



Immunization policy development in Thailand: The role of the Advisory Committee on Immunization Practice

Charung Muangchana^{a,*}, Piyanit Thamapornpilas^b, Opart Karnkawinpong^b

^a National Vaccine Committee Office, Department of Disease Control, Ministry of Public Health, Tiwanon Rd., Muang, Nonthaburi 11000, Thailand

^b Bureau of General Communicable Disease, Department of Disease Control, Ministry of Public Health, Nonthaburi, Thailand

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ABSTRACT

The Advisory Committee on Immunization Practice (ACIP) of Thailand, established nearly 40 years ago and currently consisting of 28 experts in immunization and related fields, develops written recommendations to the Ministry of Public Health (MoPH) regarding vaccines and immunization. Through careful review of available scientific data, compiled and analyzed by Working Groups set up to examine specific topics, the ACIP makes recommendations concerning the inclusion of new vaccines into the national immunization program, target groups and ages for administration, vaccine schedules, and precautions and contraindications. This paper includes a description of the composition of the ACIP; the process that the Committee uses to formulate recommendations, including required data; and areas for improvement.

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1. Introduction and background

Thailand is a middle-income country in Southeast Asia with a GDP per capita of US\$ 4115 [1], a population of about 65 million and a birth cohort of around 800,000. The public health infrastructure in Thailand is designed to cover the entire population, both in rural and urban areas, with at least one community hospital in each of the country's 926 districts, and one health care center in each sub-district. Secondary and tertiary care include general or provincial hospitals and regional or university hospitals, respectively. The expanded program on immunization (EPI) is fully integrated into these basic health services.

Thailand officially launched its nation-wide immunization program (EPI) in 1977 by expanding and strengthening the existing immunization service infrastructure [2]. Currently, the Thai EPI includes vaccines that cover the following 10 antigens: tuberculosis (BCG), hepatitis B, diphtheria, tetanus (TT), pertussis, poliomyelitis (OPV), measles, mumps, rubella, and Japanese encephalitis (JE) (Table 1) [3]. Apart from the infant EPI vaccines, flu vaccine has been given to health care workers since 2004 and to people with certain chronic diseases since 2008. There also have been a number of changes in vaccines and schedules over the years (Table 2).

Abbreviations: ACIP, Advisory Committee on Immunization Practice; EPI, Expanded Program on Immunization; WHO, World Health Organization.

* Corresponding author. Tel.: +66 025903196/8/9; fax: +66 025918425.

E-mail address: charungm@hotmail.com (C. Muangchana).

Vaccine procurement, technical support, and evaluation are carried out by the EPI at national level, while responsibility for implementing the program is decentralized to the country's 76 provincial health offices.

The Thai Ministry of Public Health has established a number of principles and policies concerning immunization. These include: the right of all people to be protected from vaccine-preventable diseases; the inclusion of immunization in the basic health services package; and the provision of safe, high-quality immunizations to all people free of charge. According to national policy, all public sector hospitals and health care centers must provide all immunizations included in the EPI schedule for free in well-baby clinics, and only private hospitals and clinics may charge for these services. Immunization services, along with other preventive and curative services, are financed by the National Health Insurance Plan (NHIP), established in 2002 [4] for all persons not covered by other health insurance plans (e.g., the social security scheme for private sector employees and the government employee health care scheme). This includes services provided both in the public sector and those provided by private providers who participate in the NHIP. Patients receiving immunizations from a private health provider who does not participate in the national insurance program, however, must cover the costs of the vaccination themselves.

From a vaccine coverage survey conducted in 2008, the coverage for BCG, the third dose of hepatitis B, the third DTP dose, the third dose of OPV and measles among children less than 1 year of age was greater or equal to 98%. The survey also found that 95% of vaccinees had received their EPI vaccines from governmental facilities [5].

Table 1
Current Immunization Schedule of the Thai EPI.

Age	Vaccines
Birth	BCG + HB1
2 months	OPV1 + DTP-HB1
4 months	OPV2 + DTP-HB2
6 months	OPV3 + DTP-HB3
9–12 months	Measles or MMR1
18 months	OPV4 + DTP4 + JE1-2
2.5–3 years	JE3
4–6 years	OPV5 + DTP5 + MMR2
12 years	dT
Pregnant women	dT1-2-3

EPI = Expanded Program on Immunization; BCG = bacille Calmette-Cuérin; OPV = Oral Poliovirus Vaccine; HB = Hepatitis B Virus Vaccine; DTP = Diphtheria-Tetanus-Pertussis Vaccine; MMR = Mump-Measles-Rubella Vaccine; JE = Japanese Encephalitis; dT = Diphtheria-Tetanus Vaccine for adolescents and adults. The number following vaccines refers to the order of vaccine doses.

This article describes the structure and function of the Thai Advisory Committee on Immunization Practice (ACIP), and outlines the process by which the Committee develops recommendations for the national immunization program.

2. Role of the Advisory Committee on Immunization Practice

In Thailand, according to MoPH regulations, policy changes regarding immunization of children and adults, including the introduction of new vaccines, are authorized and issued by the MoPH. The MoPH receives guidance from the ACIP, which issues recommendations. The Committee was established by the MoPH in 1970 – 8 years before the national EPI was created. The main reason the Committee was established was because health care professionals graduating from different medical schools were using different immunization practices.

In 2001, the Thai ACIP became part of a larger national advisory body, the Thai National Vaccine Committee (NVC). The NVC has four subcommittees to advise on the development of policies related to immunization and vaccines: (1) Vaccine Research and Development, (2) Vaccine Production, (3) Vaccine Quality Control, and (4) Immunization Practice [6].

The overall goal of the ACIP is to provide advice that will lead to the reduction in the incidence of vaccine-preventable diseases. The official terms of references for the ACIP stipulate that the Committee shall:

- provide advice and guidance on vaccines and immunization to the MoPH;

- make recommendations on the inclusion of vaccines into the EPI, appropriate immunization schedules and target groups, and methods for administering the vaccines;
- suggest areas of research related to vaccines and the epidemiology of vaccine-preventable diseases, and suggest possible sources of funding for this research;
- propose immunization policies to the MoPH and NVC; and
- appoint Working Groups to study specific issues.

The ACIP's written guidelines have undergone 15 revisions since its inception to ensure that the Committee's work remains relevant to changing times.

3. Structure and membership of the ACIP

The current ACIP consists of 28 members: a Chairperson – who is the Director of the Department of Disease Control (DDC) – and 27 members with expertise in a variety of disciplines, including vaccinology, immunology, pediatrics, internal medicine, obstetrics, public health, infectious diseases, and preventive medicine. According to the selection criteria, all Committee members must be Thai citizens from either governmental or non-governmental organizations. As shown in Table 3, ACIP members can be divided into three groups: (1) those appointed in their official capacity by virtue of their position within the Government (11 members); (2) representatives of relevant professional associations (6 members); and (3) those appointed in their individual capacity as experts (11 members).

The Secretariat of the Committee is headed by either the Director of the Bureau of General Communicable Diseases – under which the EPI is managed – or a senior medical officer within the DDC. The EPI program manager and staff also serve as assistant secretaries.

Currently, there are no representatives from consumer or community groups on the Committee. There is also as yet no policy to ensure balance on the basis of gender or ethnicity among Committee members. Vaccine producers and suppliers are not represented on the ACIP. However, technical staff from vaccine production companies may be asked to present data on the vaccine during Committee meetings.

While there are no representatives from the World Health Organization (WHO) on the Thai ACIP, the Committee benefits from and uses immunization-related recommendations and guidelines issued by WHO in such documents as the guideline for introducing new vaccines and WHO position papers for specific vaccines (e.g., Hib, rotavirus, Japanese encephalitis (JE) vaccines) [7–11].

ACIP members do not have fixed terms. While there is no formal review process, all members are appointed, and nominees are proposed by the Secretariat to the full Committee for approval. Final approval is given by the Minister of Public Health.

Table 2
Vaccines used in the Expanded Program on Immunization (EPI) over time.

1977–1981	1982–1986	1987–1991	1992–1996	1997–2001	2002–2007	2008–2009
BCG	BCG	BCG × 2	BCG	BCG	BCG	BCG
DTP × 2	DTP × 3	DTP × 4	DTP × 5	DTP × 5	DTP × 5	DTP × 2
OPV × 2	OPV × 3	OPV × 4	OPV × 5	OPV × 5	OPV × 5	OPV × 5
	Measles	Measles	Measles	Measles	Measles	Measles
	Rubella	Rubella	Rubella × 2	MMR	MMR	MMR
			HB × 3	HB × 3	HB × 3	DTP-HB × 3
			JE × 2	JE × 2	JE × 3	JE × 3
Typhoid ^a	Typhoid ^a	Typhoid ^a	–	–	–	Influenza
	TT × 2	TT × 2	TT × 3	TT × 3	dT × 3	dT × 3

BCG = bacille Calmette-Cuérin; OPV = Oral Poliovirus Vaccine; HB = Hepatitis B vaccine; DTP = Diphtheria-Tetanus-Pertussis vaccine; MMR = Mump-Measles-Rubella vaccine; JE = Japanese Encephalitis vaccine; dT = Diphtheria-Tetanus vaccine for adolescent and adults. The number following “×” = the total doses of vaccines per series.

^a Killed whole-cell parental vaccine.

Table 3
Current members of the Thai Advisory Committee on Immunization Practice, as of January 25, 2010.

	Type of member
1. Member by position	
Director General of the Department of Disease Control (DCC)	Chair
An assigned Director Deputy of the Department of Disease Control	Member
Director of the Vaccine Trial Center (VTC), Mahidol University	Member
Director of Bureau of Epidemiology, Department of Disease Control	Member
Director of the Division of Biological Products, Department of Medical Science	Member
Director of the Division of Communicable Disease Control, Department of Health, Bangkok Metropolitan Administration (BMA)	Member
Manager of Fund Administration, National Health Security Office (NHSO)	Member
Director of the National Vaccine Committee (NVC) Office, Department of Disease Control	Member
Director of the Division of Drug Control, Food and Drug Administration (FDA)	Member
Director of the Bureau of General Communicable Disease, Department of Disease Control	Secretary
Manager of the EPI program, Department of Disease Control	Assistant Secretary
An assigned EPI program staff person, Department of Disease Control	Assistant secretary
2. Representatives, from	
Infectious Disease Association of Thailand	Member
Pediatric Society of Thailand	Member
Preventive Medicine Society of Thailand	Member
The Royal College of Pediatricians of Thailand	Member
The Royal College of Physicians of Thailand	Member
The Royal Thai College of Obstreticians and Gynaecologists	Member
3. Individual Experts	
Eight pediatricians with specific specialty areas	Member
One virologist	Member
One preventive medicine expert	Member

4. Conflicts of interest

Since recommendations made by the ACIP may have implications for both the public and private sectors, including vaccine manufacturers, all candidates who are nominated for ACIP membership undergo careful screening for potential conflicts of interest before their names are submitted for final consideration. While there are no written conflict of interest rules, the Secretariat and ACIP members consider any links that a nominee may have with a vaccine supplier or producer, such as owning stock in a vaccine company or receiving grant funding from a vaccine producer. In such cases, the Committee makes a judgment on whether the relationship with the company is significant enough to bias their views and affect their partiality, when deciding whether or not to accept the nominee.

5. The process of developing recommendations

5.1. ACIP meetings

The ACIP meets at least once per year and there are often two or three meetings in a single year, depending on the number and complexity of issues to be considered. However, there is no regular schedule for ACIP meetings. The Secretariat is responsible for scheduling the meetings and the Chairperson then sends a letter to Committee members to invite them to attend. Prior to the meeting, members are given an agenda listing issues to be considered. Agenda topics can be proposed by members of the ACIP, as well as by non-members, including MoPH officials, university professors, representatives of WHO and other international organizations, vaccine industry representatives, and other stakeholders. The Secretariat makes a decisions on whether to include a proposed topic, based on whether there are sufficient data for the ACIP to consider the topic, whether the topic is considered a priority, and if there is time available on the agenda to cover the topic during the meeting, which typically last one-half day.

5.2. Scope of work of the ACIP

The Committee makes recommendations on a variety of issues regarding vaccines and immunization. These include the intro-

duction and use of new vaccines, vaccine schedules, vaccines for high-risk groups (e.g., flu vaccine for health care workers), vaccines beyond the infant immunization schedule (e.g., for travelers, adolescents, adults and certain types of workers), vaccine formulations (e.g., multivalent vs. monovalent), and choice of vaccines for a specific disease (e.g., Jeryl Lynn vs. other strains of mumps vaccine). The ACIP also recommends additional studies to conduct in order to aid decision-making, such as to estimate the local disease burden or vaccine cost-effectiveness. Examples of issues addressed in recent ACIP meetings and the recommendations made are shown in Table 4.

Meeting topics may include items that do not require a review but are presented for informational purposes. These topics may include epidemiological data on vaccine-preventable diseases, including updates on disease outbreaks; safety, efficacy, effectiveness or cost-effectiveness of a vaccine; data on a vaccine still in development; information on vaccines that are newly licensed by the Thai FDA and could be considered for the EPI in the future; or changes in vaccine supply.

5.3. Working Groups

Ad hoc Working Groups are frequently formed by the ACIP to gather, analyze and prepare information on a specific topic, such as the introduction of a new vaccine into the EPI, for presentation to the full Committee. Sometimes, a single individual is assigned this role. The Working Group members or individual experts can be ACIP members or outside experts, and are chosen for their expertise and experience (there are no strict rules for assigning Working Group chairpersons or members). While there are no rules against appointing foreigners to Working Groups, no non-Thais have been Working Group members in the past. These temporary Working Groups typically disband once decisions regarding their topic are made and there are no permanent Working Groups. The Working Group or individual expert present their findings and draft recommendations or options to the ACIP in a closed meeting. ACIP members then fully consider the information until a consensus is reached.

Table 4
Examples of issues addressed and recommendations made at recent meetings of the Thai ACIP.

Meeting date	Issue to be considered	Recommendation made by the ACIP	Status of implementation (as of January 2010)
17 July 2009	Immunization policy for health care workers	Establish expert group to draft policy for consideration by the ACIP	The policy has been drafted and is expected to be included in the next ACIP meeting for consideration
	What vaccines to add to the list required for foreign-born children living in Thailand (besides BCG, DTP, OPV and measles)	Add hepatitis B and JE to the list of required vaccines for foreign-born children	The recommendation will be implemented in Fiscal Year 2010
18 September 2009	Prioritizing groups to receive the 2009 H1N1 flu vaccine, once available	Establish small expert group to draft proposal to identify priority groups for the vaccine for consideration by the ACIP (based on data on vaccine characteristics and performance, estimated incidence and mortality rates of different risk groups, and estimated population size of each group)	The expert group's proposals were accepted and vaccination for the recommended groups started in January 2010
17 July 2008	Hib vaccine introduction	Not to introduce Hib vaccine (mainly because members doubted the estimate of the burden of Hib pneumonia)	Hib vaccines are available in private facilities and some governmental facilities and vaccinees have to pay for them
	Possible change in target ages for measles vaccination	Keep the age for the first measles dose at 9–12 months and decrease the age for the second dose (using MMR) from 7 to 4 years	The revised schedule to include the second dose of MMR has been included in the immunization reference manual and official letters sent to health facilities requesting them to follow the recommendation
	Whether to consider the use of the live attenuated SA 14-14-2 JE vaccine in place of mouse-brain derived vaccine used in the EPI	Not to use the live SA 14-14-2 JE vaccine unless the mouse-brain vaccine is not available.	SA 14-14-2 has been available in most of private facilities in big cities and some governmental facilities and vaccinees have to pay for them
27 December 2007	What specific MMR vaccine to use in the EPI for 6–12 month olds (e.g., Jeryl Lynn strain of mumps)	Stay with current MMR vaccine due to availability problems with other types and revisit the schedule and target ages for measles and MMR immunization	The EPI plans to start buying the MMR Jeryl Lynn strain in 2010
	Reconsideration of the schedule for hepatitis B immunization in infants of hepatitis B carrier mothers	Change schedule for infants from 2 months of age to 1 month for the second hepatitis B dose (first dose at birth remains the same)	The recommendation was distributed to all health care facilities nation-wide, and has been implemented
	Selection of public education messages about HPV immunization	Use already available educational materials developed by medical associations	The educational material has been put on the EPI website
	What high-risk groups should receive seasonal flu vaccine besides health workers	Seasonal flu vaccine should be given to people with chronic illnesses and funded by the NHSO	People with chronic illness have been receiving seasonal flu vaccine since 2008

5.4. Factors and evidence considered by the ACIP in developing recommendations

To formulate policy recommendations, the ACIP reviews many factors, including both “policy issues” and “programmatic issues” (Fig. 1). Policy issues include the mortality and morbidity from the

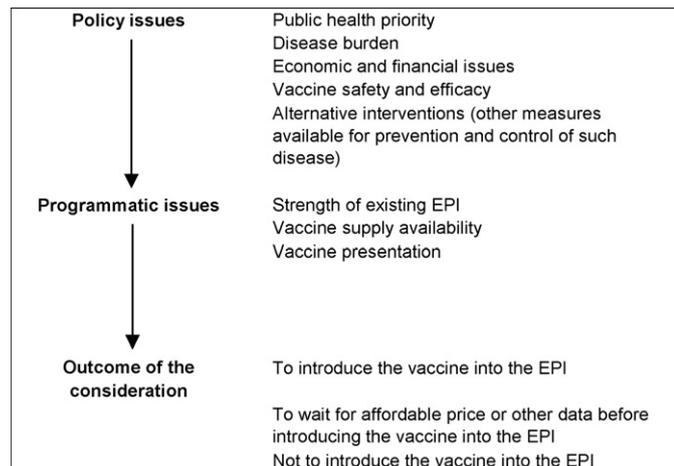


Fig. 1. Factors and evidence considered by the ACIP in developing immunization policy.

disease in both the general Thai population and in specific risk groups; the effectiveness and feasibility of alternative control measures; as well as evidence from both published and unpublished sources on the safety, efficacy, and effectiveness of the vaccine, including clinical trial results. The ACIP also routinely reviews published and unpublished economic analyses concerning the vaccines under consideration, including cost-effectiveness and cost-benefit analysis. However, the results of economic analyses are only one factor that the ACIP considers in developing recommendations.

Once policy issues are reviewed, the ACIP then considers programmatic issues to determine the feasibility of incorporating the vaccine into existing EPI programs. These issues can include the available supply of the vaccine and whether its presentation and logistical requirements (e.g., volume and cold chain requirements) are not too burdensome for the EPI program to handle. The Working Group or Secretariat may also gather information from mass media (e.g., newspapers), non-governmental organizations (NGOs) and other sources to get an indication of the public’s views concerning the disease and the vaccine in question. The Working Groups may present options for the ACIP to consider, such as whether to introduce the vaccine nationally, to wait for additional data or for the vaccine price to decrease before considering its introduction, or not to introduce the vaccine.

The quality of the data and their origin are also considered by the Committee, although there are as yet no written rules or criteria for judging the quality or relevance of data. The ACIP prefers local evidence (from Thailand), especially concerning disease and

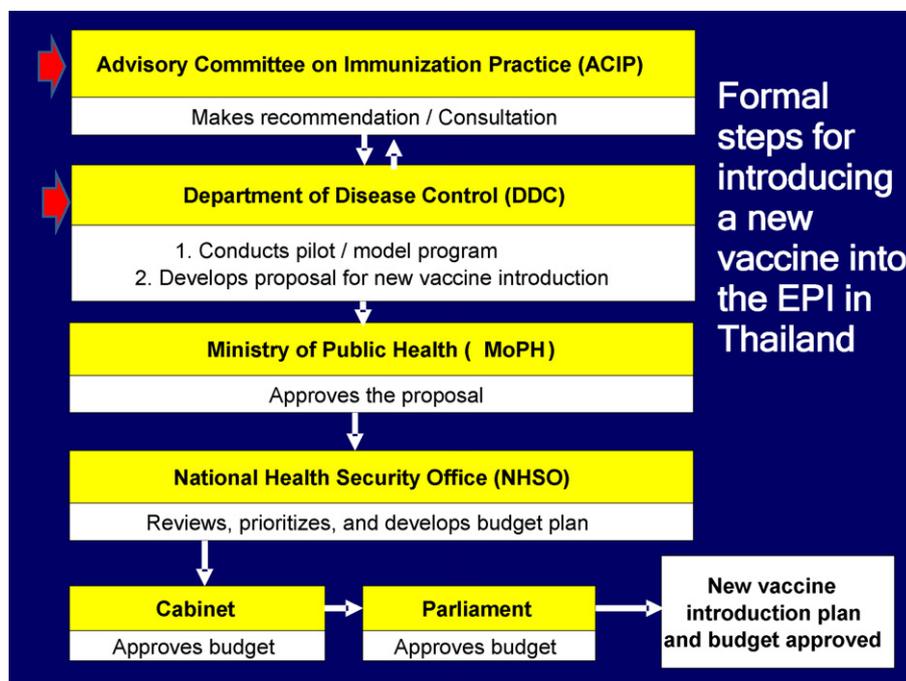


Fig. 2. Pathway for recommendations of the Thai Advisory Committee on Immunization Practice.

economic burden (e.g., the number of cases, incidence rates, deaths, disability), as well as cost-effectiveness or cost-benefit of vaccination. When these data are not available for the disease in question, the ACIP may recommend that local studies be conducted before introduction of the vaccine is considered. This was the case for Hib vaccine, for which the ACIP recommended in the 1990s that a prospective Hib disease burden study and economic evaluation be conducted in Thailand before further consideration to introduce the vaccine into the infant EPI schedule. Both studies were then conducted [12] and a decision not to introduce the vaccine was made by the Committee in 2008.

Data on a vaccine's safety and immunogenicity or efficacy in the local population are also preferred, especially in cases where the distribution of genotypes of the disease vary from country to country (and thus the vaccine's coverage of strains) or in cases where there are genetic differences in responses to a vaccine among populations. For example, before replacing DPT and monovalent hepatitis B vaccines with the tetravalent DPT-hepatitis B vaccine, the ACIP used data from a pilot study in one province to examine the vaccine's safety and immunogenicity in the local population, as well as logistical issues.

When data from Thailand are not available and local studies are not considered feasible or necessary, the Committee may use data from other countries, if they are considered applicable to Thailand. In some cases where data are lacking or inadequate, the opinion of ACIP members or other experts are used to make recommendations. Information about new ACIP recommendations that is published in official letters or in the official immunization reference book usually does not describe in detail the methods used in developing recommendations, but does describe the evidence used to inform these recommendations, such as the results of clinical trials, case-control studies, case series, expert opinion, or cost-effectiveness analyses.

After formulation by the Working Group, the draft recommendations are subjected to further extensive review by ACIP members, staff of the DDC, and members of the Working Group. Working Group or ACIP members may identify a need for additional data, corrections in the data, or modifications in the interpretation of

the data, and members may critique and challenge the opinions of experts. The Working Group then compiles all of these comments and views in an iterative process and presents options for action to the ACIP for final consideration.

5.5. Role of the ACIP in the ultimate decision-making process

While the government is not obligated to implement recommendations made by the ACIP, to date it has never rejected any ACIP recommendation. However, sometimes the recommendation cannot be implemented immediately, due to operational or programmatic considerations. For example, the ACIP agreed in 1999 that the EPI use the combination DPT-hepatitis B vaccine in place of separate DPT and hepatitis B vaccines. However, due to concerns about the programmatic feasibility of this change, including the high vaccine price and supply issues, since there was only one manufacturer producing the combination vaccine at that time, the DDC requested that the implementation of the new recommendation be delayed. The switch to the combination vaccine was subsequently implemented nation-wide in 2007, after the vaccine price had been reduced and more manufacturers had entered their DPT-hepatitis B vaccine onto the market.

6. Information dissemination and the process for approving ACIP recommendations

The minutes of each ACIP meeting are distributed to all Committee members, who are allowed to suggest revisions before the minutes are finalized. These minutes are reviewed again at the next ACIP meeting. The meeting minutes are not posted for the public, but individuals and organizations can request them in writing, if they clearly state the specific reasons for their request. Most requests are from researchers conducting research on related topics, but such requests are rare.

If a new vaccine is recommended for introduction, the Department of Disease Control will then prepare a proposal and budget for approval by the MoPH and then by the NHSO, which oversees the national health insurance plan. As shown in Fig. 2, the bud-

get for introduction of the new vaccine must be approved by the Cabinet and finally by the Parliament. Once approved, the national introduction of the vaccine may still take one or more years, however, due to the time required to revise the immunization reference manual, train health worker staff, procure an adequate supply of the vaccine, plan and implement public information campaigns announcing the new policy, and other activities to prepare for the new vaccine introduction.

Once approved, the new recommendations are distributed in an official letter or in a revised edition of the immunization reference manual to all public health facilities in the country and posted online on the website of the DDC. The new recommendations are also announced in annual refresher courses conducted by the national EPI for all health workers involved in immunizations.

7. Factors related to the success of the ACIP and remaining challenges

For many years, the ACIP has played a key role in guiding decisions related to vaccine use and immunization in Thailand and the Committee is considered an important factor in the success of the country's national immunization program. There are a number of factors contributing to the success of the Committee. These include: its formal establishment by the Minister of Public Health; the multi-disciplinary expertise among its members; and the fact that the Secretariat consists of those responsible for implementing the national immunization program.

However, the ACIP has a number of limitations which could be addressed to further strengthen the Committee and how it functions. These limitations and possible areas of improvement include the following:

- (1) There are no regulations or laws stipulating that all immunization-related policy decision must first be considered by the ACIP. There have therefore been instances in which new immunization policies were enacted without consideration by the Committee.
- (2) Other ways of reaching decisions at ACIP meetings, such as taking a vote, should be considered as an alternative to reaching a consensus. This is because some Committee members may not feel free to express their views independently.
- (3) More representatives from several other relevant fields and segments of society, including health economist, pharmacists, nurses, and consumer groups, could be considered for membership on the Committee.
- (4) Once a new vaccine is on the market, the ACIP should put a discussion of the vaccine and its possible introduction into the EPI on its meeting agenda, regardless of the current affordability of the vaccine or other concerns that policymakers may have, since these can be addressed by other government agencies. This could help to avoid the long delays between the availability of the vaccine in the private sector market and its introduction into the EPI.
- (5) There should be written rules concerning conflicts of interest among ACIP members. In addition, a Steering Committee

should be established to review all nominees, including possible conflict of interest issues, and to monitor conflict of interest matters once the nominees become members of the Committee.

- (6) Increasing the independence of the ACIP from the MoPH should be considered. For example, the Chair of the ACIP is the Director General of the Department of Disease Control (DDC), and the ACIP's mandate is to advise the DDC and the MoPH. This situation may affect the independence of the ACIP and bias its decisions in the direction that the DDC and MoPH would like it to go.
- (7) Clear and specific criteria or guidelines for decision-making when considering the introduction of new vaccines would be useful for the Committee. Examples are specific criteria on the level of disease burden that is considered high; how cost-effectiveness for a vaccine is defined; and the threshold at which a new vaccine is considered affordable.

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Conflict of interest statement

The authors state that they have no conflict of interest.

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