iDSI Guide and Template for Developing a National Framework for Health Technology Assessment

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1 Purpose

Health Technology Assessment (HTA) is defined as a "multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" (O'Rourke et al. 2020). Many countries around the world have either established HTA systems or are in the process of developing HTA to inform decision making in the allocation of health resources (WHO 2022). There is a growing interest in HTA in low- and middle-income countries (LMICs) as a tool to advance universal health coverage (UHC) through enhanced evidence-informed decision making in resource allocation. Guidance on HTA institutionalization is available from WHO, international Decision Support Initiative (iDSI), and others (Bertram et al. 2021; Castro et al. 2020; Jeffery et al. 2018; Wild et al. 2017), but no standard template exists for countries to develop a key component of HTA – a National HTA Framework. **In this paper, we aim to provide guidance on the development of an HTA Framework for countries that wish to establish a new HTA system.**

2 HTA Framework template

An HTA Framework represents a national agreement on the mandate, scope, functions, and roles and responsibilities of the HTA system. Due to the high-level and systemwide changes the Framework will recommend, it should be sponsored at the highest levels of government (e.g., by a minister or permanent secretary), and it should be part of a national reform process (i.e., placed within the overall context of health strategic planning). It is assumed, therefore, that a comprehensive situational analysis (including stakeholder analysis and capacity assessment) has already been done; if not, guidance on this is available elsewhere (HIQA 2014; Gilson et al. 2012). The analysis should then be followed up by a national action plan to deliver on the Framework. The HTA Framework should provide enough detail to communicate to stakeholders about the overall intent, scope, and breadth of the HTA system and of the mandate, as well as the functions and responsibilities assigned to the entities involved in HTA. Below we outline key information that should be included in a country's HTA Framework document.

2.1 Background

The background section provides an overview of the context within which HTA will be conducted and should achieve the following:

- Introduce HTA
- Present key findings on the local context or a situational analysis, examining topics such as how priorities are currently set, gaps in legislative mandates, upcoming changes in health policy, and the financing landscape
- Explain high-level motivation for developing the HTA Framework

2.2 Define the HTA mandate and scope

An HTA mandate refers to the purpose that HTA will serve and the power it will have (Bertram et al. 2021), which will determine how HTA is organized and delivered. This section should provide details on the following:

- The overall mandate provided to the HTA system and its source (e.g., policy, regulation, or law)
- Strategic objectives drawn from a mission and vision related to the national development goals or health policy
- The scope of HTA and the areas it will be applied:
    - Primary and hospital care? Public health?
    - All disease areas, including donor funded ones?
    - Drugs, vaccines, medical devices, public health interventions, or other health technologies?
- Specific decisions that HTA will inform, possibly including:
    - Health technologies to be funded/purchased/reimbursed:
        - Such as designing and refining national essential healthcare or health benefits packages (HBP)
        - Designing and refining prioritized interventions lists such as essential medicines lists or essential devices lists, among others
    - Input into procurement and price negotiations for medicines, vaccines, and other essential commodities
    - Input into clinical (standard treatment) guidelines and quality standards[1]
- The status of HTA recommendations and whether they will be legally binding for the health system

2.3 Define the governance structure

The mandate for HTA should be vested in an institution that will govern and coordinate the HTA process. This institution can be either a single entity or a grouping of several institutions or agencies working together to deliver on the HTA objectives, depending on the mandate and scope of the HTA system. For instance, in a national program with a wide scope geared toward national policy, its ultimate ownership usually rests with the Ministry of Health (MOH), which will then lead or appoint agencies to perform various HTA functions, whereas a focused HTA system designed to inform only an insurer's benefits package may be governed within a national insurer. Usually, a national insurer reports to or is governed by a MOH; hence accountability in this case will still be to the MOH.

In this section, the Framework should provide details on the following:

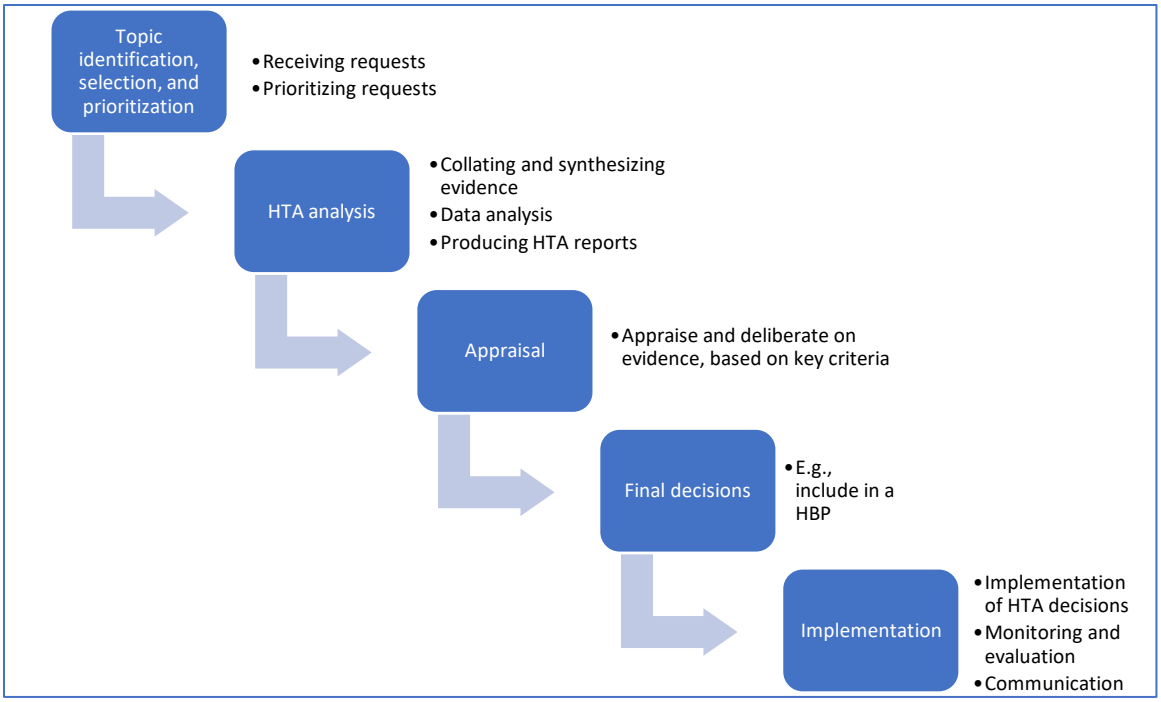
[1] https://www.nice.org.uk/standards-and-indicators/quality-standards

- Specifications on the final decision makers based on HTA recommendations
    - These decision makers may involve more than one entity (e.g., HBP revision, drug procurement, and the clinical guideline development process, which may all have independent decision-making processes).
    - Global experience suggests that committees that are inclusive of all relevant stakeholders are best placed to make such decisions and to ensure that decisions are implemented.
- High-level governance
    - Specify the individual/agency/ministry that is ultimately accountable for the HTA system (e.g., the health minister)
    - Specify the individual/agency/ministry responsible for managing and coordinating the HTA system (e.g., HTA agency director or chair of steering committee)
    - Specify the HTA governance structure that will oversee its various functions and bring together the final decision makers
- Key functions of the governance structure, which could include:
    - Ensuring that the HTA system is fit for the needs of the decision makers
    - Establishing national process, standards, guidelines, and value frameworks
    - Coordinating topic selection and HTA production
    - Ensuring stakeholder engagement
    - Overseeing the coordinated implementation of HTA decisions
- The governance structure, which will be specific to the local context, but could include:
    - A steering committee
    - An appraisal body
    - A technical advisory or working group
    - A secretariat or coordinating unit within the Ministry of Health
    - A commissioning forum or body

2.4 Specify organizational structure and assign roles and responsibilities

The conduct of the HTA generally follows five steps (Baltussen et al. 2022; Kristensen et a. 2019), which will need to be appropriately allocated to the correct organization: (1) topic selection, identification, and prioritization (TISP); (2) evidence synthesis and analysis; (3) appraisal; (4) decision making; and (5) implementation (see Figure 1 below).

Figure 1. Steps in HTA Production



Ultimately, the system that is put in place and the responsibilities of the various entities and bodies that are established to conduct HTA depend on the mandate and scope defined in the previous sections. These decisions will also determine who commissions HTAs and who produces and implements HTA, as well as how the entire HTA system is financed.

2.4.1 Topic identification, selection, and prioritization (TISP)

TISP encompasses the selection and prioritization of the decisions that will be subjected to the HTA process (Qiu et al. 2022) and therefore is usually managed closely by the decision maker. The Framework should state who can nominate topics and who will carry out TISP, as well as the broad criteria that should be used to make decisions. It should make reference to a standard TISP process guide, which should be produced later (Qiu et al. 2022). Depending on the scope of the HTA system, TISP could be organized by a forum of key decision makers or simply a unit within the MOH. An example of the TISP process for the essential medicines list (EML) in South Africa is given in Box 1 (EDP 2021).

Box 1. HTA Topic Identification, Selection, and Prioritization in the South African EML

Topic selection, identification, and prioritization for HTA in the South African Essential Medicines Selection is facilitated by the Essential Drugs Programme (EDP) unit, which coordinates the assessment of all technologies that fall within the scope of the standard treatment guidelines (STGs), the essential medicines list (EML), and the Tertiary and Quaternary Hospital Level Essential Medicines Recommendations (T&Q EMR). Topics are identified in several ways, including motivation forms submitted by stakeholders, analysis of utilization data, planned amendments to national guidelines, and new clinical or cost data. Following identification and classification of topics, more detailed information is collated to enable screening and prioritization. Specific topic screening criteria are used to assess a proposed topic in terms of (1) its applicability to the EDP HTA process, (2) the importance of the assessment to patient care, (3) the technology's availability in South Africa, (4) relevant recommendations issued about the technology by other HTA agencies, (5) the feasibility of implementation

of the technology in South Africa, and (6) potential for duplication of effort.

Technology topics considered suitable for inclusion in the EDP workplan after the initial screening are ranked for assessment order. Topic ranking is a formal process whereby suitable topics are placed in a values/benefits matrix such that their positioning for assessment is created by an explicit and visible process. The prioritized list of technology topics is presented to the commissioning body for review and the selection decision. Once a technology is selected for assessment, a draft scope for the Technology Assessment is developed by the EDP secretariat and referred to the relevant analysis committee.

2.4.2 HTA analysis

In this section of the HTA Framework, countries should specify:

- that HTAs should follow a national reference case for economic evaluation and a methods guide (Wilkinson et al. 2016), which should be produced later;
- the types of HTAs that will be conducted and whether multiple types of HTA products will be developed (e.g., rapid "adaptive HTAs" or more detailed "full" HTAs involving extensive bespoke analysis); and
- who will do the analyses.
    - For instance, evidence synthesis and analysis can be conducted by a core analysis team, dedicated technical working groups with representation from the MOH, social insurers and academia, independent academic teams, or other relevant organizations, depending on the HTA system. Private entities in industry can also be asked to undertake the analysis against a template provided by the responsible HTA body. This submission can then be appraised and approved by the HTA body.

Box 2 gives an example of the HTA analysis arrangements in the Ghanaian HTA system (MOH 2022). More detailed guidance is available in the iDSI HTA Toolkit (Jeffery et al. 2018).

Box 2. HTA Analysis Case from Ghana

In Ghana, assessments are conducted by the HTA Technical Working Group (TWG), which is established by the Minister of Health. The TWG prioritizes topics to be assessed and has a subcommittee for analysis, which coopts additional experts from academia, international partners, and other stakeholders to undertake the analyses. The TWG is supported by a functional HTA Secretariat situated in the MOH and comprised of technical experts who also participate in HTA analyses. Analytic methods are specified in the HTA process guide and reference case for HTA, which follows international guidelines and standards.

2.4.3 Appraisal and recommendations

At this step, the completed analysis report is submitted for appraisal to a dedicated body, which then applies technical and value judgments on the evidence and makes a recommendation on whether to include or exclude the evaluated technology, or, alternatively, recommends other actions based on the evidence, such as price negotiation.

Guidance on HTA appraisal can be found in various sources (Chugh et al. 2022; EDP 2021; Richardson et al. 2021). In this section, countries should specify the following:

- The remit of the appraisal committee and clarification of the committee's authority to make recommendations to one or more decision makers
- The constitution of the appraisal committee, its chair, and membership
- The committee's terms of reference, covering aspects such as transparency and the management of potential conflicts of interest
- The criteria for appraising the evidence, deliberating, and evaluating the quality of the HTA report
- The nature of the recommendations, if any, that the committee will make

2.4.4 Final decision making

The final decisions resulting from the HTA, such as the inclusion or exclusion of a technology from a HBP, can be made by the appraisal committee (as, for example, NICE in the UK works) or more typically by a separate decision-making body (usually the commissioner of the HTA). There may be more than one final decision maker. Countries should consider specifying in the Framework:

- the recipient of the appraisal report and recommendation,
- the key principles and values to be taken into consideration when making a decision, and
- the deliberative processes and mechanisms for arriving at the final decision.

Appraisals and decision making should be carried out in a fair and transparent manner; therefore, countries should consider specifying in their Framework:

- the methods for stakeholder involvement and for keeping them informed about key decisions,
- the process for making the decision and ensuring that the underlying rationale is available for public scrutiny, and
- the mechanisms for appealing recommendations and decisions.

Box 3 gives an example of the HTA appraisal and decision-making arrangements in Poland (Jeffery et al. 2018):

Box 3. Appraisal and Decision Making in Poland

Poland has an independent HTA agency known as the Agencja Oceny Technologii Medycznych i Taryfikacji (the Agency for Health Technology Assessment and Tariffs or AOTMiT). It has a wide scope of activity, including drug and nondrug economic evaluations and the assessment of all public health programs.

- Assessment of the evidence is carried out using an HTA methodological guideline.

- Appraisal of evidence is undertaken by the Transparency Council (TC). The council is an advisory committee of 20 members appointed by the minister of health. It is described as "advisory and independent." The TC gives advice ona technology in the form of a "position."
- From the appraisal, a statement and recommendation are issued by the president of the AOTMiT, which contains: information on financing, a rationale for the recommendation, an objective of the recommendation (e.g., its intended use), a brief note on the health problem, a description of the characteristics of the technology, a budget impact analysis, and recommendations for foreign HTA institutions.

Source: iDSI Toolkit (Jeffery et al. 2018).

2.4.5 Implementation of HTA decisions

The implementation of HTA decisions is a very important step that requires careful planning. The HTA Framework should include recommendations on arrangements that should be in place to facilitate the effective implementation of decisions. The Framework should include the following:

- The parties responsible for implementing the HTA decisions, including:
    - Adequate consideration of three key implementation mechanisms: service changes, commodity procurement changes, and clinical guideline adjustments
- Those responsible for leading the monitoring and evaluation of the impact of HTA decisions
- Mechanisms for communicating necessary changes to those implementing HTA decisions

2.5 Decide on the scale and financing of HTA

HTAs are significant undertakings, and countries should give careful consideration to how HTA will be funded. In this section, the Framework may wish to include the following information:

- The number of HTAs and rapid/adaptive HTAs needed each year (based on the scope agreed upon in section 2.2)
- An approximate estimate of the resources and staffing required for the HTA system
- The parties responsible for funding each component, with both domestic and donor resources taken under consideration
- A fully developed outline of HTA strategies, with costs calculated, to understand the resources required to undertake HTA (e.g., the Ghana Ministry of Health's first HTA strategy in 2019, which outlined key activities and resources required to execute the HTA functions).

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