

Avian and pandemic influenza: developments, response and follow-up, and application of the International Health Regulations (2005)¹

Best practice for sharing influenza viruses and sequence data

Report by the Secretariat

A common threat

1. Emerging new infectious diseases, such as severe acute respiratory syndrome (SARS) and avian influenza, are major threats to global security because they endanger the health of individuals and the stability of economies and societies. However, it is the prospect of the next pandemic of human influenza, triggered by the emergence of a novel influenza virus, that has caused the most concern recently. The International Health Regulations (2005) provide the international community with a new framework for preventing, controlling and responding to the international spread of diseases such as pandemic influenza. Global surveillance of influenza viruses is a critical element of that process, enabling potential threats to be identified and the risks they pose to be assessed. The timely sharing of influenza viruses and the associated genetic and antigenic information is essential for developing the diagnostic tests, vaccines, and strategies necessary to protect populations.

2. The potential for a new influenza pandemic has remained high since alarms were raised in early 2004, following reports that a new highly pathogenic strain, H5N1, of avian influenza virus was spreading across Asia, infecting both poultry and people. Although the virus has not yet acquired the capacity for sustained human-to-human transmission, it continues to undergo genetic changes and thus has the potential to develop this transmissibility. The experience of SARS has demonstrated that, today, a virus can spread throughout the world in a matter of months, if not weeks.

A global response

3. For more than 50 years, WHO has coordinated the Global Influenza Surveillance Network, the only worldwide monitoring system that has enabled the international public health community to share and analyse influenza viruses, furthering the understanding of their epidemiology and impact. The Network's purpose is to coordinate global public health efforts to detect, monitor and assess all influenza virus threats to humans and to facilitate the development of influenza vaccines and other

¹ See document EB120/16 for information on application of the International Health Regulations (2005).

crucial defences against these threats. The Network is based on the voluntary collaboration of laboratories, including its Collaborating Centres, National Influenza Centres, and H5 Reference Laboratories or other expert laboratory reference centres in Member States. Each year the Network provides information on circulating viruses, enabling development and manufacture of vaccines against seasonal influenza. It will play a central role in identifying the likely source of the next human influenza pandemic and in supplying the vaccine strains required to manufacture an effective vaccine.

Sharing the benefits

4. Developing countries carry a disproportionate burden of the risk associated with the emergence of new disease threats; industrialized countries have greater means at their disposal to offer protection to their populations. SARS and other emerging infectious diseases have shown that worldwide cooperation through the sharing of surveillance information and technology is essential for an effective public health response to a pandemic of human influenza. The benefits derived from this global system, including better access to influenza vaccines, must be shared. The recently formulated Global Pandemic Influenza Action Plan to Increase Vaccine Supply¹ sets out approaches to increasing supplies globally and ensuring that the pandemic vaccine is made available, especially to countries and regions that currently lack sufficient influenza vaccine-production capacity.

5. The results of the Global Influenza Surveillance Network's activities demonstrate that the combined efforts of countries under the coordination of WHO, form a reliable, common defence against influenza. For that to remain effective, however, the commitment by all countries to sharing viruses and data at the earliest possible opportunity is essential. To that end, and in line with resolution WHA59.2 on application of the International Health Regulations (2005), the Influenza Pandemic Task Force was created. At its first meeting (25 September 2006), the Task Force endorsed the Secretariat's proposed best practices for sharing influenza viruses and sequence data, for consideration by Member States. These best practices, set out below, reflect the principles, responsibilities and benefits of the Network. Where appropriate, each best practice is accompanied by operational recommendations for their implementation (in italicized typeface).

BEST PRACTICES FOR SHARING INFLUENZA VIRUSES AND SEQUENCE DATA

6. It is recommended that all Member States should continue to support the WHO Global Influenza Surveillance Network and its procedures for the routine collection, exchange and characterization of circulating strains of seasonal influenza viruses. It is further recommended that all Member States should participate in the establishment of mechanisms that ensure the routine and timely sharing of biological materials related to novel influenza viruses posing a pandemic threat, including the H5N1 strain.

7. The following best practices are recommended:

- Member States should designate and adequately support a national influenza centre in order to participate actively in the WHO Global Influenza Surveillance Network.

¹ Document WHO/IVB/06.13 – WHO/CDS/EPR/GIP/2006.1.

- All Member States with a national influenza centre laboratory conducting surveillance should share nationally representative samples of seasonal influenza viruses on a regular and timely basis and all novel influenza viruses on an urgent basis by sending the viruses to a WHO Global Influenza Surveillance Network Collaborating Centre or H5 Reference Laboratory of the Member State's choosing.

Operational recommendation

The Global Influenza Surveillance Network Collaborating Centres or H5 Reference Laboratories receiving viruses and information from the national influenza centres should routinely conduct genetic and antigenetic characterization of sufficient numbers of viruses and determine their susceptibility to antiviral medicines in a timely manner in order to facilitate risk assessment and vaccine development.

- The genetic sequence data and any other information of urgent public health importance derived from the analysis of influenza viruses collected through the WHO Global Influenza Surveillance Network should be made available to all Member States in an open and timely manner.

Operational recommendations

Global Influenza Surveillance Network Collaborating Centres and H5 Reference Laboratories should routinely post all genetic sequence data derived from the analysis of influenza viruses in publicly accessible data banks in a timely manner.

Any national influenza centre and other laboratory that has information of significant global public health importance should make this information known urgently to WHO and, as soon as possible, publicly available.

- The influenza viruses collected through the WHO Global Influenza Surveillance Network should be shared routinely among the Network's Collaborating Centres and H5 Reference Laboratories in order to facilitate global monitoring of influenza, risk assessment and vaccine development and production, taking all appropriate biosecurity concerns into consideration.

Operational recommendations

Global Influenza Surveillance Network Collaborating Centres and H5 Reference Laboratories should provide candidate influenza vaccine strains to any requesting vaccine producer meeting all applicable regulatory biosafety standards and requirements, for the sole purpose of developing a safe and effective influenza vaccine. Vaccine producers are encouraged to expand production and/or transfer technology in order to increase the supply and availability of influenza vaccines globally.

Any laboratory and/or vaccine producer meeting all applicable regulatory biosafety standards and requirements that wishes to obtain a specific influenza virus for purposes of research or other activity beyond the scope of the WHO Global Influenza Surveillance Network, should submit a request directly to the national influenza centre of the country where the virus was collected. Such requests would be bilateral activities not requiring the intervention of WHO.

- The individual research efforts of Member States should not be adversely affected by their participation in the WHO Global Influenza Surveillance Network.

Operational recommendation

Global Influenza Surveillance Network Collaborating Centres and H5 Reference Laboratories should not initiate any additional research beyond that needed for public health risk assessment or vaccine development without first consulting and seeking the agreement of the national influenza centre concerned. The same applies to the preparation of manuscripts on such additional research.

- Global surveillance of influenza should be a cooperative, voluntary public health activity of Member States in order to strengthen global health security and is not a profit-making activity.

Operational recommendations

No national influenza centre laboratory, Global Influenza Surveillance Collaborating Centre or H5 Reference Laboratory should charge fees or sell influenza viruses or strains or in any way seek to profit from participation in the WHO Global Influenza Surveillance Network, although such laboratories and centres may seek to recover the costs of shipping, handling or storage or other direct administrative overheads.

No national influenza centre laboratory, Global Influenza Surveillance Collaborating Centre or H5 Reference Laboratory should impose agreements or administrative procedures that may inhibit the proper functioning of the WHO Global Influenza Surveillance Network, including in particular the timely sharing of material and information and the achievement of the Network's objectives.

- The technological benefits of participation in the WHO Global Influenza Surveillance Network, including improved access to vaccines, should be available to all countries.

Operational recommendations

Member States with vaccine-manufacturing capacity and access to influenza vaccine supplies and advanced technologies relevant to protection against influenza should make specific efforts to share these benefits with Member States that do not have those capacities.

Member States should promote increased availability of, and access to, safe influenza vaccines worldwide by actively supporting the implementation of the Global Pandemic Influenza Action Plan to Increase Vaccine Supply,¹ which aims to improve influenza vaccines through research, to increase global vaccine supply, to expand vaccine-manufacturing capacity globally, and particularly to make influenza vaccines available in areas where currently this capacity is lacking or insufficient.

¹ Document WHO/IVB/06.13 – WHO/CDS/EPR/GIP/2006.1.