# Stakeholder Dissemination Meeting:

# Total Systems Effectiveness (TSE) Pilot Project in Thailand

**Date**: Thursday 2nd August 2018, 9am – 12pm

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

**Objectives**:

- To disseminate findings from the TSE rotavirus test case in Thailand
- To identify whether TSE could provide any benefit to the existing product selection process in Thailand and/or whether TSE could be strengthened by incorporating best practice from NLEM/ACIP processes
- To develop a set of recommendation for future development of TSE

**Attendees**:

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| Dr. Yot Teerawattananon (Chairperson) | HITAP, Ministry of Public Health, Thailand |
| Siobhan Botwright | World Health Organisation |
| Dr. Birgitte Giersing | World Health Organisation |
| Jos Luttjeboer | Asc Academics |
| Ery Setiawan | University of Indonesia, Indonesia |
| Dr Auliya Suwantika | University of Padjadjaran, Indonesia |
| Chonnatee Rodsawang | Institute of Research, Knowledge Management and Standards for Disease Control, Department of Disease Control, Ministry of Public Health, Thailand |
| Dr. Ponthip Wirachwong | Government Pharmaceutical Organization, Thailand |
| Evelyn Thsehla | Council for Medical Schemes, Pretoria, South Africa (HITAP interns) |
| Jacqueline O'friel | London School of Hygiene & Tropical Medicine, UK (HITAP interns) |
| Diana Beatriz Bayani | Health Policy Development and Planning Bureau, Department of Health, Philippines (HITAP interns) |
| Jatuporn Apichadsupapkajon | HITAP, Ministry of Public Health, Thailand |
| Jirata Tienphati | HITAP, Ministry of Public Health, Thailand |
| Manushi Sharma | HITAP, Ministry of Public Health, Thailand |
| Juliet Eames | HITAP, Ministry of Public Health, Thailand |
| Nuntapun Subhapatarapong | Pharmaceutical Research and Manufacturers Association, Thailand |
| Jitep Kidkasetpaisal | Pharmaceutical Research and Manufacturers Association, Thailand |
| Prof. Dr. Kriang Tungsanga | Chair of the Subcommittee for development of National List of Essential Medicines, Thailand |
| Rachel Archer | HITAP, Ministry of Public Health, Thailand |
| Rajibul Islam | HITAP, Ministry of Public Health, Thailand |
| Dr. Ritika Kapoor | National University of Singapore, Singapore |
| Saudamini Dabak | HITAP, Ministry of Public Health, Thailand |
| Mr Pramote Akarapanon | Food and Drug Administration, Ministry of Public Health, Thailand |
| Dr. Wanrudee Isaranuwatchai | HITAP, Ministry of Public Health, Thailand |
| Waranya Rattanavipapong | HITAP, Ministry of Public Health, Thailand |
| Dr. Wassana Wijagkanalan | BioNet-Asia |
| Yothin Thanomwat | National Vaccine Institute, Thailand |

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

Stakeholders were welcomed and thanked for attending the meeting. The Chair then requested participants to introduce themselves and to declare any conflict of interest. A short introduction on the purpose of the meeting was then provided. The aim of the meeting was to feedback the findings from the Total Systems Effectiveness (TSE) Thailand pilot project back to stakeholders and discuss the usefulness and applicability of TSE for the Thai setting. The Chair recapped the objectives of TSE and stated that TSE has a broader application for setting priorities in health and aims to strengthen country decision-making for vaccine product selection. The Chair explained that HTIAP has been working with the World Health Organisation (WHO) and National University of Singapore (NUS) to pilot TSE as a potential tool to support priority setting for new vaccines in Thailand. As part of the pilot project, a draft model applying TSE to rotavirus vaccine product selection was validated, evaluated and compared to existing decision-making processes in Thailand to uncover differences and similarities. Before the results were presented, The Chair made stakeholders aware that though Rotavirus has been used as a case example, hypothetical rotavirus products have been used in the model.

**Presentation of findings from TSE using rotavirus test case in Thailand**

**By Dr. Ritika Kapoor, National University of Singapore**

Dr. Ritika Kapoor presented the findings from the TSE pilot in Thailand. The following is a brief summary that highlights the major learnings, detailed results can be found in attachment 1.

Dr. Ritika first talked through the process of model validation. She explained that the model was validated using the no vaccine case, comparing the outputs in the TSE model with three existing Thai studies: Chotivitayatarakorn et al. 2010[1], Muangchanaa et al, 2012[2], and an unpublished study[3]. The criteria compared include but is not limited to: birth cohort (year and size); time horizon; disease burden estimates; proportion of cases by care setting; and cost estimates. Results for each criterion in the TSE model were similar to those reported in the three existing studies, however the figures for direct medical costs (per case in USD) were lower in the TSE model than those reported in other studies.

Dr. Ritika grouped the results of the pilot into three major findings: health outcomes (including cases averted, hospitalization cases averted, and deaths averted due to the vaccination programme); cost estimates (total programme costs, treatment costs saved, and budget impact) and cost effectiveness results. She explained that alongside the no vaccine case, five hypothetical vaccine products were used in the model. Rotavirus vaccine product 3 (RVV-3) showed the lowest budget impact (3.1 million USD over a 5 year cohort) and the lowest total incremental cost of 0.47 million USD (the total incremental cost was the sum of the healthcare cost and programme cost). In terms of nationwide findings, this pilot found that wealth quintiles had no role to play in disease incidence.

Dr. Ritika then moved on to discuss the multiple-criteria decision-making (MCDA) criteria. Seven criteria were assessed in the model: health impact, coverage, safety, commodity cost, delivery cost, health system changes, and financial impact. However criteria regarded as important to stakeholders in Thailand were also used in the analysis. In order to determine relevant criteria for the Thai context, during the first stakeholder meeting on 17th May 2018, stakeholders were asked to complete a short survey prioritising criteria for vaccine product

[1] Chotivitayatarakorn P, et al., Cost-effectiveness of rotavirus vaccination as part of the national immunization program for Thai children. Southeast Asian J Trop Med Public Health 2010;41: 114-25

[2] Muangchana C, et al., Economic analysis for evidence-based policy-making on a national immunization program: a case of rotavirus vaccine in Thailand. Vaccine 2012;30:2839-47

[3] Rochanathimoke O, et al. Economic Analysis of Rotavirus Vaccination Using Observational Data in Thailand. Unpublished report, Mahidol University, 2018.

selection and the top five criteria were extracted from the questionnaires they are as follows: safety, health impact, budget impact, delivery cost and cost effectiveness.

When assessing the products against the base case parameters, no vaccine product performed the best against all parameters (see attachment 1). In the ranking process, the higher score was given to the vaccine that performed the best across all criteria. Weighting was used to calculate the score and in this case, all criteria were assigned the same weight of 14%. When using the original criteria in the model, RVV-3, with a score of 54, was the top ranked product. Similarly, when applying the criteria chosen by stakeholders, RVV-3 was ranked best with a score of 60. RVV-2 was ranked second, and to determine the parameters that impact significantly on ranking, the team assessed which parameters can propel RVV-2 into first rank. The research team found that the significant vaccine parameters that impacted the performance and ranking of the vaccine products to be: relative risk of intussusception; number of doses; vaccine efficacy; duration of protection; and commodity cost. Dr. Ritika explained that utilising this approach can be used to identify the preferred product characteristics to help manufactures develop a product that best suits the needs of a country.

To summarise the presentation, Dr. Ritika maintained that the pilot was a proof of concept study, but the team were able to draw certain lessons learned.

- Performing an early stage health technology assessment (HTA) to inform R&D, can help identify preferred product characteristics. This may make R&D more successful and accelerate product utilization
- In order to achieve this, it is important for decision making bodies to identify decision criteria relevant to their country in an explicit manner
- MCDA provides a systematic framework to identify important decision making criteria and their relative importance

Following on from the presentation, Dr. Ritika then welcomed questions and the discussion that followed is summarised below:

- A concern was raised regarding comparing studies that deploy methods that are not comparable. For instance one of the studies used in model validation is hospital based, whereas another includes self-care.
    - The research team explained that findings from the model were compared with studies with the no vaccine case. This is because the results were not able to be compared to those from studies that use rotavirus vaccines, as TSE findings are based on hypothetical vaccines.
- The model has assumed that the rotavirus vaccine will be given alongside OPV or DTP.
- One stakeholder challenged the figures used for duration of protection. It was reiterated to stakeholders that the model uses five hypothetical vaccines, not existing vaccine products, so the figures for each vaccine product are not applicable to the real case but are just used as a testing tool.

**Presentation comparing TSE with Thai's decision making criteria (National List of Essential Medicine and Advisory Committee on Immunization Practices)**

**By Waranya Rattanavipapong, HITAP**

Waranya Rattanavipapong started her presentation by explaining to stakeholders that Thailand has a robust system already established for vaccine selection and prioritisation. An objective of the pilot study, she stated, was to compare the TSE mechanism with the existing process in Thailand. Before outlining the results, Waranya gave a brief overview of the processes of vaccine prioritisation in Thailand. The Subcommittee for development of National List of Essential Medicine (NLEM) are responsible for selecting medicines to be included in the NLEM and apply MCDA to their selection process. Advisory Committee on Immunization Practices (ACIP) is an advisory body who makes recommendations to the Ministry of Public Health regarding

the inclusion of new vaccines into the national immunization program. ACIP is the national immunisation technical advisory group (NITAG) in Thailand.

Waranya discussed and compared the measurable criteria for the prioritization of vaccines in the NLEM and ACIP mechanisms. Both committees use the following criteria: disease prevalence, disease burden and evaluation of vaccine safety and efficacy. For vaccines, the Subcommittee for development of NLEM receives information on disease prevalence, disease burden, and vaccine efficacy and safety from the ACIP in addition to information obtained from working groups. Additional criteria that the NLEM use includes: cost effectiveness analysis, budget impact, analysis and equity. The incremental cost-effectiveness ratio (ICER) is set at 160,000 THB per quality-adjusted life year (QALY) gained. While the ACIP focus on the availability of economic evaluation from literatures searches, the NLEM subcommittee, with support of Health Economics Working Group, utilise cost effectiveness and budget impact analysis.

Waranya gave a presentation on the rankings of the five hypothetical vaccines used in the model for the TSE pilot in Thailand, against the ACIP and NLEM criteria. Further details of the scorings and parameters are attached in attachment 2. The NLEM and ACIP priority setting criteria also suggest RVV-3 as the best option. The NLEM process has a choose one policy, in which only one product can be selected, so in this case it would be RVV-3. For the ACIP, the results indicate that RVV-3 would be ranked first, RVV-2 would be ranked second and RVV-1, 4, and 5 would be ranked third.

The pilot demonstrates that the three priority setting tools, i.e. TSE, ACIP and NLEM, offer the same policy choice. This may be because Thailand has already applied MCDA in the prioritization and selection processes, and the scoring is dependent on the criteria that is used so the same policy choice may have been offered because of duplicated criteria. It was proposed that TSE may be useful for countries without established health priority setting mechanisms in paving way for evidence-informed decisions.

The discussion points raised after the presentation are summarised below:

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- Since there are not just five criteria used in decision-making in Thailand, it was recommended that additional criteria should be included in TSE.
- The TSE concept uses disability-adjusted life year (DALY) rather than QALY.
- Thailand's HTA guideline utilises QALY to express the personal utility of health outcomes of the Thai society and uphold that the weight of illness depends on the perspective of the society. However, how quality is defined varies from country to country and depends on the social and economic circumstances of that country. For this reason, it may be more appropriate for a global model applicable across many countries to utilise DALYs.
- It was suggested to use a past example in Thailand instead of a hypothetical example e.g. human papilloma virus (HPV) vaccine, for the analysis. By adopting this approach, the model could be verified using original methodology and investigate whether TSE yields the same results as the NLEM and ACIP processes.
- One stakeholder asked whether the TSE concept upholds that only the product ranked first should be chosen. The WHO explained that though the model will give a ranking, the ranking will not necessarily give the output of what that country should choose. They maintained that TSE is focused on informing the deliberative process. Potentially a country may want to choose the product ranked second or third, depending on the quality of evidence, ethical issues etc.
    - Thailand has mechanisms in place for prioritising and selecting drugs and vaccines, however for medical devices, Thailand lacks an established product selection process. TSE would be useful for evaluating other technologies e.g. MRI scanners. The WHO stated that they were having discussions with other departments in WHO on the possibility of this.

- Thailand uses the ICER threshold set at 160,000 THB per QALY gained, however thresholds for cost effectiveness varies in different regions depending on gross domestic product value and other factors. Stakeholders discussed thresholds not being static and can therefore be changed in the future.
- Another question was asked on whether TSE can analyse different types of vaccines e.g. HPV compared to Rotavirus vaccines.
    - Some stakeholders spoke of the difficulty in ranking across different vaccines as different parameters are required to analyse different vaccines.
    - One stakeholder commented that since Thailand has a limited budget and resources, it is vital to know how to prioritise between vaccines. Therefore using TSE to compare across different vaccines would be useful for vaccine manufactures.

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

Dr. Yot thanked all for asking questions and engaging in thought-provoking discussions. It was made known to stakeholders that the finalised meeting minutes will be published on the HITAP website. Dr. Yot explained that there will be a TSE steering committee meeting in September held in Geneva, where those present will discuss the lessons learned from the country pilot studies and plan for the next steps. If any of the participants would be interested in participating in the published content of the TSE project, they should contact the HITAP team at hiu@hitap.net