by Angelis et al. [17], which started with a systematic literature review backed by a survey for primary data collection, is similar in method to our study. However, that study focused mainly on the implementation and outcomes of conducting HTA in eight high-income European countries and did not consider the implication that it may have for their respective health systems [17]. On the contrary, a study by Hailey et al. [15] matched our study in terms of its aim, in attempting to capture the influence/implications of HTA on, not only the economic outcomes, but also the health outcomes of the health system. However, the 19 countries included were of higher economic status (15 high-income and 4 upper-middle-income countries). In contrast, our study focused only on middle-income countries. Moreover, their results depended mainly on secondary data from a literature review without any primary data collection [15]. Furthermore, the literature review by Hailey et al. recorded 4767 studies that were identified from the literature search after the removal of duplicates, and eventually, 51 studies were included. The disparity found in comparing their search outcome to the 1455 studies we identified from our search, which ended with 44 included studies, is attributed to the difference in the search periods for the studies. Hailey et al.'s search covered literature from 2000 to 2014, but it was extended to 2015 (15 years). Our study, however, focused on studies published between 2013 and January 2020 (seven years). This represents about half the time period, yet the number of included studies was not considerably different [15]. Overall, HTA implementation may introduce a myriad of benefits to healthcare systems in MICs as well. However, policymakers should be careful with their expectations of HTA, which also has its shortcomings. Negative HTA recommendations may result in restricted patient access to non-cost-effective technologies, and positive HTA recommendations may increase healthcare costs if relatively expensive but life-extending and cost-effective technologies are reimbursed.

Limitations

Our study has some limitations. Literature on the real-world impact of HTA on broad health system goals is quite lacking, which is an issue that hinders the proper evaluation of HTA impact, and ultimately the evolution of HTA in countries with limited resources for investment in health policy tools. The problem is complicated by the heterogeneity of qualitative data collected from different publications, which makes it difficult to aggregate findings and draw generalizable conclusions.

Our survey had a relatively small sample size, especially in Indonesia. In addition, the representativeness of the survey respondents to the HTA community was not guaranteed, as survey participants were recruited through the personal network of the primary investigators. Therefore, further studies with more participants and a clearer recruitment process, including additional countries, are needed to confirm the validity of our conclusions on a broader scale.

Proposal for further studies

There is a general lack of research evaluating the impact of HTA, specifically in MICs. Furthermore, most of the research available is

based on secondary data, and there is a lack of quantitative analysis on the impact of HTA on healthcare systems. Quantitative analysis of the impact of HTA is a daunting task because of the presence confounding factors related to different health policies. Nevertheless, we still believe there is a need for more research to evaluate the impact of HTA, especially in MICs.

We recommend that future studies adopt one of the three methods for assessing the impact of HTA in a quantitative approach that minimizes the interference of confounding variables. The first is a longitudinal approach to assess decisions based on HTA evidence in light of real-world evidence; if this can be repeated for several health technologies, it could provide concrete evidence on whether the HTA being used for decision making is sufficient or needs amendment. Another more general method would be to evaluate health system indicators pre- and post-HTA implementation. Finally, a cross-sectional method would be useful to compare health system indicators in different countries with and without advanced HTA system implementation by adjusting to other potentially relevant health policy tools. Again, all these methods are considerably complex, but their benefits outweigh the effort invested.

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Author statement

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Declaration of Competing Interest

None declared.

Supplementary materials

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