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Deployment Plan for the Distribution of Pandemic Influenza Vaccine

Maldives

December 2009

National Emergency Operation Centre (NEOC)

Ministry of Health and Family

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Section 1: Maldives response to current H1N1 pandemic

Epidemiology of novel H1N1 influenza in Maldives

Influenza A H1N1virus continues to cause influenza-like illness in affected counties. The first case was an imported case detected on 25th July 2009. Internal transmission started in the Maldives from 18th of November 2009.

National Response

Upon issuance of the H1N1 pandemic alert by WHO in April 2009, the Pandemic Preparedness Plan developed for Bird flu was reviewed and activated with minor changes. The following committees responsible for command and control and planning the pandemic response was activated and work initiated.

Command and Control

Overall command and control of national response to H1N1 lies with the Ministerial committee. This committee chaired by the Minister of Health and co-chaired by the Vice President of Maldives. It is composed of 7 ministers and provide policy guidance and decisions and on the activities to prevent further occurrence of H1N1.

National Influenza Pandemic Preparedness Planning Committee

This intersectoral committee is responsible for planning and coordination of operational actions. The committee endorses the protocols and SOPs developed for national response and risk communication strategies. It ensures procurement, storage and distribution of supplies and equipments and arranges logistics to public and private health care facilities, necessary for responding to H1N1 pandemic. This committee is chaired by Ministry of Health and it consists of 39 members from various government agencies and private sector.

Health Technical Committee

This committee works on technical issues related to H1N1, chaired by Director General of Health Services. This committee provides necessary guidance on public health issues, testing of suspected cases, referrals and case management at different levels in the healthcare delivery system.

Like most of the countries Maldives has strengthened risk communication, surveillance, laboratory facilities, stockpiling of PPE and medicines, intensive care facilities in the current year. In this regard the following measures were taken;

- Establishment of a national emergency operation centre (NEOC).
- Sensitization and orientation of the health system.
- Public awareness using TV, Radio and print materials and media.
- Thermal screening and health check at the ports of entry.
- Updating the laboratory capacity to enable diagnosis of H1N1.
- Strengthen surveillance in the community as well health care facilities
- Development of national guidelines & protocols and orientation of healthcare providers.
- Development of provincial forward communication mechanism and SOPs.
- Stockpiling and distribution of PPE, antivirals, diagnostics and other supplies to health care facilities
- Establishment of an isolation wing in one of the hospitals which is designated as the referral hospital for H1N1 cases requiring intensive care at the central level.

Section 2: Country experience in Immunization

Since the official launch of the EPI program in 1985, Maldives has achieved and maintained high immunization coverage for all EPI vaccines.

Maldives provide 7 antigens in routine immunization for children and Tetanus Toxoid for the child bearing aged women (15-45). All pilgrims to Mecca, Saudi Arabia are vaccinated against seasonal influenza, meningitis and polio. In addition yellow fever and cholera vaccination are also provided by the port health section of Centre for Community Health and Disease Control. A total of 130 health workers have been trained for vaccine and cold chain management and in service. The country has adequate storage capacity with cold rooms at central level and in 3 other province and cold chain facilities (refrigerators and vaccine carriers) are available at all other health facilities throughout the country.

Disease surveillance system connects health centers to public health units at hospitals and to the Centre for Community Health and Disease Control at central level. This system

monitors all the communicable diseases including Acute Flaccid Paralysis (AFP) and Adverse Events Following Immunization (AEFI).

Section 3: Pandemic Vaccination Policy

The government of Maldives will follow the recommendations of the Strategic Advisory Groups of Experts to WHO on vaccination against H1N1. As vaccines become available, the vaccines will be provided at no cost to the identified priority groups. Syringes, needles, sharps containers and alcohol will also be provided, without charge to the health care facilities providing the vaccine.

Vaccine deployment to the atolls will be based on the size of the identified target population within the atolls.

Section 4: Vaccination Strategies

The target group outlined below will be ensured to receive the first doses of H1N1 2009 vaccines. Strategies to reach these target groups will be outlined below.

Priority Groups for Novel H1N1 vaccination

1. Health care workers working in the front line and critical care (Nurses, Doctors, Community Health Officer and Family Health Officers)
2. Pregnant women
3. Children >6months to 10 yrs
4. Persons with chronic diseases such as those with asthma, COPD, diabetes, chronic cardiovascular disease, and immune-compromised individuals
5. Elderly (>65 yrs of age)
6. Police and MNDF frontline workers

Planning assumptions for vaccination

Global vaccine production and availability is limited and the time and amount of vaccine that could be obtained is uncertain. Hence vaccination would be provided to the high risk groups.

The vaccine need for the Maldives based on target population groups is about 1,67,632 doses. However, based on the current global production capacity and vaccine demand, it may not be possible to obtain enough vaccine to provide for all of the target population groups. Hence vaccination to the target population groups will be provided in a phased manner, with further prioritization excluding children under 10 years. Even with this prioritization, 55,986 doses of vaccine will be needed.

Considering the healthcare seeking behavior of the Maldivian population and low rates of reported adverse effects associated with the H1N1 vaccine, it is assumed that there will be a high level of vaccine acceptance achieving high vaccine coverage.

Vaccination Sites

Immunizations will be conducted by the hospitals, health centers and health posts which will cover 195 islands. Outreach mobile team will carry out the vaccination session in islands where there is no health facility by the mobile teams from atoll level. Each island will identify clinic sites such as school or community centre to cover one or more wards at a time and mobile teams schedule accordingly.

Male is the administrative and commercial centre of the country with the highest population density, it will be divided into four wards and one out reach clinic will be set up in each ward, to ensure that all the target population receive the H1N1 vaccines who are living in these wards. Indira Gandhi Memorial Hospital (IGMH), Regional Hospitals and Atoll hospitals will function as referral centers for any emergencies.

The vaccination team will comprise of 1 Nurse, 1 Community Health Officer, 1 Family Health officer and 1 Assistant. 26 teams, one in each atoll and 6 in Male urban region will be selected for conducting vaccination sessions. It is strongly advised to the outreach mobile teams visited to the hardly access islands should be led by a Medical Officer. This is of utmost important in case of an AEFI emergency.

There a total of 33 islands with no vaccine centers for which detailed costing to provide outreach vaccine services by mobile teams is given in the table below and the total figure for this activity is included in the budget summary table (See Section 8, page 17, Serial No. 2 – “outreach vaccination) which will be covered by Government budget .

No	Atoll	Island	Amount
1	<i>Ha Alif</i>	Mulhadhoo	900
2	<i>Ha Dhaal</i>	Maavaidhoo	1200
4		Faridhoo	1200
5	<i>Shaviyani</i>	Narudhoo	400
6		Noomaraa	900
7	<i>Noonu</i>	Hebadhoo	200
8		Magoodhoo	500
9		Fodhdhoo	500
10	<i>Baa</i>	Kihaadhoo	600
11		Dhonfan	500
12		Kamadhoo	700
13		Fehendhoo	300
14		Fulhadhoo	500
15	<i>Alif Dhaal</i>	Kuburudhoo	400
16		Dhidhdhoo	500
17		Mandhoo	1500
18	<i>Vaavu</i>	Rakeedhoo	400
19		Fulidhoo	1000
20		Thinadhoo	200
21	<i>Meemu</i>	Veyvah	500
22		Raiymandhoo	900
23		Naalaafushi	500
24	<i>Dhaalu</i>	Vaani	500
25		Ribudhoo	700
26	<i>Thaa</i>	Gaadhiffushi	400
27		Vandhoo	300
28	<i>Laamu</i>	Gaadhoo	500
29		Mundoo	500
30		Kalhaidhoo	500
31		Kunahandhoo	500
32	<i>Gaaf Alif</i>	Kondey	800
33		Dhiyadhoo	500
Total MRf			19500
Total in US\$			1517.51

Vaccine administration

Age group	No. Doses	Route
Health care providers	1 dose	intramuscular (IM)
Pregnant women	1 dose	intramuscular (IM)
Children (> 6months to 10 years of age)	2 dose (1 month apart)	intramuscular (IM)
People with chronic diseases	1 dose	intramuscular (IM)
Elderly (> 65 years of age)	1 dose	intramuscular (IM)
Police and MNDF frontline workers	1 dose	intramuscular (IM)

- *The needle size may range from 7/8 to 1¼ inches, depending on the size of the child's deltoid muscle, and should be of sufficient length to penetrate the muscle tissue.*
- *The vaccine **should not** be injected in the gluteal region or areas where there may be a major nerve trunk in children.*

On an average two vaccinators will be assigned to each vaccination site. As in routine services, only auto-disable (AD) syringes will be used during the H1N1 vaccination. All the people who received vaccines will be advised to wait at least for half an hour after administering the vaccine, to observe for any serious AEFIs.

Waste disposal

A responsible person from the vaccination team will be identified for disposing of filled safety boxes and other wastes as per the sharps waste management guideline and the health care waste management guideline.

Section 5: Communication and Information

Communication and Information play a major role in implementing activity successful. Therefore sharing accurate information about the vaccine, target groups, AEFI, vaccine arrival details and cold chain requirements will be informed to the health service providers through orientation sessions and provision of guidelines. Approximately 30 days before mass vaccination, a workshop will be conducted to ensure that all vaccine providers are fully aware of the tasks and vaccine safety procedures as well as AEFIs.

In addition vaccinators will use mobile phone to ensure that the teams are able to communicate with the team leaders at all time.

Awareness

Prior to initiation of H1N1 vaccination program, awareness program will be conducted for the target population regarding H1N1 vaccine, AEFIs and specific vaccination sites.

Steps will be taken at national level for mobilizing media publicity in support of the program in state media and local newspapers. Medical and public health experts from the health team will provide interviews in media regarding the program to build up public confidence. Innovative tools such as facebook and sms will be used for disseminating important messages.

Posters, leaflets, banner, generic folders, video and audio spots will be developed and disseminated. Messages will focus on the disease, vaccine information as well as AEFIs.

During the vaccination session's public will be informed about possible side effects and precautions to be taken after the H1N1 vaccination. Awareness will be done by a community health officer, and whenever necessary, medical officers will be assisting them. Budget requirement for IEC Materials for H1N1 Vaccination Campaign is given in the budget table. UNICEF has already committed to provide funds for the development of these IEC materials.

Activity	Quantity	Rate	Est Budget
Animated Video spots	2	20,000.00	40,000.00
Audio spot (multicast)	2	7,500.00	15,000.00
Poster A2	20,000	15.00	300,000.00
Leaflet A4	75,000	1.25	93,750.00
Banner 25 x 3.5 ft	10	2,000.00	20,000.00
Total MRF			468,750.00
Total US\$			36,478.60

Reporting

During the training, importance of maintaining a good reporting practice during H1N1 vaccination will be highlighted to the healthcare providers. All necessary forms and registers will be supplied to all atolls adequately.

A focal point will be identified from each atoll for managing reports and follow-up of missing reports from all the health facilities within that atoll. In addition he/she will analyze the report and will be sent to CCHDC.

Section 6: Vaccine Safety

Vaccine safety is an important part of any vaccination program, however minor and rare side effects are associated with each vaccine. Ongoing clinical trials are studying the side effects on novel H1N1 vaccine and these side effects are expected to be similar to those from seasonal influenza vaccines.

The most commonly reported side effects of H1N1 vaccination remain;

- Pain
- Redness or swelling at the site of the injection
- Headache
- Fever
- Fatigue
- Muscular aches

Generally these side effects go away within two days of receiving the vaccine. However few reports of Guillain-Barre syndrome have been reported shortly after the patient receive the H1N1 vaccine.

AEFI monitoring

AEFIs surveillance serves a number of purposes. It allows officials of centre for community health and disease control to identify and respond to problems that are perceived by the community to be associated with immunization. Reporting AEFI is a part of an immunization safety surveillance system which is an effective means of monitoring immunization safety and contributes to credibility of immunization program or restore the confidence. Health care providers need to know how to recognize, treat, and report AEFI immediately.

Health care providers will be oriented to the common and possible adverse effects reported to be associated with H1N1 vaccination. Since these are service providers with several years of field experience in providing immunization under EPI, they are well aware of the protocols and procedures for identifying and reporting AEFI. However, as H1N1 vaccine is a novel vaccine, service providers may lack the necessary confidence in this regard which will be addressed by proper orientation and provision of required information. This will be done via a series of teleconferences which has been extensively used in information sharing, capacity building and orienting doctors and health managers in various aspects of H1N1 preparedness and response.

AEFI reporting will follow the existing reporting system. Health care providers are required to report all AEFIs from the island level to the Atoll hospital as soon as the incidence occurs. These incidences will be managed under the guidance of Atoll/regional hospital doctors or in consultation with specialists at the central level. All such incidences in the atoll/region will be compiled by the hospital and sent to Centre for Community Health and Disease Control (CCHDC) in Male' on a monthly basis. However, serious adverse effects will be notified immediately. Feedback is provided including acknowledgement of reports and suggestion for improvement.

Storage and Handling

The vaccine storage facilities at the central and regional locations would have sufficient capacity to accommodate the national H1N1 vaccine requirement as stated in this plan. Hence, the Maldives would have no problem to receive and store either single dose prefilled syringes, or 10-dose vials of the vaccine of the donated vaccine from WHO (approximately 30,000 doses or 10% total population), and also the additional balance of vaccine needed to cover the national demand.

Cold chain requirements need to be strictly followed. Vaccines should be stored between 2°C to 8°C (35°F to 46°F). Vaccine should not freeze and should be discarded if the vaccine has been frozen. Furthermore, vaccine should not be used after the expiration date. Appropriate cold chain monitoring will be followed using the existing cold chain monitoring system for EPI vaccines.

Section 7: Management and Organization

The overall management of H1N1 vaccine of the deployment will be conducted under the direction of vaccine deployment taskforce, who will report the actions directly to the appointed committees for responsible for command and control and planning the pandemic responses.

Estimation of vaccine requirement

In the long run there will eventually be enough novel H1N1 vaccine to administer to everyone who wants a vaccine. However as vaccines are allocated in a limited supply, government of Maldives ensures that the priority groups who are most likely to get sick and have serious complications have first opportunity to receive the H1N1 vaccine. Population distribution of the target population by atolls is given in the table below.

Atoll	Total Pop	6 M - 10 yrs	Preg women	Elderly	Chr Dis	Total target pop
Ha Alifu	13495	3047	405	870	945	5267
Ha Dhaalu	16237	3598	487	1003	1137	6225
Shaviyani	11940	2588	358	678	836	4460
Noonu	10015	2214	300	650	701	3866
Raa	14756	3560	443	833	1033	5869
Baa	9578	1950	287	509	670	3417
Lhaviyani	9190	1674	276	549	643	3142
Kaafu	15441	1973	463	514	1081	4031
Alifu Alifu	5776	1188	173	249	404	2015
Alifu Dhaal	8379	1536	251	359	587	2733
Vaavu	1606	278	48	97	112	536
Meemu	4710	854	141	326	330	1651
Faafu	3765	919	113	156	264	1452
Dhaal	4967	1014	149	275	348	1786
Thaa	8493	1782	255	514	595	3145
Laamu	11990	2610	360	547	839	4356
Ga Alifu	8262	2039	248	466	578	3331
Gaf Dhaalu	11013	2624	330	798	771	4523
Gnaviyani	7636	1852	229	461	535	3077
Seenu	18026	3695	541	1324	1262	6822
Male'	103,693	14828	3111	2790	7259	27987
Subtotal	298968	55823	8969	13968	20928	99688

**Population figures are from the 2006 census*

Following is the details of the total requirement of vaccines for the above mentioned groups plus health care workers and frontline police and national defense force staff. Vaccination would be provided to eligible population as given in the table. If the first batch of vaccines that arrives in Maldives are the 31,000 doses planned to be supplied by WHO, it would be given to the first three target groups in the table.

Target Age group	Objective	No. Doses	Total target pop
Health care providers (doctors, nurses, CHO and FHO & Lab technologist)	Protect the integrity of the healthcare system	1 dose	2164
Pregnant Women	Reduce mortality and protecting infants who cannot be vaccinated	1 dose	8969
Elderly (> 65 years of age)	Reduce mortality	1 dose	15162
Children (> 6months to 10 years of age)	Reduce transmission of pandemic viruses within the community	2 dose	55823
People with chronic diseases	Reduce mortality	1 dose	20928
Elderly (> 65 years of age)	Reduce mortality	1 dose	13968
Police and MNDF frontline workers	Maintain social order and reduce morbidity	1 dose	1600
Total:			118,614

Supplies for vaccination

The Maldives has no shortage and hence no gaps in cold chain equipments, vaccine carriers and injection safety items (AD syringes, Reconstitution syringes, and Safety boxes). As vaccination would be provided through the existing vaccine centers, injection safety items and cold chain equipments used for the H1N1 vaccination would be from the current available stocks and logistic arrangements. However, each province would have to make an estimate of additional injection safety item requirement which would be supplied from the central stock. The current central stock would last well over six months and additional supplies would be procured in advance based on the estimates and stock balance. In outreach vaccination services by mobile teams, the supplies needed for the expected number of target population, will be taken to the site by the vaccination team members

who would travel from the nearest vaccine center. Supplies that remained unused at the end of session, including unopened vaccines will be returned to the centre from where they were distributed maintaining a reverse cold chain for the vaccine.

Vaccine Procurement

Novel H1N1 vaccine will be obtained through WHO from donated vaccines and if possible purchased from the manufacturers as they become available.

Orders for vaccines will be placed by the Centre for Community Health and Disease Control and processed through the existing health supplies management system.

As there are both inactivated and live attenuated novel H1N1 vaccines, Maldives will be procuring inactivated novel H1N1 vaccine of single doses. As a study conducted in the University Campus in Michigan, 68% efficacy was found in inactivated vaccine and 36% for live attenuated vaccine (Arnold et al, 2009).

No	Vaccine	Manufacturer
1	Inactivated H1N1 Influenza Vaccine	Hualan Biological, Xingxiang, Henan, China
2	Influenza A (H1N1) 2009 Monovalent Vaccine	CSL Limited, Parkville, Victoria, 3052, Australia
3	Influenza A (H1N1) 2009 Monovalent Vaccine	Novartis Vaccines and Diagnostics Limited, Speke, Liverpool, UK
4	Influenza A (H1N1) 2009 Monovalent Vaccine	Sanofi Pasteur, Inc, France
5	Influenza A (H1N1) 2009 Monovalent Vaccine	MedImmune, LCC, USA
6	Influenza A (H1N1) 2009 Pandemic Monovalent Vaccine (Without Adjuvant)	Glaxo Smith Kline, Belgium

Vaccine Distribution Plan

Vaccines will be made available at vaccination sites around the country within a week of vaccine arrival. All the vaccines, vaccine consumables, stationeries, forms and registers will be supplied to atolls by Boat and Air. A supply audit will be conducted by CCHDC to ensure that a smooth distribution of supplies is maintained from central to atolls.

However, due to geographical difficulties 100% of vaccine stock might not be sent to some of the atolls within a week. But, 85% of vaccines will be deployed within a week to vaccination sites. And like all other routine childhood immunization vaccines, H1N1 will be stored in central cold room and distributed vaccines will be tracked via a vaccine stock register that can identify the batch number and expiry date of vaccine.

Vaccine received through WHO and that procured by the government would be distributed to the vaccination centers by the routine vaccine distribution mechanism using the government funds. Detailed costing of the vaccine and vaccine consumable distribution to the vaccination sites are given in the table below and the total figure is included in the budget summary table.

Atoll	Vaccine Handling & Shipping Cost	Consumables Handling & Shipping Cost	Land Transport	Sea Transport for Vaccine distribution in the Atoll	Total
Haa Alif	350	300	80	9000	9730
Haa Dhaal	350	300	80	12000	12730
Shaviyan	350	300	80	11000	11730
Noonu	300	250	80	8000	8630
Raa	250	200	80	10000	10530
Baa	250	200	80	7000	7530
Lhaviyani	250	200	80	5000	5530
Kaafu	300	250	80	6000	6630
Alif Alif	200	150	80	6000	6430
Alif Dhaal	200	150	80	6000	6430
Vaavu	200	150	80	3000	3430
Meemu	250	175	80	5000	5505
Faafu	250	175	80	5000	5505
Dhaal	300	250	80	6000	6630
Thaa	300	250	80	3500	4130
Laamu	300	250	80	3500	4130
Gaaf Alif	350	300	80	10000	10730
Gaaf Dhaal	350	300	80	8000	8730
Gnaviyani	400	350	80	0	830
Seenu	400	350	80	950	1780
Sub Total MRf	5900	4850	1600	124950	137300
Total in US\$					10684.82

Legal Issues

H1N1 influenza vaccine has already been approved by Maldives Food and Drug Authority using the fast track registration mechanism. Therefore, approval to import and use the vaccine by the public health authorities in the country has already been obtained and the necessary custom clearance procedures would be arranged as soon as WHO informs the government of the details of the donated vaccine product, its preparation and arrival information. There is no requirement for the manufacturer of the H1N1 vaccine to obtain a registration in the Maldives in case of the WHO donated vaccine.

Informed consent from vaccine recipients or their legal guardians will be obtained as it is a novel vaccine with limited clinical trials and field experience.

Monitoring and Supervision

Monitoring is an ongoing process and it will start from planning process and will continue until the completion of the vaccination program. Monitoring will be done at all levels as per the current IPI guideline. A copy of the draft of revised EPI guideline is attached with the plan.

The success of the program depends largely on the work of motivated and hard-working front line personnel's. Therefore, supportive supervision is very important. It will ensure how works are done by the care providers, as well correcting technical or operational errors in a gentle way and responding quickly if any action is needed.

To monitor and ensure a high quality supportive supervision, a checklist will be designed and will be used throughout the program at all places. Team leaders will also act as supervisors and ensure vaccine and all logistics are reached to the vaccination sites in prior to vaccination. In addition he/she will ensure that all the vaccinators are present at the site on time, make sure that cold chain is maintained and waste management was appropriate. Also he/she will ensure that proper and correct record keeping is maintained.

As the Maldives envisages supply of vaccine from different manufacturers and of different batches, it is important that proper record keeping is maintained for effective monitoring. The record keeping and monitoring mechanism would be designed to enable identification of the manufacturer and batch of the vaccine that is being administered to each individual to enable prompt detection of any adverse reactions associated with a particular batch of vaccine.

Monitoring data would be collected from the atolls and send to the central level by the atoll and regional hospital using the existing reporting mechanism in the health sector.

Section 8: Budget Requirement

Government does not have adequate resources to cover all cost related to the vaccination. The expenses for all logistic and human resource cost will be borne by the government. However, there is shortfall on the procurement of vaccines and items related to vaccination. Donor funding will be required for purchase of these items. Budget requirement for the H1N1 vaccine deployment is as follows.

Activity Detail	Total budget reqd (US\$)	Gov contribution (US\$)	Financial Gaps (US\$)
1. Management & Organization			
Monitoring and supervision	5,837.00	5,837.00	0
Vaccine cost*	1,341,054.08	116,732.00	1,224,322.08
Vaccine consumables	51,520.00	41,245.00	10,275.00
Transport logistics of vaccine, vaccine consumables and IEC materials	10684.82	10684.82	0
2. Vaccine Strategies			
Allowances for health care providers at atoll level	6,750.00	6,750.00	0
Outreach vaccination	1,517.51	1,517.51	0
Sundry	1,770.00	1,770.00	0
3. Communication and Information			
Developing IEC materials	36,478.60	0	UNICF funds
Advocacy and training	7,782.00	7,782.00	0
Total in US\$	1,463,394.01	192,318.33	1,234,597.08
Total in MRf	18,804,613.03	2,471,290.54	15,864,572.48

*Cost per dose estimated at US\$ 08.00