

**Ministry of Healthcare and Nutrition
Government of the
Democratic Socialist Republic of Sri Lanka**



**Deployment Plan for the Distribution of Pandemic
Influenza Vaccine in Sri Lanka 2010**

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II. Executive Summary

The Pandemic Influenza Preparedness Plan (PIPP) of the Ministry of Health care and nutrition of Sri Lanka promotes the use of a safe and efficacious vaccine, if and when it will be available, to mitigate the impact of the pandemic. The WHO's recent move to donate a stock of pandemic Influenza A H1N1 vaccine has made its use possible to respond to the pandemic and protect the most vulnerable risk groups to the infection in Sri Lanka. This vaccine will be used first to protect all frontline health care workers and supportive staff to ensure that there will be no disruption to both curative and preventive health care services in the country. The remaining stock of vaccines offered by the WHO will be used for vaccinating pregnant women. After this exercise, if there will be more vaccines remaining, these vaccines will be offered to individuals with at least one co morbidity that poses risk of complications of pandemic influenza. To completely cover this group, the Ministry of Health Care and Nutrition needs stocks of vaccines other than that offered by the WHO.

This prioritisation of risk groups for vaccination has been approved by the Advisory Committee of the Communicable Diseases (ACCD). To target the first two priority groups, country needs 575000 doses of vaccines. If the group of individuals with at least one co-morbidity is included, another 3400000 doses will be required.

The main objective of the pandemic Influenza A H1N1 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. Conclusion of the 30 year old war has already removed some operational obstacles which were experienced during the execution of other mass immunization campaigns in the yesteryears

This document outlines the feasibility, issues, challenges, suggested counter measures and budgetary requirements to ensure that the vaccine deployment will be well planned and systematically executed. This plan of vaccine deployment has been made in a manner so as to be in uniformity with other vaccine deployment plans of member countries of the WHO according to the standard formats developed during the training workshop on Deployment of Influenza A H1N1

2009 Vaccine held at the WHO SEAR office, Delhi and directives issued at the meeting held jointly by the WHO & USAID in Bangkok, Thailand to finalise country plans for vaccine deployment.

The required total cost of the budget for vaccine deployment is 4223400 US \$. However, some activities related to vaccination against H1N1 pandemic extend beyond the planned budget of immunization activities of the central government and 8 provincial ministries. Therefore, the country requires financial support from external agencies to cover these activities which were not pre planned and hence not included in the plans of the fiscal year 2010. The Government of Sri Lanka recognises this vaccination campaign as a campaign of pivotal public health importance and will contribute 61% of the total funding required to carry out this important vaccination campaign. The table below outlines the total budgetary requirement for accomplishing this task.

Table I : Total requirement of funds to conduct H1N1 vaccination campaign in Sri Lanka

	Government Funding	Unfunded	Total
Total funding required for H1N1 vaccine campaign	479490US \$	159830 US \$	639320 US \$

Expected vaccine donation from the WHO = 385000 (2%) + 1540000 (8%)

Total expected doses = 1925000

Overall external funding requirement per a dose = 0.08 US \$

The vaccine deployment plan outlines the processes and activities involved. It entails vaccination strategies, management and organization, communication and information, human resources and security, public information, pandemic vaccine deployment operations (Supply Chain Processes) and collection of medical waste required to execute a thorough and high quality vaccination campaign in Sri Lanka.

III. Introduction

Pandemics of influenza are known to have caused morbidity and mortality for a considerable period of time. Recorded since the middle of the 18th century, major antigenic shifts have occurred 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. In 1957, the "Asian flu" and the "Hong Kong flu" in 1968 caused about 20 million deaths. An antigenic shift was recorded in 1977 also.

Though it was strongly believed that the H5N1 virus 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 at the beginning of the second quarter of this year, 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 Luis Potosi in Mexico. Soon it was spreading human to human like seasonal flu. Cases were increasingly reported from countries outside Americas and the virus was proven to have established local spread in those countries leading to widespread community transmission in certain countries. Based on available epidemiological data, the World Health Organization (WHO) declared a pandemic on 11th June 2009.

As the disease started to spread, Sri Lanka introduced screening measures at the entry points with a view to preventing the entry of the disease into the country. However, Sri Lanka reported its first confirmed case of influenza A /H1N1 in June 2009. At present, the country is experiencing a sustained community transmission of the disease. While it is spreading, deaths too have been reported. As of 15th December 2009, the total death toll due to influenza A/H1N1 was 28. To mitigate the impact of the pandemic, country has implemented several control and preventive measures. Meanwhile, it has been established that the early availability of safe and effective vaccines is a critical component of efforts to prevent the A/H1N1 infection and mitigate overall

effects of the pandemic. Parallel to the need of introducing a vaccine as a strategy to mitigate the impact of the pandemic, the WHO has come forward to support developing countries by distributing a stock of vaccines to its member countries. Sri Lanka has also been offered vaccines to be deployed in the country to mitigate the impact of the pandemic.

Legal Bases or Resolutions

The NIPP has also highlighted vaccination as one of the recommended strategies for prevention and control of influenza A/H1N1 if an effective and affordable vaccine will be available. Accordingly, the National Influenza Technical Evaluation Committee has reviewed the possibility of introducing vaccine as a strategy to mitigate the impact of the current influenza A/H1N1 pandemic which is spreading in the country given the current offer of a stock of the said vaccine will be donated by the WHO for its member countries. At the prospect of this new development, the Epidemiology Unit (EU) as the focal point for pandemic preparedness and response in the country has prioritized the vaccination strategy considering the limited number of stocks that it would possess. Already the EU has forwarded it for ratification of the ACCD which is the apex body for policy decisions regarding control of communicable diseases including emerging infectious diseases such as influenza A/H1N1. After ratification of the decision to use it in Sri Lanka by the ACCD, it has been approved by the Director General of the Health Services (DGHS) and the secretary of the Ministry of Health. Ultimately, the honorable minister of health has signed the Terms of reference (TOR) with the WHO with a view to offering influenza A /H1N1 vaccine to prioritized groups as an important strategy for mitigating the impact of the current influenza A H1N1 pandemic in Sri Lanka.

Thus, the purpose of vaccinating with pandemic influenza A/H1N1 vaccine in Sri Lanka is to save lives and mitigate the overall effects of the influenza pandemic in the country. The Country has prioritized target groups for vaccination and in the rank order they are given in the table 2.

Table 2: Priority Groups to Receive Influenza A H1N1 Vaccine in Sri Lanka

Priority group	Total Population	Estimated Doses of Vaccine Required
1. Health Care Workforce	200000	200000
2. Pregnant Women	375000	375000
3. Individuals with at least one co – morbidity (Diabetics, Chronic Respiratory, Cardiac (excluding hypertension), Renal, Liver)	3472000	3472000
TOTAL	4047000	4047000

Table 3: Requirement of ancillary items to vaccinate priority Groups with Influenza A H1N1 Vaccine in Sri Lanka

Priority group	AD syringes	Safety boxes
1. Health Care Workforce	200000	2000
2. Pregnant Women	375000	3750
3. Individuals with at least one co – morbidity (Diabetics, Chronic Respiratory, Cardiac (excluding hypertension), Renal, Liver)	3472000	34720
TOTAL	4047000	40470

Though the total population targeted for vaccination in Sri Lanka is 4 million, country will receive only 1.9 million doses of vaccines through the WHO. This will enable vaccinating the entire health care workers and pregnant women in the country. The deficit to vaccinate all three target groups is about 2 million doses. The Epidemiology Unit intends to discuss the possibility of mobilizing other resources to obtain the required 2 million doses of vaccines with the ministry of health and the national treasury. In the event of this request not being able to be realized, it is necessary to prioritize vaccinating individuals with co morbidity against H1N1. Local epidemiology of the current H1N1 morbidity and mortality in Sri Lanka and additional factors such as number of existing co morbidities that further increases the risk, belonging to high risk age groups (less than 2 years, more than 65 years etc) and the nature of the job that places them at high risks, using medications such as immunosuppressants will be taken into account for prioritization of vaccines in this group. However, these criteria for prioritization will be consensually determined and ratified by the Advisory Committee on Communicable Diseases which consists of multidisciplinary experts.

IV Vaccination Strategies

Target groups for vaccination:

The advisory committee on Communicable Diseases (ACCD) of the Ministry of Health Care and Nutrition which is the apex body for ratification of all decisions with regard to immunization related activities has already approved priority groups for vaccination. In the first phase, all health care workers and pregnant women will be targeted depending on the availability of pandemic H1N1 vaccines. The strategy of how these categories are vaccinated is given below in details:

Health care workers:

Health care workers will be offered the vaccine as the first priority group for vaccination. This decision has been made with a view to preventing the collapse of health care services. Currently, as the pandemic has acquired community spread in SL, the curative care services are witnessing an increase in number of hospitalizations. This stretches the demand for increased infection control measures for which government has to spend a considerable amount of money. Though reassured, activities of some categories of the staff have significant bearings on continuity of services due to unfounded panic. Some are skeptical of infection control measures in place to mitigate the hospital acquired infections of H1N1. The health trade unions too have pressurized the government on the need of vaccines for the staff. This cannot be considered lightly as these unions are the most powerful in the country and their actions may cause disruption of services. Based on these considerations, it is appropriate to vaccinate the health care staff as the first priority group.

The vaccination will not be limited to the health staff in the public sector. It will be offered to the health staff in the private sector too. The 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 will be offered vaccination. As far as the private sector is concerned, there may be a proportion of workers who work primarily in the public sector and in their free times, employed in the private sector. This will further minimize the requirement of vaccines for the private sector.

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

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

All curative institutions (hospitals) will conduct immunization sessions to immunize their staff. 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.

The EU which is the national focal point for all immunization activities will train "TRAINERS OF TRAINERS (TOT) ". Regional Epidemiologists (RE) and Medical Officers (Maternal & child Health) (MOMCH) of all districts will be summoned to the EU for the training (There is one RE & MOMCH each for every district). These officers will return after one day training to their districts and conduct training there. Infection Control Nurse or /and the Medical Officer- Public Health at curative institutions will be responsible for immunization activities at curative care institutions. Medical Officer of Health (MOH) will be responsible for immunizing the preventive health staff.

These officers will return to their respective stations after the training. They will conduct awareness sessions for the staff in the institution. It is expected that the national training will take one day. The district training will also take one day. The required number of days may vary according to the size of the institutions. Majority of institutions will need one day while a minority of (less than 20) big institutions will take 2-3 days for awareness sessions for all the staff.

After the awareness sessions, immunization clinics will be organized at these institutions. Potential vaccine recipients will be offered a written consent form for expressing their consent for vaccination. Those who consented will be offered the vaccine.

The same procedure will be followed in private hospitals too. These hospitals will select the person to be trained and responsible for organizing immunization activities. They will be trained by the EU to carry out immunizations in their respective private hospitals.

Pregnant women

Surveillance of H1N1 in SL demonstrated that the pregnant women among others have had moderate to severe course of the disease. Among the deaths which have been confirmed as due to H1N1, a significant proportion was pregnant women. This has been given an undue media exposure which has started panicking the general public including pregnant women. These circumstances have forced considering immunizing pregnant women as equally important as immunizing the health staff. Therefore, the Ministry of Health in SL has decided to include this category also for immunization in the first phase.

It is expected to vaccinate these women through the existing antenatal clinics (ANC) network both in the curative and preventive sector. The high coverage of antenatal care of pregnant women in SL will justify selection of such a strategy. As all pregnant women are under the care of the Public Health Midwife (PHM), PHM will make them aware of the need and availability of H1N1 vaccine either on one to one basis or in groups. The potentially eligible pregnant women will fill the consent form. They will be offered the vaccine at the ante natal clinics which they attend under normal circumstances. If due to any reason, an obstetrician's opinion is required before vaccinating the pregnant woman, she will be referred to the ante natal clinics where the services of a Visiting Obstetrician & Gynecologists are available in higher level curative care institutions. Thus, two tiers of ANC will be utilized for vaccinating pregnant women.

Vaccination of individuals with co morbidity

It is anticipated that this group would be vaccinated in the second phase of the WHO offer. Since this category numbers a significant proportion of the population, community based vaccination remains the most feasible strategy. 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. Subsequently, nursing officers and PHM in MOH offices will administer vaccine. Problematic cases will be referred to specialists for decision making. If they determine the patient eligible for the vaccine, they will be offered the vaccine at the clinic of the hospitals which they were referred to.

Vaccination requirement for different priority groups by districts is given in table 4

Table 4: Vaccination requirement for different priority groups by districts

District	No of health staff targeted	No of Pregnant women targeted	No estimated with co morbidities	Total doses required
Colombo	40000	65500	417000	522500
Gampaha	30000	40500	402000	472500
Kalutara	10000	18000	196000	224000
Kandy	20000	31000	231000	282000
Matale	5000	10000	80000	95000
Nuwareliya	5000	7550	125000	137550
Galle	10000	20000	180000	210000
Matara	4000	14000	137000	155000
Hambantota	3000	6000	96000	105000
Kurunegala	10000	24000	260000	294000
Puttalam	4000	13000	135000	152000
Kegalle	5000	9000	138000	152000
Ratnapura	7500	18000	185000	210500
Badulla	6000	18250	140000	164250
Moneragala	4000	7000	76000	87000
Anuradapura	8000	16000	137000	161000
Polonnaruwa	4000	7000	68000	79000
Batticaloa	5000	16000	129000	150000
Trincomalee	3000	8000	67000	78000
Ampara	3000	5900	48000	56900
Jaffna	5000	7000	63000	75000
Kilinochchi	1000	3000	27500	31500
Mannar	1750	1600	15000	18350
Mullaithivu	1750	3400	31500	36650
Vavuniya	2000	3300	30000	35300
Kalmunai	2000	2000	58000	62000
Total	200000	375000	3472000	4047000

Distribution of vaccines that will be received under the WHO donation for different priority groups by district is given in table 5 .

Table 5 : Distribution of WHO donated vaccines for priority groups by districts

District	No of health staff targeted	No of Pregnant women targeted	Targeted individuals with co morbidities under WHO donation	Total doses to be distributed under WHO donation
Colombo	40000	65500	190000	295500
Gampaha	30000	40500	190000	260500
Kalutara	10000	18000	80000	108000
Kandy	20000	31000	90000	141000
Matale	5000	10000	30000	45000
Nuwareliya	5000	7550	48000	60550
Galle	10000	20000	75000	105000
Matara	4000	14000	50000	68000
Hambantota	3000	6000	40000	49000
Kurunegala	10000	24000	90000	124000
Puttalam	4000	13000	50000	67000
Kegalle	5000	9000	48000	62000
Ratnapura	7500	18000	55000	80500
Badulla	6000	18250	48000	72250
Moneragala	4000	7000	25000	36000
Anuradapura	8000	16000	48000	72000
Polonnaruwa	4000	7000	25000	36000
Batticaloa	5000	16000	50000	71000
Trincomalee	3000	8000	25000	36000
Ampara	3000	5900	20000	28900
Jaffna	5000	7000	23000	35000
Kilinochchi	1000	3000	10000	14000
Mannar	1750	1600	5000	8350
Mullaithivu	1750	3400	10000	15150
Vavuniya	2000	3300	10000	15300
Kalmunai	2000	2000	15000	19000
Total	200000	375000	1350000	1925000

Table 6 : Total funding required for vaccination strategy for the deployment of H1N1 vaccine

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Vaccination strategy	US\$ 337420	US\$ 337420	Not required

V Management and Organization

Organizational structure of management and deployment of pandemic H1N1 vaccine in Sri Lanka

The overall management of the deployment of the pandemic vaccine will be carried out by the EU of the ministry of Health Care and Nutrition. This unit under the leadership of the Chief Epidemiologist will be overall responsible for planning, procurement and distribution of vaccines and ancillary items to the districts, implementation of immunization, monitoring and evaluation of immunization programme, surveillance of AEFI. Additionally, it is entrusted with the task of coordination activities with other government ministries and non government organizations including the WHO & UNICEFF etc. The Expanded Program of Immunization (EPI) team and the team of the Pandemic preparedness and response of the EU will act together to deploy pandemic H1N1 vaccine in the country.

All policy decisions with regard to the deployment of the pandemic H1N1 vaccine will be taken by the Advisory Committee on Communicable Diseases. This committee will be 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. Already the committee has approved the use of pandemic H1N1 vaccine and ratified the priority groups for vaccination. Honourable Minister of Health has already signed the terms of reference with the WHO on deploying H1N1 vaccine in SL with the assistance of the WHO. The EU as the implementing agency has already briefed the secretary of the Ministry of Health and the Director

General of Health Services on deployment plan of H1N1 vaccine and secured their support for the endeavour.

Every new vaccine that is brought into the country needs registration before being used. This is carried out by the Cosmetic Drugs and Devices Authority (Drug Regulatory Authority) of the Ministry of Health. As the director of the CDDA is a member of the ACCD, the need for registration is evident and measures are already being taken by him to register the pandemic H1N1 vaccine in Sri Lanka. It has been decided to offer a waiver of registration to the stock of vaccines offered by the WHO as a donation considering the gravity of the situation.

Once shipments of vaccines and ancillary items reached the warehouses of the Sri Lankan customs, the Medical Supply Divisions (MSD) of the Ministry of Health Care and nutrition will attend to relevant procedures related to customs clearance. The EU 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 warehouse at the EU.

Sri Lanka has a devolved health system. To manage affairs, there are eight provinces with eight provincial health ministries. These eight provincial ministries have curative and preventive institutions under their administrative control. Eight provinces have 25 districts and in each district, there is a district EPI manager who will be responsible for all immunizations (EPI & non EPI). The RE will be the district EPI manager and he/she 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 Supply Divisions with warehouses to store vaccines and ancillary items under the care of the Officer In Charge of the MSD. The district has several administrative divisions and to correspond these divisions, there is a Medical Officer of Health (MOH). He is the divisional EPI manager and vaccines and ancillary items will be stored at the MOH offices. Meanwhile, vaccines and ancillary items are 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 the EU provides EPI vaccines to General practitioners and private hospitals.

There is a director of private sector health development in the ministry to coordinate with the private sector health.

Names and contact details of relevant stakeholders of the pandemic H1N1 vaccine deployment in Sri Lanka

The names and contact details of the ACCD

The names and contact details of the ACCD which is the apex body for ratifying all policy decisions related to the deployment of pandemic H1N1 vaccine in Sri Lanka are given in the Annex 1

Chief epidemiologist in her capacity as the secretary will attend to fulfilling all policy decisions taken at the sessions of the ACCD related to the deployment of pandemic H1N1 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 honorable Minister of Health Care and the Secretary of the Ministry of Health care on policy matters pertaining to the deployment of pandemic H1N1 vaccine in SL.

The names and contact details of the central team of the deployment of the pandemic H1N1 vaccine

The names and contact details of the central team of the deployment of the pandemic H1N1 Vaccine in SL are given in the Annex 2

The team will be responsible for prioritization of target groups, determining vaccination strategies, obtaining ratification from the ACCD, making national estimates, mobilizing support of the WHO for vaccines and ancillary items, getting the regulatory approval for the vaccine, releasing vaccines from the customs, designing forms for documentation, distribution to districts,

monitoring and evaluation of EPI in districts. Further, this team will be actively involved in AEFI monitoring. Team will not only liaise with the ACCD, CDDA, and MSD but also with the Health Education and promotion bureau for Information Education and Communication (IEC).

RE will act as team leaders in districts. The 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, surveillance of AEFI. REs as district team leaders are supposed to liaise with MOOH offices, curative institutions in the district and the EU to effectively coordinate pandemic H1N1 vaccine deployment in their respective districts.

Administration (Optional)

Offices of managing deployment of pandemic H1N1 vaccines

- Central team of deployment of pandemic vaccine
 - **Epidemiology Unit, 231 De Saram place, Colombo 10**
- District coordinator of deployment of Pandemic vaccine
 - Regional Epidemiologist(**Name of relevant district**) , Regional Director of Health services Office ,(**Name of relevant district**)

Description of the different staff positions

- Regional epidemiologist (district team leader)
- OIC- RMSD (district vaccine distributing officer)
- Medical Officer of Health (Divisional team leader)
- 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, MOH, Public health nursing sister, MO public health (supervisor of vaccination)
- Minor staff (laborers) – (staff responsible for waste disposal)
- Visiting physicians/ Visiting obstetricians (expert opinion regarding vaccination)

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 external donor agencies including the WHO in submitting expenditure and financial reports.

Table 7: Total funding required for Management and organization of vaccine deployment

Activity	Total Budget Required	Government Funding Allocated	Gap in required funds
Management and Organization	US\$7000	US\$ 6500	US\$500

VI Communication and information

Organizational structure of information flow and communication:

Flow of information regarding the deployment of pandemic H1N1 will occur between the central agency (EU) and the district focal points (RE). District focal points are supposed to maintain the flow of information with vaccination centers (Curative and preventive institutions). Exchange of information and communication at these two tiers are two way processes. This information collected by the RE from vaccination centers at the district level is supposed to be consolidated and fed back to the central focal point. Additionally, if needed, the vaccine centers will 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 a legally binding document; 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 categories of health staff in vaccination and procedures related to documentation.

At the centre of vaccination, health staff will be given a vaccination card. When pregnant women will be vaccinated, it will be recorded in the pregnancy record. At the clinic center, a register will be maintained to include details of all vaccine recipients. 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 will be sent to the EU. EU will consolidate these for the country and submit to the WHO. EU will comply with information requirements of the WHO on their (WHO's) standard forms.

As far as AEFI reporting is concerned, the currently existing reporting system will be adapted for the H1N1 vaccine program also.

For stock release from the warehouse at EU, currently existing system of 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 warehouses of EU and RMSD to MOH offices and hospitals while they will return a " Receipt Order" to the RMSD and EU. The MOH office, vaccination centers at hospitals and 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. EU will consolidate these for the country and submit to the WHO. EU will comply with information requirements of the WHO on their (WHO's) standard forms. These information will enable cross checking delivery and return information at the close out

A new form set will be developed for waste management. It will carry information on how waste was disposed of and supervisor's remarks and notes.

Issues, requirements and challenges regarding flow of information

Obtaining required information can be incorporated into the existing information flow which is proven to be time tested and reliable. However, it may require developing new formats, returns and records. EU has expertise to face this challenge.

As these are not pre planned activities, the government may not be able to provide money under the normal financial votes. Therefore mobilizing additional funds from external donors is required and remains a challenge for the immunization managers.

During the planning, deployment and closeout stages, communication between national, district and divisional levels is required. Government has provided communication infrastructure. However, due to the stretched demand of communication during all stages of vaccine deployment, government allocations for communication will not suffice. Allocations at sudden notice will not be possible as votes have already been allocated for the fiscal year 2010.

Vaccine distribution plan:

It is realistic to believe that the vaccines will be delivered within 7 days of receipt at the warehouse of EU. This belief is based on the experience of delivering vaccines to conduct National Immunization Days, Sub National immunization Days, catch up campaigns for measles etc. Moreover, currently the North Eastern provinces are accessible as the war has been concluded and by road access to the Northern tip of the country is a reality. The EU has its own vehicles and a trained and separate staff for delivery of vaccines to districts. As such, it is possible to deliver vaccines within seven days provided that currently existing gaps are bridged.

Issues and challenges to distribute vaccines

If vaccines are to be delivered within seven days to all 25 districts, the current lorry and small two vehicles will not be sufficient. Therefore, it may be necessary to hire a few vehicles from the private sector. Hiring such vehicles is beyond the routine budget allocated to the EU for the fiscal year of 2010. Obtaining treasury approval for hiring vehicles is possible. However, managers need to look for external avenues to mobilize financial resources for hiring vehicles.

The SL government will contribute by providing existing vehicles for utilization for vaccine distribution. Further, within the limits of pre planned fuel allocations for vaccine distribution, government will provide finances. As this has been planned for the delivery of EPI vaccines and in planning stages as the cost for delivery of pandemic H1N1 vaccine was not taken into account, the required amount of money has to be mobilized from external sources.

The current staff involved in vaccine distribution may be inadequate to meet the deadline of delivering vaccines within 7 days. Therefore, it is essential to mobilize staff involved in other activities to be used for vaccine delivery.

Table 8 :Vaccine distribution plan (distribution from the warehouse of EU)

Days	Destination	Team
Day 1	Colombo, Gampaha	One
Day 4	Kuruneagala, Trincomalee	One
Day 1	Puttalam , Anuradapura	Three
Day 2	Kalutara , Galle	One
Day 1	Matara, Hambanthota	Four
Day 1	Kandy, Matale,	Two
Day 2	Kegalle,Nuwareliya	Two
Day 5	Ratnapura, Moneragala	Three
Day 1	Polonnaruwa , Batticaloa	five
Day 4	Ampara , Kalmunai	Two
Day 3	Jaffna, Kilinochchi	Three
Day 3	Vavuniya, Mannar	Four
Day 4	Mullaithivu	Four

Table 9 : Total funding required for Communication and Information

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Communication and Information	US\$ 148000	US\$ 3570	US\$ 11230

VII Human Resources and Security

The current human resources capacity available in the health sector is adequate for executing a 7 day deployment. As such, mobilizing additional human resources is not necessary. Required

human resources will be mobilized from the curative and preventive health institutions to vaccinate the health staff. All staff in ante natal clinics will be utilized to reach the pregnant women in Sri Lanka. Both staff in curative and preventive care will be utilized for vaccinating individuals with co morbidities in the community.

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. The same staff will be utilized for providing security to warehouses and institutions where pandemic H1N1 vaccine and ancillary items are stored. Provision of security is not necessary when vaccines are delivered to districts. This was the practice even when there was the civil war in the North Eastern provinces of the country. Since there is no longer a civil war with all areas being accessible without security clearance, security concern does not arise when vaccines are delivered to the Northern and Eastern provinces.

Training of human resources:

The central EU will train trainers (Training of Trainers –TOT). 26 Regional Epidemiologists and 26 Medical Officers of Maternal & Child Health representing all districts will take part in this training. These officers after their training will initiate training programs in their respective districts. They will train NO and Medical Officers who will be responsible for vaccinating health staff in curative institutions. They will train MOH in preventive institutions. These MOH will train PHMM who will vaccinate both the health staff and pregnant women in ante natal clinics. Nursing officers who will vaccinate pregnant women in ante natal clinics in curative institutions will also be trained. Supervisory Public Health Nursing sisters, Public Health Nursing Sisters and a selected Nursing Sister from a curative institution will be trained as supervisors. Results of supervisions will be available on checklists designed for supervisory purposes. Training for all these categories will include AEFI surveillance, reporting and detailed investigation of severe AEFI according to the current guidelines of the Ministry of Health Care and Nutrition.

Table 10: Total funding required for human resources and security

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Human resources and security	US\$ 84000	US\$ 74000	US\$ 10000

VIII Public Information

Since the outbreak of H1N1 is spreading in the community, people, to a certain extent, are panicked and exploring available preventive and control methods. There is a growing interest in the vaccination against H1N1 vaccine to keep them free of the disease following medical highlights that the WHO intends to offer a stock of vaccines to the country. It is essential that true and accurate information about the prospects of the availability of the vaccine in Sri Lanka in the near future are existent and accessible to them. In this particular instance, as 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 may not be that difficult given the past experience in prioritizing JE vaccine for target groups with proper media strategy. Therefore, coupled with proper communication strategy, this may be countered well.

Media seminars are also essential for the electronic and print media personnel as a clear message is required to be brought across to the general public. Under normal circumstances, vaccine will be offered to the general public.

The first priority target group is the health staff. In Sri Lanka, health trade unions are strong and they are able to influence the success of the pandemic influenza H1N1 immunization. A

sensitization programme with representatives of all health trade unions is required to mobilize their support for the vaccination program.

Information leaflet has to be prepared to be given to the potential vaccine recipients before consenting to accept the vaccine. A consent form too needs to be developed for vaccine recipients.

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

Vaccine recipients will be given basic information about the vaccine and what is to be done if some untoward effects occur

The ministry of health has a separate specialized agency in its fold with relevant expertise to complete this task. The restriction will be financial resources as this has not been pre planned. Currently also the corporate social responsibility act of some private sector agencies has been mobilized by the Health Education Bureau (HEB) for this purpose. The HEB needs to mobilize additional required funds from external agencies to accomplish this task.

Table 11: Total funding required for public information for deployment of H1N1 vaccine

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Public information	121500	50000 US\$	71500US\$

IX Pandemic vaccine deployment operations (Supply Chain Processes)

Distribution of ancillary items will be similar to vaccine distribution as indicated in the “**vaccine distribution**” in the section VI. Same issues and challenges indicated for the distribution of vaccines in the section “**vaccine distribution**” will be encountered by the programme managers when ancillary items will be distributed. Same solutions indicated in the aforesaid section will be adopted to rectify these issues. From the district levels, vaccines and ancillary items will be delivered to the curative institutions and preventive care institutions where vaccine centers will be established. Districts also will have vehicles for distribution. However, non inclusion of funds for

fuel in the plan of action for the year 2010 will be a problem. Therefore, national managers have to secure adequate funding for providing fuel to the districts to ensure that logistics supplies are available at vaccine centers on time.

The cold storage capacity at the EU is adequate. It has been constructed having taken into consideration of future introductions of new vaccines. Therefore, the lot of H1N1 vaccine will be able to be stored at the central cold stores without any difficulty. All 26 districts too have adequate cold store capacity to store vaccines. Curative care institutions and preventive care institutions will have storage capacity adequate enough for this purpose. Many of the vaccine centers too will have adequate cold boxes/vaccines carriers. But there may be a deficiency of cold boxes/vaccine carriers in certain MOH areas in recently liberated Northern and Eastern provinces.

Table 12: Total funding required for supply chain logistics

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Supply chain logistics	US\$74600	US\$8000	US \$66600

X. Collection of medical waste resulting from a vaccination campaign using a pandemic influenza vaccine

Sri Lanka is experienced in carrying out many immunization campaigns. Obviously, there is a generation of a large amount of medical waste. However, one limitation in the Sri Lankan health system 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 handful of larger institutions, incinerators are not being used for incineration of some items. In other institutions, open burning of items in pits has been adopted. This is generally the widespread method of disposal of waste.

All immunization centers collect used items in safety boxes. Then they are locally disposed of. As such, an additional transport cost does not arise. The existing staff is also adequately trained in the need and means 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. Currently this process is being supervised by supervising Public Health Midwives and Public Health Nursing Sisters. Given the availability of these resources, an extra effort is not needed for collection and disposal of medical wastes properly. However, fuel may be necessary for igniting the burning process. Additional need of fuel and the subsequent cost is not accounted for in the financial planning for the year 2010. The program managers need to estimate the financial cost for burning medical wastes generated as a result of Influenza A / H1N1 vaccine in the country. Supervisory items of waste disposal will be included in the supervisory checklists. Duty rosters of relevant staff will include waste disposal in a manner so as medical waste will be disposed of during a reasonable period of time.

Table 13: Total funding required for disposal of medical waste

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Collection & Disposal of medical waste	-	-	-

XI Post-Marking Surveillance

Brief description of current capacity to detect AEFI

The system to detect AEFI was established in Sri Lanka in 1995-96. This was initiated with the support of the WHO and UNICEF. Currently when a case of AEFI is detected at the hospital, clinic or during a filed visit, this is reported to the MOH. At the MOH office, these are consolidated into a monthly report and submitted to the RE of the district and the EU. RE, having consolidated returns sent forms from all MOH offices in his district for the month of concern, submit to the EU on monthly basis. These are fed back to notifiers in the weekly Epidemiological Return and the Quarterly Epidemiological Bulletin. All reported cases are investigated. The investigator depends on the severity of the AEFI. Severe AEFI cases are investigated in details and submitted to the AEFI expert committee for causality assessment and making recommendations to the ACCD. ACCD implement these recommendations through the EU. There are standardized reporting forms to 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. Sri Lanka is the Global Training Network for conducting international training on AEFI in Asia.

Thus, the capacity of the Sri Lankan AEFI surveillance system is very strong given the following aspects; soundness of the reporting system linked to existing reporting system, training and technical support, efficiency, continued monitoring and evaluation ,feed back and sound communication. The same AEFI monitoring system can be used for monitoring AEFI for pandemic H1N1 vaccine. During the training programs, participants will be enlightened on possible AEFI of pandemic H1N1 vaccine. Similarly, the information leaflet will carry information on possible AEFI so as to enable recipients to report them to the relevant health officers.

Table 14 :Total funding required for Post-Marking Surveillance

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Post-Marking Surveillance	-	-	-

XII Monitoring and Evaluation

The EU, as the focal point for implementing the deployment plan, will takeover the responsibility of monitoring and evaluation. It will develop a comprehensive plan for monitoring and evaluation of the deployment plan. The strategic operational deployment plan contains following components for monitoring and evaluation:

1. vaccination strategy
2. Management and organization
3. Human resources and security
4. Information and communication
5. Supply chain logistics
6. Public information, education and communication
7. waste management

In the strategic plan of activities, there will be a responsible person for activities. This person will monitor the activities during the activation of the action plan. Additionally, there will be pre determined indicators for evaluating the overall deployment plan.

At the central level, according to the comprehensive plan of evaluation, a selected member of the pandemic preparedness and response will evaluate the national pandemic vaccine deployment plan according to pre determined indicators. Each RE will evaluate the district pandemic vaccine deployment plan.

Outline of the Deployment Termination Report

Deployment Termination 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 which is in this instance is the WHO. All RE will prepare and submit the termination reports for his/her respective district. The EU will prepare an overall termination report for the country. The report will indicate how vaccines were distributed to districts and how they had been used. The use of vaccines in these districts will be given by the priority groups vaccinated. The report will include the coverage of vaccination for respective priority groups by districts. The vaccines which were underutilized and returned to the EU will also be included. The EU will decide the future course of action with regard to these vaccines with the WHO.

Report will also include a chapter on reported AEFI. These will be classified and quantified accordingly. It will describe serious AEFI, actions taken with regard to them and how they affected the vaccination program.

For future reference, the termination report will deal with lessons learnt during the deployment exercise.

The financial report will be prepared to summarize the money received and expenditures under relevant headings approved by the WHO. The remaining amount of money secured from the WHO will be indicated for further action

Table 14: Total funding required for Post-Marketing Surveillance

Activity	Total Budget Required	Government Funding Allocated	Funding Still Required
Management & organization	US\$ 7000	US\$6500	US\$500
Vaccination strategy	US\$ 334720	US\$ 334720	-
Communication & information	US\$ 14800	US\$ 3570	US \$ 11230
Human resources	US \$ 84000	US \$ 74000	US \$ 10000
Public Information	US \$ 121500	US \$ 50000	US \$ 71500
Supply & logistics	US \$ 74600	US \$ 6000	US \$ 68600
Waste management	-	-	-
Post marketing surveillance	-	-	-
Total	US\$ 639320	US \$ 479490 (75%)	US\$ 159830 (25%)

ANNEX 1

Members of the Advisory Committee on Communicable diseases

Designation	Name
DGHS	Dr. U. A. Ajith Mendis
DDG(PHS I)	Dr. P. G. Maheepala
DDG(PHS II)	Dr R Siyambalapitiya
Senior Professor of Paediatrics	Professor S P Lamabadusuriya
Actg. Chief Epidemiologist	Dr. Paba Palihawadana
Director / Anti Filariasis Campaign	Dr. S. Settiyanayaka
Director E & OH	Dr. Pathirana
Actg. Co-ordinator – Dengue Control Unit	Dr. L. Magodaarachchi
Director / NSACP	Dr. N Edirisinghe
Virologist MRI	Dr. Omala Wimalaratne
Virologist MRI	Dr. G. Wickramasinghe
Director / NPTCCD	Dr. Sunil De Alwis
Director HEB	Dr. Sarath Amunugama
MOIC Fever Hospital Angoda	Dr. E.A.D. Senanayaka
Chairman SLMA / Communicable Diseases Com	Dr. N. Punchihewa
Actg. Director / Anti Malaria Campaign	Dr. Rabindra Abeysinghe
Director / Anti Leprosy Campaign	Dr. Thilaka Liyanage
Head, Dept of Community Medicine, Faculty of Medicine	Dr. Dulitha Fernando
Director / MCH	Dr. Deepthi de Silva
Director / NHSL	Dr. Hector Weerasinghe
Director / MRI	Dr. Lulu Raschid
DDG / (MS)	Dr. Terrance De Silva
Professor of Medicine	Professor Rizvi Sheriff
DDG Planning	Dr. Samarage
DD (Statistics) MSU	Mrs. Padmini De Silva
Representative from College of Paediatricians	Dr. Joel Fernando
Representative from College of General Practitioner	
Professor of Paediatrics, University of Sri J'pura	Professor Narada Warnasooriya
Professor of Microbiology	Professor Lalitha Mendis
Professor of Pharmacology	Professor Rohini Fernandopulle
Consultant – World Health Organization	Dr. Palitha Abeykoon
Consultant Physician , IDH	Dr. Ananda Wijewickrama
Director/PHVS	Dr P.A.L. Harishchandra
Director/Quarantine	Dr A.J.M.J.B. Walallawala
Director/MSD	Dr. D.S. Weerabandara
Director / MT&S	Dr. Benaragama

Annex 2 : List of central team responsible for deployment of pandemic H1N1 vaccine

Pandemic team

- Dr.Paba Palihawadana - paba@health.gov.lk (team leader)
- Dr.Wasu Jayasinghe - wasujayasinghe@gmail.com
- Dr. Samitha Ginige - samithag@hotmail.com
- Dr.Risinth Premarathna - risintha@yahoo.com
- Dr. Ranjan Wijesinghe - gunathilake@khalasa.com

EPI team

- Dr.T.S.R. Peiris - peiristsr@yahoo.com (team leader)
- Dr. Viginie Mallavarachchi - virginiemal@yahoo.com
- Dr. Sriyani Dissanayake - srini1102000@yahoo.com
- Dr.Risinth Premarathna - risintha@yahoo.com

For the Plan of vaccine deployment activities and budgetary requirements, please refer to the Excel sheet attached separately. The text of the current document contains breakdown of budgetary requirements (both internal and external) for broad categories of vaccine deployment activities.