

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

The Sixtieth World Health Assembly,

Having considered the report on avian and pandemic influenza: developments, response and follow-up;¹

Reaffirming obligations of States Parties under the International Health Regulations (2005);

Recalling resolutions WHA58.5 and WHA59.2, which expressed concern about the potential of the H5N1 strain of *Influenza-virus A* to cause a pandemic and urged Member States to disseminate to WHO Collaborating Centres information and relevant biological materials, including clinical specimens and viruses;

Recognizing the sovereign right of States over their biological resources, and the importance of collective action to mitigate public health risks;

Recognizing that intellectual property rights do not and should not prevent Member States from taking measures to protect public health;

Recalling the Jakarta Declaration on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits and the recommendations of the High-Level Meeting on Responsible Practices for Sharing Avian Influenza Viruses and Resulting Benefits (Jakarta, 26–28 March 2007);

Recognizing, in particular, the importance of international sharing, with WHO Collaborating Centres, of clinical specimens and viruses as a contribution to assessment of the pandemic risk, development of pandemic vaccines, updating of diagnostic reagents and test kits, and surveillance for resistance to antiviral medicines;

Stressing the need for effective and transparent international mechanisms aimed at ensuring fair and equitable sharing of benefits, including access to, and distribution of, affordable diagnostics and treatments, including vaccines, to those in need, especially in developing countries, in a timely manner;

¹ Documents A60/7, A60/8 and A60/INF.DOC./1.

Noting WHO's global pandemic influenza action plan to increase vaccine supply and its goal of reducing the gap between the potential vaccine demand and supply expected during an influenza pandemic by expanding over the medium- and long-term-supply of pandemic vaccine;¹

1. URGES Member States:

(1) to continue to support, strengthen and improve the WHO Global Influenza Surveillance Network and its procedures through the timely sharing of viruses or specimens with WHO Collaborating Centres, as a foundation of public health, to ensure critical risk assessment and response, and to aim to ensure and promote transparent, fair and equitable sharing of benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies;

(2) to support and promote research to improve the prevention, detection, diagnosis and management of influenza viral infection, with the goal of developing better tools for public health;

(3) to support WHO as appropriate in order to identify and implement mechanisms referred to in paragraph 2, subparagraph (1);

(4) to formulate as appropriate and to strengthen existing policies on influenza vaccines as an integral part of their national influenza-pandemic preparedness plans;

(5) to strengthen where appropriate the capacity of national and regional regulatory authorities to efficiently and effectively carry out necessary measures for the rapid approval of safe and effective candidate influenza vaccines, especially those derived from new subtypes of influenza viruses, and in this respect to encourage international collaboration among regulatory authorities;

2. REQUESTS the Director-General:

(1) to identify and propose, in close consultation with Member States, frameworks and mechanisms that aim to ensure fair and equitable sharing of benefits, in support of public health, among all Member States, taking strongly into consideration the specific needs of developing countries, such as, but not limited to:

(a) innovative financing mechanisms to facilitate timely and affordable procurement of pandemic vaccines for and by Member States in need;

(b) facilitation of acquisition by developing countries of capacity for manufacturing in-country influenza vaccine;

(c) access to influenza-vaccine viruses developed by WHO Collaborating Centres for the production of vaccines by all influenza-vaccine manufacturers, particularly in developing countries;

¹ Document WHO/IVB/06.13 - WHO/ODS/EPR/GIP/2006.1.

- (d) in times of public health emergencies of international concern, full access of all influenza-vaccine manufacturers to pandemic influenza-vaccine viruses developed by WHO Collaborating Centres for the production of pandemic influenza vaccines;
 - (e) technical assistance to developing countries to enhance local research and surveillance capacity, including staff training, with the objective of assuring work on influenza viruses at national and regional levels;
 - (f) upon request, provision of support to Member States, especially developing and affected countries, to improve their capacity to establish and strengthen testing capacity for H5 and other influenza viruses, including identification and characterization, and to establish and strengthen their capacity to meet WHO requirements for becoming a reference laboratory or Collaborating Centre, if desired;
- (2) to establish, in close consultation with Member States, an international stockpile of vaccines for H5N1 or other influenza viruses of pandemic potential as appropriate, for use in countries in need in a timely manner and according to sound public-health principles, with transparent rules and procedures, informed by expert guidance and evidence, for operation, prioritization, release of stocks, management and oversight;
 - (3) to formulate mechanisms and guidelines, in close consultation with Member States, aimed at ensuring fair and equitable distribution of pandemic-influenza vaccines at affordable prices in the event of a pandemic in order to ensure timely availability of such vaccines to Member States in need;
 - (4) to mobilize financial, technical and other appropriate support from Member States, vaccine manufacturers, development banks, charitable organizations, private donors and others, in order to implement mechanisms that increase the equitable sharing of benefits as described in paragraph 2, subparagraphs (1), (2) and (3);
 - (5) to convene an interdisciplinary working group to revise the terms of reference of WHO Collaborating Centres, H5 Reference Laboratories, and national influenza centres, devise oversight mechanisms, formulate draft standard terms and conditions for sharing viruses between originating countries and WHO Collaborating Centres, between the latter and third parties, and to review all relevant documents for sharing influenza viruses and sequencing data, based on mutual trust, transparency, and overriding principles such as:
 - (a) timely sharing of viruses within the Global Influenza Surveillance Network;
 - (b) application of the same standard terms and conditions to all transactions, as appropriate;
 - (c) timely consultation and sharing of information with originating countries, especially on use outside the Network;
 - (d) for any use of influenza viruses outside the scope of the terms of reference of WHO Collaborating Centres, H5 Reference Laboratories, and national influenza centres submission of a request directly to the relevant national influenza centre or other originating laboratory of the country where the virus was collected and require

appropriate response from the national influenza centre; such requests would be bilateral activities not requiring the intervention of WHO;

(e) recognition and respect of the crucial and fundamental role and contribution of countries in providing viruses for the Global Influenza Surveillance Network;

(f) increased involvement, participation and recognition of contribution of scientists from originating country in research related to viruses and specimens;

(g) attribution of the work and increased co-authorship of scientists from originating countries in scientific publications;

(h) due consideration of relevant national and international laws;

(6) to assure a membership of the interdisciplinary working group consisting of four Member States from each of the six WHO regions, taking into account balanced representation between developed and developing countries and including both experts and policy makers;

(7) to convene an intergovernmental meeting to consider the reports by the Director-General on paragraph 2, subparagraphs (1), (2), (3) and (8), and by the interdisciplinary working group on paragraph 2, subparagraph (5), that shall be open to all Member States and regional economic integration organizations;

(8) to commission an expert report on the patent issues related to influenza viruses and its genes, and report to the intergovernmental meeting;

(9) to continue to work with Member States on the potential for the conversion of existing biological facilities, such as those for the production of veterinary vaccines, so as to meet the standards for development and production of human vaccines, thereby increasing the availability of pandemic vaccines, and to enable them to receive vaccine seed strains;

(10) to report on progress on implementation of this resolution, including the work of the intergovernmental meeting, to the Sixty-first World Health Assembly, through the Executive Board.

Eleventh plenary meeting, 23 May 2007
A60/VR/11

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