REVIEW OF HTA STUDIES ON TREATMENT OF END STAGE RENAL DISEASE (ESRD) AND PULMONARY ARTERIAL HYPERTENSION (PAH) IN INDONESIA

26-30 October, 2015
Jakarta, Indonesia

Reported by Health Intervention and Technology Assessment Program

Acronyms and Abbreviations

BIA	Budget Impact Analysis
BPJS	Badan Penyelenggara Jamina Sosial (Agency for the Organization of Social Insurance)
CAPD	Continuous Ambulatory Peritoneal Dialysis, in this document referred to as "PD"
CUA	Cost Utility Analysis
DFAT	Department of Foreign Affairs and Trade
ESRD	End Stage Renal Disease
HD	Hemodialysis
HITAP	Health Intervention and Technology Assessment Program, Thailand
HTA	Health Technology Assessment
HTAC	Health Technology Assessment Committee, Indonesia
iDSI	International Decision Support Initiative
JKN	Jaminan Kesehatan Nasional (National Health Insurance)
MoH	Ministry of Health
MoU	Memorandum of Understanding
NICE	The National Institute for Health and Care Excellence
PAH	Pulmonary Arterial Hypertension
PICs	Persons in Charge
PPJK	Pusat Pembiayaan dan Jaminan Kesehatan (Centre for Health Financing and Insurance)
USAID	United States Agency for International Development
WHO	World Health Organization
WTP	Willingness To Pay

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Executive Summary

This report summarizes the proceedings of a five-day workshop held in Jakarta at the end of October 2015 to review and finalize two health technology assessment (HTA) studies in Indonesia. The studies, commissioned by Indonesia's HTA Committee, were conducted by its Persons in Charge (PICs) in collaboration with Thailand's Health Intervention and Technology Assessment Program (HITAP). Two topics, one related to the treatment of End Stage Renal Disease and the other related to the treatment of Pulmonary Arterial Hypertension, were selected for an in depth economic evaluation and budget impact analysis due to their relevance to Indonesia.

The objectives of the mission were threefold: to review and finalize the models and analyses for the two studies, to write up a draft report of the results and finally, to present the findings of these studies to selected stakeholders. During the course of the week, PICs and HITAP staff worked in groups to refine the analyses. HITAP staff provided comments to the teams on the draft report and in a joint session, participants wrote policy briefs for discussions with stakeholders. In a separate meeting with partners, HITAP representatives discussed the strategic context of HTA in Indonesia and discussed the status of a study on the Economic Burden of Seasonal Influenza. On the final day, a representative from each group of PICs presented the results of the studies to stakeholders before the floor was opened for discussion. At the end of the session, key decisions were taken on next steps, including finalizing and submitting the report to the HTA Committee, along with a sign off from other stakeholders.

The mission thus fulfilled its objectives with updated analyses, draft reports on methods and results as well as policy briefs and presentations to be used in discussions with stakeholders. The workshop with the PICs yielded fruitful discussions on the role of HTA as well as on setting of a threshold for the country. Interactions with partners and stakeholders further highlighted the importance of the HTA process in the context of the country's ambitious universal healthcare program.

Introduction

Indonesia launched its universal healthcare program in January 2014, a process that had been initiated in 2004. The scheme, Jaminan Kesehatan Nasional or JKN, is administered by a public agency called Badan Penyelenggara Jamina Sosial or BPJS Health and is expected to cover all citizens by 2019. With over 133 million participants enrolled as of December 2014, it is the largest national health insurance system in the world. A premium based system, contributions are designed to vary according to income levels with subsidies for those in need. Even though Indonesia has one of the lowest levels of spending on healthcare compared to its neighbors, the program is likely to place increasing demands on public resources with costs expected to be between $13-16 billion per year until implementation is completed.

In this context, health technology assessment (HTA) can play a significant role in prioritizing health expenditures by providing stakeholders a common ground for deliberation. In Indonesia, the HTA Committee (HTAC), set up recently in the context of the JKN, is supported by the

Centre for Health Financing and Insurance (Pusat Pembiayaan dan Jaminan Kesehatan or PPJK) in the Ministry of Health (MoH). Since its inception, HTAC has received assistance from various international partners including Australia's Department of Foreign Affairs and Trade (DFAT), PATH and the International Decision Support Initiative (iDSI) through which Thailand's Health Intervention and Technology Assessment Program (HITAP) has collaborated with its Indonesian counterparts.

As part of this collaboration, HTAC commissioned two HTA studies in 2014 on topics that were deemed to be relevant to Indonesia. The appointed Persons In Charge (PICs) conducted economic evaluations and budget impact analyses of interventions related to the treatment of End Stage Renal Disease (ESRD) and Pulmonary Arterial Hypertension (PAH) with technical assistance from HITAP. The ESRD study compared continuous ambulatory peritoneal dialysis (CAPD or PD) and hemodialysis (HD) as first line treatment options, while the PAH study compared two drugs, Beraprost and Sildenafil for treatment of PAH patients in functional classes II and III (as defined by the WHO).

A workshop was held in Jakarta between 26th and 30th October 2015, the first four days of which were held at the premises of the MoH where HITAP staff worked with PICs to review the analyses in the two studies. On the final day, a consultation meeting with stakeholders was held at the Manhattan Hotel. The fifth such workshop held since the partnership began, activities have focused on enhancing the capacity of PICs in designing the studies and conducting analyses. In addition, HITAP representatives participated in a meeting with partners supporting the HTA process in Indonesia. The objectives of this mission were to review and finalize the models and analyses for each of the studies, to prepare draft reports and policy briefs and, finally, to present findings of the report to a high level panel of stakeholders.

The rest of this report is structured to provide a summary of the proceedings of the workshop, describe the outcomes and highlight the next steps identified. Additional information on the agenda, list of participants and minutes may be found in the annex to this report.

Summary of proceedings

1. Models and Analyses

   ESRD study:

   The team discussed the various parameters and data used in the model. The team decided to use Thailand's EQ 5D (utility) value set as Indonesia does not have this information available yet and the data for Malaysia was found to be unsuitable. Inpatient and outpatient costs were also made explicit. Costs were separated into costs per visit per year and cost per patient for probabilistic sensitivity analysis. Another variable on the average number of visits per year was added, which the PICs had obtained from a panel of experts. The team discussed the estimation of indirect costs: the HITAP team impressed upon the PICs that in a cost utility analysis, including indirect costs for the patient results in double counting as the patient's utility value already captures this loss. A specific question was raised on how to treat income loss of retirees; in the case of family

members, it was decided to exclude the loss of income of retirees since they do not have to report to work and so do not incur a loss of income (some may receive a pension). In writing up the section on methods, the team clarified terms used such as the types of hospitals in Indonesia and the data collected from the survey administered to PD and HD patients.

The team discussed the difference between deterministic and probabilistic results. HITAP staff explained the use of a Monte Carlo simulation to account for uncertainty. Further, they discussed how to interpret a cost effectiveness plane as well as cost acceptability curves for this model. This topic was revisited on multiple days and the PIC team sought clarification on the nuts and bolts of the analysis as well on its significance in the study.

With regards to the Budget Impact Analysis (BIA), the discussion centered on the estimation of coverage using prevalence and incidence data. While initially, the coverage of dialysis was estimated using the National Survey 2013, it was eventually estimated using the JKN's renal replacement therapy registry, as it was found to be more accurate. The budget impact was calculated for two scenarios, one where the prevalence data reflected 53% of dialysis coverage, and the other, where it reflected 100% of dialysis coverage. The team used this coverage ratio along with cost data derived from the Markov analysis to compute the budget impact over five years from a government perspective. The HITAP team explained the process for this analysis and clarified questions related to the same, including how it differed from cost effectiveness analysis and how to interpret its results.

PAH study:

The group discussed various aspects of constructing the model for the cost utility analysis (CUA). One of the points that came up was about the drugs available to patients if their functional class worsened. Additional parameters were updated and values from questionnaires were also checked. The discussion on costs revolved around issues such as including inpatient and outpatient costs while calculating direct medical costs, excluding a VIP patient as an outlier as it was skewing the data, and consolidating costs across functional classes. There is no drug reference price in Indonesia so the prices of the drugs were taken from one hospital (according to an expert, there should not be much variation across hospitals). Originally, the team had agreed to use the originator price for both drugs but upon discussion, settled on using the generic price for sildenafil. It was noted that the team could not capture the direct medical and direct non-medical costs from other hospitals. Therefore, it was decided that the study would focus only on cost data from the main hospital that patients visited. In this case as well, HITAP staff explained why patient productivity loss needs to be excluded in a CUA since it would lead to double counting.

For the budget impact analysis, prevalence and incidence data from Thailand was used due to the limitations of data available in Indonesia. The coverage was estimated to be 100%.

2. Threshold setting for Indonesia

In order to determine whether these interventions were a good value-for-money proposition for Indonesia, a threshold value needed to be decided on. During the workshop, the PICs indicated that this issue was under discussion and that using the WHO guideline of 1-3 times GDP per capita was viewed favorably. However, the HITAP team said for the purpose of these studies, it was important to have a clear decision rule that was not too broad.

To this end, HITAP presented on what a threshold is and how it compares with a tubular approach to priority setting, where interventions are ranked according to their cost effectiveness and chosen until the budget is exhausted. If one goes for the latter, one must evaluate all interventions which is often not feasible. Hence, most countries opt for a threshold approach to determine which interventions should be supported. The use of a threshold was illustrated with country examples such as Australia, which has an implicit threshold of about AUD 30,000, the UK, which was the first country to announce its threshold in terms of a band of GBP 20-30,000 and Thailand, which established an arbitrary threshold of 1.2 times GDP per capita or THB 160,000. An alternative way of setting a threshold is to not fix one and to look at health benefits gained from interventions and chose as long as the budget is available. However, ethical considerations play a role as well since a wealthy person's life years gained would count for more than those of a poor person's. Using NICE (UK) as an example, the group discussed how setting of a threshold can serve a dual purpose of determining cost effective interventions and providing information to support negotiations with pharmaceutical companies.

For Indonesia, the PICs decided on a threshold value of IDR 40 million for the purpose of these studies. This value is approximately 1 times GDP per capita and is comparable to countries like the Philippines, Myanmar and Vietnam.

3. Results

ESRD study:

The study found that the lifetime costs of a patient with PD first treatment followed by HD in case of complications is about IDR 700 million for 6 additional life years gained, whereas for HD as a first line treatment followed by PD, it costs IDR 735 million for the same life years gained. The ICER of a PD first policy was found to be IDR 193 million per QALY as opposed to IDR 207 million per QALY for an HD first policy.
The sensitivity analysis, graphically represented using cost acceptability curves, suggest that up to a willingness to pay per QALY of IDR 195 million, supportive care is the most feasible policy option. Above that amount, a PD first policy is the most cost effective option. At no level is an HD first policy a viable option. At the identified threshold of IDR 40 million, only supportive care would be a feasible option.
The budget impact analysis showed that pursuing a PD first policy would cost IDR 40 trillion at a 53% coverage rate and IDR 75 trillion at a 100% coverage rate over a five

year period. On the other hand, an HD first policy would cost IDR 88 trillion at a 53% coverage rate and IDR 166 trillion at a 100% coverage rate over five years.
PAH study:

In this study, it was found that without discounting health outcomes, sildenafil yielded 1-3 additional life years compared to beraprost. ICER per QALY gained for using sildenafil as a first line therapy compared to beraprost is IDR 43 million and IDR 39 million for patients in functional classes (FC) II and III respectively.

The probabilistic sensitivity analysis was presented in the form of cost-effectiveness acceptability curves. At the willingness to pay (WTP) threshold of IDR 40 million per QALY gained, the probability of a prescription of beraprost to PAH patients starting in FC II being cost-effective is 51% whereas for sildenafil, it is 49%. For PAH patients starting in FC III, the probability of a prescription of beraprost being cost-effective is 49% and in the case of sildenafil, it is 51%.

While sildenafil was more expensive than beraprost in Indonesia, it would be a good value for money proposition if the price of the generic drug was reduced by 2% and in the case of the originator, by 85%. In terms of budget impact, it is estimated that additional IDR 4.2 billion would be needed over five years.

4. Interpretation and communication of results to stakeholders

On a general note, the PICs brought up questions on the representativeness of the data. The HITAP team explained how the uncertainty was accounted for using the Monte Carlo simulation. If challenged on the data, the HITAP team suggested making a request for additional data. Further, it may be worthwhile to examine the characteristics of the cohort covered by the dataset used such as whether it included more severe cases and so skewed the results. This point was used to demonstrate the role of modelling in the analysis.

In the case of the ESRD study, the PICs expressed their concern regarding the results of the study and its reception by policy makers. Members of the team pointed out on several occasions that the ad hoc panel, to whom preliminary results had been presented, found the life years gained from the intervention to be too low. Further, the panel did not agree with the recommendation of pursuing a PD first policy as the country does not have the necessary resources. On the low life years gained, HITAP recommended communicating undiscounted values. Regarding the high costs of implementing a PD first policy, the example of Thailand was given, where starting from similar situation, the government focused on building capacity for PD by encouraging hospitals to set up training centers and incentivizing doctors to adopt PD using subsidies. Further, while care was taken to not disadvantage existing HD patients, all new patients were directed to a PD first option.
The PAH study brought two broader issues to the fore: the inclusion of generic drugs in the benefits package and the coverage of off-label drugs. In Indonesia, the availability of generic drugs varies by hospital. In the case of sildenafil, the generic drug is currently not included in the benefits package and it has also not been registered for the PAH

indication thus raising the cost and risk of using this drug. These are important considerations and were to be taken up with stakeholders.
HITAP staff emphasized on various occasions that cost effectiveness was only one of the inputs in the decision making process and that other factors may need to be taken into account. Using the example of Thailand where a similar study on ESRD treatment found neither PD first nor HD first policies to be cost effective, the HITAP team pointed out that a PD first policy was still instituted given the catastrophic nature of the disease as well as concerns of equity as the insurance scheme for government employees covered this treatment. This does not discount the role of an economic evaluation as before conducting such an analysis, it was not known what the financial impact of such a policy was.

5. Discussion with international partners

- Strategy for work in Indonesia:

  Representatives from HITAP, PATH, WHO and USAID met to summarize the results of a study visit by a delegation from Indonesia to NICE, UK and to discuss next steps in terms of their work.

  WHO and USAID representatives who accompanied the delegation from Indonesia said that the visit had had a positive impact on the development of HTA in the country as high level decision makers were now aware of the importance of HTA for the development of a benefits package. They learned technical terms as well as the value of a transparent and participatory process. The delegation was impressed by the National Institute for Health Research (NIHR) and would like to involve academics in supporting HTA given capacity constraints in HTAC.

  In order to sustain the momentum, all attendees agreed that it was important to support local partners. One aspect discussed was to support the governance of the HTA process. However, there is a likelihood of changes being made to HTAC and so efforts on this front have been put on hold. Another area of work was to support the implementation process of the three HTA studies and ensure that there is an impact on policy. HITAP will share the policy briefs with partners so that everyone is on the same page. USAID and PATH representatives said that they would also discuss internally on how to elevate the conversation on these studies at high levels. A third area that partners agreed on supporting was the development of guidelines or manuals for assessment and appraisal. While guidelines for assessment have been drafted by HTAC, support is needed to finalize the same along with consultations. Further, guidelines for appraisal may require commitment from mid-level academics in Indonesia and support from NICE and HITAP.

  The WHO has planned to support several efforts. For one, it will discuss with iDSI about the possibility to have a high level delegation from Indonesia attend PMAC and have meetings with USAID and PATH as part of the delegation's visit to HITAP. WHO and HITAP agreed to coordinate these plans and share relevant information.

Another initiative is to arrange a one week workshop for 30-40 participants from various universities and academic settings in Indonesia to raise awareness on HTA and identify partners. In this regard, WHO requested technical support from HITAP, NICE and PATH. A third area of WHOs efforts is to support junior scholars from Indonesia to participate in the HTAsiaLink conference that is to be held in Singapore in May 2016. Regarding drafting an MoU between the MoH and iDSI, the WHO representative said that they would share examples of MoUs that HITAP has with various institutions. Further, the WHO urged HITAP to publish its experience of developing HTA capacity in Indonesia.

- Update on study on Economic Burden of Seasonal Influenza

  A meeting was held with all partners (Septiara Putri, HITAP, WHO Indonesia, MoH, and NIHRD) to discuss a study on the economic burden of seasonal influenza which they are collaborating on in Indonesia. The attendees discussed how this pilot study can be implemented in the country as well as the data available for the analysis.
  This study is being conducted by Septiara Putri, who has received funding to conduct a pilot study on the economic burden of seasonal influenza in Indonesia. While HITAP does not have financial support for this project, it will provide technical assistance. A representative from the WHO pointed out that due to the funding cycle, the study would need to be completed by the end of December 2015. Further, as the WHO works closely with the MoH, it was important to include them in the process. The attendees wanted more information on the protocols of the study, including the source of data. They also wanted to confirm that there are no other similar studies and that universities are made aware of this particular study. The WHO sees this study as a means of informing guideline development, conducting a field test of the guidelines, which HITAP is also helping with, and building staff capacity. This study may also be used to inform future studies as well as guidelines so that the government can take the lead next year.

  The group also discussed the inputs required from WHO HQ. These include 1) Providing feedback from their research team and counterparts on the usefulness and feasibility of using the manual in Indonesia 2) Preparing a presentation on country experiences gathered while piloting the economic burden manual and tool.

6. Draft report, policy brief and presentation

   After finalizing the models and analyses, the two teams began to write the report. The structure of the report was discussed and HITAP staff provided comments on the method and results sections of the draft report over the week. The teams wrote policy briefs for each study in a joint session led by HITAP and also prepared presentation slides for consultations with stakeholders that was to be held at the end of the week.

7. Consultation meeting with selected stakeholders on ESRD and PAH studies

On Friday, 30 October, 2015, a meeting was held with various stakeholders. Representatives of the PICs presented on the results of each study followed by a discussion with all participants present, which included clinicians, experts, members of government, the PICs and HITAP staff.

One of the issues that came up was the representativeness of the data. Some of the participants were concerned about the small number of PAH patients used to calculate the budget impact (around 500 patients). The HITAP team clarified the source of the incidence and prevalence data, which was taken from Thailand as currently there is no data available on these parameters in Indonesia. Further, given that PAH is a rare disease, the numbers are expected to be low. On ESRD, one participant asked whether the teams had considered data from other regions such as Papua, as the numbers could be very different given the high cost of transporting the consumable. This raised the question of whether the models ought to be rerun with better data, to which the HITAP team responded by saying that the data is rarely perfect and to wait for better data would only lead to a delay in implementation.

The HITAP team urged the gathering to address the issue of the benefits package covering drugs that are not registered ("off label" drugs). In the current study, sildenafil has not been registered to treat PAH but has been recommended by doctors for treatment. This point provoked substantial debate and one participant referred to it as a "challenging recommendation". The MoH, one participant said, would not take responsibility for off label drugs and added that it was the responsibility of manufacturers to register the drug for this use. Another participant asked if the drug could be registered for this indication only. Participants discussed the status of some drugs in the national formulary that are not registered and whether the MoH can include sildenafil as part of its "special access scheme" upon the recommendation of HTAC. HITAP reminded participants that it is the responsibility of the MoH to protect the health of the population and that pharmaceutical companies have their own objectives to pursue.

While determining the costs of intervention of the PAH study, one of the questions that arose related to using a generic version of sildenafil. The group discussed if it was acceptable to include only generic versions of drugs in Indonesia's benefit package. HITAP pointed out that the price of sildenafil in Indonesia is higher than in Thailand and recommended that the government use this study to negotiate the price so that it is cost effective. Additionally, it was suggested that generics be given preference unless the originator was willing to reduce the price as the effect of the drug is the same.

In the case of the ESRD study, the recommendation of a "PD first" policy engaged the group in an extensive discussion. One of the participants, representing the association of nephrologists, said that she did not agree with the recommendation and added that the chief problem with offering PD is the availability of the consumable for PD, of which there is a shortage in Indonesia. Further, the cost of the consumable itself is very high as is the cost of transport which deters hospitals from choosing this option. The low rate of

reimbursement from the government to cover hospital costs is also a concern. The other aspect of implementing a PD first policy, she explained, is that the system does not have the resources to implement such a policy. She therefore thinks that the government should support development of PD but not as a preferable option.

Members of the ESRD team responded with a suggestion to add a recommendation that deals with distribution. HITAP shared Thailand's experience with switching to a PD first policy which had parallels with Indonesia's current situation: when the policy was introduced, there were no factories producing consumables but over time, with strong government commitment to provide this service, the situation changed. Further, the government made a concerted effort to increase the capacity of hospitals and provide incentives to doctors to offer PD. Thailand's experience highlights the importance of having a clear plan to scale up services. Treatment of ESRD patients is, in general, expensive and in Indonesia, it is currently the second largest billing item for the public healthcare system. Another participant pointed out that at the moment the market for PD is small and so it is very costly but believed that once the demand increases, companies will be willing to negotiate and hospitals will adjust their strategies accordingly. He added that as an employer, he found that a PD first policy is preferable as employees can continue to work with PD but have to take time off for a couple days to get HD treatment.

Some clarifications were sought by participants with regards to the PAH study to which HITAP and PIC team members responded, citing international evidence as well as explaining the source of data. Questions were related to restriction of analysis to only two of four functional classes, use of treatment for pediatric patients and the source of prevalence data and its validity.

MoH representatives gave an overview of the HTA process in Indonesia and how these studies fit in. HITAP outlined the next steps for the group: one, to complete the reports on the studies and make them available to the public. This, it was stressed, was urgent as one would need to give external audiences time to comment on the reports. Two, aim to publish the studies in an international journal. Three, work on feasibility studies for the preferred policy options, as there were concerns about the preparedness of the system for the implementation of these policies. And finally, have the two studies signed off by the HTA Committee and relevant stakeholders. Most of the resource persons present were in agreement to move ahead, even as some added qualifications. The moderator discussed the process for signing off the studies.

Follow up actions

1. ESRD and PAH studies:
    - To revise and complete reports on the two studies and make them available to the public
    - To publish these studies in an international journal
    - To identify and conduct feasibility studies in order to address concerns on the capacity of the system and resources needed to implement the recommendations of the studies
    - To sign off the reports by the HTA Committee and experts

- Other:
    - For the ESRD study, PICs to collect data from the health bureau on cost and spending on HD machines that are imported as well the human resource requirements for providing HD. This additional information may be used to understand the true cost of an HD first policy

2. Discussions with partners
    - Sharing of results of studies: HITAP is to share policy briefs on three HTA studies with partners. USAID and PATH to discuss internally on how to highlight studies at a high level
    - PMAC and visit to HITAP: WHO to coordinate with iDSI about having a high level delegation from Indonesia attend PMAC and have meetings with iDSI, USAID and PATH during visit to HITAP. HITAP to draft one day program and WHO to send HITAP the list of participants
    - Guideline development: NICE and HITAP to support finalizing guidelines for assessment and appraisal, including consultations with relevant stakeholders
    - MoU: HITAP to share MoU between NICE and Thai MoH as well as MoU between Thai MoH and Philippine DoH to WHO. This will be shared with Indonesia's MoH to help draft MoU with iDSI.

3. Study on economic burden of influenza
    - Septiara Putri to conduct pilot study by end of December 2015 with support from Dr. Yot and Waranya
    - Inputs needed from WHO HQ:
        - Provide feedback from research team and counterparts on the usefulness and feasibility of using the economic burden manual in Indonesia
        - Prepare a presentation on country experiences gathered while piloting the first economic burden manual and tool.

Conclusion

The mission to Jakarta was concluded satisfactorily with draft reports on the methods and results sections written up and policy briefs and presentations being completed for each study. Additionally, capacity of PICs was enhanced through discussions on the data and various aspects of the analysis such as modeling uncertainty. Discussions with partners were also beneficial. Key issues were agreed upon such as the threshold for Indonesia as well as the next steps in using these studies to influence policy.

Annex 1: Agenda

A 5-day workshop on HTA studies (RRT and PAH) in Indonesia – Venue: MOH office, Adhyatma Building, 2nd floor, Room 222	
Time	**Session Activity**
26 October 2015	
9.00 – 12.00	Verifying and finalizing the model **By:** PICs and HITAP *Note: the discussion will be hold separately between the RRT and PAH group*
12.00 – 13.00	Lunch
13.00 – 17.00	Verifying and finalizing the model (cont.) **By:** PICs and HITAP *Note: the discussion will be hold separately between the RRT and PAH group*
27 October 2015	
9.00 – 12.00	Discussion on the analysis results **By:** PICs and HITAP *Note: the discussion will be hold separately between the RRT and PAH group*
12.00 – 13.00	Lunch
13.00 – 17.00	Validating the model and results **By:** PICs and HITAP *Note: the discussion will be hold separately between the RRT and PAH group*
28 October 2015	
9.00 – 12.00	Budget impact analysis **By:** PICs, HITAP, other participants
12.00 – 13.00	Lunch
13.00 – 17.00	Budget impact analysis (cont.) **By:** PICs, HITAP, other participants
29 October 2015	
9.00 – 12.00	Presenting the preliminary results of two HTA studies **By:** PICs and HITAP (lead by Dr. Yot Teerawattananon)
12.00 – 13.00	Lunch
13.00 – 17.00	Report writing and policy recommendation **By:** PICs and HITAP (lead by Dr. Yot Teerawattananon)
30 October 2015	
9.00 – 13.00	Presenting the preliminary results and policy recommendation Plan for next step and conclusion **By:** HITAP and participants
12.00 – 13.00	Working Lunch
13.00	HITAP team departs for Soekarno-Hatta airport

Annex 2: List of Participants

	Attendance					
Name	Organization	26-Oct-15	27-Oct-15	28-Oct-15	29-Oct-15	30-Oct-15
Alia Luz	HITAP	Yes	Yes	Yes	Yes	Yes
dr. Cicih Opitasari	MoH, PIC - PAH HTA team	Yes	Yes	Yes	Yes	Yes
Dr. drg. Mardiati Nadjib, M.Sc.	University of Indonesia - PPJK Officials/Consultant	Yes	Yes	Yes	Yes	Yes
dr. Eva Herlinawaty	MoH, PIC - ESRD HTA team	Yes	Yes	Yes	Yes	Yes
dr. Levina Chandra, MPH	MoH, PIC - ESRD HTA team	Yes	Yes	Yes	Yes	Yes
Nur Atika, SKM	HTA, PIC - PAH HTA team	Yes	Yes	Yes	Yes	Yes
Pitsaphun Werayingyong	HITAP	Yes	Yes	Yes	Yes	Yes
Saudamini Dabak	HITAP	Yes	Yes	Yes	Yes	Yes
Thanaporn Bussabawalai	HITAP	Yes	Yes	Yes	Yes	Yes
Ully Adhie Mulyani, Apt, Msi	MoH,NIHRD - Administrative support	Yes	Yes	Yes	Yes	Yes
Waranya Rattanavipapong	HITAP	Yes	Yes	Yes	Yes	Yes
Windi Haryani, SE	MoH - Administrative support	Yes	Yes	Yes	Yes	Yes
dr. Yusuf Subekti	MoH, PIC - PAH HTA team	Yes	Yes	Yes	Yes	No
Herlinawati, SKM., M.Sc.(PH)	MoH - PPJK Officials/Consultant	Yes	Yes	Yes	No	Yes
Nacita Putri Sunoto, S.IP	HTA - Administrative support	Yes	Yes	Yes	No	Yes
Mazda Novi Mukhlisa	MoH, PIC - ESRD HTA team	Yes	Yes	Yes	No	No
drg. Fara Rosalina	MoH, PIC - PAH HTA team	Yes	No	Yes	Yes	Yes
drg. Lusiana Siti Masytoh	MoH, PIC - ESRD HTA team	Yes	No	Yes	Yes	Yes

Dr.dr. Gema Asiani, M.Kes	MoH - PPJK Officials/Consultant	Yes	No	Yes	No	No
Anggita Bunga Anggraini, Apt	MoH, PIC - PAH HTA team	No	Yes	Yes	Yes	Yes
dr. Rosa Estetika	MoH - Administrative support	No	Yes	Yes	Yes	Yes
Febriansyah Budi Pratama, SKM	MoH - Administrative support	No	Yes	Yes	Yes	Yes
Saryo Pramono, B.Sc	MoH - Administrative support	No	Yes	Yes	Yes	Yes
Septiara Putri, SKM, MPH	CHEPS UI - PAH HTA team	No	Yes	Yes	Yes	Yes
Siti Habibah, SKM, Msi	MoH - Administrative support	No	Yes	Yes	Yes	Yes
dr. Ahmad Fuady, MSc-HEPL	University of Indonesia - ESRD HTA team	No	Yes	Yes	No	Yes
Kurnia Sari	University of Indonesia - PPJK Officials/Consultant	No	Yes	Yes	No	No
Prof. dr. Hasbullah Thabrany, Dr.PH.	University of Indonesia - PPJK Officials/Consultant	No	Yes	No	No	Yes
dr. Lusiana Siti Masytoh	MoH, PIC - ESRD HTA team	No	Yes	No	No	No
Dr. Yot Teerawattananon	HITAP	No	No	Yes	Yes	Yes
Erie Gusnellyanti, S.Si, Apt, MKM	- ESRD HTA team	No	No	Yes	No	Yes
Appolina	PATH	No	No	No	No	Yes
Astriadi Prasetio,SE	PPJK	No	No	No	No	Yes
Dewi Indriyani	WHO	No	No	No	No	Yes
dr. Afiatin, Sp.PD-KGH	DR. Hasan Sadikin Hospitals	No	No	No	No	Yes
dr. Christian S. Mamahit	PPJK	No	No	No	No	Yes
dr. Donald Pardede, MPPM	Head for Health Financing and Health Insurance (PPJK)	No	No	No	No	Yes

Dr. dr. Gema Asiani, Mkes	PPJK	No	No	No	No	Yes
Dr. dra. Agusdini Banun S, Apt, MARS	Sesditjen Binfar	No	No	No	No	Yes
Dr. dra. Erna Kristin, Apt, Msi	Gajah Mada University	No	No	No	No	Yes
dr. Lucia Kris Dinarti, Sp. PD-Sp. JP (K), FIHA	Sardjito Hospitals	No	No	No	No	Yes
Dr. Oktavia Lilyasari, Sp.JP(K), FIHA	Cardiovascular Hospital, Harapan Kita	No	No	No	No	Yes
dr. Rachmat Hamonangan, Sp. PD, FINASIM	Ci	No	No	No	No	Yes
drg. Armansyah, MPPM	PPJK	No	No	No	No	Yes
Edhie R	USAID	No	No	No	No	Yes
Fitria Mayasari	PPJK	No	No	No	No	Yes
Sita Andarini	Persahabatan Hospital	No	No	No	No	Yes

Source: PICs

Annex 3: Minutes of the Workshop

Date: Monday, 26 October, 2015. Day 1:

1. Opening session of workshop

The five day workshop was opened by the head of the Persons In Charge (PICs). She thanked all participants for attendance and expressed interest in continued collaboration between two organizations. She proceeded to introduce the agenda for the week. Logistics on the availability of the team were also discussed and later clarified.

The group separated into two groups, one on ESRD and the other on PAH, to discuss each individual study.

2. ESRD Study:

Participants in group:

Participants for the group working on ESRD were: PICs: Lisa, Luciana, Eva, Levina, HITAP: Pitsaphun Werayingyong, Waranya Rattanavipapong, Saudamini Dabak. Discussions were led by Pitsaphun and Waranya.

Cost Utility Analysis: Model parameters, data and analysis:

The team discussed the parameters, data used and assumptions made in estimating some of the variables. The PICs advised that they had received updated data, while Pitsaphun and Waranya had already modified the formulae and presentation in the existing file; thus these were combined.

The team decided to use Thailand's EQ 5D (utility) value set as Indonesia does not have this information available yet and the data for Malaysia was found to be unsuitable. Inpatient and outpatient costs were also made explicit. Pitsaphun and Waranya advised the team to separate costs into costs per visit per year and cost per patient for the probabilistic sensitivity analysis and add another variable on the average number of visits per years (104), which the PICs had obtained from a panel of experts. Another area of discussion was around estimating indirect costs: the HITAP team impressed upon the PICs that in cost utility analysis, the indirect costs for patients' results in double counting. A specific question was raised on how to treat income loss of retirees; in the case of family members, it was decided to exclude the loss of income for family members as they would receive their pension. Pitsaphun and Waranya also provided some general tips on analyzing data and housekeeping in Excel. The process and variables in the sheet on simulation were discussed in detail.

In order to determine the cost effectiveness of the intervention, Pitsaphun and Waranya asked the team about the threshold value that they would want to use to compare the Incremental Cost Effectiveness Ratio (ICER). The PICs said that this issue was still under discussion and that there was a preference to use the WHO guideline of a threshold equal to one to three times GDP per capita. It was agreed to use the value corresponding to three times GDP per capita, which is approximately IDR 128,000.

Budget Impact Analysis (BIA):
Before breaking for lunch, Pitsaphun and Waranya requested the PICs to provide additional data on prevalence and incidence of ESRD patients to calculate the number of dialysis patients and coverage of dialysis, preferably from Indonesia, which the PICs provided in the afternoon session. The coverage of dialysis was estimated using the National Survey 2013 using information on the number of ESRD cases and expected ESRD cases (an alternative coverage ratio had been estimated using data for HD only).
The team used the coverage ratio, as calculated above, and cost data derived from the Markov analysis, with the government perspective to compute the budget impact over five years. Pitsaphun and Waranya explained the process for this analysis and clarified questions relating to the same, including how it differed from cost effectiveness analysis and how to interpret the results of a BIA.

Interpretation of results of CUA:
The economic evaluation suggests that up to a willingness to pay (WTP) of IDR 195,000, supportive care is the most feasible policy option. Above that amount, a PD first policy was the most cost effective option. At no level was an HD first policy a viable option. This information was graphically represented using cost acceptability curves (AC). At the threshold identified (IDR 128,000), only supportive care would be a feasible option.
Through the course of the day, the PICs expressed their concern regarding the results of the study and its reception by policy makers. Members of the team pointed out on several occasions that the panel, to whom preliminary results had been presented, found the life years gained from the intervention (approximately 5 years, with discounting) too low. Further, the panel did not agree with the recommendation of pursuing a PD first policy as the country does not have adequate resources. Another member said that unlike the study comparing Beraprost and Sildenafil, PD and HD are not substitutes and that it was not easy to communicate the results of the same.

On the issue of the result not being acceptable to policy makers, Pitsaphun and Waranya emphasized that cost effectiveness analysis is only one of the factors that affects the final decision to adopt an intervention; other considerations such as ethical issues and impact on the budget are also important. Taking the example of Thailand, where both, PD first and HD first options were not cost effective, the government went ahead and included a PD first policy, which was relatively more cost effective, in the benefits package due to the catastrophic nature of the disease. Additional studies on the capacity of the system may also be conducted if needed.

Follow up actions for next day:
The PICs were to write up the section on methodology and results (in English, in addition to Bahasa) for discussion the next day. Pitsaphun described process to write up the study and asked to use the ESRD paper by Dr. Yot as a reference. She further requested the team to explain the parameters used, including information on primary data and results. Waranya said that after reviewing the draft, the team would do sensitivity analysis and model validation using Thai data.

3. PAH study (26 and 27 October, 2015):
Participants in group:
PICs: Atika, Yusuf, HITAP: Thanaporn Bussabawalai, Alia Luz

Summary:
To Thanaporn's question on what do clinicians do when patients receiving beraprost or sildenafil get worse, Atika replied that if patients receive beraprost and get worse, they have to switch from beraprost to sildenafil. Atika also said that beraprost is only effective for 3 months, according to clinicians. It is not possible for beraprost patients to get it for Functional Class (FC) 4. Patients who receive sildenafil and get worse will get sildenafil with higher dose as well as supportive therapy like diuretics. They start sildenafil with 20mg x 3 a day; if it gets worse, the dosage of sildenafil is increased to 40mg x 3 a day. However, this guideline is used only in hospitals where they collected data and sildenafil is available. In other hospitals, if patients receive beraprost and get worse, they will still use beraprost.

Thanaporn asked when patients become classified into functional classes. Attika replied that it is during pre-therapy and post-therapy generally. In Indonesia, patients in FC I go to inpatient not because of worsening condition, but because they need to undergo some procedure (diagnosis, or monitoring condition worsening or better). Waranya said that this should still be included, because direct medical cost includes all costs associated with this disease. Atika said that the issue is that there is one VIP patient whose data skews the cost. Waranya said that they should exclude this patient as an outlier. For FC I patients, there are 18, all of whom incurred the same costs, and excluding the one VIP patient. The number of patients in the other FCs is: FC II with 19 patients, FCIII with 10 patients and FCIV with 1 patient.

If cost is classified by FC and also by therapy, then the data will be based on very few patients/data, and there might be bias. Therefore, the PICs will use Thanaporn's suggestion that cost is classified only by FC. For FCIV, they are usually admitted to inpatient care right away, so there is no cost for OPD.

For the drug cost, they used the hospital bill because there is no drug reference price in Indonesia. The price of the drug was taken only from one hospital, but the expert said that it shouldn't differ too much from other hospitals. Thanaporn said they can use the original price and if it is not cost-effective, they can use GoalSeek to find the price that is cost-effective. The HITAP team was informed that patients may not be able to visit the doctor and get the drug on the same day, so they more often come to the hospital.

Some patient(s) have very high cost for direct non-medical cost. The study will exclude other hospitals, and focus on the main hospital, because one cannot separate OPD and IPD cost data from other hospitals. Some parameters still need to be updated and checked from the questionnaires, which will be done for the next day. The team removed patient productivity loss because this is a CUA (it will be double counting for patients given that QALY already includes productive life in a CUA). Prevalence and incidence data from Thailand will be used. They will assume 100% coverage for the treatment.

Date: Tuesday, 27 October, 2015. Day 2:

1. ESRD study:

Participants in group:

The group broke into two sub groups again to work on individual studies.
Participants in the ESRD group: PICs: Lisa, Eva, Levina, Luciana, Ully. HITAP: Alia, Saudamini (Pitsaphun, Waranya for clarifications or checking in)
Thanaporn, Waranya and Pitsaphun worked with PAH team to finalize model

Draft report on methodology used commented on and discussed:

The PICs shared a copy of the draft report on the methodology section for ESRD. Alia and Saudamini from HITAP provided written comments on a soft copy of the draft. The group then discussed the comments together. The team explained the terms used (such as hospital types) and agreed to expand on the same or describe the process (as in the case of a survey). Further, the team said they would include additional sections on uncertainty analysis and budget impact analysis.

Clarification on model simulation:

The PICs requested Waranya to explain the techniques used in the uncertainty analysis. Waranya explained what is done in a simulation as well as the variables in the analysis. The group then discussed the presentation of the results and how to interpret the results of the sensitivity analysis, including cost acceptability curves.

Interpretation of results:

Concerns about interpretation of the results by policy makers were also discussed during the day. Waranya asked the team if they had any concerns about any of the parameters.

Follow up actions for next day:

Waranya told the PICs that the team would discuss the CUA model and BIA with Dr. Yot the next day.

Date: Wednesday, 28 October 2015. Day 3:

1. ESRD & PAH Studies:

1.1 Participants:

Joint session of both groups. 6 HITAP, 9 PICs. Additional participants joined during the sessions. Sessions led by Dr Yot Teerawattananon.

1.2 ESRD study:

Reflecting on results of the studies:

Starting with results of the ESRD study, Dr. Yot observed that even though the Life Years (LYs) gained were discounted, it was lower compared to international data. He suggested that the team calculate and communicate the undiscounted value of LYs to policy makers. Dr. Yot suggested switching to a government perspective, noted that the difference in costs between PD first and HD first is smaller than using the societal perspective implying households bear a major portion of the costs in the case of HD. This may lead to more patients opting out of treatment, if they are unable to afford it.

The group then discussed the cost acceptability curves which showed that that the PD first curve cuts the curve for supportive care at approximately IDR 195,000, which is close to the IDR 193,000 ICER/QALY value in the analysis sheet of the file. Thus, if the for the government of Indonesia, a healthy LY is worth less than IDR 195,000, then a PD first policy is not good value for money. However, if the government places a higher value, then a PD first policy is good value for money. HD would not be good value for money, at least until a LY value of IDR 950,000. Dr. Yot added that this result does not mean that the government should not adopt the technology as other factors play a role as well.

Dr. Yot explained the cost effectiveness plane and how to interpret the relationship between this graph and the AC. Prompted by a question on whether only two options (PD first and HD first only) may be compared in the AC analysis, Dr. Yot said that in this type of graph, the points must add up to one as the y-axis refers to the total probability.
With regards to the Budget Impact Analysis (BIA), the discussion centered on the estimation of coverage using prevalence and incidence data. Dr. Yot double checked the data comparing LYs and noted a difference, which was primarily because of different sources of data. Eventually, the PICs decided to estimate the number of dialysis patients and coverage of dialysis from the renal replacement therapy registry of JKN because registration data was found to be more valid than national survey. The team, along with Pitsaphun, Waranya and Dr. Yot, decided to compute the BIA for two scenarios, one where the prevalence data equals approximately 50% of dialysis coverage as current situation and the other, where it equals 100% of dialysis coverage.

Interpretation of results:
For ESRD, the PICs mentioned that the panel of experts found the LYs gained to be low. In addition, the panel felt that in Indonesia, they do not have the resources to implement a PD first policy. On the low LYs gained, Dr. Yot recommended communicating undiscounted values for the same. Regarding the high costs of implementing a PD first policy, Dr. Yot gave the example of Thailand, where a similar situation prevailed when it started out with this policy: at the time, only four hospitals offered PD. The government requested these hospitals to set up training centers and encouraged other hospitals to increase their capacity over time. This was an important step as PD has more of a variable cost (trained nurses) which could be changed more easily whereas for HD, where the fixed cost of machines is higher as these are imported. Further, the government incentivized doctors to adopt PD by offering more subsidies. Care was taken to not disadvantage existing HD patients, but all new patients were directed to a PD first option. Finally, Dr. Yot asked if the panel had any concerns about the utilities, to which the PICs sought clarification on Malaysia's EQ 5D dataset in which they had encountered some issues. Dr. Yot suggested maybe connecting with another researcher in Indonesia who was using the Malaysian dataset.

1.3 PAH study:
Reflecting on results of the studies:
The team presented results of the sildenafil-beraprost study and discussed various elements of the study. On the choice of prices of drugs, Dr. Yot suggested to use the

generic price of sildenafil in the analysis instead of the original price. This, Dr. Yot explained, was acceptable and several countries include generics in their benefits package. The team explained that in Indonesia, the availability of a generic drug depends on the policy of hospitals. Another parameter that was discussed was on utility values across drugs and functional classes: the quality of life was higher for sildenafil but the sample size for beraprost was very small and so may skew the results. In lieu of a literature review to get the utility values, Dr. Yot suggested that the team combine the samples for the two treatments to estimate utility values. While discussing the survival curves for validating the model, the study shows a big dip for beraprost in the beginning but not as much later. For analysis on budget impact, the team used the rate of prevalence and incidence in Thailand and then calculated the coverage as a proportion of the population for each functional class.

1.4 Report writing:
Dr. Yot described the structure that the teams may follow while writing reports of the study and encouraged them to write in a way that would be comprehensible to non-economists. He requested the teams to work on the results section of the report in the afternoon. The key areas to be covered were health outcomes, costs, ICER and the cost effectiveness plane, uncertainty analysis and BIA.

1.5 Follow up actions for next day:
In terms of revising the analysis, the ESRD team was to work on the two scenarios identified for budget impact analysis. The PAH team, on the other hand, was to make updates to the model by one, changing utility values by combining samples for both sildenafil and beraprost and two, evaluating costs using price of generic drugs. The teams may then send a draft copy of the results section to the HITAP team members for comments.

2. Partners' Meeting (2:00 PM):
Invited: HITAP (Dr. Yot and Alia), PATH (Appolina Sidauruk), WHO (Dr. Dewi Idriani), Dr. Edhie Rahmat + Dr. Zohra Balsara (USAID). Apologies: NICE

- The partners' meeting aims to summarize the result of the study visit at NICE, UK, and talk about the concrete plan for the next steps.
- Dr. Dewi, Dr. Edhie, and Dr. Zohra who went to the UK with the Indonesian delegation concluded that the visit made a positive impact to HTA development in Indonesia. High-level decision makers are now aware of the importance of HTA for benefits package development. They also learned the difference between assessments and appraisals, as well as the importance of a transparent, participatory process. They seem to be very impressed by the National Institute for Health Research (NIHR) and now want to get academics involved in supporting HTA because they realized that the HTAC may not be able to carry out assessment work.
- All who attended the meeting agreed that we should keep this momentum by finding ways to support local partners and the following agreements and actions were made:

- We should support the development of the high-level policy mechanism and governance for HTA at the same time that we support the implementation of three HTA studies that are going to be completed by the end of this year. The former may not be very clear unless all stakeholders have a good level of understanding and experience in the use of HTA. It may also take time to arrange, for example, to see LITBANG taking over the assessment part. The latter (supporting the implementation of recommendations from 3 HTA studies) is to ensure the impact in policy and practice at the grassroots level.
- There may be a revision of the HTAC, so partners will wait and see the movement of the high-level policy mechanism development.
- HITAP will share policy briefs for the three HTA studies to all partners so that they are aware of the potential support for implementation of the recommendations. USAID will discuss with Ariel Mendez who will visit in early November in Indonesia on how to bring the discussion to the high-level stakeholders. Lina will talk to PATH team.
- WHO will coordinate with iDSI about the possible arrangement for high-level delegation from Indonesia to attend the PMAC and have a back-to-back meeting with iDSI, USAID, and PATH in Thailand as part of the visit to HITAP (potentially February 1, 2016). If this works, we may ask key persons from NICE (Sir David Haslam and Kalipso Chalkidou), USAID (Ariel Mendez), WHO (Phyllida Travis), and PATH (Ritu Kumar) to stay longer in Thailand after PMAC. HITAP will help draft the program for the one-day meeting at HITAP. WHO will coordinate who will be able to come and send a list to HITAP (name, affiliation and email).
- All partners agree that it will be necessary to support the development of guidelines or manuals for assessment and appraisal. The guideline for assessment is already drafted by the HTAC, so the next step is to support them in finalizing the guidelines including in the consultations with relevant stakeholders. The guideline for appraisal may need to have committed middle-level academics in Indonesia to help develop with support from NICE and HITAP.
- WHO will arrange a one-week workshop for 30-40 participants from various universities and academic groups throughout the country to raise awareness and identify potential partners for the HTAC. This workshop will need technical support from HITAP, NICE, and PATH.
- WHO also plans to support junior scholars from Indonesia to participate in the next HTAsiaLink conference in Singapore in May 2016.
- HITAP will share the MOU between NICE and the Thai MOH and the Thai MOH and the Philippine DOH to the WHO so that they

can share to MOH Indonesia and begin drafting their MOU between MOH and iDSI.

- WHO suggests that HITAP publishes an experience of developing HTA capacity in Indonesia.
- HITAP will ask HTAC to invite PATH, USAID, and the WHO to join this Friday, October 30, 2015, during the HTA results discussion meeting.

3. Economic Burden of Seasonal Influenza Updates (4:40 PM):

A meeting was held with all partners (Septiara Putri, HITAP, WHO Indonesia, MoH, and NIHRD) to discuss the collaboration on a study on the economic burden of seasonal influenza and how this pilot study can be implemented in Indonesia. Further, the attendees were to discuss about the data available for the analysis.

The meeting began with Dr. Yot's introduction of HITAP. Dr. Yot is part of the IVAC, and they came up with the idea of piloting this study in SEAR. HITAP does not have financial support for this but would like to provide technical assistance. Septiaria Putri, a health economics graduate from Glasgow, will conduct the study. She developed the proposal and received funding for $10,000 to conduct it. The pilot needs to be conducted in the next 1.5 months by December 2015. Septiara will conduct the test with support from Dr. Yot and Waranya.

They recognize that there may be challenges if stakeholders are not informed which is why this meeting has been convened. One of the attendees was from a unit called Disease Surveillance and Epidemiology of the WHO. The only issue is that WHO works on a 2-year cycle. As such, it is going through a closing phase of all their activities and projects. The activity must be done by end of this year 2015. In addition, the WHO works closely with the MOH so their involvement is vital. The local partners should have a meeting with the WHO partners to finalize the study. The meeting attendees also wanted to know a little more about the protocol of the study, whether centennial data can be used, as well as where the data was taken from as only three sites have good, reliable data on this in Indonesia. Another issue is to confirm that no similar activity is being conducted, and that they also collaborate with other universities so they are aware of the situation for this kind of study.

For this type of study, they only funded few countries (6 or so) and they hope Indonesia's case will be one of them. Early next week, there will be a meeting with stakeholders. The results will not be used to push policy. They aim only to inform guideline development and to conduct a field testing of the guideline, as well as build the capacity of staff like Septiara. However, perhaps this study can inform future studies as well. HITAP is helping WHO to do the testing for the guideline development - if next year they can finalize the guideline, then the government can take the lead with support from Septiara.

The group also discussed the inputs required by WHO HQ. These include 1) Provide feedback from research team and counterparts on the usefulness and feasibility of the use of the manual in Indonesia by 3 November 2) Prepare the presentation on country experiences gathered in a first piloting of the economic burden manual and tool by 15 November.

Date: Thursday, 29 October 2015. Day 4:

1. Participants:

Participants from both groups in one room. Sessions led by Dr Yot Teerawattananon

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2. Setting a threshold for Indonesia:

The group agreed to start the day's proceedings with a discussion on setting a threshold. Dr. Yot made a presentation on what a threshold is and how it compares with a tubular approach to priority setting, where interventions are ranked by cost effectiveness and chosen until the budget is exhausted. If one goes for the latter, one must evaluate all interventions which is often not feasible. Hence, most countries opt for a threshold to help determine which interventions should be supported.

He went on to give examples of countries where this was done: in Australia, for example, a committee was set up to review evaluations and while there was no formal threshold, an implicit threshold of about AUD 30,000. The UK, on the other hand, was the first country to announce a threshold as a band of GBP 20-30,000. Political pressure also plays a role as there are strong advocates for some causes such as cancer. in order to maintain neutrality, though, more data is collected to inform decision making. In response to industry's criticism of the threshold, UK's HTA institution, NICE, signed an agreement with companies to not decrease the threshold and in exchange pharmaceutical companies would cap their profits. Thus, the setting of a threshold served a dual purpose of determining cost effective interventions and allowing room for negotiation. In the case of Thailand, the threshold was arbitrary and is 1.2 times GDP per capita or THB 160,000. An alternative way of setting a threshold is to not fix one and to look at health benefits gained from interventions and chose as long as budget is available. However, ethical considerations play in role as well as a wealthy persons LYs gained is greater than those of a poor persons.

In setting of a threshold for Indonesia, one of the PICs said that while the UK and Thailand have tax based systems, Indonesia's is a premium based system. However, Dr. Yot said, that given that they are all based on public systems, they are comparable. He added that the WHO guideline of 1 to 3 times GDP is too broad and so the team present in the room must provide a definitive. While the PICs were not sure making such a decision was within their purview, Dr. Yot persuaded the team to decide for the purpose of the study on IDR 40,000,000 which is approximately 1 times GDP per capita, comparable to countries like the Philippines, Myanmar and Vietnam. Dr. Yot called this as a landmark decision.

3. Draft report and policy brief writing:

Following the discussion on setting a threshold, the group broke to work on each study. Tasks were divided so that for each study, one group worked on the methods section and the other on results along with HITAP staff. In the afternoon, the teams regrouped to work on policy briefs using the structure outlined by Dr. Yot.

4. Follow up actions for next day:

The team discussed the agenda and logistics for the next day.

Date: Friday, 30 October 2015. Day 5:

1. Participants:

PICs, resource persons (doctors and other experts), HITAP staff. Discussions took place in English and Bahasa.

2. Opening of session and presentation of results by PICs:

The session was opened by Dr. Donald Pardede. Eva introduced speakers for the two studies, Luciana for ESRD and Attika for PAH and then invited Dr. Mardiati to moderate the discussion.

3. Discussion:

One of the issues that came up was the representativeness of the data. Some of the participants were concerned about the small number of PAH patients used in the budget impact analysis (around 500 patients). Waranya provided clarification on the prevalence and incidence data used, which was taken from Thailand as currently, there is no data available on prevalence and incidence in Indonesia. Dr. Yot added that PAH is a rare disease so numbers are expected to be low. On ESRD, one participant asked whether the teams have considered data from other regions such as Papua, as the numbers could be very different given the high cost of transporting the consumables.

Another question raised with respect to the PAH study was about why the teams chose to focus only on PAH patients in functional classes II and III instead of all four. Thanaporn responded saying that international guidelines recommend using sildenafil treatment starting with functional classes II and III. Further, Dr. Yot said that there was insufficient evidence about the impact of treatment of drugs for functional class IV patients, in which case it would be better not to offer the treatment at that stage. He added that patients usually visit the doctor when they are in functional classes II and III. Responding to a question on whether this treatment can be used for pediatric patients, Dr. Yot said that in Thailand, there is evidence that children with PAH benefit from it. This aspect has been already included in the analysis.

Dr. Yot urged the gathering to address the issue of the benefits package covering drugs that are not registered ("off label" drugs). In the current study, sildenafil has not been registered to treat PAH but has been recommended by doctors for treatment. This point provoked substantial debate and one person referred to it as a "challenging recommendation". The MoH, one resource person said, would not take responsibility for off label drugs and added that it was the responsibility of manufacturers to register the drug for this use. Another participant asked if the drug could be registered for this function only. Dr. Hasbullah said that if the decision is whether to cover or not cover then they must go ahead and cover sildenafil. Other participants said there is no need for special policy for the off-label medicines because legally, if the medicine is not available in the formulary, it is possible for the hospital to procure the drug as long as the medical committee of the hospital agrees. If the hospital needs it, then they can go through with this process as long as they have signature from the director of the board. For national policy in off-label medicines, there is an agenda that the medicines can be accessed by a

special decree from the MOH so that off-label medicines can be used in Indonesia. MoH can give the "special access scheme," e.g. as was done for some malaria medication, wherein the medicine needed was not available in Indonesia and they used an alternative which was not registered for that indication. But this was not considered a long-term regulation. Dr. Yot reminded the participants that it is the responsibility of the Ministry of Health to protect the health of the population and that pharmaceutical companies have their own objectives to pursue.

While determining the costs of intervention of the PAH study, one of the questions that arose were related to using a generic version of sildenafil. Dr. Yot asked those present if it was acceptable to include only generic versions of drugs. He recommended this option unless the originator was willing to reduce its prices.

In the case of the ESRD study, the recommendation of a "PD first" policy engaged the group in an intense discussion. One of the participants said that she did not agree with the recommendation and said that the chief problem with offering PD is availability of the consumable for PD, of which there is a shortage in Indonesia. Further, the cost of the consumable itself is very high as is the cost of transport which deters hospitals from choosing this option. The other aspect of implementing a PD first policy, she explained, is that the system does not have the resources to implement such a policy such as nurses. The patient then actually won't have a choice of treatment. Moreover, the reimbursement rate of PD from government is lower than hospital cost to provide the PD solution to patients. She therefore thinks that the government should support development of PD but not as a preferable option. Members of the ESRD team responded to this by suggesting to add a recommendation that deals with distribution.

With reference to this discussion on ESRD, Dr. Yot gave the example of Thailand which had a similar situation in 2007. He pointed out that ESRD was not included in the UHC but only in the benefit package for civil servants, most of whom were in cities with access to HD. Once it was included in the UHC, the government pursued policies to encourage hospitals to offer PD and the number has grown from four hospitals in 2007 to about hundred. At the time, there weren't factories to produce consumables but over time, with strong government commitment to provide this service, the situation has changed. There was also a concerted effort to increase the capacity of hospitals. Additionally, doctors can be reimbursed for a higher amount if they provide PD. Thus, he concluded, one needs to have a clear plan to scale up the services as treatment for ESRD patients will cost the government a lot of money. Dr. Hasbullah joined in and said that the recommendation reflects a change in priority for a PD first policy. At the moment the market for PD is small and so it is very costly but thinks that once the volume increases, industry will be willing to negotiate and hospitals will adjust their strategies accordingly. He added that as an employer, he finds that a PD first policy is preferable as employees can continue to work with PD but have to go away to for a couple days for HD.

Dr. Donald said it is still at the assessment stage with these two topics; they still need appraisal. These discussions should be done again and again. Presidential decree says that HTA should provide assessment and appraisal so the implementation of the JKN can be

sustained in the long-run, thus ensuring sustainability. The results of this study can have a chain reaction to other policies, such as the sildenafil study results proving more beneficial for the health of the Indonesian population and thus be included in the formulary even as an off-label drug. However, a process to support this decision is still necessary. The question is now how the recommendations can be executed. There should be a roadmap for capacity building for the health staff, center for the training, and the supply of the medicines or dialysis modes. We are now in the process of the developing HTA, making the priority lists. The hospital-based HTA guidelines are also being done. There will also be PMAC in January for them (HTAC and PICs) to participate in. After this meeting, they will have a stakeholder consultation in Indonesia for both studies, and they also will invite HITAP. There must be improvement with conducting HTA so there is more confidence in the results. HTA staff should get more and more education to support HTA. There are offerings in research institutions to improve this.

Dr. Dewi said that the study of the CAPD is related to the study of the PEN project. In the PEN study, it was recommended that the government screen above 40 and use FBG. If the government wants to go for this option, then the government will need to include start-up costs according to the plan, with support from development partners.

4. Agreeing on next steps:

Dr. Yot outlined the next steps for the group: one, to make a report on the studies available. He said HITAP will work with PICs to revise the report as needed. This, he said, is urgent so that external audiences have time to provide comments on it. Speaking to the issue of setting a threshold, currently set at 1 times GDP per capita, he said that a professor from the University of York is willing to work with Indonesia to set a threshold in 2016. Two, aim to publish the studies in an international journal. Three, work on feasibility studies for the preferred policy options, as there were concerns about the preparedness of the system for the implementation of these policies. And finally, have the two studies signed off by the HTA Committee and relevant stakeholders. Most of the resource persons present were in agreement to move ahead, even as some added qualifications. The moderator discussed the process for signing off the studies. The participants concluded that the discussion was helpful and useful. They thanked the PICs and supporting partners.