

Report of the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative



**World Health
Organization**

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Executive summary

As part of its efforts to combat seasonal and pandemic influenza outbreaks, the World Health Organization (WHO) works to ensure equitable access to vaccines and other medicines, especially in resource-poor settings. Specific WHO activities range from deploying vaccines and antivirals to addressing the systemic problems that limit their availability in many countries. For access to be considered truly equitable, vaccines and other medicines must be available to countries when they are most needed.

In April 2009, cases of a virulent influenza were detected in Mexico and the United States of America. After determining that these cases were related, WHO issued a health advisory. In June, the 2009 H1N1 influenza pandemic was declared.

Under the mandate of the International Health Regulations (IHR; 2005) the Director-General of WHO convened a technical Emergency Committee to assess the situation and to advise on the most appropriate actions to take. As part of this, and to ensure that developing countries were able to protect the health of their populations, WHO began to mobilize and coordinate the global donation of resources needed to deploy life-saving pandemic H1N1 vaccines and ancillary products to some of the world's most vulnerable populations.

The subsequently established WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative (hereafter referred to as the “WHO Deployment Initiative”) coordinated the support of governments, foundations and manufacturers in facilitating access to pandemic H1N1 vaccines in countries eligible for assistance. In response, millions of doses of vaccines and associated ancillary products (such as syringes and safety boxes) were donated, and considerable financial and logistical support pledged. WHO's mandate was to act as the secretariat and central implementing body for the WHO Deployment Initiative, and to coordinate with all donors, recipient governments and partner organizations to ensure that vaccines reached countries in need.

Although the resulting WHO deployment team mobilized to implement vaccine deployment was temporary in nature, it was able to access expertise from various disciplines within the Organization and partner organizations. Legal, regulatory and communications support was thus provided throughout the pandemic. Such support included the development of a global donation agreement by the WHO Office of the Legal Counsel to address some of the many complexities of vaccine donation. In addition, vaccines were reviewed and prequalified by the WHO Quality, Safety and Standards team, often in record time. Communications experts were also continually on call to make sure that technical information was accessible to the public, recipient countries and experts. The deployment team itself coordinated international logistics, managed demand, and dealt with regulatory and country-preparedness issues as vaccines were scheduled for delivery. The deployment

effort was the first of its kind and moved unprecedented quantities of a new vaccine around the world.

On 10 August 2010, the IHR Emergency Committee and the Director-General of WHO declared the end of the 2009 H1N1 pandemic, based on strong indications that the pandemic virus was transitioning towards seasonal patterns of transmission worldwide. WHO continued to recommend vaccination as the virus remained in circulation and the vaccine still offered protection to those at high risk of serious outcomes.

The 2009 H1N1 pandemic provided the world with a valuable opportunity to test global capacity to respond to a public health emergency. The success of the WHO Deployment Initiative was based upon the careful and flexible planning of activities, and upon open and transparent communications between all involved parties. It was recognized, however, that the pressure to respond quickly and efficiently can create risks in managing vaccine production and availability, regulatory and quality processes, and country planning. After its conclusion, the opportunity was taken to document important issues arising from the implementation of the WHO Deployment Initiative, and to identify the lessons that need to be learnt if the world is to improve its response to future pandemics and other emergencies.

1. Global response to the 2009 H1N1 influenza pandemic

1.1 Declaring the pandemic and preparing for vaccine production and deployment

Prior to the pandemic and the WHO Deployment Initiative, a series of events and activities occurred that ultimately shaped the WHO response. Early reports on the outbreaks of H1N1 influenza activated information-sharing networks. As the incidence of serious cases increased, preparations for vaccine production and other responses began. Concerns grew in the international community for countries without access to vaccines or antivirals. These events and others contributed to the declaration of a global pandemic and the launch of the WHO Deployment Initiative. The following account is not exhaustive but does provide a chronology of significant events and activities leading up to the pandemic and the WHO Deployment Initiative.

In **April 2009**, outbreaks of influenza-like illness occurred in Mexico and the United States. By 24 April 2009, it became clear that these outbreaks were related and WHO issued a health advisory (1).

On **27 April 2009**, WHO organized a first teleconference with the WHO Collaborating Centres for influenza and Essential Regulatory Laboratories of the Global Influenza Surveillance and Response System. To allow for the development of candidate vaccine viruses, the virological characteristics of the causative virus were subsequently determined, and diagnostic resources and prototype vaccine viruses developed and shared.

By **7 May 2009**, the disease was spreading rapidly, with the number of confirmed cases rising to 2099. On 8 May 2009, WHO provided updates on the status of candidate vaccine virus development and the preparation of essential reagents.

On **14 May 2009**, WHO convened an emergency consultation of the WHO Strategic Advisory Group of Experts (SAGE) on Immunization and its ad hoc Working Group on H1N1 vaccines. SAGE was provided with data produced by WHO which indicated that up to 4.9 billion doses of monovalent pandemic vaccine could be produced over a 12-month period (2). This was based upon the assumption that yields would be equivalent to those routinely obtained for seasonal vaccine and on the use of the most dose-sparing formulations. After reviewing the available information, SAGE noted that the number of vaccine doses needed would depend on the spread of the emergent influenza A(H1N1) virus in the following weeks and on a better definition of the groups to be targeted for vaccination.

On **26 May 2009**, WHO provided an update on the characteristics of the causative virus (3), and subsequently announced that the first candidate reassortant vaccine virus was available for vaccine development (4). WHO also issued biosafety recommendations for the production and quality control of vaccines against the virus (5).

On **11 June 2009**, WHO declared the 2009 H1N1 influenza pandemic (6).

On **6 July 2009**, the Secretary-General of the United Nations and the Director-General of WHO convened a meeting and released a Joint Statement (7) expressing concern that the pandemic A(H1N1) 2009 virus could have a severe impact on low-income countries, and calling on the international community to provide assistance to help the least-developed countries to withstand these impacts. Donors attending the meeting requested that United Nations agencies and the World Bank develop a more detailed assessment of precisely what resources were required (8).

On **14 July 2009**, the first reagents needed to assess the potency of pandemic H1N1 vaccines in development became available, with the first data from a pandemic H1N1 vaccine clinical trial becoming available one month later (9).

On **19 September 2009**, WHO predicted that the amount of pandemic H1N1 vaccine that could actually be produced within a year would be “substantially less” than the previously estimated production capacity of 4.9 billion doses. While this was initially a concern, information had already emerged indicating that the vaccine could be administered as a single dose rather than as a two-dose series (10).

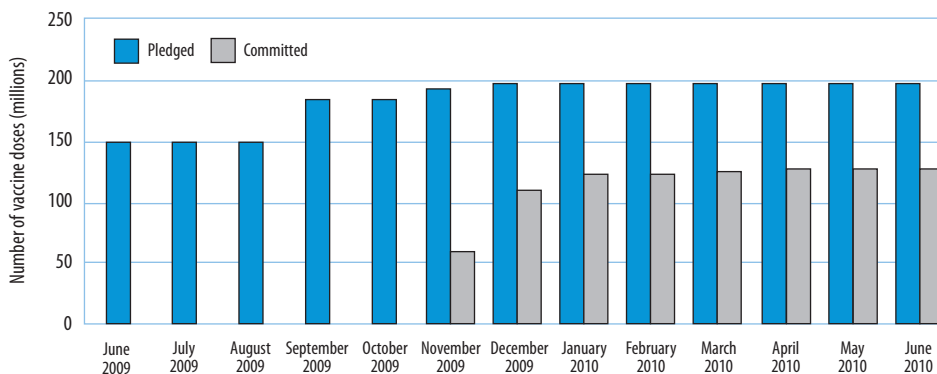
In **September 2009**, governments and other donors began to announce their official support for efforts to secure pandemic H1N1 vaccines for countries without access. On 18 September 2009, the President of the Global Health Program at the Bill and Melinda Gates Foundation announced that the global community should “take steps to protect all populations, including those without resources to protect themselves” (11). Also on 18 September 2009, nine governments announced that they would share their pandemic H1N1 vaccine supplies with low- and middle-income countries. Among these, the United States pledged up to 10% of its supply of such vaccine; it was joined by Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland and the United Kingdom (12). The United States announced that it would make pandemic H1N1 vaccine available to WHO on a “rolling” basis as vaccine supplies became available, in order to assist countries that would not otherwise have direct access to the vaccine (13). This approach ensured that vaccine would be available in a timely manner for countries in need, rather than only becoming available once national demand in the donor country had been met.

1.2 Donations of vaccines

As a result of global support and the long-standing pledges already made by some vaccine manufacturers, an initial combined pledge of 200 million vaccine doses was made (Box 1). As pledges were negotiated and donations confirmed, the final quantity of vaccines committed for deployment was 122.5 million doses (Figure 1). This was sufficient to cover 10% of the population in eligible countries that requested vaccine. Sufficient supplies of syringes

Box 1. Pledging of vaccine donations

On 15 May 2009, GlaxoSmithKline (GSK) issued a press release announcing that it would pledge 50 million doses of pandemic H1N1 vaccine to WHO once production began (14). This pledge was quickly formalized through the amendment of a pre-existing donation agreement for other types of influenza vaccines, and represented the first such public pledge. GSK later increased this pledge to 60 million doses (15). On 18 June 2009, Sanofi-Aventis announced a pledge of 100 million doses of pandemic H1N1 vaccine to support WHO efforts to ensure more-equitable access to vaccines and help strengthen national responses to the pandemic (16).

Figure 1. Cumulative vaccine doses pledged and committed by donors^a

^a Not all committed vaccine doses became immediately available for delivery.

to match the vaccine doses were either donated or procured using donated funds. By November 2009, the release of vaccines for deployment to recipient countries began.

Because some pledges included amounts to be used in future emergencies including pandemics, the amounts pledged were higher than the actual amounts committed or delivered. Other vaccine donations were subject to manufacturing schedules and were flexible as to when they would be produced. When country demand dropped later in the WHO Deployment Initiative, portions of these donations were not produced and were subsequently converted into future pledges to avoid wasting vaccines.

1.3 Donations of ancillary products

To ensure that sufficient supplies would be available to administer the vaccines, WHO also called for donations of auto-disable syringes and safety boxes for the disposal of sharps. According to current WHO guidance on injection safety (17), syringes and safety boxes should be provided in matching quantities to the vaccines to avoid syringe reuse and other safety

problems. The first consignments of ancillary products were donated by the United States Agency for International Development (USAID) and by Becton, Dickinson and Company (through the non-profit organization AmeriCares). The initial quantities were sufficient to cover the first 70 million doses of vaccine. WHO, through its partnership with the United Nations Office for Project Services (UNOPS), procured the remaining balance of required syringes and safety boxes.

1.4 Financial support

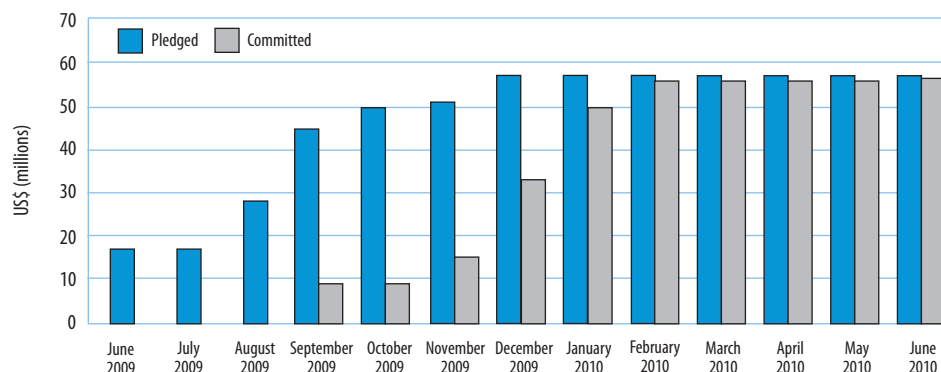
In addition to the need for vaccines and ancillary products, there was also a clear need for funding to support the costs of safely deploying vaccines to countries, and for safely distributing and administering them within the systems of recipient countries once they arrived.

Financial support was pledged as early as June 2009 and was later made available through signed commitments between September 2009 and June 2010 (Figure 2). Financial reports have been provided separately to donors in accordance with their specific reporting requirements.

Exclusive of the value of the vaccines, the total financial support provided by donors for global distribution and country-deployment activities was over US\$ 56 million. Specific activity areas included managing and responding to issues of vaccine quality and safety, legal and regulatory activities, managing deployment operations, providing technical assistance to recipient countries, and (in partnership with UNOPS) coordinating international cold-chain distribution (Box 2).

Financial support was also provided to recipient countries to cover deployment activities. Country deployment included training and communication, distribution of vaccines, immunization activities, waste management, adverse-events monitoring and addressing other needs specific to local conditions. In a limited number of cases, funds were also provided to allow for the safe destruction of expired or damaged vaccines. The provision

Figure 2. Cumulative financial support pledged and committed by donors



of financial support for other types of activities was reviewed on a case-by-case basis.

The financial support required to manage country deployment (excluding the cost of the vaccines) varied across regions. Taking into account both local funding and the financial support received through the WHO Deployment Initiative, the average cost per dose for vaccine deployment and administration ranged from US\$ 0.16 in the WHO South-East Asia Region to US\$ 0.66 in the WHO African Region.

The financial support allocated to country deployment was carefully planned and managed to ensure equitable access to the available resources, and was provided according to the needs identified and verified in the national deployment plans (NDPs) of countries. The value of country requests varied, ranging from US\$ 7500 to over US\$ 2 million, with a median request of approximately US\$ 158 000. The size of specific target populations, difficulty of access to certain geographical regions and the availability of local funding were among the issues that determined the amounts requested. Fifty-seven countries received a total of US\$ 19.2 million for in-country deployment support.

Box 2. Transportation costs of vaccines and ancillary products

The total cost of the international cold-chain distribution of vaccines from their point of manufacture to all recipient countries was approximately US\$ 3.7 million (or US\$ 0.15 per dose).

For ancillary products, air-transport costs for auto-disable syringes and safety boxes were approximately US\$ 2.7 million per recipient country (or US\$ 0.30 per set moved). A “set” was defined as one syringe plus an amortized portion of a safety box. For calculation purposes, each safety box was assumed to hold 100 used syringes. The cost of a set therefore included the cost of one syringe and one hundredth of the cost of a safety box.

As the transportation costs for some vaccines and ancillary products were paid outside the donation process as in-kind contributions, the figures for both cost per dose and cost per set do not correspond to the total number of deliveries.

1.5 Coordination of bilateral support

Although WHO coordinated all donations made through the WHO Deployment Initiative, many donors, including several that provided support to the Initiative, also provided bilateral support to countries. While WHO’s primary role was to coordinate resources donated through the WHO Deployment Initiative, it became vitally important to participate in efforts to coordinate bilateral support. The nature of bilateral contributions varied between different donors and recipient countries, and included technical assistance for planning, in-country logistics and distribution, international vaccine transport and the direct donation of ancillary products.

WHO worked constantly with donors and countries to maintain up-to-date information on the range of bilateral donations and support, coordinate its timing and inform stakeholders of WHO activities. Particular care was taken to avoid the duplication of efforts and resources and to prevent unexpected financial or other gaps resulting from a lack of coordination or shifts in bilateral support. For example, the direct bilateral donations and deliveries of ancillary products to some countries managed by the USAID | DELIVER PROJECT were carefully coordinated to ensure that supplies arrived either before or at the same time as the vaccine to avoid delays in deployment. In addition, planning for distribution activities, health-worker training and communication efforts was dependent upon the specific details of the vaccine allocated to a given country. WHO provided a weekly update and responded to requests for detailed information, initially on a daily basis.

1.6 Development of legal agreements for vaccine donation and receipt

Governments, foundations and manufacturers all contributed to the WHO Deployment Initiative by providing vaccines, ancillary products and/or financial resources. In the case of vaccine donations, the corresponding legal agreements were necessarily complex and a novel system was developed by the WHO Office of the Legal Counsel to streamline and expedite the negotiation process. This strategy was developed in response to serious concerns that maintaining a large number of different agreements between WHO and vaccine donors, each imposing different conditions on WHO with regard to recipient countries, would not be feasible, practical or equitable in a crisis situation.

Specifically, a global legal framework for all vaccine donations was developed and adopted. In addition to allowing the use of a single standard agreement, the framework was sufficiently flexible to accommodate both “direct” and “indirect” donations. The direct donation model was used when the donor (for example, a vaccine manufacturer) was in a position to warrant adherence to both current Good Manufacturing Practices (cGMP) and to the agreed specifications. Indirect donations were made when donor governments opted instead to purchase vaccines from a specific manufacturer and to then instruct the manufacturer to provide a specific quantity of vaccine free of charge to WHO. Adherence to cGMP and to agreed specifications was then warranted by the manufacturer as part of a separate agreement with WHO. The framework was also flexible in that donations could be made available according to vaccine production schedules or by using existing vaccines already in stock.

The framework did not accommodate the “earmarking” of vaccine donations for use in a specific recipient country. Given the complex allocation-planning and logistical activities involved, earmarking would

have undermined efforts to promote timely and equitable access to vaccines. Vaccines were matched to recipient countries based on many factors, including (but not limited to) country readiness and vaccine availability, existing influenza vaccines purchased by the country or donated through other sources, and logistical considerations. A sequential grouping of countries based on the likelihood of serious health consequences was also used in the early stages of the WHO Deployment Initiative (see section 4.2).

To facilitate the acceptance of vaccines by the large number of recipient countries involved, WHO developed a Letter of Agreement that was signed by each recipient-country government as a condition of receiving vaccines. This Letter of Agreement acknowledged and incorporated clauses from the donation agreement outlined above. All agreements with countries therefore included the same required terms, including those relating to limitations of liability, that were included in the agreements between WHO and donors.

Because the initial urgency of the pandemic response required an unprecedented number of doses of a new vaccine to be deployed globally in a period of only a few months, vaccine manufacturers required that all customers (primarily developed-country governments) indemnify them (or otherwise discharge them from liability) for any adverse events arising from the use of the pandemic H1N1 vaccine, except to the extent that such adverse events were caused by a failure to comply with cGMP or to meet agreed specifications.

Because of the complex legal environment, WHO provided extensive and constant support to countries in interpreting and managing the above-mentioned and other legal issues throughout the 2009 H1N1 pandemic, especially in the areas of liability, regulatory registration and the impact of changes to vaccine licensing. For example, the licences of many vaccines changed at the end of the pandemic, allowing for their use outside a pandemic period. While this was a positive development, countries required detailed information to manage this change in authorized use. In many cases, countries had to officially re-register the product and disseminate information to all levels of the vaccine-distribution network, including vaccine-administration sites, to avoid what would otherwise have become “off-label” use with undue liability.

Following the series of pledges to donate vaccine made in late 2009 (see section 1.2), agreements with all donors were concluded between November 2009 and March 2010 in accordance with the global legal framework. This framework will now be available as a time-saving option for any future emergency involving the donation of a new vaccine or other medicine.

2. Vaccine prequalification, licensing and monitoring

2.1 The WHO prequalification process

All vaccines donated to the WHO Deployment Initiative were licensed for global distribution by the national regulatory authority in the country of manufacture, including Australia, Canada, the United States and several countries in Europe following expedited review and licensing processes. National regulatory authorities in recipient countries also required product registration before a new vaccine could be imported or distributed. Some countries had well-established provisions for temporary or exceptional regulatory authorization in emergency or other urgent circumstances. However, registration processes varied across recipient countries with some requiring significant national resources and time.

The WHO prequalification process is a frequently used approach for product-quality verification in countries that lack strong regulatory agencies. Of the countries that received donated vaccines through WHO, 75% required WHO prequalification as part of local registration or exemption from it. Expedited WHO prequalification (Box 3) ensured the most rapid access possible to vaccines that met international quality standards.

The WHO prequalification process provides an independent assessment of the quality, safety and efficacy of products (such as vaccines) for United Nations purchasing agencies in order to ensure that products are suitable for intended target populations. In collaboration with regulatory agencies in manufacturing countries, the prequalification process is also used to ensure compliance with product specifications and established quality standards, and to monitor any emerging safety or efficacy concerns.

Eleven pandemic H1N1 vaccines were submitted by manufacturers and prequalified during the course of the pandemic (Figure 3). Of these, seven were among those donated to the WHO Deployment Initiative for delivery to recipient countries. In addition to providing an objective and harmonized quality-assurance process for medicines and vaccines provided through the United Nations, WHO prequalification was also crucial to many countries that had purchased pandemic H1N1 and other influenza vaccines. Regardless of whether a country received donated vaccine or purchased vaccine independently, many required WHO prequalification as part of their in-country authorization process.

2.2 Monitoring vaccine quality, stability and licensing

Vaccine approval and licensing by reference regulatory authorities in the country of manufacturer include a determination of vaccine shelf-life, and are necessarily subject to continued monitoring. During the course of the 2009 H1N1 pandemic, the shelf-life of two vaccines was retrospectively reduced by

Box 3. Expedited prequalification of pandemic H1N1 vaccines

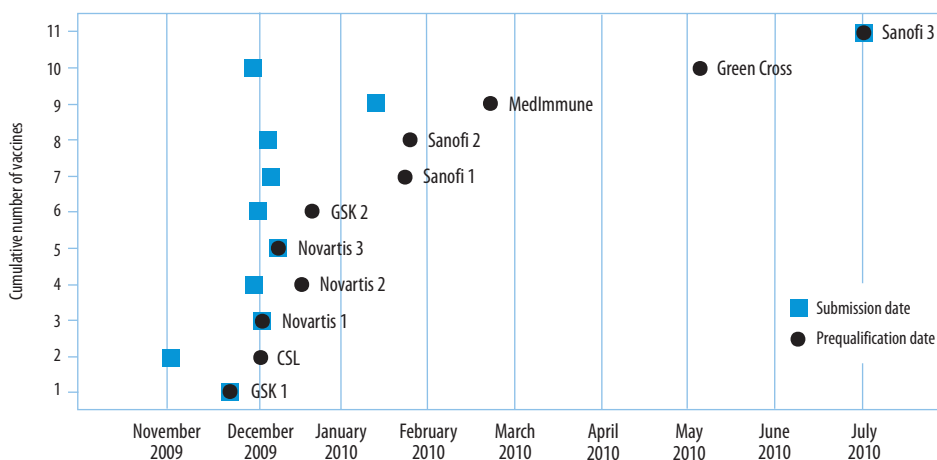
As part of facilitating rapid and equitable access to pandemic H1N1 vaccine, WHO was able to expedite its prequalification process. Within three months, eight pandemic H1N1 vaccines had been prequalified – which included all the products used in the WHO Deployment Initiative. Three additional vaccines were then submitted and approved in the months that followed (Figure 3).

The time needed to review individual pandemic H1N1 vaccine dossiers ranged from one to 20 days, depending on specific circumstances. Dossiers from manufacturers with prior experience with seasonal influenza vaccines and with the prequalification process had shorter review times. For example, where a manufacturer had previously submitted and received approval for a seasonal influenza vaccine, reviewing the pandemic H1N1 vaccine dossier took one day. For manufacturers with less experience with influenza vaccines, or those seeking WHO prequalification for the first time, the review process was necessarily more extensive. Marketing authorization from the national regulatory authority in the country of manufacture was a prerequisite for all submissions.

WHO prequalification also supported regulatory processes in recipient countries, with 75% of such countries requiring it as part of local regulatory review and authorization. In approximately 25% of countries, national regulatory systems were not available or were unable to review information and provide specific authorizations. In these countries, WHO prequalification was the sole basis for authorizing distribution of the vaccine.

WHO also provided additional support to local regulatory processes, for example by coordinating confidential manufacturing information (such as lot-release data) and coordinating information for limited clinical trials by some recipient countries. Almost 50% of all recipient countries required such additional support. Because some countries had extensive requirements and because manufacturers did not have prior experience with many of the recipient countries, there was reliance upon WHO to coordinate the process. However, WHO did not facilitate commercial registration for any manufacturer as its limited authorizations did not extend commercial registrations by manufacturers or in any way facilitate future registrations.

Figure 3. Timetable of pandemic H1N1 vaccine prequalification by WHO



GSK: GlaxoSmithKline.

the relevant reference regulatory authorities following continued monitoring of the vaccines. The shelf-life of all released batches of the GSK product Arepanrix was reduced from 18 months to 6 months in a determination made by Health Canada. In addition, the shelf-life of a limited number of batches of Sanofi Pasteur USA H1N1 2009 made by Sanofi USA was reduced. In both cases, the concern was related to vaccine efficacy after 6 months and not safety.

Ultimately, seven recipient countries were in the position of unexpectedly having to manage vaccines that had retroactively expired; that had a revised shelf-life too limited for deployment; or that had to be recalled from local distribution channels. WHO identified the location of all affected batches and developed detailed guidance for affected countries in consultation with the WHO Quality, Safety and Standards team and the regulatory authorities and manufacturers concerned. Countries with resulting unmet needs were provided with an option to receive a replacement product, and received financial support to appropriately destroy the expired doses.

Following the pandemic, the authorizations from reference regulatory agencies for some pandemic H1N1 vaccines changed. As the pandemic A(H1N1) 2009 virus continued to circulate in the post-pandemic period, vaccines remained useful and protective. However, certain pandemic H1N1 vaccines were originally labelled for use only in a pandemic situation. Using these vaccines outside a pandemic period would constitute “off-label” use in the absence of required action from regulators. Regulatory agencies in the countries of manufacture modified their respective authorizations to include general vaccination against the pandemic virus; however, authorizations issued by the national regulatory authorities in recipient countries also required corresponding updating and management. For countries directly affected, specific guidance and support was provided on managing the change, including a “frequently asked questions” document developed by WHO for use by all countries (see Annex 1).

2.3 Monitoring vaccine safety

During the pandemic, countries reported adverse events through national surveillance systems. The National Institute of Health and Welfare in Finland reported an increase in the number of cases of narcolepsy in children vaccinated with Pandemrix. Although the preliminary information was not conclusive, subsequent data indicated an increased incidence of narcolepsy in children between the ages of 4 and 19 years who had been immunized against pandemic H1N1 influenza. These increased incidences were observed only in Finland, Iceland and Sweden (where higher rates of narcolepsy normally occur) and were limited to Pandemrix with no association found with other influenza or childhood vaccines. WHO identified the location of all Pandemrix distributed through the WHO Deployment Initiative and provided detailed notifications and guidance through its Global Advisory Committee on Vaccine Safety (18).

3. Eligibility and preconditions for vaccine supply

3.1 Identifying eligible countries

In August 2009, WHO began consultations with its regional offices to determine which countries would be eligible to receive donated pandemic H1N1 vaccine. Eligibility was based on the absence of domestic vaccine production and the lack of ability to purchase vaccine on the commercial market. Ninety-five low-income and lower middle-income countries and territories had no access to vaccine and were deemed eligible (see Annex 2). Two additional countries (Chile and South Africa) were subsequently deemed eligible because of extenuating circumstances that increased the public health risk of pandemic H1N1 influenza – the catastrophic earthquake in Chile in February 2010 and the World Cup in South Africa in June and July 2010. WHO also responded to an urgent request for pandemic H1N1 vaccine from Kosovo (in accordance with Security Council Resolution 1244 (1999)).

On 22 September 2009, the Director-General of WHO formally wrote to the initial 95 countries deemed eligible for pandemic H1N1 vaccine donations (see Annex 3), informing them of the availability of vaccines and asking them to advise WHO immediately if they wished to receive pandemic H1N1 vaccine through the WHO Deployment Initiative. Countries were also informed that requests would be prioritized based upon epidemiological, programmatic and other criteria.

3.2 Providing technical support to countries

For any donation of medicines it is imperative to verify that a recipient country will realistically be capable of ensuring its effective and appropriate use. Failure to do so can lead to unanticipated burdens on a country and result in wasted donations that could have been used elsewhere. WHO country personnel therefore worked closely with recipient-country governments and in-country partners (such as USAID) to provide technical assistance to countries in preparing for vaccine importation and deployment. In collaboration with WHO, the United Nations Office for Coordination of Humanitarian Affairs (OCHA) and the United Nations System Influenza Coordination (UNISIC), in close collaboration with the International Federation of the Red Cross (IFRC), the United Nations Children's Fund (UNICEF) and the World Food Programme (WFP), also provided support to countries in preparing their response to the pandemic (19). Support was given in areas such as the development of NDPs, and communication strategies and tools. To improve the global coordination and availability of surveillance information, support was also provided for the establishment of laboratory and monitoring capacity.

WHO also supported countries by holding regional workshops in preparedness planning. Prior to the pandemic, workshops in general emergency response had already taken place in several regions, and additional

workshops were held in the remaining regions just as the pandemic began. Workshops focused on developing plans for mobilizing technical resources to implement an effective response, including vaccine deployment. The focal areas included logistics; product training for clinical service providers; communications and public information; monitoring and reporting of adverse events; injection safety and waste management; and issues specific to the country context. To support the development of national plans and address other technical needs a total of 10 regional workshops were organized by WHO (Box 4).

Box 4. Regional workshops to support country planning activities

Before the 2009 H1N1 pandemic, few low-income and middle-income countries had a national pandemic preparedness plan that included the distribution of vaccines. Between July and November 2009, WHO conducted the following workshops at which personnel from approximately 170 countries and territories were trained in the development of NDPs.^a Unless otherwise specified, one workshop was held in each location.

- African Region – Abuja, Nigeria (two workshops).
- Region of the Americas – Bogotá, Colombia; Panama City, Panama; Lima, Peru; Saint Kitts and Nevis.
- South-East Asia Region – New Delhi, India.
- European Region – Copenhagen, Denmark; Istanbul, Turkey.
- Eastern Mediterranean Region – Rabat, Morocco (20).
- Western Pacific Region – Nadi, Fiji; Manila, Philippines.

The objective of these workshops was to accelerate the preparedness of countries to respond effectively to emergencies involving vaccination, including the 2009 H1N1 pandemic. Workshop materials included multiple operational planning and implementation tools, such as those needed to calculate the cold-chain volumes required for vaccine deployment.

The workshops were ultimately vital in helping recipient countries to meet the donation prerequisite for a sufficiently developed NDP to verify their capability to promptly and appropriately use the initially limited supply of pandemic H1N1 vaccine.

^a In August 2009, WHO announced that the number of influenza cases was steadily declining in the southern hemisphere, and advised countries in the northern hemisphere to prepare for a second pandemic wave. To account for the more immediate need in the northern hemisphere, WHO conducted the corresponding workshops first.

3.3 Helping countries to meet the preconditions for vaccine supply

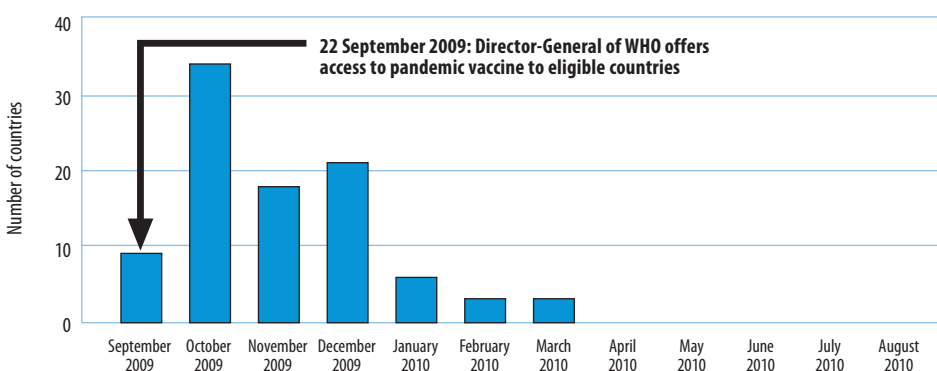
Early in the 2009 H1N1 pandemic, vaccine supply was limited and global demand was high. To ensure that limited quantities of vaccine could be effectively used by an eligible country, the donation process was made dependent on countries satisfying the following three preconditions.

1. In response to the letter sent by the Director-General of WHO (see Annex 3), the governments of eligible countries were required to submit a non-binding Letter of Intent to officially confirm their interest and anticipated level of demand.
2. To indicate agreement with the terms and conditions of the global legal framework (see section 1.6) for the supply of pandemic H1N1 vaccine through WHO, recipient-country governments were required to sign a Letter of Agreement.
3. Governments were required to submit an NDP for subsequent validation by WHO prior to receipt of vaccine.

Letter of Intent

A total of 94 of the countries and territories eligible for donated vaccines submitted a signed Letter of Intent to confirm their interest in receiving vaccine. These letters were non-binding but allowed WHO to determine the level of demand and plan accordingly. Although most Letters of Intent were received between September and December 2009 (Figure 4), 12 countries waited to request vaccines and responded between January and March 2010. Of the 94 countries that expressed interest, 78 went on to complete all the remaining preconditions for vaccine supply.

Figure 4. Number of countries submitting a Letter of Intent to receive vaccine



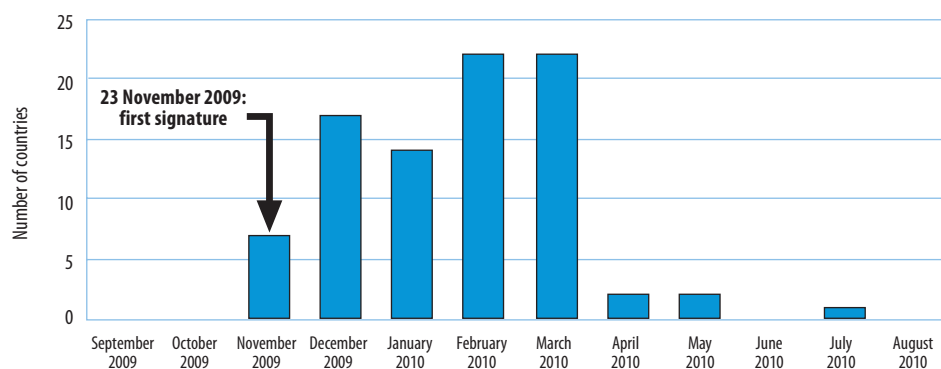
Letter of Agreement

Following receipt of the Letter of Intent, WHO provided a Letter of Agreement signed by the Director-General and ready for countersignature by the appropriate senior government representative accepting the terms and conditions of supply.

The Letter of Agreement confirmed that the recipient country was aware of (and prepared to accept and manage) the legal conditions associated with vaccine donation. In addition to liability (section 1.6), the Letter of Agreement also addressed the issue of prompt management of the processes

for drug importation, local regulatory authorization, vaccine logistics and all vaccination activities. Financial support was addressed separately. The regulatory and liability issues were noted to be complex and some countries did not have the resources to adequately interpret them and put in place measures to implement the necessary systems. While this initially caused delays in the signing of some Letters of Agreement, it also provided an early opportunity to arrange for appropriate support. Of the 94 eligible countries that submitted a Letter of Intent, 87 went on to return a countersigned Letter of Agreement to WHO, most of which were received between December 2009 and March 2010 (Figure 5).

Figure 5. Number of countries submitting a Letter of Agreement to receive vaccine



NDPs

As the final step, each eligible country was required to submit a government-approved NDP setting out how the country would safely implement pandemic H1N1 vaccination activities to protect identified at-risk populations. NDPs were prepared by recipient-country ministries of health in collaboration with local stakeholders, and with support from local WHO offices and other partners.

To support the planning process, workshops were held (see section 3.2) and NDP templates provided. In countries where additional technical assistance was needed, the USAID | DELIVER PROJECT or WHO provided additional consultants or other forms of support. Each NDP was assessed to determine the ability of the respective country to implement the following activities:

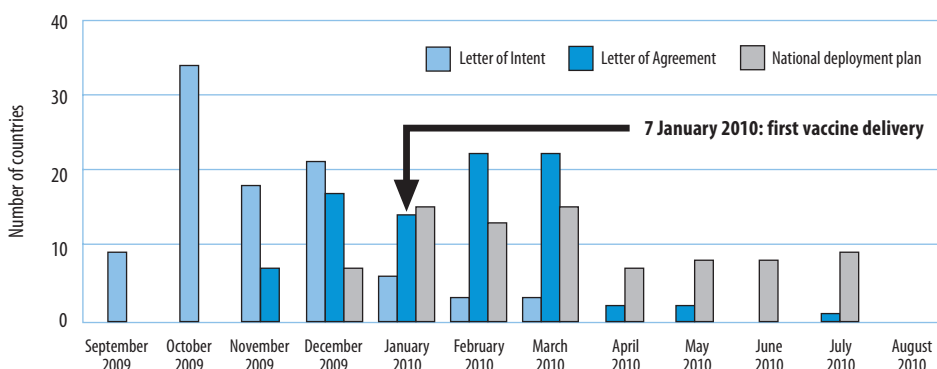
- training and communications
- recruitment of vaccination providers
- cold-chain storage and management
- distribution to appropriate health facilities
- waste management
- mobilizing and reaching target populations

- follow-up and management of adverse events
- mobilization of local funding.

Teams of regional and international technical experts reviewed each NDP and provided technical support in situations where it did not meet the minimum criteria. The NDP had to clearly define the population groups to be targeted for vaccination, as well as identify corresponding financial resources (mobilized or needed) to carry out all deployment and other vaccination-related activities. To avoid delays in receipt of the vaccine, WHO released appropriate quantities of vaccine for delivery where an NDP was technically acceptable aside from financing. WHO then worked in parallel with the country to resolve financial support issues (section 1.4). In some cases, partial shipments were released pending resolution of larger financial shortfalls.

Given the variability of individual national situations, NDPs were expected to vary. Technical approaches for managing vaccination and related costs, and the ability to mobilize local resources, differed across regions and between countries within a region. Countries also responded at varying rates in preparing and submitting NDPs, with the first arriving in December 2009. This corresponded with the first availability of vaccine to WHO. The majority of NDPs were submitted and approved between January and March 2010 with the latest arriving in July 2010, thus completing the entire precondition process (Figure 6). Factors contributing to the slower responses were informally reported to include competing public health issues (such as outbreaks of other diseases), lack of local resources, negative media coverage and in some cases a lack of familiarity with influenza-response activities. Almost all countries that met the conditions of the Letter of Intent and Letter of Agreement (94% of 87 countries) submitted a government-approved NDP that was subsequently validated by WHO.

Figure 6. Summary of fulfilment of preconditions for vaccine supply by eligible countries



4. Deployment

4.1 Global coordination

On 18 September 2009, WHO established a pandemic H1N1 vaccine deployment team at its headquarters in Geneva, Switzerland and began operational activities to deploy donated vaccines to countries. Deployment activities were coordinated with donors, vaccine manufacturers and recipient countries, and included the management of international cold-chain logistics, planning and monitoring of demand, country communications, support to in-country regulatory approval processes, financial strategies and ad hoc responses. The deployment team responded to and investigated all reports of cold-chain problems. High-risk shipments – such as charter flights carrying large quantities which are often targeted for criminal diversion and theft – were accompanied by personnel with vaccine-management experience to ensure a safe handover to the country concerned. The team also provided centralized coordination of the activities of technical units within WHO and, in partnership with UNOPS, managed freight contracts, insurance issues and international cold-chain packaging requirements.

Donated vaccines became available to the WHO Deployment Initiative in late November 2009. Vaccine availability was dependent upon several factors, most notably the ability of manufacturers to produce vaccine and the need to finalize legal donation agreements. As donated vaccines became available, the WHO Deployment Initiative aimed to immediately ship deliveries to eligible countries that had met all the preconditions for supply. In most cases, vaccine was shipped directly from manufacturers' facilities to countries. Factors that increased the complexity of vaccine deployment included the need to coordinate multiple sources of vaccines and ancillary products; unpredictable access to recipient-country logistical resources; and challenges in reaching some recipient countries, particularly those that were smaller or more geographically remote.

4.2 Determining the order in which countries would receive vaccine

The initial situation was one where demand and public concern were high, but where the supply of vaccines was limited. It was therefore important to develop a system that would ensure that the initial quantities of vaccines were distributed equitably and logically. A sequencing of countries was developed to manage the order in which they would receive vaccines. Eligible countries were assigned to a group (A, B or C) with the intention of supplying countries in that order if no other criteria emerged. Assignment depended upon the vulnerability of each country based upon factors such as geographical location, disease burden, the likelihood of an outbreak and the potential for subsequent severe public health impacts. The sequencing process also took into account the timing of winters in the northern and southern hemispheres,

prioritizing those that would experience winter earlier. Then, within each hemisphere, countries with the highest incidence of fatal pandemic influenza cases were given higher priority. The provision of vaccines, and of financial and technical support, was accordingly prioritized for those countries considered to be the most vulnerable. The first allocations of vaccines were made to such countries, and were delivered once each country was ready to receive them.

Country readiness to deploy vaccine subsequently became a more significant issue and ultimately took priority over the initial sequencing scheme. Several vulnerable countries were hesitant to accept the vaccine donation or took longer than anticipated to reach readiness milestones. Because of these issues, the strategy of sequenced and staggered shipments was shifted to accommodate a delivery schedule based on country demand and readiness. The sequencing scheme was nonetheless a key starting-point.

4.3 Determining the number of vaccine doses to provide to recipient countries

The initial aim of the WHO Deployment Initiative was to supply each recipient country with sufficient doses of pandemic H1N1 vaccine to vaccinate approximately 10% of the national population. This figure was based upon the need to cover essential personnel and groups at higher risk of severe disease and death from pandemic A(H1N1) 2009 influenza. In total, these groups were estimated to account for as much as 10% of a country's national population. According to SAGE recommendations, those most likely to be seriously affected included health care workers, pregnant women, young children and the elderly, and those with compromised immune systems (21). SAGE also recommended that countries should immunize their health care workers as a first priority to protect the essential health infrastructure, and that a step-wise approach to vaccinating particular groups may be considered.

Because the supply of pandemic H1N1 vaccines for deployment was limited, the WHO Deployment Initiative planned to initially supply each country with sufficient doses 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 the population. For reasons of efficiency, countries with a population size of less than 600 000 were offered sufficient vaccine to immediately cover up to 100% of their population.

In March 2010, in light of the changing course of the pandemic, the availability of vaccines and initial country feedback, WHO took the following steps to accelerate supply to countries.

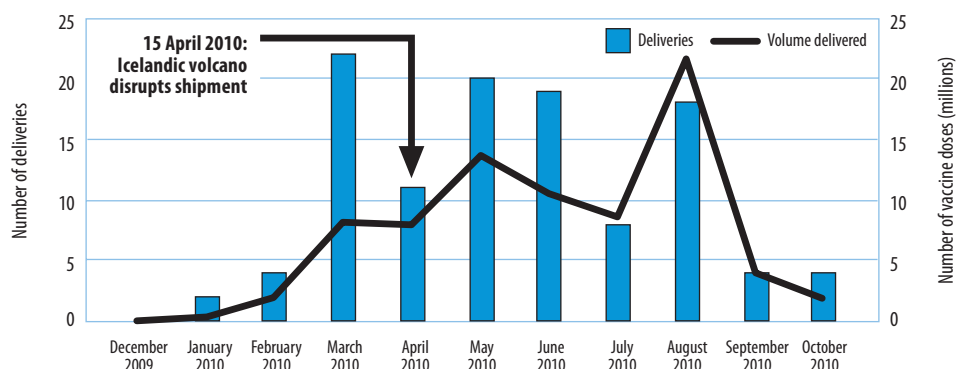
- WHO replaced the two-phase approach to deployment and developed delivery schedules tailored to country needs. Each country was encouraged to identify the optimal amount of vaccine and an appropriate schedule for arrival.

- The maximum amount was calculated as the number of doses needed to cover 10% of a country's population. This figure was estimated to be sufficient to cover those groups at highest risk. In limited cases, supply was sufficient for countries that requested a slightly higher quantity.
- Because local financial resources in most recipient countries had proven to be severely limited, some of the funding originally donated to WHO for global operations and deployment was shifted to support in-country activities.
- In some cases, delays in finalizing NDPs or other country processes were significant. If a particular lot of vaccines had been allocated to a country that experienced delays, the shelf-life of the vaccines was monitored and in some cases vaccines were re-allocated to prevent them from having an unacceptably short shelf-life prior to being deployed. Other vaccines were then provided from fresh lots once the delays had been resolved.

4.4 Quantity of vaccine delivered

Vaccine deployment to recipient countries began in December 2009 as countries started to meet the preconditions for supply through the WHO Deployment Initiative. Between January and March 2010, both the number of deliveries and the number of delivered doses increased rapidly as more countries satisfied the supply preconditions, and as more vaccines became available (Figure 7). The increase in deliveries also correlated with an increase in the number of prequalified vaccines. Although volcanic eruptions in April 2010 disrupted vaccine shipments, the number of deliveries quickly returned to previous levels in May and June 2010. In August 2010, there was a large increase in the number of deliveries and in the volume of vaccine delivered because of multiple deliveries to countries in the WHO African Region. This second peak also coincided with the declaration of the post-pandemic phase, and with the start of seasonal influenza activities in some countries. With the

Figure 7. Monthly vaccine deliveries made through the WHO Deployment Initiative



pandemic A(H1N1) 2009 virus still in circulation, some countries increased their final requests for vaccine to augment their seasonal influenza campaigns.

As demand for vaccine began to decline in May 2010, WHO acted on its option of requesting manufacturers not to start production of some pending products to avoid wasting vaccines. Instead, it accepted additional donations of existing stocks of vaccines as needed to respond to the final peak in demand that occurred in August 2010. While demand fluctuated, the final median level of request remained close to 10% of the country population (Table 1). However, due to differences in national circumstances there were very wide variations in both demand and subsequent vaccination coverage by recipient countries – with the latter ranging from 0.4% to 104.6% of the population (see Annex 4). Significant factors in determining the final level of individual country deliveries were the timing of the request and the size of the country population. Countries that received more than 10% often requested their vaccines later, when supply levels were higher and increases could be accommodated. Regardless of timing, very small countries received quantities sufficient for more than 100% coverage simply because of minimum package sizes. Several countries also anticipated challenges (such as social opposition to vaccination or accessing geographically remote regions) and adjusted their requests downwards.

Table 1. Variations in national pandemic H1N1 vaccination coverage

Parameter	Coverage (% of total country population)
Median	9.9
Average	13.5
Highest	104.6
Lowest	0.4

Cumulatively, the WHO Deployment Initiative delivered over 78 million vaccine doses (Figure 8). Almost 70% of all vaccine doses were delivered to the WHO African Region and the WHO South-East Asia Region combined. In the WHO African Region in particular there were high numbers of eligible countries, many of which had dense populations. The WHO Western Pacific Region also contained a high number of eligible countries but many of these had relatively small populations. Ultimately the WHO Deployment Initiative delivered vaccine to every region (Table 2) and to a total of 77 countries (22).

Figure 8. Cumulative vaccine deliveries made through the WHO Deployment Initiative

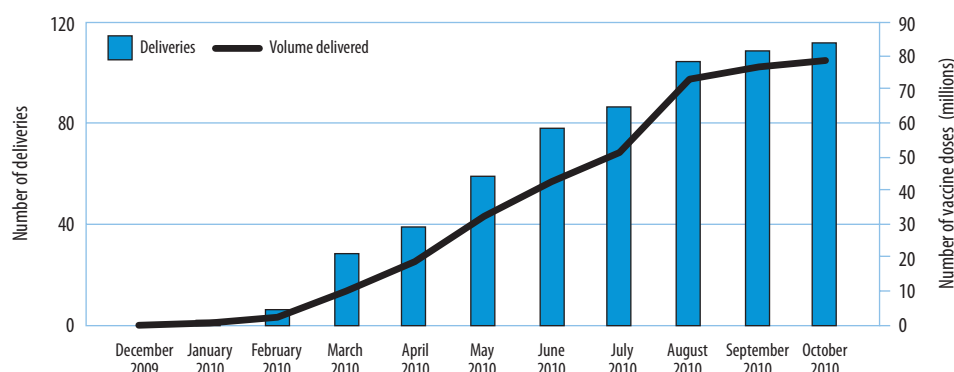


Table 2. Regional distribution of pandemic H1N1 vaccine through the WHO Deployment Initiative

WHO region	No. of vaccine doses delivered
WHO African Region	32 096 290
WHO South-East Asia Region	21 090 700
WHO Region of the Americas	10 025 000
WHO Western Pacific Region	8 722 800
WHO Eastern Mediterranean Region	4 354 000
WHO European Region	1 777 500
Total	78 066 290

4.5 Global and national logistical issues

Vaccines were shipped from Australia, Canada, France, Germany and the United States to recipient countries. Most vaccines were collected directly from the manufacturer's warehouse already packed in international cold-chain packaging. The chain of possession of the vaccines was actively managed from collection to delivery, and included the use of temperature-monitoring devices to ensure appropriate transport conditions. A customized plan was developed and coordinated with each country according to its scheduling, logistics, regulatory and importation requirements.

Because of its complex nature, the WHO Deployment Initiative anticipated a number of global logistical challenges, and additional support was requested from UNOPS. Specific challenges included managing high volumes with limited transportation options, addressing trade restrictions and dealing with the impact of national registration processes. The volumes of vaccines shipped were larger than those typically shipped for routine immunization or for vaccination campaigns, and frequently exceeded the capacities of international cargo systems. In particular, transit times were

longer than the period of validity of the cold-chain packaging, and so vaccines frequently had to be repackaged at transfer points along the way. However, few major international cargo hubs had the handling facilities to repackage large volumes of cold-chain deliveries. In addition, many of the bulky cold-chain shipments were too large for commercial flights. The options for managing these challenges were either to send multiple smaller consignments or charter special cargo shipments, depending on which option would be most effective in protecting vaccine supplies and avoiding the overloading of country systems.

Country logistics were also complex. Initially, deployment within 7 days of receipt of vaccine was expected to take place as part of the country response. However, given that country activities and campaigns required coordination across multiple sectors, this proved to be impractical. Focusing instead on the prompt and efficient coordination of flight schedules, airport and customs personnel, delivery vehicles, cold-chain experts, trainers, health officials, injection providers and others involved in deployment was considered to be the best approach.

Competing issues and/or unanticipated public health priorities, such as a cholera outbreak in one country and massive flooding in another, also had adverse impacts on deployment schedules and on the overall ability of countries to deploy vaccines.

5. Post-deployment activities

5.1 The IHR (2005) Review Committee

After the post-pandemic phase was declared in August 2010, a Review Committee under the auspices of the IHR (2005) was established to review the effectiveness of the global response to the 2009 H1N1 pandemic within the framework of the IHR (2005) and to review the role of WHO in responding to the pandemic.

As part of the range of support to Review Committee processes, information on pandemic H1N1 vaccine deployment and related activities was collated and provided by WHO. Detailed and extensive inputs were also provided by WHO staff involved in the prequalification process, the WHO Deployment Initiative, and by the WHO Office of the Legal Counsel. This involved participation in Review Committee meetings, the preparation of briefing and advisory materials, direct support of Review Committee Officers and ad hoc information support. All requests for documents, information and meetings with staff were met immediately with the exception of confidential agreements. In such situations, WHO first sought permission to release details of all or part of the agreement from the parties involved. The findings of the Review Committee can be found in their final full report of 5 May 2011 (23).

5.2 The WHO vaccine utilization and coverage survey

Between August and November 2010, WHO conducted a survey of national pandemic H1N1 vaccine utilization and coverage. The survey questionnaire was sent to all WHO Member States and responses were included regardless of whether the country received donated vaccine through the WHO Deployment Initiative (Table 3).

Vaccine utilization was defined as the percentage of all received vaccines that were used (including donated and purchased vaccines) and was found to vary by region (Table 4). The average utilization rate was found to be highest in the WHO Region of the Americas (79%) and lowest in the WHO Eastern Mediterranean Region (4%) as vaccination campaigns in the latter were limited or cancelled due to civil disturbances and other non-health-related factors, including natural disaster.

The percentage of total country population covered by pandemic H1N1 vaccination also varied between different countries and WHO regions (Table 4). The results shown are based on the responses of all countries that participated in the survey regardless of the source of their vaccine. In the WHO Region of the Americas, national coverage ranged from 4% to 28% with an average value of 15%. The low average coverage seen in the WHO Eastern Mediterranean Region (0.09%) is consistent with the low levels of vaccine utilization due to acute implementation challenges.

Table 3. Countries participating in the WHO survey

WHO region	No. of countries that participated in the WHO survey		
	Countries that received donated vaccine through the WHO Deployment Initiative	Other countries	Total
WHO African Region	14	0	14
WHO Region of the Americas	9	14	23
WHO South-East Asia Region	4	3	7
WHO European Region	6	1	7
WHO Eastern Mediterranean Region	1	8	9
WHO Western Pacific Region	16	10	26
Total	50	36	86

Table 4. Utilization and coverage of pandemic H1N1 vaccines by WHO region

WHO region	Vaccine coverage (%)					
	Vaccine utilization ^a (%)		Planned: coverage for WHO vaccine allocation ^b		Results: vaccine coverage by entire population ^c	
	Range	Average	Range	Average	Range	Average
WHO African Region	2–100	62	2–87	6	0.4–11	4
WHO Region of the Americas	25–100	79	7–37	19	4–28	15
WHO South-East Asia Region	40–78	72	10	10	3–7	7
WHO European Region	0.2–95	57	0.4–10	8	0.01–19	4
WHO Eastern Mediterranean Region	0.04–35	4	1–2	2	0.001–0.8	0.09
WHO Western Pacific Region	6–100	66	4–100	7	1.4–94	6

^a Vaccine utilization refers to the percentage of all vaccines received (donated or purchased) that were used.

^b Planned refers to the percentage of the population that was planned for coverage, taking into account the at-risk groups in the country.

^c Results refer to the percentage of the entire population that was actually vaccinated.

In all WHO regions vaccines were administered to priority target populations, particularly health care workers, pregnant women, those with underlying health conditions and children (Table 5), with high levels of uptake among health care workers reported in all recipient countries. While these target groups were similar across countries, the manner in which the actual numbers to be targeted within each group were derived was not necessarily the same. For countries receiving vaccines from the WHO Deployment Initiative, estimates were based on how many people within each of the target groups could realistically be reached. The method for determining this number differed across countries, depending upon local circumstances. As a result, direct comparisons of uptake by target group across countries are misleading unless this and other factors are taken into account. In addition, not all of the countries surveyed were able to report on utilization by target group.

5.3 WHO meeting on the main operational lessons learnt from the WHO Deployment Initiative

To reflect upon and learn from the deployment experience, WHO invited more than 50 representatives of donor and recipient governments, international organizations and industry to a meeting in Geneva, Switzerland from 13 to 15 December 2010. Following a detailed review of the experiences of vaccine deployment in all WHO regions, and discussion of the issues and processes involved, a number of priority action points were proposed to ensure that the main operational lessons of this unprecedented international effort could inform and strengthen similar efforts in the future.

Full details of the meeting – including a range of proposed action points – can be found in the meeting report (24). Among the key messages were that those involved in implementation would benefit from participation in simulation exercises, and from opportunities for training and familiarization in the deployment process. It was also noted by several vaccine manufacturers that prior to the pandemic a lack of collaborative experience with many of the recipient countries made it difficult to establish precise roles and responsibilities. Discussions also covered country regulatory systems leading to calls for a more-harmonized approach to managing new medicines in emergency settings. Countries reported that more support for communications and public-information strategies could have improved the overall uptake of vaccines. Interest was also expressed in revisiting the legal terms relating to liability. It was also reported that freight logistics had led to unexpected limitations, and that assessments of capacity at major international airports could usefully be made. Presentations from countries indicated that many of the problems which arose during vaccine deployment were due to limited communication and public-information strategies in countries, negative international media coverage of the pandemic vaccine, and unanticipated competing health issues.

Table 5. Regional uptake^a of pandemic H1N1 vaccination by target group

WHO region	Health care workers		Pregnant women		Persons with underlying conditions		Children	
	Country	Uptake (%)	Country	Uptake (%)	Country	Uptake (%)	Country	Uptake (%)
WHO African Region	17/17	84	17/17	48	14/17	66	11/17	96
WHO Region of the Americas	23/23	100	23/23	67	18/23	119	–	–
WHO South-East Asia Region	6/6	95	6/6	86	6/6	73	5/6	42
WHO European Region ^b	6/6	62	4/6	42	3/6	67	1/6	61
WHO Eastern Mediterranean Region	6/6	52	4/6	7	5/6	21	4/6	2
WHO Western Pacific Region	9/9	86	9/9	63	8/9	85	5/9	89

^a Defined as the percentage of the planned number of individuals within each target group that were vaccinated. The size of the planned population in each group was determined by individual countries and may be less than 100% of the total group population in the country.

^b Based on data from countries that received donated vaccine through WHO.

Workshops were also held by a number of WHO regional offices and are documented in separate reports. While the meeting held at WHO headquarters was intended to focus on issues common to most countries and stakeholders, the regional workshops identified and documented issues specific to countries in those regions.

Conclusion

The WHO Deployment Initiative was the first coordinated global response to an influenza pandemic. This required considerable innovation in managing a complex donation environment to promote equitable access to vaccines in countries that otherwise would not have been able to secure supplies. It was a careful yet rapid approach to meeting public health needs while protecting public health resources and interests.

Public and private sectors, nongovernmental organizations and civil society all played key roles in the response, while leaving a valuable roadmap for responding to future emergencies. Although the pandemic was ultimately not as severe as originally anticipated, launching such a coordinated global response involving highly diverse parties and stakeholders illustrated significant strengths in existing capacities and capabilities. It also called attention to areas where systems need to be adjusted and strengthened in case a future event requires an even larger-scale response.

There was a high level of public interest in the pandemic response, as evidenced by the extent of media coverage. This included a broad variety of topics, including not only the WHO Deployment Initiative itself but also the involvement and actions of specific countries. This level of attention highlighted the intense interest of civil society in understanding the unfolding events, and the vital importance of investment in communication and public information capacities both globally and in countries.

Post-pandemic meetings also highlighted growing recognition of the importance of maintaining planning and other vital capacities. However, it is also recognized that the activities needed to maintain systems and capacity, such as simulation exercises, will require substantial resources. Documenting key areas of the pandemic response is another important undertaking and in addition to this report, the WHO web site will continue to host a comprehensive range of reports and other resources covering specific aspects of the 2009 H1N1 pandemic.

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Annex 1. Post-pandemic influenza (H1N1) period questions & answers (Information Note), 27 August 2010

WHO Director-General Dr Margaret Chan declared an end to the H1N1 pandemic on 10 August 2010. The deployment of pandemic influenza A(H1N1) 2009 vaccines by WHO will, however, continue in the coming weeks. This will give effect to all donation agreements for H1N1 vaccine entered into by WHO with recipient countries prior to the end of the pandemic.

The following “questions and answers” are intended to clarify the prequalification status of H1N1 vaccines, and their use in countries (including government authorization for such use).

Question

If the pandemic is over, should countries continue to immunize against pandemic influenza (H1N1) virus?

Answer

Yes, WHO continues to recommend vaccination, in accordance with the SAGE recommendations on pandemic (H1N1) 2009 vaccines (http://www.who.int/csr/disease/swineflu/notes/h1n1_vaccine_20090713/en/) if and to the extent that vaccine is available in the country. Vaccination can be with a monovalent (single virus) pandemic influenza A(H1N1) 2009 vaccine, or a trivalent seasonal influenza vaccine (which includes the H1N1 (2009) strain, as well as other seasonal strains H3 and B), depending on which vaccine is available.

Question

Is the WHO prequalification of pandemic influenza A(H1N1) 2009 monovalent vaccines still valid?

Answer

Yes, WHO confirms that the prequalification status of all prequalified pandemic influenza A(H1N1) 2009 vaccines remains valid. The basis of prequalification is that evidence of the quality, safety and efficacy of the vaccines provides a positive benefit/risk assessment for their use in the intended population. The announcement of the end of the pandemic does not change this scientific assessment.

Question

Which monovalent pandemic influenza A(H1N1) 2009 vaccines have been prequalified?

Answer

As of 10 August 2010, 11 pandemic influenza A(H1N1) 2009 monovalent vaccines have been prequalified. These are:

- CSL “Panvax” (Australia)
- GSK “Arepanrix” (Canada)
- GSK “Pandemrix” (Germany)
- Green Cross “Green Flu-S” (Republic of Korea)
- MedImmune Influenza A(H1N1) vaccine (USA)
- Novartis “Celtura” (Germany)
- Novartis “Fluvirin-H1N1” (United Kingdom)
- Novartis “Focetria” (Italy)
- Sanofi Pasteur Influenza A(H1N1) vaccine (USA)
- Sanofi Pasteur “Humenza” (France)
- Sanofi Pasteur “Panenza” (France).

More technical information about these vaccines can be obtained at: http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html.

Question

What is the regulatory status of these prequalified pandemic H1N1 vaccines with their respective national regulatory authorities (NRA) of reference?

Answer

In some cases, the original licenses from the NRA of reference included a condition that the vaccine be used only in a pandemic period. That condition has been removed for many of the H1N1 vaccines: 9 out of the 11 prequalified vaccines are now licensed in their country of manufacture for use in the post-pandemic period.

The regulatory status of the following vaccines was not limited to pandemic use, and did not require updating:

- CSL “Panvax” (Australia)
- Green Cross “Green Flu-S” (Republic of Korea)
- MedImmune Influenza A(H1N1) vaccine (USA)
- Sanofi Pasteur Influenza A(H1N1) vaccine (USA).

The regulatory status of the following vaccines was limited to pandemic use, and did therefore require updating:

- GSK “Arepanrix” (Canada)
- GSK “Pandemrix” (Germany)
- Novartis “Fluvirin-H1N1” (United Kingdom)
- Novartis “Focetria” (Italy)
- Sanofi Pasteur “Panenza” (France).

For Novartis' vaccine "Celtura" (Germany), and Sanofi Pasteur's vaccine "Humenza" (France), an application for an update to their regulatory approval has yet to be made. Neither "Celtura" nor "Humenza" is being supplied by WHO as part of the H1N1 vaccine donation initiative.

Question

What are the implications if the regulatory approval for a vaccine has been updated?

Answer

As noted above, the regulatory approval of the following vaccines has been updated:

- GSK "Arepanrix" (Canada)
- GSK "Pandemrix" (Germany)
- Novartis "Fluvirin-H1N1" (United Kingdom)
- Novartis "Focetria" (Italy)
- Sanofi Pasteur "Panenza" (France).

The original documentation/labelling of these vaccines stated, "Prophylaxis of influenza in an officially declared pandemic situation". The new documentation/labelling approved by the respective NRAs of reference now states, "Prophylaxis against H1N1(2009) virus".

It is the responsibility of the manufacturers to provide revised documentation/labelling. The Ministry of Health and NRA in a recipient country may have established means of obtaining this documentation directly; however, WHO will ensure that the WHO country offices receive a copy as soon as it is available to us. Dissemination of the revised documentation/labelling is the responsibility of the Ministry of Health and NRA of each recipient country.

Question

What about the authorization for use of the WHO-donated H1N1 vaccines in the recipient countries?

Answer

The Ministry of Health in each country should verify that the approval from the local NRA or other relevant authority is not limited to pandemic use only. If the original authorization was provided for pandemic use only, this authorization must be updated to include post-pandemic use (prophylaxis against H1N1(2009) virus) before the vaccine can be used in the country.

Question

Does the end of the pandemic, or any of the new document/labelling, affect the expiration date of the pandemic H1N1 vaccines?

Answer

No, the declared end of the pandemic and the revision of document/labelling does not affect the expiration date or efficacy of the pandemic H1N1 vaccines. The pandemic H1N1 vaccine can be utilized through to (but not later than) the expiration date of the product.

Question

Is there any recent information with regard to reduced stability of pandemic H1N1 vaccines?

Answer

When assigning the shelf-life for the monovalent H1N1 pandemic vaccines, regulatory authorities worldwide had no real-time stability data on which to make this assessment. They decided to assign a maximum shelf-life based on the supportive data for seasonal and H5N1 influenza vaccines.

Regulatory authorities also requested that manufacturers subsequently run stability monitoring programmes and some authorities also conducted their own studies. These included the United States Food and Drug Administration/Center for Biologics Evaluation and Research, Health Canada/Biologics and Genetic Therapies Directorate, the Therapeutic Goods Administration (Australia), the Paul Ehrlich Institute (Germany) and the Agence française de sécurité sanitaire des produits de santé (France).

It is now becoming evident that the real-time stability data of monovalent pandemic influenza A(H1N1) 2009 vaccines, in general, differs from that of seasonal or H5N1 influenza vaccines. Therefore, the registered shelf-life for several vaccines has been or is being shortened on the basis of the accumulating data.

Each country has been, and will continue to be, informed of specific lots of vaccines with a reduced shelf-life.

Question

Since Finland suspended use of GSK Pandemrix on 24 August 2010, should other countries also discontinue use of that product?

Answer

No, the association of Pandemrix with narcolepsy is theoretical. WHO considers the vaccine to be effective in protecting against H1N1 and that the benefits continue to be important. Please refer to the attached link for complete information.

http://www.who.int/immunization_standards/vaccine_quality/quality_issues/en/index.html

Question

Is there any further information on the pandemic and the post-pandemic available?

Answer

Director-General's statement (10 August 2010)

http://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/index.html

What is post-pandemic? (Frequently asked questions)

http://www.who.int/csr/disease/swineflu/frequently_asked_questions/post_pandemic/en/index.html

WHO home page for pandemic (H1N1) 2009

<http://www.who.int/csr/disease/swineflu/en/index.html>

Latest information on the WHO deployment of pandemic influenza A(H1N1) 2009 vaccines

<http://www.who.int/csr/disease/swineflu/action/en/index.html>

Annex 2. List of eligible countries and territories

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

Afghanistan	Kenya
Angola	Kiribati
Armenia	Kyrgyzstan
Azerbaijan	Lao People's Democratic Republic
Bangladesh	Lesotho
Benin	Liberia
Bhutan	Madagascar
Bolivia (Plurinational State of)	Malawi
Botswana	Maldives
Burkina Faso	Mali
Burundi	Mauritania
Cambodia	Mauritius
Cameroon	Mongolia
Cape Verde	Mozambique
Central African Republic	Myanmar
Chad	Namibia
Comoros	Nauru
Congo	Nepal
Cook Islands	Nicaragua
Côte d'Ivoire	Niger
Cuba	Nigeria
Democratic People's Republic of Korea	Niue
Democratic Republic of the Congo	Occupied Palestinian Territories
Djibouti	Pakistan
El Salvador	Papua New Guinea
Equatorial Guinea	Paraguay
Eritrea	Philippines
Ethiopia	Republic of Moldova
Fiji	Rwanda
Gabon	Samoa
Gambia	Sao Tome and Principe
Georgia	Senegal
Ghana	Seychelles
Guatemala	Sierra Leone
Guinea	Solomon Islands
Guinea-Bissau	Somalia
Guyana	Sri Lanka
Haiti	Sudan
Honduras	Suriname
Indonesia	Swaziland
	Tajikistan

Timor-Leste	Uzbekistan
Togo	Vanuatu
Tokelau	Viet Nam
Tonga	Yemen
Tuvalu	Zambia
Uganda	Zimbabwe
Ukraine	
United Republic of Tanzania	

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

Chile
Kosovo (in accordance with Security Council Resolution 1244 (1999))
South Africa

Annex 3. Letter from the Director-General of WHO to eligible governments



**World Health
Organization**

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Tel. direct: +41 22 791
Fax direct: +41 22 791
E-mail :

In reply please
refer to:

Your reference:

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

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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 Matiru, Tel: +41 22 79 13971; <Email: matirur@who.int>.

Yours faithfully,



Dr Margaret Chan
Director-General

Annex 4. Vaccine doses received and vaccination coverage in recipient countries

Country	Shipment 1			Shipment 2			Shipment 3			Total	
	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	Total no. of doses	Total coverage (%)	Population
Afghanistan	500 000	22 February 2010							500 000	2.2	22 998 000
Angola	1 015 000	20 July 2010	1 015 000	19 August 2010					2 030 000	12.3	16 557 000
Armenia	11 500	30 August 2010							11 500	0.4	3 010 000
Azerbaijan	172 000	10 October 2010	172 000	1 April 2010	172 000	1 August 2010			516 000	6.1	8 406 000
Bangladesh	3 000 000	27 April 2010	12 600 000	6 August 2010					15 600 000	10.0	155 991 000
Bhutan	65 000	8 June 2010							65 000	10.0	649 000
Bolivia (Pluri-national State of)	900 000	2 April 2010							900 000	9.6	9 354 000
Botswana	1 612 800	18 June 2010							1 612 800	86.8	1 858 000
Burkina Faso	1 450 000	19 July 2010							1 450 000	10.1	14 359 000
Cambodia	1 800 000	3 May 2010	212 900	15 August 2010	700 000	15 August 2010			2 712 900	18.0	15 053 000
Cameroon	1 825 000	24 June 2010							1 825 000	10.0	18 175 000
Central African Republic	448 000	2 August 2010							448 000	10.5	4 265 000
Chile	1 200 000	6 May 2010							1 200 000	7.3	16 465 000
Comoros	20 900	29 August 2010	44 100	29 August 2010					65 000	7.9	818 000
Congo (Brazzaville)	400 000	2 August 2010							400 000	10.8	3 689 000
Cook Islands	2 000	24 March 2010	18 000	26 May 2010					20 000	102.2	19 569
Côte d'Ivoire	1 942 300	27 July 2010	254 700	28 July 2010					2 197 000	11.6	18 914 000
Cuba	1 124 000	17 March 2010							1 124 000	10.0	11 267 000
Democratic People's Republic of Korea	476 500	26 May 2010	1 899 000	21 August 2010					2 375 500	10.0	23 708 000
El Salvador	136 000	21 March 2010	540 000	30 April 2010	1 600 000	28 April 2010			2 276 000	33.7	6 762 000

Country	Shipment 1			Shipment 2			Shipment 3			Total	
	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	Total no. of doses	Total coverage (%)	Population
Equatorial Guinea	33 500	27 August 2010	79 500	18 October 2010					113 000	22.8	496 000
Ethiopia	1 500 000	7 June 2010	1 500 000	15 July 2010					3 000 000	3.7	81 021 000
Fiji	88 200	3 March 2010							88 200	10.3	854 000
Gambia	31 200	13 May 2010	132 600	22 June 2010					163 800	9.8	1 663 000
Georgia	100 000	1 May 2010							100 000	2.3	4 433 000
Ghana	2 300 000	15 May 2010							2 300 000	10.0	23 008 000
Guatemala	260 000	29 March 2010	520 000	6 May 2010	520 000	11 June 2010			1 300 000	10.0	13 029 000
Guinea	1 049 000	16 August 2010							1 049 000	11.4	9 181 000
Guinea-Bissau	160 000	3 June 2010							160 000	9.7	1 646 000
Guyana	75 000	29 March 2010	100 000	6 May 2010	100 000	27 May 2010			275 000	37.2	739 000
Honduras	140 000	18 March 2010	1 510 000	17 May 2010					1 650 000	23.7	6 969 000
Kenya	730 000	23 March 2010							730 000	2.0	36 553 000
Kiribati	10 000	4 March 2010							10 000	10.0	100 000
Kosovo (in accordance with Security Council Resolution 1244 (1999))	100 000	9 March 2010							100 000	NA	NA
Lao People's Democratic Republic	600 600	25 February 2010	400 000	19 June 2010	400 000	9 August 2010			1 400 600	21.8	6 436 000
Lesotho	195 000	7 May 2010							195 000	9.8	1 995 000
Liberia	78 000	23 April 2010							78 000	2.2	3 579 000
Madagascar	435 990	20 August 2010	620 100	20 August 2010					1 056 090	5.5	19 159 000
Malawi	300 000	19 June 2010	1 000 000	17 July 2010					1 300 000	9.6	13 571 000
Maldives	31 200	2 March 2010							31 200	10.4	300 000
Mauritania	296 400	27 June 2010							296 400	9.7	3 044 000

Country	Shipment 1			Shipment 2			Shipment 3			Total	
	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	Total no. of doses	Total coverage (%)	Population
Mauritius	127 000	28 June 2010	200 000	28 July 2010					327 000	26.1	1 252 000
Mongolia	100 000	7 January 2010	170 000	29 March 2010			300 000	17 August 2010	570 000	21.1	2 701 000
Myanmar	972 000	4 April 2010							972 000	2.0	48 379 000
Namibia	40 000	19 May 2010	176 000	19 May 2010					216 000	10.6	2 047 000
Nauru	1 000	27 February 2010	7 800	7 June 2010					8 800	88.0	10 000
Nicaragua	110 000	3 March 2010	640 000	12 May 2010					750 000	13.6	5 532 000
Niger	270 000	21 May 2010	1 104 900	23 August 2010					1 374 900	10.0	13 737 000
Nigeria	2 880 000	24 September 2010							2 880 000	2.0	144 720 000
Niue	200	26 March 2010	1 500	23 April 2010					1 700	104.3	1 630
Pakistan	3 100 000	29 March 2010							3 100 000	2.0	151 816 000
Papua New Guinea	700 000	26 February 2010							700 000	10.2	6 888 000
Paraguay	600 000	2 May 2010							600 000	10.0	6 016 000
Philippines	1 900 000	29 March 2010	1 500 000	23 June 2010					3 400 000	3.6	93 617 000
Republic of Moldova	380 000	8 May 2010							380 000	9.9	3 833 000
Rwanda	200 000	21 September 2010							200 000	2.1	9 464 000
Samoa	18 000	24 March 2010	10 000	3 October 2010	2 200	19 October 2010			30 200	16.9	179 000
Sao Tome and Principe	16 000	15 May 2010							16 000	10.3	155 000
Senegal	240 000	29 June 2010							240 000	2.0	12 072 000
Seychelles	9 000	21 April 2010							9 000	10.5	86 000
Sierra Leone	577 000	14 June 2010							577 000	10.0	5 743 000
Solomon Islands	55 000	4 March 2010							55 000	10.3	536 000
Somalia	54 000	10 November 2010							54 000	0.7	8 298 000
South Africa	3 500 000	12 May 2010	84 200	12 June 2010					3 584 200	7.4	48 282 000

Country	Shipment 1			Shipment 2			Shipment 3			Total	
	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	No. of doses	Vaccine arrival date	Total no. of doses	Total coverage (%)	Population
Sri Lanka	385 000	17 June 2010	1 545 000	28 October 2010					1 930 000	10.0	19 207 000
Sudan	700 000	29 April 2010							700 000	2.0	34 512 000
Suriname	50 000	15 April 2010							50 000	11.5	435 000
Swaziland	117 000	4 June 2010							117 000	10.3	1 134 000
Tajikistan	670 000	16 September 2010							670 000	10.1	6 640 000
Timor-Leste	117 000	21 April 2010							117 000	10.5	1 114 000
Togo	132 000	27 February 2010	531 500	12 June 2010					663 500	10.4	6 410 000
Tokelau	200	24 March 2010	1 400	16 June 2010					1 600	104.6	1 530
Tonga	10 000	3 March 2010	90 000	18 May 2010					100 000	96.2	104 000
Tuvalu	1 000	30 March 2010							1 000	10.0	10 000
Vanuatu	25 000	3 March 2010							25 000	10.2	246 000
Zambia	256 800	13 September 2010							256 800	2.2	11 696 000
Zimbabwe	1 250 000	20 July 2010							1 250 000	9.4	13 228 000

NA: not available.

In June 2009, the World Health Organization (WHO) announced that the first influenza pandemic of the twenty-first century was under way following earlier related outbreaks of a previously undetected influenza A(H1N1) virus in Mexico and the United States of America. WHO quickly assessed the potential global demand for pandemic H1N1 vaccines and started to make preparations to meet that demand, while immediately calling for solidarity in enabling fair access to effective vaccines.

To ensure that developing countries were able to protect the health of their populations, WHO began a process of mobilizing and coordinating the global donation of resources needed to deploy life-saving pandemic H1N1 vaccines to some of the world's most vulnerable populations.

The subsequently established WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative represented the first coordinated global response to an influenza pandemic. Between June 2009 and October 2010, WHO, other technical agencies, donor governments, nongovernmental organizations, and vaccine manufacturers and other private-sector stakeholders all worked together to deliver over 78 million doses of pandemic H1N1 vaccine and associated items such as syringes and safety boxes to 77 countries that would otherwise have had no access. The success of this unique collaboration required considerable innovation and the coordination of a wide range of donation, transportation and deployment activities. During the course of implementation, a number of significant strengths in existing capacities and capabilities were highlighted. However, the collaboration also revealed areas where systems needed to be adjusted and efforts strengthened in advance of future events that could potentially require an even larger-scale response.

Implementing the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative thus highlighted both the strengths and weaknesses in existing capacities and capabilities. This report of its key deployment and associated activities forms part of a broader WHO assessment and review process which is intended to document the lessons learnt and to strengthen the preparedness of the world for future public health emergencies.



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