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A systematic review of economic evaluation of sequential of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccine in elderly people

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ABSTRACT

This research aimed to conduct a systematic review of studies that involve the administration of sequential pneumococcal vaccines from an economic perspective. The relevant published economic evaluations were sourced from PubMed, ScienceDirect, Cochrane Library, Scopus, and Health Intervention and Technology Assessment Program databases. This review included national and international literature published between 2012 and 2019. The quality of the research was evaluated using the consolidated health economic evaluation reporting standards checklist. Four studies that met the inclusion criteria were included in this research work. The results showed that sequential vaccination was more cost effective than a single dose of 23-valent pneumococcal polysaccharide vaccine (PPV23), which contrasted with the recommendations of Advisory Committee on Immunization Practices 2019 and Centers for Disease Control and Prevention 2020. The factors determining the economic value of these vaccines are the effectiveness of the vaccine, the coverage of the pneumococcal vaccination in childhood, indirect effects of the pneumococcal vaccination in children that can reduce the incidence of disease, and the incidence of invasive pneumococcal disease or non-bacteremic pneumococcal pneumonia in the elderly. Administering a sequence of vaccinations in the elderly may be more appropriate and beneficial than providing only a single dose of PPV23 vaccine, because of the generally low vaccination coverage of 13-valent pneumococcal conjugate vaccine during childhood. This study may be used as a basis for decision making on the pneumococcal vaccination recommendation for the elderly in Thailand.

Keywords: economic evaluation; 13-valent pneumococcal conjugate vaccine; 23-valent pneumococcal polysaccharide vaccine

1. INTRODUCTION

Streptococcus pneumoniae is a gram-positive bacterium that has 90 serotypes. Patients with upper respiratory tract infection could serve as the carrier of this bacterium and therefore spread it to other people through droplets or nasal mucus. *Streptococcus pneumoniae* is the cause of non-invasive pneumococcal disease (non–IPD), such as pneumonia and sinusitis, and IPD, such as septicemia and meningitis (Centers for Disease Control and Prevention, 2019). In 2012, a report from the Centers for Disease Control and Prevention (CDC) regarding deaths from *Streptococcus pneumoniae* infection stated that the estimated mortality rate of the infection stood at 4,000 people per year. There were 36.4 cases of severe infections out of 100,000 people (Bennett et al., 2012), particularly, in patients aged 65 years or above. In European countries, it was reported in 2017 that the incidence of severe infections in people aged over 65 years was approximately 18.9 per 100,000 people (European Center for Disease Prevention and Control, 2017). In Thailand, a report from the Bureau of Epidemiology, Department of Disease Control, Ministry of Public Health in October 2019 commented that in each region of the country, there were 34.11% patients with pneumonia in the patient group aged over 65 years, which was considered as the largest group of all ages (Department of Disease Control, 2019). The results from the abovementioned report demonstrates that even though the *Streptococcus pneumoniae* infection is not very high as compared to the total population, it is still the cause of death of thousands of patients per year, and it is also the most prevalent morbidity among the elderly.

There are many methods such as maintaining hygiene and avoiding direct contact with infected patients, to prevent diseases caused from *Streptococcus pneumoniae* infection. However, the best method to prevent infection is through vaccination against infectious diseases (Centers for Disease Control and Prevention, 2017). Receiving vaccinations for diseases caused by *Streptococcus pneumoniae* is not only a means to protect oneself, but also creates a passive immunity for the whole society (Centers for Disease Control and Prevention, 2019). Additionally, studies have shown that receiving pneumococcal vaccines can reduce the mortality rate caused by pneumonia in the elderly (Jung et al., 2018) and prevent the occurrence of severe diseases after infection that may lead to death (Phongphet and Wiratsaengthong, 2019). At present, there are two types of vaccines against diseases from *Streptococcus pneumoniae* infection available in Thailand. The first one is 23-valent pneumococcal polysaccharide vaccine (PPV23), which is relatively safe. Patients may experience side effects, for example, pain, swelling, and redness at the injection site, but the symptoms are usually mild and will disappear on their own (National Center for Immunization Research and Surveillance, 2018). This vaccine also effectively prevents IPD; however, it has a little effect in the prevention of non–IPD (Leventer-Roberts et al., 2015). Another vaccine used against diseases caused by *Streptococcus pneumoniae* infection in Thailand is 13-valent pneumococcal conjugate vaccine (PCV13). This vaccine was developed from PPV23 by placing polysaccharide antigens on to a capsule of the germ. This compound then combines with protein carriers to change the antigen into a T-dependent antigen, which leads to the stimulation of immunological memory in the vaccine receiver. This type of immunity lasts longer than that produced by the PPV23, thereby making the administration of PCV13 advantageous over the PPV23 in this aspect (Chokephaibulkit et al., 2013). Additionally, PCV13 vaccine results in passive immunity. People receiving PPV23 tend to have a shorter carrier period that reduces the chances of spreading the infection to non-vaccinated populations (Oberdorfer, 2019). The comparison of the effectiveness of the PCV13 and PPV23 vaccines in people aged over 50 years showed that PCV13 stimulates a better response from the immune system as compared to PPV23 (Centers for Disease Control and Prevention, 2013; Shiramoto et al., 2015; Jackson et al., 2013a; Jackson et al., 2013b).

In addition to considering the effectiveness of the vaccines in stimulating the immune system to prevent disease, the different methods of administering the vaccines also need a proper evaluation. A sequential vaccination pattern, in which people receive their first vaccine and then re-immunize by injecting the second vaccine at least one year apart for most immunocompetent adults, and at least 8 weeks apart for adults with certain medical conditions (two-step vaccination), can stimulate more immunity than a single dose of vaccination (Peterson et al., 2019). Therefore, the most effective way to increase the efficiency of the vaccination in the elderly is to first administer the PCV13, followed by the PPV23 within a year (Jackson et al., 2013b; Greenberg et al., 2014; Jackson et al., 2013c). The recommendations made by the Advisory Committee on Immunization Practices (ACIP) in 2014 were based on these factors (Tomczyk et al., 2014). However, the ACIP and the CDC changed their vaccination recommendation for the elderly in 2019 and 2020, respectively. They now encourage senior populations to receive only a single dose of PPV23 vaccine, citing economic efficiency as the reason, because they consider a single dose of PPV23 to be more economically worthwhile than receiving sequential vaccines. However, after reviewing the relevant literature, it was found that some studies opposed the ACIP recommendations of 2019 and detected that sequential vaccinations have more economic worthiness than a single dose of vaccines (Atwood et al., 2018; Heo et al., 2017). This study attempted to systematically review the research with respect to the economic worthiness of administering PCV13 and PPV23 in various sequences in adults aged 65 years and above. The results of this study might be used to make decisions while choosing suitable and economically worthwhile sequential vaccination methods for the elderly.

2. MATERIALS AND METHODS

This study was conducted in accordance with the procedures of the preferred reporting items for systematic reviews and meta-analyses (PRISMA) (Moher et al., 2009). Importantly, these accredited guidelines of economic evaluation were applied while conducting this study.

2.1 Literature search

The study was introduced by using PICOS tool (population, intervention, comparators, outcomes, and study) criteria:
P (Population): adults aged 65 years and above,
I (Intervention): sequential vaccination in receiving PCV13 followed by PPV23,

C (Comparison intervention):
-sequential vaccination in receiving PCV13 followed by PCV13,
-sequential vaccination in receiving PPV23 followed by PPV23,
-sequential vaccination in receiving PPV23 followed by PCV13,
-receiving either PCV13 or PPV23,
-no vaccination,
O (Outcome): cost per quality-adjusted life years (QALYs), cost per life years gained (LYGs), cost per disability-adjusted life year (DALYs), cost per benefit, and costs,
S (Study design): economic evaluation.

The studies used in the evaluation were sourced from the following five databases: PubMed, ScienceDirect, Cochrane Library, Scopus, and Health Intervention and Technology Assessment Program (HITAP). Articles for consideration were restricted to those published in English or Thai language.

2.2 Screening process of study selection

2.2.1 Inclusion criteria

The selection criteria for research to be considered for inclusion in this study were as follows: (1) studies conducted between the years 2012 and 2019; (2) studies defined as economic evaluations of administering the following sequential vaccinations to adults aged 65 years and above: PCV13 followed by PPV23, PCV13 followed by PCV13, PPV23 followed by PPV23, PPV23 followed by PCV13, PCV13 or PPV23 only, and no vaccination.

In July 2019, working independently, the researchers initially selected studies that met the inclusion criteria by searching titles and abstracts. The researchers then reviewed the full work of the selected studies and re-evaluated them by applying the eligibility criteria again.

2.2.2 Exclusion criteria

Exclusion criteria included studies that were not published in English or Thai language**,** studies that were review articles or comments, and studies that investigated other vaccination sequences**.**

2.2.3 Data extraction

Data extraction was performed by two independent researchers (T. M. and K. R.) Information was collected based on the year of publication, location of the study, perspective, model type, study horizon, discount rate, definitions of pneumococcal diseases, vaccine strategies, incremental cost-effectiveness ratios (ICERs), LYGs, QALYs, and DALYs.

2.2.4 Assessment of reporting quality

Two independent researchers (P. S. and T. M.) evaluated the quality of all the selected research works by using the consolidated health economic evaluation reporting standards (CHEERS) checklist (Husereau et al., 2013), which comprised a 24-item checklist divided into the following six topics: title and abstract, introduction, methods, results, discussion, and others (source of funding and conflict of interest). Each item on the CHEERS checklist was marked as follows: “yes” indicating that it was presented in the research being considered, “no” indicating that no details or criteria were found on that topic, “partially met” indicating that it was not adequately reported, “not applicable” indicating that no details were found or details were found to be irrelevant. Disagreements that arose over whether to include a study or not were resolved by consensus following a further and joint examination of the concerned work.

3. RESULTS AND DISCUSSION

3.1 Literature search and screening

Figure 1 shows a PRISMA flow diagram illustrating the process by which studies were selected. A total of 3,014 studies conducted between the years 2012 and 2019 were searched in the Thai electronic database that included HITAP. The English language electronic databases searched were PubMed, ScienceDirect, Cochrane Library, and Scopus. Searches were conducted by using MeSH terms and by searching freehand. In total, 16 studies were found to be eligible to be screened for basic information. Of these studies, 4 studies were remaining after excluding the articles that were not meet the inclusion criteria.

3.2 Assessment of reporting quality

The CHEERS checklist divided the main topics in the evaluation into six topics, namely, title and abstract, introduction, methods, results, discussion, and others. The results of the research quality assessment are presented in Figure 2. Overall, 80% of the 4 studies were marked as “yes.” Only 34% reported “partially met” and 17% of the studies were marked as “not applicable”.

3.3 Reporting the data

Table 1 provides information on the selected studies, including authors, publication year, study type, study location, perspective, model type, time horizon, discount rate, clinical outcome, comparison of vaccination strategies, and economic outcomes. Two studies were conducted in South Korea by Choi et al. (2018) and Heo et al. (2017), respectively. The other two studies were performed in the United States by Smith et al. (2013) and in Canada by Atwood et al. (2018), which found that two research works had collected costs through a societal perspective and another two research works had collected costs through a health care perspective. Three of the studies compared the sequential administration of vaccines (PCV13 followed by PPV23), with the administration of just a single dose of PPV23. The remaining study compared the strategy of administering multiple vaccines in different sequences such as comparing the administration of PCV13 followed by PPV23 the administration of PPV23 followed by PPV23. The economic evaluation of administering PPV23 was revealed from the sensitivity (worst-case) analysis.

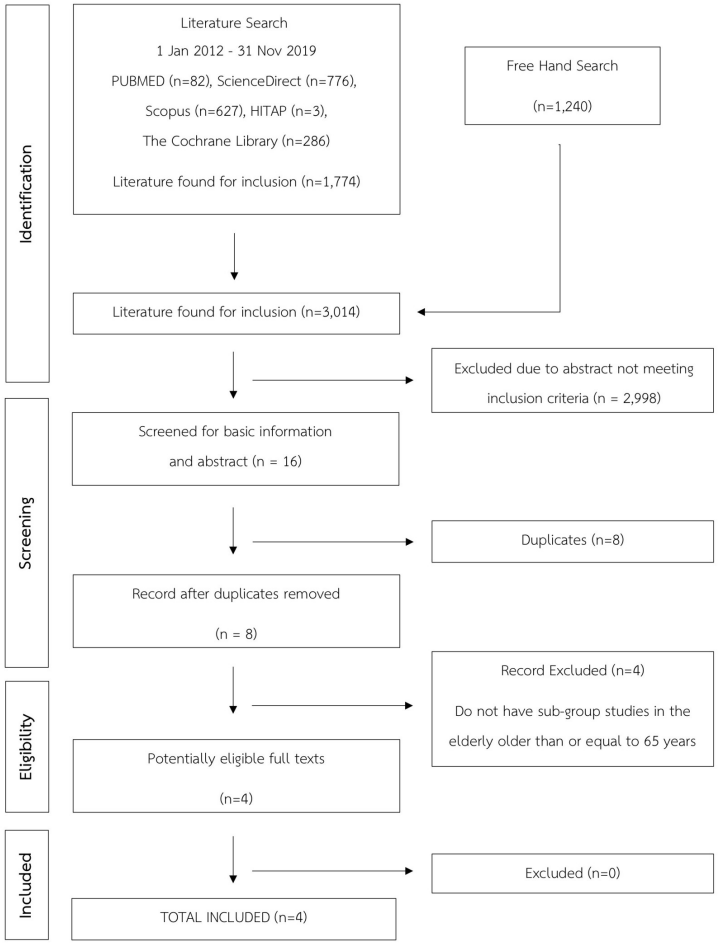

Figure 1. Preferred reporting items for systematic reviews and meta-analysis (PRISMA) flow diagram showing the selection process of studies

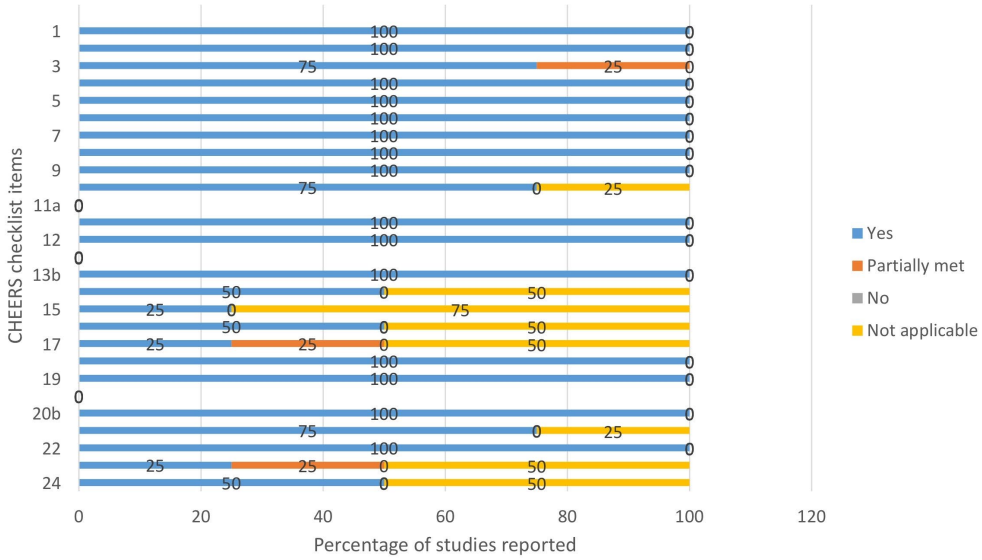

Figure 2. Summary of the reporting quality of included studies by the consolidated health economic evaluation reporting standards (CHEERS) checklist

Table 1. Characteristics of economic evaluations of the 23-valent pneumococcal polysaccharide vaccine (PPV 23), 13-valent pneumococcal conjugate vaccine (PCV13), and sequential administering of 13-valent pneumococcal conjugate vaccine and 23-valent pneumococcal polysaccharide vaccines in adults aged ≥65 years

Authors	Publication year	Study type	Study location	Perspective	Model type	Time horizon	Discount rate	Clinical outcomes	Comparison of vaccination strategies	Economic outcomes
Smith et al. (2013)	2013	CEA[1]	United State	Societal	Markov model	Life time	3%	IPD[3], NBPP[4]	-Sensitivity analysis that ultimately determines the effectiveness of PCV13 to prevent NBPP[4] (worst-case analysis). -PCV13 followed by PPV23 -PPV23 followed by PPV23 -PCV13 followed by PCV13 -PCV13 only, PPV23 only -all 5 patterns compare with no vaccination in elderly ≥65 or 75 years	-Sensitivity analysis that ultimately determines the effectiveness of PCV13 to prevent NBPP[4] (Worst-case analysis) -PPV23 only in elderly ≥65 years have the most cost effectiveness -ICER[2](USD/QALY)=98,600
Heo et al. (2017)	2017	CEA[1]	South Korea	Societal	Probabilistic markov model	15 years	5%	IPD[3], NBPP[4]	PCV13 followed by PPV23 compared with PPV23 alone	-PCV13 followed by PPV23 in elderly ≥65 years has more cost effectiveness than PPV23 alone -ICER[2](COST/QALY) (vaccine coverage 60%)=1,228 -ICER[2](COST/QALY) (vaccine coverage 80%)=10,645
Choi et al. (2018)	2018	CEA[1]	South Korea	Health system	Markov model	Life time	3%	IPD[3], NBPP[4]	PCV13 followed by PPV23 compared with PPV23 alone	-PCV13 followed by PPV23 in elderly ≥65 years has more cost effectiveness than PPV23 alone ICER[2](USD/QALY)=3,300 -PCV13 followed by PPV23 in elderly ≥65 years (Risk group) has more cost effectiveness than PPV23 alone ICER[2](USD/QALY)=3,404
Atwood et al. (2018)	2018	CEA[1]	Canada	Health system	Markov model	Life time	5%	IPD[3], all-cause pneumonia	PCV13 followed by PPV23 compared with PPV23 alone	PCV13 followed by PPV23 has more cost effectiveness than PPV23 alone (Especially in immunocompromised or high-risk groups) -ICER[2] (USD/QALY) (in healthy elderly ≥65 years) =35,484 -ICER[2] (USD/QALY) (in risk group elderly ≥65 years)=10,728

Note: [1] Cost effectiveness analysis
[2] Incremental cost-effectiveness ratios
[3] Invasive pneumococcal disease
[4] Non-bacteremic pneumococcal pneumonia

As compared to ACIP 2014 and ACIP 2019 recommendations (Table 2), more input analyzing values along with the effectiveness of PCV13 in IPD, vaccine coverage, indirect effect were demonstrated with ACIP 2014; however, these attributes did not conform to the ACIP 2019 recommendation.

As a result, regardless of the economic evaluation of the elderly population in healthy persons (without comorbidities) or person with comorbidities, sequential vaccinations were more cost effective than administering a single dose of PPV23 (Heo et al., 2017; Choi et al., 2018; Atwood et al., 2018). Although these studies had differences in the perspective and time horizon, the main results pointed in the same direction, stating that the sequence of PCV13 vaccine followed by PPV23 is worthwhile (economic perspective). However, one study found that receiving a single PPV23 was more cost effective than other vaccine strategies based on sensitivity analysis that determines the lowest effectiveness of the PCV13 vaccine in the prevention of non-bacteremic pneumococcal pneumonia (NBPP) (Smith et al., 2013).

From a systematic review of the literature, the selected four studies completely reported the quality evaluation topic of the research according to the CHEER checklist. The results of these studies were mostly consistent with the findings of ACIP 2014, which recommended administering pneumococcal vaccination to the elderly and suggesting that two types of vaccines should be administered in sequence rather than only one because it will have a greater effect on disease prevention. However, in 2019, ACIP reviewed information from the last three years and found that administering a pneumococcal vaccine to children will also have an indirect effect. It was found that vaccinating children can reduce the rate of infection by lessening the number of carriers and reducing the spread of infection. This type of vaccination also lowers the risk of developing the disease as an adult. From an economic perspective, there is a possibility that receiving PCV13 in combination with PPV23 has a lower economic value than receiving a single dose of PPV23. Therefore, in 2019, ACIP changed their vaccination recommendation by suggesting that the elderly who had never received the pneumococcal vaccine should only receive a single dose of PPV23 (this recommendation is in line with the CDC's 2020 recommendation). However, the economic perspective from which the ACIP considered their new recommendation in 2019 was based on economic values that were different from other studies that considered factors such as the estimated number of people vaccinated (which has indirect effects on reducing the number of carriers), the spread of infection, the chances of contacting the disease, and the effectiveness of each vaccine against prevention of IPD (Namkoong et al., 2016; World Health Organization, 2018). All these factors can affect the economic value of a vaccination strategy as we observed while analyzing the details (Table 2). According to ACIP 2019, the effectiveness of vaccines in preventing IPD ranged from 47% to 59%, which was less than the value of 75% presented in 2014. This evidence may raise doubts to the conclusion that sequential vaccinations have a lower economic value than a single dose of PPV23. Therefore, there was a subsequent development of the recommendation based on these considerations.

In Thailand and other countries where the vaccine is not included in the expanded program for immunization in children (low indirect effect), as well as other countries in South Asia and East Asia, the number of people who received the pneumococcal vaccine is relatively low in both adults and children (less than 20% of the population) (World Health Organization, 2018), thereby creating a high risk of adults being exposed to the disease and becoming infected with both IPD and NBPP. Moreover, the context was different from the data used in the analysis of ACIP in 2019 and it makes the adoption of ACIP 2019 principles (which suggest the elderly to receive only PPV23) somewhat confusing and difficult. In this paper, three out of the four studies analyzed economic worthiness based on the estimation that 50% or less of the total population received the vaccine. The data of population receiving the vaccine were consistent with the population in the regions of Asia (World Health Organization, 2018). The results from three out of the four studies, showing that sequential vaccinations were more cost effective than receiving one single dose of PPV23, suggested that it might be a suitable strategy for implementation in Thailand and other Asian countries.

This study differs from the previous systematic review conducted in 2019 (Shiri et al., 2019) that aimed to investigate the economic value in the administration of pneumococcal vaccines to the people of all age groups. That research work did not specifically explore the economic worthiness of administering pneumococcal vaccinations to the elderly. Therefore, this study focused on those aged 65 years and above and it can be used as a tool in choosing and implementing vaccine strategies that are suitable for the elderly in Thailand. Limitations affecting this study include the fact that only research published in English and Thai languages were considered, and that the searches were restricted to English language databases such as Embase.

4. CONCLUSION

This research paper is a systematic review of literature analyzing the economic worthiness of administering PCV13 and PPV23 among the elderly. The studies that were considered to be included in this study contained keywords relating to the topic that were published between 2012 and 2019.

Four studies were found to meet the selection criteria of being systematic review on determining the cost-effectiveness of administering PCV13 and PPV23 in sequential patterns among the elderly and were published between 2012 and 2019. Each research result indicated economic worthiness as cost/QALY. The results demonstrated that most of the studies were in agreement that receiving PCV13 followed by PPV23 was more cost effective than receiving a single dose of PPV23. Only one study that suggested that receiving a single dose of PPV23 in people aged 65 years is more valuable or cost effective than any other vaccination strategy. However, this result came from analyzing sensitivity by determining the effectiveness of the PCV13 vaccine at the lowest effectiveness in preventing NBPP.

Table 2. Comparison study among 4 studies, with ACIP 2014 and ACIP 2019 recommendations

	Smith et al. (2013)	Heo et al. (2017)	Choi et al. (2018)	Atwood et al. (2018)	ACIP 2014 recommenda-tion (2014)	ACIP 2019 recommenda-tion (2019)
Effectiveness of PCV13 in IPD	N/A	75%	75%	N/A	75%	47-59%
Effectiveness of PCV13 in NBPP	75%	45%	N/A	45%	45%	38-70%
Vaccine coverage	N/A	N/A	65-75%	N/A	<50%	92%
Indirect effect	50–80%	50%	50%	50%	50%	N/A

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