HTA 101: Moving Together Towards Universal Health Care

09 Dec 2020 (Session 2: Industry, HCPs, Offices)
9:00 - 11: 00 AM

Questions from Zoom		
Questions for Dr. Anna Melissa S. Guerrero - Overview of HTA in the Philippines		
Name of Attendee *(affiliation as indicated)*	**Question**	**Answer**
Cynthia Verzosa *(Jose R Reyes Memorial Medical Center)*	When we want to apply for inclusion of a drug in the PNDF, will the drug be now subject to HTA? Do we have a new form and set of requirements? Thanks!	In compliance to Department Circular 2020-0010 or *New Topic Nomination for Health Technology Assessment*, the Disease Prevention and Control Bureau (DPCB) shall act as the initial evaluator of submitted products prior to nomination of products to the HTA Unit. Department Memorandum (DM) No. 2020-0364 or the *Interim Guidelines on Prioritization and Initial Evaluation of COVID-19 Related Products for Health Technology Assessment* states that the DPCB shall submit the list of nominated entities to the HTAU, after discussions and vetting from the DPCB-Initial Screening Unit and the COVID-19 Planning, Procurement and Logistics (PPL), and Technical Assistance and Monitoring & Evaluation (TAME) teams. Dr. Guerrero: The process is contained in our Process Guide and can be accessed through this link http://bit.ly/HTAPGPhilippines. You may submit topics which

		include drugs you deem are important. All topics, however, are prioritized by HTAC in terms of: (1) Responsiveness to Magnitude, Severity, and Equity (2) Safety and Effectiveness (3) Household Financial Impact (4) Cost-effectiveness (5) Affordability and Viability
Jonathan Corpuz *(Southern Philippines Medical Center Adult Cancer Institute - Radiation Oncology)*	Does the HTA unit have a say in the country's health research agenda?	During assessments, the HTAC may identify some data gaps which should be addressed to further inform their recommendations on health technologies. With this, the HTAC may recommend topics for health research to the Secretary of Health.

Questions for Dr. Katherine Ann V. Reyes - AO 2020-0041		
Name of Attendee *(affiliation as indicated)*	**Question**	**Answer**
Martin-Luther Topico *(Interactive Research and Development)*	For EMRs (Electronic Medical Records) implementation, will health organization wait for the approval/result of the HTA prior to go live?	Dr. Guerrero: We shall be coordinating with DOH-KMITS on this, but in principle, if this will require DOH funding and is deemed as a priority health technology, then it may be referred to HTAC for assessment.

Janine Marie Sanciangco *(Sanofi)*	Per Dr. Guerrero, HTA can be applied at different points of the life cycle of the health technology including pre-market and during market approval. How can this be operationalized considering HTA guidelines require Phase IV study, taking into account that collection for Phase IV study for some novel therapies for serious conditions such as cancer, orphan diseases or technologies intended for public programs only are difficult or not feasible to implement? Can there be flexibility or exemptions for such situations? Thank you!	Dr. Guerrero: Right now, we are doing, for example, an early HTA for COVID-19 vaccines. We look at published evidence and data from international regulatory agencies. However, HTAC cannot issue a recommendation pending market authorization of our own FDA to ensure that the HTAC recommendation is within FDA approved marketing claims of a product. For COVID-19 health technologies, there is an explicit provision in the Bayanihan Act that results of Phase IV may be temporarily waived in light of the public health emergency considering the risk-benefit of health products, but with conditions to have postmarketing surveillance.
Donn Mc Angelo Valdez *(Roche (Philippines) Inc.)*	Is the decision-making power of the Secretary of Health/PhilHealth Board of Directors ministerial (meaning they are bound by the recommendations of the HTAC) or may they overrule the recommendation of the HTAC?	Dr. Guerrero: Per UHC Law, DOH and PhilHealth cannot fund and adopt health technologies without a positive recommendation by the HTAC. According to Section 34 of the UHC Act, investments on any health technology or development of any benefit package by DOH or Philhealth shall be based on the positive recommendation of the HTAC.
Geremiah Edison Daniel Llanes *(UP-PGH)*	Since there is a distinction in the role of the 2 decision makers, can you give examples of technologies that DOH will approve funding on but PhilHealth will not include in packages?	Dr. Guerrero: Ideally, DOH and Philhealth policies should be aligned. Philhealth uses the Clinical Practice Guidelines (CPG) adopted by DOH in costing the benefits package. We are also aligning the HTA work stream with that of the CPG formulation and clearance by the DOH. Dr. Katherine Reyes: DOH can approve general public health (population based) interventions that will not be considered in the PhilHealth (individual-based) package.
Ma Teresa Madrid *(Food and Drug*	Are softwares used to aid in the diagnosis of diseases included in the HTA assessment	Yes, as defined by AO 2020-0041, health technologies that are used for diagnosis of diseases are included under “Clinical

Administration)	process?	Equipment and Devices." However, for softwares and applications that are not essential for the direct function of a clinical equipment, such as diagnosis, these are included under "Other Health Technologies." If these would require DOH funding, then it would need to undergo HTA.
Janine Marie Sanciangco *(Sanofi)*	re Phase IV question - Thank you, Dr. Guerrero. Very clear on the case of COVID 19 and we commend the HTA team's critical role and responsiveness in this pandemic. May I ask how about other health technologies mentioned where Phase IV is difficult and not feasible to implement? Without Phase IV study, will they not be eligible for HTA review? Thank you!	Dr. Katherine Reyes: By default, we follow what is in the law. HTA can only process technologies that comply with the regulatory requirements to en`sure safety. However, in certain cases, such as a public health emergency, this provision can be discussed with policy makers and legal experts. HTA Unit is also yet to receive an official statement from FDA explicitly stating the consideration of Phase IV studies for those with full regular Certificate of Product Registration (CPR) in comparison to those with CPR-monitored release.
Peter Raul Ronque	Will HTA applications be entertained/ performed for drugs or devices used in rarer /relatively not-so-common diseases?	Dr. Katherine V. Reyes: These can be nominated and will need to go through the usual prioritization process. Any technology identified as a priority will undergo assessment.
Martin-Luther Topico *(Interactive Research and Development)*	For technologies that will be funded by NGOs or international grants, will they be included in the HTA?	Dr. Guerrero: Per AO 2020-0041, only health technologies that are to be funded by PhilHealth and DOH shall be assessed and recommended through the HTA process. Dr. Katherine V. Reyes: Although not required, the published methods guide may be useful for funding agencies. Independent researchers can conduct HTA to aid prioritization of funding agencies.
Janine Marie Sanciangco *(Sanofi)*	Which department is overseeing the development or validation of CPGs - is it under DOH or PhilHealth? Will currently	Dr. Katherine V. Reyes: Within DOH, the Health Policy Development and Planning Bureau (HPDPB) is strengthening an initiative to develop CPGs that are crucial for quality

	existing local CPGs be adopted or if still to be reviewed or validated - is there a timeline set to complete this process? Thank you!	management of the top burden of diseases. PhilHealth no longer develops CPGs. Ms. Genuino-Marfori: You may refer to Administrative Order 2018-0019 dated 02 July 2018 *(Guidelines on the Institutionalization and Implementation of the National Clinical Practice Guidelines Program)* but please note that the HPDPB is also currently developing revised implementing guidelines which will be released in the coming months. Dr. Guerrero: Currently, this is under the DOH-HPDPB but will be transitioned to the DPCB as the responsible Bureau for developing technical standards for the prevention and management of diseases. All CPGs to be adopted by the DOH and Philhealth have to undergo quality assessment and clearance by a CPG Clearing House.
Geremiah Edison Daniel Llanes *(UP-PGH)*	Since HTAC is a recommendatory body, what happens when decision makers disagree or choose not to follow HTAC recommendations?	Per UHC Law, DOH and PhilHealth cannot fund and adopt health technologies without a positive recommendation by the HTAC. According to Section 34 of the UHC Act, investments on any health technology or development of any benefit package by DOH or Philhealth shall be based on the positive recommendation of the HTAC. Dr. Guerrero: There are avenues to resolve potential disagreements or points for clarification before HTAC issues the final recommendation. Policy makers and DOH offices may submit their comments after HTAC issues its initial recommendation for appeals.
Michelle Fe Santos *(Dr. Jose Rizal Memorial Hospital)*	How is the Health Education and Promotion be empowered through the HTA?	Dr. Katherine V. Reyes: HTA is a prioritization tool and offers an evidence-based process to demonstrate the importance of investing in technology. In the case of Health Education and

		Promotion, it may be possible to show that an intervention must be funded using HTA.

Questions for Dr. Iris Isip-Tan - The HTA Process Guide		
Name of Attendee *(affiliation as indicated)*	**Question**	**Answer**
Alvin Pio de Roda *(ZP Therapeutics)*	On the average, what is the estimated time it takes to complete the HTA assessment process?	There are tracks for major applications in health technology assessments - the 'general' and 'expedited' HTA processes. Furthermore, we are also accepting submissions from the DOH National Health Programs through the 'urgent' process. The HTAC has also recently opened a track for minor applications. All processes will undergo the same steps, but differ in timelines depending on research needs. For more details, please refer to the HTA Process Guide: http://bit.ly/HTAPGPhilippines.
Lianne Santos *(Janssen / Johnson and Johnson Philippines)*	Will HTA publish review timelines? And, for those applications not included as priority review, will published results also include the reasons for non-inclusion?	Dr. Guerrero: Yes there will be tracking of assessments prioritized by HTAC and reasons for not being prioritized will also be made known to the public. Status of health technology assessments may be accessed through our website, http://hta.doh.gov.ph/.
Winniefer Nua *(Pfizer, Inc.)*	what happens to health technologies that will not be prioritized? Will health technologies not prioritized for the year be given a chance to be reviewed in the future?	Dr. Guerrero: They may be prioritized in the next cycle of topic nomination. [Dr. Isip-Tan]: In case a proposed topic is not included in the initial list of priority topics for assessment, an appeal may be submitted

		to the HTA Technical Secretariat within ten (10) working days from posting, if there are new data relevant to the prioritization criteria that may affect the result of the shortlisting. For more details, please refer to the HTA Process Guide: http://bit.ly/HTAPGPhilippines.
Alvin Pio de Roda *(ZP Therapeutics)*	How many drug applications can be accommodated/processed for the Sept 2021 applications?	Dr. Guerrero: On the average, around 20-30 health technologies are prioritized given the current capacity to assess. This will also depend on the fiscal limits of DOH and PhilHealth to adopt new technologies. The acceptance of topics shall span for a period of four (4) weeks through the HTA Technical Secretariat, who shall check the compliance of the submissions with the prescribed requirements. The UHC law mandates that within two years from establishment, the HTA Council shall review only existing health technologies. New health technologies will be accommodated in 2021, subject to availability in resources.
Ahsan Shoeb *(Novo Nordisk)*	What are the criteria for prioritization of acute Vs Chronic diseases in HTA Assessment process for a particular year	The HTAC does not delineate topics between those for acute and chronic diseases. The topics shall be ranked based on the prioritization criteria from the process guide as listed below and from this, the shortlist of topics for evaluation shall be developed by the HTAC. The criteria for existing health technologies are: a. Budget impact to DOH and PhilHealth b. Total users of health technology c. Cost-effectiveness d. Severity of disease e. Equity, ethical and social implications For new health technologies, the criteria for prioritization are:

		a. Total users of health technology b. Severity of disease c. Estimated household financial impact d. Equity, ethical and social implications e. National health service needs
	Will all diseases therapy submissions be considered for HTA assessment every year or will it be focused on a particular disease/year?	According to the Process Guide, "*HTAC considers all health technologies relevant to the Philippine health care system in improving health outcomes for patients and the general population and also add value in the delivery of care by health professionals in terms of raising quality standards, improving the effectiveness and efficiency of delivering services and providing value for money for the national government*." With this, all submissions are considered provided that the proponents comply with all the documentary requirements. These will then be prioritized based on health system priorities for that year.
Gerry Alcantara *(Boehringer Ingelheim (Philippines), Inc.)*	Not all health technologies can be judged similarly - for instance, different levels of evidence will be available for an orphan drug or a health technology for a rare disease. What flexibilities are embedded in the process for such health technologies?	Aside from the available clinical evidence, HTAC also considers the magnitude and the severity of the disease that the intervention targets, the particular populations that are affected, the household financial impact, cost effectiveness and budget impact of the heath technology, and ethical and social considerations, among others. These considerations provide flexibility for these health technologies.
Donn Mc Angelo Valdez *(Roche (Philippines) Inc.)*	How will the weights for the decision criteria be distributed?	Dr. Guerrero: There is currently no explicit weighting, but HTAC balances all relevant criteria on a case-to-case basis.
Alvin Pio de Roda *(ZP Therapeutics)*	Application for PNF inclusion is currently suspended pending the HTA implementation on Sept. 2021?	No, the application for PNF inclusion is not suspended, but we are currently prioritizing applications for minor inclusions (which include those with additional strength, changes in immediate packaging, and changes in net content for the same drug or

		molecule already listed in the PNF) and applications from National Health Programs.
Jonathan Corpuz *(Southern Philippines Medical Center Adult Cancer Institute - Radiation Oncology)*	in the dispersal of health technology to the provinces, at what stage in the process does it look at the availability of necessary resources such as manpower and infrastructure to support and sustain such technology? like if its a new treatment modality - does the area have the right doctors and allied health professional to use the equipment? are there necessary diagnostic services present to properly diagnose the disease that the treatment modality aims to treat? does HTA also communicate to government hospital recipients the recommended costing procedure for the treatment modality?	Dr. Guerrero: During the assessment, issues on implementation and feasibility are being evaluated because HTAC has to ensure that the health intervention can be smoothly adopted and integrated in our own health system. The health systems implications analysis is conducted once the clinical assessment has established that the health technology is superior or non-inferior to the current standard being used. Qualitative methods, such as in-depth interviews, focus group discussions with identified key stakeholders (e.g., DOH program managers, hospital administration, local government units, other implementers who will be affected by the adoption and management of the health technology) shall be done to assess the impact of a health technology to the current health system.
Honoree Ibarra *(Novo Nordisk Pharmaceuticals (Philippines), Inc.)*	During the application assessment process, will there be a face to face/virtual discussion with the applicants?	Dr. Guerrero: Yes, we can have virtual consultations, We are doing this now for some of the COVID-19 health technologies. During topic prioritization, a clarificatory meeting shall be conducted to further refine and filter the shortlisted topics and ensure that they respond to the prevailing health care needs in the health system. The participants shall include the proponents of the shortlisted health technology, and other interest groups (e.g., patient/ consumer groups, professional organizations, and competing companies.
Winniefer Nua *(Pfizer, Inc.)*	Can we request for editable copies of the annexes?	Editable copies of the annexes of the Process Guides, particularly the forms to be accomplished by proponents, can be requested via

		email at hta@doh.gov.ph. Thank you!

Questions for Dr. Jacinto Blas V. Mantaring III, Dr. Aleli D. Kraft, and Dr. Maria Carinnes P. Alejandria - The HTA Methods Guide		
Name of Attendee *(affiliation as indicated)*	**Question**	**Answer**
Roland Cristopher Caballar *(Quirino Memorial Medical Center)*	With regards to clinical assessment, will prior clinical trials or scientific studies carried out in other locations using the technology to be assessed be taken into consideration?	Yes, systematic reviews that include studies by other locations or countries are taken into consideration. Moreover, risk of bias assessment is performed for appraisals.
Janine Marie Sanciangco *(Sanofi)*	Would like to clarify whether "cost-effectiveness" will be primarily determined based on ICER vs threshold as some technologies will naturally have a high ICER vs threshold, e.g. cancer and orphan drugs - if it does not fall within the threshold, will it still be reviewed based on the secondary set of criteria presented, and can this overrule the 1st criteria (ICER)? Thank you!	There is no explicit cost-effectiveness threshold in the Philippines above or below which health interventions are considered cost-effective or not cost-effective. Traditional ICER thresholds set by the WHO (i.e., less than three times of GDP, or 1 GDP per capita per QALY/DALY) may be used as guides. Other decision criteria like responsiveness to magnitude, severity and equity; effectiveness and safety; household financial impact; and, affordability and viability are also considered aside from cost-effectiveness for possible coverage.
Winniefer Nua *(Pfizer, Inc.)*	In case that there no relevant publications in the country to support a local economic evaluation, how acceptable will publications from neighboring countries	In terms of cost effectiveness analysis, models from other countries may be adopted and adjusted based on our country's context. In terms of input parameters, in cases wherein we do not have sufficient local data, we may consider data from other

	be? Are there any criteria or qualifications when a publication can be considered? Are there specific countries that you would prefer?	countries as well. As much as possible, it is preferred to adopt data from countries with similar context (i.e., low to middle income countries in Asia).
Donn Mc Angelo Valdez *(Roche (Philippines) Inc.)*	Will there be opportunities for stakeholders to contribute inputs in the development of methodological guides for priority health technologies?	The current methods guide has gone through consultation with stakeholders prior to implementation. It will continue to solicit comments as health technologies evolve. The process and methods guides are "living" documents. These are going to be continually reviewed, revised as new technologies come up and as new methods are also developed in the literature. Rest assured that key stakeholders will be consulted throughout this process.
	Will the HTAC include explicit methodologies for eliciting patient preferences? If ever, how will these preferences be accounted vis-a-vis the other decision criteria?	In line with HTAC's mandate for a transparent, consultative and inclusive process, representatives from all sectors and all geographic locations will be consulted using focus group discussion and key informant interviews. The result of the consultation will be considered in the recommendation of the health technology.
Donn Mc Angelo Valdez *(Roche (Philippines) Inc.)*	For the Philippines Reference Case, will the PhilHealth case rates be used despite the rates being based predominantly on average value per claim?	Yes, HTA Philippines will use PhilHealth case rates as reference cost for economic evaluations pending the development of a National Costing Library.
Sabine Korth	So if the budget is not yet available, will the technology be considered at a later time than?	Part of the considerations in the assessment of a health technology is its implications to the total budget of the Department of Health. Dr. Kraft: Although a health technology may be deemed cost-effective, if the government cannot pay for the aggregate amount for the health technology, then that would also factor into the decision of the HTAC.

Winniefer Nua *(Pfizer, Inc.)*	It is mentioned in the methods guide that proponents can submit HTA dossier, will the HTAU/HTAC be open for discussions while the proponents are developing the dossier?	HTAC will consider the dossier to be submitted in assessment of a health technology. The proponent is notified should further documents be requested by the Council for its assessment.

Question from Facebook		
Questions for Dr. Katherine Ann V. Reyes - AO 2020-0041		
Name of Attendee *(affiliation as indicated)*	**Question**	**Answer**
Jonathan Corpuz *(Southern Philippines Medical Center Adult Cancer Institute - Radiation Oncology)*	How about professional societies as stakeholders in the HTA process?	Professional societies are encouraged to be involved in the HTA process through nomination of health technologies in HTA. The HTA office may also invite experts from these societies to inform the assessment of the health technology and the recommendation of the HTAC. Professional societies could also be part of the evidence generation group of the HTA Research Network conducting the health technology assessments through commissioned research. You may also refer to the HTA Process Guide for details: http://bit.ly/HTAPGPhilippines.