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Original Article

Cost-effectiveness analysis of single-dose or 2-dose of bivalent, quadrivalent, or nonavalent HPV vaccine in a low/middle-income country setting

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ABSTRACT

Objective: To compare the health impact and economic benefits among individuals who did not receive the human papillomavirus (HPV) vaccine to those who received a single dose, or 2 doses. The comparison was stratified by 4 types of vaccine in conjunction with primary HPV screening in a low/middle-income country setting.
Methods: A Markov model was employed to simulate HPV infection and cervical cancer in a cohort of 100,000 12-year-old girls free of HPV. The study scrutinized 9 strategies: 1 dose and 2 doses of 2vHPV (Cervarix®), 2vHPV (Cecolin®), 4vHPV (Gardasil®), 9vHPV vaccine (Gardasil9®), and no vaccination. The primary outcome measure was the quality-adjusted life year (QALY) of each strategy. Incremental cost-effectiveness ratios were estimated over a lifetime horizon, accompanied by sensitivity analyses conducted.
Results: All vaccination programs yielded 41,298–71,057 QALYs gained accompanied by cost savings of 14,914,186–19,821,655 USD compared to no vaccination. Administering 2 doses of 9vHPV vaccine emerged as the most cost-effective strategy, boasting 406 USD/QALY, within a lower willingness to pay threshold. Sensitivity analysis demonstrated an 80% probability of the cost-effectiveness of the 2 doses of 9vHPV vaccine regimen. Furthermore, uncertainty around the costs of vaccination and vaccine efficacy exerted the most substantial influence on the cost-effectiveness findings.
Conclusion: Oping for 2 doses of 9vHPV vaccine in conjunction with a primary HPV screening represents the most cost-effective option for implementing a school-based HPV vaccination program targeting 12-year-old girls in Thailand. Such findings provide valuable insights for policymakers in the realm of cervical cancer prevention.

Keywords: Cost-Effectiveness Analysis; Human Papillomavirus; Lower-Middle-Income Country; Quality-Adjusted Life Years; Uterine Cervical Neoplasms; Vaccination

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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Synopsis
Our study showed 2 doses 9vHPV vaccination for 12-year-old girls is the most cost-effective option. It is associated with an ICER of 406 USD per QALY gained within a lower willingness to pay threshold. Vaccination cost and efficacy are the 2 most influential factors on the result of cost-effectiveness findings.

INTRODUCTION

Cervical cancer ranks as the 3rd most frequent cancer among women in Thailand [1]. Current estimates indicate that every year almost half of women diagnosed with cervical cancer die from the disease (4,705 out of 9,158 women). The main cause is the persistent infection with high-risk (HR) types of the human papillomavirus (HPV). However, the major reason for high mortality is the delay in diagnosis which is associated with more advanced stage. The combination of HPV vaccination and cervical screening provides against cervical cancer. The vaccine does not only protect individuals against infection by the HPV types targeted by the vaccine, but it can also protect possibly other types (cross-protection) and reduce infection in individuals who are not vaccinated (herd immunity) [2]. Bivalent (2vHPV) and quadrivalent (4vHPV) vaccines address approximately 70% of cervical cancers through protection from HPV16 and HPV18. The nonavalent (9vHPV) vaccine contains 5 additional HPV types (31, 33, 45, 52, 58) to the 4vHPV vaccine and offers the potential to increase overall protection from 70% to approximately 90% [2,3]. The result from the phase III study showed that the 9vHPV vaccine prevented infection and disease related to HPV 31, 33, 45, 52, and 58 in a susceptible population and generated an antibody response to HPV 6, 11, 16, and 18 that was non-inferior to that generated by the 4vHPV vaccine [4]. Despite strong evidence of high effectiveness of HPV vaccination, vaccine coverage of most Asian countries was very low. Vaccine coverage in Indonesia, Philippines, and Singapore ranged from just 0.1% to 0.7%. In India, a recent study for 11-year-old girls in Punjab state found that HPV vaccination appeared highly cost-effective, however, their national coverage is still low. In Thailand, a pilot vaccination program from 2014–2016 showed 91% of 12,500 girls aged 11 years in Ayutthaya province received at least 2 doses of HPV vaccine with excellent safety and high acceptability.[5]

Cost-effectiveness analysis (CEA) of the 9vHPV vaccine compared with either 2vHPV or 4vHPV in the national school-based program has been evaluated in several countries in Asia [5-8]. All the studies showed that 9vHPV had the highest impact in terms of reducing the incidence of cervical cancer and cancer-related deaths. Given the regional difference in HPV prevalence, screening programs, vaccination strategies, and gross domestic product, the results of the economic impact analysis were not the same. The 9vHPV vaccination with a routine screening program showed a cost-effective alternative to 4vHPV in Japan [6]. The study from Taiwan also showed that the 9vHPV was more cost-effective than the 2vHPV vaccination [7]. However, in China, among 3 different vaccines, 4vHPV cost the least and gained almost the same number of QALYs as 9vHPV, while 2vHPV was dominated by 4vHPV due to higher costs and lower effectiveness [8]. The study from Singapore compared 9vHPV and 4vHPV and the result revealed that 9vHPV was unlikely to represent a cost-effective option and a price reduction would be required [9].

Moreover, growing evidence from observational studies indicated similar vaccine protection among those receiving 1 or 2 doses of vaccine [10-13]. The single-dose regimen could make

the program easier and faster, reduce costs, and achieve higher coverage. The economic study comparing one dose of HPV vaccination with 2 doses of vaccination in Uganda found that the lower efficacy of a one-dose schedule could be compensated for by improved coverage if its protection does not wane [14]. A study in a high-income country (UK) reported that a single dose of 9vHPV vaccination program was not likely to be cost-effective compared to a 2-dose program. The results were robust under the assumption regarding the properties of one dose regimen, cost, coverage, and the uncertainty of degree and duration of protection [15].

In Thailand, it has been proven that HPV vaccination (4vHPV) was more cost-effective than no vaccination program [16]. Therefore, the 4vHPV vaccine was introduced into Thailand's national immunization program in 2017. The current school-based HPV vaccination program includes 2 doses of 2vHPV or 4vHPV vaccine, only for girls at 11–12 years of age. Given the high prevalence of HPV 58, 52, and 45 in Thailand, the potential for cancer prevention would be raised if other HR HPV types were also targeted by the HPV vaccine [17]. Nowadays, 4 types of HPV vaccines are available in Thailand: bivalent (Cervarix®; GlaxoSmithKline, Brentford, UK), bivalent (Cecolin®; Innovax, Xiamen, China), quadrivalent (Gardasil®; Merck & Co, Rahway, NJ, USA), and nonavalent (Gardasil9®; Merck & Co). This study aims to determine the health impact and the economic benefit of one and 2-dose 9vHPV vaccination compared with 2vHPV and 4vHPV vaccination programs along with primary HPV screening to inform the policy maker about local vaccination strategies and funding decisions in Thailand.

MATERIALS AND METHODS

1. Model overview

A natural history of HPV infection and progression to cervical cancer was converted into a Markov model (**Fig. 1**). The economic consequences were estimated from the provider or healthcare perspective. The model consisted of 8 health states; healthy (susceptible), HPV infection, genital wart or cervical intraepithelial neoplasia (CIN) 1, CIN2/3 cancer, and post-treatment cancer, cured from cancer and death. HPV genotypes were divided into 4 classes which were low-risk HPV infection (HPV 6/11), HPV 16, HPV 18, and others HR HPV infection. CIN1 and, CIN2/3 were modeled as different states due to different rates of progression to cancer and different treatment methods. Each stage of cervical cancer (I–IV) was defined by the International Federation of Gynecology and Obstetrics (FIGO) 2009. A hypothetical cohort of 100,000 HPV-free girls at 12 years old was simulated and followed up until death. Each strategy modeled probabilities for mutually exclusive health states within a one-year cycle. Post-treatment cancer stage was a stage where patients received and responded to treatment for cancer. They would enter the cured form cancer state if stay in their current state for 10 years or more. Patients with a cure of cancer stage would be no longer followed up until expired. Non-cervical cancer (oropharyngeal, anal, and vulvar cancer) was not included in this study. The incidence rate, mortality rate, and probabilities of annual transition in each stage were derived from previous published literature and expert opinions (**Table S1**) [8,15,16,18-32].

2. Model parameters

Cervical screening program and HPV vaccination

The screening program used in this model was the primary HPV testing according to a recent recommendation by The Royal Thai College of Obstetricians and Gynaecologists [33]. It has proven to be the most cost-effective strategy in our country [34]. The target for screening

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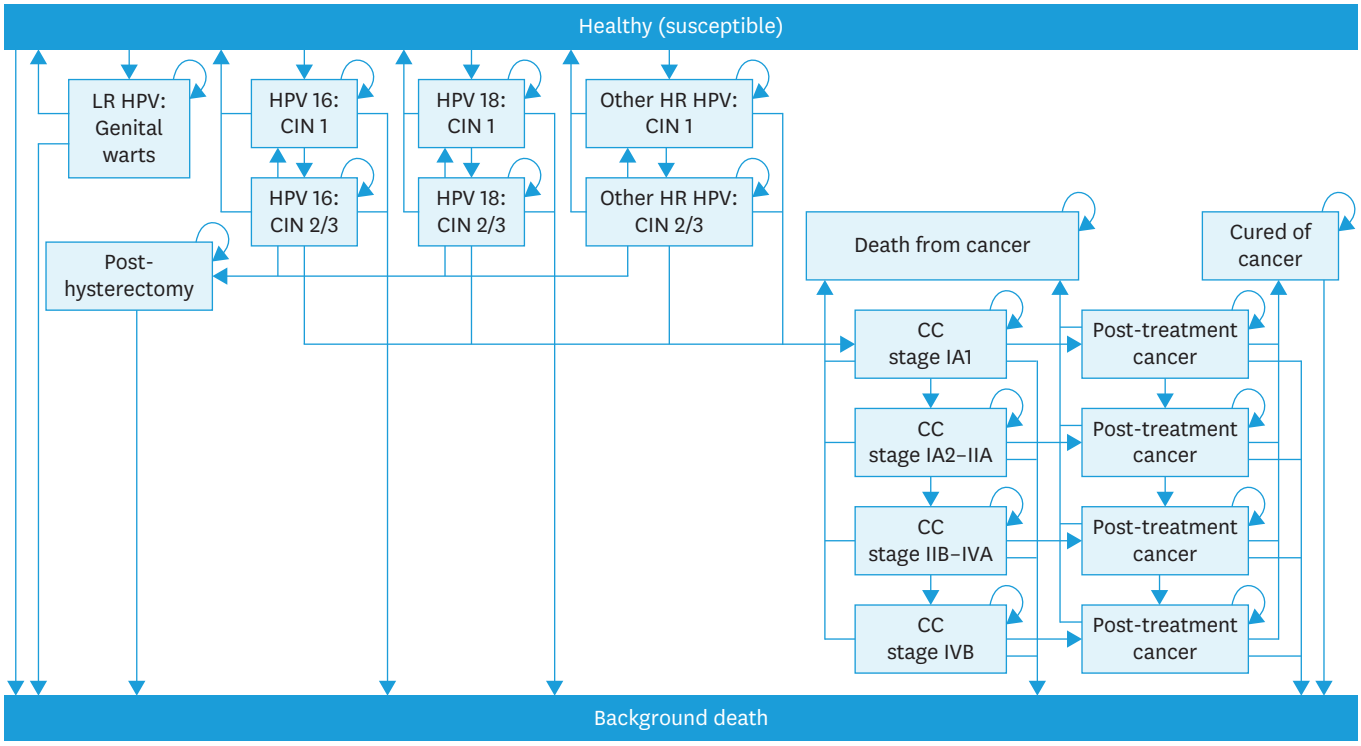

Fig. 1. A Markov model of natural history of HPV infection and progression to CC.
CC, cervical cancer; CIN, cervical intraepithelial neoplasia; HPV, human papillomavirus; HR, high risk; LR, low risk.

was women at 30–65 years of age followed by 5-yearly screening upon negative test results. A screening coverage rate was 53.9% which was derived from the survey of the National Cancer Institute, Ministry of Public Health [27]. We compared 9 vaccination options which were 2 doses and 1-dose of 2vHPV (Cervarix®), 2vHPV (Cecolin®), 4vHPV (Gardasil®), newly developed 9vHPV vaccine (Gardasil9®) and no vaccination. Vaccine efficacy was calculated by multiplying the direct efficacy targeting specific HPV types by genotype coverage reported in Thailand to derive vaccine efficacy data specific to the Thai population. Due to no head-to-head study available, the direct protective efficacy of both 2vHPV and 4vHPV vaccines against HPV 16, 18 was equivalent and set at 0.949 which was consistent with published CEA studies [9,35]. The cross-protection effect was not analyzed in this study.

In the base case, analysis, all types of vaccines were assumed to provide lifelong direct protection. The vaccine efficacy of the 2-dose regimen was non-inferior to the efficacy of the 3-dose regimen in girls aged 10–18 years [10]. The coverage rate will be assumed at 90% according to World Health Organization guidelines. The relative efficacy of 1-dose vaccination compared to 2-dose vaccination was 0.928 which was retrieved from a published health economic analysis of HPV vaccination [15].

Cost estimates and health utilities

We used only direct medical costs which included the cost of vaccination, screening, treatment, and follow-up of HPV-related diseases (**Table 1**). The costs of these parameters were referenced from our previous articles [16] and then inflated to reflect value in 2023, except 9vHPV vaccine. The costs of the 9vHPV vaccine were calculated based on procurement price. Health utilities were a measure of the quality of life and ranged from 0 (equal to death)

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Table 1. Base case results of health impact

Strategies	Incidence of HPV-related disease and deaths per 100,000 women		
	Genital wart	Cervical cancer	Deaths
No vaccination	240.7	25.8	16.5
One-dose vaccination program			
2vHPV (Cervarix®)	219.2	11.9	7.6
2vHPV (Cecolin®)	219.1	11.1	7.2
4vHPV (Gardasil®)	49.4	11.9	7.7
9vHPV (Gardasil9®)	49.8	4.7	3.0
Two-dose vaccination program			
2vHPV (Cervarix®)	217.5	10.8	7.0
2vHPV (Cecolin®)	217.5	10.0	6.4
4vHPV (Gardasil®)	34.5	10.8	7.0
9vHPV (Gardasil9®)	34.7	4.7	3.0

HPV, human papillomavirus.

to 1 (equal to perfect health) which were obtained from the quality-of-life assessment in Thai patients with cervical disease. Health benefits were assessed in terms of the quality-adjusted life-years (QALYs). An annual discount rate of 3% was applied to all future costs and QALYs.

CEA

The primary outcome was the incremental cost-effectiveness ratio (ICER) of each strategy, determined by an incremental cost per quality-adjusted life year (QALY) gain. The interpretation of ICER was based on the Thai willingness-to-pay (WTP) threshold of 160,000 Thai baht (THB) per QALY gained (1.2 times of gross national income per capita per QALY gained) for reimbursing new life-saving treatment [36].

Sensitivity analysis

Due to uncertainty in several parameters, a one-way sensitivity analysis was performed. The efficacy of vaccines, coverage of screening, cost of vaccination, follow-up activity, and treatment varied by ±20% (**Table S1**). A probabilistic sensitivity analysis was conducted based on 10,000 simulations to identify the probability of being a cost-effective strategy compared with all others. Model simulation and sensitivity analysis were conducted using Excel version 16.76. Institutional Review Board approval was not required for this article.

RESULTS

1. Base case results

Table 1 shows the cumulative number of genital warts cases, CIN cases, cervical cancer cases, and deaths per 100,000 women over a lifetime horizon. Compared with no vaccination program, all vaccination programs decrease the incidence of cervical cancer cases and cancer-related deaths by 49.6%–79% and 18.9%–79%, respectively. The model estimated that the 2-dose 9vHPV vaccination program was the most effective strategy in reducing of incidence and mortality rate of cervical cancer. It would prevent an additional 2,982 cervical cancer cases and 395 deaths per 100,000 women compared with no vaccination.

The costs, QALYs, and ICERs for the vaccination strategies were evaluated and were presented in **Table 2**. All vaccination programs resulted in 41,298–71,057 QALYs gained with a cost saving of 508,722,900–676,116,662 THB (14,914,186–19,164,655 USD) compared to no vaccination, mainly due to the decrease in number of cervical cancer cases and deaths. From

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Table 2. Base case results of costs, QALY, and ICER

Vaccine	Total costs (THB)	Total effectiveness (QALYs)	ICER (THB/QALY)
No vaccination	1,275,254,643.40	2,849,818.32	Dominated
2vHPV (Cervarix®; 1-dose)	766,531,743.04	2,891,116.77	Extended dominated
2vHPV (Cecolin®; 1-dose)	731,301,403.95	2,893,482.58	−12,457.63
2vHPV (Cervarix®; 2-dose)	754,531,827.09	2,894,586.67	Extended dominated
4vHPV (Gardasil®; 1-dose)	741,550,516.55	2,896,167.53	Extended dominated
2vHPV (Cecolin®; 2-dose)	712,464,941.82	2,897,167.51	Extended dominated
4vHPV (Gardasil®; 2-dose)	737,265,894.92	2,900,096.26	Extended dominated
9vHPV (Gardasil9®; 1-dose)	530,301,579.64	2,920,394.72	−6,101.48
9vHPV (Gardasil9®; 2-dose)	678,562,456.24	2,920,875.77	13,855.56

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life year; THB, Thai baht.

the incremental analysis, 2 doses of 9vHPV vaccine were the most cost-effective strategy with an ICER of 13,855.56 THB (406 USD)/QALY.

2. Sensitivity analysis

Fig. 2 shows the results of probabilistic sensitivity analysis in the cost-effectiveness plane. Compared to a 1-dose 9vHPV Vaccine, most iterations showed additional costs and cost-saving for a 2-dose 9vHPV vaccine.

The cost-effectiveness acceptability curve is displayed in **Fig. 3**. If WTP is equal to 160,000 THB/QALY, 2 doses of 9vHPV vaccine is the most likely strategy to be considered cost-effective with a probability of 80%. The univariate sensitivity analysis, displayed as a tornado diagram, was presented in **Fig. 4**. The considered outcome was an ICER of 2 doses compared to one dose vaccination of 9vHPV. The costs of vaccination and vaccine efficacy caused the largest variation in the cost-effectiveness findings. Vaccination cost was found to affect the ICER

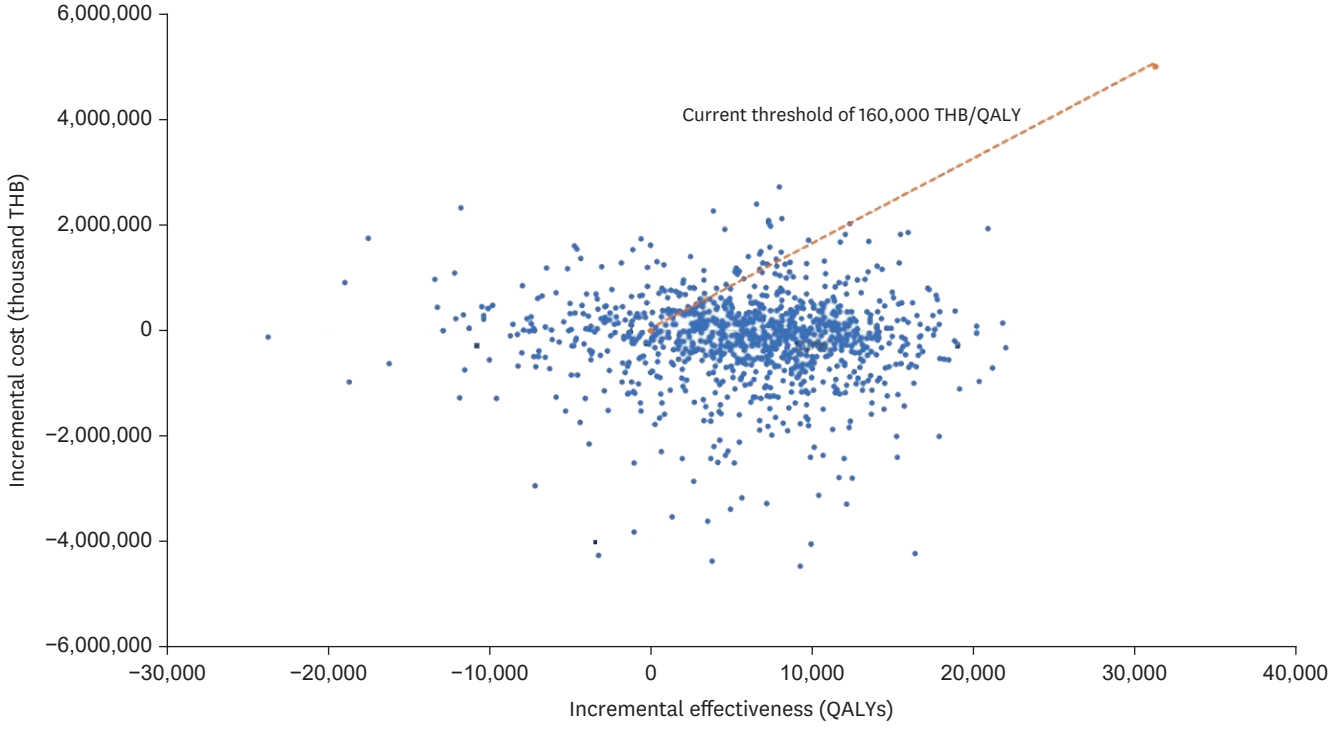

Fig. 2. Cost-effectiveness acceptability curve.
QALY, quality-adjusted life year; THB, Thai baht.

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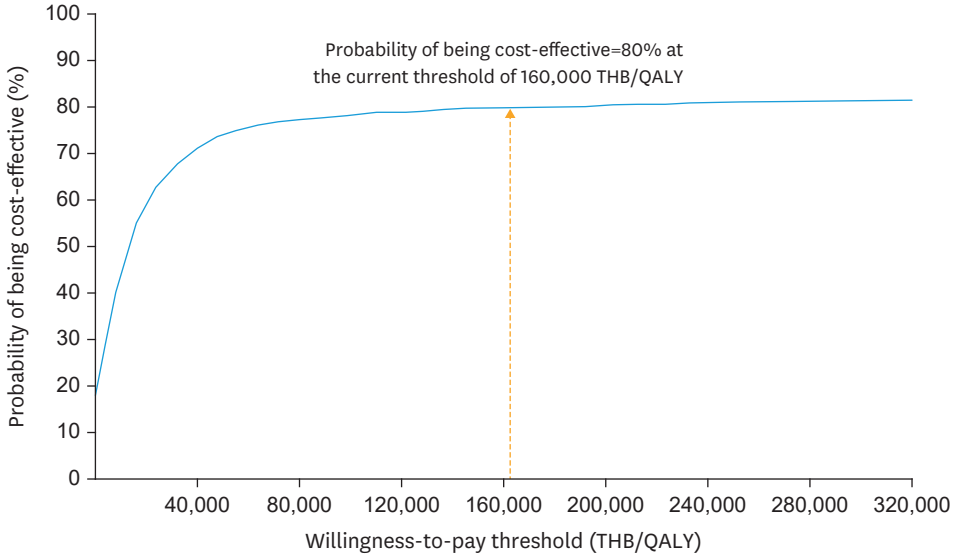

Fig. 3. A series of 1-way sensitivity analyses comparing 1-dose to 2-dose 9vHPV vaccine.
HPV, human papillomavirus; QALY, quality-adjusted life year; THB, Thai baht.

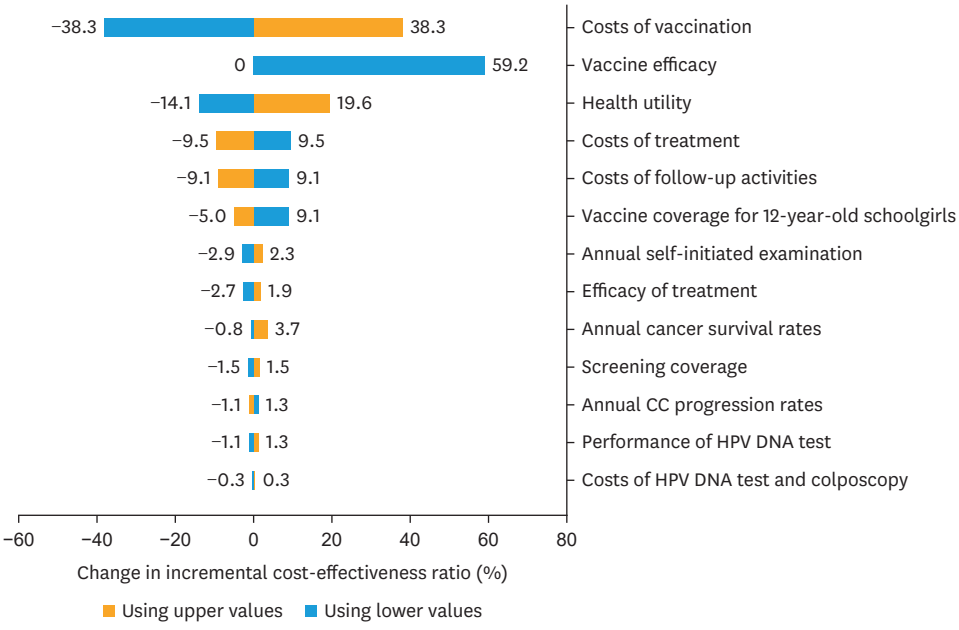

Fig. 4. Probabilistic sensitivity analysis of the incremental cost-effectiveness ratio for 2-dose compared to one-dose 9vHPV vaccine presented on the cost-effectiveness plane.
CC, cervical cancer; HPV, human papillomavirus.

with a 38% increase or decrease if the price changes by ±20%. When vaccine efficacy was decreased by 10%, ICER was increased to 22,029 THB which was the highest value (increase 59%) in this analysis.

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DISCUSSION

In this study, we found that 2 doses of 9vHPV vaccine for all adolescents at the age of 12 years was the most cost-effective strategy with an ICER of 13,855.56 THB (406 USD) compared to 1 dose of 9vHPV vaccination. In comparison to the current recommendation in Thailand (2 doses of 4vHPV vaccine), the strategy of 2 doses of 9vHPV vaccination was more effective and less costly (cost saving). This may be explained by the result of the best health impact of this strategy on reducing both cervical cancer incidence and mortality rate. Our results were consistent with previous health economic analyses in Thailand which also supported the use of prophylactic 4vHPV vaccination [16,19]. However, an ICER of 4vHPV vaccination compared to no vaccination in each study was varied due to the difference in methodology and input parameters. The first study in 2012 reported an ICER of 160,649.50 THB/QALYs [16]. After that study was published, the 4vHPV vaccine was introduced into Thailand's national immunization program in 2017. The cost of vaccination has drastically fallen. The 4HPV vaccination program was more cost-effective due to the lower cost of care. Recently, the cost-effectiveness of routine 4vHPV vaccination along with screening, and routine 4vHPV vaccination along with catch-up 4vHPV vaccination and screening, compared with no vaccination (cervical screening only) was evaluated [19]. The estimated cost per QALY gained (ICER) when compared to no vaccination in Thailand was 8,370 THB/QALY for the routine vaccination and 9,650 THB/QALY for the routine with catch-up vaccination strategy, whereas our study showed all vaccination programs were cost-saving strategies compared to no vaccination. We included HPV DNA-based cervical screening in the Markov model. It may improve the cost-effective of the vaccination program.

We also found that 9vHPV could decrease more cases of cervical cancer and death compared to other types of vaccine. One dose and 2 doses of 9vHPV vaccination provided similar effectiveness over a lifetime with 2,920,394.72 QALY and 2,920,875.77 QALY, respectively. The results of the CEA showed both one and 2 doses of 9vHPV were cost-saving compared to no vaccination. This was in line with a prior study in low-income countries [14]. However, the previous study reported that if the duration of protection of one dose did not wane and higher coverage could be achieved, one dose 9vHPV vaccine could be a more effective strategy than 2 doses 9vHPV. In our study, we assumed a lifelong duration of protection of all strategies, one dose of the 9vHPV vaccine was still less effective than 2 doses of 9vHPV. Another study in UK found that the switch to a 1-dose program from 2-dose program is associated with increases in the number of HPV-related cancer cases over 100 years. In terms of cost-effectiveness outcomes, the 1-dose HPV vaccination was not likely to be cost-effective, compared to a 2-dose program. The result of that study was affected by vaccine price, duration of protection for a single dose, and discount rate [15]. The cohort population of study by Daniels et al. [15] was girls and boys aged 13–14 years old. We couldn't directly compare our results to other countries due to the difference in population, several model inputs, costs, and WTP in each county.

Regarding the result of the sensitivity analysis, The ICER was sensitive to the vaccine efficacy and costs of vaccination. It was also congruent with the prior study [16]. Lower vaccine efficacy might affect low QALYs, and high medical costs result in higher ICER. Increased ICER was also associated with vaccination cost which is an easily modified factor. We found that even if the vaccine price per dose increases to 2,031.05 THB (an increase of 20%), the ICER still falls under the WTP (19,162 THB/QALY).

This is the first study in Thailand that included the 2-valent vaccine, 4-valent vaccine, 9-valent vaccine, and 1-dose vaccination. We developed a model through the collection and selection

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of appropriate data to represent our country's epidemiological and economic context as much as possible. Nevertheless, some limitations need to be interpreted cautiously. First, we did not consider cross-protective effects and herd immunity. Second, only genital warts, precancerous cervical lesions, and cervical cancer were considered in our model. Several studies have demonstrated that vaccine also reduces the risk of other HPV-related cancers such as vulvovaginal cancers, oropharyngeal cancer, and anal cancer [37-39]. These could underestimate the overall vaccine effectiveness and make the cost-effectiveness of each strategy less favorable. Third, we calculated only direct medical costs from the perspective of healthcare. Lastly, some parameters that could not be found from local utility data were estimated from China's studies. It is uncertain whether data from China's population may be generalizable to our country. It may limit the validity of the results.

Several countries have recommended HPV vaccination for males and females through the age of 26 years (catch-up program) as the evidence showed it could decrease the incidence of HPV-related genital warts and HPV-related cancers. In addition, HPV vaccination has also reduced the risk of recurrence of high-grade cervical dysplasia [40]. Future research should focus on expanding the accessibility of the vaccine to other populations and assess the effect of various durations of protection.

In conclusion, this study indicated that the administration of 2 doses 9vHPV vaccine for all adolescents at age 12 years along with a primary HPV test for screening program was the most cost-effective strategy. This finding will be useful in informing decision-makers about the better option to improve national cervical cancer policy.

SUPPLEMENTARY MATERIAL

Table S1
Key model input

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