

Influenza preparedness

Report by the Director-General

BACKGROUND

1. In March 2019, WHO launched the Global Influenza Strategy 2019–2030.¹ The strategy provides an overarching framework for the Secretariat, Member States and partners to approach influenza preparedness holistically through the establishment and strengthening of capacities to prevent, control and prepare for influenza at the global, regional and national levels.
2. In May 2019, the Seventy-second World Health Assembly adopted decision WHA72(12) on the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. The decision included a request to the Director-General to report on implementation of the decision to the Seventy-third World Health Assembly in 2020 through the 146th session of the Executive Board.
3. This report describes progress in strengthening influenza preparedness, notably the implementation of the Global Influenza Strategy, and in implementing the actions requested in decision WHA72(12).

Strengthening influenza preparedness

4. In 2017, the Secretariat began development of the Global Influenza Strategy 2019–2030, using a broad consultative process with Member States and relevant stakeholders.
5. The Strategy provides four strategic objectives that support the achievement of two high-level outcomes: (1) better global tools for the prevention, detection, control and treatment of influenza; and (2) stronger country capacities such that every country has an evidence-based influenza programme that meets national needs and is integrated within health security and universal health coverage efforts.
6. The Strategy builds on the success of the WHO Global Influenza Surveillance and Response System and other global assets as it integrates broader goals for influenza prevention, control and preparedness for all countries. A core principle of the Strategy is that influenza capacity-building has spill-over benefits for broader health systems strengthening, and preparedness for other infectious disease threats through the International Health Regulations (2005). Countries cannot build new systems

¹ <https://apps.who.int/iris/handle/10665/311184> (accessed 6 December 2019).

at the time of an influenza pandemic or health emergency; overall preparedness can be realized through building routine systems. The Secretariat will finalize the Strategy's indicators of success in 2020.

7. For more than 70 years, the Global Influenza Surveillance and Response System has represented the commitment of Member States to global health. This system serves as the foundation of surveillance, preparedness and response to influenza epidemics and pandemics. It is a global mechanism of alert and response for seasonal, zoonotic and pandemic influenza, and its function has a direct impact on influenza preparedness and response.

8. In June 2019, to begin implementation towards the first high-level outcome of better global tools, the Secretariat hosted a technical consultation on influenza product research and innovation.¹ The consultation allowed the Secretariat and participants from Member States, the private sector, academic institutions and civil society to:

- (a) review the product landscape and current trends in production and use for influenza vaccines, antivirals and other treatments; and
- (b) identify concrete actions and opportunities for WHO and partners to accelerate research and innovation for better global tools.

9. To support countries in strengthening pandemic preparedness, the Secretariat developed a package of tools for use by countries in developing and updating their national influenza pandemic preparedness plans and in conducting simulation exercises.²

10. In 2020, the Secretariat will host a consultation dedicated to the second high-level outcome of stronger country capacities. The consultation will identify opportunities and challenges for the strengthening of capacities for influenza surveillance, monitoring and data utilization; seasonal influenza prevention and control; and pandemic influenza preparedness and response.

Implementing decision WHA72(12)

11. In order to update Member States and relevant stakeholders on progress in implementing decision WHA72(12), a webinar was held on 7 October 2019. A recording of the webinar, along with an electronic copy of the slides presented, is available online.³ An information session on implementation of the decision was held on 1 November 2019.

Operative paragraph 1(a): Data and analysis related to influenza virus sharing

12. The Health Assembly requested the Director-General to work with the Global Influenza Surveillance and Response System and other partners, such as Other authorized laboratories and relevant institutions, to collect, analyse and present data on influenza virus sharing in a way that enables a deeper understanding of the challenges, opportunities and implications for public health associated with virus

¹ The meeting report is available at: <https://apps.who.int/iris/bitstream/handle/10665/328444/WHO-WHE-IHM-IPR-2019.1-eng.pdf> (accessed 31 October 2019).

² The package of tools is available at: <https://www.who.int/influenza/preparedness/en/> (accessed 31 October 2019).

³ <https://www.who.int/influenza/pip/governance/webinar-7Oct2019/en/> (accessed 31 October 2019).

sharing under the Global Influenza Surveillance and Response System, including by identifying specific instances where influenza virus sharing has been hindered, and how such instances may be mitigated.

13. The Secretariat is aware of four specific instances to date in which national regulation, legislation or other administrative measures have had an impact on virus sharing or other aspects of the work of the Global Influenza Surveillance and Response System. Two instances were described in the report of the analysis implementing decision WHA70(10) (2017).¹ These are summarized below.

14. In the first instance, a National Influenza Centre in the Global Influenza Surveillance and Response System network informed the WHO Collaborating Centre for Influenza that, due to national legislation related to implementation of the Nagoya Protocol, the WHO Collaborating Centre would need to satisfy certain requirements before the seasonal influenza viruses could be shipped. These requirements prevented the sharing of the viruses with the WHO Collaborating Centre in time for the September 2018 vaccine composition meeting for the 2019 southern hemisphere influenza season. A bilateral solution was reached after approximately 5–6 months which allowed the viruses to be shared in time for the next virus sharing meeting, in February 2019.

15. The second instance relates to an influenza virus shared with the Global Influenza Surveillance and Response System by a party to the Nagoya Protocol. This virus was subsequently developed into a candidate vaccine virus for inclusion in vaccines for the 2019 southern hemisphere influenza season. There was a lack of clarity among vaccine manufacturers over what procedures would be necessary to comply with national legislation related to the Nagoya Protocol in the country where the virus originated. Additional procedures, such as obtaining a registration number for use of the virus, required additional time and created uncertainties at the beginning of a time-sensitive process.

16. In addition, the Secretariat has become aware of two additional instances.

17. The first additional instance relates to two National Influenza Centres hosted by a country that is not a party to the Nagoya Protocol, but that has put into place domestic access and benefit-sharing legislation. These National Influenza Centres informed the WHO Collaborating Centre that under their national legislation, a material transfer agreement needed to be concluded before they could ship seasonal influenza viruses to the WHO Collaborating Centre. The matter was resolved when a material transfer agreement was concluded between each National Influenza Centre and the WHO Collaborating Centre. Each agreement took approximately 7.5 to 8 months to execute.

18. The most recent instance, originating in August 2019, relates to a National Influenza Centre hosted by a party to the Nagoya Protocol. The National Influenza Centre requested that a material transfer agreement be signed in order to enable the shipment of seasonal influenza virus to a WHO Collaborating Centre. The execution of the agreement is pending.

19. These four instances known to WHO to date provide evidence of some of the effects of national regulation, legislation or other administrative measures on influenza virus sharing in four countries across three WHO regions. Additional instances were reported during an information meeting in connection with the southern hemisphere influenza vaccine composition meeting in late September

¹ Approaches to seasonal influenza and genetic sequence data under the PIP Framework. Analysis. Annex 2. Geneva: World Health Organization; 2018 (https://www.who.int/influenza/pip/WHA70108b_Analysis.pdf, accessed 31 October 2019).

2019. A systematic approach is now needed to gather comprehensive information about these and other such instances that are arising.

20. To that end, the Secretariat will work in close collaboration with the Global Influenza Surveillance and Response System to gather information, using appropriate tools and mechanisms – including a questionnaire to Global Influenza Surveillance and Response System laboratories and relevant partners – to allow a thorough analysis and presentation of data on influenza virus sharing under the Global Influenza Surveillance and Response System in a way that enables a deeper understanding of the challenges, opportunities and implications for public health, including identifying specific instances where influenza virus sharing has been hindered and how such instances may be mitigated.

Operative paragraph 1(b): Legislation and regulations related to influenza virus sharing

21. The Health Assembly requested the Director-General to prepare a report, with inputs from Member States and stakeholders, as appropriate, on the treatment of influenza virus sharing and the public health considerations thereof by existing relevant legislation and regulatory measures, including those implementing the Nagoya Protocol, in consultation with the Secretariat of the Convention on Biological Diversity as appropriate.

22. To address this request, the Secretariat will, in consultation with the Secretariat of the Convention on Biological Diversity:

- (a) conduct a desk review of available existing legislation and regulations that may impact the sharing of influenza viruses, including by using information available on the Convention on Biological Diversity Access and Benefit-Sharing Clearing-House; and

- (b) based on the desk review, prepare a document summarizing the key components of available national legislation or regulatory measures that are relevant to influenza virus sharing and the public health considerations thereof.

23. A pilot of the desk review, covering 10 countries, has been completed. The methodology for the desk review was reviewed and updated to take into account lessons learned from the pilot.

Operative paragraph 1(c): Functioning, usefulness and limitations of search engine

24. The Health Assembly requested the Director-General to provide more information on the functioning, usefulness and limitations of the prototype search engine.

25. In this regard, the Secretariat will collaborate closely with relevant partners to provide more information on three key aspects of the prototype search engine: (1) functioning, including which databases are searched, the search terms used, how data are processed and presented, and who owns the data; (2) usefulness, including results obtained from piloting the search engine to identify uses of genetic sequence data from influenza viruses with pandemic potential and how information generated could potentially be used in the future; and (3) limitations, including information and data that cannot be obtained from the search engine, such as information for monitoring access to genetic sequence data at the point where the data are distributed, and where human intervention is needed.

Operative paragraph 1(d): Databases and initiatives, data providers and data users

26. The Health Assembly requested that the Director-General explore, including through soliciting input from Member States, possible next steps in raising awareness of the PIP Framework among relevant databases and initiatives, data providers and data users, and in promoting the acknowledgment of data providers and collaboration between data providers and data users.

27. In response, the Secretariat will gather information from Member States and relevant stakeholders to identify possible next steps to raise awareness, building on previous work done by the PIP Framework Advisory Group. The results of this information gathering will form the basis of a report on possible next steps in raising awareness of the PIP Framework and in promoting acknowledgment of data providers and collaboration between data providers and data users.

Operative paragraph 1(e): New developments

28. The Health Assembly requested the Director-General to continue providing information on new challenges posed and opportunities provided by new technologies in the context of the PIP Framework for the sharing of influenza viruses and access to vaccines and other benefits and possible approaches to them.

29. Since the Health Assembly in May, the Secretariat has organized several events to advance its work to harness the challenges and opportunities presented by new technologies. In June 2019, WHO held a technical consultation on better global tools: product research and innovation for influenza prevention control and treatment and organized an internal seminar on universal influenza vaccine.

30. The Secretariat plans to collect information on new developments from all three levels of the Organization and will continue to share such information.

Operative paragraph 2: Amendment to Annex 2, Footnote 1 of the PIP Framework

31. The Health Assembly decided to revise Footnote 1 in the Standard Material Transfer Agreement 2, in Annex 2 of the PIP Framework with effect from the closure of the Seventy-second World Health Assembly.

32. The Secretariat has taken the following steps to implement this decision.

(a) In 2011, following adoption of the PIP Framework, WHO developed a notice to be included with all shipments of PIP Biological Materials to alert recipients that acceptance of such materials would trigger benefit-sharing obligations under the PIP Framework. The document has been revised to alert recipients of the amendment. The revised shipping notice is in use as of 1 November 2019 and is available online.¹

(b) Templates for the three categories of the Standard Material Transfer Agreement 2 have been updated and signatories of existing agreements are being contacted to inform them of the amendment and its applicability to their agreement.

¹ https://www.who.int/influenza/pip/smta2/PIPBm_ShipNotice_Oct2019.pdf (accessed 29 November 2019).

(c) The Secretariat is in the process of publishing an updated edition of *Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*. It is anticipated that the new edition will be available in all official WHO languages by the end of 2019.

(d) The PIP webpage has been updated to inform stakeholders of the amendment.

ACTION BY THE EXECUTIVE BOARD

33. The Executive Board is invited to note this report. In its discussions, the Board may wish to focus on:

- suggestions for further sensitizing Member States to the importance of timely influenza virus sharing;
- ways to promote influenza prevention and control strategies, including through the use of seasonal vaccination.

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