

2016 PIP Framework Review Group Recommendations - Draft Implementation Tracking Tool, as of 1 October 2018

This tracking tool reports on WHO's work to implement Decision WHA70(10) (2017) which requests the Director-General, *inter alia* , to "take forward expeditiously the recommendations of the PIP Framework Review Group's report. It is a living document, which will be updated as necessary.

Rec #	2016 PIP Framework Review Group Recommendation	Responsible	Implementation Status & Actions Taken or Planned by WHO to Implement the Recommendation
Overarching			
#1	WHO should develop a comprehensive evaluation model (CEM), including overall success metrics for the Pandemic Influenza Preparedness (PIP) Framework for annual reporting. Such reporting should include an infographic that illustrates the status of overall progress in implementing the PIP Framework to allow for greater clarity on progress towards pandemic preparedness and response.	WHO	Implementation in progress. <i>Completed actions:</i> 1) A model for reporting semi-annually and annually on implementation of all elements of the PIP Framework was developed; the first such report was published in September 2018. 2) The PIP Framework was added as a <i>Special Global Project</i> in the WHO Programme Budget Web Portal (see: http://open.who.int/2018-19/our-work/category/20/about/about). <i>Actions that are planned or in progress:</i> 1) At its October 2018 meeting, the Advisory Group will consider whether the semi-annual progress reports, combined with WHO Programme Budget Web Portal reporting, satisfy the intent of the CEM.
#2	WHO should regularly and more effectively communicate the objectives and progress in the implementation of the PIP Framework to Members States, Global Influenza Surveillance and Response System (GISRS) laboratories, industry, civil society, and other stakeholders. In particular, it should better communicate:	WHO	Implementation in progress. See Recommendation 2(a)-2(d), below.
	a) Progress against the comprehensive evaluation model;	WHO	Implementation in progress. See Recommendation 1.
	b) Partnership Contribution implementation measures; these should be highlighted in regular Advisory Group reports and post-meeting briefings so that progress is more visible and clearly recognized;	WHO	Implementation completed. <i>Completed actions:</i> 1) PIP Framework Implementation is now reported under the WHO Programme Budget Web Portal. This is the WHO corporate tool most commonly used by WHO stakeholders. 2) The Secretariat has developed a semi-annual report, which will provide information on implementation of all PIP Framework elements, including milestones (activity level), and will provide linkages between financial progress and deliverables. 3) A regular feature of the bi-monthly PIP Framework newsletter is PC stories from the field. 4) Reports of the PIP AG now more systematically highlight PC activities and achievements.
	c) Communication and transparency should be enhanced around issues such as selection of countries to receive Partnership Contribution implementation support for improved understanding of the PIP Framework among Member States;	WHO	Implementation completed. <i>Completed actions:</i> 1) An independent group of 8 experts was convened to review and provide scientific and technical guidance and advice to support, improve and finalize the PC funded work plans. This group, the Partnership Contribution Implementation Technical Expert Mechanism (PCITEM) held its first meeting in October 2017. 2) PC implementation was also highlighted in the March 2017 PIP AG meeting report, as well as the PC Annual Report, published in 2017. 3) Broad consultations were held as part of the process of developing High-level Implementation Plan II. These included consultations on country selection criteria.
	d) The significance of stakeholder voluntary contributions, and in-kind Member States' commitments, including support and maintenance of GISRS through provision of routine running costs of laboratories.	WHO	Implementation in progress. <i>Actions that are planned or in progress:</i> 1) The Secretariat is working to develop options to showcase Member State financial and other support of GISRS.

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#3	The Director-General should undertake a study to determine the implications and desirability of including seasonal influenza viruses in the PIP Framework.	WHO	<p>Implementation in progress.</p> <p>The 70th World Health Assembly adopted decision WHA70(10) which, <i>inter alia</i>, requested the Director-General to undertake a study to determine, <i>inter alia</i>, the implications of including or not including, seasonal influenza viruses in the Framework.</p> <p><i>Completed actions:</i></p> <p>1) A Scoping Paper and supporting evidence, was developed and published in October 2017;</p> <p>2) A Consultation with Member States and stakeholders was held 6-7 November 2017;</p> <p>3) An Information Session with Member States and stakeholders was held 10 April 2018;</p> <p>4) A draft Analysis, translated into all WHO official languages, along with supporting Fact Sheets, was developed with support from the PIP Advisory Group and WHO GISRS CC and ERL Directors, and published in September 2018;</p> <p><i>Actions that are planned or in progress:</i></p> <p>1) Member State and stakeholders will convene for a consultation on the draft Analysis, 15-16 October 2018.</p> <p>2) The final text of the Analysis will be submitted to WHA72 (May 2019) through EB144, as requested in decision WHA71(11).</p>
#4	The PIP Framework is a foundational model of reciprocity for global public health that could be applied to other pathogens; however, the current scope of the PIP Framework should remain focused on pandemic influenza at this time.	WHO	Recommendation was noted.
#5	Member States should agree the timing of the next review of the PIP Framework, which should be before the end of 2021.	Member States	To be considered by Member States.
Virus Sharing			
#6	The Review Group welcomes the PIP Framework Secretariat's study of the reasons for the recent decline in the sharing of influenza viruses with human pandemic potential. The Advisory Group should, as a priority, follow-up on the results of this study in order to ensure the timely sharing of all viruses.	PIP Advisory Group; WHO	<p>Implementation in progress.</p> <p><i>Completed action:</i></p> <p>1) WHO, in close collaboraiton with WHO GISRS CCs, developed and published <i>Operational Guidance on Sharing Influenza Viruses with Human Pandemic Potential (IVPP) under the Pandemic Influenza Preparedness (PIP) Framework</i> (see: http://apps.who.int/iris/bitstream/handle/10665/259402/WHO-WHE-IHM-GIP-2017.3-eng.pdf;jsessionid=DA50F28EA66C62062D36333315930910?sequence=1). Implementation began 1 July 2017.</p> <p>2) Compliance with the <i>Guidance</i> is an indicator in HLIP II.</p>
#7	Given the recent decline in the sharing of influenza viruses with human pandemic potential, WHO should continue to provide technical operational guidance and training for National Influenza Centres to ensure that they are fully aware of their roles as agreed in the Standard Material Transfer Agreement 1, the effective use of the Influenza Virus Traceability Mechanism, and the importance of appropriate sharing of all PIP biological materials and genetic sequence data.	WHO/GISRS	<p>Implementation in progress.</p> <p><i>Completed action:</i></p> <p>See Recommendation 6.</p> <p><i>Actions that are planned or in progress:</i></p> <p>1) A comprehensive revision of IVTM is under way. Release of IVTM 2.0 is planned in early 2019.</p> <p>2) A non-technical brochure to be used as an awareness-raising tool for the <i>Guidance</i> (see Recommendation 6) is under development. Publication of the English version on the WHO website is planned.</p>
#8	WHO should provide clarification to GISRS laboratories on the interpretation of the terms "timely" and "as feasible" with respect to the sharing of PIP biological materials from all cases of A(H5N1) and other influenza viruses with human pandemic potential (section 5.1.1 of the PIP Framework).	PIP Advisory Group; WHO; GISRS	<p>Implementation completed.</p> <p><i>Completed action:</i></p> <p>1) The <i>Guidance</i> (see Recommendation 6) clarifies the terms "timely" and "as feasible".</p>
#9	Although genetic sequence data do not fully substitute for the physical virus, in cases where it is not possible to ship PIP biological materials rapidly, genetic sequence data should, if available, be shared immediately.	PIP AG; GISRS; WHO	<p>Implementation completed.</p> <p><i>Completed action:</i></p> <p>1) The <i>Guidance</i> (see Recommendation 6) addresses the sharing of GSD.</p>

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#10	The WHO Global Influenza Programme should strengthen contacts and linkages with, and processes between, the GISRS system and non-GISRS laboratories and other networks.	WHO; GISRS	Implementation completed. <i>Completed actions:</i> 1) National labs not part of GISRS have been invited to participate in several activities, e.g. annual EQAP, training workshops, reagents, etc. 2) Linkages have been established with labs of excellence in research academia with specific expertise in areas such risk assessment. 3) Linkages have been established with other networks, e.g. OFFLU & the respiratory syncytial virus (RSV) community on influenza surveillance and response, and efforts have been made to use the GISRS platform for other diseases of public health significance.
#11	WHO, GISRS, the Food and Agricultural Organization of the United Nations, the World Organization for Animal Health, the OFFLU and others should collaboratively establish guidance for GISRS and animal laboratories to strengthen their relationships and enhance surveillance and risk assessment of influenza viruses at the animal-human interface.	WHO with GISRS; UN Food and Agriculture Organization; World Organisation for Animal Health; OFFLU and others	Implementation completed. <i>Completed actions:</i> 1) OFFLU representatives are invited to the WHO Working Group Meeting on polymerase chain reaction (PCR) and next-generation sequencing (NGS) to coordinate lab diagnostics. 2) Risk assessment of zoonotic outbreaks are conducted jointly and communications are coordinated. 3) FAO and OIE contribute twice a year to vaccine composition recommendations, in particular on the update of zoonotic influenza vaccine viruses.
Genetic Sequence Data			
#12	The Director-General should request Member States to consider amending the definition of PIP biological materials in section 4.1 of the PIP Framework to include genetic sequence data.	Member States; WHO	Implementation in progress. The 70th World Health Assembly adopted decision WHA70(10) which, <i>inter alia</i> , requested the Director-General to undertake a study to determine, <i>inter alia</i> , the implications of including or not including, genetic sequence data in the definition of PIP biological materials (PIP Framework section 4.1). Actions to address this and other GSD-related recommendations are covered under Recommendation 3.
#13	The Director-General should request Member States to consider clarifying Annex 4, section 9, which currently states that “The WHO GISRS laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement”, by amending it to: “The WHO GISRS laboratories will submit genetic sequences data to one or more publicly accessible database of their choice in a timely manner consistent with the Standard Material Transfer Agreement”.		
#14	The Director-General should request Member States to consider updating and correcting the statement in section 5.2.2 of the PIP Framework, which currently states “Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and there is a movement towards the use of public-domain or public-access databases such as Genbank and GISAID respectively;” by amending it to: “Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and use is made of public-domain or public-access databases such as GenBank and/or GISAID, respectively;”		
#15	It is critical that the PIP Framework adapts to technological developments, and that the Advisory Group produces with urgency recommendations to clarify the handling of genetic sequence data. The Advisory Group should consider asking WHO Collaborating Centres to report on how genetic sequence data are actually handled, with a view to providing information about the operational realities in GISRS in relation to the acquisition, sharing and use of such data, to inform the Advisory Group’s recommendations on the optimal handling of genetic sequence data under the PIP Framework.	PIP Advisory Group	
#16	The Director-General should enlist the support of Member States to ensure that influenza virus genetic sequence data remain publicly accessible in sustainable databases, to enable timely, accurate and accessible sharing of these data for pandemic risk assessment and rapid response.	WHO; Member States	
#17	Noting that genetic sequence data may be generated from many entities outside of GISRS, and that there are diverse views on the optimal traceability and monitoring mechanism, the Advisory Group should give consideration to broadening and deepening engagement with all stakeholders.	PIP Advisory Group	

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Standard Material Transfer Agreements 2			
#18	The PIP Framework Secretariat should improve communication of progress and achievements in securing SMTA2s by better highlighting the rationale and prioritization strategy for concluding these agreements, and clarifying the intended use of the antivirals, vaccines and other products secured through these agreements.	WHO	Implementation in progress. <i>Completed actions:</i> 1) SMTA2 is an Output level indicator in the WHO Programme Budget Web Portal. 2) The PIP Framework webpage was updated to showcase the number of vaccine, antiviral, diagnostics and other pandemic influenza response products, secured by WHO through legally binding SMTAs2. 3) An internal, cross-Cluster/cross-Departmental meeting was held in April 2018 to analyze the state of pandemic vaccine deployment readiness. 4) The PIP webpage was updated to clarify the strategy that was used to approach negotiations with influenza vaccine manufacturers. <i>Actions that are planned or in progress:</i> 1) Identify key steps to operationalize SMTA2 vaccine supply commitments.
#19	The PIP Framework Secretariat should develop, for consideration by the Advisory Group, and ultimate decision-making by Member States, an approach to include the provision of financial contributions, specimen collection and processing materials as options for category B SMTA2 commitments in Annex 2.	Member States; PIP Advisory Group; WHO	Implementation in progress <i>Completed actions:</i> 1) The SMTA2 template for Category B companies was adapted. 2) Benefit-sharing options for Category B manufacturers were developed based on anticipated needs at the time of pandemic response, and presented to the PIP AG for provided discussion and feedback. 3) An approach to handle benefit sharing from veterinary manufacturers that use PIP BM was presented to the PIP AG for discussion and feedback. <i>Actions that are planned or in progress:</i> 1) Approach Category B companies to conclude SMTAs2 that secure benefits other than diagnostic kits.
#20	The Director-General should consider requesting that Member States remove section 6.9 in the PIP Framework on pandemic influenza preparedness vaccine stockpiles, since it is no longer relevant.	WHO; Member States	Recommendation was noted Member States have not yet taken action on this item.
#21	The Director-General should request Member States with in-country vaccine production capacity to commit to allow manufacturers to release to WHO on a real-time basis, pandemic vaccines and other products secured by WHO under SMTA2s.	WHO; Member States	Recommendation was noted The Director-General will continue to remind relevant Member States of their commitments under the PIP Framework.
#22	WHO should rapidly finalize and communicate the Interim Pandemic Influenza Risk Management (PIRM) Framework, which will provide clarity on the implementation of the switch from seasonal to pandemic vaccine production.	WHO	Implementation in progress <i>Completed action:</i> 1) PIRM was published in May 2017. <i>Action that is planned or in progress:</i> 1) A 4th meeting on the switch from seasonal to pandemic influenza vaccine production is planned for early 2019.
Partnership Contribution Collection			
#23	The Advisory Group should consider updating the 2010 estimate of GISRS running/operating costs, as input to a revision of the Partnership Contribution formula calculation, in collaboration with industry, to facilitate the timely payment of Partnership Contribution, and its sustainability as a financing mechanism for implementation of the PIP Framework.	PIP Advisory Group; WHO	Implementation in progress <i>Actions that are planned or in progress:</i> 1) Options for updating the estimated GISRS running costs have been developed and will be discussed by the PIP AG at its October 2018 meeting. 2) Discussions on the Partnership Contribution formula are ongoing among the four manufacturers' associations and WHO has offered its support.
#24	Given the successful use, following a recommendation by the Advisory Group, of a stepwise approach for the agreement of SMTA2s, the Advisory Group should consider developing a similar escalation response to underpayment, late payment or default of Partnership Contribution.	WHO	Implementation in progress. <i>Completed actions:</i> 1) The Secretariat has developed a stepwise approach that was considered by the PIP AG in April 2018. <i>Actions that are planned or in progress:</i> 1) Revise PC collection SOPs, as necessary. 2) An analysis of the reasons for unpaid contributions from 2013-2017 has been undertaken and will be discussed by the PIP AG at its October 2018 meeting.

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Partnership Contribution Implementation			
#25	The Advisory Group should consider for inclusion in the 2018-2022 Partnership Contribution Implementation Plan, the development of process measures to enable better monitoring of progress for key Areas of Work.	PIP Advisory Group	Implementation completed. <i>Completed actions:</i> 1) Process indicators have been incorporated into HLIP II. 2) A process for global planning meetings has been established. Meetings are scheduled to take place on a yearly basis.
#26	The Advisory Group should request regular financial reports and audits and ensure that appropriate financial accountability mechanisms are in place; it should also request the PIP Framework Secretariat to illustrate how the Partnership Contribution Response funds will be severely inadequate in a pandemic.[1]	WHO; Member States; PIP Advisory Group	Implementation completed. <i>Completed actions:</i> 1) The Audit completed and published along with the Management Response in December 2017. All recommendations of the audit have been implemented. 2) Information on the costs of the A(H1N1) pandemic response, and an analysis of their likely insufficiency, were presented to the PIP AG in Nov 2017
Governance			
#27	The Director-General should consider options for retaining continuity and knowledge in the Advisory Group, including members being able to serve a second term of flexible duration.	WHO	Implementation completed. <i>Completed action:</i> 1) All outgoing AG Members are now offered a second term of flexible duration.
#28	The structure of the Advisory Group's Annual Reports to the Director-General and the Director-General's Biennial Reports to the World Health Assembly should be harmonized to simplify reporting.	PIP Advisory Group	Implementation completed. <i>Completed action:</i> 1) After discussion, the PIP AG agreed to maintain the current reporting system.
#29	The PIP Framework Secretariat and Advisory Group should broaden and deepen engagement with civil society to a greater number of participating organizations.	WHO; PIP Advisory Group	Implementation completed. <i>Completed actions:</i> 1) The Secretariat undertook a canvassing of all potentially interested CSOs and developed a comprehensive listing that included 197 organizations. All were invited to a virtual information session on the PIP Framework. 5 CSOs joined. 2) Following the information session, all CSOs in the listing are now invited to participate in the regular bi-monthly call with the PIP Framework Secretariat.
#30	Noting the critical role of the WHO Collaborating Centres in the GISRS network, the Advisory Group should undertake more regular engagement with the WHO Collaborating Centres and other key GISRS laboratories, including when setting up technical working groups.	PIP Advisory Group	Implementation completed. <i>Completed action:</i> 1) An arrangement for GISRS representation at PIP Framework meetings was agreed in Oct 2017. Starting in Nov 2017, GISRS representatives have participated in relevant technical sessions of all AG meetings.
#31	The Director-General should address the issue of the lack of a formalized representation for the GISRS network, and encourage the WHO Global Influenza Programme and GISRS to establish such representation as soon as possible.	WHO	Implementation completed. <i>See recommendation 30, above.</i>
#32	The Director-General should ensure that any internal reorganization of WHO departments under the new Health Emergencies Programmes should ensure that the activities of GISRS and the PIP Framework remain closely aligned and integrated with the WHO Global Influenza Programme to ensure stronger scientific and technical leadership in the implementation of the PIP Framework.	WHO	Implementation completed. <i>Completed action:</i> 1) A new Influenza Preparedness & Response (IPR) unit was established within the Department of Infectious Hazard Management, in the WHO Health Emergencies Programme. IPR brings together two groups: the Global Influenza Programme and the PIP Framework Secretariat. The Chief of IPR was appointed and assumed functions in Aug 2017.
#33	The Director-General should continue to make available the necessary human and financial resources to implement the growing activities of the PIP Framework and the Recommendations of this Review.	WHO	Implementation completed. <i>Completed action:</i> 1) In April 2018, the PIP AG recommended that 10% of invoiced PC (a minimum of US\$ 2.8M annually) be directed to the PIP Secretariat for the period of HLIP II.
Linkages - Global Action Plan for Influenza Vaccines			
#34	The PIP Framework Advisory Group should consider lessons learned from the Global Action Plan for Influenza Vaccines (GAP), which closes in November 2016, to identify any aspects that would support implementation of the PIP Framework.	PIP Advisory Group	Implementation completed. <i>Completed action:</i> 1) HLIP II includes work on vaccine hesitancy and establishment of a vaccine production help desk.

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Linkages - International Health Regulations (2005)			
#35	Activity under the PIP Framework should be undertaken with the provisions of the International Health Regulations (2005) (IHR (2005) in mind, and capacity building efforts should be aligned, supportive and complementary to those under the IHR (2005). This could be addressed by closer interaction at all three levels of WHO regarding implementation of the IHR (2005) and the PIP Framework to maximize synergies and efficiencies.	WHO	Implementation completed. <i>Completed action:</i> 1) HLIP II clearly identifies activities that support IHR core capacity strengthening.
Linkages - Nagoya Protocol to the Convention on Biological Diversity			
#36	The PIP Framework should be considered as a specialized international instrument to clarify the implementation of the Nagoya Protocol in relation to pandemic influenza preparedness and response:	Member States; Parties to the Nagoya Protocol; WHO	Recommendation was noted; action rests with the Parties to the Nagoya Protocol. <i>The following actions have been taken in relation to this matter:</i> 1) A joint Questions and Answers document was prepared with the Secretariats of the CBD, FAO and OIE 2) A workshop on Access and Benefit Sharing in the context of public health was held in Geneva, in collaboration with the CBD Secretariat. <i>The following actions are planned:</i> 1) WHO will continue to collaborate with the CBD Secretariat (and other relevant international organizations) on access to pathogens and fair and equitable sharing of benefits, particularly in the context of public health emergencies 2) WHO plans to participate as an observer in the November 2018 Nagoya Meeting of the Parties.
	- The December 2016 Meeting of the Parties of the Nagoya Protocol provides an opportunity to consider recognizing the PIP Framework as a specialized international instrument for pandemic influenza preparedness and response. In the view of the Review Group, it would serve the aims of the PIP Framework if the Meeting of the Parties took up this opportunity.		Recommendation was noted. 1) WHO participated as an observer to the Meeting of the Parties to the Nagoya Protocol in December 2016 and provided a statement on the potential public health implications of implementation of the Nagoya Protocol. 2) The executive summary of the Secretariat's study on the public health implications of implementation of the Nagoya Protocol was shared as an information document to the Meeting of the Parties.
	- Further, the 2017 World Health Assembly should address the recognition of the PIP Framework as a specialized international instrument under the Nagoya Protocol.		Recommendation was considered by the World Health Assembly. 1) In decision 70(10) the World Health Assembly decided to "reaffirm the importance of the PIP Framework in addressing present or imminent threats to human health from influenza viruses with pandemic potential, and emphasize its critical function as a specialized international instrument that facilitates expeditious access to influenza viruses of human pandemic potential, risk analysis and the expeditious, fair and equitable sharing of vaccines and other benefits."