Main operational lessons learnt from the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative

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Preface

In April 2009, the World Health Organization (WHO) reported that outbreaks of a previously undetected influenza A(H1N1) virus in Mexico and the United States of America were related. In accordance with the International Health Regulations (2005) WHO rapidly responded to the emerging situation. This included working with a range of international agencies, vaccine manufacturers and other parties under the direction and coordination of a WHO secretariat to assess the potential global demand for vaccines and to make preparations to meet that demand. In June 2009, WHO declared the 2009 H1N1 influenza pandemic and called for solidarity in enabling fair access to effective vaccines.

To mobilize donations of pandemic vaccines and coordinate their rational and equitable distribution to countries in need, WHO established the Pandemic Influenza A(H1N1) Vaccine Deployment Initiative (hereafter referred to as the "WHO Deployment Initiative"). Between June 2009 and October 2010, technical agencies, donor governments and private-sector organizations collaborated through this initiative to deliver over 78 million doses of pandemic H1N1 vaccine to 77 countries.

To reflect upon and learn from the deployment experience, WHO invited more than 50 representatives of donor and recipient governments, international organizations and vaccine manufacturers to a meeting in Geneva, Switzerland from 13 to 15 December 2010. The objectives of the meeting were:

- to provide an overview of the implementation of the WHO Deployment Initiative (section 1);
- to review the issues and processes involved in pandemic vaccine deployment, and identify ways to improve similar future efforts (section 2);
- to hold panel discussions with key donation-process stakeholders, namely donor governments and vaccine manufacturers (section 3);
- to discuss preliminary reports of deployment activities and operational lessons learnt in each of the six WHO regions (section 4).

During the course of the meeting, a number of proposed action points for improving vaccine deployment during a pandemic were documented and reviewed during plenary sessions. A total of 49 proposed action points were discussed and analysed before being allotted to the following six aspects of deployment (see Annex 1).

1. Donation
2. Global planning and coordination
3. National planning and coordination
4. Prequalification and registration of pandemic vaccines
5. Global and national communication
6. Management and delivery of supplies.

Meeting participants then prioritized 12 of these proposed action points as having the greatest relevance to the effectiveness of similar deployment initiatives in the future (section 5).

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List of abbreviations

LOA: Letter of Agreement

LOI: Letter of Intent

NDP: national deployment plan

NRA: national regulatory authority

UNOPS: United Nations Office for Project Services

USAID: United States Agency for International Development

WHO: World Health Organization

WHO Deployment Initiative: WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative

1. Overview of the WHO Deployment Initiative

The four crucial aspects of the pandemic H1N1 vaccine deployment process were:

- securing donor commitments
- prequalifying vaccines
- helping countries to satisfy the prerequisites for supply
- managing global deployment.

Donor commitments in support of the WHO Deployment Initiative were generous. However, the first vaccines were not available for release until December 2009 and presented several challenges in allocation and delivery because they came from many different sources, at different times, and included a variety of different products.

The prequalification of donated vaccines was a requirement of the WHO Deployment Initiative, and this process began in November 2009 when manufacturers submitted their product dossiers for evaluation. Compared with its normal duration the prequalification process in this context was greatly accelerated, especially where a manufacturer had previously had influenza vaccines prequalified by WHO.

Before vaccine was delivered to a country it had to satisfy three major prerequisites. A Letter of Intent (LOI) from the government to WHO (officially indicating the country's desire to receive donated vaccine) was considered the least challenging prerequisite for most countries to satisfy. The second major prerequisite was a Letter of Agreement (LOA) between the country and WHO. This entailed legal agreement on complex issues that required government clearance (such as waiving any liability for donated vaccine) and understandably took longer than the LOI to complete. The final prerequisite was that a national deployment plan (NDP) had to be developed and put in place to ensure that the initially scarce supply of vaccines went to countries that were able to quickly use them. The NDP was typically the last of the prerequisites to be completed by countries as few if any had a national pandemic influenza preparedness and response plan that included vaccine deployment. As a result, countries required significant time, assistance and financial resources to finalize an NDP. Countries began to meet all three prerequisites for supply in December 2009.

Vaccine deliveries to countries through the WHO Deployment Initiative started in January 2010, accelerated in March 2010 and were set back in April 2010 by the disruption to shipping across Europe caused by volcanic eruptions in Iceland. Deliveries then continued with a gradual decline in the number of doses requested and delivered per month until August 2010 when a second peak occurred. Although donated vaccine was deployed worldwide, countries in Africa received significantly more doses than those in other regions.

An analysis of the effectiveness of pandemic H1N1 vaccine deployment in terms of the numbers of people reached has been carried out using

information obtained from 124 countries, including 50 countries that received pandemic H1N1 vaccine from WHO. This analysis was based upon a survey conducted by WHO from August to November 2010, and upon supplementary information such as regional updates on vaccine utilization, termination reports on the implementation of NDPs, and data from the Vaccine European New Integrated Collaboration Effort (VENICE) project (http://venice.cineca.org/the_project.html).

Preliminary results of the analysis indicate that most countries relied upon the public sector to conduct pandemic H1N1 vaccination-related activities, with the private sector playing a larger role in some countries in areas such as public communication and in-country distribution of vaccines. Vaccine coverage varied between regions, with overall coverage (doses administered per country population) highest in the WHO Region of the Americas (24%). Vaccine utilization (mean percentage of donated vaccines used) ranged from 57% to 73% across regions, with the exception of the WHO Eastern Mediterranean Region where a reported figure of 15% was largely attributed to natural disasters and political unrest in three countries.

The targeting of priority groups in the vaccination campaigns was consistent, with as many as 100% of targeted pregnant women, health-care workers, children and people with underlying conditions receiving pandemic H1N1 vaccine in some countries. The numbers targeted within each group were country estimates and were not necessarily equivalent to the total population size of that group. The analysis also revealed that public concern surrounding the safety of pandemic H1N1 vaccines was almost universal. Public media (particularly in North America and Europe) advised populations against vaccination, thus raising questions on how to better address safety concerns through improved communication efforts during future pandemics.

There was broad consensus among meeting participants that the international community should operate under the assumption that similar health emergencies will occur in the future, and that advance cooperation between the international community and government ministries in developing countries will be essential for effective preparedness and response efforts. There is an opportunity to learn lessons from the 2009 H1N1 pandemic. In particular, it was recognized that if the pandemic had been more virulent then the timelines for vaccine deployment would have been extremely concerning as deliveries only began in early 2010. There is therefore a need to review the deployment process in search of limiting factors, so that it can be streamlined where possible and appropriate to speed up deployment. The following issues may have delayed deployment and could be addressed in advance of a future pandemic.

- National regulatory issues – each recipient country had a unique regulatory process for ensuring that the vaccines were legally imported and distributed, ranging from one-time waivers to clinical trials for registration. A harmonized regulatory approach for emergencies would help to avoid bottlenecks related to regulatory processes.

- Legal agreements with donors and beneficiary countries – given the multiplicity of donors and beneficiary countries, and the legal issues to be addressed, it proved challenging to establish a single legal framework that was acceptable to all parties. Having such a framework in place now could expedite future negotiations and vaccine deployment.
- National deployment planning – a significant amount of time and resources were spent in preparing NDPs. If these NDPs are updated and maintained they could be reactivated during a future pandemic event, thus reducing the time required for country planning.

Regardless of the advance preparations made, it remains the case that vaccines cannot be deployed until they have been manufactured, quality approved and released for distribution. In the case of pandemic H1N1 vaccines, yields were lower than expected and this contributed to delays in availability.

2. Improving pandemic vaccine deployment

2.1 Global coordination and planning

Greater access to information on vaccine allocations (i.e. the type and quantity of vaccine allocated to each country) and on the state of readiness of countries to receive deliveries would allow for earlier and more-effective logistical planning. It would also provide direction for strong technical assistance to countries and support the communication needs of stakeholders.

Stronger coordination of the technical assistance provided to countries is likely to be highly beneficial, particularly if national needs are assessed in advance of deployment and a plan for addressing them is defined and shared among stakeholders. Such a plan must clearly define the roles and responsibilities of the various stakeholders, and leverage their strengths and capacities. This would empower donors to mobilize the resources necessary for interventions, improve partner coordination, and reduce redundancies and gaps in assistance.

Policies for pandemic vaccine deployment (such as the requirement that donated vaccines be prequalified by WHO) are recognized as necessary to ensure that country needs for pandemic vaccine are met appropriately and responsibly. Policy decisions that have implications for deployment should be made in consultation with stakeholders. This would ensure that such policies are informed by the best information available and that stakeholders are better equipped to adhere to them.

Some manufacturers and implementation partners indicated that initial orientation and training on the launching of deployment activities would have better prepared them to meet their responsibilities and to recognize any potential gaps in the information that was available.

There is also a need to designate and agree upon the roles and responsibilities of stakeholders, especially in relation to the managing of technical information. For example, product information and other details related to vaccines are a crucial aspect of the planning and training activities of multiple parties. As part of this, closer collaboration is needed between stakeholders that plan and implement global, regional and country-level communication activities.

Identifying factors that affect vaccine demand and availability

Changes in vaccine demand during the pandemic strained management resources, planning processes and shipment-planning capacity. Better ways are needed to anticipate, assess and manage levels of demand over time. Four key factors that affected demand during the 2009 H1N1 pandemic were:

- the changing epidemiology of the pandemic
- the quality of communications and information
- vaccine availability and cost of country deployment
- extenuating circumstances.

The *changing epidemiology of the pandemic* resulted in changes in demand for H1N1 vaccine. Early in the pandemic, governments and the international community established deployment goals and calculated their vaccine needs based upon a worst-case scenario. Subsequently, countries planned for a potentially more-virulent second pandemic wave. As a result, there was initially a high demand for a limited amount of vaccine. As the epidemiology of the pandemic changed and the level of concern about the virus diminished, however, there was a fall in demand from countries. Many countries lowered their vaccine requirements after taking into account the cost of vaccine-deployment activities, negative public perceptions of vaccine campaigns, competing health priorities and other factors. Although the WHO Deployment Initiative responded well to epidemiological conditions, particularly during the worst-case scenario for demand, future initiatives must incorporate contingency planning to manage changes in demand more quickly and adapt their deployment activities and communications accordingly.

The *quality of communications and information* was itself a factor that affected demand. While recognizing the importance of properly educating populations about influenza and vaccines, it is equally important to avoid creating demand in countries where the government cannot respond. In the case of the WHO Deployment Initiative, vaccines were also not available for deployment as quickly as originally planned. Such unmet expectations and delays can have negative implications for future vaccination campaigns. As the pandemic progressed, negative media coverage influenced public perceptions about the use of vaccines and contributed to decreased demand. To address this, future initiatives should improve the management of country demand by better communication of the uncertainties involved, by enhancing information to countries on alternative programmatic options that can complement vaccine

deployment, and by helping them to leverage stakeholders and capacity outside the health sector. It will be equally important to communicate to donors and governments the uncertainties inherent in such efforts, so as not to set false expectations in terms of resource needs and project outcomes.

Vaccine availability and cost of country deployment was also considered to have significantly influenced demand levels. The initial scarcity of vaccines limited the scope of deployment plans, but as vaccines became available, countries scaled up plans and demand rose accordingly. However, the cost of deploying vaccine was a constraining factor that limited the quantity of pandemic H1N1 vaccine demanded by countries – particularly as the level of concern surrounding the pandemic decreased.

Several *extenuating circumstances* also influenced the demand for pandemic H1N1 vaccine, such as competing health priorities, armed conflict and natural disasters. Programmatic changes (including reductions in the vaccine dosage required) also contributed to the reduction in demand.

2.2 Prequalification and registration of pandemic vaccines and ancillary products

Prequalification of pandemic vaccines and ancillary products

The WHO prequalification process provides an independent assessment of the quality, safety and efficacy of products (such as vaccines) for United Nations purchasing programmes. The process also ensures that products are suitable for the intended target populations. In collaboration with reference regulatory agencies, it also monitors compliance with product specifications and established quality standards, and identifies any emerging concerns. Only prequalified pandemic H1N1 vaccines could be donated to countries through the WHO Deployment Initiative.

Although WHO product prequalification typically takes 12–24 months, an urgent need was created by the pandemic. In response, the WHO Prequalification Programme worked alongside the WHO Deployment Initiative to implement an expedited procedure for pandemic H1N1 vaccines. Although there were significant challenges in expediting prequalification while still meeting established standards, pandemic H1N1 vaccines were able to be prequalified in as little as one day after submission of the dossier by the manufacturer. As of October 2010, 11 pandemic H1N1 vaccines had been prequalified.

National registration of pandemic vaccines

Because national regulatory requirements also have a significant impact on the deployment of pandemic influenza vaccines, it is vital to seek early engagement with national regulatory authorities (NRAs). As a standard prerequisite for releasing a vaccine or any other medicine for shipment, documented approval from the NRA must be secured to ensure that importation processes are legal and that the shipment will not be delayed by

customs procedures. Securing this documentation from countries proved challenging during pandemic H1N1 vaccine deployment, and in some cases delayed the deployment process.

Some countries provided one-time authorizations based upon a review of the technical documentation for the vaccine, while others required vaccine samples or trials to support full or alternative national registration processes. In over half of the recipient countries, prequalification by WHO of a vaccine was not sufficient to obtain regulatory approval. In general, WHO prequalification alone was sufficient only in countries whose national laws stated that products donated by the United Nations did not require national registration.

In one country, changing the delivery schedule necessitated switching to the product of a different manufacturer. This had significant ramifications, including the need to repeat the regulatory submission process and to obtain new importation and related approvals, which compounded the delay in delivering vaccines. Such events highlight the challenges of deploying a new vaccine during an emergency situation – especially in countries with no experience in the deployment of influenza vaccine.

2.3 Management and delivery of supplies

Only a small percentage of the products donated to the WHO Deployment Initiative was shipped by donors to beneficiary countries. In most cases, the United Nations Office for Project Services (UNOPS) was responsible for the delivery of donated vaccines and ancillary products (such as 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 the WHO Deployment Initiative, representing approximately 977 metric tonnes of material and 6000 m^3 of cargo space. The work of all the different agents in the supply chain was coordinated by the WHO deployment team.

Rapidly delivering pandemic H1N1 vaccine and ancillary products to a large number of geographically distributed countries in a short time frame is highly challenging. In many countries, particular difficulties arose because of issues such as varying geographical features, political conditions and regulatory requirements. Although current shipping technologies have the potential for faster and more efficient transport, the infrastructure in some countries was insufficient for these technologies to be employed. Some countries also underestimated the space required to store donated products and realized that they lacked the necessary space only after products arrived.

The planning options for vaccine delivery were also constrained by global infrastructure limitations. For example, processing capacity at European airports for cold-chain shipments was often insufficient to allow for simultaneous or large-scale releases of vaccines. Unpredictable events (such as disruptions to shipping caused by volcanic eruptions) meant that plans had to be repeatedly changed, leading to further delays.

The variety of vaccines that were donated also created logistical challenges, such as issues caused by differences in their means of administration, shelf-life and cold-chain packaging. In some cases, the original cold-chain packaging was insufficient for transit times of more than 1–2 days and vaccines had to be repackaged en route. Although the generally high quality of various cold-chain packaging materials was beneficial, some of these could not be easily recycled or reused and created waste-management problems in some countries. In addition, retrospective reductions in the shelf-life of some products led to a need for replacement shipments and for duplicate NRA applications.

The stockpile of ancillary products donated by the United States Agency for International Development (USAID) proved to be highly useful during the WHO Deployment Initiative. Although this was also supplemented by a second stockpile donated by Becton, Dickinson and Company (facilitated by the non-profit organization AmeriCares) some procurement was also required. According to UNOPS, the process of procuring ancillary products demonstrated that their global availability was limited and would have been insufficient to meet demand. Countries seldom have sufficient (if any) stockpiles, and the use and subsequent replenishment of any existing supplies would lead to stock-outs for other programmes because of the high volumes required. Without the stockpiles donated by USAID and Becton, Dickinson and Company, it would have been extremely difficult for the WHO Deployment Initiative to deliver sufficient numbers of ancillary products to countries on time.

In future, the international community must work more closely with technicians in countries to ensure sufficient capacity for product storage and distribution. Organizations that have experience and expertise in the global transportation of vaccines and the use of cold chains should be engaged in advance for participation in pre-planning exercises with implementing agencies and manufacturers. Strategies for limiting or managing waste should also be incorporated into deployment planning, for example through the use of easily recyclable or reusable packaging materials.

In conclusion, effective coordination both between and among actors in the deployment process is a critical aspect of effective deployment. Given that it is not efficient for the international community to build capacities during an emergency, core systems and resources should be identified, developed and maintained so that these are in place in advance. This includes the use of a systems-based approach for evaluating pandemic vaccine deployment and for increasing the speed of deployment processes. Process steps should be examined to see where additional information or an amended approach could accelerate them. Where possible, preparatory work (for example, between the WHO Prequalification Programme and vaccine manufacturers, or between WHO and donors) should be conducted early to minimize bottlenecks. Support should also be given to the development of harmonized regulatory procedures in countries in relation to the approvals for vaccines and ancillary products during an emergency.

3. Stakeholder perspectives on the donation process

3.1 Donor governments

From the perspective of the Australian Government, the essential elements in securing a decision to donate were high-level support within the Government, the leadership shown by other donors (such as the United States Government), and a history of collaboration with WHO.

However, the donation process itself was delayed by the need to mitigate complex public health and legal risks. Product prequalification was required before donated vaccines and ancillary products could be accepted. As some ancillary products made available for donation were not prequalified, it was necessary to purchase products instead. In addition, the need to reach agreement on indemnity and liability issues required significant negotiation at the global level and in some beneficiary countries.

Even when vaccine-donation agreements were completed, vaccine delivery was often slowed by factors such as the lack of cold-chain capacity and the complexity of making multiple small deliveries to countries with access limitations. In addition, the process of developing and approving NDPs penalized countries that did not have the capacity to prepare appropriate plans quickly.

Donation efforts in a future pandemic could potentially be improved by exploring alternative approaches to risk mitigation that introduce fewer delays. Although global coordination proved responsive and able to address issues quickly, designating a single point of contact for donors would also improve communication and reduce uncertainty. The conducting of exercises simulating vaccine deployment by the international community could further improve preparedness.

In the view of the Australian Government, the success of the WHO Deployment Initiative was based upon strong leadership from donors, the high levels of cooperation and flexibility shown by manufacturers in facilitating deliveries, and the coordinating efforts of the WHO teams involved.

Many of these viewpoints and experiences of the WHO Deployment Initiative were echoed by the representatives of other donor governments that participated in the panel discussion (Canada, Germany, Japan, Norway and the United States). The deployment of pandemic H1N1 vaccine was perceived to be a complex project that required interacting and interdependent contributions from many different stakeholders and agents. Although the system put in place ultimately succeeded in deploying vaccines, it was felt that it could be improved and that the international community could be better prepared to implement such a system during a future pandemic.

Discussions emphasized the need for advance planning of pandemic vaccine deployment, with a legal framework for vaccine donations

incorporated into the resulting plan. Such a framework should build upon the legal agreements and experiences of pandemic H1N1 vaccine deployment, while seeking ways to accelerate contractual agreements for donation (for example, by reassessing the approaches taken to indemnification and liability). Advance planning would facilitate donations during a pandemic by making available the information needed to advocate for resources in governments, such as information on the planned approach, on the roles and responsibilities of different stakeholders, on the resources needed and on the anticipated impact that donations would have.

Periodically simulating the deployment system would help to prepare the international community and countries for a future pandemic. Routine exercises would also allow the system to be continually improved, and would provide an opportunity to test the assumptions made during pandemic H1N1 vaccine deployment – such as the assumption made that the advantages of allocating one vaccine per country outweighed the disadvantages of a more-flexible approach to vaccine allocation.

3.2 Vaccine manufacturers

Representatives of Becton, Dickinson and Company, CSL Limited, GlaxoSmithKline Biologicals, Novartis Vaccines and Diagnostics, and Sanofi Pasteur provided a manufacturer perspective on the WHO Deployment Initiative. It was felt that its success was the result of both multiple contributions and strong leadership by governments and WHO. Strong corporate leadership also led to the provision of important support from the manufacturing industry.

A desire to support similar future initiatives was also expressed. It was emphasized, however, that support for pandemic H1N1 vaccine deployment had been challenging at times and that efforts should be made to improve elements of this process in advance of a future pandemic. The confidence, trust, working relationships and tools developed during the WHO Deployment Initiative were felt to be important building blocks for the future.

One contributory factor to successful deployment was regular communication between vaccine manufacturers and WHO. Manufacturers reported that they had little experience with some beneficiary countries, and that support from experienced institutions (such as DHL, UNOPS and WHO) and donor governments made it possible to respond to requests more quickly. Assigning manufacturing staff to work with the WHO Deployment Initiative also facilitated improved communication and more-effective cooperation.

One important challenge for manufacturers, however, was balancing support for the WHO Deployment Initiative against commitments to other customers. In some cases, responding to demands required large investments in physical infrastructure and human resources. Manufacturers expressed concern that support for the WHO Deployment Initiative may have disrupted business in other areas and reduced their competitive strength. It was felt that

stockpiling products in advance, where appropriate, could facilitate industry support while avoiding such business penalties.

Manufacturers also reflected on the WHO Deployment Initiative process of allocating products to countries. Allocating products generated requirements for detailed product information and complex documentation (such as that required for importation and registration in countries). Meeting such requirements was both time-consuming and resource-intensive for manufacturers, and required access to information on country regulatory processes that was often difficult to obtain. Reallocating products once this work had begun led to additional work for manufacturers and delayed delivery to countries. It was suggested that the international community develop a more-flexible framework for allocating products that minimizes changes to allocations, for example by taking a regional approach to product allocation.

Challenges were also identified in meeting the complex regulatory requirements of countries. In some cases, vaccine was available but could not be delivered due to delays in national regulatory approval. The need for full registration (including clinical trials in some cases) was provided as an example of a national requirement that hindered deliveries. While recognizing that some documentation is necessary for importation, manufacturers called on countries to consider the use of a standard minimal set of regulatory documentation to facilitate deliveries in the future. It was agreed that a common database of information on country documentation and regulatory requirements would also facilitate a more-rapid response in the future.

Other challenges highlighted included the process of reaching legal agreement on donations to the WHO Deployment Initiative; complications introduced by complex title-transfer arrangements between donor governments, manufacturers and beneficiary countries; and the time and resources required to prequalify products.

4. Experience of pandemic H1N1 vaccine deployment in WHO regions

The following sections summarize the preliminary reports and impressions of participants from each of the six WHO regions. In many cases, the figures presented below were obtained from early surveys of deployment activities and are not intended to be definitive. In addition, caution should be exercised in the interpretation of data on issues such as vaccine coverage and utilization as these were affected by several complex factors. In general, countries estimated the percentage of people within the at-risk population groups that could realistically be targeted for vaccination. Because of the emergency situation, initially limited supplies and the difficulty in either defining the at-risk groups (such as those with "underlying" conditions) or in some cases reaching individuals in remote or dangerous areas, only an estimated

proportion of all at-risk individuals were targeted. In countries in which such estimates proved accurate the utilization rates of vaccine tended to be higher.

4.1 WHO African Region

Although beneficiary governments in the WHO African Region demonstrated great willingness to facilitate donations and received a great deal of assistance from development agencies (particularly in developing NDPs), many still found the process difficult and time-consuming. Meeting the WHO Deployment Initiative requirements for pandemic H1N1 vaccine donations, receiving vaccine deliveries and deploying them took longer than anticipated for most countries. On average, vaccines were delivered to countries 117 days after the signing of an LOA with WHO and were deployed within countries 47 days after delivery. The overall average time between expressing interest in receiving donated vaccines and deployment in countries was 261 days. Most deliveries to African countries arrived during or after the peak of the 2009 H1N1 pandemic, with the utilization of donated vaccines varying widely between countries.

Among the key lessons learnt were the important role that existing immunization systems, infrastructure and education played during deployment, and the positive effects of cooperation between different agencies, such as WHO and USAID. In addition, negative media coverage and rumours did not have as much of an effect on vaccine utilization in countries that had high-profile government support for deployment. Actual costs per person for vaccination were also lower than originally budgeted for by countries.

The challenges experienced included limited influenza surveillance systems (and a lack of infrastructure for seasonal influenza surveillance in particular), which led to public uncertainty about the extent of the pandemic, and made it difficult to rally political support and commitment in some countries. The timing of delivery of donated vaccines also coincided with a decrease in the perceived threat of the pandemic, and associated decrease in priority compared with other health problems faced in the Region such as measles and polio. In some countries vaccination campaigns were not completed because actual deployment started at the same time as the number of cases of infection with the pandemic A(H1N1) 2009 virus began to decline in the Region.

Satisfying the requirements of the WHO Deployment Initiative and taking delivery of vaccines in the Region were both delayed by a range of factors, including competing health priorities, complicated donation requirements, lack of country capacity and fragmented communication efforts within countries. Efforts that could be made by beneficiary countries, WHO, technical partners and manufacturers to accelerate vaccine deployment during a future pandemic include the following.

- Designating a national body to take responsibility for satisfying donation requirements – such a proactive step would help to overcome the lack of "ownership" of the deployment process by beneficiary countries which contributed to delays. Governments could facilitate the work of

such a body by establishing preparedness plans in advance that could be activated during a pandemic, and by institutionalizing national task forces to oversee and support the pandemic response.

- Clearly defining the roles and responsibilities of secretariat teams at the global, regional and national levels of WHO. In addition, simplifying administrative processes (such as the LOA) and increasing the usability of technical guidelines would also expedite the satisfying of WHO requirements by countries.
- Strengthening the approach adopted by the WHO Deployment Initiative to determine the order in which countries received vaccines – one impression expressed during the meeting was that this appeared to have been based on feedback from workshops and that the political willingness of beneficiary countries had been insufficiently considered. This highlights the need to strengthen transparency and raise awareness of the actual processes and criteria used.
- Enhancing the technical assistance provided by partners, including greater support for national communication efforts to facilitate a more-rapid response to a future pandemic. As such assistance efforts in some countries were delayed by practical requirements (such as access to visas), establishing an enabling environment in advance would help to maximize the impact of assistance during an emergency.
- Increasing country access to product information from manufacturers and ensuring that such information is consistent with guidance from WHO and other technical agencies.

4.2 WHO Region of the Americas

The number of countries and territories in the WHO Region of the Americas with seasonal influenza vaccination policies increased from 10 in 2003 to 35 in 2008. Seasonal influenza activities in these countries have led to the establishment of the necessary infrastructure. Furthermore, inter-institutional collaboration facilitated the deployment of pandemic H1N1 vaccine through increased capacity for surveillance; vaccine quality assurance, transportation and storage; and crisis prevention and management.

WHO and other partners in the Region enhanced these deployment capacities by developing technical guidelines for pandemic H1N1 vaccination, conducting workshops for national staff, assisting countries in the development of communication strategies, and mobilizing resources for vaccine deployment.

More than 31 countries and territories conducted pandemic H1N1 vaccination campaigns in the Region. Countries that manufactured or purchased vaccines (Argentina, Brazil, Canada, Mexico and the United States) had access to them before countries that received assistance through

the WHO Deployment Initiative. Ten countries received donated vaccines, and some augmented donations with purchases from manufacturers or through the Pan American Health Organization Revolving Fund for Vaccine Procurement. Of the 141 million doses of pandemic H1N1 vaccine accessed by countries in Latin America and the Caribbean, 10 million were donated through the WHO Deployment Initiative.

Most countries in the Region followed the recommendations of the WHO Strategic Advisory Group of Experts (*1*) and Technical Advisory Group on Vaccine-Preventable Diseases (*2*) for vaccination against pandemic H1N1 influenza. As with other regions, vaccination coverage varied between countries. Although coverage in the Region was generally high among targeted at-risk groups, coverage among pregnant women was lower (on average 67%) and faced challenges from the medical community in some countries, such as physicians reportedly refusing or failing to recommend the vaccine for this group.

Nevertheless, pandemic H1N1 vaccine deployment in the Region benefited from a broad support base in many countries, ranging from the highest political level to local authorities. The engagement of scientific organizations and societies was crucial in reaching target groups, as was the sharing of knowledge and experiences between countries. Coordination mechanisms established for seasonal influenza and pandemic preparedness facilitated more-efficient mobilization of resources.

In addition to vaccinating populations, several secondary benefits of pandemic H1N1 vaccine deployment were noted. For example, the importance of surveillance systems was highlighted in all countries, and the complexity of the campaign warranted technical assistance that strengthened the planning and operational capacity of national teams.

Despite these benefits, there are some aspects of the deployment process that could be improved in future. Access to donated vaccines was delayed in some countries by the need for regulatory approval, and by the process of approving NDPs which required separate evaluations at the regional and global level using different criteria. The strategy of vaccinating populations in phases was felt to be inefficient, and vaccinating some population groups while not offering vaccine to the general public presented communications and other challenges. In future, communication strategies should be designed to set more-realistic expectations for the timing of vaccine deployment and to avoid creating a public demand that cannot be met.

During deployment, there was also a gap between the recommendations made by national programmes and the compliance of local medical staff. To address this, supervision of medical staff should be increased, and greater efforts made to educate target populations and specialist health personnel to counter misinformation, such as that disseminated in the media by anti-vaccine groups.

4.3 WHO South-East Asia Region

Countries in the WHO South-East Asia Region adopted different approaches to pandemic H1N1 vaccine deployment. Several countries received and deployed donated vaccines, while two eligible countries (Indonesia and Nepal) did not request the vaccine. Two countries that were not eligible for donated vaccine (India and Thailand) purchased pandemic H1N1 vaccine with government funds. Some countries experienced delays and other problems in vaccinating their populations during the pandemic. Where stocks of viable vaccine remained after the pandemic, some countries used it during seasonal influenza vaccination campaigns on the grounds that the pandemic A(H1N1) 2009 virus continued to circulate with seasonal viruses, and that seasonal vaccines were not always available. Based on the best data available, 24.4 million doses of vaccine were delivered to the Region of which 51% was utilized.

Previous experience with immunization programmes facilitated successful deployment in some countries. Enabling factors included existing systems for effective planning, importation, storage and delivery, vaccination, adverse-event monitoring and waste management. Deployment efforts were also facilitated in countries where functioning NRAs and national policies for seasonal influenza were in place. In addition, workshops for countries generated interest in pandemic H1N1 vaccine deployment, helped governments prepare for deployment and collected valuable information for regional planning. WHO support for pandemic H1N1 vaccine manufacturing in the Region was another positive factor.

However, the tight time frames imposed by the rapid spread of the pandemic and the changing expectations of populations also made vaccine deployment challenging. Under such conditions, legal tasks such as the signing of the LOA and regulatory approval of vaccines were more complex than usual. In some cases, long and arduous negotiations with governments and national agencies were required before vaccine could be deployed.

Few countries in the Region had a pandemic preparedness plan that comprehensively addressed vaccine deployment, necessitating extensive deployment planning in a short period of time. Such planning was more challenging because some logistical information (such as the type of vaccine, number of doses and expected dates of delivery) was not available to countries early in the WHO Deployment Initiative. Funding to support national deployment efforts was inflexible and could not always be provided to countries quickly enough.

Public concerns about the safety, efficacy and necessity of pandemic H1N1 vaccines also made deployment more difficult, particularly in light of competing public health priorities, including other planned vaccination campaigns.

Several recommendations and other suggestions for improving future vaccine deployment were made during regional meetings. Prominent among these was a call for national reviews of the experience of pandemic H1N1 vaccine deployment, and for these reviews to inform comprehensive deployment

plans within national pandemic preparedness and response plans. Another suggestion was to consider enhanced diligence and dialogue with countries in relation to sensitive legal issues such as liability and regulatory requirements.

4.4 WHO European Region

Forty-one countries in the WHO European Region deployed approximately 74 million doses of pandemic H1N1 vaccine. Almost two million of those doses were received by six countries through the WHO Deployment Initiative. Three other countries (Kyrgyzstan, Ukraine and Uzbekistan) were eligible but did not complete the process for receiving donated vaccine.

Coverage of pandemic H1N1 vaccine among target groups varied widely (4–88%) among the 41 countries that deployed the vaccine. However, almost one third of these countries only accessed vaccine after the peak of the pandemic had passed, contributing to the low coverage recorded in some settings.

Working with countries to develop NDPs and satisfy other WHO requirements for donated vaccine was considered to be time-consuming and resource-intensive. Fortunately, the limited number of eligible countries in the Region allowed WHO and its partners to provide significant assistance. National pandemic preparedness plans should therefore be developed and made flexible to reduce the corresponding efforts required during a future pandemic.

As in other WHO regions, inaccurate or misleading information reported by the media contributed to widespread concerns about vaccine safety, efficacy and necessity. Although significant efforts were made to respond to such information, it was felt that not enough was done to engage the media in the deployment effort. Communication challenges in the Region were compounded by a critical lack of accurate information and education about the use of pandemic H1N1 vaccine in health-care workers. Communications and social mobilization efforts are therefore needed to equip countries to educate health-care workers, and to conduct information campaigns that target other specific at-risk groups.

In several eligible countries cold-chain capacity was insufficient to allow for the effective storage and distribution of the vaccine allocated to them. Cold-chain capacity should be evaluated and efforts made to strengthen it in advance of a future pandemic.

4.5 WHO Eastern Mediterranean Region

Four countries in the WHO Eastern Mediterranean Region received donated vaccines through the WHO Deployment Initiative. These countries received vaccines later in the pandemic than high-income countries in the Region. Utilization of donated vaccines was lower than anticipated. This and the incomplete monitoring of vaccine usage due to limited capacity and other

challenges (such as floods and political disturbances) may have contributed to the low utilization rates reported by some countries.

Preparation activities in countries were time-consuming and in some cases the requirements of the deployment process were frustrating. The piloting of vaccine use in areas that are ready, rather than waiting for entire countries to be prepared, was identified as a possible solution to this.

Although countries were provided with standard guidelines for vaccine deployment, and participated in joint workshops to develop or improve NDPs, many ultimately employed specific strategies to protect target populations (such as requiring vaccination for Hajj pilgrims in some countries, while cancelling the Hajj in others) and/or different clinical approaches to vaccination (such as dosage differences). This highlights the difficulty of establishing guidelines for vaccine deployment that are useful across a range of countries each with a particular perspective (Box 1), and the importance of country ownership and investment in national planning activities.

Communication issues also made deployment challenging. Public concerns about the safety and efficacy of pandemic H1N1 vaccine likely contributed to its low rates of utilization. National adverse-event monitoring systems in the WHO Eastern Mediterranean Region were inadequate for confirming or denying reports of adverse events propagated in the

Box 1. Recipient government perspective – the experience of Afghanistan

The deployment of pandemic H1N1 vaccine delivered through the WHO Deployment Initiative was a success in Afghanistan with a large majority of all vaccines donated targeted at health-care workers and pregnant women.

As a country that does not have a routine vaccination programme for seasonal influenza, the deployment of pandemic H1N1 vaccine helped to build immunity among new population groups, and improved the national capacity to conduct future vaccination campaigns. Sustaining the progress made will require continued political and financial support for the national vaccination programme, and for periodic and systematic exercises to maintain national preparedness.

The challenges faced during vaccine deployment included the complications arising from the presidential election. In addition, a lack of effective monitoring systems and funding for communication activities made it difficult to counter rumours of adverse events and to address shifting public perceptions of the virulence of the pandemic. Misinformation about donated products further challenged systems that were already inexperienced in influenza vaccine deployment.

Although the national deployment of H1N1 vaccine should be considered a success, better national and international coordination is needed between those who estimate demand, those who mobilize resources and those who administer the vaccine.

media. Even minor errors made in communication campaigns sometimes contributed to misunderstandings by target populations. Lack of education for health-care workers was also identified as a critical gap in the Region.

Although there is concern that negative media reporting might also hinder future seasonal influenza vaccine campaigns, current information suggests that this has not occurred. It was noted that both during and after the 2009 H1N1 pandemic there was a significant increase (almost double in some cases) in the demand for seasonal influenza vaccination.

4.6 WHO Western Pacific Region

Countries in the WHO Western Pacific Region received vaccines comparatively quickly, with 14 countries receiving their full allocation by the end of March 2010. The success of vaccine deployment in the Region was attributed in large part to regular and transparent communication, both between WHO regions and headquarters, and between international agencies and country ministries. This was felt to be of particular importance during pandemic conditions.

Key challenges in the Region included the general lack of experience in many countries of conducting vaccination campaigns, and the challenge of gaining this experience during a pandemic. As in many regions, this factor was complicated by the effect of misinformation and negative reporting in the global media. Other factors that hampered rapid vaccine deployment included late changes to NDPs, shifting political commitments, and complexities associated with varying country requirements for supply documentation. The mobilizing of financial support for vaccine deployment in countries also proved challenging.

There is a continuing need in the Region to refine NDPs and guidelines for national planning, to improve communication and training of national-level communication officers, and to establish sufficient cold-chain capacity.

5. Selection of key proposed action points

Throughout the meeting, a range of potential action points were proposed for improving vaccine deployment during a pandemic and for maintaining important resources (Annex 1). On the final day, each meeting participant was allotted 10 votes and asked to allocate them to the action points considered to be of greatest relevance to the effectiveness of similar future deployment initiatives. Participants were able to allocate multiple votes to a single suggested action or to divide their votes among several suggestions. The key proposed action points which received most votes were as follows.

1. Reach agreement with all stakeholders on an overall framework of activities, roles and responsibilities relating to vaccine deployment during a pandemic for all actors in that framework. Periodically review the framework and assess where it needs to be updated or revised.
2. Prepare in advance and maintain a framework for legal agreements with donor governments and manufacturers (explaining issues such as indemnification, and how to deal with ownership and title transfer) to expedite legal agreements during future pandemic events.
3. Review pandemic epidemiological trends and the timeline of pandemic vaccine deployment activities to assess how best to align the latter with the former, with a particular focus placed on anticipating emerging changes and mitigating their impact.
4. Regularly engage major global stakeholders in readiness training for future pandemics, including simulation exercises for pandemic vaccine deployment.
5. Investigate if and how regulatory processes for pandemic vaccines can be shortened at global and national levels during a pandemic.
6. Investigate the possibility of a better-harmonized licensing approach for vaccines during a pandemic.
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.
8. Evaluate current global cold-chain capacity and, where necessary, identify approaches for ensuring sufficient surge capacity to handle large volumes of vaccine during a pandemic.
9. Align country NDPs with overall national pandemic preparedness and response plans, and with health-sector and intersectoral strategies and plans/budgets.
10. Study the interplay between pandemic and seasonal influenza vaccination and evaluate how best to advise countries in this regard.
11. Establish a cross-function, cross-region communication channel that involves all stakeholders to facilitate information sharing and to support the timely and effective efforts of the different actors during pandemic vaccine deployment.
12. Document the process of pandemic H1N1 vaccine deployment to serve as a basis for deployment planning during future pandemics.

Conclusions

The WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative was the first operation of this kind by WHO. Although it proved extremely challenging to deploy a new influenza vaccine during a global emergency, the WHO Deployment Initiative was able to deliver over 78 million doses of pandemic H1N1 vaccine to 77 of the poorest countries in the world. It was able to accomplish this because of the generous contributions, strong leadership and high degree of cooperation of the many donors, governments, technical agencies and private-sector organizations involved.

In addition to highlighting the delivery of life-saving vaccines, this meeting revealed other benefits of the WHO Deployment Initiative. Surveillance systems were improved, as was the capacity of country teams to plan and implement large-scale vaccination campaigns. The adaptation of preparedness plans to local conditions was also important and led to several significant successes. The confidence, trust and working relationships established between governments, technical agencies and manufacturers during the WHO Deployment Initiative will have long-term benefits for global public health efforts.

The meeting also highlighted the urgent need to learn the lessons of the WHO Deployment Initiative in advance of a future pandemic. Many weaknesses in the global response were brought to light, such as a failure to communicate effectively among partners and with countries, inadequate transport capacity, complex donation processes and a lack of preparedness in many countries. Maintaining preparedness at the global level was recognized as a crucial aspect of future responses, and this could be enhanced by conducting periodic simulation exercises. A concerted effort must now be made to improve upon the systems established during the WHO Deployment Initiative to respond more effectively to the needs of countries in the future. ■

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Annex 1. Full list of proposed action points

Throughout the meeting, participants highlighted a broad range of proposed action points that could be considered as part of strengthening preparedness for a future pandemic vaccine deployment effort. To provide a structure for analysis and discussion, each of the proposed action points were allocated as shown below to the following six categories of vaccine deployment.

1. Donation
2. Global planning and coordination
3. National planning and coordination
4. Prequalification and registration of pandemic vaccines
5. Global and national communication
6. Management and delivery of supplies.

Following discussion and further refinement, meeting participants then developed a list of key proposed action points considered to be of greatest relevance to the effectiveness of similar future deployment initiatives (see section 5).

Proposed action point	
1. Donation	
1.1	Prepare in advance and maintain a framework for legal agreements with donor governments and manufacturers (explaining issues such as indemnification, and how to deal with ownership and title transfer) to expedite legal agreements during future pandemics.
1.2	Hold ongoing dialogue between WHO, donors and manufacturers on how to further align agreements between governments and manufacturers with the needs of recipient countries.
1.3	Provide detailed information to donors early in the pandemic response on what resources are required (including human expertise) and what would be done with those resources to facilitate a fast, efficient and effective response.
1.4	Identify a mechanism for streamlining contacts with donors and potential donors, such as the designating of a single focal point to work with each donor.
2. Global planning and coordination	
2.1	Reach agreement with all stakeholders on an overall framework of activities, roles and responsibilities relating to vaccine deployment during a pandemic for all actors in that framework. Periodically review the framework and assess where it needs to be updated or revised.
2.2	Review pandemic epidemiological trends and the timeline of pandemic vaccine deployment activities to assess how best to align the latter with the former, with a particular focus placed on anticipating emerging changes and mitigating their impact.
2.3	Regularly engage major global stakeholders in readiness training for future pandemics, including simulation exercises for pandemic vaccine deployment.
2.4	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.
2.5	Document the process of pandemic H1N1 vaccine deployment to serve as a basis for deployment planning during future pandemics.

	Proposed action point
2.6	Conduct a mapping exercise to show how the different United Nations organizations could contribute in future responses.
2.7	Establish a clear, logical and efficient framework and share with all stakeholders (including donors and manufacturers) in advance. The allocation process should minimize changes once a product has been allocated to a country.
2.8	Develop and maintain a skills matrix for future technical-assistance needs.
2.9	In addition to bilateral and multilateral agencies, involve ministries of health and other relevant ministries in global planning.
2.10	Manufacturers should attempt to standardize vaccine packaging wherever possible to facilitate transportation.
2.11	Link NDPs to implementation of the International Health Regulations (2005).
2.12	Identify ways to borrow lessons from other pandemic response activities; for example the deployment and use of antivirals.
2.13	Conduct an assessment of how risk was managed during pandemic H1N1 vaccine deployment to document what was learnt and identify ways in which this aspect could be improved.
2.14	Assess the needs for surge personnel at the international and regional level and identify strategies to meet such needs.
2.15	Work with influenza surveillance networks to more broadly reflect the patterns of influenza in all regions to inform and guide pandemic vaccine campaigns; apply modelling techniques where needed to fill in gaps.
2.16	All stakeholders should share the outcomes of internal evaluations of the pandemic H1N1 vaccine deployment process (e.g. lessons learnt) with each other.
3. National planning and coordination	
3.1	Align country NDPs with overall national pandemic preparedness and response plans, and with health-sector and intersectoral strategies and plans/budgets.
3.2	Involve NRAs to reach consensus on regulatory information requirements during the pre-planning phase.
3.3	Identify ways to streamline the process of developing and approving NDPs; consider ways to ensure that countries maintain up-to-date pandemic preparedness and response plans.
3.4	Building on the experience with pandemic H1N1 vaccination campaigns, help establish seasonal vaccination campaigns in countries that are not currently conducting them.
3.5	Work even more closely with national expanded programmes on immunization (EPI) to integrate pandemic vaccine response into immunization activities OR work more closely with national influenza programmes OR encourage EPI and national influenza programmes to collaborate.
3.6	Review country operational costs to determine the extent to which this could inform future budgeting at the country level.
3.7	Be more proactive about providing support to health-care workers, who should be viewed as gatekeepers and agents of change.
3.8	Work with countries to create or enhance cold-chain capacity.
4. Prequalification and registration of pandemic vaccines	
4.1	Investigate if and how regulatory procedures for pandemic vaccines can be shortened at global and national levels during a pandemic.
4.2	Investigate the possibility of a better-harmonized licensing approach for vaccines during a pandemic.

	Proposed action point
4.3	Leverage WHO prequalification in countries to reduce or eliminate country-specific registration or other regulatory delays.
4.4	Clarify roles and responsibilities in relation to the requirements of national regulatory agencies in countries using donated vaccines.
4.5	Encourage more manufacturers to prequalify more seasonal influenza vaccines.
4.6	Investigate whether the use of provisional licences in countries of manufacture and later conversion to full licensure has any impact on the overall regulatory process.
5. Global and national communication	
5.1	Study the interplay between pandemic and seasonal influenza vaccination and evaluate how best to advise countries in this regard.
5.2	Establish a cross-function, cross-region communication channel that involves all stakeholders to facilitate information sharing and to support the timely and effective efforts of the different actors during pandemic vaccine deployment.
5.3	Identify better ways to communicate on vaccine safety, the benefits of vaccination, who the target populations are and why they were chosen, and on other issues that can improve uptake.
5.4	Identify communication strategies and approaches targeting senior policy-makers and leaders in countries so as to create greater political commitment and support for national vaccine campaigns.
5.5	Investigate the core issues behind the negative attitudes to vaccination of some health-care workers, and why they discouraged people from being vaccinated in some countries.
5.6	Develop a global procedure for monitoring adverse events.
5.7	Building on the experience of pandemic H1N1 and other disease programmes (e.g. for HIV) establish a subnational communications framework that can be tailored for targeted populations, and create capacity in country programmes for implementing effective behaviour-change strategies.
5.8	Update the WHO guidelines on the packaging of vaccines to include more information on influenza.
6. Management and delivery of supplies	
6.1	Evaluate current global cold-chain capacity and, where necessary, identify approaches for ensuring sufficient surge capacity to handle large volumes of vaccine during a pandemic.
6.2	Consider alternative packaging technologies to address efficiency and environmental concerns.
6.3	Develop stockpiling strategies for ancillary products.
6.4	Consider all possible modes of transport and storage (such as the purchasing or renting of reefer containers).
6.5	Develop and make available a database of the importation and regulatory requirements of countries.
6.6	Review the costs and benefits of different outsourcing models for various logistical activities.
6.7	Define all elements of the vaccine-deployment system, and capture all the relevant experiences gained at each stage. Analyse the time it took to make decisions and complete tasks. Determine the necessary and unnecessary reasons for the time required and for the delays experienced.

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