

Visit by Delegation from the Department of Health, Philippines to conduct health technology assessment (HTA) studies

17-20 April 2019

Report

Health Intervention and Technology Assessment Program (HITAP)

Abbreviations

AHEAD	Advancing Health Through Evidence-Assisted Decisions
BIA	Budget impact analysis
BMGF	Bill and Melinda Gates Foundation
CD4	Cluster of differentiation 4
DOH	Department of Health
FEC	Formulary Executive Council
GIS	Geographic Information Systems
HARP	HIV/AIDS Registry of the Philippines
HITAP	Health Intervention and Technology Assessment Program
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HPV	Human Papilloma Virus
HTA	Health technology assessment
iDSI	International Decision Support Initiative
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
NICE	National Institute of Health and Care Excellence
PCV	Pneumococcal conjugate vaccine
PMTCT	Prevention of mother-to-child transmission
PNDF	Philippine National Drug Formulary
RRT	Renal Replacement Therapy
STEP	Sentro ng Pagsusuri ng Teknolohiyang Pangkalusugan
UHC	Universal Health Coverage
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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Executive Summary

As part of the pursuit of universal health coverage (UHC), the Philippine Department of Health (DOH) has been taking concrete steps to institutionalize Health Technology Assessment (HTA), a mechanism that enables the integration of evidence in policy making for health investments, and a fair priority-setting process among stakeholder groups. In line with this, DOH sought the assistance of the Health Intervention and Technology Assessment Program (HITAP) to develop and strengthen HTA capacity in the country.

With the support of UNICEF and under the Bill and Melinda Gates Foundation (BMGF) through the International Decision Support Initiative (iDSI) Plus, HITAP is providing technical assistance to the DOH's HTA office through various capacity building projects, including three HTA studies on priority topics identified by DOH and PhilHealth, the agency entrusted with achieving UHC. The topics are economic evaluations of renal replacement therapy (RRT) and universal screening of human immunodeficiency virus/acute immune deficiency syndrome (HIV/AIDS) for pregnant women, and feasibility of ultrasound screening among pregnant women. To work on the three topics, HITAP invited researchers from the HTA unit called the HTA Study Group and later, STEP (*Sentro ng Pagsusuri ng Teknolohiyang Pangkalusugan*), to come to HITAP for a four-day visit in April 2019.

The HTA research team made significant progress during its time at HITAP. The study on universal HIV/AIDS screening is the first study to utilize Plant-A-Tree, a decision tree software supported by iDSI. The assessment on ultrasound screening evolved from being a qualitative study on women's views on ultrasound screening in general, to a broader feasibility study looking into budget impact, survey of health system capacity and acceptability of the intervention among stakeholders. The economic evaluation on RRT coverage policies is in its final stages and nearing completion. A stakeholder consultation is planned for early June, and the manuscript for publication is already being drafted.

A special session on budget impact analysis was conducted by HITAP for use in the ultrasound and RRT studies. The visit was concluded by recapping next steps for each study, and discussions on other areas for potential engagement and support.

Background

Health Technology Assessment (HTA) is not completely new to the Philippine health system. There have been several efforts to institutionalize a systematic process of generating policy-relevant evidence to inform service coverage. Local policies in the form of administrative issuances and national laws have been developed to support HTA policy and practice, and several activities ranging from research and capacity building have been carried out since the early 2000s.

In 2012, the Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Thailand and NICE International, the National Institute of Health and Care Excellence (NICE), UK provided technical assistance to the Department of Health (DOH) – Pharmaceutical Division (PD) with the support of the Rockefeller Foundation. This support resulted in economic evaluations of two vaccines, one on pneumococcal conjugate virus (PCV) and Human Papillomavirus (HPV), being conducted to inform their inclusion in the Expanded Programme on Immunization.

In 2017, an HTA unit called the HTA Study Group and later, STEP (*Sentro ng Pagsusuri ng Teknolohiyang Pangkalusugan*), was established in the Health Policy Development and Planning Bureau as part of the Advancing Health Through Evidence-Assisted Decisions (AHEAD) Fellowship Program of the Department of Science and Technology – Philippine Council for Health Research and Development. The HTA unit's main function was to generate evidence to inform listing of drugs in the Philippine National Drug Formulary (PNDF) and development of new health benefit packages of the Philippine Health Insurance Corporation (PhilHealth), the agency entrusted to manage the UHC program. Majority of the research undertaken in their first year was on drugs, based on identified priority topics of the Formulary Executive Council (FEC).

Recognizing the need to further build technical and sectoral capacity in HTA, Imperial College London (formerly NICE International) and HITAP were awarded a grant by the United Nations Children's Fund (UNICEF) in 2018 for a one-year technical assistance project to strengthen HTA capacity, focusing on non-drug interventions related to maternal and child health. While the main objective of the project was to strengthen evidence-to-policy decision making, a key component was to ensure that Filipino researchers develop skills in critically appraising evidence and conducting systematic reviews and economic evaluations. To apply these skills on a specific topic, the HTA unit conducted a scoping exercise among relevant stakeholders, based on the existing priorities of the programs on safe motherhood and HIV/AIDS, and PhilHealth's Benefits Development and Research Department. The two areas identified where there

are existing evidence gaps were: 1) human immunodeficiency virus/acute immune deficiency syndrome (HIV/AIDS) screening and 2) ultrasound screening, both for pregnant women.

In addition to the UNICEF technical assistance, HITAP is also supporting other HTA activities in the Philippines through a grant received under the International Decision Support Initiative (iDSI) as part of its third phase. Areas of collaboration include technical support for economic evaluation studies, individual capacity building through formal and informal means, and enabling a policy environment for HTA in the country. One study being supported under this is the economic evaluation of renal replacement therapy (RRT) coverage policies, a priority topic of PhilHealth and a common subject for assessment among countries in the region.

This report summarizes discussions from a series of meetings conducted between April 17-20, 2019 when the Philippine HTA research team visited HITAP for assistance on the three studies previously mentioned. The main objective of the visit was to finalize the research protocol and develop preliminary models for the maternal and child health studies, while finetuning the results and presentation for the RRT economic evaluation. Highlights are organized per study, with additional notes from a lecture on budget impact analysis.

Cost effectiveness of HIV/AIDS Screening for Pregnant Women

During one of the structured teleconference calls prior to the visit to HITAP, the study team led by Mr. Geovin Dexter Uy provided an overview of how the topic was selected. He also shared the proceedings of the consultation meetings held in early February, where the background and rationale for conducting the study was discussed. The Philippines has one of the fastest growing HIV epidemics in the world, despite its low prevalence. While only 6.3% of the cases are among females, there is a high risk of transmission to children given that 93% of these cases happen among those in their reproductive age. Thus, more emphasis is required on preventing mother-to-child transmission (PMTCT) as the burden of the disease is borne by both, the woman and the infant throughout their lifetime. PhilHealth covers antenatal care on an outpatient basis, although HIV testing is not explicitly covered in the package. There is an outpatient benefit package under PhilHealth for HIV/AIDS which includes testing for CD4 (cluster of differentiation 4) or white blood cell level, viral load and monitoring antiretroviral toxicities for confirmed HIV+ patients. These are pertinent information needed to monitor the health of their immune system, disease progression and response to antiretroviral therapy. However, HIV screening test is not included in any

existing PhilHealth benefit. Many international guidelines recommend HIV/AIDS screening among pregnant women and these recommendations are supported by evidence of cost-effectiveness done in low to high prevalence settings. Having local data on value for money of such screening programs may inform PMTCT programs and PhilHealth's reimbursement for antenatal care services. As such, the team decided to embark on a study to determine the cost effectiveness and budget impact of introducing universal HIV/AIDS screening among pregnant women, from the government payor's perspective.

Mr. Uy raised during the first day of the visit that one of the biggest concerns in conducting an economic evaluation is the lack of local data. He also sought clarification on how to incorporate treatment regimens, sensitivity and specificity of the HIV tests and protocols for vertical transmission in the model. Dr. Yot Teerawattananon suggested that a good data collection plan is necessary to ensure that results will be valid and would still address the policy questions. Model validation and steps to verify parameters should be conducted later in the study. Mr. Uy mentioned that there is an HIV/AIDS Registry of the Philippines (HARP) which can serve as the primary source for epidemiological data. Another potential source is UNAIDS, which has population-based estimates across different settings. At the end of the first day, the research question was finalized to assess the cost-effectiveness of universal versus ad-hoc screening, the latter being the current scenario whereby only 5% of the population of pregnant women are screened for HIV/AIDS.

A decision tree model was developed to reflect the different policy strategies. Aside from universal screening, there are other combinations of interventions that can be reflected in the model such as mode of delivery, provision of infant feeding, provision of infant prophylaxis and use of raltegravir as aggressive treatment. The model was revised to reflect prevalence of HIV/AIDs first and incorporating timing of antenatal care as early or late (less than 6 weeks before last menstrual period). Mr. Uy developed the decision tree using the Plant-A-Tree software supported by iDSI, which is in its early beta-testing phase.

The second day was spent reviewing literature and refining the proposal to reflect changes in the policy options discussed. Changes were also made to the model in Excel which was organized so as to easily reflect changes in parameter values once better data becomes available. On the third day of the visit, the study team consulted on the validity of certain assumptions made in the model. Prevalence of HIV/AIDS among pregnant women was a crucial parameter and needed extensive review to ensure a precise estimate. It was noted that further review of literature and stakeholder consultations were needed to collect data on identify other parameters (e.g. acceptance and effectiveness of each intervention).

In terms of collecting cost and outcomes data, it was mentioned by Mr. Uy that conducting primary data and securing ethics clearance would be challenging since the research deals with a vulnerable population group. Other secondary data sources were suggested: PhilHealth database, completed costing studies, and existing literature for health utilities. Mr. Uy was tasked with designing a data collection plan and revising the model based on agreements and run the analysis using Thai or other secondary data until local data was available.

Feasibility of Ultrasound Screening for Pregnant Women

Ms. Bernadette Almirol, the lead investigator for the study on the feasibility of ultrasound screening for pregnant women, gave a background of the research prior to the consultation. She shared that ultrasound imaging has become an essential diagnostic modality in the field of obstetrics and is being used extensively to evaluate pregnancies. The Philippines adopts the World Health Organization's (WHO) guideline that recommends one ultrasound scan before 24 weeks of gestation (early ultrasound) to estimate gestational age, detect fetal anomalies and multiple pregnancies and reduce induction of labor for post-term pregnancy. There is currently a growing demand to explicitly cover ultrasound screening in the maternity care package of PhilHealth, which has an antenatal care component. Since the current package only covers essential laboratory and diagnostic tests, PhilHealth is interested in potentially expanding this package to include ultrasound as a mandatory test for all those utilizing the benefit. During the stakeholder consultation, two research objectives were identified: 1) to determine effectiveness and safety of ultrasound screening and 2) to determine the feasibility of including ultrasound screening as one of the mandatory diagnostic tests in the antenatal care package. The feasibility study involves a budget impact analysis, a spatial analysis of ultrasound facilities and human resources, and a qualitative study on stakeholder views on ultrasound screening.

Dr. Teerawattananon emphasized the importance of conducting a feasibility study to support coverage decisions. The first part of the research will focus on the effectiveness of the intervention, while the feasibility study will investigate the health system capacity in implementing the policy, if approved. Integral to this component is determining whether there are enough ultrasound machines to make the screening mandatory, and whether there are enough health personnel that are trained in conducting the exam and interpreting the results. In addition to the number of resources, distribution is also crucial to understand. It was suggested to conduct a mapping of facilities and personnel and utilize tools from geographic information systems (GIS). Similar to a study done in the UK, an acceptability survey will also

be conducted. Dr. Teerawattananon suggested including more stakeholders such as health care providers (midwives, general practitioners and OBGYN specialists) in the target participants, apart from interviewing women in reproductive age only.

The second and third days were spent reviewing the questionnaire for the key informant interviews and focus group discussions to be conducted. Dr. Teerawattananon and Ms. Alia Luz provided comments on the draft question guide, and these were improved by Ms. Almirol shortly after. Three versions of the questionnaires were prepared, each having a different target audience: pregnant women, women who have had experience with an ultrasound but not currently pregnant, and women who have never been pregnant. Strategies to improve the phrasing of questions were also given. Lastly, Ms. Almirol also worked on the framework for a budget impact analysis, with the training provided by Ms. Waranya Rattanavipapong.

Ms. Almirol was assigned to revise the interview guides and the protocol for submission to an institutional ethics review board. However, while waiting for ethics clearance, Ms. Almirol mentioned that she can already start with the umbrella review to determine the effectiveness of ultrasound screening.

Economic Evaluation of Renal Replacement Coverage Policies

The study to evaluate cost effectiveness of RRT coverage policies was started by Ms. Diana Bayani in mid-2018 as part of her internship at HITAP. The assessment was urgently requested by PhilHealth as RRT is currently the second highest pay out of the corporation, and is interested in knowing whether it is worth expanding the current coverage or whether it should incentivize use of other modalities to ensure sustainability. During her time at HITAP, Ms. Bayani developed the model and utilized secondary data (e.g. data from the Thai Renal Replacement Registry) with the intent of collecting primary local data upon her return to the DOH. The objective for this visit was to finetune the results using newly collected local data, prepare for the presentation at HTAsiaLink and a plan a stakeholder consultation in June, and have an outline for a manuscript for publication.

As a recap, the study aims to evaluate different policy options for RRT in the Philippines. It asks whether it is good value for money, from the perspective of PhilHealth to 1) shift to providing adequate hemodialysis (156 sessions per year) or 2) shift to a peritoneal dialysis first policy or lastly 3) shift to a peritoneal dialysis first policy and promote more pre-emptive kidney transplants. All these options were

compared to the current scenario where only 90 sessions of hemodialysis are covered; 94% of patients use this modality.

On the first day, Ms. Bayani presented results from the primary data collected at the National Kidney and Transplant Institute from March – April 2019. She also consulted on key parameters and assumptions used in the model which include rates of medical contraindication, frequency of hemodialysis sessions, and survival parameters. It was recommended by Dr. Teerawattananon to assume equal effectiveness between adequate hemodialysis and peritoneal dialysis, thus the model would only reflect survival of inadequate hemodialysis in the current policy comparator. He also suggested highlighting the issue of who decides on frequency of dialysis sessions in the discussion section of the planned manuscript. The study relies heavily on the assumption that patients are underdialyzing (utilizing 2 sessions or less per week) due to their (in)ability to pay, and not because they are well enough and would not need that third session in a week. In addition, the government's provision of only 90 sessions assumes that patients can co-pay for the remaining 66 sessions that are not covered, which does not happen in practice. Ms. Bayani explained that this was clarified during earlier consultations with the nephrology specialists. Suggestions to improve the presentation were given, alongside additional visualizations to communicate results of the probabilistic sensitivity analysis.

Ms. Almirol conducted data analysis for the utility parameters used in the economic evaluation. Dr. Teerawattananon suggested publishing the results of the quality of life survey separately from the main paper. He also proposed stratifying the results according to each modality and dependent variable (such as age, sex and educational attainment).

Ms. Bayani gave a mock presentation on the second day of the visit to solicit comments on the overall organization of the research results, as well as feedback on the slide deck and manner of presentation. Ms. Luz, Ms. Avnee Patel and Ms. Juliet Eames asked clarification questions and gave substantial suggestions to improve the explanation of key results of the study. Some revisions on the budget impact analysis and probabilistic sensitivity analysis were also provided.

During the third day, Ms. Almirol and Ms. Bayani worked together to improve the visualizations of the study results, particularly on the presentation of the patient survey. They also started planning for the consultation meeting scheduled on 4 June 2019, where results are to be presented to relevant stakeholders. It was discussed that HITAP is keen to attend this meeting and will provide additional assistance as needed, to disseminate the results to inform local policy makers.

Budget Impact Analysis Lecture

During the second day of the study visit, a lecture on conducting budget impact analysis (BIA) was led by Ms. Rattanavipapong. She started her presentation by explaining that evidence on budget impact is now commonly requested by many HTA agencies prior to approval of health technologies for reimbursement, alongside cost-effectiveness analyses. Examples from Thailand (imiglucerase for Gaucher disease type 1, galantamine for Alzheimers) were cited to show how results of a budget impact study are used to inform coverage policies. While only a few countries have context-specific guidelines on conducting BIA, there are existing guidelines published by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and in health economics journals. These may serve as valuable resources for countries without local economic evaluation guidelines.

Ms. Rattanavipapong explained that there are three key elements in conducting a BIA: the model structure, input parameters and the reporting format. She added that the recommended perspective is usually that of the budget holder or the government payor. The time horizon is also usually shorter (3-5 years) compared to an economic evaluation which takes a lifetime perspective. On the other hand, methods of handling uncertainty in BIA is similar to what is done in economic evaluations. Scenario and sensitivity analyses can also be undertaken by varying the range of the input parameters or taking extreme values. Lastly, when reporting BIAs, total and incremental impact on the payer's budget must be presented. Ms. Rattanavipapong also showed budget impact models for reference and prepared an exercise using a hypothetical disease to demonstrate how a Markov trace can be incorporated in a BIA.

Next Steps

The fourth day of the visit was spent by the Philippine HTA research team working independently at the HITAP office. Next steps and plans for the next face-to-face meeting were noted and are listed as follows:

For the HIV/AIDS economic evaluation, Mr. Uy is expected to revise the study protocol and update the model for review by Dr. Teerawattananon. The data collection protocol also needs to be developed, and a consultation with HIV/AIDS experts from the San Lazaro Hospital is scheduled in the following month.

For the ultrasound screening feasibility study, Ms. Almirol will finalize the study protocol including the qualitative survey tool for submission to the ethics review board of the DOH as soon as possible. The data collection plan can be drafted after ethics approval is secured. The budget impact and spatial analysis

(GIS) can also be conducted as soon as data is collected from the Health Facilities Development Bureau and PhilHealth.

Preparations are already underway for the second stakeholder consultation on the RRT HTA. This will be held in early June, together with other meetings that will be held in the DOH. Remaining tasks related to this study include finalization of presentation slides for HTAsiaLink, planning for the stakeholder consultation meeting in June, and drafting of publication manuscript and policy briefs.

Appendix

Study Visit Agenda

Time	Session	Description	Person(s) Responsible
17 th April 2019			
09:00 – 09:30	Introductions	<ul style="list-style-type: none"> • Introductions and overview of the meeting objectives and schedule; discuss aims from the study visit 	HITAP
09:30 – 11:00	HIV/AIDS screening for pregnant women	<ul style="list-style-type: none"> • Present and discuss the proposal and methodology for the HIV/AIDS study <ul style="list-style-type: none"> ○ Model structure ○ Interventions ○ Perspective and time horizon ○ Model input parameters <ul style="list-style-type: none"> ▪ Epidemiological data ▪ Clinical efficacy ▪ Health utility ▪ Resource and cost ○ Model validation ○ Analysis (cost-effectiveness analysis, sensitivity analysis) 	STEP + HITAP
11:00 – 12:00	Modelling session	<ul style="list-style-type: none"> • Introduction to the Plant-a-Tree software • Discuss changes to the current decision tree model (according to above discussion) 	STEP + HITAP
Lunch			
13:00 – 15:30	Ultrasound Feasibility and Budget Impact Study	<ul style="list-style-type: none"> • Present and discuss the proposal and methodology for the ultrasound study <ul style="list-style-type: none"> ○ PICO (especially in terms of the health personnel to conduct the ultrasound) ○ Perspective and time horizon ○ Parameters (literature reviews) ○ Health facility/equipment survey ○ Patient population survey 	STEP + HITAP

Time	Session	Description	Person(s) Responsible	
		○ Key Informant Interviews		
15:30 – 17:30	Renal Replacement Therapy Economic Evaluation	<ul style="list-style-type: none"> Discuss the methodology Updates on the data collection and analysis Written outputs (manuscript, report, and policy brief) outlines (as relevant) 	STEP + HITAP	
18 th April 2019				
09:00 – 09:30	Reflections	<ul style="list-style-type: none"> Summarize the main points and ideas from the day before; discuss today's sessions' goals 	STEP + HITAP	
09:30 – 17:30	Independent work	<p>HIV/AIDS Economic Evaluation</p> <ul style="list-style-type: none"> Model development: revise current decision tree Literature search for parameters <p>Ultrasound Screening Budget Impact and Feasibility Study</p> <ul style="list-style-type: none"> Literature review as needed GIS learning session Prepare the tools for costing, surveys, and key informant interviews <p>Renal replacement therapy economic evaluation</p> <ul style="list-style-type: none"> Input parameters from data collection Revise the model as needed/conduct regression analyses Literature review as needed 	STEP	
19 th April 2019				
09:00 – 09:30	Reflections	<ul style="list-style-type: none"> Summarize the main points and ideas from the day before; discuss today's sessions' goals 	STEP	
09:30 – 12:30	Updates on progress from previous day	<ul style="list-style-type: none"> All three studies Discuss revisions and changes 	STEP + HITAP	
Lunch				
13:30 – 17:30	Independent work	HIV/AIDS Economic Evaluation	STEP	

Time	Session	Description	Person(s) Responsible
		<ul style="list-style-type: none"> • Prepare the data collection tools for costing, health outcomes, and epidemiological data • Prepare the plan and objectives to be met by deadline <p>Ultrasound Screening Budget Impact and Feasibility Study</p> <ul style="list-style-type: none"> • Prepare the tools for costing, surveys, and key informant interviews • Prepare the plan the objectives to be met by deadline <p>Renal replacement therapy economic evaluation</p> <ul style="list-style-type: none"> • Prepare the manuscript, policy brief, and report write-up outlines and plans • Prepare the plan the objectives to be met by deadline 	
20 st April 2019			
09:00 – 09:30	Reflections	<ul style="list-style-type: none"> • Summarize the main points and ideas from the day before; discuss today's sessions' goals 	STEP
09:30 – 12:00	Independent work	<ul style="list-style-type: none"> • All studies continue with previous days' tasks 	STEP
Lunch			
13:00 – 16:00	Next steps	<ul style="list-style-type: none"> • Discuss the revisions to the methodologies, tools, models • Discuss plans for next steps of each study 	STEP + HITAP
16:00 – 17:00	Plans for the next visit	<ul style="list-style-type: none"> • Discuss the plan to visit the Philippines in June and August as well as the timeline for the overall collaboration 	HITAP
17:00	Closing	<ul style="list-style-type: none"> • Thanking partners 	HITAP

List of Participants

Delegates from the Philippine Department of Health

Bernadette Joy Almirol	Research Fellow
Diana Beatriz Bayani	Research Fellow
Geovin Dexter Uy	Research Fellow

HITAP Staff present during the study visit

Dr. Yot Teerawattananon	Secretary General of the Foundation and Senior Researcher
Alia Luz	Project Associate
Avnee Patel	Project Associate
Juliet Eames	Project Associate (ODI Fellow)
Saudamini Dabak	Technical Advisor
Waranya Rattanavipapong	Researcher

Photos from the Study Visit



The DOH HTA unit members Diana, Geovin and Bernadette with Alia Luz and Dr. Yot Teerawattananon from HITAP



The DOH team while working on their studies on HIV/AIDS, Ultrasound and Renal Replacement Therapy



DOH and HITAP teams together after the welcome dinner hosted by HITAP

Budget Impact Analysis Lecture Presentation

Slides can be accessed through this link: <http://bit.ly/BIA-04182019>

Blog Post at Global HITAP Website

Link to the blog posted on the HITAP website can be accessed through this link:

<http://www.globalhitap.net/the-philippines-hta-unit-step-visits-hitap/>