PANDEMIC INFLUENZA A (H1N1)

Donor Report
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EXECUTIVE SUMMARY

As the leading international agency for human health, WHO assumed a global leadership role in response to H1N1. The international community looked to WHO to lead countries through the crisis, from emergence through to each subsequent wave. WHO headquarters, regional offices, and country offices successfully carried out greatly expanded functions, around the clock, in coordinating global responses and limiting impacts. WHO has the experience, knowledge, and foundation upon which to build further structures, core capacities, and pandemic preparedness plans, worldwide. What the response to pandemic A (H1N1) has highlighted is that advances in reducing the impact and pervasiveness of a pandemic of influenza have been achieved. Today, there is unprecedented opportunity to undertake appropriate protective actions; given the alarming increase in emerging and re-emerging diseases, now is the time to strengthen collaboration for the sake of global health security worldwide.

This report highlights the ways in which WHO drew upon its resources, the impact of its activities and the ways in which it has used these opportunities to improve future responses. It is presented in four sections: WHO’s initial response, WHO global response plan, the vaccine deployment initiative and the IHR Review Committee. WHO’s response to H1N1 involved all levels of the Organization, working in close collaboration with partners. The overarching goal was to mitigate the impact of the pandemic by coordinating essential global activities and strengthening the readiness and response capacities of countries and communities, particularly the world’s most vulnerable populations. This innovative, cross-cutting, and dynamic functional approach was effectively adapted to the evolving pandemic situation.

INTRODUCTION

On 25 April 2009, the Director-General of the World Health Organization (WHO) announced a Public Health Emergency of International Concern. The emergence and rapid spread of a novel influenza virus, influenza A (H1N1), posed a pandemic threat. On 11 June 2009, WHO declared that an influenza pandemic was underway (Phase 6) because sustained human-to-human transmission was occurring at the community level in countries in two or more WHO regions. The 2009 influenza pandemic spread internationally with unprecedented speed and pandemic viruses were reported in all WHO regions in less than six weeks. As of 1 August 2010, worldwide more than 214 countries and overseas territories or communities reported laboratory-confirmed cases of pandemic influenza H1N1 2009, including over 18449 deaths.\(^1\)

In early August 2010, the World Health Organization officially announced the end of Phase 6 of the Influenza Pandemic Alert, with a global shift into the post-pandemic period. On behalf of the WHO, an Emergency Committee of external scientists met to review the epidemiological situation around the world. They noted that the H1N1 virus began to take on the behaviour of a regular seasonal flu virus, and that pandemic flu disease activity largely returned to levels normally seen for seasonal flu, thus fulfilling the criteria for declaration of the post-pandemic phase. During this phase of the virus, the UN Medical Services, including WHO Health and Medical Services and Regional Medical Services, continues to remain vigilant, maintain

\(^1\) World Health Organization. Weekly Update Pandemic (H1N1) 2009. 5 August 2010.
surveillance, evaluate previous responses, and revise pandemic preparedness plans accordingly. Annex Two contains a diagram of the pandemic phases.

From the initial outbreak in April 2009 to the recent shift into the post-pandemic period, WHO has emphasized adequate surveillance, good patient care, and appropriate risk communication as the basis for reducing the health impact of the pandemic. WHO's response to H1N1 involved all levels of the Organization, working in close collaboration with partners. The overarching goal was to mitigate the impact of the pandemic by coordinating essential global activities and strengthening the readiness and response capacities of countries and communities, particularly the world's most vulnerable populations. This innovative, cross-cutting, and dynamic functional approach was effectively adapted to the evolving pandemic situation.

Most national health systems were able to cope with the onset of H1N1. However, in some countries, outpatient, emergency and intensive-care services have been severely stressed during peak periods of activity. From the outset of the pandemic it was feared that the people in the least-resourced countries would be most affected because of the higher prevalence of risk factors, including limited capacities of health systems and the relative difficulty in accessing recommended vaccines and antiviral medicines. In particular, greater-than-usual numbers of patients with acute respiratory problems have placed significant stress on intensive-care support systems, even in developed countries.

As such, in consultation with its partners, UN agencies, and other relevant stakeholders, WHO developed and implemented strategic action plans to support Member States’ capacity to cope, specifically in least resourced countries, and to lessen the impact of pandemic A (H1N1) overall.

WHO’s response can be divided into four complementary activities. These consist of the initial response to the pandemic A(H1N1), the global pandemic response plan, the vaccine deployment initiative and the work of the IHR Review Committee. By pursuing these interventions WHO mitigated the impact of pandemic influenza A (H1N1) and strengthened the readiness and response capacity of countries and communities, particularly among the world's most vulnerable populations. These are outlined in more detail below:

- WHO’s initial response to the pandemic A(H1N1) consisted of responding to the crisis using the networks and systems which had been developed and refined over the past decade. These include implementing a rapid containment strategy and protocol and antiviral stockpile deployment as well as using tools such as the Global Outbreak and Alert Response Network, the Event Management System and WHO event-based information products.
- The global pandemic response plan In May 2009, WHO's headquarters and regional offices collaborated to build the Influenza A (H1N1) Global Pandemic Response Plan. This preparedness and response package was structured around six strategic actions aimed at strengthening the readiness and response of countries to the pandemic, including monitoring and tracking global and regional progression, transmission and impact of the pandemic; generating and sharing authoritative information to support country interventions and mitigation strategies; providing direct technical guidance and field support to countries in need; accelerating development of and access to vaccines; accelerating access to antivirals and other essential medicines; and providing global health leadership and mobilizing regional and global partnerships across sectors to combat H1N1. Through strategically
implemented initiatives related to these objectives and those noted above, the Organization significantly diminished and contained the impacts of the public health crisis.

- Vaccine deployment constitutes another section of the response. To help countries protect people from developing severe disease from pandemic influenza H1N1 infection, the World Health Organization (WHO) is coordinated the distribution of donated pandemic influenza vaccine to eligible countries through efforts to mobilize resources, ensure a sufficient supply of prequalified vaccines, support country readiness and deploy vaccines and ancillary products to countries.

- The IHR Review Committee is charged with conducting the assessment of the global response to the pandemic. It has three key objectives: to assess the functioning of the International Health Regulations (2005); to assess the ongoing global response to the pandemic A(H1N1) (including the role of WHO); and to identify lessons learned important for strengthening preparedness and response for future pandemics and public health emergencies. The Review Committee will deliver a report to the World Health Assembly in May 2011.
1. INITIAL RESPONSE:

In late April 2009, the World Health Organization (WHO) received reports of sustained human-to-human infections with a new influenza A (H1N1) virus in Mexico and the United States. In less than nine weeks, the virus had spread to all six WHO regions. Given the widening risk of disease caused by this virus and its unique genetic and antigenic characteristics as an influenza A (H1N1) variant of animal origin, WHO, in accordance with established procedures, increased the influenza pandemic alert level from phase 3 to phase 4 on 27 April 2009, to phase 5 on 29 April and to phase 6 on 11 June 2009. The virus has spread with unprecedented speed around the globe. The figure in Annex Three shows a timeline for event management in this initial phase.

In April 2009, WHO convened a group of experts to develop the initial guidance for clinicians on the management of human disease caused by the new influenza A (H1N1) virus. The advice was based on available information about the new influenza A (H1N1) virus as well as data on the natural history, pathogenesis and clinical characteristics of human infections caused by seasonal and avian influenza viruses. Additional data and experience from relevant animal models, other respiratory viral infections such as SARS (severe acute respiratory syndrome) and associated syndromes, particularly acute respiratory distress syndrome (ARDS) attributable to other causes, were also reviewed. The guidance and recommendations were regularly updated according to the evolution of the pandemic and the availability of new data.

1.1 Rapid containment of pandemic influenza: strategy and protocol

The purpose of the rapid containment strategy is to help national authorities, with the assistance of WHO and international partners, to stop/slow down, where possible, the progression of an emergent pandemic influenza when it is initially detected and before the virus has been able to spread widely.

The strategy evolved from 1) recognition that the potential for widespread harm and social disruption from an influenza pandemic is considerable; 2) recognition, based in part on the experience with SARS, that mobilization of large and complicated public health operations is possible in the modern era; and 3) from mathematical modelling studies suggesting that containment of a pandemic might be possible in the initial stages if the initial outbreak of human cases is localized and antiviral prophylaxis, movement restrictions, and non-pharmaceutical interventions are implemented in the affected area within the first 3 weeks1.

The WHO interim protocol2 Rapid operations to contain the initial emergence of pandemic influenza outlines a strategic approach to contain the initial appearance of pandemic influenza. It broadly lays out what should be done and to a lesser extent how a containment operation would be undertaken. It is expected that this general strategy would have to be tailored to meet specific conditions of the country in which the operation may be implemented.

The protocol builds on earlier versions and incorporates input from technical consultations of experts and WHO staff experienced in the areas of operational planning, outbreak response, logistics, epidemiology, laboratory diagnosis, infection control, ethics, social mobilization, and public and media communications. In addition, WHO headquarters, regional training workshops, consultations and
exercises on rapid containment in 2006, 2007 and 2008 have helped to refine protocol concepts and operational aspects.

Countries have been strongly encouraged to develop and integrate containment planning into their national pandemic influenza preparedness plans. Table-top, functional and field level exercises have been conducted by Member States and supported by WHO. These have been based largely on assumptions rooted in H5N1 influenza epidemiology, to test the response capabilities, operational plans and procedures necessary to mount a containment operation. These experiences, processes and practices were critical in allowing WHO and Member States to rapidly deploy antiviral stockpiles in the early stages of pandemic A(H1N1) in May of 2009.

1.2 Global Outbreak and Alert Response Network: A(H1N1) Initial Alert and Response

The Global Outbreak Alert and Response Network (GOARN) was established in April 2000 by WHO and technical partners to strengthen the coordination of international outbreak response. This work was crucial in establishing the resources and networks for the initial response to pandemic influenza A(H1N1). Partners agreed on the need for an early alert system to trigger rapid international response, and better response mechanisms to coordinate deployment of multi-disciplinary teams to assist countries in responding to outbreaks and to support WHO. GOARN was established to optimize the use of existing networks and institutions to respond to known and unknown diseases, and to support good operational practice as well as timely and transparent decision-making around the deployment of experts and field teams. Since 2000, GOARN has provided an operational framework for partners to respond to major outbreaks of avian influenza, cholera, dengue, encephalitis, meningitis, plague, SARS, viral haemorrhagic fevers, yellow fever, and other emerging pathogens such as Nipah virus. GOARN alerts, requests for assistance, operational updates, offers of technical support and details of deployments (in epidemiology, infection control, laboratory support, social mobilization, risk communications and logistics) are posted on the GOARN SharePoint website. The GOARN SharePoint website was developed primarily for operational communications within the Network, but has now added networking communications and advocacy and public relations as other communication-related components accessible via the SharePoint website. GOARN field missions are based operationally on WHO administrative rules and procedures, technical guidelines and standard epidemiological investigation protocols, and the Guiding Principles of International Outbreak Alert and Response as agreed with partners. Over the past 10 years GOARN has responded to over 139 missions in 75 countries.

The GOARN Alert and Request for assistance in Mexico began on 24 April, 2009, when WHO Alert and Response Operations issued a confidential Alert to GOARN partners about reports of Influenza-Like Illness (ILI), cases of swine Influenza A (H1N1), and severe pneumonia in the US and Mexico, and details of WHO's response. WHO/PAHO provided direct technical assistance immediately on infection control, field epidemiology and risk assessment, while a PAHO regional outbreak response team was deployed to the field to carry out rapid risk assessments and develop/implement response strategies. Additional outbreak response logistics field support in Mexico City was provided from WHO HQ. At PAHO’s request, GOARN supported coordination and information exchange with bilateral field teams from CDC, Atlanta and the Public Health Agency of Canada. (PHAC). Additional coordination and response planning were coordinated through GOARN with the World Organization for Animal Health (OiE), Paris and the United Nations Food and
Agriculture Organization (FAO), through the Centre FAO/OIE Crisis Management Centre - Animal Health (CMC-AH) in Rome, Italy. Regional activities were as follows:

- **PAHO Regional Response**: In close collaboration with PAHO, and in support of the regional response plan and activities, GOARN supported operational planning and coordination with key partners in the Americas, and deployed experts from partner institutions to support regional, sub-regional and country level response activities. The Field Information Management System (FIMS), was introduced through several PAHO country offices to allow its implementation by the Ministries of Health when managing epidemiological cases. Weekly web training sessions were organized by PAHO and supported by ARO. A PAHO/GOARN Review of regional operations was held in Panama in December 2009 to look at lessons-learned, tie down the potential role for partners in field missions, and levels of expectation from WHO.

- **Regional Office for the Western Pacific (WPRO) Response**: WPRO has implemented several regional activities to support the development of GOARN, including network advocacy with technical institution and Member States in the region, annual meetings of partners, regional and national training course and workshops for GOARN partners. GOARN partners in the Western Pacific region provided support to the Regional Office based in Manila, the Philippines, and also participated in H1N1 field missions in Malaysia and Mongolia. WPRO and ASEAN organized a joint GOARN Outbreak Response Training Course, including adapted sessions on A(H1N1) pandemic response in Luang Prabang, Laos - 3-9 May, 2009.

- **Regional Office for the Eastern Mediterranean (EMRO)**: An EMRO/GOARN regional outbreak/pandemic response training course on operational readiness, event management, coordination of response operations, surveillance, case investigation, risk communication and infection prevention and control took place in Cairo, Egypt, 15-18 June 2009.

The primary objective of the WHO H1N1 Global Response Plan was to mitigate the impact of pandemic influenza A (H1N1) by strengthening the readiness and response capacity of countries and communities, particularly throughout the world's most vulnerable regions. To ensure that Member States were provided with adequate support, the Pandemic Functional Teams structure was set up across clusters and departments to concentrate core activities for the implementation of the Global Response Plan, and to provide rapid interventions and support at global, regional, national and local level. The Pandemic Response Operations Team coordinated activities with regional offices to ensure operational, logistics and technical guidance and support to member States. A key output of the Team was providing direct technical assistance and field support to targeted countries.

GOARN's primary role was to rapidly provide direct multi-disciplinary support to countries to strengthen technical and operational capacity to respond to the A(H1N1) pandemic. GOARN also supported collaboration and engagement of international technical institutions and links to partners at all levels in the broader networking activities of the pandemic A(H1N1) global response. The GOARN Steering Committee held a meeting by teleconference on 14 May to discuss the A(H1N1) situation and current response, and activities of GOARN partners at national and international levels in support of the WHO A(H1N1) Global Pandemic Response Plan. For preparedness and contingency planning, on 30 April, 2009 the GOARN support team reviewed the GOARN partner's profiles to develop a resource mapping
of the expertise on standby, or potentially available for international deployment, including particularly staff who had completed the GOARN Outbreak Response Training. On 25 June, a further request for assistance was issued to GOARN to identify epidemiologists to support the Risk Assessment and Decision Support (ADS) team which is responsible for epidemic threat detection, risk assessment, monitoring the epidemiology of the disease and facilitating risk communications under the IHR. The ADS team works closely with threat-specific and operational programs at HQ, ROs, COs, the Global Influenza Programme, Information Technology (IT), and Geographical Information Systems (GIS) Departments and programmes. GOARN partners participated in WHO technical, scientific and planning teleconferences, including to disseminate scientific information and current knowledge with the scientist/researcher/investigators responding in the field, e.g. GiP Scientific Conference – 29 April, and May 5, 2009, WHO-OFFLU teleconference - 4 May 2009.

Key deliverables included rapid assessments; planning and organization of crisis management of health services; technical support, including epidemiology, infection prevention and control, case management, risk communications and social mobilization, and laboratory diagnostics support; as well as training, contingency planning, development and adaptation of intervention protocols. GOARN partners supporting the pandemic response are as follows:
- Association of Public Health Laboratories (APHL), USA.
- Burnet Institute, Australia.
- Caribbean Epidemiology Centre (CAREC), Trinidad and Tobago
- Centers for Disease Prevention and Control in Atlanta, USA; and Oficina Regional del CDC para Centroamérica y Panamá (CDC-CAP), Guatemala.
- Center for Infections (CFI) Health Protection Agency (HPA), UK
- European Centre for Disease Prevention and Control (ECDC), Sweden, including the European Network for Diagnostics of Imported Viral Diseases (ENIVD), based at the Robert Koch Institute (RKI), Germany; and the European Programme for Intervention Epidemiology Training (EPIET)
- Hospital Clinico, Universidad de Chile
- Imperial College, London, UK
- Institute of Health and Community Health (IHCH), Universiti Malaysia Sarawak, Malaysia
- Institut Pasteur(IP), France and Cayenne, and IP Global Network
- Institut National de Veille Sanitaire (InVS), France, and Cellules de l'Institut de veille sanitaire en région (CIRE) Antilles-Guyane.
- Instituto de Salud Carlos III, Madrid, Spain
- Instituto Nacional de Salud (NIH), Peru
- International Epidemiological Association (IEA), Egypt.
- London School of Hygiene and Tropical Medicine (LSHTM), UK
- Ministries of Health of Argentina, Brazil, Chile, Peru, and Spain
- National Influenza Centre, Instituto Nacional de Saúde, Portugal
- National Center for Epidemiological Surveillance and Disease Control Ministry of Health, Mexico
- PATH, Nicaragua
- Public Health Agency of Canada (PHAC), including the Centre for Emergency Preparedness and Response, Field Epidemiology Training Programme, and National Microbiological Laboratories (NML)
- Robert Koch Institute (RKI), Germany.
- Universidade Lusófona, Portugal.
- University of Texas - Medical Branch (UTMB), Galveston, Texas, US
- University of Valparaiso, Chile.
1.3 Country operation support and logistics coordination: antiviral stockpile deployment, May 2009

In 2005, WHO established a stockpile comprising 3 million treatment courses of oseltamivir (“Tamiflu”) to support the rapid containment of an emerging pandemic influenza virus. Between 2005 and 2009, the Global Alert and Response department developed plans and procedures for the release and deployment of the Rapid Response Global Stockpile that was held on behalf of WHO by the manufacturer Roche at two locations – Basel, Switzerland and Joppa, MD, USA.

In the first weeks of the response, WHO provided logistics support to work directly with the outbreak response team of the Ministry of Health in Mexico. An ad-hoc inter-cluster logistics group was established at WHO Headquarters and at the Regional Office for the Americas to support the WHO’s response and the Event Management Team within the Strategic Health Operations Centre (SHOC). On 29 April 2009, an Antiviral Task Force as established at WHO Headquarters to oversee the release and deployment of the stockpile. Once a rapid containment operation was no longer deemed feasible, the decision was taken, on 2 May 2009, to distribute the antiviral treatment courses held in the Rapid Response Global Stockpile to 71 lower-income countries as well as to Mexico. On 3 May, a definitive list of beneficiary countries was agreed, and written confirmation was provided to the manufacturer. A detailed distribution plan was rapidly developed to enable coordination with the targeted countries, to address legal aspects, to accelerate shipping processes, to facilitate custom clearance processes and to coordinate delivery schedules with WHO Country Offices and forwarding agents.

Timeline of significant dates:

3 May 2009 – Document processing for shipment of antivirals begins
7 May 2009 – First shipments (to Gambia, Ethiopia and Angola) to arrive in the countries
15 May 2009 – 80% of the stockpile has been successfully delivered to the beneficiary countries
25 May 2009 – Final shipment arrives in the Ukraine

In addition to the deployment of the global stockpile, the WHO Regional Office for Africa decided to release a regional stockpile of antiviral treatment courses, pre-positioned at the UNHRD in Dubai, UAE. Each of the 46 Member States of the African region was to receive 1000 treatment courses and an additional 10,000 treatment courses were to be made available to each of the Inter-country Support Teams (IST) in the African region. WHO Regional Office for Africa and Headquarters coordinated closely on this complementary response. Operations in coordination with UNHRD Dubai began on 5 May and were completed by 20 May 2009. In addition to supplies of antiviral treatment, respiratory syndrome investigation kits were prepositioned in all Member States, via WHO country offices, between May and October 2009.

1.4 EMS (Event Management System)

The Event Management System (EMS) is a project of the Alert and Response Operations (ARO) team within the Department of Global Alert and Response (GAR), developed over a decade, which has played a crucial role in collection, sharing and analysis of data on pandemic influenza A(H1N1). EMS is WHO’s repository information system to support decision-making and (risk) management of acute public health events. EMS contains 10 years of event-based data and provides a historical overview of events of potential international concern by region, country, hazard (threat) and disease/event type. As of 22 May 2010, there were 305 users of the EMS in 91 sites. EMS is used in all regional offices (12 sites), an increasing number of country offices (60 sites in AMRO/PAHO, AFRO and EURO) and 19 sites (teams) in HQ with new requests for access and training ongoing. Roll-out of the EMS is supported by the EMS Implementation Working Group (EMS IWG) constituted of expert users and trainers at WHO HQ and all regional offices.

The key objectives of the EMS project are to support the WHO global team in collecting, sharing and analyzing information on events and assessing risk for effective and seamless public health action; inform key decisions by presenting available information in a single place which can be accessed by many users; and accommodate and promote IHR (2005) specific activities and reporting as part of standard operating procedures for managing events.

In 1999, WHO initiated the development of a database (MS Access EMS) to improve communication and coordination of international outbreak alert and response. The application was designed to handle critical information, including event descriptors, quantitative epidemiological and laboratory data and situational updates. It provided an audit trail for key actions and decisions for each outbreak event, from initial report through response and event closure. Incoming information was triaged against the four criteria that were subsequently adopted by the IHR process as the screening criteria in Annex 2 of the IHR (2005): serious public health impact; unusual/unexpected; potential for international spread; and potential interference with international travel or trade.

The first version of EMS, which went live in January 2001, was primarily used at WHO HQ due to the technical limitations of MS Access as a multi-user platform, and
as such had limited functionality. SARS demonstrated the need to take event management and the EMS concept further by developing a technologically advanced management tool that would be fully integrated and compatible with the overall IT strategy of WHO, accessible by all key players in outbreak alert and response – in headquarters, regional and country offices – and able to handle all types of global public health emergencies, irrespective of scope and complexity. The new web EMS is a tool for the global WHO alert and response team that meets the needs of the all-hazards approach under the IHR (2005). WHO is now able to make full use of a single platform for event-based technical and operational information management, and its utility in this regard is demonstrated by the successful roll-out of the EMS to teams responsible for aspects of global public health security at all levels of WHO.

GAR/ARO will continue to support and enhance EMS in collaboration with the EMS Implementation Working Group (EMS IWG) represented by ARO’s technical counterparts in communicable disease surveillance and response units in all regional offices. The EMS IWG was convened in 2009 to coordinate the roll-out of the EMS and to provide ongoing technical input into the next phase of development. All regional offices have committed to rolling out the EMS and several have already delivered training to sub-regional teams and country offices. The project was effectively institutionalized in 2010 with the signing of a formal service agreement with the ITT Global Service Desk in Kuala Lumpur for EMS IT support. In parallel with the roll-out process, GAR/ARO will continue scoping further development and functionalities for the next phases of EMS.

Timeline - Key events

Jan 2001 - WHO launches its first version of the MS Access-based Event Management System. User base is in HQ.
May 2005 - Requirements gathering for the web Event Management System Project. The aim of the project is to develop a sophisticated secure web-based solution.
Jun 2006 - AMRO/PAHO starts using MS Access EMS, through remote connection to WHO network. EURO follows soon after.
May 2007 - MS Access EMS is modified to accommodate all hazards and natural disasters. In addition, changes are made to accommodate requirements under IHR (2005).
May 2009 - Web EMS goes live in its first (beta) version. First batch of current events migrated from MS Access EMS to web EMS.
Jun 2009 - EMS Implementation Working Group (EMS IWG) comprising staff at HQ and all regional offices created. All members of the EMS IWG are provided with Expert User training for the new web EMS.
Jul 2009 - EMS IWG completes migration of events in each region from MS Access EMS to web EMS.
Aug 2009 - EMS Expert Users are provided with a week-long training of trainers.
Mar 2010 - EMS goes live in its full version. EMS is now being used in all regional offices, several country offices and several departments at HQ.

1.5 WHO event-based information products

WHO’s information channels to external partners on acute public health events have included the Outbreak Verification List (OVL), Disease Outbreak News (DON), ShareGOARN, and most recently the Event Information Site for IHR National Focal Points (EIS). The objective of event-based risk communication and information products is to enable critical information exchange between WHO, Member States and key partners, as well as operational communications within WHO. GAR/ARO
has aimed for low to medium volume, high quality reports about public health events across all hazards within WHO's mandate, i.e. a highly selective sub-set of the universe of public health events. There has been no intention to compete with the genre of global disease alert and early warning systems such as electronic mailing lists (e.g. GPHIN) and websites (e.g. MedISys, ProMed, HealthMap etc). Potential information products are driven by the joint risk assessment process involving the WHO country offices, regional offices and HQ.

Information needs include: Information for immediate public health action including actions required to prevent the occurrence of similar incidents in unaffected countries (compliant with Article 11 of the IHR (2005)), Information for operational preparedness (e.g. GOARN partners), Information to correct misinformation and/or prevent inappropriate actions from Member States or others, and public information to address broader community interest, media interest and to help maintain WHO’s profile in area of global health security.

Over a period of 10 years from ~1998-2007, the weekly electronic publication of the OVL established WHO’s reputation among public health professionals and technical institutions as a source of relatively timely, reliable and unbiased information about acute public health events of interest to the international public health surveillance, response and research communities. OVL communications were supplemented by operational information provided directly to GOARN partners and general updates in the public domain on the Disease Outbreak News (DON) section of the WHO website. There was considerable overlap between OVL and ShareGOARN readership.

In accordance with the more stringent confidentiality requirements under the IHR (2005) that came into force on 15 June 2007, the OVL was phased out on 6 June 2007. It was replaced with the EIS, a secure (password protected) low-medium volume, high profile website accessible to IHR National Focal Points, heads of WHO country offices (WRs), staff at Heads of WHO Country Offices (WRs), staff at WHO HQ and regional offices, and selected intergovernmental organizations (IGOs). The aim of establishing the EIS was to fulfil WHO’s information-sharing obligations under the IHR (2005), using the NFPs as the conduit of that information to all in-country health protection agencies and professionals who need to know.

A user satisfaction survey and needs assessment of the EIS carried out in the second half of 2010 will inform a requirements gathering exercise to redevelop the site from an information technology perspective in order to accommodate communication needs not anticipated in the original design e.g. issue-specific pages, regional situational reports, event linkage and a variety of announcements.

The EMS is the source of most event-based information provided by WHO for external and internal audiences – formerly the OVL and currently the EIS, ShareGOARN, DON and internal operational communications. This inter-relationship and inter-dependence is enabling ways of streamlining further development of the various communication products. The 2009 (H1N1) pandemic has substantively increased the number of users and readership of the EIS. GAR/ARO is working with regional and country offices to maintain this momentum.

Timeline - Key events
Jan 1996 - Cholera in Burundi appears as the first event in Disease Outbreak News (DON) http://www.who.int/csr/don/en/
13 May 1998 - First Outbreak Verification List (OVL) is distributed (sent weekly to an electronic mailing list for ~10 years)
1 Jan 2001 - MS Access EMS goes live at WHO HQ with data transfer to OVL and later to EIS
15 Jun 2007 - The (secure) Event Information Site for IHR National Focal Points (EIS) is launched http://apps.who.int/csr/alertresponse/ihreventinfo/
May 2009 - The (secure) Web EMS goes live in its first (beta) version http://ems.who.int

2. WHO INFLUENZA A (H1N1) 2009 GLOBAL PANDEMIC RESPONSE PLAN

Within the framework of the 2005 International Health Regulations (IHR), the World Health Organization mobilized technical capacity across the Organization and with its partners to coordinate the response to H1N1. In May 2009, WHO’s headquarters and regional offices collaborated to build the Influenza A (H1N1) Global Pandemic Response Plan. This preparedness and response package was structured around six strategic actions aimed at strengthening the readiness and response of countries to the pandemic. These included:

- Monitoring and tracking global and regional progression, transmission and impact of the pandemic;
- Generating and sharing authoritative information to support country interventions and mitigation strategies;
- Providing direct technical guidance and field support to countries in need;
- Accelerating development of and access to vaccines;
- Accelerating access to antivirals and other essential medicines; and
- Providing global health leadership and mobilizing regional and global partnerships across sectors to combat H1N1.

WHO’s Influenza A (H1N1) Global Pandemic Response Plan has served to guide the Organization as a whole in its work to minimize the impact of pandemic influenza A (H1N1). A key component of the plan was to provide global health leadership and facilitate collaboration with WHO’s partners to mobilize resources and technical expertise to respond decisively and effectively to the pandemic. Through strategically implemented initiatives related to these objectives and those noted above, the Organization significantly diminished and contained the impacts of the public health crisis.

2.1 Monitoring and Tracking Global and Regional Progression, Transmission, and Impact of the Pandemic

In order to respond effectively to H1N1, it was crucial that WHO track and assess regional and global progression and transmission of the virus, as well as monitor the impact of human infection so as to provide countries, the public and its partners with the best information upon which to act.

WHO carries out event-based surveillance for clusters of acute respiratory disease and other signals of unusual respiratory disease activity as part of the early warning system for emerging respiratory diseases, including new influenza virus activity. These events are entered into WHO’s global Event Management System (EMS) and a process of event verification and risk assessment is initiated via the International
Health Regulations (2005) mechanism (IHR National Focal Point) and other relevant government authorities and influenza networks. Report findings, event mapping, and risk assessments are rapidly communicated through appropriate channels to Member States worldwide. To achieve this, WHO has focused its efforts on three main outputs:

- Regular, timely, and authoritative information on disease spread and impact;
- Rapid identification, verification, and characterization of events in newly affected countries; and
- Ongoing pandemic assessment.

The following section elaborates on how well-executed initiatives rolled out since April 2009 enabled the Organization to fulfill these outputs and to effectively monitor and track pandemic A (H1N1).

**Regular, timely, and authoritative information on disease spread and impact**

A key requirement for countries’ preparedness for pandemic (H1N1) 2009 was to have regular, timely, and authoritative information on disease spread and impact. Since April 2009, the worldwide monitoring of pandemic disease has been ongoing. For one, data on the number of specimens positive for pandemic H1N1 and seasonal influenza viruses have been collected through FluNet, an internet-based data query and reporting tool developed by WHO to facilitate global influenza reporting, as well as to gather information directly from WHO Collaborating Centres (CCs). As of 21 November 2009, a total of 82 countries reported data on the number of specimens positive for pandemic through FluNet. The total number of specimens reportedly positive for influenza viruses by NIC laboratories was 309204. Of these, 220641 (71.4%) were pandemic H1N1.²

The epidemiological information collected through global reporting systems, such as FluNet, helps to support the collection of detailed situation reports, which are then published weekly. Through the WHO website, *Weekly Epidemiological Report (WER)*, and other publications information is easily exchanged between and with Member States. In addition to FluNet, the situation updates are derived from a number of different data sources, including reports on ministries of health websites, reports submitted by WHO offices, and monitoring of media and other informal data sources. These data are displayed graphically to describe different facets of pandemic progress. The reports cover viruses, geographical spread, trends in acute respiratory infection (ARI) and influenza-like illness (ILI), intensity of the disease, and the impact on health services. Country reports on cases and deaths are likewise reported but not systematically. Antiviral resistance is also monitored, with cases reported regularly.

Technical work is also ongoing to standardize the reporting of risk factors for country reporting. This will aid in monitoring for changes in the epidemiology or virulence of the virus but will also help to further clarify the role of newly recognized risk factors for severe disease such as obesity. Standardization of reporting also greatly helps to facilitate the ability to aggregate and summarize data. Improvements will lead to a better understanding of the contribution of each of these factors to severe outcomes with pandemic influenza. WHO staff are writing an annex to the *Pandemic Guidelines for Surveillance* that will standardize reporting for risk factors and fatal cases.

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Rapid identification, verification, and characterization of events in newly affected countries

Strong laboratory capacity in countries is essential for detection, monitoring, and controlling pandemic influenza. To ensure rapid and reliable diagnosis of H1N1 in countries, WHO supports Member States by providing operational support to influenza sample shipment systems. WHO also provides guidance facilitating the efficient implementation of pandemic influenza laboratory diagnostics to allow rapid identification and risk assessment of events in newly affected countries.

WHO surveyed the urgent needs and priorities of 62 developing countries. The results revealed that less than one-third of countries have fully functioning National Influenza Centres (NICs) and the majority of the laboratories surveyed required some form of assistance in order to ensure that they could perform their diagnostic functions adequately during the pandemic. Therefore, in 2009 WHO focused on laboratory capacity building efforts for the diagnosis of pandemic H1N1, with special training sessions and the development and implementation of guidance documents recommending containment conditions for work with pandemic (H1N1) 2009, as well as viral subtypes of avian H5N1.

From the start of H1N1 pandemic (19 April 2009) through 28 November 2009, 150 countries shared a total of 19284 specimens (14879 clinical samples and 4405 virus isolates) with WHO CCs for confirmatory diagnosis and further characterization. These shipments were facilitated by the WHO global shipment fund project. For example, in response to outbreak in the Ukraine, shipments of 227 vials were sent from the Ukraine Central Sanitary Epidemiology laboratory to the National Institute for Medical Research (NIMR) in London.

Ongoing pandemic assessment

To maintain an ongoing pandemic assessment WHO collects and analyses clinical information; develops and rolls out surveillance reporting standards; and generates a system for country level data reporting. WHO also has the capacity to regularly review and generate clinical, epidemiological, and virology trend data. Countries profit from WHO’s systematic reviews of all surveillance data published in web updates, peer reviewed publications, and other briefing notes.

In addition, WHO coordinates a Global Influenza Surveillance Network (GISN), which monitors influenza viruses, including their molecular and antigenic evolution. The GISN also analyses other virus properties (e.g. antiviral drug sensitivity), and provides a risk assessment of the public health implications. To date, GISN is comprised of:

- 128 National Influenza Centres (NICs) in 99 countries;
- Five WHO Collaborating Centres for Reference and Research on Influenza (WHOCC);
- Four Essential Regulatory Laboratories (ERLs); and
- 11 WHO H5 Reference Laboratories.4

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3 Ibid.
4 World Health Organization, UN Office for the Coordination of Humanitarian Affairs, and UN System Influenza Coordination. Urgent Support for Developing Countries’ Responses to the H1N1 Influenza Pandemic. 31 March 2010.
The work done by the GISN has been the scientific foundation for many other response measures, such as the preparation of guidance documents and materials, use of antiviral drugs and the development of vaccine. Under the coordination of WHO, GISN laboratories detected the emergence of the pandemic (H1N1) 2009 virus; provided updated laboratory diagnostic assays and reagents; analysed trends among the proportion of circulating pandemic and seasonal influenza viruses; and provided vaccine composition recommendations. From 19 April through 12 December 2009, 152 countries shared 20112 specimens (15037 clinical samples and 4486 virus isolates) with WHO CC laboratories.

GISN is also alerted to mutations of public health importance. Viruses with mutations are being detected in both severe and non-severe cases. Assessing risk associated with this and other mutations requires linking virological, epidemiological, and clinical data. All relevant networks have been notified to link these data for a comprehensive risk assessment. Systems and tools for making these linkages have been identified or developed. Global teleconferences are held to review routine and emergency laboratory response and virological findings. Participants include GISN members, WHO regional offices, the World Organization for Animal Health (OIE)/ UN Food and Agriculture Organization (FAO) Network of Expertise on Animal Influenza (OFFLU), and external research institutes. Virus characterization, diagnostic preparedness and situation updates are shared.

2.2 Generating and Sharing Authoritative Information to Support Country Interventions and Mitigation Strategies

WHO supports national, regional and international assessment, response and mitigation efforts by generating scientific, evidence-based knowledge that can be rapidly shared to achieve optimal effectiveness of interventions. Information-sharing and coordination are essential to avoid duplication or divergent activities and better address the needs in this resource-limited area of work. Generating and transferring knowledge is a cross-cutting activity that impinges on all other strategic actions in the Global Pandemic Response Plan.

WHO has organized and managed an extensive use of teleconferences and technical meetings, enabling the Organization to generate and share knowledge and information. Regular teleconferences are held on virus monitoring, epidemiology, patient care, pandemic modeling, societal and individual measures, and risk communication. These teleconferences include weekly meetings with UN partners to ensure consultation and information sharing with Member States through missions briefings, Regional Committee meetings, and direct contacts with national authorities. These ongoing weekly teleconferences continue to ensure communications and consistency of messaging.

Beyond the weekly meetings with UN partners, rapid communication and information exchange has also been facilitated among partners and influenza experts worldwide through larger, global teleconferences. Two international meetings on clinical management and research resulted in revised guidance on patient care and a global research agenda on pandemic and seasonal influenza. On 14-16 October 2009, for instance, the clinical management team, in conjunction with the Pan-American Health Organization, hosted a global consultation on management of the H1N1 pandemic. Over 100 clinicians, virologists, epidemiologists, and other experts convened to review global knowledge and develop recommendations for clinical management of the disease. Other teleconferences held during September - December 2009 included:
8-9 September: Infection Prevention and Control Network Meeting to share information on the revision of Infection Control guidance for H1N1.

7 October: Global teleconference on virological monitoring of the pandemic H1N1 virus with GISN members, regional offices, and other experts. A summary of the findings was prepared.

14-16 October: WHO Global Consultation on the Clinical Aspects of Pandemic H1N1 Influenza.

3 November: Technical consultation with WHO CCs to update them on H1N1 virus characterization; antiviral susceptibility monitoring; diagnostic kit and protocols development, availability, and distribution; and vaccine viruses and reagents, their development, availability, and distribution.

1-4 December: 2009 meeting of National Influenza Centres.

Publications available on WHO's website, in WER, and in journals have contributed significantly to knowledge and information sharing. Based on the request of Member States, guidance documents have been developed by WHO. To coordinate worldwide research efforts, WHO shapes the public health research agenda for H1N1 identifying knowledge gaps and priority research topics. The Global Influenza Programme (GIP) hosted a global consultation to develop a public health research agenda for influenza comprising on five streams of public health research topics:

- Reducing the risk of emergence of pandemic influenza;
- Limiting the spread of pandemic, zoonotic and seasonal epidemic influenza;
- Minimizing the impact of pandemic, zoonotic and seasonal epidemic influenza;
- Optimizing the treatment of patients; and
- Promoting the development and application of modern public health tools.

Over 150 participants, including public health decision makers, researchers, and representatives from 76 institutions in 37 countries, reviewed the draft version of the research agenda and exchanged ideas on public health research topics related to influenza that should be prioritized over a medium- to longer-term period.

A research information database on published works on H1N1 is already being developed. WHO aims for all published works to be evidence-based, systematically prepared, and transparently reported. Once published, they are then regularly reviewed and updated as new data becomes available, with a special emphasis on information from low- and middle-income countries. Annex Three contains a list of documents related to pandemic influenza published in the last several years.

In addition to these documents and the regular international teleconferences, WHO supported assessment, response, and mitigation efforts by generating scientific, evidence-based knowledge, which allowed for increased effectiveness of interventions. Detailed incidence reporting has occurred weekly in WHO and, as noted in the previous section, data is shared via FluNet. In September 2009, the epidemiological group developed a new way of weekly data reporting in collaboration with Geographic Information Systems (GIS) team. Annex Four illustrates the specimens that tested positive for pandemic H1N1 2009 worldwide.

WHO communications and technical staff have also held weekly virtual press briefings and briefed journalists on the pandemic situation at the United Nations in Geneva twice per week. Communications staff likewise prepared materials to support
the Organization and Member States in their communications interactions, and monitor the media in order to improve communications. To this end, the WHO website was and continues to be a key vehicle for delivering information to diverse audiences. The website provides technical guidance to health professionals, personal protection measures to individuals, and general information and updates to journalists and the general public.

2.3 Providing Direct Technical Guidance and Field Support to Countries in Need

One of the key goals of WHO is making guidance accessible and providing field and technical support to strengthen capacity for health readiness and mitigation in countries and communities, especially in the world’s most vulnerable regions. Guidance and support material covers clinical management, preparedness, and intervention, while country support includes rapid detection and alert, investigation mechanisms, access to diagnostics, infection control, case management, vaccine post-marketing surveillance, and community interventions. To build preparedness and reduce transmission, WHO supports the implementation of societal and individual measures in schools, workplaces, and municipalities. Furthermore, WHO provides support to requests from countries for specific technical consultation/training.

Strategic guidance for national preparedness measures

The Global Outbreak Alert and Response Network (GOARN) is a partnership of over 190 technical institutions worldwide, coordinated by WHO. Through GOARN, WHO has facilitated the deployment of consultants to developing countries worldwide, to strengthen their health systems and their pandemic preparedness plans. When the H1N1 virus first emerged, WHO issued an alert to GOARN on 24 April 2009 and over the following months, technical institutions in the network have provided experts, including epidemiologists, laboratory scientists, clinicians, infection prevention and control experts, outbreak logisticians, and communications experts in response to requests for assistance from ministries of health and WHO country offices.

In addition, 188 missions deployed to 27 countries were carried out to further strengthen international operational coordination and national preparedness and response. The support provided ranged from pandemic situation assessment, to partners coordination through risk communication, patient triage and care, infection control, laboratory diagnostic, and specimen shipping, among others. The missions also focused on capacity building, including through the development of guidelines for managing the pandemic. Following these missions, debriefings composed of presentations and reports, circulated through GOARN's SharePoint so that team members could follow through on action points. Support to countries was coordinated through the J.W. Lee Strategic Health Operations Center (SHOC) in connection with Regional Operations Centers/Units. During the acute phase of pandemic A (H1N1), activities took place around the clock.

WHO also participated in various meetings and consultations in order to assist Member States enhance their national communications and preparedness strategies. In September 2009, for example, WHO provided an overview of the global context of the pandemic at the Public Health Agency of Canada's meeting on Severe H1N1 Disease: Preventing Cases, Reducing Mortality. WHO provided information on H1N1 and workplace preparedness to the Finnish Institute for Occupational Health, as well.
Adapted technical guidance for national/community application

Developing frameworks and technical documentation adaptable to national contexts is an important part of WHO’s work on guiding and supporting countries. For instance, the Organization has developed and published the *Interim planning considerations for mass gatherings in the context of pandemic (H1N1) 2009 influenza*. The purpose of this document is to outline key planning considerations for organizers of mass gatherings in the context of pandemic A(H1N1) 2009 influenza. It should be used in conjunction with WHO’s *Communicable disease alert and response for mass gatherings - key considerations, June 2008*. The food safety section of the latter has also been updated to include information about pandemic (H1N1).

WHO also developed a series of guidance documents related to case management of pandemic H1N1 on ships, airplanes, and at borders. The *WHO interim technical advance for case management of pandemic (H1N1) 2009 on ships*, is one such example. This series is updated regularly and can be accessed on the WHO website. The target audience includes competent authorities at ports and national public health officials, as well as ship operators, port administrators, other port personnel, ship crew members, and port authorities and stakeholders involved in ship travel. Likewise, WHO also published a document entitled, *Case management of influenza A (H1N1) in air transport*. This document is the result of collaboration between the IHR Coordination Department and the Task Force for the pandemic (H1N1) 2009 response at WHO, the International Civil Aviation Organization, and the Air Transport Association. It compiles recommendations from existing guidelines for air travel and health, as well as specific WHO guidelines related to the pandemic H1N1 2009 virus where applicable for air transport. It also outlines measures to be taken by aircraft operators, airport operators, airport personnel, crew members, and national authorities. These represent just a few examples of the many training materials and technical documentation that WHO has published since April 2009, in order to guide and support Member States in dealing effectively with pandemic A (H1N1).

Urgent training and workshops for readiness, mitigation and community intervention

In line with the Global Response Plan, WHO has developed training and workshops to increase preparedness and build capacity for mitigation and community interventions at regional and sub-regional levels. Some of the achievements include:

- A community health worker training module for home-care, health education, and case management of influenza-like-illness was finalized and field-tested in Sierra Leone and Tajikistan.
- A district hospital training package for management of severe respiratory disease has been completed, and was field tested in South Africa, Ethiopia, and Uganda.
- Development has begun of a pandemic influenza clinical management training curriculum for health-care professionals.

WHO has developed training and workshops to increase preparedness and build capacity for mitigation and community interventions at regional and sub-regional levels. Two sessions of biosafety level 3 (BSL-3) laboratory hands-on training were organized by WHO. At one workshop, experts from Emory University (Atlanta, Georgia, USA) were invited as trainers; the training took place in the BSL-3 laboratory in the French Food Safety Agency. 17 participants from National Influenza Centres in developing countries, which have or are about to have BSL-3 facilities, participated in the training.
Finally, WHO remained vigilant about providing direct guidance to countries and partners on surveillance, care, and risk communication, societal and individual measures. Responses to questions and issues raised by countries were regularly provided by e-mail, phone, and videoconferences.

**Direct technical assistance and field support to targeted countries**

WHO’s work in guiding and supporting countries entails providing accessible guidance and direct technical assistance for capacity strengthening and field support to countries and communities for readiness and response. During this reporting period, WHO received several requests for technical and material assistance from countries across Eastern Europe, Afghanistan and Mongolia. Typically, countries that request assistance from WHO have weak health systems and large populations with risk factors for disease severity. WHO must ensure coordinated, equitable and comprehensive responses. To this end, the Operations team is involved in providing the requested support and is actively engaged in ensuring, through the SHOC room facilities, a comprehensive follow-up of the requests received and responses provided, to help avoid both gaps and duplications among headquarters teams, and between WHO headquarters and the regions.

Likewise, WHO worked with countries to procure critical supplies and equipment to build laboratory capacity. WHO worked with 62 least resourced countries to procure critical supplies and equipment to build laboratory capacity. Action plans for the WHO African Region, WHO Region of the Americas, and WHO Eastern Mediterranean Region were prepared and funding from bilateral sources was secured. In collaboration with United States Centers for Disease Control and Prevention (CDC), primers and probes for detecting the H1N1 virus, as well other essential laboratory consumables and transport equipment have been distributed worldwide. To date, 1,142 diagnostic kits for real-time RT-PCR were shipped to 153 countries and include the following distributions to WHO regions: African Region, 93 kits; Region of the Americas, 497 kits; South-East Asia Region, 80 kits; European Region, 186 kits; Eastern Mediterranean Region, 104 kits; and Western Pacific Region, 74 kits.\(^5\) In addition, a WHO mission to China concluded that the NIC in China should be designated as a WHO Collaborating Centre for Reference and Research on Influenza. It will be the 6th WHO CC on influenza in GISN.

Finally, in addition to those noted above, there were several other instances where WHO was able to provide technical assistance directly to countries in support of major international special events, including:

- Providing guidance to the Kingdom of Saudi Arabia related to planning for this year’s Hajj. WHO published health requirements for people entering the country for the Hajj in the WER on 13 November 2009.
- Making recommendations and undertaking a mission to South Africa to implement the public health planning roadmap for the FIFA World Cup in 2010.
- Collaborating with the Health Protection Agency in the UK to develop a checklist assessment tool for event planner. This will be piloted during the planning of the 2012 Olympic Games in London.
- Capturing international data on travellers and prioritizing a list of communicable diseases, as well as ensuring proper use of WHO resources

\(^5\) Ibid.
for disease management and communication strategy, for implementation during the World Expo 2010 in Shanghai.

2.4 Accelerating Development of and Access to Vaccines

As soon as the first human cases of new influenza A(H1N1) infection became known, WHO supported the development of candidate vaccine viruses. Since then, WHO has worked to facilitate and accelerate the availability and access of quality vaccine to countries. The Organization has initiated consultations with vaccine manufacturers worldwide in order to facilitate the availability of all materials necessary to begin production on the pandemic (H1N1) 2009 vaccine.

In August 2009, WHO convened a group of national and supra-national regulators to monitor and share results from clinical trials of H1N1 vaccine. In weekly teleconferences, critical information has been shared confidentially among regulators, allowing for a joint approach to address issues and for accelerated registration of pandemic vaccines. The first commercially-available pandemic influenza vaccines were registered for use in September 2009. Also in September 2009, an expedited prequalification procedure was established to respond to the need for emergency immunization with the pandemic vaccine. This was updated on 2 November. To date, two pandemic influenza A (H1N1) vaccines have been prequalified for purchase by UN agencies.

In December 2009, WHO launched a second survey of all influenza vaccine manufacturers to update the first estimates of global production capacity for pandemic vaccine, which had been published in Vaccine (Nicolas Collin, Xavier de Radiguès and the World Health Organization H1N1 Vaccine Task Force, Vaccine production capacity for seasonal and pandemic (H1N1) 2009 influenza, Vaccine (2009)). Results of the new survey provided accurate information on how much vaccine was produced in 2009 and on how much supply should be expected in 2010.

The role of developing country manufacturers has been an important strategy pursued by WHO and its partners in order to help meet worldwide demands for vaccines available during pandemics. WHO provided technical assistance to two developing country vaccine manufacturers to accelerate the preparation of clinical trials of pandemic vaccines. As a result, the Governmental Pharmaceutical Organization of Thailand (GPO, Bangkok, Thailand) and Serum Institute of India Ltd (SII, Pune, India) were to initiate clinical trials before the end of December 2009, aiming to register a pandemic vaccine in their countries during the first quarter of 2010.

Status of development and availability of candidate vaccine viruses and potency testing reagents for 2010-2011 vaccine production, is updated frequently and published on WHO’s website.6

As noted above, WHO plays a leading role in influenza virology and diagnosis. This includes setting up norms and standards for global surveillance and public health response, and on the ongoing epidemic and pandemic risk assessment. In February and September each year, the Virus Monitoring, Assessment and Vaccine Support (VMV) team organizes a vaccine composition consultation with WHOCGs, ERLs, and NICs to select the viruses to be included in seasonal and pandemic influenza

vaccines for the following winter seasons in northern and southern hemispheres. The strain selection meeting for the southern hemisphere was held on 19-23 September 2009 in Melbourne, Australia. Recommendations for the strain selection were also discussed at a teleconference with the Strategic Advisory Group of Experts (SAGE) on Immunization members and regulators on 21 September. The vaccine composition recommendations were published in the 9 October 2009 issue of WER, entitled *Recommended composition of influenza virus vaccines for use in the 2010 influenza season (southern hemisphere winter)*. During its October 27-29 meeting, the SAGE once again reviewed the options for southern hemisphere seasonal influenza vaccine formulations for use in 2010. These recommendations were published in the 4 December 2009 issue of *WER*. As of 5 November, a total of 549 shipments of candidate pandemic vaccine viruses had been sent to vaccine manufacturers and institutes. More on vaccine deployment is discussed in the second half of this report.

### 2.5 Accelerating Access to Antivirals and Other Essential Medicines

Growing international experience in treating pandemic H1N1 infections indicates the importance of early treatment with antiviral drugs, especially for patients at increased risk of developing complications, such as those with severe illness. As part of its Global Pandemic Response Plan, WHO provides technical and logistics support to facilitate and accelerate the availability and access of effective antivirals.

During pandemic A (H1N1), the majority of developing countries requested assistance from WHO with access to and procurement of antiviral medicines. In September 2009, WHO estimated that between 3% and 6% of the population in least resourced countries could require antiviral treatment. For the least resourced countries, it was estimated that around 78 million treatment course would therefore need to be provided in order to ensure that those with severe illness could be treated.\(^7\)

WHO subsequently established global stockpiles of influenza antivirals and personnel protective equipment, including stockpiles to support Rapid Containment Operations and stockpiles to support regional preparedness and rapid deployment to Member States. Since April 2009, WHO has deployed over 4.7 million treatment courses of oseltamivir to 72 countries worldwide from combined global and regional stockpiles. To help targeted countries distribute and replenish their stocks from available international antiviral stockpiles, WHO created an Antiviral Task Force (ATF). The Task Force also assesses regional manufacturing capacity.

Initially convened in April 2009, the Antiviral Task Force was established as part of WHO’s early pandemic response measures to provide information and support to senior management with allocation, deployment, and distribution of antivirals (primarily oseltamivir). In the development of a medium-term response structure, it was agreed that there was a continued need for an ATF to provide guidance on measures and issues related to use of and access to antiviral medicines including (but not limited to):

- Strategic planning for WHO global strategic antiviral stockpile, including management of rapid containment stockpiles, coordination with international stockpile holders;

\(^7\) WHO, UNOCHA, and UNSIC. Urgent Support for Developing Countries’ Responses to the H1N1 Influenza Pandemic. 30 June 2010.
Global production capacity assessment (antiviral availability, affordability, cost);
• Enhancing global production capacity (liaison with industry, prequalification, essential medicines list (EML));
• Access (liaison with donors, NGOs, distribution, support country/regional procurement);
• Regulatory support and advice (national registration and labeling, shelf life, disposal, counterfeit);
• Plan for damage control (antiviral resistance); and
• Monitoring development of new formulations, presentations and new antivirals (those which are in advanced stages of clinical trials).

The ATF provides technical expertise and operational support to WHO Pandemic H1N1 Management and Senior Policy Group (SPG) on matters relating to development, production, quality, access, distribution, and use of antiviral medicines. It has also developed and maintained an action plan for equitable access and timely distribution of antivirals, as well as served as in an advisory role to SPG, Pandemic Management, and others to implement this place. Lastly, ATF provides support for effective communication and collaboration across WHO functions and groups for overall implementation of the Global Pandemic Response Plan, in addition to other matters, as required.

Finally, in addition to logistics support, WHO also provides policy guidance on regulatory issues and supply chain management, advocating for applications for prequalification or to support capacity building and negotiating price and procurement contracts for prequalified antivirals for developing countries. To rapidly provide countries with up-to-date guidance, WHO has initiated an accelerated review process of WHO treatment guidelines for pandemic H1N1 influenza.

2.6 Providing Global Health Leadership and Mobilizing Regional and Global Partnerships Across Sectors to Combat the Pandemic

WHO fulfils its global leadership role by overseeing international efforts to manage the resources required to implement the pandemic response plan. The newly formed H1N1 group ensures optimal allocation and use of resources, and avoids duplication of efforts. Also, with regards to communications with Member States, other UN agencies, and with the public, the H1N1 group enables uniformity of pandemic messaging. WHO guides the global response in close collaboration with the UN Secretary-General, UNSIC, and other UN agencies. Global coordination efforts include, amongst other activities, the provision of technical advice and support to external partners and sharing of relevant information on home-based care and community health guidance with international organizations. Some additional collaborative activities in which WHO has participated in with its partners to confront the pandemic include:

• Undertaking a cooperative research effort with the International Federation of Acute Care Trialists (InFACT), to facilitate multicentre studies on the national history and response to therapy of patients with H1N1, as well as its impact on health-care systems. Data collection on critical cases of H1N1 cases has been initiated via the InFACT website, and through the World Federation of Societies of Intensive and Critical Care Medicine website.
- Participating in the World Tourism Organization's (UNWTO) Workshop on Travel and Tourism under Pandemic Conditions. Experts from WHO presented an overview of the status, transmission and impact of the virus.
- Coordinating operational activities related to the deployment of pandemic antivirals and vaccines.

Moreover, the Urgent Needs Identification and Prioritization (UNIP) exercise performed by WHO, UN System Influenza Coordination (UNSIC), and Pandemic Influenza Contingency (PIC) Unit/Office for the Coordination of Humanitarian Affairs (OCHA) in August and September 2009 covered 77 developing countries and provided relevant information that allowed WHO to better guide and support countries most in need. WHO also organized or participated in more than fifty meetings and consultations to assist countries with their national communications and preparedness for the H1N1 pandemic.

Additionally, working closely with the Global Influenza Programme, IHR Coordination has played a major role in the WHO response to the pandemic. In response to the first reported cases of H1N1 and in accordance with the IHR, the WHO Director General decided to convene, on 25 April 2009, the first meeting of the IHR Emergency Committee. As Secretariat for the H1N1 emergency committee, its role in supporting the National Focal Point (NFP) Network, ensuring access to the secure NFP website, and maintaining NFP contact details and the roster of the IHR experts was put to the test. The administrative procedures developed during earlier global exercises were crucial for the successful organization and running of Emergency Committee meetings. With a total of six Emergency Committee meetings and numerous response activities, IHR Coordination staff were on call and working around the clock over a period spanning several months.

All six IHR Coordination teams were involved in the pandemic response at different levels. Seven technical and guidance documents were published, specific training sessions organized and networks mobilized. The teams provided support to Member States for drafting emergency response plans, regulations and documents on laboratory safety, diagnosis, travel, biohazards, and risk communication to name only a few areas. Thousands of calls and questions were answered and guidance was regularly provided.

### 2.7 Conclusion
Through providing a framework for WHO's strategic response, the response plan facilitated the work of WHO in significantly diminishing and containing the impacts of the public health crisis.
3. WHO PANDEMIC (H1N1) 2009 VACCINE DEPLOYMENT INITIATIVE

In June 2009, the World Health Organization (WHO) declared the first influenza pandemic in 40 years. Many elements were needed to respond effectively to the H1N1 pandemic, such as education and communications, but one of the most effective ways of protecting people from developing severe disease was – and remains – through vaccinating populations at risk.

The current estimated global manufacturing capacity for pandemic vaccines is at most 4.9 billion doses per year, provided the following assumptions are met: all production capacities are used to generate monovalent vaccine; there is a utilization of adjuvanted formulations to maximize antigen-sparing; and the production yield for the pandemic vaccine is equivalent to that obtained routinely for seasonal vaccine.

However, for the monovalent vaccine production of pandemic A(H1N1) 2009, these conditions could not be met, and subsequently, only about 500 million doses were produced by end December 2009. It was therefore expected, even in the best-case scenario, that demand for these vaccines would initially outstrip supply and access to the vaccine would vary among countries. The countries least able to access vaccine would include the world's poorest but also many middle-income countries as well. The Secretary General of the United Nations and the Director-General of WHO thus called upon the international community for solidarity and assistance to ensure an equitable distribution of vaccine.

The WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative was a mechanism to mobilize donations of Pandemic H1N1 vaccine and coordinate their rational distribution and supply to countries in need. Between December 2009 and December 2010, 17 different donors, governments, private sector organizations and technical agencies worked together through the WHO Vaccine Deployment Initiative to deliver over 78 million doses of Pandemic H1N1 vaccine to 77 countries.

3.1 Objectives & Results:

Objective 1: Emergency supply of Pandemic H1N1 Vaccine to countries

The H1N1 vaccine was not developed far enough in advance of the pandemic for it to be stockpiled. Therefore, a different strategy was adopted: as donors made vaccines available, they would immediately be shipped to beneficiary countries that had fulfilled all criteria for supply. They would be shipped directly from their present location to the beneficiary. In most cases, this was directly from the manufacturer's facility.

The WHO supply mechanism therefore needed to accommodate multiple supply sources and the diverse needs of countries. It also needed to account for the availability of supply, trade restrictions and logistical issues of moving to certain locations. To support this, the mechanism established by WHO and partners to deploy vaccines to countries was designed to be flexible about the logistics of supply,

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Activity 1.1: Preparing Countries

Of the estimated 95 eligible countries, WHO assisted 77 countries to receive and use pandemic H1N1 vaccine. The 18 countries that did not receive vaccine was either due to failure to meet some of the pre-requisites highlighted below or cancellation by the Government of their initial request for vaccine.

WHO asked all eligible countries to meet the following pre-requisites prior to receiving support:

1. Submission of a Letter of Intent (LOI) to WHO, asking to be considered for supply of pandemic vaccine.
2. Sign a formal Letter of Agreement (LOA) with WHO specifying the terms and conditions of WHO support.
3. Submission of a National Deployment Plan (NDP) to demonstrate that a country had the financial, logistical and technical resources to promptly and appropriately make use of the limited supply of vaccine.

Although some countries had developed pandemic preparedness plans in early 2009, few included a vaccine deployment plan. WHO therefore conducted 9 workshops in all WHO regions, from July to December 2009, in which approximately 170 countries and territories were trained in developing NDPs.

The objectives of these workshops were to share country experiences through presenting and discussing achievements and challenges related to the preparation of NDPs; to improve the preparedness of countries in responding effectively to the H1N1/09 pandemic through review of vaccine strategies of defined risk groups and timely and effective use of a pandemic vaccine; to brief participants on the operations, structures and resources needed to deploy and administer the H1N1/09 vaccine once available in a country; and to train countries in how to use operational planning tools, such as a tool for calculating the cold-chain volumes required by the pandemic vaccines.

In August 2009, the WHO announced that the number of flu cases was steadily declining in the Southern Hemisphere, and advised countries in the Northern Hemisphere to prepare for a second wave of pandemic spread. "Countries with tropical climates, where the pandemic virus arrived later than elsewhere, also need to prepare for an increasing number of cases" (WHO Pandemic (H1N1) 2009 briefing note 9, 8/28). To account for the more immediate need in these regions, WHO scheduled those workshops first:

- July-August: Workshops in EMRO, PAHO and WPRO
- September-December: AFRO and SEARO
Challenges:

The design of the NDP, proved to be the most challenging for recipient countries because hardly any of them had a National Deployment Plan that could be used for Pandemic H1N1. This therefore required significant time, technical assistance and financial resources to finalize and was typically the final pre-requisite satisfied by countries. As a result, the first countries began to meet all three pre-requisites for supply in December 2009 as opposed to the initially projected month of October 2009.

The approval by each government of the draft plans prepared in the WHO workshops was also slow because of the required co-financing of the planned activities.

Activity 1.2: Preparing the Supply Chain

There was a joint effort by Governments, the supply community and international agencies to deploy these vaccines to eligible countries. These partners helped make an inventory of current capacity and identified what needed to be replaced or purchased so that the cold chain could be maintained and that the ancillary supplies reach the target populations.

WHO decided to adopt a coordinated, global approach with all vaccine donors, so as to allow WHO to issue one standard agreement (covering all vaccine donations) to recipient countries. It was felt that different agreements between WHO and vaccine donors, imposing different conditions on WHO for different countries, would not work in practice in a crisis situation.

Thus, after having completed negotiations with GSK (the first company to offer vaccine to WHO), WHO developed a template donation agreement to be used for all donations. Subsequent negotiations with vaccine donors were either based on this template (for direct donations) or on an indirect donation model pursuant to which governments facilitated donations by companies with whom WHO had concluded the template agreement. The LOA with recipient countries also formed an integral part of this template.

The LOA also required countries to agree to the following conditions prior to receiving supply of H1N1 vaccine from the WHO:

- Ensure registration of the vaccine or otherwise authorize its use in the country
- Accept liability for any rare adverse reactions or side effects of the donated pandemic vaccine
- Commit to appropriate and ethical use of the vaccine donation
• Handle the importation, customs clearance and distribution of vaccines; and
• Notify WHO of the occurrence of any unexpected adverse events, or an unexpected high occurrence of adverse events.

Challenges:

A key issue that delayed the negotiation of agreements for vaccine donations was that of liability.

In particular, all recipients of H1N1 vaccine were required to indemnify and hold the manufacturers harmless from adverse events arising out of its use, except to the extent caused by failure of the manufacturers to produce the vaccine in compliance with current Good Manufacturing Practices (cGMP) and agreed specifications.

This requirement was necessary due to the urgency of the pandemic, which meant that an unprecedented number of hundreds of millions of doses of a new vaccine needed to be deployed in a short period of time. Thus, all H1N1 vaccine manufacturers required all their customers (and not just those receiving vaccine from WHO) to discharge them from any liability for adverse events as aforesaid.

It should be noted that if and to the extent it is shown that the vaccine was not produced in accordance with cGMP and agreed specifications, the manufacturers would be responsible for adverse events arising out of the use of the vaccine.

Activity 1.3: Global coordination

Vaccine and ancillary supplies were safely and efficiently deployed to eligible countries under WHO’s accessible guidance, direct technical assistance and field support to countries and communities, especially in the world’s most vulnerable regions.

Vaccine donations were received in November/December 2009 but were difficult to allocate and deliver because they came from many different sources, at different times, and included a variety of different products. Prequalification, a WHO requirement for vaccines deployed through the Initiative, began in November/December 2009 when manufacturers started to submit their product dossiers for evaluation and was a typically rapid process, except in some cases in which the manufacturer had not previously had vaccines prequalified by WHO.

Challenges:
Even once these prerequisites were fulfilled, deployment still proved to be complicated by a complex web of factors, including but not limited to:

- Regulatory filings and approvals required by manufacturers and recipient country authorities, which took between 1-8 weeks even in fast-track mode and was dependant on counter-signature by the recipient country of the donation agreement;

- Securing uninterrupted cold chain integrity for shipping non-standard volumes to remote destinations;

- Repackaging vaccines originally intended for bi-lateral donor populations so that they could be optimally configured for the different population sizes and geographic locations of recipient countries.

**Activity 1.4: Country readiness**

From July 2009 to 1 December 2009 WHO conducted 9 workshops in which approximately 170 countries and territories were trained in developing NDPs. Despite this training, the time taken for NDPs to be submitted by countries to WHO and for final approval to be granted was more than 5 months for even relatively well resourced countries.

A preliminary analysis of the effectiveness of vaccine deployment in terms of the numbers of people reached, based on a survey conducted by WHO from August to November 2010 (and supplementary data\(^\text{10}\)), amongst 124 countries, including 50 countries that received Pandemic H1N1 vaccine from WHO reflected the following:

- Most countries reportedly relied on the public sector to conduct H1N1 vaccination-related activities, although the private sector played a minor role in some countries (such as for public communication and vaccine storage, packaging and transport).

- Vaccine coverage varied from region-to-region, with overall vaccination coverage higher (18%) in countries that received vaccine from WHO than countries that relied on other sources (10%)

- Overall, coverage was highest in the Western Pacific region (27%). Utilization of vaccines was highest in Africa and the Eastern Mediterranean

\(^{10}\) Including the VENICE survey, regional updates, termination reports on the implementation of H1N1 pandemic influenza vaccine deployment and vaccination plans, and national deployment and vaccination plans.
Globally, priority groups were consistently targeted in Pandemic H1N1 vaccination campaigns, with as many as 100% of pregnant women, health care workers and persons with underlying conditions receiving H1N1 vaccine in regions. In some countries, children were the target for vaccination campaigns.

Challenges:
Public concerns, in particular about the safety of pandemic H1N1 vaccine, were universal. This was associated with intensive communication activities worldwide, but particularly in Europe and North America, advising populations against vaccination. This raised questions about how to better communicate about vaccine safety during future pandemic events.

Activity 1.5: Operational planning
A small percentage of the products donated to the WHO Initiative were shipped by donors to beneficiary countries. In most cases, however, UNOPS was responsible for the distribution of donated vaccines and ancillary products (e.g. safety boxes and syringes) to countries. Three freight forwarders that had long-term agreements with UNOPS (DHL Global Forwarding, Kuehne + Nagel and Scan Global Logistics) transported more than 300 shipments of vaccines for UNOPS and the WHO Initiative, representing approximately 977 tons of material and 6000 cubic meters of cargo space. The work of the different institutions in the supply chain was facilitated by frequent communication and close cooperation between dedicated focal points from each.

Challenges:
Many countries posed unique challenges because of varying geographical features, political conditions and regulatory requirements, the main challenge therefore was how to rapidly deliver H1N1 vaccine and ancillaries to a large number of geographically distributed countries in a short time frame. Although shipping technologies had the potential for faster and more efficient transport, country infrastructure was not always sufficient. Some countries underestimated the space required to store donated products and only realized they lacked the space after the products arrived.

Global conditions also made it difficult to plan and deliver shipments. The lack of throughput in European airport facilities often did not meet the space requirements of large cold chain shipments. Unpredictable externalities, such as disruptions in shipping caused by volcanic eruptions, required late changes to plans and delayed deliveries.
The variety of products that were donated also created logistical challenges, such as issues caused by differences in packaging and shelf life. In some cases, original packaging was not appropriate for a shipment so products had to be repackaged. The quality of packaging materials was generally high, but some materials were difficult to destroy, and in large quantities created a waste management problem in countries. Shorter than anticipated shelf life of some products required that products be substituted in some cases and necessitated new documentation for country regulatory authorities.

**Activity 1.6: Logistics and supply**

Logistics and supply experts in WHO worked with partners and supply agents to carefully plan and monitor deliveries so that sufficient quantities of compatible vaccines and syringes, often coming from different sources and by different means of transport, arrived in time for countries. UNOPS provided distribution services for the pandemic vaccine initiative, which included managing the freight forwarding agents that ship supplies from manufacturers and government donors to recipient country ports.

Furthermore, some donors agreed to provide delivery services for donated vaccines and ancillaries. For example, in addition to its financial contribution and donation of vaccine, the USA donated syringes and safety boxes to complement the supply by WHO of H1N1 vaccine to 54 countries (45 million doses of vaccine). The USA arranged for some of these ancillary materials to be delivered directly to recipient countries. Other materials were supplied to WHO for distribution to recipient countries.

**Challenges:**

The vaccine supply process was complicated by the various formulations (e.g. both adjuvanted and non-adjuvanted vaccine) and presentations of donated supplies.

**3.2 Accomplishments:**

- 78 million doses of Pandemic H1N1 vaccine to 77 countries.
- 200 million doses of vaccine secured for deployment to developing countries.
- 82 countries developed and completed National Deployment Plans.
- 11 pandemic influenza influenza A (H1N1) vaccines were prequalified by WHO.
- $56.3 million raised for global and in-country operations.

**3.3 Impact:**
Many resource constrained developing countries were able to receive donated volumes of pandemic H1N1 vaccine thereby mitigating the number of lives that would have been lost as a result of lack of resources to purchase and deploy the vaccine to target populations.

Additionally, the required cooperation between members of the international community and Ministries in developing countries proved to be essential to an effective response. This helped establish an efficient coordinated mechanism in all regions for the deployment of vaccine.

The attached annexes to this report provide detailed evidence of the impact of the vaccine deployment initiative in all regions.

3.4 Lessons Learned:

Most partners in this initiative agree that it was fortunate to have had the opportunity to learn from the 2009/2010 H1N1 pandemic. Had the H1N1 pandemic been more virulent, the timelines of deployment (with deliveries beginning in early 2010) would have been concerning. There is therefore need to review the deployment process in search of rate limiters, so that the process can be collapsed where possible and appropriate to speed up deployment. Below are examples of issues that may have slowed deployment, and which could be addressed in advance of a future pandemic, such as:

- **National regulatory issues.** Some countries required that clinical trials be conducted in country before a donated vaccine could be accepted. National laws could be established in such countries to allow for importation without clinical trial during emergencies.

- **Legal agreements with donors and beneficiary countries.** Given the multiplicity of donors and beneficiary countries, and the legal issues to be addressed, it was challenging to establish a single legal framework that was acceptable to all parties. Having a framework in place in advance could expedite negotiations and deployment in the future.

- **National deployment planning.** A significant amount of time and resources were spent in preparing NDPs that could be activated during a future pandemic event. If these NDPs are maintained and improved upon, they could reduce the time required for country planning during a future pandemic.
Key lessons learned

The following provides a list of key suggestions (in order of priority) made by participants for improving vaccine deployment during a future pandemic.

<table>
<thead>
<tr>
<th>Suggestion</th>
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<tbody>
<tr>
<td>1. Agree with all stakeholders on an overall framework for vaccine deployment during a pandemic and on the roles and responsibilities of all actors in that framework. Periodically review and assess where it needs to be refreshed or revised.</td>
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<tr>
<td>2. Prepare in advance and maintain a framework for agreements with donor governments and manufacturers (explaining issues such as indemnification, how to deal with ownership and title transfer) in order to expedite legal agreements during future pandemic events.</td>
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<tr>
<td>3. Review pandemic epidemiological trends and the timeline of pandemic vaccine deployment activities to assess how to better align the latter on the former.</td>
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<tr>
<td>4. Regularly engage major global stakeholders in readiness training for future pandemics, including simulation exercises for pandemic vaccine deployment.</td>
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<tr>
<td>5. Investigate if and how regulatory processes for pandemic vaccines can be shortened at global and national levels during a pandemic.</td>
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<tr>
<td>6. Investigate the possibility of a better-harmonized licensing approach for vaccines during a pandemic.</td>
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<tr>
<td>7. Identify and agree upon a standard, minimal set of product/regulatory documentation that would be provided for each shipment of donated vaccines or ancillary products during a pandemic.</td>
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<tr>
<td>8. Evaluate current global cold chain capacity and, where necessary, identify solutions to ensure sufficient capacity to handle large volumes during a pandemic.</td>
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<tr>
<td>10. Look at the interplay between pandemic and seasonal influenza vaccination and how to advise countries in this regard.</td>
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<tr>
<td>11. Establish a cross-function, cross-region communication channel that involves all stakeholders in order to facilitate information sharing and support the timely and effective work of different actors during pandemic vaccine deployment.</td>
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<tr>
<td>12. Document the H1N1 vaccine deployment processes to serve as a basis for deployment planning during future pandemics.</td>
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Please refer to Annex 8 for a detailed report on the chronology of the vaccine deployment initiative 2009-2010. This will be published as an independent report.
4 IHR REVIEW COMMITTEE

The International Health Regulations (IHR) is an international legal agreement that is binding on 194 States Parties across the globe, including all of the Member States of WHO. The basic purpose of the IHR is to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. The pandemic H1N1 is the first public health emergency of international concern to occur since the revised IHR came into force. The IHR played a central role in the global response to the pandemic and so review of the IHR and review of the global handling of the pandemic influenza are closely related.

In January 2010, the WHO Executive Board requested a proposal from the Director-General on how to assess the international response to the pandemic influenza, and approved her suggestion to convene the IHR Review Committee to review both the pandemic response and the functioning of the IHR. The review has three key objectives: (1) to assess the functioning of the International Health Regulations (2005); (2) to assess the ongoing global response to the pandemic H1N1 (including the role of WHO); and (3) to identify lessons learned which are important for strengthening preparedness and response for future pandemics and public health emergencies.

The assessment of the global response to the pandemic H1N1 is conducted by the International Health Regulations Review Committee, made up of approximately 29 members who have been selected from the roster of experts under the IHR structure or other WHO expert committees. The committee members represent a broad mix of expertise, practical experience and backgrounds, and includes experts from developed and developing countries. The members are some of the leading experts in the world in their respective fields. They are not WHO staff, nor do they receive funding from WHO for their contributions to the review process. Names of the committee members were made public prior to the first meeting. The IHR Review Committee is considered a WHO expert committee and so its operations and structure follows regulations for WHO expert advisory panels and committees, and provisions of the IHR.

The IHR Review Committee convened its first meeting from 12 to 14 April 2010 at WHO headquarters in Geneva. Professor Harvey V. Fineberg was elected as chair; Professor Babatunde Osotimehin was elected as vice chair; observers invited to the first meeting include representatives of all States Parties to the IHR (194 countries), United Nations organizations and relevant intergovernmental organizations, and nongovernmental organizations in official relations with WHO. During this meeting, committee members agreed the scope and methods of work. This included the creation of five technical subcommittees to better explore the critical issues around the WHO’s response to the pandemic: capacity and preparedness, alert and risk assessment, IHR functions, communications and response.

The Review Committee members continued their deliberations via electronic exchanges and two rounds of teleconferences by each of the subcommittees were
held from 4 to 11 May and from 31 May to 4 June. Three pandemic-related technical subcommittees have continued their review of capacity and preparedness, alert and risk assessment and response, organizing their work according to decisions taken during the H1N1 (2009) pandemic. A fourth technical subcommittee focused its work on reviewing the functions of the IHR with an emphasis on public health events outside of the pandemic as well as experiences, surveys and studies providing insights into progress with various aspects of IHR implementation. The fifth technical subcommittee reviewed communication issues related both to the pandemic and the IHR.

The IHR review was on the agenda of Committee A of the WHA (item 11.2) The Chair of the Review Committee attended Committee A for these discussions, listened closely to interventions by Member States and responded to issues related to the Committee and the IHR review process.

All subcommittees continued their deliberations initiated during the April meeting to identify key issues and information needs. They also identified key groups of persons to be invited to assist in contributing to the review through interviews that the RC will conduct. These groups include national authorities at political and technical levels such as the IHR national focal points, international organizations including WHO secretariat, industry, media and critics. The first round of interviews took during the second review committee meeting from 30 June to 2 July 2010; additional interviews were conducted during the summer and fall of this year. Following the third meeting of the IHR Review Committee in September 2010, the Committee continued its work during the month of October, through teleconferences and electronic exchange, gathering evidence and discussing and drafting sections of the report.

From 3 to 5 November 2010, the Committee met in deliberative sessions and continued its work on the report, focusing on the following areas: the story of influenza A (H1N1) 2009; the background and context of previous emerging infections, the development of the International Health Regulations (2005) and pandemic preparedness; first notifications of H1N1 and situation assessments; response, interventions, and implementation of pandemic preparedness plans; analysis of the functions of the IHR and their effectiveness; communications; and conclusions and recommendations.

The Committee met in January 2011 in closed, deliberative sessions. The Chair of the Committee will present a progress report during the Executive Board meeting in January 2011. A fourth meeting of the Review Committee to which representatives of States Parties to the IHR and the United Nations and its specialized agencies and other relevant intergovernmental organizations or nongovernmental organizations in official relations with WHO are invited will take place in March or April 2011 (precise date to be determined). The final report will be presented to the WHA in May 2011.

CONCLUSION

As the leading international agency for human health, WHO assumed a global leadership role in response to H1N1. The international community looked to WHO to lead countries through the crisis, from emergence through to each subsequent wave. And as illustrated in the preceding sections, WHO headquarters, regional offices, and country offices successfully carried out greatly expanded functions, around the clock, in coordinating global responses and limiting impacts. WHO has the experience, knowledge, and foundation upon which to build further structures, core capacities, and pandemic preparedness plans, worldwide. What the response to pandemic A
(H1N1) has highlighted is that advances in reducing the impact and pervasiveness of a pandemic of influenza have been achieved.

Still, emerging and re-emerging infectious diseases can have a major impact not only on the health sector, but also on national, regional, and global economies. The consequences can be catastrophic. Scenarios of events during the first influenza pandemic of the 21st century painted a grim picture for human health the world over, the survival of existing development projects, and the health of the global economy. Furthermore, influenza pandemics are remarkable events in that they can spread, within a matter of months, to affect all countries. All populations are fully susceptible to pandemic viruses, and all countries are equally at risk.

Pandemic influenza is a global threat from which no country is immune and the actions required are a shared responsibility of the international community. The interdependence of today’s world necessitates a strong cooperative effort for all nations to benefit from better regulation, foresight and advanced preparation, and risk management. Today, there is unprecedented opportunity to undertake appropriate protective actions; given the alarming increase in emerging and re-emerging diseases, now is the time to strengthen collaboration for the sake of global health security worldwide.
Annex One: Timeline of WHO Response to pandemic (H1N1) virus

- **10 April 2009**: Mexico reported an outbreak of influenza-like illness to WHO in the small community of La Gloria, Veracruz.
- **15-17 April 2009**: MoH Mexico received notification of clusters of rapidly progressive severe pneumonia occurring in Distrito Federal (metropolitan Mexico City) and San Luis Potosi. A case of atypical pneumonia in Oaxaca State promoted enhanced surveillance throughout the country.
- **15-17 April 2009**: First two cases of the new A(H1N1) virus infection were identified from two southern California counties in U.S.A.
- **23 April 2009**: new influenza A (H1N1) virus infection, previously identified in two children in the United States, was confirmed in several patients in Mexico.
- **25 April 2009**: upon the advice of the Emergency Committee called under the rules of the International Health Regulations, the Director-General declared this event a Public Health Emergency of International Concern. The establishment of the Committee, which is composed of international experts in a variety of disciplines, is in compliance with the International Health Regulations (2005).
- **26 April 2009**: 38 cases reported from Mexico and the US
- **27 April 2009**: Canada and Spain reported confirmed cases
- **27 April 2009**: On the advice of the Committee, the WHO Director-General raised the level of influenza pandemic alert from the phase 3 to phase 4. The change to a higher phase of pandemic alert indicates that the likelihood of a pandemic has increased, but not that a pandemic is inevitable. This decision was based primarily on epidemiological data demonstrating human-to-human transmission and the ability of the virus to cause community-level outbreaks.
- **As of 27 April 2009**: the United States Government reported 40 laboratory confirmed human cases of swine influenza A(H1N1), with no deaths. Mexico reported 26 confirmed human cases of infection with the same virus, including seven deaths. Canada reported six cases, with no deaths, while Spain reported one case, with no deaths.
- **29 April 2009**: Based on assessment of all available information, and following several expert consultations, the WHO Director-General decided to raise the current level of influenza pandemic alert from phase 4 to phase 5.
- **29 April 2009**: an Antiviral Task Force was established at WHO Headquarters to oversee the release and deployment of the stockpile.
- **2 May 2009**: The WHO Collaborating Centre for influenza in CDC Atlanta USA developed diagnostic kits which were made globally available.
- **5 May 2009**: WHO convened a technical consultation to assess the severity of disease caused by influenza A(H1N1) infection.
- **26 May 2009**: The majority of the novel influenza A(H1N1) isolates are antigenically and genetically related to the A/California/7/2009 (H1N1)v virus. It was recommended that vaccines for novel influenza A(H1N1) contain A/California/7/2009 (H1N1)v virus.
- **27 May 2009**: Candidate reassortant vaccine virus was made available on WHO website
- **As of 27 May 2009**: 48 countries have officially reported 13,398 cases of influenza A(H1N1) infection, including 95 deaths.
- **11 June 2009**: Upon the guidance and advice of the Emergency Committee called under the rules of the International Health Regulations, the Director-General decided to raise the level of influenza pandemic alert from phase 5 to phase 6. On the basis of available evidence, and expert assessments of the evidence, the scientific criteria for an influenza pandemic have been met.
As of 11 June 2009: nearly 30,000 confirmed cases have been reported in 74 countries. Further spread is considered inevitable. Globally, this pandemic, at least in its early days, assessed as of moderate severity.

24 June 2009: WHO Consultation on suspension of classes and restriction of mass gatherings to mitigate the impact of epidemics caused by the new influenza A (H1N1)

As of 17 June 2009: 39,620 cases of influenza A (H1N1) infection, including 167 deaths have officially reported to WHO.

13 July 2009: The Strategic Advisory Group of Experts (SAGE) on Immunization made recommendations related to vaccine for the pandemic (H1N1) 2009. SAGE was established by the WHO Director-General in 1999 as the principal advisory group to WHO for vaccines and immunization. In July 2009, the experts identified three different objectives that countries could adopt as part of their pandemic vaccination strategy: protect the integrity of the health-care system and the country’s critical infrastructure; reduce morbidity and mortality; and reduce transmission of the pandemic virus within communities.

As of 1 July 2009: 77,201 cases of influenza A (H1N1) infection, including 332 deaths have been officially reported to WHO.

17 August 2009: Collaborative call to action to reduce impact of pandemic H1N1 2009. WHO, IFRC, UNSIC, OCHA and UNICEF, prompted by the humanitarian imperative, will work with partners such as the Red Cross and Red Crescent Societies, NGOs and civil society to support governments and communities to reduce the impact from the pandemic (H1N1) 2009.

September 2009: The first commercially-available pandemic influenza vaccines were registered for use and an expedited prequalification procedure was established to respond to the need for emergency immunization with the pandemic vaccine.

As of 6 August 2009: 177,457 cases of influenza A (H1N1) infection, including 1,462 deaths have been officially reported to WHO.

28 August 2009: WHO reports that most countries in the Southern Hemisphere (represented by Chile, Argentina, New Zealand, and Australia) appear to have passed their peak of influenza activity and returned to baseline activity.

In the Northern hemisphere, pandemic influenza A (H1N1) peaked between late October and late November 2009 and has continued to decline since.

As of 4 October 2009: worldwide there have been more than 375,000 laboratory confirmed cases of pandemic influenza H1N1 2009 and over 4500 deaths reported to WHO.

13 November 2009: In its 74th update, the WHO reports early signs that that the early flu season has peaked in North America, even as the pandemic intensifies across much of Europe and Central and Eastern Asia

20 November 2009: publication of Clinical management of human infection with pandemic influenza (H1N1) 2009: Revised guidance November 2009

21 November 2009: As of 21 November 2009, a total of 82 countries reported data on the number of specimens positive for pandemic through FluNet

27 November 2009: WHO reports that H1N1 mutations have led to roughly 75 people worldwide developing Tamiflu resistance. Furthermore, the separate D222G or D225G mutation which helps the virus to reach deep into the lungs has been reported in cases both severe and mild in Norway, Ukraine, Brazil, China, Japan, Mexico and the United States.
• **28 November 2009:** As of this date, 150 countries have shared a total of 19284 specimens (14879 clinical samples and 4405 virus isolates)\(^ {11}\) with WHO CCs for confirmatory diagnosis and further characterization.

• **December 2009:** WHO launches a second survey of all influenza vaccine manufacturers to update the first estimates of global production capacity for pandemic vaccine

• **18 Dec 2009:** WHO Global Advisory Committee on Vaccine Safety (GACVS) reviewed the safety of pandemic (H1N1) 2009 vaccines, concluding that pandemic vaccines are as safe as seasonal influenza vaccines and that side effects seen so far are similar to those observed with seasonal influenza vaccines.

• **January 2010:** To help countries protect people from developing severe disease from pandemic influenza H1N1 infection, the World Health Organization (WHO) has coordinated the distribution of donated pandemic influenza vaccine to eligible countries.

• **As of 3 January 2010:** worldwide more than 208 countries and overseas territories or communities have reported laboratory confirmed cases of pandemic influenza (H1N1) 2009, including at least 12799 deaths.

• **23 February 2010:** The Emergency Committee held its seventh meeting. The Director-General sought the Committee’s views on the determination of the pandemic status. The Committee advised that it was premature to conclude that all parts of the world have experienced peak transmission of the H1N1 pandemic influenza and that additional time and information was needed to provide expert advice on the status of the pandemic.

• **As of 7 February 2010:** worldwide more than 212 countries and overseas territories or communities have reported laboratory confirmed cases of pandemic influenza H1N1 2009, including at least 15292 deaths.

• **12-14 April 2010:** First meeting of the IHR Review Committee. An external WHO panel advises against winding down the pandemic alert level until experts have tracked the southern hemisphere’s traditional autumn and winter flu season. Accusations of undue influence from the pharmaceutical industry were also addressed.

• **10 June 2010:** 'Use of Influenza Rapid Diagnostic Test Kits' brochures distributed to all ROs (100 copies, English version).

• **14-16 June 2010:** A WHO Informal Consultation took place for improving the influenza vaccine virus selection process. The Consultation was attended by 117 experts from all six WHO Regions, from GISN, National regulatory agencies, research academia, veterinary sector and vaccine manufacturers.

• **17-18 June 2010:** A WHO PCR Working Group meeting reviewed issues related to influenza laboratory function, including PCR diagnostics, serology and antiviral susceptibility testing.

• **10 August 2010:** The World Health Organization officially announced the end of Phase 6 of the Influenza Pandemic Alert, with a global shift into the Post-Pandemic period.

• **10 September 2010:** Influenza activity is currently most intense in the temperate areas of the Southern Hemisphere and southern Asia.

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\(^ {11}\) Ibid.
Annex Two: Pandemic Phases
Annex Four: List of Guidelines related to H1N1

- Updated annex to Global Surveillance during an Influenza Pandemic, to standardize reporting for risk factors and fatalities;
- Summary of available candidate vaccine viruses for development of pandemic (H1N1) 2009 virus vaccines;
- WHO information for laboratory diagnosis of pandemic (H1N1) 2009 virus in humans - revised 23 November 2009;
- Oseltamivir resistance in immunocompromised hospital patients;
- Laboratory biorisk management for laboratories handling human specimens suspected or confirmed to contain influenza A (H1N1) causing the current international epidemics, 30 November 2009;
- Summary of available potency testing reagents for pandemic (H1N1) 2009 virus vaccines;
- Clinical management of human infection with pandemic (H1N1) 2009: revised guidance;
- The Whole of Society pandemic readiness: WHO guidelines for pandemic preparedness and response in the non-health sector - including guidance on developing business continuity plans and identifying critical interdependencies;
- Schools workplaces and municipalities - developed in collaboration with other UN agencies and technical partners;
- Behavioural targets for communications officers to provide consistent messaging on prevention and mitigation techniques;
- The clinical team, with input from outside experts and disaster medicine specialists, is preparing lists of equipment and materials necessary to support middle-resource countries with ICU-level medical care;
- Pandemic influenza A (H1N1) 2009 virus vaccine – conclusions and recommendations from the July and October 2009 meetings of the immunization Strategic Advisory Group of Experts;
- Recommended composition of influenza virus vaccines for use in the 2010 influenza season (southern hemisphere winter);
- Oseltamivir-resistant pandemic (H1N1) 2009 influenza virus;
- Transmission dynamics and impact of pandemic influenza (H1N1) 2009 virus;
- WHO external quality assessment project for detecting influenza virus subtype A by polymerase chain reaction – summary analysis, 2009;
- Global influenza surveillance network: laboratory surveillance and response to pandemic H1N1 2009-12-03;
- Interim planning considerations for mass gatherings in the context of pandemic (H1N1) 2009 influenza;
- Technical guidance for Hajj pilgrimage management;
- Evolution of a pandemic: A(H1N1)2009 April 2009-March 2010
- Advice on the use of masks in the community setting in Influenza A(H1N1) outbreaks
- Availability of a candidate international standard for antibody to A/California/7/2009 (H1N1)v-like viruses
- Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development CBER-RG2
- Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development NIBRG-121
- Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development X-179A
• Availability of a candidate reassortant vaccine virus for the novel influenza A (H1N1) vaccine development: IDCDC-RG15
• Availability of a candidate reassortant vaccine virus for the novel influenza A(H1N1) vaccine development IVR-153
• Availability of a new candidate reassortant vaccine virus for pandemic (H1N1) 2009 vaccine development
• Availability of a new candidate reassortant vaccine virus for pandemic (H1N1) 2009 virus vaccine development NIBRG-121xp
• Availability of four new candidate reassortant vaccine viruses for pandemic (H1N1) 2009 virus vaccine development IDCDC-RG18, IDCDC-RG20, IDCDC-RG22 and NIBRG-122
• Availability of two new candidate reassortant vaccine viruses for pandemic (H1N1) 2009 virus vaccine development X-181 and X-181A
• Behavioural interventions for reducing the transmission and impact of influenza A(H1N1) virus: a framework for communication strategies
• Biocontainment requirements for vaccine production from and quality control of the reassortant candidate vaccine virus CBER-RG2
• Biocontainment requirements for vaccine production from and quality control of the reassortant candidate vaccine virus IVR-153
• Biocontainment requirements for vaccine production from and quality control of the reassortant vaccine candidate viruses IDCDC-RG15, NIBRG-121 and X-179A
• Call to action
• Case management of Influenza A(H1N1) in air transport
• CDC protocol of realtime RTPCR for influenza A (H1N1)
• Characteristics of the emergent influenza A (H1N1) viruses and recommendations for vaccine development
• Clean hands protect against infection
• Clinical management of adult patients with complications of pandemic influenza A(H1N1) 2009 influenza: Emergency guidelines for the management of patients with severe respiratory distress and shock in district hospitals in limited-resource settings
• Clinical management of human infection with pandemic (H1N1) 2009: revised guidance
• Considerations of influenza A(H1N1) and HIV infection
• Consultation on potential risks of pandemic (H1N1) 2009 influenza virus at the human-animal interface
• Countries able to perform PCR to diagnose influenza A (H1N1) virus infection in humans
• Gene sequences of the reassortant candidate vaccine viruses for the novel influenza A (H1N1)
• Global surveillance during an influenza pandemic
• Human infection with pandemic (H1N1) 2009 virus: updated interim WHO guidance on global surveillance
• Infection prevention and control in health care for confirmed or suspected cases of pandemic (H1N1) 2009 and influenza-like illnesses
• Infection prevention and control of epidemic- and pandemic-prone acute respiratory diseases in health care
• Influenza A(H1N1) patient care checklist
• Instruction on how to obtain CDC realtime RT-PCR kits for detection of influenza A(H1N1)
• Instructions for storage and transport of suspected or confirmed human and animal specimens and virus isolates of pandemic (H1N1) 2009
• Interim planning considerations for mass gatherings in the context of pandemic (H1N1) 2009 influenza
• Joint WHO-OFFLU technical teleconference to discuss human–animal interface aspects of the current influenza A (H1N1) situation
• Laboratory biorisk management for laboratories handling pandemic influenza A (H1N1) 2009 virus
• Pandemic influenza A (H1N1) 2009: considerations for tuberculosis care services
• Pandemic influenza preparedness and mitigation in refugee and displaced populations. WHO guidelines for humanitarian agencies.
• Pandemic influenza preparedness and response
• Pandemic influenza prevention and mitigation in low resource communities
• Pregnancy and pandemic influenza A (H1N1) 2009: information for programme managers and clinicians
• Preliminary review of D222G amino acid substitution in the haemagglutinin of pandemic influenza A (H1N1) 2009 viruses
• Protocol for antiviral susceptibility testing by pyrosequencing
• Recommendations of the Strategic Advisory Group of Experts (SAGE) on Influenza A (H1N1) vaccines
• Reducing excess mortality from common illnesses during an influenza pandemic.
• Reducing transmission of pandemic (H1N1) 2009 in school settings
• Safe transport of pandemic influenza A (H1N1) 2009 virus cultures, isolates and patient specimens as Biological Substance, Category B
• Sequencing primers and protocol
• Statement from WHO Global Advisory Committee on Vaccine Safety about the safety profile of pandemic influenza A (H1N1) 2009 vaccines
• Status of candidate vaccine virus development for the current Influenza A(H1N1) virus
• Summary of available potency testing reagents for Pandemic (H1N1) 2009 virus vaccines
• Summary report of a High-Level Consultation: new influenza A (H1N1)
• Surveillance recommendations for Member States in the post-pandemic period
• Update of WHO biosafety risk assessment and guidelines for the production and quality control of human influenza pandemic vaccines
• Viral gene sequences to assist update diagnostics for influenza A (H1N1)
• Viral gene sequences to assist update diagnostics for influenza A (H1N1) - GenBank accession numbers
• WHO ad hoc scientific teleconference on the current influenza A(H1N1) situation
• WHO Consultation on suspension of classes and restriction of mass gatherings to mitigate the impact of epidemics caused by the new influenza A (H1N1)
• WHO Guidelines for Pharmacological Management of Pandemic (H1N1) 2009 Influenza and other Influenza Viruses
• WHO information for laboratory diagnosis of pandemic (H1N1) 2009 virus in humans - revised
• WHO interim technical advice for case management of pandemic (H1N1) 2009 on ships
• WHO recommendations on influenza A(H1N1) vaccines; and
• WHO Technical Consultation on the Severity of Disease Caused by the new influenza A (H1N1) virus infections
Annex Five: Pandemic (H1N1) 2009: Countries, Territories, and Areas with Lab-Confirmed Cases and Number of Deaths as reported to WHO – as of 7 February 2010
Annex Six: Completed Vaccine Deliveries by the End of the Project

<table>
<thead>
<tr>
<th>Country</th>
<th>No. of Doses</th>
<th>Country</th>
<th>No. of Doses</th>
</tr>
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<td>Swaziland</td>
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<sup>12</sup> Ibid.
Annex Seven: List of documents related to H1N1 vaccine deployment initiative - an analysis from a global, regional and country perspective

- Final Vaccine Deployment Update to all donors
- Vaccine Deployment initiative analysis charts (presentation of the initiative from inception to end of project)
- Lessons learned about social mobilization and communication, access to vaccine and logistics, planning and implementation, and others.
- Preliminary analysis report of the effectiveness of vaccine deployment in terms of the numbers of people reached
- WHO Regional Office for Africa: Pandemic H1N1 vaccine deployment in the region & on pre-deployment planning activities conducted in the Africa region.
- WHO Regional Office for the Eastern Mediterranean: Pandemic H1N1 vaccine deployment in the region, including indications of coverage and utilization.
- WHO Regional Office for the West Pacific: Pandemic H1N1 vaccine deployment in the region
- WHO Regional Office for the Americas: Pandemic H1N1 vaccine deployment in the region.
- WHO Regional Office for South-East-Asia: Pandemic H1N1 vaccine deployment in the region
- WHO Regional Office for Europe: Pandemic H1N1 vaccine deployment in the region
- Presentation on the impact of national regulatory requirements on the deployment of vaccines process of Pandemic H1N1
- Presentations on vaccine transportation to beneficiary countries, the logistical challenges that were faced and suggestions for improving transportation during future pandemic events.
- Link to the video clip of the H1N1 vaccine deployment initiative
WHO Pandemic Influenza A (H1N1) Vaccine Deployment Initiative
Chronology of Vaccine Deployment
2009-2010

Introduction
The World Health Organization (WHO) Pandemic Influenza A(H1N1) Vaccine Deployment Initiative (i.e., the WHO Initiative) was a mechanism to mobilize and deploy donations of Pandemic Influenza A(H1N1) (i.e., H1N1) vaccine to countries in need.

This document provides a chronology of the WHO Initiative. It highlights key events and trends in H1N1 vaccine deployment, from the detection of the new influenza virus in April 2009 until the end of deployment activities in October 2010.

The chronology in this document is presented in two parts:

- **Events preceding H1N1 vaccine deployment** describes key events that took place after the virus was detected, but before the H1N1 vaccine was available (i.e., end of September 2009).
- **H1N1 vaccine deployment** describes H1N1 vaccine deployment activities during the pandemic and post-pandemic periods.
Events preceding H1N1 vaccine deployment

- In April 2009, an outbreak of Influenza-like illness occurred in Mexico and the United States of America (USA). By 24 April 2009 it became clear that the outbreaks were related and WHO issued a health advisory.\(^\text{13}\)

- On 27 April 2009, the WHO Secretariat organized a first teleconference with WHO Influenza Collaborative Centers (WHO CCs) and Essential Regulatory Laboratories (ERLs) of the Global Influenza Surveillance Network (GISN). Virus characteristics, diagnostic tools, and prototype vaccine viruses were identified to allow production of candidate vaccine viruses.

- The disease spread rapidly, with the number of confirmed cases rising to 2,099 by 7 May 2009. On 8 May 2009, WHO provided a global update on the status of candidate H1N1 vaccine virus development, using both reverse genetics and classical reassortant technology, as well as H1N1 essential reagent preparation.

- Shortly after, on 14 May 2009, WHO convened an emergency virtual consultation of the WHO Strategic Advisory Group of Experts (SAGE) and its Ad hoc Working Group on H1N1 vaccines. SAGE was presented with data produced by the WHO Secretariat, which estimated that “up to 4.9 billion doses [of monovalent pandemic vaccine] could be produced over a 12‐month period after the initiation of full‐scale production”\(^\text{14}\) if yields were equivalent to that routinely obtained for seasonal vaccine and if the most dose‐sparing formulations were systematically used. After reviewing the information presented, SAGE made several recommendations, including that the number of needed doses of H1N1 vaccine would “depend on the spread of influenza A (H1N1) virus in the next few weeks and on a better definition of the groups to be targeted.”\(^\text{15}\)

\(^{13}\) www.who.int/csr/don/2009_04_24/en/index.html

\(^{14}\) www.who.int/csr/resources/publications/swineflu/SAGEH1N1vaccinerecommendation2009_05_19.pdf

\(^{15}\) ibid
On 15 May 2009, GlaxoSmithKline (GSK) announced that it would convert its existing donation to WHO of 50 million doses of H5N1 vaccine to H1N1 vaccine once production began (see Box 1). This was the first public pledge by a government or manufacturer to donate H1N1 vaccines for an international response. (GSK would later increase this pledge to 60 million doses.)

On 19 May 2009, the United Nations (UN) Secretary-General (SG) and WHO Director-General (DG) met with the Chief Executive Officers of all known influenza vaccine manufacturers to advocate for equitable access of developing countries to H1N1 vaccine.

On 26 May 2009, WHO provided an update on the characterization of H1N1 viruses. Subsequently (27-28 May 2009), WHO announced that the first candidate reassortant vaccine virus was available for H1N1 vaccine development and issued biosafety recommendations for the production and quality control of H1N1 vaccines.

On 11 June 2009, WHO declared the H1N1 pandemic.

Box 1: Most vaccine donations pledged early in pandemic
From May to June 2009, 150 million doses of H1N1 vaccine were pledged to the WHO Initiative by GSK and Sanofi-Aventis. GSK’s initial pledge (50 million doses of vaccine) was later increased to 60 million doses. In September 2009, eight governments pledged a combined 37 million doses. Between November and December 2009, two additional governments and two manufacturers pledged 12 million doses more.

Ultimately, approximately 122 million of 200 million pledged doses became available for deployment by the WHO Initiative. This was sufficient for 10% population coverage of all countries that requested that vaccine. Sufficient supplies of syringes to match committed vaccine were made available through in-kind contributions or procured using donated funds.
On 18 June 2009, Sanofi-Aventis announced that it would donate 100 million doses of H1N1 vaccine to WHO to help developing countries respond to the pandemic.²³

Throughout July 2009, government, industry and international leaders continued to discuss new developments in the pandemic and plans for an international response, such as during a 2-3 July 2009 high-level meeting on H1N1 in Mexico. Access to H1N1 vaccine was a high priority agenda item.

On 6 July 2009, the UN SG and WHO DG released a joint statement, expressing concern that the H1N1 virus could have a severe impact on low-income countries and calling on the international community to provide resources to help the least resourced countries to withstand these impacts. Although this reflected a need for increased donations of vaccines, it also emphasized the need for funding to support the costs of delivering vaccines to countries and for establishing the infrastructure in countries to properly manage and deploy donated vaccines (see Box 2). At this meeting, donors asked the UN agencies and the World Bank to develop a more detailed assessment of what resources were required.²⁴

During an extraordinary meeting on 7 July 2009 to discuss H1N1, SAGE recommended that countries “immunize their health-care workers as a first priority to protect the essential health infrastructure.” SAGE also pointed out that limited doses of H1N1 vaccine might be managed by vaccinating in phases: “As vaccines available initially will not be sufficient, a step-wise approach to vaccinate particular groups may be considered.”²⁵

From 12-15 July 2009, the WHO Eastern Mediterranean Regional Office and international experts conducted a workshop in Morocco on H1N1 vaccine deployment planning for

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²⁴ www.undg.org/docs/10592/UNIP_REPORT_18_(final).pdf
²⁵ www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090713/en/index.html
countries in the Region. This was the first of nine regional workshops organized by WHO (see Box 3). WHO guidelines for the deployment of pandemic influenza vaccine were reviewed and discussed in details with all participants. It was estimated at the time that all participating countries (from the Eastern Mediterranean Region) would have national deployment plans (NDPs) finalized by 15 August.  

- On 14 July 2009, the first H1N1 vaccine potency reagents (required to assess the potency of vaccines in development) became available.
- In an interview on 15 July 2009, the WHO DG stated that an H1N1 vaccine “should be available soon, in August.”
- A workshop was held in Colombia from 27-31 July 2009, as part of the Pan American Health Organization Regional Plan for the Preparation of the Introduction of a Pandemic Influenza Vaccine.
- On 18 August 2009, the first data from an H1N1 vaccine clinical trial became available.
- The WHO Regional Office for Europe held a regional meeting on the H1N1 response from 25-26 August 2009 in Denmark.

Box 3: Workshops helped countries plan for vaccines

Before the pandemic, few (if any) low and middle income countries had a national pandemic preparedness plan that included a national vaccine deployment plan (i.e. NDP). A completed NDP was a pre-requisite for supply of donated vaccines through WHO. These NDPS were needed to ensure that a country had the financial, logistical and technical resources to promptly and appropriately make use of the limited supply of vaccine.

From July through November 2009, WHO conducted 11 workshops during which approximately 170 countries and territories were trained to develop NDPS:

- **July-August 2009** Workshops were held for countries in the WHO Region of the Americas (Bogota, Colombia), Eastern Mediterranean Region (Rabat, Morocco), European Region (Copenhagen, Denmark) and Western Pacific Region (Manila, Philippines).

- **September-November 2009** Workshops were held for countries in the WHO African Region (Abuja, Nigeria), South-East Asia Region (New Delhi, India), European Region (Istanbul, Turkey) and Western Pacific Region (Nadi, Fiji), as well as in the Region of the Americas (Lima, Peru; Panama City, Panama; Saint Kitts and Nevis).

The objectives of these workshops were to accelerate the preparedness of countries to respond effectively to the H1N1 pandemic and to train them in operational planning tools, such as tools for calculating the cold-chain volumes required to deploy H1N1 vaccine.

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26 www.emro.who.int/csr/h1n1/pdf/vaccine_deployment_guidelines.pdf
27 www.guardian.co.uk/world/2009/jul/14/swine-flu-vaccination-who-chan
29 www.bloomberg.com/apps/news?pid=newsarchive&sid=aDT9iV5L1Dow
From 31 August-4 September, the WHO Regional Office for the Western Pacific held an H1N1 vaccine deployment workshop in the Philippines.\(^{31}\)

In an article published in *The Lancet* on 2 September 2009, Dr. Marie-Paule Kieny (WHO) provided an update on H1N1 vaccines. In the article, Dr. Kieny projected that the first doses of vaccine would likely become available to governments in September 2009 and she described efforts to secure H1N1 vaccines for developing countries through the WHO Initiative.\(^{32}\)

The WHO Regional Office for South-East Asia held a workshop in India from 14-18 September 2009 to help countries in the Region prepare for H1N1 vaccine deployment, including development of NDPs.\(^{33}\)

In September 2009, donors began to increasingly announce their official support for the WHO Initiative. On 18 September 2009, Dr. Tachi Yamada, President of the Global Health Program at the Bill and Melinda Gates Foundation, wrote in *The New England Journal of Medicine* that the global community should “take steps to protect all populations, including those without resources to protect themselves.”\(^{34}\)

Also on 18 September 2009, nine governments announced that they would share their stock of H1N1 vaccine with low- and middle-income countries. Among these, the USA pledged up to 10 percent of its vaccine supply; it was joined by Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland and the United Kingdom.\(^{35}\) The USA announced it would make H1N1 vaccine available to WHO on a rolling basis as vaccine supplies become available, “in order to assist countries that will not otherwise have direct access to the vaccine.”\(^{36}\)

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**Box 4: Evaluation of vaccine quality was expedited**

Shortly after declaring the H1N1 pandemic, WHO emphasized the importance of striving to achieve equitable country access to vaccine. One way that WHO sought to facilitate access was by implementing an expedited WHO Prequalification process for H1N1 vaccines.

National regulatory authorities typically require product registration before a vaccine can be imported into a country, which can demand significant national resources and time and have the effect of delaying access. However, some countries have provisions for temporary waivers from registration if a product is prequalified by WHO. Although local regulatory registration is necessary for continuing supply, rapid WHO Prequalification and temporary waivers expedited access during the pandemic to H1N1 vaccines that met international quality standards.

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\(^{31}\) www.wpro.who.int/sites/epi/meetings/MTG_H1N1_AUG2009.htm

\(^{32}\) www.scielo.org/scielo.php?pid=S0042-96862009000900007&script=sci_arttext

\(^{33}\) 203.90.70.117/PDS_DOCS/B4452.pdf

\(^{34}\) www.nejm.org/doi/full/10.1056/NEJMp0906972

\(^{35}\) af.reuters.com/article/topNews/idAFJOE58H0372009090918?

\(^{36}\) www.whitehouse.gov/the_press_office/President-Announces-Plan-to-Expand-Fight-Against-Global-H1N1-Pandemic/
On 19 September 2009, WHO predicted that production of H1N1 vaccine over the following year would be "substantially less" than the 4.9 billion doses previously forecast. While this was initially a concern, information had already emerged indicating that the vaccine could be administered as a single-dose, and not a two-dose series.37

On 18 September 2009, WHO established an H1N1 Vaccine Deployment team at its Headquarters in Geneva, Switzerland and began operational activities to deploy donated H1N1 vaccines to countries.

On 23 September 2009, the WHO DG formally wrote to 95 countries deemed eligible for H1N1 vaccine donations, informing them of the WHO Initiative and asking them to inform WHO immediately if they wished “to be considered for the possible supply of pandemic vaccine by WHO” (see Annex II).

37 www.reuters.com/article/idUSTRE58H1N120090918
H1N1 vaccine deployment

In Quarter 3 of 2009, the WHO approach to H1N1 vaccine deployment was finalized. Several aspects of this approach are described below:

- Coordinating a global approach to vaccine donations
- Identifying eligible countries
- Determining the order in which countries would be supplied
- Determining how many doses of vaccine to provide each country
- Establishing a supply mechanism
- Meeting pre-conditions for supply
- Delivering vaccines and ancillary supplies to countries

Coordinating a global approach to vaccine donations

WHO decided to adopt a coordinated, global approach with all vaccine donors, so as to allow the issuance of one standard agreement, covering all vaccine donations to recipient countries. It was felt that different agreements between WHO and vaccine donors, imposing different conditions on WHO for different countries, would not work in practice in a crisis situation.

Thus, after having completed negotiations with the first company to donate H1N1 vaccine, WHO developed a template donation agreement to be used for all donations. The Letter of Agreement (LOA) with recipient countries (see Meeting pre-conditions for supply) formed an integral part of this template.

Subsequent negotiations with vaccine donors were either based on this template (for direct donations) or on an indirect donation model pursuant to which governments facilitated donations by companies with whom WHO had concluded the template agreement. Most agreements with donors were concluded between November 2009 and March 2010 (see Box 1).

Identifying eligible countries

In August 2009, WHO began consultations with its Regional Offices to determine eligibility of countries to receive H1N1 vaccine donations. Ninety-five (95) low- and lower-middle income countries and territories without access to H1N1 vaccine were deemed eligible (see Annex I). Eligibility was based on the absence of domestic production or ability to purchase vaccine on the commercial market.

Note Two additional countries (Chile and South Africa) were later deemed eligible because of extenuating circumstances that increased the public health risk of H1N1 for them: the catastrophic earthquake in Chile in February 2010 and the World Cup in South Africa from June-July 2010. WHO also responded to an urgent request from the territory of Kosovo for H1N1 vaccine.
Determining the order in which countries would be supplied

Because not all vaccine donations were immediately available, each eligible country was assigned to a group (A, B or C) with the intent to supply countries in that order if no other criteria emerged. Assignment depended on the vulnerability of each country and its readiness to deploy vaccine.

- **Vulnerability** Country vulnerability was determined based on the geographical location of the country, as well as its disease burden. At the time when the sequence was developed, cases were declining in the Southern Hemisphere. Therefore, the initial sequence emphasized countries in the Northern Hemisphere and later shifted to countries in the Southern Hemisphere. To prioritize within a hemisphere, countries with the highest numbers of fatal H1N1 cases were given priority.

- **Readiness** Country readiness was determined based on the programmatic readiness of the country to deploy H1N1 vaccine.

The sequence was planned in this way so as to supply countries with H1N1 vaccine prior to when cases of H1N1 were likely to begin emerging in their region. Unfortunately, vaccine became available too late to serve countries in the Northern Hemisphere before the onset of winter and the plan to deliver vaccine to countries according to this sequence was abandoned.

Determining how many doses of vaccine to provide each country

The initial plan of the WHO Initiative was to supply each country with sufficient doses of H1N1 vaccine to vaccinate approximately 10% of the country’s population. This was based on the need to cover essential personnel and groups at higher risk of severe disease and death from H1N1.

Because the supply of H1N1 vaccines for deployment was limited, the WHO Initiative planned to first supply each country with sufficient doses of H1N1 vaccine to vaccinate 2% of its population (i.e. health care workers). This was to be followed by a second delivery of vaccine sufficient to vaccinate an additional 8% of its population. Countries with a population size less than 600,000 were offered sufficient vaccine to cover up to 100% of their population.
Establishing a supply mechanism

As donated vaccine became available, the WHO Initiative planned to immediately ship the vaccine to beneficiary countries that had met all criteria for supply. In most cases, vaccine was shipped directly from manufacturer facilities to countries.

Some of the factors that made vaccine deployment complex were the need to accommodate multiple sources of vaccines and ancillary supplies, unpredictable access to limited resources and other logistical challenges associated with the geography of some beneficiary countries (such as smaller, more remote countries in the Western Pacific Region).

To address this complexity, the WHO Initiative approach to deploy vaccines was designed to emphasize flexible and efficient delivery – while strictly adhering to policies of product quality and country support.

- The vaccine deployment mechanism was flexible about logistics in order to respond to different country needs (e.g. the timing of deliveries) and demographic/geographical conditions. The model also needed to be flexible to accommodate changes in the course of the pandemic, fluctuating demand from countries and irregular availability of vaccines, ancillary supplies, and financial and human resources to support the response. Although the WHO Initiative maintained a policy of supplying only one vaccine per country (because of the complexity of managing different, new products) it was necessary to be flexible about this when the volume of vaccine needed by a country exceeded the amount of any single product that was available.

- The mechanism had to efficiently and cost-effectively process and deliver orders so as to supply vaccines to countries as quickly as possible with the limited resources that were available. For example, WHO leveraged existing UN transport contracts by contracting the UN Office for Project Services (UNOPS) to provide distribution services for H1N1 vaccine and ancillary supplies.

- The mechanism had to set and abide by strict rules for product quality and country preparedness. Only WHO Prequalified vaccines would be deployed (see Box 5) and countries were required to meet minimum readiness measures to avoid shipping a limited resource to a country that did not have the means to effectively make use of the vaccine.

Lastly, the mechanism was set up to be temporary because it was anticipated that the effort to deploy H1N1 vaccines would be limited in time.
Key supply partners

To safely and efficiently deploy H1N1 vaccines and ancillary supplies to countries, the WHO Initiative called on the strengths of many organizations and institutions. In addition to efforts to prequalify vaccines and mobilize donations to support the Initiative, several of these organizations and institutions played key roles in the supply process.

- **Preparing recipient countries:** The UN Office for Coordination of Humanitarian Affairs (OCHA) and the UN System Influenza Coordination (UNSIC), in close collaboration with the International Federation of the Red Cross (IFRC), the UN Children’s Fund (UNICEF), the World Food Programme (WFP) and WHO helped countries to prepare their response to the H1N1 pandemic (including national vaccine deployment plans), develop communication strategies and tools and establish laboratory and monitoring capacity. WHO staff in countries worked closely with beneficiary governments and in-country partners, such as USAID, to satisfy the WHO Initiative requirements for supply and to prepare countries for receipt, importation and use of donated H1N1 vaccines.

- **Delivering products:** The vaccine supply process was complicated by the various formulations (e.g. both adjuvanted and non-adjuvanted vaccine) and presentations of donated supplies. Logistics and supply experts in WHO worked with partners and supply agents to carefully plan and monitor deliveries so that sufficient quantities of compatible vaccines and ancillary supplies (i.e. safety boxes and syringes), often coming from different sources and by different means of transport, arrived in countries concurrently (see Box 6). UNOPS provided distribution services for the WHO initiative, which involved managing the freight forwarding agents that shipped supplies from manufacturing sites and stockpiles to recipient country ports.

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38 WHO, Office of the Coordination of Humanitarian Affairs, UN System Influenza Coordination, “Urgent Support for Developing Countries’ Responses to the H1N1 Influenza Pandemic,” September 2009.
Some donors agreed to provide delivery services for donated vaccines and ancillary supplies. For example, in addition to its financial contribution and donation of vaccine, USAID donated syringes and safety boxes to complement 45 million doses of H1N1 vaccine delivered to 54 countries. The USA arranged for some of these ancillary supplies to be delivered directly to recipient countries. Another donor, GSK, complemented its donation of vaccines with in-kind delivery services to several of the countries that benefited from its vaccine donation.

- **Coordinating operations:** The WHO Secretariat directed and coordinated the vaccine deployment effort. This was a complex process that involved securing donated supplies, assessing country needs and reaching agreement with countries on supply schedules that balanced the available resources against the readiness and vulnerability of countries. Although many contributed to deployment, a central H1N1 Vaccine Deployment team at WHO Headquarters coordinated this work. Key roles on the team included:
  - an overall operations manager and a deputy/information manager, to facilitate the work of (and information sharing between) implementers and stakeholders;
  - a portfolio manager to lead communications with beneficiary countries and to guide them through the process of preparing for and receiving vaccines;
  - a contracts officer to coordinate with the WHO Legal Office on the contractual aspects of vaccine deployment and with WHO resource mobilization teams; and
  - a procurement officer to plan, monitor and manage order logistics.

### Meeting pre-conditions for supply

As described above, the WHO DG formally wrote to the 95 eligible countries on **23 September 2009**, asking them to advise WHO immediately if they wished “to be considered for the possible supply of pandemic vaccine by WHO.” Countries were informed that requests would be evaluated according to WHO’s established criteria to determine country eligibility and readiness. Before receiving donated vaccines:

1. The Government of the eligible country was required to submit a signed, official Letter of Intent (LOI) to WHO in response to the letter from the WHO DG.
2. The Government was required to sign a Letter of Agreement (LOA) with WHO,
indicating the country’s agreement to the terms and conditions applicable to the supply by WHO of H1N1 vaccine.

3. The Government was required to submit a Government-approved NDP that was subsequently validated by WHO.

Below, each of these pre-conditions of supply is described in detail.

Letters of Intent

From September-December 2009, WHO continued to secure pledged donations of vaccines and the resources needed to deploy them. As more vaccines became prequalified, more of the vaccines were deployed.

Simultaneously, the WHO Initiative standardized its supply processes, communicated these processes to countries and worked to help countries satisfy the three pre-conditions of supply (see above). The first of these pre-conditions was the submission of a signed LOI in response to the WHO DG letter of 23 September 2009.

Most signed LOIs were submitted to WHO within three months of the WHO DG letter. Of the countries and territories deemed eligible for donated vaccines, 97 in total submitted a signed LOI.

Following receipt of the LOI, WHO submitted a LOA to the eligible country, signed by the WHO DG and ready for countersignature by the country.

Letters of Agreement

As described above, before a country could receive donated H1N1 vaccine, a senior representative of its Government (usually its Minister of Health) had to countersign a LOA with WHO, accepting the terms and conditions of supply. By countersigning the LOA, the Government of the country confirmed that the vaccine had received regulatory approval or was otherwise authorized for use in the country.
In addition, countersignature confirmed that the Government of the country would be responsible for handling the importation and customs clearance of the vaccine and for arranging for any subsequent storage and transportation of the vaccine and its delivery to patients. The Government also agreed to notify WHO of any information it received on the occurrence of serious adverse events, an unexpectedly high occurrence of adverse events or any other significant safety information. Countersignature also indemnified donors and WHO from any liability for supply (Box 7).

Of the 97 countries that submitted a LOL, 87 countries returned a countersigned LOA to WHO. Most were returned between December 2009 and March 2010.

Many countries found it difficult to quickly countersign the LOA. The legally binding nature of the LOA and the requirement that countries indemnify donors from liability may have contributed to this.

National Deployment Plans

Each eligible country was required to submit a Government-approved NDP that explained how the country would assure that safe delivery of H1N1 vaccine and ancillary supplies would lead to protection for populations at risk. The NDP was required to clearly describe the population...
groups targeted by vaccination as well as the actions to be taken upon arrival of the vaccine in the country and the steps to be taken to vaccinate target populations.

Upon receipt of the NDP by the WHO Secretariat, teams of regional and international technical experts reviewed the plan to assess whether it met technical criteria established by WHO and was financially sound (meaning the costs of implementing the plan had been met through known sources of funding).

If the NDP was not technically acceptable, then the country had to address the outstanding technical issues before supply could begin. If the NDP was technically acceptable (and all other pre-requisites for supply had been met) but in-country funding gaps existed, then the country received the first phase of supply (sufficient to vaccinate 2% of its population) while these gaps were filled. After financing gaps were filled, the country received the remainder of the allocated vaccine.

During the WHO Initiative, 82 countries (94% of countries that signed a LOA with WHO) submitted a Government-approved NDP that was validated by WHO. Approved NDPs continued to be submitted to WHO through July 2010.

**Delivering vaccines and ancillary supplies to countries**

As countries satisfied the WHO Initiative conditions for supply, vaccines were deployed. The first vaccine orders were placed in mid-December 2009 for two countries simultaneously: Azerbaijan and Mongolia.
From January to March 2010, the number of vaccine deliveries (and doses delivered) increased as countries satisfied the preconditions for supply and as more vaccines became prequalified and available from donors.

In early 2010, WHO responded to a consolidated request from several island countries in the Western Pacific leading to a significant increase in the number of deliveries made during March 2010. Volcanic eruptions in April 2010 disrupted shipments of vaccines to countries during that month, however deliveries returned to earlier levels in May and June 2010.

In August 2009, there was a large increase in the number of deliveries and the volume of vaccine delivered because of multiple deliveries to countries in the African Region and a large delivery (to Bangladesh) of more than 12 million doses of vaccine.

While the number of orders and volume of vaccine delivered fluctuated each month in 2010, the lead time (the number of days to deliver the vaccine after an order was placed) steadily decreased (see Box 8). It is likely that proficiency with the supply chain system and a greater understanding by all partners of roles and responsibilities contributed to this improved performance.
Revised vaccine deployment strategy

In March 2010, in light of the changing course of the pandemic and based on its understanding of country need and the support that had been pledged by donors, WHO took several steps to accelerate supply to countries:

- WHO replaced the two-phase approach to deployment where possible and began to supply sufficient vaccines to cover 10% of the country population in a single order. Countries that received a full 10% in a single order included Cameroon, Ghana, Sierra Leone and Swaziland.

- Because financial resources in countries for national vaccination campaigns had proven to be severely limited, some of the funding that had been donated to WHO for global operations and deployment was shifted to support in-country activities.

- Because of the delay in finalizing NDPs, vaccines with shorter shelf life were prioritized in order to maximize the utilization of donations. This sometimes meant that vaccines that were originally planned for a country, but had yet to be produced, were substituted with a different formulation of vaccine that had already been manufactured.

---

Information Note to Partners, WHO, 14 March 2010.
Conclusion

On 10 August 2010, the WHO International Health Regulations (IHR) Emergency Committee and the WHO DG declared an end to the H1N1 pandemic based on strong indications that influenza was transitioning toward seasonal patterns of transmission worldwide. The WHO emphasized, however, that during the post-pandemic period the H1N1 virus would likely take on the behaviour of a seasonal influenza virus and continue to circulate, with localized outbreaks of H1N1 of different magnitudes. WHO recommended vaccination of high-risk populations in countries where vaccine was available.

In total, from January through October 2010, the WHO Initiative delivered 78,066,290 doses of H1N1 vaccine to 77 countries. The table below presents the number of doses of H1N1 vaccine delivered to countries through the WHO Initiative between January and the conclusion of deployment efforts in October 2010.

**H1N1 vaccine doses delivered through the WHO Initiative**

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<th>Country/territory</th>
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### Annex I: List of eligible countries and territories

#### Countries and territories initially deemed eligible to receive donated H1N1 vaccine

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#### Countries and territories subsequently deemed eligible to receive donated H1N1 vaccine

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<td>Kosovo</td>
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<td>98</td>
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Annex II: WHO DG letter to eligible governments

22 September 2009

Dear Minister,

I am pleased to announce that several manufacturers and donors have responded positively to our efforts to secure access to pandemic influenza vaccines for developing countries in need, and have made commitments to donate vaccines to WHO or make such vaccines available to WHO for procurement at a preferential price.

Although it is as yet unclear what quantity of vaccines WHO will actually be able to secure and make available to countries in need, it is hoped that the first doses of vaccine will become available later this year, and WHO will endeavour to rapidly distribute these supplies to certain priority countries in need. Bearing in mind that the quantity of vaccines which WHO hopes to secure will be very limited, WHO will only be able to provide limited supplies to certain countries, prioritized based on epidemiological, programmatic and other criteria which are in the process of being developed. It is expected that these criteria will, among others, include:

- a plan for use of the vaccines, including the identification of priority groups to be vaccinated (based on WHO guidance);
- readiness to receive, distribute and use pandemic vaccine (including (i) the availability of adequate storage facilities for storage under appropriate conditions; (ii) training of country healthcare workers to handle and administer the pandemic vaccines; (iii) availability of locally translated leaflets, if necessary, etc.).

WHO will, in the near future, communicate further with your Ministry in respect of the above-mentioned criteria.

ENCL: As stated
In addition, recipient governments will need to accept other important requirements related to a possible donation of pandemic influenza vaccine, including but not limited to: registration or authorization of the vaccine for use in the country, adherence to all recommendations for the proper handling and administration of the vaccine as provided in the approved product labeling, agreement to use the vaccine exclusively for the agreed purpose, liability and indemnification, etc. These requirements are further described in the attached annex to this letter.

WHO is ready to provide technical assistance to recipient governments for vaccine deployment in close collaboration with other UN agencies and partners.

Based on the information provided to WHO, I understand that your country currently lacks access to pandemic vaccine. Should you wish to be considered for the possible supply of pandemic vaccine by WHO, please inform me immediately. On receipt of your request, it will be evaluated according to the above-mentioned criteria to determine country eligibility and prioritization.

Should it ultimately be possible and decided to fulfill your request, WHO will provide you with a letter of agreement to be signed and returned to WHO, prior to deployment of vaccine.

Should you have any questions concerning access to the donated vaccines, please contact Mr Robert Matinu, Tel: +41 22 79 13971; <Email: matinu@who.int>.

Yours faithfully,

[Signature]

Dr Margaret Chan
Director-General
Annex III: Requirements to be met before vaccine supply

Prior to receiving donated H1N1 vaccine from WHO, eligible countries/territories had to satisfy the following requirements:

1. Ensure registration of the vaccine or otherwise authorize its use in the country.

2. Agreement to indemnify and hold WHO and the manufacturer of the vaccine harmless from any claims and liabilities arising from any bodily injury, illness, suffering, disease or death caused by use of the vaccine in the country.

3. To the extent that labelling, packaging or leaflets of the vaccine are not available in the official language(s) of the country, liaise with the relevant medicines agency in the country to prepare leaflets in the official language(s) of the country, and distribute the leaflets (whether provided by the manufacturer, WHO or prepared with the relevant medicines agency) to healthcare professionals who prescribe, supply or administer the vaccine.

4. Ensure that the quantity of vaccine supplied will:
   - Be distributed according to a National Deployment Plan for use of the vaccines, that has been screened, evaluated and approved by WHO and includes the identification of priority groups to be vaccinated (based on SAGE guidance) as well as details on readiness to receive, distribute and use pandemic vaccine (including (i) the availability of adequate storage facilities for storage under appropriate conditions; (ii) training of country healthcare workers to handle and administer the pandemic vaccines; (iii) availability of locally translated leaflets, if necessary).
   - Not be used for any purpose other than the immunization of persons against the currently circulating A (H1N1) virus, and, where applicable, not use the adjuvant component of the vaccine for any purpose other than for the administration with the antigen component of the vaccine.
   - Only be provided to persons in the country who have been prioritized in accordance with the country’s outbreak response measures or pandemic preparedness plans, as applicable; and
   - Not be sold, exported or otherwise made available for use outside the country (but will only be provided to patients in the country free of charge or at nominal cost to recuperate reasonable expenses incurred in connection with delivery to patients).

5. Agreement to handle the importation and customs clearance of the vaccine into the country and arrange for any subsequent storage and transportation of the vaccine and its delivery to patients.

6. Ensure that all healthcare practitioners and others administering the vaccine to patients are fully aware of, understand and will ensure adherence to all recommendations for the proper handling and administration of the vaccine as provided in the approved product labeling and with any necessary arrangements for reporting adverse events and effecting product recalls.

7. Acknowledgement that: (i) neither the manufacturer nor WHO can guarantee the extent to which the use of the vaccine will be successful in reducing morbidity and mortality or containing or delaying the spread of an influenza outbreak; and that (ii) the supply of the vaccine by WHO is not a replacement for national stockpiles.

8. Agreement to notify WHO, in writing, as soon as reasonably possible, of any information received by it on the occurrence of any unexpected adverse events, or an unexpected high occurrence of adverse events with respect to the use of the vaccine.

9. Acceptance that the supplies of vaccine would be provided in accordance with the terms of the Basic or Technical Advisory Assistance Agreement concluded with the government.