

PHILIPPINE HTA COUNCIL MEETING

Methods and Process Guidelines
March 4, 2020

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List of Acronyms

ASEAN	Association of Southeast Asian Nations
COI	Conflict of Interest
COVID-19	Coronavirus Disease
DALY	Disability-Adjusted Life Year
DOH	Department of Health
DOST	Department of Science & Technology
FDA	Food and Drug Authority
FEC	Formulary Executive Council
HITAP	Health Intervention and Technology Assessment Program
HIU	HITAP International Unit
HTAC	HTA Council
HTA	Health Technology Assessment
iDSI	International Decision Support Initiative
IT	Information Technology
KMITS	Knowledge, Management, and Information Technology Services
MoU	Memorandum of Understanding
NCIP	National Commission on Indigenous Peoples
NCPAM	National Center for Pharmaceutical Access and Management
PCV	Pneumococcal Conjugate Vaccine
PD	Pharmaceutical Division
PITAHC	Philippine Institute of Traditional and Alternative Healthcare
PMAC	Prince Mahidol Award Conference
PNDF	Philippine National Drug Formulary
PNFS	Philippine National Formulary System
PRO	Patient Reported Outcomes
QALY	Quality-Adjusted Life Year
TAMA	Traditional and Alternative Medicine Act
UHC	Universal Health Coverage
UN	United Nations
WHO	World Health Organization

Introduction

In early 2019, the Philippines passed a Universal Health Coverage (UHC) Act that automatically enrolls all Filipino citizens in a national health insurance scheme under the Philippine Health Insurance Corporation (PhilHealth).¹ Their aim, to improve the breadth and depth of healthcare coverage for Filipino citizens, is bolstered by the application of a tool called Health Technology Assessment (HTA). HTA supports the prioritization of interventions through the generation of value-for-money evidence as well as incorporating social, ethical, financial protection, and affordability factors. A systematic, fair, and participatory process is also an integral part of the HTA system.

The HTA provisions in the Act specified the creation of an HTA Council (HTAC), the first of its kind, tasked with facilitating provision of evidence to the Department of Health (DOH), PhilHealth, and other relevant bodies for UHC. This Council, which has a core committee and subcommittees dedicated to specific topic areas, was formed in mid-2019, with operations commencing in earnest later in the year. To support their work and build capacity of the members, the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand, provided a training² on 28-30 October 2019 in Clark, with a broader policy symposium on 31 October 2019, in Manila, Philippines. HITAP is a semi-autonomous unit under the Thai Ministry of Public Health and a part of the International Decision Support Initiative (iDSI), a network of institutions supporting the development of priority-setting institutions in Asia and around the globe. iDSI is supported by the Bill and Melinda Gates Foundation, the United Kingdom's Department for International Development (DFID) and the Rockefeller Foundation.

This collaboration built on previous efforts to support HTA development in the Philippines which began in 2012 and has since continued to be strengthened with the sustained support of the iDSI. On 7-9 January 2020, HITAP also supported the conduct of a joint HTA Training³ with the DOH and the Saw Swee Hock School of Public Health of the National University of Singapore (NUS), which researchers from all over the world also participated in. During the Prince Mahidol Award Conference (PMAC), an HTAC member also joined as a panel speaker in the side meeting entitled '*PMAC 2020: Accelerating the Progress Towards UHC*,' on 28 January 2020, to provide inputs and share a perspective from the Philippines along with partners from Kenya.⁴

With the support of the DOH HTA Unit (HTAU), the secretariat of the HTA system, the Council has met multiple times to discuss the administrative and management aspects of the development of the HTA system, specifically on the process and methods guidelines as well as plans in the near term. On

¹ Republic of the Philippines, 'RA No. 11223: An Act Instituting Universal Health Care for All Filipinos, Prescribing Reforms in the Health Care System, and Appropriating Funds', 2019.

² For more information, please see "Report: Evidence Appraisal Workshop for the Philippine HTA Council."

<http://www.globalhitap.net/resources/reports-publications-2/>

³ Please see the following blog for more information: <http://www.globalhitap.net/participation-at-the-hta-workshop-in-manila-philippines-7-9-jan-2020/>;

<https://sph.nus.edu.sg/2020/03/strengthening-healthcare-decision-making-in-the-philippines-and-beyond/?fbclid=IwAR2Q3C3NmUU2npB3y71NbFSsrFRZ6lBxoixmYYvETORzBl2KYteKusONAYU>

⁴ Please see the following blog for more information: <http://www.globalhitap.net/guest-blog-reflections-on-pmac-2020-from-a-canadian-student-perspective/>

4 March 2020, in Manila, HITAP joined as an observer in one of the HTAC meetings as well as a meeting between the HTA Council Subcommittee on Traditional Medicine and the Philippine Institute of Traditional and Alternative Health Care (PITAHC). The HTAU and HITAP also discussed the potential collaborations between the two organizations in the coming two years.

This report summarizes the discussions and activities from this visit, divided into the following sections: HTA Council Meeting, Inclusion of Traditional Medicines in the UHC Benefits Package; Future Collaborations; and, Next Steps.

HTA Council Meeting

The HTA Council met on 4 March 2020 at the DOH to continue discussion on the process and methods guidelines as well as raise new issues.⁵

The meeting began with a detailed discussion on the items remaining from the previous meeting. The following were salient points, focusing specifically on steps or items in the process guidelines:

Presentation of results

The Council agreed that public consultations shall be conducted for each technology. Proponents and interest groups will be included in the participants, who will be provided with a peer-reviewed preliminary report. The assessment team shall present the rationale, methods, and results of the assessment. An open forum shall be conducted after the presentation to be moderated by the HTAU or HTAC. Issues will be raised and recorded.

One of the major discussion points for this section was on the appropriate acknowledgement of stakeholders' inputs. The Council agreed that there will be clear objectives for each meeting to reduce misunderstandings. The summary of issues raised during the consultation shall be presented after the consultation. The HTAC shall then meet to deliberate and discuss the points that were raised during the public consultation before making a recommendation. HTAC will publish their final decision afterwards.

The HTAC agreed to coordinate with the Knowledge, Management, and Information Technology Services (KMITS) or the Department of Science and Technology (DOST) Information Technology (IT) for the development of an online platform for submissions and progress updates.

Information available on the HTAC website

The Council agreed that the shortlist of topics, the progress on appeals for shortlisted topics and, more broadly, the progress of a specific technology in the HTA process, and the HTAC recommendation along with a summary of evidence and HTA report will be published online. The

⁵ This summary is for reporting purposes by HITAP and may not reflect all points covered during the meeting.

latter may be renamed as the HTAC Decision post-consultation. The Council will revisit the existing template on evidence summary of the Formulary Executive Council (FEC) to be used as a basis for the HTAC template. Letters of appeal will not be posted online.

A major discussion on this topic was on the online publication of peer-reviewed assessment reports. Some potential problems highlighted in the publication were the following: proponents tweaking reports to try and 'game' the system based on what has been previously published; inappropriate behavior from stakeholders towards the HTAC, the proponents of the study, and/or the accessors/commentators of the report; and, the management of inputs from different stakeholders. On the first point, the HTAC will be publishing peer-reviewed reports with sufficient inputs from economic experts; this will create a model for high quality research reports. Further, the HTAC ensures that their decisions have concrete, accessible evidence for all decisions made. On the second point, the HTAC will explore how to protect those involved, e.g. removing names from public domain but ensuring that they have declared their conflicts of interest (COI). The third point will be managed through the stakeholder consultation meetings. To ensure transparency and credibility, the Council agreed to publish the results post consultation under the HTAC Recommendation section; participants in the consultations will be provided with the soft copy prior to meeting. Publishing the results of studies in international journals to ensure academic rigor was also recommended.

Rules on the appeal on shortlisted and prioritized topics

For appeals on shortlisted and prioritized topics, proponents may submit their appeal using a prescribed form including a recital of explanation of how their new data may affect the prioritization of the HTAC within ten (10) working days from posting. The HTAC Subcommittee shall decide within 15 working days from receipt of the relevant documents on whether or not it should be reassessed for prioritization.

Restrictions on inclusion of industry as a proponent

The HTAC agreed that industry will be allowed to propose topics and use the same form as other groups. A major point on this item included the proposal to allow industry topics to be submitted only through other stakeholder groups such as patients or professional associations. However, disempowering the industry may result in the cost of lobbying coming back to the public, e.g. potentially indirectly causing a rise in prices to compensate for investing even more to lobby for their interests through other groups.

Schedule of topic nominations

A topic list will be prepared at the start of every calendar year, in January; this schedule is still under consideration.

Transitory Formulary Executive Council (FEC) tasks

Thirty-six drugs were nominated for assessment in 2018/9. These drugs were processed using the old criteria and system. A transitory FEC will be tasked with appraising the output of the evidence review group and to make recommendations to the HTAC following existing Philippine National Formulary System (PNFS) guidelines until new guidelines are adopted by the HTAC. The transitory FEC will be composed of HTAC members who were previous members of the FEC. The research will be funded by the DOH Pharmaceutical Division (PD) or the HTAU.

For new issues, the following points were raised:

Assessment of the pneumococcal conjugate vaccine (PCV)

A presentation was made on research to be conducted on the national provision of PCV in response to a request from the Secretary of Health and a formal letter from the DOH. The background for this study is the publication of a news report on the reassessment of the current policy providing PCV 13, which has been in the national immunization program since 2014 (with procurement of single dose vials and provision of three doses as part of a primary series). This decision was contested by industry.

A previous study supported by HITAP under iDSI in partnership with National Center for Pharmaceutical Access and Management (NCPAM) was conducted in the Philippines, which found that both PCV 10 and 13 were cost-effective: PCV 13 provided better value for money while PCV 10 was more affordable.⁶ This choice could have significant implications in terms of budget impact for a populous country such as the Philippines. For the current study, researchers have conducted a preliminary literature review, finding that both vaccines have substantial impact against pneumonia. At present, there is insufficient evidence on the difference in net impact of the two products on the overall disease burden, though PCV 13 may have additional benefits in settings where the disease is attributable to serotype 19A or 6C.

Policy questions include comparison of the clinical effectiveness of the two vaccines in preventing mortality and morbidity due to invasive pneumococcal disease, clinical pneumonia, and acute otitis media of children under 5 years of age; cost-effectiveness of the PCV vaccines; budget impact; etc. The timeline for the study is from March to end of May 2020 as results are required prior to the next procurement process in June 2020. A recommendation was made to use previously conducted systematic reviews and models for the reassessment.

Feedback report on HTAC subcommittee meetings

There were requests to assess proposed interventions for the coronavirus disease (COVID-19), though the WHO already has proposed interventions. The following were some of the proposed technologies from producers: Far-UVC; Cepheid molecular test for 2019-nCov; 50x50 nCov reaction

⁶ Haasis, Manuel Alexander, et al. "Do pneumococcal conjugate vaccines represent good value for money in a lower-middle income country? A cost-utility analysis in the Philippines." *PLoS one* 10.7 (2015).

kits (for the Subcommittee on Clinical Devices and Equipment); and, TelenetDoctor Telehealth System (for the Subcommittee on Other Health Technologies).

The definition and scope of each HTAC Subcommittee was discussed in detail including the criteria and submission forms. For example, though the UHC law used a narrow definition of traditional medicines, the HTAC decided to take a broader approach and incorporate the Traditional and Alternative Medicine Act (TAMA) definition as well, which includes alternative medicines. The following were proposed exclusions: cross-cutting interventions; therapeutic food; preventive and promotive health services for healthy/sick population; cosmetic surgery; and, vaccines for cancer. These operational definitions were to be revised in time for the first external consultation meetings.

For the criteria to be used, the following were agreed upon for topic prioritization: population may be noted in terms of prevalence and/or counts depending on the intervention/disease; severity will be scored depending on the diseases; estimated household impact will be calculated using the latest household survey; equity/ethical/social considerations will include rare diseases under disabilities; and, national health service needs (priorities) will be either a 3 or 5-level scoring system (automatic prioritization of DOH and PhilHealth submissions remains to be discussed). A unidirectional scoring system will be used.

Budget impact calculations and thresholds will be discussed during the consultation meetings with DOH and PhilHealth. Submission forms were open for comments from the subcommittees.

The Council ran through the process guideline timeline. The proposed timeline was four years for the process; it was proposed to be cut down to one to two years.

The process and methods guidelines were scheduled for presentation to different groups of stakeholders throughout March and April. The final consultation with all stakeholders is scheduled for 20 April 2020.

Inclusion of Traditional Medicines in the UHC Benefits Package

After the HTAC meeting, HITAP attended as an observer in a meeting of the HTA Council Subcommittee on Traditional Medicine with the PITAHC, which is an attached agency of the DOH with a mandate “to improve the quality and delivery of healthcare services to the Filipino people through the development of traditional and alternative medicines and its integration in the national care delivery system”.⁷ The HTA definition includes traditional and alternative medicines as part of its scope; however, there may be a different process for the assessment.

⁷ For more information, please visit: <http://pitahc.gov.ph/transparency/116-2/>

The agenda included: (a) to give the invited organization a brief overview on the institutionalization of HTA in the Philippines and the scope of assessment, (b) to clarify the role of PITAHC in the process of HTA implementation, and, (c) to align the research agenda.

Salient points discussed during the meeting include:

- Traditional medicine provision has primarily been through single providers who often worked independently of each other, which makes it difficult for them to form collective knowledge or organize a system for their work. Further, there is a proliferation of alternative medicines in indigenous, often nomadic/hard to reach populations. For these reasons, it would be easier for topics to be proposed only through the PITAHC.
- Due to the reasons previously cited, there is a difficulty in accounting for traditional and alternative medicines currently practiced; PITAHC may consider conducting an anthropological assessment of existing practices. They may partner with the National Commission on Indigenous Peoples (NCIP). It would be easier to penetrate the indigenous communities through this organization as they give ample protection to the rights of these communities.
- Practitioners should be registered through PITAHC to generate a list of potential topics to be proposed to the HTAC.
- Data and funding may be provided by PITAHC in support of the topics to be submitted for assessment, however, there will be a conflict of interest if the submissions were made through PITAHC because they are also in charge of certifying the practitioners as part of the requirements for topic submission (per the point above).
- A proposal was made to emphasize “locally developed” practices versus “locally introduced” ones (e.g. acupuncture). In addition, during the prioritization, it was discussed that locally developed products shall serve as “trigger” because, according to Dr. Isidro Sia, the Subcommittee Chair, the public should recognize these products as their “national pride.” If the parameter on National Health Service Needs pertains to the World Health Organization (WHO) top causes of mortality/morbidity, it was mentioned that it would be a disadvantage to the health technologies classified under traditional medicine.
- However, as with any topic, traditional and alternative medicines will have to undergo the prioritization process. Further, it was discussed whether these topics should automatically have the highest score in the ‘national health service needs’ criterion given that they are likely to be excluded from the shortlist due to lower scores in other criteria. There is also a law (TAMA) that prioritizes protection and provision of traditional medicines.
- These interventions should still be required to prove to have a health impact and account for negative/adverse effects. Therefore, they need to be registered with the Food and Drug Administration (FDA). There should be guidelines for each of these interventions, e.g. the Philippine traditional massage (*hilot*).
- The proposed bill of the revised TAMA which focuses on the regulatory functions of PITAHC shall include their jurisdiction over products (in about 5 to 10 years), but it shall be transitory because the FDA is yet to relinquish its regulatory powers over the said products.
- Patient reported outcomes (PROs), case reports, and similar types of data may be used to generate evidence in the absence of clinical trials information. PITAHC will have the responsibility to generate evidence on all types of traditional and alternative medicines prior

to submission for prioritization assessment. Research and data collection may also be done through mobilization of universities.

- The following research agenda were also highlighted:
 - Impact assessment of community-based herbal medicine preparation and basic acupuncture.
 - Profiling of practitioners throughout the country.

Future Collaborations

A meeting between HITAP and the HTAU was then conducted to discuss potential areas of collaboration and support from HITAP and iDSI in the coming two years. Table 1 summarizes these areas of collaboration:

Table 1: Areas of Potential Collaboration

No.	Description	Partners	Timeline
1	Review of the benefits package <ul style="list-style-type: none"> - As per the HTA law, the immediate concern of the HTAC is the assessment of the existing, basic PhilHealth benefits package. HITAP proposed a methodology of assessing high-impact interventions for their safety, efficacy, and cost-effectiveness. HITAP is awaiting a response on this proposed methodology. - There will be a new set of interventions in the pipeline which will be excluded from the assessment but will be open for future assessments. 	HTAU, HTAC, PhilHealth, HITAP	2 years (starting from October 2019)
2	Finalize the process and methods guideline <ul style="list-style-type: none"> - The HTAU and HTAC will be gathering comments and inputs from stakeholders in the coming two months. HITAP continues to support the process and provide inputs. 	HTAU, HTAC, HITAP	2-4 months
3	Create local capacity-building programs <ul style="list-style-type: none"> - HTAU and HTAC aim to support the creation of programs that include HTA as an integral part of the curriculum. This is intended to develop a pipeline of HTA researchers in the long run. Students will be funded through scholarships, with dissertations required to be HTA topics under consideration and a contract for government work post-program completion. 	HTAU, HITAP, DOST, University of the Philippines, NUS, TBD Mahidol University	2+ years, starting in August / September 2020

No.	Description	Partners	Timeline
	<ul style="list-style-type: none"> - HITAP can support as a partner providing visiting professors, thesis advisers, and scholarships (for example, in the Mahidol HTA program). 		
4	<p>Collaborate on joint assessments in ASEAN</p> <ul style="list-style-type: none"> - Common topics/concerns across the region can be assessed; HTAU and HITAP are already partnering on an assessment of HTA capacity in ASEAN and a potential study on regional thresholds. 	HTAU, HITAP	TBD based on the topics
5	<p>Support PCV Reassessment</p> <ul style="list-style-type: none"> - HITAP can provide peer-review support, starting with the protocol and presentation from the current meeting. 	HTAU, HTAC, HITAP	6 months, starting from January 2020
6	<p>Support advanced Modelling Course</p> <ul style="list-style-type: none"> - Courses are available in HITAP's partner institutions, e.g. NUS, for advanced economic evaluation trainings. 	HTAU, HITAP, NUS	TBD, likely third quarter of 2020
7	<p>Build capacity of HTAC and high-level DOST staff</p> <ul style="list-style-type: none"> - A study visit to join appraisal meetings in Thailand was proposed for the HTAC and high-level DOST staff to learn and understand HTA and its processes in action. This will raise awareness on the issue. 	HTAU, HTAC, DOST, HITAP	TBD, likely in the second half of 2020
8	<p>Support HTAsiaLink attendance</p> <ul style="list-style-type: none"> - The Chair of the HTAC will join and present during the HTAsiaLink in one of the panel sessions. 	HTAU, HTAC, HITAP	TBD October 2020
9	<p>Feature HTAC in the next HTAsiaLink newsletter</p> <ul style="list-style-type: none"> - To celebrate and highlight the new HTAC, an article will be written in the HTAsiaLink newsletter. One of the HTAC members will be interviewed. 	HTAU, HTAC, HITAP	1-2 months
10	<p>Collaborate on traditional and alternative medicine assessment</p> <ul style="list-style-type: none"> - This is a new area of exploration but common and important to countries in Asia (and potentially elsewhere). There is still a lack of research, evaluation, and clinical guidelines for traditional and alternative medicines. However, there are already some studies in Thailand and other countries. - HTAU and HITAP discussed creating a regional working group for the use of traditional and alternative medicines and all related considerations. - Work has begun with preliminary literature review being conducted in HITAP and NUS for the creation of traditional and alternative medicine guidelines. 	HTAU, HITAP, NUS	TBD; TBD October 2020 for HTAsiaLink

No.	Description	Partners	Timeline
	<ul style="list-style-type: none"> - A side meeting may be held during HTAsiaLink 		
11	<p>Sign HTA-specific Memorandum of Understanding (MoU) between Thailand and the Philippines</p> <ul style="list-style-type: none"> - HITAP and HTAU continue to pursue signing of the MoU to support activities. The MoU is currently undergoing DOST approval. 	HTAU, HITAP	TBD May 2020 (World Health Assembly)
12	<p>Share information regionally on COVID-19 interventions</p> <ul style="list-style-type: none"> - HTAU has received many requests on assessment of interventions to deal with the current outbreak. A proposal was made to gather evidence and information from other HTAsiaLink members on effective/current gold standard interventions. Joint assessments may also be conducted for rapid reviews. 	HTAU, HITAP	TBD
13	<p>Explore discount rate to be proposed in the reference case</p> <ul style="list-style-type: none"> - The Philippines will include a discount rate of 7% in the reference case, which is in line with other agencies. However, they may explore what is best in the Philippine context. HITAP can provide comments and support for the research. Note: Thresholds are not expected to be explicit. 	HTAU, HITAP	TBD
14	<p>Support the evaluation of the remaining drugs topics as well as other HTA topics</p> <ul style="list-style-type: none"> - With respect to the priority topics, HITAP can support other studies in the pipeline based on discussions with HTAU. Additional topics, e.g. cancer medicines, may also be discussed in the coming year. 	HTAU, HITAP	TBD

Next Steps

HITAP planned to join as an observer in the first external meeting with PhilHealth, DOH, the HTAC, and the HTAU on 10 March 2020 in Manila, Philippines, to discuss the process and methods guidelines. There may be further discussions on areas of collaboration. However, due to the on-going COVID-19 outbreak, travel between countries has been put on hold. HITAP will discuss next steps further with partners.

Appendices

Appendix 1: Agenda of the HTAC Meeting

AGENDA

HTA Council Meeting, March 4, 2020

- I. Call to Order
- II. Declaration of Quorum
- III. Approval of the Proposed Agenda
- IV. Declaration of Conflict of Interest
- V. Review and approval of the minutes of the 3rd HTAC meeting (10 February 2020)
- VI. Business Arising
 - a. Revised grounds for appeals c/o Atty. Bu (3rd HTAC meeting)
 - b. Policy statement on “restrictions” in listing industry as proponents (1st HTAC Meeting)
 - c. Schedule of topic nominations
 - d. Transitory FEC
- VII. New Matters
 - a. Report of Subcommittees re definition and scope of technologies, applicability of prioritization criteria and submission forms
 - b. Reassessment of Pneumococcal Conjugate Vaccine
 - c. Presentation of the revised draft of Process Guide, Methods Guide, Administrative Order and program for the Consultative Meetings
- VIII. Other matters
9. Schedule of Next Meeting
10. Adjournment