Pharmacoeconomic Guidelines in Indonesia, Malaysia and Thailand

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Pharmacoeconomics in Indonesia: HTA, Universal Coverage and PE Guidelines

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This report will touch on three dynamic aspects of pharmacoeconomic development in Indonesia, including health technology assessment protocols, health care reform and universal coverage and pharmacoeconomic guidelines.

Actually, there has been HTA in Indonesia since 2003. It has been under the Ministry of Health, but there was no economic evaluation nor required pharmacoeconomic analysis undertaken to support the decision-making for a long time. Thus in 2012 an ad hoc technical team on HTA was assigned by the MOH and there were three working groups included in this ad hoc technical team, which covered procedure, drugs, and medical devices. These groups conducted more than 30 assessments, with the majority on the procedures that need to be included as part of the program within the Ministry of Health.

With regard to health reform, in 2014 a new financing scheme has been introduced. Indonesia is moving toward universal health coverage under a single payer system, with the goal of creating a systematic and institutionalized HTA process, particularly related to the decision of inclusions to the benefits package. The current policy under the national health insurance, or otherwise referred to as Jaminan Kesehatan Nasional or JKN was established with the single payer scheme starting in January of 2014. This single payer system is not tax-based financed but rather mandated. The government covers the poor and the employer and the employee also contribute and all the funding is centrally managed. In 2013 the Government mandated in Article 26 of the legislation for explicit inclusion of new medical technologies and that the benefit package should be based on HTA, with emphasis on the safety, efficacy and equality of interventions, as well cost-effective and efficient resource allocation. It was further stipulated in Article 43 that HTA falls under the jurisdiction of the Ministry of Health.

Pharmacoeconomic guidelines were finalized in 2011 to serve key health care stakeholders like health professionals at MOH, health care facilities, industry, and academicians. Their initial aim was to raise the awareness of the importance of pharmacoeconomics in determining benefits within the social health insurance scheme. Guidelines provided background on pharmacoeconomics, definitions, costing methods including cost minimization, cost effectiveness, cost benefit, and cost utility, and other considerations, and the procedures of the economic evaluation. Looking ahead to the next iteration of the guidelines, it will be important to provide more guidance on HTA as well as step by step guidance on conducting pharmacoeconomic analyses. Ultimately, guidelines will need to be continually refined to be systematic, credible, and practical, for use by decision makers. Finally, it will be very important to include budget impact analysis. We may follow the example of other countries that have developed their own thresholds, like Thailand in following developed institutions like the UK's NICE.

To View Indonesia's PE Guidelines please view here.

Pharmacoeconomic Guidelines in Malaysia

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Malaysia has been undergoing continual process of developing and refining pharmacoeconomic guidelines to decide on the processes that are going to be involved when drugs are submitted by agencies and companies who are interested to include this in the financing mechanisms of the country. In Malaysia a lot of resources still come from the tax-based system. Most of the health systems in the world grapple with the four key issues: – trying to achieve accessibility, quality, efficiency, and equity. And when we talk about drug submission, probably the most important aspect is ensuring that we have enough resources to provide the services to all people in the country.

Another important area of focus is ensuring that the services are equitably distributed and people who are in the lower income category have access to the services. Malaysia spends around 4 to 4.5% of GDP which is much smaller proportionally than many other countries, so a large focus on pharmaceutical production is required after setting up the necessary infrastructure. Pharmaceuticals are very expensive, and may cost as much as $1 billion to produce one drug. A great portion of the cost is spent on the stages of preclinical as well as the clinical trials. And nearly 30% of the resources are being spent on the Phase I, II, and III of the drug development. As policymakers in this country we are concerned about how the companies are going to recoup this investment, but at the same time we have to balance this with the available resources. In hospitals, drugs and consumables expenditure make up about 14% of medical cases and as much as 10% of the surgical cases.

Malaysia has introduced, and officially published the drug formulary and guideline for pharmacoeconomics within the past 2 years. These pharmacoeconomic guidelines may be accessed here. The areas covered in the guidelines include – the types of economic evaluation that need to be carried out by companies which are involved in trying to register the drugs, the costing approaches that are acceptable, the outcome issues, discounting, sensitivity analysis, time horizon, the acceptable CE ratio, and also the budget impact analysis. This will help to actually formulate an effective document for submission. The future benefit for standardizing the process of utilizing economic evaluation to support decision making, will be to enhance quality of pharmacoeconomic data for drug submission. It will also help to promote local data and economic evaluation which again will help the decision makers and improve overall evidence-based policy decisions.

Of course, there are a number of challenges that Malaysia and many other developing countries in the region are facing. For example, one area is lack of technical capacity to conduct and evaluate pharmacoeconomic studies, especially from the committees who are involved in the decision making. Lack of funding for good quality research, as well as local data will have an impact. Limited sharing of information between various players in the country including hospitals, lack of transparency in decision making and the limited role HTA agencies are all challenges.

In developing countries like Malaysia, the limited body of research which is critically needed to support guidelines implementation will be a target area for improvement in the future. Economic evaluation studies are becoming more and more important, and I think in the future capacity will be cultivated to meet the demand.

To view this presentation, please click here.

Pharmacoeconomics and HTA in Thailand

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Pharmacoeconomics and HTA have a longer history in Thailand, but that is not to say it was an easy journey. The HTA guideline came out in 2007, two years after the establishment of the ISPOR Thailand Chapter in 2005. The guideline was developed under HITAP through consultations with experts. With the initiation of HTA guidelines back in 2006, the originally idea was for it to be also more like a textbook as well, to educate, to be used in a university or college, which wasn't an ideal format. But throughout the development process, it was a learning experience through much expert feedback. The first version was widely considered to be too technical in its language for useful application. This was remedied in 2008 with revisions. There were also two versions: English as well as Thai, which was published in 2009. It was then listed on the Journal of the Medical Association of Thailand with the strategy to have it approved by the National List of Essential Medicine Committee which is something that everybody should comply with.

There were two major challenges that we faced in putting out the guidelines. The first edition was referred to as an HTA guideline but actually it wasn't because it just focused on only economic evaluation. As you are aware, economic evaluation and HTA are not exactly the same thing because you've got to include some other things. For example, budget impact, social impact, ethical impact and so on. The other

problem was that we formatted it to more like a textbook, which made it hard for lay people to understand and use. So five or six years later in 2012, the second edition was developed. HITAP worked to develop systematic analyses to refine the process, and consulted with experts and stakeholders. After feedback and dissemination, the new version included all of the other issues including budget impact analysis, social and ethical implications, as well as deeper economic evaluations for infectious diseases and their modeling methods. The new Thai version was also published and made available for the public. For other countries that are currently working on developing guidelines, there are some lessons to be learned from the Thai experience. There are some important questions to ask. For example, who should lead the guideline development? That's very important. And what kind of funding will be available for developing the guideline? Who will be the users? Who should be included, like the authors of the guideline? How do you encourage others to use and comply with the guideline? It's important to remember that is a learning process, and that the final outcome will be the product of much trial and error and fact finding. Again, while there is long history of HTA and pharmaceoconomics in Thailand, it has not been without its challenges. However, through continual collaboration and diligence, the field has grown into a mature foundation for health care decision making in Thailand.

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