Strengthening the capacity of National Committees for Immunization Practices for pandemic influenza preparedness

Report of the Workshop
Jakarta, Indonesia, 25-28 March 2008

World Health Organization
Regional Office for South-East Asia

SEA-IMMUN-15

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1 Introduction

Since the launch of the Expanded Programme on Immunization (EPI) in the early 1970s, national immunization programmes (NIP) focused on delivering six basic antigens, namely BCG[1], DTP[2], measles and OPV[3]. No new antigens were added to the NIPs at least in most developing countries till the turn of the century. Consequently, most countries did not have to worry about policies or strategies about vaccines and immunization because they were well established and well known. But in the late 1990s new and more expensive vaccines developed by the vaccine industry came on to the market. These vaccines, unlike the traditional EPI vaccines, were rather expensive. With the launch of the Global Alliance for Vaccines and Immunization (GAVI) in 2000, new funding opportunities for adding new antigens emerged for the world's poorest countries of the world.

With several new and underutilized vaccines on offer from GAVI, countries suddenly were faced with the necessity to make decisions regarding the need, appropriateness and affordability of these new vaccines. A few Member countries of World Health Organization's (WHO) South-East Asia (SEA) Region had established technical advisory groups to advise the governments on immunization policies, especially in relation to the introduction of new vaccines. Most countries in the Region are dependent on external advice. Therefore, it was felt important for all countries to establish a national committee on immunization practices (NCIP) to provide the governments the technical advice and expertise necessary for them to make informed decisions regarding the addition of any new antigen to national immunization programmes.

Discussions on the establishment of NCIPs were initiated in early 2007 and at the meeting of EPI Program Managers and Technical Consultative Group in July 2007 at New Delhi, a recommendation was adopted endorsing the need for all countries to establish an NCIP. WHO developed a generic guideline on the establishment of NCIP and circulated the same to all countries [Annex I]. Member countries of the SEA Region except for Nepal, Bangladesh, Maldives and Timor-Leste had established such a body by December 2007.

1 Bacille Calmette Guerin
2 Diphtheria, Tetanus and Pertussis
3 Oral polio vaccine

2 Objectives of the workshop

The WHO South-East Regional Office and WHO headquarters, Geneva, organized a workshop on strengthening the capacity of National C mmittees for Immunization Practices (NCIP) for pandemic influenza preparedness in collaboration with the UNICEF, New York, and with funding support from the Government of Japan. The workshop, in Jakarta from 25–28 March 2008, had the following objectives:

- Orient NCIPs on the NCIP Framework and functioning and to the potential role they can play in providing policy guidance on seasonal and pandemic influenza vaccines to their respective ministries of health.
- Review current national EPI policies and strategies, with particular focus on seasonal influenza vaccination, and identify policy gaps and strategies that need attention.
- Examine national policies, commitments and strategies for pandemic preparedness with the focus on development and deployment of a pandemic influenza vaccine in the event of a pandemic.
- Promote networking opportunities between NCIPs, Regional Technical Advisory Bodies as well as global bodies such as the Strategic Advisory Group of Experts (SAGE) on Immunization.

3 Relevance of NCIPs

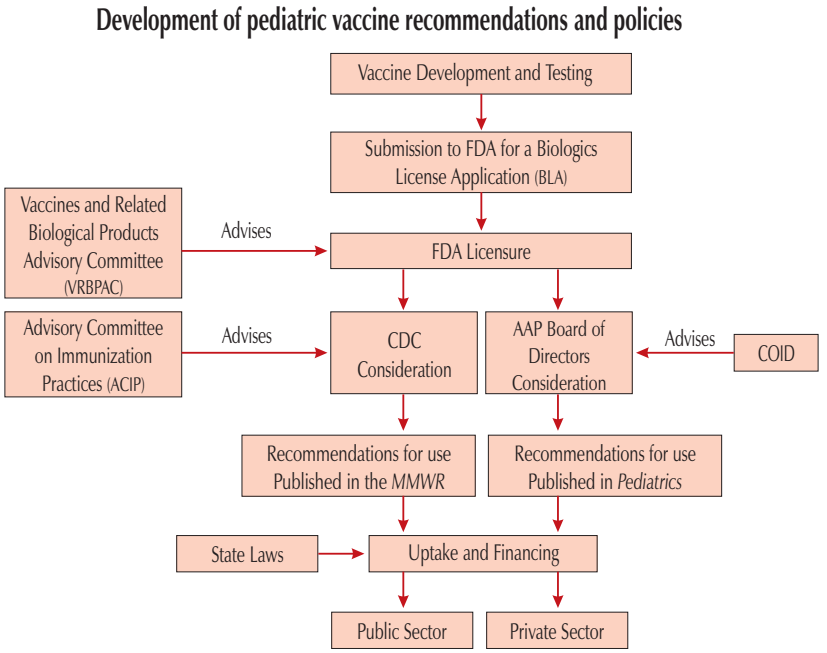
The workshop examined the experience of countries in the Region that had technical advisory bodies already established. In addition, representatives from the US Advisory Committee on Immunization Practices (ACIP) and Korean Advisory Committee on Immunization Practices (KACIP) were also invited to this meeting to share their experiences. The representatives from the Influenza Task Force of the International Federation of Pharmaceuticals Association (IFPMA) and the Developing Countries Vaccine Manufacturers (DCVM) also explained their role in facilitating the deliberations on the introduction of vaccines into a country's immunization schedule.

Thailand had such a body established as early as in 1970. The Thai Immunization Committee is part of a larger national body, the Thai National Vaccine Committee (NVC). The NVC has four subcommittees: (i) Research and Development, (ii) Production, (iii) Quality Control, and (iv) Immunization Practice**.** The immunization committee had well-established terms of reference (TORs) but these have undergone at least 15 revisions in the past decades to ensure that the work of such a committee remains topical and relevant to changing times. **Sri Lanka** too had such a committee that had been in existence for more than 30 years under the Epidemiology Unit , which in turn has been functional since 1959. In recent years **India** established its National Technical Advisory Group on Immunization (NTAGI). Following the discussions of July 2007 several other countries have established similar bodies of their own. The rest of the Member countries are on track to establish their own technical advisory groups before the end of 2008.

The US ACIP existed since 1964 and its mandate is to provide advice and guidance to the office of the Secretary, Department of Health and Human Services (DHHS) and the Director of the Centers for Disease Control and Prevention (CDC), on most effective means to prevent vaccine-preventable diseases in the civilian population and provide advice on antigens and related agents (e.g. vaccines, antisera, immune globulins, antiviral agents, chemotherapy and chemoprophylaxis) and their use. The committee has well-established norms on selection of members, frequency of meetings and procedures for arriving at a consensus on an issue pertinent to immunization practice or vaccine use.

The US ACIP meets three times a year, has 15 voting members, eight ex-officio members representing other US government agencies/bodies (Church Mission Society (CMS), Department of Defense (DOD), Department of Veterans Affairs (DVA), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Institute of Human Studies (HIS), National Institute of Health (NIH), National Vaccine Programme Office (NVPO), and 25 liaison members representing professional societies and organizations responsible for vaccine development and immunization programmes. The pathway to a decision from a vaccine licensure to actual use in practice is as shown in Figure 1. The number of antigens in the US immunization programme has risen from 7 in 1985 to 16 in 2006, and the decision to use any of these antigens is based on the recommendations of the ACIP.

Fig 1: Pathways for ACIP recommendation



Modified from Pickering LK, Orenstein WA. Development of pediatric vaccine recommendation and policies. *Semin Pediatr Infect Dis.* 2002;13:148-154. Reprinted with permission.

They have clear and well-established procedures, including ways to deal with conflicts of interest. The advisory body is totally independent and members are selected on the basis of their individual capacity and expertise. During the meetings of the ACIP, outsiders can witness the proceedings and experts can be invited to give their opinion. However, voting rights are limited to only ACIP members.

The **South Korean** Advisory Committee for Immunization Practices (KACIP) was established in June 1992 and is supported by the Division of Vaccine Preventable Diseases Control and National Immunization Programme. The KACIP was given a legal basis in August 1994. It has less than 15 core members and its mandate is also to offer advice on the standardization of the immunization practices (type of vaccine, age, numbers of dose, dosing interval, precautions, etc.) and policy decision on the inclusion of new antigens.

A careful review of existing NCIPs in some of Member countries of the Region showed wide variation in composition, procedures, roles and responsibilities. In Thailand there are well-established terms of reference and procedural rules. In Sri Lanka, the NCIP has functioned fairly competently without explicitly written terms of reference for the group. In both countries senior officials from the ministry of health chaired NCIP meetings. In some of the more recently-formed NCIPs there are areas that need to be strengthened. For example the number of members on the NCIP of Indonesia is thought to be too large because rather than have a group of experts to provide independent advice, the aim seemed primarily to have representation. However at the meeting the opinion of the participants was that this is not the major purpose to guide the establishment of an immunization advisory body. The Indian NTAGI, although well balanced in terms of the expertise required to be on the group, can be strengthened to establish clear procedural rules and improve management of the advisory group's proceedings. The issue of senior government officials chairing the meetings of immunization advisory groups were discussed at length. However, it was finally agreed that having a key government official provides the required policy support needed for the work of national immunization advisory bodies. It was agreed that declaration of conflict of interest for members of the advisory group is a must, and manufacturers cannot be members of the advisory group but can be invited only as observers.

It was also agreed that countries need not necessarily call their immunization advisory bodies by the name "National Committee on Immunization Practices (NCIP)" as suggested in the generic guidelines. Instead, they can call it by whatever is appropriate for the country as long as the terms of reference reflect the correct nature of the work that such bodies are expected to perform.

After considering countries that delivered presentations on their NCIPs and those that had plans to establish similar bodies, the meeting then examined the strengths, weaknesses and core elements that should be included in the terms of reference of such bodies. Also, the terms of reference of the generic guidelines for NCIP issued by the Regional office were examined against the ToRs of other advisory bodies and a final set of core elements that should form the terms of reference of future NCIPs (see Annex II) was agreed to.

One of the key issues that emerged from the group discussion was the need for proper preparation of NCIP meetings. It was strongly recommended that an agenda and the supporting documents should be available at least one month before a meeting. Where necessary, technical subcommittees may be formed to deal with specific topics and provide consolidated report(s) to the national advisory committee for final policy decisions. Those NCIPs that do not have working sub-committees/groups or similar mechanisms should consider their establishment to assist the NICP in its work as and when needed.

4 Policies on seasonal influenza vaccine use and its implication on pandemic preparedness

This workshop was the first occasion anywhere in the world where the national technical advisory bodies were brought together in one WHO region to discuss the importance of such advisory bodies and the important roles they play in guiding their government towards informed decisions on vaccines and immunization practices. The organizers of the meeting were of the opinion that, after a clear understanding of the need, roles and responsibilities of national technical advisory bodies the participants would benefit from the workshop if they evaluated the real policy issues; procedures for the conduct of such a policy deliberation; the format of such policy recommendations; and the data and evidence that are required from an assessment for crafting the kind of policy desired for a possible use of the seasonal influenza vaccine. As no country in the SEA Region currently has a policy on the regular use of seasonal influenza vaccine it was deemed that introduction of seasonal influenza vaccination should be considered earnestly.

There are reports in both India and Indonesia that Hajj pilgrims receive seasonal influenza vaccination but this is either by the private sector or by a government office and the national immunization programmes are not involved. In Thailand limited quantities of seasonal influenza vaccines were regularly used for specific groups of individuals, notably health workers. However, it is known that the vaccine is used in the private sector in many Member countries of the SEA Region but the exact quantities used are unknown.

In 2006 WHO sent out to all countries a questionnaire titled *'Mapping the Landscape, WHO Global Influenza Survey'* but there were many inconsistencies in filling the required details in the form. Many countries with large populations also did not complete the survey form or failed to provide key information. Based on the quality of the data received and the responses missed by some Member States, WHO was unable to make a definitive analysis of the state of global pandemic vaccine preparedness. However, there were important lessons to be learnt from the exercise itself and several recommendations were made (see Box 1).

The importance of the use of seasonal influenza vaccine to boost vaccine production capacity worldwide is an important and necessary step to prepare the world for a possible pandemic influenza. Currently, seasonal influenza vaccine is

produced only in developed countries where its use is well established. However, the existing capacity is less than half a billion doses, but with process optimization of the influenza vaccine production process and also increased uptake in countries already using seasonal influenza vaccine it is possible to reach a goal of about a billion doses when needed. But that is still too little to cater to the needs of the entire global population.

Box 1: Recommendations following the WHO mapping survey, 2006-2007, SEA Region Countries

- All countries need to review their influenza pandemic preparedness plans to assure:
  - that the role of vaccination is clearly spelt out.
  - that a logistical plan/map showing the distribution of all points is included.
  - that a command and control protocol is part of the distribution plan.
  - that disease surveillance for influenza is adequately addressed.
  - that plans are made to stockpile or assure access to the required syringes for the application of a parenteral immunization.
- All countries need to review with their NRAs the regulatory pathways that need to be strengthened or developed for lot release licensing and post-marketing of these vaccines.
- All countries with plans for introducing seasonal influenza vaccines into their national immunization schedules need to consider all the issues and impact of this policy decision. Most importantly discuss with their suppliers and or other procurement agencies the availability of this product.
- The Regional office should consider organizing a Task Force to prepare a Regional Influenza Pandemic Preparedness Plan with its Member States.

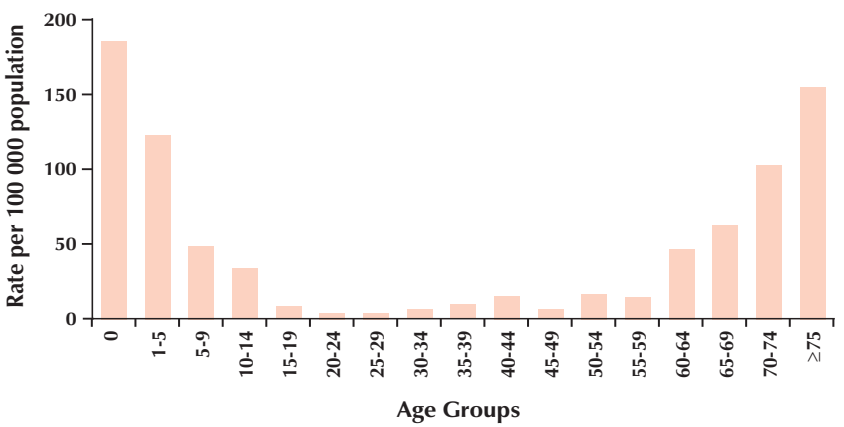
It is also known that currently existing capacity for influenza vaccine production is very limited. Countries which are resource-rich have established advance purchase agreements with the major international influenza vaccine manufacturers for obtaining a pandemic influenza vaccine when it becomes available. Therefore, even if a pandemic influenza vaccine becomes available, countries with poorer resources which do not currently use seasonal influenza vaccine or have no vaccine production capacity will also have no access to pandemic influenza vaccine as there will be no excess capacity. Therefore, it is vital for countries to put in place policies on the use of the seasonal influenza vaccine and commit resources to ensure a sustainable seasonal influenza vaccination programme in countries in order that the vaccine suppliers increase their production capacity.

5 Influenza surveillance in the Region

There are several sentinel sites in Member States of the SEA Region that are part of the global influenza surveillance network that routinely collect samples from patients to provide to WHO for information on circulating influenza viruses and to track changes. This enables WHO to make appropriate recommendations on the composition of seasonal influenza vaccines. Since 2002 **Thailand** set up a population based prospective seasonal influenza surveillance programme in addition to the routine surveillance and avian influenza surveillance already in place. The population-based surveillance programme includes about 1.1 million people covered by 20 hospitals. The influenza surveillance in Thailand is backed by a network of 12 participating laboratories.

Contrary to the general belief that seasonal influenza is not a public health issue in Asia, the Thailand influenza surveillance clearly shows that it is a major public health burden with significant morbidity and mortality. For example, 10% of all cases of hospitalized pneumonia were caused by influenza virus, and about 23% of outpatient cases with influenza-like illnesses were confirmed to be caused by the influenza virus. Further, the highest risk for influenza was of those aged less than five and more than 65 years [see Fig. 2].

Fig 2: Baseline, annualized incidence of Influenza Pneumonia Sa Kaeo and Nakhon Phanom: 2005-2006 (n=661)



Based on the data generated from the influenza surveillance, the following conclusions were arrived at:

- Seasonal influenza is an important cause of pneumonia and outpatient visits in Thailand.
- There is a consistent seasonal peak through June to October with year-to-year variability.
- The primary risk age-groups for the disease and its complications are those <5 years and >65 years, with underlying cardiac and respiratory diseases and hospitalization within the last one year as important risk factors.
- The use of seasonal influenza vaccine is limited but increasing.

The Royal Government of Thailand in early 2008 adopted the following policy decisions:

- To extend the benefits of seasonal flu vaccination (protect risk groups) and support the national pandemic vaccine capacity project as part of pandemic preparedness.
- To finance seasonal influenza vaccination under Universal Health Service Coverage (UC/NHSO).
- To start with the most vulnerable/cost-effective target: individuals with underlying diseases aged 65 years or above, and extend stepwise to other priority groups (eg. individuals with underlying diseases under 65 years, all people over 65 of age, children between six months and two years old).
- To implement seasonal influenza vaccination as part of EPI in campaign approach and to start the pilot programme in June 2008.
- To evaluate the pilot program (for burden reduction, cost-saving, acceptance, etc.) to justify further expansion.

This is an excellent example of where high-quality surveillance systems were put in place to generate reliable data and based on that data the national authorities were able to make rational decisions for the use of seasonal influenza vaccine. The importance of high-quality surveillance as the first necessary step towards a comprehensive approach to tackle the problem of seasonal influenza and to prepare better for a potential pandemic cannot be over-emphasized.

The example of Thailand is consistent with best practices of having high-quality disease surveillance on which to base rational policy decisions. The seasonal influenza surveillance system in South Korea has two components: Korean Influenza Surveillance Scheme, and a school-based surveillance system. The Korean Influenza Surveillance Scheme focuses on 702 clinics and 240 primary health-care centres to track and monitor influenza-like illnesses (ILI). The school-based surveillance system has about 249 participating schools where trends for absenteeism due to influenza and/or common cold are monitored. For the purpose of prioritization of the use of pandemic vaccine in DPR Korea, the Advisory Committee for Pandemic Influenza deliberated the prioritization of the use of pandemic vaccine in the event of a pandemic actually happening.

The prioritization principles adopted by the Advisory Committee for Pandemic Influenza for the use of pandemic vaccine are: (i) to ensure that critical health services are maintained; (ii) minimize the impact on basic social functions and social order; and, (iii) review and revise constantly during a pandemic u sing epidemiological information to guide decisions. Based on these principles they categorized as first priority (i) ***health-care workers*** (health-care workers, first responders to outbreak, emergency service responders etc.); and, (ii) ***essential service providers*** (police, fire-fighters, utility workers, communications and media workers, transport staff, critical administrative personnel, military forces, etc.) as the first to receive pandemic vaccine. The second priority group includes: (i) ***high-risk groups*** (chronic care residents, patients with underlying medical conditions, pregnant woman, children aged between six and 23 months) and then finally, (ii) ***others*** (healthy adolescents, children aged 2-18 years and healthy adults). Rough numbers of how many people were there in each category were estimated to forecast vaccine demand and to prepare detailed vaccine deployment plan.

Similarly in the United States of America the work of pandemic vaccine prioritization is a joint endeavour of US the Department of Health and Human Services (DHHS) and the Vaccine Advisory Committee. The recommendations from these groups were included in the 2005 DHHS Pandemic Plan which provided guidance to the states and local administration units, and also to stimulate further discussions on the evolution of this plan with the passage of time. The principles guiding prioritization are that there will not be sufficient vaccine available for the entire population and, therefore, targeting groups for earlier or later vaccination will best support pandemic response goals to reduce the health, societal and economic impact of a pandemic. Following exhaustive discussions the choice was finally narrowed to about 57 groups which were defined as priority based on job profile, age and health status. Then an interagency group rated the extent to which each group met occupationally related objectives. Further, CDC and external experts rated the extent to which each met “science-based” objectives, and applied weights based on public and stakeholder values. Based on the results of such ratings, each group was then prioritized and rough estimates of population numbers worked out to develop a comprehensive plan for a tiered vaccination approach which would target the most critical group first but eventually reach the entire population.

6 National Committees for Immunization Practices (NCIP); Concluding statement from the workshop

(1) National Committees for Immunization Practices (NCIP)

- The participants of the Workshop on Strengthening National Committees for Immunization Practices (NCIP) for pandemic influenza preparedness, held at Jakarta on 25-28 March 2008, acknowledge the need and the value of an advisory body to guide national governments on immunization policies and practices. To that end, several Member States had such bodies in existence for many years and, more recently, several others have begun the process to establish them.

- The formation of functioning advisory bodies to support national governments to make evidence-based decisions, be it introduction of a new technology or a new vaccine, is seen as an integral component of systems development and national ownership is deemed essential for its long-term sustainability. Therefore, the workshop participants urge all governments to ensure that the activities of such advisory bodies are integrated into the national processes of annual work plan development and budget allocation.

- The participating countries of the workshop commit themselves to strengthening such immunization advisory bodies where they exist and take urgent steps to establish where none exist now. The participating countries also urged all other countries who were not at the meeting to do the same.

- It is agreed that the terms of reference (ToR) of existing immunization advisory bodies will be reviewed and, if necessary, updated to reflect current needs and have it approved as appropriate. This task will be completed latest by 31 December 2008 and copies transmitted to the WHO Regional Office for South-East Asia.

- WHO is encouraged to provide the leadership and technical support to those countries that are yet to establish an immunization advisory body and also to help improve the currently existing advisory bodies. Further, WHO is requested to assist Member States to strengthen immunization

advisory bodies in countries through the exchange of experience and expertise among Member States, between Member States and the international and regional bodies in the coming years.

(2) Seasonal influenza surveillance and seasonal influenza vaccine use in the SEA Region

- The epidemiology of seasonal influenza infection is relatively unknown in the countries of the SEA Region. Consequently, surveillance data does not enable countries to make any judgement on the need for vaccination although the disease is certainly known to occur in all countries.

- However, realizing the importance of surveillance to establish evidence of disease and gauge its burden, several countries have initiated processes to put in place sentinel surveillance systems to study the epidemiology of seasonal influenza. In this respect Thailand is the most advanced in setting up a surveillance system and the participants lauded Thailand's decision to begin pilot seasonal influenza vaccination with the aim of ultimately integrating influenza immunization as an integrated component of their national immunization programme. The advisory bodies of other Member States fully realized the need to place the issue of flu vaccination on the agenda of future immunization advisory body meetings in their respective countries.

- The world's current total capacity for seasonal influenza vaccination is around 300 million doses. If all efforts are made to enhance this to its full capacity, a capacity for around 580 million doses exists today. Enhancing production capacity is necessary to meet the global needs in the event of a pandemic outbreak.

- The immunization advisory bodies realize the need to invest in research and development for influenza vaccines in this Region and to promote production of seasonal influenza vaccine to prepare for a looming pandemic threat. However, this is not feasible in the absence of any visible demand from Member States or in the absence of a policy on routine use of flu vaccine in most countries. Therefore, the immunization advisory bodies participating in this workshop will review their country-specific situations at their future meetings.

7 Next steps and follow-up actions

- Provide technical assistance to the countries that still have not formed national committees for immunization practices.
- Encourage NCIPs to discuss the issue of use of seasonal influenza vaccine and encourage national governments to review their needs for influenza surveillance.
- Support exchange of experiences between NCIPs of countries and keep NCIPs fully updated with the latest policies on immunization and vaccines.
- Small-scale financial support may be needed, at least for a limited period, at the beginning, but all agreed that routine costs of NCIPs should be factored in the annual budgets of national EPI programmes.

Annex-1

World Health Organization
Regional Office for South-East Asia

IVD
IMMUNIZATION AND VACCINE DEVELOPMENT

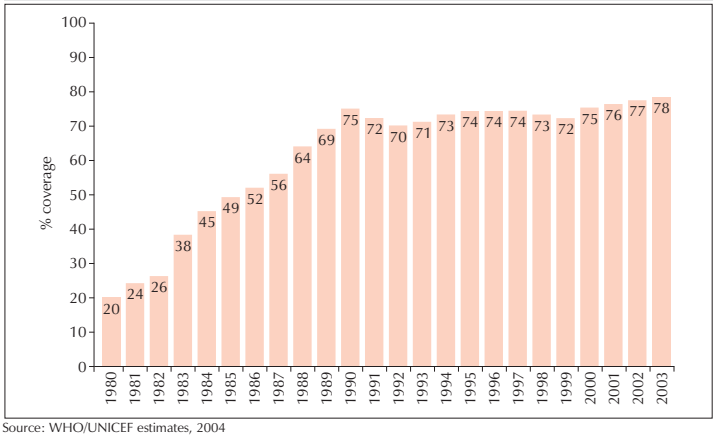
National Committee for Immunization Practices (NCIP)

A general framework for its establishment and functioning

1 Background/Rationale

Immunization is considered to be one of the most cost effective public health interventions leading to measurable and significant reductions in the morbidity and mortality. Since the intensification of immunization activities in the early 1980s, the world achieved tremendous progress resulting in the declaration of Universal Childhood Immunization achievement in 1991. However, by mid 1990's there has been a slackening of achievements where coverage plateaued in most countries[1] (see fig 1) and actually took a downward trend in several others. WHO and UNICEF estimate that currently up to 30 million children globally, including 10 million in India alone, do not receive the six basic vaccines of EPI (Polio, DTP, Measles, & BCG): Indonesia and Bangladesh each has close to a million unimmunized children annually. Searching for innovative ways to reach those hard to reach and enhance access to the millions that do not avail routine services are challenges that countries must address.

Figure 1: Global Immunization 1980-2003, DTP3 coverage



Source: WHO/UNICEF estimates, 2004

[1] WHO/UNICEF retrospective estimates of coverage

While access to existing vaccine still remains a challenge for many countries, with new global initiatives such as Global Alliance for Vaccines and Immunization (GAVI), even for the world's poorest countries (those with GNI <1000 US $), a fresh injection of needed resources as well as the opportunity to put back immunization on development agenda are now available. With support from the GAVI Alliance, many countries have embarked on the introduction of new or underutilized vaccines such as *Haemophilus influenzae* type b (Hib) and hepatitis B. And there are other new vaccines already in the market against diseases such as rotavirus, pneumococcus, human papillomavirus, Japanese encephalitis and typhoid. New vaccines and technologies and the need to introduce them are realities that countries must strive to take advantage of. However, it is ideal that such decisions are made by the countries themselves, based on their national priorities and capacities. In order to enable countries to make strategic evidenced-based decisions on measures to increase coverage and achieve disease control or on the introduction of new vaccines or technologies, each country must have the technical capacity to assess the country's need, evaluate the available strategic options, new vaccines and technologies and make appropriate strategic and policy decisions.

At present, in the South East Asia region of WHO, India, Thailand, and Sri Lanka have formally constituted national advisory bodies to guide immunization policies; other countries such as Indonesia and Nepal are currently working towards establishment of such bodies. It is necessary, therefore, to encourage those countries that do not have such bodies to constitute a National Committee for Immunization Practices (NCIP). However, NCIP should not be considered synonymous with the Interagency Coordinating Committees (ICC) that is already established in almost all countries: ICC is more of a coordinating entity that brings together stakeholders and mobilize resources to implement policies and strategies recommended by the NCIP if the recommendations are accepted by the government. On the other hand, a body such as the NCIP is the technical body that provides the state of the art knowledge on immunization, vaccines and vaccine delivery technologies. NCIP's role is to guide national governments on issues of vaccine quality and safety, immunization choices and strategies, new vaccines and new delivery technologies. The NCIP will be the technical resource to assist the national authorities in evidence-based decision making, and be the technical arm that supports the country's stewardship immunization programme.

2 Objective:

The general objective is to establish a functioning NCIP at the national level in each country in SEAR. The main role of the NCIP is to provide technical guidance to MoH/EPI on immunization policies, norms and practices. The broad general terms of reference (TOR) for such a group is outlined below.

3 Terms of reference

The TOR outlined below is broad-based and not necessarily exhaustive; each country must adapt it to their individual needs and priorities. The TOR of the NCIP are to provide advice on:

- Immunization schedules, their adequacy and effectiveness, both in the public and private sector
- Introduction of new vaccines, both in the public and private sector
- Standards on the delivery of immunizations (standards regarding vaccine storage, mode of administration and vaccine safety)
- Provide state of the art knowledge and information on the recent advances in the development of new vaccines of relevance with future potential for inclusion in the national immunization programme.

- Norms regarding the contraindications to be followed by all service providers to offer immunization services.
- Norms and standards for reporting adverse events following immunization
- Protocols to be followed for reporting of diseases and taking of specimens
- Surveillance standards and case definition for disease preventable by immunization for both public and private sector
- Policy analysis and determining the most optimal national EPI Policy and strategies.
- Provide technical advice to help the government make decisions and develop policy regarding vaccine security issues, including quality and safety
- Advise, where appropriate, organizations, institutions or government agencies in the formulation of policies, plans and strategies for research and development in new vaccines and vaccine delivery technologies of the future
- Evaluate data from monitoring of adverse events following immunization and advise national authorities on issues related to vaccine safety.

4 Composition of NCIP

While there are no fixed rules to say who should or who should not be members of such a group, a general framework can be drawn up to ensure that a right mix of technically sound and experienced individuals are represented. Broadly the composition of NCIP may be grouped into three categories: (i) ***Core Members*** who are independent experts without any conflicts of interest or personal stake in immunization programme, (ii) ***Liaison Members*** who need to be at the meeting to provide key perspectives such representative from regulatory bodies, and (iii) ***Secretariat Members*** who coordinate the meeting such as the EPI Program Manager and team. While it is up to the national governments to identify which individuals should be on the group, it is recommended to include at least the following:

- An (infectious disease) epidemiologist
- Representative either from the National Regulatory Authority or drug/vaccine licensing body
- A senior pediatrician
- Representative from the National Control Laboratory
- Public health expert
- Representatives of the national pediatric association or medical association
- National EPI Program Manager
- An independent expert in child health/or public health/or vaccines
- WHO and any other technical partner(s) as appropriate

In larger countries, particularly in those countries where capacity for vaccine research and development, and where vaccine manufacturing capacity already exist, there may be need to establish (i) ***sub-committees*** either to deal on specific issues as a one time activity or (ii) permanent or ad hoc ***technical sub-groups*** that are constituted to tackle specific areas of immunization and vaccines on a regular basis, and provide technical recommendations for consideration by the larger NCIPSpecial invitees, either national or international experts, may be included as and when deemed relevant to the issue for discussion.

5 Modes of functioning of the NCIP

(a) Meeting frequency

It is recommended that ministry of health budget this activity in their annual plans; it is suggested that the NCIP meet on a quarterly basis if feasible, but certainly, at least twice a year.

(b) Conduct of meeting

The NCIP, from amongst its members, will decide on the chair and, in the absence of chair, a co-chair that assumes the role of the chair. The convener (MoH/EPI) should appoint the chair with endorsement and support from other members. The National EPI Program Manager will function as the Secretary to all the meetings of the NCIP. Summary minutes of each meeting must be available; the last meeting's minutes endorsed by the group in the next meeting.

6 Potential role of WHO in support of NCIP

WHO, through its country offices, can help with the establishment of such a body at the national level. Once established, WHO can assist with the functioning of the NCIP in several ways. This may include,

- Assist national counterparts in conducting critical evaluation of epidemiology, research and economic data to generate the evidence needed for decision-making
- Share technical information and experiences from other countries and regions with the NCIP to help with formulation of immunization policies and strategies for VPD control. This will include access to relevant WHO documents and position papers.
- Providing regular updates and latest developments in new vaccines, vaccine delivery technology, VPD surveillance, safety and quality data/information etc
- WHO also can support the assessment, at some appropriate point of time in future, the impact and utility of such a body to the national government

7 Relationship between NCIP and other bodies

The formation and the functioning of an expert group at the national level would enhance the national government' s capacity to make informed decisions about the choices in vaccines and immunization. Having competent bodies such as NCIP at the national level will also contribute to building regional capacity and that, in turn, will contribute to global capacity.

A Regional Technical Consultative Group (TCG) already exists and functions to provide technical and policy guide to Immunization and Vaccine Development (IVD) unit. This is an important body that contributes to the development of a Regional Strategic Framework to promote immunization, research and development in immunization. The policy directions of the TCG would be helpful to the work of the NCIP and, vice-versa, the inputs from NCIPs would be important for TCG deliberations.

8 Title of the advisory body

While, for the sake of simplicity, the title of National Committee on Immunization Practices is used here, countries are free to name it the way it best serves their purpose. Therefore, it is not necessary that such body be called NCIP in all countries.

Annex-2

Core elements in a ToR of a national immunization advisory body

The following are the core elements recommended to be part of the terms of reference (ToR) for a national immunization advisory body:

A. Schedules, effectiveness of immunization.

B. New vaccines introduction considerations:

   (i) Disease burden (epidemiology),

   (ii) Vaccine quality, vaccine effectiveness, vaccine safety and adverse events,

   (iii) Vaccine cost effectiveness,

   (iv) Any other issues of societal concern related to the use of vaccines.

C. Use of immunoglobulin.

D. Norms and standards for vaccine delivery and immunization practices.

E. Policy analysis and decision on optimal EPI policy for the country.

F. Guidance for research and development on vaccines, immunization and immunization delivery technologies.

G. Guidance during emergency or disease outbreaks.

H. Shall provide recommendations on the appropriate immunization schedule, vaccine administration to include but not limited to:

   (i) prevention and control measures,

   (ii) disease reporting measures,

   (iii) reporting of adverse events,

   (iv) contraindications,

   (v) vaccine supply.

Annex-3

Programme

25 March 2008

08:30 Registration

09:00 Welcome remarks by Dr Pem Namgyal

09:05 RD opening remarks (to be read by WR)

09:30 National Committees for Immunization Practices (NCIP) – An overview of the progress of their establishment in SEA Region: Dr Pem Namgyal

10:30 WHO Survey on the use of influenza vaccine in SEA Region countries: Dr Peter Carrasco

11:00 Organization, terms of reference, operations and challenges, NCIPs in SEA Region countries:

- Thailand – Dr Charung Muangchanna
- Sri Lanka – Dr Nihal Abeysinghe
- India NTAGI – Dr RK Aggarwal
- Discussions

14:30 Organization, terms of reference, operations and challenges, NCIPs in SEA Region countries (continued):

- Indonesia – Sri Rezeki Hadinegoro
- Discussions

16:30 Influenza surveillance in Thailand: Dr Supamit Chunsuttiwat

17:15 Global seasonal influenza vaccine production and consumption, the issue of the need to generate demand for seasonal influenza vaccine to build capacity for pandemic vaccine production: B. Palache

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09.00 Organization, terms of reference, operations and challenges, NCIPs in other countries:

- USA ACIP: Dr Dale Morse
- Discussions

11:00 Organization, terms of reference, operations and challenges, NCIPs in other countries (continued):

- South Korean ACIP: Dr Woo Joo Kim
- Discussions

1200 Work Group: Analysis of ToRs of NCIPs in SEARO: What are the commonalities and differences and what recommendations can be made to enhance their effectiveness?

14:30 Feedback from work group

15:00 The role of pediatric Associations:

- Indian Academy of Pediatrics – Dr RK Aggarwal
- American Academy of Pediatrics – Dr Dale Morse
- Indonesia Pediatric Association – Dr Sukman Tulus Putra

16:30 The role of pediatric associations (continued)

Discussions

17:00 Presentation of evidence

Disease surveillance for influenza:

- Influenza surveillance in the US – Dr Anthony Fiore
- Influenza surveillance in Indonesia – Dr Endang RS
- Influenza surveillance in SEA Region – Dr H Caussy
- Discussions

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09:00 WHO GISN: Global Virus Surveillance:

- national influenza surveillance centres – Dr Harry Caussy
- India Influenza Foundation – Dr RK Aggarwal

11:00 Choice of vaccines:

- Killed Inactivated Influenza Vaccines – Dr Peter Carrasco
- Live attenuated influenza vaccines – Dr Anthony Fiore
- Discussions
- Safety and efficacy of influenza vaccines and post marketing Surveillance – Dr Dina Pfeifer

14:30 Review of immunization schedules

- Korea – Dr Dong Han Lee
- USA – Dr Anthony Fiore
- Discussions

16:30 Influenza immunization schedule used in private sector in SEARO countries:

- Thailand – Dr Charung M
- Indonesia – Dr Carmelia Basri
- Bangladesh – Dr Md Tazrul Islam
- Discussions

17:30 The Role of vaccine industry in NCIPs:

- USA – Dr Dale Morse
- Indonesia – Dr Iskandar
- Developing country vaccine manufacturers – Dr Dori Ugiyadi
- Discussions

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09:00 Pandemic influenza preparedness, assessing the role of vaccine to interrupt pandemic:

- Overview of H5N1 influenza vaccine – Dr Peter Carrasco
- Evidence to date for use of a pandemic influenza vaccine for mitigating the influenza pandemic – Dr Peter Carrasco
- WHO stockpile of H5N1 influenza vaccine – Dr Peter Carrasco
- Prioritization of the use of a pandemic influenza vaccine USA – Dr Anthony Fiore

11:00 Prioritization of the use of a pandemic influenza vaccine (continued):

- Korea – Dr Dong Han Lee
- Discussions

11:45 Local level preparedness: Presentation from the preparedness

- State of New York – Dr Dale Morse

12:15 Pandemic vaccine influenza and potential vaccine production capacity, manufacturers' perspectives and the challenge for countries - DCVM

- Discussions

14: 30 Enhancing seasonal influenza vaccine productions in the SEA Region:

- Bior Farma – Dr Sukaman Tulus Putra
- Discussions

15:00 NCIP Perspective, round table discussion: Next steps for policy recommendations for increasing the use of seasonal influenza vaccine:

- Moderator – Dr Pem Namgyal
- Bangladesh, India, DPR Korea, Myanmar, Maldives, Nepal, Sri Lanka, Thailand

15:30 Summary conclusions of the meeting:

- Dr Pem Namgyal

16:00 Adjournment and Coffee

Annex-4

List of participants

Sl. No	Name	Designation	Country
1	Dr MRN Abeysinghe	Chief Epidemiologist, EPI Unit	Sri Lanka
2	Dr N Siriwardena	Medical Officer, Polgahawela	Sri Lanka
3	Mr AKM Zafar Ullah Khan	Secretary, MoH, Mohakali	Bangladesh
4	Dr Md Tezul Islam	EPI Program Manager	Bangladesh
5	Prof. Dr Abdul Mannan Miah	Dept of Paediatrics, BSMMU	Bangladesh
6	Ms Karma Tshering	EPI Program Manager	Bhutan
7	Dr RK Aggarwal	President, Ind Acad of Paed	India
8	Dr AK Prasad	India Influenza Foundation	India
9	Mr Ahmed Khaleel	Dy. DG, MoPH	Maldives
10	Dr Supamit Chunsuttiwat	Senior Expert, MoPH	Thailand
11	Dr Charung Muangchanna	Director, NVCO, MoPH	Thailand
12	Mr Mateus Cunha	EPI Program Manager	Timor-Leste
13	Dr Carmelia Basri	EPI Program Manager	Indonesia
14	Dr Sukman Tulus Putra	Chairman, Indonesian Acad of Paed	Indonesia
15	Prof. Sri Rezeki Hadinegoro	Chairman, Indonesia Imm. TAG	Indonesia
16	Drs. Dori Ugiyadi	VVPM, Bio Farma	Indonesia
17	Dr Endang R S	Director, NIHRD	Indonesia
18	Drs Iskandar	P&D Director, Bio Farma	Indonesia
19	Dr Antony Fiore	CDC, Atlanta	USA
20	Dr Dale L Morse	ACIP, CDC, Atlanta	USA
21	Dr Dong Han Lee	NCIP, Seoul	Republic of Korea
22	Dr Woo Joo Kim	Chairman, IVS-C, NIAC, DoIM	Republic of Korea
23	Dr Bram Palache	IFMPA IVST ITF PC, BSC	Netherlands
24	Dr Peter Carrasco	WHO/HQ	Geneva
25	Dr Dina Pfeifer	WHO/HQ	Geneva
26	Dr Pem Namgyal	WHO/SEARO	India
27	Dr Deoraj Caussy	WHO/SEARO	India
28	Dr Bardan Rana	Medical Officer, EPI, WCO	Indonesia
29	Ms Asmaniar, SKM	EPI, WCO	Indonesia
30	Ms Gina Saman	CRS, WCO	Indonesia
31	Mr Frank Mahoney	CRS, WCO	Indonesia
32	Ms Sylvia	WCO	Indonesia
33	Ms Deasy	WCO	Indonesia

National Committees for Immunization Practices (NCIP) are important technical advisory bodies that provide the basis for informed and rational decision-making on the choice of vaccines and immunization technologies. Several countries of the WHO South-East Asia Region have had long established and well functioning NCIPs or its equivalents. However, several Member States do not have such bodies. With the advent of new vaccines and injection technology, the choice for countries has widened. The decision to choose a particular vaccine to be included into national immunization programme is a complicated process. NCIPs play critical roles in guiding the governments towards an informed and evidence-based decision.

A workshop on strengthening the capacity of National Committees for Immunization Practices (NCIP) for pandemic influenza preparedness was held in Jakarta, Indonesia, from 25 to 28 March 2008. The objectives of the workshop were to orient NCIPs on the NCIP Framework and their potential role in providing guidance on seasonal and pandemic influenza vaccine; review current national EPI policies and strategies, with particular focus on seasonal influenza vaccination; examine national policies, commitments and strategies for pandemic preparedness and promote networking opportunities between NCIPs, regional technical advisory bodies and global forums. This publication is a report of this meeting.

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