

Advancing evidence-based decision-making in Bhutan: development of a health technology assessment framework

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Summary

Bhutan is currently transforming its health system and has updated its Health Technology Assessment (HTA) framework. This revision is designed to prioritize health initiatives and ensure the sustainability of the health system. This updated framework has been developed through an iterative process involving a desk-based review and stakeholder consultations at the beginning and after the development of the draft framework. The framework outlines the stages of the HTA process and identifies the stakeholders with their roles and responsibilities. The framework has been contextualised to Bhutan's needs and has been endorsed by the high-level decision-making authority for the health sector. The experience highlights diverse challenges and solutions including international collaborations for the institutionalisation of HTA and the lessons learned from this process offer insights for HTA efforts in other settings.

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Introduction

In the pursuit of the Sustainable Development Goals (SDGs) by 2030, many Low- and Middle-Income Countries (LMICs) are striving to advance Universal Health Coverage (UHC).¹ This realisation of UHC hinges upon the evidence-informed allocation of scarce healthcare resources.² Health Technology Assessment (HTA) emerges as a pivotal tool in this context of evidence-informed resource allocation. HTA aids policymakers in making informed decisions about healthcare resource distribution by evaluating the effectiveness, cost, and impact of healthcare technologies.³ Its role is increasingly recognised as fundamental in guiding LMICs towards effective and sustainable healthcare solutions for achieving UHC.⁴

The cornerstone of Bhutanese UHC lies in the constitutional mandate to provide free basic public health services. This positive policy environment for UHC was further supplemented by the establishment of the Essential Drugs Program in 1989 to ensure access to quality medicines and improve its supply system. Subsequently in 2008, aligning with the World Health Assembly (WHA) resolution⁵ advocating for the use of HTA for achieving UHC, the Essential Medicines and Technology Division (EMTD), now Health Intervention and

Technology Assessment Division (HITAD), was designated as the national HTA body. The National Health Policy 2011 further mandated the use of HTA for the introduction of new health technologies in the country. In 2013, HITAD issued the first edition of the national HTA process guideline, detailing the HTA process along with the roles and responsibilities of stakeholders involved which was later revised in 2018.⁶ Notably, this supportive policy environment facilitated the evidence-informed decision on introduction of the pneumococcal conjugate vaccine (PCV)⁷ and the rotavirus vaccine⁸ for children into the national routine immunisation services for children under five years of age since 2018 in Bhutan.

However, much like other low-resource settings, the lack of technical capacity, difficulty in achieving adequate buy-in for HTA institutionalisation from stakeholders, and insufficient funding for HTA have impeded the progress of HTA in Bhutan.⁹ These challenges are compounded by other additional barriers specific to the country. These include: (i) small market size affecting Bhutan's purchasing and negotiating power; (ii) limited technical capacity coupled with the lack of retention of technical expertise in the country; (iii) limited link between evidence generation and procurement of health technologies; and (iv) a large number of referrals to other countries, given the right to health. These challenges have affected the feasibility of implementing the previously developed

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HTA process. Thus, an updated HTA framework designed to address some of these issues became imperative.

In the wake of the newly introduced Civil Service Reforms Act of Bhutan, the Government spearheaded transformations in the health sector. This transformation aimed to distinguish the policy formulators and policy implementors. The Department of Health Services (DHS) as the nodal agency within the MOH was tasked with the former, while the National Medical Service (NMS), an autonomous agency from the MOH mandated for service provision was tasked with the latter ([Supplementary Material 1](#)). The core mandates of the DHS, under which HITAD is situated, include guiding HTA or evidence synthesis for health technology adoption and informing policy actions, developing policies and guidelines for investment planning in the health system, and ensuring access to equitable, accessible, and affordable quality healthcare services sustainably. Distinguishing these departmental mandates helped minimize conflicts of interest between HTA producers and users, thus creating an enabling environment for transparent, accountable, and trustworthy use of HTA evidence into policies.

These reforms coupled with the recurring challenges faced while implementing the existing HTA process guideline provided a window of opportunity to update the national HTA framework by leveraging the institutional changes to support contextual needs. This manuscript describes the process of developing this HTA framework for Bhutan, highlights key features of the framework, and discusses challenges and potential solutions in this process. We believe lessons shared in paper will be useful to those striving to institutionalize HTA into decision-making process in their settings. This undertaking was led by HITAD with technical support from the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand and supported by the Access and Delivery Partnership (ADP) which is hosted by the United Nations Development Programme (UNDP). We utilised the following steps to develop the framework.

Preliminary stakeholder engagement

Preliminary stakeholder consultation with prospective producers and users of HTA (i.e., policymakers, HTA suppliers, healthcare professionals, academia, pharmaceutical companies, development partners, and patient representatives) was organised by HITAD and UNDP Bhutan in June 2022 in Bhutan, with HITAP joining remotely. The objective of this consultation was to gain deeper insights into the existing practises of HTA in Bhutan, identify the challenges in HTA institutionalisation, and map the solutions to address these challenges.

During the consultation, participants were divided into breakout groups to brainstorm on predefined

questions. These questions focused on the strengths and weaknesses of the existing HTA process guidelines, lessons learned from their implementation, stakeholder identification and their roles in HTA, and challenges along with potential mitigation measures. The outcomes from these group discussions were subsequently deliberated upon and validated in a larger groups. During this meeting, there was a consensus on the need to update the HTA framework to better suit Bhutan's context and incorporate wider stakeholders' viewpoints. The entire exercise was documented as a record of discussion.

Review of international guidelines

A targeted desk-based review was conducted to identify and understand the HTA processes of select countries. The primary objective of this review was to assess different HTA processes and compare them with the Bhutan HTA framework, i.e., the second edition of Bhutan's HTA process guideline. A pragmatic search was conducted to identify the relevant documents. The search involved consulting the website of the HTA bodies of the selected countries and accessing the HTA methods guide. Specifically, HTA manuals and guidelines of Thailand,¹⁰ the Philippines,¹¹ Singapore,¹² and the United Kingdom¹³ were reviewed at this stage. The primary reason for the selection of these countries was their recognised success in establishing and integrating HTA systems within their respective healthcare frameworks. Given the time limitations, only a few countries were selected for this review.

Data on steps in the HTA process, prioritisation criteria, timeline for each step in the process and assessment methodologies employed in other settings were extracted and reviewed during this step. Despite the contextual differences, studying these different models of HTA allowed us to identify practices that could potentially be adapted to Bhutan's context. A comparison of different HTA frameworks from these countries can be found in [Supplementary Material 2](#).

Stakeholder consultation

A stakeholder consultation and HTA sensitisation workshop was organised in Bhutan from 28th May to 2nd June 2023. The objectives of this meeting were to inform the benefits of using HTA in decision-making and to gather inputs from relevant stakeholders on the initial draft of the HTA framework. The workshop followed the practises of using workshops as a research methodology,¹⁴ utilizing a collaborative participation mode to ensure inclusivity and active engagement from all participants. Participants were carefully selected to ensure diverse representation among HTA stakeholders, including both users and suppliers of HTA in Bhutan. During the workshop, facilitated discussions were held in small groups to address the different aspects of the HTA process including the sequential steps

in the HTA process, the relevant participating stakeholders, the timeline for each step, and the different criteria and/or considerations employed at each stage of the HTA process. The discussions were facilitated by experts in the field of HTA ensuring active participation and targeted discussion. On the final day, the updated framework, informed by discussions during the workshop, was presented for verification and additional inputs. Detailed notes and audio recordings were taken during the workshop for data collection. The collected data was analysed to identify key suggestions and the findings from the workshop were internally deliberated to inform revisions to the initial draft of the HTA framework.

Comprehensive review of feedback and finalisation

After the consultation, a report detailing the updated HTA framework, based on the above steps, was prepared. The initial draft of the framework was shared with stakeholders and practitioners of HTA, from Bhutan as well as other countries. They were asked to share their inputs through a feedback form (see [Supplementary Material 3](#)) on the clarity, completeness, and feasibility of implementation of the proposed HTA framework. The feedback was systematically categorised and analysed, with major suggestions incorporated into the final version of the framework.

Results

Based on the desk-based review and several rounds of deliberation, an initial draft of the Bhutan HTA framework was formulated. The newly developed framework is detailed below.

HTA framework for Bhutan

The HTA framework for Bhutan consists of eight main stages: (i) proposal submission (topic nomination), (ii) topic screening and prioritisation, (iii) assessment, (iv) critical appraisal of evidence and recommendations to decision-makers, (v) decision-making, (vi) dissemination by broadcasting the findings through the Bhutan Broadcast Service (BBS) or announcing on MOH social media pages, (vii) implementation, and (viii) ongoing monitoring and evaluation. Additionally, all the health technologies suggested to be not cost-effective following the critical appraisal of the evidence will be subjected to an additional price negotiation step. The framework identifies all the relevant stakeholders involved in each stage of the process, along with their roles and responsibilities. Furthermore, acknowledging the urgency of decision-making during public health emergencies (PHE), the framework outlines a rapid assessment process to be used for decision-making in cases of PHEs. This enables the decision-making process to be rooted in evidence while also enabling timely decision-

making during emergencies. [Fig. 1](#) illustrates the HTA framework for Bhutan.

Key features of the new HTA framework

Some of the new features of the HTA framework in comparison to the previously published second edition of the HTA process guidelines are:

Alignment of the HTA process with the budgetary cycle

Financing of HTA was frequently cited as a challenge in institutionalising HTA in Bhutan. Financing of HTA in this context refers to the financial requirements of relevant departments to conduct all activities associated with the assessment of the proposed health technologies, including conceptualisation of the assessment, data collection, and analysis along with the continued stakeholder consultation throughout the HTA process. To address this barrier, the steps in the HTA process align with the fiscal and procurement cycle of Bhutan. This ensures the timely allocation of budgets to relevant departments, facilitating the effective operationalisation of HTA. To illustrate, the Ministry of Finance (MOF) requests budget submissions from various departments between January and March annually. With the new framework, topic prioritisation will be finalised by February, enabling informed budget proposals to the MOF for financing activities pertaining to the assessment of all the prioritised topics.

Context-specific prioritisation criteria

Given the human and financial constraints within the Bhutanese context, assessing all proposed health technologies is not feasible. Hence, it is important to develop a system that can prioritise the health technologies for assessment. The new HTA framework employs a three-point scoring system consisting of eight components for prioritisation (see [Supplementary Material 4](#)), with the highest-scoring health technology taking the top priority.

Additionally, it is significant to prioritise health technologies based on a set of components that are contextually relevant while also ensuring effective and transparent resource allocation. To this end, the components in prioritising the proposed technologies are reflective of the health system challenges of Bhutan. For example, it was identified that the high number of referrals from Bhutan to other countries was a major cause of financial strain for the health system of the country. This led to the inclusion of 'impact of referral' as one of the components used in prioritisation, where a higher rate of referral linked to a specific condition targeted by the health technology corresponds to a higher score. Additionally, for the HTA system to be consistent with the political commitment and the national health strategies of the country, one of the components for prioritisation is the proposed health technology's alignment with the national health action

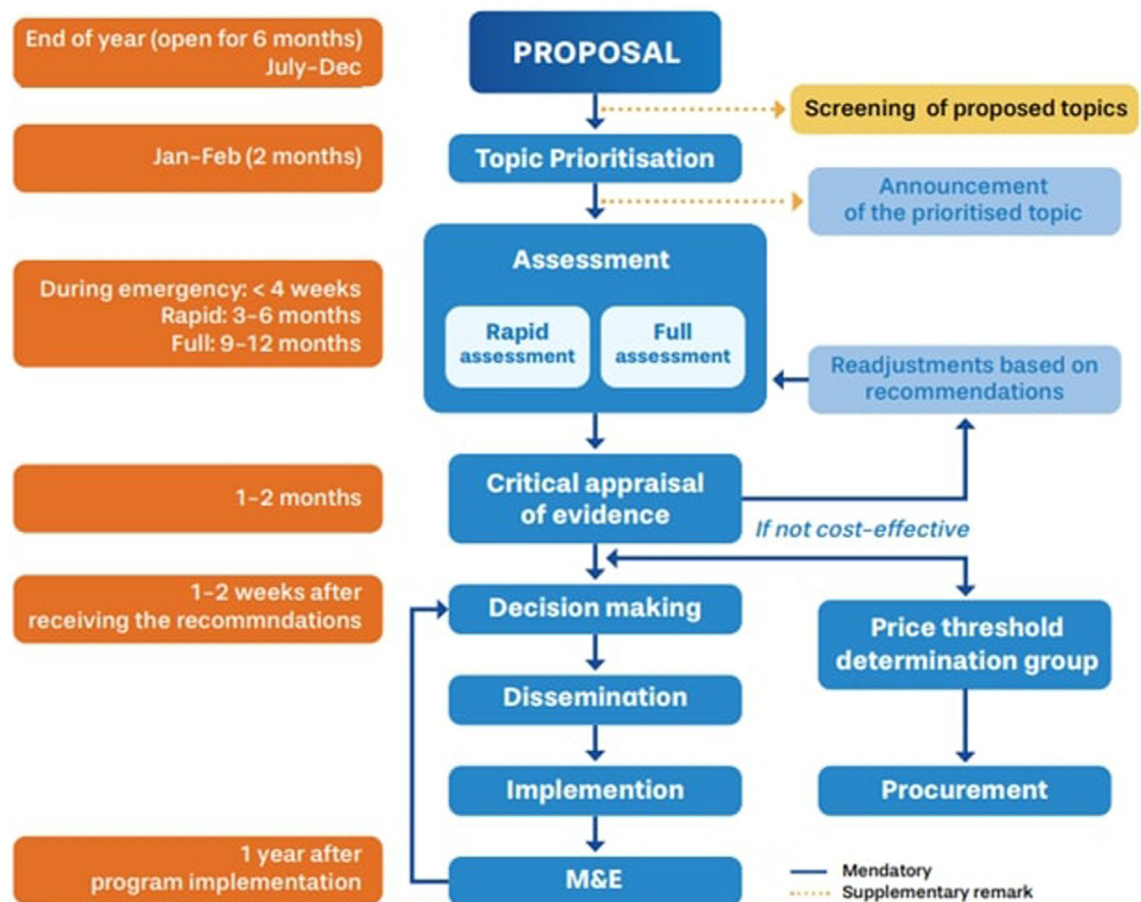


Fig. 1: The HTA Framework of Bhutan along with the timeline.

plan. That is, a technology that facilitates the realisation of health commitments in the national strategy receives a higher score than one that does not.

Development of the Price Threshold Determination Group

To address the disconnect between recommendations from HTA and procurement, the Price Threshold Determination Group (PTDG) was established. The group is composed of representatives from the Bhutan Health Trust Fund (an autonomous fund that supports the financing of all essential medicines and vaccines for the country), Health Financing Division, Department of Medical Products and HITAD. Key responsibilities of the PTDG include: (1) collaborating with the tender committee and the procurement agency to ensure that the procurement of the health technology aligns with the evidence from HTA; and (2) negotiating the price of the non-cost-effective health technologies with the industry using the threshold price (price at which the intervention becomes cost-effective) recommended by HTA. This approach of oversight of the procurement process by a committee enables the translation of HTA evidence into informed procurement choices.

Collaborative effort in evidence generation

The lack of technical capacity to generate evidence has limited the institutionalisation of HTA in Bhutan. In the new framework, this challenge is addressed by the provision to involve stakeholders beyond the MOH in the evidence-generation process. HITAD's HTA secretariat can commission research groups from Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB), the Royal University of Bhutan (RUB), the Center for Bhutan Studies (CBS), independent researchers, and national or international research agencies to assess health technologies, ensuring timely availability of evidence to support decision-making in the absence of adequate human resources. The list of stakeholders involved in each stage of the HTA process is highlighted in [Supplementary Material 5](#).

Discussion

Bhutan has been taking steps to institutionalise HTA to fulfil its constitutional mandate to provide healthcare to its population in a sustainable manner. In the context of ongoing reforms, an HTA framework was developed

based on a desk-based review of HTA processes in other countries, a review of existing processes in Bhutan, deliberations with national stakeholders and input from international experts. This multi-step deliberative and participatory process ensured that different perspectives were incorporated into the framework, while also offering an opportunity for the stakeholder to learn from each other's views.¹⁵ Such a participatory and deliberative process can ensure a certain degree of ownership of the final output to those actively engaged in the process.¹⁵ Notably, this approach also revealed additional contextual information that had not been identified through the desk review.

The framework delineates the steps, roles and responsibilities of stakeholders, and provides templates for practical implementation of HTA in the country. The framework was finally endorsed by the highest decision-making body in the health sector in Bhutan on 5 June 2023. The framework was published in the Bhutan MOH website and also disseminated to relevant stakeholders through official correspondences. Lastly, it must be noted that the framework will be updated periodically to ensure its relevance to the country's context. The approach used in developing the HTA framework in Bhutan offers several lessons that may be relevant for other settings at different stages of HTA institutionalization. These key lessons are detailed below.

Bridging the disconnect between evidence generation and health technology procurement to address low bargaining power

A barrier observed in Bhutan during the period of implementation of the first edition of the HTA process guideline was the disconnect between HTA recommendations and procurement decisions. The disconnect between HTA research findings and policy recommendations is a commonly encountered challenge in various contexts.⁹ However, Bhutan presented a distinctive issue wherein the HTA guideline did not provide recommendations on how the assessment findings would inform the procurement process. Consequently, instead of the HTA results failing to translate into policies, Bhutan encountered the unique challenge of the procurement decision not aligning with the HTA findings. Furthermore, the procurement process that occurred after the public payer committed to procuring the health technology, coupled with the small market size also adversely affected the nation's negotiation power. To address this barrier, the current framework prescribes the PTDG to collaborate with the stakeholders who make the procurement decisions to ensure that the health technology is procured as per the benchmarked price that is cost-effective for Bhutan. Also, the new HTA framework ensures that the price negotiation for non-cost-effective technologies takes place before the public payer commits to its procurement. Engaging in price negotiations before the payer commits to

procuring the health technology ensures stronger negotiating leverage. In contrast, if negotiations for medical technologies occur after the final decision-making, it puts the industry at an advantage.

Similar approaches of collaboration between different stakeholders involved in the HTA process to ensure that the procurement process is in line with the evidence generated can be seen in other settings as well. For instance, in both Italy and the UK, the HTA report for medical devices is to be used as the most reliable source of information about the safety and cost-effectiveness of the device during the procurement process, thus directly linking the HTA and procurement.¹⁶ Additionally, the example of price negotiation before the government commits to include a particular medicine in the reimbursement list is seen in Thailand.¹⁷

While these solutions help bridge the disconnect between evidence generation and procurement, the feasibility and efficiency of this approach depend on the trust and efficiency of the collaboration between different committees. Thus, in addition to embedding the solution in the HTA framework, it is important to continually sensitise all relevant stakeholders about the need for close collaboration for the sustainability of UHC when adopting such strategies.

Leveraging the window of opportunity to integrate HTA into the decision-making process

The adoption and implementation of HTA are inherently political decisions, where alignment with political agendas and commitment can significantly influence institutionalisation. A pivotal lesson drawn from Bhutan's experience in HTA institutionalisation underscores the crucial importance of seizing the window of opportunity to facilitate its integration into the policy landscape.

In Bhutan, the original plan for formulating the HTA framework and initiating the deliberative process was scheduled for a later date. However, issues such as low levels of accountability in service provision, overlapping mandates among different departments, and the need for enhanced efficiency in public service delivery led to reforms within the MOH. These reforms created a unique opportunity to elevate the importance of HTA as a policy solution. Recognizing this opportunity, the decision was made to align the development of the HTA framework with the ongoing reforms. By doing so, Bhutan aimed to set the political agenda for HTA institutionalisation, effectively capitalizing on the window of opportunity presented during this period of transformative changes.

A similar example of seizing the window of opportunity to further push the agenda for HTA can be seen in other settings as well. Taking Ethiopia as an example, in response to challenges in HTA institutionalisation, the MOH in Ethiopia strategically incorporated HTA as

a key component of the Health Sector Transformation Plan (HSTP II).¹⁸ This deliberate integration of HTA into the broader health policy framework is reflective of leveraging the new opportunities to further advance HTA.

These experiences highlight that the institutionalisation of HTA is not a one-size-fits-all process. Instead, it necessitates a keen understanding of the local political context and a proactive approach in aligning with broader health sector reforms. Seizing the window of opportunity, as demonstrated in these examples, becomes paramount for successful HTA institutionalisation, ensuring its effective contribution to evidence-informed decision-making in healthcare resource allocation.

Strategic planning to facilitate further advancements in the HTA process

Furthermore, a pivotal learning from Bhutan's experience in HTA institutionalization is the need to proactively identify challenges in the new HTA framework and subsequently develop strategic plans to mitigate them. Some of the significant challenges with the new HTA framework and their mitigation strategies deliberated and identified are as follows:

1. The current HTA framework addresses the lack of sufficient technical capacity by engaging with various stakeholders to leverage their clinical, public health, and political expertise for evidence generation. However, it is critical to identify a plan to increase the capacity in the country for the sustainability of the HTA ecosystem in Bhutan. To this end, different strategies for building and strengthening capacity have been identified. Short-term strategies focus on raising awareness and gathering support for HTA from diverse stakeholders. These include conducting regular HTA sensitisation workshops and organising HTA roadshows. Mid-term strategies aim to bolster technical proficiency within the nation. This includes offering specialised training for the critical appraisal committee and introducing structured introductory and advanced HTA courses at universities. Finally, long-term strategies involve professional development opportunities such as internships at established HTA agencies outside the country.
2. The cost of illness, regardless of being a crucial factor in decision-making, is not a primary criterion in prioritising the health technologies for assessment. The team recognises the importance of having this as a criterion but is cognisant of the absence of reliable good quality data to access that in Bhutan. While the present framework does not explicitly consider the cost of illness while prioritising interventions for evaluation, strategies for the

development of platforms for collecting relevant data for the HTA process will be established, leading to a reassessment of this prioritisation criteria.

Impact and implications for the health system

The updated framework is poised to have profound long-term effects on the country's healthcare system. By aligning closely with national health priorities and the budgetary cycle, this framework is expected to enhance the allocation of limited healthcare resources, directing them toward cost-effective and equitable interventions that yield the greatest benefit.

Strengthened evidence generation through improved capacity of both evidence generator and users, and strategic price negotiations for health technologies will foster more systematic and evidence-informed policy decisions. These decisions will be better aligned with the country's strategic health goals, ensuring that investments in health are not only efficient but also impactful in terms of providing better health outcomes. Existing interventions and policies can also be optimized under this framework to maximize health outcomes, ensuring that Bhutan's health system remains both sustainable and effective.

This also brings to the forefront the need for continuous monitoring of the health intervention or technology once introduced in the system to understand the intended and unintended consequences of a policy decision and to ensure that HTA can cater to the dynamic needs of the health system of the country. Understanding the importance of M&E, the new HTA framework for Bhutan has identified the stakeholders and timeline for the periodic evaluation of the health interventions and technologies and integrated that into the work plan of the HTA mechanism. However, in addition to the identification of the stakeholders and defining their roles, it is imperative for Bhutan to further identify and describe the indicators of success for the evaluation of the services.

Going forward, monitoring the implementation of the HTA framework in Bhutan will also be important and additional mechanisms will need to be considered. As a first step, building capacity for HTA is being implemented, as recommended in the HTA framework.

Building collaborative partnerships for HTA institutionalisation

Another lesson learned from Bhutan's HTA journey is the importance of fostering close working relationships with external partners to bridge the human and financial resource gaps. Recognising its limited technical capacity for HTA, HITAD partnered with external agencies like Thailand's HITAP and joined networks like the HTA-siaLink (a community of HTA researchers in Asia-Pacific) to strengthen Bhutan's local HTA capacity. This has provided Bhutan avenues to receive training, engage

with other HTA researchers, co-conduct HTA studies, and take lessons from other settings. Such international partnerships not only address the capacity gaps in the country but can also enhance the credibility and legitimacy of a country's HTA efforts, thereby increasing political buy-in.

However, such partnerships require resources and in the absence of domestic funding for HTA research, development partners can play a crucial role. In Bhutan's case, the Access and Delivery Partnership (ADP) has supported the institutionalisation of HTA in the country.¹⁹ Such effective partnerships, however, require (i) alignment of priorities between the funders and recipient country to allocate funds efficiently, (ii) good understanding of the local context and stakeholders involved by the technical partner to ensure fit-for-purpose support is being provided, (iii) setting realistic milestones between the recipient country and the technical partner such that both parties are accountable to the funders, and (iv) strong and active commitment by the recipient country to ensure momentum and support from the funders and the technical partners do not fade away.

This approach of triangular collaboration between domestic HTA agencies (or MOH in certain cases), international technical partners, and funders has proven to be effective while institutionalising HTA and has been adopted by several countries including India, Indonesia, Philippines, Ghana, and Kenya to name a few.²⁰ While this approach can be useful in the short to medium term, it is essential to (i) build technical partners within the country (through local universities) who routinely conduct HTA and (ii) have dedicated domestic funding for HTA research (either from MOH budget or through domestic research funders) to sustain the use of HTA in policymaking in the long run. The revision of this framework took approximately nine months with minimal budget and involved three HITAD staff, three HITAP staff, and one UNDP country focal person. Despite not being a typical research undertaking, such activities can be time consuming and resource intensive (especially if technical partners are needed). Hence, commitment and persistence from all parties involved and setting a realistic timeline will be beneficial.

Lastly, while the development of the updated HTA framework for Bhutan was conducted through a multi-method qualitative approach, the methodological limitations must be acknowledged. A key strength of the development process was its participatory approach, which fostered a sense of ownership among stakeholders, crucial for successful implementation. However, this inclusivity also introduced potential limitations. Firstly, the stakeholder consultation process may have been subject to inherent biases, with responses potentially influenced by participants' personal and professional experiences and perspectives. Secondly, conformity bias may have occurred during group

discussions, where some participants might have conformed to the opinions of more dominant voices, potentially skewing the outcomes.

Additionally, the desk-based review focused on a limited number of international HTA guidelines, which, may not fully capture the diversity of global HTA practices, particularly in other low- and middle-income countries. The development process was also conducted within a constrained timeline and with limited resources, possibly affecting the depth of analysis and stakeholder engagement.

Conclusion

The process of HTA institutionalisation in Bhutan showcases the multifaceted nature of the challenges encountered in HTA institutionalisation while underscoring that there is no universal solution to address these challenges. Engaging effectively with the producers and end-users of evidence from HTA to co-create a framework that is contextually relevant and practically applicable is paramount in HTA institutionalisation in any setting. However, sustainable use and growth of HTA in the country demands investment into strengthening local capacity and dedicated funding for research. Lessons shared in this paper from the process of developing a national HTA framework may be useful to other countries embarking on a similar journey.

Contributors

AP, Pempa, KCS, SD and UT conceptualised the study. AP, KCS and SD planned and managed project execution. AP conducted the review and consolidation of international guidelines. AP, Pempa, TD and KCS drafted the manuscript. All authors critically reviewed and edited the manuscript. All authors reviewed the revised version of the manuscript for submission. KCS and SD were responsible for funding acquisition. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Declaration of interests

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Appendix A. Supplementary data

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