Concept Note for HTA guideline Project (A stepwise guide for HTA guideline development)

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Background and rationale

Countries have committed to providing affordable, quality essential health services to all by 2030, through the 2012 United Nations resolution on universal health coverage (1). In low- and middle-income countries (LMICs), health technology assessment (HTA) is increasingly being adopted as a multi-disciplinary policy tool to inform decisions around the set of health products and services governments provide (2-4), often referred to as the health benefit package. Establishing HTA as the basis for national health priority setting requires countries put in place legal and governance frameworks for using HTA in decision-making, as well as mechanisms and capacity building for data collection, analysis, and evidence appraisal by relevant stakeholders (2, 5).

National HTA methods and process guidelines (hereon in referred to as HTA guidelines) have been identified as a key factor in establishing a well-functioning HTA system (6, 7).

- A *HTA process guideline* details the steps to identify and conduct HTA studies, with the aim to promote good governance of HTA research. HTA processes generally follow the steps of (i) topic priority setting, (ii) assessment and appraisal of health technologies, (iii) dissemination of results and recommendations, and (iv) monitoring and evaluation. HTA process guidelines may also include principles of HTA (e.g., transparency, accountability, timeliness, inclusiveness, quality, consistency, and contestability), mechanisms for stakeholder engagement and deliberative processes, and governance framework (e.g., roles and responsibilities of different institutions in the conduct of HTA).
- *A HTA methods guideline* details methodological and reporting standards, including setting out a reference case to ensure consistency and quality of HTA studies. Depending on country-specific decision criteria, the guideline may entail methods for clinical and economic assessments; evaluation of social, legal, and ethical implications; or health systems impact of a technology.

While many high-income countries (HICs) have already developed HTA guidelines (8), this is not the case for most LMICs.

A number of resources already exist for countries seeking to develop their own HTA guidelines. The Practical Guide on Evidence-Informed Deliberative Processes sets out a comprehensive set of considerations for defining a process for HTA (9). ISPOR and GEAR both host links to national methodological guidelines for HTA and/or economic evaluation (8, 10, 11), with Sharma et al. having completed a comparison of economic evaluation guidelines across countries (12). The iDSI Health Technology Assessment Toolkit also provides general guidance for compiling HTA evidence and initiating an inclusive, transparent and consistent process for HTA, targeted at technical staff (13), whilst WHO has developed a more generic guide for institutionalising HTA (14). A number of reviews of aspects of methodological guidelines exist, such as incorporating utility data (15-17), implementation challenges (18), ethical and equity considerations (19-22), or uncertainty (23, 24), as well as reviews for specific

technologies, such as medical devices and orphan oncology drugs (20, 25-28). Other reviews have also compared criteria (29) applied in different countries and specific elements of HTA processes, such as disinvestment mechanisms (30), or multi-criteria decision analysis to weigh up trade-offs (31). However, to our knowledge, there exists no specific guidance for the development and successful adoption of good quality HTA methods and process guidelines. In particular, there is a gap in terms of how to start, set up the system, and evaluate the impact for HTA guidelines.

Aim and Objectives

This project aims to provide stepwise practical guidance and recommendations for LMICs developing or updating national HTA methods and/or process guidelines.

Specific objectives include:

1. To synthesise best practice (key consideration) and lessons learned from country experience in developing and implementing HTA guidelines,
2. To generate a comprehensive and pragmatic set of recommendations for technical stakeholders in LMICs seeking to develop national HTA methodological and/or process guidelines for their country.

Scope of work

The focus of HTA in this project is HTA for benefit package design. The main output will be a step-by-step guide for HTA methods and/or process guideline development, starting from key considerations in the initial phase to support the set-up of a conducive environment for good HTA, steps to follow including key literature and reference during the stage of generating guidelines, and recommendations in the implementation phase after the guidelines are developed. Please see also the conceptual framework of the project in **figure 2**. Institutional arrangements and policy statements/legal frameworks are outside the scope of this project.

However, this project recognises that the HTA guideline development has shown to be a part of or a crucial factor driving the HTA institutionalisation process for functioning HTA system[1]. Simultaneously, the success of the guideline can also be influenced by the overall institutionalisation. Although the success is context-dependent, in this case it was defined as the ability of the guideline to help generate good quality HTA studies that inform policy, improve clinical practice, and the perceived legitimacy and longevity of HTA.

[1] World Health Organization. Regional Office for the Western Pacific. (2015). Factors conducive to the development of health technology assessment in Asia : impacts and policy options. WHO Regional Office for the Western Pacific. https://apps.who.int/iris/handle/10665/208261
Kim, T., Sharma, M., Teerawattananon, Y., Oh, C., Ong, L., Hangoma, P., Adhikari, D., Pempa, P., Kairu, A., Orangi, S., & Dabak, S. V. (2021). Addressing Challenges in Health Technology Assessment Institutionalization for Furtherance of Universal Health Coverage Through South-South Knowledge Exchange: Lessons From Bhutan, Kenya, Thailand, and Zambia. Value in health regional issues, 24, 187–192. https://doi.org/10.1016/j.vhri.2020.12.011

Beneficiaries of this work

Our primary audience is technical staff in the Ministry of Health or HTA agency of an LMIC, charged with introducing and institutionalising HTA for universal health coverage in their country, as well as local or international agencies providing support for the development of HTA guidelines.

This project is not specific to certain country contexts, in terms of stage of HTA institutionalisation, mandate of HTA, insurance and payer systems, or decentralisation. During Phase 1: setting up a conducive environment for good HTA (see figure 2 below), we intend to outline considerations based on country profile, including whether there are any pre-requisites to help generate a good local guideline that promotes good quality HTA for policy at a later stage.

The project mainly aims to support countries that do not currently have HTA guidelines, but we expect that many of our findings will also be relevant for countries in the process of updating their HTA guidelines. Whilst our focus is on providing guidance and recommendations for LMICs, we will not initially limit our data collection and evidence review, since published literature or case studies/experiences from HICs may also be applicable to LMIC settings.

Approach and method

This project will synthesise the experience of countries that have developed, or are in the process of developing or revising, national HTA guidelines. We plan to employ semi-structured interviews, supplemented by desk review (figure 1), to identify conducive factors and barriers to the development and successful implementation of good quality HTA guidelines. Potential interviewees may include representatives from HTA agencies and policymakers who have been involved in HTA guideline development and implementation, HTA researchers who have provided support in country HTA capacity building, and among others (see also table 2). The snowball technique will also be used to identify further interview samples. We plan to utilise existing platforms and HTA networks (e.g., InaHTA, HTAsiaLink, etc.). Although this is context-dependent, in this study, we will consider success as having a HTA guideline that produces quality studies that inform clinical practice and policy, and that it helps improve the perceived legitimacy of the HTA process.

Proposed outputs

An important component of this work will be to support technical counterparts to navigate their local context, in terms of facilitating factors that they can leverage and potential barriers that they should be aware of and plan for. The main output will be a stepwise framework for how to develop HTA guidelines across three phases: before guideline development (key principles and pre-requisites to generate a good environment for HTA guideline development), during guideline development (guiding through key resources across different criteria, as well as best practice for involving stakeholders and reviewing guideline quality), and after guideline development (including monitoring and evaluation, communication and dissemination, and training). See figure 2.

Although the framework will be stepwise, it can also accommodate countries that are in various stages of HTA development, as they do not necessarily need to start from the phase 1. The outputs are anticipated to also inform technocrats on guidance to leverage their available opportunities and fit to their context constraints, supporting the success of the guideline development.

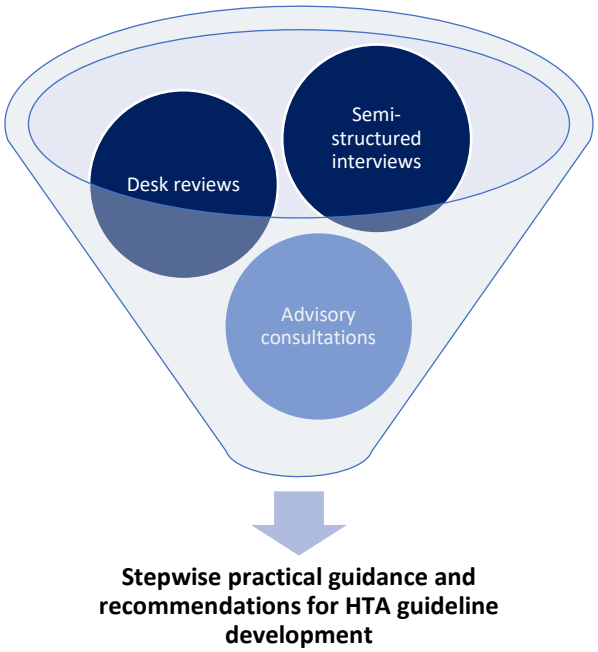

Figure 1 Overview methods planned for this project

Current working structure

Advisory Group Members: *(alphabetical order)*

1. Prof. Anna Vassall, London School of Hygiene & Tropical Medicine (LSHTM), United Kingdom (UK)
2. Prof. Anthony Culyer, the National Institute for Health and Clinical Excellence (NICE), and the Office of Health Economics, UK
3. Prof. Edwine Barasa, KEMRI-Wellcome Trust Research Programme, Kenya
4. Dr. Gavin Surgery, Radboud University Medical Center, The Netherlands
5. Dr. Gihan Hamdy El-sisi, HTA office and Faculty of Pharmacy, Future University, Arab Academy for Science and Technology & Cairo University, Egypt
6. Dr. Hugo Turner, Imperial College London, UK
7. Dr. Izzuna Mudla Bt Mohamed Ghazali, the Malaysian Health Technology Assessment Section (MaHTAS), Malaysia
8. Dr. Jasmine Pwu, Fu Jen Catholic University and Taipei Medical University, Taiwan
9. Prof. Kun Zhao, Division of Health Policy Evaluation and Technology Assessment, CNHDRC, China
10. Dr. Manuel Espinoza, Pontificia Universidad Católica de Chile, Chile
11. Dr. Oresta Piniazhko, HTA Department, State Expert Centre of MOH, Ukraine
12. Prof. Shankar Prinja, Post Graduate Institute of Medical Education and Research (PGIMER), India
13. Dr. Somsak Chunharas, National Health Foundation (NHF), Thailand
14. Prof. Tracy Merlin, the International Network of Agencies for Health Technology Assessment (INAHTA) and the University of Adelaide, Australia
15. Dr. Wija Oortwijn, Radboud University Medical Centre, the Netherlands
16. Dr. Ying-Li Chen, Centre for Drug Evaluation (CDE), Taiwan
17. Dr. Yot Teerawattananon, Health Intervention and Technology Assessment Program (HITAP) and National University of Singapore (NUS), Singapore

Role of the Advisory Group:

1. provide strategic guidance to the project team,
2. advise on synthesis of results and recommendations,
3. leverage their networks to solicit input from important stakeholders throughout the process,
4. actively engage in producing and reviewing the final manuscripts and guidance document or other outputs produced,
5. disseminate findings to relevant stakeholders.

Project Members: *(alphabetical order)*

1. Dr. Angela Kairu, KEMRI - Wellcome Trust
2. Dr. Diana Beatriz Samson Bayani, NUS
3. Ms. Kanchanok Sirisorn, HITAP
4. Ms. Kinanti Khansa Chavarina, HITAP
5. Mr. Manit Sittimart, HITAP
6. Ms. Siobhan Botwright, HITAP

The role of the project team:

1. develop the project plan and protocol,
2. conduct the research, draft the recommendations, and write the final guidance/manuscript.
3. act as the secretariat for the advisory group.

Figure 2 A conceptual framework of the project: a stepwise guide to HTA guideline development

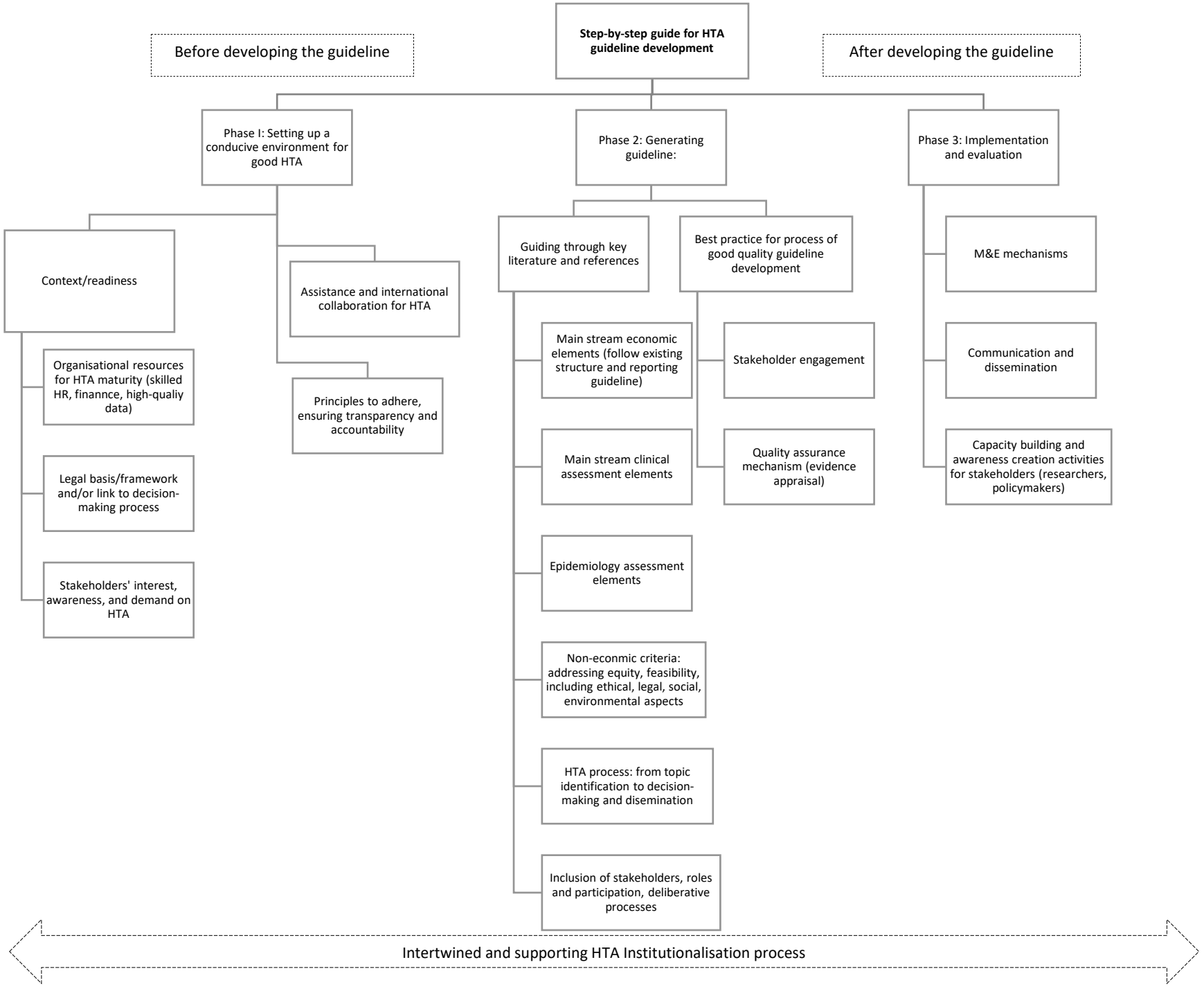

Table 1 Timeline of the project (expected to complete within 1.5 years)

Activities	Indicators	Timeframe														
		2022							2023							
		Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Concept note development	▪ Concept note															
Advisory Group (AG) formation	▪ AG convened															
Protocol development	▪ Protocol developed															
Ethics application	▪ Ethical approval submitted															
2nd AG consultation	▪ AG meeting conducted															
Data collection*	▪ Interview participation confirmed ▪ Interviews conducted ▪ Interview scripts developed															
Data analysis	▪ Preliminary analysis results ▪ Final analysis results															
3rd AG consultation	▪ AG meeting conducted															
4th AG consultation	▪ AG meeting conducted															
Knowledge dissemination	▪ Draft output ▪ Policy Brief ▪ Webinar/information session (TBC)															

*Activities included semi-structured interviews supplemented by desk-reviews; green indicates current stage whereas blue is upcoming stage and plan.

Table 2 Overview of countries recruited in the data collection (desk-reviews/interviews)

		Current status of HTA methods/process guideline			
		HTA methods guide launched (~3-4 countries)	**HTA process guide Launched (~3-4 countries)**	**Started but not launched**	**Currently developing/revising**
Samples from		**Brazil, South Africa, Indonesia, The Philippines, Colombia, Canada, Tunisia, New Zealand, India**	**Brazil, Ghana, Indonesia, The Philippines, Colombia, Canada**	**Vietnam**	**the Netherland**
Type of key informants	**User of guide**	**Researcher(s) that conduct HTA studies in the country**	**Member of agency/ department with HTA secretariat function**	**N/A**	**N/A**
	Developed guideline content	**e.g., author of the guide or member of a technical working group developing content for the guide**			
	Coordinated guideline development process	**e.g., member of the secretariat team for the guideline development process**			

Note: these criteria are not mutually exclusive, meaning same participants may meet more than one criterion

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