



Immunization Newsletter

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Poliovirus Containment: The American Region has Successfully Completed Phase I

Introduction

The American Regional Commission for Certification of Poliovirus Laboratory Containment and Verification of Polio-free Status (AMR RCC) held its 5th meeting in Buenos Aires, Argentina, from 4-5 March 2010. The AMR RCC was established by the Director of the Pan American Health Organization (PAHO) in February 2004 to independently document that the Phase I requirements for wild poliovirus (WPV) laboratory containment had been fulfilled and to verify that the polio-free status of the Region remained unchanged. The purpose of this 5th meeting was to review the final report from Brazil and report update from Canada, and to verify the completeness and quality of Phase I activities of all Member States of the Region.

Current Status

Phase I laboratory containment for infectious and potentially infectious (WPV) materials requires each Member State to conduct a nation-wide survey of biomedical facilities and compile an inventory of all facilities holding infectious WPV materials. Phase I provides the facility database for all subsequent steps towards global poliovirus containment. At its previous meeting in Punta del Este, Uruguay, the RCC concluded that the American Region was nearing completion of Phase I. It requested Canada to present an updated report and Brazil to present a final report at this current 5th Meeting in Buenos Aires.

As of March 2010, a total of 82,678 laboratories/institutions were identified in the Region of the Americas. Of these, 59,618 (72.1%) were selected for the survey in accordance with the Phase I global guidelines. All laboratories/institutions were classified into three risk categories (high, medium, low).

Eighty-six percent of low-risk laboratories/institutions and 100% of high- and medium-risk laboratories/institutions were included in the survey. While most countries surveyed all low-risk laboratories/institutions, eight countries surveyed representative samples of 13-59% of laboratories/institutions to validate their classification as low-risk. Responses were obtained from all laboratories/institutions included in the survey.

The surveys identified 215 laboratories/institutions with infectious or potentially infectious WPV materials in nine countries. Thirty-three countries and territories reported no laboratories with infectious or potentially infectious WPV materials, and three (Colombia, Cuba, and Panama), destroyed all WPV materials identified during the survey process. The countries retain-

American Regional Commission for Certification of Poliovirus Laboratory Containment and Verification of Polio-free status Buenos Aires, Argentina

4-5 March 2010

Hereby, the American Regional Commission for Certification of Poliovirus Laboratory Containment and Verification of Polio-free status (AMR RCC) concludes and declares at their 5th meeting held in Buenos Aires, Argentina, 4-5 March 2010, that the WHO Region of the Americas has successfully completed phase I of poliovirus containment.

Signatures of AMR RCC members

Dr. Carlyle Guerra de Macedo
President

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Member

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Pandemic Influenza (H1N1) 2009 and Vaccine Safety

Although the current influenza (H1N1) 2009 pandemic is considered moderate in severity, the pandemic influenza virus has caused an average of 6-14 deaths per 1 million population. In the Americas, as of 16 April 2010, there have been at least 8,309 deaths from confirmed cases reported in 28 countries of the Region. From September 2009 to 16 April 2010, over 350 million doses of the vaccine against pandemic influenza (H1N1) were administered around the world to health workers, high-risk groups, and the general population. In the Americas, as of 16 April 2010, 49.4 million doses had been administered in 22 countries of the Region: Anguilla, Argentina, Bahamas, Barbados, Belize, Bermuda, Brazil, Cayman Islands, Colombia, Costa Rica, Ecuador, El Salvador, Guatemala, Honduras, Mexico, Montserrat, Nicaragua, Panama, Peru, Suriname, Trinidad and Tobago, and Uruguay.

Criteria for the Definition of the Influenza (H1N1) 2009 Pandemic

The influenza (H1N1) 2009 pandemic is a scientifically documented event in which a new influenza virus caused unusual disease patterns worldwide, predominantly impacting young people.

In 2005, the World Health Organization (WHO) published a global plan

ing infectious and/or potentially infectious WPV materials are Argentina, Brazil, Canada, Chile, Costa Rica, Guatemala, Mexico, Trinidad & Tobago, and the United States.

The AMR RCC also reviewed evidence presented by PAHO on vaccination coverage and acute flaccid paralysis (AFP) surveillance, confirming the Region's uninterrupted polio-free status. The last case of poliomyelitis due to a WPV was reported in 1991, and the American Region was certified as free of endemic WPV circulation in 1994.

AMR RCC Conclusions

The RCC commended Brazil for its excellent report and presentation and concludes that Brazil has successfully completed Phase I containment activities. The RCC was pleased with Brazil's comprehensive approach to national implementation of Phase I activities and that Brazil had taken full advantage of the opportunity to establish a database of laboratories with application far beyond the goal of poliovirus containment.

The RCC also commended Canada for its presentation comparing the list of laboratories registered as a result of the Human Pathogens and Toxins Act (2009) to the list of laboratories identified and surveyed during the 2002-2004

process. Canada's successful application of the Act for control and tracking of polioviruses and other infectious agents in institutions validates the advanced Canadian system as a potential model for other countries, both within the Region and globally.

The RCC congratulated all PAHO Member States and their National Committees for the submission of final country reports. The RCC was impressed with the quality and completeness of the reports and the enormity of the effort put forth by all countries to meet Phase I goals and objectives. The RCC was appreciative of Member States' efforts to address recommendations made at previous meetings of the Commission. The RCC was confident that the reports and presentations from every country of the Region demonstrate that all facilities with infectious or potentially infectious WPV materials have been identified.

The RCC will provide a report on the finalization of Phase I to the Global Certification Commission (GCC) by the end of May 2010. The RCC notes the lack of activity of the GCC and expresses its concerns on this respect.

Recognizing the current progress in global polio eradication, the RCC encourages the Secretariat

to initiate efforts in collaboration with WHO/Geneva, to develop guidelines and plans to assist Member States in developing legislative or regulatory text consistent with global policy on post-eradication destruction or containment of WPV materials.

The RCC notes that after 19 years of not having detected WPV with similar or better surveillance than was present in 1991, the evidence that the American Region remains polio-free is at least as strong, if not stronger, as it was at the time of certification in 1994. However, the RCC has identified some countries in the Region that do not meet the required AFP surveillance standards and high polio immunization coverage and may constitute a risk for WPV circulation in the event of importation, or for the emergence of circulating vaccine-derived poliovirus. The RCC reaffirms its terms of reference "to evaluate annual PAHO and requested National Containment Commissions reports on polio immunization, surveillance, and laboratory performance in accord with GCC criteria".

Finally, the American Regional Commission concluded that the American Region had successfully completed phase I of poliovirus containment. ■

Fifth Meeting of the AMR RCC: Recommendations

Phase I reports from countries of the American Region demonstrate the completeness and quality of the national survey and inventory activities, and provide critical documentation for the eventual Global Certification of the Eradication of Poliomyelitis. The Regional and national infrastructures that have been created and the information gained through this significant achievement are valuable assets that must be maintained as polio eradication nears, full WPV containment is implemented, and global certification is eventually declared. To ensure Member States remain alert and prepared to meet subsequent poliovirus requirements, the RCC recommends the following:

Containment

1. Member States should ensure the national inventory of WPV-holding facilities is maintained and updated annually along with maintenance of the Phase I report, supporting documentation (both paper and electronic), and the national laboratory database. An updated national inventory should

be submitted to PAHO on an annual basis.

2. Member States should ensure that the national committee and a designated responsible government official is continued as long as required by the GCC. The name of the responsible official should be communicated to PAHO annually.
3. Member States with facilities listed on the national WPV inventory should encourage destruction of unneeded infectious and potentially infectious materials and submit documented evidence of destruction to its National Containment Commission and PAHO.
4. PAHO Headquarters should ensure that the Regional Report, which includes documentation (both paper and electronic) submitted from Member States, is securely maintained for future reference.
5. The process and achievement of Phase I completion in the American Region should be documented and published in the *Weekly Epidemiological Report (WER)* of the World Health Organization (WHO) and the *MMWR* of the U.S. Centers for Disease Control and Pre-

vention.

6. The Secretariat, in collaboration with WHO/Geneva, should report to the RCC at their next meeting on progress towards guidelines and plans to assist Member States in developing legislative or regulatory text consistent with global policy on post-eradication destruction or containment of WPV materials.

Maintenance of polio-free status

7. The Secretariat should provide the RCC at their next meeting with a detailed overview of AFP surveillance and polio immunization activities in countries of the Region, with specific attention to Member States with sub-optimal performance. The information should include a detailed analysis of data at national and first sub-national levels.
8. PAHO should ensure a designated staff member continues to be responsible for oversight of polio activities, including containment, AFP surveillance, polio immunization, and security and maintenance of documents, as long as is needed to complete Global Certification.

ProVac: Essential Components of a Cost-effectiveness Analysis for Rotavirus Vaccine

Introduction

The fourth Regional ProVac meeting was convened in Managua, Nicaragua, from 2-3 March 2010. The ProVac initiative seeks to enhance national capacity to make evidence-based decisions regarding new vaccine introduction. The objective of the workshop was for participants to understand the main components of a cost-effectiveness analysis and discuss possible data sources, using rotavirus vaccine as an example. Even though some of the countries attending the workshop had already introduced the rotavirus vaccine, this vaccine was chosen because a concrete vaccine example was needed, rotavirus vaccine is an expensive vaccine, and there are still many countries interested in evaluating its introduction.

Ninety participants from 19 Latin American and Caribbean countries attended the workshop. The members of each multidisciplinary country team were the PAHO focal point in that country, the EPI manager, a health economist, and the surveillance manager for new vaccines.

Representatives from the following organizations also participated in the workshop: Ministries of Health, the Center for Disease Control and Prevention (CDC), Canadian Public Health Association (CPHA), SIVAC Initiative, Harvard University, the London School of Hygiene and Tropical Medicine (LSHTM), and the University of Medicine and Dentistry of New Jersey (UMDNJ).

H1N1 from page 1

defining six phases of a pandemic in order to identify increasing levels of risk. The document, which provided recommendations to guide national authorities in pandemic planning, was the result of a December 2004 WHO advisory meeting to recommend national and international steps to take before and during pandemics. In the plan, pandemics are defined not in terms of their severity, but of the transmission of a new subtype of influenza virus with broader and sustained transmission throughout the community. After consultations in 2008, in April 2009 WHO published an updated version of the 2005 global

Methodology

The methodology used for the workshop was a combination of plenary sessions and practical exercises performed by the country teams. Plenary sessions covered all components of a cost-effectiveness analysis, which included disease burden, vaccine efficacy and coverage, vaccination program cost, health service utilization and costs prevented, as well as results and scenarios. The country teams performed exercises to address each of the model components in greater details. Each country team was provided with a computer loaded with the model and internet access to the ProVac e-Support Center (www.paho.org/provac). To the extent possible, these country teams exercised populating the model with their national data. Participants were asked to think of possible local data sources for each model component. They were also challenged to consider the quality of different data sources. The final session focused on country experiences using the ProVac cost-effectiveness model, challenges, and lessons learned. At the end of the workshop, forms were distributed to the participants to collect feedback that would allow for future model and workshop improvements.

Conclusions and Recommendations

The following comments were received as feedback regarding the model and the methodology of the workshop:

- Participants gave very positive feedback about the model itself, and there was general accep-

tance of the methodology and assumptions of the model.

- Participants acknowledged the positive impact of the incorporation of requested changes from the Paraguay workshop (otitis media, herd immunity, flexible schedules).
- The model is more user-friendly than previous versions, participants understood the Excel background and found it more useful than the Visual Basic interface presented in Paraguay.
- Participants who had attended the Paraguay workshop perceived progress from the Paraguay workshop's approach of "playing with a model" to the current approach of discussing possible national and international data sources to perform a country-level analysis.
- Participants acknowledged a very good level of oral presentations.
- The ProVac Centers of Excellence have the right profile for a balanced approach that couples scientific rigor with a practical methodology to be implemented in countries of the Region.
- The training on the utilization of scientific tools by EPI managers was considered a success.
- Promoting the formation of working teams in each country was considered very important.

The following are suggestions received for future workshops:

- Oral presentations should be integrated with the practical exercises.
- Some exercises should be conducted in general sessions using one single data set.
- Sharing the model and exercises with the participants in advance of the workshop.
- Considering a virtual introductory presentation prior to the workshop to expose participants to the model and the terms and definitions of each variable to be discussed. ■

plan, which retains the six-phase structure of the response but regroups and redefines the phases to more accurately reflect the pandemic risk based on observable phenomena. (Figure 1, page 4)

Chronology of the Declaration of the Pandemic

Pursuant to the procedures established in the International Health Regulations (IHR-2005) and adopted by WHO Member States in 2005, WHO Director-General Dr. Margaret Chan called a meeting of the emergency committee on 25 April 2009 to assess the situation and advise the

Director-General on an appropriate response.

In the emergency committee's second meeting on 27 April 2009, the decision was made that the epidemiological data from Canada, Mexico, and the USA showing person-to-person transmission was sufficient to recommend that the Director-General raise the Phase from 3 to 4. On 29 April, based on evidence of sustained transmission in North America and the emergency committee's recommendations, the Director-General raised the Phase from 4 to 5. On 11 June, when the pandemic virus had already shown sustained circulation in more than one WHO Region, the Director-General declared Phase 6 of the pandemic.

Definition of a pandemic

A pandemic is defined as the emergence of a new influenza virus that has caused sustained community outbreaks in two or more countries in a WHO Region and sustained community outbreaks in at least in one other country in a different WHO Region. The criteria for the definition of a pandemic remain geographical dispersion and viral transmission. The clinical severity of the disease is an important consideration but differs from geographical dispersion, and is not currently included in the definition of a pandemic. WHO is working in substantial and measurable ways to incorporate definitions of clinical severity in the general definition of a pandemic.*

* World Health Organization. Current phases of alert of the pandemic according to WHO (Internet); accessed on 19 April 2010 at: <http://www.who.int/csr/disease/influenza/pandemic/en/index.html>.

Severity of the Pandemic

- 1. Estimates of mortality from seasonal influenza:** During the annual peak of seasonal influenza, some 90% of deaths occur in individuals aged >65 years who often already have underlying illness. Although influenza can exacerbate these preexisting conditions, diagnostic tests for influenza are usually not conducted, and the deaths are often attributed to the underlying condition. Deaths from seasonal influenza are estimated using mathematical models to determine the excess deaths caused by influenza.
- 2. Deaths from pandemic influenza:** The number of deaths from the pandemic influenza (H1N1) 2009 reported by national authorities and compiled by WHO are laboratory-confirmed cases and not estimates. These

numbers do not reflect the actual mortality rate during the pandemic, which is undoubtedly higher than the laboratory-confirmed cases indicate. Since the signs and symptoms of pandemic influenza are similar to those of many common infectious diseases, physicians often do not suspect infection due to the pandemic influenza (H1N1) 2009 and thus do not order diagnostic tests. It is especially frequent for cases to go undiagnosed in developing countries, where deaths from respiratory diseases (especially pneumonia) are common. Even when tests confirm infection with the pandemic influenza (H1N1) 2009 virus in patients with some underlying illness, many physicians attribute the death to the latter and not to influenza; therefore, these deaths do not appear in the official statistics.

The impact of mortality from the pandemic

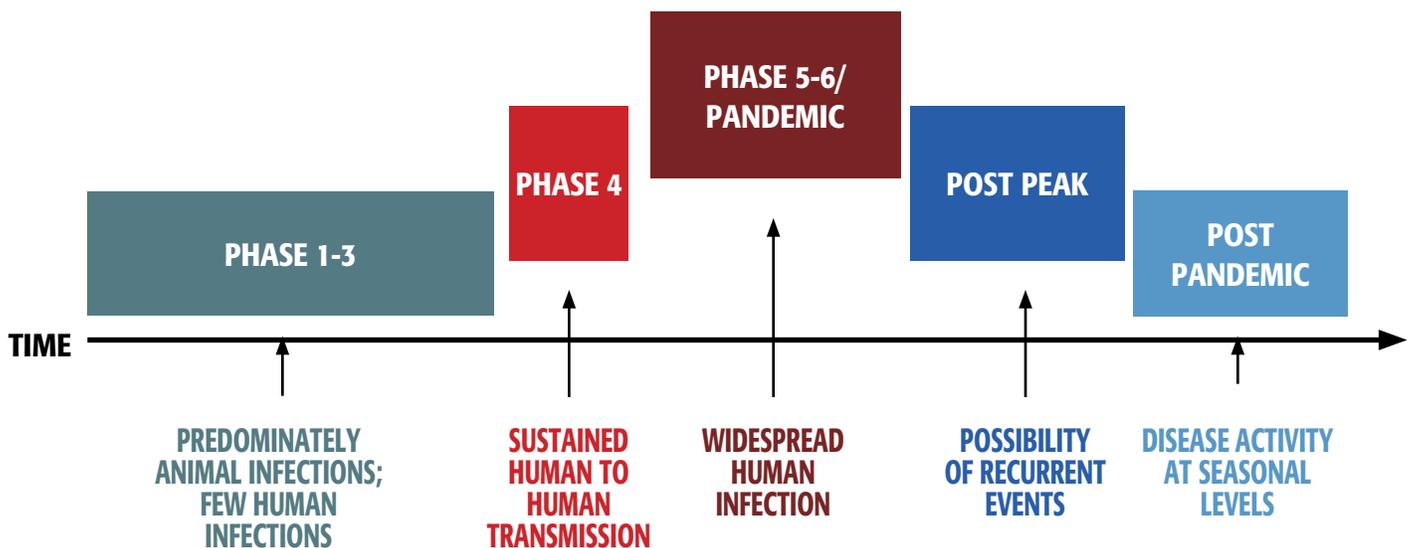
influenza (H1N1) 2009 differs from that of seasonal influenza, since pandemic influenza predominantly affects young people, who get infected more often, end up hospitalized, require intensive care, and die. WHO continues in the view that the pandemic influenza has had a moderate impact. Most likely, it will be impossible to calculate the precise number of deaths and mortality rates until a year or two after the pandemic has peaked, and that calculation will be based on methods similar to those used to calculate excess mortality during seasonal influenza epidemics.

Safety of the Pandemic Influenza (H1N1) 2009 Vaccine

The safety profile of the pandemic influenza (H1N1) 2009 vaccine is quite similar to that of the seasonal influenza vaccine. Since vaccination activities began, **no event has occurred that puts into question the safety of the pandemic influenza vaccine:**

- No increase has been observed in the rate of abortion or intrauterine fetal death in pregnant women who received the pandemic influenza (H1N1) vaccine, compared with pregnant women who have not been vaccinated.
- The reported rate of anaphylaxis continues to oscillate in the expected range (0.1-1.0 cases/100,000 doses). Special emphasis has been placed on the detection, accurate diagnosis, and treatment of anaphylaxis in

Figure 1. Pandemic Influenza Phases, 2009



Source: World Health Organization (http://www.who.int/csr/disease/avian_influenza/phase/en/).

Vaccine Production: Types of Vaccine and Efficacy

The process for producing the pandemic influenza (H1N1) 2009 vaccine has been the same used to produce seasonal influenza vaccines. Because of the urgency to rapidly produce the pandemic vaccine, some production phases were accelerated. However, vaccine production quality standards have been maintained, which can be confirmed by the constant drug surveillance established by the manufacturing laboratories themselves and by quality controls established by the countries.

The pandemic vaccine used in the countries of the Region is inactivated, with and without adjuvant. There is also a trivalent vaccine, which includes the pandemic strain (H1N1) and seasonal (H3N2) and Brisbane strains. This formulation is similar in the Northern and Southern Hemispheres. Some countries in the Region have procured the trivalent vaccine through PAHO's Revolving Fund. This formulation was recommended by WHO for the 2010-2011 period.

Current data show that the pandemic influenza (H1N1) 2009 vaccine is immunogenic. A single dose is recommended for adults to obtain high immunity and two doses for children aged <9 years.

order to avoid fatal outcomes. To this end, the Brighton Collaboration Group developed definitions and degrees of diagnostic certainty that were included in the Pan American Health Organization's field guide *Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) Linked to the Pandemic Influenza (H1N1) 2009 Vaccine and Crisis Prevention*.

- Only two deaths associated with program errors have been reported (in Canada and the Netherlands). In the case in Canada, **timely adequate medical treatment was not given to the person, who developed anaphylaxis**, which triggered death. In the case in the Netherlands, **insulin was administered** instead of the vaccine.
- The regulatory authorities in several countries around the world have jointly examined the adverse effects of the vaccine that were identified in clinical trials and compared these results with those for seasonal influenza. The conclusion reached was that the safety profiles of the two vaccines coincide; that is, the adverse effects of the pandemic vaccine observed in clinical trials are similar to those of the seasonal influenza vaccine.
- After analysis of the data reported by the VAERS system (U.S. Vaccine Adverse Event Reporting System) from October-November 2009, it was concluded that the pandemic influenza (H1N1) vaccine continues to be safe, since there was no increase in ESAVIs reported compared with the frequency of ESAVIs reported with the seasonal influenza vaccine.

ESAVI Monitoring

One of the countries' concerns—among the authorities and general public alike—is vaccine safe-

ty. Steps have, therefore, been taken to improve ESAVI monitoring. Surveillance begins with the report of an ESAVI. An ESAVI consists of clinical symptoms occurring after an individual has received a vaccine that raise concerns and are supposedly attributable to the vaccination. It is important to stress that although denoting a association in time, an ESAVI **does not necessarily imply a cause-and-effect relationship**. Subsequent investigations of the case will determine

the causality between the event and the vaccination. Once the investigation has concluded, the case can be classified as coincidental (without a causal relationship), a program error (related to an operational aspect of the vaccination), or a vaccine-associated event (causal relationship with one or more components of the vaccine).

As of 19 April 2010, 1,198 ESAVIs have been reported in the Americas. Of these, 113 were classified as serious.¹ However, a thorough investigation will help countries classify serious events as coincidental, programmatic errors, vaccine-related, or inconclusive.

The sensitivity of the surveillance systems in Northern Hemisphere countries such as Canada, China, European countries, and the United States (the first to administer the vaccine), was stepped up substantially in order to capture any ESAVI from the pandemic influenza (H1N1) vaccine, which was being administered on a large scale. These countries are now analyzing the compiled data so that they can provide sound and consistent evidence on the vaccine's safety. Updates on the adverse events reported are no

¹ An event is serious if it leads to death, hospitalization, prolonged hospitalization, persistent disability and/or constitutes a threat to life. Serious is not a synonym of severe (intensity/severity).

H1N1 Pandemic Vaccine Safety: Results from Clinical Trials

Results on the H1N1 pandemic vaccine safety are available from three recent clinical trials in China¹ (12,691 people aged 3-87 years/different formulations of the vaccine), the United States² (children and adults/vaccine without adjuvant) and Hungary³ (355 people aged 18-60+/vaccine without adjuvant). The following are the main conclusions of the studies:

- The adverse events reported were moderate and limited; the most commonly reported ESAVIs were pain at the injection site, cough, rhinorrhea, and nasal congestion. The most common severe event was fever.
- The incidence of systemic reactions was similar in all age groups in China's multicenter, randomized, double-blind, placebo-controlled trial. On increasing the amount of antigen (7.5-30 µg), the number of adverse events increased as well. On the other hand, with increasing age, the number of adverse events decreased.
- The incidence of local reactions ranged from 12-50%, while systemic reactions ranged from 16-49% in all age groups (study in the United States). The most common systemic reactions reported in adults were headache, myalgia, and discomfort. Most common in children were frequent crying, irritability, loss of appetite, and insomnia.
- The number of events increased when the pandemic vaccine without adjuvant was administered at the same time as the seasonal influenza vaccine (from 10-18%). This difference is due to moderate soreness at the injection site reported by individuals who received the two vaccines (study in Hungary).

¹ X-F Liang, H-Q Wang, J-Z Wang et al. Safety and immunogenicity of 2009 pandemic influenza A H1N1 vaccines in China: a multicentre, double-blind, randomized, placebo-controlled trial. *Lancet* 2009. Published online December 16. DOI: 10.1016/S0140-6736(09)62003-1.

² E Plennevaux, E Sheldon, M Blatter, M-K Reeves-Hoché, M Denis. Immune response after a single vaccination against 2009 influenza A H1N1 in USA: a preliminary report of two randomized controlled phase 2 trials. *Lancet* 2009. Published online December 16. DOI 10.1016/S0140-6736(09)62026-2

³ Z Vajo, F Tamas, L Sinka, I Jankovics. Safety and immunogenicity of a 2009 pandemic influenza A H1N1 vaccine when administered alone or simultaneously with the seasonal influenza vaccine for the 2009-10 influenza season: a multicentre, randomized controlled trial. *Lancet* 2009. Published online December 16. DOI 10.1016/S0140-6736(09)62039-0.

longer issued as often as they were at the beginning of vaccination (daily or weekly reports vs. monthly or quarterly).

Some studies have been published estimating the rate of adverse events that could occur in mass immunization campaigns against influenza (H1N1) 2009. For example, in 2009, Steven Black et al. published an article in the *The Lancet* stating that in a six-week period, for every 10 million people vaccinated, 22 cases of Guillain-Barré Syndrome (GBS) would occur in the United Kingdom, 83 cases of optic neuritis in the United States, and 397 miscarriages the day following vaccination for every 1 million pregnant women vaccinated.

It is important to note that these are the number of cases expected for each of these pathologies for a population of 10 million in a six-week period. However, these estimates do not indicate the number of cases of GBS, optic neuritis, or

miscarriages that could occur as a result of the vaccination. The comparison between what is anticipated and what is observed serves as one more element for assessing the causal relationship between vaccination and the ESAVIs identified.

Without denying the usefulness of predicting estimates prior to vaccination activities—since they help assess the vaccine's safety—it is important to note the following:

- Identifying reliable base rates for any disease is difficult, due to the lack of systematic reporting of diseases, underreporting, lack of standardized case definitions, different methodologies for identifying cases, etc.
- The denominator used is also an estimate and is often unknown (for example, the number of individuals vaccinated), and it is critical information in determining whether the number of events observed is greater than expected. In

many estimates, the number of doses distributed, not the number of doses administered.

As a result, due to the uncertainty in estimating reliable base rates for some diseases, caution should be used in interpreting these data, bearing in mind the assumptions used when the estimates were calculated since they could raise false alarms or lead to counterproductive information on the safety of the vaccine.

Some countries have been able to closely monitor adverse events associated with the influenza (H1N1) 2009 vaccine during mass vaccination. The health authorities of Taiwan, for example, estimated that 27 GBS cases would occur during the six weeks following vaccination, after 15 million doses had been administered. However, by 16 March 2010, 5.66 million people had been vaccinated and only four GBS cases had been confirmed during the following six weeks.

See **H1N1** page 8

8th Vaccination Week in the Americas

The 8th annual Vaccination Week in the Americas (VWA) was celebrated throughout the Region of the Americas from 24 April to 1 May 2010. Under the slogan of “Reaching everyone,” countries and territories realized a wide variety of vaccination and social communication activities and some also took advantage of VWA to integrate other preventative interventions with vaccination. Prior to the initiative, countries and territories had planned to vaccinate approximately 42 million people, including 27 million individuals against influenza. Final activity reports from the countries are expected to arrive shortly for consolidation into the final VWA 2010 report.

Regional VWA launching events took place in Nicaragua, on the United States/Mexico border (in conjunction with National Infant Immunization Week in the U.S.), in Haiti and the Dominican Republic, and on the border between French Guiana and Suriname. The latter can be considered as the first ever bi-regional launch (Americas-Europe), as French Guiana is a French overseas department and, therefore, part of the European Union. All VWA regional launching events counted on the participation of high level authorities, including political and religious leaders, heads of international organizations and community leaders. Smaller scale, tri-national, bi-national, and national launching events also occurred in the majority of other countries in the Region. Ad-

ditional information on VWA 2010 can be found online at www.paho.org/vwa.

This year, PAHO also hosted two delegates from the African Region of the World Health Organization (WHO), Drs. Levon Arevshatian and Richard Mihigo, to learn more about the organization and implementation of VWA, in preparation for the

launch of WHO/AFRO's first vaccination week in 2011. Dr. Mihigo participated in the VWA launching events in Haiti and the Dominican Republic, and both delegates spent two days in Washington after VWA had concluded to meet with Pan American Health Organization staff involved in the initiative. The Americas look forward to supporting Africa in the organization of their vaccination week and to continue working towards the goal of a Global Vaccination Week. ■



PAHO Director, Dr. Mirta Roses, vaccinating a child in Jimaní, Dominican Republic, during the 2010 VWA.

How to perform the “Shake Test”

The “shake test” was designed to detect freeze damage in aluminum-based, adsorbed, freeze sensitive vaccines such as DTP, DT, Td, TT, typhoid, and hepatitis B. These vaccines must never be frozen as this reduces their immunogenicity. When these vaccines freeze, the alum content gets loose, tends to agglomerate, and sediments faster than vaccines that have not suffered freeze damage.

If you suspect that a vaccine has been frozen (e.g., thermometer marks temperature $<0^{\circ}\text{C}$), conduct a “Shake test”:

Step 1.

Freeze a vial until it is solid; this will be your control vial – call it “FROZEN”.

Step 2.

Allow FROZEN vial to thaw completely.

Step 3.

Select one sample of each vaccine you suspect has been frozen – call it “SUSPECT”.

Step 4.

Shake FROZEN and SUSPECT vials.

Step 5.

Observe FROZEN and SUSPECT vials side-by-side to compare how they sediment (5-15 minutes).

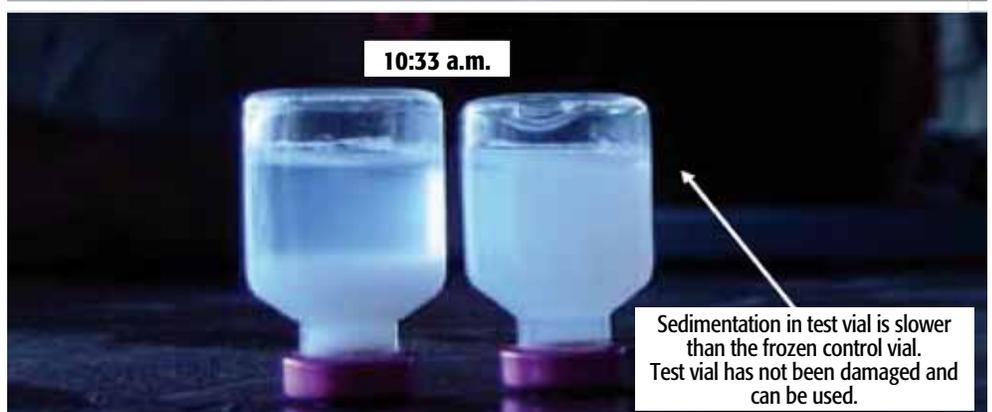
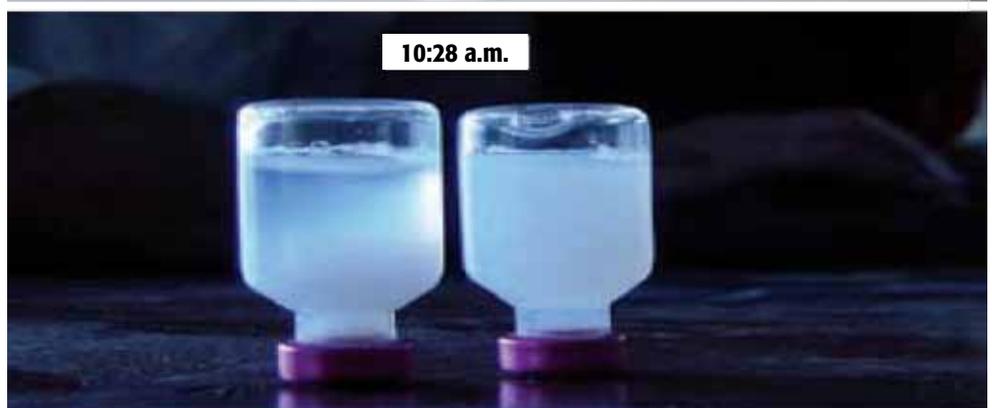
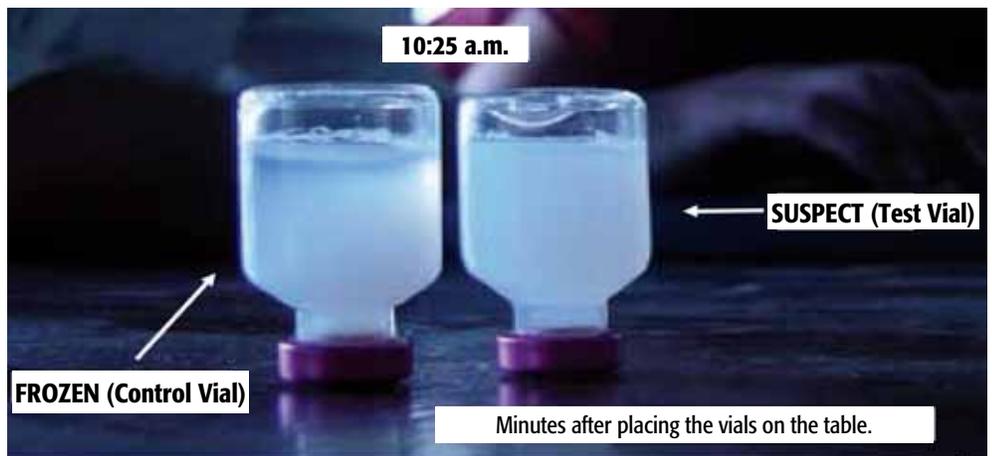
IF SUSPECT vial sediments slower than FROZEN vial → USE (see Figures at left).

IF SUSPECT vial sediments at the same rate as or faster than FROZEN vial → DO NOT USE.

A Shake Test must be performed for each separate batch of vaccine.

Further information:

- To see a step-by-step video on the Shake Test, go to <http://vimeo.com/8389435>.
- To download a WHO learning guide on how to use the shake test, go to https://apps.who.int/vaccines-access/vacman/temperature/shake_test_learning_guide.htm.
- PATH Poster: *Has your vaccine been damaged by freezing?* Available at: http://www.path.org/files/TS_cc_shake_test.pdf.



H1N1 from page 6

In general, a misinterpretation of estimated base-rate and/or the results of ESAVIs could not only damage pandemic influenza (H1N1) vaccination activities but also contribute to a loss of public confidence in the vaccine and undermine the credibility of the health services.

Communication in Risk Situations

Faulty communication strategies and uncertainty about the vaccine's safety may have caused the news media to report on pandemic vaccination in a way that contributed to lower coverage. Immunization remains the cornerstone of a pandemic response.

Public health officials and the news media should know how to respond jointly and appropriately to any misunderstanding or inaccuracy about the safety of the vaccine that could trigger panic in the population. A joint health/news effort calls for partnerships with the media, as well as the implementation of a plan for crisis and risk communication.

Procurement of the Pandemic Vaccine in the Americas

All vaccines procured by the countries of the

Region through PAHO's Revolving Fund come from laboratories that have been prequalified by WHO. As is known, the world's principal reference on vaccines for public health is WHO, which monitors and certifies the quality and good practices of the manufacturing laboratories. Pandemic vaccine purchase for countries of the Americas was made through the Revolving Fund; a few countries also opted to purchase directly from the manufacturing laboratories; and others received donations from WHO and/or industrialized countries.

Regarding donations from industrialized countries to developing countries, it is untrue that the reason for these donations is that the vaccine is ineffective or that the donor countries' own populations have refused vaccination. Developed countries prioritized the vaccination of up to 50% of their population and, as a result, purchased large amounts of vaccine. As the pandemic evolved, these countries adjusted their vaccination plans, putting the emphasis on the three main risk groups, which account for approximately 20% of the total population. The result was a vaccine surplus.

The use of the pandemic influenza (H1N1) 2009 vaccine is a great opportunity for preventing

infections and deaths from this disease. It is important that the population be properly informed about the benefits of vaccination and the safety of the vaccine. Its use should be promoted and reliable technical and scientific information provided.

Assessment

An external assessment of the global response to the influenza pandemic has begun. The purpose of the assessment is to identify ways to improve the international community's response to public health emergencies in order to protect the public. PAHO/WHO welcomes with satisfaction the opportunity to learn from this exercise and expects the assessment committee to provide clear, critical, transparent, reliable, and independent feedback to reinforce successful activities and rethink the less successful ones, facilitating a more effective response to the next health emergency. ■

This article is adapted from *Facts About the Definition of the Pandemic Influenza (H1N1) 2009 and Vaccine Safety*. The full version of the document (with a complete list of references) is available at: www.paho.org/PandemicH1N1_VaccineSafety.

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