United States Government Feedback for the 2016 Pandemic Influenza Preparedness Framework Review

Nagoya Protocol and Genetic Sequence Data

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The United States thanks the Director-General, the Pandemic Influenza Preparedness (PIP) Framework Secretariat and the members of the PIP Framework Review Group for the opportunity to provide input. The United States maintains its commitment to global influenza preparedness and response through implementation of the PIP Framework and encourages WHO's continued prioritization of pandemic influenza. In addition to previous written comments provided throughout the review process, the United States is providing feedback to specific findings which require further consideration and/or clarification. We look forward to the opportunity to review the Review Group's full findings report.

Nagoya Protocol

The United States does not consider the Nagoya Protocol to the Convention on Biological Diversity to be applicable to either influenza viruses with pandemic potential or seasonal influenza viruses. There should not be any conflict between the Nagoya Protocol and issues related to public health. The objective of the Nagoya Protocol "is the fair and equitable sharing of benefits arising from the utilization of genetic resources,…thereby contributing to the conservation and sustainable use of biodiversity." WHO Member States aim to eliminate influenza viruses, not conserve them. The Nagoya Protocol, therefore, does not apply to these viruses. We note that the current system for the development of pandemic and seasonal influenza vaccines is very time-sensitive. If the Nagoya Protocol were interpreted to apply to influenza viruses necessary for the development of diagnostics, vaccines, or therapeutic responses, the necessary international response to seasonal and pandemic influenza could be delayed and, in particular, could result in sub-optimal influenza vaccines.

Genetic Sequence Data

The PIP Framework should continue to facilitate the rapid and timely collection, curation and sharing of genetic sequence data (GSD) of influenza viruses with human pandemic potential (IVPP). Open, rapid sharing of and access to GSD from currently circulating influenza strains to the WHO's Global Influenza Surveillance and Response System (GISRS) and the broader research community engenders critical benefits for the international community, including: the ability of WHO to monitor the emergence and evolution of variant seasonal viruses and make timely decisions and recommendations on the composition of influenza vaccines, antiviral drug use and molecular diagnostic methods; collaboration opportunities and sharing of research and development results, specifically in the development of novel predictive modeling algorithms

that can facilitate WHO vaccine virus selection; improved risk assessment in candidate virus selection to avoid mismatch; integration of these data sets with other publicly accessible data sets; and a publicly accessible archive for the valuable data generated by GISRS. Benefits of sharing IVPP GSD include use for pandemic risk assessment and pandemic preparedness efforts including the development of sensitive virus detection methods and the generation of candidate vaccine viruses. Additionally, open and timely access to GSD from currently circulating influenza strains provides information directly used to produce licensed recombinant influenza vaccine and could potentially also allow egg- and cell-based vaccine manufacturers to use synthetic genomics to construct candidate vaccine viruses.

Ensuring that the global system has the best technologies at its disposal to analyze viruses and contribute to the production of influenza vaccine remains critical. This includes the data management systems that the GISRS relies upon. The United States encourages the Review Group to explore various avenues of ensuring that the databases upon which GISRS relies are sustainable and resilient, including but not limited to developing standard operating procedures for such databases or potential terms of reference for GISRS-affiliated databases. The United States encourages the Review Group to consider the use of partnership contribution resources for ensuring the sustainability and resilience of such databases, which is an important component of improving global pandemic influenza preparedness and response.

A successful data repository supporting the efforts of the PIP Framework and GISRS requires stable funding and structure and a forward thinking strategy to meet the future needs of GISRS beyond current needs in terms of increases in data volume and complexity and advanced computational tools. To meet GISRS needs for rapid and transparent sharing of GSD, databases would need to support real-time availability of GSD with a comprehensive set of associated and searchable epidemiologic and virologic data. It is also important to make sure that GSD from these data management systems are sufficiently curated and archived so that important historical data is not lost.