REPUBLIC OF GHANA
MINISTRY OF HEALTH

PROCESS GUIDELINES FOR HEALTH TECHNOLOGY ASSESSMENTS (HTA) IN GHANA

1st Edition 2022

Defining the stepwise approach for HTA in Ghana

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1.1 Acknowledgment of stakeholders

This guide was developed with support from the Access and Delivery Partnership, implemented by PATH. The following stakeholders and resource persons need to be acknowledged for their role in developing the HTA process in Ghana.

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World Health Organization (WHO) TDR and Country Office for Ghana
International Decision Support Initiative (iDSI)
London School of Hygiene and Tropical Medicine
Norwegian Institute of Public Health (NIPH)

1.2 List of abbreviations

FDA	Food and Drugs Authority
HTA	Heath Technology Assessment
TWG	Heath Technology Assessment Technical Working Group
MDAs	Ministries, Departments and Agencies
NHIA	National Health Insurance Authority
NHIS	National Health Insurance Scheme
SC	Steering Committee
SOPs	Standard Operating Procedures
TWG	Technical Working Group
UHC	Universal Health Coverage
WHA	World Health Assembly

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1.5 Preface

Health Technology Assessment (HTA) is 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. The HTA process evaluates the social, economic, organizational and ethical issues related to health interventions or health technologies. The health intervention or technology can be a test, device, medicine, vaccine, procedure, program or system.

The Government of Ghana acting through the Ministry of Health has demonstrated commitment to the use of HTA in decision making to optimise allocation of resources in achieving Universal Health Coverage (UHC). This has been through the establishment of the governance structures for HTA, the development and launch of a 5-year strategy for HTA, and the development of this HTA process guideline for Ghana.

The HTA governance structure includes (i) the HTA Steering Committee providing oversight of all activities and decisions, (ii) the HTA Technical Working Group conducting technical work including assessments, appraisals, etc. and (iiI) the HTA Secretariat situated within the Pharmacy Directorate of the Ministry of Health and managing the implementation of the HTA process as well as supporting HTA operations, offering routine technical assistance and ensuring the day-to-day functioning of HTA activities in Ghana.

The process for conducting HTA is as important as the output of HTA and associated recommendations and decisions. In developing the process guide for HTA in Ghana, key principles followed were multi-stakeholder involvement and consultation, transparency, and the use of evidence in a deliberative process.

This process document shall guide the conduct of HTA in Ghana, in line with the above principles and governance structures.

All entities within the health sector shall commit to the outcomes of this HTA process, and work with relevant stakeholders towards implementation in a manner that maximises health outcomes.

KWAKU AGYEMAN-MANU (MP)
MINISTER FOR HEALTH

2 Introduction

2.1 Overview

Health Technology Assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. A health technology refers to an intervention developed to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organize healthcare delivery. The intervention can be a test, device, medicine, vaccine, procedure, program or system.[1]

The purpose of HTA is to inform decision-making in order to promote an equitable, efficient, and high-quality health system. HTA evaluates the social, economic, organizational and ethical issues related to health interventions or health technologies.[2]

In 1988, Ghana published its Essential Drugs List & National Formulary with Therapeutic Guidelines, 1st Edition. This was reviewed in 1993, 1996, 2000, 2004, 2010 and 2017. In 2020, Ghana developed its provisional COVID-19 guidelines. The development and review of these guidelines demonstrates a country-led, evidence-informed, context-driven, consensus-building multi-stakeholder process.[3–10] The value of global evidence applied to the country context has been demonstrated within statutory processes for medicines selection in Ghana.[11] This process provides in-country lessons for the use of evidence in a deliberative process and has informed the approach to establish a process for conducting HTA in Ghana.

Ghana envisages HTA as an instrument to be used in the underlisted areas, as illustrated in Figure 1, below:

- Policy prioritization
- Benefits package design including clinical services and reimbursement
- Determination of essential health services
- Selection of health technologies
- Pricing strategies for health technologies
- Procurement of pharmaceuticals and other health technologies

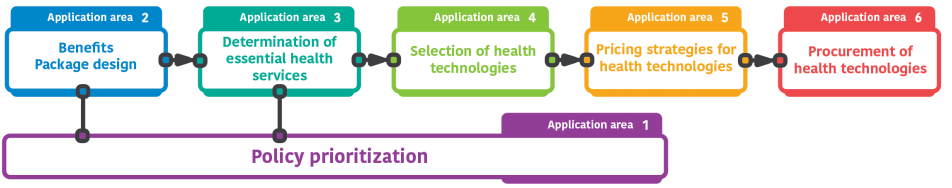


Figure 1: Areas for application of HTA within the health system

The Ghana HTA process defines the steps required for HTA, indicates the related responsibility, and provides an estimate of the associated timelines as well as the resource inputs required[1]. The process contains core steps and auxiliary actions which feed into the process. (See Figure 2: Illustration of the Ghana HTA process flow, for a summary of the main steps in the process and the actors involved).

The HTA process guidelines has been developed in response to the HTA strategy for Ghana, which defines a clear strategic area for evidence-based manuals and guidelines to strengthen the conduct of HTA and the uptake of HTA recommendations.[12]

The HTA process is established under governance structures as follows: the HTA Steering Committee (responsible for governance), the HTA Technical Working Group (TWG; responsible for technical functions) and the HTA Secretariat (responsible for the support and management of all HTA work and processes in Ghana), with clear roles defined per their respective Terms of Reference. [13]

The process for conducting HTA is deemed as important as the recommendations from HTA assessments. Therefore, in the development process for HTA in Ghana, the principles of multi-stakeholder involvement and consultation, transparency; and the use of evidence in a deliberative process have been upheld. This is to ensure multi-stakeholder buy-in, inclusion and acceptance, as well as a structured approach to conducting HTA and commitment to the implementation of HTA recommendations.

2.2 The strategic perspective to the Ghana HTA process

The goal of the Ghana National Health Policy (NHP) revised edition, 2020, is to promote, restore and maintain good health for all people living in Ghana through the strengthening of the healthcare delivery system, to be resilient and ensuring sustainable financing for health. [14] These objectives of the NHP clearly set the agenda for priority setting in support of country efforts in achieving Universal Health Coverage (UHC). HTA is a proven priority setting tool which can also support UHC in Ghana.

In line with the above policy direction, the National Medicines Policy (NMP), 3rd edition 2017, defines the policy priorities for HTA and also recommends implementation steps, which would give traction to HTA. [15] The NMP among other recommendations, indicates under section 2.2.2 that "*there shall be developed and regularly updated HTA guidelines, which shall detail methods, processes, benchmarks, perspectives and agreeable standards for the conduction, dissemination and use of HTA in-country*". [15] This is to be achieved in the development of explicit guidelines for the HTA process governed by the national structures for HTA.

The strategic perspective to the HTA process in Ghana is that because clear guidelines, are critical for the success of HTA in Ghana, the processes and mechanisms for guidelines and manuals development and updates would be based on consensus and inputs from various stakeholders to ensure acceptance of the outcomes produced through application of HTA guidelines and manuals.

[1] The resource requirements for this process guideline is estimated in the administrative notes accompanying this process guideline.

It is a strategic imperative therefore, that the HTA structures ensure that guidelines and manuals exist and are regularly updated to meet the evolving needs of the health system. [12]

The HTA process guideline builds on the establishment of functional governance structures for HTA and the development of an HTA Strategy as major pillars in the HTA institutionalisation mechanism in Ghana. Considering the direction set by the HTA strategy, the HTA process guidelines are developed based on local context and evidence and would be disseminated widely as a public document.

2.3 What the HTA process seeks to achieve

The broad objective of this HTA process document is to guide the conduct of HTA, in line with the principles of multi-stakeholder consultation and involvement, transparency and the use of evidence in a deliberative process; using the HTA structures for Ghana.

It seeks to further entrench the broad HTA strategic objective of strengthening the science and practice of HTA to support evidence-based decisions for the health sector.

The guidelines provide detailed guidance on the processes to follow throughout the various stages for HTA, from selecting which technologies to evaluate through assessment and appraisal of technologies to decision-making on recommendations on health technologies, including guidance on standardised reporting.

The aim of the HTA process guidelines are to ensure consistency of approach for assessment and appraisal leading to more consistent and transparent decision-making.

3 The HTA process

The HTA process in Ghana is a step-wise mechanism, which details actions to be taken, the entities responsible for these actions and the estimated timelines.

Step 1 – **Topic nomination**: Stakeholders submit potential topics to the Secretariat
Step 2 – **Topic selection** and **Topic approval**: The TWG assesses proposed topics based on topic selection criteria, thereafter the Steering Committee prioritises and approves topics for assessment
Step 3 – **Scoping and stakeholder engagement**: The TWG defines the objectives and research questions of the HTA based on the approved topic and conducts a stakeholder engagement
Step 4 – **Assessment**: The TWG analysis sub-group assembles the evidence base on which the health technology is evaluated. TWG analysis sub-group or co-opted expertise[2] conducts analysis of the health technology in a process technically supported, directed and managed by the HTA secretariat to ensure adherence to process, standards and residual capacity building.

[2] Co-opted expertice could come from HTA networks, HTA teams, HTA consortia, HTA research teams, as well as individual technical experts in various institutions both locally and internationally.

Step 5 – **Appraisal**: The TWG appraisal sub-group critically evaluates the evidence collected, analysed and presented, to feed into the subsequent deliberation step.
Step 6 – **Deliberation and recommendation**: The Steering Committee makes critical judgements on the evidence presented and takes decisions on presented recommendations.
Step 7 – **Communication and appeals**: The Secretariat communicates the decisions (on recommendations) reached by the Steering Committee to the relevant stakeholders. The Secretariat also reviews any appeals from stakeholders, submitted on the decision.
Step 8 – **Implementation**: The relevant implementing stakeholder(s), progress with implementation. While this happens, the Secretariat may conduct implementation research to optimise the implementation process. The Secretariat also conducts assessment to monitor impact. Step 8, however is considered part of HTA uptake and not part of the HTA production process.

Notes:

1. The TWG is established with flexibility to create sub-groups in a responsive manner. The key sub-groups relevant for this process include: Analysis sub-group, Appraisal sub-group, Capacity development sub-group and Appeals sub-group.

2. TWG members can belong to multiple sub-groups however, they cannot be in both the analysis and appraisal sub-groups at the same time.

3. While the TWG represents a multi-disciplinary skills-set, any further required skills could be co-opted into the HTA TWG in a responsive manner. This way collaborations and partnerships would strengthen the implementation of the HTA process in Ghana, while developing capacity alongside.

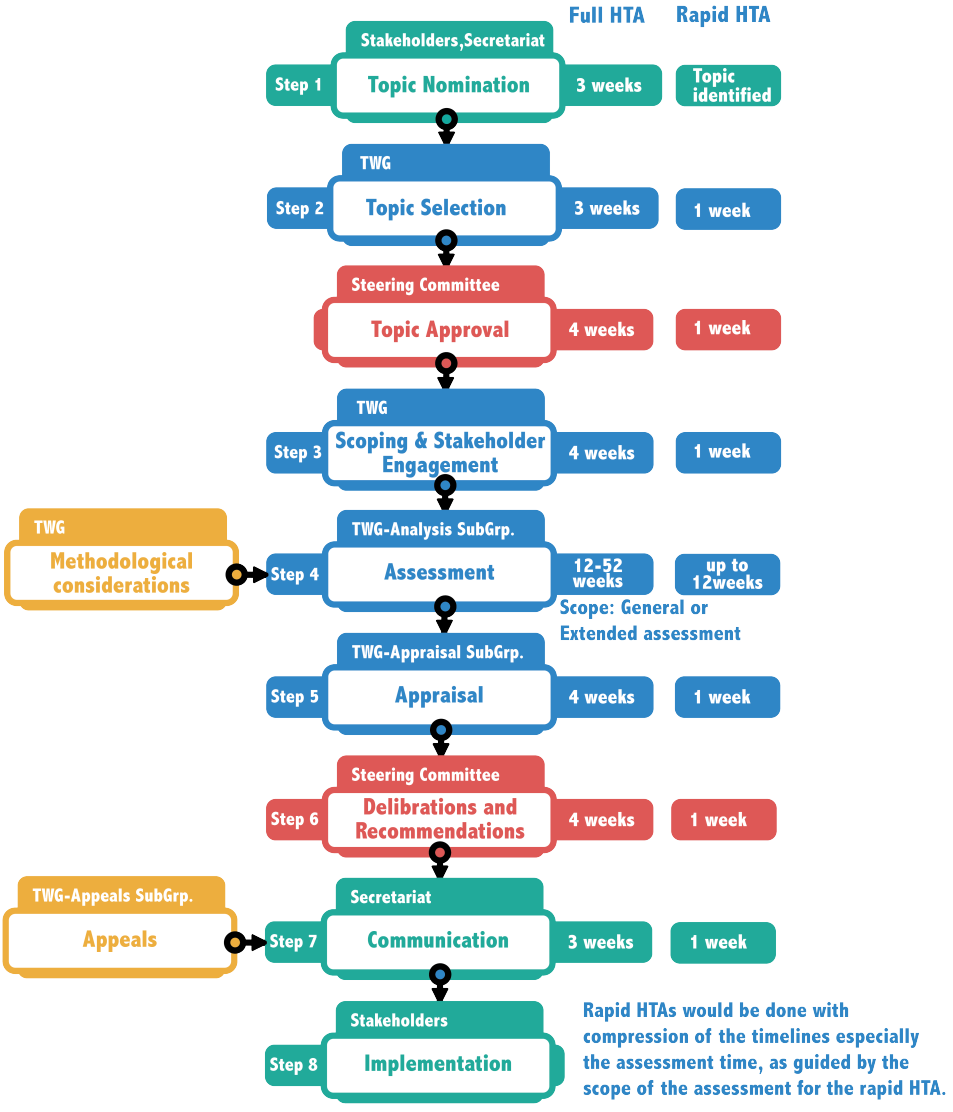


Figure 2: Illustration of the Ghana HTA process flow

Step 1 – Topic Nomination

Topic nomination is a process for deciding which health technologies are appropriate for evaluation. Topics should be motivated by specific government policy direction, Ministry of Health priorities, and or particular public health problems, or they could be identified through consultations with or nominated by key stakeholders. These can include existing technologies that have not been reviewed or any new technologies being considered for introduction into the health system in Ghana.

Figure 3: Summary of step 1 – Nomination of topics

Topics can be submitted for:

1. New Health Technologies which are defined as health technologies that have never been introduced and would have implication on national programmes and policies.
2. Existing Health Technologies where there are concerns about safety, efficacy or effectiveness, and economic implications or new applications of existing technologies.

- Topics may be submitted to the HTA Secretariat by the MoH, NHIS, GHS or other stakeholders if need be (e.g. in public health emergencies, etc.). Topics may be submitted by industry, civil society and other stakeholders when a formal call for topics is made.
- A formal call for topic nomination may be issued bi-annually by the HTA Secretariat through website announcements and or through electronic mail to all stakeholders and the general public.
- Topics would be nominated (submitted) using the most current version of the Ghana HTA topic nomination Form, made available to the general public[3]. Topic nomination shall be done per the required information in the most current version of the Ghana HTA topic nomination Form at the time of topic nomination. The nomination may be guided by the following criteria:
  - Evidence on safety/efficacy – mandatory
  - Budget impact (and burden of disease as relevent) – mandatory
  - Potential economic impact on the household – mandatory
  - Total (potential) users of the health technology, (also considering interventions aligning with public health priorities) – optional
  - Cost-effectiveness (potential) - optional
  - Equity in health considerations (demographic or marginalised population groups) - optional

  Note: In addition to the above information, the following information is relevant for topic nomination:
  - a clear statement about why the analysis is required,
  - the review question(s) to be answered
  - details around the economic impact, potential budget impact, novel drug, or a form of conditional recommendation (may be included)

- The nominated topics along with any summary data will be collected and compiled by the HTA Secretariat put forward for Topic selection.
- The list of health technologies nominated will be published online giving stakeholders an opportunity to comment.
- The Ghana HTA topic nomination Form, is should be completed for topics nominated through a formal call and topics nominated as needed (by the relevant stakeholders).

[3] Note: all forms, templates and tools are available in the Administrative notes document accompanying this process guideline

Step 2 – Topic selection

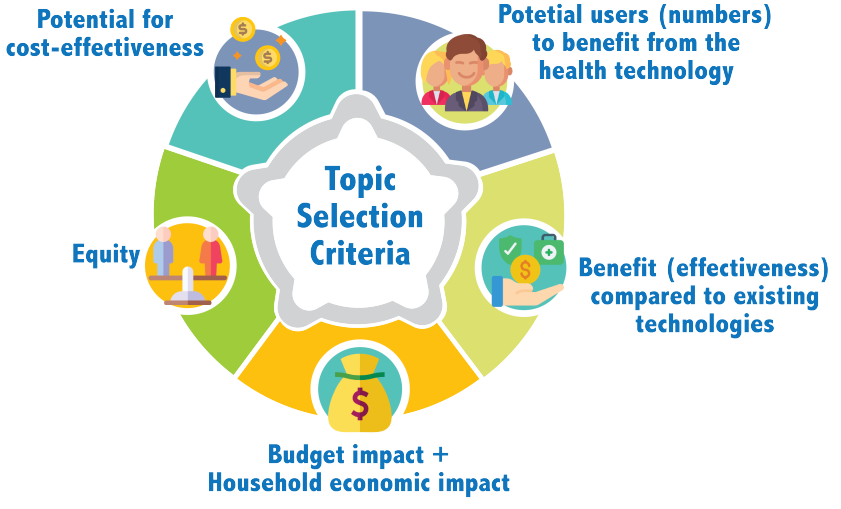
The number of technologies to assess in the health sector is high and not every one of these technologies may have a significant impact. In effect not all technologies need to be evaluated ensuring that time and effort invested will derive the greatest value for money. The approval of topics involves the selection of technologies that are most important to evaluate.

Figure 4: Summary of step 2 – Selection of topics

- The topics for assessment are prioritized by the TWG according to the topic selection criteria below, using the current version of the Ghana HTA Topic Selection Tool [4].
  - Total (potential) users of the health technology, (also considering interventions aligning with public health priorities)
  - Benefit compared to existing treatments
  - Cost-effectiveness (potential)
  - Economic burden of the disease: Budget Impact and in addition, potential economic impact on the household
  - Equity in health considerations (demographic or marginalised population groups)

- The topics shall be ranked and shortlisted by the TWG based on their scores. The shortlisted topics shall be put forward to the steering committee for review and approval.

Figure 5: Guidance on topic selection criteria



[4] Note: all forms, templates and tools are available in the Administrative notes document accompanying this process guideline

Step 3 – Scoping and stakeholder engagement

Scoping involves defining the objective and research questions of the HTA, which will form the basis of the assessment. It provides important input for the assessment of health technologies in that it provides a framework for topics subject to evaluation. It helps define what evidence needs to be collected and formulate the most appropriate policy question to be answered by ensuring that relevant considerations are included in the technology assessment.

Figure 6: Summary of step 3 – Scoping of topics

The scope will specify the population, intervention, comparator, and outcomes (PICO). This will be used to guide the assessment and production of the report and evidence summary for decision making.

- Issues for consideration in the evaluation that are described in the scope include:
  - **Description of the health technology, disease, health condition etc.** being evaluated
  - **The population(s)** that is likely to be eligible for the health technology being evaluated; the use of the health technology in local practice as well as the setting for its use
  - **Comparator** which reflect status quo or a logical comparator relevant for the analysis
  - **The effectiveness and safety outcome** measures appropriate for the analysis;
  - **The ethical, legal, or social issues** associated with the health technology as well as any other factors that may influence the implementation of the health technology in Ghana.

  A draft technology assessment scope will be developed by the TWG members assigned to the HTA topic. The scoping steps may involve any co-opted expertice involved in the assessment. The draft scope will be shared with **technical** stakeholders, including healthcare professionals etc. to provide their initial views on the use of the technology in relation to the current local situation, clinical practice, etc. before the draft scope is finalised.

- The development of the scope includes:
  - ensuring the relevant policy question(s) is/are well defined – this should reflect the context in which the assessment is carried out. The policy question(s) should be clearly stated in the HTA protocol as well as in the technical report (i.e., the detailed document), and the executive summary of the report.[5] Table 2: Aspects to be included in the Policy Question, outlines aspects that should be answered in the policy question
  - scanning peer-reviewed published literature, as well as grey literature.
  - consulting with stakeholders including external individuals, patients, clinical and technical experts, government partners, academics, industry etc.

[5] Busse R, Orvain J, Velasco M, Perleth M, Drummond M, Gurtner F, Jorgensen T, Jovell A, Malone J, Ruther A, Wild C. Working Group 4 Report. Best practice in undertaking and reporting health technology assessments. Intl. J. of Technology Assessment in Health Care.2002;18(2):361-422

- exploring relevant information to establish the population, intervention, comparator(s), and outcome of the intervention (PICO) to help inform the research questions.

- Scope is completed and agreed on/approved by the TWG, while a detailed workplan is developed by HTA Secretariat working collaboratively with the analysis subgroup or lead reviewer indicating the anticipated timeline for completing the assessment.
- The workplan may include:
  - a review plan
  - a economic project plan
  - a stakeholder engagement plan

Table 1: PICO Description

PICO Criteria	Description
Population	• Patient or population group eligible to receive the health technology under assessment. Specifics to be included are: condition/disease, age, sex, comorbidities and subgroups (if any)
Intervention	• The health technology under evaluation and its place in the current care pathway. • Detail if it will replace or be an addition to current therapy. Detail specifics on dose, duration, delivery mode, co-intervention(s), setting (i.e. inpatient / outpatient).
Comparator	• Current standard currently used in routine practice in Ghana or alternative option that it can be compared with
Outcome	• What are the desired effects or outcomes (health-related quality of life and mortality)? • What effects are not wanted (any other and or undesired effects with this option)? • Time it takes to demonstrate outcomes.
Potential data sources	• *Systematic/rapid reviews* • *Clinical practice guidelines* • *NHI reimbursement lists* • *HMIS* • *Primary studies (in order of preference: RCTs, Observational studies, case studies)*
Where necessary the above PICO criteria may be expanded to include part of all of the following: T – time, E - ethical issues, A - adaptability and M - modelling uncertainty. (PICOTEAM).	

Table 2: Aspects to be included in the Policy Question

Question	Examples
Who initiated the report?	Policy makers Healthcare providers Third-party payers Patient advocates
Who comminissioned it?	Ministry of Health, Pharmacy Directorate National Health Insurance Authority Ghana Health Services
Why the assessment is needed right now?	New technology Changes in old technology New indication for old technology

Question	Examples
	New findings Economic concerns Safety concerns Ethical concerns
What decision is it going to support?	Investment decision Inclusion / exclusion from benefits catalogue Planning of capacities Guidance for best practice Investment in further research
Who are the primary target audience for the assessment?	Ministry of Health policy makers Third-party payers Hospital managers / administrators Clinicians Citizens / patients

Table 3: Examples of outcomes relating to each criteria

Aspect of assessment	Outcomes
Safety	Mortality directly related to the use of the technology Morbidity/disability/adverse effects directly related to the use of the technology
Effectiveness	Change in overall/condition-specific mortality Change in morbiditydisability/disease-free survival Change in quality of life Change in quality-/disability-adjusted life-years (QALYs /DALYs)
Cost	Cost and changes in cost compared to current practice (if applicable)
Cost-effectiveness	Within cost-effective threshold. Improved cost-effectiveness
Budget Impact	Budget impact compared to current practice (if applicable)
Equity	Target of priority group (if applicable)

Step 4 – Assessment

The assessment involves the construction of the evidence based on which the health technology is evaluated. The assessment of health technologies includes various activities including systematic evidence collection on the decision criteria; synthesizing the evidence including an analysis of its quality; analysis and conducting economic evaluations (where necessary); an independent review of the evidence, and reporting of the findings and implications.

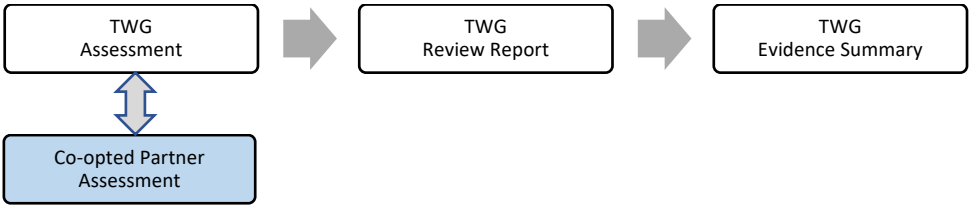


Figure 7: Summary for step 4 – Assessment

The assessment stage is split into two, depending on the level of analysis needed. Part A of the assessment stage involves a general assessment which needs to be conducted for all interventions under assessment and will in most cases be sufficient to inform a decision regarding the inclusion (or exclusion) of a health intervention. If the General Assessment is not sufficient, and a higher level of analysis is needed, then an extended assessment can be considered (Part B).

Part A: General assessment

The general assessment focuses on evidence collation and contains detailed information on the technology, a description of the review question(s), a review of evidence on efficacy and safety, a review of the economic evidence including costs as well as a summary of other HTA agency decisions (if relevant), equity considerations, feasibility issues and (if relevant) ethical, legal, or social issues that may need to be considered.

The assessment may follow the methods of the Cochrane Rapid Reviews Methods Group (RRMG) which is established to inform rapid review methodology, and has an evidence-informed guidance document for conducting rapid reviews.[6] Rapid reviews (RRs) are frequently used to quickly and effectively collate and present relevant evidence to inform healthcare decisions.

The General Assessment, which entails a review of existing evidence, will be sufficient in most cases however, in some instances additional analysis, referred to as extended assessment, will be needed as defined in Table 5: Extended assessment - areas of consideration.

Trade-offs between certainty of evidence, urgency and available resources will need to be made. A request for additional levels of efficacy/effectiveness analysis as well as economic analysis can be made based on discussions between the HTA Secretariat and the TWG. The chair of the TWG can give approval for additional analysis and may also consult with the steering committee (if required).

[6] Garritty C, Gartlehner G, Nussbaumer-Streit B, King V, Hamel C, Kamel C, et al. Cochrane Rapid Reviews Methods Group offers evidence-informed guidance to conduct rapid reviews. J Clin Epidemiol. 2020

As agreed by the TWG, an extended technical assessment may be undertaken with additional analyses at the same time as the initial assessment with sufficient motivation (e.g. If there is significant budget impact).

Reporting should follow the General Assessment Report template[7].

Table 4: General assessment - areas of consideration

Note: the conduct of analysis and reporting should be in line with the version of the Ghana HTA refernce case effective at the time of analysis

Area of assessment	Description
Rapid review of evidence on effect (efficacy and/or effectiveness)	A rapid review accelerates the process of conducting a traditional systematic review through streamlining or omitting specific methods to produce evidence for stakeholders in a resource efficient manner. Each evaluation should include a review of existing efficacy/effectiveness studies on the intervention. The search strategy should be reproducible and selection criteria and procedures clearly presented. The review should reveal the best available up-to date evidence for the efficacy/effectiveness of the drug relative to its comparator(s). The evidence should be critically appraised and its quality assessed.
Review of economic evidence	A review of literature will help identify previous analyses of the assessed technology to inform decision-making and (where required) give an indication of the need for further analysis. When presenting the economic evidence, the following should be described: **Relevance** of the analysis i.e. is the policy and/or research question posed sufficiently similar? **Reliability** i.e. an assessment of the quality of the report **Transferability** i.e. guidance on issues for consideration when applying to the target setting
Budget Impact estimation	The budget impact represents an estimated summative total cost (or savings) to the health budget. This criteria is used as a low level of analysis to represent the expected differences in costs between (new) technology and related comparator to support decision making. The following principles apply to budget impact estimation conducted for general assessment reports: **Target population**: The assessment should estimate the potential size of the target population and uptake. These should be described and justified. **Comparator**: The assessment should estimate the predicted financial impact of subsidising an intervention compared to the current situation. **Costs and outcomes**: Prices should be kept constant over the years (i.e. not inflated). **Time horizon**: The time horizon depends on the length of time needed for treatment. This should be described and compared with the comparator. **Discount rate**: Future costs and savings should not be discounted.
Feasibility considerations	**Operational feasibility**: The availability of resources to implement and maintain use of the health technology

[7] Note: all forms, templates and tools are available in the Administrative notes document accompanying this process guideline

Area of assessment	Description
	Legal feasibility: An assessment of any legal or regulatory concerns regarding the implementation
Severity of the disease	Severity of the condition under study as well as health condition of patients treated with the technology (or severity of the health condition that is to be prevented) with respect to mortality, morbidity, disability, function, impact on quality of life, clinical course (i.e., acuteness, clinical stages).
Equity considerations	A consideration of the target group and if they are a priority group, or a group worse off or have any other characteristics that need to be taken into account.
Note: The estimated time to complete all areas of the general assessment is up to 12 weeks.	

Part B: Extended assessment

The extended assessment focuses on evidence generation. It should be considered which areas of analysis should be undertaken as not all areas will necessarily be needed for decision making.

Decisions need to be made across different medicines, interventions and disease areas. It is therefore crucial that analyses of efficacy/effectivess and cost-effectiveness undertaken to inform the evaluation adopt a consistent approach. To ensure this, a 'reference case'[8] is defined with an aim to promote high-quality analysis and encourage consistency in analytical approaches. The reference case specifies the preferred methods that should be followed.[9]

Table 5: Extended assessment - areas of consideration

Note: the conduct of analysis and reporting should be in line with the version of the Ghana HTA refernce case effective at the time of analysis.

Area of assessment	Description
Systematic review of evidence on efficacy/ effectiveness (up to 12 months)	A systematic review of the existing studies on the intervention and comprehensive search of published economic studies includes best available up-to-date evidence for effectiveness of the technology; ongoing studies should be mentioned. More sources (more databases, wider search of grey literature) should be included in the search. The following characteristics should be defined: • Reproducible search strategy • Transparent selection criteria and selection procedures • Quantitative and qualitative evidence synthesis • Critical appraisal and quality assessment of the evidence

[8] Ghana HTA Reference case, Ghana HTA Technical Working Group, MOH (2022).
[9] ibid

Area of assessment	Description
Economic evaluation calculation (up to 6 months)	Where a more **detailed level of analysis** is needed an economic evaluation is recommended to be conducted within Part B: extended assessment. Types of economic evaluation can include: - cost-effectiveness analysis (CEA) - cost-minimisation analysis (CMA) - cost-utility analysis (CUA) Economic models should be based as much as possible on (primary) data from efficacy/effectiveness studies comparing the study treatment and the comparator, on data from validated databases and/or from published literature. Model inputs and outputs should be consistent with existing data. Justification of model structural assumptions and data inputs should be provided. If relevant cost to household could be considered in the anlaysis.
Budget Impact	Where a budget impact analysis is needed for financial planning and there has been agreement to model this, these will be modelled approapriate to the financial planning period under consideration. This would consider budget impact from the perspective of the payer.
Note: Depending on the area chosen, this is estimated to take up to 52 weeks.	

- A lead reviewer from the TWG is assigned responsibility for the assessment of the health technology in question. Technical partners may be co-opted based on analysis required.
- The assessment will be carried out in accordance with the reference case to promote high-quality analysis and encourage consistency in analytical approaches. Any deviation from the reference case needs to be stated with justification.
- The key elements of assessment are summarised in Table 4: General assessment - areas of consideration and Table 5: Extended assessment - areas of consideration.
- The final report should include standardized evidence summaries for each criterion, a critical evaluation of the available evidence and related uncertainty, and an overview of missing information.
- The assessment and reports should be independently reviewed and discussed by relevant stakeholders. This may lead to revisions of the final report.
- The assessment team (lead reviewer with support of TWG team, excluding the co-opted experts) will complete Technology assessment template (Table 6: Technology assessment summary) as part of the technology assessment report.

Table 6: Technology assessment summary

Note: The Ghana HTA reference case should guide reporting of the analysis.

	Summary description – evidence from HTA report and costs obtained from MoH sources
Intervention name (technology)	
Short description	

	Summary description – evidence from HTA report and costs obtained from MoH sources
Standard of Care (Comparator)	
Severity of disease	
Safety	
Effectiveness	
Level of Evidence (LOE): Effectiveness	
Cost-effectiveness (CE)	
LOE: CE	
Incremental costs	
Budget Impact	
Equity	

Step 5 - Appraisal

In the appraisal step, the committee is required to evaluate the evidence that feeds into the deliberation. This involves a 'critical appraisal' of the evidence at hand including the strength or level of evidence given the various biases of research and different related degrees of uncertainty.

Figure 8: Summary of step 5 – Appraisal

The appraisal sub-working group conducts the first part of the appraisal, reflecting on the efficacy/effectiveness and value-for-money.

- A lead reviewer from the TWG (appraisal sub-working group) is assigned responsibility for leading the appraisal of the health technology. The reivewers involved in the appraisal should not have had any involvement in the assessment of the health technology. The responsibilities of the appraisal sub-group (working under the lead reviewer) include:
  - Scrutinizing and interpreting the evidence presented in the HTA report (assigning classifications for each);
  - Arriving at a consensus from members on a classification for each criteria based on the evidence using the criteria classification options: Table 7: Criteria classification options
  - Making a careful assessment of the evidence presented in the report taking into account the quality/strength of the evidence.
  - Assigning classifications to other criteria that may potentially impact disadvantaged populations e.g. equity. Table 7: Criteria classification options
  - Preparing briefing notes for Steering Committee;
  - Presenting findings and guidance for the Steering Committee

- The HTA Secretariat working with the TWG would ensure that the criteria for delibrations as detailed in Table 7: Criteria classification options, as well as the decision guide Figure 9: Guidance on the inclusion of health technologies, are integrated into the operations of the HTA Steering committee.

Table 7: Criteria classification options

Criteria	Classification options		
Relative Safety	1. Better than comparator	2. No difference	3. Worse than comparator
Effectiveness	1. Effective (better than comparator)	2. Comparable effectiveness	3. Not effective (worse than comparator)
Level of evidence: Effectiveness	1. Very confident	2. Moderately confident	3. Limited confidence
Cost-effectiveness	1. Highly cost-effective	2. Moderately cost-effective	3. Not cost-effective
Level of evidence: Cost-effectiveness	1. High level of evidence	2. Moderate level of evidence	3. Low level of evidence
Severity of disease	1. Severe	2. Moderately severe	3. Not severe
Costs	1. Less expensive	2. Equal cost	3. More expensive
Budget Impact (BI)	1. Low BI	2. Moderate BI	3. High BI
Equity	Targets a priority group		Does not target a priority group

Guidance on the inclusion of health technologies

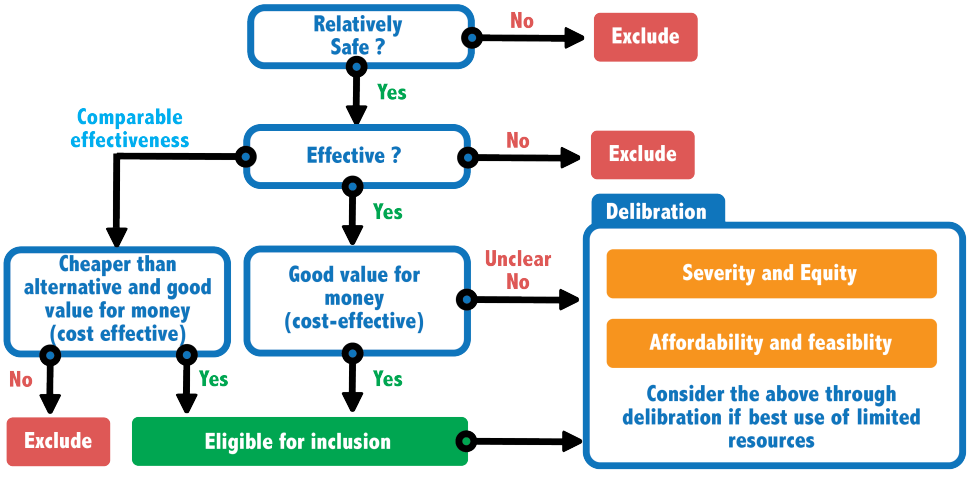


Figure 9: Guidance on the inclusion of health technologies

Step 6 - Deliberation and recommendation

This step involves the Steering Committee deliberating on the evidence presented and coming to a decision regarding recommendation/use of the health technology in the health system. Recommendations are not necessarily limited to 'recommend' or 'do not recommend' health technologies. Often, they are defined in terms on conditional recommendation, i.e. to only recommend a health technology if certain conditions are met. These conditions could be imposed by the payer (e.g., a restriction on the population eligible for the health technology, a price-volume agreement or funding tied to the achievement of effect outcomes), or agreed between the payer and the health technology provider as an interim measure during evidence development (e.g., managed entry or coverage with evidence development arrangements).

Figure 10: Summary of step 6 - Deliberation on results and final recommendations

The core task of the Ghana HTA Steering Committee is to balance the judgments of the results from the appraisal and to take into account any other special circumstances such as equity, social impact and feasibility of implementation. From this they are required to make a recommendation for implementation (investment or disinvestment).

As part of the delibration step, key stakeholders may be invited in attendance if necessary with relation to the specific issue under discussion.

- The evidence will be presented to the Steering Committee using the evidence report template and the evidence summary along with criteria classifications and guidance developed on evidence.
- The Steering Committee shall form their own judgements on the decision criteria and deliberate on the evidence presented arriving at a judgment and recommendation on the public funding and use of the health technology in the health system.
    - The Steering Committee chairperson has responsibility to work towards formulating recommendations on health technology (intervention) presented.
    - Each Steering Committee member is required to express their own preferences and vote in each round (verbally and written). The meeting will follow a deliberative process in garnering views and arriving at a recommendation.
- The Steering Committee is required to consider the values in the decision framework - Table 8: Decision framework of the Steering Committee.
- As part of the feasibility, the Steering Committee is required to consider the organizational and health system impact of adopting a health technology in terms of the healthcare resources required and feasibility (e.g. human resources, training and skills, infrastructure, capacity for implementation of national and local health systems). The necessary health system changes for the effective adoption and use of the health technology needs to be taken into account noting the current gaps in resources and barriers for implementation.
- In the event that the Steering Committee finds that the health technology does not represent good value for money and there is a strong desire to include the health technology, the

chairperson may refer this for a price negotiation process with the pharmaceutical/device company.

- During the decision-making process, the Steering Committee will aim for consensus first. Should any Committee member disagree with the recommendation of the majority, the Steering Committee shall discuss the rationale of the dissenting opinion. In the event that the final recommendation cannot be reached thru consensus, voting shall be conducted.
- The decision of the majority (i.e., one half plus one) of the members of the Steering Committee present during the vote shall be considered as the decision of the Committee. Any Committee member who disagrees with the decision should state their recommendation officially on record and it should be recorded in the Minutes of the Meeting stating reasons for dissent. Recommendations from the Committee may be one of the following:
    - Approve unconditionally [10]
    - Approve conditionally (i.e. with restrictions/conditions of use)
    - Disapprove [11]
- For health technologies where there are price/cost issues, final recommendations shall be withheld until settled after the price negotiation process.
- The Steering Committee must document and provide a rationale for its recommendation and how they considered each criterion to develop the final recommendation. There is no weighting applied to each criterion as judgements vary on a case-to-case basis depending on the issues that may arise in each situation and each Committee member is likely to prioritise criteria differently. The Committee will be explicit and transparent on how the relevance of each criterion was taken to develop the overall decision.
    - Templates will be provided to facilitate this process. These will include evidence summaries, and decision frameworks. The decision criteria augmentation will need to be completed by each member.
- Voting is a crucial element of the deliberative process: it requires members to provide argumentation to justify their votes which enables members to each and individually express their views ensuring all viewpoints are adequately represented.
- The decision framework (Table 8) needs to be used by the Steering Committee to show where the uncertainties are and how it could be factored into their decisions.

Table 8: Decision framework of the Steering Committee

Decision Criteria	Yes	No	Justification	Description
Safety and effectiveness				The intervention should be shown to be safe and effective as shown by best source of available evidence on efficacy/effectiveness.
Cost-effectiveness				The intervention should represent good value for money and provide overall health gain to the health system, outweighing the opportunity costs of funding other health technologies. It must represent a more efficient use of health care resources

[10] Unconditional approval refers to the question that was posed – review question from Step. 1 Within the context of pharmaceuticals, that is "in line with the licenced indication(s)".

[11] Further information could be requested to inform a decision.

Decision Criteria	Yes	No	Justification	Description
				compared to the alternative health technologies
Severity				The health intervention should address the top medical conditions that place the greatest burden on the population, including severity or health loss by an individual as a result of the disease such as death, handicap, disability or pain target conditions of the poorest and most vulnerable populations (target worse off)
Equity				The health intervention should target conditions of the poorest and most vulnerable populations (target worse off)
Affordability				The intervention should be affordable in the Ghana health system and the cost thereof must be viable to the financing agents.
Feasibility				The intervention must be feasible to implement and adopt, given existing health care resources at the local or national level
Final recommendation				Final decision should state what the recommendation is and the reason for it: i. Recommend unconditionally ii. Recommend conditionally (i.e. with restrictions/conditions of use, e.g subject to negotiation etc.) iii. Not recommended

Step 7 – Communication and appeal

Communication and appeal are important for the legitimacy of decision-making by making the decision and underlying argumentation public. Effective communication ensures responsiveness and accountability. It also creates an understanding of why and how decisions are reached.

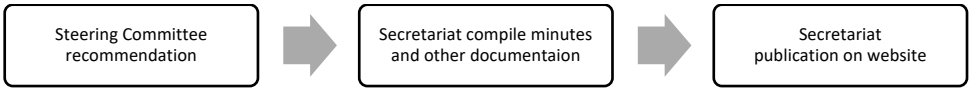


Figure 11: Summary of step 7 - Communication

- The Secretariat shall publish the decision/agreements of the Steering Committee with the peer reviewed assessment report and summary of evidence through the official MOH website (HTA sub-domain or section).
- The draft recommendation of the Steering Committee shall be posted on the official MOH website for two (2) weeks to inform the public on the recommendations and elicit feedback and appeals from the stakeholders, if any. Comments and feedback shall be considered by the Steering Committee in finalizing the recommendation.

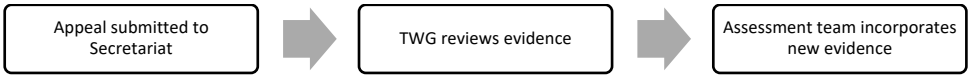


Figure 12: Summary of step 7 - Appeals

- An appeal, with supporting evidence, may be submitted to the Secretariat within ten (10) working days from posting of the Steering Committee recommendation, if there is data that was not considered and may impact the recommendation.
  The procedure for submitting the appeal will require:
  - A completion of the template prescribed for appeal – Ghana HTA Appeals Form.
  - Additional evidence to substantiate the appeal
  - A convincing explanation of how the new evidence supplied could affect the result of the assessment process.

- If new data or insights are available and viable, the TWG and Steering Committee shall be given the opportunity to request a review to a decision should the outcome be significant.
- No request for extension of time to submit an appeal is allowed.
- The appeal shall be presented to an different reviewer for screening and validation of the merits of the appeal and consideration of relevant additional documents or information.
- The decision to consider an appeal will be within 15 working days from receipt of the documents.
- Where a decision is made to consider an appeal, the publication of results of the contensted results will be delayed.
- The assessment will be revised accordingly and assessed on the same basis as prescribed above.
- The documentation will include decisions on the inclusion or exclusion of services, the rationale for the HTA recommendation, and how each criterion was considered.

- If new data or insights become available, stakeholders shall be given the opportunity to request a review to a decision should the outcome be significant.

Figure 13: Summary of step 7 – Dissemination

- The HTA Secretariat develop and publish communication materials, policy briefs and evidence summaries for healthcare professionals, patients and policy makers on the appropriate use of health technologies based on the appraisal and recommendations of the HTA Steering Committee.
- The Secretariat is responsible for the publication documentation related to the recommendations.
- The Steering Committee chairperson shall approve content of the communication materials before public dissemination.

Step 8 – Implementation

- The Minister will ensure that the implementation by related actors including the MoH, service providers, NHIA and other implementing stakeholders with devolved powers takes place.
- The HTA secretariat shall monitor the implementation of the recommendations and report to the Steering Committee on the process.
- An impact assessment framework shall be developed as part of the recommendations of each HTA to support implementation.

4 Impact assessment and Monitoring and Evaluation

As part of the scoping and framing stage for HTA topics, an impact assessment framework may be developed by the TWG (analysis sub-group) in line with the Strategic area for implementation and follow-through action. The impact assessment framework may also be done alongside the recommendations by the TWG (appraisal sub-group).

This impact assessment framework would serve as the basis for monitoring the implementation of HTA recommendations.

Monitoring would be done by the implementing agencies (and relevant data shared with the HTA secretariat). Impact assessment would be done by the HTA Secretariat.

5 Annexes

5.1 Guidelines for appraisal

Prior to each meeting, the sub-group will receive a copy of the technology assessment report, which includes evidence summaries. Each member will then need to rate each criteria based on the classification options.

Each meeting will start with an introduction and each member will declare any conflict of interest using the Standard Ghana HTA conflict of interest declaration form [12]. Members will give their input into the evidence summaries presented and a round of clarification questions and answers will take place. The lead of the appraisal team will then present their criteria ratings and give each member an opportunity to comment whether they agree or disagree. If agreement is not reached on the ratings, then members should agree on how the rating should be made. There should be unanimous agreement on the ratings of each of the criteria. Where there is any disagreement on ratings this should be noted.

Each member should then determine if the health technology is recommended to be eligible or not based on (i) safety, (ii) effectiveness and (iii) value for money using Figure 9: Guidance on the inclusion of health technologies as guidance.

If the health technology meets all these criteria, then the health technology can automatically be eligible (e.g. inclusion) and this recommendation can be passed onto the steering committee for final decision on recommendations. If the health technology does not show good value for money (or shows questionable value for money), while being effective and safe, then this finding is passed over to the steering committee for further deliberation on additional circumstances.

Based on the members votes, the chairperson will then invite each member to share their reasoning followed by group discussion. Subsequently, members give their last vote and the chairperson will summarise the final voting results.

[12] Note: all forms, templates and tools are available in the Administrative notes document accompanying this process guideline

5.2 Guidelines for evidence deliberation and decision making

Prior to each meeting, the committee will receive a copy of the technology assessment report, which includes evidence summaries, and the findings from the appraisal team. Each committee member will then need to describe how each decision criteria meets (or does not meet) their requirement for eligibility. This will be done using the template in Table 8: Decision framework of the Steering Committee.

Each meeting will start with an introduction and each member will declare any conflict of interest using the Standard Ghana HTA conflict of interest declaration form [13]. This will then be followed by a deliberative process.

Each member will give their input into the evidence summaries presented and a round of clarification questions and answers will take place. This will give members an opportunity to reassess their initial decision criteria.

The chairperson will then give each member an opportunity to present their augmentation on each decision criteria - Table 8: Decision framework of the Steering Committee. **Error! Reference source not found.**

An initial voting will take place by Steering Committee members whereby each member categorises the intervention as per one of three recommendations:

- Unconditional recommendation: eligibility;
- Conditional recommendation on conditionality: eligibility only under restricted/limited conditions;
- No recommendation (recommendation against inclusion, adaptation etc)

Based on the votes, the chairperson will then invite each member to share his/her argumentation followed by group deliberation. Subsequently, members give their last vote and the chairperson will summarise the final voting results and argumentation. A final decision should be reached by consensus. If consensus cannot be reached, then a majority should be taken and it should be noted that consensus could not be reached and reasons given for that.

Table 9: Steering Committee recommendation

Note: e.g. in the case of benefit package decisions as well as decisions on inclusion of health technologies on the essential medicines list, recommendations can take the form as indicated below. This would however be adapted to suit recommendations (not based on inclusion/exclusion) when considering other health technologies.

Recommendation for inclusion:	eligible under general inclusion	
Recommendation on conditionality:	eligible only under restricted/limited inclusion	
Recommendation against inclusion:	exclude from package of services	

[13] Note: all forms, templates and tools are available in the Administrative notes document accompanying this process guideline

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