

**National Pandemic Influenza Vaccine  
Deployment Plan (NVDP)  
Sri Lanka**

**2012-2015**

**Epidemiology Unit  
Ministry of Health  
Sri Lanka**

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**Members of the Advisory committee on Communicable diseases**

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**AEFI Surveillance system in Sri Lanka**

## Acronyms

ACCD	-	Advisory Committee on Communicable Diseases
AEFI	-	Adverse Events Following Immunization
ANC	-	Ante Natal Clinic
COA	-	Certificate of Analysis
COPP	-	Certificate of Pharmaceutical Product
DESC	-	Drug Evaluation Sub Committee
DGHS	-	Director General of Health Services
DRA	-	Drug Regulatory Authority
EPI	-	Expanded Programme on Immunization
EU	-	Epidemiology Unit
FHB	-	Family Health Bureau
GOSL	-	Government of Sri Lanka
HEB	-	Health Education Bureau
ICNO	-	Infection Control Nursing Officer
IEC	-	Information, Education & Communication
MOH	-	Medical Officer of Health
MoH	-	Ministry of Health
MO	-	Medical Officer
MO MCH	-	Medical Officer Maternal & Child Health
MSD	-	Medical Supplies Division
MT & S	-	Medical Technology & Supplies
NCL	-	National Control Laboratory
NIPP	-	National Influenza Pandemic Preparedness Plan
NO	-	Nursing Officer
NVDP	-	National Pandemic Vaccine Deployment Plan
PHM	-	Public Health Midwife
QEB	-	Quarterly Epidemiological Bulletin

RE	-	Regional Epidemiologist
RDHS	-	Regional Director of Health Services
RMSD	-	Regional Medical Supplies Division
TOR	-	Terms of Reference
TOT	-	Training of Trainers
UNICEF	-	United Nations Children's Education Fund
WER	-	Weekly Epidemiological Report
WHO	-	World Health Organization

## **Executive Summary**

The National Pandemic Influenza Vaccine Deployment Plan (NVDP) of the Ministry of Health of Sri Lanka promotes the use of a safe and efficacious vaccine, if and when it will be needed or available, to mitigate the impact of the pandemic. Use of a pandemic vaccine in an organized vaccination campaign is one of the key activities identified under one of the five strategies in pandemic response recommended presently by global health authorities; reducing the spread of the disease. It has been cited as an effective measure under the approach - Pharmaceutical Interventions along with use of anti viral agents and other pharmaceuticals to prevent or treat influenza.

Pandemic Influenza A H1N1 vaccine was used during the first and second waves of the H1N1 pandemic in the country (in 2009 and 2010). During this time WHO moved in to donate stocks of pandemic Influenza A H1N1 vaccine on request and made it possible to respond to the pandemic and protect the most vulnerable risk groups to the infection in Sri Lanka. This vaccine was used first to protect all frontline health care workers and supportive staff to ensure that there was no disruption to both curative and preventive health care services in the country. Once this target group was covered, vaccines offered by the WHO were used for vaccinating pregnant women. The next target group that was covered after pregnant women was individuals with at least one co-morbidity that posed a risk for complications of pandemic influenza. This prioritization of risk groups used for vaccination was approved by the Advisory Committee of the Communicable Diseases (ACCD) and this method of approval ensured maximum use of vaccine stocks received.

The main objective of a pandemic Influenza vaccination campaign is to save lives and protect those at the highest risk of serious infection with pandemic virus. Based on experience of previous mass immunization campaigns in Sri Lanka, it is anticipated that it is possible to deploy vaccines within 7 days to all vaccination points in the entire island. This document outlines the feasibility, issues, challenges, suggested counter

measures and budgetary requirements to ensure that any such vaccine deployment will be well planned and systematically executed in a future pandemic event. This plan of vaccine deployment has been prepared to be in uniformity with other vaccine deployment plans of member countries of the WHO according to the updated conceptual framework suggested by global health authorities. Some activities related to vaccination against a pandemic would extend beyond the planned budget of immunization activities of the central government and provincial ministries. Therefore, the country would require financial support from external agencies to cover these activities which would not be pre planned and hence not included in routine fiscal plans. The Government of Sri Lanka recognises that a pandemic vaccination campaign to be of pivotal public health importance and will contribute a considerable amount of the total funding required to carry out this important vaccination campaign.

The vaccine deployment plan outlines the processes and activities involved. It entails the main strategies identified required to execute a thorough and high quality vaccination campaign in the country. Management and Organization strategy maps out details of the framework that has been designed to ensure a smooth vaccine deployment process. Under Communication and Information, issues that concern capacity of the existing information system in supporting the vaccine deployment process are addressed. Availability of adequate numbers of health care staff is ensured under the strategy Human Resources. Under Public Information, measures to ensure a supportive environment within the community are detailed. Under pandemic vaccine deployment strategy, capacity of the system to carry out the pandemic vaccination process is ensured. Vaccine Strategy with Post Marketing Surveillance strategy details on improving quality and safety of vaccination process. Indicators to be used during the programme to assess and redesign directions are described under the strategy Monitoring & Evaluation.

## **Introduction**

Pandemics of influenza are known to have caused morbidity and mortality throughout the history of global health. Recorded since the middle of the 18<sup>th</sup> century, major antigenic shifts have occurred in influenza virus strains which had resulted in pandemics at intervals averaging 30 years. The pandemic which was triggered in 1918 is believed to have caused deaths in the range of 20-40 million. "Asian flu" was reported in 1957 and "Hong Kong flu" in 1968 and altogether these caused around 20-50 million deaths. An antigenic shift was recorded in 1977 as well.

Though it was strongly believed that the H5N1 virus that emerged in Asia by 2003 would probably trigger the pandemic of the new millennium, it so far has not acquired the ability to spread from human to human easily despite all other requirements of a pandemic being fulfilled. But in early 2009, a novel influenza virus was detected in California, USA and it was found to be influenza A/H1N1. It was a quadruple reassorted virus which contained influenza A genes from pigs found in Europe and Asia, humans and birds. Later it was found out that this new virus was responsible for the acute respiratory tract infection outbreak recorded in La Gloria and San Louis Potosi in Mexico.

It soon spread from human to human like seasonal influenza. Cases were increasingly being reported from countries outside Americas and the virus established local spread leading to widespread community transmission in other countries. World Health Organization (WHO) declared a pandemic on 11th June 2009. It spread through the globe to over 214 countries and overseas territories by 1<sup>st</sup> August 2009 resulting in a pandemic with 18,449 reported deaths. On 10<sup>th</sup> August 2010 WHO officially declared the post pandemic phase of the first wave signaling the end of the pandemic proper. There were 642 laboratory confirmed cases and 48 deaths in the country during this first

wave while in its second wave in 2010 there were 580 laboratory confirmed cases and 29 deaths.

One of the important lessons learnt through this pandemic was that early availability of safe and effective vaccines is a critical component of efforts to prevent the infection and to mitigate overall impact of the pandemic. WHO provided support to developing countries in supplying pandemic vaccine stocks during the H1N1 pandemic.

This document outlines the basic steps in a process where pandemic vaccine is deployed to prevent impact of a pandemic event. These steps are described in detail along the main strategies identified by the WHO and would prove to guide an effective pandemic vaccine deployment process.

### **Main Strategies**

- 1. Management & Organization**
- 2. Human Resources**
- 3. Communication & Information**
- 4. Public Information**
- 5. Vaccine strategy & Post marketing surveillance**
- 6. Pandemic vaccine deployment**
- 7. Monitoring & Evaluation**

## **1. Management and Organization**

### **1.1 Objectives**

Objective of this strategy is to map out details of an effective managerial framework that will ensure a speedy and smooth vaccine deployment process.

### **1.2 Organizational structure for planning, organization, coordination and management of vaccine deployment**

The overall management of the deployment of the pandemic vaccine will be carried out by the Epidemiology Unit (EU) of the Ministry of Health. This unit under the leadership of the Chief Epidemiologist will be responsible for planning, facilitation of procurement and distribution of vaccines and ancillary items to the districts, implementation of immunization, monitoring and evaluation of immunization programme, surveillance of Adverse Events Following Immunization (AEFI).

Additionally, it is entrusted with the task of coordination of activities with other government ministries, non-government organizations and international agencies including the WHO & UNICEFF etc. The Expanded Program of Immunization (EPI) team and the team of the Pandemic Influenza Preparedness and Response of the EU will act together to deploy pandemic vaccines in the country.

Sri Lanka has a well-organized structured healthcare delivery system. MoH at Central level works closely with the nine provincial health ministries in the respective nine provinces. These provincial ministries have curative and preventive institutions under their administrative control. Provinces together have 26 districts and in each district, RE is responsible for all immunizations (EPI & non EPI). RE liaises with the EU on matters pertaining to immunizations while being under the administrative control of the Regional Director of Health Services (RDHS). Each district has a Regional Medical Supplies Division (RMSD) with warehouses to store vaccines and ancillary items under

the care of the Officer In Charge of the RMSD. Each district has several administrative divisions and for each of these divisions, there is a Medical Officer of Health (MOH). He/she is responsible for all immunization activities in his/her area and vaccines and ancillary items of these divisions will be stored at the MOH offices under his/her responsibility. Meanwhile, vaccines and ancillary items are also stored in institutions belonging to the central Ministry of Health and directors of these hospitals are directly responsible to the EU. Currently, the EU is not directly involved in EPI vaccinations in the private sector except for instances where it provides selected EPI vaccines to General practitioners and private hospitals free of charge. There is a director of private sector health development in the Ministry to coordinate with the private sector health.

### **1.3 Mechanism for policy decisions, review and changes for vaccine deployment and implementation**

National Technical Committee for Pandemic/ Avian Influenza Preparedness and Response is the working group of high level technical officers of the two main Ministries involved with handling the national preparedness programme i.e. Ministry of Health and Ministry of Livestock Development & Agriculture and other relevant government, non-government and international donor agencies. The committee is co-chaired by the Director General of Department of Animal Production & Health of the Ministry of Livestock Development & Agriculture and the Director General of Health Services of Ministry of Health.

Its membership include representatives from all the important key stakeholders involved in the scope of the preparedness programme such as heads of main laboratories and research centers in the two sectors, senior technical officials from different sectors covering epidemiology, health education, agriculture, veterinary science, education, disaster management, wild life and environment, representatives from supplies departments of both sectors, directors of major curative human and

animal health institutions, representatives from government information department, officials from main non-government organizations and donor agencies related to two sectors and officials representing armed forces. There is representation from private health sector through the director private health sector development in the MoH. These members meet every month to monitor and evaluate the progress of the ongoing activities and to offer guidance and solutions to improve activities within the programme.

National Technical Committee for Pandemic/Avian Influenza Preparedness and Response is responsible for supervising the influenza surveillance programme in the country and would review the possibility of introducing a vaccine as a strategy to mitigate the impact of a future influenza pandemic spreading in the country. Epidemiology Unit as the focal point for pandemic preparedness and response in the country would forward it for ratification of the Advisory Committee on Communicable Diseases (ACCD). This committee is comprised of high level ministry officials of relevant departments, university academics and representatives of professional health organizations such as colleges of pediatrics, physicians, Obstetricians etc. It is the apex body for policy decisions regarding control of communicable diseases including emerging infectious diseases such as influenza. The committee will also ratify the priority groups for vaccination.

After ratification of the decision to use it in Sri Lanka by the ACCD, it would be approved by the Director General of the Health Services (DGHS) and the Secretary of the Ministry of Health. Minister of Health would sign the Terms of reference (TOR) with the WHO or the agency providing the vaccine.

All changes or reviews in policy decisions with regard to the deployment of a pandemic vaccine will also be taken by the Advisory Committee on Communicable Diseases.

In an event where the stocks of vaccine being received is inadequate to cover all intended target groups the Epidemiology Unit intends to discuss the possibility of mobilizing other resources to obtain the required stocks of vaccines with the Ministry of Health and the national treasury. If such a plan is not realized, it will be necessary to prioritize individuals requiring vaccines. Local epidemiology of the morbidity and mortality of the prevailing pandemic and additional factors such as co morbidities that further increases the risk, high risk age groups (less than 2 years, more than 65 years etc.) and occupational factors that places persons at high risks, use of medications such as immunosuppressants all will be taken into account for prioritization of vaccines. However, these criteria for prioritization will be consensually determined and ratified by the ACCD.

#### **1.4 Mechanism for authorization, procurement, importation and clearance**

As per national pharmaceutical regulatory system all new vaccines/drugs/cosmetics that are brought into the country need registration for importation and use. This is carried out by the directorate of Medical Technology & Supplies (MT & S) of the Ministry of Health under which the Cosmetic Drugs and Devices Authority (Drug Regulatory Authority - DRA) functions. As the director of the DRA is a member of the ACCD, the need for registration is evident and measures could be taken to register the pandemic vaccine in Sri Lanka as a priority.

Routinely all registration procedures for vaccines or drugs would entail providing the DRA a set of essential documents usually by the local agent for the product. The manufacturer through the local agent importing the vaccine/drug should forward original copies of Certificate of Pharmaceutical Product (COPP) and Certificate of Analysis (COA). It is necessary to submit the Lot Release Certificates for a minimum of 4 batches of the product issued by the National Control Laboratory (NCL) of the country of manufacture, detailed procedures of production and quality testing and stability reports

of the product, a copy of the local agent's Wholesale Importation License issued by DRA along with the completed registration application form of DRA to the authority. Also post marketing surveillance information of the product is mandatory.

Once technical documentation is approved through the Drug Evaluation Sub-Committee (DESC) which is an independent evaluation panel of experts, DRA could issue the registration certificate. However if the DESC decides that submitted documentation needs further evidence through processing samples of the product a sample importation license will be issued to bring down samples. Samples brought down under this license will be evaluated at National Control Laboratory (NCL) before registration is granted.

Once registered the local agent could import the stocks from the manufacturer and the registration certificate is required to be forwarded to Sri Lanka Customs when clearing the stocks.

As for vaccines imported by the Government of Sri Lanka (GOSL), samples from each batch cleared are forwarded to the NCL for re-evaluation of the documentation and a Lot Release Certificate is issued thereafter.

This whole procedure may take a variable length of time and in an urgent situation a 'fast track registration' will take place where the process is given priority over other routine procurement and expedited. However all the essential documents mentioned above are required with a few exceptions even in a fast track registration.

Once shipments of vaccines and ancillary items reach the warehouses of the Sri Lankan customs, the Medical Supply Divisions (MSD) of the Ministry of Health will attend to relevant procedures related to customs clearance. Epidemiology Unit will coordinate with the MSD and there is a separate financial vote under which nominal customs

clearance payments are made to the SL customs. Once released, the stocks are delivered to the Central Vaccine Stores at the EU.

Vaccines may be procured by the private health sector for their own use but it is mandatory that all these procedures and regulations would have to be followed. Also, when procured or donated stocks of vaccines of public sector are supplied free of charge to the private health sector, the vaccine cost should not be borne from clients/patients and they may only charge a nominal service fee.

Further, when vaccine stocks are provided free of charge to private sector it should be ensured that all relevant policies and guidelines on vaccination, reporting and monitoring process be strictly applied within the private sector. It should also be noted that private health sector is made well aware of these existing government policies and regulations regarding vaccination.

#### **1.5 Mechanism for coordination with non-health governmental/private sector and non-governmental organizations**

National Technical Committee for Pandemic/Avian Influenza Preparedness and Response which is a body with varied stakeholders will handle all coordination activities between its members and also solicit necessary actions to garner support from any other non-member and private sector organization or institution.

#### **1.6 Mechanism for mobilizing available and additional resources**

In an event where the stocks of vaccine being received is inadequate to cover all intended target groups the Epidemiology Unit with support from National Technical Committee for Pandemic Influenza Preparedness and Response intends to discuss the possibility of mobilizing other resources to obtain the required stocks of vaccines with the Ministry of Health and the national treasury.

## **1.7 Summary of financial rules and reporting requirements**

Existing government regulations under the financial regulations of the Democratic Socialist Republic of Sri Lanka will be used for standardization of expenditure and financial reports. The EU will comply with the requirements of the external donor agency involved in vaccine deployment in submitting expenditure and financial reports from both public and private sector.

### **1.7.1.1 Responsibilities of major stakeholders of the pandemic vaccine deployment in Sri Lanka**

**Advisory Committee on Communicable Diseases (ACCD):** Designations of members of the ACCD which is the apex body for ratifying all policy decisions related to the deployment of pandemic vaccine in Sri Lanka are given in Annex 1.

Chief epidemiologist in her capacity as the secretary of ACCD will attend to fulfilling all policy decisions taken at the sessions of the ACCD related to the deployment of pandemic vaccine in Sri Lanka. DGHS will be responsible for making all these decisions legally binding in the form of circularizing them to health institutions. Furthermore, he will advocate the Minister of Health and the Secretary of the Ministry of Health on policy matters pertaining to the deployment of pandemic vaccine in the country.

**Influenza team in the Epidemiology Unit:** This team will be responsible for facilitating operational activities in the pandemic vaccine deployment process which will include prioritization of target groups, determining vaccination strategies, obtaining ratification from the ACCD, making national estimates, mobilizing support of donor agencies for vaccines and ancillary items, getting the regulatory approval for the vaccine, releasing vaccines from SL Customs, designing forms for documentation, distribution to districts and monitoring and evaluation of vaccination in districts including AEFI monitoring. This team will also liaise with the Health Education and Promotion Bureau for Information Education and Communication (IEC).

**Regional team:** Regional Director of Health Services (RDHS) will act as the team leader in a district with technical support from Regional Epidemiologist (RE) and MO/MCH. Responsibilities of the district team include ensuring availability of adequate stocks of vaccines, ancillary items and forms for documentation at vaccine centers in the districts, ensuring vaccination centers are established for vaccinating all prioritized target groups, monitoring and evaluation of vaccination programme and surveillance of AEFI. Regional Director of Health Services (RDHS) is supposed to liaise with MOOH offices, curative institutions in the district and the EU to effectively coordinate the pandemic vaccine deployment in their respective district with the help of RE and MO MCH who as district technical advisors would be responsible for technical supervision of all activities.

#### **Description of the Regional Team**

- RDHS (district team leader)
- Regional epidemiologist (Technical advisor&supervisor of vaccination)
- MO MCH (Technical advisor&supervisor of vaccination)
- Consultant Physicians/Consultant Obstetricians (expert opinion regarding vaccination)
- Officer-In-Charge (OIC) - RMSD (district vaccine distributing officer)
- Medical Officer of Health (Divisional team leader&supervisor of vaccination)
- Director / Medical Superintendent/ District medical officer /Medical Officer in charge (institutional team leader)
- Public health nursing sister, Nursing Officer, Public health midwives (Vaccinators/AEFI monitoring)
- RE, MOMCH, MOH, Public health nursing sister, MO public health (supervisors of vaccination)
- Minor staff (laborers) – (staff responsible for waste disposal)

### **Other Institutions**

Health Education Bureau: This department of Ministry of Health would be responsible for deployment activities related to information communication.

Family Health Bureau: This institution would oversee field level activities related to vaccination through MOO MCH especially the target group of pregnant women.

## **2. Human Resources**

### **2.1 Objectives**

To ensure availability of adequate numbers of trained, skilled and motivated staff to support the vaccine deployment process.

### **2.2 Available human resources for different aspects of deployment**

The current human resources capacity available in the health sector is adequate for executing speedy deployment, even within a 7 day period. This was evident in the previous Pandemic H1N1 vaccine deployment programme in 2010. Required human resources will be mobilized from the curative and preventive health institutions to vaccinate the health staff. All MOH staff in relevant clinics will be utilized to reach the pregnant women and other relevant high risk groups such as children. Both staff in curative and preventive care will be utilized for vaccinating individuals with co morbidities in the community.

### **2.3 Mechanism for mobilizing additional human resource requirement for a rapid deployment**

This will be carried out on the surge capacity planning in contingency plans of each district and health institution. Such planning in private health sector institutions will be coordinated by the responsible arm of the MoH.

## **2.4 Mechanism for protecting vaccine and workforce**

The Ministry of Health has employed security staff in all warehouses, curative and preventive institutions. It is the duty of these security staff to provide security to vaccines and ancillary items in the routine programme. The same staff will be utilized for providing security to warehouses and institutions where the pandemic vaccine and ancillary items are stored in a pandemic vaccine deployment programme. Provision of security is usually not necessary when vaccines are delivered to districts.

Although safety of health workers have not been endangered in an outbreak situation before, it would be wise to consider such a scenario and be prepared. All staff providing security at vaccine warehouses/cold stores, RMSD and hospitals would be alerted and in a graver situation police would be called upon to keep peace by the head of the institution.

## **2.5 Business continuity plan**

Business continuity plan of each health institution in both public and private sector would entail how the personnel are deployed during a disaster/pandemic event to enable continuity of the services without a disruption and to accommodate inevitable absenteeism among the staff.

## **2.6 Mechanism for training human resources**

### 2.6.1 Categories of staff

Regional Epidemiologists (REE) and Medical Officers of Maternal & Child Health (MOO MCH) will be trained by the Epidemiology Unit as trainers in a Training of Trainers (TOT) programme. There is a RE and a MO MCH each in all 26 districts. They will be responsible to conduct training programs in their respective districts for Medical Officers (MO) and Nursing Officers (NO) in curative institutions who will be responsible for vaccinating health staff and public through their own immunization clinics. These

trainers will also train MOOH in preventive institutions who will train PHMM who will vaccinate both the health staff and public through their clinics.

Trainers will also conduct training on supervision for all supervisory staff which should include Supervisory Public Health Nursing Sisters and Public Health Nursing Sisters in the preventive sector and a selected Nursing Sister each from all curative institutions to act as supervisors of the programme. Training of trainers in private health institutions would be the responsibility of the relevant RE and these trained officers would be responsible for training relevant staff in their respective institutions. It is expected that the national training will be a one-day programme. District training will also take one day. For institutional training the required number of days may vary according to the size of the institutions. Majority of institutions will need one day while a few (less than 20) larger institutions may take 2-3 days for awareness/training sessions for all the staff. Training for all relevant staff in the country should be covered within 3 weeks.

#### 2.6.2 Areas of training

Training for all these categories will include vaccination procedures, maintaining records & registers, reporting requirements, AEFI surveillance & reporting and detailed investigation of severe AEFI according to the current guidelines of the Ministry.

Introduction of a new vaccine in a mass vaccination programme is a likely opportunity to detect new signals; new, previously unreported vaccine reactions. Therefore all relevant staff should be trained in detecting these signals.

#### 2.6.3 Resources required for training

Resources will be allocated both from central Ministry funds and Provincial funds according to the severity and the urgency of the pandemic event. Emergency funding from the government through the Disaster Management Ministry may also be mobilized. These funds will be used to develop training material and to cover expenses for training sessions.

### **3. Communication and information**

#### **3.1 Objectives**

To review issues that may concern the capacity of the country's present communications and information system in supporting a two-way flow of information within a pandemic vaccine deployment process

#### **3.2 Organizational structure of information flow and communication**

Flow of information regarding the deployment of pandemic will occur between the central level - Epidemiology Unit and the district focal points REE. District focal points are supposed to maintain the flow of information from vaccination centers (curative and preventive institutions). Information received by RE from vaccination centers at the district level should be consolidated and fed back to the Epidemiology Unit. Additionally, if needed, vaccine centers should be able to freely contact the pandemic vaccine deployment team at the EU.

To ensure availability of standardized information on the vaccine and related procedures and to ensure existence of a legal support for the programme; a guideline will be prepared by the EU for circulation among the health institutions. This is the standard practice and the requirement when a new vaccine is introduced to the system. The circular will deal with aspects such as information on the vaccine (schedule, dose, contraindications, precautions, storage conditions, potential side effects) procedures to be followed in an event of an anaphylactic shock, roles of identified for categories of health staff in vaccination and procedures related to documentation.

At all vaccination centers, vaccinees will be given a vaccination card. When pregnant women are vaccinated, it will be recorded in the pregnancy record. At each center, a register will be maintained to include details of all vaccine recipients. Information contained in these will be transferred to a return which will be sent to the district focal

point (RE). RE will consolidate all these returns of vaccine centers to a district return and it will be sent to the EU. Epidemiology Unit will consolidate these for the country and submit a national report to the WHO and will comply with information requirements of the WHO on their standard formats.

As far as vaccine safety is concerned, the existing AEFI surveillance system with risk communication approach will be practiced for any future pandemic vaccine program also.

For information on stock positions of the vaccine, currently existing information system on distribution of vaccines will be used. The stock movement register at the EU will carry data on stocks of vaccines and ancillary items moved to RMSD at respective districts. From the RMSD, the same stock movement registers will be used to record stocks moved to hospitals and MOH offices. "Issue Orders" will be issued from the central cold stores of EU and RMSD to MOH offices and hospitals while they will return a "Receipt Order" to the RMSD and EU. MOH office, vaccination centers at hospitals and vaccination centers at clinics will maintain "Vaccine Movement registers" to indicate the stock balance. At the close out, they will send the district focal point (RE) a return on the status of vaccines at hand. RE in return will consolidate these returns and submit it to the EU. This information will enable cross checking of delivery and return information at the close out.

A new form set will be developed and used to collect information on waste management. It will carry information on how waste is disposed of with remarks and notes from the supervisor.

### **3.3 Mechanisms and modes of Information on programme related Data**

Obtaining required information can be incorporated into the existing modes of information flow which is proven to be time tested and reliable. However, it will require developing new formats, returns and records.

An information leaflet should be prepared to be given to the target group to aid informed decision making. This would include basic information about the vaccine and what is to be done if some untoward events occur.

A message to the pregnant women on the need for vaccination and availability of vaccines at the state health care network would also be required.

### **3.4 Time lines for dissemination of information**

All information regarding pandemic vaccination is required by the close out in order to analyze and report on the effectiveness of the current programme and also to fulfill global health requirements. Therefore returns and records pertaining to the vaccination programme should be available without delay.

### **3.5 Mechanisms for emergency communication**

A hierarchical communication structure had already been identified and established within the national influenza preparedness programme through its national communication strategy. This strategy is based on the risk communication principles of WHO and identifies the spokespersons and their roles and responsibilities in an event such as a pandemic which calls for emergency action.

## **4. Public Information**

### **4.1 Objectives**

To ensure that a supportive environment exist within the community to boost the vaccine deployment process

### **4.2 Communication plan/strategy**

There has been a growing interest among public on the role of influenza vaccination in preventing the disease following the previous H1N1 pandemic in 2009 where pandemic influenza vaccine was first used in a wide vaccination drive in the country. This programme made the health sector realize the importance of public information in making the programme a success.

It is essential that accurate and updated information about any vaccine used in a pandemic event are available and accessible to public. In such an event where vaccines are offered to selected and prioritized categories, designing and delivery of messages to general public as to why certain groups are targeted is important. This need is exaggerated by the fact that the frontline health workers are the first priority for vaccination. If the message is not properly delivered, that may lead to the erroneous belief that the health sector will first prioritize themselves before the rest of the population. Convincing the population on such prioritization for specific groups has been proven in the past in JE vaccination programme and more recently during H1N1 pandemic vaccine programme through planning, developing and operating a proper communication strategy.

#### 4.2.1 Areas of communication message development

Under ideal circumstances, vaccine will be offered to the general public. But if not, reasons for prioritizing specific groups for pandemic vaccination should be clearly explained to the public. This should include financial limitations for such a strategy and

why protecting these groups are necessary. With a highly literate population in the country, this task would not be difficult given careful planning.

One of the first priority target group in a pandemic vaccination programme would be the health staff. Public should be especially made aware how this group should be protected first in order to continue an uninterrupted health service or they may interpret this as selfish action.

The other important area would be safety issues and possible AEFI of the vaccine if any.

#### 4.2.2 Communication modes/channels

Media seminars are essential for the electronic and print media personnel as a clear message is required to be brought across to the general public through these conventional modes.

All service providers offering Short Message Services (SMS) through their mobile networks should be approached for their co-operation in sending a uniform clearly thought out short message to their customers.

News website operators would also be an important group to catch, in order to spread information as a considerable section of the population use this mode of communication.

In Sri Lanka, health trade unions are strong and they are able to influence the success of the vaccination programme. A sensitization programme with representatives of all health trade unions can be useful to mobilize their support for the vaccination program especially in public information.

#### **4.3 Mechanism for communication resource mobilization for a deployment process**

Ministry of health has a separate specialized agency with relevant expertise to handle this aspect in the deployment process which is the Health Education Bureau (HEB) and mobilizing human resources will not be difficult. Advocacy measures would be applied by HEB to overcome financial limitations and to obtain emergency funding from the

government, global health donor agencies and also through private sector via their corporate social responsibility services.

#### **4.4 Mechanism for risk communication in relation to pandemic vaccines**

The same mechanism that has been described in the national communication strategy on influenza preparedness would be applied (Please see page 20).

### **5. Vaccination Strategy & Post-Marking Surveillance**

#### **5.1 Objectives**

To achieve optimum benefit from available vaccines by meticulous planning and to improve quality of the vaccination programme and to ensure safety with minimal occurrence of avoidable Adverse Events Following Immunization (AEFI)

#### **5.2 Mechanism for identifying vaccination strategies and target groups for vaccination**

Known high risk groups for the disease which is targeted by vaccination would be selected on available scientific evidence for vaccination. These may change according to evolving evidence that come up. However based on financial restraints these groups may have to be sorted on a priority basis and only a limited number of groups would be selected for the programme.

##### **5.2.1 Known high risk groups**

Health care workers, those in extremes of age, pregnant women, persons with co-morbidities and immune suppressed persons have been identified as high risk groups for seasonal influenza. Pregnant women and persons with co-morbidities were among the prioritized target groups for the pandemic vaccination programme during the 2009 H1N1 influenza pandemic that were approved by the Advisory Committee on

Communicable Diseases (ACCD). In the event of a future influenza pandemic, the ACCD will re-review the high risk groups for vaccination.

#### **5.2.1.1 Health care workers**

Health care workers were offered the vaccine as the first priority group for vaccination during the previous pandemic. This decision was made with a view to prevent disruption of health care services by worker absenteeism that may have significant bearings on continuity of services. Also it is aimed to prevent possible negative repercussions from panic related activities of healthcare staff despite reassurances. Based on these considerations, it was decided to vaccinate the health care staff as the first priority group during the last H1N1 pandemic.

If such a decision is taken pandemic vaccination should be made available to both public sector and private sector healthcare workers. However it would be the responsibility of the management of all private health care institutions to ensure timely procurement and vaccination of their staff. As far as the private sector is concerned, there may be a proportion of workers who work primarily in the public sector and employed in the private sector on part time basis. This will further minimize the requirement of vaccines for the private sector.

Public sector health care workers are categorized into curative care workers and preventive care workers by nature of their work. Both these categories of workers should be offered vaccination.

In curative care institutions, the targeted staff will include doctors, nurses, paramedical workers (lab technologists, radiographers, ECG technicians, physiotherapists etc.), attendants, ward laborers, clerical staff, transport staff, cleaning staff and security staff.

In preventive care institutions, the targeted staff will include doctors, Public Health Nursing Sisters, public Health Midwives, Public Health Inspectors, clerical staff and other supportive staff.

Animal health workers will be considered to be vaccinated as a priority group depending on the type of the pandemic disease/event.

#### **5.2.1.2 Pregnant women**

Pregnancy is a known high risk condition for severe consequences of influenza. Data on the 2009 H1N1 pandemic in the country also demonstrated that this group have had moderate to severe course of the disease. Among the deaths which have been confirmed as due to H1N1 during the pandemic, a significant proportion was pregnant women. These factors would be considered in selecting this group for vaccination as a priority in a future pandemic event.

#### **5.2.1.3 Individuals with co-morbidity**

This group is also considered a known high-risk category for complications of seasonal influenza and was ear marked to be vaccinated during the second phase of the pandemic vaccination programme during the previous pandemic. However since this category includes a significant proportion of the population, community based vaccination remains the most feasible strategy for immunizing this group.

#### **5.2.1.4 New groups identified during past pandemic & Use of surveillance data**

Analysis of data from the previous pandemic did not reveal any new target groups that a future pandemic vaccination programme should cater to. However routine data from the ongoing influenza surveillance programme are being analyzed regularly in order to identify new areas to target such a vaccination programme.

### **5.2.1 Vaccination Strategy**

#### **5.3.1 Strategy for different target groups**

5.3.1.1 Health care workers: All curative institutions (hospitals) will conduct immunization sessions to immunize their staff. Head of the institution will have the

responsibility of organizing this activity through the Infection Control Unit or/and the Medical Officer- Public Health or any other Unit/officers that is designated for the activity. Medical Officer of Health (MOH) offices which is the functional units of preventive care institutions in the country will conduct immunization sessions at these offices to target their staff and this responsibility would lie with the MOH.

Informed consent will be taken from all potential vaccine recipients and vaccine will be offered to those who consented.

Same procedure will be followed in private hospitals. Heads of these hospitals will select the person to be trained and responsible for organizing immunization activities in each of their hospitals. They will be trained by the EU or at regional training sessions to carry out immunizations in their respective private hospitals.

5.3.1.2 Pregnant Women: Pregnant women would be offered pandemic vaccine through the existing antenatal clinics (ANC) network both in the curative and preventive sector as done during the previous pandemic. The high coverage of antenatal care of pregnant women in the country could justify selection of such a strategy. As all pregnant women are under the care of the Public Health Midwife (PHM), PHM can be used to educate them on the importance and availability of the vaccine offered, either on one to one basis or in groups.

All eligible pregnant women who agree to accept vaccination through informed consent will be offered the vaccine at their own antenatal clinics which they routinely attend. If due to any reason, an obstetrician's opinion is required before vaccinating pregnant women, she will be referred to an antenatal clinic in curative care institutions where services of a Specialist Obstetrician are available. Thus, two tiers of ANC will be utilized for vaccinating pregnant women.

5.3.1.3 Individuals with co-morbidity: Both curative and preventive networks will be utilized for vaccination. Clinics will be organized at the MOH offices, primary and

secondary curative care institutions. Tertiary care institutions which conduct clinics for non-communicable diseases will also be invited to organize vaccination clinics. Medical Officers will be responsible for determining the eligibility of vaccination. Nursing officers in hospitals and PHM in MOH offices or any other designated person as decided by the heads of these institutions will administer vaccine. Complicated cases will be referred to specialists for decision making. If they determine that the patient is eligible for the vaccine, they will be offered the vaccine at the clinic of the hospitals which they were referred to.

### **5.3.2 Approach for target groups which are not covered by EPI**

Above described high risk groups except pregnant women are not usually covered by the routine system of EPI. Therefore stringent protocols included in above vaccine strategies described should be strictly adhered to, in order to achieve high immunization coverage among these groups.

### **5.4 Existing policy for Adverse Events Following Immunization (AEFI) monitoring**

The system to detect AEFI was established in Sri Lanka in 1995-96. Screening of all children for AEFI following previous immunization is mandatory at all immunization sessions. All serious and non-serious AEFI are required to be reported. Currently when a case of AEFI is detected at the hospital, clinic or during a filed visit, it is reported to the MOH using the Notification Form for AEFI. These are entered in either Clinic AEFI Register or MOH AEFI Register depending on the source of information. At the MOH office, all reported AEFI are consolidated into a monthly report and submitted to the RE of the district as the Monthly Surveillance return of AEFI a copy to the Epidemiology Unit. RE consolidates all MOH returns in the district for the month and submits a monthly return to EU using AEFI Consolidated Return from Regional Epidemiologist. Feedback information on these data is provided in the Weekly Epidemiological Return

(WER) and the Quarterly Epidemiological Bulletin (QEB). A description of this system is shown in Annex III.

All reported cases are investigated using an AEFI Case Investigation Form by an investigator (either an epidemiologist or the MOH) who would vary on the severity of the AEFI reported. Severe AEFI cases and deaths are investigated in detail by the epidemiologists in the EPI team of the EU and a report submitted to the AEFI National Expert Committee to conduct causality assessment and to make recommendations to the ACCD. ACCD implements these recommendations through the EU. Further, information of all AEFI cases investigated are shared with DRA at MoH and WHO Upasala monitoring centre. The standardized reporting forms being used ensure the uniformity of data reported. There is a system for monitoring and evaluation of the AEFI surveillance system at three tiers namely National, District and Divisional levels.

#### **5.5 Proposed services for AEFI monitoring during vaccine deployment**

Capacity of the existing AEFI surveillance system in the country is very strong given the following aspects; stability of the reporting system linked to existing reporting system, training and technical support, efficiency, continued monitoring and evaluation, feedback and sound communication. Therefore same AEFI monitoring system was used to monitor AEFI during the previous pandemic and can be used for a future pandemic vaccine.

During the training programmes on introducing a pandemic vaccine, participants should be educated on possible AEFI of such a vaccine. Similarly, an information leaflet produced will carry information on all possible AEFI so as to enable recipients to report them to the relevant health officers.

## **6. Pandemic vaccine deployment**

### **6.1 Objectives**

To ensure best possible capacity of the system to receive, store and deliver the pandemic vaccine and related ancillary items safely and in optimum quality to the recipients within the required time period

### **6.2 Mechanism for delivering vaccines from central level to local delivery points**

It is realistic to believe that the vaccines will be delivered within 7 days of receipt at the central cold stores of EU. This belief is based on the past experience in delivering vaccines to conduct National Immunization Days, Sub National immunization Days, Catch up Campaigns for measles etc. within the EPI. Epidemiology Unit has its own vehicles and a trained and separate staff for delivery of vaccines to RMSD of districts from which their own vehicles and personnel would distribute vaccines to each service delivery point. These regional staff attached to RMSD and RDHS involved in EPI have been well trained in this activity. As such, it is possible to deliver vaccines within seven days provided that currently existing gaps are bridged.

All points delivering EPI vaccines are equipped to store vaccines and ancillary items in optimum conditions. Cold storage capacity at the EU is adequate with its large central cold stores. It has been constructed having taken into consideration of future introductions of new vaccines. Therefore, this facility could accommodate stocks of pandemic vaccine without any difficulty. All districts too have adequate cold store capacity to store vaccines in their RMSD. Routine vaccine delivery points at curative care institutions and preventive care institutions will have storage capacity adequate enough for this purpose. These centers will also have adequate cold boxes/vaccines carriers.

### **6.3 Mechanism for mobilizing transport requirements for rapid deployment**

It may be assumed that vehicles and personnel usually involved in routine EPI activities at the center as well as at regional level would suffice even in a pandemic vaccine drive.

But since stocks of vaccines and other ancillary items are to be delivered within seven days to all districts and then on to delivery points, existing transport options and personnel may not be adequate. Therefore, it may be necessary to have plans drawn up to obtain services of more vehicles and personnel. Vehicles could be hired if funds could be arranged, obtained from other government institutions on the gravity of the pandemic event or obtained from private sector through their respective Corporate Social Responsibility drives.

Extra personnel could be deployed from same institutions involved in routine EPI activities by mobilizing those involved in non-essential activities other than EPI or by mobilizing staff according to contingency plans of these institutions.

#### **6.4 Mechanism for rapid vaccination of target groups**

With timely information and communication measures targeted at healthcare staff, they could be motivated to initiate a rapid activation of pandemic vaccine deployment process.

#### **6.5 Mechanisms for estimating requirement & redistribution of unused vaccine stocks**

Requirements of pandemic vaccine would be estimated once the specific target groups are selected and finalized by the main agency involved, Epidemiology Unit. Data used for vaccine requirement estimation within the EPI would be used for this activity.

All unused vaccines would be redistributed to centers in need based on stock position monitoring formats in use within the pandemic vaccine deployment process.

### **6.6 Mechanism for vaccine delivery for hard to reach groups**

As the routine EPI immunization centers would act as pandemic vaccine delivery points both in the preventive and the curative sector it could be safely assumed that all such groups could be reached with ease as done in the routine EPI programme.

### **6.7 Mechanism for involving non-government/private sector in vaccination process & coordination with regional levels**

This would be done through the main working group of MoH that collaborates with various sectors such as other governmental, non-governmental and private, National Technical Committee for Pandemic/Avian Preparedness. All members of the influenza team and the EPI team at the central Epidemiology Unit and all other personnel involved in routine EPI activities at the central and regional level both in public and private health sector would be involved in the pandemic vaccine deployment process and they will liaise and collaborate with other agencies at each level.

Influenza team of the Epidemiology Unit would closely work with regional levels within the country during the pandemic vaccine deployment process.

### **6.8 Mechanism for issuing directives/guidelines to those who provide vaccinations**

The Influenza team and the EPI team of the Epidemiology Unit would closely work with the ACCD and be responsible for issuing directives/guidelines on pandemic vaccination.

### **6.9 Mechanism for disposal of medical wastes in vaccination process**

In the pandemic vaccine deployment process waste disposal will be done according to national guidelines and best practices and will be the responsibility of EU at the central level and RDHS at district level.

A major limitation in the health system in the country is that it does not have a proper system to dispose of medical waste. The environmental ministry has intensified its focus

on systematization of disposal of medical waste in the future. However, at present, except in a few larger institutions, incinerators are not being used to dispose medical waste. In these other institutions, open burning of items in pits has been adopted. This is generally the widespread method of disposal of medical waste.

All immunization centers collect used items in safety boxes. Then they are locally disposed of mostly by burning in open pits. As such, an additional transport cost does not arise. Existing staff is also adequately trained in this method of disposal of medical wastes. Every immunization center in the country has delegated this responsibility to identified health workers as a part of their routine duty. Given the availability of these resources, an extra effort would not be needed for collection and disposal of medical wastes during the pandemic vaccination process. Any additional costs should be estimated by the district team leaders and arrangements should be made to obtain the cost from local health budgets. If this cost is considerable emergency funding would be mobilized from the Disaster Management Ministry budget at the central level.

Supervisory items of waste disposal will be included in the supervisory checklists. Duty rosters of relevant staff will be adjusted by relevant team leaders to include the quick disposal of extra load of waste during the pandemic vaccination.

If any vaccine stocks are left unused due to cold chain issues or expiry, they will be disposed according to the system practiced within the EPI.

#### **6.10 Mechanism for terminating the deployment operation**

Vaccine deployment process will be concluded once all vaccination activities are completed. If a second dose of the vaccine has to be given the complete vaccination process must continue to be in place till such activity is completed. Termination of operations will mainly include returning of resources such as items, equipment and personnel that had been used in the process to their original agencies or duty stations, documenting on resources used up and recording lessons learnt during the process.

Termination of operations will be announced by the central agency Epidemiology Unit. It will be responsible for compiling the main deployment termination report. This report will have two sections: technical and financial reports. It will be prepared in a manner to be transparent and accountable to the donor agency/agencies that funded the deployment process. All RE will prepare and submit the district termination reports for his/her respective district. The EU will prepare a final main deployment termination report for the country. The report will indicate how vaccines were distributed to districts and how they had been used. The district report will include the coverage of vaccination for respective priority groups within the district. Vaccines which were underutilized and returned back to the EU will also be included. The national report compiled by the Epidemiology Unit will be based on the district reports and will include national vaccine coverage's for each target group.

The report will also include a chapter on reported AEFI during the pandemic vaccination. These AEFI will be classified and quantified according to standard methods. This section of the report will describe serious AEFI, actions taken with regard to them and how they affected the vaccination programme. Data on AEFI for the national report will be obtained from the district reports.

For future reference, the termination report will also include lessons learnt during the deployment exercise. All REE will be instructed to include their own lessons learnt at district level in their reports and this section in the national report will be compiled based on these

The financial report will be prepared to summarize the money received and expenditures incurred under relevant headings as approved by the funding agency. The remaining funds will be indicated for further action.

## **7. Monitoring and Evaluation**

Epidemiology Unit as the focal point for implementing the deployment process will take over the responsibility of monitoring and evaluation. It will develop a set of comprehensive indicators for this purpose. These indicators will cover all the main strategies included in the pandemic vaccine deployment plan.

In each district, the team leader for the district, the RE would monitor the activities within the process according to indicators set out. He/she would be assisted by the locally responsible person for each activity at each center who would monitor these activities during the process.

Each RE will evaluate the district pandemic vaccine deployment plan. At the central level, Epidemiology Unit will evaluate the national pandemic vaccine deployment plan according to pre-determined indicators.

### **7.1 Indicators for monitoring and evaluation**

Other than the indicators listed below all existing indicators being used to evaluate the EPI will be used in pandemic vaccine deployment process.

#### **7.1.1 Management & Organization**

1. Level of vaccine stocks at each RMSD
2. Vaccine coverage at district level

#### **7.1.2 Human Resources**

1. Proportion of training programmes held out of scheduled
2. Proportion of trained hospital personnel at district level
3. Proportion of health institutions with BCP

### **7.1.3 Communication & Information**

1. Completeness of due consolidated vaccine returns from districts
2. Timeliness of due consolidated vaccine returns from districts

### **7.1.4 Public Information**

1. Proportion of media seminars held out of scheduled
2. Number of novel modes of communication (SMS, news web sites) used

### **7.1.5 Vaccine strategy & Post marketing surveillance**

1. Number from each chosen high risk group vaccinated
2. Completeness of AEFI returns from districts
3. Timeliness of AEFI returns from districts

### **7.1.6 Pandemic vaccine deployment**

1. Proportion of districts receiving vaccine stocks within 7 days of receipt at central level
2. Number of extra personnel recruited for deployment process in each district
3. Number of unused vaccines per each district



## **ANNEX 1**

### **Members of the Advisory Committee on Communicable diseases**

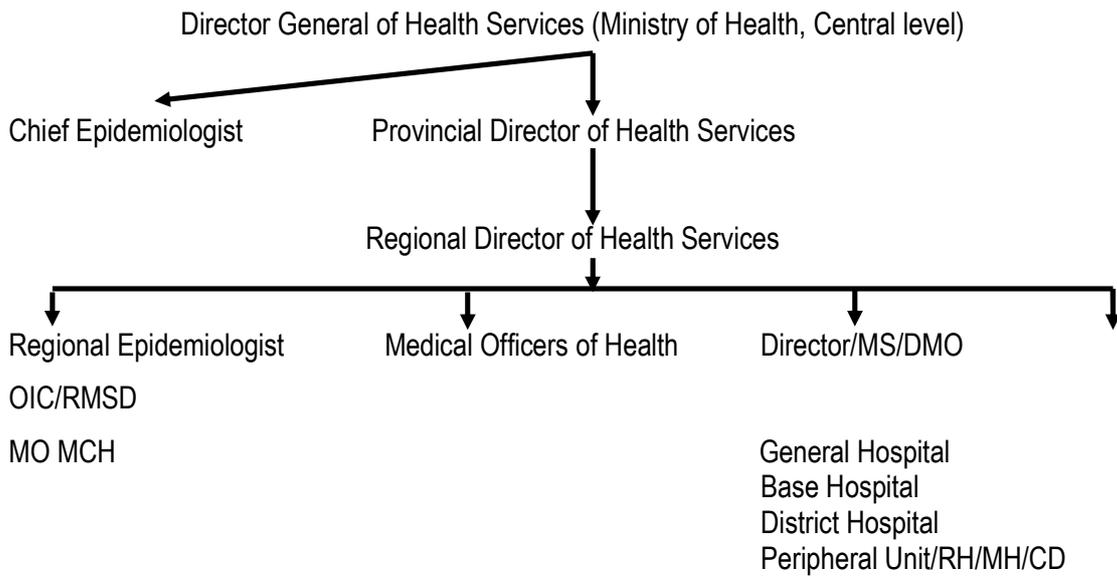
#### **Designation**

Director General Health Services  
Deputy Director General (Public Health Services I)  
Deputy Director General (Public Health Services II)  
Senior Professor of Paediatrics  
Chief Epidemiologist  
Director / Anti Filariasis Campaign  
Director Environment & Occupational Health  
Director, National STD & AIDS Control Programme  
Virologist Medical Research Institute  
Virologist Medical Research Institute  
Director National Programme for Tuberculosis Control & Chest Diseases  
Director Health Education Bureau  
Director Infectious Diseases Hospital  
Chairman Sri Lanka Medical Association / Communicable Diseases Sub Committee  
Director Anti Malaria Campaign  
Director Anti Leprosy Campaign  
Head, Department of Community Medicine, Faculty of Medicine, University of Colombo  
Director Maternal & Child Health  
Director National Hospital of Sri Lanka  
Director Medical Research Institute  
Deputy Director General (Medical Services)  
Professor of Medicine, University of Colombo  
Deputy Director General (Planning)  
Deputy Director (Statistics) Medical Statistics Unit  
Representative from College of Paediatricians  
Representative from College of General Practitioners  
Professor of Paediatrics, University of Sri Jayawardanapura  
Professor of Microbiology University of Colombo  
Professor of Pharmacology University of Colombo  
Representative from World Health Organization  
Consultant Physician, Infectious Diseases Hospital  
Director Public Health Veterinary Services  
Director Quarantine Unit  
Director Medical Supplies Division  
Director Medical Technologies & Supplies  
Coordinator, Dengue Control Unit



## ANNEX II

### Organogram and Structure of Ministry of Health





# ANNEX III

## AEFI Surveillance System in Sri Lanka

