

Theme Submission

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Introducing health technology assessment in Tanzania

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Abstract

Objectives. Health technology assessment (HTA) is a cost-effective resource allocation tool in healthcare decision-making processes; however, its use is limited in low-income settings where countries fall short on both absorptive and technical capacity. This paper describes the journey of the introduction of HTA into decision-making processes through a case study revising the National Essential Medicines List (NEMLIT) in Tanzania. It draws lessons on establishing and strengthening transparent priority-setting processes, particularly in sub-Saharan Africa.

Methods. The concept of HTA was introduced in Tanzania through revision of the NEMLIT by identifying a process for using HTA criteria and evidence-informed decision making. Training was given on using economic evidence for decision making, which was then put into practice for medicine selection for the NEMLIT. During the revision process, capacity-building workshops were held with reinforcing messages on HTA.

Results. Between the period 2014 and 2018, HTA was introduced in Tanzania with a formal HTA committee being established and inaugurated followed by the successful completion and adoption of HTA into the NEMLIT revision process by the end of 2017. Consequently, the country is in the process of institutionalizing HTA for decision making and priority setting.

Conclusion. While the introduction of HTA process is country-specific, key lessons emerge that can provide an example to stakeholders in other low- and middle-income countries (LMICs) wishing to introduce priority-setting processes into health decision making.

Health technology assessment (HTA) is a pillar to support the achievement of universal health coverage (UHC) in a resource constrained environment. Without HTA there is little to guide the allocation of resources. The process of institutionalizing HTA in a low-income country (LIC) raises two pertinent questions:

- (1) How does one introduce the concept of HTA such that HTA becomes an integrated part of routine decision making for planning and operational policy within the healthcare system?
- (2) What should an HTA system look like in a resource-limited setting? How does one establish a solid and comprehensive (“evidence based”) foundation for decision making for the introduction and utilization of health technologies at all levels in the healthcare system?

With a focus on the first question, this paper outlines the process of introducing concepts of HTA: the journey during which an HTA committee became established from the initial engagement through the activities leading to the successful inception of the committee. This is the first attempt to systematically document the stages of introducing HTA in a LIC in sub-Saharan Africa (SSA). While some processes followed in Tanzania are unique to the country, the paper will highlight several lessons that can be learned and applied in other countries that aspire to introduce HTA.

HTA to Inform Spending Decisions

HTA is a mechanism to support decision making in health toward setting more cost-effective priorities. It has increasing recognition of its role as an important component to achieving UHC through more efficient allocation of resources (1), yet its use is mostly limited to high- and middle-income countries. HTA considerations in decision-making processes are

almost nonexistent in the SSA region (2). However, there is a need for HTA to ensure value for money due to tighter resource constraints as many countries transition out of dependence on development aid and aim toward UHC.

While HTA is generally recognized as an important mechanism to ensure efficient resource allocation (see Figure 1 for HTA agencies worldwide) it is seldom an integral component of the health system in countries that are most in need of better resource allocations. The sub-Saharan African region faces significant challenges in the consolidation and explicit linking between HTA and decision making. Its absence is due to the difficulty of implementation and capacity requirements. Countries are not yet familiar with the concepts, or if they are, they have limited capacity for the implementation (2).

Challenges to Institutionalizing HTA

There are many challenges to institutionalizing HTA in a LIC, including technical, operational, political, and human resource constraints. Financial constraints might also hinder the institutionalization of HTA—while there may be long-term financial benefits to HTA, there is a need for the upfront funding and financing of HTA operations and related work. There are technical capacity challenges: HTA requires a specialized set of skills in health economics to undertake economic evaluations (supply side) and then to evaluate the evidence for policy implementation (demand side) (3). The operational challenges are closely linked to political will and financial constraints: by whom will the HTA body be constituted, where will it sit within the legislative structures, what will its entity status be, how will it inform decisions or policy to be enacted?

Introducing HTA is a disruptive policy change, as it redefines the systems and dynamics for policy decision making. While the underlying principle for HTA is a transparent, well-defined system for decision making, it shifts the power away from the traditional decision-making system. Understanding and meeting these challenges will be important if countries are to introduce a functioning HTA system and get the best value for money from its existence.

Methodology

Our aim for this paper was to systematically document the process of engagement by the various role players (see Table 1 for definitions of key players), which led to the formal establishment of an HTA committee in Tanzania. A situational analysis (4) was conducted to map the current decision-making structures in Tanzania and identify potential areas where there was a need for HTA. An in-depth understanding of the existing decision-making structures allowed us to develop appropriate recommendations for the institutionalization of HTA in Tanzania.

Continuous engagement with key actors throughout the study process was inevitable in order to improve the authors' understanding and experience of the health system in Tanzania. In addition, a review of available meeting minutes and documentation was undertaken. This paper is the culmination of detailed discussions with various actors involved in shaping the health system in Tanzania.

Many high-income countries (HIC) use HTA to inform spending decisions to ensure the best value for money in healthcare spending. Some have even established their own specialized HTA institutions. The International Network of Agencies for Health Technology Assessment (INAHTA) currently has 55 members from 32 countries. In the Asia Pacific region, Thailand (est. in 2007) has a more mature and highly functional HTA system while China officially launched HTA in 2018 (4, 5). Viet Nam and Indonesia have begun to prepare for an HTA entity.

Fig. 1. HTA agencies worldwide (23;24).

Table 1. Key Players and Definitions in the Tanzanian Health System

GoT	Government of Tanzania
PO-RALG	President's Office Regional Administration and Local Government
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
PSU	Pharmaceutical Services Unit
CMO	Chief Medical Officer
NMTC	National Medicines and Therapeutic Committee
STG/EMLIT	Standard Treatment Guidelines/Essential Medicines List, Tanzania
SOP	Standard Operating Procedure

Health and Health System in Tanzania

Tanzania is categorized as a LIC with a total population of approximately 54 million, a per capita gross domestic product (GDP) of US\$601 (2015) and a per capita expenditure on health of about US\$32 per year. Government revenue as a percent of GDP is 20.7 percent (2014) and in 2015, total health expenditure accounted for 6 percent of the country's GDP (5). The country faces a high burden of noncommunicable diseases (NCDs), which account for approximately 31 percent of all deaths in Tanzania (6).

The Government of Tanzania (GoT) operates a decentralized healthcare system such that the management and governance of the health sector is heavily influenced by the process of the devolution of functions to regional and district governments.

At the national level, the MoHCDGEC plays the lead role in stewardship and regulation of the sector and is in charge of the provision of health services at national-level hospitals and regional referral hospitals. The Ministry establishes the policy framework for all health interventions, which include the STG and NEMLIT—within the Ministry this responsibility falls under the Pharmaceutical Services Unit (PSU). The Ministry also coordinates the functions of semi-autonomous institutions like the Medical Stores Department (MSD). MSD is responsible for the procurement, storage, and distribution of medicines to public health facilities.

The National Health Insurance Fund (NHIF) is a statutory health insurance scheme established by parliament in 1999. It is currently the largest health insurance scheme in the country and is compulsory for civil servants. The contribution is 6 percent of the employee's gross salary, which is shared equally between the employer and the employee. The NHIF covers the cost of drugs procured through MSD for those who are covered by the health insurance.

The STG/NEMLIT determines the type of treatment/medicine which should be provided by the medical officer at each facility level, and similarly the procurement and reimbursement of medicines in Tanzania should be guided by the NEMLIT.

Priority Setting in Tanzania

There is no formalized priority-setting mechanism in the Tanzanian healthcare system, and current decision-making processes do not incorporate health economic analysis. Decisions are taken by the leadership at the national level and are made in a bureaucratic fashion, with little or no evidence to underpin them. Decisions related to specific programs and initiatives are assigned to individual committees charged with providing recommendations to the Minister. Examples of such committees are the National Malaria Steering Committee and the National Medicines and Therapeutic Committee (NMTC). These decision-making bodies generally comprise leaders at the Ministry of Health as well as district-level managers and directors in charge of specific programs and initiatives. Many of the committees are chaired by the chief medical officer (CMO) who oversees all of the service delivery sections at the Ministry of Health.

A review of government policy documents (7) shows that some elements of HTA are referred to. For example, the draft National Health Policy 2017 states that the government will [among other things] “improve adequate knowledge in HTA for evidence-based selection of quality and safe technology as well as realizing value for money” (8). The standard operating procedure (SOP) for reviewing the STG/NEMLIT also emphasize that recommendations should consider “cost-effectiveness” and “available resources (affordability)” (9) however, there are no guidelines or details for inclusion or exclusion of a medicine; a decision that is still left at the discretion of the reviewer (Figure 2). However, research shows that there is little capacity to undertake HTA (10) and the authors experience is that it is at all levels (academic, national, and local).

The country is committed to moving toward UHC by ensuring everybody has access to needed health services of high quality and is protected against financial risks that could arise as a result of paying for health care (11;12). As Tanzania moves toward universal coverage reforms are focused on improving efficiency and equity, for example, through the strategic purchasing of goods and services. Given the political drive, there is a need and an opportunity to link HTA to product selection, procurement, pricing negotiations, strategic purchasing, and provider payment. As the health services provided by the Government of Tanzania are not well defined, there is an opportunity for HTA to help define priority services as well as a process for doing so, in order to ensure best value for money and broader stakeholder buy in of coverage decisions.

Introducing HTA into the Health Decision-Making Process

Typically, a national HTA strategy pursues two general aims (13;14): to establish a solid and comprehensive “evidence-based” foundation for decision making for the introduction and utilization of health technologies at all levels in the healthcare system and to ensure that HTA becomes an integrated part of routine decision making for planning and operational policy within the healthcare system.

Engagement with the Government of Tanzania began in 2014 with PATH (an international nongovernmental organization)

through the access and delivery partnership (ADP), which is a project aimed to help LMICs expand their capacity to access and introduce new health technologies (15). This helped provide sensitization on the HTA topic and created understanding that integration of HTA processes into the Tanzanian context will support health resource allocation. In order to introduce HTA into the system, discussions on a demonstration project took place, this project could then help show the value of HTA.

Ministry officials have expressed concerns around efficiency and pricing and they have looked to HTA as a potential solution in addressing these issues. To this end, a workshop on HTA was hosted by the Ministry of Health in collaboration with PATH in early 2015. Partners from Thailand—the health intervention and technology assessment program (HITAP), and South Africa—the priority cost effective lessons for system strengthening (PRICELESS SA) participated in the workshop. Both HITAP and PRICELESS are core members in the international decision support initiative (iDSI), which is a global network working to increase the value and impact of health spending. The workshop aimed to raise awareness of HTA and its role in informing decisions as well as serving as a platform where the experience and knowledge from both HITAP and PRICELESS could be shared. HITAP is a semi-autonomous research unit with the responsibility for appraising a wide range of health technologies and programs to inform policy decisions in Thailand. PRICELESS is a research to policy unit based at Witswatersrand University School of Public Health, South Africa, whose mission is to provide analysis that will inform the way in which resources are allocated and priorities are set to improve public health.

The following questions were considered at the meeting:

- (1) What are the potential applications of HTA for evidence-based policy development?
- (2) What factors are conducive to introducing HTA, and what are the barriers?
- (3) Who are the key stakeholders in supplying HTA and who are the target users of HTA results?

Several key points emerged, including a strong political will to establish a structured mechanism to prioritize health technologies and interventions that would bring value for money to Tanzania. A success factor was the identification of a particular project, representing a good starting point for establishing a priority-setting mechanism in Tanzania: using priority setting for NEMLIT revision. At the time, Tanzania had an urgent need to update their STG/NEMLIT and it was agreed that this would be a good opportunity to use an HTA, evidence-informed process to do so.

A follow-up workshop was then held towards the end of 2015 to identify gaps in technical skills and capacity relating to the medicine selection processes with representatives from the Ministry of Health. The workshop brought to light a number of challenges about how to actively practise evidence-based medicine, which include a lack of understanding of how to define PICO (population, intervention, comparator, outcome) and use appropriate search terms and secondary databases such as Pubmed to identify relevant sources of evidence and limited skills to conduct a critical appraisal of the literature. In previous reviews, the participants had relied on informal searches using universal search engines such as Google or ad hoc articles as source evidence. Other challenges included lack of understanding of activity-based costing (ABC) analysis of medicine and missing data on medicines quantification to assist in the priority setting

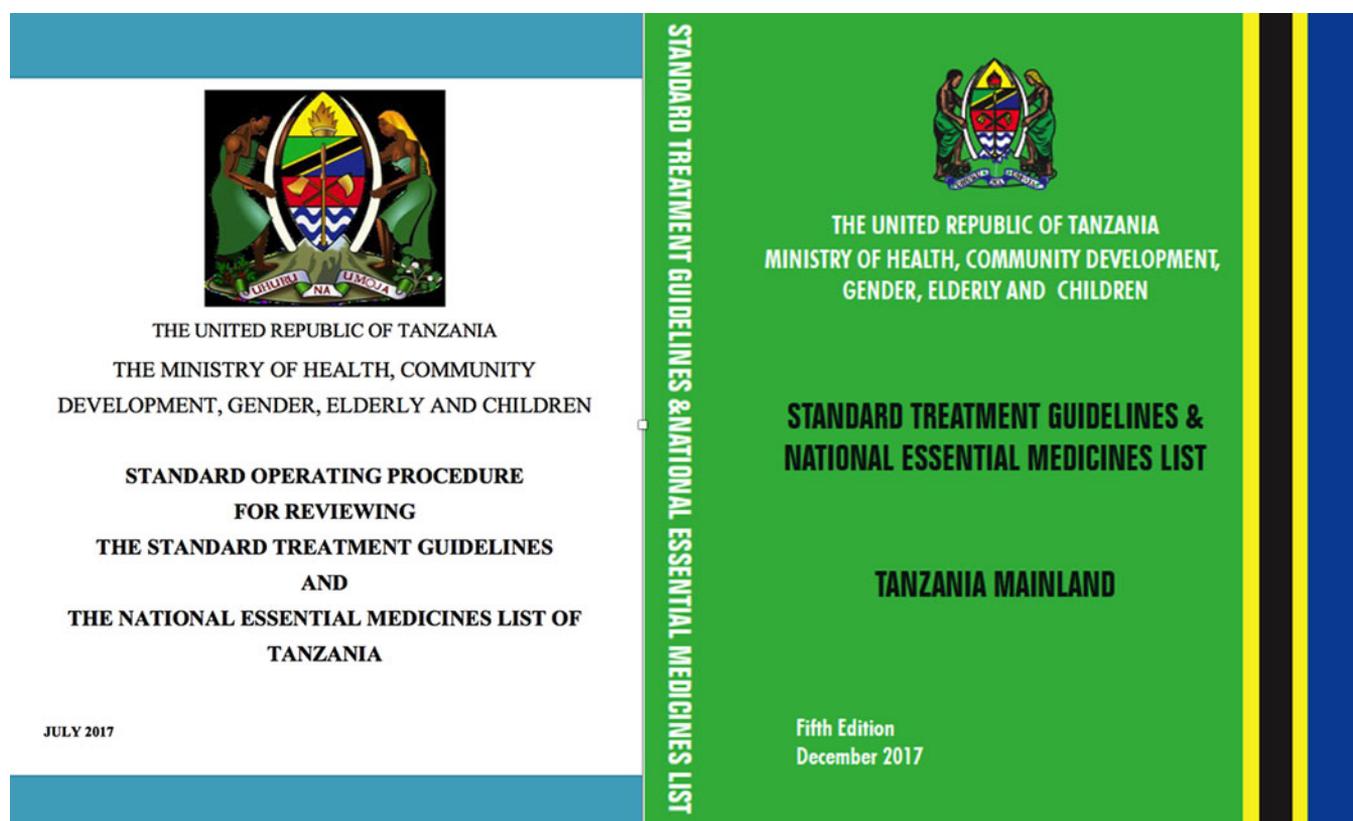


Fig. 2. SOPs for reviewing the STG/NEMLIT and the STG/NEMLIT documents.

process. The participants in the workshop showed some concerns around the pharmacoeconomics and how to go about doing this due to a lack of skills in costing and economic evaluation. It was necessary to introduce basic costing skills as a first step and over the course of the workshops it became clear that the clinicians would prefer to hand this over to the pharmaceutical services unit (PSU) and health economists on the team.

The PSU, under the Ministry of Health, led the development of the fifth edition (2017) of the STG/NEMLITs. The PSU is the secretariat to the expert review team (ERT) who are responsible for developing/reviewing the STG/NEMLIT, tasked by the National Medicines Therapeutic Committee to update the guidelines. The ERT undertake the review, update, and then present their revisions to the National Medicines Therapeutics Committee who then approve changes.

It was noted in the workshop, that historically there has been very little collaboration between academic units and the Ministry. At this time (in 2015) there was a list of essential medicines, however, these medicines were drawn from the STGs. There was, in reality, an unlimited access to any of the registered medicines in Tanzania—procurement, affordability and availability issues notwithstanding. There was no specific adherence to any particular list of medicines.

The Essential Medicines List and Revision Process

The essential medicines list (EML) is among the earliest efforts to inform explicit priority setting in LMICs (16). Tanzania was one of the pioneers of the essential medicines program having produced its first list of essential medicines in the early 1970s.

The concept was later adopted by the World Health Organization (WHO) with the first WHO modal list of essential drugs being produced in 1977 (17). The medicines selected are based on public health relevance, and evidence on efficacy and safety. Listed essential medicines are considered to be cost-effective buys (18;19) and the list is considered as a tool to promote health equity (20). Countries' EMLs need to be regularly updated to ensure they contain key commodities and that they reflect up-to-date evidence on effectiveness and safety.

The NEMLIT can be used to guide the procurement and supply of medicines in the public sector, which is directly linked to the STGs and can be an important information and education tool used by health professionals. The STG/NEMLIT has a role to play in informing the health benefits package and it ensures treatment offered is “best practise” for the country setting based on available resources (equipment, medical personnel etc.) (21).

The NEMLIT is updated every 4–6 years by a committee of experts who come from different institutions, and is approved by the NMTC, a multidisciplinary team, chaired by the CMO, with 16 members. Historically, the selection criteria in Tanzania have been loosely based on efficacy, safety, availability, and compliance with WHO recommendations. There was little to no consideration of cost-effectiveness criteria, which is evidenced by the committee having no knowledge of cost-effectiveness (17).

The 2017 development and revision of the STG/NEMLIT involved capacity-building workshops and on-going engagement between the Tanzanian ERT and continuous technical support from HTA experts contracted to PRICELESS SA. Such engagement

enabled in-country stakeholders to gain an in-depth understanding and practical experience of evidence-based selection of medicines while simultaneously developing their knowledge base on the principles of HTA. Training and support was given on using evidence-based medicine and costing for priority setting in medicines. These linkages to the HTA process again provided the affirmation that HTA has a critical role to play in decision making.

To ensure transparency and sound methodology of the revision of the medicines, a guidance document, in the form of an SOP (9) was developed by a group of national and international experts aimed at providing systematic guidance for developing and reviewing the STGs, vertical program treatment guidelines and associated medicine lists (NEMLIT inclusive), that could be used in future review processes. It was subsequently endorsed by the National Medicines Therapeutic Committee (NMTC), chaired by the CMO.

The guidance document outlines the approach to the review of the STG/NEMLIT and describes the process of topic prioritization. A notable aspect to the guidance is the incorporation of cost-effectiveness in considering medicines or treatment options. While there is no direct reference on how to establish thresholds for inclusion or exclusion of medicines, this is the first time that the guidance for the development of the STG/NEMLIT has incorporated cost-effectiveness.

Compared to previous revisions of the NEMLIT, the SOP enables the incorporation of a new principle, ensuring that any addition or deletion from the EML needs to be on the “basis of proven scientific data regarding effectiveness, safety and cost-effectiveness.” The SOP further goes on to state that appropriate treatment options need to be linked to the evidence gathered and that “these recommendations should consider efficacy, safety and cost-effectiveness” instead (9). The revised STG/NEMLIT was finalized in the first quarter of 2018. The final list of medicines had approximately 140 medicines removed, while approximately 170 new products were added. The inclusion criteria for medicines considered efficacy, safety, cost-effectiveness as well as registration with the Tanzanian Food and Drugs Authority (TFDA). These criteria were not individually weighted. While the 2017 NEMLIT still contains some questionable drugs regarding their inclusion in the EML—for example, the medicine levobupivacaine is not yet registered for use by the TFDA and the medicine bevacizumab has a lack of proven efficacy in certain cancers (22), there were a number of drugs which were excluded due to cost-effectiveness criterion not being met. The skills built through this process provide an opportunity for further revisions of the NEMLIT and have set the foundation for establishing an HTA mechanism in Tanzania.

Establishment of the Tanzanian HTA Committee

While the process of the revision of the STG/NEMLIT was underway, the first HTA meeting was convened by the acting CMO in September 2017. The purpose of this meeting was to define the terms of reference for the committee and to give an overview of HTA. Committee members were nominated from various units/departments based on their seniority.

A second HTA committee meeting was held in May 2018, supported by PRICELESS/iDSI, which discussed the need for capacity building among the committee members. It was agreed that HTA committee meetings would be used as a platform for ongoing HTA mentorship and capacity building.

During this process there has been recognition of inefficiencies in the system, for example, the disconnect between the procurement list at the Medicines Stores Department (MSD) and NEMLIT and the National Health Insurance System (NHIS) benefit package. MSD makes available a list of medicines and medical supplies via its price catalogue, which facilitates its use as a guide to place orders. MSD then distribute drugs to public health facilities through its nine zonal offices. The procurement of essential medicines at the MSD is not limited to the EML. Medicines for tertiary care can be procured under request of health institutions offering care and management. According to a manager in the NHIS, “43% of items in the NHIF benefit package are not listed in NEMLIT.”

The HTA process has since been recognized as an appropriate mechanism to align the NEMLIT and the National Health Insurance Fund reimbursement list; as a participant from a recent workshop stated “HTA will help us fix this”—that is, begin to align the EML with the National Health Insurance Fund reimbursement list of medicines. If the medicines that are reimbursed are limited to those on the EML it could generate large financial savings for the scheme which may help reduce subscription costs by enlarging the pool of members.

Factors Contributing to Success

A number of important factors contributed to the successful introduction of HTA and establishment of an HTA committee in Tanzania, some of which are generalizable and can be applied in countries that aspire to introduce HTA. A summary of key lessons is outlined in Figure 3.

The Tanzanian experience teaches us that engagement of policy makers and the identification of an appropriate entry point during the initial phases are key success factors, particularly while there is momentum and political will. A demonstration project needs to be selected that is not just an academic exercise but which also contributes to the creation of demand (for HTA). Using a project, which is seen as a necessity for the country, provides opportunity to engage further and sustain efforts around HTA topics. This reinforces the HTA messaging and also gives opportunity to provide capacity building around health economics topics.

Strengthened individual, institutional, and organizational capacity was crucial for the creation of the HTA committee. This could not have been achieved without the strong partnership between development partners and local officials which was key to influencing strategic direction. The major lesson learnt from the experience was that, strong political will was generated by multiple influential partners and by ongoing, in-depth engagement. Despite some movement of individuals within the Ministry, there has been one consistent focal point who has been fully engaged from the beginning, which has been a significant factor in the establishment of an HTA committee and the

- Capacity building initiatives, including on the job training, are valuable
- Early demonstration projects can show potential uses of HTA and drive further demand
- Using HTA to inform the EML and to then link insurance scheme coverage, pricing and reimbursement decisions with the National EML, may be a useful entry point for HTA

Fig. 3. Key lessons learned.

incorporation of evidence-informed priority setting in decision making (within the EML).

Discussion

This paper describes the journey of introducing HTA in Tanzania and outlines emerging lessons that can guide future HTA-related initiatives in similar resource-limited settings. In Tanzania, it has been recognized that HTA can play a critical role in an efficient healthcare system. For the first time, cost-effectiveness has been considered in the development of the EML and adherence to the STG/NEMLIT is being enforced by the Ministry. By using the process of the revision of the NEMLIT, an opportunity was created to demonstrate that HTA is not only a concept for discussion, but can be translated into a workable process in practice.

Three specific strategic objectives were achieved during the process:

- (1) Establishment of a political commitment to promote (facilitate) HTA uptake.
- (2) Foundation of structures for utilization of HTA information.
- (3) Increased demand for HTA.

The Tanzanian government has shown commitment to ensuring value for money and to delivering UHC. To achieve this, HTA has been identified by the country as a critical element. HTA is the international gold standard for utilizing health economic principles to comparatively assess evidence for cost, clinical effectiveness, safety, and equity to provide evidence as to whether an intervention is a cost-effective investment within a given health system and to assist in the prioritization of health resources.

Introducing the concept of HTA and building capacity on topics related to HTA began in 2015 when an introductory workshop was held in Dar es Salaam, with the aim of providing a forum for stakeholders in Tanzania to learn about the HTA process, its need, and applications with examples in developing/low-resource settings.

The introduction of HTA was made possible through a demonstration project, in this case a revision of the STG/NEMLIT. Activities related to this project resulted in opportunities for capacity development, and reinforcement of messages related to HTA. The revision was an extensive exercise, during which Tanzania was able to set up and establish an HTA committee. The establishment of a committee is an achievement and is a key building block to institutionalizing HTA for evidence-informed decision making.

The Challenges Ahead and Future of HTA in Tanzania

Despite the significant progress, there are still a number of challenges ahead. A major factor is a lack of financial resources—there is no dedicated funding to support the HTA workstream as yet. Given the number of competing priorities between workstreams in the Ministry, individuals' time is split between various activities, which means the pace of progression can be slow at times.

The capacity for understanding HTA is also limited. While there is recognition of how HTA could enhance the health system, the overall understanding of the potential power of HTA and the capacity to interpret results and convert those into policy, needs to be harnessed. There are a number of economics' studies, however, these have not effectively been translated into policy and the HTA ecosystem is yet to be defined.

Tanzania has shown remarkable political will to establish an HTA process. To develop and implement a functional and robust national HTA system to best inform the provision of healthcare services, development and amendment of the relevant policy and legislative framework is needed. A systematic process for the incorporation of HTA would help institutionalize HTA for decision making in the health system. Linking outputs with the explicit decision-making needs of the health system provides the best opportunity to realize a functioning and sustainable HTA system in Tanzania. The revision of the NEMLIT provided an opportunity to use HTA in the selection of essential medicines. By using this process it has been possible to demonstrate the potential power of HTA as a policy tool. This has led to the creation of the Tanzanian HTA committee, while at its infancy there is momentum to build capacity for HTA and to integrate this into the Tanzanian health system. A functional HTA entity will enable transparency in terms of setting priorities as universal health care unfolds in Tanzania.

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