
# BHUTAN
# HEALTH TECHNOLOGY ASSESSMENT FRAMEWORK

**SEPTEMBER 26, 2023**

HEALTH INTERVENTION AND TECHNOLOGY ASSESSMENT DIVISION (HITAD),
MINISTRY OF HEALTH, BHUTAN

# CONTENTS

# CONTENTS

# LIST OF TABLES



# LIST OF FIGURES

# LIST OF ABBREVIATIONS

| | |
|---|---|
| BBS | Bhutan Broadcast Service |
| BHTF | Bhutan Health Trust Fund |
| CBS | Centre for Bhutan Studies |
| DHS | Department of Health Service |
| EMTD | Essential Medicine and Technology Division |
| GEAR | Guide to Economic Analysis and Research |
| HFD | Health Financing Division |
| HITAD | Health Intervention and Technology Assessment Division |
| HITAP | Health Intervention and Technology Assessment Program |
| HLC-HS | High-Level Committee for Health Sector |
| HTA | Health Technology Assessment |
| KGUMSB | Khesar Gyalpo University of Medical Science of Bhutan |
| MoH | Ministry of Health |
| NDP | National Drug Policy |
| NHTAC | National Health Technology Appraisal Committee |
| NEML | National Essential Medicines List |
| NMS | National Medical Service |
| NMC | National Medicines Committee |
| PHE | Public Health Emergencies |
| RGoB | Royal Government of Bhutan |
| RUB | Royal University of Bhutan |
| SDG | Sustainable Development Goals |
| UHC | Universal Health Coverage |
| WHA | World Health Assembly |
| WHO | World Health Organization |

# VERSION HISTORY

This is the 1st Version of the HTA framework for Bhutan, made publicly available on 26th September 2023.

# PREFACE

In the Kingdom of Bhutan, Universal Health Coverage (UHC) is a constitutional mandate, as stated in Section 21 and 22 of Article 9 of the constitution. However, the growing demand for advanced health technologies by citizens has led to higher health expenditures for the nation. To address this, the National Health Policy 2011, specifically in sections 8.4, 9.8, and 9.9, emphasises the use of Health Technology Assessment (HTA) as a crucial tool for rational decision-making and prioritisation of limited healthcare resources.

In 2008, the Essential Medicines and Technology Division (EMTD) was established as the HTA agency within the Ministry of Health (MoH). To streamline the process of introducing health technologies in the country, the first HTA process guideline was developed in 2013 and later updated in 2018.

In a significant move to further strengthen the HTA process and institutionalise the HTA system across the health sectors in Bhutan, this new HTA framework has been approved by the High-Level Committee for Health Sector (HLC-HS) during the 2nd HLC meeting on 5th June 2023. This framework is set to take effect from 1st July 2023.

This HTA framework applies to all departments of health sectors and health centers under the Royal Government of Bhutan (RGoB), ensuring a comprehensive and consistent approach to evaluating and incorporating health technologies into the healthcare system.

# FOREWORD

It is with great pleasure and a sense of accomplishment that I present the Health Technology Assessment (HTA) Framework for the health sectors under the Royal Government of Bhutan. This framework marks a significant milestone in our journey towards accessible, equitable, and sustainable healthcare. It represents a crucial step towards achieving Universal Health Coverage while responsibly managing the increasing demand for advanced health technologies and addressing the rising healthcare expenditures.

As in many other countries, Bhutan has been experiencing a growing demand for advanced health technologies, which poses challenges in managing healthcare costs while meeting the evolving needs of our population. In response to this, the Ministry of Health recognised the importance of HTA as an important tool for informed decision-making, shaping our healthcare priorities, and optimally allocating scarce resources.

The establishment of the Essential Medicines and Technology Division (EMTD) within the Ministry of Health (MoH) in 2008 laid the foundation for HTA in Bhutan. Subsequently, the development and revision of the HTA process guideline in 2013 and 2018, respectively, set the stage for streamlining the introduction of health technologies in the country.

To further strengthen and institutionalise the HTA process, a comprehensive and standardised evidence-based approach was required, leading to the development of this new HTA framework. This framework was crafted through extensive collaboration and collective efforts involving experts from within and outside the country, policymakers, and stakeholders. It is designed to guide rational decision-making, enhance transparency, promote more participatory decision-making processes, and prioritize the allocation of limited resources for the benefit of our citizens.

The approval of this HTA Framework by the esteemed High-Level Committee for Health Sector, with its implementation set for 1st July 2023, signifies a major stride forward in our commitment to strengthening the healthcare landscape of Bhutan. This framework will apply to all departments of health sectors under the Royal Government of Bhutan, with the aim of achieving better healthcare outcomes, ensuring value for money, and striking a balance between innovation and affordability.

I extend my heartfelt gratitude to all those who have contributed to the development and refinement of this HTA Framework. I also express my appreciation to our citizens, whose trust and engagement in the healthcare process inspire us to strive for excellence in realising the goal of "nation with the best health". At the core of our endeavors remains the well-being of our people.

Best wishes,

**(Pemba Wangchuk)**

**Acting Secretary**
**Ministry of Health**

# ACKNOWLEDGEMENTS

This Health Technology Assessment (HTA) Framework has been developed by the Health Intervention and Technology Assessment Division (HITAD), Ministry of Health, Bhutan, in collaboration with the Health Intervention and Technology Assessment program (HITAP), Ministry of Public Health, Thailand. The development of the HTA framework has been supported by the Access and Delivery Partnership (ADP), hosted by the United Nations Development Programme (UNDP).

The development of this framework involved contributions from following individuals during the stakeholder consultation meeting held on 29th May – 2nd June 2023: Ms. Pema Yangzom and Mr. Jangchup Peljor, National Medical Service (NMS); Dr. Sonam Chhoden and Khesar Gyalpo, University of Medical Sciences of Bhutan (KGUMSB); Mr. Tshewang Dorji, Department of Public Health; Mr. Jigme Tenzin, Bhutan Food and Drug Authority (FDA); Mr. Sonam Phuntsho, Ministry of Health's Policy and Planning Division; Dr. Gyem Tshering (PhD), Ms. Sangay Zangmo and Mr. Tshering Dorji, Royal Centre for Disease Control; Mr. Karma Jurmin, Department of Health Service; Dr. Chhabi Lal Adhikari, Dr. Tenzin Lhadon, Dr. Dechen Nidup, Dr. Sonam Jamtsho, Dr. Kuenzang Wangdi, Mr. Tashi Penjore, Mr. Kezang Tshering, Mr. Choki Dorji and Ms. Tshering Yangzom, Jigme Dorji Wangchuck National Referral Hospital; Mr. Karma Tobgay, Bhutan Cancer Society and Mr. Tashi Namgay, Bhutan Kidney Foundation as representatives from the Civil Society Organizations.

We extend our appreciation to Dr. Yot Teerawattananon from HITAP and Prof. Shankar Prinja from the Post Graduate Institute of Medical Education & Research, Chandigarh, India for their insightful comments of the HTA process for Bhutan.

The Hon'ble Members of the High-Level Committee for Health Sector (HLC-HS) provided their valuable comments and directives in line with the national policy-making context before the framework was endorsed by the Committee for implementation.

Finally, we want to express our appreciation to the Director of the Department of Health Services (DHS) for his consistent support and insightful guidance in advancing the institutionalisation of HTA within the MOH.

The following persons, institutions and partners are acknowledged for their support in writing and reviewing this document.

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# INTRODUCTION

# INTRODUCTION

## OBJECTIVE AND TARGET AUDIENCE

The objective of this framework is to establish a process and define the roles and responsibilities of various stakeholders involved in conducting Health Technology Assessment (HTA) in Bhutan.

The primary audience for this document is HTA practitioners and users in Bhutan. Practitioners refers to the producers of HTA such as national HTA agencies, local universities or academics. Users are the consumers of HTA who generate the demand for evidence, such as the decision makers. In the context of Bhutan, some of the practitioners of HTA would include the Health Intervention and Technology Assessment Division (HITAD), Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB) and Royal University of Bhutan. The High-Level Committee for Health Sector (HLC-HS) and Health Financing Division (HFD) are examples of users of HTA.

## HEALTH TECHNOLOGY ASSESSMENT

### NEED FOR PRIORITY SETTING

Resources for health are limited and the demand for medicines and health products consistently exceeds available resources. This challenge is further intensified by the growing availability of an array of expensive and advanced health technologies and interventions, leading to a rise in healthcare expenditure [1]. As countries strive to achieve Universal Health Coverage (UHC) as part of their commitment to the Sustainable Development Goals (SDGs), there is a need to allocate limited healthcare resources in an efficient, equitable and affordable manner. HTA is one approach to tackle the issue of resource allocation to define the benefits package offered, which is one of the dimensions of WHO's UHC cube (Figure 1).

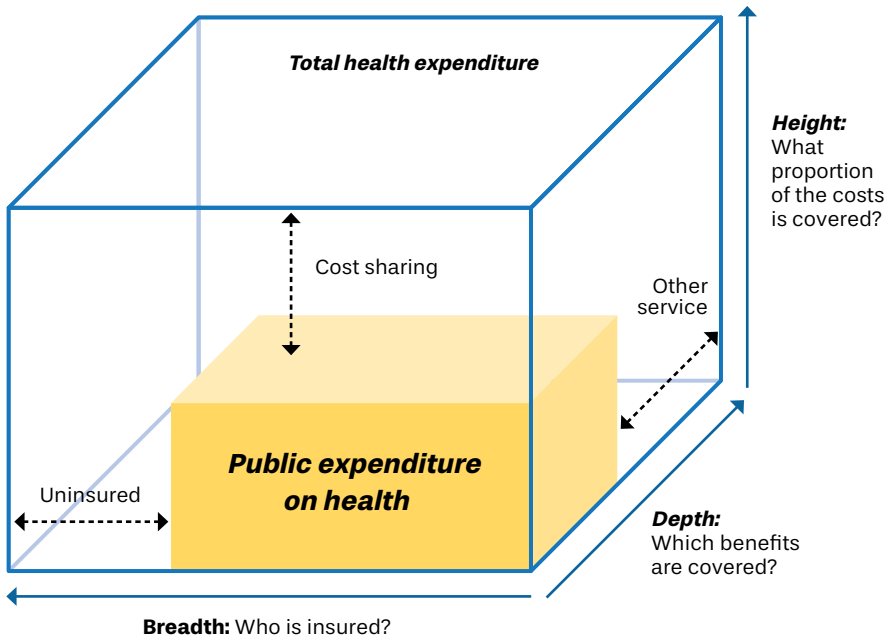


**Figure 1:** WHO's UHC Cube. Adapted from [2]

## DEFINITION AND SCOPE

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. Its purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system" [3]. The World Health Organization (WHO) Member States have acknowledged the importance of using HTA for achieving UHC at the global and also at the regional levels through resolutions [4]. It should be noted that HTA is not only a technical exercise but also embedded in a process. HTA provides a framework for the assessment of the clinical effectiveness, cost-effectiveness, safety, and broader societal impacts of healthcare technologies [3]. By systematically assessing these factors, HTA provides evidence-informed insights on the value and impact of different interventions which can consequently enable decision-makers to make informed choices about resource allocation and prioritisation in healthcare.

Additionally, it is important to highlight that "health technologies" refer to medical devices, medicines, medical services, medical and surgical procedures aiding in the prevention, diagnosis, treatment and rehabilitation of disease [5]. Thus, the scope of HTA is not restricted to any specific type of health intervention and extends to evaluating various technologies across the healthcare spectrum.

## PURPOSE

HTA is used to allocate limited resources to health interventions and technologies. It is typically used to inform the design of health benefits packages that are reimbursed by governments [1]. The results of economic evaluations or analyses conducted as a part of the assessment can also serve as the basis for negotiating the prices of health technology. Additionally, HTA may be used to support the development and regular revision of clinical practice guidelines, healthcare policies, protocols for public health programmes and service delivery among others [6]. This active involvement contributes to the continuous expansion of the knowledge base for improving quality of healthcare [1]. The use of HTA may vary depending on the income level and health system of a country and HTA may be used for planning and budgeting purposes, or to define packages for essential services depending on the country need [1, 6, 7].

## CORE PRINCIPLES

There is no single approach to designing and operationalising HTA process in a country. Decision-makers can design priority-setting tools like HTA such that it suits the local setting and political context. Although different settings can have different HTA frameworks, it is of paramount importance to develop an HTA arrangement that is fair and transparent [8]. A transparent HTA process creates trust and acceptance among the suppliers and users of HTA, thus ensuring sustainability of the institution.

HTA is anchored in the "accountability for reasonableness" (A4R) framework proposed by Daniels and Sabin [9]. This framework highlights the significance of a fair and equitable HTA process, where transparency is ensured by making all decisions and their justifications publicly available. Additionally, decisions are based on well-founded reasons and considerations to maintain relevance. The framework also allows for revisability, providing mechanisms for appeals, revisions, and updates to decisions. To uphold the integrity of the process,

Furthermore, a robust HTA process should reflect the interests and viewpoints of all stakeholders [10]. To achieve this, it is vital to establish a structured participatory approach involving a diverse range of stakeholders. Such an inclusive and participatory HTA process can help gather data and judgments from various relevant perspectives, fostering a comprehensive decision-making process. Notably, such active and inclusive engagement with all relevant stakeholders can significantly promote legitimacy, trust and confidence in the HTA process. When involving different stakeholders, there is also a need to manage the conflict of interest. Timeliness is another important principle that can apply to different parts of the process to ensure that HTA remains policy relevant. WHO has outlined a range of principles that apply to use of HTA for benefits package design; these include basing the development of the benefits package on national values and criteria and linking the benefits package to financing mechanisms [10].

## HTA GLOBALLY AND IN ASIA

A global survey by WHO in 2020/21 revealed that more than a hundred respondents had established systematic health decision-making processes at the national, sub-national or both levels. Likewise in Asia, there has been a noticeable increase in the number of HTA agencies over the years, as countries strive to achieve UHC in a sustainable manner. However, there are variations in the practice of HTA in the region since the HTA process is shaped by local context, history, the existing health system, values and available resources. Despite these variations, similarities were observed in the processes and the role of HTA in informing funding decisions for pharmaceutical products across the Asian countries [11]. Given the heterogeneity in country and health systems, HTA was applied to define health benefits packages, identify priority interventions in existing packages or to design and assess the feasibility of health programmes in the countries of the region [6, 7, 12]. Additionally, some common challenges in institutionalising HTA can be mapped from the experiences of the countries in this region. These include limited capacity for HTA, availability of financial resources, engagement of relevant stakeholders in the process and availability of infrastructure for HTA [11, 13, 14]. To respond to the needs and facilitate collaboration, HTAsiaLink, a regional network of HTA organisations. was established in 2011 [15] . Among its activities, it hosts an annual conference that serves as a capacity building platform for researchers in the region and also offers opportunities for joint initiatives [16].

Lastly, ongoing learning and critical reflection on present HTA practices and systems are imperative to effectively adapt to the ever-changing landscape of HTA in Asia. A promising approach to tackle capacity gaps and improve the overall effectiveness of HTA implementation involves fostering collaborations among HTA agencies within the region, exemplified by initiatives like the HTAsiaLink network, as well as forming partnerships with global counterparts. These collaborative efforts can bring about substantial advancements in HTA processes, ensuring better health outcomes and sustainable healthcare decision-making in the region.

# FROM PAST TO PRESENT: THE JOURNEY OF HTA IN BHUTAN

## CONSTITUTIONAL AND POLICY CONTEXT FOR HTA

Guided by the principles of Gross National Happiness Index (GNHI), Bhutan prioritises the overall well-being of its citizens. The cornerstone of ensuring the overall health of its population is the constitutional mandate to free health services. In Section 21 and 22 under Article 9 of the constitution of the Kingdom of Bhutan, it is stated that "the state shall provide free access to basic public health services in both modern and traditional medicines" and "the state shall endeavor to provide security in the event of sickness and disability or lack of adequate means of livelihood for reasons beyond one's control", respectively. This constitutional mandate can be considered as the foundation for Universal Health Coverage (UHC) in the country.

A fundamental driver of the advancement of HTA in any context is the presence of sustained policy support [17]. In Bhutan, the National Health Policy 2011 stands as a testament to this support, enabling the development and progress of HTA within the country. The sections under the policy that mandates the operationalisation and implementation of HTA are:

- Section 8.4: Introduction of any new health technologies shall be allowed only after assessment and evaluation for its safety, efficacy, quality, indication and cost- effectiveness by the Health Intervention and Technology Assessment Panel.
- Section 9.8: MOH shall ensure to prioritise investment in more cost-effective and cost beneficial health care interventions.
- Section 9.9: MOH shall explore and institute appropriate mechanisms suitable to the Bhutanese context to ensure efficient utilisation of health resources and maximise value for money.

## JOURNEY OF HTA IN BHUTAN

Bhutan started its HTA journey in 1986, when the Essential Drugs Program was instituted to ensure access to quality medicines and improve it supply system. Subsequently, in 2008 the Royal Government of Bhutan (RGoB) approved the establishment of Essential Medicines & Technology Division (EMTD) under the Department of Medical Services (DMS) as the national HTA agency within the Ministry of Health (MoH). This was in alignment with the WHO resolution during the 67$^{th}$ World Health Assembly (WHA) advocating the use of HTA for achieving UHC. Mandates of EMTD included developing policies and guidelines related to health technologies, National healthcare service standards, a National Medical Device List and a National Essential Medicines List (NEML), Standard Treatment Guidelines, etc.

Furthermore, to strengthen the HTA system and establish a standard procedure for the introduction of health technologies in the country, the HTA process guideline was developed and later endorsed by the MoH in 2013. Subsequently, this guideline underwent revision, leading to the publication of a second edition in 2018. In addition to the development of the process guideline, several HTA studies including evaluating the Package of Essential Non-communicable (PEN) disease interventions [18], pneumococcal [19] and rotavirus vaccines [20] which informed policies have been carried out by the national HTA agency in Bhutan. EMTD has been collaborating with the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand to develop technical and institutional capacity for HTA. Importantly, EMTD in collaboration with Hitotsubashi University in Japan is working on an empirical determination of the cost-effectiveness threshold for Bhutan since 2019. Once the threshold is defined for Bhutan, it is expected to guide the decision-making with regards to the cost-effectiveness of health technologies. This is in line with available evidence recommending a country-specific cost-effectiveness

threshold rather than the use of a conventional WHO threshold based on Gross Domestic Product (GDP) per capita [21, 22]. Additionally, Bhutan is also a member of the regional HTA network, HTAsiaLink. Networks like HTAsaiLink, with their annual conferences not only offer a platform to share the study results and learn from other settings during, but also contribute to the development of important tools for HTA such as the regional guidance on the use of Real-World Data (RWD) and Real-World Evidence (RWE) for HTA [23] which can be imperative for quality evidence generation.

## KEY CHALLENGES

Over the years, several challenges in institutionalising HTA have been identified. The main among them include:

- limited link between evidence generated and policy,
- limited capacity for conducting or appraising HTA,
- providing referrals for citizens, as this is required, given the right to health, and
- a predominantly publicly funded healthcare system with a relatively small market size that limits the negotiating power for purchasing health technologies.

## RECENT REFORMS IN HEALTH

In pursuit of overall governance reforms in Bhutan, the Parliament of the Kingdom of Bhutan passed the Civil Service Reform Act of Bhutan in 2022, leading to the restructuring, consolidation, and establishment of various agencies under the RGoB [24]. As part of this ongoing reform process, significant changes have been introduced in the health sector to enhance its efficiency, effectiveness, transparency, and accountability, along with clarifying roles, mandates, functions, and duties.

In light of these reforms, the EMTD has been renamed as the Health Intervention and Technology Assessment Division (HITAD), operating within a newly created department called the Department of Health Services (DHS). This strategic move has created an opportunity to improve HTA and health financing within the Bhutanese health system. HITAD and the Health Financing Division (HFD) under DHS are entrusted with the responsibility of facilitating informed decision-making in resource allocation and healthcare prioritisation.

Furthermore, as part of the transformation in the health sector, the DMS has been upgraded to a bigger agency within the health sector and is now known as the National Medical Service (NMS). The primary focus of NMS is to provide clinical services, while the Ministry of Health (MoH) will concentrate on policymaking and healthcare regulation across the country.

## RATIONALE FOR THE DEVELOPMENT OF THE HTA FRAMEWORK

There has been increasing demand for better health among citizens and newer health technologies from healthcare providers. However, the new health interventions and technologies are usually costlier and contribute to rising health expenditures which is a major challenge to a resource constraint country like Bhutan. In this context, the HTA process can ensure that a new technology is not added until it is proven to be effective. Meanwhile, an older technology is not removed from the health package until it is shown to be ineffective or not cost-effective. Therefore, HTA has increasingly gained importance and is seen as an important approach to guide health policy for the allocation of scarce resources for healthcare. HTA is even more important for Bhutan where health care is provided free of cost by the state despite the scarcity of resources.

Although the HTA agency was instituted within MoH in 2008 and the HTA process guidelines are available, there have been several challenges in enhancing HTA and using HTA in decision-making and priority setting in the country. Engagement of multiple stakeholders in various independent decision-making processes, lack of institutional capacity, lack of awareness among the decision-makers and stakeholders on HTA principles, and lack of resources for HTA work were some of the major challenges. Therefore, institutionalising a robust HTA process engaging all relevant stakeholders involved in HTA and establishing a clear workflow and responsibilities was deemed to be critical in improving evidence-informed decision-making for the sustainability of free healthcare in Bhutan.

In view of the above, the objectives of this HTA framework are:

- To institutionalise the HTA process for decision-making for health and priority setting for the allocation of scarce resources for healthcare.
- To enhance the institutional capacity of HTA.

# METHODS

# METHODS

HITAD, the Access and Delivery Partnership (ADP) and HITAP co-organised a brainstorming session (hybrid format) on 13th June 2022, to better understand the landscape of the HTA process in Bhutan and to identify the next steps in the furtherance of HTA institutionalisation in Bhutan. This session was pivotal in not only increasing the understanding of the then HTA practices in Bhutan, but also in identifying the potential stakeholders and challenges in implementation of HTA in Bhutan, both of which informed the development of the framework presented herein. Appendix G summarises the key risks and mitigation strategies identified during this session. After this session, conducting a situation analysis to better understand the current state of HTA in Bhutan emerged as the appropriate initial step to further enhance the advancement of HTA in Bhutan.

Subsequently, a meeting between HITAD and HITAP was held in conjunction with the HTAsiaLink 2022 Annual Conference in Pattaya, Thailand to outline the methodology and subsequent steps in HTA framework development for Bhutan. During this meeting, several issues were highlighted, including the existing disconnect between evidence generation and procurement of health technologies, and the increasing number of referrals in Bhutan which have implications for the use of healthcare resources available in the country. The reiteration of these challenges and the recognition of potential opportunities offered by the anticipated reforms that could facilitate HTA institutionalisation prompted a shift from the initially proposed situational analysis methodology to a desk review and consultation approach.

A desk-based review was conducted to identify and assess the HTA processes of other countries. This involved searching of PubMed and exploring grey literature, including public websites containing HTA manuals, process guidelines, and online resources such as the Guide to Economic Analysis and Research (GEAR). The findings from the review were compared with the second edition of Bhutan's HTA process guideline. Based on this desk-based review and several rounds of internal deliberation, an initial draft of the HTA framework was formulated for Bhutan.

Since contextual factors play a critical role in the development and further implementation of the HTA framework in any setting, engaging with stakeholders and gathering their inputs on the initial draft of the HTA framework was considered to ensure effective institutionalisation of HTA. Consequently, an HTA sensitisation event, accompanied by stakeholder consultation was organised in Bhutan on 28th May – 2nd June 2023. Various stakeholders who would play key roles in the implementation of HTA in Bhutan were invited to participate in this consultation. During the event, facilitated discussions were held to address the different aspects of the HTA process including the sequential steps of the process, the relevant participating stakeholders, the timeline for each stage, and different criteria and/or considerations employed at each stage of the HTA process. The proceedings of this event can be found here.

Consistent with the challenges identified during the previous consultations with the stakeholders, the need for the price determination process, the lack of connection between price determination and procurement and managing Conflict of Interest (CoI) were reiterated during this stakeholder consultation. Taking into account the suggestions and insights shared by the stakeholders, modifications were subsequently made to the HTA framework. The revised framework was finally presented to the High-Level Committee for the Health Sector (HLC-HS) for endorsement on 5th June 2023, and their suggestions were also incorporated. By engaging in this consultative process with the stakeholders responsible for HTA implementation in Bhutan, the HTA framework tailored to the specific needs and context of Bhutan was developed.

Lastly, an initial draft of the framework was shared with stakeholders and practitioners of HTA, who would be subsequently involved in the HTA process in Bhutan. They were asked to share their inputs on the clarity, completeness and feasibility for implementation of the proposed HTA framework. Recognising the significance of learning from other settings, feedback from members of other countries who are at different junctures of HTA institutionalisation was also sought. To facilitate this review, a feedback form **(Appendix H)** was provided to all reviewers alongside the initial draft of the framework. Subsequently, the HITAD and HITAP teams reviewed the inputs and discussed how to address and incorporate these comments effectively. These stakeholders also identified various factors that could influence the successful implementation of HTA in Bhutan **(Appendix I)**. Recognising and appropriately addressing these factors will be crucial during the subsequent revision of the HTA framework in Bhutan. Such a collaborative effort was aimed to enhance the overall effectiveness and smooth implementation of the HTA process in Bhutan.

# THE HTA FRAMEWORK IN BHUTAN

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## OVERVIEW OF HTA FRAMEWORK IN BHUTAN

The HTA process in Bhutan follows international practice on the main steps for HTA [11] and has been adapted for Bhutan. The HTA process begins with the proposal stage, where topics for HTA are submitted; these will then be screened, and topics will be prioritised based on certain criteria. The topics selected will then be assessed for a full assessment or a rapid assessment. The topics proposed for public health emergency purposes will be put into the expedited rapid assessment process. The assessment will be followed by a critical appraisal of evidence, with feedback provided to the research team as needed. Recommendations will then be submitted for decision-making and if the health technology is not found to be cost-effective, it will be forwarded to a price threshold determination group. The results will be disseminated and once it is approved for implementation, will follow the procurement process which will also apply to those health technologies that underwent the price threshold determination process. Once implemented, a monitoring and evaluation (M&E) system will be applied. The endorsed framework is presented in **Figure 2** and each step is described in the subsequent section. Additionally, **Appendix A** enlists the stakeholders, their roles and responsibilities at each step of the HTA process.

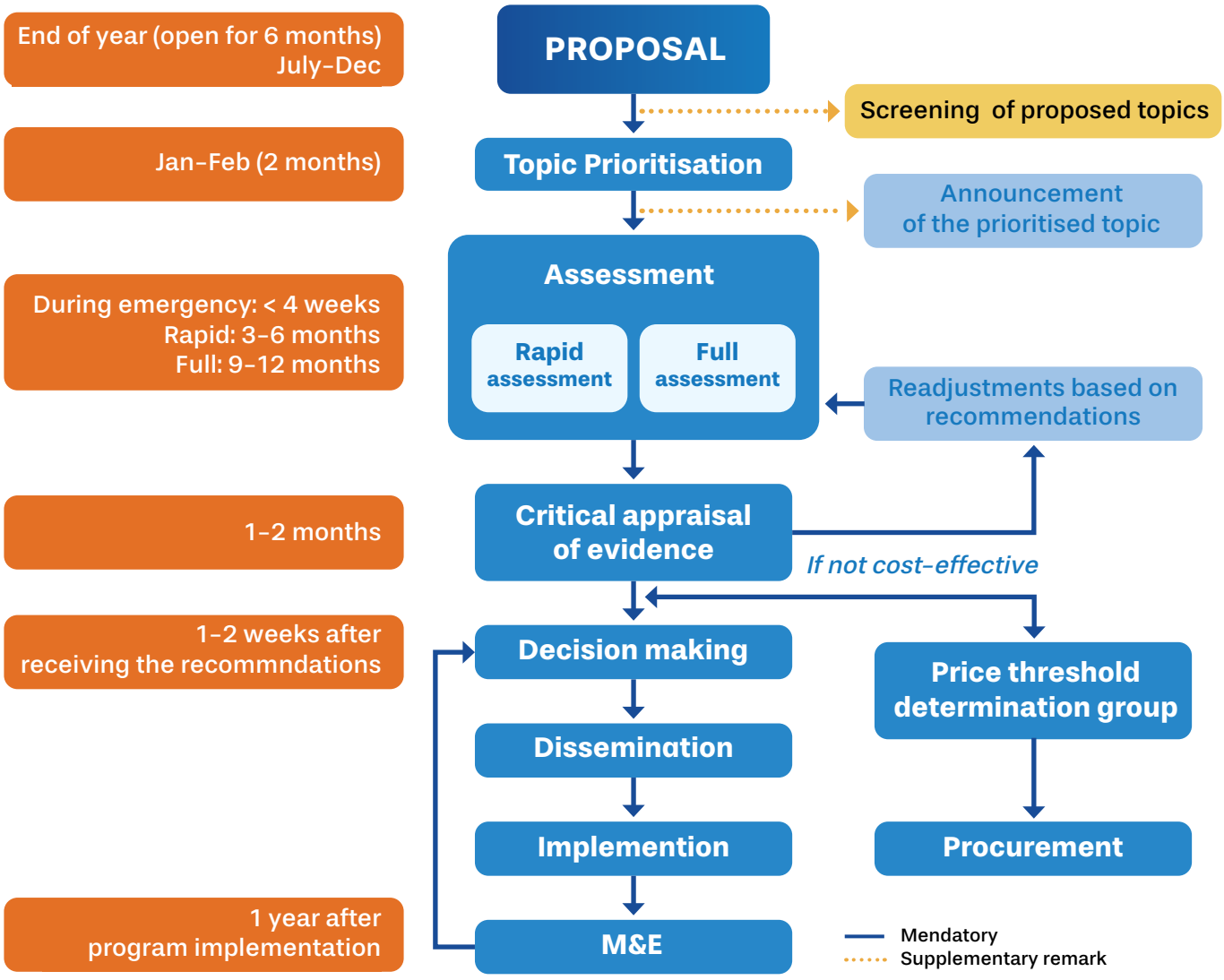


Figure 2: HTA framework along with the timeline

# HTA FRAMEWORK IN BHUTAN

## PROPOSAL SUBMISSION

The process of proposal submission (also known as topic nomination) is the process of recommending health technologies to HITAD for further assessment and appraisal.

A call for proposal submission will be issued by HITAD through website announcement and official notification through email to departments within the MoH and National Medical Service (NMS). Templates for proposal submissions **(Appendix D)** may be downloaded from the MoH website. All proposals should be submitted with supporting documents. All the submitted additional supporting documents will be subject to further review by HITAD. Any incomplete submissions will not proceed to the prioritisation stage.

### *TIMELINE*

Proposals can be submitted annually between the months of July and December, allowing for a submission period of six months. To complete the submission process, the full proposals, accompanied by any necessary supporting documents, can be sent via email to the HTA secretariat at hitad@health.gov.bt.

### *STAKEHOLDERS INVOLVED*

The proposals for health interventions and technologies can only be submitted by the departments under the MoH and departments under the National Medical Service (NMS). It must be noted that the proposals can only be made by the department, not by an individual person or entity. Any other agencies or individuals wishing to propose a health intervention and technologies may submit the ideas/proposals directly to HITAD. Based on the nature of the proposal, HITAD will be directing it to the relevant departments under the health sector for further review and submission to HITAD.

## PRIORITISATION

The process of prioritisation entails employing pre-determined criteria to identify proposals that warrant further assessment and appraisal.

Given the context of the health system, challenges and the nature of the HTA process, not all health technologies necessarily be subjected to the HTA process. Following are the situations where health technologies may be exempted from the HTA process:

- Extension of existing medicines in NEML to lower level of healthcare facilities: the National Medicines Committee will continue to be the competent authority to decide on extension of medicines in NEML.
- Health technologies for research purposes: Bhutan FDA will continue to be the competent authority to issue the certificate to use health technologies for research purpose based on safety and other parameters.

The process of prioritisation can be broken down into two main steps:

1. Proposal screening
2. Proposal prioritisation

The following section describes each of these steps

### STEP 1: PROPOSAL SCREENING

Prior to prioritising the proposals submitted to the HTA Secretariat, a preliminary screening will be conducted to exclude topics that do not align with the aim of the HTA process in Bhutan. The screening criteria encompass the following three dimensions:

1. Submission not following the framework/guideline
2. Products without any medical claims/therapeutic indications (e.g. cosmetics)
3. Not approved by functional regulatory authority for e.g., BFDA, US FDA, EU, Singapore.

### STEP 2: PROPOSAL PRIORITISATION

Once the exclusion of topics is completed, the remaining topics will be prioritized using a predetermined scoring system **(Appendix E).** This three-point prioritisation criteria have eight equally weighted dimensions, which includes:

1. Burden of Disease.
2. Infectiousness of the disease
3. Disease severity
4. Safety profile of the proposed health intervention/technology
5. Efficacy profile of the proposed health intervention or technology
6. Health impact of the proposed health technology
7. Impact on referrals
8. Alignment with national goals

The topics which obtain the highest score will be the topmost priority for the assessment and the priority decreased as the score reduces.

Apart from the pre-defined criteria, equity, prevention/health promotion, and health expenditure on disease area may also be used as additional consideration for the prioritisation of topics.

In conclusion, the step of prioritisation can be summarized as below:

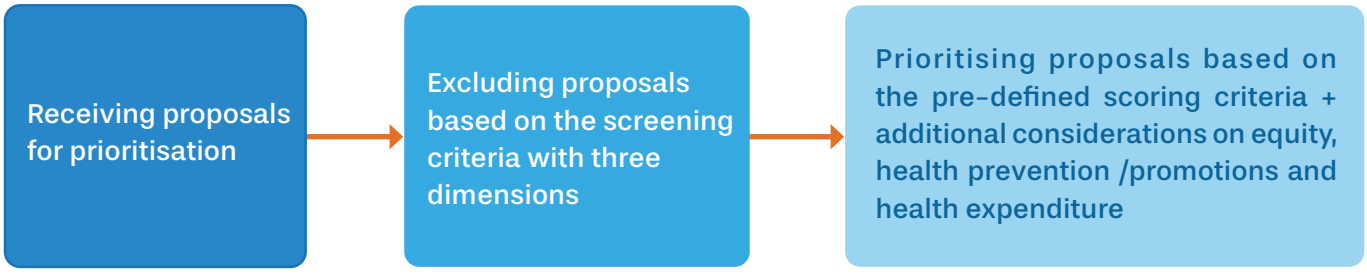


**Figure 3:** Schematic representation of the prioritisation step

In addition, it must be highlighted that the team is cognisant of health expenditure, despite being a crucial factor, is an additional consideration for prioritisation and not a primary criterion. This is because of the current absence of reliable good quality data to estimate the direct and indirect medical cost. It's important to highlight that as Bhutan advances in HTA institutionalisation, platforms for collecting relevant data for the HTA process will be established, leading to a reassessment of this prioritisation criteria.

It must be noted that the prioritisation of topics may be subject to change if supported by substantial and well-founded rationale. HITAD will maintain a record of any such deviations in ranking, with the aim of continually improving the scoring criteria to better align with the disease burden and healthcare context of Bhutan. Furthermore, the outcomes of the prioritisation process will be published on the MoH website (https://www.moh.gov.bt/) to uphold transparency throughout the entire process.

### *TIMELINE*

The two-month period, from January to February, following the closure of the proposal submission will be dedicated to the prioritisation of the submitted topics.

### *STAKEHOLDERS INVOLVED*

Upon receiving all proposal submissions, the HTA Secretariat (HITAD) will employ pre-defined criteria to prioritise the proposed topics. This prioritisation process involves reviewing all supporting materials submitted during the proposal submission stage and conducting additional targeted review of the literature to assign accurate scores to the submitted topics.

## ASSESSMENT

Assessment or evidence generation is the process of using formal scientific methodologies to evaluate the clinical and economic impact of introducing a new health technology. Depending on the nature of the health technology, available data and urgency of the situation, evidence can be generated through either rapid assessment or full assessment.

a. Rapid assessment: This refers to an expedited process of evidence generation due to time and resource constraints

b. Full Assessment: This involves a comprehensive evidence generation process, often including a valid comparator, to produce reproducible and comprehensive evidence that can inform policy makers

The format of the study that falls under the category of full and rapid assessment are as follows:

| | FULL ASSESSMENT | RAPID ASSESSMENT |
|---|---|---|
| **Clinical evidence** | • Literature review on safety, efficacy, and effectiveness | • Literature review on safety, efficacy, and effectiveness |
| **Economic evidence** | • Costing<br>• Economic evaluation<br>• Budget impact analysis | • Budget impact analysis |
| **Feasibility** | Feasibility studies on:<br>• Availability of HR/training requirement<br>• Availability of infrastructure | Feasibility studies on:<br>• Availability of HR/training requirement<br>• Availability of infrastructure |
| **Others** | • Acceptance by patience and service providers | • Acceptance by patience and service providers |
| | • Acceptance by patience and service providers | • Environmental impact (when required) |

**Table 1:** Study format for full and rapid assessment

To ensure consistency and transparency, it is critical to have explicit criteria to determine whether a rapid review or a comprehensive assessment should be conducted. These criteria are listed in Table 2.

| FULL ASSESSMENT | RAPID ASSESSMENT |
|---|---|
| • Lack of local cost-effectiveness study or conflicting evidence on safety, efficacy, and cost-effectiveness<br>• Availability of minimum local data required to conduct economic evaluation<br>• Reintroduction or disinvestment of interventions | • Public health emergency (*may not require budget impact analysis)<br>• Lack of local data if they are completely new technology in the country<br>• Expansion of existing services to other health facility<br>• Policy urgency |

**Table 2:** Criteria for full and rapid assessment

### *TIMELINE*

The timeline for completing rapid and full assessments may vary. Table 3 highlights the duration for assessment following the commissioning of the research team by HITAD.

| TYPE OF ASSESSMENT | DURATION (IN MONTHS) |
|---|---|
| Full assessment | 9–12 |
| Rapid assessment | 3–6 |

**Table 3:** Duration for completion of full and rapid assessment

### *STAKEHOLDERS INVOLVED*

Various stakeholders can be involved in the evidence generation process. The HTA secretariat typically commissions the research group responsible for conducting the assessments. This research group can consist of HITAD, Khesar Gyalpo University of Medical Science of Bhutan (KGUMSB), Royal University of Bhutan (RUB), Centre for Bhutan Studies (CBS), independent researchers, and national or international research agencies.

## CRITICAL APPRAISAL

Critical appraisal is a systematic process of evaluating the quality of evidence generated during the assessment stage and assessing its reliability and relevance to the Bhutanese context. The purpose of critical appraisal is to ensure that the research evidence is unbiased and applicable to Bhutan, which is crucial for making informed decisions. It involves a thorough examination of all aspects of the study using a predefined appraisal form.

### *TIMELINE*

The critical appraisal process is expected to be completed within a timeframe of 1–2 months. Please refer to **Appendix F** for the specific review and critical appraisal form to be used during this stage of evaluation.

### *STAKEHOLDERS INVOLVED*

The National Health Technology Appraisal Committee (NHTAC) is tasked with conducting the critical appraisal. As an independent body, the NHTAC thoroughly and objectively examines the evidence generated by the research group, assessing its quality, validity, and relevance to Bhutan. Based on their evaluation, the NHTAC formulates recommendations for:

1. Decision makers: The NHTAC provides recommendations to decision makers regarding potential policy options associated with health technology under evaluation. These recommendations aim to guide decision makers in making informed choices about the adoption of the health technology in Bhutan.
2. Research group: The NHTAC offers feedback and recommendations to the research group responsible for conducting the study. This feedback may include suggestions for necessary amendments or revisions to the study, aiming to enhance its quality, validity, or relevance for further consideration or improvement.

3. Price threshold determination group: In cases where the study demonstrates that the health technology is not cost-effective, the NHTAC provides recommendations to the price threshold determination group. These recommendations guide the determination of the maximum threshold at which the technology can be considered cost-effective within the context of Bhutan.

In summary, the NHTAC plays a crucial role in critically appraising evidence, offering recommendations to decision-makers, providing feedback to the research group, and contributing to price negotiations when necessary. The official Terms of Reference (ToR) for the NHTAC will be drawn up with reference to the mandates listed in **Appendix B and Appendix C.**

## PRICE THRESHOLD DETERMINATION

The price threshold determination process, commonly known as price negotiation process, is of paramount importance in obtaining health technologies at prices that are more affordable to the government and the consumers alike. The main objective of this step is to negotiate the price of the health technology such that it is closer to the cost-effective price and then set a price threshold for the procurement process.

A dedicated group, known as the price threshold determination group, will be responsible for this negotiation. The group will collaborate with manufacturers or suppliers to explore possibilities for reducing the price of health technology, making it cost-effective or closer to the cost-effective range. Subsequently, the NHTAC will utilise the outcomes of the price threshold determination process to develop policy recommendations for the High-Level Committee for Health Sector, who will ultimately make the final decision.

It must be noted that the price negotiation for non-cost-effective technologies will take place before reaching a final decision. Engaging in price negotiations before the government commits to procuring the health technology empowers the price threshold determination group with stronger negotiating leverage. In contrast, if negotiations for medical technologies occur after the final decision-making, it puts the industry at an advantage.

### *STAKEHOLDERS INVOLVED*

The process of the price negotiation will be undertaken by the price threshold determination group. The group consists of representatives from the:

- Bhutan Health Trust Fund (BHTF)
- Health Financing Division under the Department of Health Services (DHS)
- Department of Medical Products, NMS
- HITAD

These stakeholders will work together to engage with manufacturers or suppliers to seek ways to bring down the price of health technology and ensure it is more cost-effective.

## FINAL DECISION MAKING

This step involves the translation of evidence and policy recommendations into the final decision regarding the public funding of the health technology in Bhutan. To ensure transparency in this evidence-informed decision-making process, the following factors will be taken into consideration:

- Prioritisation criteria
- Value for money
- Budget impact
- Feasibility for the health system
- Ethical, legal and social implications

### *TIMELINE*

The decision-making process is expected to be completed within a timeframe of 1-2 weeks after receiving the recommendation from the NHTAC.

### *STAKEHOLDERS INVOLVED*

The final decision-making authority lies with the High-Level Committee for the Health Sector (HLC-HS). The decision-making will be supported by the policy recommendations submitted by NHTAC based on the evidence available.

Regarding the extension of existing medicines in the National Essential Medicines List (NEML) to lower-level health facilities, the authority responsible for approval remains with the National Medicines Committee (NMC) in accordance with the National Drug Policy (NDP) of 2007. The NMC will continue to oversee this process and determine the appropriate level of availability of medicines based on the specific health facility level and the presence of qualified healthcare professionals.

## DISSEMINATION

Dissemination refers to the vital process of conveying the results and findings of the HTA process to healthcare professionals, patients, and policymakers. This crucial step serves not only to inform users and suppliers of HTA but also plays a significant role in shaping their perspectives and behaviors towards HTA [25]. The dissemination process will involve both publishing HTA reports and broadcasting the findings through the Bhutan Broadcast Service (BBS) or announcing on MoH social media pages. By making HTA reports publicly available and utilising broadcasting on the BBS or MoH social media pages, the crucial outcomes of the assessment will reach a wide audience, ensuring effective communication of the assessment's results to healthcare professionals, patients, and policymakers.

### *STAKEHOLDERS INVOLVED*

The HTA secretariat will be tasked with the responsibility of both publishing the HTA reports and overseeing the broadcasting or announcing of the final output of HTA.

## IMPLEMENTATION AND PROCUREMENT

After the HLC-HS makes the final decision to invest in health technology, the next step is its procurement, if applicable. The procurement of health technology will adhere to the existing procurement rules and regulations of the Royal Government of Bhutan. However, it is essential to highlight that the evidence generated from the HTA process, particularly the price threshold information, must be mandatorily used during the procurement process. This ensures that the valuable insights and cost-effectiveness considerations from the assessment and appraisal are integrated into the procurement decisions, promoting informed and effective acquisition of health technology.

### *STAKEHOLDERS INVOLVED*

As per the mandate of the RGoB, procurement of the medical products will be carried out by the Department of Medical Products under NMS and the Tender Committee.

## MONITORING AND EVALUATION (M&E)

Following the implementation of health technology, it becomes crucial to assess its effectiveness within the health systems. This involves the routine collection of data based on specific indicators of progress, enabling a comprehensive assessment of the service's advancement. The process encompassing routine data collection is referred to as monitoring and the latter process of assessment of the data is known as evaluation.

This process of monitoring and evaluation works in tandem, offering a comprehensive understanding of the progress of the implementation. It provides valuable guidance on potential areas for improvement, helps identify successes, and offers valuable lessons learned, ultimately supporting informed decision-making and enhancing the overall effectiveness of the health technology within the healthcare system.

### *TIMELINE*

In conjunction with routine monitoring, the evaluation of the program or service will be conducted one year after its implementation. This evaluation process complements the ongoing monitoring efforts, providing a more comprehensive and in-depth assessment of the program's performance and effectiveness.

### *STAKEHOLDERS INVOLVED*

The routine collection of data pertaining to the clinical and non-clinical effectiveness of the implemented service or program will be the responsibility of relevant departments within the Ministry of Health (MoH). These departments include:

- National Medical Services (NMS)
- Bhutan Food and Drug Authority (BFDA)
- Department of Public Health (DoPH)
- Health Service Quality Assurance Division (HSQAD), DHS

In addition, HITAD will be in charge of evaluating the impact of the service using the data collected. This collaborative effort among these departments ensures a comprehensive and systematic approach to monitoring and evaluating the effectiveness of the implemented health service or programme.

## EXPEDITED HTA PROCESS FOR PUBLIC HEALTH EMERGENCIES

The regular HTA process, from topic proposal to the implementation of the health technology, usually takes over 12 months. However, for public health emergencies (PHE) purposes, a quick and timely response is essential for effective management. To address this need, the HTA secretariat has developed an expedited HTA framework specifically designed for public health emergencies.

In the case of a PHE, relevant health technologies crucial for the successful management of the emergency will be prioritised by technical experts. Acknowledging the significance of rapid response, the strict scoring tool for prioritisation may not be used in such situations. Instead, the technical expertise of the experts will guide the prioritisation stage.

During PHEs, evidence will be generated through rapid assessment only, with a timeframe of no more than 4 weeks. This approach adheres to the principle of evidence-based decision-making even during emergencies. While the rest of the steps in the HTA process will remain the same, the timeline for moving from nomination to implementation will be reduced to 4-6 weeks in response to emergencies.

The expedited HTA process is shown in Figure 3.

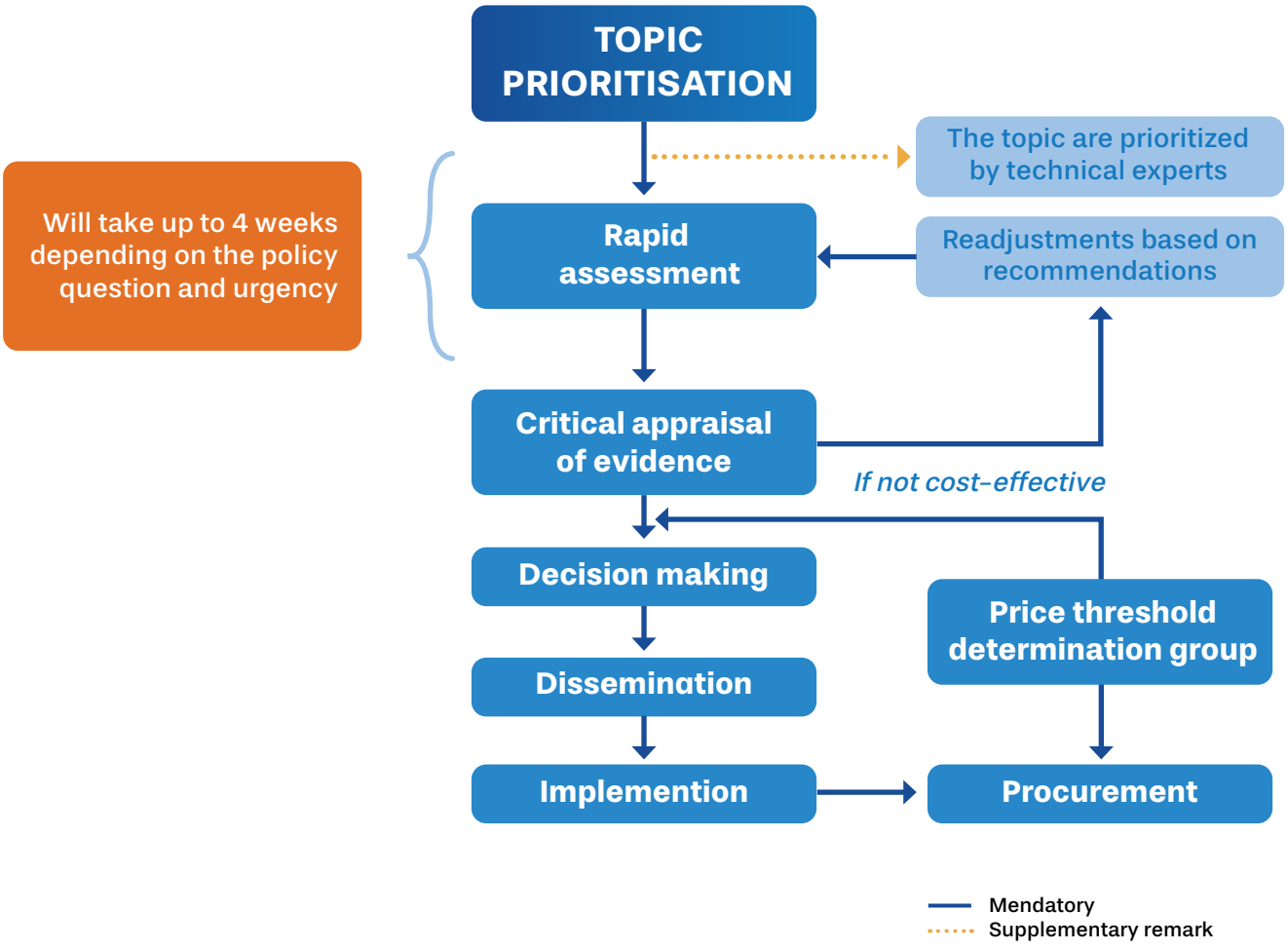


**Figure 4:** Process for rapid assessment

# HTA IN BHUTAN: FUTURE DIRECTIONS

# HTA IN BHUTAN: FUTURE DIRECTIONS

The HTA framework marks an important milestone in the development of HTA in Bhutan and is a step towards institutionalising the use of evidence to inform policy for health. Building on previous experiences and seizing this window of opportunity in Bhutan when reforms are taking place, this framework will give direction to the way forward for HTA in the country.

The immediate priority will be to establish the processes and systems for HTA based on the framework. This will involve developing forms, ToRs, lines of communication between units and a communication plan for each step of the process. Managing conflict of interests (CoI) among stakeholders involved in the process will also need to be considered and resources will need to be secured to ensure that the process and system is functional. "Road shows" with relevant teams will also need to be conducted to raise awareness on the HTA framework, address questions and ensure that there is a basic level of understanding of the process.

Crucially, a capacity development plan will need to be developed for the short, medium and long term. The different training needs of researchers and users of HTA will need to be addressed. Technical training may be conducted for researchers in the country or through short-term trainings at the regional level. On-the-job training will be most helpful, and researchers can directly apply their learnings to practice and defend their analysis to reviewers. In addition to technical skills for economic evaluations, trainings in conducting research and academic writing will also be useful. The research module at the KGUMSB can accommodate HTA training modules and serve as a capacity-building avenue to train the next generation of HTA researchers for Bhutan. Furthermore, long-term capacity-building activities such as enrollment of staff in HTA courses in nearby countries and also developing a course for HTA domestically, for example at KGUMSB, can assure a longer-term pipeline of talent within the country.

In light of the need for capacity building, HITAD and HITAP team identified some of the possible strategies for building and strengthening capacity. These were:

| | |
|---|---|
| **Short-term strategies** | • Conducting regular stakeholder sensitisation sessions<br>• Organising HTA roadshows |
| **Intermediate-term strategies** | • Providing technical training for the critical appraisal committee<br>• Providing university based structured introductory and advanced courses on HTA |
| **Long-term strategies** | • Professional development activities in the form of internships at HITAP<br>• Supporting advanced degrees on HTA and health Economics |

**Table 4:** Capacity development strategies identified by HITAD and HITAP team

In addition to the researchers tasked with producing evidence, commitment to developing the relevant skills by other participating stakeholders are crucial to the success of the HTA process in the country. Some of the additional competencies to be considered to further enhance the HTA process are:

- skills to interpret the results and understanding the broader institutional and health system context for the NHTAC;
- skills such as understanding of the price negotiation processes will be relevant to those in the price determination group; and
- communication skills to effectively engage with the stakeholders throughout the HTA process.

Concurrent with the training for the development of necessary capacity for HTA, it is of paramount importance to retain the capacity. Strategies to better involve and engage with the youth will be critical in retaining and thus sustaining the HTA process in Bhutan.

Nothing succeeds like success. Use of HTA to inform policy will increase an appreciation for use of HTA in policy. The link to policy will need to be tracked and enforced to ensure that the system works. High-level commitment to HTA will also facilitate inter-organisation coordination and use of results from the process. M&E processes can help with understanding the impact of HTA over time. Processes for ensuring accountability will also need to be established.

An extensive network has been identified as a key characteristic of a successful HTA agency [26]. Therefore, active engagement in HTA networks plays a vital role in the process of institutionalising HTA. Participation in these networks such as HTAsiaLink can provide a platform to share knowledge, experience and best practices, thus contributing to the continuous improvement of Bhutan's HTA process.

It will be important to conceive of this entire process as an eco-system, with a network of institutions involved and engaged. This system will need to be cultivated and a variety of stakeholders will need to be engaged, for example, from the MoH, academia, clinicians and others. Not only domestically, regional and global networks will also be beneficial in addressing the capacity needs in the country. The "Individual, Node (Organisational), Network and Environment" or INNE approach may be taken to develop capacity; this encompasses training, but also development of guidelines and processes (such as this framework), nurturing networks and also creating an enabling environment for HTA to flourish.

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# REFERENCES


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# APPENDICES

# APPENDICES

## APPENDIX A:
## ROLES AND RESPONSIBILITIES OF THE STAKEHOLDERS INVOLVED

| STAGES | STAKEHOLDERS | ROLES AND RESPONSIBILITIES | REMARKS |
|---|---|---|---|
| **Nomination** | • Departments from MoH<br>• Departments under NMS | • Nominate topics<br>• Submit supporting evidence as per the submission form | These nominations can only be made through their respective organisations and not individually. |
| **Prioritisation** | • HITAD | • Use the pre-defined criteria to prioritize the topics | Priotitisaton criteria will be strictly adhered by HITAD while scoring and the result would be publicized to ensure transparency |
| **Assessment** | • KGUMSB, RUB, CBS, Independent researchers, National or international research agencies | • HITAD as the secretariate will be commissioning the group for evidence generation | |
| **Critical appraisal and recommendation** | • The National Health Technology Appraisal Committee (NHTAC) consisting of:<br>o Epidemiologist (permanent member)<br>o Health economist (permanent member)<br>o Public health specialist (permanent member)<br>o Clinical experts (recruited based on the topic)<br>o Ethical experts | • NAC will be nominated on the basis of the topic of appraisal | |
| **Price negotiation** | • Bhutan Food and Drug Authority (FDA)<br>• Bhutan Health Trust Fund<br>• Health Financing Division, Department of Health Services<br>• Procurement team<br>• HITAD | • To use the results from the cost-effectiveness and budget impact analysis to negotiate a price that is closer to the cost-effective price | |

| STAGES | STAKEHOLDERS | ROLES AND RESPONSIBILITIES | REMARKS |
|---|---|---|---|
| **Final-decision making** | • High level committee for health sector | • To use the following to deliberate and make a final decision:<br>1. pre-defined criteria for decision-making<br>2. presented evidence to deliberate<br>• To take forward the decision proposal to the Ministry of Finance | |
| **Procurement** | • Department of Medical Product<br>• Tender Committee | • Procurement committee will refer to the HTA results | |
| **Dissemination** | • HITAD | • Publish cost-effectiveness/ budget impact analysis results<br>• Announce the final decision to the public | |
| **Implementation** | • NMS<br>• MOH | • To provide the included services to the public | |
| **M&E** | • Monitoring team:<br>o DHS<br>o NMS<br>o PPD<br>o BFDA<br>• Evaluating team:<br>o HLC<br>o HITAD | • Collect data on programme implementation and share the stat with the evaluation team<br>• Evaluation of the implemented services and make a decision whether a re-evaluation should inform new decisions | |

# APPENDIX B: TERMS OF REFERENCE FOR THE NATIONAL HEALTH TECHNOLOGY APPRAISAL COMMITTEE

**Title:** Terms of Reference for the National Health Technology Appraisal Committee (NHTAC)

**Name of Committee:** National Health Technology Appraisal Committee (NHTAC)

**Membership:**

The NHTAC will be composed of an operational team with the Health Intervention and Technology Assessment Division (HITAD) serving as the secretariat. The operational team will consist of three permanent members:

1. Epidemiologist
2. Health economist
3. Public health specialist
4. Clinician
5. Ethical Expert

Additionally, the committee will include other clinical experts as co-opted members. The recruitment of these experts will be based on the specific topic of appraisal under consideration.

**Mandate:**

The NHTAC shall operate with the following key responsibilities:

1. Development of Guidelines and SOPs: The committee will be responsible for creating comprehensive guidelines and Standard Operating Procedures (SOPs) for Health Technology Assessment (HTA), including the incorporation of economic evaluation and budget impact analysis for proposed health interventions and technologies.
2. Establishment of Ad-Hoc Working Groups: The NHTAC will propose the formation of ad-hoc working groups, as needed, to address specific tasks or topics assigned by the committee.
3. Quality Review and Appraisal: The NHTAC will conduct a thorough review of HTA reports submitted by research teams, ensuring their quality, accuracy, and relevance to the proposed health technologies.
4. Recommendation to price threshold determination group: In cases where the study demonstrates that the health technology is not cost-effective, the NHTAC provides recommendations to the price threshold determination group. These recommendations guide the determination of the maximum threshold at which the technology can be considered cost-effective within the context of Bhutan.
5. Policy Recommendations: Upon conducting the HTA, the committee will translate research findings into policy recommendations. It shall prepare a policy brief, including executive summaries and policy recommendations, for the proposed health technologies. These recommendations will be submitted to the High-Level Committee for Health Sector (HLC-HS) to inform decision-making. In this process, the committee will take into consideration various factors, such as the system's readiness, the urgency of health policies, alternative treatments, ethical considerations, and political implications.
6. Additional Tasks: The NHTAC may be assigned other tasks by the High-Level Committee for Health Sector (HLC-HS) to address health technology appraisal matters.

# APPENDIX C: TERMS OF REFERENCE FOR THE PRICE THRESHOLD DETERMINATION GROUP

**Title:** Terms of Reference for the Price Threshold Determination Group

**Name of Committee:** Price Threshold Determination Group

**Membership:**

The Price Threshold Determination Group shall consist of an operational team, with the Health Financing Division and Department of Medical Products serving as the secretariat. The operational team will include representatives from:

1. Bhutan Health Trust Fund
2. Health Financing Division
3. Department of Medical Products
4. Health Intervention and Technology Assessment Division

**Mandate:**

The Price Threshold Determination Group shall operate with the following key responsibilities

1. Assessing Health Technology Cost-Effectiveness: The group will be responsible for assessing cases in which a health technology is considered not cost-effective due to its high price, as indicated by the results from the Health Technology Assessment (HTA) report.
2. Engaging with Manufacturers and Suppliers: The committee will initiate discussions with manufacturers or suppliers to explore the feasibility of adjusting the price of the health technology to align it closer to a cost-effective threshold, as identified in the HTA report.
3. Establishing Price Threshold: Based on the outcomes of the discussions, the Price Threshold Determination Group will determine the optimal price threshold at which the manufacturers or suppliers can viably provide the health technology.
4. Producing a Price Threshold Report: The committee will compile a comprehensive report detailing the process and findings of the price threshold determination. This report will be submitted to the National Health Technology Appraisal Committee (NHTAC) for appraisal and further consideration.
5. Collaboration with Tender Committee and Procurement Agency: The Price Threshold Determination Group will collaborate with the tender committee and the procurement agency (Department of Medical Products) to share the established price threshold. This information will be utilised during the procurement process to ensure cost-effective acquisition of health technologies.

# APPENDIX D: PROPOSAL SUBMISSION FORM

This is the submission form for proposing new health technologies or interventions intended for use in healthcare system within Bhutan. Kindly be informed that the proposal can only be submitted by the departments under the Ministry of Health (MoH) and departments under the National Medical Service (NMS), not by an individual person or entity. Any other agencies or individuals wishing to propose a health intervention and technologies may submit the ideas/proposals to the relevant departments under NMS or MoH.

Through this form, the proponent will have the opportunity to (i) propose or nominate any health technology they consider essential for inclusion in the Bhutan's healthcare system and (ii) provide relevant additional information for the Health Technology Assessment (HTA) Secretariat's consideration.

Please note that health technologies encompass medical devices, medicines, medical services, public health programs and medical and surgical procedures aimed at aiding in disease prevention, diagnosis, treatment, and rehabilitation.

Instructions

The proponents must complete four sections of the submission form, which include: (i) Proponent Details, (ii) Details of the Proposed Health Technology, (iii) Details of the Current Standard of Care and (iv) Checklist of Topics Addressed in the Supplementary Information Document.

To be considered for further assessment, proponents are required to submit all relevant additional information as a separate document titled "Supporting document." Incomplete submissions without supplementary information will not be eligible for consideration.

Please refer to the appendix for the list of topics that should be highlighted in the "supplementary information" document.

Please submit the duly filled application form and the relevant supplementary information electronically to hitad@health.gov.bt.

**For any further clarification, contact:**

Health Intervention and Technology Assessment Division (HITAD)
Department of Health Services
Ministry of Health
Kawajangsa, Thimphu
Email: hitad@health.gov.bt

SECTION 1: PROPONENT DETAILS

1) Name of the proposing Department:
    - ○ Department of Public Health
    - ○ Department of Clinical Services
    - ○ Department of Biomedical Engineering
    - ○ Department of Medical Product
    - ○ Department of Health Service
    - ○ Royal Centre for Disease Control
2) Telephone: .....
3) Email address: .....

SECTION 2: DETAILS OF THE PROPOSED HEALTH TECHNOLOGY

1) Type of the proposed health technology
    - ○ Pharmaceutical
    - ○ Medical device for diagnosis or treatment
    - ○ Public health Intervention

2) Type of proposal
    - ○ New introduction of new health technology
    - ○ Expansion of existing health technology
    - ○ Upgradation of existing health technology
    - ○ Removal or deletion of existing health technology

3) Name of the Proposed Health Technology

    .....

4) Disease / Condition in which the Health Technology will benefit

    .....

5) Target population that the proposed Health Technology will serve

    .....

6) Level of health facility till which the Health Intervention and Technology is to be made available or removed from
    - ○ National Referral Hospital
    - ○ Regional Referral Hospital
    - ○ Cluster Hospital
    - ○ District Hospital
    - ○ 10–bedded hospital
    - ○ Primary Health Center

SECTION 3: DETAILS ABOUT THE CURRENT STANDARD OF CARE

1) Are there any existing health technologies or interventions in the health system of the country for the prevention or diagnosis or treatment of the condition mention in question 3 under section II?
   - ○ Yes
   - ○ No

2) If YES, please indicate the existing health technology in use

   .....

3) Please specify whether the proposed technology will substitute or add to the currently existing technologies
   - ○ Substitute
   - ○ Add

SECTION 4: CHECKLIST OF TOPICS ADDREESED IN THE SUPPLEMENTARY INFORMATION DOCUMENT

1) Please indicate the topics on which you have given addition relevant information in the supplementary information document
   - ○ Burden of disease
   - ○ Infectiousness of the disease/condition
   - ○ Severity of the disease/condition
   - ○ Adverse events associated with proposed technology along with those associated with the current standard of care.
   - ○ Efficacy of the proposed technology along with the efficacy of the current standard of care.
   - ○ Improvement in the Quality of Life (QoL)
   - ○ Proportion of referrals related to the disease/condition in the past 5 years.
   - ○ Alignment of the disease/condition with the national 5-year strategy or plan.

Applicant Signature Date

APPENDIX

Please provide evidence-based, accurate, and up-to-date information concerning the following:

1) Burden of disease in the targeted population in the last five years.
2) Infectiousness of the disease/condition being prevented/diagnosed/treated by the health technology (if applicable).
3) Severity of the disease/condition (e.g., mortality rate) being addressed by the health technology.
4) Adverse events associated with proposed technology along with those associated with the current standard of care.
5) Efficacy of the proposed technology along with the efficacy of the current standard of care.
6) Improvement in the Quality of Life (QoL) attributed to the proposed technology.
7) Proportion of referrals related to the disease/condition being prevented/diagnosed/treated by the health technology in the past 5 years.
8) Alignment of the disease/condition being addressed with the national 5-year strategy or plan.

Note that the additional information can be submitted as a separate document.

# APPENDIX E: CRITERIA FOR TOPIC SELECTION

| S.no | CRITERIA | INDICATORS | 1 | 2 | 3 |
|---|---|---|---|---|---|
| 1 | Burden of disease | Prevalence | 0–10% | >10 – 20% | >20% |
| 2 | Infectiousness of the disease | Use the National Early Warning, Alert Response Surveillance (NEWAR) system | Mild | Moderate | Severe |
| 3 | Disease Severity | Mortality (% of total number of cases) | 0–1% | >1–2% | >2% |
| 4 | Safety profile of proposed health intervention or technologies | No. of adverse events resulting from the interventions | 1/10 | 1/100 | 1/1000 |
| 5 | Efficacy profile of proposed health intervention or technologies | Percentage | 0–30% | 30% - <=80% | >80% |
| 6 | Health impact of the proposed health technology* | Improvement in life expectancy and QoL | Prolong life & no improvement in QoL | Prolong life & improvement in Quality of Life (QoL) | Cure (back to normal condition) |
| 7 | Impact on referral | Proportion of referral in last five years | 5–15% | 15–30% | >30% |
| 8 | Aligning with National Goals | Either it is mentioned in the national plans document | Not included in any national strategy or plan | Complements a national strategy or plan | Yes, included in any national strategy or plan |

**Note:** *This criterion may not be used for health prevention and promotion technologies

# APPENDIX F: RESEARCH QUALITY REVIEW AND APPRAISAL FORM

RESEACH QUALITY REVIEW AND APPRAISAL

The members of the National HT Appraisal Committee, hereafter referred to as "reviewer", will use this document to (i) objectively and critically assess the quality of the study and (ii) provide transparent comment on their assessment of the study.

Instructions

The reviewers are asked to complete 9 questions including: (i) reviewer's name, (ii) project name, (iii) clarity of the study proposal, (iv) methodological rigour, (v) coherence of the results and policy recommendations (vi) quality of research work, (vii) suggested revisions, (viii) whether the study should be considered for policy recommendation and (ix) additional comments.

Reviewers are expected to maintain objectivity while critically appraising any given study.

Reviewers are expected to critically appraise a given study across several study attributes, listed in the Appendix.

Research critique form for the Reviewer

1. Reviewer's name:

2. Project name:

3. Provide your opinions regarding the research question, background, rationale and objectives.
   *Please provide detailed feedback on the strengths and weaknesses of these sections of the study. You may refer to the appendix for the list of attributes to consider during your evaluation.*
   .....
   .....
   .....
   .....
   .....

4. Provide your opinions regarding the research methodology, data analysis, economic evaluation, and sensitivity analysis.
   *Please provide detailed feedback on the strengths and weaknesses of these sections of the study. You may refer to the appendix for the list of attributes to consider during your evaluation.*
   .....
   .....
   .....
   .....
   .....

5. Provide your opinions regarding the conclusions, and policy recommendations.
   *Please provide detailed feedback on the strengths and weaknesses of these sections of the study. You may refer to the appendix for the list of attributes to consider during your evaluation.*
   .....
   .....
   .....
   .....
   .....

6. Overall opinion about the quality of this research work, please choose from the following options:
   - ○ The study is of high quality and does not require any changes
   - ○ The study is of moderate quality and must be improved/revised/expanded upon
   - ○ The study lacks sufficient quality for any further consideration

7. If you suggest that the study requires improvement, revision, or expansion, kindly list the specific revisions you would like to witness.
   *This may include, but not restricted to, enhancements to the reporting quality of the study, modifications to model parameters, or the inclusion of additional uncertainty analysis.*
   1. .....
   2. .....
   3. .....
   4. .....
   5. .....

8. Should the study be employed to inform policy recommendations.
   - ○ Yes
   - ○ No

9. Please provide the reason for your response
   *Please assess the relevance and importance of the study within your specific context when considering its suitability for policy recommendations. You may highlight any other aspect of the study that you would like to recommend for further consideration by the Secretariat.*
   *Apart from the quality of the study, you may take into account ethical, legal, or political considerations that may influence its applicability. Other attributes that may be considered include (i)the degree of uncertainty related to specific parameters, which may necessitate gathering more data to strengthen the conclusions, (ii) conducting additional scenario analyses that focus on a controllable variable for policy-setting purposes and monitoring parameters that exhibit high levels of uncertainty.*
   .....
   .....
   .....
   .....
   .....

Applicant Signature Date

Appendix

An overview of specific attributes that can be considered in addressing questions 3, 4 and 5 is provided in Table 1. These attributes can serve as a framework to aid the reviewers in evaluating the study.

Please keep in mind that these attributes are not exhaustive, and you are encouraged to emphasise aspects that are not included in the list below.

| 3. Provide your opinions regarding the research question, background, rationale and objectives. | 4. Provide your opinions regarding the research methodology, data analysis, economic evaluation, and sensitivity analysis | 5. Provide your opinions regarding the conclusions, and policy recommendations. |
|---|---|---|
| Research question<br>• Clearly stated research question that is relevant for health policy<br>Background<br>• Clearly described broad context of the study<br>Rationale<br>• Clearly stated the policy or decision problem<br>• Clearly justified rationale for the study<br>Objectives<br>• Clearly defined and measurable study objective<br>• Study objective consistent with the decision problem | Research methodology<br>• Clearly stated research methodology<br>• Research methodology used in the study is appropriate to answer the stated policy problem<br>Data analysis<br>• Model parameters generated by appropriate statistical and epidemiological techniques<br>• Estimates of baseline outcomes, relative treatment effects, resource use, and cost of resources from the best available source<br>Methods of economic evaluation<br>• Appropriate choice of comparator(s) & interventions<br>• Appropriate choice of the model<br>• Reasonable modeling assumptions<br>• Use of relevant health outcome<br>• Use of sufficiently long time horizon<br>• Use of relevant analytical perspective<br>• Inclusion of all relevant resources and costs based on the chosen analytical perspective<br>• Use of recommended discount rates for both costs and outcomes<br>Uncertainty analysis<br>• Relevant analysis conducted to account for uncertainty | Conclusion and policy recommendations<br>• All analytical parameters i.e., values, ranges and references reported<br>• Consistency of the conclusions with the data presented<br>• Justified recommendations |

**Table 1:** Additional attributes to be considered for study appraisal.

Table 1 was developed following the review of established reporting guidelines and quality appraisal tools for economic evaluation. These included the Consolidated Health Economic Evaluation Reporting Standards 2022 (CHEERS 2022), the Criteria for Health Economic Quality Evaluation (CHEQUE) tool, the Guidelines for Authors and Peer Reviewers of Economic Submissions to the BMJ by Drummond et al., the guideline provided by The National Institute for Health and Care Excellence (NICE), and the Recommendations for Conduct, Methodological Practices, and Reporting of Cost–effectiveness Analyses by Sanders et al.

# APPENDIX G: RISK FOR HTA IMPLEMENTATION IN BHUTAN AND MITIGATION MEASURES

The following table highlights the risk and the corresponding mitigation methods identified during the brain storing session held on 13th June 2022

| RISKS | MITIGATION |
|---|---|
| Low political commitment | Advocacy and sensitisation to policy makers and leaders |
| Lack of suppliers, economy of scale | Increased stakeholder involvement through collaboration and partnership |
| Lack of capacity to conduct HTA | Strengthen HTA capacity– exchange of best practices |
| Heavily reliant on external evidence and experts | Clear HTA guideline (inclusion and exclusion HTA criteria) |
| Unclear policy and guideline | Seek consultations at different levels ensure transparency |
| Inadequate data–baseline information | Strengthen data management system |
| Delay in projects | Classify types and levels of HTAs |

## APPENDIX H: CONSULTATION FORM

### CONSULTATION FORM
### REQUEST FOR COMMENTS: Updated Health Technology Assessment framework for Bhutan

**INFORMATION**

Thank you for participating in this feedback gathering process for the Health Technology Assessment (HTA) framework for Bhutan.

Through this review process, we are interested in your inputs on:

1. Coherence and clarity of this HTA framework
2. Completeness and relevance of the HTA framework
3. Implementation and Feasibility
4. Any additional comments that need to be addressed

Please note that the comments collected through this process will be used to improve and update the HTA framework for Bhutan. Comments regarding the framework itself fall outside the scope of this feedback gathering process.

**SUBMITTING YOUR RESPONSE**

Please use this consultation form to provide your comments. Please note that the questions are meant to assist your review, but you are welcome to include any other suggestions or comments that may not be covered by these questions. You do not have to provide comments for all sections.

Consultation responses and requests for further information should be emailed to Mr. Pempa at pemba@health.gov.bt by end-of-day, **August 23, 2023.**

We welcome feedback from interested individuals and institutions. However, we regret that we won't be able to respond to individual comments or suggestions.

Your co-operation in this regard is appreciated.

**ABOUT YOU**

To help us understand your comments better and acknowledge your contributions, please share information on you and your organisation. If providing comments as a group, please list all relevant contributors.

| PARTICULAR | RESPONSE |
|---|---|
| Name(s) | |
| Position(s) | |
| Organisation | |
| **Type of organisation** | *Select one*<br>○ Ministry of Health<br>○ Other health agencies<br>○ Research institute or academic organisation<br>○ Public / patient advocacy group<br>○ Industry<br>○ Regulatory body<br>○ Other |

**COMMENTS ON THE HTA framework guideline**

Please provide your specific comments about the HTA framework guideline below. Please note that the provided questions are meant to assist your review, but you are welcome to include any other suggestions or comments that may not be covered by these questions.

Section 1: Coherence and Clarity

| |
|---|
| 1. Do you have comments on the overall structure of the framework guideline? Is it coherent and easy to understand? |
| *Response:* |
| 2. Which sections or parts of the guideline, if any, do you find unclear or difficult to understand? Please provide specific details. |
| *Response:* |
| 3. Are there any inconsistencies or contradictions within the guideline that you noticed? If yes, please specify. |
| *Response:* |
| 4. Are there any factual inaccuracies that should be corrected in this HTA framework? |
| *Response:* |

Section 2: Completeness and Relevance

| |
|---|
| 1. Do you feel that the guideline covers all relevant aspects of the HTA process adequately? |
| *Response:* |
| 2. Are there any areas or topics that you believe this framework should address but have not been included? If so, kindly describe them. |
| *Response:* |
| 3. Are there any sections that you think should be added to the framework? |
| *Response:* |

Section 3: Implementation and Feasibility

| |
|---|
| 1. Based on your expertise and experience, are there any factors that should be considered while implementing this HTA framework? |
| *Response:* |
| 2. Based on your expertise and experience, do you foresee any challenges in implementing this HTA framework? |
| *Response:* |

Section 4: Additional Comments

| |
|---|
| 1. Do you have any other general comments, suggestions, or improvements for this HTA framework? |
| *Response:* |

# APPENDIX I: THE STAKEHOLDER-IDENTIFIED FACTORS FOR SUBSEQUENT REVISIONS OF THE HTA FRAMEWORK

The adaptability of the HTA framework to effectively meet emerging needs and a specific context is essential for ensuring the long-term viability of the process. Consequently, it is imperative to address the concerns raised by both HTA suppliers and users. To this end, the initial draft of the HTA process was shared with stakeholders from Bhutan, India, and Thailand. These stakeholders identified various factors that could influence the successful implementation of HTA in Bhutan. Recognising and appropriately addressing these factors will be crucial during the subsequent revision of the HTA framework in Bhutan.

The following table highlights some of the factors highlighted by the stakeholders that can be considered during the subsequent revisions of the HTA framework:

| HTA STEPS | SUGGESTIONS |
|---|---|
| Overall HTA process | • Strategies can be developed to increase stakeholder buy-in and engagement in the HTA process, e.g., budget allocation for advocacy and awareness |
| Prioritisation | • The proposed scoring criteria can be revised to better address the gaps that are identified during the initial stages of its use |
| Final decision-making consideration | • Equity can be considered as an explicit criterion for final decision making |
| Dissemination | • Systemic way of disseminating the evidence generated not only within Bhutan but also to the global community can be devised |
| Separate HTA process for donated health technologies | • HITAD is currently developing a document that can guide the introduction and assessment of donated health technologies in Bhutan. The document awaits MoH endorsement. |

# BHUTAN
# HEALTH TECHNOLOGY ASSESSMENT FRAMEWORK

**SEPTEMBER 26, 2023**

HEALTH INTERVENTION AND TECHNOLOGY ASSESSMENT DIVISION (HITAD),
MINISTRY OF HEALTH, BHUTAN