Report of the Regional Workshop on Influenza Vaccines

WHO-SEARO, New Delhi, 2–4 April 2012

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Abbreviations

AEFI	adverse events following immunization
DPRK	Democratic People's Republic of Korea
EMR	emergency medical relief
EPI	Expanded Programme on Immunization
GAP	Global Action Plan
GISN	Global Influenza Surveillance Network
GISRS	Global Influenza Surveillance and Response System
HQ	headquarters
HPV	human papilloma virus
ILI	influenza-like illness
IEDCR	Institute of Epidemiology, Disease Control and Research
IEC	information, education and communication
NCIP	National Committee on Immunization Practice
NIC	national influenza centres
NIPPRP	national influenza pandemic preparedness and response plans
NIPVDP	national influenza pandemic vaccine deployment plan
NRA	National Regulatory Authority
NTAGI	National Technical Advisory Group of Immunization
PIP	pandemic influenza preparedness
SARI	severe acute respiratory illness

SEA	South-East Asia
SMTA	Standard Material Transport Agreement
SOP	standard operative procedures
VPD	vaccine-preventable diseases
WHO	World Health Organization

Executive summary

A regional workshop on influenza vaccines was held at the WHO Regional Office for South-East Asia, New Delhi from 2-4 April 2012. The objective of the workshop was to strengthen the efficient deployment of pandemic influenza vaccines and review the feasibility of introducing seasonal influenza vaccines in Member States of the South-East Asia Region. All countries in the Region had identified pandemic influenza vaccine deployment as a major response strategy to an influenza pandemic in their pandemic preparedness and response plans. Nine countries in the Region either procured or received pandemic influenza vaccines from WHO and eight countries deployed pandemic influenza vaccines during the influenza A/H1N1 (2009) pandemic.

In the first session after presentations on the global and regional experiences of pandemic vaccine deployment, all Member States shared their experiences and lessons learnt in the pandemic. Member States that deployed pandemic influenza vaccines shared lessons learnt in the deployment operation and how this experience was used to update their national influenza pandemic preparedness and response plans (NIPPRP) including the national influenza pandemic vaccine deployment plans (NIPVDP). Member States that did not deploy vaccines shared experience of containment of Influenza A/H1N1 (2009) pandemic without vaccine deployment and how lessons learnt in the pandemic helped updating the NIPPRP including the NIPVDP.

The other sessions were used to update the participants on the framework for preparedness and response for avian/pandemic influenza in the South-East Asia Region, need for seasonal influenza vaccine introduction and planning for strengthening influenza surveillance based on the experience of vaccine-preventable disease surveillance network. In the final session, participants worked through three group work sessions that focused on rapid and efficient pandemic vaccine deployment, feasibility of seasonal influenza vaccine introduction in Member States and strengthening influenza surveillance in the Region. Participants made recommendations to Member States and to WHO in relation to these three areas focused in the group work.

1. Introduction

The WHO Regional Office for South East Asia (SEA) conducted a regional workshop on planning for the deployment of pandemic influenza vaccines in September 2009 in New Delhi. At the time of this workshop, the pandemic vaccine deployment was completely new to the Region. Hence, this workshop was primarily intended to facilitate gaining knowledge to develop national influenza pandemic vaccine deployment plans (NIPVDP), and to define actions and responsibilities for delivering the vaccine in seven days to all distribution points once it would be available in the pandemic.

Despite uncertainties regarding the availability and adequacy of vaccines and funding for vaccines and operational costs, Member States deployed pandemic vaccines with a varying degree of success. In this process, they encountered a multitude of challenges and barriers to implementation. The response to the influenza A/H1N1(2009) pandemic demonstrated that due to complexities related to key requirements of delivering vaccines to countries such as delayed planning for vaccine deployment, difficulties pertinent to registration or authorization for use, issues related to custom clearance or delivering vaccines to vaccine centres, the vaccine deployment process was hampered. Given the rapid spread of a pandemic, these delays could impact on the effectiveness of pandemic vaccines in delivering its ultimate objective. Therefore, based on the past experience, the need for reviewing pandemic response including vaccine deployment and updating NIPVDP within the overall national influenza pandemic preparedness and response plans (NIPPRP) has been elaborated in recommendations of several regional meetings.

A regional workshop on pandemic and seasonal influenza has been viewed as the best way to achieve this objective. Such a regional workshop enables reviewing the degree to which pandemic vaccines were utilized in Member States, identifying barriers to vaccine deployment, comparing vaccine utilization rates across countries, being aware of different vaccine delivery methodologies used, listening to successes and failures in vaccine deployment in Member States in the Region, interacting with each other and learning from each other's shared experience. These lessons could be utilized for effective planning in optimizing vaccine deployment in a future

pandemic in the Region. Further updates on seasonal influenza vaccines and discussions with country managers facilitate looking into country perspectives of the necessity and feasibility of introduction of seasonal vaccines in Member States. The possibility of introducing seasonal influenza vaccines in the Region will offer a ray of hope for better preparedness for future pandemics by sustaining the regional manufacturing capacity of influenza (seasonal/pandemic) vaccines.

1.1 General objective of the workshop

The general objective of the workshop was to strengthen efficient deployment of pandemic influenza vaccines and introduction of seasonal influenza vaccines in Member States of the South-East Asia Region.

1.2 Specific objectives of the workshop

The specific objectives of the workshop were to:

- review deployment of pandemic influenza vaccines by Member States during the Influenza A/H1N1 (2009) pandemic;
- identify mechanisms to further strengthen national influenza pandemic vaccine deployment plans and incorporate them into the national influenza pandemic preparedness and response plans;
- review the feasibility of introducing seasonal influenza vaccines in Member States of the South-East Asia Region.

The regional workshop was attended by participants from 10 out of 11 Member States representing their national programmes of immunization and programmes of pandemic influenza preparedness and response. In addition, staff from all the WHO country offices involved in the Expanded Programme on Immunization (EPI) and pandemic influenza preparedness and response also participated in the workshop. The list of participants is available in Annex 1 and the detailed programme is given in Annex 2. The Regional Director, Dr Samlee Plianbangchang, inaugurated the workshop. In his address, the Regional Director highlighted the usefulness of the regional workshop as a platform for sharing individual country experiences in pandemic vaccine deployment in 2009 with a view to developing

effective and comprehensive planning for vaccine deployment in a future pandemic within the overall NIPPRP. He also highlighted the appropriateness of using the regional forum to discuss the feasibility of introducing seasonal influenza vaccines in the Region. He invited participants to study the Thailand experience in this regard. Dr Shashi Khare, Head, Department of Polio Laboratory, National Institute of Communicable Diseases, Ministry of Health and Family Welfare, Government of India, chaired the meeting. Dr Soe Lwin Nyein, Director, Central Epidemiology Unit, Department of Health, Myanmar, was the co-chair while Dr Aishath Thimna Latheef, Public Health Programme Manager, Centre for Community Health and Disease Control, Ministry of Health, Maldives, acted as the rapporteur.

2. Proceedings of the regional workshop

2.1 Session I: Pandemic vaccine deployment

The session started with the presentation on "Pandemic influenza vaccines: lessons learnt in the 2009 pandemic" by Dr Wengqing Zhang, WHO-HQ. Dr Zhang highlighted the fact that among the multitude of challenges, early detection of the pandemic virus, sharing candidate vaccine virus, rapid development of a vaccine and ensuring its availability, were the key challenges at the global level. Dr Zhang also highlighted the factors that worked well and those that did not work as anticipated in the pandemic vaccine deployment in 2009. She presented an outline of activities that should be taken into consideration in formulating an effective and efficient pandemic vaccine deployment in future. The suggested activities included early detection of novel viruses with pandemic potential, optimization of donor and candidate influenza vaccine viruses, improving vaccine antigen standardization (potency testing), improving vaccine production capacity and formulating policies and guidelines to increase the demand of seasonal influenza vaccine use with the view to sustaining current global influenza vaccine manufacturing capacity and increasing investments to expand it.

Dr Nihal Abeysinghe, Regional Adviser, Vaccine Preventable Diseases, WHO Regional Office for SEA presented the regional perspective of the pandemic vaccine deployment in the 2009 Influenza A/H1N1 pandemic. He emphasized that Member States in the Region had deployed pandemic vaccines post-peak of the first wave when there was low demand.

However, according to him, 24.4 million doses had been deployed in eight countries of the Region. India and Thailand had procured vaccines from their national budgets. Among the countries that had been supplied pandemic vaccines by WHO, the utilization rate was 51%. Dr Abeysinghe shared the key factors at the country level that facilitated successful vaccine deployment in the Region. Similarly, he shared with the participants the challenges faced by Member States and the WHO Regional Office in the deployment operation. He also explained that there were seven manufacturers of pandemic influenza vaccines with an adequate manufacturing capacity in the Region, and that there was a regional need for sustaining this capacity to respond to another influenza pandemic in the future. In conclusion, he presented the regional recommendations issued by WHO in the post-pandemic period, and activities of the Immunization and Vaccine Department planned on the basis of regional recommendations.

The next two segments of this session were allocated to country presentations. The first segment was for Member States that deployed pandemic vaccines while the second was for Member States that did not. In the first segment, Bangladesh, Bhutan, DPR Korea, India, Maldives, Sri Lanka, Thailand and Timor-Leste shared lessons learnt and explained how they used this experience to update their NIPPRP including NIPVDP.

Though Bangladesh's overall usage rate of pandemic vaccine was 74.3%, it was as low as 53% in the first phase due to the receipt of close-expiry-date vaccines and some misconceptions regarding pandemic vaccines. They had encountered issues such as delays in receiving vaccines, receiving vaccines with close expiry dates, receiving two types of vaccines in the two phases, operational problems associated with using the vaccines supplied with two containers containing antigen and liquid adjuvant during the pandemic vaccine deployment. Collaborative actions of the Department of Disease Control, Institute of Epidemiology Disease Control and Research (IEDCR) and the EPI enabled timely decision-making regarding vaccine deployment while the experience of the EPI in conducting mass-scale vaccination campaigns contributed immensely to the operational success. The communication with the media was effectively carried out by the Ministry of Health at the national level, health administrators at the local level and the field staff at the inter-personal level. Health-care providers at all levels were given quality orientation with special focus on the private sector workers for whom micro-plans were prepared. Management of finances received from different sources,

maintenance of law and order at vaccination centres due to high demand from non-priority groups by involving law enforcement authorities, were highlighted as the key challenges. The presentation underscored that despite these challenges, the successful pandemic vaccine deployment reflected the trust of the Bangladeshi people in their national immunization programme. The strong communication between policy-makers and implementors; establishment of a technical and scientific committee to oversee the deployment; and a 24- hour national monitoring cell, were reported as the contributory causes for success.

Bhutan's reported utilization rate of pandemic vaccines was 91%. Bhutan highlighted that there were delays in finalizing the NIPVDP in consultation with WHO, signing the agreement with WHO to receive vaccines and receiving relevant documents from WHO for obtaining temporary registration from the National Regulatory Authority (NRA). Having to deploy vaccines parallel to the human papiloma virus(HPV) vaccination campaign, not having a specific budget for emergency use such as the pandemic vaccine deployment, the high demand of pandemic vaccines from non-priority groups, practical difficulties in close supervision and monitoring vaccine deployment, training health workers especially those who were without adequate competencies and technical knowledge in remote areas, and finding competent trainers for training and fulfilling communication needs, were seen as the key challenges to implementing the pandemic vaccine deployment. The communication needs revolved around dispelling the negative public perceptions on safety and efficacy of pandemic vaccines. Overall, the experience was a learning curve for Bhutan to face *ad hoc* vaccination campaigns such as the pandemic vaccine deployment. Bhutan intends to update the NIPVDP in the future.

In the Democratic People's Republic of Korea (DPR Korea), the overall utilization of pandemic vaccine was 70%. This was low compared to the coverage standards in DPR Korea for routine EPI vaccines. The low coverage is explained by the decreased felt need of vaccines by the general public given the phase of the pandemic in which vaccines were available in the country. There was a delay in receiving vaccines. Vaccines were received when the pandemic was contained resulting in low acceptance of vaccine. However, among the factors that contributed to the successful pandemic vaccine deployment, high political commitment, the strong system of incident command and control, early decision-making, specific planning of vaccine deployment and close collaboration with other government agencies, the network of family doctors and the active role of

the community in activity monitoring, were viewed as exemplary in DPR Korea.

In India, 1.5 million doses of pandemic influenza vaccines were procured by the national government. The target group for vaccination was all health-care workers in all states. The overall utilization rate was 76%. A unique feature was that all states prepared model district pandemic vaccine deployment plans and established district task forces to oversee the implementation. Strong political commitment, quick decision-making by the team constituted by the centre, fast-track execution of all procedures by the task force under the chairmanship of the health secretary, execution and coordination of the operation by the Director/Emergency Medical Relief (EMR) and establishment of state monitoring committees enabled rapid and efficient vaccine deployment. As the sole target group for vaccination was health-care workers, there was no acute shortage of human resources for the deployment of vaccines. As influenza was not seen as a priority, there was a low acceptance as well as resistance to vaccine deployment in some areas. The less virulent nature of the pandemic virus, overlapping with the pulse polio programme, waiting for the locally made intra-nasal pandemic influenza vaccines were some factors that affected an effective pandemic influenza vaccine deployment. Augmenting quality and quantity of human resources required for a pandemic vaccine deployment, efforts for increasing community demands of vaccines, addressing programmatic issues, improving monitoring and supervision, immunization reviews as was done for polio and increasing indigenous pandemic influenza vaccine manufacturing were viewed as the key areas for India to address in the future in terms of preparedness for a future pandemic vaccine deployment.

In Maldives, 47 410 doses of three types of pandemic influenza vaccines from three different sources were deployed. There was a delay in receiving the first shipment of vaccine. It is noteworthy that the Maldivian government, with the direct involvement of the finance ministry, identified an emergency fund for the pandemic and its contribution in the form of immediate release of US$ 2.3 million was highly significant for vaccine deployment. High political commitment, not depending entirely on the stock supplied by WHO, role of the technical advisory committee, fast-track registration of vaccines by the NRA, contribution of the Maldivian police and National Defence Force in supply of additional human resources, and establishment of immunization centres by the Disaster Management Centre were the key factors for an effective vaccine deployment. While front-line

health workers were engaged in the deployment operation, quick mobilization of medical personnel of the Maldivian National Defence Force, volunteers and organizing rapid orientation covered the gaps in human resources to rapidly deploy pandemic vaccines. Intersectoral committees acted as the main forum for "between-agency" communication while there was a designated focal point in each atoll for communication with the central level. A single media focal point was used for directly disseminating constant updates on the pandemic and vaccine deployment. Based on the experience of the pandemic, Maldives has already updated its NIPVDP and intends to establish a quarantine facility and a National Influenza Centre (NIC).

The overall vaccine use in Sri Lanka was 59%. Timing of the delivery of vaccines that coincided with the end of the first wave of the pandemic in the country shifted the position of the NRA from waiving the registration to a requirement for a fast-track registration. It was highlighted that there was a further delay in registration of the pandemic vaccines due to delays in obtaining relevant documents and nonavailability of an intermediate local agent for registering the vaccine in the NRA as the vaccine was donated by WHO. Developing clear-cut criteria for waiving or fast-track registration of vaccine by the NRA, networking with the Disaster Management Centre in future for efficient pandemic vaccine deployment, identifying an emergency fund for emergency vaccine deployment, planning for security threats specially when target groups are prioritized, ensuring availability of vaccines for out-of-pocket purchase in the private sector to ease off the demand of non-priority groups, mobilizing and training non-EPI and private sector health personnel to rapidly deploy vaccines, planning for professional risk-benefit communication, using information technology for rapid sharing of technical and management information between health and non-health agencies were reported as the key areas to focus in a future pandemic vaccine deployment. Based on these experiences, Sri Lanka has updated the NPIVDP and incorporated it into the NIPPRP.

Thailand stated that it considers preparedness and prompt response to a pandemic as the major step in ensuring its national security. Thailand's response strategies were adjusted to the dynamics of the pandemic in the country. However, in the second wave, in addition to the strategies used in the first wave, pandemic vaccines were available. The pandemic vaccination in Thailand targeted health-care workers and high-risk groups. Thailand deployed 2 million doses with an overall usage rate of 77%. However, the initial uptake of the vaccine was low. Public concerns over

vaccine safety following 24 deaths among recipients of seasonal influenza vaccines in the previous season and the media highlighting these despite not having causal links to the vaccine resulted in a low pandemic vaccine uptake. This situation was addressed by communicating the benefit of vaccines, their safety and need for demonstrating the social responsibility of Thai citizens by taking the vaccine through village health volunteers, local administration, health volunteers and nongovernmental organizations. The timelines for vaccination were extended and target groups (household contacts of pregnant women, military recruits, prisoners, health volunteers) were expanded to deliver the benefits of vaccination to the public

The lessons learnt in Thailand in the pandemic 2009 highlighted that vaccination is a complementary intervention in the total package of pandemic response measures specially given the fact that vaccine development takes a window period from the beginning of a pandemic. Political and high-level administrative support and community involvement (multisectoral participation and support) were proven to be of utmost importance to the success of the vaccine deployment in Thailand. In order to garner political and administrative commitment, it was highlighted that rapid response to rumours on Adverse Events Following Immunization (AEFI) and ensuring trust in the programme by prompt investigation of reported incidents were crucial. The AEFI surveillance with early response and risk communication emerged as essential methods to enhance the effectiveness of pandemic vaccine deployment. Planning public communication on vaccine deployment, training competent spokespersons on emergency communication and improving utilization of communication "intelligence", including media monitoring, call lines, and delivery of information through the village health volunteer network were the other measures that were suggested for effective risk communication based on the Thai experience to ensure the effectiveness of the pandemic vaccine deployment.

In Timor-Leste, the overall pandemic vaccine usage rate was 48%. The pandemic response in the country was handled by the National Task Force led by the Minster of Health. The Expanded Programme of Immunization was not involved in the pandemic vaccine deployment in 2010, and this fact was highlighted as a point for future consideration given its ability to effectively deploy pandemic vaccines. Timor-Leste had to obtain funding from WHO to release the vaccine stock as it had not been budgeted in the NIPVDP. Given the lack of capacity in the country, the expatriate staff rendered the required technical expertise to plan and manage the vaccine

deployment operation. Prioritization of vaccine recipients had not caused any chaotic situations as observed in some Member States. The lack of adequately capable human resources, non- mobilization of additional human resources as indicated in the NPIVDP, and inadequate involvement of local leaders in communication campaigns were the major factors that affected the success of the pandemic vaccine deployment in the country. Active involvement of the EPI manager in the national task force for the pandemic response, identifying and coordinating with partners to fill the gaps in logistics, community mobilization, communication and staff training are the key areas that the country needs to focus on in preparing for a future pandemic vaccine deployment. Based on these experiences, Timor-Leste intends to update the NIPVDP and integrate it into the NIPPRP.

The Member States that made their presentations in the second segment were Indonesia, Myanmar and Nepal. Though Nepal had planned for a pandemic vaccine deployment, it did not do so during the pandemic. Non-reporting of any influenza A/H1N1 (2009) cases after February 2010, a limited number of reported pandemic influenza cases (172) and deaths (3), reported incidents of narcolepsy among vaccine recipients in Finland, and confining the effectiveness of the vaccine only to the 2009 pandemic, were cited as reasons for non-deployment of pandemic vaccines. However, Nepal has updated the NIPVDP and is waiting for endorsement by the Ministry of Health and Population to incorporate it into the NIPPRP.

Myanmar, in its presentation, highlighted that the country had signed the letter of agreement and finalized the NIPVDP to deploy pandemic vaccines in the country. Myanmar received the initial shipment of 972 000 doses of pandemic vaccines corresponding to the need of 2% of the population. Nevertheless, they were not used as the received stock of vaccines had already expired. The second shipment was not accepted. Myanmar also stressed the fact that given the receipt of vaccines in a period of 14 months after the establishment of the pandemic, vaccination could only be one of the complementary strategies among multiple strategies of pandemic response. Myanmar has updated its NIPVDP within the overall NIPPRP in 2011.

Indonesia stated that though they had developed an NIPVDP, they did not consider pandemic vaccine deployment as a response strategy in the Influenza A/H1N1 (2009) pandemic. It was felt that given the existing infrastructure for routine immunization and manufacturing capacity of influenza pandemic vaccines in the country, Indonesia was capable of

successfully deploying pandemic vaccines in a future pandemic in the same way that it had adopted planning for responding to an avian influenza A/H5N1 outbreak to effectively respond to the Influenza A/ H1N1 (2009) pandemic. Indonesia's NIPVDP is within the overall NIPPRP and has been updated recently.

The three Member States that did not deploy vaccines underlined the fact that they have strengthened their influenza surveillance activities, are ready to use pandemic vaccination as a strategy to respond to pandemics and have the capacity to deploy pandemic vaccines.

2.2 Session 2: Avian/pandemic influenza – a framework for preparedness and response in the South-East Asia Region

This session began with a global update on avian influenza (H5 N1) by Dr Gayanendra Gongal. He pointed out that as of 26 March 2012, 598 laboratory-confirmed human cases of avian influenza (A/H5N1) had been reported from 15 countries since 2003. He noted that at least three human cases of mild infection were discovered through the influenza-like illness (ILI) surveillance. Interestingly, 51% of human cases of avian influenza (H5N1) reported from 2008 were from Asian countries.

Focusing on the regional situation, he informed that since 2003, human cases of avian influenza (A/H5N1) had been reported from eight countries of the Asia-Pacific region whereas poultry outbreaks had been reported from 16 countries. Drawing attention of participants to Indonesia, he explained that 55 out of 497 districts in Indonesia had reported laboratory-confirmed human cases predominantly from rural areas.

On the basis of the increasing importance of influenza in animals with zoonotic or pandemic potential, Dr Gongal underscored the need for some concrete activities to address the issue of influenza at the human-animal interface. These included policy development, close collaboration between the public health and animal health sectors, strengthening surveillance, epidemiological methods and risk assessments. Given the continuing genetic and antigenic evolution of influenza A(H5N1) viruses, he underlined the need for surveillance of cases occurring in epidemiologically-linked clusters, characterization of un-subtypeable influenza A specimens in specified laboratories, joint risk assessments and

linking influenza data in time and space to be useful for assessment of public health risks from animal influenza viruses.

Dr Vason Pinyowiwat briefly introduced the Global Influenza Surveillance and Response System (GISRS). The chronological order of global response to influenza was described from 1947 to 1952 when the Global Influenza Surveillance Network (GISN) was established. He explained how global efforts were expanded and how the network's name was changed to GISRS after adoption of the World Health Assembly resolution 64.5. He explained that GISRS was a global mechanism and familiarized the audience with its role, work, function, management, laboratories and public health output. Having taken the response to the recent pandemic of influenza A/H1N1(2009) as the basis, he demonstrated that the value of GISRS lay in laboratory diagnostics, monitoring the evolution of viruses, providing laboratory support, enhancing the laboratory capacity of Member States, vaccine virus selection and development of pandemic vaccines. Dr Vason ended his presentation by citing challenges to the GISRS that included timely detection and sharing of new viruses, ensuring a representative coverage of surveillance information, enhancing current knowledge and technology, generating supplementary evidence and tackling the currently experienced scaling down of its activities in the face of difficult economic conditions.

The next presentation was on Influenza Vaccine Development for Novel/Potential Pandemic Influenza Viruses by Dr Wenqing Zhang from WHO headquarters (HQ). Dr Zhang highlighted the fact that WHO 's response to influenza of pandemic potential lay in development of representative candidate vaccine viruses and corresponding potency reagents in order to enable national authorities to consider using one or more of the candidate vaccine viruses for pilot vaccine production, clinical trials and other pandemic preparedness purposes. Dr Zhang informed participants that current influenza vaccines are safe, efficacious, standardized on haemagglutinin content to induce neutralizing antibodies and vulnerable to antigenic drifts and shifts. Describing the complexities related to influenza vaccines, Dr Zhang explained that there was a long established production process of these vaccines predominantly on embryonated eggs, and that it was a time-consuming, costly year–round process. Its unpredictable yield, growth properties and poor response to surge capacity for a pandemic were also highlighted. Dr Zhang enlightened the participants on the current status of pre-pandemic vaccine development and new developments in influenza vaccines. In the latter case, special care

was taken to explain vaccine attributes, technology challenges of live attenuated influenza vaccines, recombinant virus-like particles, and plant-based expression systems. Dr Zhang described the attributes and potential technological challenges encountered in universal vaccine development. In conclusion, Dr Zhang listed safety, scalability, formulation and potency determination, complicated/uncertain regulatory pathways and funding issues as overall challenges to new vaccine development.

Dr Richard Brown, Regional Adviser, Disease Surveillance and Epidemiology, WHO Regional Office for SEA, introduced the pandemic influenza preparedness (PIP) framework for the sharing of influenza viruses and other benefits. He also provided the background of the PIP framework and referred to World Health Assembly resolution WHA 60.28, which recommended developing a framework and a mechanism for benefit sharing, establishing an international stockpile of influenza A (H5N1) vaccine and preparing guidance on vaccine distribution. He referred to the document "Pandemic Influenza Preparedness Framework" adopted through World Health Assembly resolution WHA 64.5. He explained that according to the PIP framework, countries were requested to provide PIP biological materials from all influenza viruses with human pandemic potential to a WHO reference laboratory of their choice in a timely manner. It is also implicit that in providing such materials, Member States give consent for their onward transfer and use by third party institutions, subject to provisions in a Standard Material Transfer Agreement (SMTA). He emphasized that the PIP Benefit Sharing System will provide information, build capacity for pandemic surveillance, risk assessment, early warning purposes, ensure prioritization of benefits, including antiviral medicines and vaccines to developing (especially affected) countries based on public health risks and needs particularly where countries lack capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. According to him, the framework urges countries to share all influenza viruses with pandemic potential with the view to using them to help inform risk assessment, development of vaccines and preparing for the next pandemic. Dr Brown discussed in detail the SMTA 2 benefits in terms of partner contributions, sharing of partner contributions between countries, its use and partner contributions to pandemic response. From the regional perspective of implementation of the PIP framework, he cited that a regional consultation on implementation of the PIP framework was held on 5-6 March, 2012 and the following consensus was reached:

- Advocacy for laboratories of GISRS network, in consultation with policy/decision-makers to adopt the terms of references defined by the framework
- Continued sharing of influenza viruses in a timely manner, including those with pandemic potential
- In order to reflect national/regional priorities, consideration should be given to reviewing the process for prioritization of benefits for different technical areas through the Partnership Contribution to allow input from Member States
- Accelerating the process for negotiation of SMTA
- Developing a mechanism to allow Member States to provide input into the process of negotiation of SMTA 2 arrangements for "non- financial" contribution.

2.3 Session 3: Seasonal influenza vaccination

Opening the session, Dr Julia Fitzner, WHO-HQ, introduced the global perspective of seasonal influenza vaccines and shared the Global Action Plan (GAP) for influenza vaccines and its three major objectives. Under the objective of increasing seasonal influenza vaccine use, Dr Fitzner explained that the influenza working group for the Strategic Advisory Group of Experts is currently conducting an evidence-based review and updating of WHO recommendations on the use of seasonal influenza vaccines (e.g. priority target groups) with the particular focus on low-income and middle-income countries. Dr Fitzner noted that this would lead to updating the 2005 WHO influenza vaccine position papers. It was announced that the new position paper on seasonal influenza vaccination was expected to be published soon.

Regarding the influenza vaccine policy and implementation, Dr Fitzner shared the current global status of seasonal influenza vaccine use. Increasing the proportion of Member States with seasonal influenza vaccination as part of the national immunization programmes, meeting the target of the World Health Assembly resolution WHA 56.19 (75% coverage in the elderly by 2010), tackling the high vaccine costs, giving influenza its due place among competing priorities and changing the public opinion on influenza vaccines were viewed as major challenges.

As per increase in production capacity, Dr Fitzner said that two vaccine production targets by 2015 were:

- Target 1 (GAP target) : Vaccinating 100% of the world with two doses of a pandemic vaccine within six months of its availability
- Target 2 based on evidence of herd immunity: Vaccinating 70% of the world with two doses of a pandemic vaccine within six months of its availability.

However, global mapping demonstrated that the global pandemic influenza vaccine production capacity is still insufficient and strategies to increase production capacity include shifting to higher yielding technologies including live attenuated vaccines, use of adjuvants and building (and maintaining) new capacity. It was stated that even with the projected expansion, the multinational capacity will be insufficient to allow access of developing countries to pandemic vaccine in a timely manner. Consequently, the GAP technology transfer project focuses on helping developing countries to develop influenza vaccine manufacturing capabilities, the capacity for pandemic readiness and achieving sustainable influenza vaccine production capacity. Dr Fitzner concluded her presentation by sharing the next steps for the technology transfer initiative that entails sustaining both technical and financial support for the new manufacturers until registration of a product, strengthening capacity of their respective NRAs, initiating new projects in under-served regions and expanding the currently available types of technologies.

Dr Ranjan Wijesinghe in his presentation titled "Need for introducing seasonal influenza vaccines: the regional perspective" cited epidemiological and economic evidence from industrialized countries and highlighted that influenza was a significant public health problem. He also pointed out that though it affected all age groups, there was a differential risk for high-risk groups in terms of severe morbidity and mortality. While acknowledging that seasonal influenza had been accorded less priority in the developing world due to its unknown burden, inadequate surveillance and other competing priorities, Dr Wijesinghe cited regional evidence to highlight that it merited attention in the South-East Asian Region. He quoted evidence from Bangladesh that seasonal influenza was prevalent in the country with well established epidemiology and seasonality. However, the need for quantifying national rates and determining the economic evidence exists for scaling up vaccination in Bangladesh. The other extensive regional evidence

cited by him was from Thailand, which is a pioneer in seasonal influenza vaccination in the Region. He presented the disease burden information in terms of annual incidence rates, proportion of influenza among hospitalized pneumonia cases based on surveillance data and the vaccine-preventable paediatric disease load of pneumonia due to influenza in Thailand based on economic studies. Thirdly, he shared the epidemiological evidence from the 2009 pandemic in Sri Lanka indicating the higher proportion of patients with underlying morbidity conditions among the hospitalized patients of severe acute respiratory infections due to confirmed and probable influenza A/H1N1 (2009) infection, excessive influenza-specific mortality among pregnant women, age-specific case fatality rate of confirmed influenza A/H1N1 (2009) patients and risk factors among deaths due to laboratory-confirmed influenza A/H1N1 (2009) infection, which were demonstrated to be similar to seasonal influenza in Sri Lanka. Based on this local evidence, he concluded that seasonal influenza vaccines are underutilized despite the fact that there is a regional need for it at least for limited high-risk groups even on the basis of limited available regional evidence.

Highlighting the disastrous impact of the 1918 pandemic in India and Sri Lanka based on available peer-reviewed literature, Dr Wijesinghe articulated that there was a need for preparedness to a severe pandemic in the future with a view to minimizing severe morbidity and mortality. Quoting vaccine deployment timelines in the Region in the pandemic, he argued that there was a need for an earlier pandemic vaccine deployment than was done in the 2009 pandemic. If it is to be done, early identification, early sharing of the pandemic virus and fast-track development of a vaccine were the essential steps. To reduce the window period of deployment from the beginning of the pandemic, he opined that the current regional influenza vaccine manufacturing capacity of at least the present seven regional manufacturers should be sustained. If this capacity is to be sustained, there is a need for increasing the demand for seasonal influenza vaccine in the Region by using it at least for very limited high-risk groups. This is a win-win formula for manufacturers, health managers and, more importantly, for people in facing a future pandemic. In this context, the SEA Regional vaccine priority workshop held from 11-13 May 2009 in Bangkok, recommended the seasonal influenza vaccine as an immediate "priority" vaccine for the SEA Region. He concluded that there was a regional need for introducing seasonal influenza vaccines at least for selective high-risk groups to reduce severe morbidity and mortality given the other regional vaccine priorities and to ensure sustainability of the local

influenza vaccine manufacturing capacity as a regional preparedness mechanism for a future pandemic.

Dr Wenqing Zhang introduced the regulatory aspects of available seasonal flu vaccines. She explained the rationale for prequalifying pandemic influenza vaccines given the need for ensuring their availability in a short time, and for addressing the emerging needs under the circumstance of H5N1. Then she described the expedited procedure for evaluating seasonal influenza vaccines that included meeting two annual submissions for prequalification, acceptance of only licensed vaccines and fulfilling the critical functionality criteria of NRAs. Subsequently she described the expedited measures in detail. She listed the criteria required for considering the possibility of a waiver of testing and a waiver of site visits. Dr Zhang also focused on expedited procedures of prequalification of pandemic influenza vaccines in 2009. She deliberated on vaccine technologies that were covered, application categories I,II,IIIA,IIIB. After having introduced WHO prequalified influenza A/H1N1 (2009) pandemic vaccines and seasonal influenza vaccines prequalified during the 2009 pandemic, she shared the details of reintroduction of seasonal vaccines into the prequalification process in 2010. She also noted that the revised prequalification process consisted of reviewing the general production process, reviewing quality control procedures, testing of consistency of lots and WHO site audit to manufacturing facilities with observers from the relevant NRA. In relation to the assurance of continued acceptability, she explained that reassessments were done at regular intervals, targeted testing of lots supplied through UN agencies was done to monitor continued compliance with specifications and complaints from the field, and that reports of AEFI were followed up. She summed up her presentation by stating that influenza vaccine prequalification was an ongoing process, pending submissions were being evaluated and that new submissions were expected. Moreover, lessons learnt from the pandemic influenza vaccine prequalification process are incorporated into the revised procedure. According to Dr Zhang, influenza vaccines will be shortly smoothly integrated into the main pre-qualification procedure of WHO, replacing the 2006 prequalification practice for specific seasonal influenza vaccines.

In the last presentation of Session 3, Dr Zhang dealt with the influenza vaccine cycle and regulatory considerations. She introduced the calendar of events of the northern hemisphere seasonal influenza vaccines and then moved on to classical reassortment and reverse genetics techniques in generation of high-growth reassortants of influenza viruses. She also shed

light on vaccine potency reagents by referring to antigen reference reagents and anti-serum reagents. Subsequently, she explained the batch release process that entails independent testing by the official control laboratory, laboratory testing, review of manufacturer's protocol and potency testing. She highlighted that all these procedures were the outcomes of extensive public and private sector collaboration. Among the specific regulatory issues brought to the attention of participants by Dr Zhang, limited experience of the majority of NRAs on influenza vaccines, consideration of influenza vaccines manufactured by new technologies as new products and some reported AEFI (such as Guillan Barre syndrome) after licensure despite the general safety of influenza vaccines, were mentioned as the key issues. Another important aspect that was underpinned in Dr Zhang's presentation was regulatory research and development. The areas for focus entailed correlates of immunity, evaluation of new approaches/technologies, evaluation of alternative potency assays and risk communication on safety of influenza vaccinations. In conclusion, Dr Zhang remarked that international scientific regulatory standards were essential to ensure the efficacy, safety and quality of a vaccine product, strengthening of local NRA capacity was a priority of WHO within the PIP framework, and that such strengthening should go parallel to the strengthening of manufacturing facilities to sustain the influenza vaccine manufacturing capacity.

2.4 Session 4: Planning for "integration" of effective influenza surveillance into the Vaccine Preventable Diseases Surveillance Network

Dr Julia Fitzner in her presentation focused on consideration of epidemiological evidence for introduction of seasonal influenza vaccines. She highlighted that influenza surveillance was useful to guide influenza control and prevention strategies. She said that monitoring the viral and disease activity, estimates of influenza burden and better understanding of influenza epidemiology were the essential tools for better decision-making. However, she noted that the lack of standardization of rapid reporting systems, of data dissemination mechanisms and lack of publication and sharing of results were the constraints for effective use of epidemiological evidence. As per burden estimates, she presented the available global evidence of influenza burden among pregnant women and children under five years. While extensively dealing with the available evidence to the effect that pregnant women were clearly at a higher risk of influenza-

specific hospital admissions, she said that they were also more likely to develop severe respiratory complications of influenza, and that the protective effect of vaccination on both respiratory and obstetrical risk had been demonstrated. However, she listed a series of complexities, limitations and constraints to interpreting such evidence, as well as the so far unanswered or incompletely answered questions related to pregnancy. She also compared estimates of the burden of pneumonia due to influenza in children with that of other important pathogens. Dr Fitzner concluded that burden data were still sparse and difficult to compare, and that more comparable studies were needed in different settings. She informed participants that the WHO surveillance and burden tools were useful for Member States. Participants were familiarized with FluID, which is a web-based collection of epidemiological data and FluNet, which is a web-based data collection and reporting tool for laboratories. She also mentioned about the available assistance for shipment of samples, diagnostic guidance for influenza laboratories, global influenza surveillance manual and the manual for burden of disease estimate both of which are targeted for publication at the end of 2012. She stressed the need for having a global picture of virological (FluNet) and epidemiological data (FluID) to be able to understand local issues, qualitative data to provide information even from areas that do not have any formal surveillance systems and quantitative epidemiological data to support the interpretation of virological data and to generate accurate qualitative data. She also demonstrated the ways and means of accessing this information through various WHO products. The key take-away message of Dr Fitzner's presentation was that the local Severe Acute Respiratory Illness (SARI) and influenza like illness (ILI) surveillance were needed for national disease burden and risk groups' description, the sum of all the local data were essential for generating the global picture and identifying patterns, and that this global picture helped in interpretation of influenza in the local context. She concluded with the request to strengthen information gathering at the national level, standardize data collection and share information with regional and global networks.

Dr Rajesh Bhatia, Acting Director, Department of Communicable Diseases, updated the status of laboratory-based surveillance in the SEA Region. He stressed that the entire Region had the capacity to diagnose influenza and undertake its surveillance at the national level. It was an ideal background for dealing with other emerging and re-emerging infections. He said that the Region had eight national influenza centres (Bangladesh, DPR

Korea, India, Indonesia, Nepal, Sri Lanka, Thailand, Myanmar) three national diagnostic laboratories (Bhutan, Maldives, Timor-Leste), one Regional Influenza Reference Laboratory in Thailand, and one global H5 Regional Laboratory in Indonesia. It was highlighted that India had 45 laboratories for sentinel surveillance, and that it intended to propose a National Influenza Surveillance programme for 2012-2017. Dr Bhatia described the functions of influenza laboratories that include diagnosis of influenza, laboratory and disease surveillance of ILI and SARI, monitoring of drug resistance, virus molecular characterization and contributing to GISRS. He also noted that important evidence on influenza in the Region had emerged from the activities of influenza laboratories at country level. He cited many examples of collaboration of influenza laboratories within and outside the Region. Dr Bhatia listed rendering technical support to Member States; facilitating regional and global collaboration; strengthening infrastructure; organizing annual regional meetings of NICs to review progress; providing updates on new issues related to early detection of influenza and novel influenza strains; monitoring of antiviral resistance; and support for onsite laboratory training as the functions of the WHO Regional Office in influenza surveillance.

The major issues identified in relation to influenza surveillance were:

- inadequate surveillance plans for public health action and use of vaccines
- inadequate capacity to diagnose all H types
- limited access to diagnostic services
- nonavailability of NIC in three countries
- lack of coordination with the animal health sector
- non-revision of NIPPRP in the post-pandemic period
- data management and information-sharing issues
- lack of indigenous reagents' production
- issues related to the quality system.

Dr Bhatia noted that future plans of WHO included supporting surveillance for decision-making for introduction of seasonal influenza vaccines, establishing NIC in all Member States, hand-holding by

established NIC for new and upcoming NICs, support for revision of NIPPRP, facilitating collaboration with the animal health sector, data sharing and strengthening of the quality systems.

The final presentation in this session was on "Integrated Influenza Surveillance in Vaccine Preventable Disease Surveillance in SEAR" by Dr Mainul Hasan. Dr Hassan listed the strengthening capacity of Member States on preparedness and response to influenza with pandemic potential; performing surveillance with a view to responding to seasonal and pandemic influenza; strengthening laboratory infrastructure; building laboratory and epidemiology capacity; and accurate and prompt diagnosis of seasonal influenza and influenza with pandemic potential, as the main objectives of integrated influenza surveillance. One proposed activity in this regard is to strengthen and integrate the capacity of Member States of the Region to carry out surveillance and response to seasonal and pandemic influenza. The other activity is to strengthen laboratory infrastructure and build laboratory and epidemiological capacity to accurately and promptly diagnose seasonal influenza and influenza with pandemic potential. The WHO Regional Office expects to organize regional/national meetings, conduct national/subnational influenza surveillance training, co-financing for VPD surveillance networks, upgrading laboratories for early detection/rapid diagnosis of influenza, ensuring availability of laboratory consumables and onsite laboratory training. Dr Hassan also informed participants that a pilot project on integrating seasonal influenza surveillance into the existing VPD surveillance was being organized in Nepal.

2.5 Session 5: Building intersectoral collaboration in seasonal and pandemic influenza vaccination

Session 5 consisted of a presentation on Thailand's experience on introduction of seasonal influenza vaccines and a group work. The presentation was meant to be used as an introduction to the practical aspects of intersectoral collaboration with multiple stakeholders by Thailand in their pursuit to introduce seasonal influenza as a long-term preparedness measure for pandemic. It was ultimately expected to help participants in preparation for the group work.

Dr Opart Kankawinpong shared the experience of nearly a quarter century in the evolution of EPI in Thailand. He showed how Thailand

achieved the control of vaccine-targeted diseases over the years with high vaccine coverage. Parallel to these achievements, Dr Kankawinpong pointed out how Thailand gathered epidemiological and economic evidence on seasonal influenza in order to develop policies on control and prevention. What was noteworthy was the number of collaborations Thailand had had with different stakeholders to generate this evidence base. A health economic analysis had demonstrated that influenza vaccinations would reduce the incidence of pneumonia in the elderly by half, be effective in 76% of chronic obstructive pulmonary disease patients, save medical costs amounting to 736 million bahts and indirect costs amounting to 800 million bahts. All these were achievable with a vaccine cost of US$ 35-56 million in a target population of 7 million. Meanwhile, in 2004 after the country was affected by avian influenza outbreaks, economic analyses demonstrated that in 2004 alone, the effect of the outbreak on the Gross Domestic Product was 0.39%. In the event of avian influenza A/H5N1 acquiring pandemic potential the effect of such a pandemic was estimated to be in the range of 6.5-26 million cases and 6500-143 000 deaths in two extreme scenarios (best and worst case scenario). Therefore, strategizing for preparedness and response to a pandemic influenza was proven to be an important priority for the country. Two major directions in this regard were securing national access to pandemic vaccines by establishing local production capacity and ensuring increased use of influenza vaccines to provide a market for locally produced seasonal influenza vaccines in the inter-pandemic period. These actions were not *ad hoc*, but systematic decisions based on epidemiological and economic evidence including cost-effectiveness, feasibility (financial, logistic and programmatic) of seasonal influenza vaccine introduction and its acceptability by the community. He described how dynamic the expansion of the target group profile had been over the years. He also shared the Thai experience on other important areas such as supply chain management, communication and public information as well as AEFI monitoring. Importantly, he highlighted the fact that the overall cost remained high despite the fact that the vaccine cost had been decreasing over the years. He also discussed the need for assessing the cost-effectiveness of vaccines in the country context. He concluded that over the years, acceptance of seasonal influenza vaccines in Thailand had increased, thereby contributing to decreased influenza burden and sustenance of local influenza vaccine manufacturing capacity. The key hints that may appear to be useful for other Member States from the experience of Thailand are as follows: generating adequate epidemiological and economic information for

decision-makers, using EPI as the launching pad for introduction of seasonal influenza vaccines, developing country-specific vaccination strategies, establishing a good mechanism of monitoring and evaluation and a well thought-out public information and communication programme.

Subsequent to the presentation, all participants participated in group work. The first group identified activities, responsible agencies, partners, their roles and mechanisms to synchronize collaborative actions for a rapid and efficient pandemic vaccine deployment. The second group addressed barriers for introducing seasonal influenza vaccines and specified the role of different stakeholders in introducing seasonal influenza vaccines in Member States. The third group identified the current status of influenza surveillance in the Region, existing gaps, and the anticipated roles of national governments and partners including WHO in bridging the identified gaps.

2.6 Outcome of group work

Group I

Group I discussed the following key questions:

- What are the key priority areas for intersectoral collaboration for the seven major strategic areas (planning and organization, prioritization of target groups, information and communication, public information, preparedness and response for AEFI and human resource management) in a pandemic vaccine deployment.
- What are the expected roles of national and international collaborative agencies including WHO for the identified priority areas ?
- What are the suggested mechanisms to improve synchronized actions by these agencies for the prioritized activities to achieve rapid and effective vaccine deployment in a pandemic ?

Outcome of the work of Group 1

Task 1: Priority activities for intersectoral collaboration for major strategic areas in a pandemic vaccine deployment.

Strategic area	Priority areas/activities where collaboration is needed
Planning and organization (from policy-making to delivery of vaccine to end-user)	Soliciting political commitment and commitment of other relevant stakeholders • Engaging all government stakeholders • Engaging professional organizations • Engaging vaccine manufacturers, suppliers • Soliciting media support
	Ensuring an emergency fund for a pandemic vaccine deployment
	Developing agreed Standard Operating Procedures (SoP) for licensing and customs clearance of vaccine • NRA fast-track acquisition of vaccine • Customs fast-track acquisition of vaccine • Transportation within and outside country
Prioritization of target groups for vaccination	Health workers
	Pregnant women
	Essential personnel (police, army, fire fighters, electricity and water supply persons)
	Elderly and people with underlying chronic diseases
	Children
Information and communication (management information and communication within and between agencies)	Identification of focal persons at all levels within the ministry of health
	Identification of communication channels and developing protocols
	Formation of communication committees • Periodic meetings • Updates (daily or weekly as per requirement) • Generate report

Strategic area	Priority areas/activities where collaboration is needed
Public information	Developing communication plans
	Advocacy, information, education communication (IEC) and social mobilization
	Developing information helplines, hotlines
	Media orientation activities
	Coordination with the ministry of information and broadcasting
Preparedness and response for AEFI	Strengthening and reorientation of AEFI committees at different levels
	Establishing AEFI hotlines/helplines
	Ensuring AEFI reporting, investigation and feedback
	Establishment of AEFI management teams with appropriate logistics
	Coordination with relevant agencies/persons for quick referral
	Mapping of AEFI centres
	Strengthening communication and feedback
Human resource management	Mapping and mobilization of additional vaccinators and other categories of health staff from private hospitals, nursing homes, medical colleges, police and army hospitals
	Training, communication and capacity building
	Defining and assigning roles and responsibilities
	Identification of human resources for transportation and other logistics support
Vaccine deployment	Vaccination storage, transportation and distribution from centre to delivery point within seven days Forecasting vaccine and other logistics requirement
	Planning for use of routine immunization syringes for pandemic and prior dispatch
	Mapping of cold storage facilities (public, private)
	Waste management

Task II: Expected roles of national and international collaborative agencies including WHO for identified priority areas.

Key areas	Role of national agencies	Role of international partner agencies	WHO role
Vaccine supply	Securing vaccine supply	Information sharing, facilitating procurement	Technical guidance and coordination
Resource mobilization	Mobilization of contingency funds	Assisting to meet gaps	Advocacy and assistance to meet gaps
Communication	Developing a predetermined communication strategy involving all stakeholders	Supporting logistics and advocacy	Information and technical support
Planning, implementation and monitoring	Developing the NIPVDP and implementing activities accordingly	Identifying specific areas that need support and providing support	Technical assistance for implementation and monitoring

Task III: The suggested mechanisms to improve synchronized actions by these agencies for the prioritized activities to achieve rapid and effective vaccine deployment in a pandemic.

- Establishing a mechanism to involve all relevant stakeholders during development of a pandemic vaccine deployment plan within the NIPPRP
- Agreement for formation of a core group (task force) for regular follow-up
- Making pandemic vaccine deployment an agenda item for discussion at all relevant national committees at appropriate timelines
- Developing a Memorandum of Understanding and SoP within and outside the government.

Group II

Group II discussed the following key questions:

- What are the current strengths of national programmes of immunization to introduce seasonal influenza vaccines in Member States?
- What are the potential barriers to introduce seasonal influenza vaccines in Member States?
- What are the expected roles of WHO and other international partners in supporting the introduction of seasonal influenza vaccines in Member States?

Outcome of the work of Group II

Tasks I and II : Potential strengths and barriers to introduce seasonal influenza vaccines in Member States.

Major areas for focus	Potential strengths for introducing seasonal influenza vaccines in the Region	Potential barriers for introducing seasonal influenza vaccines in the Region
Evidence/ information	Priority given to evidence for decision-making in all Member States A majority of Member States have surveillance systems for influenza Eight national influenza centres are available in 11 Member States .	Inadequate epidemiological and economic evidence
Vaccines/ ancillary items/technology	Vaccines are already part of the public programme in **Thailand** Vaccine is licensed and available in the private sector in **Bangladesh, India, Indonesia, Sri Lanka and Thailand** Provided by government to *Hajj* pilgrims in **Maldives** Availability of experience in deployment of different pandemic vaccines in eight Member States in the Region Availability of experience in management of vaccines/ancillary items in immunization campaigns and routine immunizations Availability of seven regional manufacturers	No experience of seasonal influenza vaccines in **Bhutan, DPR Korea, Myanmar, Nepal Timor-Leste** No experience of pandemic **vaccines in Indonesia, Myanmar and Nepal** No idea as to which vaccine to be used (northern or southern hemisphere) Decreased affordability of the vaccine Inadequate cold chain space requirement Low influenza vaccine demand for sustaining the available capacity

Major areas for focus	Potential strengths for introducing seasonal influenza vaccines in the Region	Potential barriers for introducing seasonal influenza vaccines in the Region
Leadership/ governance	Availability of well-functioning NTAGI/NCIP	
Financing		Decreased financial resources for vaccine procurement
Human resources	Trained manpower in routine immunization and immunization campaigns Existing manpower in EPI (for children and pregnant women) and the hospital health staff (for people with chronic diseases, elderly etc.) can be used without requiring additional human resources	The increased burden depending on the size of the target population and the short window period for vaccination
Service delivery access and coverage		Low acceptance among the healthy but recommended target age groups (leading to low coverage) Geographical difference in coverage
Miscellaneous	Availability of good AEFI surveillance system Availability of AEFI expert committees	Fear on safety due to media coverage of AEFI during the 2009 pandemic

Task III: Expected roles of WHO and other international partners in supporting the introduction of seasonal influenza vaccines in Member States.

- Sharing the regional Technical Advisory Group meeting report on seasonal influenza vaccines with the National Technical Advisory Group of Immunization (NTAGI)/National Committee on Immunization Practice (NCIP) of all Member States
- Rendering technical support to national programme managers and members of the NTAGI/NCIP
- Mobilizing resources for introduction of seasonal influenza vaccine if the need arises
- Providing support for cold chain and logistics, contingent upon request
- Coordinating with the Global Alliance for Vaccines and Immunization (GAVI) to explore the possibility of seasonal flu

vaccines being included in the portfolio of new and underutilized vaccines

- Coordinating with regional manufacturers to provide vaccines at an affordable price to Member States with a view to increasing the use of seasonal influenza vaccines in the Region
- Advocacy for seasonal influenza vaccines-related matters at the World Health Assembly and other global and regional forums.

Outcome of the work of Group III

Group III discussed the following key questions:

- What is the current status of influenza surveillance in the Region?
- What are the current gaps in influenza surveillance in the Region?
- What roles can national governments play in bridging the stated gaps?
- What roles can WHO and other international agencies play in bridging the stated gaps?

Task I: The current gaps in influenza surveillance in the Region

- Lack of integration of different systems
- Lack of information on risk groups for influenza (risk groups do not constitute a part of the surveillance datasets for some Member States)
- Non-optimization in linking of surveillance data with policy-making
- Often the availability of only laboratory surveillance makes it difficult to estimate the disease burden due to the lack of its integration into epidemiological information
- Difficulty in maintaining a sustained supply of laboratory reagents
- Non-availability of NICs in three countries that demand laboratory capacity improvement in some Member States

- Difficulties in financial sustainability
- Varying capacity to analyse the data.

Task II: Role of national governments, WHO and other international agencies in bridging the identified gaps.

Role of national governments

Identify the gaps (with all stakeholders) and discuss solutions pertinent to:

- capacity building, training
- resource mobilization, advocacy for surveillance
- commitment for sustainability
- review of policy, review of pandemic preparedness plans
- identification of capacity of vaccine manufacturers
- Identification of the needed data to make a decision for (or against) introducing seasonal influenza vaccine in the country
- Analysis and use of data for public health decision-making
- Sharing data with FluNet and FluID.

Role of WHO

- Vaccine recommendations
- Developing guidelines for surveillance and laboratory
- Organizing a regional meeting once the global manual is launched to discuss regional implementation and data collection
- Advocacy for standardization of surveillance approach
- Resource mobilization
- Clarifying the roles of different stakeholders at the regional level
- Supply of diagnostic reagents
- Support for capacity building
- Strengthening pandemic preparedness and response and organizing a meeting when the global guideline is ready.

3. Conclusion and recommendations

The regional workshop on influenza was concluded with the following recommendations made by participants to the Member States and WHO.

(1) Rapid and efficient pandemic vaccine deployment in future pandemics

- Member States need to work towards obtaining high-level political commitment through better advocacy programmes to update pandemic vaccine deployment plans and incorporate them into NIPPRPs

  To identify a lead agency:

  - to be responsible overall for vaccine deployment including planning and management of the pandemic vaccine deployment
  - for supply of logistics to plan the delivery of vaccines and other ancillary supplies.

- Member States need to develop standard operating procedures for key activities of NIPVDP:

  - Legal and regulatory requirements for new pandemic influenza vaccines
  - Fast-track acquisition of delivered vaccines from customs and transportation within the country
  - Identify country-specific priority target groups for vaccination
  - Identify communication focal points, communication protocols, channels of communication and formation of communication committees and public information
  - AEFI reporting, referral for management, investigation, communication, feedback and roles of AEFI committees
  - Identifying, mobilizing, training and assigning roles and responsibilities to different stakeholders, mobilizing resources and establishing the chain of command
  - Mapping available resources, forecasting logistic needs, delivery of vaccines and ancillary items from the centre to delivery points within seven days, and waste management.

(2) Introduction of seasonal influenza vaccination

- To generate and collate country-specific evidence (i.e. disease burden, economic impact and cost-effectiveness of vaccination etc.) on seasonal influenza
  - Member States to collate and synthesize available country evidence
  - WHO to collate and synthesize regional and global data on influenza disease and economic burden
- Member states to discuss at the NCIP/NTAGI, the feasibility of introduction of seasonal flu vaccine for high-risk groups and make a decision
  - Review the decision at a meeting among various stakeholders (i.e. national programme managers, NCIP members, national research institutions, WHO/UNICEF and vaccine manufacturers etc.).

(3) Strengthening influenza surveillance based on the experience of VPD surveillance network

- Member States to verify details of influenza surveillance to gain a complete understanding of existing gaps in relation to :
  - Lack of information on risk groups
  - Lack of a verification mechanism between laboratory and disease surveillance data (passive and active)
  - Nonavailability of a regular system to provide reagents and other supplies to laboratories
  - Nonavailability of NICs in three Member States in the Region and the inadequate capacity for data analysis
  - Non-sharing of data with the fluNet and fluID networks
- WHO and Member states to clarify the roles and responsibilities of different stakeholders in influenza surveillance.

Annex 1

List of participants

Member States

Bangladesh

Dr Tajul Islam Bari
Programme Manager/DPM
EPI
DGHS
Ministry of Health & Family Welfare
Mohakhali, Dhaka

Dr Shahid Md. Sadiqul Islam
Deputy Programme Manager
Avian & Pandemic Influenza Programme
DGHS
Ministry of Health & Family Welfare
Mohakhali, Dhaka

Bhutan

Mr Tshewang Dorji Tamang
Programme Officer
Department of Public health
Ministry of Health
Thimphu

Ms Roma Karki
Programme Officer
Department of Public health
Ministry of Health
Thimphu

India

Dr Ajay Khera
Deputy Commissioner (CH&I)
Ministry of Health and Family Welfare
Government of India
Nirman Bhawan
New Delhi

Dr Shashi Khare
Head of Department
Polio Laboratory, National Institute of Communicable Disease
Ministry of Health and Family Welfare
Government of India
Nirman Bhawan
New Delhi

Dr Suresh Dalpat
Deputy Director
State Child Health & Immunization Officer
Chandigarh
Haryana

Indonesia

Dr Theresia Sandra Diah Ratih
Head, Sub-directorate of Immunization
Directorate of Surveillance, Immunization
Quarantine and Matra Health
Bali

Dr Arie Bratasena
Head, Sub-directorate of Acute Respiratory Infection Control
Directorate of Communicable Diseases Control, DG of Disease Control and Environmental Health
Ministry of Health RI
Jakarta

Maldives

Ms Aishath Thimna Latheef
Public Health Programme Manager
Centre for Community Health and Disease Control
Ministry of Health and Family
Male

Mr Mohamed Rameez
Director
Centre for Community Health and Disease Control
Republic of Maldives
Male

Myanmar

Dr Soe Lwin Nyein
Director
Central Epidemiology Unit
Department of Health
Nay Pyi Taw

Dr Myint Oo
State Health Director
State Health Department
Kachin State
Myitkyeena

Nepal

Dr Saroj Prasad Rajendra
Deputy Director-General
Department of Health Services
Ministry of Health and Population
Ramshah Path
Kathmandu

Mr Parashu Ram Shrestha
Senior Public Health Administrator
Department of Health Services
Ministry of Health and Population
Ramshah Path Kathmandu

Sri Lanka

Dr W.A. Somaratne
Regional Epidemiologist
Office of Regional Director of Health Services
Matara
Colombo

Thailand

Dr Pornsak Yoocharoen
Medical Officer, Sr. Professional Level
Bureau of General Communicable Diseases
Department of Disease Control
Ministry of Public Health
Nonthaburi

Dr Rungrueng Kitphati
Director, Bureau of Emerging Infectious Diseases
Department of Disease Control
Ministry of Public Health
Nonthaburi

Timor-Leste

Mr Jose Lima
EPI Field Officer
Ministry of Health
Dili

Mr Antonio Da Costa
Planning Officer
Ministry of Health
Dili

Temporary Advisers

Dr Opart Kankaingpong
Director
Bureau of General Communicable Diseases
Department of Disease Control
Ministry of Public Health
Nonthaburi, Thailand

Dr Prima Yosephine
Chief of Standardization Section
Immunization Subdivision
Directorate, Surveillance, Immunization and Matra Health
Ministry of Health
Jakarta, Indonesia

Dr P. Raveendran
Director, Emergency Medical Relief
Directorate-General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi, India

Dr Pushpa Ranjan Wijesinghe
Consultant Epidemiologist
Epidemiology unit
231 De Saram Place
Colombo 20, Sri Lanka

WHO Secretariat

WHO-HQ

Dr Julia Fitzner
Medical Officer
Pandemic and Epidemic Diseases
Health Security and the Environment

Dr Wenqing Zhang
Project Lead (GISRS)
Pandemic and Epidemic Diseases
Health Security and the Environment

WHO-SEARO

Dr Prakin Suchaxaya
Ag.IVD & Ag. FHR

Dr Rajesh Bhatia
Ag. Director
CDS

Dr Nihal Abeysinghe
Regional Adviser (VPD)

Dr Patrick O'Connor
Regional Adviser (POL &SUR)

Mr Stephane Guichard
Technical Officer (VSQ)

Ms Uttara Aggarwal
Technical Officer (Immunization)

Mr Luis Homero Hernandez
Technical Officer (RMI)

Dr Richard Brown
Regional Adviser (DSE)

Dr Vason Pinyowiwat
Technical Officer (Public Health)
DSE

Dr Murari Shrestha
TIP-Measles/IVD

Dr Mainul Hasan
TIP-Surveillance/IVD

WHO Country Staff

Dr Jayantha Liyanage
Medical Officer
WHO- Bangladesh

Dr Zobaidul Haque Khan
Medical Officer (CDS/EPI)
WHO DPR Korea

Dr Paul Francis
NPO (Medical Epidemiology/IVD)
WR India office

Dr Stephen Sosler
Deputy Project Manager
(Universal Immunization Programme)
NPSP

Dr Bardan Jung Rana
Medical Officer (EPI)
WHO Indonesia

Dr Graham Tallis
Team Leader for Communicable Diseases
Surveillance Programme
WHO Indonesia

Dr Vinod Kumar Bura
Medical Officer (EPI)
WHO-Myanmar

Dr Rajendra Bohara
NPO (IPD)
WHO Nepal

Mr Chawalit Tantinimitkul
NPO/ CDS
WHO Thailand

Secretarial Support

Ms Chitra Salil
Secretary

Mr Bansi Lal Bhatia
Secretary

Ms Mohita Dawar
Secretary

Annex 2

Agenda

Session I : Pandemic vaccine deployment

Pandemic Influenza Vaccines : Lessons learnt in the 2009 Pandemic – Dr Wenqing Zhang- WHO-HQ
Pandemic vaccine deployment – Regional perspective: Dr Nihal Abeysinghe – IVD, WHO-SEARO
Country presentations on vaccine deployment, lessons learnt and using experience of the H1N1 pandemic to update the NIPPP, including National Pandemic Vaccine Deployment Plan: **Bangladesh, Bhutan, DPRK, India**
Country presentations on vaccine deployment, lessons learnt and using experience of the H1N1 pandemic to update the NIPPP: **Maldives, Sri Lanka, Thailand and Timor Leste**
Country presentations on experience of H1N1 pandemic and how it helped updating the NIPPP and the proposed plan and areas of focus for updating the national pandemic vaccine deployment plan as a strategy of overall pandemic planning and incorporation into the NIPPP – Nepal, Indonesia, Myanmar

Session II: Avian/pandemic influenza: Framework for Preparedness and Response in the South East Asia Region

H5N1 global update - **Dr Gayanendra Gongal**
GISRS - **Dr Vason Pinyowiwat-** DSE, WHO-SEARO
Influenza Vaccine Development for Novel/Potential Pandemic Influenza Viruses- **Dr Wenqing Zhang** – WHO headquarters
PIP Framework- **Dr Richard Brown –** DSE, WHO-SEARO

Session III: Seasonal influenza vaccination

Seasonal flu vaccines-global perspective: **Dr Julia Fitzner WHO-HQ**
Seasonal flu vaccines- Regional perspective: **Dr Ranjan Wijesinghe**

Regulatory aspects of available seasonal flu vaccines – I **Dr Wenqing Zhang, WHO-HQ**
Regulatory aspects of available seasonal flu vaccines –II **Dr Wenqing Zhang, WHO-HQ**

Session IV: Planning for integration of effective influenza surveillance to the VPD surveillance network

Consideration of epidemiological evidence for seasonal flu vaccines introduction: Burden of disease, influenza surveillance **– Dr Julia Fizner, WHO-HQ**
Influenza – laboratory surveillance in the Region – **Dr Rajesh Bhatia,** WHO-SEARO
Integrated influenza surveillance in VPD Surveillance at SEARO – **Dr Mainul Hassan** – IVD, WHO-SEARO

Introduction of seasonal influenza vaccines in the Region: Thailand experience - **Dr Opart Kankawinpong** –MoH, Thailand
Introduction of groups and tasks for the group work
Familiarization with the group work

Session V: Building intersectoral collaboration in seasonal and pandemic influenza vaccination

Group work by participants • Streamlining activities for facilitating rapid and effective vaccine deployment in the SEAR Region • Integration of influenza surveillance • Opportunities for introducing seasonal flu vaccines
Group work continued (preparation for presentation)
Group presentations (groups 1 and 2)- (IVD/DSE)
Group presentations (groups 3 and 4)- (IVD/DSE)

Annex 3

Address by Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia

Distinguished participants, colleagues, ladies and gentlemen,

It is with great pleasure that I welcome you all to this Regional Workshop on Influenza Vaccines. Your participation and suggestions will be very useful as we embark on strengthening the response to seasonal and novel variants of influenza in the Region.

Since the new strain of Influenza A/H1N1 (2009) virus was confirmed in April 2009, it has had a rapid global spread, demanding dynamic and evolving response to control both its spread and impact. By the time of declaration of the post-pandemic stage on 1 August 2010, 76 302 laboratory-confirmed Influenza A/H1N1 (2009) cases had been reported from the Member States in the South-East Asia Region.

Though the majority of those affected experienced uncomplicated, self-limited illness, some categories appeared to be at an increased risk of severe disease, complications and deaths. Vaccination against pandemic influenza was seen as an effective way of preventing these complications. Therefore, WHO launched extensive efforts to collaborate with vaccine manufacturers and national governments to ensure an equitable and real-time vaccine access to all countries. WHO provided 21 million doses to seven countries in the Region, while India and Thailand deployed vaccines that they purchased from government funds.

In the process of vaccine deployment in the Region, countries encountered many barriers and challenges from authorizing new pandemic vaccines to their delivery to end-recipients. Given the rapid spread of the pandemic, these barriers and challenges affected the pandemic vaccine deployment in the Region as a pandemic response measure. Not only the Member States, but WHO also encountered enormous challenges in this endeavour.

Ladies and gentlemen, the lessons learnt in this process are many and they differ from country to country. This regional meeting facilitates sharing of experiences of different countries to ensure effective planning in future to maximize vaccine deployment in the Region. It aims to assist countries to update their national pandemic vaccine deployment plans based on the lessons learnt, thereby enabling effective deployment in the future. The meeting should also provide an opportunity for WHO colleagues to interact with country representatives to identify challenges common to the Region and specific to individual countries, which were encountered during the previous pandemic vaccine deployment. This interaction, hopefully, will stimulate countries to comprehensively plan for future vaccine deployment as an overall strategy of pandemic preparedness and response.

An effective pandemic preparedness and response is an outcome of synergistic actions of many stakeholders with the intention of achieving the same goal. This involves very close collaboration and cooperation of national as well as international stakeholders in public and private sectors. In order to emphasize this concept for achieving an effective pandemic preparedness and response, colleagues from the Immunization and Vaccine Development Unit, Regional Office for SEA and the Department of Surveillance and Epidemiology, WHO-HQ are jointly organizing this regional workshop. The issues of pandemic response that they intend to discuss in this regional consultation with country representatives are also cross-cutting. Adhering to the same concept, the country-level participation also represents the two key and complementary areas of pandemic response, namely surveillance and vaccine deployment. The discussions may have the potential to generate contradictory viewpoints, ideas and criticism. But, in my opinion, they will lead to a constructive dialogue between WHO and Member States.

Ladies and gentlemen, WHO has now declared the post-pandemic phase of the Influenza A/H1N1 (2009) pandemic. In order to prepare the Region for vaccine deployment for any influenza pandemic or an emerging or re-emerging disease epidemic, it is essential to review the effectiveness of pandemic deployment in the just-concluded pandemic, identify the challenges encountered, and prepare the Region and countries for effective vaccine deployment. Furthermore, this interaction will help stimulate countries to think about generating evidence required for assessing the burden and impact of seasonal influenza in the Region. Countries and WHO should be able to learn from the experiences of Thailand, which is a pioneer in using seasonal influenza vaccines in the Region. I consider that

the early post-pandemic period is the most appropriate for all these purposes.

Judging by the presence of experienced and dedicated regional experts, WHO experts from both headquarters and the Regional office, I look forward to valuable and pragmatic recommendations to strengthen our efforts in rapidly responding to pandemics and epidemics of emerging and re-emerging diseases through vaccine deployment.

In conclusion, let me wish you all success in your deliberations and a pleasant stay in New Delhi.

Thank you.

WHO assists Member States of the South-East Asia Region to periodically review and discuss various issues relating to national immunization programmes. Deliberations on these issues lead to tangible improvements in the management of national immunization programmes.

This publication is the report of the regional workshop on influenza vaccines held at the WHO Regional Office for South-East Asia in New Delhi, India on 2-4 April 2012. The objective of the workshop was to strengthen efficient deployment of pandemic influenza vaccines and introduction of seasonal influenza vaccines in Member States of the South-East Asia Region. The report covers the experiences from the deployment of pandemic influenza vaccines by Member States during the influenza A/H1N1 (2009) pandemic.

The report also includes recommendations for consideration of Member States to help them in their efforts to achieve rapid and efficient pandemic vaccine deployment in future influenza pandemics, introduce seasonal influenza vaccines and strengthen influenza surveillance based on the experiences of VPD surveillance network.

World Health Organization

Regional Office for South-East Asia

World Health House
Indraprastha Estate,
Mahatma Gandhi Marg,
New Delhi-110002, India
Web site: www.searo.who.int

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