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Review Article

Policy Perspectives of Health Technology Assessment in Ethiopia: Review

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Abstract

Background: Health technology assessment (HTA) is a topic of increasing interest for all countries. However, policymakers in Ethiopia may face challenges in identifying the grounds on which the HTA process should be established. This review assessed the availability of HTA-related policy documents in Ethiopia to guide the future HTA system.
Methods: A descriptive analysis of HTA-related content was conducted within Ethiopian policy documents. An iterative search of policy documents was carried out from May 1–30, 2021, using organizational websites and advanced Google Scholar searches. Additional documents were obtained by consulting field experts. The synthesis considered the four major policy periods in Ethiopia and specific relevant policy documents.
Results: Review findings were organized according to the four different policy periods, focusing on HTA directions in Ethiopia. The policy recommendations stated in the reviewed documents included: the need to establish a national HTA center, the development of an HTA system, and the formation of an HTA team within the Ministry of Health. In HSTP II, attention was also directed to incorporating HTA and adaptive mechanisms.
Conclusions: When establishing a national HTA system, it is important to consider policy recommendations already stated in existing documents. Special attention should be given to the development of HTA guidelines, strategic documents, and policy documents that can link HTA results to decision-making processes. This could help close the gap between regulatory HTA processes and HTA implementation in Ethiopia. The findings of this review can also be used to inform policy contexts regarding HTA in countries with similar settings.
Keywords: Health Policy; HTA; Ethiopia

1. Background

The Ethiopian health care system focused on improving the health status of the population. Achieving universal health coverage (UHC) is one of the four objectives of the health policy of the Ministry of Health in Ethiopia. Population coverage, benefit coverage, and financial protection constitute the three core dimensions necessary for achieving UHC. Progressing toward full coverage of essential health services and protecting people from financial hardship, especially underserved populations, remains a policy priority (1).

Health technology assessment (HTA) is increasingly recognized as an important approach for prioritizing health interventions when introducing, managing, and /or reimbursing health technologies as part of the interventions provided by their national health systems (2). HTA is defined as a multidisciplinary field of policy research that provides evidence on the consequences of adopting and using health technologies (3). It uses explicit methods to determine the value of health technology at different stages of its lifecycle. The overall purpose is to inform decision-making and promote an equitable, efficient, and high-quality health system (3).

HTA is used for planning and budgeting in 78% of low-income, the majority of middle-income, and high-income countries (2). According to the 2021 WHO survey, the top three functions of HTA were planning and budgeting, the development of clinical practice guidelines, and the design of health benefit packages (1). However, only 30% of countries reported routinely using HTA information for decision-making (2). To address this problem, WHO underscores the need for establishing evidence-based decision-making (2). In line with this, governments use regulations, guidelines, and self-regulatory codes of conduct to manage health risks and foster healthier environments (4).

Ethiopia has implemented different policy periods, all aimed at strengthening preventive and curative health care. The first was the Basic Health Service (BHS) period, during which the Ministry of Public Health was established in 1948 to provide adequate medical care and health services to the whole population. The second period, primary health care (PHC), focused on reaching the underserved majority of the Ethiopian population, and Ethiopia adopted the Health for All (HFA) declaration in 2000 using a PHC-centered approach (5). The third period

was the Health Sector Development Plans (HSDPs), which were developed to support the national development plan for Accelerated and Sustained Development to End Poverty (PASDEP) and progress toward the Millennium Development Goals (6,7). The fourth period introduced the Health Sector Transformation Plan (HSTP), implemented in two phases: Alongside the HSDPs (1-IV), Ethiopia launched and implemented the HSTP I in 2015/16 to 2019/20, followed by HSTP II covering the period from 2019/20 to 2024/25 (8).

A Ministry of Health (MoH) with jurisdiction over HTA should determine the influence of public law on all HTA-related activities and the regulatory rules that apply. Thus, health decision-makers interested in HTA must learn to navigate the legal system, starting by situating it in the country's legal apparatus. As a result, establishing a national HTA system requires establishing a clear legal pathway for HTA (4).

However, health decision-makers in developing countries, including Ethiopia, may face challenges in justifying the policy basis on which health technologies are introduced, prioritized, reimbursed, or discontinued (2). Therefore, this review placed particular emphasis on the HTA directions stated in policy documents across different policy periods in Ethiopia.

Methods

A descriptive analysis of qualitative data was used to explore the historical evolution of HTA within Ethiopian policy documents. The synthesis considered the four major policy periods in Ethiopia and the specific policy documents associated with each period. The review of online policy documents focuses on the HTA-related directions and recommendations expressed in each identified document.

Between May 1 and May 30, 2021, an iterative search for policy documents was conducted, resulting in the identification of 21 documents from the websites of the Ministry of Health, research centers, various national agencies, and advanced Google searches. Two additional documents were obtained by contacting experts at the Ministry of Health. Search terms such as "health policy," "health development/transformation plans," and "health technology assessment" were considered. Accordingly, all suggestions, recommendations, and directions about HTA were emphasized during the document review. Policy documents published between 1953 and 2022 were included.

Results

We organized the review findings according to the four policy periods: the BHS, PHC (5), HSDPs (6,7), and HSTPs (Figure 1). We organized the review findings into specific policy documents categories: regulatory issues related to HTA, directives and strategic documents, health policy regarding HTA, declarations and guidelines, Disease Control Priorities (DCP_3), and Global Burden of Diseases (GBD) reports (9,10). These specific documents were developed from post-PHC to HSTP II (Figure 2). The following findings were identified:

Regulatory Issues Related to Health Technology Assessment

In Ethiopia, regulatory approval is mandatory for registering new health technologies in the national medical procurement list. Excluding economic considerations, the Food and Drug Authority (FDA) approves pharmaceutical products for sale (issuing marketing authorization), based on scientific criteria of quality, safety, and efficacy of the medicinal product in question (11-13). Before executing HTA, regulatory approval may be required as a prerequisite. HTA, on the other hand, focuses on evidence regarding clinical effectiveness, safety, cost-effectiveness, and social, ethical, and legal implications of using health technologies when applied extensively (14).

Directives, Strategy, and Health Policy Documents Toward Health Technology Assessment in Ethiopia

The Ethiopian Medical Device Directives have been in place since March 11, 2021, as part of the MoH's "Medical Device Directive". In accordance with this directive, the MoH was expected to establish multidisciplinary HTA teams responsible for conducting HTA and providing recommendations to the MoH in consultation with relevant stakeholders (15).

Prior to this, the National Medical Device Policy and Strategy was developed in 2019 through the development of proper regulatory and management structures to ensure the provision of quality, safe, and effective medical devices at all levels of the health system. The policy was intended to guide the development of effective governance structures for the proper management of

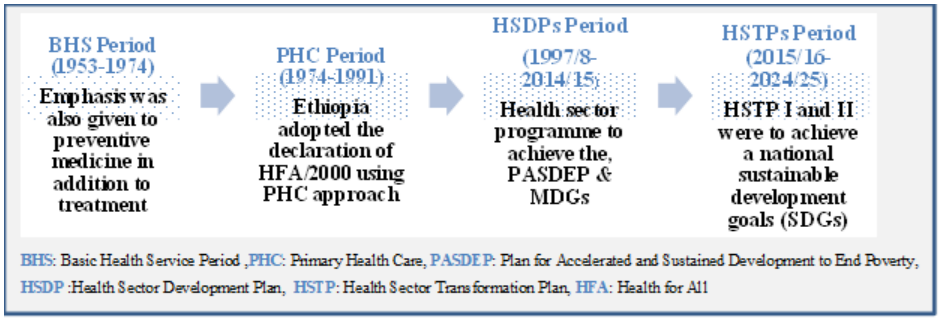

Figure 1. Timeline of Key Periods in the Focus of Health Technology in Ethiopia, 1953 to Present

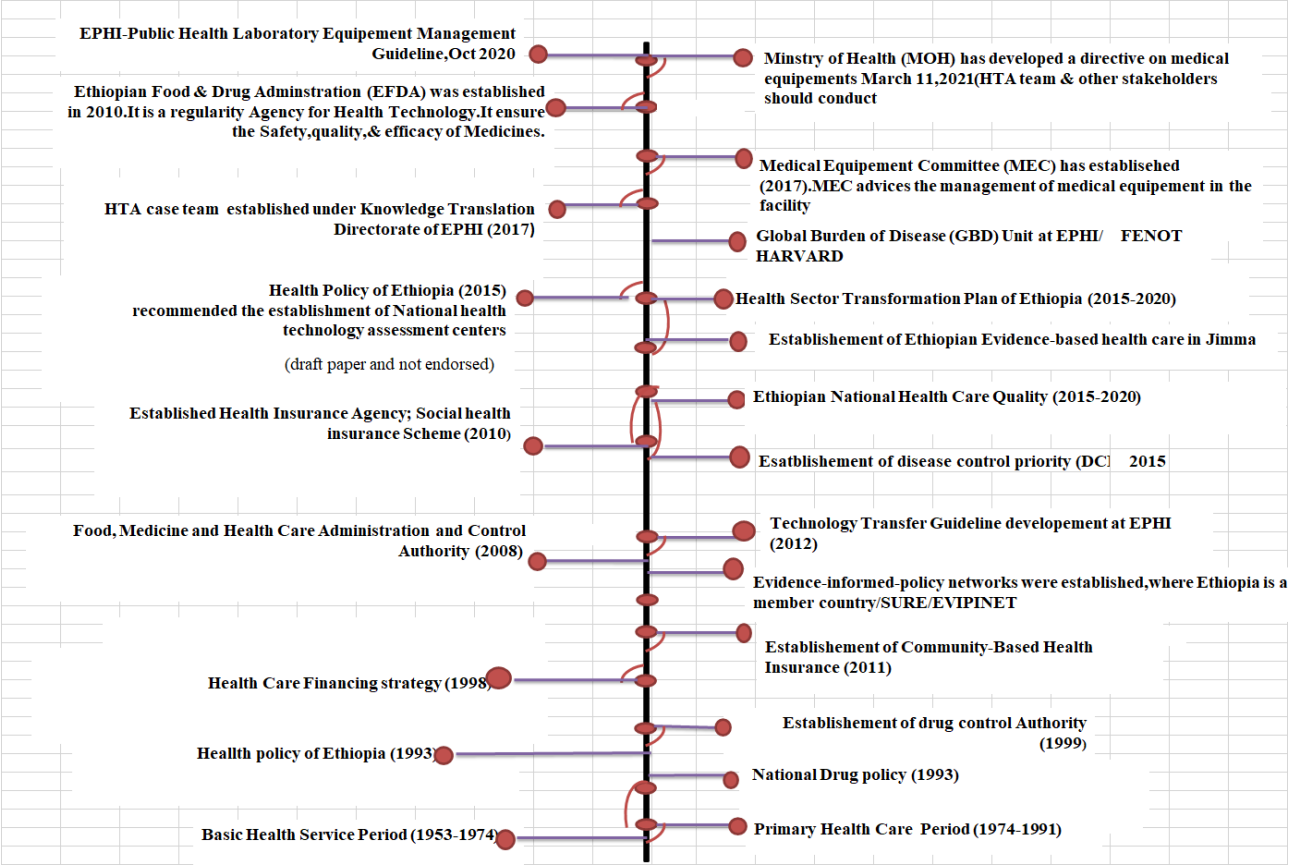

Figure 2. Historical Overview of HTA, in Ethiopia's Policy Documents (2022-1953). The figure includes regulatory documents, directives, national health policy documents, proclamations, HSDP/HSTP documents, DCP3-related documents, and relevant guidelines, presented in descending chronological order. Note. HTA: Health technology assessment; HSDP: Health sector development plan; HSTP: Health sector transformation plan; DCP3: Disease control priorities, 3rd Edition

medical devices from selection to disposal (15).

In 2010, the Ministry of Finance (MoF) issued the General Public Procurement Directive, which declared that procurement processes must achieve maximum value for money by ensuring economy, efficiency, and effectiveness. It also mandated that all criteria applied in making procurement decisions must be transparent to all involved parties (16). The second national health policy of Ethiopia, developed in 2015 (but not formally endorsed), highlighted the need to establish a national HTA center (17).

Moreover, the health policy of the Transitional Government of Ethiopia, established in 1993, placed strong emphasis on decentralization and democratization, which were considered key elements of the health policy's general strategies. In addition, the policy highlighted the importance of preparing and regularly updating lists of essential and standard drugs and equipment for all levels of the health service system, which were also included as elements of the general strategy in this policy (18).

Proclamations Towards Health Insurance and Establishment of FMHACA in Ethiopia

Social health insurance proclamation No.690/2010 has been effective since 19 August 2010, and Ethiopia has been implementing community-based health insurance (CBHI) schemes as pilots since 2011. This aligns with UHC goals by ensuring access to necessary services for all while protecting against financial risks (19). A proclamation for food, medicine, and health care administration and control, Proclamation No. 661/2009, became effective on January 10, 2010. This proclamation was deemed necessary to protect the general public from unsafe, inefficacious, and poor-quality modern and traditional medicines, as well as from health risks arising from unsafe and poor-quality food (11).

Health Development and Transformation Plans Towards Health Technology Assessment in Ethiopia

Following the HSDPs (1-IV), Ethiopia has launched and implemented the HSTPs for 2015/16-2019/20, with the second HSTP covering 2019/20-2024/25. The overarching goal is to progress towards UHC and ultimately achieve UHC for all Ethiopians. Investing in primary health care through health extension packages (HEP) and prioritizing UHC policy components-financial protection, service provision, and coverage mechanisms- are also strongly stressed within the HSTP document (7,8).

Health Technology Transfer Guideline and Public Health Laboratory

Equipment Management Guideline Towards Health Technology Assessment in Ethiopia

When carrying out technology assessment, the following factors must be taken into account: the cost of health technologies, whether the technology meets the country's policy needs, the availability of trained personnel, technical support, and existing capacity-building opportunities, and the durability of the technology, while also considering its impact on community health and the environment (20). The EPHI guideline on public health laboratory equipment management stressed the importance of HTA in terms of technical, ethical, social, and economic impact, as well as the clinical effectiveness of specific equipment (21).

Disease Control Priorities and Global Burden of Diseases

Under DCP3-Ethiopia, health policy priority setting and the cost-effectiveness of selected health interventions were established as key HTA roles in Ethiopia (9). In addition, under the GBD unit, all available data sources meeting quality criteria were used to estimate the national burden of disease and synthesize evidence using premature mortality and disability rates to measure disease burden (10).

During the review of policy documents, we identified several gaps related to the role of HTA in Ethiopia. First, there is no national framework for HTA policies and no HTA strategy that clearly defines how HTA should be implemented in Ethiopia. In addition, health insurance documents do not specify mechanisms to align with other available policy documents regarding the prioritization, selection, implementation, and disposal of health technologies. As a result, it would be challenging to establish transparent mechanisms for selecting, prioritizing, and implementing health technologies in Ethiopia. Similarly, although policy documents emphasized the importance of HTA and expressed an interest in setting up a national HTA system, none outline clear mechanisms for achieving this.

Discussion

Similar to other sub-Saharan African countries, HTA-like activities are frequently conducted in Ethiopia by gathering information and synthesizing evidence (22). This review included all relevant grey literature, including Ethiopia's health policies, health sector plans, guidelines, directives, and government reports. The different policy periods of Ethiopia were taken into consideration to provide a historical overview of policy documents in the context of HTA. In contrast, specific policy documents were analyzed to audit specific policy documents in terms of regulatory frameworks, policy plans, directives, and guidelines related to the establishment of an HTA system in Ethiopia.

Ethiopia has a favorable policy environment for establishing an HTA system. The medical device directive and related policies stress the need to establish multidisciplinary HTA teams (15). Accordingly, an HTA team is expected to be established at MOH; however, none currently exists, except the HTA team at EPHI, established in 2017. The second national health policy of Ethiopia emphasized the establishment of a national HTA center (17). In many of Ethiopia's policy documents, the importance of HTA has been acknowledged in various ways (Tables 1 and 2). Regulatory documentation, for instance, highlights approving new health technologies before HTA is conducted, while other documents underscore the need to establish national HTA structures and technical capacity. Similarly, the social health insurance document was developed with the objective of achieving UHC in Ethiopia (Table 2). Additionally, HSTP II stresses the importance of health technology innovation and assessment as prerequisites for adopting and diffusing new, cost-effective health technologies to enhance health sector performance (8).

Unfortunately, the recommendations mentioned in each identified policy document were not utilized to develop a step-by-step plan for establishing a functional HTA system in Ethiopia. There was no national HTA strategic document capable of aligning health plans with national health insurance. As a result, there was no clear procedure in Ethiopia for the prioritization and selection of health technologies, creating challenges for strengthening HTA practice to support evidence-based policy and decision-making in the country.

Other studies of a similar nature have been conducted in various African countries and international settings. In a South African study evaluating the HTA legal and policy landscape, the authors identified and analyzed relevant national and international documentation (23). They proposed the development of legislation and policy to support a functional HTA system in South Africa. Our review differs from this study in that it focuses solely on national policy documents relevant to HTA in Ethiopia.

According to Vainieri et al and Akinbobola et al, the availability of resources, absorptive capacity, and management strategies are crucial for HTA development (24,25). In addition, this type of policy research is associated with needs, demand, and supply, whereas the success of HTA depends on maintaining a balance among these three aspects. The findings of this study may be relevant to the Ethiopian context in that during the early phase of health policy in Ethiopia (HSDPs I-IV), the need for HTA existed, but the demand was neither recognized by decision-makers nor promptly addressed by scholars, resulting in no progression in HTA development. During the HSTP period, when needs were identified and demand was recognized by the decision makers, diverse stakeholders made notable efforts to produce HTA-relevant documents, which served as a pre-requisite for establishing an HTA system in Ethiopia (7).

The analysis conducted by Mueller (26) examined the challenges in the formal implementation and utilization of HTA in South Africa's public health sector. The study identified an appropriate legislative and policy framework for informing healthcare decision-making. Limited

Table 1. Regulatory Documents, Directives, Strategies, and National Health Policy Towards HTA in Ethiopia

Policy Document	Proclamation/Directive No./National Health Policy Document	Description of HTA and HTA-related activities
Regulatory documents towards HTA in Ethiopia		
FDA document	Regulatory document	In Ethiopia, regulatory approvals are mandatory for the registration of new health technologies included on the medical list. The FDA ensures the Safety, quality, and efficacy of medicines (11,12).
Directives and strategy documents towards HTA in Ethiopia		
National medical device policy and strategy (15)	Medical device policy and strategy	• The Ministry shall establish a multidisciplinary HTA team. • HTA is one core element of the MDP issues, alongside the regulation of medical device management, medical device research and development, governance, and financing of medical devices. • Establishing an HTA system in Ethiopia is a major policy implementation strategy under the MDP. • An HTA advisory team reporting to the Minister of Health will be established and connected to relevant national and international stakeholders. • A formal system for evaluating the appropriateness, safety, and cost-effectiveness of medical devices will be developed and used to guide the selection of appropriate medical devices for the country. • Continuous monitoring and evaluation will ensure that selected medical devices meet expectations, and findings will be used for informed decision-making.
Public procurement directive (16)	Proclamation No. 649/2009, Article 19	• This Directive applies to all Federal Public Procurements subject to Proclamation. • Procurement must ensure maximum value for money-i.e. economy, efficiency, and effectiveness. • All criteria applied in procurement decisions and the decisions themselves must be transparent to all concerned parties.
National health policy of Ethiopia towards HTA		
National health policy of Ethiopia, 2015 (17)	Health policy document	• Proposed establishing a national Health Technology Assessment Center as of 2015. • The policy document emphasized promoting the use of health technologies for data generation, storage, research, and development.
Health policy of Ethiopia, 1993 (18)	Health policy document	• Decentralization and democratization were key strategies of the transitional government's health policy in Ethiopia. • Preparing lists of essential and standard drugs and equipment. • Developing a standardized and efficient system for procurement, distribution, storage, and utilization of products was part of the general health policy strategy.

Note. HTA: Health technology assessment; FDA: Food and drug authority; MDP: Medical device policy; R &D: Research and Development; FDRE: Federal democratic republic of Ethiopia; MoH: Ministry of health; UHC: Universal health coverage.

political support, insufficient local capacity, and low awareness of HTA were found as barriers to HTA adoption. Adequate financial resources, as well as the availability and sharing of quality data, were noted as primary drivers for HTA development. Effective governance, collaboration, and cooperation among key healthcare stakeholders were also recommended to support HTA institutionalization (26). These insights can help Ethiopia better understand and give appropriate attention to these basic components of an HTA framework, which can help the country in establishing a governance structure that adequately covers all HTA functions.

Generally, consideration was given to the gap analysis of policy contexts and the implications for the future direction of HTA in two different countries (25,26). Based on this, further development of relevant HTA policies and frameworks is needed to inform appropriate UHC. The success of HTA requires a balance of need, demand, and supply to effectively inform the end-user. Moreover, effective governance, collaboration, and cooperation among key healthcare stakeholders were consistently recommended for HTA institutionalization. Our study benefits from the gap analysis of the policy contexts and provides insights into future directions for HTA.

Strengths and Limitations

This review, titled "Policy Perspectives of Health Technology Assessment in Ethiopia" has not been previously conducted in Ethiopia and can guide efforts to strengthen the institutionalization of HTA in Ethiopia. The graphical presentation of findings illustrates key aspects of the history of health policy in Ethiopia and highlights the future direction of HTA. This would enable end-users to easily understand developments related to HTA within policy documents from 1953 to 2021. One limitation of this review is that the current views of policymakers were not captured.

Conclusions and the Way Forward

Over the past 69 years (1953-2022), several health policies, directives, proclamations, strategies, health plans, and guidelines, which can serve as inputs for Ethiopia's health system, have been developed with great care. Although policy declarations related to HTA appear in many policy documents, they have not yet been integrated to establish a functional, integrated national HTA system. In developing a national HTA system in Ethiopia, it is essential to use the existing policy documents and statements as a foundation. Key informant interviews with different stakeholders will be required to inform future HTA policy direction in Ethiopia. In addition, policy documents related to HTA methods and process guidelines, HTA strategy documents, and policies linking HTA outcomes to decision-making are necessary for establishing a national HTA system. These actions could facilitate the institutionalization of HTA in the country

Table 2. Proclamations, Health Sector Development/Transformation Plans Towards HTA in Ethiopia

Policy document	Proclamations, health sector development/ transformation plans	Description of HTA and HTA-related activities
Proclamations towards health insurance and establishment of FMHACA in Ethiopia		
Establishment of FMHACA (11)	Proclamation	• The proclamation was established to protect the general public from unsafe, inefficacious, and poor-quality modern and traditional medicines.
Proclamations towards health insurance (19)	Social health insurance	• The Social Health Insurance proclamation No.690/2010 became effective on 19 August 2010, and Ethiopia has been implementing CBHI schemes as pilots since 2011.
Health sector development/transformation plan documents		
HSDP (6)	Health plans	• The HSDPs span four periods from 1997/98 to 2014/15 • HSDP I (1997/98-2001/2) focused in increasing the number of health facilities, and improving service coverage and utilization across all levels of the Ethiopian healthcare system. HSDP II (2002/3-2005/6), focused on launching the Health Extension Program in addition to continuing HSDP I activities (6). The goal of HSDP III (2005/6-2009/10) was to improve the health status of the Ethiopian people and achieve MDGs. During HSDP III, BPR resulted in redesigning research and technology transfer as a core function of the FMOH (6). In HSDP III, BPR resulted in redesigning research and technology transfer as a core process of the FMoH.
The health sector transformation plan (8)	HSTP 2015/16-2019/20	• The goal of HSTP II is to progress toward UHC and ultimately achieve UHC for all Ethiopians. Investing in primary health care through HEP and prioritizing UHC strategies: financial protection, service provision, and coverage mechanisms are also well stressed in the HSTP document (8). • The aims of HSTP I and II were to achieve the national SDGs by enhancing the use of technology, expanding national capacity to conduct HTA, contextualizing global knowledge, and supporting transparent and accountable decision-making in HSTP I. In HSTP II, further emphasis was placed on improving the utilization of digital health technologies and integrating HTA and adaptive mechanisms (Figure 1).
Guidelines		
Health TTG (20)	Guideline	• Technology assessment considers the cost of health technologies, whether the technology meets the policy needs of the country, availability of trained personnel and technical support, and opportunities for capacity building.
Public health laboratory equipment management guideline (21)	Guideline	The guideline highlights the technical, ethical, social, and economic implications, as well as the clinical effectiveness of specific equipment, value for money, and budget impact of equipment, as key components of HTA (20).

Note. HTA: Health technology assessment; FMHACA: Food, medicine and health care administration and control authority; TTG: Technology transfer guideline; CBHI: Community-based health insurance; HSDP: Health sector development plans; BPR: Business process re-engineering; FMOH: Federal ministry of health; UHC: Universal health coverage; HEP: Health extension packages; SDG: Sustainable development goal.

by taking several incremental actions involving key stakeholders. The findings of this review could serve as a resource for researchers and academics. This analysis can also provide an initial basis for assessing HTA policy perspectives and informing policy contexts in countries with similar settings.

Authors' Contribution

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Investigation: All authors.
Methodology: All authors.
Project administration: All authors.
Resources: All authors.
Software: All authors.
Validation: All authors.
Visualization: All authors.
Writing–original draft: All authors.
Writing–review & editing: All authors.

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