Factors influencing the institutionalization of Health Technology Assessment in Kenya.

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Abstract

Background

There is a global interest in institutionalizing health technology assessment (HTA) as an approach for explicit healthcare priority-setting. Institutionalization of HTA refers to the process of conducting and utilizing HTA as a normative practice for guiding resource allocation decisions within the health system. In this study, we aimed to examine factors influencing institutionalization of HTA in Kenya.

Methods

We conducted a qualitative case study using document reviews and in-depth interviews with 30 participants involved in the HTA institutionalization process. We used a thematic approach to analyze the data.

Results

We found that institutionalization of HTA in Kenya was being supported by factors such as establishment of organizational structures for HTA; availability of legal frameworks and policies on HTA; increasing availability of awareness creation and capacity-building initiatives for HTA; policymakers’ interests in universal health coverage and optimal allocation of resources; technocrats’ interests in evidence-based processes; presence of international collaboration for HTA; and lastly, involvement of bilateral agencies. On the other hand, institutionalization of HTA was being undermined by limited availability of skilled human resources, financial resources, and information resources for HTA; lack of HTA guidelines and decision-making frameworks; limited HTA awareness among subnational stakeholders; and industries’ interests in safeguarding their revenue.

Conclusions

Kenya’s Ministry of Health can facilitate institutionalization of HTA by adopting a systemic approach that involves: - a) introducing long-term capacity-building initiatives to strengthen human and technical capacity for HTA; b) earmarking national health budgets to ensure adequate financial resources for HTA; c) introducing a cost database and promoting timely data collection to ensure availability of data for HTA; d) developing context specific HTA guidelines and decision-making frameworks to facilitate HTA processes; e) conducting deeper advocacy to strengthen HTA awareness among subnational stakeholders; and f) managing stakeholders’ interests to minimize opposition to institutionalization of HTA.

Background
Health systems resource constraints and continued resource wastage have led to growing interest in explicit healthcare priority-setting processes to inform universal health coverage (UHC)-related decisions [1, 2]. Explicit healthcare priority-setting processes are deliberative, evidence-based, inclusive, systematic, and transparent processes for informing resource allocation decisions [1]. An example of an explicit healthcare priority-setting approach is health technology assessment (HTA). HTA is “a multidisciplinary process that uses explicit methods to determine the value of a health technology to inform decision-making towards an equitable, efficient and high-quality health system” [3]. A health technology is any intervention that can promote health; prevent, diagnose, or treat disease; prolong lives; or inform health service delivery. Examples include diagnostic tests, medicines, vaccines, procedures (medical and surgical), policies, and programs [3, 4].

With the ever-growing demand for health technologies arising from UHC commitments, advancements in scientific knowledge, larger older population groups and rising burden of communicable and non-communicable diseases, the need for HTA to inform explicit healthcare priority-setting becomes more crucial as health systems budgets remain limited [5-7]. Integrating HTA into healthcare priority-setting processes is a good governance measure that strengthens health systems by promoting transparency, inclusivity, and accountability in decision-making through systematic, deliberative, and inclusive processes [8]. HTA also promotes good governance by providing policymakers with an efficient means of allocating resources thus promoting sustainability in resource limited health systems striving to achieve UHC [7].

The impact and sustainability of HTA as an approach for explicit priority-setting in healthcare is dependent on its institutionalization [9, 10]. Institutionalization of HTA refers to the process of conducting and utilizing HTA as a normative practice for guiding healthcare priority-setting processes [10]. This requires development of institutional and organizational structures and processes that produce and utilize HTA in decision-making [9, 10]. In countries where HTA has been institutionalized, it is routinely conducted as a way of informing health policy decisions on:- a) development and revision of health benefits packages for pharmaceutical and non-pharmaceutical products; b) development of clinical guidelines; c) market authorization of health technologies; and, d) pricing and reimbursement regulations for health technologies [8-10].

There are more high- and upper-middle-income countries that have institutionalized HTA as an explicit approach for healthcare priority-setting than low and lower-middle-income countries particularly in Sub Sahara Africa [11, 12]. Literature shows that institutionalization of HTA is affected by factors that may be context or country-specific [13-15]. Examining and identifying which country-specific factors are influencing institutionalization of HTA is important as it enables policymakers and technocrats to introduce appropriate measures to address them [13-15]. However, studies examining factors that influence institutionalization of HTA in low and lower-middle income countries remain limited [16]. We conducted the following study in Kenya to identify factors influencing institutionalization of HTA in this context.
Methods

Study design

We conducted a qualitative case study with the case as institutionalization of HTA in Kenya.

Conceptual framework

We used a conceptual framework developed from a scoping review of empirical literature on factors influencing institutionalization of HTA across countries of different income levels globally [16]. We identified five sets of factors that influenced a country’s capacity to conduct and utilize HTA as a way of allocating resources in the health sector. These factors included: -a) organizational resources for HTA; b) legal frameworks, policies, and guidelines for HTA; c) learning and advocacy for HTA; d) stakeholder-related factors; and e) collaborative support for HTA. These factors were complexly interlinked as presented in the conceptual framework on Figure 1. This interlinkage meant that the factors could influence each other. We utilized this framework to develop questions for our data collection tool, to generate themes during data analysis, and to synthesize findings from the data.

Study setting

Kenya is a lower-middle income country in Sub Sahara Africa with a population of approximately 53.8 million people [17]. It has a devolved governance system with administrative, fiscal and political roles split among one national and forty seven county governments [18]. Within the national government, the Ministry of Health (MOH) is responsible for building capacity, developing health policies, overseeing service delivery in national referral healthcare facilities, and providing technical assistance [18]. Within the county governments, the County Departments of Health are responsible for implementing national health policies and overseeing service delivery in county healthcare facilities such as primary healthcare facilities (community units, dispensaries and health centres) and secondary healthcare facilities (primary and secondary referral hospitals) [18].

Study population and sampling strategy

We used purposive and snowballing techniques to sample participants. The aim was to obtain rich descriptions of the case study by involving knowledge-rich participants. The purposive criterion was a participant’s known involvement in activities related to the institutionalization of HTA in Kenya. The purposively selected participants were subsequently asked to identify other participants who were active in the HTA institutionalization space. We stopped sampling at saturation, that is, when no new information was emerging from additional interviews [19]. We interviewed 30 stakeholders (Table 1). We do not provide any demographic information to preserve the anonymity and confidentiality of the study participants.
Data collection methods

We used in-depth interviews and document reviews to collect data between January and April 2022.

In-depth interviews

We requested participants to engage in the study via telephone or email- none refused participation. Participants reviewed the study’s information sheet and provided informed consent. We conducted interviews directly via face-face or remotely via zoom videoconferencing at a time of convenience to the participant. Interviews were guided by a semi-structured interview guide, and they lasted between 25 and 80 minutes. All interviews were recorded using an encrypted audio recorder.

We also took fieldnotes during interviews to identify points that needed further clarification and to summarize emerging themes. We linked each fieldnote to the respective interview using the same identifier. Following the interviews, fieldnotes were transferred to Microsoft word to prevent data loss.

Document reviews

We reviewed various documents as shown in Table 2. These documents included organizational and media reports with relevant information on institutionalization of HTA. We identified these documents from study participants, online searches, and two members of the study team who had previously been involved in HTA-related activities in Kenya. We conducted interviews and document reviews simultaneously to enable triangulation of data from each of these data sources.

Data analysis

We transcribed all audio-files verbatim. We then verified the quality of transcription by comparing each transcript to the respective audio-file. We uploaded all transcripts, field notes and electronic documents to NVIVO Pro software (QSR International, Massachusetts) for effective organization during data analysis. We analyzed the data thematically using the Braun and Clarke 6-step approach [20]. Firstly, we immersed ourselves in the data through reading and re-reading. Secondly, we developed a list of codes deductively based on the concepts outlined in the study’s conceptual framework. Thirdly, we grouped similar codes into themes. Fourthly, we checked for coherence between the themes and the coded data extracts. Fifthly, we applied the approved themes across the data by extracting quotes, excerpts and images that matched them. Lastly, we synthesized the findings and linked the discussion of these findings to existing literature.

Reflexivity
2 of the authors have participated in HTA-related processes in Kenya. This participation not only influenced their interest in studying HTA but also facilitated their access to participants and documents required for this analysis.

**Trustworthiness**

To build trustworthiness in our study findings, we employed the following strategies. Firstly, we triangulated study methods by collecting data using more than one data collection method. Secondly, we triangulated data sources by interviewing participants from different organizations to explore multiple perspectives. Lastly, we held peer debriefing sessions during data collection and analysis to mitigate against bias that may have otherwise been introduced by 2 of the authors from their previous involvement in HTA-related processes in Kenya [21, 22].

**Results**

The data shows that Kenya has embarked on institutionalizing HTA. Several factors were influencing this journey as discussed below.

1. **Limited availability of organizational resources for HTA**

   **A. Establishment of organizational structures for HTA**

   Since 2018, the MOH has established new organizational structures to conduct and utilize HTA, and to oversee implementation of HTA. This followed the Government’s prioritization of UHC in 2017 [23]. These organizational structures included the Health Benefits Package Advisory Panel (HBPAP), a HTA focal point, the Medicines Affordability Pricing Advisory Committee (MAPAC) and, a HTA technical working group.

   HBPAP, a semi-independent panel, was established in 2018 to develop an essential and affordable health benefits package for UHC [24]. HBPAP used a HTA approach to develop a health benefits package for UHC. HBPAP also developed a draft framework for institutionalizing HTA in Kenya [25].

   ‘The establishment of the Panel [HBPAP] was the first attempt to set up a government driven HTA system where they recognized the use of HTA mechanism in decision-making’ MOH official 5

   A focal point for HTA was created within the MOH in 2020. It was tasked with overseeing and coordinating HTA institutionalization activities within the country. According to participants, the HTA focal point has overseen several HTA capacity-building and advocacy creation activities.

   ‘We applaud the ministry for creating a HTA office. This office has been responsible for helping stakeholders walk the journey towards implementing HTA’ Participant 8, Semi-autonomous government
MAPAC was established in 2021 to promote access, availability, and affordability of pharmaceutical products. To this end, MAPAC aims to use HTA to promote transparency of the healthcare priority-setting processes for medicines. MAPAC also aims to use HTA to regulate and negotiate pricing of medical products towards making them affordable [26].

‘MAPAC was inaugurated to develop strategic interventions to bring down healthcare costs. One of the strategic interventions the group has identified is HTA which can promote price transparency and visibility to everybody’ Participant 1, Semi-autonomous government agency

Lastly, a HTA technical working group was established in 2021 to develop a HTA strategy for Kenya. This technical working group is an 18-member team comprising of technocrats from:- a) the MOH such as the Department of Health Policy, Research and Development, Department of Health Products and Technology, Department of Health Financing, and UHC secretariat; b) Semi-autonomous government agencies such as Pharmacy and Poisons Board and Kenya Medical Supplies Agency; and c) local research organizations such as KEMRI-Wellcome Trust [27].

In addition to the creation of new organizational structures for HTA, participants reported that the existence of multiple organizations involved in the regulation, procurement and purchasing of health technologies offered an opportunity to institutionalize HTA across these functions. Examples of these organizations included: - a) the Pharmacy and Poisons Board which regulates health technologies by ensuring they are of good quality to be efficacious and safe; b) the Kenya Medical Supplies Agency which procures health technologies for government-owned healthcare facilities; and c) purchasers such as the national government, the county government, and the National Health Insurance Fund which purchase health technologies for government-owned healthcare facilities.

‘We have institutions in strategic positions that deal with regulation, procurement and purchasing. Their presence provides a very good opportunity for introducing HTA as a priority-setting mechanism for their functions’ Participant 4, Semi-autonomous government agency

**B. Limited availability of skilled human resource for HTA**

In Kenya, the number of human resources with the technical skills to conduct HTA remain limited. A landscape analysis on HTA capacity in Kenya showed that more than 65% of health sector organizations had less than 5 individuals with formal training in HTA-related subjects such as health economics, mathematical modelling, statistics, evidence synthesis and epidemiology [28]. In addition, the analysis showed that more than 70% of health sector organizations had less than 5 individuals with practical experience in conducting systematic reviews or meta-analyses, cost-effectiveness analysis and budget impact analysis [28].

‘We do not have many people with the technical skills required to conduct HTA. The country is still in its infancy stages with regards to skills in evidence synthesis and economic evaluation. This inadequate
local capacity is a barrier towards HTA’ Participant 9, Semi-autonomous government agency

C. Limited financial resources for HTA

The Government of Kenya has historically underfunded research. For example, approximately 3.5% of the government’s health budget is allocated to research which accounts for less than 30% of the resources required [29]. As a result, more than 70% of funding for research is obtained from external sources such as donors [29]. Given the limited funding, participants reported that the MOH could not meet the costs of conducting HTA which undermined institutionalization of HTA in Kenya.

‘The lack of financial resources is a big stumbling block for institutionalization of HTA. At the moment, a lot of research activities are donor funded’ Participant 2, local research organization

D. Limited availability of information resources for HTA

Limited availability of information resources for HTA was reported as another factor limiting institutionalization of HTA in Kenya. Participants reported that despite improvements in Kenya’s health management information system, completeness, and timeliness of data reporting at the facility, county, and national levels were still limited. They also reported that data on costs were not routinely reported, and databases across purchasers were poorly linked. All these factors undermined the availability and quality of data which limited the capacity to conduct HTA.

‘HTA processes are data hungry. For example, we need a database of costs to conduct economic evaluation and budget impact analysis. However, we do not have such a database’ Participant 10, Semi-autonomous government agency

2. Adequate availability of legal frameworks and policies, but limited availability of guidelines for HTA

A. Adequate availability of legal frameworks and policies on HTA

Several legislation and policies on HTA exist in Kenya. These documents recognize various organizational and institutional aspects on institutionalization of HTA as shown in Table 3. According to participants, the establishment of organizational structures for HTA was partly a fulfilment of these legislation and policies.

‘We are already seeing HTA in action within the current life of the Kenya Health Policy with the establishment of the panel [HBPAP] and MAPAC’ Development Partner 1

[Insert Table 3]
While policies highlighting institutional and organizational arrangements for HTA exist in Kenya, they do not explicitly indicate sources and amounts of funding to be allocated for HTA-related activities. According to participants and document reviews, all organizational and institutional arrangements for HTA need to be explicitly defined and legislated to support institutionalization of HTA [30].

‘To institutionalize the proposed HTA process, it is proposed that a HTA policy be developed, and the requirement for HTA in benefit package decision-making be enshrined in the law. This could be in the form of an amendment to the Health Act’ Document excerpt [30]

B. Lack of HTA guidelines and decision-making frameworks

Kenya lacks standardized process and methods guidelines as well as decision-making frameworks for HTA. For example, there were no process guidelines that would inform which rules and procedures would guide the different stages (nomination, selection, assessment, appraisal and decision-making) of the HTA process. There were also no methods guidelines or tools to inform choice of costing perspective and discount rates, or to measure quality adjusted life years. Lastly, there were no decision-making frameworks such as cost-effectiveness threshold to inform decision-making. The lack of HTA guidelines and decision-making frameworks undermined the country’s capacity to conduct and utilize HTA.

‘We do not have a cost-effectiveness threshold or a quality adjusted life year set for Kenya. We must develop these tools if we are to use HTA routinely for decision-making’ Participant 1, local research organization

3. Increasing availability of learning and advocacy for HTA

A. Increasing availability of HTA capacity-building initiatives

Several short-term HTA training workshops and courses have been conducted in Kenya since 2018 [31, 32]. These capacity-building initiatives were targeted at HTA users such as national and county-level policymakers and, HTA doers such as academics and researchers in local universities, research centres, and semi-autonomous government agencies. Approximately 150 HTA doers and users across the health system have been trained on cost-effectiveness analysis and systematic evidence synthesis. According to study participants, these capacity-building initiatives not only built technical capacity but also raised individual and organizational awareness and understanding of the value of HTA in healthcare priority-setting. The initiatives also helped to build a network of champions for HTA.

‘We have had several workshops which are good for building technical capacity. They also sensitize people to understand the value of HTA. In turn, these people are getting other key stakeholders within the organizations to appreciate what HTA is about.’ Participant 7, Semi-autonomous government agency

A local research organization has also created a mailing list for sending monthly HTA newsletters. These newsletters aim to promote continuous dissemination of HTA knowledge to HTA doers and users.
‘Every month, we send out a newsletter with interesting topics related to HTA such as economic evaluations, HTA-related conferences, or any forthcoming trainings. We do this to keep HTA relevant on people’s minds.’ Participant 3, local research organization

Despite the increasing availability of short-term capacity-building initiatives, long-term capacity-building initiatives such as undergraduate and postgraduate training in HTA remain limited. This undermined the availability of skilled human resource for HTA. Study participants therefore called for the introduction of HTA-related courses at undergraduate and postgraduate level in public and private universities to strengthen individual and organizational capacity for HTA.

‘We need more HTA courses in our universities. Their curriculum should be structured to ensure that aspects of health economics and research methodologies such as data analysis and evidence synthesis are captured’ Participant 5, local research organization

B. Increasing availability of advocacy and awareness creation for HTA

There have been several advocacy and awareness creation initiatives for HTA in Kenya such as study tours, advocacy meetings, and stakeholder engagement workshops. For example, Kenyan stakeholders namely the Parliamentary Health Committee, the Senate Health committee, the MOH, the County Governments, Academics, HBPAP, and the National Health Insurance Fund Health Financing Experts Panel have gone on study tours to Thailand to learn about UHC and the role of HTA in UHC-related decisions (Fig. 2).

High-level policy advocacy meetings for HTA have also been held in Kenya with participants including Thai Government officials and Kenyan stakeholders from the Council of Governors, MOH and National Treasury. There have also been stakeholder engagement workshops for HTA involving policymakers from the MOH and semi-autonomous government agencies. These advocacy meetings and stakeholder engagement workshops were aimed at raising awareness among key policy and decisionmakers on the definition of HTA, its role in healthcare priority-setting processes and policy decisions and, its value in generating budget savings through price negotiations [34–36].

The study tours, high-level policy meetings, and workshops have increased HTA awareness among key policy and decision-makers in government and semi-autonomous government agencies. A landscape assessment of HTA awareness among major health sector agencies at the national level in Kenya showed that over 60% of the respondents indicated that the leadership of these agencies were aware of HTA and were willing to support development of HTA within their organizations by allocating resources [30].

4. Stakeholder-related factors
A. Varying stakeholders’ interests towards HTA

i. Policymakers’ interests in UHC and optimal allocation of resources

Participants reported that policymakers’ interest in achieving UHC and the accompanying need to define a publicly funded health benefits package for the UHC programme drove their support for explicit and evidence-based approaches such as HTA. In addition, policymakers’ interests in allocating scarce health system resources optimally generated further interest in HTA as a tool for informing resource allocation decisions. This need intensified during the Covid-19 pandemic which exposed the inability of Kenya’s health system to meet increased healthcare needs. Consequently, MOH policymakers requested local research organizations to conduct HTA to inform government’s resource allocation decisions during the Covid-19 pandemic.

‘COVID not only highlighted but also amplified the gaps in our health system in terms of lack of finances, human resources, infrastructure and medicines. The ministry’s decisions on what to prioritize during the pandemic had to be made systematically using evidence and HTA provided that. It is one of the positive things that Covid did for us’ MOH official 4

ii. Technocrats’ interests in evidence-based resource allocation processes

Participants reported that technocrats supported institutionalization of HTA given their interests in evidence-based resource allocation processes. These technocrats included Kenyan health economists and health systems experts within the MOH, local academic and research organizations, and development partners. Technocrats supported HTA as they believed it would provide an evidence-based approach for improving affordability, sustainability, and equitable distribution of health benefits packages in Kenya. They were also responsible for recommending various institutional and organizational arrangements for HTA as presented in the health policies outlined in Table 3.

‘Health economists and other specialists who sat in committees at the national level were instrumental in designing the content of those policies which catapulted the agenda for transforming the health system through evidence-based processes such as HTA’ MOH official 7

iii. Industries’ interests in safeguarding their revenue

In Kenya, lack of price regulation of health technologies has resulted in importer mark-ups ranging between 54%-256% and 133%-748% for generic and originator products respectively [26]. While this generated higher profits for industries and other associated organizations, it led to unaffordability and inequitable access to health technologies. The MOH, through MAPAC, is seeking to use HTA to regulate pricing of health technologies to enable equitable and affordable access. However, according to
participants and media reports (Fig. 3), this was likely to reduce the profit margins for industries and importers of health technologies leading to resistance to institutionalization of HTA.

‘One barrier will be industries that have been benefitting from the lack of HTA. If we introduce HTA, then they are not going to benefit from the lack of transparency and they are likely to resist’ Participant 1, Semi-autonomous government agency

B. Limited HTA awareness among officials in county governments and health facilities

Despite growing awareness of HTA among policymakers at the national level, study participants reported that awareness of HTA and its value in policymaking was still low among policy and decision-makers at the county government and hospital levels. These stakeholders were important given Kenya’s devolved health system structure. Their limited awareness was therefore undermining institutionalization of HTA in Kenya. Participants called for greater inclusion of sub-national stakeholders in training and advocacy initiatives to support institutionalization of HTA through greater stakeholder awareness, acceptability, and ownership.

‘For institutionalization of HTA to take place, we need everyone to buy into HTA starting from the policymakers at the ministry to the frontline workers. For this to work countrywide, counties must be involved. There is need for further sensitization’ Participant 4, Semi-autonomous government agency

5. Collaborative support for HTA

A. Presence of international collaboration for HTA

International collaboration for HTA in Kenya occurred through a bilateral agreement between Kenya and Thailand. In February 2019, Kenya and Thailand’s ministries of health signed a bilateral memorandum of understanding on Health Collaboration (Fig. 4) to support institutionalization of HTA in Kenya [38]. As part of this memorandum, the Thai Government- through the Health Intervention and Technology Assessment Program (HITAP) - has provided Kenya’s MOH with technical assistance to develop the HTA institutionalization framework, to build individual and organizational technical capacity for HTA, and to conduct HTA pilot studies of priority to the country. The Thai government has also provided scholarships for HTA at Masters and Doctor of Philosophy level in an effort to promote Kenya’s technical capacity for HTA [38].

‘The Kenyan government in partnership with the Thai government are working to do a technical transfer between the two countries showing goodwill bilaterally’ MOH official 3

International collaboration for HTA in Kenya also occurred through global health networks such as the International Decision Support Initiative (iDSI). iDSI aims to support low and middle-income countries to
reform their healthcare priority setting processes. Since 2019, the iDSI has financially supported several HTA workshops with the aim of building organizational capacity for HTA.

‘In terms of international efforts, the iDSI has been working with its local partner in Kenya to build capacity for HTA through workshops.’ Participant 6, local research organization

B. Involvement of a bilateral agency

The Japan International Cooperation Agency (JICA)- a bilateral agency- has offered Kenya a conditional grant to support institutionalization of HTA [39]. The disbursements of this conditional grant were tied to specific HTA institutionalization deliverables such as the development of a strategy for HTA institutionalization and capacity building [39]. These loan conditions incentivized Kenya's MOH to conduct capacity-building workshops and to develop a strategic framework for institutionalizing HTA.

‘JICA is financing HTA institutionalization efforts in Kenya’ Participant 4, Development partner

Discussion

In this paper, we set out to examine factors influencing institutionalization of HTA in Kenya. The key insights derived from this study include the following.

The first key insight is that Kenya's journey towards institutionalizing HTA is being supported by factors such as: - a) establishment of organizational structures; b) availability of legal frameworks and policies; c) increasing availability of awareness creation and capacity-building initiatives; d) policymakers’ interests in UHC and optimal allocation of resources; e) technocrats’ interests in evidence-based processes; f) presence of international collaboration for HTA; and g) involvement of bilateral agencies. The supportive influence of these factors on institutionalization of HTA has been reported in other settings. For example, the establishment of organizational structure(s) expanded the capacity of countries such as Canada [40] and the United Kingdom [41] to conduct and utilize HTA. Secondly, the availability of legislation and policies on HTA in Denmark [42], Germany [43] and Thailand [44] supported institutionalization by defining institutional and organization arrangements for HTA. Thirdly, the availability of awareness creation activities increased the visibility of the value of HTA to health systems stakeholders in Spain [45] while the availability of short and long-term capacity-building initiatives in Thailand strengthened the human resource capacity for HTA [44, 46]. Fourthly, government’s interest in UHC and efficient allocation of resources promoted development of HTA in Netherlands [47, 48]. Fifthly, technocrats interests’ in the use of HTA to improve health system performance supported institutionalization of HTA in Mexico [49]. Sixthly, international collaboration through iDSI contributed to increased HTA awareness creation and capacity-building initiatives in Indonesia [50], Ghana [51], and South Africa [52]. Lastly, involvement of bilateral agencies such as the World Health Organization and the World Bank supported funding of HTA projects and capacity-building initiatives in China [53] and Indonesia [50].
The second key insight is that several factors were undermining Kenya’s journey towards institutionalizing HTA namely: - a) limited availability of organizational resources such as skilled human resources, financial resources, and information resources for HTA; b) lack of HTA guidelines and decision-making frameworks; c) limited HTA awareness among policy and decision-makers at the subnational level - that is, county governments and health facilities; and d) industries’ interests in safeguarding their revenue. The limiting influence of these factors on institutionalization of HTA has been reported in other settings. For example, limited availability of skilled human resource for HTA undermined capacity to conduct HTA in India [54], Iran [55], South Africa [52] and Tanzania [56]. Secondly, limited availability of financial resources undermined institutionalization of HTA in Iran [57], South Africa [52] and Tanzania [56]. Thirdly, limited availability and completeness of data for HTA undermined institutionalization of HTA in several high, middle and low-income countries globally [15, 58]. Fourthly, the lack or limited availability of contextually relevant process and methodological guidelines, and decision tools has undermined utilization of HTA in Sub Saharan countries [11]. Fifthly, the limited awareness of HTA, its concepts and relevance among policy and decision-makers in Malaysia [59] and South Africa [52] undermined institutionalization of HTA. Lastly, manufacturers’ interests in safeguarding pricing of their health technologies undermined institutionalization of HTA in the United States of America [60, 61].

The third key insight is that factors influencing institutionalization of HTA in Kenya were interlinked. These interlinkages have also been identified in other studies. For example, international collaboration for HTA increased the availability of HTA awareness creation and capacity-building activities in Kenya. Countries involved in international collaborative networks across Europe and Asia also reported similar findings [62, 63]. Secondly, policymakers’ interests in defining a health benefits package for UHC and regulating pricing of health technologies led to the creation of organizational structures for HTA in Kenya. Similar findings have also been reported in several high and upper-middle-income countries in Asia [46, 64] and Europe [47, 48] where policymakers had similar interests. Thirdly, availability of legislation and policies on HTA partly led to the creation of organizational structures for HTA in Kenya. Several high-income countries in Europe with legislation and policies on HTA reported similar findings [63]. Fourthly, technocrats’ interests in HTA influenced development of policies on HTA in Kenya. Similarly, technocrats in several high- and middle-income countries in Asia developed policies on HTA due to their interests in HTA [59, 65]. Lastly, the limited availability of long-term capacity-building initiatives undermined the availability of skilled human resource for HTA in Kenya. Similar findings have been reported in other countries globally with limited availability of long-term capacity-building initiatives [52, 58, 66, 67].

The fourth key insight is that the study findings offer important policy implications on how the MOH can nurture and sustain the institutionalization process in Kenya. This can be achieved through a systemic approach that addresses the current limitations in Kenya’s capacity to conduct and utilize HTA. In this systemic approach, the MOH should earmark funds from the national health budget to ensure adequate availability of financial resources for HTA. The MOH should introduce a cost database and promote timely data collection through trainings and incentives to strengthen information resources for HTA. The MOH should introduce undergraduate and postgraduate training in HTA to ensure availability of skilled human resource for HTA. The MOH should develop contextually relevant process and methods guidelines
and decision tools for HTA to facilitate HTA processes. The MOH should conduct wider advocacy to increase HTA awareness among national and sub-national stakeholders. The MOH should manage stakeholders’ interests through sensitization and persuasive framing of the value of institutionalizing HTA to minimize opposition. Lastly, the MOH should strengthen international collaborations through south-south collaborations to facilitate the institutionalization process.

The last key insight is that, by applying the conceptual framework outlined in this study, we demonstrated its empirical utility in identifying factors that were influencing institutionalization of HTA in Kenya. This framework can therefore be adopted or adapted by future researchers who aim to examine factors influencing institutionalization of HTA in other contexts.

**Limitations**

A potential limitation of this study is social desirability bias whereby participants alter responses in the belief that this would make the responses more acceptable. However, by triangulating data sources and methods, we strengthened the trustworthiness of the findings. It is also possible that the previous involvement of 2 of the authors in HTA-related processes in Kenya may have biased the interviews and analysis. However, we mitigated against this bias by reviewing documents to corroborate the findings and by holding peer debriefing sessions as a study team to ensure that findings were based on collected data.

**Conclusion**

Examining factors that influence institutionalization of HTA is substantially relevant in low and middle-income countries where institutionalization of HTA remains limited. In this study, we used a conceptual framework based on five sets of factors that were identified from a scoping review on factors influencing institutionalization of HTA across countries of different income levels. By applying this conceptual framework, we were able to identify factors that were supporting and limiting institutionalization of HTA in Kenya. These findings offer useful policy implications that policymakers within the MOH can implement to facilitate progress towards institutionalization of HTA in Kenya. Researchers seeking to examine factors influencing institutionalization of HTA in other contexts can also adopt or adapt this framework.

**Abbreviations**

- HBPAP: Health Benefits Package Advisory Panel
- HTA: Health Technology Assessment
- iDSI: International Decision Support Initiative
- JICA: Japan International Cooperation Agency
Declarations

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Author's contribution

RM was responsible for the conception, design, data collection, data analysis, interpretation, and drafting and critical revision of the manuscript. AV, LG, and EB were involved in data interpretation, and critical revision of the manuscript. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

Ethical approval and consent to participate

This study involves human participants, and all its methods were performed in accordance with the relevant guidelines and regulations of the Declaration of Helsinki. It has also received ethical approval from two appropriate ethics committees namely the London School of Hygiene and Tropical Medicine Ethics Committee (Reference Number: - 25640) and the Kenya Medical Research Institute Scientific and
Ethics Review Unit, Nairobi, Kenya (Reference Number: - KEMRI/SERU/CGMR-C/185/4018). All participants provided written informed consent before participating in the study.

**Consent for publication of primary data**

To protect participants’ identity, none of the quotes used in this paper contains their demographic information.

**Consent for publication of secondary data**

Figures 2 and 4 of this manuscript consist of images that are publicly available on the internet therefore permission for further use is implied. However, the ownership of the images is acknowledged in the references.

**Data availability**

The primary datasets generated and/or analysed during the current study are not publicly available due ethical reasons that include maintaining participants’ confidentiality and anonymity but are available from the corresponding author on reasonable request.

**Funding**

This study is part of a PhD project funded by the Commonwealth Scholarship Commission, UK. Additional funds from the Bill and Melinda Gates Foundation funded International Decision Support Initiative and a Wellcome Trust core grant awarded to the KEMRI-Wellcome Trust Research Program (#092654) supported this work. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

**References**


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35. HITAP: **Kenya's Health Benefits Advisory Panel [HBAP] Study visit to Thailand.** In. Thailand; Health Intervention and Technology Assessment Program; 2018: 27.

36. KEMRI-Wellcome Trust: **Study visit by the Health Benefits Package Advisory Panel to Thailand on Health Technology Assessment.** In. Nairobi: KEMRI-Wellcome Trust Research Programme; 2018: 23.


### Tables

**Table 1: List of participants**

<table>
<thead>
<tr>
<th>Category</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development Partners</td>
<td>n=6</td>
</tr>
<tr>
<td>Local Research organizations</td>
<td>n=6</td>
</tr>
<tr>
<td>Ministry of Health (MOH)</td>
<td>n=8</td>
</tr>
<tr>
<td>Semi-Autonomous Government Agencies</td>
<td>n=10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
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**Table 2: List of documents reviewed**
<table>
<thead>
<tr>
<th>Types of documents</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government documents (national policies and laws)</td>
<td>• Health Act 2017&lt;br&gt;• Health Products and Technologies Supply Chain Strategy 2020-2025&lt;br&gt;• Kenya Health Policy 2014-2030&lt;br&gt;• Kenya Health Sector Strategic and Investment Plan 2013-2017&lt;br&gt;• Drafts of the Kenya Health Financing Strategy 2015-2030</td>
</tr>
<tr>
<td>Local Research Organizations’ documents</td>
<td>• Reports on stakeholder engagement workshops&lt;br&gt;• PowerPoint presentations made during stakeholder workshops&lt;br&gt;• Reports on HTA capacity in Kenya</td>
</tr>
<tr>
<td>Health Benefits Package Advisory Panel’s (HBPAP) documents</td>
<td>• Final Report of the Universal Health Coverage Health Benefits Package&lt;br&gt;Advisory Panel Report on the study visit by the Health Benefits Package&lt;br&gt;Advisory Panel to Thailand on HTA&lt;br&gt;• HBPAP reports and annexes&lt;br&gt;• HBPAP PowerPoint presentations</td>
</tr>
<tr>
<td>Development partners’ reports</td>
<td>• Mission report on Health Benefits Package Advisory Panel Study visit to Thailand&lt;br&gt;• Japan International Cooperation Agency Loan policy action on HTA&lt;br&gt;• Mission report on National Hospital Insurance Fund Health Financing Reforms Experts Panel visit to Thailand on UHC and HTA</td>
</tr>
<tr>
<td>Media reports</td>
<td>• Web media e.g., Development Partners websites and MOH websites&lt;br&gt;• News media e.g., Online newspaper reports&lt;br&gt;• Social media e.g., Twitter</td>
</tr>
</tbody>
</table>

Table 3: Laws and policies on HTA
<table>
<thead>
<tr>
<th>Examples of laws or policies</th>
<th>Aspects of HTA institutionalization recognized in the document</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Act 2017 [30]</td>
<td>• Recognizes the role of HTA in: -</td>
</tr>
<tr>
<td></td>
<td>• supporting financing decisions towards UHC</td>
</tr>
<tr>
<td></td>
<td>• Regulation (e.g., market approval) of health technologies following assessment by a technically competent organization</td>
</tr>
<tr>
<td></td>
<td>• Recognizes priority-setting criteria for HTA namely safety and effectiveness</td>
</tr>
<tr>
<td>Kenya Health Policy 2012-2030 [31]</td>
<td>• Recognizes the need for: -</td>
</tr>
<tr>
<td></td>
<td>• A national HTA mechanism for assessing new health technologies</td>
</tr>
<tr>
<td></td>
<td>• A national framework for regulating health technologies</td>
</tr>
<tr>
<td></td>
<td>• Recognizes priority-setting criteria for HTA namely quality, safety, efficacy/effectiveness, and affordability</td>
</tr>
<tr>
<td>Health Sector Strategic and Investment Plan 2013-2017 [32]</td>
<td>• Recognizes: -</td>
</tr>
<tr>
<td></td>
<td>• establishment of a national HTA mechanism for health technologies and a national framework for regulation of health products as priorities</td>
</tr>
<tr>
<td></td>
<td>• priority-setting criteria for HTA such as clinical-effectiveness, quality, safety, cost-effectiveness and, ethical and cultural considerations</td>
</tr>
<tr>
<td></td>
<td>• the role of HTA in developing essential medicines list and clinical guidelines</td>
</tr>
<tr>
<td>UHC policy 2020-2030 [33]</td>
<td>• Recognizes: -</td>
</tr>
<tr>
<td></td>
<td>• the role of HTA in guiding investment decisions on health technologies and promoting their rational use</td>
</tr>
<tr>
<td>Kenya Health Financing Strategy 2020-2030 [34]</td>
<td>• Recognizes: -</td>
</tr>
<tr>
<td></td>
<td>• The need to create a Health Benefits and Tariffs Authority to host national study and research functions on HTA</td>
</tr>
<tr>
<td></td>
<td>• the role of HTA in informing investments on new health technologies and revising the UHC health benefits package</td>
</tr>
<tr>
<td>Health Products and Technology Supply Chain Strategy [29]</td>
<td>• Recognizes the need for: -</td>
</tr>
<tr>
<td></td>
<td>• a HTA policy to support management (e.g., pricing and market authorization) of health products and technologies</td>
</tr>
<tr>
<td></td>
<td>• a national roadmap for institutionalization of HTA</td>
</tr>
<tr>
<td></td>
<td>• building HTA capacity at national government agencies and county governments involved in health products and technology supply chain</td>
</tr>
<tr>
<td></td>
<td>• increased involvement of stakeholders in the HTA process at the national and county government to create demand and use of HTA</td>
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</tbody>
</table>
• surveys to assess use of HTA in pricing and market authorization of health products and technologies

<table>
<thead>
<tr>
<th>Strategy for HTA in the Kenyan Health Sector [35]</th>
<th>Recognizes: -</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The mandate of HTA in developing, revising, or updating the essential medicines list, essential medical devices list, benefit package for UHC, and the national vaccines list</td>
<td></td>
</tr>
<tr>
<td>• The mandate of HTA in price negotiation for medical devices, medicines, and vaccines</td>
<td></td>
</tr>
<tr>
<td>• The organizations whose decisions will be informed by HTA namely the Kenya Medical Supplies agency, the National Health Insurance Fund and, the MOH</td>
<td></td>
</tr>
<tr>
<td>• The organizational and institutional architecture for HTA in Kenya including their roles and professional composition to support the HTA functions of topic nomination, topic selection, assessment, appraisal, and decision-making.</td>
<td></td>
</tr>
<tr>
<td>• The priority-setting criteria for topic selection in HTA namely effectiveness and safety, burden of disease, severity of disease, equity, catastrophic health expenditure, congruence with existing priorities, health workforce requirements and service, health commodities, and technologies requirements</td>
<td></td>
</tr>
<tr>
<td>• The priority-setting criteria for assessment stage namely cost-effectiveness analysis and budget impact analysis.</td>
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</table>

**Figures**

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<table>
<thead>
<tr>
<th>Organizational resources for HTA</th>
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</thead>
<tbody>
<tr>
<td>1. Establishment of organizational structures for HTA</td>
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<tr>
<td>2. Availability of skilled human resource for HTA</td>
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<tr>
<td>3. Availability of financial resources for HTA</td>
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<td>4. Availability of information resources for HTA</td>
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<table>
<thead>
<tr>
<th>Collaborative support for HTA</th>
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<tbody>
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<td>1. International collaboration</td>
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<tr>
<td>2. Involvement of bilateral and multi-lateral agencies</td>
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<table>
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<th>Stakeholder-related factors</th>
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<tbody>
<tr>
<td>1. Stakeholder awareness and understanding</td>
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<tr>
<td>2. Stakeholders’ interests</td>
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<table>
<thead>
<tr>
<th>Legal frameworks, policies, and guidelines for HTA</th>
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</thead>
<tbody>
<tr>
<td>1. Availability of legislation and/or policies on HTA</td>
</tr>
<tr>
<td>2. Availability of HTA process and methods guidelines</td>
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</table>

<table>
<thead>
<tr>
<th>Learning and advocacy for HTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Availability of capacity-building initiatives for HTA</td>
</tr>
<tr>
<td>2. Availability of HTA awareness creation activities</td>
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</tbody>
</table>
```
Figure 1

A conceptual framework on factors influencing institutionalization of HTA

Figure 2

A study tour to Thailand by Kenyan Delegates [33]
Reference Pricing Likely To Be Detrimental To Drugmakers' Revenues In Kenya

Fitch Solutions / Pharma & Healthcare / Kenya / Fri 08 Nov, 2019

Figure 3

Illustrative media reports on industries' interests [37]
Figure 4

Signing of the bilateral collaboration between Kenya and Thailand [38]