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An Outcome Evaluation of the Philippine Health Technology Assessment Program

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Abstract

The passage of the UHC law in 2019 mandated the creation of the Health Technology Assessment (HTA) Program to identify and recommend the most cost-effective health technologies for the Philippine government to procure. Since its inception, the HTA has mostly assessed COVID-19 related technologies. But with changing demands, current HTA processes must be evaluated for its relevance and usefulness post-pandemic, and performance relative to international best practices. More importantly, there is a need to assess far-reaching impacts of pricing and procurement on end-users themselves. Given these indices, this study reviewed HTA policies and assessed outcomes through end-user responses. Special attention was given to the utilization, assessment, and satisfaction with the processes, reports and recommendations of the HTA.

The HTA roadmap has been delayed by multiple factors, including changes in leadership and the COVID-19 pandemic. However, end-users still utilize HTA assessments and recommendations in agenda-setting, policy-formulation, decision-making, and procurement. This was especially apparent for technologies related to COVID-19. But despite these achievements, much can be improved. HTA must navigate through the challenges of inadequate local data. It must also consider adopting international best practices and adding human resources to increase capacity for assessments and improve current processes. Finally, the program must transition to essential medicine and technologies for high-burden diseases and widen its scope, given its value to agencies involved in improving public health.

Keywords: health technology assessment, HTA, outcome evaluation, Philippines

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Abstract

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The HTA roadmap has been delayed by multiple factors, including changes in leadership and the COVID-19 pandemic. However, end-users still utilize HTA assessments and recommendations in agenda-setting, policy-formulation, decision-making, and procurement. This was especially apparent for technologies related to COVID-19. But despite these achievements, much can be improved. HTA must navigate through the challenges of inadequate local data. It must also consider adopting international best practices and adding human resources to increase capacity for assessments and improve current processes. Finally, the program must transition to essential medicine and technologies for high-burden diseases and widen its scope, given its value to agencies involved in improving public health.

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Introduction

Provisions for the institutionalization of the health technology assessment (HTA) program were driven by the goal of building a cost-effective and equitable healthcare system (Congress of the Philippines, 2019). With the passage of the Universal Health Care (UHC) Law, there is a need for such evidence-based guidance in procurement and purchasing, especially with the country's long and controversial history of similar activities, which had far-reaching consequences on the general population. In 2016, the government purchase of P3.5B worth of dengue vaccines (Dengvaxia) despite inconsistencies with recommendations of a scientific panel halted the immunization program, compromised public funds and eroded public trust in government and medicine, which manifested in patterns of vaccine hesitancy (Cepeda, 2017). In response, the Department of Health (DOH) created the Health Technology Assessment Council (HTAC), but its iteration coincided with the SARS-CoV-2 pandemic in 2020. Resources were thus mobilized to prioritize recommendations for covid-related RT-PCR tests, antibody tests, medicines, vaccines, procedures, and antigen tests. With expedited processes, recommendations for 32 covid-related technologies were crafted over a span of two years.

With a decrease in demand for covid-related assessments, the HTA is transitioning back to its pre-pandemic roadmap, which sought to transfer the program from the DOH to the Department of Science and Technology (DOST) within a three-year period. However, both agencies have yet to develop an operational plan to support and actualize task delegation and transfer.

In planning for the said transition, it is crucial to assess how effective the HTA program has been in influencing policy decisions on technology procurement over the past two years. Cost-effectiveness studies have been utilized to measure the impact of HTA recommendations, but these studies are both complex and time and resource-consuming to carry out. A practical alternative would be to instead evaluate translatability of recommendations into policy decisions, through the following indices: use in agenda-setting and policy formulation and implementation, engagement, and communication, and fit within the healthcare system. (Millar et al., 2021). By examining these mechanisms, it is possible to measure the progress of the program towards its goals.

This report aims to evaluate the effectiveness of the process through which HTAC recommendations are translated into policy decisions. This will be done by evaluating the end-users' utilization, knowledge, and satisfaction with the service and technical products produced by the program. Findings will likewise be juxtaposed with mandates of the UHC Law and international best practices. This review will be the first of its kind.

The study seeks to provide useful insight to relevant stakeholders, particularly the DOH and the DOST, regarding the HTA program: how recommendations are effectively translated into

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policy decisions, how it is progressing toward the fulfillment of the UHC Law mandates, and whether investments to the infrastructure are justified or not. Furthermore, it aims to contribute to the efforts in improving interagency transition and the HTA program overall.

HTA in the Philippines

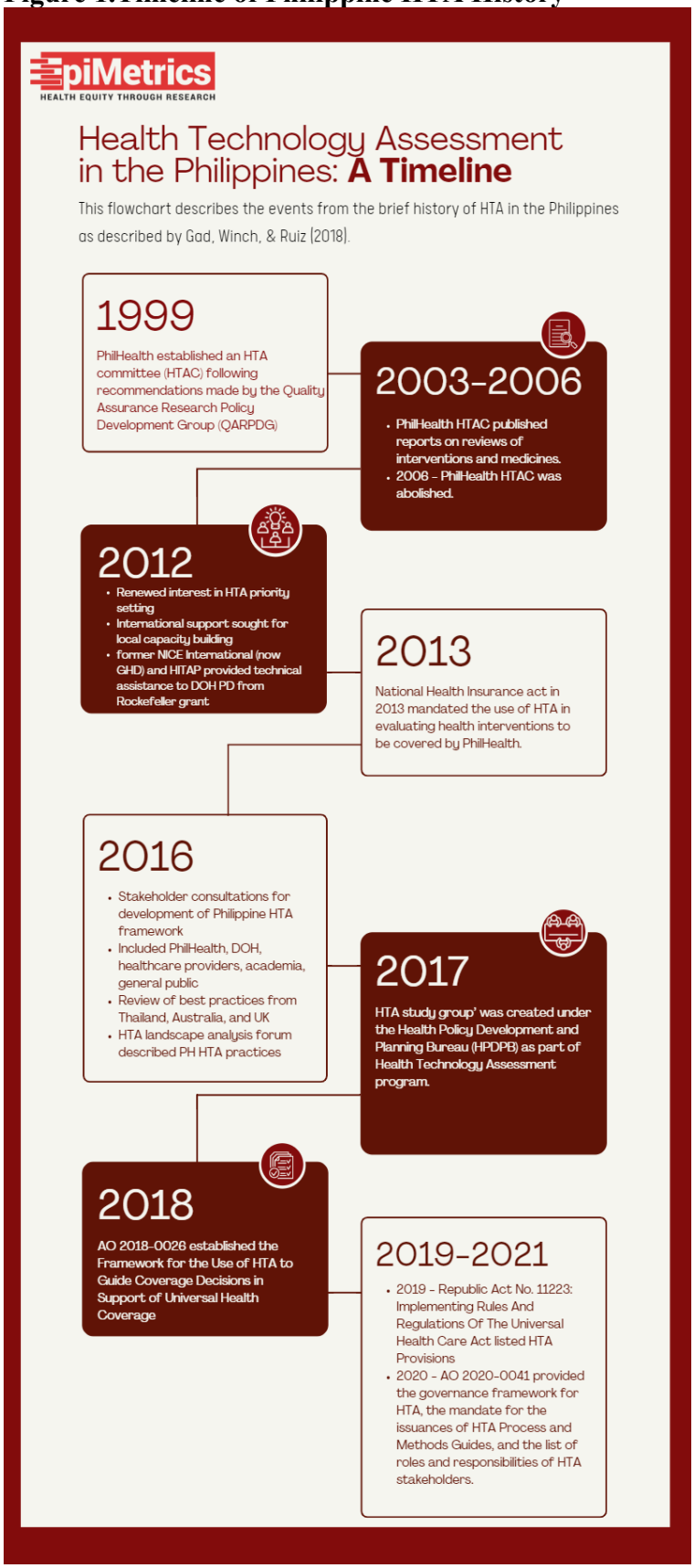
Brief History

The roots of HTA can be traced back to the 1970s, when it was introduced as a form of systematic inquiry on the effectiveness, cost and safety of technology in society (Goodman, 2004). It was utilized to evaluate the first Essential Medicine List of 1977 and the first cost-effectiveness program in health of 1998 (Ibid). Technology assessment was further developed by the US National Research Council in biomedical technologies, and has since been formally defined by the WHO (2021) as the "systematic evaluation of properties, effects and/or impacts of health technologies and interventions" that covers both their direct and indirect intended and unintended consequences.

Despite its longstanding history, it was only in 2014 that the World Health Assembly mandated the global support for countries in developing health technology and intervention assessment mechanisms. This was stipulated under Resolution 67.23, also known as Health Intervention and Technology Assessment for Universal Health Coverage (Ibid.).

Figure 1 summarizes the key events of Philippine HTA history (Gad, Winch, & Ruiz, 2018):

Figure 1.Timeline of Philippine HTA History



Source: Authors' illustration

Even prior to UHC, HTA was already utilized by various agencies (Bayani, 2016). As early as 1999, the Philippine Health Insurance Corporation (PhilHealth) utilized HTA and even established an HTA committee which was later abolished in 2006. It staged a comeback in 2012, and technical assistance for priority setting was sought from organizations like the National Institute for Health and Care Excellence (NICE) International (now Global Health and Development Group or GHD) and Health Intervention and Technology Assessment Program Thailand (HITAP).

The National Health Insurance Act of 2013 mandated its use in developing guidelines for Philhealth service coverage. This assures Filipinos of health packages that have undergone a thorough process of prioritization, assessment, assembly, actuarial study and approval prior to implementation" (Bayani, 2016).

In 2016, the New Implementing Guidelines of the Philippine National Formulary System (PNFS) required medicine in the PNF to first undergo risk-benefit assessment, cost-effectiveness, affordability and public health relevance. Nominated drugs are then assessed annually against a set criteria by the Formulary Executive Council (FEC) (Department of Health, 2016). The FDA CDRRR focused on medical devices regulation while the DOH FHO implemented the National Expanded Program on Immunization (Bayani, 2016).

Limited consultation with relevant stakeholders, a lack of clear criteria or guidelines for evaluation, and a lack of transparency in the decision-making processes are some of the challenges and issues that have been seen in the HTA process (Ibid). Additionally, irregularities in the reporting of epidemiologic data, particularly on burden of disease, affected the quality of reports utilized for nominations and decisions (Reyes, Ursu, & Obermann, nd.). Finally, economic data and evaluation, as well as product data and national clinical practice guidelines, were either scarce or non-existent (Ibid). With the passage of UHC, it is critical to streamline processes and organize a separate unit that would specialize on HTA.

Without a formal decision-making process and appropriate legal framework, policy-makers are vulnerable to external influences on reimbursement decisions (WHO, 2021). The inclusion of Dengvaxia in the national vaccination program without the approval of the FEC in 2016 is an example of how the lack of formal HTA processes in the Philippines is a major concern (Cepeda, 2017). The Dengvaxia Controversy sparked outrage and led to public distrust in policymakers and science. Dengue was just the eighth leading cause of mortality in the Philippines during this period, but PHP 3.5 billion was awarded for the Dengvaxia contract. This outweighed all the other vaccines from the General Appropriations Act that were only allocated a total budget of PHP 3.2 billion (Press and Public Affairs Bureau, 2017). Its procurement was also the fastest in DOH history, despite warnings on its risks and objections to its urgency (Ibid.). Vaccine supplier Sanofi and DOH both bypassed the standard FEC post-marketing surveillance requirement. Unfortunately, clinical trial data later revealed that there was an increased risk of hospitalization for severe cases of dengue infection among children who had not previously been infected. The immunization program was suspended given these findings, but 830,000 children had already been vaccinated without proper screening (Cepeda, 2017).

The magnitude of its consequences illustrated the need for a transparent and institutionalized HTA program. Systems for regulation were not yet in place, and this allowed for the bypass of essential protocols. The disregard for priority-setting is one example.

This disregard for protocols in procurement and health programs implementation, compounded by the lack of strict regulatory mechanisms, proved to be detrimental to public health. The 2019 UHC law then mandated the formation of an HTA program that addresses these limitations.

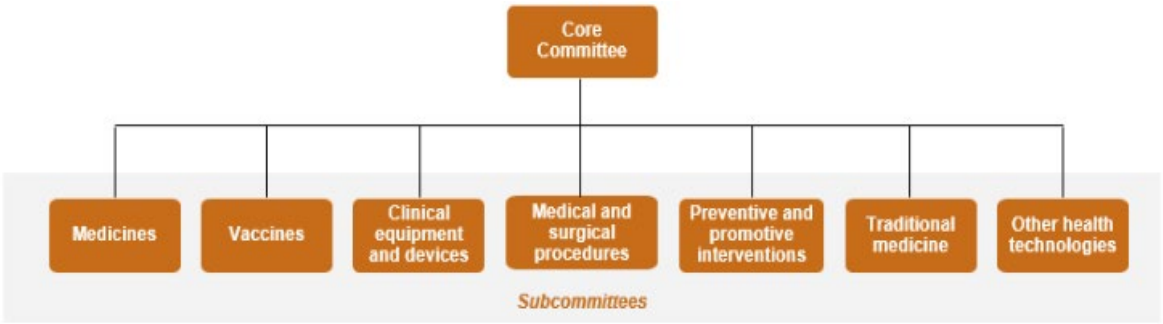
Institutional Design of the Current HTA Program

AO 2018-0026 established the Framework for the Use of HTA to Guide Coverage Decisions in Support of Universal Health Coverage in 2018. This provided an explicit framework for a systematic and consistent use of HTA to guide health coverage decisions of both the DOH and PhilHealth (Department of Health, 2018). This was reinforced by Republic Act No. 11223 that highlighted a "fair and transparent priority-setting mechanism" to improve responsiveness of DOH and PhilHealth interventions to magnitude, severity, and equity.

Based on the UHC Law, the HTA will be led by a council (HTAC) with a Chairperson and nine voting members, namely: a public health epidemiologist, a health economist, an ethicist, a citizen's representative, a sociologist or anthropologist, a clinical trial or research methods expert, a clinical epidemiologist or evidence-based medicine expert, a medico-legal expert, and a public health expert. The elected chairperson will preside over all HTAC meetings and ensure the fidelity of HTAC to the published process and methods guide. All core committee members are likewise expected to monitor HTA outputs for their quality and ability to meet the international standards.

Subcommittees for the following products will also be created, to be enjoined by technical experts during assessments: medicines, vaccines, clinical equipment and devices, medical and surgical procedures, preventive and promotive health interventions, traditional medicine, and, other health technologies. Their roles include, but are not limited to: (1) control the quality, quantity, and timeliness of HTA reports; (2) consider stakeholder inputs and include this in the preliminary recommendations to the Core Committee; (3) monitor compliance to methods and process guides, and; (4) assess and endorse the draft HTA report to the Core Committee for finalization.

Figure 2. HTA Council Organizational Structure

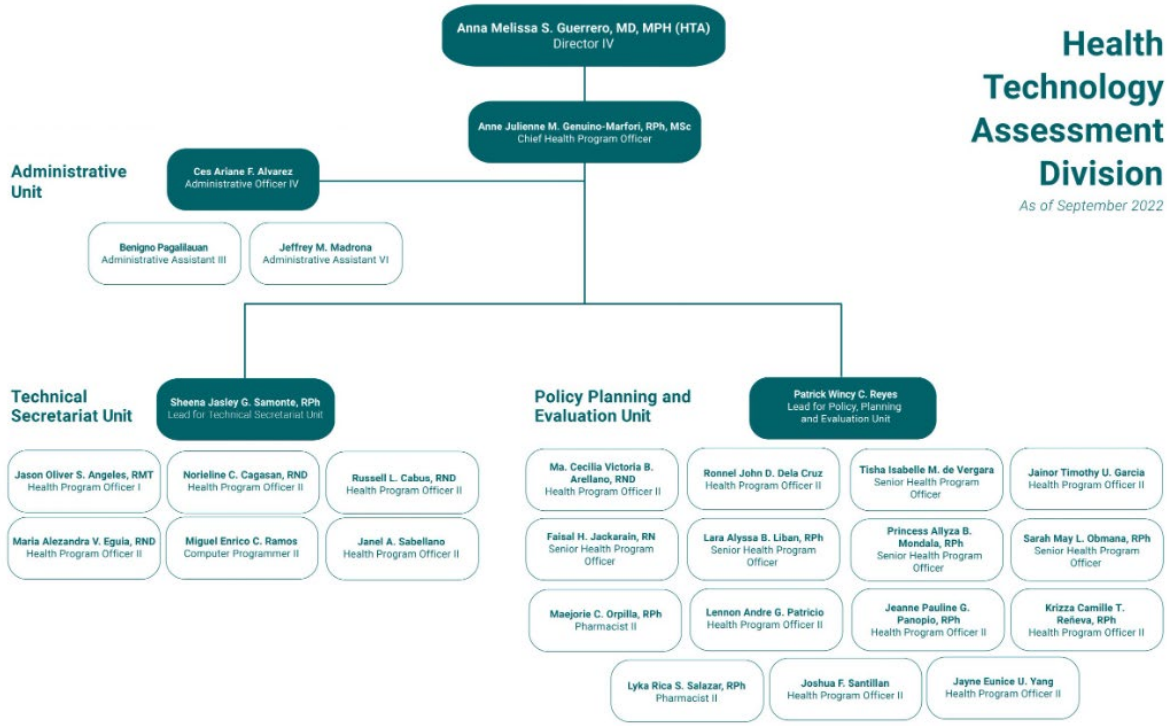


Source: DOH HTA Website as of November 2022

As of writing, the HTA Council has already been created, and has undergone their first training, high level forum, and strategic planning (Department of Health, nd.). A Secretariat and Technical Unit for Policy, Planning, and Evaluation has already been formed as well. (Congress of the Philippines, 2019).

In support of RA 11223, the DOH published its guidelines for the institutionalization and implementation of HTA in 2020. (Department of Health, nd.). AO 2020-0041 provided the governance framework for HTA, the mandate for the issuances of HTA Process and Methods Guides, and the list of roles and responsibilities of HTA stakeholders. It also enumerated the guidelines on the creation of the HTAD (Health Technology Assessment Division) consisting of: (1) a Technical Secretariat team to support HTAC in orientation and trainings, and; (2) a Policy, Planning and Evaluation Unit to lead the actual conduct of assessments and appraisals for HTAC.

Figure 3. HTA Division Organizational Structure



Source: DOH HTA Website as of September 2022

The required HTA process has not been specified, but agencies are mandated to publish their method and process guides and review them periodically.

Published in September 2020, the HTA Methods Guide provided guidelines and the tools to be used in assessing prioritized topics and reporting HTA outputs These included critical appraisal tools, data extraction tables, and sample costs tables. An HTA Process Guide was also published shortly after, which detailed HTA process flow, including topic nomination and appeals, and stakeholders' responsibilities. Currently, the HTA general process includes 9 main activities, estimated to last for a minimum of 57 weeks (13 months) up to about 128 weeks (or about 30 months), depending on the complexity of topic assessment (i.e., critical appraisal only or systematic review or other advanced economic evaluations). The summarized timeline of activities are presented below and additional details can be found in the HTA Process Guide Annex E (DOH HTA Website, 2020).

Table 1. Timeline for the Normal HTA Process

Activity #	Activity	Timeline (weeks)	Cumulative Timeline (weeks)
1	Topic Nomination	8	8
2	Topic Prioritization	16	24
3	Scoping and Protocol Development	4	28
4	Topic Assessment*	Minimum: 12 Maximum: 35	Minimum: 40 Maximum: 111
5	Evidence Appraisal	4	Minimum: 44 Maximum: 115
6	Initial Recommendation	4	Minimum: 48 Maximum: 119
7	Resolution	6	Minimum: 54 Maximum: 125
8	Final Recommendation	1	Minimum: 55 Maximum: 126
9	Decision	2	Minimum: 57 Maximum: 128

Source: Authors' compilation

Note: *Example for the shortest topic assessment is a "Critical appraisal (CA) of the whole dossier with complete assessment performed and submitted by the proponent" while the longest topic assessment can be a Systematic Review (with or without Meta-Analysis/ Network Meta-analysis) on clinical evidence plus a Cost-Effectiveness Analysis/ Cost-Utility Analysis (CEA/CUA) + Budget Impact Analysis (BIA) + Ethical, Legal, Social Impact (ELSI) and Health System Implications (HSI)

An expedited HTA process has also been made available and was in fact used in the 2021 Annual Report (Health Technology Assessment Unit, 2021). As opposed to the original methods, this process is estimated to take 6 weeks up to 16 weeks, cutting the bulk of topic assessment from 12 to 35 weeks to 2 to 12 weeks.

Mechanisms of dissemination of HTA outputs were also stated in the process guide. For instance, it illustrated the process of deliberating HTAC recommendations, from drafting to communicating. Stakeholders and public feedback will be collected within two weeks of draft posting on the DOH website. A peer-reviewed assessment report, along with the summary of evidence, will then be posted by the HTAD. Appeals may then be submitted within ten (10) working days of posting, and discussions will be made within fifteen (15) days from receipt of appeal documents. Finally, the HTAD is to develop and publish all communication materials (e.g., policy briefs) upon the review and approval of HTAC. (Department of Health, 2020a).

As of writing, 46 technology assessments were completed from 2020 to 2022, with most reports (46% or 21 of 46) accomplished in 2021. These are published by the HTA Division on their website, but a breakdown is provided in Appendix A. European HTA agencies reported a 2-3 month and 3-6 month turn-around time for the assessment, review, and reporting of pharmaceuticals and medical devices, respectively. (WHO, 2021). An increase in number of assessments indicated shorter turn-around times, and uncompromising quality despite efficiency was taken for progress (Ibid.).

Assuming that it would ideally take 3 months to assess a single drug, HTAC should at least complete 8 assessments within a two-year period. In 2022, the agency surpassed estimates and logged a completion rate of 1.5 months per assessment, with a total of 46 reports in 31 months. 13 of them were pharmaceutical assessments. However, it is important to note that the expedited HTA process was utilized for these assessments. (Health Technology Assessment Unit, 2021). This is a limitation that could affect the overall quality of the assessments.

Table 2. Completed HTA Assessments

Type	Count (%)
Vaccines	19 (28.8)
Preventive and promotive health services	18 (39.1)
Clinical equipment and devices	13 (19.7)
Drugs	13 (19.7)
Medical and surgical procedures	2 (3.0)

Source: Authors' compilation

Currently, assessments are on-going for 28 additional medicines: 12 internal assessments, 11 external commissioning, and 5 at the phase of finalization of recommendations after appeals. The specific drugs are listed below.

Table 3. HTA On-going Assessments (as of Nov 2022)

Type of On-going Assessment	List of Drugs[2]
On-going internal assessment (12)	Zoledronic acid for prevention of skeletal-related events in cancer patients
	Ticagrelor for the prevention of thrombotic events among patients with Acute Coronary Syndrome
	Rivaroxaban for myocardial infarction with atrial fibrillation
	Nilotinib as first-line treatment for Chronic Phase-Chronic Myeloid

[2] List of drugs are hyperlinked.

	Leukemia
	Ivabradine for the treatment of stable angina pectoris among adult patients with coronary artery disease
	Enzalutamide (40mg soft gel capsule) for adult men with metastatic castration-resistant prostate cancer (mCRPC)
	Eltrombopag olamine in the treatment of refractory thrombocytopenia among patients with chronic immune thrombocytopenia (ITP)
	Dapagliflozin (5mg/10 mg tablet) for adult patients with Type 2 Diabetes Mellitus patients inadequately controlled on metformin monotherapyDapagliflozin
	Dabigatran for myocardial infarction with atrial fibrillation
	Citicoline for acute and recovery phase of cerebral infarction (e.g., ischemia due to stroke)
	Cerebrolysin for patients with acute ischemic stroke, dementia and traumatic brain injury
	Abiraterone for adult men with prostate cancer
For External Commissioning (11)	Tirofiban HCl for treatment of unstable angina or non-Q wave myocardial infarction
	TACE with Mitomycin C for patients with non-resectable Hepatocellular Carcinoma
	Sunitinib for Renal Cell Carcinoma
	Sitagliptin for Uncontrolled Type 2 Diabetes Mellitus
	Ranibizumab for visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO)
	Pazopanib as treatment for Renal Cell Carcinoma
	Insulin lispro (Mix - P 814 3ml pre-filled pen (100 U/mL); Insulin Lispro 100 Units/mL, 10 ml vial)
	Insulin glulisine (100 IU/mL, 10 mL vial and 3 mL pre-filled pen) for Type 1 and Type 2 Diabetes Mellitus
	Insulin aspart (100 U/mL) for Type 1 and Type 2 Diabetes Mellitus

	Dexamethasone for diabetic macular edema
	Aflibercept for wet age-related macular degeneration
For finalization of recommendation after appeals (5)	Rituximab SC for Non-Hodgkin's Lymphoma
	Pertuzumab for HER2+ Breast Cancer
	Insulin glargine (100 IU/mL, 10 mL vial and 3 mL pre-filled pen) for Type 1 and Type 2 Diabetes Mellitus
	Insulin detemir (100 U/mL) for Type 1 and Type 2 Diabetes Mellitus
	Eribulin for Metastatic Soft Tissue Sarcoma (mSTS)

Source: Authors' compilation

Status of HTA Policies

The UHC IRR specified the grounds of involvement of the HTA and its proponents (Table 4) for HTAC, HTAD and other stakeholders, such as the PhilHealth, FDA and DOH. Relevant HTA provisions include: (1) the program's role and responsibilities as a priority-setting mechanism and a recommendatory body to DOH and PhilHealth, (2) the human resources needed to fulfill these roles, and (3) transitory provisions like the transfer of the HTA program from DOH to DOST.

Table 4. HTA-related provisions in UHC IRR

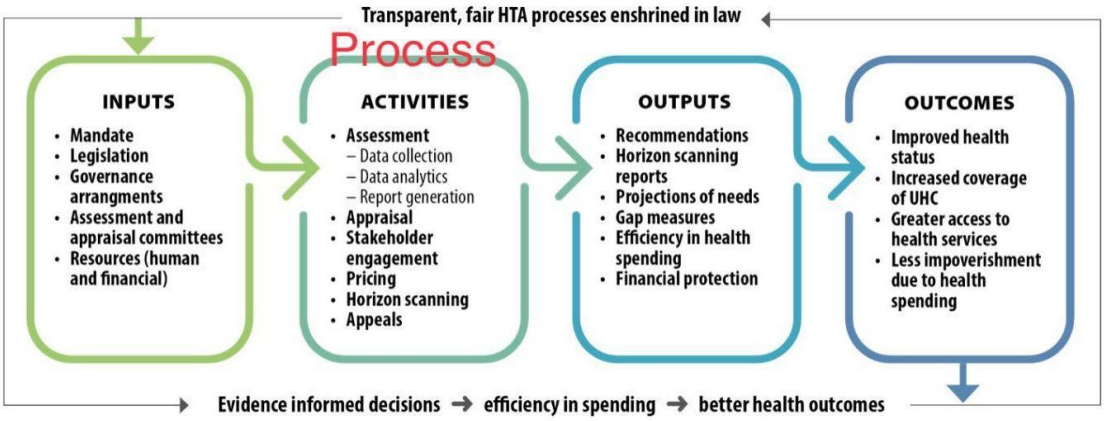
Type	Provisions Related
HTA Program's Role and Responsibilities	Section 6. Service Coverage 6.1 (p.7): NHIP Service Coverage for all Filipinos with goods and services determined through a fair and transparent HTA process 6.3 (p. 7): By 2021, comprehensive outpatient benefit package (outpatient drug benefit and emergency medical services) developed by PhilHealth using HTAC recommendations Section 34. Health Technology Assessment 34.1 (p. 47): Health Technology Assessment (HTA) institutionalization as a fair and transparent priority setting mechanism for DOH and PhilHealth that shall be recommendatory Section 34. Health Technology Assessment 34.2.c (p. 47): HTA process shall adhere to ethical soundness, inclusiveness and preferential regard to the underserved, evidence-based and scientific defensibility, transparency and accountability, efficiency, enforceability and availability of remedies, and due process 34.9.a (p. 48): Health Technology Assessment Council duties includes (1) facilitate provision of financing and/or coverage recommendations on health technologies to be financed by DOH and PhilHealth 34.9.b (p. 48): Health Technology Assessment Council duties includes (2) oversee and coordinate the HTA process within DOH and PhilHealth 34.9.c (p. 48): Health Technology Assessment Council duties includes review and assess existing DOH and PhilHealth benefit packages
Human Resources	Section 34. Health Technology Assessment 34.8 (p. 48): HTAC, composed of health experts, be created within the DOH and supported by a Secretariat and a Technical Unit for Policy, Planning, and Evaluation 34.10.a (p. 48): Core committee should include 9 members (public health epidemiologist, health economist, ethicist, citizens' representative, sociologist or anthropologist, clinical trial or research methods expert, clinical epidemiologist or evidence-based medicine expert, medico-legal expert, public health expert) and elect a Chairperson. 34.10.b (p. 48): Sub-committees should include Drugs, Vaccines, Clinical Equipment and Devices, Medical and Surgical Procedure, Preventive and Promotive Health Services, Traditional Medicine (with a minimum of 1 and maximum of 3 non-voting members for each sub-committee)

	34.16 (p. 49): The HTA Technical Unit for Policy, Planning and Evaluation, in coordination with the HTA and other stakeholders, shall establish the process and methods to guide the HTA implementation as it shall be reviewed periodically. 34.11 (p. 48): Technical Resource Persons may be called from PhilHealth, FDA, patient groups, clinical medicine experts, representatives from private sector and health care providers
Transition-related	Section 34. Health Technology Assessment 34.18 (p. 49): By 2024 (within 5 years of establishment and effective operations), HTAC will transition into an independent entity separate from DOH and attached to DOST. Section 41.Transitory Provisions Sec 41.7 (p.62). HTAC under DOH to be established within 1 year and existing health benefit package rationalized within 2 years of HTAC establishment

Source: Implementing Rules and Regulations of the UHC Act 2019

Published issuances from 2019 (Table 5), categorized as input-, process-, or output-related, and annual reports from 2019 to 2021 (Table 6) were reviewed to assess the status of the mentioned provisions.. Categories were determined on the basis of the logical framework for HTA mechanism (WHO, 2021) as seen below:

Figure 4. Edited Logical Framework for HTA Mechanism



Source: World Health Organization 2021

Input-related issuances correspond to necessary legislation and human resources in the HTA program (i.e., screening committee, pool of experts). Processes document the roles and responsibilities of HTA, and specifies the methods and process guides, memorandums on topic nomination requirements, and other HTA guides to be used for assessments (e.g., selection guide for the Philippine Essential Medical Device List). Outputs only cover calls for consultations or comments and surveys.

Table 5. Summary of Issuances[3]

Input	Process	Outputs
REPUBLIC ACT NO. 11223: Implementing Rules and Regulations of the Universal Health Care Act	AO 2020-0041: The New Implementing Guidelines on Health Technology Assessment to Guide Funding Allocation and Coverage Decisions in support of Universal Health Care	[Memo To DOH Internal Offices] Consultation For Covid-19 Vaccines Evaluation Framework
Department Personnel Order No. 2021-2780: Creation Of Pool Of Clinical Experts For Consultation On The Evaluation Of Assessment Topics	Consultative Meeting For Administrative Order 2020-0041	Department Circular No. 2021- 0348: Coresia Vaccine Certificate Survey For Key Stakeholders
Department Personnel Order No. 2022- 2780 – A: Amendment To The Department Personnel Order No. 2021-2780 Entitled "Creation Of The Pool Of Clinical Experts For Consultation On The Evaluation Of Assessment Topics" To Include Expert Advisory Committee As Additional Experts	Department Memorandum No. 2021- 0079: Endorsement Of Topic Submissions From National Health Programs For Health Technology Assessment	[Memo] Request For Comments On Evaluation Framework For Covid-19 Vaccines (Version 2)
Department Personnel Order No. 2022- 2048: Creation Of A Screening Committee For The Appointment Of Health Technology Assessment Committee (HTAC) Members	Department Memorandum No. 2021- 0075: Compliance To Dissemination Of The Recommendations Of The Health Technology Assessment Council (HTAC)	[Advisory] Draft Guidelines On The Application Of Philippine Social Values On Health Technology Assessment For Public Consultation From 21 September To 05 October 2022
	Department Circular No. 2021- 0079: Health Technology Assessment Council'S (HTAC)	

[3] Issuances are hyperlinked.

	Recommendations On Health Technologies Requiring Full Certificate Of Registration (CPR) From The Food And Drug Administration
	Department Circular No. 2021- 0273: HTAC Issuance On Acceptance And Processing Of Health Technologies Under Monitored Release With Phase Iv Trial Data
	Department Circular No. 2021- 0376: Interim Requirements For The Health Technology Assessment (HTA) Of Medical Devices
	Department Circular No. 2022- 0254: Updates On The HTAC Processing Of Minor Inclusion Application
	Department Circular No. 2022- 0257: Changes To The Topic Nomination And Appeals Processes Of The Philippine HTA Process Guide
	Department Circular No.2022 - 0290: Changes To The Topic Nomination And Appeals Processes Of The Philippine HTA Process Guide
	Department Memorandum No. 2022- 0379: Updated Checklist Of Requirements For The Health Technology Assessment Of Covid-19 Health Technologies To Be Referred By The Disease Prevention And Control Bureau (DPCB) And National Vaccine Operations Center (NVOC)

	[Advisory] Draft Department Memorandum On The Methodology Of PEMDL Draft Interim Guidelines On The Process And Methods For The Selection Of Medical Devices For Inclusion In The Philippine Essential Medical Device List (PEMDL) For Comments Until 21 September 2022
	For Dissemination: DM Methodology Of PEMDL
	For Dissemination: Draft HTA Social Values Guide Draft
	Call For Interested Parties: Development Of The Health Technology Assessment (HTA) Research Network

Source: Author's compilation

On the other hand, annual reports provided further insight on the current status of HTA implementation. A summary of the 3-year accomplishments and challenges in its implementation is outlined in Table 6.

Table 6. Summary of the 3-Year Accomplishments and Challenges in the HTA Program

ACCOMPLISHMENTS	**2019**	**2020**	**2021**
Governance			
HTA Policies and Implementation Guides	x	x	x
HTAC and HTAD Staffing	x	x	x
Internal Capacity-Building	x	x	x
Assist DOH and PHIC		x	x
Reviews and Assessments			
Rapid Reviews	x	x	x
Full Assessments	x	x	
Expedited Assessments		x	x
Projects and Initiatives for Stakeholders			
Consultations		x	x
Webinars and Workshops		x	x
Formal Partnerships			x
CHALLENGES	2019	2020	2021
Governance			
Delay in release of technology-specific guides or methodological guides for UHC priority health technologies		x	x
Unmet Staffing Requirements		x	x
Issues on Data Availability		x	x
Delayed Transition from DOH to DOST			x
Reviews and Assessments			
Delayed Assessments on Pending Topics (e.g., from FEC, Benefit Packages)		x	x
Projects and Initiatives for Stakeholders			
Limited Formal Partnerships		x	x
Concerns on Outputs Translation and Applicability			x

Source: Author's compilation

i. Governance

HTAC and HTAD were able to draft their process and methods guide in 2019, to release them to the public by 2020, and to have them undergo revisions as needed.

HTAC and HTAD recruitment is continuously ongoing, evidenced by the Department Personnel Orders (DPO) and Call for Applicants in their websites. Onboarding and training with Thailand's Health Intervention and Technology Assessment Program (HITAP) and UK National Institute for Health and Care Excellence (NICE) had also been conducted from 2019 to 2021. These initiatives, however, were still inadequate to supply skilled manpower deficiencies. Issues on data availability also hampered the fulfillment of HTA assessments.

ii. Assistance provision to DOH and PhilHealth

Only 2 full assessments were completed in 2019, and another reassessment in 2020. Expedited assessments were more commonly utilized from 2020 to 2021 given the demands of COVID, and only one non-COVID output (reassessment of PCV-13) was produced during that period. These circumstances hindered HTAC from assessing existing benefit packages of PhilHealth and DOH, specifically the drug topics requested by the FEC. Insufficient staffing, complicated by concurrent COVID-19 assessments, also delayed the release of other methods guides (e.g., technology-specific).

Toward the end of 2021, the HTA welcomed nominations for non-COVID concentrations and has resumed its discussions with PhilHealth on the benefit packages. Data on the influence of HTA assessments on the benefits packages have yet to be explored.

iii. Transitioning for DOH to DOST

The pandemic also posed challenges on the program's transition from DOH to DOST, and the organization makeup of HTAD (e.g., limited staffing, high turnover rate). Plans to coordinate were revived in 2021, but DOST must still form a dedicated HTA counterpart within its agency to officially begin the process.

iv. Responsibility to other stakeholders

Only calls for comments and consultations were documented in the review of issuances. However, annual reports stated that consultations and workshops/webinars have been conducted since 2020.

Formal partnerships are being accomplished but at a slow pace. For instance, the UP-HTA program and the HTA research network collaboration has yet to be fully realized. The HTA program identified certain barriers, such as limited stakeholder engagement during assessment and output translation. Although there are resources to facilitate information dissemination, **the HTA program acknowledges the challenge of translating technical recommendations into clear and actionable for the end-users. This may be attributed to**

the lack of science communication specialists in the current HTAD and the limited awareness of all stakeholders, policy-makers and the public alike, on what HTA outputs are for (Co et al., 2021).

Review of Related Literature

This section describes a global benchmark to establish HTA using EUnetHTA's handbook (EUnetHTA, 2008). HTA progress across various countries is highlighted, as well as the challenges and gaps encountered.

Benchmarking HTA Globally and in the ASEAN Region

To build a national HTA, EUnetHTA (2008) enumerated steps to establish HTA in countries using the following domains: **building a national HTA, aims and scope, work processes, and disseminating HTA products.** Table 7 outlines EUnetHTA's guidance and compares the Philippine progress vis-a-vis mature HTA systems, like the United Kingdom (UK) and Canada, and Thailand and Malaysia in the ASEAN region.

Table 7. Comparing EUneHTA's Guidance across Global and Regional HTA

Country and HTA Nodal Agency	Building a National HTA	Aims and Scope	Work Process	Disseminating HTA Products
EUnetHTA's G uidance	Legal mandate Long-term funding Full-time permanent staff with different disciplines	**Aim:** "to provide input that helps decision-making in policy and practice" **Scope:** local-regional, international, and/or national levels	Processes for: Identifying technologies for assessment Priority-setting Assessment Other work processes like database and management information systems	Processes for: Identifying target audiences Elaboration of key messages per target audience Formal dissemination strategies with manpower and budget
UK: National Institute for Health and Care Excellence (NICE)	Independent organization by the government mandated by law Funded by Department of Health and Social Care More than 600 employees with different disciplines	**Aim:** "to create consistent guidelines and end rationing of treatment by postcode across the UK" **Scope:** local-regional and national levels but provides guidance internationally	Processes for topic identification, prioritization, and assessments are complete Established HTA database for reports with knowledge and library hubs	Complete processes for dissemination and communication of NICE Guidance
Canada: Canada's Drug and Health Technology Agency (CADTH)	Not-for-profit organization with no legal mandate Private, such as the industry, and publicly funded More than 200 internal employees across different fields	**Aim**: "to provide health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in Canada's healthcare system"	Processes for topic identification, prioritization, and assessments are complete Established HTA database for reports	Established unit called "Implementation Support and Knowledge Mobilization Team" to formalize communication processes

		Scope: local-regional and national levels		
Thailand: Health Intervention and Technology Assessment Program (HITAP)	Semi-autonomous, non-profit with no legal mandate Publicly funded with donors 51 internal staff across different disciplines	**Aim:** "to take responsibility for appraising a wide range of health technologies and programs (...) to inform policy decisions in Thailand" **Scope:** national level but provides guidance internationally	Processes for topic identification, prioritization, and assessments are complete with equity and ethical dimensions found in "Health Technology Assessment Process Guidelines"	Dissemination guidelines are included under "Health Technology Assessment Process Guidelines"
Malaysia: Malaysian Health Technology Assessment Section (MaHTAS)	No legal mandate Publicly funded 43 internal staff across different disciplines	**Aim:** "to ensure that safe, effective and cost-effective technology is being used in the MOH facilities and be the center of excellence for informed decision making for better healthcare" **Scope:** national level	Processes indicated in the Health Technology Assessment Manual but with optional ethical, social, and legal considerations Reports are linked to the INAHTA database	Dissemination guidelines are included under said manual
Philippines: Department of Health's Health Technology Assessment Council (HTAC) and Health Technology Assessment Division (HTAD)	HTA Council Mandate under UHC law Publicly funded 11 internal staff only under medical and public health disciplines	**Aim:** "to provide evidence and recommendations to decision makers, specifically the DOH and PhilHealth" **Scope:** national level	Processes indicated in the HTA process and methods guide without ethical, social, and legal aspects for priority-setting and assessment process yet No HTA studies database	Dissemination through: HTA website Email Government issuances Electronic reports Department Memorandum No. 2021- 0075 states compliance to dissemination recommendations

Source: EUnetHTA descriptions are from the Handbook on HTA Capacity Building (EUnetHTA, 2008).

Note: United Kingdom data are from National Institute for Health and Care Excellence (n.d.), while data on Canada are from "CADTH - Canadian Agency for Drugs and Technologies in Health" (INAHTA, n.d.) and *Canada's Drug and Health Technology Agency*, n.d. Thailand's descriptions are from *HITAP: โครงการประเมินเทคโนโลยีและนโยบายด้านสุขภาพ* (n.d.); Malaysia's data from *Portal Rasmi Kementerian Kesihatan Malaysia* (n.d.), and the Philippines' from ASEAN & Department of Health (2021). Other data for the ASEAN countries are from the ASEAN & Department of Health (2021); Co et. al. (2021); and Downey et. al. (2017).

Challenges and Gaps in Achieving Best Practices

Although it has been achieving milestones since 2019, HTA in the Philippines continue to face significant challenges. International best practices and proposed solutions to the identified gaps are presented in Table 8.

Table 8. Challenges and Gaps across Global and Regional HTA

Country	Building a National HTA	Aims and Scope	Work Process	Disseminating HTA Products
United Kingdom	Lack of local technical capacity to conduct HTA	Scope: Criticized as too narrow because "reports cover the effectiveness, safety, and economic impact of technologies better than the organizational, legal, and ethical consequences"	Insufficient involvement of patients and relevant representatives in its processes	Circuitous routes and methods of dissemination for HTA evidence (HTA primary research will need to be incorporated into systematic reviews or other HTA reports before it is accessible to most decision makers)
Canada	Recommendations has no legal power	Scope: Complicated HTA network; "complex system, adaptive and composed of individuals with diverse perspective"	Unclear HTA findings (ie. conflicting results)	Insufficient engagement with stakeholders
Thailand	No legislative mandate Lack of local technical capacity to conduct HTA (particularly in the area of health economics and pharmacoeconomics)	Scope: Unclear role in decisions on including or excluding particular medicines on the National List of Essential Medicines	Scarcity of local data Lack of transparency in conducting appraisals	Limited HTA awareness among policy makers
Malaysia	Lack of overall political support for the uptake of HTA in health policy Lack of local technical capacity to conduct HTA	Scope: Overlap of assessments with the other formulary management branch that also conducts assessments like the Pharmacy Practice & Development Division	Scarcity of local data	Limited HTA awareness among policy makers
Philippines	Lack of trained personnel with limited training	Scope: Problems in engaging relevant	Scarcity of local data such as economic, costing,	Limited HTA awareness among policy makers

	opportunities (e.g. locally available courses) Need more *plantilla* positions for technical and secretarial support Lack of political buy-in No mandate to use local data	stakeholders in the process	and epidemiological data Lack of clear criteria or guidelines for evaluation	No dedicated media personnel Insufficient engagement among clinicians, patient, and the public

Source: United Kingdom Stevens et. al. (2004), Canada from Wranik et. al. (2021). Thailand, Malaysia, and Philippines data are from ASEAN & Department of Health (2021); Co et. al. (2021); Sharma et.al (2021), Downey et. al. (2017) Bayani (2016) (Tantivess et. al. (2012) and Shafie et al. (2019)

Regardless of HTA maturity, similar challenges are shared across countries under these domains are, including:

- **Building a national HTA**: insufficient stakeholder engagement and limited HTA awareness among policy makers
- **Work process:** lack of technical capacity
- **Disseminating HTA products:** scarcity of local data

To address **insufficient stakeholder engagement and limited awareness among policy makers**, countries with an established HTA form formal expert committees that include healthcare providers, researchers and members of the public to examine and deliberate on the scientific evidence provided by assessments. Forsythe et al. (2017) affirmed that these "deliberative approaches" effectively ensure a systematic, transparent participatory HTA process. This improves the policy and practicality of the process, enhances transparency and facilitates accountability of decisions.

The best practices in the established HTA system like the United Kingdom and Canada are:

- **Canada**: HTA International (HTAI) unit creates linkages between relevant groups within and external to their organizations (Martin et al., 2016).
- **United Kingdom:** developed the Evidence and Value: Impact on Decision Making (EVIDEM) framework to facilitate knowledge transfer, to support the deliberative process through systematic consideration of all decision criteria, to prioritize health care interventions and to enhance communication of the decisions (Tanvejsilp et al., 2019b)

The best practices in the ASEAN countries like Malaysia and Thailand are:

- **MaHTAS (Malaysia):** conducts awareness workshops, training on evidence informed decision making and relevant work processes for stakeholders, policy makers, and healthcare professionals (Roza et al., 2019). They also established a

formal feedback mechanism and measures the impact of HTA studies by surveying key stakeholders who requested HTAs (Sharma et.al 2021).

- **Thailand:** have distinguished, transparent, participatory HTA processes including stakeholder involvement in the selection of HTA topics and the dissemination of results not only to decision-makers but also to a wide range of stakeholders (Sharma et.al 2021).

The Philippine HTA already publishes reports, assessments, and guides on its website. Dissemination is also done The dissemination of through email exchanges, government issuances and electronic reports (ASEAN et. al., 2021). Public access to manuals and documents necessary for decision-making is considered a best practice, (Co et. al., 2021; Downey et. al., 2017) but publishing under international journals is likewise recommended to complement dissemination efforts (ASEAN et. al., 2021). More formal and complex strategies would also require a dedicated staff and budget for communication (EUnetHTA, 2008).

- Technology appraisal and assessment require many skills from the HTA. This is a challenge shared across countries, and strategies have been done to address this. It is critical to identify skill sets that are already developed and those that do not address the **lack of technical capacity** in the HTA system. Some best practices include:,
- **Canada:** developed an important research capacity in HTA. They have three Evidence-Based Practice Centers that conduct assessments in partnership with the Agency for HealthCare Research and Quality in the United States (Battista et. al, 2009).
- **United Kingdom:** providing training for staff, endeavor in recruitment of trained staff and collaboration with universities and hospitals (EuNetHTA, 2008).
- **Malaysia:** had postgraduate training on pharmacoeconomics, health economics and other related HTA disciplines before establishing formal HTA agencies (HITAP. 2016) they also have continuous capacity building and training of personnel (Shafie et al., 2019).
- **Thailand:** conducts education and information programs annually and sought collaborations with HTA and academic institutes in developed countries such as the UK NICE, the London School of Hygiene and Tropical Medicine, University of East Anglia, the Korean Health Insurance Review Agency (HIRA) and the Center for Drug Evaluation of Taiwan (Tantivess et. al., 2012)

Without formal HTA training for healthcare professionals, staff training is a challenge in the Philippines. Vocational training in national universities has been recommended, as this will guarantee employment opportunities in HTA (Sharma et. al., 2021). This would entail support and commitment from end-users and policy-makers, especially because political will is a crucial component to program development, particularly in developing countries. (Co et. al, 2021; Uzochukwu et. al., 2020). (Co et. al, 2021).

ASEAN countries struggle with **scarcity of local data**, but only the Philippines lacks local economic and costing data (ASEAN et. al., 2021). Access to available data is also burdensome, having to request and coordinate with different agencies (e.g., DOH, PhilHealth) (Co et. al, 2021).

Best practices that might help the country in addressing this gap are as follows:

- **United Kingdom:** expansion of the source of data this includes real world data
- **Canada:** have coordinated Field Evaluation systems and generating and using real world data**.** HTA producers also resort to using modeling techniques and sensitivity analyses to examine parameters such as longer time frames and possible variations in efficacy (Menon & Stafinski, 2009).

In the ASEAN countries:

- **Malaysia:** created HTA databases that compile all available HTA-related studies to support national and local decision-makers
- **Thailand:** developed a costing menu (a list of direct medical, direct non-medical, and indirect costs that represent the costs for different types of health facilities and households) to avoid collecting the same kind of cost data and to ensure comparability across studies (HITAP. 2016).

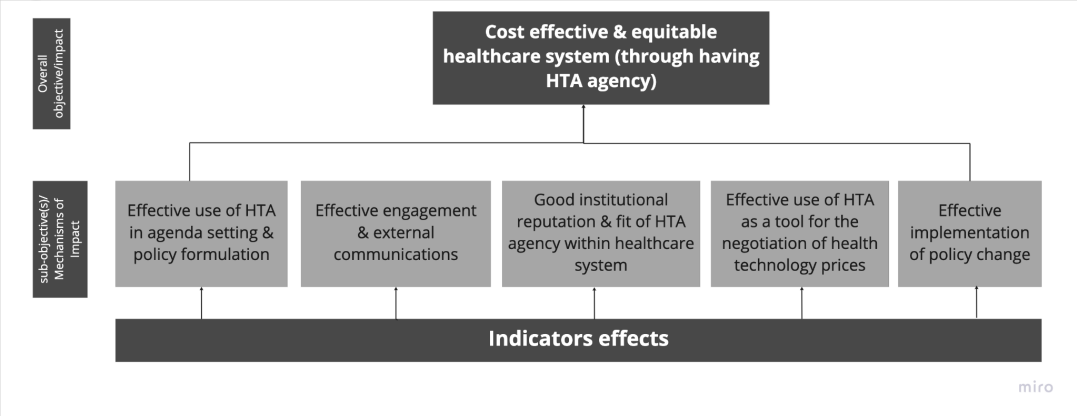
More of these challenges and the best practices acquired by the HTA in the Philippines will be discussed in the Results and Discussion section.

Methodology

Study Design

The impact of HTA agencies in different countries have already been well-evaluated. Gerhadus et al. (2008), cited in Millar et al. (2021), illustrated a six-stage model of impact that highlighted awareness, acceptance, policy process, policy decision, practice, and outcome of the HTA reports generated by the agency. However, the lack of data from HTA agencies have hindered previous assessments from conducting a full and in-depth analysis using the tool. (Gerhadus et al., 2008). Millar et al. (2021) attempted to evaluate the HTA using a modified value tree that generated from an impact mapping exercise (Figure 5).

Figure 5. Value Tree Framework

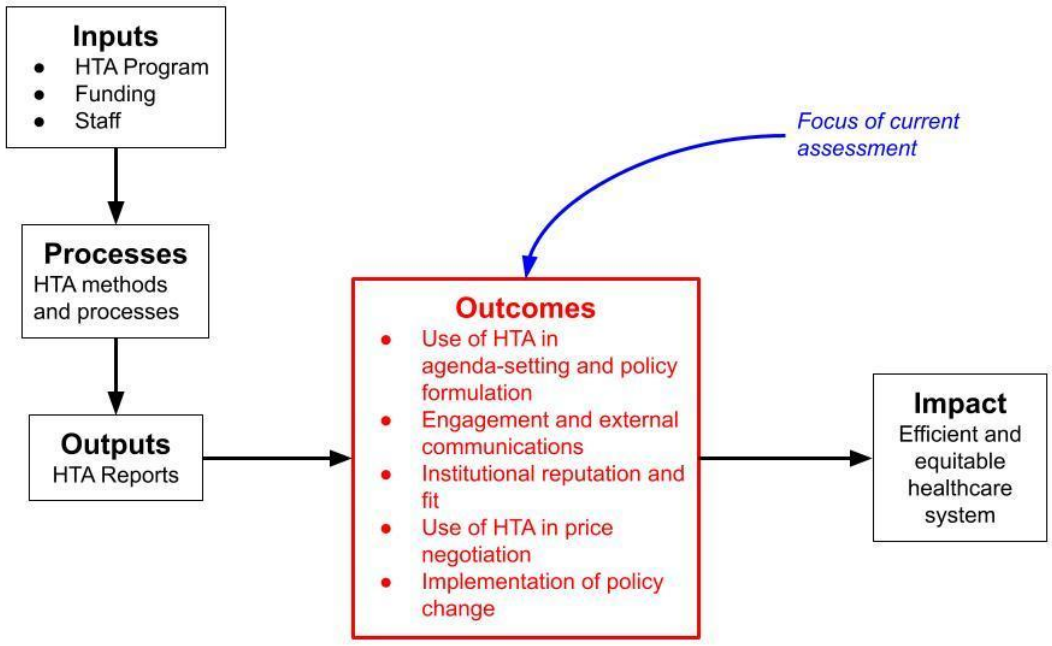


Source: Millar et al (2021)

The value tree framework presented above identified important elements for the evaluation of HTA programs and illustrated the pathway through which HTA achieves its overall objectives.

Adapting the Donabedian model of healthcare quality to the HTAP, we can visualize the value chain along which the HTAP will deliver its impact of an efficient and equitable health care system:

Figure 6. Application of the Donabedian model to the HTAP



Source: Adapted from Donabedian, 1999 with modifications by the authors

For the current study, the focus of the evaluation will only be on outcomes. The variables that will be measured will be the mechanisms by which the HTA reports and recommendations lead to a better health system (Ibid).

The International Network of Agencies for Health Technology Assessment (INAHTA) explored the basic indications of short-term HTA influences and broader impact for evaluation. Specifically, they studied the following:

- "HTA considered by decision-maker (the HTA was considered but further influence was not obvious/ apparent).
- Acceptance of HTA recommendations/conclusions (clear acceptance of HTA findings often, but not necessarily, linked to action by the decision maker).
- HTA demonstrated that a technology met specific program requirements (in circumstances where the HTA and its findings are linked to a program, for example where minimum standards must be met before some type of approval is given).
- HTA material is incorporated into policy or administrative documents (material in an HTA is cited in subsequent documentation).
- HTA information is used as reference material (the HTA is used by decision makers, and others, as an ongoing source of information).
- HTA is linked to changes in practice (the HTA may be one of a number of factors influencing such change)
- No apparent influence" (International Network of Agencies for Health Technology Assessment, 2014).

These can be measured through end-user data on dissemination, satisfaction, utility, relevance, and intention to adopt the recommendations (ibid.).

Tool Development

The interview tool developed was based on literature (Millar et al. (2021); Liu et al. (2018)), following the framework proposed in this study. It included (1) Likert-based questions that assess stakeholder perception on HTA publications, (2) observations on the adaptation or acceptance of HTA recommendations in their settings, and (3) open-ended questions that further probed outcomes of HTA recommendations on its end-users. The themes explored revolved around the place of HTA recommendations in agenda-setting, policy formulation, and decision-making, and how the facilitators and barriers of using HTA recommendations in their decision-making process. See Appendix C for the complete tool.

Data collection techniques

The study team utilized the value tree impact mapping framework by Millar et al. (2021) to conduct an **outcome assessment** of the HTA. A thematic content analysis was done with the collected inputs from stakeholder consultations with various government agencies (e.g., (DOH), (PhilHealth), a representative from a pharmaceutical company and representatives from a medical society and the (HTAC), the Health Technology Assessment Unit (HTAU)) were involved in the process. Relevant documents, such as the UHC law and the HTA reports, were reviewed.

A case study was also developed to further understand the HTA process. Information was retrieved from interviews, publications, relevant documents, and evidence reports. Data gathered for the case study will be presented below.

Data Collection Plan

Interview of the HTA end-users and HTA team

Careful purposive sampling was done to identify respondents that would more accurately and more broadly represent the stakeholders of the HTA system.

A review of relevant policies and ordinances was likewise conducted to assess compliance, challenges, and issues experienced during implementation.

Sampling

1. Target respondents (public and private organizations):
    a. HTA end-users, stakeholders, and recipients receiver of HTA program/HTAC technology appraisals, evaluations, and priority-setting's recommendations from different organizations
        i. government offices
        ii. industry or manufacturers
        iii. academe
        iv. clinical experts

v. patient organizations / civil society organizations,
vi. Healthcare providers (i.e. any hospitals, primary care providers or professional organizations)

Sampling design

The project team initially consulted one five respondents from the target study sites, and each represented a particular stakeholder group. Two (2) representatives from HTA, two (2) representatives from HTAC Sub-Committee and one (1) representative from HTAC Core Committee were likewise consulted for input on the HTA team experience.

Key informant interviews were done with three (3) government offices, three (3) from manufacturers, two (2) from an organization of clinical experts and (7) seven from HTA team.

Table 9. Summary of the respondents

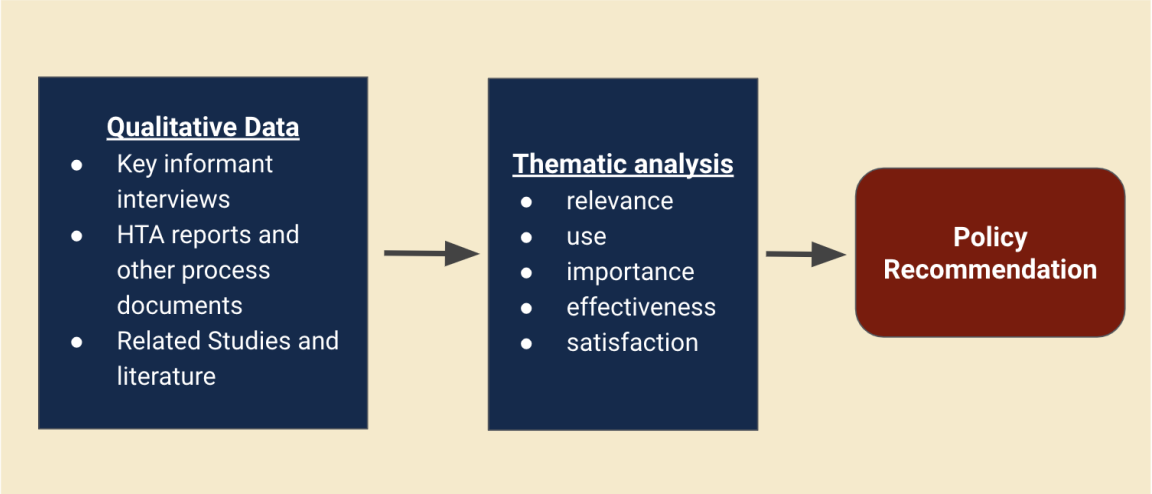
Target Population	Actual Respondents*
Government offices	3
Industry or manufacturers	3
Patient organizations / civil society organizations	1
Clinical experts (CEs)/ Medical Civil Society	2
Healthcare providers (i.e. any hospitals, primary care providers or professional organizations)	1
Health Technology Assessment Division (HTAD)	3
Health Technology Assessment Council Sub-Committee (HTAC SC)	2
Health Technology Assessment Council Core Committee (HTAC CM)	2

Source: Author's compilation
Note: * in terms of offices

Analysis Plan

Data Processing and Analysis

Figure 7. Data Processing and Analysis Flow



Source: Author's illustration

The study team was able to gather useful end-user data on HTA process and impact.
For the KII, a semi-structured interview tool was designed to: (1) identify the purpose and mandates of the organizations, (2) understand HTA processes, and (3) assess the usefulness, effectiveness, relevance and importance of HTA reports to their respective offices. Likert-based questions on satisfaction were also included to elicit recommendations. Responses were documented and prepared for data processing and analysis. Data gathered from these went through deductive thematic content analysis and were then triangulated with KII responses, best practices, and recommendations from the literature.

Deductive thematic content analysis

Deductive thematic content analysis on the stakeholder interviews was done to assess the impact of HTA on its end-users e. A coding framework was developed using the themes from the conceptual framework by Millar et al (2021). Transcripts were coded in a spreadsheet, and categories and subcategories were assigned to each theme. Codes were compared and reviewed to ensure accuracy of each theme The frequency of the appearance of each category was tallied, and the most common perceptions and thoughts across different types of stakeholder groups for each method of impact (Millar et al., 2021) were visualized. The ratings of HTA processes and performance for each theme was also summarized through this coding framework (Appendix B).

Results

The results will be discussed accordingly: (1) the HTA processes from the end-users' perspectives, (2) the HTA processes from the Program's perspective, and (3) case studies of three technologies and their assessment process.

End-Users' Perspective of the HTA Process

This section presents the findings of our interviews with the end-users of HTA. For privacy and confidentiality purposes, personal information has been de-identified and each participant has been assigned a code name. Table 10 describes and summarizes the involvement of each organization or agency with HTA.

Table 10. Summary of Stakeholders' Involvement with the HTA

Code	Stakeholder Type (n = 5)	No of Participants (n=9)	Involvement with HTA
GA 1: R1, R2	National health insurance provider	2	Main stakeholders of the HTA program and receiver of HTA recommendations as mandated by the UHC law for their target health investments (e.g., financing of health technologies, inclusion of benefit packages, or procurement for public health programs).
GA 3	A department bureau	4	Submits topic nominations to HTA and also provides supporting documents or evidence to the HTA when requested. main stakeholders of the HTA program and receiver of HTA recommendations as mandated by the UHC law for their target health investments (e.g., financing of health technologies, inclusion of benefit packages, or procurement for public health programs). Submits topic nominations to HTA and also provides supporting documents or evidence to the HTA when requested.
GA 2	A regulatory board	1	Assess the efficacy and safety of drugs and medical devices prior to market authorization Not familiar with the HTA process Not a recipient of HTA reports/recommendations
M1, M2, M3	Multinational pharmaceutical company	4	Nominate topics like the company's pharmaceutical products for assessment and inclusion of Philippine National Formulary (PNF) with the aim of collaborating with the HTA in promoting access to innovative medication.
CE	A medical society	2	Submits topic and uses HTA reports as a reference guide to provide better treatment for their patients
	A Professional Civil Society	5	Develop clinical practice guidelines and provides support to HTA in terms of evidence generation
PH	A Private Hospital	1	Not directly involved with HTA but follows the HTA recommendations for patient medications
PO	Patient Organization	1	Submits topics and provides patient perspectives as requested by HTAC

Source: Authors' compilation

GA2 (regulatory board) and GA3 (department bureau)
GA2 and GA3 are both the main stakeholders and end-users of the HTA program. As mandated by the UHC Act, they have dedicated teams that closely coordinate with the HTA for their Bureau and Department's target health investments. They abide by HTA recommendations for funding or financing of all health technologies, including benefits packages or coverage reimbursement, and designing health technologies' deployment.

GA 1 (national health insurance provider)
The GA1 is detached from the Health Technology Assessment Division (HTAD), and only responds to requests for information needed in assessments, such as a list of registered drugs for specific diseases and a Certificate of Product Registrations (CPR). These are used in the evaluation process, where the proposed health products for review are first verified by their office on the grounds of safety and efficacy.

Unlike GA2 and GA3, GA1 is not considered an end-user of HTA. The respondent thus inhibited from answering related questions.

M1, M2, M3 (multinational pharmaceutical companies)
As a multinational pharmaceutical company, they seek to promote access to innovative medication and nominate its pharmaceutical products for inclusion in the Philippine National Formulary (PNF). By inclusion in the PNF, any government agency can purchase the products for use in government hospitals or for patients in public health facilities.

Clinical Experts (medical society)
With limited knowledge on cost-effectiveness and public health implications, clinicians from the Medical Society reported utilizing HTA findings and recommendations in selecting the appropriate medicine for their patients.

Clinical Experts (Professional Civil Society)
A professional organization of infectious diseases specialists. They are involved in developing the clinical practice guidelines and disseminating the guidelines to medical professionals, hospitals, and the general public.

A Private Hospital
A direct beneficiary of HTA assessments, current involvement is through compliance with the HTA recommendations.

PO (Patient Organization)
Patient organizations are known to be the main recipients of the HTA recommendations. PO has no direct involvement in the entire HTA process but provides patient perspectives when needed.

SO 1: The effective use of HTA in the agenda-setting and policy formulation processes

Table 11. Content analysis of SO1

Effective use of HTA in the agenda-setting and policy formulation processes	Count 102
Categories	
HTA is critical in providing patient services	37
Lack of prioritization and delay recommendation and access to other health technology, special population, rare diseases	19
Lack of other perspectives and PH health system realities in HTA process	11
Related appeals to the HTA recommendations	11
HTA is critical in deciding on health investments	10
HTA is critical in making policies and agenda-setting	10
HTA recommendations helped in COVID-19 technologies access	6
Industries not affected by HTA recommendations	5
Issues on topic prioritization and its scoring system	4

Source: Authors' compilation

HTA is critical in making policies, agenda-setting, and decision-process on health investments

End-users expressed that the HTA recommendations were critical in their organizations' decision-making process and policy formulation, specifically to some units' health investments. These were most useful in policy drafting and agenda-setting, particularly in decisions on cost-effectiveness and innovative technology and medications that can improve the access of Filipinos to health services and medicine. GA1 expressed the need for HTA guidance in better designing their benefit packages. With HTA and GA2, regular consultations and alignment meetings are conducted as HTA is an input or a reference to their health policies and to streamline and rationalize the financing of services and service delivery among their units.

> **GA2:** "HTA is critical to our work. We are doing a sectoral initiative that there are health services and products accessible to all (or by the law) and with recommendation of the HTA, they become health investments. We work closely with them with our prospective investments. We make sure our policies, especially for implementation, are backed up by the HTA recommendation."

Since HTA recommendation is required before deploying health technologies and benefits packages; thus, the end-user expressed that it can also cause some delays in the internal processes, such as agenda-setting, formulation process, and program direction. Despite this, GA1 believed that HTA is a layer of process that will protect them from pressures to release

recommendations without following the processes. A respondent from GA1 shared an account that best illustrates the delays because of HTA recommendations.

> ***GA1:*** *"HTA can influence or delay our agenda setting and policy process. Even [if] we want to issue something, like a second booster, eh walang HTA, hindi namin siya magagawa. We also need to incorporate the timeline of HTA. If the HTA will say that they can evaluate 12 commodities in a year, kung 18 ang gusto namin i-expand next year, for sure, hindi namin yun magagawa. Concretely, it can delay our work especially if mas matagal sila."*

HTA is critical in providing patient services and COVID-19 technologies

HTA recommendations influence the inclusion or non-inclusion of innovative health technology in the Philippine National Formulary (PNF), specifically public and government health facilities, as they are the direct beneficiaries of PNF. Moreover, during COVID-19, the role of HTA was highlighted in having immediate access to COVID-19 technologies during a health emergency. Our participants from civil society shared that they follow the HTAC recommendations in creating guidelines for vaccination and disseminating clinical practice among health specialists during the pandemic.

> **CE:** *"May impact sa amin so that's why yung buong process ng trying to get [a] drug in, trying to get the recommendations in, we really try to, as much as we can, dapat yung sa simula palang pulido na. Kasi kung hindi pulido yung data, hindi pulido yung pagkasulat. …it doesn't get through. At the end of the day, when we look at the patients, wala kaming magagawa. Kasi ano ba ang majority ng patient na we see in the government hospital? They are not well off, that's why they're there. That's why we have to have treatment options as well so no one gets left behind."*

As for our participants from multinational pharmaceutical companies and private hospitals, they shared that they are not directly beneficiaries of HTA recommendations. However, pharmaceutical companies envision cooperating with HTA to promote their goal of bringing innovative medicines to the country and widening access to innovation among the patients, regardless of the capacity to pay. Innovative technologies without HTA backup are inaccessible to patients in government facilities (e.g., government hospitals), and they believed that patients who rely to government facilities are the most affected by HTAs implications (e.g. delay release of recommendation and issues on its prioritization) as it will lead to more out-of-pocket expenses should they be availed these innovative medicines in private hospitals, not recommended by the HTA.

> **M1:** *"… Because we are committed to improving access [of] FIlipino patients to innovative medication.. Very critical in that regard is the inclusion of these innovative medications in the PNF. Hence, we are really intent on working with the HTA to make this possible to improve access."*

Issues in the HTA prioritization process and other perspective in HTA assessments

For this, a pharmaceutical company (M1) suggested reflecting the realities of the Philippine healthcare system and its patients' out-of-pocket expenses and limitations to pay in HTA recommendations. They believe that innovative technologies may not be available to patients because of HTA's restrictive process of focusing only on the cost-effectiveness (and affordability) of technologies and not emphasizing the value of these life-saving technologies. After focusing first on the assessments of COVID-19 technologies, HTA started to focus on the assessment of other health technologies and accepted topic nominations in 2022. They believe that some disease areas and special populations are not prioritized in the HTA process, and raised the delays of timeliness for evaluating these life-saving technologies. As an example, a pharmaceutical company (M2) expressed that some topic prioritization is universal truth already, and it should not require comprehensive analysis. They also shared that they experience waiting for two to four years for a technology assessment that's even a WHO listed and essential medicine listed.

M1: *"They have been using price referencing for HTA based on other countries, but the thing is, these countries have realities of their healthcare system that are not existent in the Philippines. For example, it's fully reimbursed, unlike in the Philippines that it's still out-of-pocket. It would not really be fair to use evidence, with the proper context. You use price referencing, but you disregard the realities of the countries from which you got the price reference. Their healthcare system is fully-funded. They have a robust insurance system. Which is not present in the Philippine healthcare system. I think it will not resolve in a robust assessment."*

M2: *"For example, when you look at the topic prioritize now, there are intervention there are universal truth already. For example, mammography to screen breast cancer. HTA is still sub-contracting that to evaluate its cost-effectiveness. Pero, I think, it's standard of care already na parang hindi na nila kailangan ng sobrang grabeng analysis to decide on that. Parang it's something already in the hospital. It's just of matter probably a design that they would recommend. So, parang, dapat ganuun lang ka-simple yung recommendations. Kasi, imagine, their evaluating mammography, na may topic nominations, they sub-contracting it.for thirdparty agency to evaluate it."*

Participants from a pharmaceutical company (M3) also recommended revisiting the topic prioritization of the HTA, specifically the scoring system. They believed that the scoring system dilutes the prioritization of technologies applicable to specific population groups and disease areas that will be neglected. They suggested increasing the number of evaluators and expanding the research network within the HTA so that topic prioritization as a process could be omitted and all HTA applications are decked and reviewed. Below are their specific recommendations to improve the topic prioritization of HTA and other perspective in the HTA process:

M3: *"Employ multivariate statistical techniques (eg. discriminant analysis) to determine which criteria are the scores most sensitive to. Explore omitting/revising identified criterion that does not contribute to the variability of scores. Explore a sensitivity analysis where unequal weights are assigned per criterion and check how this will change the distribution of scores. Employ simple descriptive statistics (measures of dispersion and location) to gauge whether the criteria and scoring system could really differentiate one nominated topic from another. Indicators that the scoring system is effective – high standard deviation, high range, high variance. Consider*

using the distribution of collected data per criteria as the basis for the cut-off scores (use quintiles) if supporting literature is not available."

M2: "*I hope they look at it beyond just economic evaluation. Kasi at the end of the day, even if HTA does not recommend, I think the end-users will be affected. The methods are there, it's really comprehensive. It's nice. But then again, how do you balance the other interplay, other values, cost, among others and what the government cannot actually support? That's the decision-making that hopefully something that they invest on studying more because that;s more complicated than computing for cost-effectiveness, that's beyond numbers. Kasi grabeng negotiation, mas grabeng consideration kailangan nilang i-employ. And I think it's the HTAC who would actually balance it out. At the end of the day, yung HTA, their division will generate evidence, but then again, it's up to the committee to actually balance those out."*

SO 2: The program's effective engagement and external communications

Table 12. Content analysis of SO2

Effective engagement and external communications	Count
	81
Categories	
Communication exchanges and issues between end-users	38
Lack of understanding or communication on the role of HTA and its process	21
Communication of HTA recommendations to relevant stakeholders	13
Alignment meetings with HTA	4
Consultation and involvement in the HTA process	2
Lack of explanation of why the topic nomination was denied	3

Source: Authors' compilation

Communication exchanges and issues between end-users

Respondents expressed satisfaction with the communication platforms used for Health Technology submissions and updates, including Viber, messaging, or personal SMS. They also appreciate HTAD responsiveness and prompt delivery of necessary information, but mentioned that communication may be invasive of personal time when they are done beyond office hours.

GA3*: "We have constant communication to iron out and harmonization… Pero, minsan kasi, kalat-kalat yung pag-communicate nila. That could be improved. So, syempre, medyo nahihirapan din yung team. Abala na, pa- putol-putol pa yung communication."*

"May times na hindi nare-respect yung personal time, kasi may after office na email. Piecemeal po yung mga follow ups."

To address this issue and avoid redundancy, GA3 recommended consolidating all HTA information requested in one correspondence. On the other hand, GA2 highlighted the need to establish rapport and more deliberately engage with other units to improve communication and manage the workload in coordination. In line with this, stakeholders suggested

appointments of point persons for drugs and devices, to avoid delays in feedback and follow-up.

> **GA2*: "It's kinda complicated**. When sending data requests, HTAD sends messages to our office, sometimes to the [their office] action center or at the office of the DG (Director General), sometimes addressed to the Center director. This causes a delay because the request is **not timely received** by the right office."*

Furthermore, communication between industries and the HTA team needs to be improved. Industries are willing to collaborate with the HTA team but interaction is short and communication is very limited to email, Facebook and official letters. Proactive and facilitative communication was then suggested to ensure that they are updated on the progress of the assessments and that their concerns are addressed promptly.

> **M2: "***Generally, because the communication is still very limited to email and official letters. That's good. But then again, discussing the full context of the HTA, what we think about the topics among others, hopefully it's something that could add value and their process of evaluation. But currently, that's not happening. So, probably, that is the reason why 3 or 4. We're happy that there is communication, but there could be more, especially in the scientific space."*

> **M3: "***They are responsive to be fair, they respond but they need constant follow ups to get the response that you want. So more proactive, more open communication and involve us in the conversation even if we're not the proponent, even if it's the medical society but if it involves our product we want to be a part of that conversation. Everything is uploaded on the website but it takes time to load and then through email it is very responsive. But we also want us to be involved in the conversation because we are willing to help, this will help them lessen their burdens"*

Lack of understanding or communication on the role of HTA and its process

The end-users raised the need to communicate the HTA results to the relevant stakeholders and the public. Although highlighted during the COVID-19 pandemic, the majority of the respondents believed that the general public, including doctors and patients, are still unaware of the HTA's vital role in medical practice and the greater healthcare system. For PO, patients are having a hard time understanding its processes because it's too technical for them.

> **M1:** *"I don't know if I can answer this question, because I don't have the means to know if the public is aware. But even within the doctors, they have vague understanding, vague awareness of HTA. They hear it and mention it, but what it is and implications to the healthcare system, and implications on their healthcare practice is still vague for them."*

> **PO:** *"If you're talking about the public, I don't think so, they don't understand the role of HTA. Maybe they just hear it, maybe they just know they are the ones that recommend if medicine/technology is good or not, but deeper than that, I don't think so. Even in patient groups, when we tell them —okay we will help you submit your nomination, but it's not that*

appealing for them. Going through the process is a challenge for them, maybe because it's too technical."
M3: "*For me, baka hindi. If the medical societies, patient groups, hospitals hindi ganun na gets yung role nila, yung general public pa kaya? So I think hindi sila ganun ka-aware."*

GA1 and PO also raised the need to advocate for the HTA. Reaching out to local governments was suggested to improve public awareness regarding HTA's relevance in the healthcare system. Translating recommendations into layman language - for both the stakeholders and the general public - was also proposed as a solution. This will be particularly useful in developing and justifying recommendations on urgent requests for health technologies and benefits packages.

GA3*: Ang kulang talaga ay marketing na naiintindihan in simple language. For example, [for] our purposes, at our level, we can digest the technical report. When it comes to communicating to the management and to the board, it would really [helpful] if there is such an effort to make HTA more understandable. Maybe, packaging the HTA… Yung barrier nga ay kung yung report ay hindi ma-convert into something more useful. They have to be for public consumption. They [shouldn't] stay on the desk. They have to be read.*
PO: "*Siguro partnership with the NGOs kasi kung sila lang yung mag e-encourage parang medyo mahirap talaga kung baga yung topic itself medyo mahirap na. Siguro when they partner with katulad samin they partner with us, we help promote them para mas may understanding and to be able to explain na how important for them to learn about HTA, siguro baka akala lang nila ayy baka ano lang naman yan, ganito lang yan, hindi nila alam na may impact ang HTA, hindi nila alam na kapag nag deny yan wala silang gamot."*

PO mentioned that they have constant communication with HTAC because they work closely with them and guide them on every step of the topic submission. HTAC also conducts training for patient organizations to better understand the process. The only concern mentioned are the topics that are not being prioritized by HTA. PO proposed to have a discussion or a report wherein HTAC explains the reasons why some topics are not prioritized or are disapproved.

PO: *"So maybe they can explain more on their recommendation, or have a discussion with a certain patient group or whoever submitted on why was your topic nomination denied?. For me, we spend time on something then all of a sudden there was no positive response, it's sad. Wasted time and effort. For me, what's lacking? We understand that they cannot approve all but it's better if they can tell"*

Communication of HTA recommendations for the public and other stakeholders

Industries raised the importance of collaboration with key players of HTA not just with public but with private sectors as well (e.g., Medical/Professional Societies, Academe). For M2, M3 and PH this will strengthen the coordination between key stakeholders as well as lessen the burden on reviewing and generating evidence during the assessments.

M2: *"Have more comprehensive evaluations because sometimes, when they email, it's only a Q&A session that is happening. For example, whenever we have any inputs that we also share to HTA, we're doing it even if we are not being asked to help. but we're not sure if that's being appreciated by the HTA. I think HTA can leverage that. Consultations were also to help them firm up their reports and recommendations among others. That's something I think they need to also invest in. Especially, many stakeholders will be working with HTA in the future."*
M3 R1: *"You know what we can give them is not just the application forms but already the evidence na they will just appraise then magkaka-decision na diba? So I think it's the only way talaga para ma-reduce yung burden kasi hindi naman mawawala, hindi mababawasan ng applications every year"*
M2: *"Really open up on how the government can work in organizations like us, to really expand access to the medicines. Because I think like the DOH, the context, like pharmacy, has really changed. I think in the past, pharmaceutical companies were happy just selling their technologies to those who can afford it. I mean, technically, there are organizations that can live to that even if we still have it on patent. Parang we don't need to wait for generic comparators to actually come, to get a fair and transparent supply agreement with our organization. And I think that's something HTA can take advantage of. Especially, for those companies who are very much willing to work with HTA and facilitate access in government. I think that's very important especially in the context now."*
PH: *"Ang hindi ko lang alam how much consultation is being done with professional society, like if you don't own a particular outcome or policy they're like "I was not consulted on that". I'm just wondering in terms of how professional societies are involved. If there's natural coordination, it gives more credibility and push. Your partners become your ally, they will be the first to say if you're making the right decision."*

HTA under DOST is also an important step for the HTA team in strengthening their process, capacity and their collaboration with the relevant stakeholders.However, CS mentioned that HTA should inform the end-users on the HTA plans and what to expect from them now that they are under DOST.

CS R1: *"kailangan din with HTAC ngayon, kasi dati noon sa COVID, they needed to really come up with good recommendations using data from other countries.But because they actually need research data locally, they should also advocate for research to be done locally. And you know with that, DOST kasi fund research. PCHRD is there. So, yung kailangan ng HTAC, i-support ng DOST. And then they should also support researchers. They should actually make the research environment more, more conducive, so that more researchers can be involved in generating evidence that can be used by HTAC para hindi na tayo nagde-depend sa data from other countries."*
M2: "*I think the most important role of the HTA is to really balance the interests of different stakeholders, including the Department of Health. I think that's really important and I think*

that's the reason they moved the HTA to the DOST. So that at least, they can have very neutral ground to decide what's best for the patient."

Despite the points for improvement mentioned, many stakeholders (n=12) are still satisfied with the overall HTA communication process. In particular, they commended the constant exchange with HTA, especially when technical inputs for assessment are needed.

SO 3: The program's institutional reputation and fit within the healthcare system

Table 13. Content analysis of SO3

Good institutional reputation and fit within the healthcare and policy-making system	Count 83
Categories	
Value of HTA and its recommendation	13
Independence, Conflict of interest and outside pressure in the HTA	12
Trust on the methods and process of HTA	11
Impact of the HTA and its recommendation to organizations	10
Scientific rigor of the HTA recommendation	10
Acceptability of the HTA recommendation	9
Relevance of HTA recommendations	9
Satisfaction on the methods and process of HTA	9

Source: Authors' compilation

General rating of HTA and its recommendations

HTA is regarded as having a high impact and high relevance given its influence on access to health technology, clinician practice, patient treatment, and designated space on end end-users' overall policy-making. HTA also received high ratings for scientific rigor, value, and credibility, acceptability of HTA recommendations as it gives government programs the science behind its policy. Finally, HTA received high satisfaction and trust in their Methods and Process. However, participants still have suggestions for improvement of the improvement of HTA Methods and Processes. These are the inclusion of genuine patient consultation and other stakeholders, improving the restrictive process that impedes bottlenecks and affects the timeliness of the recommendation, allowing a facilitative process to access innovative medicines, revising topic prioritization, and communication of recommendations.

Respondent: *"It's a multi-disciplinary assessment, so somehow it's comprehensive in nature. [It's] understandable [that] it will take time for rigorous recommendation. What we can do is to streamline the process and provide clearer criteria. Kasi nagiging bottleneck when it comes to access."*

Conflict of interest in the HTA

Due to a lack of experts in a number of specialized fields, respondents believed that conflict of interest is inevitable in the HTA program. However, GA3 stressed that it is critical for the HTA to maintain its reputation of independence and manage outside pressure to release recommendations. Meanwhile, M1 expressed that this conflict of interest should not hinder stakeholder involvement, and instead alternatively proposed measures to mitigate and resolve conflicts of interest.

> **M1:** *"Perhaps, try to involve more stakeholders with the caveat that conflicts of interest should be acknowledged and measures to address and mitigate these conflicts of interests. It's a balancing act. You want to involve patients, [pharmacists], doctors, the general public, and hospital administrators that are affected [by] the approval of these technologies. You have to recognize every stakeholder's interest. Those interests or conflicts should be acknowledged and mitigated. But you shouldn't use those conflicts of interest to limit the participation of stakeholders."*

SO 4: HTA as a tool for the negotiation of health technology prices

Table 14. Content analysis of SO4

Effective use of HTA as a tool for the negotiation of health technology prices	Count
	20
Categories	
HTA not open for price negotiation	10
HTA report not used for price negotiation	8
Consideration for price negotiation	1
Works with Price Negotiation Board	1

Source: Authors' compilation

HTA not open for price negotiation

Industries are not doing price negotiation with the government yet but they are open for negotiation of prices using HTA as a tool however the process is programmatic and problematic. For M2 and M3, negotiation should be fair and transparent for both the organizations, innovators and the government because currently there's no proper avenue or space for the industries regarding negotiation of prices and to have a similar practice (e.g., confidential agreements) of other international HTA agencies like the UK NICE.

> **M2:** *"We also compromise but how do you compromise if you don't have the space to actually talk about it? I think that's the problem. To add, they decide even if they didn't even trigger a negotiation. So, there's instances like–"we reject this because it's super expensive." But why did you reject it? Is it because of the cost only?"*

> **M2: "***The problem with DOH and this is something they need to consider, in terms of how they do negotiation. It seems it's just to push down prices without considering other factors. For example, when you see yung UK NICE, they negotiate with the organizations. They do confidential pricing.*

And these are very important components when you negotiate. I think in the future, if HTA is really serious in getting all of these innovations, up to the hands of the patients in government facilities, they also need to look beyond how they are doing it now. And study how effective negotiations would really work in the Philippines. Yun ang problema. We are very open to negotiation."

M3:*"Maybe better if they -assess the price first? Before they actually quote for full economic evaluation? Just like in UK NICE, so that's one. And second is, at least for us, we are open to exploring lower prices if it means that's the way to have access to the government but in our current experience, we are prepared, we're looking at our prices if ever HTA asks, we will be ready to give an offer but it's not like a very involved discussion. I think sayang lang, there is a missed opportunity there. And it's something we are looking forward to exploring."*

HTA report not used for price negotiation

Most of the respondents mentioned that HTA was not utilized for negotiation of technology prices, especially because it is not included in their mandates but they believed it was relevant for price negotiations handled by a separate board in the DOH.

SO 5: The implementation of policy change

Table 15. Content analysis of SO5

Effective implementation of policy change regarding health technologies	Count
	16
Category	
No policy change because of HTA recommendations	12
Updating of policy because of HTA recommendation	4

Source: Authors' compilation

No policy change because of the HTA recommendations

It was difficult to assess the direct impact of HTA recommendations on policy changes because it is still in its early implementation stages at the time of data collection. However, Government Agencies mentioned that they adjust and ***update their policy and guidelines when HTAC updates their recommendations*** (e.g., COVID 19 packages).

G1 R2: *"What I can recall are the covid packages. So we have just come from a pandemic. It's still ongoing. When HTAC releases recommendations like what I've mentioned, the testing, if there's an update, we adjust our policy, and if they come up with a new recommendation and if they say "no evidence of this " we will not include it in our packages."*

Table 16 summarizes additional HTA processes that were not classifiable under the main mechanisms.

Table 16. Other Challenges in the HTA Processes

Key Challenges and Barriers regarding HTA recommendations	Count
	79
Category	
Lack of stakeholders involvement in the HTA process (e.g. patient group)	28
Timeliness and delays in the HTA process	19
HTA transferring the responsibility to fill forms or gather evidence	8
Limited capacity of HTA	4
Unclear Recommendation	4
Questions on the transition of HTA to DOST	3
Other issues on the HTA process	2

Source: Authors' compilation

Lack of stakeholders involvement in the HTA process (e.g. patient)

The COVID-19 pandemic limited HTA-end user engagement to virtual meetings and consultations. Although appeals were recognized and actions were taken as promptly as possible, there were limited opportunities for genuine collaborations.

> **Respondent 1:** *"They had several Zoom meetings. But I think it's more for consultation and presentation of policies and not for recommendation. We have raised the issue of improving transparency, improving inclusion of stakeholders, [and] participation. The concept of consultation is more than Zoom where the HTAC presents and the stakeholders merely listen. They ask questions and HTAC promises they will get back but they won't get back. The feedback generated during the consultation meeting, in the larger scheme of things, [can] really influence or change."*

PO mentioned that HTA in the country should have a patient representative to ensure that patient perspectives and concerns are being addressed given that they are the main end-user of the HTA recommendations; this was echoed by one of the HTAC members.

> **PO: "***There's still lots of things to improve. One is to put patients on board. When you're deciding on things a user should know about it, if you're the user and you can't say anything about it is like you bought an iphone but your mother did it for you. I just noticed there are some health programs that are not succeeding because when they formulate something patients are not involved. Patients are present at the orientation, only when it's ready to deploy. That practice may sometimes cause failure of the program. I've seen it personally. There's a program where medicine is there but no patients. It's like it's fine because there's policy, there's process, there's medicine, diagnostics or whatever but they wouldn't see the other side; the patient's experience in the process. Who would be a better person to say something about the program? Is the program patient friendly, patient centered?"*

Timeliness and delays of the HTA process

As previously mentioned, the tedious HTA process causes delays that affect the timeliness of recommendations. GA1 shared that they would have to turn to other resources, such as laws,

expressed public interest, and compassionate use, when developing benefits packages. However, these alternatives and temporary arrangements aren't available to other groups, such as civil societies and clinicians. CE1 recognized the value of the comprehensive and evidence-based HTA recommendations, but also highlighted the need for immediate approval of medicines, especially for vulnerable end-users such as cancer patients. CE1 shared that the recommendations of medicines for cancer patients were sometimes delayed and, as quoted:

CE 1: *"Patient cannot wait... They have a few years of survival, and then when they approve,when are they going to use it?"*
GA 1: "*Medyo matagal. Pero kasi matagal dahil yung capacity ay hindi optimal. We have to understand. Hindi naman natin bibigyan ng judgment dahil sa mabagal. Dahil lang gusto nila maging mabagal. It's just that the capacity is limited."*

To add, industries are not satisfied with the timeliness of the HTA recommendations. M2 and M3 stated that it takes time for the HTA team to accomplish their reviews.

M2: *"Timeliness. Super delay. In my experience, I submitted a technology in 2019. It's even WHO listed and essential medicine listed. We're saying we're good. This will be fast because it's already in WHO. But now, it's still being contracted in the PCHRD. Submitted in 2019. 2020. 2021. 2022. 2023. Four years. And then they will sub contract it to PCHRD, probably it would take six months to officially endorse. The analysis will run, probably initial recommendation ng 2024. So once they release the result, five years. Five years. When it's WHO listed medicine. So, imagine the timeliness. I think it's really one or two? to really see improvements, they need to de-clog to their own system. They really need to act quickly on the standard of care. I don't think it would create much impact."*
M3: "*timeliness siguro yung number 1, kasi meron din kasi silang recent na ni-released meron silang sinasabi dun na – "we are approving the inclusion of this technology to the PNF kasi in terms of economic considerations yung gamot na 'to mag e-expire na yung patent, so we are expecting lower price from generic companies". Yun yung nakalagay sa economic considerations. So it took too long to review that and then na expired na yung patent. So, on manufacturers perspective kapag sobrang tagal nung review and mag eexpire yung patent and papasok yung mga generic, in a way parang na delay yung access sa patient kasi nga matagal yung review. So instead na available na sya sana sa government sector hindi kasi matagal yung review, so na delay yung access sa patients, so hindi yun fair sa amin na naghihintay ng review. So yung ganun sanang consideration din na sana i-improve ni HTA yung mindset nila kasi hindi pwedeng sa lahat ng technology hintayin mo munang matapos yung patent to ensure na mas mababa yung price offer, kasi kausapin mo na kami ngayon kasi baka we can do something about it naman."*

Furthermore, timeliness of the HTA assessments also needs to be addressed because for industries this affects the rigor and relevance of the HTA recommendations.

M2: "*I think when it comes to the timeline, I think it's something that HTA should be really conscious of. Classic example, submission of 3 years ago, 4 years ago, may not be the same medicines that's recommended now. And we see HTA missing some items. For example, they are still contracting evaluation of health technologies, that only if they ask or only if they check if what is recommended. So, they should just drop it and focus on something. I'm not*

sure if it's a process issue or an implementation issue. I think it's more of really an execution issue that they have. Because, again at the end of the day, in the methods, they do clinical evidence and appraisal. But clinical evidence appraisal should also tell you upfront if the topic nominations have value as of the current date or not. And if it's you not, you got to actually not proceed with it. We don't really see that happening yet in HTA. Probably, because they feel it's their commitment to actually finish all the appraisal. Where in fact, they don't exactly have to because in reality, evidence review, it's the recommendation they can already drop that specific health technology that they are trying to evaluate. And there are reasons to discontinue din. We see this as a problem also in the HTA."

As the COVID-19 pandemic becomes less severe, M1 suggested that the HTA should transition and prioritize treatment medicines for vulnerable populations (e.g., cancer patients), treatment costs are higher compared to antimicrobials both M1 and CE2 attributed delays with the review of pandemic commodities.

Limited capacity of the HTA

The HTA is challenged to expand on their recommendations due to its limited capacity. GA2 shared that HTA, at its current state, is able to recommend financing and best technology. However, it would be helpful to also provide input on the feasibility of technology and the facilitators and barriers to its implementation, especially when they are deployed for public health use.

Meanwhile, M1 suggested prioritizing internal capacity and core functions, such as recruitment, capacity-building, establishing best practices, and adapting processes to better fit the local setting. Other stakeholders, such as private payers and patients, must be consulted, and additional perspectives (e.g., health systems, societal) must be considered to craft recommendations that are more responsive to the realities of the Philippine healthcare system.

M1: "*So, there's still a lot of improvement [needed]. At the same time, HTA should recognize the realities of the Philippine healthcare system. For example, they are insisting on payers' perspectives. But the payer, in Philhealth, is what? Covering 20% or 30% of actual cost? And predominantly out-of-pocket. So those realities should be taken into consideration. We are a mix of public and private institutions. There is variability of pricing within the government hospitals."*

M1: "*They really need to build their capacity. Only a fraction of medicines are actually in the PNF. [And we] are talking about patients in public hospitals that have not been able to afford life-saving medicines because they are not in the PNF. So, they need to build capacity. They need to find ways to hasten the process. If they can sort of adopt recommendations of other HTA bodies as to shorten the process. Reliance pathway. Something like that."*

Other factors that affect delays in HTA

Health technology is assessed by the FDA, and the manual generation of its data was identified as another cause of delay. However, the agency claims that they are currently in the process of database automation expected to be fully operational in 2022. Additionally, it was suggested that HTA conduct product safety assessments as well, instead of solely relying on FDA data.

The HTAD and HTAC's Perspectives of the HTA Processes

This section will present the results of our Thematic Analysis for the second batch of interviews, where the HTA program implementers, provided insights about the HTA processes. We interviewed seven members of HTAD and HTAC (both core and sub-committee). We will provide themes to describe the HTA program implementers' views, experiences, and challenges about the HTA processes.

Table 17. Participants' profile from HTA Program Implementers

Code	Profile
HTA Program Implementer - 1	HTAD Member
HTA Program Implementer - 2	HTAD Member
HTA Program Implementer - 3	HTAC Member
HTA Program Implementer - 4	HTAC Member
HTA Program Implementer - 5	HTAC Member
HTA Program Implementer - 6	HTAC Member
HTA Program Implementer - 7	HTAD Member

Source: Authors' compilation

Table 18. Initial and Institutional work of the HTA

Initial and Institutional Work of the HTA	Count
	33
Categories	
Creating the HTA process and methods guide	18
Forming the team of HTA and its experts	9
HTA in Philhealth	4
Inclusion of the HTA in the UHC Act	2

Source: Authors' compilation

The passage of the UHC Act in 2019 mandated the creation of HTA in the Philippines. According to the respondents, the concept of the HTA in the Philippines is not new as there was an initial HTA unit under the PhilHealth; thus, it was easy for the champions of the UHC act to lobby for the re-establishment and institutionalization of the HTA program. However, the HTA unit in PhilHealth was dissolved, as the champions in the HTA unit left PhilHealth. Participants believe that the specific provision from the UHC Act mentioning the HTA is instrumental in defining and materializing the necessary components of HTA, such as its structure, governance, and organizational development. One participant also shared that the HTA's institutionalization is driven by the need for a transparent governance process to avoid public controversies like vaccine controversies.

HTA Program Implementer_7*: "I think, when we inserted in the UHC law, it was very easy to justify, kasi unang-una, hindi naman siya bago. As we said, as you know, there was already an HTA in the Philhealth, and were already included in the National Formulary. Yung formal methods na incorporated, I guess yung naging use niya sa Formulary is rationalizing yung drugs to be included. Yung inclusion ng very transparent na economic evaluations that led to the acceptance. In fact, hindi pa kami nag-lobby. Outside stakeholders ang nag-lobby nito… I guess, this was also driven by, syempre may vaccine controversy and we know that because of those, we need a governance transparent process, na fair to all, so we can avoid yung mga ganung vaccine controversies."*

In building the Process and Methods Guides of the HTA, the HTA program implementers stated that they incorporated some of the methods from the Philippine National Formulary (PNF) and learned from its gaps and focused not only on drugs or medicines but also other necessary health technologies. Benchmarking from the HTA programs in other countries, such as the UK's NICE, Thailand's HITAP, Canadian Agency for Drugs and Technologies in Health, and Singapore's Agency for Care Effectiveness), and adopting international methodological standards (e.g., PRISMA, Meta-analysis, Cochrane methods) were also mentioned.

After benchmarking from the existing HTA program in other countries, HTA program implementers shared that they made sure that the Process and Methods guide is feasible and adaptable in the Philippine setting or local context. There was also a chance for collaboration or partnership with academic institutions and technical assistance or peer review in the initial drafting of the Process and Methods guide. The HTA program implementers aim now to continuously evaluate the HTA Methods and Process guide and continue the best practices during COVID-19 with the other health technologies.

HTA Program Implementer_1: *"We start the draft by reviewing processes and methods from other countries. We benchmark, especially for the timelines, because we wanna make sure that the timeline will be fair and justifiable to our stakeholders and is something that is really workable based on the experience of other countries."*

HTA Program Implementer_7*: "I mainly based it on the existing process of the PNF, because the concept of the HTA is very similar to the PNF process,. It''s basically HTA for drugs. I thought that it would be easier to begin with that, to pattern with the PNF process, because people are already very familiar with the PNF process. And when you look at the actual HTA process, it's really very similar. The only difference is it has more consultations. We eventually completed the process. Like even in scoping, and it has questions, such as topic prioritization. It has many consultations and public consultations mostly for appeals."*

Regarding the formation of the HTA and its experts, members shared that they were carefully selected by the Executive Committee members of the DOH and DOST based on their expertise and qualifications. A call for the nomination was open to the Academe and Medical societies for the selection process. Fortunately, the initial members received a series of training and workshop sessions from the partner UK's NICE and Thailand's HITAP. Participants shared that they still receive support, technical assistance, and capacity-building training from the partners with HITAP and Singapore. Moreover, regular meetings and orientations were conducted before the pandemic to form the HTA. The HTA opens the team to health care professionals and social science people to allow a multi-disciplinary HTA.

Challenges in the HTA processes during the COVID-19 pandemic and other key challenges

Table 19. Key challenges in the HTA processes

Challenges in the HTA processes during the COVID-19 pandemic	Count
	162
Categories	
Urgency of assessments and other adjustment on timelines during the pandemic	18
Limited capacity of HTA or HTAD	18
Communication of HTA recommendations or other related HTA communication	16
Lack of data and evidence during appraisal	15
Collaboration with end-users	15
Consultation and involvement from other stakeholders	13
Lack of engagement with HTA end-users and other stakeholders	13
Monitoring of recommendations and HTA process and methods	9
Outside Pressure for HTA to release recommendations	9
Involvement of FDA for the EUA	8
Deliberation of recommendation between HTAC Core and SubComm	6
Parallel work or initial background work while waiting EUA	6
Continuous evaluation of the HTA process	4
Appraisal of evidence and policy question	3
Limited understanding on the role of HTA	3
Benchmarking on the other reviews from other countries or agencies	2
Comprehensive HTA process	2
Familiarization with the process and role	1
Mainly conducting virtual meetings	1

Source: Authors' compilation

Refocus of assessments to COVID-19 technologies

Unfortunately, COVID-19 happened when the HTA was still finalizing its operations, the Process and Methods guide, forming the HTA team, and necessary adjustments were made to the operation of the HTA. Participants described the COVID-19 assessments as a "baptism of fire" for the HTA program. The pandemic disrupted processes and benchmarking and assessment efforts of the HTA. Review of COVID-19 technologies were prioritized over the 15-20 topic nominations it had originally planned to assess. The HTA program was overwhelmed with appeals as well, and technical capacity was inadequate to accommodate all requested appraisals. Priorities changed and many parts of the UHC law were not implemented, including revisiting the PhilHealth packages or designing the Primary Benefit Package of PhilHealth. The first and succeeding HTA assessments were about the COVID-19 technologies and through expedited or rapid reviews. Other technologies were still assessed in between COVID-19 urgent assessments, including the priorities of DOH, PhilHealth, and hospitals. The HTA members admitted that cutting the long Process and Methods Guide requires making decisions quickly during an emergency. The HTA still ensured they followed the procedures and balanced the rigor.

HTA Program Implementer_1: "*COVID-19 happened so we were just starting and we were still finalizing our guidelines and our processes and then COVID-19 happened and immediately we have to start our operations. I think that was the most challenging part."*

HTA Program Implementer_6: *"I described it as a baptism of fire, we were just beginning and then suddenly we were challenged with all kinds of assessments that we have to do right away. The developed processes and methods we had to apply right away.*

Limited capacity of the HTA

The HTA program implementers acknowledged that its technical capacity is insufficient to which sometimes affects or compromises the HTA process, timeline, and priorities. As for the sustainability of positions inside the HTAD, they requested plantilla positions to complement the needs of the HTA to the Department of Budget and Management (DBM); however, the granted request was less than the expected number of positions. Although personnel have shown dedication to their work, most of the staff in the HTAD are Job Orders status and they aren't entitled to benefits nor overtime pay. As they have limited capacity and with the increased pressure to conduct assessment and release recommendation in a pandemic, the HTAD team has overlapping roles, are overworked, extending meetings beyond work hours, and affecting the mental health of the staff. This results in a high number of HTAD staff leaving or resigning from their HTA positions or pursuing other careers. As one HTA program implementer shared, the workload of the HTA increases, but they do not have additional staff.

HTA Program Implementer_7*: Hopefully, DBM will give our requested plantilla position. […] The total number of staff we requested is 120. Even if they only give 40 [positions] this year. Even if it's only other years the succeeding positions, until we reached the 120 [positions]. I said that. It's not really enough. And the assessment, you have to look at it sectorally. Not just an office. That's what I'm saying to the staff, not all of us will do it. […]*
We need to build academic partners, partnerships with medical societies and health care professionals. To help disseminate the recommendations later on. What are the challenges and barriers? First, it's DBM. We want to expand ng capacity. But DBM is the bottleneck."

HTA program implementers also shared that because of the limited capacity of the HTAD and during the pandemic, they could not yet fully expand their topic prioritization, their assessment to other health technologies or PhilHealth benefit packages related to UHC, which is supposed to be accomplished in the fourth quarter 2020. There is a need to increase the plantilla positions in the HTA, and they hope that as the HTA transitions to the DOST office, they will be able to increase the number of plantilla positions inside the HEAD. One program implementer shared that they hope to also address the professional development of the HTAD staff in the span of two to three years so that it capacitates them in the HTA field and nurtures their career. Since then, senior staff who have stayed from the HTA train and capacitated the new staff. HTA program implementers also envision the expansion of the HTA into having a local and regional level HTA, and not only a national office in the country, similar to other countries with the HTA program. HTA program implementers believe it will expand the recommendation on the ground and its implementation monitoring.

HTA Program Implementer_6: *"What really the issue is the very fast turnover of the HTAD staff. The work of the HTAD is very important as it's very technical and it has a learning curve. Every time you hire a new staff, there is also a learning curve. If we always start off that learning curve, it is also added work for Senior members of the staff who always train new staff. What is the issue why there is a very fast turnover of the HTAD staff? Number one, they are Job Orders. They have very unstable positions. They might not see a career track within the job. So we are trying to address that and I think our transition to DOST is going to facilitate. Because one of our plans is to make it such that the staff have a career track and have a professional development track."*

Communication, engagement, collaboration, with HTA end-users or other stakeholders

HTA echoed the need to improve their program's communication and admitted that one significant HTA process, like a consultation with end-users and other stakeholders, was not conducted during the COVID-19 assessments due to the urgency of the assessment. Moving forward, HTA program implementers envision having a consultative process and more effective patient group representation in the HTA process. They also intend to have more dialogues with the public and improve in communicating the HTA recommendation. HTA program implementers shared that they have established a working relationship with the end-users, specifically from government agencies like DOH, PhilHealth and FDA. HTAC confirmed that they have regular consultations and alignment meetings are conducted with end-users from DOH and PhilHealth. Similarly, HTAD claimed that they constantly coordinate and incorporate end-user feedback into their agenda, priorities and topic nominations.

HTA Program Implementer_5: *"If you're asking me what else can we be doing to improve, we should have stronger patient's voice. I'm recommending that we have HTAC representative that would be a patient group member. […] My recommendation is get a patient as to get their perspective and that will be loud and clear that he's a patient. If there's a problem, let's say with understanding the processes of HTAC, it's good to also parang teach or empower or upskill the patient groups because they need to understand the HTAC. There is always a lot to say about a patient's voice being strong in HTAC. If you're asking me of how else can we improve, that would be it."*

HTA aims to strengthen the understanding of the stakeholders or public in the role of HTA in the Philippine health system and also to understand the priorities of the stakeholders. They also intend to translate the science of HTA recommendations into layman's terms to avoid misinterpretation of the HTA recommendation, especially from the policymakers. HTA starts to form a database of patient organizations, consumers, organizations, and companies, to facilitate accessible communication and consultation with stakeholders. HTA also starts forming a communication team focusing on this aspect. More specifically, it recommended improvements in language, presentation and dissemination of information, as well as upgrades of their web-based platform. This would require the assistance of the larger IT department of the government, which they hope to tap once they move to DOST.

Lack of evidence during the appraisal and best practices

HTA program implementers shared that the lack of evidence on COVID-19 technologies posed a major challenge to regulatory agencies in the early days of the pandemic and little to

no evidence is available. In place of peer-reviewed studies, HTAD reviewed preprints, real world data and Philippine CPG group, and conducted de-novo evidence synthesis instead. HTA shared that one of their best practices was benchmarking to other countries. They relied on international data or evidence from some countries that are advanced with the assessment or already have their countries' EUA. Eventually, the WHO became the global reference as they led the governance and evidence generation, collated evidence for COVID-19 technologies and led the clinical trials. Since it is an emergency, HTA shared that they have been proactive in conducting assessments. One best practice was that they start collecting evidence data and perform background work even without the official request to start the assessment.

> ***HTA Program Implementer_7****: "At the beginning of the pandemic, it's hard. Towards, after one year, it became easy because if global governance. What I say with global governance, WHO for example led the generation ng clinical trials. There was eventually global portal of evidence of COVID-19 vaccine. It was easily downloadable yung mga data. It became easy to HTAC in synthesizing the evidence because everything is in one portal."*

> **HTA Program Implementer_5:** *"The greatest challenge might be the lack of data and the lack of good data. Sometimes, we really don't have the data. If we have data, it's not a good data and very low level in terms of the results. ou have to make a decision in that instance, do you just say no because the level of the data that we have is poor? Or do we say okay, it's a preliminary recommendation while we wait for more data? Then of course, if we put out our preliminary recommendations, we need to be scanning the literature constantly so that if there's a new study, then that will be incorporated immediately into the preliminary recommendation."*

To release a timely recommendation and speed up the process, another best practice that the HTA shared was that they were doing parallel work while the FDA was processing the CPR of a COVID-19 technology. This allowed the HTA to release the recommendation immediately after the FDA released the EUA and CPR. Another strategy that the HTA adjusted as they concluded the released assessments as an Interim and that it is for revision accordingly if there is new evidence. One HTA program implementer said they want to continue these best practices, including the parallel work with FDA for immediate drug access and other life-saving health technologies. However, there were problems because they needed help in accessing details or information from private companies about specific products. This is because of the non-disclosure and confidentiality agreement between the FDA and companies acquiring CPR. HTA program implementers said they hope to amend this law to allow openness to data among government institutions, specifically for HTA or DOH. HTA program implementers also want to improve collaboration and communication with FDA. One HTA participant shared that they advocate more research collaboration with academic institutions to increase generation of local data and evidence. They are pushing to have an HTA course in academic institutions.

Outside Pressure for HTA to release recommendations

HTA program implementers envisions to address outside pressures that HTA program implementers experience (mainly political pressure and business interest) to perform assessments and release recommendations. They believe that this comes from the limited understanding of the role of HTA. One HTA program implementer shared that despite its

valuable role in the COVID-19 pandemic, the agency is perceived as part of the bureaucracy or an additional barrier or red tape and its evidence-based recommendations continue to be underappreciated. There is a demand to release recommendations without evidence and conflict of interest. Recently, the HTA was blamed for the expiry of COVID-19 vaccines. One HTA program implementer explained that HTA is an independent agency and recommendation comes before the procurement, and HTA is not part of the deployment process of the technologies. They also defend that the HTA recommendation applies only to government purchases and not to purchases of private organizations or donations. Finally, they added that the HTA does not monitor the implementation of the HTA recommendation. Hopefully, HTA will perform more monitoring of recommendations that are implemented in the future as they progress and transition from non COVID-19 technologies assessment.

HTA Program Implementer_6: *"… we understand what you want to happen. But we also have to go by our methods, and our processes, our methods, require that we have to have adequate evidence to support our recommendation. Without that adequate evidence we can't give recommendations because we are going against our own guidelines. We cannot go against our own guidelines."*

Below is the summary of challenges in the HTA process experienced by the HTA program implementers that have been discussed and possible proposed action plans in addressing these challenges.

Table 20. HTA Program Implementation Summary of Challenges and Action Points

Challenges	Possible Action Points
Refocus on COVID-19 assessments. COVID-19 assessments is described as a "baptism of fire" for the HTA program. Few technologies were still assessed in between COVID-19 urgent assessments and rapid review, including the priorities of DOH, PhilHealth, and hospitals.	As the HTA has established lessons learned and best practices in the HTA process during the COVID-19 assessments, these will be useful in transitioning now to the assessment of other health technologies and continuous evaluation of the HTA Methods and Process guides.
Lack of evidence during the appraisal. HTA program implementers shared that one major problem during the appraisal is the little to no evidence, especially since the COVID-19 pandemic is a health emergency and these COVID-19 technologies are new and still need to be tested.	Advocate more research collaboration with academic institutions to generate local evidence. Besides the WHO as a reference and leading governance, HTA will still benchmark with other evidence from other countries' HTA units.
Limited capacity of HTA. The HTA program implementers admitted that there is really a limited capacity in the HTAD and it sometimes affects or compromises the HTA process, timeline and priorities. They requested plantilla positions to complement the needs of the HTA to the DBM, but the granted request was less than the expected number of positions. Most of the staff in the HTAD are Job Order and a high number of HTAD staff leaving or resigning their positions or pursuing other careers because of workload.	There is a need to increase the plantilla positions in the HTA to expand its role and capacity. HTA will continue to lobby for the increase of plantilla positions in their office and will also continue to collaborate with other countries' HTA units for the staff's capacity building, advancing their skills in the HTA and professional development.
Communication and engagement with HTA end-users or other stakeholders. Program implementers envision having stronger stakeholders and patient groups' representation in the HTA process, as the process should be consultative. One significant HTA process, like a consultation with end-users and other stakeholders, was not conducted during the COVID-19 assessments due to the urgency of the assessment.	HTA program implementers aim to have more dialogues with the public and improve in communicating the HTA recommendation. They also intend to translate the science of HTA recommendations into layman's terms to avoid misinterpretation of the HTA recommendation, especially from the policymakers. HTA has started forming a communication team focusing on this aspect.

Source: Authors' compilation

Case Studies

The three case studies below illustrated the process of assessment of HTA. The process and challenges encountered by the HTA during the assessment were also discussed in the case studies.

Box 1. Case Study 1: Reassessment of the 10- versus the 13-valent Pneumococcal Conjugate Vaccines (PCV) in the Philippines

Reassessment of the 10- versus the 13-valent Pneumococcal Conjugate Vaccines (PCV) in the Philippines

In the Philippines, pneumonia is still one of the leading causes of death among Filipino children under 5 years old (PCV Full HTA Report [FINAL] .Pdf, n.d.) A study on invasive pneumococcal infections by Capeding et al. (2013) estimated a mortality rate of Invasive Pneumococcal Disease at 25-34 deaths per 100,000, which is equivalent to 3,300 deaths in children under 5 years old annually. Pneumococcal infections, which can be prevented by vaccination have been shown to lead to serious infections like meningitis, sepsis, clinical pneumonia, Invasive Pneumococcal Disease (IPD), and Acute Otitis Media (AOM) (Capeding et al., 2013). Given this, immunizing infants with either of the two vaccines is necessary to help prevent mortality and morbidity among children.

There are two kinds of PCV available in the country: PCV10 and PCV13. In 2012, the Department of Health (DOH) procured PCV10, a decavalent PCV, which provides protection against 10 serotypes of *S. pneumoniae*. However, in 2014, the Formulary Executive Council (FEC) recommended the inclusion of PCV13 in the Philippine National Formulary (PNF) as the result of two cost-effectiveness studies conducted by the World Health Organization (WHO), which showed PCV 13 as a more cost-effective choice over that of PCV 10. In February 2019, the WHO released a position paper stating that, when given to infants and children under 5 years, both PCV 10 and PCV 13 have a substantial impact against pneumonia, vaccine-type pneumococcal disease, and nasopharyngeal carriage (*WHO - Weekly Epidemiological Record*, 2019).

The reassessment of PCV was prioritized by HTAC as the country still remained undecided on which PCV to administer and the previous PhilHealth PCV benefit package allowed either to be used. Given updated studies on the clinical efficacy and effectiveness of both PCV10 and PCV13, as well as price quotations for the new multi-dose vial (MDV) preparation for both products, the DOH requested HTAC to review PCV with the aim of determining "which PCV will be the most appropriate to meet the objectives of the DOH on universal health coverage and the reduction of overall pneumococcal disease burden in the Philippines" (*DOH Continues to Use PCV13 Contrary to Reports*, 2019).

Research questions were focused on the: (1) efficacy and effectiveness, (2) value for money, (3) budget implication on the Expanded Program on Immunization (EPI) and on PhilHealth benefits programs, and (4) the ethical, legal, social and health system implications of immunizing infants with either PCV10 or PCV13 to prevent mortality and morbidity due IPD, clinical pneumonia, and AOM. These questions were answered through the conduct of a systematic review of the clinical efficacy of both vaccines, a budget impact analysis using

a Markov model adapted from Kulpen et al. (2013), and a series of consultations, surveys, and interviews with relevant stakeholders (PCV Reassessment Evidence Summary. 2019).

The reassessment was headed by the HTAC Vaccine SubCommittee (VSC) following the standard FEC processes and methods for making inclusion/exclusion decisions for medicines. As mandated by the UHC, the HTAD conducted the evidence review while the VSC conducted the appraisal. Overall, the entire process followed the international standard for HTA processes except that it was expedited due to the urgent needs of the DOH. The timeline given for this reassessment was three months, lasting from March until the end of May of 2020, which was significantly shorter than the usual eight-month process. HTA assessments normally collaborate with outside experts during the assessment of a health technology, so it must be noted that the PCV reassessment was done internally as the HTA team had gained some internal capacity and developed a new tool for HTA assessments by the time the review was initiated.

During the assessment, the VSC looked at the evidence to develop their initial recommendation. This was then reviewed by the HTAC's Core Committee who had final authority for approval. The initial recommendation was posted on the HTA website to assist in the consultation process with relevant stakeholders; this was necessary to further refine the recommendations and to help ensure that they will be responsive to the needs of the proponents of the technology and other interest groups. For PCV, the stakeholders consulted were representatives from the National Immunization Program (NIP), the Philippine Health Insurance Corporation (PhilHealth), the Pediatric Infectious Disease Society of the Philippines (PIDSP), the Philippine Alliance of Patient Organizations (PAPO) and the companies which manufacture PCV. After considering all the comments from the stakeholders, the final recommendation was sent to the DOH Secretary of Health for approval. *Comments and concerns raised from this consultation were not publicly available.*

Concerns and challenges in the availability and the quality of data were raised during the review process. Based on the information from the VSC respondent, there was much difficulty in doing this reassessment due to the lack of local data, even within the DOH. This concern was reflected in the HTA full report. According to the HTAC, "there is limitation with regards to the strength and conclusiveness of evidence on serotype prevalence and distribution in the country which could guide decision-makers on the appropriateness of existing PCV vaccines based on our serotype profile. The impact of implementing PCV vaccination over the past years cannot be determined as well due to this limitation on epidemiologic surveillance." (PCV Full HTA Report [FINAL] .Pdf, n.d.). To resolve this, the HTAC proposed actions for better monitoring of cases of PCV and to more reliably support future assessments for PCV in the country. These include:

- Program evaluation should be in place to measure the impact on the burden of pneumococcal disease and changes in serotype distribution with the use of PCV vaccines
- The DOH should ensure high-quality surveillance, following WHO guidelines, and this should begin within the year to enable the conduct of impact monitoring and assessment.
- The DOH should also consider periodic surveys of nasopharyngeal carriage that will characterize changes in serotype distribution
- Future studies should be commissioned to determine the clinical and economic burden of pneumococcal diseases in the Philippines

Regardless of the limitations mentioned, the representative from the VSC stated that they did the best they could with the existing data gathered from the DOH, the Research Institute of Tropical Medicine (RITM), the NIP and published data.

In the Philippines, the HTAC was able to **initially recommend** the multi-dose vial preparation of PCV indicated for the serotypes relevant to the country. They also stated that the price at which both vaccines that will be offered during the actual purchase should be taken into consideration. In 2020, the DOH issued a Department Memorandum Order stating that the Secretary of Health has approved this recommendation (Department Memo No. 2020- 0366). In May 2022, the DOH released a Department Memo that ordered relevant agencies and stakeholders to **shift from Pneumococcal Conjugate Vaccine 13 (PCV13) to Pneumococcal Conjugate Vaccine 10 (PCV10)** in the Routine Immunization for Children as PCV 10 was found to be more affordable and cost effective than PCV 13.

In terms of efficacy and cost effectiveness, PCV has been evaluated using HTA in a variety of countries and populations and has now been included in NIPs in 150 countries across the world (Bencina et al., 2022). Several countries like Indonesia, Belgium, Canada and Morocco have switched from PCV13 to PCV10 (or vice versa) in their infant immunization programs. All have their own advantages and disadvantages from switching between PCVs since recommendations vary based on their local epidemiology and programmatic factors in their respective NIPs (Suwantika et al., 2020).

Box 2. Case Study 2: Use of Rapid Antigen Test Kits For the diagnosis of COVID-19

Use of Rapid Antigen Test Kits For the diagnosis of COVID-19

In response to the nationwide limited capacity to perform laboratory-based tests and the need for accelerated expansion of testing coverage, the DOH requested HTAC to do the appraisal of the Rapid Antigen Test (RAT) (Annex a_Rapid Review on COVID-19 Rapid Antigen Tests (24 September 2020).Pdf, n.d.).

RATs belong to a class of rapid diagnostic tests which detects the presence of viral proteins or antigens expressed by the COVID-19 virus in a sample from the respiratory tract of the person (WHO, 2020). This point-of-care diagnostic test produces results quickly (within approximately 15–30 minutes), is easy to use, offers rapid results at low cost and is generally less sensitive than real-time reverse transcription polymerase chain reaction (RT-PCR) (CDC., 2020).

The assessment was focused on the RAT and if this should be considered for diagnosing of COVID-19 in the Philippines. It specifically assessed its (1) regulatory approval, (2) performance characteristics, (3) global guidelines and position on use and (4) resource requirements. This was headed by the Sub-Committee on Clinical Equipment and Device (CED) and HTAD's Policy Planning and Evaluation (PPE) Team. The assessment followed the **Expedited HTA Process;** a process used for health technologies during Public Health Emergencies in this case the pandemic. RAT assessment took 3 months lasting from May 29 until July 14, 2020 following the timeline of 2 to 12 weeks of the request for an expedited review process but because of the urgent need of the results, the HTAD team were able to produce reports and updates in as fast as 2 weeks due to urgent need for decision making in the government thus this assessment provided a lot of pressure for HTAC and HTAD.

The methods used for this assessment were a combination of targeted and systematic literature search. Five reviewers searched for RAT approved use cases, validation testing requirements and reviewed its performance characteristics. For critical appraisal, a standard data extraction tool and evaluation of Articles on Diagnosis (Dans et al, 2017) tool was used to evaluate the quality of the included clinical accuracy studies. All the analyses were performed using Review Manager (RevMan) version 5.3.5 and Microsoft Excel for Microsoft 365 (HTAC Recommendation on RATs for COVID-19 (as of 01 August 2020).Pdf, n.d.)

After the assessment review, the PPE team presented the results to the Sub-Committee on CED. The final evaluation was submitted by the SC to the HTAC Core Committee for finalization of the report and recommendation. The report was then submitted to the DOH Secretary for approval. It is important to note that there is no requirement for public consultation for expedited reviews. Results are usually presented, if needed, to the relevant stakeholders and to the end users once the assessment is done to guide them in their bidding and use.

During the appraisal, the HTAD and PPE team had to deal with pre-print studies, and limited epidemiological local data. To resolve this, they relied more on Real World Data and used information from the target product profile by the UK Medicines and Healthcare products Regulatory Agency (MHRA) (2020b) and interim guidance by the WHO (2020). Given the

limitations mentioned, the following are the other overarching recommendations of the HTAC:
Publicize standards on diagnostic performance to address the observed wide variability of performance in all COVID-19 testing kits in the market
Strengthen system for monitoring and evaluation of compliance of manufacturers to regulatory standards and post-marketing requirements. Departmental constraints must be addressed to enable strict compliance and to add teeth to implementation.

In light of the rapidly evolving evidence on COVID-19 testing, RAT assessment underwent 3 interim guidelines for April, May and June 2020 because there was new data and evidence that they had to review. On their last update in 2021, RITM was consulted for the resource requirements for RATs. In addition, guidance documents to inform policy makers and the public on the appropriate use and experience across countries and settings were also developed. This also states under which conditions RT-PCR tests and RATs are to be used.

To complement RT-PCR testing, several countries like Health Canada and the US Centers for Disease Control and Prevention (CDC) and WHO have already started clinical validation of RATs' performance and have recently issued guidelines for the use of RATs and integrated RATs use in their national testing strategies (ECDC.2020).

Currently, RT-PCR remains the standard confirmatory test for diagnosing COVID-19 in the Philippines as it more accurately determines the presence of coronavirus and if a person is currently infected. While RATs have been considered to help in addressing the limitations of RT-PCR testing, they remain not to be recommended in the Philippine testing guidelines as a standalone test to definitively diagnose or rule out COVID-19, and must be used in conjunction with RT-PCR (Use of RAT Kits for the Diagnosis of COVID-19 (April 2021 Assessment). This evaluation has also led to the integration of RAT kits in the Omnibus Interim Guidelines on Prevention, Detection, Isolation, Treatment, and Reintegration Strategies for COVID-19 (DM 2020-0439) and was approved after 1 and a half year by PhilHealth and developed its own package titled Facility-Based COVID-19 Rapid Antigen Testing Benefit Package (PhilHealth Circular No.2022-0010). As of October 24, 2022, there are 14 approved RAT brands by the Philippine Food and Drug Administration (PH FDA) validated by the Research Institute for Tropical Medicine (RITM).

Box 3. Case Study 2: Use of BNT162b2 Pfizer–BioNTech COVID-19 vaccine

Use of BNT162b2 Pfizer–BioNTech COVID-19 vaccine

To protect from getting infected and build immunity to COVID-19, the scientific community immediately paved the way for the development of a COVID-19 vaccine. Rapid research for vaccine technology like Pfizer has been expedited to respond to the public health emergency. WHO also released an interim recommendation of the BNT162b2 Pfizer–BioNTech COVID-19 vaccine first issued last January 2021 and granted it for Emergency Use listing last December 2020.

Pursuant to the role of the HTAC to develop coverage recommendations particularly in the selection and financing of COVID-19 vaccines, evaluation of the Pfizer vaccine was conducted.In January 2021, FDA released the EUA of Pfizer–BioNTech COVID-19 vaccine in response to a COVID-19 public health emergency. This was followed by the assessment of the BNT162b2 Pfizer–BioNTech COVID-19 vaccine which aims to determine if this is recommended for emergency use to reduce COVID-cases, severe infections, and deaths. For a vaccine technology to be deployed in the country, HTAC listed in their released guidance the three requirements to inform the public: (1) an Emergency Use Authorization (EUA) by the Philippine FDA, (2) a positive recommendation based on a WHO recommendation, and (3) preparation of the National COVID-19 Vaccination Operations Center (NVOC) implementation guidelines (HTA, June 2022)

During the assessment, HTAD followed the expedited review process and utilized an HTAC evaluation framework assessment to assess the Pfizer–BioNTech COVID-19 vaccine. The criteria used are: "(1) responsiveness to magnitude and severity; (2) clinical efficacy and safety; (3) affordability and viability; (4) household financial impact; (5) social impact; and (6) responsiveness to equity" (p.3). The two reviewers from HTAD also evaluated the risk of bias and summarized the HTAC interests in eight vaccine efficacy outcomes and four safety outcomes of the Pfizer-BioNTech through the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) Approach. Just like in other COVID-19 technology assessments, the HTAD team faced problems in gathering data. As mentioned in their report, they were limited to one published clinical trial about the Pfizer–BioNTech COVID-19 vaccine by Polack et al. (2020). This study is the only available data during the assessment. Aside from the limited data, HTAD also has problems communicating with the FDA. According to HTAD, there's no proactive notification about the authorization of a particular product or technologies from the FDA. To speed up the process, HTAD start's the assessment while waiting for the FDA regulatory review. In addressing the issue in limited evidence, HTAD found guidance on the efficacy of vaccines from major agencies like WHO and International Vaccine Access Center (IVAC) initiated by the Johns Hopkins Bloomberg School of Public Health. HTAC and HTAU also mentioned the availability of real world effectiveness evidence for vaccines but with the caveat that they also appraised these observational data. HTAC and HTAU noted in their recommendations that they would follow up data to establish the safety and efficacy of vaccines.

Eighteen days from the release of the EUA from FDA, on February 2021, HTAC provided the first positive recommendation of the emergency use of the COVID-19 vaccine for the Pfizer–BioNTech COVID-19 vaccine "to reduce the burden of COVID-19 among identified

priority groups aged 16 years and older" (HTAC & HTAU, February 2021, p.4). While the first vaccination roll-out started in March 2021 for health workers with Sinovac's CoronaVac vaccine, the Philippines received the first doses of Pfizer–BioNTech COVID-19 vaccine only on May 2021.

Because of the temporary limited supply of the vaccine, "HTAC [for a while] also maintains its recommendation among identified priority groups aged 16 years and older only" (p.4). HTAC noted that the high risk population will be prioritized for vaccination and that they will revise their recommendations to expand to other populations as supply increases. HTAC updated their recommendations on the use of Pfizer–BioNTech COVID-19 vaccine to the pediatric population for adolescents 12 to 17 years old and Children 5 to 11 Years Old last October 2021 and February 2022, respectively. Furthermore, the HTA recommendation was released last October, 2021 also for the first booster vaccination among Priority Groups administration of second booster for 50 years and older and 18 to 49 years old with comorbidities is the latest HTAC recommendation released last August 2022. Vaccines that are recommended for a second booster are Pfizer-BioNTech and Moderna.

Discussion

This study assessed end-user experiences, perspectives, and challenges with regard to HTA. It also obtained insights from the HTA team to better understand the current HTA processes in the country.

End-users recognized the value of HTA and utilized its recommendations in agenda-setting, policy-formulation, decision-making, and procurement. Stakeholders also recognized the rigor and expertise that the HTA program placed in their processes. However, its current capacity hindered it from efficiently delivering its outputs. Public health emergencies (e.g., the COVID-19 pandemic) also delayed the assessment of technologies for other high-burden diseases, and consequently affected access to essential medicine and patient outcomes. Adopting international best practices and adding human resources have been proposed as solutions to further refine current processes. Moving forward, strategies to improve coordination, communication and the HTA process must also be explored. The pandemic has limited HTA and stakeholder engagement to virtual consultations, which made it challenging to establish rapport. A stakeholder reported experiencing one-sided consultative meetings without sufficient follow-up. Information was also communicated in a language that was too technical to understand. Multi-stakeholder cooperation is paramount to HTAD, and it plans to strengthen engagement by developing a separate framework that would explicitly detail their involvement. It also plans to add to its methodologies other relevant provisions, such as real-world effectiveness and distributional cost effectiveness analysis. These will be incorporated into their Methods and Process Guide.

Limited capacity was likewise identified to delay HTA recommendations. End users suggested improvements in HTA core functions through additional hiring and capacity-building training. It is also crucial to establish a set of best practices, which entails careful consideration of multiple perspectives, including health system and private payers' perspectives. Moreover, while they see that HTA affects policy, stakeholders also recommended that implementation and contextual issues should be laid out and discussed post-release of HTA recommendations.

Lessons learned from the pandemic

HTA has gained increased recognition in the country during the COVID-19 pandemic, but this period proved to be most demanding for the agency as well. Lack of local data, long wait periods on FDA data requests, and limited manpower were some of the issues that consistently challenged HTAD.

Across countries, there was a lack of peer-reviewed and randomized, comparative evidence. Study samples were underpowered, with a high risk of confounding factors. These limited the reliability of the clinical evidence base and increased the uncertainty in making assessments (Eldivge et al., 2021).

Insufficient data challenged decision-makers in all five ASEAN HTA countries, but only the Philippines lacked local and economic costing data (ASEAN et al., 2021). The local HTAD had to rely on existing systematic reviews or M&Es performed by other HTA agencies and the WHO, which turned out to be one of the agency's most notable practices. This reflects the potential of real-world evidence (RWE) in guiding HTA decision making, especially if data provide useful insights quickly and robustly (Eldivge et al., 2021). RWE is widely used by different industries and institutions. For example, the US FDA uses real world data to monitor postmarket safety and adverse events and to make regulatory decisions. The healthcare community uses this to support coverage decisions and to develop guidelines and decision support tools for use in clinical practice and medical product developers use RWE to support clinical trial designs (e.g., large simple trials, pragmatic clinical trials) and observational studies to generate innovative, new treatment approaches (US FDA 2022).

Although this was a mechanism to efficiently and effectively respond to urgent needs, there is still an opportunity to find more viable solutions for the inadequacy of local data. The HTAC and HTAD could create and publish a data inventory of data sources, gaps, and quality (Co et al., 2021). This can be done through landscape analyses of studies, data inventories, mapping of data sources, encouraging data harmonization and, lastly, publicizing the need for comprehensive monitoring and evaluation. This might also encourage current agencies to maintain and even improve their work. Other HTA agencies have tried using this in collaborating and disseminating their HTA reports. They have developed dedicated evidence portals containing COVID-19 assessment reports, data and news, to rapidly disseminate relevant information to decision makers. This strategy includes taking a more collaborative approach and creating knowledge-sharing initiatives beyond the pandemic (Eldivge et al., 2021).

Apart from improving on data, there is also a need to improve on communication and dissemination of technical information. . Among the suggestions mentioned: (1) improving their process and methods through including a specific section for end-users and relevant stakeholders, (2) involving them in the process by conducting more public consultations, and (3) creating a communication team capable of communicating HTA reports and concepts to different audiences. Finally, HTA-informed policy must be expanded and regularly introduced through strong political commitment and consistent stakeholder engagement.

Given that the HTA in the Philippines has only been established in 2019, this study can only evaluate its processes or mechanisms and not its impacts. There is limited quantitative information to assess the HTA beyond the number of their published and on-going assessments. The ratings provided by the stakeholders were prone to recall biases and are

subjective. The study was also not able to achieve data saturation due to the limited availability of the stakeholders.

Recommendations

The following are action, policy, and research recommendations based on the initial results.

Action

i. The HTAD should perform an inventory of existing data systems to identify the types of data needed for HTA (e.g, burden of disease, serological profile, costs, etc.). This inventory should include possible sources of data, scope of data in terms of place and time, quality, completeness, and format (i.e., analog or digital). Formal collaborations with both public and private hospitals, medical societies, academe, and medicine and device manufacturers should be explored.
ii. The HTAD should open a dialogue with the FDA to improve communication and coordination.
iii. The HTA Technical Secretariat should:
    a. perform a time-and-motion analysis of the assessment process to identify delays and barriers and take steps to reduce or eliminate redundant processes or to run processes in parallel.
    b. allocate sufficient staffing to ensure that all processes are efficiently done.
    c. create a strategic communication plan that identifies its key audiences, its core messages on the HTA processes and appraised technologies whether or not they are approved, and its communication platforms. It should also hire staff with communications expertise to manage the HTAC's communication and engagement with its multiple stakeholders.
    d. communicate with its stakeholders, in a transparent manner, on how it manages and mitigates conflicts of interest.
    e. establish a dashboard that enables stakeholders to track the progress of a technology under review.

Policy

i. The HTA provision in the UHC Law should be amended to no longer require level 4 clinical trials nor a WHO recommendation. Instead, alternative sources of equivalent strength of evidence should be acceptable, e.g., critically-appraised phase 3 trials, meta-analyses, or clinical practice guidelines.
ii. The HTAD should:
    a. perform a landscape analysis of priority diseases (e.g., the 48 diseases contributing to 80% of the DALYs) and potential innovative technologies that are not yet available in the country and prioritize them for assessment. There should be an active nomination process to supplement the current passive nomination process.
    b. develop alternative and more rapid assessment processes for technologies that are of same/better effectiveness but of lower cost (and, potentially, low budget impact).
    c. create a larger consortium of universities and research institutes that can be commissioned for technology assessments.
iii. The HTAC should:
    a. request for increased funding to increase the capacity of its assessment teams with the objectives of shortening the period for approval, of increasing the

annual number of technologies that can be reviewed, and of expanding the types of technologies that can be approved. For example, the methods and processes for the approval of medical devices are still poorly developed.

b. expand the breadth of its assessments and appraisals to also consider: implementation arrangements, health system capacity, and ethical, social, and legal aspects of the target technologies.
c. conduct consultations that not only listen to stakeholder concerns but also make genuine efforts to provide feedback in a timely manner.
d. communicate, in a transparent manner, its rationale for approving or disapproving a technology through HTA briefs, in addition to its full report.
e. The DOH should explore alternative policy options for the financing of technologies for special populations. Because HTA takes a utilitarian approach, technologies for persons with disabilities, persons with rare diseases, and similar populations will be unlikely to be prioritized.

Research

i. The HTA Technical Secretariat should:
    a. undertake annual performance reviews of the HTA program
    b. create a monitoring and evaluation framework for the HTA program
    c. design an HTA impact evaluation study to be conducted in the long-term (>10 years from HTA inception) but immediately initiate the creation of an information system for the measurement of impact

Conclusion

The stakeholders of the HTA program are satisfied with its value in agenda-setting and policy formulation and in its institutional reputation and fit with the healthcare system. On the other hand, they are dissatisfied with its performance in stakeholder engagement and external communications, timeliness of HTA reviews and with the lack of implementation guidance in its recommendations. As of this writing, no information is available yet on the effect of HTA on price negotiations.

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Appendix A. Table of Accomplished Assessments by the HTA Division

NAME OF HEALTH TECHNOLOGY	TYPE OF HEALTH TECHNOLOGY	ASSESSMENT STATUS	RECOMMENDATION STATUS	DECISION STATUS	DATE OF PUBLICATION
CoronaVac COVID-19 Vaccine for children 6 to 17 years old	Vaccines, Preventive and promotive health services	Complete	Complete	Available	05 October 2022
insulin glargine and insulin detemir for type 1 and type 2 diabetes mellitus	Drugs	Complete	Complete	Available	03 October 2022
Second Booster of COVID-19 vaccines for the prevention of COVID-19 among individuals aged 50 years old and older and individuals with comorbidities aged 18 to 49 years old	Vaccines, Preventive and promotive health services	Complete	Complete	Available	23 August 2022
Rituximab for the Treatment of Non-Hodgkin's Lymphoma	Drugs	Complete	Complete	Available	29 July 2022
eribulin in the treatment of soft tissue sarcoma patients with previous treatment of two other chemotherapeutic agents for metastatic disease	Drugs	Complete	Complete	Available	13 June 2022
Lapatinib in treatment of HER2-positive breast cancer patients	Drugs	Complete	Complete	Available	31 May 2022
tocilizumab for the treatment of COVID-19	Drugs	Complete	Complete	Available	11 May 2022
Potassium Citrate [1620 mg (15mEq)] tablet	Drugs	Complete	Complete	Available	11 May 2022
Fourth dose of COVID-19 Vaccines among the immunocompromised population (ICPs)	Vaccines, Preventive and promotive health services	Complete	Complete	Available	21 April 2022
Use of Self-Administered Antigen Testing for COVID-19	Clinical equipment and devices	Complete	Complete	Available	07 April 2022
Vasopressin 20 I.U./mL (I.V./I.M./S.C.)	Drugs	Complete	Complete	Available	02 March 2022

Pfizer-BioNTech (10ug/dose) COVID-19 Vaccine for Children 5 to 11 Years Old	Vaccines, Preventive and promotive health services	Complete	Complete	Available	11 February 2022
Sambong 250mg tablet for anti-urolithiasis (kidney stones)	Other Health Technologies	Complete	Complete	Available	14 January 2022
Use of casirivimab+imdevimab for the treatment of COVID-19	Drugs	Complete	Complete	Available	24 December 2021
Emtricitabine + Tenofovir DisoproxilFumarate fixed-dose combination as OralPre-Exposure Prophylaxis (PrEP) toreduce the risk of sexually acquired HIVinfection	Drugs	Complete	Complete	Available	17 December 2021
Sputnik V Gam-COVID-Vac COVID-19 Vaccine for the prevention of COVID-19(December Reassessment)	Vaccines, Preventive and promotive health services	Complete	Complete	Available	December 14, 2021
Covovax for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	December 14, 2021
Whole Virion, Inactivated Corona Virus [Covaxin] for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	November 29, 2021
COVID-19 Vaccine Sinopharm for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	November 29, 2021
Booster and Additional Dose Vaccination for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	03 November 2021
RapidAntigen Test Kits for the Diagnosis ofCOVID-19 (September 2021 Updates)	Clinical equipment and devices	Complete	Complete	Available	27 September 2021
Tenofovir/Lamivudine/Dolutegravir for treatment-naive and treatment-experienced adolescents and adults living with HIV	Drugs	Complete	Complete	Available	August 24, 2021

SARS-CoV-Vaccine (Vero Cell), Inactivated[CoronaVac] for the prevention ofCOVID-19 (July Updates)	Vaccines, Preventive and promotive health services	Complete	Complete	Available	30 July 2021
Two-dose Inactivated Polio Vaccine (IPV) versus One-dose IPV for the prevention of Poliomyelitis	Vaccines, Preventive and promotive health services	Complete	Complete	Available	July 13, 2021
Sputnik V, Pfizer - BioNTech, Janssen, AstraZeneca(June Reassessments)	Vaccines, Preventive and promotive health services	Complete	Complete	Available	25 June 2021
COVID-19 MRNA Vaccine (Nucleoside Modified) (COVID-19 Vaccine Moderna) for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	28 May 2021
Use of RT-PCR Testing for COVID-19 (April 2021 Reassessment)	Clinical equipment and devices	Complete	Complete	Available	30 April 2021
Janssen Ad26.COV2.S (COVID-19) Vaccine for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	30 April 2021
Use of Rapid Antigen Test Kits for the Diagnosis of COVID-19 (April 2021 Assessment)	Clinical equipment and devices	Complete	Complete	Available	30 April 2021
Sputnik V Gam-COVID-Vac COVID-19 Vaccine	Vaccines, Preventive and promotive health services	Complete	Complete	Available	12 April 2021
SARS-CoV-2 Vaccine (Vero Cell), Inactivated [CoronaVac]	Vaccines, Preventive and promotive health services	Complete	Complete	Available	09 April 2021
effectiveness and safety of pazopanib in the management of metastatic soft tissue sarcoma post-chemotherapy	Drugs	Complete	Complete	Available	23 February 2021
COVID-19 Vaccine (ChAdOx1-S [recombinant]) (COVID-19 Vaccine AstraZeneca) for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	08 February 2021

BNT162b2 (Pfizer-BioNTech COVID-19 Vaccine) for the prevention of COVID-19	Vaccines, Preventive and promotive health services	Complete	Complete	Available	02 February 2021
High-Flow Nasal Cannula Oxygen Therapy for the treatment of Acute Hypoxemic Respiratory Failure for COVID-19	Clinical equipment and devices, Medical and surgical procedures	Complete	Complete	Available	01 December 2020
Use of Pooled Testing for the screening and surveillance of COVID-19	Clinical equipment and devices	Complete	Complete	Available	28 October 2020
Use of Rapid Antigen test kits for the diagnosis of COVID-19	Clinical equipment and devices	Complete	Complete	Available	02 October 2020
Extracorporeal Membrane Oxygenation (ECMO) for COVID-19 patients with ARDS	Clinical equipment and devices, Medical and surgical procedures	Complete	Complete	Available	10 September 2020
Rapid antibody tests (RATs)(May 2020 reassessment)	Clinical equipment and devices	Complete	Complete	Available	01 August 2020
Pneumococcal Conjugate Vaccine 13 (PCV-13)(2020 Reassessment)	Vaccines	Complete	Complete	Available	01 July 2020
Reverse Transcriptase - Polymerase Chain Reaction (RT-PCR)	Clinical equipment and devices	Complete	Complete	Available	18 May 2020
AMTI uAI-Discover-PNA	Clinical equipment and devices	Complete	Complete	Available	14 April 2020
Huawei Cloud AI-Assisted Diagnosis	Clinical equipment and devices	Complete	Complete	Available	13 April 2020
Favipiravir	Drugs	Complete	Complete	Available	08 April 2020
Cycloferon	Drugs	Complete	Complete	Available	07 April 2020
Rapid antibody tests (RATs)(March 2020 assessment)	Clinical equipment and devices	Complete	Complete	Available	25 March 2020

Appendix B. Table summary of satisfaction rate given by the respondents from FDA, DOH, and PhilHealth

Satisfaction rate	GA 1	GA 2	GA 3	M	CE note: 2 representatives
Theme 2: Effective use of HTA in the agenda-setting and policy formulation processes Scientific rigor	NA	5	5	4-5	CE 1: 5 CE 2: 5
Relevance	NA	5	5		CE 1: 5 CE 2: 6
Theme 3: Effective engagement and external communications Communication	5	4 and 5	5 and 3	4-5	CE 1: 4 CE 2: 5
Theme 4: Good institutional reputation and fit within the healthcare and policy-making system Value of HTA reports and recommendations	NA	5 and 6	5	4-5	CE 1: 5 CE 2: 6
Trust on the method and process	NA		5 (Methods) and 3 (Process)	3-4	CE 1: 5 CE 2: 5
Theme 5: Effective use of HTA as a tool for the negotiation of health technology prices HTA findings cited as reference for price negotiation	NA	NA	NA	NA	NA

HTA findings lead to price reductions of a health technology	NA	NA	NA	NA	NA
Theme 6: Effective implementation of policy change regarding health technologies How often they adopt HTA findings as evidence in their policy changes	NA	No observable policy change.	No observable policy change.	No observable policy change.	CE 1: Occasionally CE 2: Never
Theme 7: Key challenges and barriers regarding HTA recommendations Timeliness of the recommendations	NA	4	3	3-4	CE 1: 3 CE 2: 3
Relevance and significance of the recommendations	NA	5	5	6	CE 1: 5 CE 2: 6
Satisfaction with the HTA reports and recommendation	NA		3	3-4	CE 1: 5 CE 2: 5
Acceptability of HTA reports and recommendations	NA	5	5	3-4	CE 1: 5 CE 2: 5
General impact of the HTA to their organization/office	Moderate	High	Can't assess as they believe HTA is still on early implementation	High	Both High

Appendix C. Revised KII guide

Theme 1: Knowledge and involvement about the HTA program

Could you explain what you know about the HTA program in the Philippines?

Probe:

- Are you familiar with HTAC and HTAD? What do they do?
- What are their processes?
- What is the purpose of the HTA reports and recommendations?
- What do you think is the current role of the program in the health system?

- Could you explain how your organization is involved with the HTA program?
  - What is the purpose of HTA in your organization? (e.g., coverage or reimbursement decisions, support for pricing decisions, support for clinical guidance, other: specify)
  - How does it fit with the mandate of your organization?
  - What type of information* do you receive from the HTA program? (e.g., appraisals, evaluations, and priority-setting recommendations, etc.)
  - What can you say about your access to HTA information?
    - What are your expectations on access to HTA information?
      - Were these expectations met? If not, what are your recommendations to increase access to HTA information for organizations like yours?
  - What other support do you receive from the HTA program?

**information - refers to technical products from the HTA program, including but not limited to appraisals, evaluations, and priority-setting recommendations. Alternately use with the terms: recommendations and reports*

Theme 2: Effective use of HTA in the agenda-setting and policy formulation processes

Have you been able to use the report developed by HTA to meet the specific needs of your organization?

To what extent?

- Impact of HTA on their:
  - mandates

- Agenda-setting
- Policy formulation process
- decision making

- If not, why?
- Can you describe how the information provided by the HTA program influences (or contributes to) your organization's agenda setting and policy formulation/making processes?
  - Can you describe how you explicitly utilize the HTA reports/recommendations?
  - Can you describe an instance in which information from the HTA are used as **reference material or cited** as material incorporated in policy or administrative documents?
- Can you describe an instance in which your **agenda setting process** was more effective because of HTA reports and recommendations? If you can't think of such an instance, why not?
- Can you describe an instance in which your **decision-making was rigorous and informed** because of the use of HTA reports and recommendations? If you can't think of such an instance, why not?
- Can you describe an instance in which your **policy formulation process** was more effective because of HTA reports and recommendations? If you can't think of such an instance, why not?
- Can you describe **other applications** of HTA reports and recommendations in your practice (e.g. clinical practice, change of practice)?
- Does your organization agree with the recommendations of the HTA agency? If not, specify an instance when your organization disagreed with an HTA recommendation or have requested reconsiderations from the received of HTA recommendations. Why did you disagree?
  - Have you ever appealed a decision that you disagreed with? If not, why not?
  - On a scale of 1-6, with 6 being the highest score, how would you rate the **scientific rigor** of the HTA report? Can you please explain why you gave that rating?

1	2	3	4	5	6

- What needs to be improved in the rigor and or relevance of the report?
- On a scale of 1-6, with 6 being the highest score. How would you rate the **relevance** of HTA findings to policy making? Please justify your answer.

1	2	3	4	5	6

**Agenda setting: create windows of opportunity for HTA, conduct policy analysis for HTA policies.*

**Policy formulation: benchmark existing good practices, situational and key stakeholder analyses, HTA: what for, when and how*

Theme 3: Effective engagement and external communications

- Can you describe how the HTA reports and recommendations are communicated with you or your organization?
- On a scale of 1-6, with 6 being the highest score. How would you rate the communication between your organization and the HTAC/HTAD?

1	2	3	4	5	6

- What needs to be improved in the communication between HTA and your organization?
- Can you describe an instance in which HTA reports and recommendations influenced your [social] perceptions and increased awareness and understanding of the challenges faced by the healthcare system?
- Is HTA perceived to have influenced conversations between different actors and stakeholders within your organization?
    - How did it enable the actors to focus more on evidence of effectiveness and cost-effectiveness of a health technology?

Theme 4: Good institutional reputation and fit within the healthcare and policy-making system

- **What do you think should be the other possible role of the HTA in the current health system?**
- What do you think should be its role?
- On a scale of 1-6, with 6 being the highest score. How much does your organization value the HTA reports and recommendations?

1	2	3	4	5	6

- How credible does your organization perceive them to be? Can you please explain why?
- Where appropriate, has your organization changed their behavior or decision (for example clinical practice, regulatory actions, sales or purchasing) as a result of HTA reports and recommendations?
- On a scale of 1-6, with 6 being the highest score. How much does your organization trust the method or process of HTA reports and recommendations and its evidence generation?

1	2	3	4	5	6

    - What needs to be improved?

Public engagement

Do HTA studies inform public debate?

    - How aware do you think the public is of the role of the HTA agency?
        - How positively do they perceive it?
        - Why do you think that is?
    - What mechanisms are you aware of that the HTA agency has for engaging members of the public in its deliberations?

- Are you aware if the HTA agency integrates the findings from public engagement with other forms of evidence (e.g., scientific evidence) to inform decisions or recommendations?
- Are there any challenges related to engaging the public in HTA processes and or findings?

*** This theme is specific for stakeholders who are involved with technology prices (e.g. Medicine Price Negotiation Board, Department of Trade and Industry (DTI) and Pharmaceutical Division). Ask these questions in the theme if applicable.*

Theme 5: Effective use of HTA as a tool for the negotiation of health technology prices

- Are HTA reports and recommendations used in negotiations with manufacturers? Have the negotiators reported price reductions or other benefits such as risk-sharing agreements as a result?
- In your opinion, how often were HTA findings cited as reference by manufacturers and other end-users? Please, justify your answer
    - always
    - often
    - occasionally
    - seldom
    - never
- How often did the HTA findings/recommendations lead to price reductions of a health technology? Please justify your answer

- always
- often
- occasionally
- seldom
- never

- How have you or your organization used HTA reports/recommendations as a price negotiation tool?

Theme 6: Effective implementation of policy change regarding health technologies

- How have your existing health technology's policies been amended and changed as a result of HTA reports/recommendations?
    - What were the steps through which the health technology's policies were amended or changed?
- How often does your organization adopt the HTA findings/recommendations as evidence in your policy changes?
    - Always
    - often
    - occasionally
    - seldom
    - never
- If applicable, Can you describe an instance in which reports and recommendations from HTA resulted in observable changes in practice***? Is it possible to attribute the change in practice to the HTA agency recommendation?

Theme 7: Key challenges and barriers regarding HTA recommendations

What are the key issues or challenges your agency/organization is facing with regard to HTA?
_____

- *Mode of dissemination of HTA findings*

Which version of reports, workshops, website, collaboration with media (press releases and interviews) did you receive?

- electronic
- print
- others, specify: _____

How effective were they?

What are the barriers to using this kind of mode of dissemination?

_____

What strategies or modes do you think would be more effective?

Do you have any comments or recommendations regarding dissemination of HTA findings?

- *Timeliness of the recommendations*
  - On a scale of 1 to 6, with 6 being the highest: How would you

  rate the timeliness of the recommendations?

  (Please, justify your answer)

1	2	3	4	5	6

- *Relevance and significance of the recommendations*
  - On a scale of 1 to 10, with 10 being the highest: How would you

  rate the relevance and significance of the recommendations?

  (Please, justify your answer)

1	2	3	4	5	6

  - What is your opinion about the general impact of the HTA to your organization? (Please, justify your answer)

- High
- moderate
- few
- none

- Is further work needed with their recommendations? (Yes or No)
    - If yes, how might the HTA program improve on the timeliness, relevance, and significance of their recommendations?
- On a scale of 1 to 6, with 6 being the highest score:
    - How satisfied are you with the HTA reports/recommendations/guidance?

1	2	3	4	5	6

please , justify your answer

    - How acceptable is the HTA reports/recommendations/guidance?

1	2	3	4	5	6

Please justify your answer

- Are there barriers to using HTA reports and recommendations in decision-making or intention to adopt the reports and recommendations?
    - Can you describe these barriers?
    - What needs to be improved?