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Brief communication (Original)

Cost-utility evaluation of influenza vaccination in patients with existing coronary heart diseases in Thailand

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Background: Influenza can exacerbate chronic coronary heart diseases (CHD) and health policy recommends influenza vaccination in this population group. However, cost effectiveness of influenza vaccination in protecting CHD population has not been, to our knowledge, well studied before especially in CHD patients with different disease severities.

Objectives: To assess life-time cost utility of influenza vaccination in CHD patients either with angina and/or cardiac arrest/myocardial infarction (CA/MI) and to identify the most cost-effective influenza vaccination strategies.

Method: The Markov model of CHD progression concurrent with the influenza infection was developed to quantify life-time costs and health effects of the three influenza vaccination strategies compared with no influenza vaccination (base case): (1) influenza vaccination in all CHD patients, (2) influenza vaccination in CA/MI patients-only, and (3) influenza vaccination in angina patients-only. The cost-effectiveness analysis (CEA) was based on the societal perspective. Deterministic and probabilistic sensitivity analyses were performed to identify variables that influence the sensitivity of the results and examine the effects of model parameters uncertainty, respectively.

Results: For the base case, the expected value (EV) results of no influenza vaccination, influenza vaccination in all CHD groups, influenza vaccination in angina patients, and influenza vaccination in CA/MI are 346,437 Thai baht (THB) yielded 18.26 Quality adjusted life year (QALYs), 454,664 THB yielded 21.46 QALYs, 360,786 THB yielded 19.96 QALYs, and 437,901 THB yielded 19.72 QALYs; respectively. CEA graph comparing all influenza vaccination strategies shows that vaccination in all CHD patients groups and angina patients are in the cost-effectiveness frontier, but not influenza vaccination in CA/MI patients. The cost-effectiveness rankings report shows that the willingness-to-pay (WTP) threshold (100,000 THB) is greater than the incremental cost effectiveness ratio (ICER) of vaccination in all CHD groups (ICER = 33,813 THB per QALY gained) and angina group (8,420 THB per QALY gained) and therefore the vaccination in all CHD groups, which is more expensive, but more effective would be recommended. The deterministic sensitivity analysis shows the most influential parameters driving the cost-effectiveness of vaccination strategies are the effect of influenza vaccination on CHD both for acute myocardial infarction and cardiovascular death, respectively. The probabilistic sensitivity analysis shows the same influenza strategy recommendation (vaccination in all CHD groups) as the base case analysis.

Conclusion: From a societal perspective, influenza vaccination in all CHD groups is recommended. The information from economic modeling should be confirmed by primary economic research.

Keywords: Coronary heart disease, cost-utility, influenza vaccine, Markov model, Thailand

Abbreviations
CHD = Coronary heart diseases
CA/MI = Cardiac arrest/Myocardial Infarction
CEA = Cost-effectiveness analysis
QALYs = Quality adjusted life year
WTP = Willingness-to-pay
ICER = Incremental cost effectiveness ratio

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A leading chronic illness among Thais is cardiovascular disease. Twenty-eight percent of Thais have some form of cardiovascular disease. Heart attack and stroke kill 65,000 Thais per year [1]. Individuals with chronic coronary heart disease (CHD) may have increased risks for complications from influenza infection leading to severe illness or death. Recent reports have detected an increase in the number of patients with acute coronary syndromes (ACS) during the influenza season. More recently, case-control studies of patients with prior infarction have shown that influenza vaccination significantly reduces the risk of myocardial necrosis and strokes [2]. This evidence has led to recommendation that influenza immunization be given to people with coronary and other atherosclerotic vascular disease [3].

While the health impact and treatment/intervention expenditures for CHD at different severities are different, the annual influenza vaccine recommendation for patients with heart diseases is not severity specific. The Advisory Committee on Immunization Practices (ACIP) recommends annual influenza vaccination to the elderly and to people of any age with chronic medical conditions, which generally includes patients with CHD at all severities (4). The American Heart Association (AHA) and American College of Cardiology (ACC) are more specific, but does not particularly include disease severity in the consideration [5]. Moreover, angina patients who have similar functional limitations differ substantially in their symptom tolerance, as measured by utility. Therefore, it is suggested that guidelines for the ischemic heart disease management should also include patient preferences, rather than symptom severity alone [6].

For Thailand, the National Health Security Office (NHSO) provides influenza vaccination to patients with high risk medical condition that cover heart disease, but the disease severity is also not included in the provision consideration [7].

Resources are always limited and patients with CHD are increasing each year. As a result, costs of annual influenza vaccination for all CHD patients are high and may not be cost effective, especially in patients with mild disease. Therefore, the pharmcoeconomic evaluation (PE) to compare the cost utility of influenza vaccination in patient with CHD, with the subgroup analysis of different disease severities, angina and CA/MI, is proposed.

Materials and methods

The traditional approach of economic evaluation, incremental cost-effectiveness analysis, which compares additional costs and health outcomes of moving from one intervention, was used in this study. We developed a Markov model and applied it to coronary heart patients concurrent with influenza infection. The coronary heart disease component of the model and the movement probability between states were adopted from a Markov Model of Disease Progression and Cost-effectiveness of Coronary Heart Disease for Type 2 Diabetes, which is an abbreviated version of the Coronary Heart Disease Policy Model developed at Harvard University, but the study model was begun from patients with history of CHD [8,9].

The Markov model as shown in **Figure 1**, illustrates the mutually exclusive health states that a patient commencing influenza vaccination either in angina or history of CA/MI state. The model includes three CHD states which are symbolized in the solid-line ovals. State numbers 1, 3, and 5 represent angina, history of CA/MI, and death, respectively, where individuals end up at the end of each year. These are the actual states that are programmed in the model. The diamonds and arrows express what happens to the individuals within the course of each year as they move between states (thus the shading for “Within Year Events”). These events are incorporated within the model’s transition probabilities. We also developed sub-states (dotted-line ovals) to reflect the difference in rates of influenza infections between the two alternative modalities, vaccination, and no vaccination. Because influenza vaccination is recommended annually and we evaluated life-long vaccination; therefore, the model used a 1-year cycle length for full health state. The model was started from patient aged 35 which is the age commonly identified as having coronary heart disease and was run 46 cycles until the patient was aged 80, which is the age with the highest incidence of coronary heart disease [10].

It was assumed that patient remained in the same alternative modality and has not moved from vaccination to nonvaccination and vice versa. The model was used to quantify the costs and effect of the two alternatives long-term managements for influenza vaccination in coronary heart diseases patients starting vaccination with either angina or CA/MI condition. TreeAge Pro 2011 (TreeAge Software, Williamstown, MA) was used for the calculation of the costs, outcomes, uncertainty and scenario analyses.

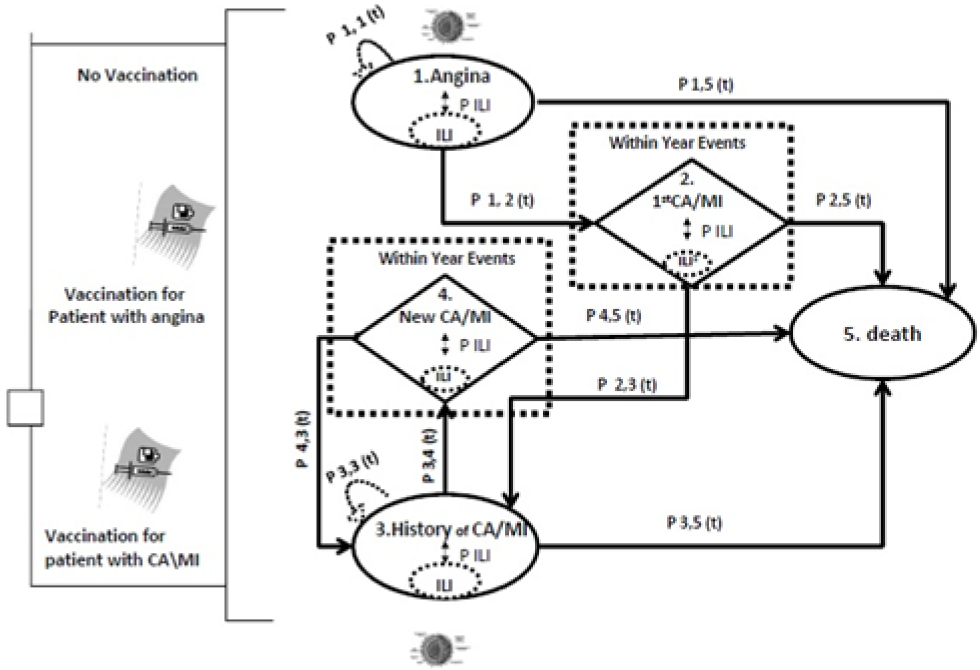


Figure 1. Health states in Markov model and 3 alternatives

Data sources and outcome measures

Table 1 shows data inputs for our model with distributions and sources. When possible, data came from published meta-analyses.

The various figures and assumptions used as inputs for various calculation and scenario analysis are summarized as follow;

1. The probabilities of coronary heart disease progression in the model were derived from the probabilities outlined [9, 11].

2. The adjusted factors for influenza infection were derived from a pooled analysis of the Cochrane review [12]. Two randomized controlled trials were included in this analysis. The pooled analysis of cardiovascular death showed risk ratio 0.39, 95% confidence interval (CI), 0.20 to 0.77. For acute myocardial infarction, the risk ratio was 0.85, 95% CI, 0.44 to 1.62.

3. Influenza incidence: this is an economic assessment that aims to assess effectiveness; therefore influenza-like illness (ILI), which is the clinical symptom was assessed instead of laboratory confirmed influenza infection. ILI incidences were incorporated in disease states and events except the death state. ILI data was derived from one stratified, randomized double blind, placebo-controlled trial in Thai participants aged 60 years and older [13]. The results showed that the incidence of ILI was 4.83% in the vaccinated group compared with 10.88% in the placebo group. The relative risk reduction was 56% (95%CI, 14% to 77%).

a. Utility data for an angina patient: Utility data of a patient with angina was derived from a study conducted by Nease et al. [14] and Hayashino et al. [15]. The result showed utility score of patient with angina at 0.947 (range, 0.663–1.0).

b. Utility data for CA/MI patient: utility data of a patient with CA/MI was derived from study conducted by Tsevat et al. [16]. The result showed the mean utility score of a CA/MI patient at 0.87 (95% CI, 0.84 to 0.93).

c. Influenza Like illness: utility data of patient with influenza was derived from study conducted by Velasco et al. [17]. The study showed Quality of Life mean in sick patient at 0.294 with a standard deviation of 0.430 and in healthy people at 0.94 with a standard deviation of 0.120.

4. Costs: costs were derived from a systematic search of the Thai published literature and relevant reports. They included all items of resources used, i.e., labor and material costs of healthcare providers, and real and opportunity costs lost by patients, i.e., patient treatment time, and cost of sick leave.

Table 1. Lists data inputs for economic model with distributions and source

Parameter description	Distribution	Mean	SE	Ref
Relative Risk of death in influenza vaccination compared with no vaccination group	Log normal	0.39	0.3439	Keller et al. 2008
Relative Risk of AMI in influenza vaccination compared with no vaccination group	Log normal	0.85	0.3325	
Hospitalization because of influenza infection (compared with no influenza)	no statistically significant			Jefferson et al. 2010
Influenza Relative Risk from influenza vaccine	Log normal	0.44	0.3278	Rungnirand et al. 2005
Probability of ILI in influenza vaccination group	Beta	0.0483		
Probability of ILI in no influenza vaccination group	Beta	0.1088		
Quality of Life				
Quality of Life in CA/MI patient 1st year	Beta	0.87	0.0255	Tsevat et al. 1994
Quality of Life in angina patient	Beta	0.997	0.0008	Nease et al. 1995
Quality of Life in CA/MI patient (subsequence year)	Beta	0.91	0.0255	Tsevat et al. 1994
Quality of Life in influenza patient	Beta	0.294	0.0608	Valasco et al. 2009
Quality of Life in healthy (compare to influenza)	Beta	0.941	0.0170	
Direct medical cost - adjusted to 2010 (cost/year)				
Average direct health care cost (ACS)—first year	Gamma	123473	849.6206	Anukoolsawat et al. 2006
Average direct health care cost (ACS) —subsequent year	Gamma	13252.82	91.1930	
Treatment cost of influenza - direct—adjusted to 2010 (one time cost)	Gamma	793	0.1007	Simmerman et al. 2006
Cost of influenza vaccine, admin, and logistic (one time cost)	Gamma	451	1.5662	Market survey
Median cost of medication and hospitalization (ACS)paid by household (first year)	Gamma	1016.13	9.1428	Anukoolsawat et al. 2006
Median cost of medication and hospitalization (ACS) paid by household (subsequence year)	Gamma	13148.13	118.3029	
Direct non-medical cost				
Median direct nonhealthcare costs (ACS)—first year	Gamma	3300	29.6924	Anukoolsawat et al. 2006
Median direct nonhealthcare costs (ACS)—subsequent year	Gamma	4772.74	42.9437	
Transportation cost (influenza)		85	0.0108	Simmerman et al. 2006
Indirect cost opportunity lost due to disease or death				
Median indirect costs because of morbidity exclude hospitalization (ACS)—first year	Gamma	27168	244.4494	Anukoolsawat et al. 2006
Median indirect costs due to ACS admission and FU - first year	Gamma	4532	40.7776	
Median indirect costs due to morbidity exclude hospitalization (ACS)—subsequent year	Gamma	15557.08	139.9779	
Value of lost work because of outpatient influenza	Gamma	933	0.1213	Simmerman et al. 2006
Missing day from influenza	Gamma	4.5	0.0006	
Parent missing day from influenza	Gamma	3.3	0.0004	

a. CHD: the costs of lifetime treatment of acute coronary syndrome were derived from study at Ramathibodi Hospital, Thailand [18].

b. Influenza: the costs of influenza were derived from study conducted in the Thai population [19].

c. Influenza vaccination cost: influenza vaccine costs were derived from a market survey (price list form pharmaceutical companies) and influenza vaccine administration cost was derived from the standard cost lists for health technology assessment [20].

All costs was converted to Thai baht and adjusted to cost in 2010 by CPI (Medical care) 2010. To comply with the Thai National Health Technology Assessment Guidelines all costs and outcomes were discounted at the rate of 3%.

Uncertainty analysis

Deterministic Sensitivity Analysis (DSA): a one-way DSA was conducted to identify variables that influence the sensitivity of the results.

Probabilistic Sensitivity Analysis (PSA): Monte Carlo Simulation was carried out by Tree Age 2011. All input parameters were assigned a probability distribution to reflect the feasible range of values that each input parameter could attain. The beta-distribution was the choice of distribution for probabilistic and utility parameters that were bounded zero-one; the gamma-distribution, which ensures positive values, was modeled for unit cost parameters; and log normal-distribution was the choice for distribution for relative risk, whose logarithm is normal distribution. The simulation then drew one value from each distribution simultaneously and calculated cost and effectiveness pairs. This process was repeated 10,000 times to provide a range of possible values given the specified probability distributions.

Results

The Markov Model of 4 alternatives; no influenza vaccination and influenza vaccination in all CHD groups, angina patient-only and CA/MI patient-only is shown in **Figure 1**. **Table 2** shows the lifetime (from ages 35 to 80 years) results of the economic analyses which include QALYs, costs, and incremental cost effectiveness ratio (ICER) of all influenza vaccination strategies.

From a societal perspective, providing lifetime influenza vaccination to an angina patient-only is the highest cost-effective strategy (ICER = 8,420 THB/ QALY gained; lifetime costs are 360,786 THB yielded 19.96 QALYs). However, influenza vaccination in all CHD groups (angina:CA/MI ratio = 0.75:0.25), which is less cost-effective (ICER = 33,813 THB per QALY gained) is recommended as the most optimal strategy because its ICER is still within the WTP threshold (100,000 THB per QALY gained) and it provides more effectiveness (lifetime costs are 454,664 THB yielded 21.46 QALYs).

Figure 2 shows CEA of 4 influenza vaccination strategies based on cost and effectiveness. The line connecting the 3 strategies (no vaccination, vaccination in angina patient-only, and vaccination in all CHD groups) is the cost-effectiveness frontier. An absolute dominated strategy is found in the vaccination strategy in CA/MI patient-only demonstrating that this strategy would not be in the effectiveness frontier and would be rejected.

Table 2. Lifetime costs, quality-adjusted life year, and cost-effectiveness ratios of influenza vaccination strategies in coronary heart disease patients

	Lifetime costs	Lifetime QALYs	ICER (THB/QALY)
No influenza vaccination	346,437	18.26	
Influenza vaccination in all CHD groups	454,664	21.46	33,813
Influenza vaccination in angina patients-only	360,786	19.96	8,420
Influenza vaccination in CA/MI patients-only	437,901	19.72	62,711

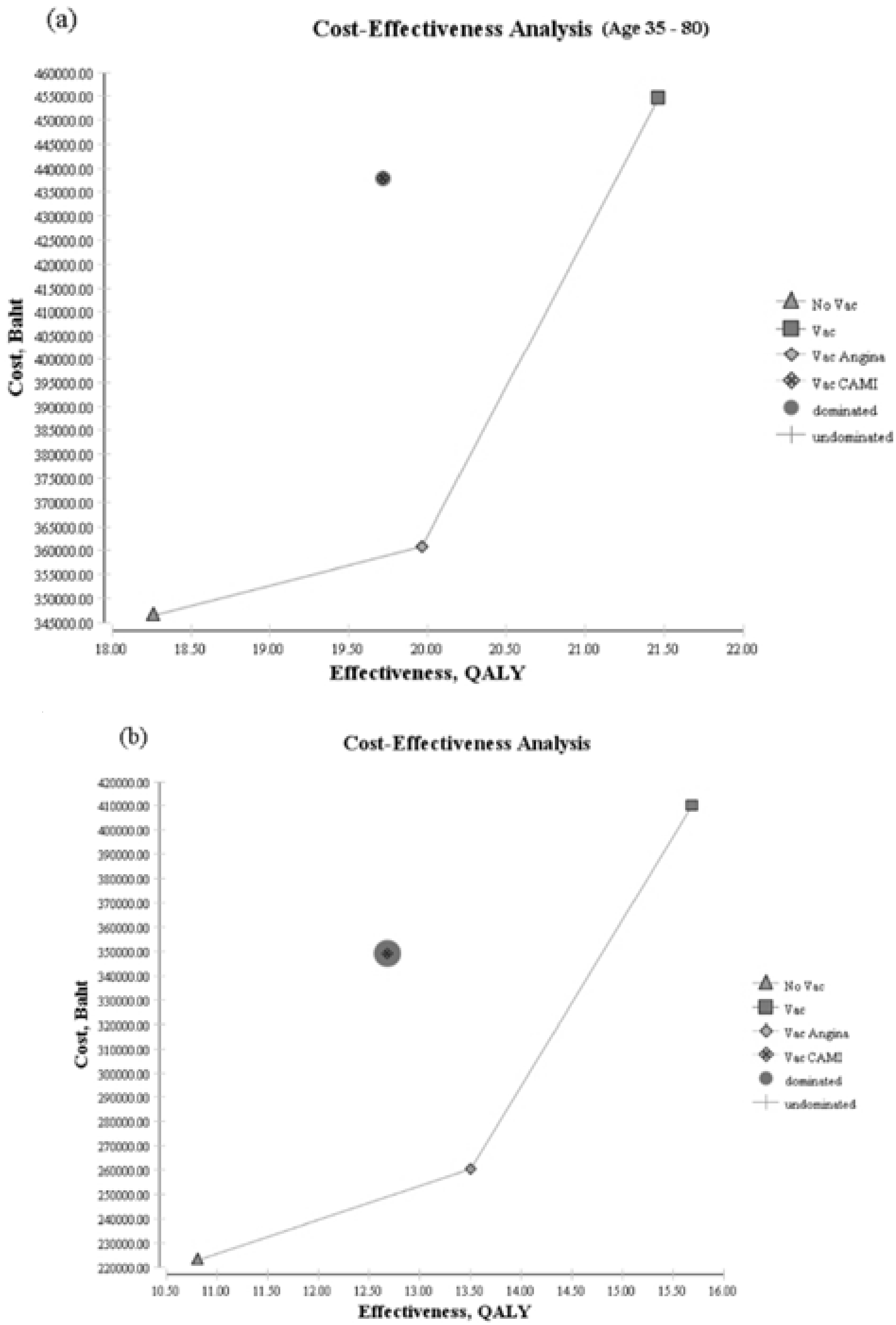


Figure 2. CEA graph shows 4 influenza vaccination strategies based on cost and effectiveness. (a) Base case (b) Monte Carlo simulation

Uncertainty analysis

Deterministic sensitivity

The Tornado diagram in **Figure 3** shows that the projected cost-effectiveness of influenza vaccination in CHD patients is most sensitive to efficacy of influenza vaccination to reduce CHD event and death from coronary disease representing as RRCAMI and RRcd, respectively. Other input parameters that also influence cost-effectiveness are quality of life and costs of CA/MI (direct medical cost, indirect cost). The input parameters with the least effect to cost

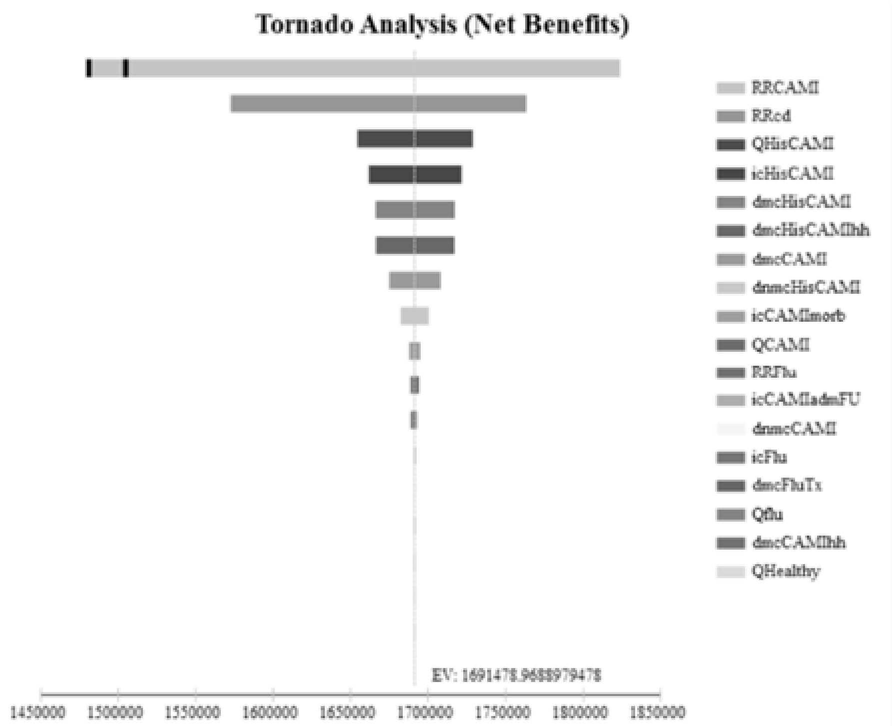
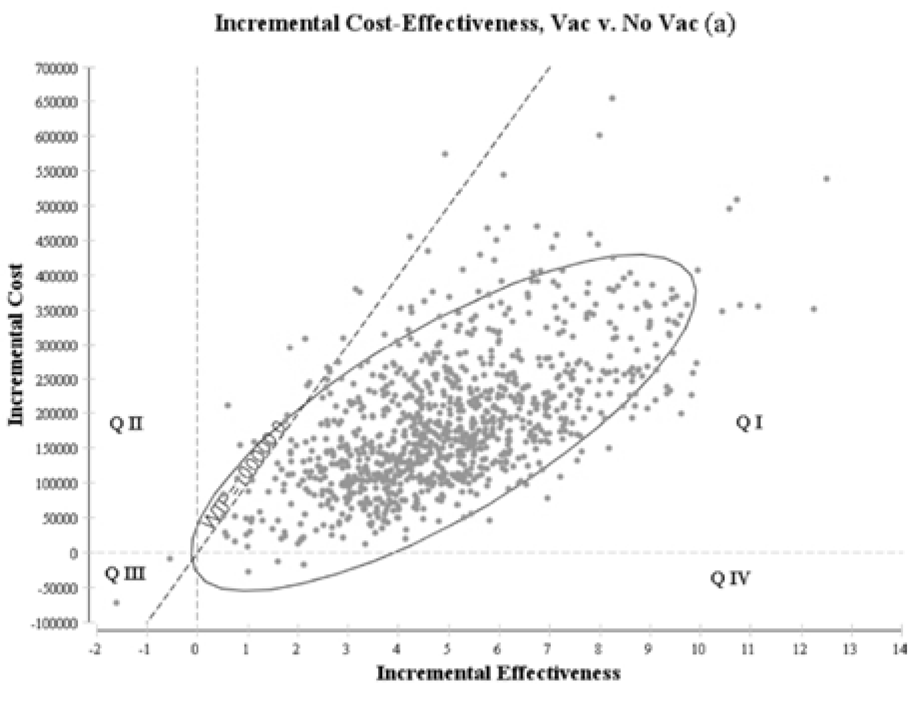


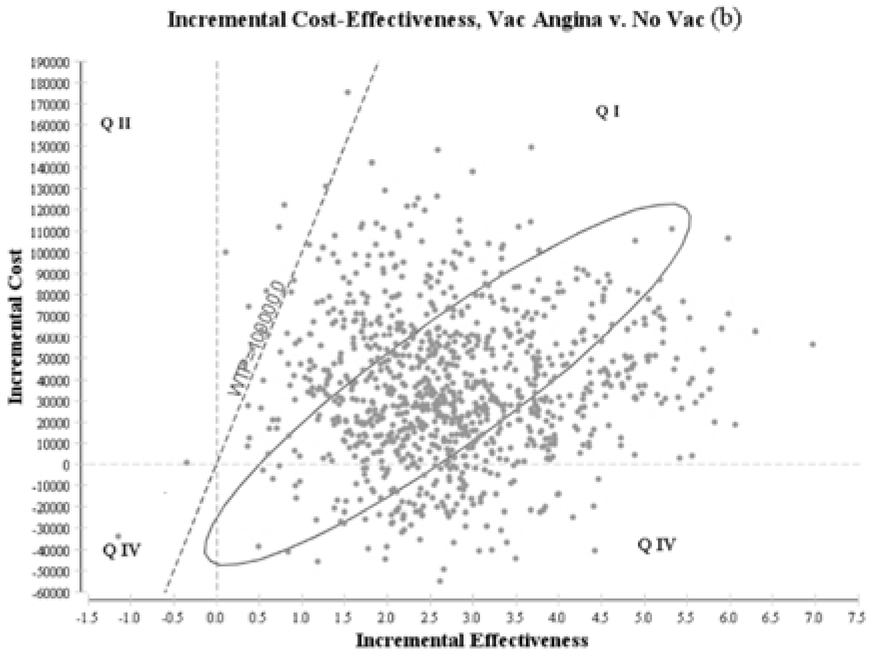
Figure 3. Tornado diagram comparing the relative importance of model parameters on estimated cost-effectiveness

effectiveness are quality of life in healthy and angina patient.

Probabilistic sensitivity

The Monte Carlo simulation shows less lifetime costs and effectiveness, but still shows the same highest cost-effectiveness influenza vaccination strategy (in angina patients-only), the most optimal influenza vaccination strategy (in all CHD groups), and the rejected influenza vaccination strategy (in CA/MI patients-only) as base case analysis does. ICE scatterplot graph of all influenza vaccination strategies (**Figure 4**) demonstrates the majority of iterations below and to the right of the WTP threshold of 100,000 THB. So it is also suggested that influenza vaccination strategies that are more costly and more





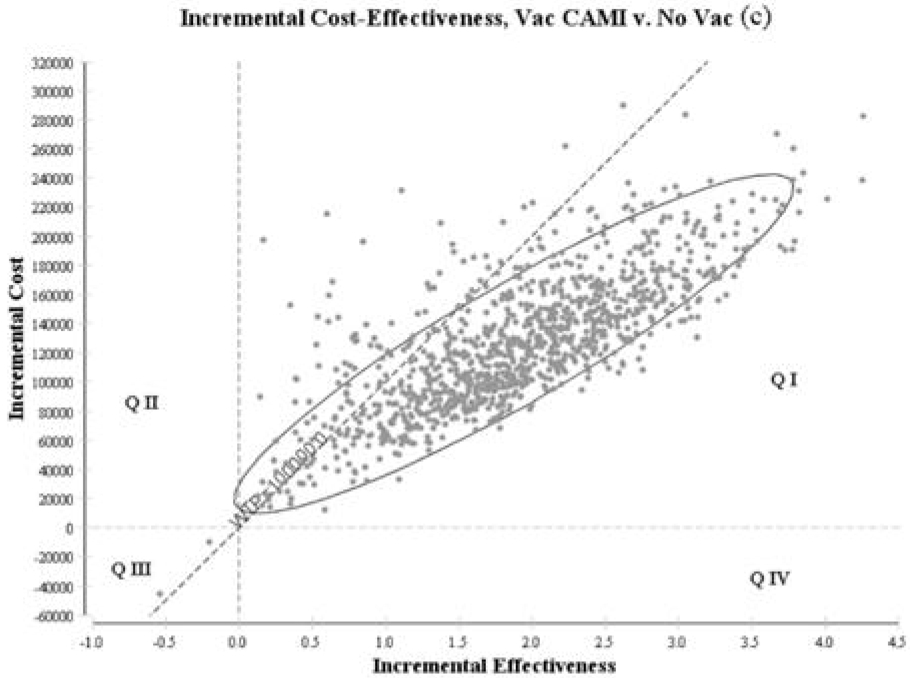


Figure 4. The ICE scatterplot graph (**a**) influenza vaccination vs. no influenza vaccination (**b**) influenza vaccination in angina patients vs. no influenza vaccination, and (**c**) influenza vaccination in CA/MI patients vs. no influenza vaccination

expensive comparing with no vaccination would be recommended (vaccination in all CHD).

The Acceptability Curve depicted in **Figure 5** shows percentage of iterations cost-effective at 90.3%, 8.3%, and 0.14% for influenza vaccination

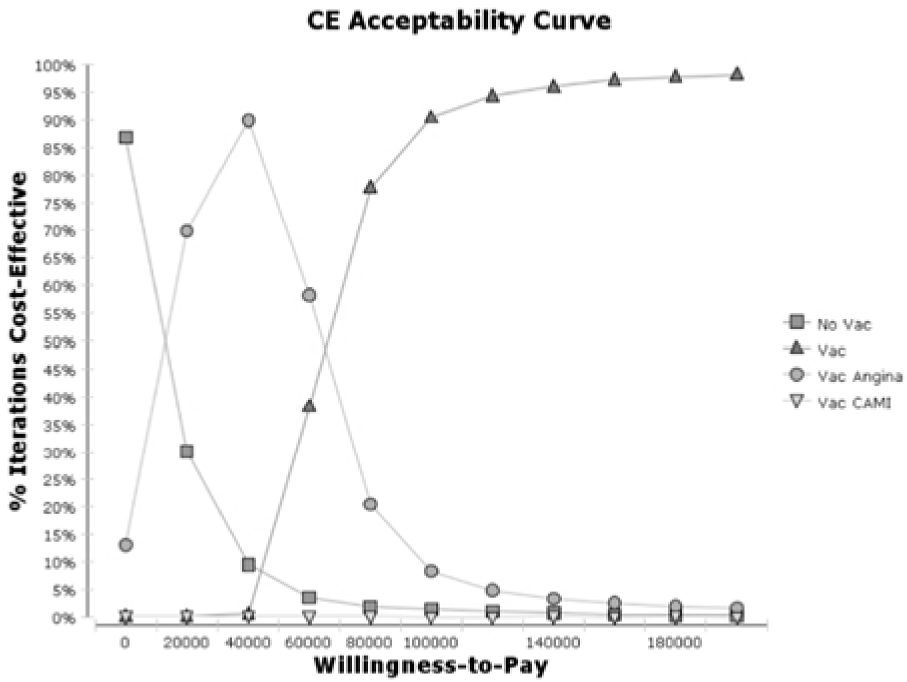


Figure 5. Monte Carlo simulation CE acceptability curve

to all CHD groups, angina patients-only, and no vaccination, respectively, given a WTP of 100,000 THB.

Discussion

Because of the novel 2009 influenza pandemic, public health policy has extended the influenza vaccination program to cover the broader high risk groups. The program allocated 1,798,872 influenza vaccine doses to a high risk population and the uptake was 1,366,724 doses (75.98%) [21]. The underutilization of vaccine suggested that high risk patients and healthcare providers are not fully aware of the influenza vaccine benefit. Therefore, the cost-effectiveness result from economic evaluation should be disseminated to healthcare providers so that they are fully aware of influenza vaccine benefit and would therefore then recommend influenza vaccination to their CHD patients.

Though the results of influenza vaccine benefit to CHD patients are clearly demonstrated from economic modeling, primary data in the Thai population would be required in order to provide a solid recommendation at national policy level. In particular, to implement an influenza vaccination strategy to all CHD patients would require about 1.8 million vaccine doses annually [22, 23], which would highly impact the health budget. As such, primary economic research is recommended to support decisions at a policy level.

Like any model-based evaluation, our study synthesized data from multiple sources with assumptions when data were incomplete or unavailable. In addition, influenza vaccine effectiveness data were drawn from foreign patients as data in Thai patients were not available. Other limitation is that the cost data related to CHD were obtained from single source, being a tertiary care hospital that might not well represent the overall costs for Thailand as well as the data for vaccine effectiveness in preventing influenza events was also used a surrogate for influenza (ILI) instead of the laboratory confirmed influenza infection.

There are number of pharmacoeconomic evaluations (PEs) conducted in other population group, but not specifically in CHD patients. Therefore, direct comparison with other PEs could not be performed. Comparing to other PEs in the high risk population, a consistent cost-effectiveness was demonstrated. However, those PEs were mainly conducted in developed countries where healthcare and living costs are higher than in Thailand. There is only one PE in South East Asia, but the study population was chronic obstructive pulmonary disease whose disease is severe and symptoms are directly impacted by influenza infection.

The PE clearly shows a higher lifetime cost effectiveness in all CHD groups and angina patients. As CA/MI patients are likely to get more severe cardiac event/complications and death; therefore, vaccine prioritization during a pandemic may need to include a short-term benefit and severity complication of CA/MI patients into the consideration.

CHD progression is increased by age, which leads to a different health benefit to patients at a specific age. Therefore, age specificity should be considered for future PEs of CHD influenza vaccination.

As a result, if future primary research specific in the Thai population and/or specific research in CHD patients at different disease severities are conducted, those future results may be used as input parameters into this economic model and/or to adjust the model for future economic evaluation.

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