Strengthening COVID-19 Response in the Philippines through Health Technology Assessment

20 October 2020 | 9:30 - 11: 30 AM | Zoom webinar: bit.ly/webhc-day

[UNANSWERED QUESTIONS]*

Attendee *(Affiliation, as indicated)*	Question	Panelist: Answer
Zoom		
Donn Mc Angelo Valdez *(Roche - Philippines Inc.)*	Do we have an update on the assessment for other COVID 19 related technologies, such as investigational drugs (tocilizumab and remdesivir)?	Following the rapid reviews for evidence of efficacy conducted by *Philippine Society for Microbiology and Infectious Diseases* in partnership with the *University of the Philippines Institute of Clinical Epidemiology* and *Asia Pacific Center for Evidence Based Health Care* and the Asia Pacific Center, HTAC adopted the results of the said review that showed lack of robust evidence to support the use of tocilizumab and remdesivir in the management of COVID-19. WHO SOLIDARITY trial interim results on repurposed antiviral drugs for COVID-19 (Remdesivir, Hydroxychloroquine, Lopinavir-ritonavir, and Interferon B1a) also showed that the drugs randomly given to 11,266 patients in 405 hospitals across 30 countries had little to no effect on the patients qualified by discussing mortality, use of ventilators, and length of hospital stay. (https://doi.org/10.1101/2020.10.15.20209817) In another study by Stone, et al., tocilizumab was found not effective in preventing intubation or death in moderately severe COVID-19 patients. (DOI: 10.1056/NEJMoa2028836)

**We appreciate the interest of our webinar participants. With the large number of questions we received during the webinar, HTA Philippines took appropriate steps to make sure we've responded to all queries within its scope. We have thus excluded questions beyond the webinar scope and our sphere of competence.*

Alia Cynthia Luz *(Health Intervention and Technology Assessment Program (HITAP), Thailand)*	*Follow up Question:* May I also ask how the topics for COVID 19 have been prioritized?	Dr. Marita V. Tolentino-Reyes: All COVID-19 topics were assessed based on requests from DOH and PhilHealth and did not undergo prioritization. HTA Unit: We are also working closely with the Disease Prevention and Control Bureau (DPCB) for the prioritization of other requests to review COVID-19 technologies which did not emanate from DOH or PhilHealth.
Cary Amiel VIllanueva *(Philippine General Hospital)*	What sort of opportunities are open for young clinicians and health professionals to get involved with HTAC?	Dr. Marita V. Tolentino-Reyes: HTAC in collaboration with the DOST-PCHRD is currently developing an academic network that will enable it to tap various expertise from the academe. Additionally, in partnership with the UP College of Medicine, the UP College of Public Health and the College of Economics it is pushing for the development of formal courses in HTA. Periodically, HTAC announces openings for positions in the Health Technology Unit that may interest "young clinicians and health professionals". We are also aware of existing research organizations with whom HTAC works with in some of its assessments.
Chris Mercado *(Asia Pacific Malaria Elimination Network)*	Could any of our speakers share their views on how we can monitor/measure the impact of HTA decisions?	Dr. Marita V. Tolentino-Reyes: Thank you for this question. This is an issue that we are also grappling with and the short and brief answer is to check the following: (1) Has the recommendation been adopted in the public health programs of DOH and/or the benefit packages of PhilHealth? (2) Has its recommendation led to improved prevention of disease and promotion of health? (3) Has the recommendation supported universal health care objectives? HTAC has initiated discussions on putting in place a monitoring and evaluation program. Wish us luck!!

Anonymous Attendee	Will it be possible for DOH to regulate the rate of RT PCR test to all DOH Accredited Laboratories. Knowing that RT PCR is the gold standard test for COVID 19. Some molecular labs charge 20K per test.	Dr. Anna Melissa Guerrero and Dr. Kim Patrick Tejano: We do not set the procurement ceiling yet for test kits like PCR but we have used the Foundation for Innovative New Diagnostics (FIND) benchmark of less than 30USD just for the test kits.
Anonymous Attendee	Is there a way for the government to make these tests--especially, RT-PCR more affordable for all? These test kits have become mandatory for travel both local and international.	Dr. Marita V. Tolentino-Reyes: This should be the direction of the national COVID-19 response.
Anonymous Attendee	How sure are we po regarding the asymptomatics from local areas having low and mild prevalence not needing to go through rt pcr test? This is regarding tourists.	Dr. Marita V. Tolentino-Reyes: We cannot be "sure." We are working in the context of probabilities, risks and feasibility. For example, the sensitivity of RT-PCR is 80% - it will still miss some cases of COVID-19 if the test is all that we will depend on. This is the reason why we advise very strict and comprehensive symptomatic and exposure checks, and keep the public health precautions.
Facebook		
Rey Oliveros	Good Morning Ma'am Lazarte, tanong lang po ako tungkol sa Tuob na ginamit sa Cebu kung meron ba ito epekto sagot sa COVID-19 dahil sa laki nga ng babayaran mo kapag magpa swab test ka ito ang paraan ginagamit nila kahit wala patunay na gagaling sa COVID-19	Dr. Cecilia Maramba-Lazarte: Philippine Institute of Traditional and Alternative Health Care (PITAHC) already had a statement on this. It is not recommended as a standard of care for COVID 19. Pediatric Infectious Disease Society of the Philippines (PIDSP) also does not recommend this for children as it might lead to burns or even spread of disease.
Alex Mendoza *(Abbott)*	*Follow up Question:* Can the evaluation [of test kits] be done thru local reputable hospital in parallel to RITM evaluation?	Dr. Marita V. Tolentino-Reyes: Unfortunately - not yet.

Email		
Haide Berberabe *(Batangas Medical Center)*	What are we going to do with emergency patients like trauma, obstetrics patients without RT PCR swab results, but need immediate interventions and treatment?? What is the best screening test for covid 19 to be requested?? Thank you.	Dr. Marita V. Tolentino-Reyes: In these cases - the rapid antigen test may be used.

[ANSWERED QUESTIONS]

Attendee *(Affiliation, as indicated)*	Question (Zoom)	Panelist: Answer
Presentations		
Manuel Villegas *(Asian Hospital)*	On Yen's presentation: Will an expidited assessment be of less quality and accuracy compared to a full HTA? *Follow up Question:* Will DOH HTA produce two assessments if a rapid assessment is requested? A rapid or expedited assessment and a full assessment after?	Ms. Anne Julienne Genuino: No. Some steps are just undertaken to shorten the process. Examples would be limiting the search to published studies only, limiting to English publications only, reviewing/ appraising synthesized evidence instead of doing de novo synthesis. This is an acceptable method that many agencies are conducting right now. The WHO produced a practical guide on how to perform RRs: https://www.who.int/alliance-hpsr/resources/publications/rapid-review-guide/en/ Dr. Anna Melissa Guerrero: The idea is that the rapid review responds to a particular need now. There is an immediate question of what we need to do, but that should not limit HTAC in doing a more comprehensive assessment later on when more evidence becomes available. There is a rapid review, but there will also be a full HTA that will be done later on.
Madeleine Valera *(FHI 360)*	On Yen's presentation: Yeng - if there is no local evidence yet what shall be the process? ie Gestational Diabetes - your program officer at DOH asked for HTA to be done.	Ms. Anne Julienne Genuino: Limitations in our local data are a cross-cutting problem that limits our decision-makers in developing more sound decisions and policies. For clinical data, we can refer to international data as clinical data is generally transferable. Other domains, however, in HTA (such as economic,

		social, ethical, legal) will require local context. In these cases, data collection is aimed at a feasible level (an example would be limiting the sample size). If no local data are available at all, we can also conduct validation with local experts for adoption/ adaptation in our context. What is important is these are tested/ investigated through uncertainty analysis and/or transparently declared in the study limitations with explanations on likely implications. Our policy-makers, the recipient of the information, should understand the implications of these data limitations in their decisions and their application.
Enrico Ragaza *(Philippine College of Surgeons)*	With the solidarity trial finished, how does this impact the ongoing study on HCQ?	Dr. Anna Melissa Guerrero: The Solidarity Trial for HCQ focuses on severe hospitalized patients, so the results apply to this specific population where it was shown that there was no benefit. What are the subsets of the population where the HCQ studies are still being conducted?
Mary Ann Lansang	Given the rapidly growing body of evidence for these tests, how often does HTAC update its reviews and re-evaluate whether its recommendations need to be updated or revised?	Answered Live by Dr. James Delos Santos: It really depends on the technology that the HTAC is assessing. It also depends on the need for assessment and with the turnaround of data. For example, our assessment for Rapid Antibody Tests as mentioned by Prof. Agnette, underwent three interim guidelines for April, May and June 2020 because there was overflow of data and evidence that we have to review. We have mentioned in the early part of this webinar that when it comes to RT-PCR, we still refer to the May 2020 Guidelines, but since there has been a lot of data on assessment or making a cycle threshold (CT) value for diagnosis even having validation

		and methodology studies for this, we will now be coming up with new interim guidelines for this. I guess the pacing for each kind of technology will depend on the need to reassess it with the new evidence and data that is coming in. The HTA Unit is always on the lookout for new evidence, so we will know if there is any new evidence.
Loyda Amor Cajucom *(University of the Philippines)*	What do you recommend should be done by health professionals in cases of those with negative PCR test, positive IgM and IgG and remaining to e symptomatic but mildly asymptomatic (i.e., still has no sense of smell)	Answered Live by Dr. James Delos Santos: This scenario is perfectly understandable because the patient might already be in the late phase of the disease, so the positivity of RT-PCR is really low while the use for antibody tests becomes more useful. Here, clinical diagnosis is of more importance already, together with other diagnostic features like regression/ progression of infiltrates on chest x-ray (CXR) or chest computed tomography (CT). Since the patient is still mildly symptomatic, the patient should be dealt with appropriately still as an infected or positive person. Serial follow-up then might be recommended for these conditions with strong consideration for clinical features.
Ma Evangeline Reveche *(Quirino Memorial Medical Center)*	Why do we have to use the RAT if their result is not that accurate as the RT-PCR?	As mentioned in the presentation, the rapid antibody test kit may be used as an adjunct to diagnosis of patients among symptomatic patients with greater than or equal to 15 days symptoms onset, tested negative twice to PCR and with clinical and diagnostic manifestations of COVID-19. While rapid antibody tests are not to be used as a standalone test, they may provide additional clinical information which can help determine the best course of management for the patient.

Alia Cynthia Luz *(HITAP)*	Are there explorations for early HTA for potential COVID 19 vaccine and treatments?	Dr. Anna Melissa Guerrero: We would like to do this for the priority topics of the government, especially COVID-19 vaccines. Dr. James Delos Santos: The issue here, Ma'am, is that HTAC can only start assessment with the regulatory body approved first before doing any review; however, rest assured that the issue is always on the table of the Council, so that we will be prepared once health technologies, such as vaccines are approved.
Rey Anthony Leung *(BGHMC)*	What is the HTA insights on stand-alone Chest X-ray with artificial intelligence as an alternative to screen for and detect COVID without validation? Any legal issues? Cont'd.. I mean validation by a FIlipino radiologist A unit is being set up in Baguio authorized by local officials without the concurrence of health experts	Per the HTAC recommendation on the use of artificial intelligence (AI) on chest CT for diagnosis: 1) Imaging is not a standard for diagnosis, and should be used with caution and with other clinical parameters. 2) These are platforms still in need of proof of concept and thus these kinds of platforms should be addressed as validation studies needing a sound ethical assessment. This has been the general recommendation of HTAC. 3) Under the PMA Medical Act, the Filipino physician, in this case the radiologist, should be the primary assessor of the platform, and the standard for diagnosis since we are dealing with Filipino patients and data. There should be strong caution on utilization of these platforms in order to protect the data of the Filipino people which is a responsibility of every healthcare worker or health professional.
Nerissa Sta. Ana *(Veterans Memorial Medical Center)*	How importance is re-swab in patient tested positive what interval of each swab test?	Per the Omnibus Interim Guidelines on Prevention, Detection. Isolation Treatment, and Reintegration Strategies for COVID-19: "Patients with mild

		symptoms who have completed at least 10 days of isolation from the onset of illness either at home or a temporary treatment and monitoring facility inclusive of 3 days of being clinically recovered and asymptomatic can be discharged and reintegrated to the community without the need for further testing, provided that a licensed medical doctor clears the patient."
Q&A Session		
Anonymous Attendee	Please correct my understanding, RAgTs is not recommended at the current time. With that, RITM/FDA has not released any approval for validation test?	HTAC has provided recommendations for minimum requirements; however, based on the validation studies released by RITM, none of the kits currently registered with the Philippine FDA have passed these minimum specifications. Rest assured, RITM is continuously doing validation studies for other antigen test kit brands.
Von Philip Perez	For Usec Vergeire: How many days po ang hihintayin para po malaman ang swab test at sa quarantine facility po ba dadalhin kapag asymptomatic ang pasyente	Dr. Kim Patrick Tejano: Turnaround time of labs from being swabbed to receiving the results has improved already. If before, there are labs that give out results 3 to 5 days after getting swabbed, most labs now release 24-48 hours already. In compliance with the IATF resolution, confirmed cases, whether asymptomatic or symptomatic and symptomatic close contacts, shall be isolated in the Temporary Treatment and Monitoring Facilities (TTMF). Asymptomatic close contacts who have not been tested yet may opt to home quarantine provided that they comply with the requirements of the DOH-DILG JAO 2020-0001. Once they tested positive, then they shall be referred to TTMF.

Attendee *(Affiliation, as indicated)*	Question (Facebook Live)	Panelist: Answer
Myka Galicha-Paras	Please announce which country are exempted from swab testing	Swab testing exemptions are not within the scope and responsibility of the HTA Council. Kindly wait for the official issuance and announcements from the DOH Central Office and the COVID-19 IATF.
Alex Mendoza *(Abbott)*	**Question for Dr. delos Santos:** Does DOH have a recommended CT value to distinguish positivity and negativity of COVID sample. Example Korea has National Cut off of 30 CT value and Singapore has 29 CT value cut off. **Question for Prof. Cat Lee Ramos:** If a sample was negative to Rapid Antigen and is positive for RT PCR like low viral load samples, will it mean that the patient is still infectious?	No, we have not set a national cycle threshold (CT) value for the detection of SARS-CoV-2 using RT-PCR. We are currently preparing for an update of our rapid review in RT-PCR. We may explore setting CTs and its corresponding impacts on viral transmissibility. This would depend on the brand of the antigen test kits. RAgTs have lower sensitivity than RT-PCR, so in case of contradictory RT-PCR results, the RT-PCR is the standard. It should be emphasized, however, that patients should be managed with regard to clinical symptoms and epidemiological history. As for the Ct value, HTAC aims to perform another round of review for RT-PCR which will cover questions on Ct values.
Luigi Patrick Sealtiel	Is there ever a conflict role between HTA of the DOH and the FDA in terms of approving tests or medicines?	Answered live by Dr. Anna Melissa Guerrero: We have to understand the role of the regulatory agency first. They need to issue authorization, so that the products can be marketed in the country. I think we can assess, but we cannot allow the use of a product that has not been authorized by the FDA. As an example, we can only assess a particular drug based on the approved indications and use of the FDA. We have to be aligned in terms of review of the clinical evidence and we

		also have to align with the regulation of FDA. There should be no conflict.
Polaris Orb *(Nill Taal Philippine Society of Medical Laboratory Scientist)*	Rapid test kits has been long used before and the international health community knows its capability varies greatly, its quality is very much affected by manufacturing, storage and handling procedures. Why don't we focus on the use of saliva/sputum? Singapore has the technology that can utilize those sample which skips the extraction process in RT-PCR procedure. This reduce greatly the risks to medtechs (who are mostly unrecognized and least mention in this health crisis while they do the essential service). Why don't we expedite the use of saliva like you do in flooding the market with RATS be it antigen or antibody.	The use of saliva as alternative specimen for RT-PCR testing is currently being reviewed by HTAC.
Raymond Castillo	What are the recommended medicines used for COVID that are not included in the PNF?	All medicines for COVID-19 which are recommended by HTAC are recommended for reimbursement and government procurement.