

## **Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits**

### **Update on the pandemic influenza A (H1N1) 2009 virus**

#### **Report by the Secretariat**

1. In April 2009, the first cases of infection with pandemic influenza A (H1N1) 2009 virus, a new virus of swine origin not previously detected in humans, were reported from North America. On 25 April, in accordance with the provisions of the International Health Regulations (2005), the Director-General, after consulting the IHR Emergency Committee, declared a Public Health Emergency of International Concern for the first time since the Regulations came into force. On 27 April, the level of pandemic alert was raised to WHO Pandemic Phase 4, to Phase 5 on 29 April, and to Phase 6 on 11 June. The incremental increase in phases reflected the geographical spread of the disease. Independent of the spread, WHO assessed the severity of the pandemic infection's impact on the health of populations as "moderate". The severity assessment has not changed thus far, but it could be raised or lowered in the future, depending on the global situation.
2. The Director-General also issued Temporary Recommendations, in accordance with her mandate under the International Health Regulations (2005), concerning appropriate health measures for global implementation in response to this emergency. These recommendations were made based upon technical advice from the IHR Emergency Committee, which assessed the best available scientific evidence from both the current outbreak and previous experience in public health emergencies, especially the severe acute respiratory syndrome and H5N1 avian influenza.
3. As at 30 October 2009, the pandemic influenza A (H1N1) virus had been detected in 198 countries and territories. In most infected persons, it generally causes a self-limiting, uncomplicated, febrile respiratory disease known as influenza-like illness. However, this virus also has a greater affinity for infecting lower respiratory tract tissues than seasonal influenza viruses, resulting in many cases of viral pneumonia that are rapidly progressive, difficult to treat, and often fatal.
4. Children and young adults appear to develop severe or complicated illness from pandemic (H1N1) 2009 more often than the elderly, a pattern that is different from seasonal influenza. Groups at increased risk of complications and death include pregnant women, particularly in the third trimester, children younger than two years of age, and those with underlying health conditions such as asthma and other chronic lung diseases, chronic heart disease, diabetes and immunosuppression. Obesity may be an independent risk factor for severe illness but firm evidence to verify this is still insufficient.

Disadvantaged and indigenous populations also appear to show a high prevalence of severe or complicated illness, which may primarily reflect the above and other risk factors.

5. In 2009 in the northern hemisphere, pandemic disease activity during the summer was highly visible with “hot spots” in some countries and regions but generally lower than may occur in the winter. In the southern hemisphere during the 2009 winter months, activity levels were generally higher. In the tropics, disease levels were variable, with significant outbreaks in some settings. In the Northern Hemisphere autumn, influenza-like illness from pandemic infections has been observed much earlier than is usual for seasonal influenza, in Japan and in some countries of North America and Europe.

6. Most countries have been able to cope with the impact on health systems. However, in some countries, outpatient, emergency and intensive-care services have faced significant challenges during peak periods of activity. In particular, greater than usual numbers of patients with the acute respiratory problems have placed significant stress on intensive-care support systems, even in developed countries.

7. In all countries, the basis for effective mitigation of the pandemic includes adequate surveillance, good patient care, and appropriate risk communication, including information on the evolving situation, risk factors, and instruction on when and where to access care.

## **WHO'S RESPONSE<sup>1</sup>**

8. WHO's response to the pandemic has been made using several mechanisms that involve all levels of the Organization. The determination of a Public Health Emergency of International Concern, based on advice to the Director-General from the IHR Emergency Committee, triggered initial detection and follow-up activities. That advice has continued in a timely manner. The WHO Event Management System has been used to document pandemic events reported by National IHR Focal Points and WHO regional and country offices. Since the start, continual assessment of the pandemic has been carried out by WHO staff, with the input of external experts through epidemiological, virological, clinical and modelling networks. New surveillance mechanisms of monitoring, aimed at sustained follow-up over a longer period of time, are in development. Weekly situation updates as well as web postings of important findings have been provided since the onset of the pandemic.

9. The WHO Global Influenza Surveillance Network has provided laboratory kits and free shipping of clinical samples to designated centres from countries with no laboratory capacity. The Global Outbreak Alert and Response Network has made technical experts and support available to Member States for assessment, preparedness and response activities. Countries in need have been provided antiviral medicines (five million courses of treatment donated and delivered to 122 countries). Some 200 million doses of vaccine have been pledged by several countries and manufacturers. WHO is working with these partners to ship vaccine and ancillary supplies to 95 developing and middle-income countries for the protection of health-care workers. This effort is aimed at ensuring the continued provision of health care and other essential services.

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<sup>1</sup> See also document EB126/5.

10. Extensive technical guidance has been developed to support surveillance, clinical and pharmacological management, infection control, and individual and community measures, such as reduction of transmission in schools, workplaces, at mass gatherings, and on board ships and aircraft. Guidelines are being updated as new data become available.

11. Strengthening equitable access to critical materials, such as antiviral medicines, antibiotics, and vaccines, remains a pressing concern, especially in low-income countries. WHO has worked closely with the office of the United Nations System Influenza Coordinator and other agencies in the United Nations system in order to develop the Urgent Needs Identification and Prioritization process. The latter's procedures enable identification of the most pressing needs and interventions to mitigate the effects of the pandemic in the most vulnerable countries. A major goal of this initiative is to secure donor support that will allow the provision of medicines and vaccines to developing countries. The minimum targets for population coverage are 4% for antiviral medicines and up to 10% for vaccines, depending on their availability.

12. WHO has continued to support increased global manufacturing for antiviral medicines through prequalification programmes and capacity building, especially in developing countries. Expressions of interest in prequalification programmes have, nonetheless, been limited. It is important, nonetheless, that these programmes be encouraged.

13. Because the emergence of widespread resistance to antiviral agents is a possibility, careful global monitoring and assessment of resistance are continuing tasks. At the time of writing, 39 viruses resistant to oseltamivir had been reported to WHO, mostly people receiving chemoprophylaxis or less often in those undergoing treatment. WHO will continue to assess and report on these events and their implications. There is no evidence that such viruses are in widespread circulation and none has been associated with increased severity of disease. Clinicians, laboratories and agencies have been urged to notify WHO promptly of any cases of oseltamivir-resistant pandemic (H1N1) 2009 virus and to provide relevant clinical and epidemiological data.

14. WHO has supported the timely development of and access to pandemic vaccine. The Global Influenza Surveillance Network and its WHO collaborating centres for influenza and Essential Regulatory Laboratories have provided the vaccine industry worldwide with both candidate vaccine viruses and reagents for vaccine production and quality control. WHO facilitated a virtual network of regulators in order to accelerate registration of pandemic vaccines and harmonize licensing procedures, and organized expert consultations on technical issues. In May 2009 WHO surveyed all potential manufacturers of pandemic (H1N1) 2009 vaccine and their associations in order to assess global capacity for pandemic (H1N1) 2009 vaccine production. Based on the survey results and information on pandemic (H1N1) 2009 vaccine purchase contracts already in place, WHO drew up scenarios on improving vaccine availability for developing and middle-income countries. WHO has pursued direct discussions with manufacturers and donor countries in order to secure rapidly donations for vaccines, enhanced technical assistance and technology transfer to developing-country manufacturers. As of 30 October 2009, 178 million doses of vaccine had been pledged to WHO to support its pandemic (H1N1) 2009 vaccine initiative. WHO is also implementing an accelerated pandemic vaccine prequalification procedure to ensure the quality of vaccine donated to developing countries through that vaccine initiative.

15. On 7 July 2009, the WHO Strategic Advisory Group of Experts on immunization recommended that all countries immunize health-care workers with pandemic (H1N1) 2009 vaccine as a first priority. As more vaccine becomes available, the Advisory Group suggested an incremental approach to vaccinating groups considered at risk, with countries determining their order of priority based on country-specific conditions. The Advisory Group met again (Geneva, 27–29 October 2009) and made

the following recommendations: (1) the use of a single dose of vaccine for those aged 10 years and older – this recommendation is supported by available results obtained through clinical evaluation of pandemic vaccines and is made under the proviso that this use is consistent with regulatory authorities' indications; (2) priority should be given to providing one dose of vaccine to as many children as possible for those six months old to 10 years of age where priority has been assigned to this group by national authorities, given the context of limited supplies and limited immunogenicity data currently available; (3) seasonal and pandemic vaccines can be administered together, provided that both do not contain live attenuated viruses; (4) any licensed pandemic vaccine may be used in pregnant women, in the absence of a specific contraindication by the regulatory authority; (5) both trivalent influenza vaccine (containing the pandemic influenza A (H1N1) 2009, seasonal A (H3N2) and influenza B viruses) and bivalent seasonal vaccine options (containing influenza A (H3N2) and influenza B viruses) should remain open for formulating the vaccine for seasonal influenza vaccination in the southern hemisphere in 2010, subject to national needs. This bivalent vaccine version may be supplemented with a separate monovalent pandemic (H1N1) 2009 vaccine. The Advisory Group noted that adverse effects from pandemic vaccines reported thus far were within the range of those noted with seasonal vaccines. Despite this excellent safety profile, monitoring for adverse events should be continued.

16. WHO moved quickly to respond to pressing needs for information of Member States, the scientific community, and the general public. There were two million visitors to WHO's web site in one four-hour period alone. Many interviews, live and virtual press conferences and briefings for Geneva-based permanent missions were held, while web updates were posted regularly. Plans call for the provision of more extensive support to Member States in order to help them to disseminate effective messages about the pandemic.

17. WHO's response to the pandemic created a surge in demand within the Secretariat for human and financial resources. Emergency operational procedures were implemented that were originally developed for earlier events and that reflected lessons learnt from the Public Health Security Exercises of 2007 and 2008. The J.W. Lee Strategic Health Operations Centre served as the central hub within the Secretariat for operations, meetings and briefings.

18. In September 2009, several governments and pharmaceutical manufacturers responded to the joint call by the Director-General and the United Nations Secretary-General for global solidarity. In addition, several donors gave direct funding to the WHO Public Health Emergency Fund in order that WHO could maintain its support to Member States. To date, these funds total approximately US\$ 12 million.

## **PRELIMINARY OBSERVATIONS**

19. The combination of pandemic preparedness activities initiated in response to the emergence of avian H5N1 influenza, as well as better surveillance, new laboratory techniques, and the extensive use of electronic communications technologies allowed the world to detect, identify, monitor and respond to the emergence of a new pandemic influenza virus better than at any other time in the past. Furthermore, the availability of the International Health Regulations (2005) as a legal framework has greatly facilitated the global health response.

20. Nonetheless, further improvements are greatly needed in the areas of surveillance, laboratories, patient care, and individual and societal mitigation measures, as well as in access to vaccines, medicines, and other critical materials, especially in developing countries. Significant progress in

international solidarity has been achieved, through donations by developed countries and manufacturers, but overall access to antiviral medicines and vaccines in developing countries remains limited. The availability of antiviral medicines and vaccines will have limited impact on reducing the burden of disease in developing countries. Therefore it is important that other nonpharmaceutical measures be available.

21. The current pandemic has underscored the critical importance of communications in providing messages for the public and in reducing public anxiety. Once the current pandemic is over, the Secretariat will review the experience gained and continue its work to further strengthen the world's state of preparedness for the next pandemic.

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