

**Stakeholder Consultation Meeting on
Pneumococcal Conjugate Vaccine (PCV) Project in
Bhutan**

MISSION REPORT

Thimphu, 26 June 2016

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Abbreviations

BHTF	Bhutan Health Trust Fund
BIA	Budget Impact Analysis
CEA	Cost Effectiveness Analysis
DFID	Department for International Development
EE	Economic Evaluation
EMTD	Essential Medicines and Technology Division
FDA	Food and Drug Administration
HITAP	Health Intervention and Technology Assessment Program
HLC	High Level Committee
HPV	Human Papilloma Virus
HTA	Health Technology Assessment
ICER	Incremental Cost-Effectiveness Ratio
IVIR-AC	Immunizations and Vaccine Related Implementation Research Advisory Committee
KGUMSB	Khesar Gyalpo University of Medical Sciences of Bhutan
LMIC	Low Middle Income Country
MOH	Ministry of Health
NCIP	National Committee for Immunization Practices
NLEM	National List of Essential Medicines
Nu	Ngultrum
PCV	Pneumococcal Conjugate Vaccine
PPD	Policy Planning Division
QALY	Quality Adjusted Life Year
RCDC	Royal Center for Disease Control
REBH	Research Ethics Board of Health
UHC	Universal Health Coverage

WHA	World Health Assembly
WHO	World Health Organization
WHO PEN	WHO Package of Essential Non communicable disease
WHO SAC	World Health Organization Scientific Advisory Committee

Introduction

Bhutan achieved Universal Child Immunization in 1991 and has maintained high immunization coverage over the past decades. Since Bhutan transitioned from Gavi support in 2016 after the country's economic classification changed to lower-middle income country, the government is now responsible for allocating money on new vaccines and considerations around value for money, budget impact and financial sustainability of introducing new vaccines is of critical importance. Recognizing the importance of priority setting in the context of universal health coverage (UHC), Bhutan officially established an Essential Medicines and Technology Division (EMTD) under Ministry of Health (MOH) in 2008 which is the only Health Technology Assessment (HTA) unit in the country responsible for providing evidence to the decision makers in Bhutan by assessing health technologies or interventions. In September 2016, officials from EMTD and Policy Planning Division (PPD) under MOH approached the Health Intervention and Technology Assessment Program (HITAP) to provide technical support for this study in Bhutan.

HITAP has worked with local and international partners to support development of health technology assessment (HTA) in many LMICs through the International Decision Support Initiative (iDSI), a network of priority setting agencies from across the world supported by the Bill and Melinda Gates Foundation, Department of International Development (DFID) and Rockefeller Foundation. In Thailand, HITAP plays an important role in supporting decision making by generating key HTA evidence for UHC and the National List of Essential Medicines (NLEM). This study was the second collaborative work between HITAP and MOH in Bhutan. HITAP's collaborative works span areas such as building technical capacity and providing support, conducting economic evaluation studies and institutionalization of HTA by supporting local partners in those countries. HITAP's first visit to Bhutan was in 2013 to conduct another project titled "Economic Evaluation (EE) of World Health Organization (WHO) Package of Essential Non communicable disease (WHO PEN)".

The economic evaluation of Pneumococcal Conjugate Vaccine (PCV) study was completed over a period of nine months (October 2016-June 2017). This study was financially supported by WHO country office and iDSI. The first visit was made in November 2016 to build technical capacity for the Bhutanese research team conducting this study and to develop a clear proposal for the study. During the second visit in February, the HITAP team assisted the data collection process. The third visit was in April when Bhutanese research team came to HITAP for data analysis. This report summarizes the fourth and final visit of HITAP staff to MOH, Bhutan, for a stakeholder consultation meeting where core team researchers showcased the findings of the study to all relevant stakeholders. The list of participants can be found in [Appendix 1](#) while the agenda of the visit can be found in [Appendix 2](#).

Summary of the meeting

Mr. Sonam Phuntsho, a researcher for the PCV study and Program Officer at the Policy Planning Division opened the meeting and offered his gratitude to all the stakeholders and high level delegates present in the room. He provided the background, rationale and objectives of the study. The cost effectiveness study on introducing PCV in Bhutan was conducted in collaboration with HITAP, which provided technical support. The objective of the stakeholder consultation meeting was to disseminate the findings of this study to all relevant stakeholders and to get feedback from them. This study not only looked at the cost effectiveness of PCV but also assessed the value for money proposition of introducing PCV, the long term financial sustainability of the vaccine in Bhutan and its impact on human resources for health. He shared that this collaborative study has been a good opportunity for the MOH officials to build technical capacity by engaging throughout the process of conducting the study. He invited the Honorable Secretary Dr. Ugen Dophu to provide opening remarks.

On behalf of the MOH, Hon. Sec. Dr. Ugen Dophu thanked the HITAP team and MOH Thailand for continuous support to MOH Bhutan, both in the past and present, and for building capacity of MOH officials. Not only in the field of HTA, but in overall area of health, MOH Thailand has been very supportive towards MOH Bhutan in capacity building of doctors, nurses, technicians and other health professionals. In the past, clinicians in Bhutan conducted a study on the burden of pneumococcal diseases which are pneumonia, meningitis, bacteremia, and otitis media, and that study recommended introduction of PCV in Bhutan. However, the MOH couldn't make any evidence informed decision. Therefore MOH recommended to conduct this cost effectiveness study to inform policy decision makers in Bhutan to show whether introducing PCV is good value for money or not. He thanked the HITAP team for providing technical support in conducting this study to make available more evidences in introducing PCV. This has been a good evidence building process and the next step would be to present the study findings to high level committee and the cabinet to inform policy makers to make decision on introducing the PCV. With the presence of Director of Bhutan Health Trust Fund (BHTF) in the meeting, it is important to seek his views as BHTF as they are the donor for MOH. In Bhutan, among various population groups, especially children, disease burden of pneumococcal diseases is very high, so introduction of PCV would definitely benefit the country. He also thanked WHO Bhutan for providing financial support for this study.

The next session was an introductory session from Dr. Yot Teerawattananon, Program Leader of HITAP, who reiterated the cordial relationship between MOH Thailand and MOH Bhutan since long time ago till date for sustainable development. This decade long relationship between two governments is a two-way learning process, sharing and learning from each other and fostering collaboration. He gave an overview of the objective and agenda

of the meeting and stated that this meeting would not only be about a particular project or cost effectiveness of one vaccine, but it's going to be about the importance of this study since it is the first step for future development of capacity of MOH in terms of HTA. Globally, value for money assessments are being implemented everywhere, for instance the Global Fund which is spending money at the global level to support LMICs on HIV, Tuberculosis, Malaria, Hepatitis etc. The Global Fund has been requesting more and more assessment studies on value for money to guide investments in LMIC through value for money policy. Another example is the WHO model of list of essential medicines which also recommends the role of HTA or value for money assessment to inform essential medicine list because the country cannot include new medicines without considering value for money as there are too many medicines available in the market. Without value for money assessments, it is difficult for the government to say why they include certain medicines and excluded others. In Thailand, there are about 20,000 medicines registered in Thailand under Food and Drug Administration (FDA), but only about 900 medicines are included in the pharmaceutical benefits package. These medicines have been assessed for having strong evidence to treat diseases at a reasonable price through HTA studies to inform development of benefit package. If doctors or patients want to use medicines outside this list, they need to incur out-of-pocket expenditure. In terms of vaccines, Dr. Yot Teerawattananon shared that there is an Immunization and Vaccine Related Implementation Research Advisory Committee (IVIR-AC) which gives advice to a scientific advisory group of experts including WHO Scientific Advisory Committee (WHO SAC). While WHO makes recommendations regarding individual vaccines, IVIR-AC provides the evidence. The WHO SAC cannot make good recommendations on vaccines for global use without information on the value for money or evidence.

In Thailand, value for money assessment is not only used for looking at the package but also for price negotiation. When assessing the value for money for many medicines in Thailand, it was found that some medicines were too costly, so it was recommended that these medicines be included in the benefits package only if the price charged by companies is reduced by a certain percentage, in line with what had been proven through strong scientific evidence. Another example of importance of HTA globally is the WHO Resolution on World Health Assembly (WHA) which mentions the importance of having strong scientific evidence through HTA studies. However, Dr. Yot shared that evidence alone cannot make a policy move without stakeholders participation and support. Therefore this stakeholder consultation meeting was crucial in making this study move forward to transform it into policy.

Following introductions of all participants present in the meeting, preliminary results of "Cost-Utility Analysis of 10- and 13-valent Pneumococcal Conjugate Vaccines in Bhutan" were presented by Mr. Kinley Dorji as a principal investigator of the project. The

presentation was divided into background and rationale of the study, followed by methodology used and results and findings. The presentation also briefed the policy recommendations. The main findings from economic evaluation showed that given a threshold of 176,000 Bhutanese Ngultrum per QALY gained, providing PCV vaccine, both PCV 10 and PCV 13, to children under 1 year old is cost-effective in the context of Bhutan. Comparing two types of vaccine, introduction of PCV 13 is more preferable than PCV 10, as it yields better health outcomes in terms of death averted and more episodes averted. The additional budget of introduction of PCV 10 and PCV 13 compared to no vaccine are 38.4 and 37.6 million Bhutanese Ngultrum (Nu), respectively. The results showed that implementing PCV13 can save more lives over a five-year budget period than PCV10. In addition, human resources for health such as pediatricians and nurse time can also be saved if PCV is introduced. Therefore, an inclusion of PCV at the current price in the national immunization program is recommended. The presentation can be accessed [here](#).

After the presentation there was discussion and question and answer session. The WHO Representative raised questions on the vaccine price and the time horizon of five years that was used of Budget Impact Analysis (BIA). While the discounted price of PCV 10 and PCV 13 is 198 Nu or 231 Nu depending on the vaccine, Bhutan may not be able to get the discounted Gavi rate and have to pay a higher price per dose ten years from now. This relates to the long term sustainability of the intervention and policy makers need to have this information as well. Ms. Wantanee shared that Thailand is not eligible for Gavi price so Thailand uses the market price. The Thai study has showed that for PCV 13, the per dose price is around 60 USD which is much higher than Gavi price. In Thailand if the price of PCV is reduced to 3.5 USD as Gavi access price, both PCV vaccines would be cost effective. In Bhutan, the current price is 198 Nu for PCV 10 and 231 Nu for PCV 13, and at these prices both PCV vaccines are cost effective. However, in the future, if Bhutan cannot purchase the vaccine at the Gavi price, they will have to pay more but it would still be cost effective if the price of PCV 10 is less than 515 Nu and if price of PCV 13 is less than 562 Nu.

Dr. Yot sought clarification regarding the Gavi access price and whether Gavi can continue to offer the vaccine at a discounted price for former Gavi eligible countries such as Bhutan. He stated that if Gavi can assure that they can offer PCV to Bhutan for the next five years, the issue of price will not be a major problem. While conducting BIA, one usually does not look beyond a five year timeframe because the treatment of diseases changes rapidly and this may change the options available to governments. For instance, there might be more a competitive market with a new PCV type such as PCV 12. The time horizon is aimed to reflect the fact that new health technologies are being developed rapidly. A new PCV vaccine may be launched in the near future which may allow the Bhutanese government to reconsider its decision. If the Bhutanese government is serious about investing in PCV, it may be

worthwhile discussing with Gavi about how long they can offer or guarantee the discounted price to Bhutan. It was suggested that the researchers confirm the issues related to Gavi pricing before presenting this study in the cabinet meeting.

Dr. Yot said that BHTF may not need to bear all of the cost incurred during vaccine introduction given that it can save on treatment cost within a short timeframe. Unlike the Human Papilloma Virus (HPV) vaccine, where one cannot see benefit until fifteen years later, for PCV, the benefits are visible in terms of lives saved and treatment cost within one year. In Thailand when the Thai government decided to introduce seasonal influenza vaccine under UHC, the researchers informed the government that if they introduced the vaccine, the savings were equivalent to the cost of vaccination so the government decided to introduce the vaccine but didn't give more money to the UHC program. Rather, it recommended that the UHC manager use the budget saved from inpatient care to buy the vaccine.

In addition to exploring options of continued Gavi support, there were other suggestions for dealing with the issue of vaccine price. One way could be to negotiate the price of the vaccine with the manufacturers. A second option is to find additional funding to support the provision of PCV vaccine such as through a government funded agency, Bhutan Health Trust Fund. Finally, there were suggestions for conducting further studies to predict the number of years required to successfully eradicate pneumococcal diseases in Bhutan.

There was also a question about the source of vaccine efficacy. Since there is no publication on the vaccine efficacy of PCV 13, vaccine efficacy of PCV 13 was extrapolated and adjusted based on efficacy of PCV7 by taking into account reduced immunogenicity for serotypes 6B and 23F. This approach was applied and published elsewhere. Clinical data for vaccine efficacy are only available for PCV 7 and PCV 10, and most studies suggest that PCV 10 is relatively better than PCV 7, possibly due to cross protection and more serotype coverage. In this study too, the researchers have tried to extrapolate the same logic that PCV 10 is better than PCV 13 given that PCV 7 and PCV 13 are from same company and use same vaccine components. Having said that, Dr. Yot shared that all modeling techniques are not without their shortcomings.

An interesting point was raised about the impact on the loss of lives due to pneumococcal diseases given that Bhutan is now witnessing reduced birth rate. It is therefore important to account for the suffering caused by the disease and the value of human life. Dr. Pandup Tshering shared that cost may not be the only concern for the government while considering introduction of the vaccine, so while sharing a concept note for cabinet, it is important to note that they might ask for more clarifications on questions such as whether this vaccine would prevent pneumococcal disease, is the vaccination only an option or are there other cost effective interventions, what is the probability of children getting infections, etc.

There are altogether six pediatricians and about 500 nurses in Bhutan which shows that the workforce for pediatrics in Bhutan is limited. This is a unique study that has attempted to estimate human resource impact from introducing vaccine globally in academic area too. The study also recommends introducing PCV into routine immunization plan and would provide good value for money given that Bhutan could still access GAVI negotiated vaccine prices. Although both vaccines (PCV 10 and PCV 13) are seen to be cost-effective compared to no vaccination, it was seen that PCV 13 yielded better health outcomes and lower five year budget. If PCV is introduced, this study suggests that each pediatrician time could be potentially saved. During this meeting, it was also noted that more discussions are needed internally about training of health assistants while introducing this vaccine.

Conclusion and potential next steps/collaborations:

In conclusion, the results of the study were well accepted by all stakeholders. Pneumococcal infections have a high burden in Bhutan and cause severe morbidity and mortality. The introduction of PCV vaccine in Bhutan can not only reduce burden of pneumococcal diseases but also offer a good value for money. The results of this study will be presented to High Level Committee (HLC) for its endorsement. The recommendations from this study will be submitted to the cabinet by the end of July 2017. It was noted that one of the benefits of this collaborative study has been building of HTA capacity in Bhutan. Dr. Kinzang, who is the president of Medical Science University, made a positive statement during his closing remarks saying that he will encourage academics to do more research including HTA to inform policy. Dr. Yot concluded the meeting by saying that this study was the first of its kind and that the NCIP Bhutan should continue to support this type of work. Further, this study is unique given the setting of Bhutan and is a good example for developing countries. It is therefore important to publicize this work across the world. This work could also potentially open doors for future collaborations with Bhutan MOH to work on various similar projects.

Appendices

Appendix 1: List of participants

#	Name	Designation	Office
1.	Dr. Ugen Dophu	Secretary	MOH
2.	Dr. Pandup Tshering	Director General, Department of Medical Services	MOH
3.	Dr. Karma Lhazin	Director	Department of Public Health
4.	Dr. Sonam Phuntsho	Director	Bhutan Health Trust Fund (BHTF)
5.	Dr. Kinzang. P. Tshering	National Committee on Immunization Practice (NCIP) member	Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB)
6.	Dr. Suraj Man Shrestha	WHO Representative	WHO
7.	1 participant	WHO Representative	WHO
8.	Mr. Tashi Penjore	Chief Planning Officer	Policy and Planning Division, MOH
9.	Mr. Dechen Choiphel	Chief Planning Officer	Essential Medicines Technology Division (EMTD), MOH
10.	Mr. Sonam Wangchuk	NCIP member	Royal Center for Disease Control (RCDC)

11.	Mr. Jigme Tenzin	Drug Regulatory Authority	Drug Regulatory Authority
12.	Mr. Tshewang Tamang	Senior Program Officer	Vaccine Preventable Disease Program (VPDP), Department of Public Health (DoPH)
14.	Mr. Kinley Dorji	Deputy Chief Program Officer	Health Technology Assessment Section, EMTD
15.	Mr. Sonam Phuntsho	Program Officer	Policy and Planning Division
16.	Mr. Pempa	Program Officer	Health Technology Assessment Section, EMTD
17.	Dr. Yot Teerawattananon	Program Leader	Health Intervention and Technology Assessment Program (HITAP)
18.	Ms. Waranya RattanaVIPapong	HITAP International Unit Head	Health Intervention and Technology Assessment Program (HITAP)
19.	Ms. Wantanee Kulpeng	Researcher	Health Intervention and Technology Assessment Program (HITAP)
20.	Ms. Suthasinee Kumluang	Researcher	Health Intervention and Technology Assessment Program (HITAP)
21.	Mr. Sarayuth Khuntha	Researcher	Health Intervention and Technology Assessment Program (HITAP)
22.	Ms. Sneha Rajbhandari	Project Associate	Health Intervention and Technology Assessment Program (HITAP)

Appendix 2: Agenda of the meeting

26th June, 2017

Time	Scheduled Activity	Responsible person
9:00-9:15	Introduction of workshop and participants	Bhutanese delegates and All participants
9:15-9:40	Brief Presentation on PCV study	Bhutanese research team
9:40-10:00	Tea break	
10:00-11:30	Q&A	All
11:30-12:00	Closing remarks and conclusion	All