



SITUATIONAL ANALYSIS OF HEALTH TECHNOLOGY ASSESSMENT IN ETHIOPIA, 2022

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Primary challenges related to HTA in Ethiopia are the lack of an adequate legal framework with clear governance arrangements including the lack of a central coordinating body for HTA, limited local data, capacity constraints and lack of defined linkages between production and use of HTA. Additionally, there is minimal awareness among researchers and decision-makers about HTA and the importance of incorporating HTA in priority-setting activities in Ethiopia.

Three key ways to strengthen HTA in Ethiopia are:

1. Create a framework for HTA in Ethiopia and an enabling environment which would include a HTA legal provision, a clear priority-setting governance structure, which might involve a central HTA authority and clear structure and scope for HTA
2. Bridge the capacity gap by strengthening national and international partnerships, leveraging non-government and foreign expertise, and building human capacity with strategic training programs
3. Develop a national roadmap for HTA, and identify windows of opportunity to draft and pilot contextualized strategies for institutionalizing HTA.

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ACRONYMS

CBHI	Community-Based Health Insurance
EFDA	Ethiopian Food and Drug Administration
EHIA	Ethiopian Health Insurance Agency
EHSP	Essential Health Services Package
EPHI	Ethiopian Public Health Institute
EPSA	Ethiopian Pharmaceutical Supply Agency
FMoH	Federal Ministry of Health
GDP	gross domestic product
HBP	health benefits package
HEFA	Health Economics and Financing Analysis
HSDP	Health Sector Development Program
HSTP	Health Sector Transformation Plan
HTA	health technology assessment
iDSI	International Decision Support Initiative
KTD	Knowledge Translation Directorate
NHA	National Health Account
OOP	out-of-pocket
PCD	Partnership and Cooperation Directorate
PHCU	Primary Health Care Unit

PPL	Pharmaceuticals Procurement List
RHB	regional health bureau
SHI	Social Health Insurance
WHO	World Health Organization

1. EXECUTIVE SUMMARY

In low- and middle-income countries, systematic priority setting is increasingly seen as critical to the achievement of universal health coverage, by ensuring that the highest-value healthcare is provided given limited national budgets. One approach to systematic priority setting in the healthcare system is health technology assessment (HTA), which is defined as a multidisciplinary undertaking that assesses the effects, benefits, and harms of a health technology across a range of issues, including social, economic, and ethical issues. Following a World Health Assembly resolution in 2014, many countries are now developing the capacity to use HTA to set their health priorities.

This situational analysis, conducted by the Ethiopian Public Health Institute and the International Decision Support Initiative, aims to describe the current landscape of HTA in Ethiopia. It describes how priority setting is currently undertaken, the extent to which evidence is considered, and how priority-setting decisions are implemented. The assessment also considers the current capacity to conduct HTA and provides recommendations on how to strengthen evidence-informed priority setting and HTA in the country.

Background

Ethiopia is a low-income country with an estimated population of 104.6 million, the second largest in Africa. The country's total health spending as a share of gross domestic product (GDP) is 4.2 percent, with funding mainly coming from donors, the government, and out-of-pocket payments by patients (35 percent, 32 percent, and 31 percent, respectively). Government spending is managed by regional health bureaus (RHBs) (48 percent) and the Federal Ministry of Health (FMoH) (44 percent).

The FMoH is mandated to formulate national policies and strategies and develop standards in consultation with RHBs. Ethiopia developed its first national health sector plan in 1997 and implemented it with a rolling five-year program called the Health Sector Development Program (HSDP). Healthcare priority setting was introduced in 2005 during the third strategic plan (HSDP III).

Current priority-setting mechanisms

Currently, three centrally conducted processes define explicit priorities in Ethiopia's health sector: the Essential Health Services Package (EHSP), the Pharmaceuticals Procurement List (PPL), and the Health Benefits Package (HBP). Since there is no legally delegated priority-setting unit at the national level, priority-setting activities are undertaken by three different organizations, following their own diverse methodologies. The FMoH has the responsibility to lead and manage the EHSP, the Ethiopian Health Insurance Agency (EHIA) is responsible for the HBP, and the Ethiopian Pharmaceutical Supply Agency is responsible for the development and implementation of the PPL.

Use of HTA

Although key principles associated with HTA, such as value for money, cost-effectiveness, and affordability, are included as core values in the national health policy, and the latest EHSP included cost-effectiveness as a prioritization criterion, HTA evidence is not considered as an explicit input in the three priority-setting mechanisms currently in place in Ethiopia. This might be because HTA concepts are vaguely understood, there is no legal mandate for incorporating HTA evidence into decision making, HTA efforts are fragmented, a functional network of professionals who can conduct and use HTA does not exist, and there is limited local evidence that can be used for economic evaluations.

Though there are attempts to make use of evidence in priority-setting decisions in Ethiopia, most of these decisions are based on expert opinion and are the responsibility of stand-alone task forces.

Capacity for HTA and available data sources

Ethiopia, in addition to having no formal and central coordinating body for HTA, has no national standard guidelines for conducting HTA. However, some academic institutions, partner organizations, and independent research institutions have implemented initiatives to generate relevant cost-effectiveness analysis and engage in priority setting to inform health policy decision making.

The World Health Organization (WHO) has also recognized the lack of reliable national cost data and has developed two tools to support national costing studies, WHO-CHOICE (CHOosing Interventions that are Cost-Effective) and the OneHealth Tool. Depending on the specific question being examined, there are many other potential sources, which are summarized in Table 1 on page 21.

Way forward

Three steps need to be taken to develop HTA in Ethiopia.

First, a framework and enabling environment needs to be established. A range of stakeholders are involved, both technically and financially, in priority-setting activities in Ethiopia, and an organized structure of linkages is important for sustainable involvement, contribution, and responsibility. A road map for HTA institutionalization will need to be developed and agreed to by stakeholders, and consideration will need to be given to its appropriate governance and legal framework.

Second, for HTA to be executed, it will be important to bridge the capacity gap. This can be addressed by building human capacity, structural definition, and institutionalization. Consequently, capacity-building activities focused on developing the skills of researchers, decision makers, and knowledge brokers at various organizations, and strengthening national

and international partnerships, are key areas for immediate focus. It is also imperative to recognize the importance of benefiting from other countries' HTA experiences and create broader networks for building advanced capacity.

Third, Ethiopia should draft and pilot contextualized strategies for institutionalizing HTA in which there will be a clear demand and supply chain for priority setting and undertaking HTA. This should indicate a clear requirement for the use of HTA in priority-setting activities such as EHSP. In addition, the roles and responsibilities of institutions that should be involved in HTA, on both the demand and supply sides, should be defined. With the current assessment and the country's existing structure, the FMoH and agencies such as the EHIA could be on the demand side, while research wings of the FMoH, universities, and other stakeholders should be equipped to supply HTA products for decision making.

2. BACKGROUND ON THE SITUATIONAL ANALYSIS

Ethiopia is a low-income country in which thorough analysis and contextualization are required for health resource allocation. One of the main activities that can support this process is the development and use of health technology assessment (HTA). However, the development and use of HTA in Ethiopia is not well documented. Thus, this situational analysis has been prepared to understand the current landscape of HTA and to serve as a base for the creation of a sustainable HTA system by identifying stakeholders, assessing the process of healthcare priority setting, and evaluating local capacity.

This study was initiated after establishing contact with the International Decision Support Initiative (iDSI), which aims to strengthen capacity to undertake HTA and support the use of HTA for decision making in low- and middle-income countries. The Knowledge Translation Directorate (KTD), which works to advance evidence-informed decision making and is based at the Ethiopian Public Health Institute (EPHI), took the initiative to contact iDSI. This situational analysis of HTA in Ethiopia was conducted by the KTD at EPHI, with financial and technical support from iDSI. The preparation of this study has included the development of the study protocol, ethical review, data collection (through a desk review of key documents and interviews with key informants from organizations involved in priority setting), data analysis, and report write-up.

3. BACKGROUND ON HTA AND PRIORITY SETTING

Priority setting in healthcare is currently at the center of policy and political attention globally. Many countries are moving toward attaining universal health coverage; however, they struggle to ensure the sustainability of their health systems in the presence of competing demands. Where trade-offs are inevitable, a process that uses evidence to set priorities is essential [1].

In low- and middle-income countries, priority setting is increasingly seen as critical to the achievement of universal access to reasonably comprehensive care of reliable quality, but mechanisms for priority setting are less established. A popular mechanism in the healthcare system is HTA, which is defined as a multidisciplinary undertaking that assesses the effects, benefits, and harms of a health technology across a range of issues, including social, economic, and ethical issues [1].

HTA can be used to guide universal health coverage policies such as benefits packages and essential medication lists and to improve the efficiency and equity of the healthcare system.

A key milestone in achieving an effective HTA system is the institutionalization of HTA, which refers to establishing legislative arrangements that promote structures and processes suitable to producing HTA. Successful institutionalization of HTA is realized with the presence of political commitment, funding availability, adequate technical capacity, and inclusion of stakeholders. It should be noted, however, that organizational integration of HTA bodies within healthcare systems can differ between countries.

Institutionalization also requires that the process of conducting HTA and priority setting be defined. Hence, the HTA process can generally be characterized by the five steps of defining the decision space or topic selection, analysis, appraisal, decision making, and implementation. It should also be emphasized that beyond developing HTA documents, designing a contextualized strategy for and approach to implementation is vital.

4. BACKGROUND ON THE COUNTRY

Ethiopia is the second-most-populous country in Africa, after Nigeria. The country is bordered by Eritrea to the north, Djibouti and Somalia to the east, Sudan and South Sudan to the west, and Kenya to the south. According to the projections from the 2007 population and housing census, the total population for the year 2021 is estimated to be 104.6 million. Ethiopia is among the least urbanized countries in the world, with 82 percent of the population living in rural areas. The pyramidal age structure reflects a feature of populations with high fertility levels; children under the age of 15 and adults over the age of 65 account for 40 percent and 4 percent of the total population, respectively [2].

The governance of Ethiopia's healthcare system is a reflection of the country's political system. In the mid-1970s, during the Derg regime, a health policy was formulated that emphasized disease prevention and control. This policy gave priority to rural areas and advocated community involvement. The current health policy, promulgated by the Transitional Government of Ethiopia in 1993, takes into account broader issues such as population dynamics, food availability, acceptable living conditions, and other essentials of better health [3]. The policy was formulated with an emphasis on increasing all population segments' access to a basic package of quality primary healthcare services. Since the formulation of this policy,

Ethiopia has developed and aggressively implemented several health sector programs and policies.

Ethiopia's Federal Ministry of Health (FMOH) is mandated to formulate national policies and strategies and develop standards in consultation with regional health bureaus (RHBs). Governance includes administrative decentralization to RHBs and district-level health offices where decisions are made through consultation forums and joint decision-making processes. The Ethiopian health system comprises institutional frameworks that coordinate and provide stewardship in the implementation of the health sector programs and initiatives.

The complex and diverse Ethiopian health sector includes the public/government sector, the private health sector, the informal health sector, and health consumers. Health services are delivered in a three-tier system, that is, primary-, secondary-, and tertiary-level care. Primary Health Care Units (PHCUs) are composed of health posts, health centers, and a primary hospital and form the foundation of the tier system. Secondary-level care includes general hospitals that receive referrals from the PHCUs, and the top (tertiary) tier consists of specialized hospitals that are referral centers for the general hospitals [4, 5].

According to global experience and evidence, priority-setting determines the strategic direction of national health programs. Priority setting in health is critical for governments that seek to promote equitable access to essential packages of health services and to achieve universal health coverage [1]. Cognizant of this reality, Ethiopia has focused on universal health coverage and is making efforts toward priority setting.

5. OVERVIEW OF ETHIOPIAN HEALTH FINANCING AND SERVICE PROVISION

Health financing is a critical factor affecting the ability to improve a country's health system and thus the health of the population. The goal of universal health coverage can be achieved, and people can enjoy the highest standard of healthcare, only if the required health resources are properly mobilized, pooled, and spent. Ethiopia's current health sector plan, Health Sector Transformation Plan II (HSTP II), also emphasizes enabling the community to access all needed quality health services without being exposed to financial hardship [3, 4].

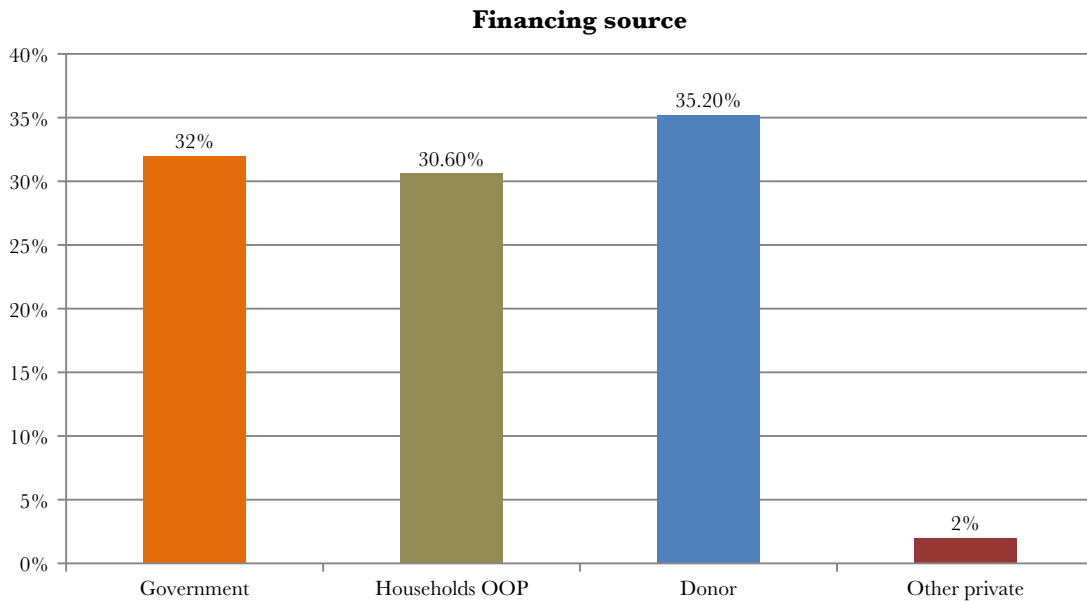
In line with the emphasis of HSTP II, the Ethiopian government has drafted various strategies to enhance financial access to healthcare services and to ensure financial protection. These include user fees that are to be retained and utilized by each facility, a targeted fee waiver scheme for the poor, establishment of private wings at various hospitals, Community-Based Health Insurance (CBHI), and the mobilization of external resources from development partners [6].

Compared to the expected health spending share of low-income countries (5 percent) and the global average (9.2 percent), Ethiopia's total health spending share of GDP is low, at

4.2 percent [7]. According to the seventh-round National Health Account (NHA) report, Ethiopia's total health expenditure (recurrent and capital) was estimated at ETB72 billion (US\$3.10 billion) [7].

The sources of financing for Ethiopian healthcare are still dependent on donor contributions and out-of-pocket (OOP) payments. The government contributes 32 percent of the financial resources for healthcare, while donors' contributions account for 35 percent and OOP payments account for 31 percent, as highlighted below in Figure 1. The latter two sources are unpredictable and unsustainable ways of financing healthcare [7].

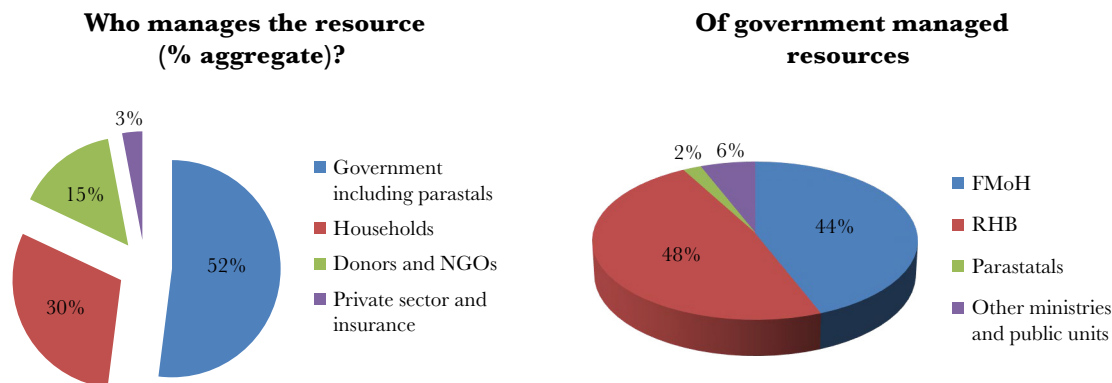
Figure 1. Total health expenditure by source of financing, 2016/17



Regarding health resource management, the NHA report shows that more than half of total health resources (52 percent) in Ethiopia are managed by the government, while households account for the next largest share, managing 30 percent of healthcare spending at the time of seeking healthcare. Donors and nongovernmental organizations manage 15 percent, and the remaining 3 percent is managed by insurance companies and private employers.

Of total government-managed resources, RHBs manage almost half (48 percent) and the FMoH (including affiliate federal organizations and federal hospitals) manages 44 percent, while other ministries and parastatal organizations manage the remaining 8 percent of the resources as outlined in Figure 2.

Figure 2. Total health expenditure by financial management



More than half of the country’s recurrent health spending (53 percent) in 2016/17 was on curative healthcare services. This was followed by preventive care services, which accounted for 30 percent of recurrent health spending. Governance and health system administration accounted for a little over 10 percent of the country’s recurrent health spending. The remaining 6 percent went to other health functions, including long-term care, medical goods not specified by function, and other healthcare provisions [7].

6. CURRENT PRIORITY-SETTING MECHANISMS

Ethiopia’s health priority-setting values and guiding principles are drawn from the values reflected in the national health policy and health sector strategic plans. Ethiopia developed the first national health sector plan in 1997 and implemented it with a rolling five-year program called the Health Sector Development Program (HSDP). There have been four phases of HSDPs: HSDP I (1997/98–2001/02), HSDP II (2002/03–2004/05), HSDP III (2005/06–2009/10), and HSDP IV (2010/11–2014/15) [8]. Following the successful implementation of these HSDPs, Ethiopia developed and implemented a five-year Health Sector Transformation Plan (HSTP I) for the period 2015/16–2019/20, which was in line with the country’s growth and transformation plan. The second Health Sector Transformation Plan (HSTP II) is the current five-year strategic plan, for the period 2020/21–2024/25 [6].

The idea of healthcare priority setting was introduced in 2005 during the third strategic plan [9]. HTA is considered a “gold standard” to guide explicit healthcare priority setting [10]. Although the 2015 Essential Health Services Package (EHSP) discusses considering cost-effectiveness in setting priorities, interviews carried out as part of this landscape assessment found that HTA is not used as a standard approach, despite some deliberation processes’ use of a few prioritization criteria such as cost-effectiveness findings for healthcare priority setting in Ethiopia. Current practices related to priority setting in the health sector include the EHSP, the Pharmaceuticals Procurement List (PPL), and the Health Benefits Package (HBP) [5, 11, 12].

The EHSP identifies the country's priority health interventions that are deemed appropriate, affordable, and equitable to address the most pressing health problems. Though there is no explicit linkage between the EHSP and the other two priority-setting activities (PPL and HBP), according to interviews with key informants at the FMoH, the EHSP document is the reference for the development of PPL and HBP. The linkage of the three priority-setting activities with the health expenditures outlined in the section above is also not clear. The details of these priority-setting activities, including their processes and the stakeholders involved, are discussed below.

Generally, the EHSP is the master document that guides both the PPL and HBP.

A. Essential Health Services Package (EHSP)

As indicated above, healthcare priority setting was introduced in 2005 to improve the efficiency and equity of the healthcare system in Ethiopia. The EHSP defines appropriate priority health services and represents a major strategy to maximise the benefits from the demographic dividend by improving the health status of Ethiopians. This package focuses on health promotion, disease prevention, and curative and rehabilitative services. The EHSP document acts as a guide for the development of other important strategic and operational documents that can improve health services delivery in Ethiopia. It also serves as a guiding framework to progressively achieve universal health coverage in the country [5, 12].

The first EHSP remained in force for around 14 years with no revisions, despite having some limitations. In recognition of these limitations, the FMoH undertook a revision in 2019 based on the following three rationales: (a) the demand for health services has substantially increased; (b) health service practice has evolved, including the addition of interventions that were not part of the 2005 EHSP; and (c) Ethiopia has undergone tremendous demographic and epidemiological changes, which have led to a double burden of disease [5].

EHSP revision process

The EHSP was revised using a participatory approach, with frequent appraisal and feedback before decision making. First, a road map document that guided and informed the overall process and each step of the revision was prepared and presented to the management of the FMoH. After the FMoH management had endorsed the road map, a technical working group, composed of 30 senior experts on various health system dimensions, was established. Then several consultative technical workshops were conducted to define the scope of the revision, develop a complete list of health interventions, develop prioritization criteria, gather evidence, and compare and rank health interventions according to a range of criteria.

A universal list of interventions was identified through an exhaustive search of the Ethiopian health sector's plans, strategies, and national publications, along with the WHO data repository, WHO-CHOICE database, Disease Control Priorities third edition (DCP3), and Tufts Global Health Cost Effectiveness Analysis Registry [12]. Through this process, the FMoH identified a total of 1,442 interventions. After developing the comprehensive list of interventions, the

technical working group set seven prioritization criteria: disease burden, cost-effectiveness, budget impact, equity, financial risk protection, public acceptability, and political acceptability. Based on these criteria, a priority score was computed for each intervention and a ranking assigned. A total of 1,019 interventions were selected as EHSP components and were defined as lower, medium, and higher priority [12].

Despite all the efforts to use scientific evidence to apply the aforementioned prioritization criteria, equity and financial risk protection scores were generated based on expert opinion, using the Delphi technique. Additionally, limited local evidence of economic evaluations was mentioned as a challenge, and HTA data were not used as an input for the revision of the EHSP. One of the interviewees explained the HTA process as follows:

There is an initiative of HTA here and there in the country. It is fragmented and it is more of an academic exercise and it is not used as an input for the priority setting. Even the revision of EHSP was an academic exercise, let alone the HTA products.

The Health Economics and Financing Analysis (HEFA) team in the Partnership and Cooperation Directorate (PCD) at the FMoH was a central coordinating body for the EHSP revision in Ethiopia. The revised EHSP was planned to be used for five years after its launch and is expected to have subsequent regular updates. The revised EHSP is the foundation for the country's national development program and its long-term strategic plans for the health sector. The PPL and HBP designs are also expected to be aligned with the EHSP.

Stakeholder involvement

The main stakeholders involved in the EHSP priority-setting process include the RHBs, Addis Ababa University (priority-setting unit), Addis Centre for Ethics and Priority Setting, the Clinton Health Access Initiative, WHO Ethiopia, the UK's Department for International Development, the Harvard Fenot Project, the Bill and Melinda Gates Foundation, Abt Associates, hospitals, Gondar University, Jimma University, and Haramaya University.

According to the interviewees, stakeholders' engagement levels differed depending on specific activities throughout the priority-setting process. For instance, the Gates Foundation supported the process financially through the Disease Control Priorities–Ethiopia project, and the WHO also supported the priority-setting process financially, while the other stakeholders provided technical support.

B. Pharmaceuticals Procurement List (PPL)

The Ethiopian Pharmaceutical Supply Agency (EPSA) is a legally delegated public institution established to ensure continuous availability of quality pharmaceuticals at an affordable price to public health facilities through need-based pooled procurement. Before 2018, EPSA managed requests for all types of pharmaceuticals without having a defined list of pharmaceuticals for procurement. This left the agency unfocused, with no reference list against which its performance could be measured.

In 2018, the agency developed the first edition of the PPL, which served for three years. The second edition of the list was endorsed in January 2021 and is now in use. This PPL will be used for the annual quantification and procurement of pharmaceuticals for the next three years and is scheduled to be revised every three years. The PPL includes medicines, medical supplies, medical equipment, and laboratory chemicals and reagents [11, 13].

PPL 2021 preparation process

To undertake the revision of the PPL, EPSA establishes a taskforce called the Pharmaceuticals Procurement List Preparation Taskforce. This taskforce, which is responsible for preparing the draft PPL, is composed of various experts such as doctors and nurses from numerous organizations, including the FMoH, the Ethiopian Food and Drug Administration (EFDA), EPHI, professional associations, hospitals, and several directorates of EPSA.

The taskforce critically reviews the previous pharmaceuticals list and past trends of pharmaceutical requests and adapts international criteria from organizations such as the WHO to develop contextualized criteria to be used in the development of the draft list [11, 13]. The annual requests from health facilities are assumed to have undergone a series of consultations within each health facility and received the approval of the health facility's Drug and Therapeutics Committee.

This assessment shows that there is no clear use of HTA in revising the PPL. This was stated by an interviewee as follows:

As for evidence use, we depend on criteria and expert opinion to include medications to the PPL but we don't use HTA. It is a new concept for me.

Once the draft list has been prepared, EPSA facilitates a series of consultations with experts from relevant stakeholders to critically review the list. Finally, the PPL is published and disseminated to be used as a reference standard in all operations. EPSA uses the PPL for the annual quantification and procurement within the government's procurement policy.

Stakeholder involvement

Representatives from each category of health facilities, the FMoH, RHBs, EPHI, EFDA, regional hubs, universities, development partners, professional associations, and EPSA are involved in the consultative meetings.

The 2021 PPL indicates that Results for Development (R4D), the Global Fund, and Chemonics International are involved, providing both technical and financial assistance.

An expert interviewed explained that the PPL is financed by both governmental and nongovernmental or donor budget sources:

It is financed by both the government and nongovernmental sources. The governmental source includes SDG [Sustainable Development Goal] budget and Revolving Drug Fund and the donor source includes Global Fund and Chemonics International.

C. Health Benefits Package (HBP)

The government of Ethiopia is committed to universal health coverage and increasing access to healthcare. Changing the way healthcare is financed is critical to create more efficient and fair systems and reduce OOP expenditures, especially those catastrophic in nature. The methods for designing HBPs vary from country to country. One major method selected by the Ethiopian government for HBP design is health insurance through the Community-Based Health Insurance (CBHI) and Social Health Insurance (SHI) schemes [14]. These two insurance schemes were endorsed following recommendations from a technical committee that worked on the development of Ethiopia's health insurance strategy.

The aim of CBHI is to reach and cover the very large rural agricultural sector and small and informal sector in urban settings. The FMoH first launched CBHI (following a pilot) and later established SHI, which targets formal sector employees and their families [15, 16].

CBHI development process

The FMoH took a first step toward initiating the CBHI pilot by preparing a road map and identifying key stakeholders, from the federal to the grassroots (*kebele*) level, and defining their respective roles. Based on this road map, 13 pilot and 4 control *woredas* were selected from four regions. Committees were established at the federal, regional, *woreda*, and *kebele* level to facilitate policy development, implementation, and monitoring and evaluation of the schemes.

At the federal level, a CBHI National Coordination Unit was set up under the supervision of the FMoH and Ethiopian Health Insurance Agency (EHIA) to serve as the executive unit. At the regional level, regional CBHI implementation units were established to serve as executive secretariats to regional steering committees led by the RHBs. The committees provided technical and operational support in the design and implementation of CBHI in each region.

At the *woreda* level, Woreda Health Insurance Steering Committees, comprised of relevant sector offices, were responsible for facilitating the design and setup of CBHI in their *woredas*. Each *woreda* has a single health insurance pool, and *kebele* sections form the network of local schemes. At the *kebele* level, Kebele Health Insurance Initiative Committees facilitate the design and setup of CBHI at the community level.

Following initial feasibility studies, implementation began, with training for various stakeholders, the introduction of CBHI design concepts, and the strengthening of implementation and monitoring capacity. *Kebele*-level discussions ultimately determined where pilot schemes were initiated. In early 2011, communities in the 13 pilot *woredas* held general assembly meetings at which board members were elected. A general assembly and board of directors oversee the governance of CBHI schemes at the *woreda* level, where major decisions on CBHI are made.

An executive body under the board of directors manages the daily operations of the scheme at the *woreda* and *kebele* levels. At each *woreda*, this body is responsible for signing agreements with

healthcare providers or health facilities, reimbursing healthcare providers, administering the fund (keeping financial records, preparing financial statements), and managing the database (which contains data on members, contributions, and utilization). The executive body at the *kebele* level is responsible for registering members, collecting premiums, and channeling funds to each *woreda* scheme. The general assembly and subsequent decisions on the bylaws and selection of board members herald the official start of each scheme.

All the pilot *woredas* in four regions started registering members in January 2011, and the share of *woredas* with a functioning CBHI scheme had reached 70 percent (770 *woredas*) nationally as of June 2020.

SHI development process

The government adopted SHI, following CBHI, to cover formal sector employees and pensioners. The legal framework and institutional structure for SHI is in place, and EHIA is the body responsible for the scheme's implementation. The SHI regulation passed in 2012 has a negative listing, which shows the health services excluded from the package rather than those covered. This approach has greatly impacted the implementation of the insurance scheme, and interviewees also stated that the preparation, scope, and development process of the first SHI remains unclear. For example, one interviewee said:

We are not able to find any documentation regarding the first SHI development process and we do not know how the negative listing was made. We would be happy if you could find and share with us.

At the time of data collection for this study, the agency was preparing the SHI scheme by using five of the seven prioritization criteria used in EHSP development (all except for political acceptability and public acceptability). In contrast to the first SHI scheme, the agency is intending to use positive listings [17, 18]. Although the SHI proclamation and regulation were endorsed in 2010 and 2012, respectively, the scheme has yet to be launched in 2022. Since the SHI scheme is under development, we are not able to document the full process [17–19].

According to the sources available during this assessment, HTA was not used as an input in the development of either the CBHI or SHI scheme.

Stakeholder involvement

Multiple stakeholders were involved at different levels in the development of CBHI. Specifically, the FMoH, EHIA, RHBs, *woreda* health offices, and *kebele* administrations and health facilities were involved in the general process. The specific roles of these stakeholders are outlined in the process described above.

7. THE LEGISLATIVE FRAMEWORK FOR PRIORITY SETTING AND HTA

One of the indicators of and necessary criteria for a well-institutionalized systematic priority-setting process including HTA is the presence of a well-defined and legally recognized mandate for incorporating evidence into key decision making, coupled with an ecosystem of suppliers and users of HTA evidence. The legislative framework underpinning the creation of the HTA body must have rules around consistent and transparent operation, recruitment, and a well-defined conflict-of-interest policy [20].

Although a legally delegated priority-setting unit or entity has not been established at the national level, priority setting is practiced to some degree in the Ethiopian health sector.

As indicated in this document, there are a few priority-setting activities undertaken in Ethiopia, including the development of the EHSP, HBP, and PPL. These activities are undertaken by specific responsible organizations. The FMoH is a designated organization that has the responsibility to lead and manage the EHSP, EHIA is responsible for the HBP, and EPSA is responsible for the development and implementation of the PPL.

This is also supported by a statement from a key informant interview:

PCD at the MoH has the responsibility to manage resources within the ministry through different channels. PPD takes the list of priority health service areas developed by HEFA (PCD) and uses it for the health sector planning like HSDP and HSTP.

The same cannot be said about the process of HTA in Ethiopia, since there is no legally responsible organization for the production and use of HTA. This situational analysis has shown that HTA is a vaguely understood process that is undertaken in a fragmented manner. Currently, the HEFA team in the PCD at the FMoH and the HTA team at the Knowledge Translation Directorate (KTD) of EPHI have made some efforts to conduct HTA. But although HEFA has developed some aggregated or program-based costing activities, and the KTD of EPHI has developed some HTA briefs, it is challenging to identify the full-blown application of HTA in these activities. As one expert from EPHI said:

We have been trying to conduct a few HTAs in the past. But it has been challenging to undertake a full HTA that adheres to all the necessary steps.

Additionally, it is expected that the development of priority-setting documents and activities will be supported by HTA; however, this is not the case in Ethiopia, as highlighted in this landscape assessment. One FMoH interviewee noted:

For instance, benefits package design (insurance scheme) needs HTA but is not included. And HTA needs a detailed database center or repository for each intervention which could be done by EPHI.

8. CAPACITY FOR HTA

Ethiopia, in addition to having no formal, central coordinating body for HTA, has no published national standard guidelines for conducting HTA. However, there have been some initiatives by academic institutions, partner organizations, and independent research institutions to generate relevant cost-effectiveness analysis and engage in priority setting to inform health policy decision making.

Some of the institutional capacity that could be used in conducting HTA includes the HEFA unit at the FMoH. This team is tasked with the application of evidence-based healthcare decision making in Ethiopia by organizing the available evidence, performing costing interventions, and defining effectiveness measures for the various health programs, and then supporting policymakers at the national and regional levels [21]. Further institutional capacity is represented by the presence of the KTD at EPHI, which is responsible for producing knowledge translation tools such as HTA, evidence briefs, rapid reviews, and systematic reviews to support evidence-informed policymaking [22].

Other regional institutes and universities engage in evidence synthesis and research activities, in the majority of cases for academic purposes.

This landscape assessment shows that a conducive policy environment for evidence-informed priority setting has been outlined in most policy documents reviewed. The presence of some fragmented HTA activities in the country can be considered a step forward. Although the currently identified priority-setting documents, including the EHSP, HBP, and PPL, have minimal to no utilization of HTA, the HEFA team at the FMoH, the KTD team at EPHI, and the Evidence-Based Health Care program at Jimma University are entities that could be used to build HTA capacity and evidence-informed policymaking practices in the country. The engagement of stakeholders and global partners in supporting these priority-setting activities could also serve as a good opportunity to bring in more advanced technical and financial contributions to support the activities.

HTA and evidence-informed policymaking in general in Ethiopia are challenged by the lack of a central coordinating body and priority-setting governance structure. The fieldwork revealed that there is generally minimal awareness among researchers and decision makers about HTA and the need for incorporating HTA in priority-setting activities [21]. Lack of senior HTA experts in the governmental structure, coupled with decisions that are greatly influenced by expert opinion, has contributed to the absence of an HTA system in Ethiopia. Most priority-setting processes in Ethiopia are influenced by donor interests, and limited domestic financing further contributes to the poor sustainability of initiatives.

9. DATA SOURCES FOR HTA

Evidence-based policy decisions depend on the availability of reliable, locally generated evidence. High-quality and timely health data create a strong foundation for a high-functioning health system, but reliable health information systems are generally lacking in low- and middle-income countries, including Ethiopia.

At the global level, the WHO has also recognized the lack of reliable national cost data and has developed two tools to support national costing studies: WHO-CHOICE (Choosing Interventions that are Cost-Effective), which provides county-level estimates of unit costs for inpatient and outpatient services for the public and private sectors but is now largely outdated, and the OneHealth Tool, which helps policymakers and health service planners to understand the framework for scenario analysis, costing, health impact analysis, budgeting, and financing of strategies for all major diseases and health system components. However, it requires local-level data to inform these scenarios.

Depending on the type of policy questions to be addressed, different HTA data categories can be used. These categories include clinical efficacy, cost, epidemiology, quality of life, service use/consumption, and equity [23].

Even though HTA is not implemented in an organized manner in Ethiopia, there are potential data sources available for the above HTA data categories, with their own limitations. The following table shows the potentially available data sources in Ethiopia that could support HTA.

Table 1. Summary of potential key data sources for HTA in Ethiopia

HTA-related information	Data sources	Institution	Collection method
1. Epidemiological data			
Demographics and population profile	Census	CSA	Census
	Vital Events Registry	VERA	Register and verbal autopsy
Demography and health	DHS	ECSCA/EPHI	Survey
Disease profiles	DHIS 2 and DHS	FMoH and universities	Routine data report, surveys, and surveillance
2. Clinical efficacy			
Efficacy: trials	Reports	EFDA/AHRI	Register
Efficacy: systematic reviews	Databases	Various	Systematic review
Safety	Reports	EFDA	Register
Medical research	Surveys and experimental studies	Research institutes and universities	Surveys
3. Costs			
Health expenditure	NHA	FMoH	Surveys
Health services	NHIS tariffs	EHIA	Central decisions
	Private insurance	Private entities	Review
OOP costs	NHA	FMoH	Surveys
4. Service use			
Health services	NHIS	EHIA	Review
	DHIS II	FMoH	Routine report
	Health facility and community surveys	EPHI/universities	Surveys
5. Quality of life			
DALY	GBD study	IHME	Database
6. Equity			
Epidemiology	DHS	CSA/DHSS sites	Survey
Service use	NHIS	EHIA	Database
	DHIS II	Health institutions	Routine data report
Equitable strategies	EQUIST tool	UNICEF	Collation
Healthcare access and quality index	GBD study	IHME	Collation

Note: AHRI = Armauer Hansen Research Institute; CSA = Central Statistics Agency; DALY = disability-adjusted life year; DHIS = District Health Information System; DHS = Demographic and Health Survey; EFDA = Ethiopian Food and Drug Administration; EHIA = Ethiopian Health Insurance Agency; EPHI = Ethiopian Public Health Institute; EQUIST = EQUitable Impact Sensitive Tool; FMoH = Federal Ministry of Health; GBD = Global Burden of Disease; IHME = Institute for Health Metrics and Evaluation; NHA = National Health Account; NHIS = National Health Insurance Scheme; OOP = out-of-pocket; VERA = Vital Events Registration Agency.

10. SUMMARY OF EXISTING SITUATION VIS-À-VIS BUILDING A SUSTAINABLE HTA SYSTEM

Apart from the acknowledgment of the need for evidence-informed decision making and the presence of a few initiatives within the FMoH and its agencies, HTA is virtually invisible in Ethiopia, and there is no coordinating body for HTA. This was seen in the deliberation processes for the 2005 and 2019 EHSPs, where HTA was very limited or absent [8, 21].

The establishment of the PCD at the FMoH, the existence of the KTD—more specifically, the HTA team at EPHI—and the existence of the Evidence-Based Health Care program and the launch of the PhD program at Jimma University in 2021 represent some potential opportunities to move toward HTA in Ethiopia.

The EHSP developed in 2019 has taken a step in trying to ensure that the process and implementation of the package are informed by evidence. The deliberation process in the development of the EHSP, which sought various country experiences and the engagement of local authorities, decision makers, and other stakeholders, can also be taken as an encouraging practice [5].

The HTA governance structure, processes, and effort to engage in local and global networking in informing priority setting with HTA in Ethiopia are generally weak.

The EHSP priority-setting process in Ethiopia is carried out primarily by a group of experts or task forces with diverse professional backgrounds. While the experts who developed the current EHSP stated their need for a body of evidence to define the package, the use of evidence was very limited. Moreover, some of the criteria (equity impact and financial risk protection) used to set priorities were based solely on expert opinion (the Delphi technique). The 2019 EHSP document has also clearly recognized the lack of contextualized cost-effectiveness analyses, which is a key feature of HTA that aims to compare the costs and consequences of different choices [5, 8].

Moreover, the first SHI scheme deliberation lacked transparency with regard to the development process. The document was also based on a negative listing, which included only services that are not provided. This approach has greatly impacted the implementation of the insurance scheme [17].

The ever-evolving global HTA network could also be considered as a resource on which the country could rely, while contextualizing HTA to the country's health system.

11. RECOMMENDATIONS AND NEXT STEPS

This landscape assessment shows that HTA is not used as a standard approach in Ethiopia and is present only as fragmented initiatives in a few organizations. Furthermore, HTA is not used as an input in healthcare decision making such as priority-setting activities, although some deliberation processes use a few prioritization criteria.

With regard to HTA in Ethiopia, the main identified gaps that require attention include the lack of standardized HTA use in priority-setting activities, the lack of awareness of the application and importance of HTA (at both the researcher and policymaker levels), the absence of a national guiding document for HTA, the absence of a coordinating body for HTA, and a skill gap among personnel who might conduct and interpret HTA.

Recommendations

The following recommendations are provided based on the findings of the assessment.

1. Create a framework and enabling environment.
 - a. Legal provisions: A clear road map for HTA is important to guide the application of HTA in a contextualized manner. A national HTA road map/guiding document that details methods, structure, processes, and standards targeting mandatory use of HTA is important. Formal mechanisms to link HTA outputs to decision making and the involvement of various parties for the execution, dissemination, and use of HTA in-country should also be clearly stated.
 - b. A central authority: Coordination of HTA activities is imperative given the multisectoral nature of the process, with a number of parties involved. This coordination can be achieved by having a central body that has authority to undertake the role of coordination, setting priorities and establishing advisory boards or technical working groups for HTA.
 - c. Establishment of structure and scope: One of the main milestones on the way to institutionalizing HTA is the establishment of a structure and scope for the process, which should take into consideration funding availability, national technical capacity for HTA, and existing interest for both performing and using HTA.

2. Strengthen demand for HTA.

It is important to advocate for HTA and place it on the agenda at the leadership level to strengthen political will and gain buy-in. Platforms and openings to advocate for HTA and to keep it on the agenda should be pursued.

This can be achieved through the following.

- a. Raising awareness at all levels: Activities to create awareness can range from sensitization to full-blown long-term training, depending on the goal to be achieved and target groups (e.g., policymakers, knowledge brokers, and evidence producers).
- b. Identifying policy champions: One strategy that can be used to influence policy is to find and encourage champions for HTA policy. Policy champions could be

- organizations and individuals interested in HTA who can amplify the message about HTA importance, pave the way for easier implementation, or be supporters to aid efforts. These champions should be identified and brought into HTA discussions.
- c. Identifying windows of opportunity: It is critical to build capacity on the demand side in order to be able to identify when and where HTA is needed. This will not only support the producers of HTA but also allow users to be able to request HTA where it will be most useful. This window of opportunity could, for instance, be identified by responsible organizations or individuals working on priority-setting activities such as the development of the EHSP or PPL. This enables HTA producers to produce HTA for utilization.
3. Strengthen the supply of HTA.
 - a. Budget: Public investment in HTA research is important for creating HTA systems. Public investment indicates the political will and the commitment of governmental officials to implement HTA and use it for decision making in healthcare. In addition, it ensures the sustainability of HTA and reduces conflicts of interest. Thus, it is important to have regular financial support for HTA to ensure that sustainable HTA research is embedded in the healthcare decision-making process. Specifically, this involves allocating budget for HTA units or teams for the HTA production process, including dissemination, where there is an attractive environment to retain high-caliber staff.
 - b. Capacity building: As HTA needs highly skilled professionals in a multidisciplinary approach, the building of human resources capacity should be a critical element of HTA road maps. There are currently limited options for HTA training, with most related to specific projects or focused on providing HTA workshops or short courses. These may not offer adequate hands-on training experience. In addition, it should also be noted that capacity building should not focus only on HTA producers with advanced technical skills, as without decision makers' understanding and commitment, HTA implementation cannot be accelerated. Existing local and global networks such as iDSI can be used for capacity building. Mentorship and co-production could be helpful to build the skills of local staff.

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14. APPENDICES

Appendix I: Institutions participated in this study

- Federal Ministry of Health
- Ethiopian Pharmaceutical Supply Agency
- Ethiopian Health Insurance Agency
- Ethiopian Food and Drug Administration
- Armauer Hansen Research Institute
- Jimma University
- University of Gondar
- Amhara Public Health Institute

Appendix II: Relevant documents

- HSTP I (Ethiopia-health-system-transformation-plan.pdf)
- HSTP II (Ethiopia-health-system-transformation-plan.pdf)
- Essential health service package of Ethiopia, 2019
- Pharmaceuticals procurement list, 2018
- Social health insurance proclamation, 2010