## Stakeholder Meeting:

## Introduction to Total Systems Effectiveness (TSE) Pilot Project in Thailand

**Date:** Thursday 17th May 2018, 9am – 12pm

**Location:** Health Intervention and Technology Assessment Program (HITAP), Ministry of Public Health, Nonthaburi, Thailand

**Objectives:** To introduce stakeholders involved in vaccine decision-making in Thailand to TSE and receive initial feedback on the project.

**Attendees:**

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| Dr. Yot Teerawattananon (Chairperson) | HITAP, Ministry of Public Health |
| Raymond Hutubessy | World Health Organisation |
| Siobhan Botwright | World Health Organisation |
| Jos Luttjeboer | Asc Academics |
| Dr. Ijeoma Edoka | PRICELESS, South Africa |
| Dr. Ritika Kapoor | National University of Singapore |
| Prof. Dr. Kriang Tungsanga | Chair of the Subcommittee of National List of Essential Medicines |
| Dr. Netnapis Suchonwanich | Subcommittee of National List of Essential Medicines |
| Somruethai Supannakul | Subcommittee on the Benefits Package |
| Narisa Mantharngkul | Representative from the Topic Selection for the Health Economic Working Group |
| Prof. Dr. Punnee Pitisuttithum | Faculty of Tropical Medicine, Mahidol University |
| Dr. Suchada Jiamsiri | Department of Disease Control, Ministry of Public Health |
| Worrawan Klinsupa | Department of Disease Control, Ministry of Public Health |
| Sirirat Techathawat | National Vaccine Institute (Public organization) |
| Anyarat Thamjaroen | National Vaccine Institute(Public organization) |
| Wannisa Theantawee | Food and Drug Administration, Ministry of Public Health |
| Varawoot Koolsing | Bureau of the Budget, Prime Minister's Office |
| Anongnuch Nettayakul | Pharmaceutical Research and Manufacturers Association |
| Dr. Thavirap Tantiwongse | Pharmaceutical Research and Manufacturers Association |
| Dr. Nantasit Luangasanatip | Mahidol Oxford Tropical Medicine Research Unit, Mahidol University |
| Ery Setiawan | University of Indonesia (Intern at HITAP) |
| Waranya Rattanavipapong | HITAP, Ministry of Public Health |
| Rachel Archer | HITAP, Ministry of Public Health |
| Manushi Sharma | HITAP, Ministry of Public Health |
| Saudamini Dabak | HITAP, Ministry of Public Health |
| On-iriya Fugthaworn | HITAP, Ministry of Public Health |
| Rajibul Islam | HITAP (ODI Fellow), Ministry of Public Health |

**Welcome** **Dr. Yot Teerawattananonn, HITAP**

- Dr**.** Yot Teerawattananon welcomed and thanked stakeholders for convening.
- Round table introductions
- A brief overview of the objectives of this meeting was provided:
    - To better understand vaccine decision-making processes in Thailand
    - To introduce the Total Systems Effectiveness concept
    - To discuss whether TSE can fit into vaccine decision-making processes in Thailand
- Dr**.** Yot explained that the World Health Organisation (WHO) and HITAP are leading the TSE pilot in Thailand.
    - In addition to Thailand, the TSE pilot is taking place in Indonesia, Mali and Zambia.
    - The pilot will use the rotavirus as a case study.

**Drug and medicinal product selection process and criteria in National List of Essential Medicines (NLEM)**

**By Prof. Dr. Kriang Tungsanga, Chair of NLEM subcommittee**

Prof. Dr. Kriang Tungsanga presented a brief background of the three health insurance schemes in Thailand: the Civil Servant Medical Benefits Scheme, the Social Security Scheme and the Universal Health Coverage Scheme. The NLEM covers a list of essential pharmaceutical interventions for solving the health problems for all the Thai population under three schemes. The NLEM subcommittee is responsible for selecting the interventions to be included in the NLEM.

Prof. Dr. Kriang Tungsanga shared the current process and mechanisms of the prioritization and selection process. The whole process involves several national expert panels and working groups. A multiple-criteria decision analysis (MCDA) has been applied in the process. The predefined criteria includes: cost, safety, compliance and efficacy through ISafE score (Information, Safety, administration restriction, Frequency of drug administration, and Effectiveness). For high cost medicines including new vaccines, local cost-effectiveness analysis is considered. If the medicines are not cost-effective, the products will not be enlisted in the NLEM unless price negotiation is arranged, item by item, to adjust the price to the cost-effective level. Other factors such as budget impact, equity and feasibility are discussed at the final stage of the decision-making process by the NLEM subcommittee as well as the joint committee of the main three public funding agencies. High cost medicines will be enlisted in the NLEM after going through these steps.

For vaccines, the process is synchronised with Advisory Committee on Immunization Practices (ACIP), a subcommittee under the National Vaccine Committee (NVC) and Department of Disease Control (DDC) who are responsible for the Expanded Program on Immunization (EPI). The ACIP by DDC will submit the evidence on disease prevalence, diseases burden, safety and efficacy of vaccine to the NLEM subcommittee. Evidence on cost-effectiveness, budget impact, and equity is required for the NLEM subcommittee to consider in the decision-making process. The Health Economic Working Group (HEWG), which functions under the NLEM subcommittee, generates local evidence on economic evaluation and budget impact analysis to support decision-making, and assures the quality of studies.

The details of presentation are attached in attachment 1.

After the presentation, clarifying questions were asked on the procurement of vaccines and ISafE score. The discussion points are summarised below:

- The procurement and distribution of vaccines starts from the central storage level to the district storage level and then to the level of vaccine administration facility. Commencing from the fiscal budget of 2018 (October 2017), the National Health Security Office (NHSO) who is responsible for vaccine budgeting, must submit the vaccine requirement for the next-coming fiscal year to Director of Rajavithi Hospital, a tertiary care referral centre under the Department of Medical Science, Ministry of Public Health. The Procurement Committee, who work for NHSO board, are responsible for vaccine specification, price negotiation and ensuring demand forecasting aligns with the NHSO budget. The Rajavithi hospital takes action to procure vaccines according to the resolution of the Procurement Committee. Rajavithi Hospital is responsible for purchasing vaccines and the NHSO is for budgeting and vaccine distribution. Finally, GPO is outsourced to manage vaccine stock and vaccine distribution system.
- Vaccines for foreigners are procured at the hospital level. For 2019, the process will be integrated into the same procurement system to increase the power of price negotiation and reduce the problems regarding different types and the amount of vaccines in the health system.
- ISafE score is a composite index and an item with a higher score has a better critical value. The scoring is both useful and practical, but is limited in that it cannot be applied to drugs without any parameters. As a result, some flexibility is given for expert opinion to fine-tune.
- For a new vaccine to be enlisted in the NLEM, the ACIP shall submit an application to the NLEM. The Expert Panel Working Group on Infectious Disease under the NLEM Subcommittee shall rapidly screen, approve, and pass the application to the NLEM for further evaluation. With a shortened processing time, the Expert Panel Working Group shall assume that scientific documents submitted by the ACIP have already been thoroughly evaluated. Most of the new vaccines are high cost and have a high budget impact and must go through the steps mentioned above.

**Vaccine prioritization in Advisory Committee on Immunization Practices (ACIP)**

**By Dr. Suchada Jiamsiri, Secretariat of ACIP**

Dr. Suchada Jiamsiri provided an overview of the vaccine prioritization and selection processes within the ACIP. The ACIP are responsible for proposing the list prioritized vaccine to the National Vaccine Committee for introduction into the EPI. Vaccines are reviewed by the Working Group on Vaccine Prioritization together with a group of experts in health policy using the following factors that include but are not limited to: importance of health problems, vaccine characteristics (safety, efficacy, and effectiveness), economic impact, vaccine availability, and equity/ethical issues and social implications. Six measurable criteria including: 1) burden of disease, 2) disease severity, 3) efficacy/effectiveness, 4) safety, 5) budget, and 6) vaccine production in country, will be given a score between one and five. Target population and age group for vaccination as well as non-measurable criteria such as equity/ethical concerns and economic evaluation, are also considered by the working group. The trade-offs between multiple criteria are made in a way that is supported by the evidence and sometimes expert opinion is drawn upon to critique when data is limited.

Further details of the presentation are attached in attachment 2.

Following on from the presentation, questions were asked on data availability and economic considerations. Discussion points are summarized below:

- The ACIP must consider relevant factors in the local context, thus Thai evidence is preferred to inform vaccine prioritisation. In the case where there is a lack of local data, global evidence is considered depending on the nature of the vaccine.
- Both presentations demonstrated that the ACIP and NLEM subcommittees are already applying MCDA to decision-making. Though, there are different perspectives and definitions of a common criteria used such as economic evaluation and cost. The ACIP focus on the availability of economic evaluation from literatures searches. Whereas the NLEM subcommittee with support from HEWG, examine the economic evaluation and budget impact analysis that are conducted in the Thai context.

**Introduction to Total Systems Effectiveness (TSE) Pilot Project in Thailand**

**By Raymond Hutubessy, World Health Organisation (WHO)**

Raymond Hutubessy started by outlining the mission of the WHO and more specifically the mission of the WHO department on Immunisation, Vaccines and Biologicals (IVB). The IVB aim to support all countries in delivering quality immunisation services, and their activities span the full vaccine development process from facilitating early stage research and development to supporting vaccine procurement and uptake. Whereas in Thailand the process of decision-making is systematic, explicit and transparent, in their experience the WHO have found that in many low and middle income countries (LMICS), decision-making occurs on an ad-hoc basis. Furthermore, priority setting is traditionally based on cost effectiveness analysis or severity of disease and other influential factors such as equity issues are not incorporated into the decision-making.

TSE is a multi-criteria decision-making framework for the vaccine product selection process. TSE currently takes the form of an excel model and quantifies inputs to inform decision-making at the country level and for research and development (R&D). At the country level, TSE aims to make explicit the trade-offs between different criteria e.g. economic considerations, safety and coverage, determine the most important criteria for decision-making and compare vaccine products against these criteria. At the R&D level, TSE aims to better communicate to innovators the needs and preferences of LMICS and assess the value proposition. It is the overarching mission of TSE to improve cohesion between country uptake and product development.

Raymond explained that the pilot is based on the country-use perspective and is using the rotavirus vaccine as a case study. Whilst in the future, there may be potential for TSE to be used to compare multiple vaccines, this pilot focuses on the one-vaccine case. The pilot is taking place in four countries: Thailand, Mali, Indonesia and Zambia. Given each country is different in terms of their health systems and capacity, TSE has to be flexible to account for country differences. The pilot aims to see whether TSE is useful for and applicable to, product selection decision-making in Thailand.

Further details of the presentation are attached in attachment 3.

Raymond then welcomed questions and a discussion centred on the applicability of TSE to product selection decisions in Thailand and general feedback on the TSE concept followed. The main discussion points are summarised below:

- There are existing and robust HTA and MCDA processes in Thailand. TSE is therefore more suited for countries that have yet to well-establish these processes and that lack infrastructure and the human resource to manage vaccine delivery.
- It was maintained that TSE is more useful for the R&D case in Thailand. TSE has the potential to inform the R&D process, including the demand forecast, nationally and internationally. Many comments were made on this matter including:
    - There is potential for TSE to encourage public-private collaboration which can help reduce the price of new vaccines and ensure a smooth supply.
    - Whilst there is an opportunity for TSE to inform the R&D process, it should not be tied into the commitment from the government.
    - TSE can aid private pharmaceutical companies launching drugs into the market sooner. Yet, there is a safety concern associated with advanced market assessment.
    - For TSE to be accepted within pharmaceutical companies, a pilot study with robust evidence is required.
- The TSE framework will require both epidemiological data and cost data. However in Thailand there is a limitation with data, especially with epidemiological data, which leads to an inaccurate estimation of budget impact analysis for vaccines. Thus, when an intervention is covered in the benefit package, it often incurs higher budget impact than is estimated. On the other hand, an advantage of the pilot project is it can provide surveillance data for the vaccine safety concern.
- Another comment is related to TSE being run by a single public authority, meaning there might potentially be a loop hole of conflict of interest. In Thailand, the organization which is responsible for introducing the national vaccine program (ACIP) is different and independent from the NLEM Subcommittee. This is a check-balance mechanism to confirm that introducing new, high-cost vaccine to the National Program is cost-effective, sustainable and affordable for the country.
- Vaccine security and the supply chain are crucial issues in Thailand. It is for this reason why in Thailand, pilot programmes of vaccine are introduced before the national program implementation. TSE should consider that decision-makers need to be certain there is a secure supply of new vaccines before a national programme is launched.
- A concern raised by several stakeholders was how TSE can be harmonized in different contexts given that all four countries it is being piloted in, have different healthcare systems.
- Investment in biologicals is expensive and requires strong support and commitment from government. Adopting new vaccines requires a lot of financial and human resource and is not the only priority within biologicals.
- The field of vaccines is advancing and evolving rapidly and there is potential for the TSE framework to fast track the decision-making process. However the concern is that the criteria that TSE is built on now may not be applicable for the future.

**Questionnaire distribution and findings**

**By Dr. Yot Teerawattananon, Saudamini Dabak and Rajibul Islam, HITAP**

Dr. Yot asked stakeholders to complete a short survey on the criteria for the vaccine product selection. Stakeholders were asked to identify a list of criteria for priority setting and weigh their relative importance by

ranking. All respondents could choose to make their decision based on current use (how they would prioritise in the current process in Thailand) or future use (how they might prioritise in the future).

Saudamini Dabak presented the preliminary findings from the survey, they are as follows:

- The participants represented a variety of organisations in Thailand, such as the National Vaccine Institute, Subcommittee of NLEM, Mahidol University and Pharmaceutical Research and Manufacturers Association.
- From the total of 15 respondents, 14 respondents ranked the parameters for current use and one answered the questionnaire ranking the parameters for future use.
- For each parameter, the frequencies were summarised based on the ranking from the questionnaire. Most respondents gave their highest scoring to health impact and vaccine safety, indicating these criteria as priority areas. Other parameters given priority include: financial impact, efficacy, delivery cost and commodity cost.
- Additional parameters that were suggested include: access to vaccine, efficacy, cost and budget impact, logistic availability and cost, equity, effectiveness, cost/ cost effectiveness, feasibility, vaccine security, burden of disease, global and national policy, price and provider, commodity profile and acceptability.

Further details of the presentation are attached in attachment 4.

**Closing remarks** **Dr. Yot Teerawattananon, HITAP**

- Dr. Yot thanked stakeholders for participating in the discussion
- The next step is for the research team (HITAP and WHO) to conduct the TSE model using the criteria obtained from the survey today. Results from the Thailand pilot will be shared in a dissemination meeting at the end of July/start of August.