



Comprehensive Family Immunization
Family and Community Health Area



Regional Vaccination Plan in Case of Influenza Pandemic

Washington, D.C., 26 May 2009

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Foreword

The present Regional Plan for Pandemic Influenza Vaccination falls under the activities of PAHO's technical cooperation with Member States of the Region to address a possible pandemic. One of the best prevention method is the administration of a vaccine specifically against the virus that causes the pandemic. Therefore, countries must be prepared to administer the vaccine, if necessary.

One aspect of the preparation is the strengthening of seasonal influenza vaccination, because it represents a way to decrease the disease burden of seasonal influenza and reduce the possibility of reassortment of seasonal and pandemic viruses. Moreover, the experiences and lessons learned in vaccinating different risk groups can be applied in the event of a pandemic. In this regard, this plan prioritizes introduction of the seasonal vaccine in Member States where it has not yet been introduced in the public sector. In Member States that have already introduced the vaccine, support will be provided to expand its use to other risk groups.

In regard to pandemic preparedness, most of the Region's Member States have included pandemic influenza vaccination in their preparedness plans. It is important for Member States to update their vaccination plans, including clear prioritization of risk groups, which should be clearly defined with anticipation. Moreover, it is important to estimate the needs for pandemic vaccine and other supplies, plan training for health workers, and prepare the infrastructure necessary for carrying out vaccination.

The information in the national plans for pandemic influenza vaccination complements this Regional Plan, which is why it emphasizes several key components that Member States should consider in their own plans.

The purpose of the present document is to provide PAHO technical cooperation to its Member States for the pandemic vaccination component, emphasizing both strengthening of seasonal vaccination and activities necessary for supporting the preparedness of Member States for vaccination against a pandemic strain.

1. Introduction

a. Background

Influenza, or the flu, is an acute viral disease of the respiratory tract, spread primarily by the airborne transmission of respiratory secretions. It is estimated that annual influenza epidemics cause from 3 to 5 million cases of acute disease and from 250,000 to 500,000 deaths worldwide.^(1,2) It also can cause pandemics, understood as epidemics that affect a large number of Member States, associated with high morbidity, excess mortality, and severe social and economic disruption.

Three influenza pandemics occurred during the 20th century: the Spanish Flu [Virus A(H1N1)] in 1918-19, the Asian Flu [Virus A(H2N2)] in 1957-58, and the Hong Kong Flu [Virus A(H3N2)] in 1968-69. The best known is the Spanish Flu, which is estimated to have caused approximately 40 to 50 million deaths worldwide.⁽³⁾ The main characteristics of this pandemic were its rapid dissemination and high mortality in young adults. The other pandemics caused high mortality, although less than the Spanish flu, and primarily affected people over the age of 65 and people with chronic diseases.

There are three types of influenza viruses: A, B, and C. The most important strains of human influenza are types A and B, which cause large outbreaks every year, although only type A produces pandemics. There are two important phenomena related to the changes in influenza viruses. **Antigenic drift** involves constant and usually small changes in the antigenic composition, which requires making corresponding variations in the composition of influenza vaccines every year. **Antigenic shift** involves the appearance of a new subtype, against which people do not have immunity, which constitutes a serious problem from a public health standpoint because of the risk of a pandemic.

The risk of a pandemic occurs when a sudden and marked transformation of the influenza A virus takes place, either through mutation, or from the exchange of genes between animal (in general avian) and human influenza viruses that infect a single host at the same time (for example, the pig) that is susceptible to both. This risk also exists from the transfer of the entire virus between different host species.

If these new viruses acquire the capacity to cause disease in the human host and to be transmitted efficiently from one person to another, then widespread and rapid dissemination can occur that can result in a pandemic, since a high proportion of individuals in the community will not have antibodies to the new virus.

Pandemics can occur in several waves (periods with a high occurrence of cases) and can last from 1 to 3 years. After this period, usually most of the population acquires some degree of immunity and the virus then causes annual epidemics of smaller magnitude.

b. Epidemiological status of influenza A(H1N1)

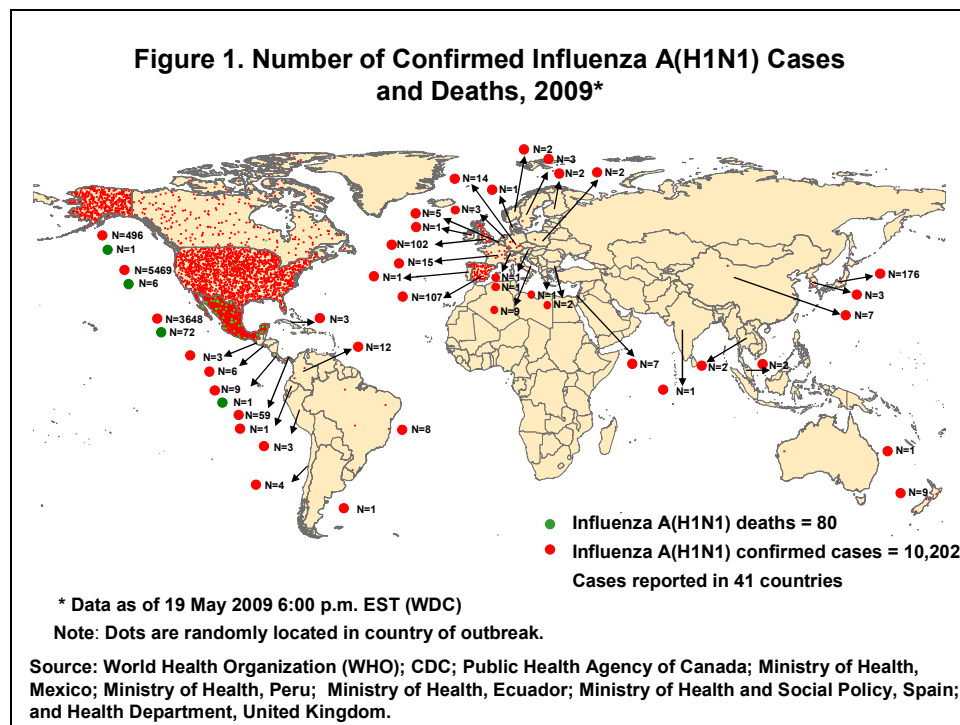
Starting in mid-March 2009, the surveillance systems in Mexico began to register an increase in cases of a severe influenza-like illness in Mexico City. This increase began during a period when cases of seasonal influenza normally begin to wane. The number of reported cases continued to grow in the first weeks of April and geographical expansion was seen with more clusters of severe pneumonia cases in young and normally healthy adults. On 17 April, Mexico stepped up surveillance for cases of acute respiratory disease. The country sent samples from suspected cases to the reference laboratory of the Public Health Agency of Canada. On 23 April, a new influenza A strain (H1N1) was identified in 17 of the 18 samples sent.

In the United States, on 24 April, the Centers for Disease Control and Prevention (CDC) reported eight cases of influenza A(H1N1) in the states of California and Texas. This strain was confirmed as being genetically similar to the one isolated from the cases in Mexico. On the following days,

the number of cases continued to grow, with a concentration of reported cases in a school in New York City, where a group of students had returned from vacationing in Mexico.

As of 19 May 2009, a total of 10,202 confirmed cases of influenza A(H1N1) had been recorded, including 80 deaths, in 41 Member States of the world, of which 14 are in the Americas (Argentina, Brazil, Canada, Chile, Colombia, Costa Rica, Cuba, Ecuador, El Salvador, Guatemala, Mexico, Panama, Peru, and the United States), 17 in Europe, and 10 in other regions (Figure 1).

Mexico, the United States, and Canada have reported the highest number of cases at the worldwide level. As of 13 May, the average age of cases in Mexico has been 22 years (ranging from 0-69 years), with 49% in males. In the United States, the average age of cases has been 16 years (ranging from 3 months-81 years), with 50% in males. The age range of cases in Canada has been from 2-62 years, with 46.7% of reported cases in males. As of 19 May, Mexico, the United States, Canada, and Costa Rica were the only Member States that had reported deaths from influenza A(H1N1): 72, 6, 1, and 1 deaths, respectively.

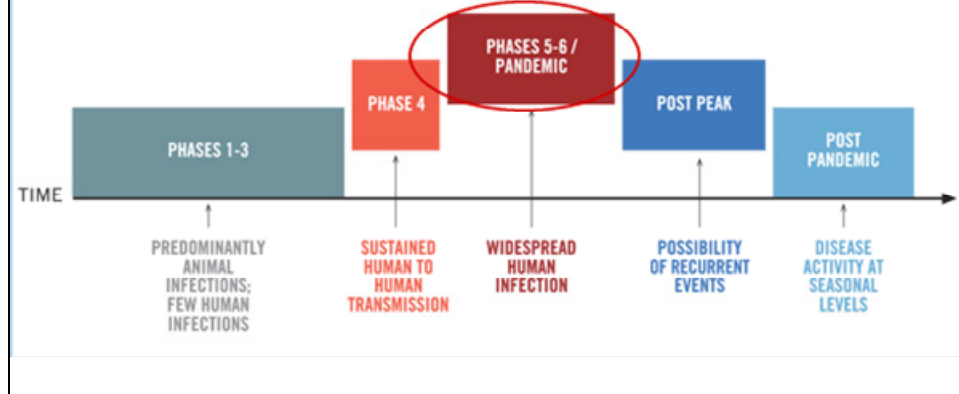


c. World Health Organization (WHO) recommendations

Since 1999, WHO has offered Member States technical guidance for the preparation of National Influenza Pandemic Preparedness Plans; this guidance was updated in April 2009.⁽⁴⁾

This updated version includes a redefinition of the phases, in order to manage earlier response during the period of pandemic alert and in order to conduct risk management. This does not imply the ability to prevent a pandemic, but rather to make better use of available resources to reduce the spread of the disease and the impact of secondary catastrophes, and to prevent panic in the population (Figure 2). The phases are defined according to the geographic spread of the disease and not necessarily according to its severity.

Figure 2. WHO Pandemic Influenza Phases



Given the emergence of a new influenza A(H1N1) virus of porcine origin, WHO declared phase 4 on 25 April 2009. Subsequently, on 29 April 2009, it declared phase 5, which is characterized by spread of the virus between humans in at least two Member States in one Region of the world. Moving to phase 6 would be done because of the geographical spread of the virus, with community-level transmission in other regions, not necessarily because of the severity of the disease.

The Pan American Health Organization has been supporting different pandemic preparedness activities in Member States, as can be seen in the Strategic and Operational Plan for Responding to Pandemic Influenza,⁽⁵⁾ which includes a vaccination component.

2. Influenza Vaccines

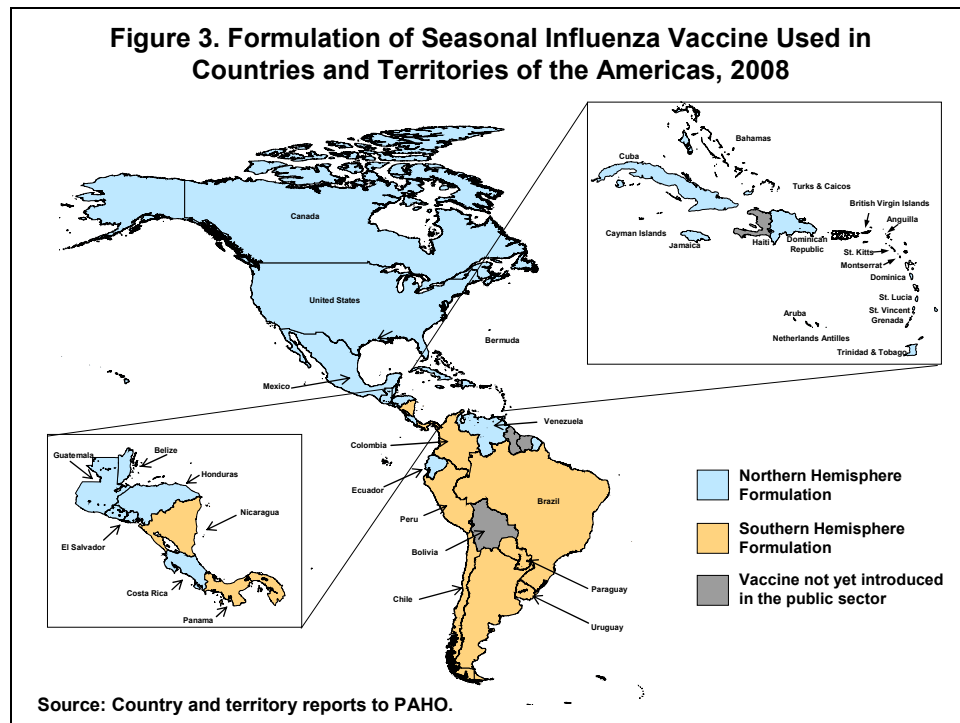
Since the viruses evolve every year (antigenic drift), the seasonal influenza vaccine is produced annually from a composition based on the most relevant strains identified through the Global Influenza Surveillance Network (FluNet). Twice a year (February for the Northern Hemisphere and September for the Southern Hemisphere), WHO holds a consultation to give recommendations on the composition of the trivalent vaccine, containing one virus type A(H3N2), one type A(H1N1), and one type B. Since 1977, the influenza A(H1N1) virus, the influenza A(H3N2) virus, and the influenza B virus have been circulating globally.

Currently, vaccine production is approximately 900 million doses worldwide and vaccine is manufactured mainly in Australia, Europe, Japan, and North America. The production of a pandemic vaccine will rely primarily on the infrastructure and technology for production of the seasonal vaccine, which has been available for over 60 years, and which has been demonstrated safe and effective. Influenza vaccines are normally produced by growing seed virus in fertilized chicken eggs. It takes approximately 5-6 months from the time the strain is identified until the vaccine is available. With the development of new technologies, vaccine production in cell culture is also now available.

a. Recommendations for seasonal vaccine use

The PAHO/WHO Technical Advisory Group on Vaccine-preventable Diseases (TAG) recommends that Member States vaccinate traditional risk groups against seasonal influenza to reduce the incidence of serious forms of disease and premature death. These groups are the elderly, health workers, pregnant women, people over 6 months of age with chronic heart or pulmonary diseases or metabolic diseases, as well as institutionalized persons, and children aged 6-23 months (2004 and 2006 TAGs). In 2003, WHO recommended that Member States increase the use of the seasonal vaccine in risk groups to reduce the burden of disease and to increase demand, which will enable boosting production capacity.⁽⁶⁾

In the last 5 years, the Member States and territories of the Americas have followed the recommendations of the World Health Assembly and of the TAG, and the Region has seen a rapid introduction of the seasonal vaccine. From 2004 to 2008, use of the seasonal vaccine has increased from 13 to 35 Member States and territories, of which 26 currently use the Northern Hemisphere formulation and 9 use the Southern Hemisphere formulation (Figure 3).



Optimizing the use and increasing the coverage of seasonal influenza vaccine will help lower the burden of disease from annual influenza epidemics. In addition to reducing morbidity and mortality from seasonal influenza, seasonal influenza vaccination decreases the genetic risk from the reassortment of animal and human strains by preventing human influenza infection.

Although the seasonal vaccine **does not protect** against a pandemic strain, a greater demand for this vaccine will enable increasing production capacity and better meeting the demand in a future pandemic.⁽⁶⁾

b. Pandemic virus vaccine

Pandemic influenza vaccination is an essential component of an adequate response to the pandemic. However, it will not be possible to have vaccines during the first phase or wave of the

pandemic and when these are available, the supply of vaccines will be very limited, which could lead to major disparities in supply, especially for non-vaccine-producing Member States.⁽⁷⁾

As to the question of whether pandemic influenza vaccine can reduce the number of cases in a second pandemic wave in a country, the answer is yes, if certain basic characteristics are fulfilled, such as:

- The vaccine has high antigenic similarity to the circulating virus;
- Prioritization of risk groups is adequate, with reassignment of groups to be vaccinated in accordance with epidemiological information;
- There is adequate availability of the vaccine, especially for populations where the virus has not yet widely circulated; and
- The health system has a plan to deploy vaccine out to the local level in a period of no more than 7 days, with the ability to possibly administer two doses of this vaccine (World Health Organization. *Guidelines for the Deployment of a Pandemic Influenza Vaccine*. Geneva: WHO; 2008. In press).

According to WHO, moving from Phase 5 to Phase 6 does not mean that WHO would automatically recommend that producers of influenza vaccine stop production of seasonal vaccine and switch to production of a pandemic vaccine. Situation monitoring needs to be continued and the cumulative evidence reviewed in order to consider whether industrial-scale production of this vaccine should be recommended. At present, it is estimated that approximately 4.9 billion doses of a monovalent vaccine against the Influenza A(H1N1) virus could be produced in one year.

3. Objective of the Regional Plan

The objective of the Regional Plan for Pandemic Vaccination is to provide the framework for PAHO's technical cooperation with its Member States to strengthen seasonal influenza vaccination and support Member States in preparing for pandemic vaccination.

4. Target population for vaccination

Considering that vaccine production capacity will be limited in the beginning, Member States should set criteria for prioritizing groups to vaccinate; these will depend on the country's main objectives:⁽⁸⁾

- If the **objective** is to keep the country's basic infrastructure functioning and minimize social disruption, then vaccinating essential personnel will be a priority.
- If the **objective** is to prevent the greatest number of deaths possible, then vaccinating groups at high risk for influenza-related mortality would be the first priority.
- If the **objective** is to reduce pandemic viral transmission within the community, then targeting children is a consideration.

The setting of goals and priorities involves logistical, ethical, moral, cultural, and legal considerations, as well as ongoing analysis of the epidemiological situation, in order to target measures to the most affected groups. Member States should rely on the National Committees on Immunization Practices, Ethics Committees, and WHO ethical guidelines,⁽⁹⁾ as well as the broad involvement of all sectors, to support those who make decisions on goals and priorities.⁽¹⁰⁾

There are other population groups in the Region of the Americas that should be considered when setting priorities, for example, indigenous peoples and vulnerable groups living in urban fringe

areas and prisons, among others. Furthermore, vaccination coverage of $\geq 95\%$ should be reached in each priority group.

The following is an example of the classification of possible priority groups in the event of a probable pandemic:

- Group 1: Essential workers, including health workers, public service workers, and decision-makers.
- Group 2: People at high risk for disease and death.
- Group 3: Healthy adults.
- Group 4: Children aged 6 months to 18 years.

Group 1: Essential workers, including health workers, public service workers, and decision-makers

Health and public health sector workers who have to support field investigations will be the first line of response. Hospitals should be considered, along with public and private physicians' offices, ambulances and paramedical services, pharmacies, and laboratories.

Personnel necessary for keeping society functioning will also be considered: police force; fire department; emergency and disaster workers; armed forces; water, electricity, and communications company employees, funeral home employees; and personnel working with institutionalized populations, public transportation, and transportation of essential goods, such as food; among others. Key government employees should also be considered: mayors, governors, and ministers, among others.

Group 2: People in high-risk categories for Influenza A(H1N1)

For planning purposes, this priority group is based on the epidemiology of the current pandemic. It has been observed that some types of people are more affected than others: people with underlying chronic conditions, health personnel, pregnant women, and healthy young people. The latter probably because they would be easier to mobilize and because of their propensity for national and international travel.

Group 3: Healthy adults

Individuals aged 18-60 years, who do not have high-risk medical conditions. In annual seasonal flu epidemics in this group poses a low risk. However, during the pandemic of 1918, this group was one of the most affected, which included the bulk of the workforce, and it had an enormous socioeconomic impact.

The vaccination of healthy adults would reduce the demand for medical services; it would permit individuals to continue their daily activities, and there would be less overloading of health services.

Group 4: Children aged 6 months to 18 years

Historically, school-age children as a group are at lower risk of having severe outcomes during annual epidemics, but this group plays a key role in the spread of the disease. The absence of children at school does not have a direct impact on economic disruption, but can have an indirect effect because of adults having to care for sick children.

5. Vaccination Strategies

In order to reach the vaccination goal, it is essential for vaccination strategies to be set at national level for each priority group in a pre-established timetable, considering that the vaccines will arrive in limited quantities in the Member States. As a result, vaccination should be planned for different phases. These strategies should be periodically evaluated and revised, based on an analysis of the attainment of goals and of operational aspects.

Suggested vaccination strategies for priority groups:

1. Public health and emergency workers should be vaccinated in the corresponding health services. Other workers in essential public services should be vaccinated on the job in vaccination sessions, according to the timetable.
2. People at high-risk should be vaccinated in small groups in institutions such as nursing homes, day-care centers, hospitals, prisons, among others. Other places where there may be clusters of high-risk people should be considered. Vaccination for this group could also be conducted in health posts.
3. Healthy people should be vaccinated in institutions such as schools, universities, factories, companies, and public agencies. Moreover, small groups should be considered for soccer stadiums, churches, plazas, and fairs, among others.
4. Vaccination of children should be conducted in accordance with the strategies used in the local-level routine vaccination program.

Given the high demand expected for this vaccine, public safety aspects, as well as organizational and logistical aspects, should be considered.

6. Vaccination Period

Considering the epidemiological behavior of the disease, vaccination should begin as soon as possible and be conducted progressively in a short period, depending on the availability of vaccine and health services infrastructure for providing vaccine to the end user.

7. Technical Components

This regional plan includes both a project for introducing seasonal vaccine aimed at Member States that are not yet using this vaccine in the public sector, and the principal components of a plan for pandemic vaccination. Moreover, this plan emphasizes interprogrammatic approaches with Occupational Health to promote vaccination of health workers and with Public Information for conducting media campaigns to support Member States.

As part of the interprogrammatic approach between PAHO's Occupational Health and Immunization projects, work is being done to promote better conditions for workers' health through vaccination against influenza and other vaccine-preventable diseases. A survey will be conducted soon to learn the influenza vaccination status of health workers (Annex 2) in the Americas.

The Comprehensive Family Immunization Project (IM) of the PAHO/WHO Regional office has organized sub-working groups for responding to influenza A(H1N1) vaccination. Furthermore, it will provide technical cooperation for all activities related to influenza vaccination. All country requests for technical cooperation on vaccination and all vaccination reports will go through the

FCH-IM project, which in turn will coordinate with other PAHO/WHO areas and projects as necessary. This is essential to ensure a uniform, integrated, and coordinated effort around regional activities.

In the Member States, the FCH-IM focal points will provide technical cooperation in all areas related to vaccination activities. Moreover, technical cooperation will be provided with short-term consultants external to the organization in accordance with requests from Member States and may include epidemiologists, cold chain technical personnel, and training, among others.

The following are among the principal aspects to consider in the regional plan for vaccination programming/implementation:

- Interagency coordination;
- Coordination among PAHO/WHO areas and projects involved;
- Mass communication;
- Training of health professionals;
- Provision of vaccines and syringes through the Revolving Fund, according to Member States' requests;
- Record-keeping and information systems;
- Monitoring of events supposedly attributable to vaccination or immunization (ESAVIs) reported by Member States;
- Dissemination of information; and
- Operations research.

a. Regional Plan for strengthening seasonal influenza vaccination

Currently, Member States and territories are vaccinating high-risk groups such as the elderly, children, and health workers. Of the 35 Member States and territories using the seasonal vaccine, 22 are vaccinating children in age groups ranging from 6-23 months to 6 months-18 years; 31 Member States vaccinate health workers; 7 vaccinate pregnant women; and 11 Member States vaccinate workers in contact with birds, among other risk groups.

Currently, 26 Member States and territories are using the Northern Hemisphere formulation and 9 Member States and territories administer the Southern Hemisphere formulation. In 2008, approximately 166.3 million doses of seasonal vaccine were administered in the Region, including Canada and the United States. Most Member States purchase the vaccine through the PAHO Revolving Fund.

In the Region, 9 Member States and territories (Aruba, Bolivia, Dominica, Guyana, Haiti, St. Kitts and Nevis, St. Maarten, St. Vincent and the Grenadines, and Suriname) have not introduced seasonal influenza vaccine into the public sector. The recent emergence of the influenza A(H1N1) virus with pandemic potential makes introduction of the seasonal vaccine in the aforementioned Member States a priority, so they will be better prepared to face the imminent risk of a pandemic.

This regional effort to strengthen vaccination against seasonal flu has the following objectives:

- Support the 9 Member States and territories in the Region that have not yet introduced seasonal influenza vaccine; and
- Scaling-up of vaccination to other groups in Member States that have already introduced the seasonal vaccine.

In order to achieve these objectives, the following activities are being conducted:

- Mobilize resources aimed at supporting Member States and territories that have not yet introduced seasonal influenza vaccine.
- Support these Member States and territories in determining the populations, risk groups, and operational strategies to vaccinate against seasonal influenza.
- Scale-up vaccination to other risk groups: Some Member States that have already introduced seasonal influenza vaccination have manifested their interest in expanding vaccination target groups. These include Nicaragua, Paraguay, and Caribbean Member States, such as Anguilla, Antigua, Barbados, Belize, Bermuda, British Virgin Islands, Cayman Islands, Grenada, Montserrat, St. Lucia, Trinidad and Tobago, and Turks and Caicos Islands. Annex 2 shows estimates for seasonal flu vaccine, its formulation, and vaccine-related costs.

b. Biologicals and supplies for influenza A(H1N1) vaccination

Vaccine procurement, supply, storage, and distribution are critical components of this plan. The regional level will consolidate the needs of the Member States and territories, based on the Member States' action plans, including requests for vaccines and syringes in accordance with the priority groups that will be vaccinated (Annex 3). Each country and territory should request vaccines from the Revolving Fund (RF), which in turn will issue purchase orders and plan their shipment to the Member States according to availability.

For the purpose of promoting equity and access of pandemic vaccine to poor populations in the Region, PAHO has presented a project for US\$12,000,000 to different donors for the creation of a strategic fund to procure influenza A(H1N1) vaccine, which is still being negotiated.

Each country must identify the additional cold chain capacity and needs to guarantee the timely and adequate administration of this new vaccine. If needed, additional resources must be mobilized, through national funds, the Inter-agency Cooperation Committee, or other donors.

c. Training

Training of personnel involved in immunization on the technical and operational components of influenza A(H1N1) vaccination is a priority. At the Regional level, several activities will be conducted to support training of national professionals and vaccination planning/implementation.

A group of consultants will be trained so they can support the different Member States in accordance with identified needs.

For national professionals, the head of the Expanded Program on Immunization (EPI), and the National Pandemic Coordinator, three-day training workshops will be held, divided into three subregional workshops: one workshop for Southern Cone and Andean Region Member States; one workshop for the Member States of Central America, Mexico, and the Spanish-speaking Caribbean; and one workshop for English-speaking Member States.

A technical-operational vaccination manual will be prepared that will be distributed to the Member States that can be adapted at the national and other levels in the country.

d. Social mobilization

At the Regional level, communication materials will be published, such as fliers and posters, to inform the population about vaccination and other disease prevention measures. These materials will be distributed to the Member States and will also be available via electronic media for replication.⁽¹¹⁾

Systematic reporting will continue on the behavior of the disease and on vaccination activities that PAHO is conducting in coordination with other institutions, so that this information is transmitted to national authorities. In social mobilization from the regional level out to all other levels it will be very important for messages to be clear, objective, and above all consistent. Each person in the public and private sector should be encouraged to promote vaccination according to the priority groups in the country.

e. Safe vaccination

Monitoring of events supposedly attributable to vaccination or immunization (ESAVIs) is of special importance in vaccination against a pandemic strain, since this will be a new vaccine and will be used for the first time on a large scale in several Member States at the same time. Furthermore, there will be enormous public demand for the vaccination, which could increase the possibility of program errors.

PAHO/WHO will provide Member States with a tool for surveillance of ESAVIs; for this, Member States are being sent a survey on pre-implementation of the surveillance information system (Annex 4).

In planning for vaccination, it will be important for each country to create an investigation and response team that includes the national vaccination program, epidemiology, the national regulatory authority, the laboratory, communication departments, and other relevant departments at the national level. Before beginning vaccination activities against a pandemic strain, it should be clearly established how ESAVI reporting and investigation will flow and how a crisis will be rapidly and opportunely addressed. Health services should have health professionals trained to deal with possible adverse events. It is important for the committee on immunization practices and scientific associations to be trained to support the national authorities in the event of a crisis during vaccination. At each level, an ESAVI crisis plan should be available.

f. Information system

Timely, good quality information will enable making adjustments and corrections to the influenza A(H1N1) vaccination strategies in order to achieve high vaccination coverage. Consequently, PAHO will support Member States in having efficient information systems that permit daily consolidation of data by municipality and state/department/province. For those who desire, a computerized data consolidation tool previously used in vaccination campaigns, "SIVAC," will be available.

Data should be collected at the local level, in a standardized format for all municipalities, broken down by priority group, age group, and sex. Subsequently, the consolidated data should be entered into the computerized system by health service and municipality, in accordance with the established flow for sending the information through the municipality, state/department/province, and country, guaranteeing the availability of decentralized information at all service delivery levels, which will enable monitoring, analysis, and decision-making in the immunization program.

Countries can post the results of vaccination activities on their Websites and health services can monitor vaccination using coverage progress charts or "vaccination thermometers."

g. Monitoring and evaluation

During administration of the influenza A(H1N1) vaccine, and considering the diversity of vaccination modalities for priority groups, it will be necessary to conduct rapid coverage monitoring (RCM), as required, and a final evaluation to verify the extent to which the $\geq 95\%$

vaccination coverage goals were reached for each priority group. Once vaccination activities have concluded, a final report will be prepared that includes the results of the vaccination coverage verification process.

Furthermore, it will be important to evaluate the contribution of each health institution, both in human resources and in the number of people vaccinated, in relation to each country's programming. Given the importance of generating knowledge on effective vaccination strategies and tactics in different groups and in this situation, analysis will also be done of the lessons learned using methods such as SWOT (strengths, weaknesses, opportunities, and threats) analysis, and of innovative experiences that are implemented during vaccination activities.

Recognizing the importance of vaccination performance monitoring for the purpose of detecting and correcting difficulties and obtaining and systematizing lessons learned, PAHO/WHO will provide technical cooperation for the evaluation of this intervention.

h. Research needs assessment

Recognizing that questions still remain that should be resolved in the field of emergency influenza vaccination during a pandemic, technical and operational areas should identify research needs. It is important to consider that several research questions will evolve over time, with some being resolved and new ones appearing.

Some of the topics that could be addressed immediately include:

- Impact assessment of influenza A(H1N1) vaccination.
- Identification of potential signs related to the safety of the influenza A(H1N1) vaccine.
- Effectiveness of the influenza A(H1N1) vaccine in different groups.
- Documentation of the lessons learned from this emergency vaccination against influenza A(H1N1).

i. Dissemination of information

At the Regional level, the status reports on Influenza A(H1N1) vaccination will be included in the PAHO *Immunization Newsletter*. The experiences will also be presented in regional (TAG) and subregional meetings of immunization managers, which serve as a forum for sharing experiences and disseminating information.

Member States are encouraged to include a section on pandemic flu in their epidemiological bulletins, with distribution to all health workers in the network, and to publish their experiences.

j. National Plan of Action

In order to ensure that the objective for influenza A(H1N1) vaccination is met, every country needs to prepare its own national managerial action plan that includes prioritization of the groups to be vaccinated.

Recognizing the limited resources available in the Ministries of Health of some Member States, maximizing efforts to mobilize resources is crucial. To this end, the actions that the national Interagency Coordinating Committee (ICC) undertakes will be essential in this process. All Member States are urged to continue convening the ICC as the mechanism for resource mobilization, discussion of strategies, progress review, and coordination of the distribution of supplies and program activities. As previously mentioned, the Committee on Immunization Practices, Ethics Committees, and scientific associations have a key role in determining which priority groups to vaccinate and in evaluating these recommendations.⁽¹²⁾

Effective management and coordination of vaccination activities will be vital to successful coping with the current influenza A(H1N1) situation. Effective management will depend on a clear line of command under the person responsible for the pandemic response determined by the country, to ensure that immunization managers from the national level out to the local level receive guidance and provide feedback.

Furthermore, involvement of the authorities at all levels and interprogrammatic collaboration are crucial to the planning and management of vaccination activities. This coordination is important because no institution will have all the resources necessary for responding rapidly to the situation.

Effective management at all levels is determined by the capacity to make quick decisions and effectively conduct a response planned in an emergency. Each country's plan of action should include all activities related to influenza A(H1N1) and should identify the functions of all participating agencies and what additional cooperation is needed from PAHO and other participating agencies. These needs should be reflected in formal agreements.

8. Budget

As shown in the following table, it is estimated that implementation of the Regional Plan for Pandemic Vaccination will require approximately US\$18,6 million.

Activity	Cost in US\$
I. Introduction of seasonal influenza vaccine (9 Member States and territories)	2,520,000
II. Scaling-up of seasonal influenza vaccination (14 Member States and territories)	3,264,075
III. Strategic reserve of Influenza A(H1N1) vaccine	12,000,000
IV. Training (for introducing Influenza A(H1N1) vaccine):	
• Training for consultants	30,000
• Subregional workshops	210,000
• Support for national workshops	115,000
• Support to Member States through consultants	220,000
V. Mass Communication	100,000
VI. Safe Vaccination	60,000
VII. Operations Research	80,000
VIII. Dissemination of Information	30,000
Total	18,629,075

9. Chronogram

Schedule of Activities - 2009 Regional Plan Vaccination Against Influenza A(H1N1)								
Activities	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Development of Regional Plan of Action								
- Vaccination Safety Surveys								
- Needs (vaccines, syringes, safety boxes)								
Update of National Plan of Action								
Development of a vaccination manual for technical and operational aspects								
Training of consultants								
- 2 Regional workshops, Spanish-speaking countries								
- 1 Regional workshop, English-speaking countries								
Support to countries requiring it, with short-term consultants								
Support to national workshops								
Production and printing of promotion materials								
Design and implementation of vaccination safety information system								
Monitoring implementation of national Plans of Action								

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11. Annexes

Annex 1: Seasonal Influenza Immunization Survey Among Health Care Workers

Date of Survey Completion: ____ / ____ / ____ (day/month/year)

1) Name of facility: _____

2) Name of town/city: _____

3) Number of years in current profession: _____

4) Gender: Female Male

5) Age: _____ (years)

6) Check job category below: (check one box only)

- | | | |
|---|---|--|
| <input type="checkbox"/> Doctor | <input type="checkbox"/> Dentist | <input type="checkbox"/> House Keeper |
| <input type="checkbox"/> Nurse | <input type="checkbox"/> Laboratory Worker | <input type="checkbox"/> Security/Porter |
| <input type="checkbox"/> Laundry Worker | <input type="checkbox"/> Student | <input type="checkbox"/> Midwife/Birth-attendant |
| <input type="checkbox"/> Allied Health Worker | <input type="checkbox"/> Medical Orderly/Ward Assistant | <input type="checkbox"/> Volunteer |
| <input type="checkbox"/> Other, describe: _____ | | |

7) Approximately how many hours do you work in a typical work week? ____ hours per week.

8) Have you been vaccinated against seasonal influenza this year? (Check one box only)

- Yes No Uncertain

9) Please indicate (check one box only for each question):

a. Is the seasonal influenza vaccine available to you free of charge?

- Yes No Don't know

b. Is the seasonal influenza vaccine available to you in your workplace?

- Yes No Don't know

c. Is the seasonal influenza vaccine mandatory for workers in your workplace?

- Yes No Don't know

10) If no, please indicate the reasons (you can check more than one box):

- Cost of the vaccine
- Fear of needles
- Unavailability of the vaccine in the workplace
- Concerns related to safety of the vaccine
- Concerns related to potential adverse effects of the vaccine
- Your risk to contract seasonal influenza is low

Other reasons for declining the seasonal influenza vaccine: _____

Annex 2.

PROPOSAL FOR THE INTRODUCTION OF SEASONAL INFLUENZA VACCINE IN 9 COUNTRIES OF THE REGION

(to be implemented before August 2009)

	Member States	Formulation	Proposed high-risk groups	Vaccine Requirements	Formulation
Member States planning to introduce the influenza vaccine	Aruba	N. Hemisphere		40,000	40,000 - Adult
	Bolivia	S. Hemisphere	Elderly >65 years (449,532)	600,000	600,000 - Adult
			Health workers (37,440)		
			Persons with chronic diseases (100,000)		
	Dominica	N. Hemisphere		20,000	11,700 - Adult 8,300 - Pediatric
	Guyana	N. Hemisphere	Elderly persons and adults with underlying medical conditions (25,000)	30,000	25,000 - Adult 5,000 - Pediatric
			Children with underlying medical conditions or any other medical underlying cause. (5,000)		
	Haiti	N. Hemisphere	Health care workers and persons >60 years	100,000	100,000 - Adult
	St. Kitts & Nevis*	N. Hemisphere	Persons >65 years	4,500	4,500 - Adult
	St. Maarten		Health care workers and several risk groups	14,000	13,000 - Adult 1,000 - Pediatric
St. Vincent & the Grenadines	N. Hemisphere	Health care workers	1,000	1,000 - Adult	
Suriname	N. Hemisphere	Elderly >65 years (25,000)	20,000	20,000 - Adults	
		Persons with chronic diseases (3,000)			
		Health care workers (3,000)			
		Other priority groups (4,000)			
Total				829,500	825,200 (Adult) 14,300 (Pediatric)

* Population estimate for ≥ 60 years. *Health in the Americas 2007*. Vol.II, PAHO.

Annex 3.

For: Pan American Health Organization	Area of Family and Community Health
Regional Office of the World Health Organization	Immunization Project, FCH/IM
	Revolving Fund
525 23 rd . St. N.W. Washington, D.C. 20037, USA Tel: 202-974-3248 Fax 202-974-3635	
Requesting country or entity: _____ Calendar year: _____	Activity: _____

Pandemic Vaccine Requirements by Risk Group

	Possible Priority Groups	Population	Dose/ Person	Total Doses	Estimated Average Cost/Dose US \$	Total Cost US \$
1	Essential workers, including health-care workers, public service workers and decision-makers		1	0	\$3,0	\$0
2	High-risk populations (morbidity and mortality)		1	0	\$3,0	\$0
3	Healthy adults		1	0	\$3,0	\$0
4	Children aged >6 months to 9 years		2	0	\$3,0	\$0
5	Children aged >9 years to 18 years		1	0	\$3,0	\$0
6	Other		1	0	\$3,0	\$0
	Specify					
	Vaccine Total (Adult)					
	Vaccine Total (Pediatric)					

Assumptions

- a) Until the present date, it is estimated that 1 dose of Pandemic Influenza Vaccine will be required for adults and two doses for children aged >6 months to 9 years.
- b) The approximate cost is \$3.0/dose, based on the cost of seasonal influenza vaccine.
- c) The inclusion of different groups depends on the epidemiological analysis and the availability of vaccine.

Observations:

Name _____ Signature _____ Date _____
 Manager of the Expanded Program on Immunization

Name _____ Signature _____ Date _____
 Authorized Representative of the Ministry of Health

F-173S

Annex 4.

Vaccine Safety Monitoring Member State Questionnaire

Country: _____ Date: _____

Person completing the survey: _____

It is proposed that the national focal point for ESAVI surveillance and/or the FCH/IM Consultant complete the questionnaire.

The following questions will be useful to establish country profiles to document baseline information on selected variables at the onset of the network.

1.	Does your country have mandatory or voluntary reporting of ESAVIs?
2.	Describe briefly the reporting flow for ESAVIs in your country including whether it is centralized (from local level to national level at the same time as to regional level) or decentralized (from local level to regional level only) reporting. Please attach a diagram in addition to your description.
3.	Which institution is responsible for ESAVI reporting - Immunization program? Epidemiological surveillance? National Regulatory Authority? Pharmacovigilance Center? If it is the joint responsibility of various institutions, briefly describe the primary and most important responsibilities of each one.
4.	Do you have a national pharmacovigilance centre? If so, which institution serves in this capacity?
5.	Are ESAVI reports forwarded to the pharmacovigilance centre? If so, by whom?
6.	Does your country report adverse events to the Uppsala Monitoring Centre (UMC)? If so, do you report both drug and vaccine, drug only or vaccine only adverse event data?
7.	If you responded yes to Question 6 for vaccines, which institutions report vaccine adverse event data to UMC?
8.	How often do you report data to UMC?

9.	Have you conducted training on ESAVI surveillance for health workers or professionals involved in ESAVI surveillance, when, and regarding what?			
10.	If you responded yes to Question 9 for 2007-2008, please complete the table below (in a detailed manner)			
	Dates of Training	Title of Training	Total hours	Number of Participants
11.	Are you familiar with the Brighton Collaboration?			
12.	Have you used any of the Brighton Collaboration case definitions in your ESAVI surveillance activities (routine monitoring or studies)?			
13.	Which case definition(s)? (Enter case definition(s) in 1 st column below and place an "X" in the appropriate column)			
	Case Definition(s)	Routine Reporting	Data Analysis	Special Study
14.	What case definitions do you use for the rest of ESAVIs?			
15.	Do you have an electronic database for your ESAVI records?			
16.	What coding do you use for the rest of ESAVIs? (MedDRA, WHOART or Other; specify if other)			
17.	Please attach your standard list of ESAVIs eligible for reporting and reporting case definitions.			

	Management of Syringes
18.	For vaccines used in the Immunization Program, please indicate what type of syringe is currently used in the country. <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> AD (Auto-Disable) Standard (disposable) Both
19.	If the country uses standard syringes only, please indicate the degree of knowledge on the use of AD syringes. None <input type="checkbox"/> Little <input type="checkbox"/> Sufficient <input type="checkbox"/>
20.	If you indicated that the country uses standard syringes for the Immunization Program, please indicate if the country would use AD syringes during mass vaccination of the population in the context of an influenza pandemic. YES <input type="checkbox"/> NO <input type="checkbox"/>
21.	In your opinion, do you feel that a training for health workers in the use and management of AD syringes is required? YES <input type="checkbox"/> NO <input type="checkbox"/>
22.	In your opinion, how many syringes do you believe would be required in the event of mass vaccination of the population against pandemic influenza? AD _____ Standard _____
	Management of Safety Boxes
23.	In the case of an influenza pandemic, please indicate if the country has a plan to ensure that each health service would have at least one safety box. YES <input type="checkbox"/> NO <input type="checkbox"/>
24.	Please indicate if the influenza pandemic plan has a budget for the purchase of safety boxes. YES <input type="checkbox"/> NO <input type="checkbox"/>
	Management of Final Disposal of Syringes and Needles
25.	Do national policies for the final disposal of hospital waste exist? If you response is "no" or "unknown", do not answer questions 26 and 27. YES <input type="checkbox"/> NO <input type="checkbox"/> Unknown <input type="checkbox"/>
26.	Are there specific guidelines for the final disposal of immunization syringes and needles?
27.	Has there been an evaluation of the implementation of this policy in all the establishments and/or health services? YES <input type="checkbox"/> NO <input type="checkbox"/> Unknown <input type="checkbox"/>
28.	In what percentage of health services in the country have practices on the final disposal of sharp objects been evaluated the in the last 24 months? <input type="checkbox"/> % Unknown <input type="checkbox"/>

29 .	Has your office or the office responsible for the management of hospital waste produced by health services estimated the quantity of waste that needs to be processed weekly during a mass vaccination of the population in the context of an influenza pandemic? YES <input type="checkbox"/> NO <input type="checkbox"/>																		
30 .	Of those stated below, according to the urban or rural denomination, which are the methods most frequently used in the country for the disposal of syringe and needle waste? Select all that apply. <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">o Incineration (private or public)</td> <td style="width: 20%;">Urban</td> <td style="width: 20%;">Rural</td> </tr> <tr> <td>o Burn in open area</td> <td>Urban</td> <td>Rural</td> </tr> <tr> <td>o Burial</td> <td>Urban</td> <td>Rural</td> </tr> <tr> <td>o Municipal waste services</td> <td>Urban</td> <td>Rural</td> </tr> <tr> <td>o Latrines</td> <td>Urban</td> <td>Rural</td> </tr> <tr> <td>o Other(s) _____</td> <td>Urban</td> <td>Rural</td> </tr> </table>	o Incineration (private or public)	Urban	Rural	o Burn in open area	Urban	Rural	o Burial	Urban	Rural	o Municipal waste services	Urban	Rural	o Latrines	Urban	Rural	o Other(s) _____	Urban	Rural
o Incineration (private or public)	Urban	Rural																	
o Burn in open area	Urban	Rural																	
o Burial	Urban	Rural																	
o Municipal waste services	Urban	Rural																	
o Latrines	Urban	Rural																	
o Other(s) _____	Urban	Rural																	
31	Is there a directory or map that shows facilities that adhere to national regulations and specifications at each level for final disposal of hospital waste? YES <input type="checkbox"/> NO <input type="checkbox"/> Unknown <input type="checkbox"/>																		
32 .	In previous vaccination campaigns, have problems occurred with the final disposal of contaminated syringes during a period of a week? YES <input type="checkbox"/> NO <input type="checkbox"/>																		
33 .	In your opinion is a plan required to ensure an adequate capacity for the final disposal of hospital waste in the event of a mass vaccination campaign against pandemic influenza? YES <input type="checkbox"/> NO <input type="checkbox"/>																		
34 .	Is there a plan that considers adequate vehicles for the collection and safe transportation of hospital waste? YES <input type="checkbox"/> NO <input type="checkbox"/>																		

Thank you and please enclose the ESAVI investigation form currently in use.