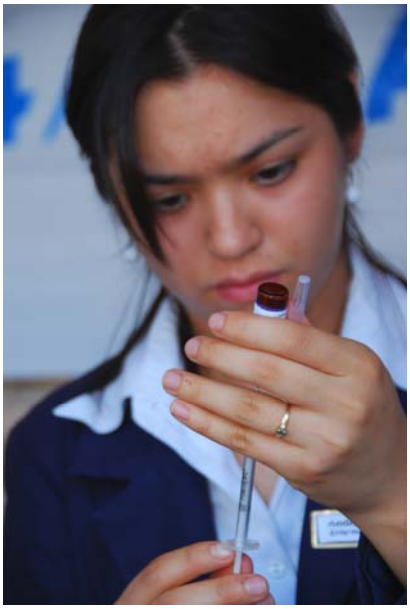
2009

Technical Guidelines for Vaccination against the Pandemic Influenza Virus



Pan American Health Organization

Regional Office of the World Health Organization

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Lineamientos Técnicos para la Vacunación contra el Virus de la Influenza Pandémica

This document is the result of the union of many efforts to face the H1N1 influenza pandemic. It was developed through meetings with consultants and validated with immunization program managers. The topic of vaccine deployment was adapted from the document on pandemic vaccine deployment of the World Health Organization. The Pan American Health Organization has developed the present publication as a reference to support countries and territories of the Region in preparing for the introduction of the pandemic influenza vaccine.

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Acronyms

CDC	Centers for Disease Control and Prevention (United States)
DNA	deoxyribonucleic acid
EPI	Expanded Program on Immunization
ESAVI	event supposedly attributable to vaccine or immunization
FluNet	Global Influenza Surveillance Network (WHO)
GACVS	Global Advisory Committee on Vaccine Safety (WHO)
GBS	Guillain-Barré syndrome
HIV	human immunodeficiency virus
LAIV	live attenuated influenza virus
NGO	non governmental organization
NRA	national regulatory agency
PAHO	Pan American Health Organization
PESS	Poliomyelitis Elimination Surveillance System
RCM	rapid coverage monitoring
RNA	ribonucleic acid
SAGE	Strategic Advisory Group of Experts (WHO)
SIBASI	Sistema Básico de Salud Integral (Basic Integrated Health System)
SILAIS	Sistemas Locales de Atención Integral en Salud (Local Integrated Health Care Systems)
SIVAC	Sistema de Información para Vacunación (Vaccination Information System)
TAG	Technical Advisory Group on Vaccine-preventable Diseases (PAHO)
TIV	trivalent inactivated influenza vaccine
WHO	World Health Organization

Foreword

The *Technical Guidelines for Vaccination Against the Pandemic Influenza Virus* are part of the technical cooperation efforts of the Pan American Health Organization/World Health Organization (PAHO/WHO) with its Member States in the Region. Pandemic influenza vaccine recently became available worldwide and will be an essential tool for the prevention and mitigation of the pandemic within national pandemic preparedness and mitigation plans.

Lessons learned in the immunization program of the Americas, particularly the mass vaccination strategies of populations against measles and rubella, as well as national experiences using the seasonal influenza vaccine to target specific, non-traditional risk groups, are useful in order to identify and implement the best vaccination strategies and tactics to use in a pandemic. This should be done while also considering the special issues inherent when there is a high level of unsatisfied demand for a vaccine, and the consequent risk of conflicts due to the limited availability, as occurred in the yellow fever outbreaks of 2008.

Since the pandemic vaccine is new, it is important to take into account those technical and logistic considerations related to the introduction of a new vaccine, such as the identification of groups with the highest burden of disease and mortality, the availability of syringes, and the cold chain. Due to the uncertainty surrounding the amount of vaccine that will be available and the needs in each country, it is advisable to plan for scenarios of progressive vaccine use in the groups defined. Since the vaccine will be produced and released rapidly, using new technologies and adjuvants, and without knowledge of all the potential adverse effects, it is also essential to reinforce the surveillance of events supposedly attributable to vaccine and immunization (ESAVIs) and to maintain active crisis committees.

The components related to deployment of the pandemic vaccine in these guidelines have been adapted from the pandemic influenza vaccine distribution guide prepared by WHO, taking into account the conditions in the countries of the Region of the Americas.

In the current situation, mass communication strategies are complex since messages need to promote vaccination of specific population groups, as opposed to encouraging indiscriminate demand, which has been done in other campaigns. Audiences, media, and messages that seek to reduce social pressure should be considered. Information should be provided on preventative measures other than vaccination, and non-pharmaceutical methods should be strengthened.

This manual supplements the information found in the national pandemic influenza vaccination plans. Since it provides information for decision-making and the organization of vaccination efforts, it is designed for health services managerial staff. It can also be adapted at the national and subnational levels to serve as a basis for a manual directed towards operations personnel.

1. Introduction

Acute respiratory diseases continue to be one of the main causes of infectious disease-related mortality in developing countries. Diseases may be caused by different bacteria and viruses such as the influenza virus, which can cause viral pneumonia or induce additional bacterial infections.[1]

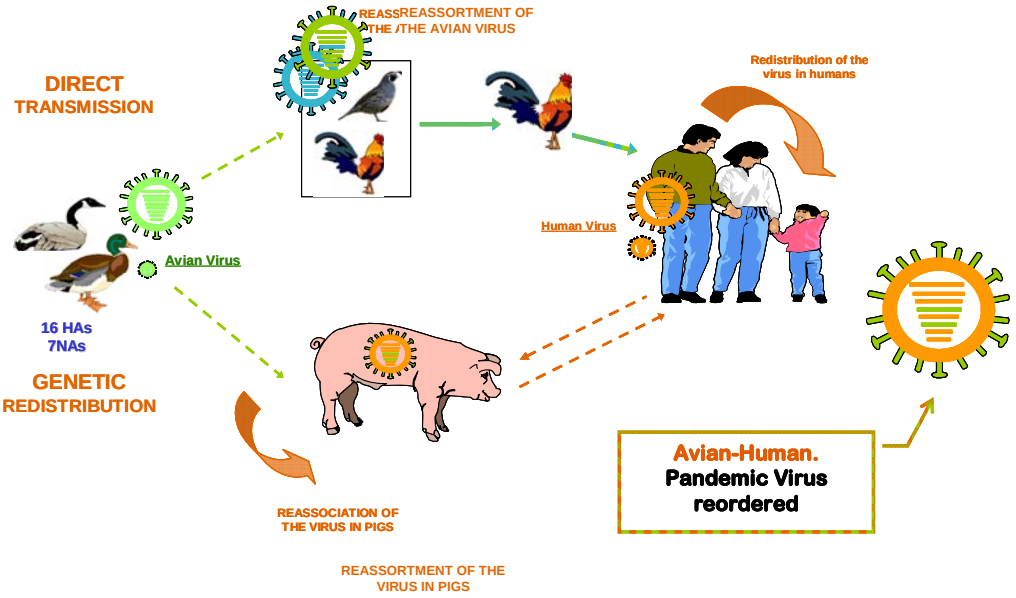
The name "influenza" comes from an epidemic that occurred in Italy in the 16th century, which was attributed to the “influence of the stars.” Influenza, also known as the flu, is a contagious acute viral disease of the respiratory tract that spreads in the environment when an infected individual expels aerosols by coughing or sneezing. However, close contact with an infected person, defined by a distance of at least 1 meter, is required for airborne transmission to be successful. Transmission by objects contaminated with respiratory secretions of infected persons is usually more common.

The virus was isolated for the first time in 1933 and successfully cultured in fertilized hen eggs by M. Burnet in 1936. This event led to characterization of the virus and the development of vaccines.

The genome of the virus is made up of ribonucleic acid (RNA) belonging to the Orthomyxoviridae family. Three types of virus antigens have been described: A, B and C. Type A and type B produce clinically detectable infections and cause outbreaks each year. However, only type A has been associated with pandemics. Type B is responsible for smaller outbreaks, mainly in children. There are two important phenomena that affect influenza viruses: antigenic drift and antigenic shift. Antigenic drift is related to constant and usually minor changes in composition of the virus antigen, which require introduction of appropriate changes in the composition of the vaccine each year. Antigenic shift is a more significant change that leads to emergence of a new type of virus for which the population lacks immunity. This is a public health problem due to the risk of a pandemic. Influenza A subtypes are determined by the molecular characteristics of the hemagglutinin (H) and neuraminidase (N) surface proteins. The subtypes of hemagglutinin bind to the host cell receptor. The subtypes of neuraminidase participate in cell penetration and dissemination of the virus in the host cells.

The usual hosts of influenza A virus are birds, mainly wild and aquatic birds. However, the virus can infect others species of mammals. Pigs can be infected by avian viruses as well as human viruses (Figure 1). Coinfection of pigs by avian and human viruses can lead to genetic recombination and reassortment of the virus, which can cause pandemics.

Figure 1. Forms of Transmission of the Influenza A Virus: The Beginning of a Pandemic Strain



Source: Centers for Disease Control and Prevention (CDC)

2. Seasonal Influenza

Outbreaks of seasonal influenza cause 3-5 million cases of acute disease and 250,000 to 500,000 deaths worldwide each year. Although 30-50% of seasonal influenza infections are asymptomatic, both symptomatic and symptomatic infections can transmit the virus to susceptible individuals. The average incubation period is 2 days, with a range of 1-4 days. The communicable period as of the time of the onset of symptoms is 1-5 days, and may last up to 7 days. Transmission from 1-2 days to 2 weeks before the onset of symptoms has occurred in children, and over a more prolonged period in immunocompromised patients.

The clinical manifestations can be mild, moderate, or very severe. They are characterized by abrupt onset of fever, usually over 38ºC, cough, headache, muscle aches, runny nose, and poor general condition. In children, up to 25% of the cases have nausea, vomiting, and diarrhea.

In countries with well-defined seasons, deaths due to pneumonia and other respiratory conditions often increase in the winter. This occurs at the same time as the seasonal increase in cases of influenza and influenza-related deaths. In tropical countries transmission of influenza occurs year-round.

3. Pandemic Influenza

When influenza viruses are transmitted at the community level in two regions of the world it is referred to as a pandemic. The current influenza A(H1N1) pandemic is considered to be a “moderate” pandemic due to the number of cases, deaths, and the impact the virus has

had on health services. However, pandemics can occur with high morbidity, excess mortality, and significant social and economic disruption. At least four pandemics are known to have occurred in the 19th century and three in the 20th century.

The Spanish flu [virus A(H1N1)] in 1918-19 was the first 20th century pandemic and the first to be described as reassortment in pigs.[2] The Asian flu [virus A (H2N2)] occurred in 1957-58 and the Hong Kong flu [virus A (H3N2)] in 1968-69. The most well-known pandemic is the Spanish flu, which is estimated to have caused 40-50 million deaths worldwide. Its main characteristics were rapid circulation and high mortality in young adults. The Asian and Hong Kong influenza pandemics had less mortality than the Spanish flu, and mainly affected persons over 65 years of age and persons with chronic diseases.[3]

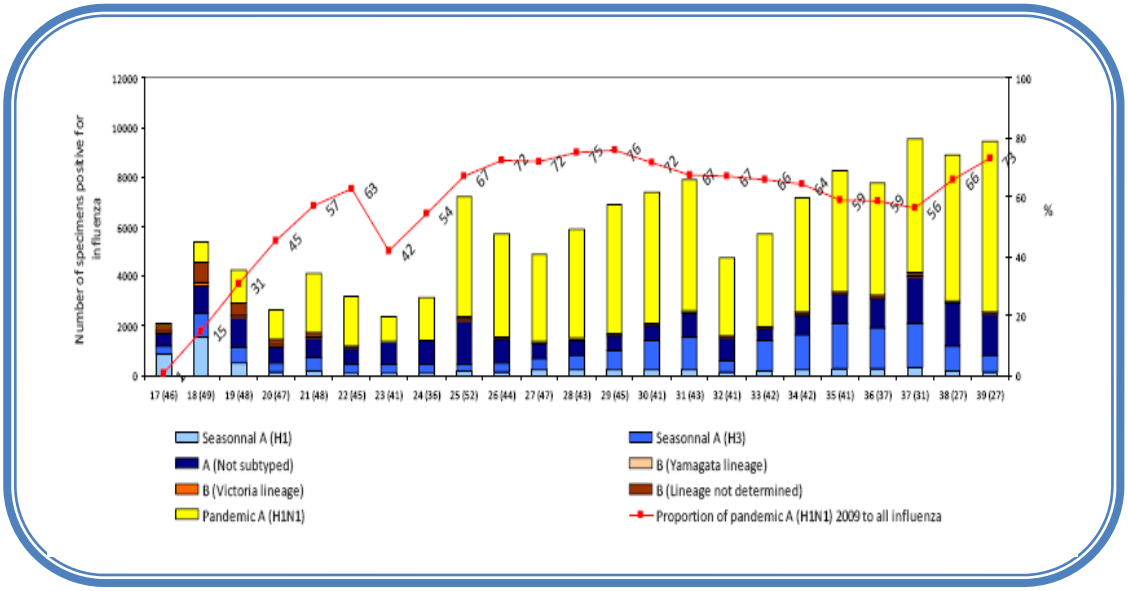
As mentioned earlier, there is risk of a pandemic when an abrupt and pronounced change occurs in the virus. This is due to mutation or genetic exchanges between animal (avian) and human influenza viruses that infect the same host (e.g., the pig, which is susceptible to both viruses) at the same time. It can also be caused by transmission of the complete virus between host species. If these new viruses acquire the capacity to cause disease in humans and are effectively transmitted from person to person, there can be rapid and widespread circulation. This can result in a pandemic, such as the novel influenza A(H1N1) virus, which includes genome sequences of porcine, avian, and human origin.[4] Once the new virus has spread on an international level, waves of incidence lasting from 1 to 3 years can be expected. After this period, most of the population has usually acquired some degree of immunity and the virus causes smaller annual epidemics.

3.1 Epidemiological Situation of Pandemic Influenza

One reason for concern is the fact that pandemic influenza A(H1N1) has some elements of avian virus A(H5N1) due to mechanisms of coinfection in the countries where the avian virus A(H5N1) is endemic in the bird population. A serious situation would ensue if genetic reassortment between the two viruses occurred, contributing to increased transmission and severity.[5]

On 9 October 2009,[6] over 378,223 cases and more than 4,525 deaths had been recorded in 190 WHO Member States and Territories. In America all of the countries have been affected. Countries with the highest number of cases are the Argentina, Brazil, Canada, Chile, Mexico, and the United States. The highest case fatality rates have been recorded in Suriname (18.2%), St. Kitts and Nevis (16.7%), Brazil (9.72%), Paraguay (6.7%), and Argentina (5.96%). The presence of breathing difficulties, low blood pressure, vomiting, persistent diarrhea, an altered state of consciousness, such as confusion or lethargy, or worsening of chronic conditions, such as congestive heart disease, immunodeficiency, diabetes, high blood pressure, kidney disease, or systemic lupus erythematosus in adults, are considered to be warning signs for the clinical progression of patients.

Figure 2. Number of Positive Samples of Influenza by Subtype (19 April to 26 September 2009)



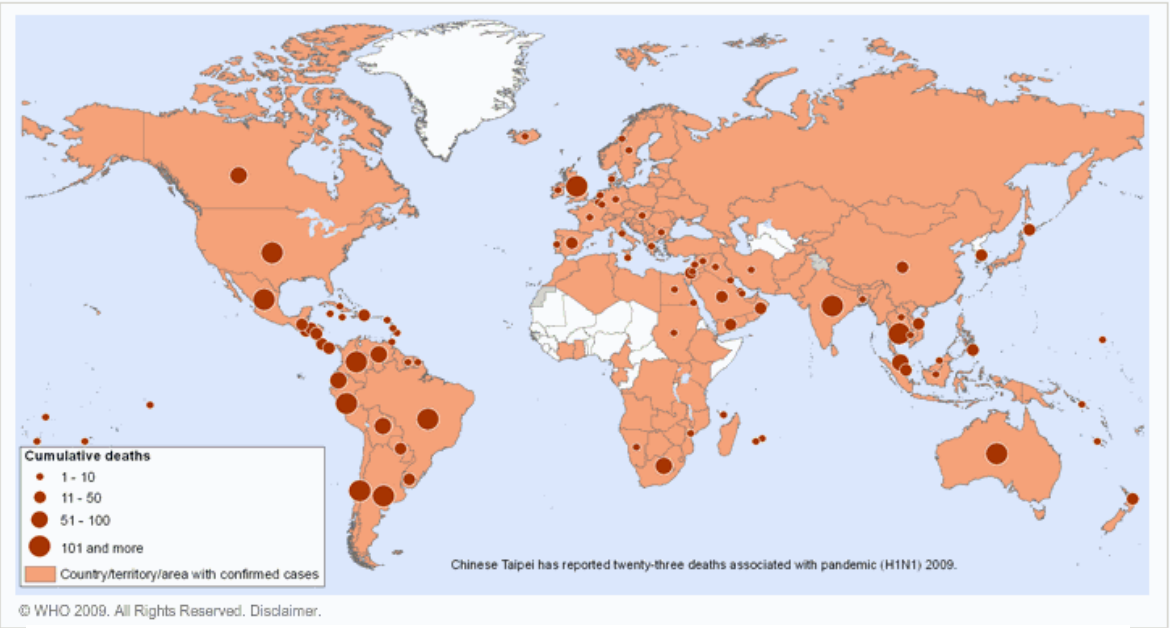
Source: Virologic data. WHO. http:/www.who.int/csr/don/jvirologicaldata2009_09_18.pdf

In children, fever over 38ºC, rejection of oral intake, breathing difficulties, respiratory rate greater than or equal to 50 breaths/min in children aged 2-11 months and older, or equal to 40 breaths/min in children aged 1-4 years, convulsions, and/or altered state of consciousness are considered to be warning signs.[7]

In many countries patients have not required hospitalization. A total of 6% of the cases have been hospitalized in Mexico, 2-5% in the United States and Canada,[8] and 3.8% in Chile.[9] Few of the cases hospitalized were persons over 60 years of age. It is noteworthy that 64% of the cases hospitalized in the United States and 46% of the deaths in Mexico had underlying conditions of pregnancy or health problems, such as asthma, other pulmonary diseases, diabetes, morbid obesity (body mass index ≥40), autoimmune diseases, immunodeficiency, neurological disorders, and cardiovascular disease (Table 1).[10,11] Persons born prior to 1957 have been found to have a lesser risk of infection or complications. This could be attributed to greater exposure to virus A(H1N1) different from the pandemic virus in the past that may provide some protection for this age cohort.[12]

On 12 September, Mexico had confirmed 39,489 cases and 255 deaths. A total of 41.2% of cases occurred in persons under 30 years of age and 21.2% of cases were in persons under 20 years of age. Forty-nine percent of the total number of cases occurred in women.[13] Sixty-nine percent of deaths occurred in the age groups ranging from 20 to 54 years. The most frequent clinical manifestations in the deceased were fever (85.5%), cough (86.3%), dyspnea (69.0%), and poor general condition (52%). In the United States the average age of the cases has been 12 years, 20 years in hospitalized persons, and 37 years in the deceased.[14]

**Figure 3. Number of Laboratory-confirmed Cases and Deaths*
Pandemic Influenza, 2009****



* The information from the United States includes cases that have not been laboratory-confirmed.
** Information as of 23 July 2009.

Source: WHO. Map of countries affected and deaths as of 18 October 2009. Laboratory-confirmed cases of pandemic (H1N1) 2009 as officially reported to WHO by States parties to the International Health Regulations (2005). Available at : http://gamapserver.who.int/h1n1/cases-deaths/h1n1_casesdeaths.html

Table 1. Risk Factors for Pandemic Influenza-related Complications or Death

Persons with high risk of illness or death	Characteristics
Persons with underlying conditions: ▪ Pregnant women	▪ Pneumonia, abortion, premature rupture of membranes
▪ Congestive heart disease, diabetes, asthma, pulmonary emphysema, or immunodeficiency (including human immunodeficiency virus [HIV]) infection, morbid obesity (BMI ≥40)	▪ Higher probability of viral or bacterial pneumonia, or clinical worsening of health condition
▪ Healthy young adults (average age < 30 years)	▪ Risk of severe pneumonia

Source: WHO. Human infection with new influenza A(H1N1): clinical observations from Mexico and other affected countries, May 2009. *Wkly Epidem Rec* 2009; 84:185-189, available at http://www.who.int/wer; CDC. Update: Novel influenza A(H1N1) virus infection worldwide, May 6, 2009. *MMWR* 2009; 58:453-458, available at http:/www.cdc.gov/mmwrhtml/mm5817a1.htm; CDC. Intensive care patients with severe novel influenza A(H1N1) virus infection. Michigan, June 2009. *MMWR* 2009; 58:1-4, available at http:/www.cdc.gov/h1n1flu/guidance/obstetric.htm.

3.2 Types of Pandemic Control Interventions

Since 1999, WHO has offered its Member States technical guidelines for preparation of national influenza pandemic preparedness plans; these guidelines were updated in 2005[1] and in April 2009.[8] The pandemic influenza control strategy combines both non-pharmaceutical and pharmaceutical interventions (Table 2).[15,16] Non-pharmaceutical interventions are based on general measures (Table 3) such as respiratory hygiene, consisting of coughing and sneezing while covering the nose and mouth with a disposable tissue, forearm or inner elbow (shirt or blouse sleeve). These procedures are known as "respiratory etiquette". [17,18] Pharmaceutical measures consist of the use of antiviral drugs and vaccines.

Since the hands can become contaminated with the influenza virus, hygienic measures for the hands should be strengthened by proper and frequent washing with soap and water. This should also be done after using public transport due to exposure to potentially contaminated objects such as the bars used to remain standing while travelling. Households, classrooms, offices, businesses, and shops should be well ventilated, clean, and free from objects contaminated with aerosols.[19] The surface of objects that are handled often should be kept clean.

Table 2. Types of interventions in the control strategy

Interventions	Characteristics	Objectives
Non-pharmaceutical	Based on hygienic measures, health promotion and education	▪ Prevent contagion through health self-care ▪ Prevent and limit transmission in the community by using hygienic measures and social distancing
Pharmaceutical	Use of antiviral drugs and specific vaccines against the pandemic virus	▪ Prevent disease through vaccination in accordance with the control objectives established ▪ Provide appropriate treatment for cases and chemoprophylaxis in accordance with health care guidelines

Source: World Health Organization. Non-pharmaceutical interventions: their role in reducing transmission and spread. 2005, available at http:/www.who.int/csr/disease/avian_influenza/pharmaintervention2005_11_3/en/i ndex.html

One of the most important non-pharmaceutical interventions is social distancing. This consists of reducing the likelihood of contact between infected persons and susceptible individuals.

The recommendations have been reconsidered in view of the evidence of lower severity and case fatality associated with the new pandemic virus. Persons with symptoms have been advised to stay home with the following instructions: ensure the household is well-ventilated, increase fluid consumption for seven days (communicable period), and go to see health services only if warning signs are present.[20,21,22]

[1] World Health Organization. WHO global influenza preparedness plan: the role of WHO and recommendations for national measures before and during pandemics. Doc No. WHO/CDS/CSR/GIP/2005.5 Available at http://www.who.int/csr/resources/publications/influenza/ WHO_CDS_CSR_GIP_2005_5.pdf.

Table 3. Non-pharmaceutical influenza interventions

Activity	Characteristics	Objective
Respiratory hygiene	Respiratory etiquette: ▪ Cover nose and mouth when coughing or sneezing with forearm or inner elbow (shirt or blouse sleeve) or with a disposable tissue and place it in a paper/ plastic bag to throw it away in the trash	▪ Prevent contamination of hands with respiratory secretions ▪ Prevent contamination of commonly used objects ▪ Prevent contamination of hands of persons being greeted
Hand hygiene	▪ Frequent hand-washing with soap and water or with an alcohol-based antibacterial solution after coughing, sneezing, blowing one´s nose, or touching a potentially contaminated surface	▪ Reduce risk of transmission to other persons and oneself
General hygiene	▪ Clean the surface of commonly used objects ▪ Keep households, classrooms, offices, workplaces, and common areas well-ventilated and free from objects contaminated with respiratory secretions	▪ Reduce risk of transmission
Social distancing	▪ Do not visit crowded places (e.g., cinema, discotheque, shopping center) ▪ Close schools that have outbreaks, in accordance with the epidemiological evaluation by local authorities due to the risk of dissemination to other groups ▪ Voluntary confinement of persons with febrile respiratory symptoms (>38°C) of abrupt onset	▪ Reduce likelihood of secondary cases and spreading the outbreak ▪ Interrupt the chain of disease transmission locally

Source: World Health Organization. Non-pharmaceutical interventions: their role in reducing transmission and spread. 2005, available at http://www.who.int/csr/disease/avian_influenza/pharmaintervention2005_11_3/en/i_ndex.html; World Health Organization writing group. Non-pharmaceutical interventions for pandemic influenza, international measures. *Emerg Infect Dis* 2006; 12:81-87; PAHO/WHO. Clean hands protect against infection. http://www.who.int/gpsc/clean_hands_protection/en/index.html; PAHO/WHO. Information for personnel and their families in the case of a pandemic influenza: Recommendations for trips, respiratory and household safety and domestic supplies (in Spanish). https:/intranet.paho.org/AM/HRM/HU/Informacion_para_el_Personal_y_sus_familias .pdf.

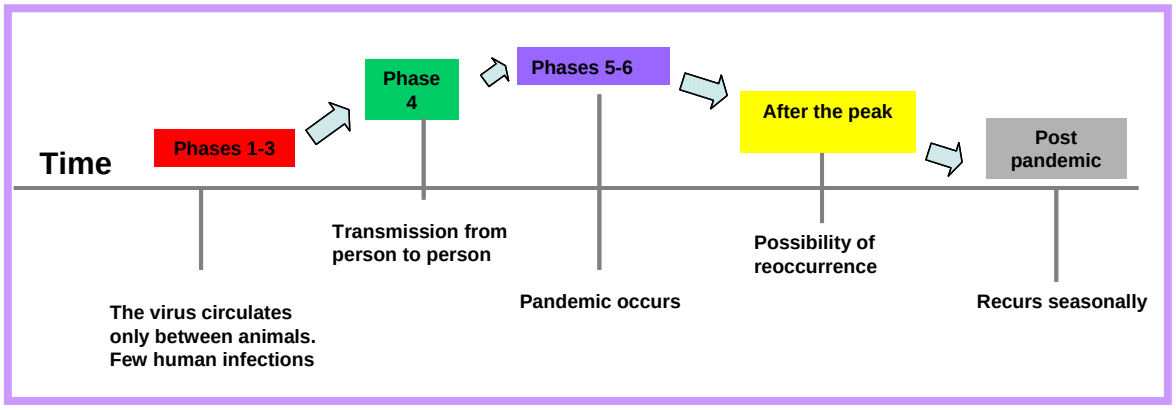
Persons living with cases of influenza can continue their lives as usual. They should monitor for the presence of fever and respiratory symptoms and, if symptoms occur, follow the household confinement guidelines. Since concentration in closed areas such as school classrooms favors transmission and spreading of the outbreak to other population groups,[23,24] in some cases it has been recommended that school be closed for a period, depending on the epidemiological analysis of the cases. However, if there is already transmission in the community, stopping classes is less important. In these situations, it is recommended that students and school personnel that fulfill the definition of suspect case not attend classes or work.[25] The education and health authorities can decide on these measures based on the local situation.

Pharmaceutical interventions are based on use of vaccines and antiviral drugs such as oseltamivir and zanamivir. Since access to the vaccine for the novel virus is currently limited, non-pharmaceutical interventions should be combined with pharmaceutical interventions, taking into account that the success of the intervention depends on the

timeliness with which it is introduced by the health services. Vaccination should be introduced in accordance with WHO guidelines.[26] According to these guidelines, the time required for distribution of the vaccine from the national level to the local level of administration should be no greater than 7 days, once the vaccine is in the national warehouse.

In view of emergence of the novel influenza A(H1N1) virus, WHO declared phase 4 on 27 April 2009. Phase 5, characterized by human-to-human transmission of the virus in at least two countries in a single region of the world, was declared on 29 April 2009. Phase 6 was declared on 11 June due to the extent of the geographic spread of the virus with community transmission in two or more WHO Regions; this declaration was not related to the severity of the disease (Figure 4).

Figure 4. Pandemic Phases Established by WHO



PAHO has supported its Member States in preparation for the pandemic as outlined in the Influenza Pandemic Strategic and Operational Response Plan, which includes vaccination. Due to the official declaration of a pandemic, the following activities are recommended:

WHO RECOMMENDATIONS FOR COUNTRIES AFFECTED

a) Pandemic influenza surveillance

1. Evaluate the first cases.
2. Monitor geographic distribution, trends and impact.
3. Document changes in the epidemiological and clinical characteristics.
4. Maintain adequate virologic surveillance in order to detect antigenic and genetic changes as well as susceptibility and pathogenicity.
5. If necessary, modify the case definitions and update the clinical and laboratory algorithms.
6. Depending on the extent of transmission, performance of a confirmatory test for each case and monitoring of viral circulation will not be required in some patients.
7. Report the trends, geographic extension, impact on the health services, and influenza-and acute respiratory infection-related mortality to PAHO/WHO each week.
8. Report immediately any changes in intensity of transmission in the most affected age group, increases in percentage of hospitalization, case fatality, antiviral sensitivity, unusual clusters of severe respiratory disease or deaths.
9. When the vaccine is available, report any sign of vaccine failure or loss of efficacy.

b) Monitoring and assessment of the impact of the pandemic

1. Monitor the essential resources: medical supplies, personal protective equipment, antiviral drugs, vaccines and other pharmaceutical resources, availability of health workers, hospital beds, alternative health units, and supplies of laboratory materials.
2. Evaluate the impact on morbidity, mortality, work and school absenteeism according to the region and risk group, and the availability of essential services personnel.
3. If sufficient resources are available, predict the disease trends and the economic impact.
4. Evaluate the impact of the mitigation measures implemented.
5. Evaluate the need for human, material, and financial resources if there are new waves of incidence.
6. Identify the lessons learned, the best surveillance and control options for the new waves of incidence, and share the experience gained with the international community.

4. Influenza Vaccines

4.1 Seasonal Influenza Vaccines

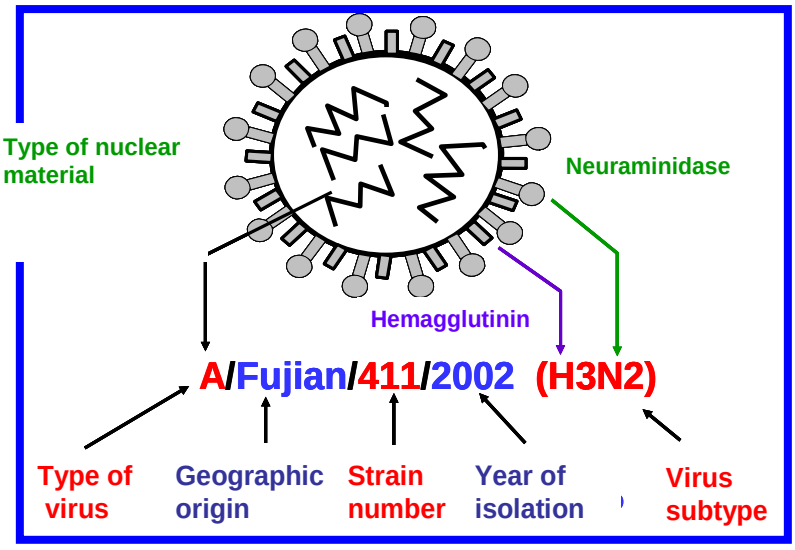
Two types of seasonal influenza vaccines are currently available: the trivalent inactivated influenza vaccine (TIV) and the live attenuated influenza vaccine (LAIV). The inactivated vaccine is most commonly used worldwide.[27] The current global production of seasonal vaccine is approximately 900 million doses. Manufacturing is conducted mainly in Australia, Europe, Japan, and North America.[28] The vaccines are usually produced by growth of the seed virus in fertilized hen eggs. The time between identification of the strain to be included in vaccine composition and availability of the vaccine is approximately 5 to 6 months (Annex A).

Given that seasonal influenza viruses undergo small genetic changes (drift) that enable them to evolve each year, the antigen composition of the vaccine is updated on an annual basis to include the most common strains identified by the WHO Global Influenza Surveillance Network (FluNet). Based on the findings of this global network, twice a year, WHO recommends the composition of the trivalent seasonal vaccine, which contains two type A viruses (H3N2) and (H1N1) and one type B virus. These recommendations are made in February for the Northern Hemisphere and in September for the Southern Hemisphere. The formulation recommended by WHO for the seasonal influenza vaccine in the Northern Hemisphere in 2009-2010 was A/Brisbane/59/2007 (H1N1), A/Brisbane/10/2007 (H3N2), and B/Brisbane/60/2008.[29]

For the southern hemisphere the composition for the 2010 seasonal vaccine will be: A/California/7/2009 (H1N1), A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008. The strain A/California/7/2009 corresponds to the current pandemic strain, which is being incorporated into the seasonal vaccine.

The nomenclature that identifies these viruses consists of the following parts (Figure 5):

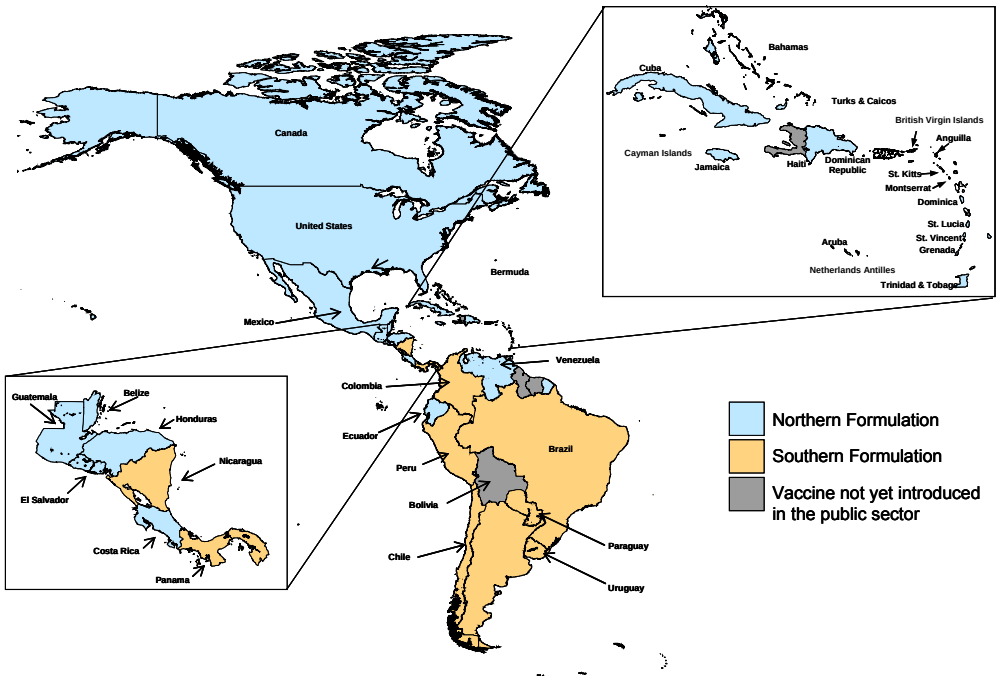
Figure 5. Morphology and Nomenclature of Influenza A Virus



The efficacy of the seasonal influenza vaccine in healthy adults ranges from 70-90% depending on the similarity of the virus in the vaccine formulation to the circulating strains, the age of administration, and the immunocompetence of the individual recipient. In persons 65 years of age and older, the vaccine can prevent 30-70% of hospitalization cases due to pneumonia and influenza. In same-age persons living in institutions for the elderly, the vaccine can prevent 50-60% of hospitalization cases and up to 80% of influenza-related deaths.[30] Vaccination of children aged 6 months to 18 years can induce herd or group immunity by decreasing circulation of the virus in the population, indirectly reducing the risk of infection in other age groups.

In the Americas, the seasonal influenza vaccine has been introduced rapidly in the past 5 years (2004-2008). Use of the vaccine in the public sector increased from 13 countries and territories in 2003 to 35 countries and territories in 2008. Twenty-six of these areas use the Northern Hemisphere formulation and 9 of them use the Southern Hemisphere formulation (Figure 6).

Figure 6. Use of Seasonal Influenza Vaccine in the Americas According to Formulation (2008)



Source: Reports of countries and territories to PAHO/WHO

Although studies conducted in the United States have found that persons over 60 years of age vaccinated against seasonal influenza have neutralizing antibodies for the pandemic virus, the history of exposure to influenza viruses in these adults should be considered, as it is greater than the exposure in other, younger age groups. This could have generated a range of antibodies with the capacity to recognize some of the molecular properties attributable to the genetic diversity of the current novel pandemic virus. Since the potential of these antibodies to protect against the natural challenge of infection is unknown, it is assumed that the vaccine against the seasonal influenza virus A(H1N1) does not protect against the pandemic virus A(H1N1).[31]

- **The antibodies generated by the seasonal influenza vaccine do not protect from infection by the pandemic influenza virus.**
- **It is important to maintain seasonal influenza vaccination because it reduces the annual burden of disease associated with seasonal virus while also reducing the risk of co-circulation and genetic reassortment of human and animal strains.**
- **Lessons learned from seasonal influenza vaccination in some areas, such as ways for vaccination programs to reach non-traditional groups, can be applied to vaccination during the pandemic.**

Expected reactions to the seasonal vaccine

The expected local and systemic reactions to the seasonal vaccine include the following:

- Local inflammatory reactions, usually minor, are very common (< 65%): pain, edema, erythema, induration, usually minor and rarely lasting more than 24-48 hours
- Systemic reactions (≤15%): fever, muscle aches, arthralgia and headache, with onset 6-12 hours after vaccine administration and lasting for 1-2 days

4.2 Pandemic Influenza Vaccine

Development of vaccines to combat pandemic influenza is a high priority. The specific vaccine to combat the novel pandemic virus is a tool for mitigation of the pandemic. According to the WHO survey, worldwide, vaccine producers have the capacity to produce 3 billion doses in 12 months.[32] Use of this vaccine should follow the recommendations for introduction of a new vaccine as included in the Field Guide for New Vaccines.[2] Although it has already been defined as a public health priority, some specific factors should be analyzed in regards to the pandemic vaccine:

- Characteristics of the vaccine and planning feasibility
- Vaccine availability
- Monitoring adverse events
- Impact on the cold chain
- Cost of the vaccine and its impact on national budgets
- Impact studies and other special research

Availability of the vaccine and its level of use depend on the following conditions:

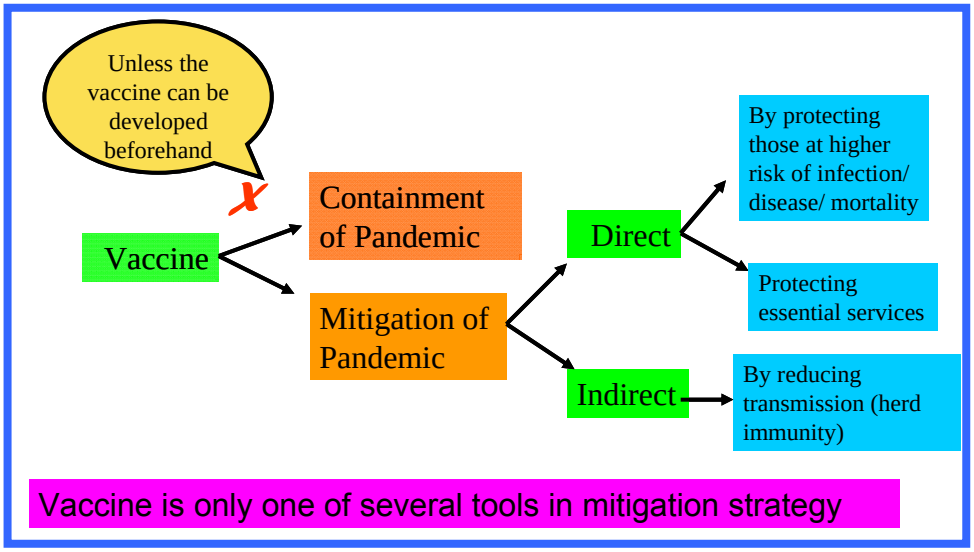
- Reduction of production time, including early preparation of seed viruses and reagents to test vaccine potency (see Annex A).
- Exploration of alternative methods of production such as fermentation technology, yield of viruses in tissue culture, and production of antigens by recombinant DNA technology. The current production of seasonal vaccine is based on growth of viruses in fertilized eggs and takes 5 to 6 months.
- Use of adjuvants that economize use of the antigen while also maintaining or increasing equivalent effectiveness at low doses of antigen, considering the number of doses required in immunologically naïve populations in order to ensure protection.

[2] Pan American Health Organization. Introducción e implementación de nuevas vacunas. Guía práctica. Publicación Científica y Técnica No. 632. 2009. Available at http://www.paho.org/spanish/ad/fch/im/GuiaPractica_NuevasVacunas.pdf.

- Existence of a vaccine distribution plan to the local level to get vaccines to individuals as soon as possible, or within 7 days of receipt at the national warehouse. Additionally, there needs to be the capacity to administer two doses if required.
- Prioritization of risk groups to be vaccinated according to epidemiological information.

The impact of vaccine use for mitigation of a pandemic occurs directly and indirectly, as shown in Figure 7. The vaccine is not useful for containment because it is prepared after identification of the virus causing the pandemic. Production of the vaccine requires several months.

Figure 7. Vaccine Impact in a Pandemic



4.2.1 Characteristics of the Pandemic Influenza Vaccine

Different types of pandemic influenza vaccines are now available worldwide, including inactivated vaccines with or without adjuvants and attenuated vaccines.

The presentation of these vaccines ranges from single-dose vaccines in pre-filled syringes or vials to multi-dose vaccine vials ranging in size from 2 to 10 doses, with different quantities of antigen and adjuvant.

Table 4. Characteristics of the Current Pandemic Influenza Vaccines

Producer	Type of vaccine		Adjuvant		Preservative		Presentation		Age groups	Dose	Number of doses	Form of administration	Interval between doses
	Inactivated	Live attenuated	YES	NO	YES	NO	Multi-dose vial	Prefilled syringe					
A	X					X		0.25 mL	6 a 35 m	0.25 mL	2	IM	≥ 3 wks
	X					X		0.5 mL	≥ 36 m	0.5 mL	1 o 2*	IM	≥ 3 wks
	X				X		5 mL		≥ 6 m	0.5 mL	1 o 2*	IM	≥ 3 wks
	X		X		X		1.5 mL + 4.5 mL adjuvant ***		≥ 3 yr	0.5 mL	1 o 2**	IM	?
B	X				X		5 mL		≥ 4 yr	0.5 mL	1 o 2	IM	≥ 3 wks
	X				X			0.5 mL	≥ 4 a	0.5 mL	1 o 2	IM	≥ 3 wks
	X		X		X		10 doses, cellular		??	0.5 mL	2	IM	?
	X			X	X		10 doses, eggs		≥ 4 yr	0.5 mL	1 o 2*	IM	4 wks
	X			X		X		0.5 mL	≥ 4 yr	0.5 mL	1 o 2*	IM	4 wks
C	X					X		0.5 mL	≥ 18 yr	0.5 mL	1	IM	
	X				X		5 mL		≥ 18 yr	0.5 mL	1	IM	
D	X		X		X		10 doses 2.5 mL + 2.5 mL adjuvant		≥ 18 yr	0.5 mL	2	IM	≥ 2 wks
E	X			X		X		0.25 mL	6 a 35 m	0.25 mL	2	IM	≥ 3 wks
	X			X		X		0.5 mL	3 a 8 yr	0.5 mL	2	IM	≥ 3 wks
	X			X		X		0.5 mL	≥ 9 yr	0.5 mL	1	IM	
	X		X		X		10 doses 1.25 mL + 1.25 Adjuvant		??	0.25 mL	2?	IM	?
F	X		X		?	?	2 doses 1 mL		3 a 60 yr	0.5 mL	1	IM	
	X		X			X	1 doses 0.5 mL		3 a 60 yr	0.5 mL	1	IM	
	X		X			X		0.5 mL	3 a 60 yr	0.5 mL	1	IM	
G	X		X		?	?	1 doses 0.5 mL		6 a 35 m	0.25 mL	2	IM	4 wks
	X		X		?	?	5 doses 2.5 mL		3 a 9 yr	0.5 mL	2	IM	4 wks
	X		X		?	?	5 doses 2.5 mL		≥ 10 yr	0.5 mL	1	IM	
H		X		X		X		Spray 1 doses 0.2 mL	2 a 49 yr ****	0.2 mL	1	Intra nasal	

* One dose for population > 9 yrs

** One or two doses depending on the results of clinical trials

*** Use within 24 hours of reconstitution

**** Healthy individuals

Figure 8. Different Presentations of the Pandemic Vaccine

Standard Multi-dose Vial

or

or

Standard Pre-filled Syringe

Multi-dose Vial and Adjuvant Vial

4.2.2 Challenges to Introduction of the Pandemic Influenza Vaccine

For the immunization programs, introduction of the pandemic vaccine is a major technical and logistic challenge due to the development of different types of vaccines and dosage forms. Some of the most noteworthy challenges are:

- Reception of different types of formulations at the same time, attenuated virus vaccines and inactivated vaccines, vaccines with or without adjuvants; complete viruses, fractionated viruses; viruses produced in eggs or cell culture.
- New products such as virus-like particles (VLP) or recombinant vaccines which may also be available on the market.
- Concomitant administration of the seasonal influenza vaccine and the pandemic influenza vaccine.
- Monitoring vaccine safety and impact.
- Vaccination of specific groups (e.g., persons with chronic diseases).

5. Objectives of Pandemic Influenza Vaccination[33]

Each country should define the main objective(s) to be reached with pandemic influenza vaccination:

- Protect the integrity of the health system and the essential infrastructure of the country.
- Reduce severe morbidity and mortality associated with the pandemic influenza. [34]
- Reduce transmission of infection in the community.

Each country will establish the priority groups to be vaccinated with the support of the national councils, national committees on immunization practices, ethics committees, and scientific societies in order to create an alliance that endorses and supports the technical decision. This procedure makes it easier for the official spokesmen to provide information to the general public on the groups to be vaccinated. It also serves to involve members of these bodies in dealing with crises caused by unsatisfied demand for vaccines or pressure from outside groups.

6. Target Populations

Since the initial worldwide production of pandemic influenza vaccine will be limited, high-risk groups should be granted priority for vaccination based on the epidemiological evidence available. To date, the pandemic has been considered moderate since most patients have an illness that remits spontaneously and does not leave sequelae. However, some groups, such as pregnant women, persons with chronic diseases, and healthy young adults, have a higher risk of serious symptoms or even death as a result of the disease. The criteria stated below are essential for defining the groups to be vaccinated. They are dynamic and their relevance must be updated on an ongoing basis.

6.1 WHO Recommendations on Priority Groups

The WHO Strategic Advisory Group of Experts (SAGE) on Immunization has emphasized that the target population groups to be vaccinated will be based on the objectives defined

at the national level. Table 5 shows the alternatives for the populations to be vaccinated based on adaptation of the SAGE recommendations to the Region of the Americas.

The national decision to achieve one or more of these objectives will depend on the epidemiological situation, resources, and access to vaccines, as well as the capacity to conduct vaccination campaigns for the target groups and implement mitigation measures other than vaccination. Vaccination should be considered a supplementary tool in response to the pandemic that includes non-pharmaceutical as well as pharmaceutical interventions other than the use of vaccines.

6.2 TAG Recommendations on Priority Groups

Since the current epidemiological situation of the influenza virus pandemic is dynamic, the PAHO/WHO Technical Advisory Group (TAG) on Vaccine-preventable Diseases supports the current recommendations of the WHO SAGE group regarding the use of the pandemic influenza vaccine. However, it recognizes that these recommendations may be revised according to current information. The following recommendations were established:

- The national objectives for pandemic influenza vaccination should be to reduce morbidity/mortality and maintain health services operational. Therefore, the priority groups for vaccination should be health workers, pregnant women, and patients with chronic conditions for more than 6 months (e.g., heart disease, diabetes, respiratory disease, immunodeficiency, morbid obesity). According to the epidemiological situation, the resources available, and the EPI capacity, the TAG recommends that countries and territories grant priority to the following risk groups: children aged 6 months to 4 years, healthy children aged 5 to 18 years, and healthy adults aged 19 to 49 years.
- Since the high annual morbidity and mortality rates are associated with the seasonal influenza viruses, seasonal influenza vaccination should be continued. When appropriate, the technical recommendations for simultaneous administration of both flu vaccines should be followed. Ongoing epidemiological surveillance of the circulating influenza strains should be conducted in order to make well-founded decisions about the future composition of the flu vaccines.
- To ensure comparability, the countries should follow the PAHO/WHO guidelines on strengthening and standardization of surveillance systems.
- The Ministries of Health should continue to strengthen the national influenza centers and influenza diagnostic laboratories by allocating more resources.
- The countries should conduct hospital-based retrospective studies to obtain more accurate information on seasonal and pandemic influenza-related morbidity and mortality.

Table 5: Population to Vaccinate According to SAGE and TAG Recommendations

SAGE (WHO)	TAG (PAHO)
1. Health care workers	1. Health workers
2. Pregnant women	2. Pregnant women
3. Population >6 months with underlying chronic conditions	3. Population >6 months with underlying chronic conditions
4. Healthy young adults (>15 years and <49 years)	4. Health population as follows: - 6 months to 4 years - >5 years and <18 years - between 19-49 years
5. Healthy children (<15 years)	
6. Healthy adults (>49 years and <65 years)	
7. Adults >65 years	

Table 6. Population Groups According to Vaccination Objective and Sources for Calculation of Goals

Objective	Group according to objective	Technical rationale	Groups and subgroups	Sources for calculation of goals
To protect the integrity of the health care system	Health workers	High priority since they are responsible for patient care. Health workers are responsible for maintaining prevention, surveillance, and field investigation. Maintain operation of the health services in order to meet demand	▪ Health workers in the public and private sector that provide direct care for patients ▪ Public health program staff: vaccinators, brigade members, field staff ▪ Ambulance and paramedical services staff ▪ Volunteers or personnel from other institutions assigned to vaccination or logistic support ▪ Administrative personnel in medical units who are in contact with patients	Salary of permanent, temporary and part-time employees in the public and private institutions where they work

To reduce severe morbidity and mortality	**Persons over 6 months of age with risk factors or underlying conditions with high risk of severe disease and risk of death**	The epidemiological evidence indicates that some groups have higher frequency or risk of acute disease, hospitalization, complications or higher mortality. For example: ▪ Persons with vulnerability associated with underlying chronic diseases, morbid obesity, asthma, immunocompromised persons, etc. ▪ In pregnant women an increased risk of severe disease has been observed, resulting in miscarriage and death, especially in the 2nd and 3rd trimester of pregnancy. In pregnant women with pneumonia due to pandemic influenza, increased rates of miscarriage and premature delivery have been reported. The risk of complications in this population group is high due to the physiological changes that occur during pregnancy, including cardiovascular, respiratory, and immunological alterations[35]. Pregnant women with underlying conditions, such as asthma, have a higher risk of complications. There is an indirect benefit of vaccination of pregnant women since children under 6 months of age are protected from seasonal influenza infection. Vaccination of pregnant women reduces incidence of febrile clinical symptoms by 36% and has shown 29% effectiveness in prevention of influenza in children under 6 months of age [36]. Prevention of influenza as a cause of fever reduces the risk of neural tube closure defect, associated with high temperature, if infection occurs during the first trimester of pregnancy [37]. ▪ In poor populations, such as indigenous populations, an apparent increase in the severity of pandemic influenza has been observed, probably due to difficulty in access to health services, high prevalence of chronic diseases and poor general health status. This was observed in Australia, Canada, the United States, and New Zealand.	▪ Pregnant women ▪ Persons with chronic diseases ▪ Immunocompromised persons ▪ Morbidly obese patients ▪ Persons with asthma ▪ Older adults (≥60 years) ▪ Poor populations	▪ Statistical database of hospital and outpatient visits according to diagnosis at time of discharge or final diagnosis respectively ▪ Identification of patients in visits to specialists ▪ Number of these patients in institutions, hospitals, health centers, clinics, and public and private consultations ▪ Data from associations or NGOs for diabetics; persons with renal problems, HIV, heart problems, hypertension, obesity; therapy groups and specialized services ▪ Surveys on prevalence of chronic disease

	Healthy adults aged 19 to 49 years	A high percentage of severe cases and deaths in healthy adults under 50 years of age in some countries (e.g., in Mexico 61.6% of deaths in persons 20-49 years of age. In the United States the average age of death is 37 years and the average age of hospitalized patients is 20 years). Given that the highest percentage of the work force is in this age group, this condition could have a significant negative socioeconomic impact in the countries.	▪ Healthy young adults aged 19 to 49 years	Forecast of population of age group to be vaccinated based on the most recent population census available

To reduce transmission of the pandemic virus in communities	**School-age population**	In the past, schoolchildren have had a high percentage of seasonal influenza infection. However, they have less risk of severe clinical symptoms in annual epidemics and they play a key role in spreading disease. Influenza-related school absenteeism does not have a direct impact on economic disruption, but it may have an indirect effect as a result of the care adults must provide to sick children. The experience acquired with the seasonal influenza vaccination has shown that vaccination of school children generates herd or group immunity that limits circulation of the virus. As a result, it reduces the risk of infection in other population groups such as older adults and persons of reproductive age,[38] [39]as well as in persons living with children and adolescents. Mathematical modeling suggests vaccinating 80% of children aged less than 19 years of age against influenza could be almost as effective as the vaccination of 80% of the population.[40]	▪ Children aged 5 to 18 years ▪ Population aged 6 months to 4 years	▪ Population forecast based on the most recent population census available ▪ School population from primary, secondary, and upper-level secondary education ▪ Immunization programs
Others		Groups identified by epidemiological surveillance and clinical information on cases		

7. Goal

All of the countries should reach the goal of vaccination of at least 95% of the priority groups and subgroups selected.

8. Components of the Pandemic Influenza Vaccination Plan

8.1 Pandemic Influenza Vaccination Strategies

The pandemic influenza virus vaccination will be administered within a short period lasting from 4 to 6 weeks as a special strategy (day or campaign). The vaccination tactics will be determined according to the target population. They will include a safety component that protects the staff, vaccines, supplies, equipment, and facilities. Some differences between seasonal influenza vaccination and pandemic influenza vaccination are shown below

Table 7. Differences Between Seasonal Influenza Vaccination and Pandemic Influenza Vaccination

Seasonal influenza vaccination	Pandemic influenza vaccination
For population risk groups identified in the past: children, older adults, health workers, persons with chronic disease, immunocompromised persons, and pregnant women	For groups or subgroups selected according to the objectives or priorities identified in each country Health workers and workers in other essential services, pregnant women, chronically ill patients, immunocompromised patients, school-age population, and young adults
Sufficient doses of the vaccine are available and are planned annually according to the specific formulation (Northern or Southern Hemisphere)	The amount of vaccine doses available may vary depending on worldwide availability and national economic resources, which are difficult to plan in advance
The vaccine requirement is planned one year earlier and the date of vaccination is predetermined	Planning for requests and administration is variable
Preventive use of the vaccine	Use of the vaccine as another mitigation tool
Objective of reducing morbidity, mortality, and complications	Objectives will be defined by each country
Combination of all the vaccination tactics	Vaccination tactics subject to the risk group to be vaccinated
Social communication to promote widespread demand for the vaccine	Differential communication according to audiences, promoting selective groups
Training of additional human resources is required	Training of additional human resources is required: vaccinators, supervisors, logistics, security, drivers
The information system for the regular program is used	New groups to be added to the information system
Planned budget	Additional budget to cover gaps and partial financing

Seasonal influenza vaccination	Pandemic influenza vaccination
Basic program logistics used	Additional logistics must be developed for: ▪ Heads of the logistics system ▪ Additional cold chain equipment ▪ Storage, packing, and repacking ▪ Transportation units and drivers ▪ Security of vehicles, facilities, staff, supplies, and equipment
Distribution according to regular planning	Distribution as rapid as possible
Passive surveillance of ESAVIs: ▪ Known adverse reactions	Active surveillance of ESAVIs: ▪ Unknown adverse reactions ▪ Increased planning errors ▪ Increased surveillance ▪ Updated crisis plan

To ensure that the logistics meets the objective of delivering the supplies to the local level vaccination sites in a maximum of 7 days, it is essential to estimate the gap between resources available and resources required. In addition, it is important to identify possible sources of financing, guarantee recovery of unused supplies/equipment, and ensure that human resources return to their institutions and everyday tasks.

To protect vaccination as a public good, and maintain public trust and credibility of the vaccination program, the vaccination safety component (i.e., safety of persons vaccinated, vaccinator, and the environment; ESAVI surveillance; crisis plan) needs to be developed.

Unsatisfied demand will be one of the most important challenges for mass communication efforts. Given the limited availability of the vaccine and the exclusive selection of some population groups for vaccination, the population that requests the vaccine should be informed that spontaneous demand cannot be filled. The reason for this situation should be explained and information should be provided on other individual and collective mitigation measures that are required. In short, mass communication will target specific audiences in order to promote vaccination of some groups and prevent uncontrolled demand by the groups that were not selected.

The information system should show the progress of vaccination. It should also record the logistics of distribution, vaccine use, human resources, transportation, equipment used, waste management and collection of excess supplies, reporting, research, and classification of ESAVIs, as well as monitoring and supervision reports. Such information will enable the preparation of the final report.

8.2 Pandemic Influenza Vaccination Tactics

The main vaccination tactics according to target group are shown below.

Table 8. Tactics according to the target population

Target group	Recommended tactics
Health workers in public and private institutions	▪ Institutional vaccination of captive population
Volunteers or personnel from other institutions assigned to vaccination or logistic support	▪ In the health services at the sites assigned according to the task to be performed
Pregnant women	▪ Case-finding in public and private prenatal departments, passively or by generating demand through social communication ▪ Community microconcentration
▪ Chronically ill patients ▪ Immunocompromised persons ▪ Morbidly obese patients ▪ Asthmatics	▪ Passive case-finding in specialized health services or by generating demand through social communication ▪ Microconcentration at headquarters of the respective organization, association or institution ▪ Partnership with professional associations
Vulnerable populations (indigenous)	▪ Passive case-finding in health services or by generating demand through the local media ▪ Community microconcentration or channeling ▪ Door-to-door vaccination
Healthy young adults aged 19 to 49 years	▪ Vaccination of captive population in public and private institutions ▪ Passive case-finding in health services or by demand generated in the local media ▪ Community microconcentration (e.g., fairs, churches, stadiums and recreation areas)
Children aged 5 to 18 years	▪ Vaccination of captive population in public and private educational institutions ▪ In health services and community microconcentration (e.g., fairs, churches, stadiums, parks)
Population aged 6 months to 4 years	▪ Passive case-finding in health services or by demand generated through mass communication ▪ House-to-house vaccination ▪ Community microconcentration
Pregnant women	▪ Case-finding in public and private prenatal departments, passively or by generating demand through mass communication ▪ Door-to-door vaccination ▪ Community microconcentration

Tactics will be defined according to the groups or subgroups selected to receive vaccination; for example, health workers will be vaccinated at their workplaces by their own institutions (vaccination of captive population) following an order based on the level of complexity and demand. If necessary, priorities will be established according to the level of risk or responsibility in individual/collective care of patients, such as performance of public health activities or vaccination.

Vaccination will be introduced by stages, in an orderly and progressive manner, in the institutions, groups, or subgroups identified previously. **A total of 95% or more of all institutions, groups or subgroups should be vaccinated.**

Another important practice is to introduce vaccination in urban or populated rural areas to achieve greater efficiency in the mobilization of resources, reduce dose wastage, and implement the lessons learned in previous mass campaigns, such as selecting the appropriate days and times for specific populations. The target groups of persons that live in remote areas or areas with difficult geographical or sociocultural access will be vaccinated at a later time, without overlooking the need to implement mitigation measures and ensure herd immunity.

9. Organization and Planning

Organization at the national, subnational, municipal, and community levels is supported or backed by two committees, **one made up of political authorities** that seeks to provide political support, endorse vaccination as a priority and a matter of national security, and ensure the financial support required for successful vaccination. **The second committee is the technical operational** committee, which should be formed and operate at all levels of management. This committee is responsible for planning, organizing, managing, monitoring, and evaluating the national or local plans, including a solid component for logistic support and security. The national technical committee will define the target groups and subgroups and will mobilize the resources that ensure implementation of the national plan (See Table 9).

It must be pointed out that the immunization practice committees, national health councils or similar entities should be included in the technical committee and form part of the permanent core group of this body. There should be functional and organic communication between the national pandemic preparedness committee and the political and technical committees of the plan regarding the use of the vaccine to combat the pandemic.

Table 9. Proposal for Formation of Committees and Functions According to Level

Level	National	Regional	Local
Political Committee	▪ President of the Republic ▪ Person responsible for pandemic plan at the national level and head of logistics ▪ Ministers of Health, Education, Women, Development and Social Welfare, Justice, Interior, Defense, Tourism, Economy and Finance ▪ Social Security ▪ Armed forces and police ▪ Professional associations, academies, and scientific societies ▪ Heads of legislative and judicial branches ▪ Churches, universities, entrepreneurs, and media ▪ NGOs that represent or channel groups to be vaccinated ▪ National mayors' association ▪ International organizations ▪ National emergency operations committee ▪ Interagency Coordinating Committee	▪ Subnational and local health authorities ▪ Governors ▪ Representatives from each institution at the national level ▪ All government organizations or NGOs that represent or mobilize groups to be vaccinated at the national or subnational level	▪ Mayors and governors ▪ Representatives from churches and community organizations ▪ Directors of educational institutions ▪ NGOs that represent or mobilize groups to be vaccinated at the local level
Functions	✓ **Provide political support to implement vaccination as a mitigation strategy against the pandemic** ✓ **Guarantee the safety component in all stages of vaccination** ✓ **Guarantee financing and support with the required human resources, equipment, and logistics** ✓ **Ensure coordination and active participation in multisectoral actions** ✓ **Lead the implementation of pandemic vaccination**		

Level	National	Regional	Local
Technical Committee	• Ministries of Health and Defense, Armed Forces and police commanders • Director of emergencies and disasters • Person on the national level responsible for pandemic preparedness plan • Head of logistics • General director of personal health • Immunization coordinator • National directors: administration, statistics and computer science, epidemiology, drugs, and mass communication • Chronic disease specialists • National Committee on Immunization Practices	• Subnational directors • Personal care director • EPI Coordinator • Managers of administration, statistics and computer science, epidemiology, drugs, communication	• Director of the network and/or micro network • Health chiefs • Local EPI coordinator • Multidisciplinary team
Functions	✓ **Plan, organize, manage, monitor, and evaluate the national plan, including the logistic support and security component** ✓ **Mobilize resources that guarantee implementation of the national plan and resources to correct the gaps identified** ✓ **Define the groups and subgroups to be vaccinated** ✓ **Guarantee the supply of vaccines, syringes, and other supplies** ✓ **Define the work duties and methodology of the technical teams responsible for each component** ✓ **Prepare technical and operational guidelines** ✓ **Confirm the mass communication strategy on vaccination for the public, authorities, and health workers** ✓ **Prepare the final campaign report**		

At each level of management (state/department/province, district/jurisdiction, municipality/canton) a general coordinator and a head of campaign logistics should be appointed, both of whom will report to the general coordinator of the pandemic response plan at their respective level.

10. Planning and Micro-planning

Planning for the different phases of vaccination is essential. It should include micro-planning at the local level. For the purposes of this campaign, micro-planning will be adapted to the groups to be vaccinated according to partial vaccine delivery and considering the administration of two doses to individuals aged less then 9 years with a minimal interval between doses of 2 to 4 weeks, depending on the vaccine's presentation. For pandemic influenza vaccine micro-planning, the same instruments should be utilized as those used in the campaigns against rubella and congenital rubella syndrome.

To be efficient and effective due to the limited availability of vaccine, TACTICS should be framed in local micro-planning to ensure coverage of 95% or more of the goal established for each group or subgroup

Table 10. Key elements to micro-planning according to the target population

Target group	Key points for micro-planning
Health workers in public and private institutions	▪ Easy access since they are captive ▪ Previous census based on institutional listing ▪ Easy identification and approach of subgroups ▪ Supervision and strict monitoring of coverage is required ▪ Timetable for delivery of supplies and vaccination ▪ Require detailed technical information ▪ Coverage is feasible in the short term
Volunteers or personnel from other institutions assigned to vaccination or logistics	▪ Vaccination of personnel ▪ Require general information ▪ Coverage is feasible in the short term ▪ Coverage monitoring is required
Pregnant women	▪ Vaccination in health services or the community ▪ Variable accessibility ▪ Require information on vaccine safety ▪ Medium- to long-term coverage ▪ Need to generate demand by mass media, local media, or social networks
• Chronically ill patients • Immuno-compromised persons • Morbidly obese patients • Asthmatics	▪ Hard-to-reach (fear, limited culture of prevention, unaware of condition, unorganized groups, limited service offer) ▪ Census of institutions where it is feasible to find them ▪ Census of patients from institutions identified ▪ Require detailed technical information ▪ Coverage is feasible in long term due to difficult case-finding
Vulnerable populations (indigenous) concentrated	▪ Poor access to health services (geographical and cultural) ▪ Requires development of all micro-planning components and tactics ▪ Requires massive use of communications media in their own language ▪ Require general information ▪ Medium- to long-term coverage is feasible ▪ Need to establish priorities for urban and populated rural areas
Healthy young adults aged 19 to 49 years	▪ Census of captive working and student population ▪ Require general information ▪ Coverage of the captive population is feasible in the short term
Children aged 5 to 18 years	▪ Census of the captive population in public and private educational institutions ▪ Fulfill the timetable for two rounds if necessary ▪ Require general information ▪ Short-term coverage is feasible
Population aged 6 months to 4 years	▪ Need to generate demand by mass media, local media, or social networks ▪ Require general information for parents and caregivers ▪ Coverage of captive population in the short term is feasible ▪ Fulfill timetable for two rounds

11. Vaccination Safety

Vaccination safety includes different elements, from production to quality control of the product, its evaluation and efficacy and safety guarantee, transport and distribution, implementation of adequate practices for the use and administration of the biological, and an adequate surveillance system after commercialization.

Seasonal influenza vaccines have been developed and introduced in the countries safely and efficiently. Most of the new pandemic influenza vaccines are being manufactured with the same technologies used for production of the seasonal vaccine. However, some manufacturers are using new technologies (e.g., production in cell lines) or new adjuvants. This could lead to the need to consider these products as new developments and the implementation of controls to guarantee their safety and efficacy. Additionally, the use of a vaccine presentation where adjuvants are supplied in a separate vial from the antigen is not found in any other current vaccines being used in the EPI program. This new presentation increases the possibility of programmatic errors. Moreover, use of adjuvants that have not been used (or have been used on a very limited basis) in humans could cause adverse reactions that are unknown, or for which there is no evidence of their association with a vaccine. There may also be increased reports of evens supposedly associated with the vaccine on temporary basis. This scenario could lead to an unforeseen public health crisis. If such a situation is not managed appropriately and efficiently, it may negatively impact the level of trust of the population in vaccination and be detrimental to the credibility of the health services. For these reasons, the importance of strengthening ESAVI surveillance systems needs to be emphasized to countries.

- **Vaccine quality assurance from the time of manufacture until the batches are released in the country by the National Regulatory Authority.**
- **Storage, conservation, and transport of the vaccine and other supplies in appropriate cold chain conditions to maintain their quality and safety.**
- **Safe injection practices and appropriate open vial practices.**
- **Biosafety, handling, and final waste disposal standards and practices.**
- **Timely, thorough, and transparent ESAVI surveillance.**
- **Prevention of crises due to ESAVIs or conflicts over unsatisfied demand for the vaccine.**

The population's fear of disease associated with insufficient vaccine availability could generate an unjustified level of demand that cannot be met and could lead to social crises, as occurred during the yellow fever outbreak in Paraguay in 2007. In order to prevent the risk of such crises, it is essential to have a social communication strategy that involves the mass media and includes spokespersons with superior technical credibility from the highest political and professional levels. Therefore, crisis plans must be reviewed and updated without delay. The fundamental cornerstones of safe vaccination are based on guaranteeing three elements:

1. Safety of the persons vaccinated
2. Safety of the vaccinator
3. Safety of the environment

11.1 Regulatory Considerations for the Pandemic Vaccine

Pandemic influenza vaccines represent a new challenge for the national regulatory agencies (NRAs), which should establish new mechanisms for evaluation of these products that allows them to guarantee their safety and efficacy while also facilitating timely access to such products.

As part of the pandemic influenza preparation plan, the World Health Organization has assembled groups of regulators from throughout the world. Special guidelines have been established for regulation of these new products due to the need for their immediate use. The WHO documents *Biosafety risk assessment and guidelines for the production and quality control of human influenza pandemic vaccines* (WHO TRS No. 941, 2007, pages 265-290) and *Regulatory preparedness for human pandemic influenza vaccines* (WHO/BS/07.2074) offer a series of tools that are useful for regulation and control of these products.

If a manufacturer has produced seasonal influenza vaccines with consistent quality, the regulatory agency has evaluated their production facilities in compliance with Good Manufacturing Practices, and no severe adverse effects have been reported in association with the product, implementation of accelerated (fast-track) procedures for registration and release of these products is recommended.

A regulatory challenge is presented by those manufacturers offering vaccines developed with new technologies that have not been evaluated previously, as well as those manufacturers using new adjuvants as part of their pandemic vaccines, for which there is limited experience of use in humans. These products will require a more rigorous evaluation, such as the one applied to any new product, including product registration, inspection of Good Manufacturing Practices, laboratory testing, batch release, clinical studies, and active post-commercialization surveillance.

11.2 Injection Safety

The response to an influenza pandemic implies an increase in the amount of syringes used. Therefore, the authorities should create the additional capacity required to safely collect the syringes, needles, and vaccine vials, transport them to the designated sites, and dispose of them properly. The main activities to be developed and monitored to ensure safe injection are summarized in Table 11.

Table 11. Safe practices before, during, and after the campaign

Logistics activities before the campaign	Logistics activities during the campaign	Logistics activities after the campaign
▪ Training for supervisors ▪ Storage ▪ Storeroom management ▪ Stock syringes and biohazard containers ▪ Review of the pandemic vaccine presentation ▪ Review of good practices for administration of the injection: ✓ Techniques for administration of the injection ✓ Management of open multi-dose vials ▪ Prepare a plan for collection of sharps waste	▪ Use sterile injection equipment ▪ Inspect the integrity of the packaging ▪ Select the site for administration of the injection ▪ Do not leave the needle in the vial stopper ▪ Follow the open vial policy: ✓ When adjuvant is used, dispose of the vaccine within 6 hours or according to the instructions provided by the manufacturing laboratory ✓ When adjuvant is not used, dispose of the vaccine within 4 weeks or according to the manufacturer's instructions	▪ Prevent needle injuries - Do not recap the needle ▪ Appropriate collection of safety boxes ▪ Appropriate transport of safety boxes to the final disposal site

Aspects Related to Good Injection Safety Practices

1. Whenever possible, use devices and procedures designed to prevent needlestick injuries that have been proven to be effective.
2. The use of autodisable syringes is preferred because they prevent reutilization, reducing programmatic errors and needle stick accidents by health care personnel.
3. Wash hands (i.e., wash or disinfect them) before preparing material and administering the vaccine.
4. Wash hands with soap and water between injections, particularly if they have been in contact with dirt, blood, or body fluids.
5. Avoid administering a vaccine in areas of the skin with local infection or another skin disease (e.g., exudative dermatitis, skin lesions, cuts).
6. It is not necessary to clean vaccine vials or bottles with an antiseptic or disinfectant.
7. If you clean the vaccine vial stopper with an antiseptic, use a clean, single-use cotton pad.
8. Do not use moist cotton pads that are kept in a multi-use container.
9. Use a sterile syringe and needle for each vaccine dose administered.
10. Clean skin with a cotton pad moistened in sterile water using a circular motion.
11. Use a syringe for each dose of reconstituted vaccine.
12. Use disposable needles and syringes of certified quality.
13. Inspect the integrity of the syringe packaging.
14. Discard the syringes and needles with packaging that has been perforated, broken or damaged as a result of exposure to moisture.
15. Prepare each dose of vaccine in an appropriate place to prevent contamination.
16. If multi-dose vaccine vials must be used, use a different needle and syringe to load each dose.
17. Never leave a needle in the vial stopper.
18. Inspect and dispose of visibly contaminated vaccine vials that are no longer complete (e.g., breakage, submerged in water, unlabeled, leaks).
19. Follow the recommendations for use, conservation, and handling of the vaccine.
20. Dispose of any needles that have been in contact with a non-sterile surface.
21. Plan for abrupt movements by the patient during and after the injection, and take measures to prevent them.
22. Do not recap the needle.
23. Collect the used syringes and needles in the biohazard container recommended by the program and seal the container when it is full. The biohazard container should be located in the place where the vaccine is administered.
24. Seal the biohazard containers before transporting them to a safe area until they are disposed of.
25. After closing and sealing the containers, do NOT reopen, empty, reuse, or sell them.

11.3 ESAVI Surveillance

In accordance with the TAG recommendations, countries should conduct retrospective studies to calculate the baseline rates of Guillain-Barré syndrome (GBS) in order to facilitate detection of any changes in GBS incidence associated with circulation of the pandemic influenza that may be related to the pandemic influenza vaccines.

Countries should monitor the following events during introduction of the vaccine:

1) severe events (events that require hospitalization, are life-threatening, cause disabilities, or are fatal),
2) new events,
3) Rumors,
4) events occurring in population groups, and
5) programmatic errors.

11.3.1 Activities Prior to Vaccine Introduction

- Establish the GBS baseline based on PESS data (AFP surveillance) and estimate the rate per million children under 15 years of age.
- Conduct retrospective institutional active case-finding and estimate the rate of GBS per million inhabitants in other age groups based on the database for hospital discharges in the past 5 or 10 years.

11.3.2 ESAVI Surveillance During Vaccination

To conduct ESAVI surveillance, the main events to be monitored[41] are as follows:

1. Conditions characterized by acute flaccid paralysis in the target groups with the following medical diagnoses:
    a. Guillain-Barré syndrome (GBS)
    b. Polyradiculoneuritis or nonspecific polyradiculopathy
    c. Transverse myelitis (TM)
2. Unusual clinical symptoms, clusters of ESAVIs in vaccinated persons or deaths.
3. Anaphylaxis.
4. Rumors.

Guillain-Barré Syndrome

The annual incidence rate for GBS with any etiology is approximately 1 to 2 cases per 100,000 adults (CDC, 1998) and 0.91 cases per 100,000 in children under 15 years of age (Olivé and Castillo Solorzano, 1997). The relative risk of GBS after seasonal influenza vaccination was not statistically significant in several studies (Kaplan et al., 1982; Hurwitz et al., 1981). Another study recognized that GBS is an authentic adverse reaction. However, the estimated risk of 1 or 2 cases per million vaccinated persons is less than the risk of developing severe influenza (Lasky et al., 1998). The literature also reports an attributable risk of 9.5 cases of GBS per million doses of swine flu vaccine administered in 1976. In this case the vaccine was withdrawn from the market (Hurwitz et al., 1981). These findings provide a rationale for monitoring GBS during epidemics, inter-epidemic periods, and vaccination campaigns.

On the other hand, the WHO Advisory Committee on Vaccine Safety (GACVS) considers that large-scale studies of GBS incidence before and after vaccination are needed to identify a possible causal relationship between the seasonal vaccine and GBS.

11.3.3 Committee and Crisis Plan

The committees should be reactivated and the crisis plan should be updated to guarantee the following results:

- **Rapid response to investigation, including rumors**
- Timely and transparent approach regarding the ESAVI with the patient and family members, as well as with the media.
- **Identification of the spokesperson in charge of presenting a positive outlook to the news and/or the rumor and ensuring the media are considered as partners.**
- Involve the Immunization Practice Committee and the scientific societies to endorse and circulate the results.
- **Maintain the trust of the population in the vaccines and protect the credibility of the program and the health services.**
- Include the legal aspects and explore the feasibility of implementing mechanisms to guarantee the financing of care in the acute phase of the clinical manifestations.

Finally, the ESAVIs reported should be recorded, investigated, and classified according to the WHO/PAHO or country manual on vaccination safety. Such events should also be included in the final report.

As of October 2009, the available data in more than 20 countries with several million doses administered show that vaccine are safe. As of now there are no data related to severe adverse events.

PAHO/WHO, as well as National Regulatory Authorities and national public health authorities, maintain a close ESAVI surveillance.

12. Logistics of Distribution and Security

Logistics is defined as "the art of managing and controlling the supply chain in order to ensure the flow of sanitary material, vaccines, auxiliary supplies, and other resources in distribution or redistribution within a country or region." Well-managed logistics will support a good deployment plan. **The supply chain logistics includes:**

- Reception, storage, packing and transport of vaccines and other supplies,
- Definition of supply chain processes,
- Identification of the need for additional resources that will be required according to the gap between "what is possible today" and "what will be needed" for distribution, and
- Performance of simulations in order to evaluate how prepared the country is to respond.

Each country should document the capacity of the supply chain to safely receive, store, pack, and distribute the vaccine and other supplies to the distribution sites from the designated national and subnational warehouses at all levels under the supervision of the persons responsible for logistics.

ONCE THE VACCINE IS IN THE NATIONAL WAREHOUSE MUST BE SENT TO THE APPROPRIATE AREAS AS SOON AS POSSIBLE.

12.1 Vaccine Characteristics

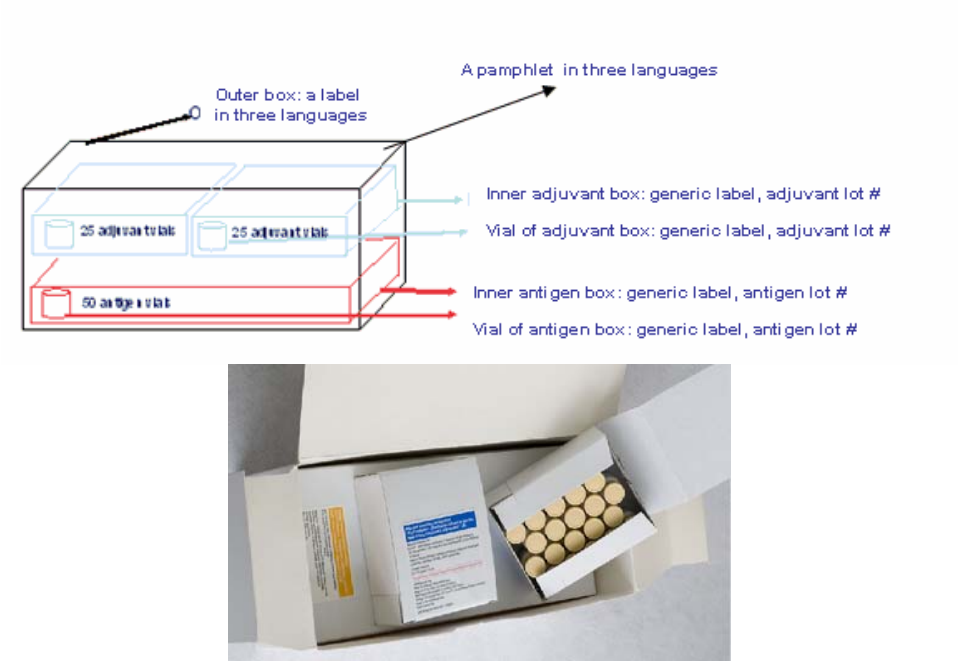
To estimate the storage capacity for vaccines, the following data should be taken into account:

- ✓ Name of vaccine (description on label),
- ✓ Manufacturing laboratory,
- ✓ Origin of vaccine, shipment date, and transport data ,
- ✓ Lot number and amount of doses received for each lot,
- ✓ Date of manufacture and expiration,
- ✓ Vaccine presentation (pre-filled syringes or single- or multi-dose vials),
- ✓ Presentation with adjuvant separate,
- ✓ Volume of each vial or pre-filled syringe,
- ✓ Volume of primary packaging material for vials, adjuvant, or pre-filled syringes,
- ✓ Volume of secondary packaging material for vaccines and syringes,
- ✓ Percentage of wastage according to the open vial policy (see vaccine insert).

This information will be used to estimate the needs for the cold chain, storage, and transport of vaccines, syringes, and safety boxes, using the Excel tool designed for this purpose.

The pandemic influenza vaccine should be stored and transported at temperatures between 2ºC to 8ºC in order to conserve its potency. The appropriate containers should be used for transport in order to maintain the vaccine at these temperatures. The syringes should be stored in dry conditions. They should not be exposed to materials or liquids that discharge chemical gases.

Figure 9. Packing Pandemic Influenza Vaccines and Adjuvant



12.2 Basic Duties and Responsibilities of the Head of Logistics

The head of logistics and his team are responsible for performance of supply chain logistics. His main duty is to plan and arrange for supply chain operations, including financing and management.

The logistics process involves:

- **information on inventories: timely monitoring of movement of vaccines and other supplies,**
- **storage: materials received and dispatched,**
- **packing and repacking of materials: vaccines in cold boxes and syringes in other boxes,**
- **timetable for distribution and forms of transport: land, air, and sea or river.**

12.2.1 Planning Prior to Pandemic Vaccination

- Describe the objectives and activities in the deployment plan that are related to the supply chain processes;
- Evaluate the capacity of the central and subnational warehouses to store and rapidly repack the quantities of pandemic influenza vaccine for shipment to the assigned distribution sites;
- Establish the current logistics capacity to ship a vaccine within at least 7 days and determine the gaps between "what can be done today" and "what will need to be done as soon as the vaccine is available";

- Prepare a diagram of the supply chain that describes movement of vaccines and other supplies from the national level to all state levels, until they reach end users at the local level;
- Plan the supervision required for effective monitoring of vaccine distribution throughout the supply chain;
- Coordinate with the persons responsible for information and communication to determine the variables, data, and other specifications of the information required to support the supply chain processes;
- Document the estimated distribution costs and update the calculations on a regular basis;
- Prepare a plan with national security institutions, armed forces, police, and private companies to provide **security for logistics personnel, equipment, facilities, vaccines, and other supplies**.
- Formulate, review and update contracts with all transportation companies and suppliers that support distribution. Check their regular operations in order to ensure they can provide support during vaccination.

12.2.2 Basic Data on the Supply Chain and Logistics Plan

- Calculation of the amount and volume of vaccine and other supplies to transport to each site.
- Calculation of the capacity to temporarily store the vaccines and supplies by level.
- Calculation of the amount of cold boxes and containers for vaccine transport to each site.
- Calculation of the current and additional capacity to produce ice packs by levels.
- Calculation of the available and additional resources for transport by air, land, and waterways.
- Design procedures, forms, checklists, and reports to support distribution, including contact lists, shift planning forms, inspection or supervision visits with checklists to authorize warehouses, reception sites, repacking processes, call registries, etc.
- Budgets and resources.
- Dates planned for evaluations and simulations.

The following needs and capacities should be evaluated at each level:

- Storage capacity;
- Volume of vaccines and other supplies to be received and stored;
- Amount of vaccine and other supplies to be repacked; time and resources required;
- Distribution sites and their needs for cold boxes or transport containers;
- Current ice pack production capacity, including own capacity and private sector;
- Transport network: percentage of sites accessible by land (e.g., car, bus, motorcycle or bicycle), water (e.g., sea, lake, or river), and by other means (e.g., air);
- Percentage of distribution sites that are **connected** to the communications network;
- Cost per kilometer/hour traveled, according to type of transport;
- Insecure sites that require protection of personnel, equipment, and supplies;
- Companies that can be or are hired for supply chain services.

Tools such as **flow charts and geographic information systems** can help with evaluation and improve the successful delivery of vaccines and other supplies

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12.2.3 Distribution of Vaccines and Other Supplies

The deployment operation includes the seven operations described below as well as the activities performed before and during vaccination.

1. Reception of vaccines and other supplies
2. Storage
3. Repacking
4. Production or purchase of ice
5. Transport
6. Management of supply chain information
7. Communications technology

The experience gained in the vaccination campaigns is very useful for understanding the required logistics and supply chain. Once an action plan is available for the supply chain, all activities should be tested in order to validate their effectiveness.

During pandemic vaccination, the safety of the supply chain and the personnel that support vaccine storage, distribution and transport should be guaranteed. It is essential to forecast the safety levels for the personnel, facilities, and equipment required.

12.2.3.1 Reception of Vaccines and Other Supplies

Description: Tracking of all shipments of vaccines and other supplies received and stored in the warehouses	
Before vaccination	**During vaccination**
• Create a map with the sites (national warehouses and others) and record each site in the information system. If the private companies provide warehouses, record them also.	• Record the arrival of vaccines and supplies by signing for reception and maintenance in the management information system registry (e.g., number of doses, batch numbers and expiration dates). • Use the registries to determine the person responsible for vaccine reception, repacking and shipment • Issue reports on vaccine reception at the destination sites immediately in order to confirm arrival of the shipments and keep a record of the items stored at each distribution site

12.2.3.2 Storage of Vaccines and Other Supplies

Description: Temporary storage of vaccines and other supplies in the national warehouses before they are shipped to the designated sites	
Before vaccination	**During vaccination**
• Determine the public establishments at the national, subnational and local levels that can store vaccines and other supplies that require a cold chain. • Contract private refrigeration warehouses when required as supplementary storage capacity. • Keep signed copies of the contracts and ensure that they are valid at the time of vaccination. • According to EPI standards, evaluate in each establishment: - Operation of the cold rooms to ensure correct temperature range - Procedures to detect and report temperatures outside the appropriate range - Train staff on vaccine storage, packing, and shipment - Security system to prevent supply losses - Continuous temperature recording device and auxiliary generators to ensure electricity supply if there is a power outage • Define the data for monitoring cold chain temperatures and establish an accountability process for storage of vaccines and other supplies.	• Notify the public establishments of the beginning of deployment operations and activate the storage facilities. • Safeguard the delivery of support services (e.g., food, water, hygiene) for the personnel in charge of the warehouse. • Call the personnel to the workplace in the event of emergency. • Report on the status of the shipments en route to the warehouses. • Ensure that only authorized personnel enter and leave the warehouses, which should be controlled by security personnel. • Evaluate on a periodic basis, without prior notice, whenever there is a change in the administration of the private warehouses.

12.2.3.3 Repacking Vaccines and Auxiliary Supplies

Description: Divide the shipments into smaller shipments, repack in cold boxes or refrigeration trucks, and send to the designated sites	
Before vaccination	**During vaccination**
• Plan the minimum number of repacking operations. Define the size of the shipments according to the needs of the population at each destination and ship the vaccines through the smallest possible number of distribution sites required to reach their destination. • Plan the supply of enough cold boxes of different sizes to ship different amounts of vaccines according to the requirements of the local populations. • Inspect the physical integrity of the containers on a regular basis and replace them as needed. • Ensure that sufficient trained staff is available. • Determine the need for training of the staff that will receive, store, repack, and ship the vaccine.	• Indicate the number of vials per pack and the expiration date on the outer part of the transport containers and cold boxes. • Adhere to the cold chain management protocols. • Use procedures and devices to prevent improper handling. • Provide temperature control devices in each shipment box or cold box so that the warehouses or others that receive them can verify that the temperatures have been maintained at the correct levels. • Inspect the physical integrity of the cold boxes and replace them as needed. • Repack the vaccines, needles, syringes, and other supplies together so that the health services can administer the vaccine.

Observations

Take into account that repacking vaccines multiple times is inefficient, leads to errors and vaccine wastage and wasted time. Shipments should be unpacked and repacked in functional packages. The size of the packages will depend on the needs of the department and the vaccination brigades. The repacking of vaccines and other supplies should be performed in accordance with the vaccine packing protocols established by the ministries of health and the manufacturers.

12.2.3.4 Production or Purchase of Ice for Vaccine Repacking

Description: Produce sufficient ice or freeze sufficient ice packs to maintain the vaccine and the shipments at all levels	
Before vaccination	**During vaccination**
• Calculate the amount of ice or ice packs that should be available for the shipments. • Evaluate the capacity of the public and private facilities and equipment available to provide ice or ice packs. • Contact private companies if the production of ice or ice packs is insufficient.	• Monitor the production of ice and ice packs on a continuous basis to detect and resolve any problems that can affect deployment

12.2.3.5 Transport of Vaccines and Other Supplies

Description: Transport the vaccines and auxiliary supplies to the designated sites by land, air or sea	
Before vaccination	**During vaccination**
• Determine how to transport the vaccines and other supplies to the predetermined distribution sites and then classify them by type of route and means of transport required. • Determine the routes that are high risk due to geographical or security conditions in order to identify resources that guarantee protection of personnel and products. • Establish delivery and shipment calendars for each level. • Determine the number and location of trucks, ships, airplanes and other available means of transport; transport operators (e.g., drivers, pilots, ship operators) and the location of the fuel supply and repair sites. • Calculate the transportation costs, including the per diem expenses for the transport operators. • Update the contact information of the transport operators on a regular basis. • Organize simulations of the transport operations and resupplying fuel.	• Monitor availability of all transport resources and operators. • Ensure the availability of fuel. • Monitor the establishment of timetables and procedures for shipment of remittances. • Monitor the progress of the shipments to detect security problems, climate conditions and road conditions that could affect the delivery periods. • Work with the law enforcement agencies to provide security. • Ensure that the peripheral warehouses and health services promptly report the arrival and condition of the shipments. • Guarantee sufficient inventory of appropriate containers for vaccine shipment if refrigerated vehicles are not used.

12.2.3.6 Management of Supply Chain Information

Description: Provide the supervisors and personnel access to the reliable and timely information required to handle the supply chain activities	
Before vaccination	**During vaccination**
• Evaluate the management information system and change it, or if necessary, create a new system for supply chain operations. • Record and disseminate information on transport, reserves, and human resources and ensure that the managers and personnel have access to data on: - Transport: details of the network, type of transportation available (e.g., trucks, ships, and airplanes); location and operational condition of these; public and private institutions that provide the vehicles; time calculated to travel each route; amount of fuel and oil required and location of fuel and repair providers; - Inventory of supplies at all levels: balance, expiration date and batch number of the vaccines and other supplies; wastage of vaccines and other supplies; date and form of shipment of orders; conditions of reception; condition of the warehouses. - Human resources: list that shows the type and number of human resources by required function at each level; condition of human resources (availability and health). • Prepare with civil authorities the information protocols that the system will provide on the condition of the vaccines and other supplies. • Use the data from the information system to confirm and document the existing resources for transportation, supplies and human resources (according to capacity and availability), mobilization of resources and additional capacity required for deployment within 7 days. • Test the management information system before a pandemic. • Train personnel on use of the management information system.	• Use the information system to: - Contact the warehouses and mobilize their personnel; - Monitor the delivery of vaccines in order to identify delays due to traffic, climate, threats, or other factors to be resolved by the head of logistics and the security agencies; - Dispatch the vehicles and operators; - Withdraw vaccine lots at the request of the Ministry of Health due to ESAVI or damage; - Determine whether there is insufficient personnel at the distribution sites; - Contact the transport companies and locate additional human resources; - Report on the status of the operations to the supervisors - Update the information system in order to record reception, shipment of vaccines and other supplies, the condition of the shipments and the transportation resources, when required

12.2.3.7 Communications Technology

Description: Provide the head of logistics, managers and supervisors with communications media and access to the information they need in order to perform deployment effectively; implement effective controls and make rapid decisions to resolve problems promptly	
Before vaccination	**During vaccination**
• Define the current national communications network together with the appropriate ministry and, if necessary, with private companies with communications networks and services. • Evaluate the current system to determine all distribution sites in the country can be connected. • Determine and document the areas that lack communication with the distribution sites and the transport operators. • Document the gaps where supplementary capacity will be required during the deployment operations. • Ensure that the communications equipment (e.g., radios, fixed phones, cellular and satellite phones, radio phones and e-mail) are maintained, configured and prepared for immediate deployment to support the flow of data, reports and updates at all times. • Record appropriate information (e.g., frequencies, telephone numbers, e-mail addresses) in the information system in order to communicate with the head of logistics, managers and the persons that use the communications system. • Plan and configure the communications system to ensure that the managers have access to the information on transport, the inventory of supplies, and human resources. • Train personnel on use of the communications equipment and usual communications protocols.	• Safeguard the constant availability of technical personnel to support the communication system and equipment during deployment.

12.3 Security

The fear caused by the pandemic in the community and the limited availability of the vaccine for the entire population may lead to insecure situations or conflicts. These circumstances should be foreseen and activities should be planned to ensure the safety of the persons, facilities, equipment, and vaccines.

Description: Protect the deployment and logistics personnel, equipment, facilities, and vaccine inventories. Vaccines should arrive at the distribution site without any incidents and be stored in secure facilities to prevent theft.	
Before vaccination	**During vaccination**
• Determine the high-risk areas where there could be civil disturbances. • Coordinate the preparation of a plan to protect deployment personnel, equipment, facilities, and vaccines with the appropriate agencies, armed forces, and local authorities. • Consider the security requirements in high-risk areas with community leaders and request their assistance to provide security. • Determine the degree and location of the security components that can be supplied by the government offices and obtain their consent to provide them. • If necessary, hire private security companies to provide the additional services required for the deployment operations. • Perform risk assessments on a regular basis, particularly in high risk areas, and use the results to improve the security of fixed facilities and routes.	• Ensure that supervisors report on the security situation in their respective areas on a regular basis. • Ensure that the transport operators have communication devices to report any security problem and request assistance in transit. • Monitor the climate conditions, construction activity, and other factors to determine the delivery routes that should be avoided.

12.4 Waste Management

Purpose: **Plan the supplementary capacity required to collect the waste generated by pandemic vaccination without risk, transport the waste to the designated sites, treat it, and safely dispose of it.**

Waste management is the process of collection and disposal of the sanitary waste produced by vaccination. Appropriate collection and final disposal of hazardous waste will eliminate the potential risk to the health of health workers and the public, and protect the environment.

Hazardous waste disposal is usually managed through national or local laws in each country. The head of logistics should know the relevant regulations and request the hazardous waste disposal standards from the office responsible for waste disposal. If the specific regulations are insufficient, the head of logistics and the office responsible for waste disposal should develop additional measures to ensure safe waste disposal.

The head of logistics should establish direct coordination with the municipal offices responsible for safe collection and disposal of hazardous waste and ensure that they understand:

- The amount of waste that will be generated by vaccination;
- The importance of active participation in waste management planning prior to vaccination as well as management during the event.

The response to an influenza pandemic will generate a large amount of hazardous waste (e.g., vaccine vials, needles, and syringes) at vaccination sites throughout the country. The authorities should mobilize resources and additional capacities during deployment for collection, transport, and disposal of hazardous waste. These actions should be conducted based on a plan to minimize the risks.

The Expanded Program on Immunization (EPI) includes the national standards for disposal of hazardous waste. Countries have also had the experience of campaigns with a high volume of waste. Therefore, additional management and disposal measures are required. The pandemic influenza campaign will generate significant amounts of waste depending on the target group. Countries should plan now to ensure they have sufficient capacity to handle the waste generated by pandemic vaccination activities.

12.4.1 Objective of the Waste Management Component

The objective of the waste management component is to provide guidelines to be followed by the head of logistics and staff members responsible for planning and management of disposal of used injection materials, vaccine vials, and other hazardous waste using the current sanitary waste management systems and develop supplementary skills for management of vaccination-related waste. The need for detailed records on the activities

of this component in the information system is also described, emphasizing collaboration with the municipal authorities, other entities, and private companies.

12.4.2 Steps

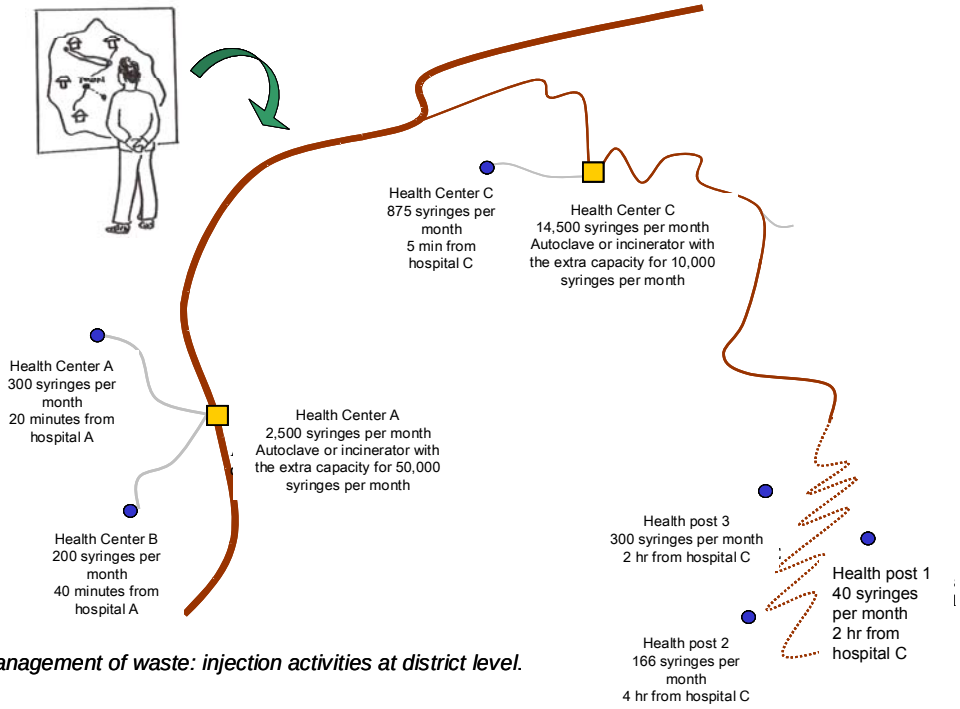
The preparation of a hazardous solid waste management plan consists of three steps.

Step 1: Evaluate the current capacity

- Prepare a list of national regulations and codes related to collection and disposal of hazardous waste, especially waste from injections.
- Use the technical know-how of other departments and sectors, including those responsible for environmental issues.
- Locate the current waste disposal facilities that can be used for disposal of hazardous waste and record their data in the information system.
- Calculate the total daily amount of waste that each vaccination site will generate based on the size of the population to be vaccinated and determine the capacity and cost of waste collection and disposal.
- Define the routes for collection and transport of waste to the disposal sites.
- Determine the amount and type of transportation required for waste collection. Due to the risk of pollution when transporting waste from the health services to the final disposal site, dedicated and closed vehicles should be used.
- Calculate the time that each vehicle (including boats) will take to travel the assigned collection routes.
- Document the locations without waste disposal service, the distance to the closest location with capacity, or the lack of means to transport waste.[3]
- Inspect the current waste treatment sites to ensure that they comply with the recommended practices:
  - ✓ Examine the quality and integrity of the waste incineration equipment;
  - ✓ Ensure that the personnel or company responsible use acceptable methods and comply with technical specifications for disposal of hazardous waste;
  - ✓ Ensure that the equipment meets the correct technical specifications for incineration temperatures;
  - ✓ Record the date of the last inspection of facilities;
  - ✓ Request that each private or public waste collection company provide an inspection certificate or similar document that confirms use of safe waste management procedures.
- Ensure that the budget includes funds for coverage of additional waste disposal services provided by public or private companies.
- Establish contracts with private or public companies if necessary and update the current contracts as needed.

[3] The distance the head of logistics and other transport authorities can transport the injection waste from very remote areas for collection or final disposal will depend on available resources. If this is not feasible, the head of logistics and the authorities should provide alternative methods for safe disposal of injection waste from these remote areas. The supervisors should document the final method of disposal used to ensure that the injection materials used are not reused and the method applied does not present a risk to the local community.

Figure 10. Example of hazardous waste collection routes



Source: WHO. *Management of waste: injection activities at district level.*

Step 2: Select the methods used for waste collection, transport, treatment, and disposal

Based on the national codes and laws, the country should decide which methods will be used for waste collection, transport, treatment, and disposal. This decision should be communicated to all staff members responsible for waste management during the pandemic. Staff should always be discouraged from recapping needles after injection. A sufficient supply of biohazard containers at all vaccination sites should be ensured.

The head of logistics and his/her counterparts at all levels should perform the following activities.

- Determine the number of syringes and biohazard containers required at each vaccination site and record this information in the inventory and information systems.
- Ensure shipment of the correct number of biohazard containers to each site with the vaccines and syringes.
- Record the disposal sites and contact data in the information system.
- Coordinate with environmental, sanitary, and municipal authorities the collection practices and services that have worked well in the past, as well as the factors that have prevented improvement of these practices.
- Determine whether waste collection practices have been evaluated recently. If so, examine the results and confirm implementation of the recommendations. If not, or

if the recommendations have not been implemented, determine the reason and adopt corrective measures.

- Coordinate with health care providers, health managers at municipal/district/canton and department/state/provincial level and the civil authorities at these levels to define the waste management methods that will be adopted, which may be a combination of public and private capacities available locally.

Step 3: Definition of a hazardous waste management strategy

Based on step 1, evaluation of current capacities, countries should define strategies for mobilization of resources and additional capacities. The authorities at the different levels, with the technical assistance of environmental authorities and the vaccination program, should review the current systems, determine the strategy for mobilization of resources, and specify the additional capacity for treatment of the volumes of waste expected. Countries should formulate a detailed plan for waste collection, transport, and disposal during the pandemic and use the plan to obtain financing and other resources for implementation of the plan.

This step will probably reveal a variety of methods of disposal, depending on the amount of waste, the location (rural or urban) of the waste, and the availability of local disposal facilities. The methods should be safe, respect the environment, and comply with the national laws and codes on health and safety. They should not include open-air incineration due to the environmental risks associated with burning.

An effective waste management strategy includes the following activities:

- Verifying the regulations on transportation of sanitary waste.
- Training supervisors and personnel to comply with the laws, codes, standards, and practices that govern safe disposal of vaccination waste. In order to support this training, the authorities should:
  - ✓ Prepare a "code of safe practices" for waste management;
  - ✓ Distribute documents on waste management;
  - ✓ Notify all authorities, supervisors, and health workers of the practices and methods agreed on with significant advance notice prior to vaccination (a good method for completing this step is to use a work aid).
  - ✓ Use simple indicators to monitor the quality of waste management and disposal.
- Designating a trained supervisor at each level to ensure compliance with waste management procedures.
- Providing technical assistance to improve waste management practices.
- Guaranteeing trained supervision for compliance with waste management practices by public or private companies. Effective supervision is essential for successful implementation of the waste management plan.

When deployment activities have concluded, the supervisors will measure compliance with the standards. The following performance indicators have been proposed:

- Percentage of health services with sufficient biohazard containers for collection of needles and syringes during pandemic vaccination activities;
- Percentage of urban sites with waste collection:
  - ✓ 1 week after deployment has concluded.
  - ✓ 2 weeks after deployment has concluded.
  - ✓ 3 or more weeks after deployment has concluded.[4,5]
- Percentage of vehicles that completed their collection routes and delivered the hazardous waste to the treatment and final disposal sites:
  - ✓ 1 week after deployment has concluded.
  - ✓ 2 weeks after deployment has concluded.
  - ✓ 3 or more weeks after deployment has concluded.
- Percentage of sites that reported waste was not collected.

Countries should:

- **Review their waste management plans often;**
- **Update the plans based on changes in vaccine delivery systems or waste management technology;**
- **Test the plans to verify their effectiveness;**
- **Adapt the plans when the tests detect operational gaps that prevent safe and rapid collection of sanitary waste.**

12.5 Budget and Financial Management

The authorities should calculate the cost of the deployment operations, and review and update them on a regular basis. The financial information compiled will be part of the final report prepared by the head of logistics and the person responsible for national response coordination as part of the activities for conclusion of deployment. The financial information will be useful for a similar emergency response.

[4] Based on the original national pandemic preparation plan, the reports can be monitored by phone, Internet, or supervision visits in order to identify the sites that have not reported completion of waste collection.

[5] In remote rural areas where transport is difficult or there are no waste disposal services, WHO recommends burying the waste as the best method of disposal. For additional details, see the document *Management of injection waste activities at district level. Guidelines for district health managers* World Health Organization, Geneva (2006).

Description: Establish a budget to support supply chain operations, establish clear guidelines for disbursement of funds, and specify how expenditures are reported during deployment	
Before vaccination	**During vaccination**
• Establish procedures to transfer funds to each location so that deployment operations are not halted due to lack of resources for a specific activity. • Understand and document the accounting procedures required to ensure appropriate follow-up of financial obligations and expenditures. • Agree on the requirements and format to report expenditures. • Define and document how and when supervisors will report the information and administrative and financing actions. • Record the expenditures in the management information system. • Inform personnel of their fiduciary responsibilities and provide training so that they can comply with the information requirements established in the financial rules and regulations. • Organize tests to verify the financial and information procedures. • Monitor the transfers.	• Assign a person responsibility for financial management to ensure compliance with administrative regulations, appropriate disbursal and transfer of funds, so that deployment operations are conducted without delay. • Organize emergency procedures to transfer additional funds when required to prevent interruption of deployment activities if, for example, funds are required to resolve an unexpected event. • Monitor implementation.

12.6 Human Resources and Training

Training should cover subjects on a differential basis depending on the audience present: managers, operational personnel, logistics personnel. The contents will be oriented towards two groups of people, those responsible for vaccination and those responsible for logistics.

Human resources responsible for vaccination

The human resources responsible for logistics will be trained on the following topics:

1. Reception, storage, management, conservation, distribution, packing, transportation, Kardex management, waste management, waste recovery, and logistics information system;
2. Determine the storage capacity for the amount and volume of vaccine needed and the current capacity;
3. Identify repacking centers and means of transport, equipment, transportation routes and distribution sites;
4. Communications media to track and receive information on vaccine delivery and other logistics information;
5. Types of current waste disposal and how to dispose of waste generated by vaccination;
6. Coordination to ensure vaccine safety during transport to the collection centers;
7. Behavior to follow in the event of acts of aggression or criminal violence.

Human resources responsible for administration

1. Population to vaccinate:
    a. risk groups
    b. capturing strategies
2. Vaccine description:
    a. presentation
    b. reconstitution
    c. conservation
3. Mode and site of injection
4. Dosage
5. Vaccination safety procedures:
    a. type of syringes and needles
    b. waste management
6. Date of administration
7. Information system for dose registration
8. Supervision
9. ESAVIs

Ensure that training is performed from the national level to the local level, guaranteeing the maximum quality at all levels.

13. Risk Communication and Social Mobilization

Social communication before and during performance of vaccination is en essential element Unlike other vaccination campaigns where the objective was to generate indiscriminate demand, now the objective is to simply inform the population that vaccination will be introduced gradually on a selective basis so that the public understands the reasons for this decision and social pressure is reduced.

TAG recommends that countries prepare mass communication strategies to:

a) Maintain the trust of the public by providing clear and transparent information;
b) Ensure that individuals and their families use mitigation interventions to prevent contagion;
c) Ensure that the public fully understands the recommendations and reasons why priority groups are vaccinated; and
d) Understand the general benefits and risks of vaccination-related events when they occur.

Participation by the national, regional and local media is important. Based on previous experiences, there is a need to involve well-known social figures that can have a positive influence on promoting vaccination of selected groups and dissuade others from requesting the vaccine. This includes noteworthy members of scientific societies, spokesmen, and opinion leaders.

Another important consideration is social mobilization. For this purpose, it is crucial to prepare an information packet containing materials explaining the rationale, sensitization, key activities, and how the public can participate. Finally, linkage at the intersectoral and multisectoral levels is important, as well as with public and private institutions, scientific societies, churches, international cooperation entities, nongovernmental organizations and grassroots organizations.

In summary, the design of the risk communication and social mobilization plans faces three challenges:

- Selective channeling of the demand for vaccination by priority groups or risk groups;
- The need to provide clear information on the fact that there are two vaccines (one for prevention of seasonal influenza and one for prevention of pandemic influenza);
- Insufficient information about vaccine safety and secondary effects; and
- Positioning vaccination as an additional mitigation measure.

Planning and implementation of two types of strategies is recommended: risk communication and social mobilization. *Risk communication* refers to activities of interchange of information and ideas about risks and actions to attenuate the real and potential dangers that can be generated by indiscriminate or unsatisfied demand. *Social mobilization* is participation by different sectors of society in a variety of activities (e.g., information, rendering services, persuasion, donation of resources) in order to achieve common objectives.

Annex D, "Risk communication and social mobilization to support pandemic influenza vaccination in the Americas" specifies the steps to be taken in order to perform risk communication and social mobilization activities effectively. The communication plan should identify the objectives, target populations, messages, channels, spokespersons, and materials required. The following steps are also suggested for design and implementation of the social mobilization plans: contact potential partners, select objectives, identify tasks, assign tasks/roles and responsibilities, and establish mechanisms for coordination and monitoring of activities.

Messages differentiated according to the audience, encouraging persons with risk factors to visit vaccination services and informing the population that will not seek vaccination about other individual and collective mitigation measures.

Sensitization messages explaining the rationale for vaccination of groups with higher risk of severe disease and death (e.g., increased complications in pregnancy, death of persons with diseases such as diabetes, heart disease, obesity).

14. Information Systems

In vaccination activities conducted to strengthen the pandemic control plan, the information system should satisfy two main needs in terms of information:

1. Know and monitor the results of vaccination in the population groups to be vaccinated, with a breakdown according to variables of age, institution, and location (health district/area, municipality, SILAIS, SIBASI, province, state, department and country).
2. Record, monitor, and evaluate the efforts of the logistics support components (i.e., inventory; needs; quantification of gaps; mobilization of human, logistic, and financial resources; distribution activities; reception; means of transport; routes; volume of waste; sites with adequate final disposal; results of supervision, reports of ESAVIs; conflicts and crises occurring; number of doses left over and recovered at the end of vaccination). These constitute the basic information that can be used for the final or closing report.

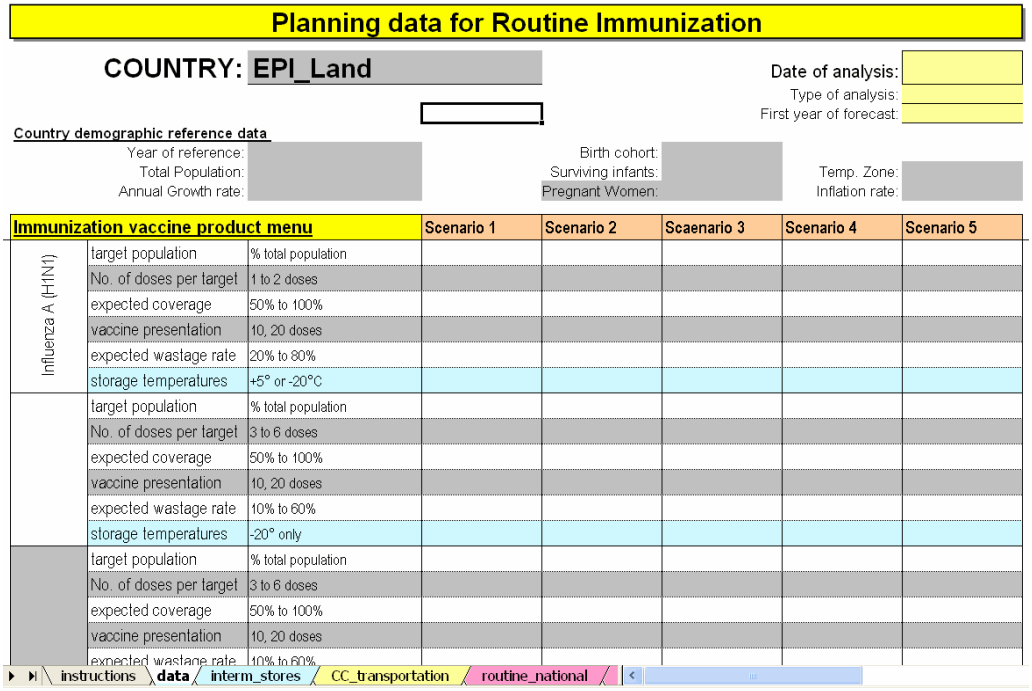
In order to satisfy the first need, a SIVAC that has been adapted to the characteristics of the special pandemic strategy can be used. For the second need, an Excel tool developed by WHO that estimates the needs for syringes, cold chain equipment for vaccine transport and storage, biohazard containers for waste, and transportation costs based on the target population can be used. At this time, a database needs to be created that includes the minimum activities and the variables planned and implemented for performance of the deployment component (i.e., distribution and logistics).

14.1 Information Subsystem for Vaccine Distribution and Logistics

PAHO has adapted the EPI logistics planning tool developed by WHO to forecast vaccines, syringes, biohazard containers, and cold chain equipment. This tool is designed in an Excel platform. The spreadsheets are connected to calculate the demand for specific vaccines, supplies such as syringes, biohazard containers, and the storage capacity required for vaccines, syringes, and biohazard containers. It can also be used to calculate the additional human resources and financial resources to be mobilized (See Operational Manual for WHO Needs Estimate Tool, Annex E).

In addition to this tool, countries should consider the use of another tool to document the mobilization of human resources for logistics and vaccination, training, transport, telecommunications, supply chain, vaccine transport, waste disposal, supervision, rapid coverage monitoring, security, budgets, and sources of financing (e.g., national, subnational, local and external).

Figure 11: Tool for the Logistical Planning of the EPI



Planning data for Routine Immunization

COUNTRY: EPI_Land

Date of analysis:
Type of analysis:
First year of forecast:

Country demographic reference data

Year of reference:
Total Population:
Annual Growth rate:
Birth cohort:
Surviving infants:
Pregnant Women:
Temp. Zone:
Inflation rate:

Immunization vaccine product menu			Scenario 1	Scenario 2	Scaenario 3	Scenario 4	Scenario 5
Influenza A (H1N1)	target population	% total population					
	No. of doses per target	1 to 2 doses					
	expected coverage	50% to 100%					
	vaccine presentation	10, 20 doses					
	expected wastage rate	20% to 80%					
	storage temperatures	+5° or -20°C					
	target population	% total population					
	No. of doses per target	3 to 6 doses					
	expected coverage	50% to 100%					
	vaccine presentation	10, 20 doses					
	expected wastage rate	10% to 60%					
	storage temperatures	-20° only					
	target population	% total population					
	No. of doses per target	3 to 6 doses					
	expected coverage	50% to 100%					
	vaccine presentation	10, 20 doses					
	expected wastage rate	10% to 60%					

instructions | data | interm_stores | CC_transportation | routine_national

14.2 Information System for Pandemic Influenza Vaccination During Campaigns (SIVAC)

PAHO/WHO offers a computerized data consolidation tool called SIVAC. Data is recorded at the level local on standardized forms. The information for each group to be vaccinated is differentiated according to the variables of age, residence, origin, and the institution where vaccination is performed.

Each country will define a data collection level according to their computer and connectivity capacity, and establish the information flow from the local level to the national level and vice versa. SIVAC guarantees decentralized information at the municipal level that can be used for monitoring, analysis, and decision-making

SIVAC contains several reports for the different variables defined in the country that can be used for a daily analysis by geographic and/or administrative area. The results of vaccination can be presented on the Web site of each country and vaccination can be monitored by progress charts. An example of a format for vaccination and the input screen of the SIVAC is shown below (See Operational Manual for Information System, Annex F).

Figure 12. SIVAC Input Screen

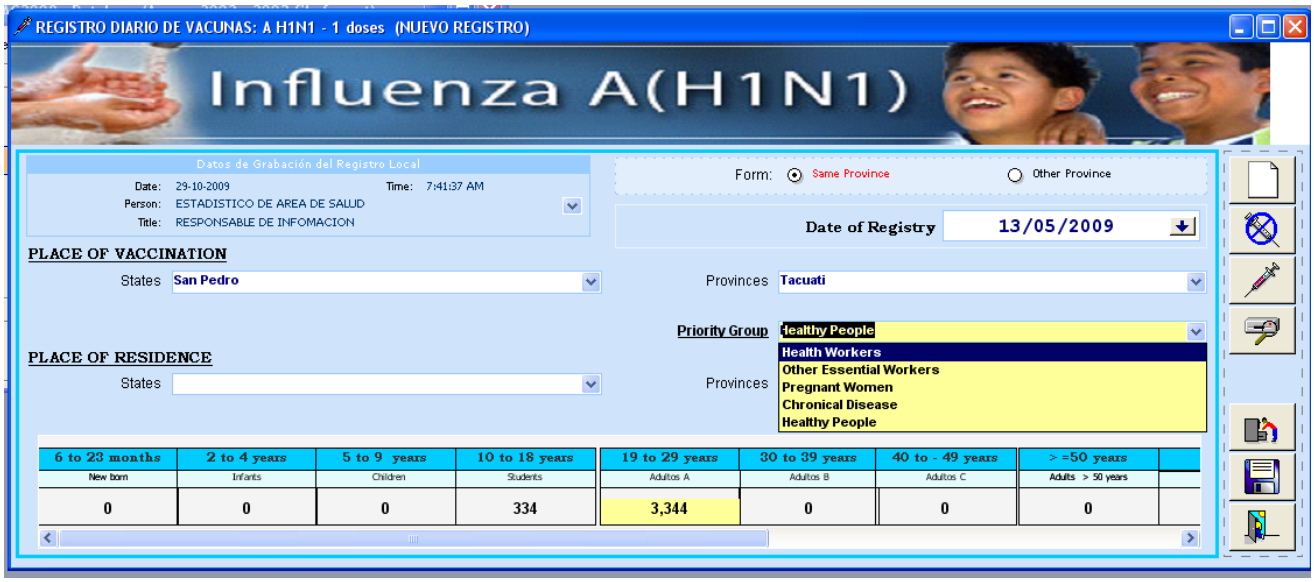


Figure 13. Format of Daily Vaccination (SIVAC)

Pan American Health Organization
Regional Office of the World Health Organization

Format for daily aggregated doses of vaccination against Influenza H1N1 for priority groups

Province: _____ **District :**_____ Date _____

Priority Groups	Health Workers	Other Essential	Pregnant Women	Chroical Disease > 6 months	Healthy People	Total
6 A 23 Months						
2 A 4 Years						
5 A 9 Years						
10 A 18 Years						
19 A 29 Years						
30 A 39 Years						
40 A 49 Years						
50 y más Years						
Total						

15. Supervision and Monitoring

Supervision by levels in order to train the local health teams should be performed at two times: a) to confirm the progress of the managerial processes in the intermediate and operational level plans, and b) during the campaign, to verify operation of the processes and results. Supervision will be performed in conjunction with monitoring to ensure continuous verification of the SIVAC data, which will indicate the priority locations to be supervised. Rapid coverage monitoring of the target population should also be performed during the supervision visits to measure the effectiveness of the micro-planning.

This component is implemented through the information system and internal communication. The distribution sites, shipments, condition of the routes, and delivery of vaccines and other supplies are tracked through the supervision reports. These reports are based partly on the checklists.

The countries have standards and instruments for supervision that are usually adapted for implementation of special strategies. For pandemic vaccination, PAHO/WHO offers a variety of checklists that can be used in the countries with their respective specific adaptations.

This component provides information that is essential for systematizing the lessons learned and preparing the final report or campaign report.

16. Evaluation

Evaluation of the intervention should include two subjects:

1. The results of vaccination, and
2. The work conducted to ensure distribution, use, logistics, security, training, supervision and monitoring, communication and social mobilization, final waste disposal, recovery of vaccines and supplies, and human resources and teams returning to their respective institutions.

When vaccination has been completed, a process of consolidation and estimation of the coverage for each target group will be conducted based on the goals established for the census of the captive population according to the SIVAC.

16.1 Vaccination Results and Process Indicators

- Percentage of coverage with first and second dose by target group
- Percentage of dropouts between first and second dose
- Doses administered each day and week according to first or second dose, as applies
- Percentage of weekly vaccination coverage for each target group
- Percentage of institutions visited compared to institutions planned: institutions visited/institutions planned
- Percentage of vaccine wastage

16.2 Availability and Process Indicators for Other Components

- Number and percentage of supervision visits performed compared to visits planned

- Number and percentage of rapid coverage monitoring (RCM) procedures conducted compared to RCM planned
- Number and percentage of RCM procedures according to range of results (= 95%; 90-95%, 80-89%, <80%)
- Number of participants according to institution of origin (i.e., health institution, volunteers, and others)
- Number of persons trained and number of training workshops according to level
- Average number of persons trained at each training workshop
- Percentage of persons trained out of total number planned or participating in vaccination
- Number and percentage of logistics personnel (e.g., drivers, supervisors, security personnel, packagers, loaders, communications personnel, heads of logistics) according to job or task performed out of total personnel assigned to logistics
- Number and ratio of vaccinators per supervisor
- Number and percentage of ESAVI investigated/reported
- Number and percentage of severe unusual ESAVI in clusters out of events investigated
- Number and percentage of ESAVI classified/investigated
- Number and percentage of doses recovered out of total doses distributed (doses recovered = doses distributed - (doses administered + dose wastage)
- Number and percentage of health services with adequate disposal (source: supervision)
- Ratio of syringes used (doses administered) for number of biohazard containers used
- Percentage of biohazard containers received out of total amount needed (source: WHO Excel or 1 container for every 100 syringes)
- Total cost for each dose administered and for complete series
- Cost of vaccine transport from national level to local level (source: WHO Excel)

17. Activities for Activity Closing and Final Report: Lessons Learned

When vaccination has been completed, the human resources assigned by other institutions or the community will return to their places of origin. The logistics management should recover the unused supplies, equipment, and vaccines, which will be recorded in the information subsystem used for deployment.

The criteria for closing of the intervention are:

1. **Fulfillment of goals in the target groups**
   (verified by rapid coverage monitoring)
2. **Vaccine supply has been depleted**

The technical teams responsible for vaccination and logistics should perform a qualitative evaluation at the end of the activity in order to identify the weaknesses, difficulties, and lessons learned, which will be sent to the next highest level. The systematization of all these reports along with analysis of the results of coverage achieved will be included in the final report.

The information system for the logistics activities and other components can be used to record the activities and prepare process/cost indicators. These will be used as input for the final report, along with the results indicators provided by SIVAC.

18. Identification of Research Needs

The questions to be answered will require the participation of the technical and operational areas in order to identify the research needs. Some of the subjects that could be considered immediately include:

- Population studies of seroprevalence, in order to estimate the size of the target population. Studies are currently being conducted in Chile and Argentina.
- Evaluation of impact of influenza A(H1N1) vaccination
- Identification of potential signs related to vaccine safety
- Effectiveness of the vaccine in different groups
- Identification of changes in the pandemic virus genome
- Documentation of lessons learned from this emergency vaccination

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