Pandemic Influenza Preparedness Framework
(“PIP Framework”)
Advisory Group Annual Report to the Director-General
Under PIP Framework Section 7.2.5
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### Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>AVWG</td>
<td>WHO Expert Working Group on Surveillance of Influenza Antiviral Susceptibility</td>
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<tr>
<td>CC</td>
<td>WHO Collaborating Centre of the Global Influenza Surveillance and Response System</td>
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<tr>
<td>CSO</td>
<td>civil society organization</td>
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<tr>
<td>CEM</td>
<td>comprehensive evaluation model</td>
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<td>CVV</td>
<td>candidate vaccine virus</td>
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<td>ERL</td>
<td>WHO Essential Regulatory Laboratory</td>
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<td>EQAP</td>
<td>External Quality Assessment Programme</td>
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<td>GAP</td>
<td>Global Action Plan for Influenza Vaccines</td>
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<td>GISN</td>
<td>WHO Global Influenza Surveillance Network</td>
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<td>GIP</td>
<td>WHO Global Influenza Programme</td>
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<tr>
<td>GISRS</td>
<td>WHO Global Influenza Surveillance and Response System</td>
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<td>GSD</td>
<td>genetic sequence data</td>
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<td>HLIP</td>
<td>High Level Implementation Plan</td>
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<td>HQ</td>
<td>WHO headquarters</td>
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<tr>
<td>ISST</td>
<td>Infectious Substance Shipping Training</td>
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<td>IVPP</td>
<td>influenza viruses with human pandemic potential</td>
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<tr>
<td>IVTM</td>
<td>Influenza Virus Traceability Mechanism</td>
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<tr>
<td>NAI</td>
<td>neuraminidase inhibitor</td>
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<tr>
<td>NIC</td>
<td>National Influenza Centre of the Global Influenza Surveillance and Response System</td>
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<tr>
<td>PC</td>
<td>Partnership Contribution</td>
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<tr>
<td>PC ITEM</td>
<td>PC Independent Technical Expert Mechanism</td>
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<td>PIP</td>
<td>pandemic influenza preparedness</td>
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<td>PIP BM</td>
<td>pandemic influenza preparedness biological material</td>
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<tr>
<td>PCR</td>
<td>polymerase chain reaction</td>
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<tr>
<td>RO</td>
<td>WHO Regional Office</td>
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<tr>
<td>SMTA</td>
<td>Standard Material Transfer Agreement</td>
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<tr>
<td>SWOT</td>
<td>Strengths, Weaknesses, Opportunities and Threats</td>
</tr>
<tr>
<td>TIPRA</td>
<td>Tool for Influenza Pandemic Risk Assessment</td>
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<tr>
<td>TOR</td>
<td>Terms of Reference</td>
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<tr>
<td>TWG</td>
<td>Technical Working Group</td>
</tr>
<tr>
<td>VCM</td>
<td>WHO biannual vaccine composition consultation meetings</td>
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<td>WHA</td>
<td>World Health Assembly</td>
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<td>WHO</td>
<td>World Health Organization</td>
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EXECUTIVE SUMMARY

1. The Pandemic Influenza Preparedness Framework (the “PIP Framework” or “Framework”) was adopted by Member States in 2011 to help ensure that the global community is ready to respond to the next pandemic. The central tenant of the Framework – that sharing of influenza viruses with human pandemic potential must be balanced with the sharing of benefits on equal footing – steers the work of an array of diverse stakeholders, including Member States, industry and civil society.

2. Each year the PIP Advisory Group submits a report to the Director-General on its evaluation of the implementation of the Framework. This year’s report covers 1 September 2016 through 31 August 2017.

3. It has been a busy and eventful year. Of particular note:

- The first Partnership Contribution (PC) High Level Implementation Plan (HLIP I) which defined a programme of work to increase global preparedness in five Areas of Work -- laboratory and surveillance, knowledge of influenza disease burden, regulatory preparedness, risk communications and planning for deployment -- is drawing to a close. A second five-year PC High Level Implementation Plan (HLIP II) will roll out in 2018, setting a course for the next five years.

- In 2016, an independent group of experts (the “PIP Review Group”) undertook a comprehensive review of the first five years of implementation of the PIP Framework. The 70th World Health Assembly subsequently requested the Director-General to take forward their recommendations. Work is ongoing to do this as expeditiously as possible. A plan to implement these recommendations has been developed.

- The 2017 Berlin Declaration of the G20 Health Ministers recognized both the Global Influenza Surveillance and Response System (GISRS) and the PIP Framework as indispensable global assets in preparing for the next influenza pandemic.¹

4. Our report provides a synopsis of accomplishments and challenges toward realizing the goal of pandemic preparedness achieved through an equitable sharing of viruses and benefits. Progress is palpable reflecting the combined and enthusiastic efforts of the World Health Organization (WHO), Member States, industry, civil society and other stakeholders. Continued progress, however, will be dependent on heeding the lessons learnt from the first six years of implementation as well as addressing persistent challenges – many of which were underlined in the Report of the PIP Review Group.

1.1 Virus sharing: key findings

5. From 1 September 2016 to 31 August 2017, 177 IVPP from 10 countries, Areas and Territories (Annex 2) were shared with WHO CCs compared to 87 IVPPs from four countries in the same period last year. In addition, to improve sharing of IVPP, GIP developed operational guidance for NICs and other national authorized laboratories which has been in effect as from 1 July 2017.

6. The number of countries consistently reporting epidemiological data through FluID and virological data through FluNet has steadily increased and now exceeds the PIP PC established targets.

7. In both 2016 and 2017, 87% of laboratories participating in WHO’s external quality assessment programme (EQAP) correctly identified 100% of all the influenza virus samples provided in the test panel – an improvement compared to recent previous years. Improvements in the proportion of participants correctly identifying 100% of the H5 and H7 viruses in the panel also were observed (Annex 2).

8. A review process of all National Influenza Centres (NICs) has begun, in compliance with the updated NICs TORs, in collaboration with the WHO regional offices. It is possible that some inactive NICs, most of which were designated in the earlier days of the 65-year old GISRS, may be discontinued.

9. The Tool for Influenza Pandemic Risk Assessment (TIPRA) has been used to assess the precursor of the A(H1N1) 2009 pandemic virus, H5N6, H7N9, and H9N2. Among those assessed, A(H7N9) is estimated to have the highest likelihood of sustained human-to-human transmission with an impact on public health comparable to that of A(H5N6), should either become transmissible among humans.

1.2 Benefit sharing: key findings

10. The conclusion of 11 Standard Material Transfer Agreements 2 with vaccine and antiviral manufacturers, including with all the large multinational companies and six of seven companies with a prequalified influenza vaccine, which vary in size from large multinationals to medium sized companies, will allow WHO to access approximately 400 million doses of vaccine at the time of the next pandemic. This is four times the amount of vaccine that was available to WHO during the 2009 pandemic. Concluding agreements with diagnostic manufacturers is proving more elusive due in part to a restructuring of the diagnostics industry.

11. Since 2013, ≥90% of the annual PC of US$ 28 M has been collected. However, the loss or delay in receipt of one large payment (as happened in 2016) can result in a significant shortfall with the potential to affect PC implementation activities.

12. Approximately US$ 43.8 million in PC funds, including approximately US$ 17.1 million in 2016, have been spent to support activities across five different Areas of Work. In all five areas, progress towards meeting targets in the HLIP I is on track.

13. Much of the last 12 months has been spent developing the HLIP II through a highly collaborative process involving all levels of WHO and external stakeholders. Its development was guided by the findings from various processes including the 2016 PIP Review, an analysis of gaps and needs and an independent external evaluation of HLIP I. A collaborative and consultative process then followed to design and develop the draft HLIP II. The HLIP II will promote synergies between the PIP Framework, the International Health Regulations (2005) and the experience and lessons learned
from the Global Action Plan for Influenza Vaccines. HLIP II includes an additional area of work, Influenza Pandemic Preparedness Planning, bringing the total number of areas of work to 6.

1.3 Governance: key findings

14. The Advisory Group is committed to providing its expertise and experience to assist the Director-General in taking forward decision WHA70(10). The decision specifically cites the role of the PIP Advisory Group in paragraph (8)(b) regarding the analysis of issues raised in connection with the PIP Framework Review Group’s recommendations concerning seasonal influenza and genetic sequence data. The overall recommendations of the Review Group also identify key roles for the AG going forward.

15. Effective communication with Members States, GISRS laboratories, industry, civil society, and other stakeholders continues to be a persistent challenge. Processes to develop the HLIP II and to implement WHA70(10)(8(a) and (b) have included different modalities of communication with stakeholders. The Global Influenza Programme has drafted a formalized procedural approach for representation of the GISRS at Advisory Group meetings; starting in November 2017, three GISRS representatives will participate in relevant technical sessions of Advisory Group meetings.

16. Consistent with a PIP Review Group recommendation,\(^2\) reporting of success metrics for the PIP Framework, including the Advisory Group’s Annual Report, will move to a “comprehensive evaluation model” next year in an effort to join up several lines of reporting and make information more accessible.

17. Based on the findings of the 2016 PIP Review, the Director-General decided to offer a second consecutive term to each member of the Advisory Group to enhance institutional memory and stability.

1. INTRODUCTION

1. Influenza pandemics – unpredictable in their occurrence – are sobering reminders of the necessity of tireless preparation on the part of governments, industry and civil society. The Pandemic Influenza Preparedness Framework (the “PIP Framework” or “Framework”) was adopted by Member States in 2011 to help ensure that the global community is ready to respond to the next pandemic. At its core the Framework is structured around two objectives which are to be pursued on equal footing: sharing of influenza viruses with human pandemic potential; and access to the benefits that result from the sharing of such viruses, notably vaccines and antiviral medicines.

2. Each year, the PIP Advisory Group submits to the Director-General of the World Health Organization (WHO) a report on its evaluation of the implementation of the PIP Framework.

3. The Framework specifies that the Annual Report include seven topic areas (indexed in Annex 1). The Advisory Group’s findings in these areas are organized into three sections: virus sharing, benefit sharing and governance. This year’s report covers 1 September 2016 through 31 August 2017. Any exceptions to these time frames are noted in the Report.

4. In 2016, an independent group of experts (the “PIP Review Group”) undertook a review of the first five years of implementation of the PIP Framework. In May 2017, the 70th World Health Assembly (WHA) adopted decision WHA70(10). This decision requested the Director-General, inter alia, to take forward expeditiously the recommendations of the PIP Framework Review Group. A plan to implement these recommendations has been developed. The Annual Report updates, when possible, progress in implementing the recommendations of the PIP Review Group.

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1 The seven areas specified in PIP Framework, Section 7.2.5 and Annex 3, Section 2.6 are: necessary technical capacities of the WHO GISRS; operational functioning of WHO GISRS; WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building); increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential; the Influenza Virus Traceability Mechanism; the sharing of influenza viruses and access to vaccines and other benefits; and the use of financial and non-financial contributions.

2 This first review was provided for under section 7.4.2 of the PIP Framework, which states that the PIP Framework and its Annexes should be reviewed by 2016 “with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, through the Executive Board”. The Review Group’s Report can be found at http://apps.who.int/eb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1.

2. VIRUS SHARING

2.1 Global Influenza Surveillance and Response System

Overview

5. The Global Influenza Surveillance and Response System (GISRS) – the WHO-coordinated voluntary surveillance network of public health laboratories which underpins the PIP Framework – marks its 65th anniversary this year. Since 1952, GISRS has grown to a network of 143 institutions in 113 WHO Member States, which are recognized by WHO as National Influenza Centres (NICs); six WHO Collaborating Centres (CCs); four WHO Essential Regulatory Laboratories (ERLs); 13 WHO H5 reference laboratories; and ad hoc groups established to address specific issues. Existing NICs and new possible NICs are being assessed currently with all WHO Regional Offices and the process will continue in 2018.¹

6. Over 200 participants from 98 countries attended a WHO global meeting of NICs in July 2017 in Geneva on the occasion of the 65th anniversary of GISRS (formerly known as the Global Influenza Surveillance Network [GISN] until 2011) in 2017 to review the 65-year path of the global network and plan for the future. Key outcomes included a refreshed trust and collaborative spirit in GISRS; a self-assessment of GISRS preparedness and response capacities; an agreed way forward for the creation of a 5-year GISRS development plan as part of a new initiative to produce a WHO Global Influenza Strategy; and an agreed approach for the representation of the GISRS at PIP Framework Meetings.

7. Updated Terms of Reference (TORs) for NICs have been developed⁵. These updated TORs define activities to serve as a NIC of GISRS to handle seasonal influenza viruses and viruses of pandemic potential. The latter includes IVPP⁶ and non-IVPP e.g. influenza viruses from animal or environmental specimens. TORs that pertain to influenza viruses with human pandemic potential (IVPP) and PIP biological materials (PIP BM) remain as described in Annex 5 of the PIP Framework. Coincident with the development of updated TORs, a review process of all NICs by GISRS and GIP in collaboration with WHO ROs anticipated to continue into 2018; reviews have begun in collaboration with the regional offices in The Americas and Europe. Possible outcome could be the discontinuation of inactive NICs, most of which were designated in earlier days during the past 65 years. The review process will also identify NICs in need of capacity building support to improve their performance to meet the updated TORs during the coming years.

8. As a follow-up to the Advisory Group’s discussions during its October 2016 meeting to interact with GISRS members on a regular basis,⁷ and consistent with a PIP Review Group recommendation,⁸ and the Advisory Group invited GISRS members to participate in its March 2017

⁴ See http://www.who.int/influenza/gisrs_laboratory/en/
⁵ See http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/tor_nic.pdf. These were published 31 Oct 2017.
⁶ IVPP definition is under Section 4 of the PIP Framework.
meeting. Consistent with a PIP Review Group recommendation,9 the Global Influenza Programme (GIP) has coordinated a procedural approach for representation of the GISRS at PIP Framework meetings; starting in November 2017, GISRS representatives will participate in relevant sessions of Advisory Group meetings.

Global Influenza Surveillance and Response System: capacities and functioning

9. The WHO external quality assessment programme (EQAP) is a voluntary programme that assesses the ability of NICs and other national laboratories to detect seasonal and non-seasonal influenza viruses by polymerase chain reaction (PCR). In 2017, 173 laboratories participated. In both 2016 and 2017, 87% of participants correctly identified 100% of all the influenza virus samples provided in the test panel – an improvement compared to recent previous years. Improvements in the proportion of participants correctly identifying 100% of the H5 and H7 viruses in the panel also were observed (see Annex 2 for more detailed information).

10. WHO, in collaboration with the WHO CC in Melbourne, implemented a pilot EQAP programme in the South-East Asia and Pacific Regions in 2016 to assess proficiency for isolation and identification of influenza viruses using egg and/or cell culture techniques. Most of the 21 participating NICs performed well; follow-up training was offered to NICs that under-performed. A second pilot has started in 2017; 29 NICs from the Region of the Americas and the African and Eastern Mediterranean Regions are enrolled.

11. The WHO Expert Working Groups on PCR (PCRWG) and on Surveillance of Influenza Antiviral Susceptibility (AVWG) support GISRS by providing updated and practical guidance to NICs. The WGs meetings produce information products on updated protocols for the detection of influenza viruses using molecular techniques and on neuraminidase inhibitor (NAI) susceptibility testing of seasonal and emerging influenza viruses.10 Although an increasing number of NICs perform NAI susceptibility testing, this specialized capacity varies considerably by WHO region; more than half of the 47 participants in the 2016 EQAP NAI susceptibility testing exercise were from the WHO European Region.11 Future plans call for increased monitoring of antiviral susceptibility among viruses with pandemic potential.

12. The PCRWG and AVWG have published several updates, most recently in 2017 on PCR protocols for the molecular detection of influenza viruses and influenza susceptibility to NAI12. The NAI assay data were generated by five WHO CCs on samples received from GISRS laboratories.

Strengthening surveillance systems

13. Partnership Contribution (PC) resources are being used to strengthen GISRS laboratory and surveillance systems to detect, monitor and report human influenza caused by a new subtype.13

9 Ibid, see Recommendation 31.
12 See http://www.who.int/influenza/gisrs_laboratory/molecular_diagnosis/en/
number of countries consistently\textsuperscript{14} reporting epidemiological data through FluID and virological data through FluNet has steadily increased and now exceeds the PIP PC established targets (Table 1).

14. GISRS activities that have contributed to these increases include improvements in the WHO FluMart platform to facilitate information sharing and usability including linking with regional Platforms; training opportunities for countries in data reporting using the WHO influenza platforms; and engagement and support to regional offices, three of which now have the capacity to manage FluMart users in their region.

Table 1: Countries reporting influenza data to WHO global platforms, 2013-2017

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<tbody>
<tr>
<td>No. of countries reporting (No. reporting consistently)*</td>
<td>FluID (epidemiological data)</td>
<td>64 (59)</td>
<td>66 (64)</td>
<td>77 (64)</td>
</tr>
<tr>
<td>FluNet (virological data)</td>
<td>122 (114)</td>
<td>131 (116)</td>
<td>136 (125)</td>
<td>134 (127)</td>
</tr>
</tbody>
</table>

* Consistently means that a country reports most of the weeks during influenza season(s).

Shipping of influenza viruses and training on infectious substance transport

15. The WHO Shipping Fund Project established in 2005, strengthened and funded through the PIP Partnership Contribution since 2014, provides support for shipment of influenza viruses including both IVPP and unsubtypeable influenza viruses and/or clinical specimens in addition to seasonal influenza viruses. Significant increase in the numbers of countries shipping viruses to WHO CCs was observed in 2015-2016 reporting period and maintained in 2016-2017 reporting period. Similar observation was also obtained on the number of shipments and laboratories shipping viruses (Table 2). The AG noted that the increase in shipments may be due to changes in WHO policy which has increased the number of shipments that can be made under the Fund. They also noted that there are also a larger number of countries sharing which is a clear improvement.

16. The average cost per shipment in 2016-2017 (US$ 1,747 US$; range US$ 627 to US$ 5,479 per shipment) was essentially unchanged compared with 2015-2016 (US$ 1,736). The availability of reliable funding through the PIP PC helps to absorb year-to-year variations in shipping costs.

17. Correct packaging, labelling and shipping documentation are essential for the safety of people and the environment and helps ensure that specimens arrive quickly and in suitable condition for testing. In addition to the GISRS training workshops (Table 2), WHO certified trainers (staff) lead in-person training sessions (WHO ISST)\textsuperscript{15} on the international regulations for the transport of infectious substances and provide access to the WHO Refresher on-line eISST training\textsuperscript{16}.

\textsuperscript{14}Consistently means that a country reports most of the weeks during influenza season(s).

\textsuperscript{15}http://www.who.int/ihr/i_s_shipping_training/en/

\textsuperscript{16}Shipping Infectious Substances - a Refresher Course for Shippers
Table 2: WHO Shipping Fund Project activities, 2013 – 2017

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<tbody>
<tr>
<td>Number of shipments (seasonal viruses and IVPP)</td>
<td>122</td>
<td>118</td>
<td>213</td>
<td>213</td>
</tr>
<tr>
<td>Number of participating countries, areas and territories</td>
<td>73</td>
<td>74</td>
<td>95</td>
<td>97</td>
</tr>
<tr>
<td>Number of participating laboratories</td>
<td>82</td>
<td>83</td>
<td>112</td>
<td>114</td>
</tr>
<tr>
<td>Funds expended (US$)</td>
<td>209,577</td>
<td>192,341</td>
<td>369,783</td>
<td>372,783</td>
</tr>
<tr>
<td>Number of GISRS training workshops on infectious substance transport</td>
<td>2</td>
<td>11</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Number of participants</td>
<td>NA</td>
<td>259</td>
<td>165</td>
<td>115</td>
</tr>
<tr>
<td>Number (%) of participants awarded certificates</td>
<td>NA</td>
<td>205 (79)</td>
<td>139 (84)</td>
<td>92 (80)</td>
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Risk assessment and response

18. Risk assessment is an integral function of GISRS. Timely sharing of representative viruses, genetic sequence information for IVPP and associated epidemiological and clinical information is critical for a complete assessment of the risk posed by these viruses. Assessments of the likelihood of sustained human-to-human transmission of IVPP are conducted and results are published by GIP regularly.17 Twice a year, through the WHO biannual vaccine composition meetings (VCM), a thorough risk assessment based on the characterization of IVPP and associated information available is conducted and published.18 To complement the routine risk assessments, ad-hoc assessments e.g. are conducted as needed, such as the surge in human infections with avian influenza A(H7N9) virus reported by China since October 2016.19

19. In August 2017 WHO summarized the epidemiological and virological features of laboratory-confirmed human cases of infection with non-seasonal influenza viruses of animal origin with onset from January 2015 through to April 2017, including avian influenza A(H5), A(H7) and A(H9N2) and swine-origin viruses.20 Sustained human-to-human transmission was not observed for any virus. The number of reported human infections of A(H5N1) has markedly decreased in recent years.

20. In May 2016 GIP launched the Tool for Influenza Pandemic Risk Assessment (TIPRA) to provide a standardized approach for risk assessment of IVPP. To date, TIPRA has been used to assess the precursor of the A(H1N1) 2009 pandemic virus, H5N6, H7N9, and H9N2. The assessments yielded the following conclusion: “Among those assessed, A(H7N9) is estimated to have the highest likelihood of sustained human-to-human transmission with an impact on public health comparable to that of A(H5N6), should either transmit from human to human.”

Pandemic influenza preparedness through guidelines and best practices

21. In March 2017, WHO published the findings of a second Informal Consultation held in June 2016 on influenza vaccine response during the start of a pandemic. A main focus was to propose solutions to bottlenecks and problems that would interfere with making a timely switch from seasonal to pandemic vaccine. WHO organized small working groups to take these proposals forward. A third Informal Consultation was held in June 2017 to consider the progress of the expert working groups.

22. WHO finalized and published an updated version of its guide on pandemic influenza risk management in May 2017. The main updates include alignment with relevant United Nations policies for crisis and emergency management and strategies for pandemic vaccine response during the start of a pandemic. The guidance stresses the importance of repeated risk assessment at global, national and local levels and provides information on how to assess pandemic influenza severity.

2.2 Influenza Virus Traceability Mechanism

Tracking of PIP biological materials

23. The Influenza Virus Traceability Mechanism (IVTM) is an electronic, internet-based tool used to track the sharing of PIP BM. The initial entry of PIP BM into GISRS, as well as new, modified PIP BM derived from this original PIP BM, are recorded in the IVTM. For example, a single human case specimen yielding wildtype virus can generate multiple modified PIP BM, e.g. reassortants, candidate vaccine viruses (CVVs), and nucleic acids. The transfer of PIP BM to other GISRS laboratories and to external entities, such as manufacturers of vaccines and research and academic institutions, is also recorded in the IVTM, unless the transfer falls under the Operational

21 Ibid.
25 See PIP Framework, Section 4.1 for definition of PIPBM.
24. As of 31 August 2017, a total of 1332 PIP BM (690 original specimens, 573 viruses and 69 nucleic acids) have been entered in the IVTM since its establishment. During this six-year period, 25 subtypes of IVPP (this does not include five H9 viruses, one H5 and one H1 which do not have the neuraminidase subtype specified) have been recorded in the IVTM. During this reporting period (1 Sept 2016 - 31 August 2017), a total of 204 PIP BM of human origin were recorded in IVTM. The subtypes of the PIP BM recorded during this reporting period are shown in Table 3.

25. The GIP, in collaboration with WHO IT department, developed and implemented functions in IVTM to allow for the recording accession numbers and the hyperlink to genetic sequence databases of PIP BM recorded in IVTM. This function will facilitate access by users to genetic sequence data of IVPP published in publically accessible databases. In addition, in collaboration with the WHO IT Department, a feasibility study was coordinated by GIP in 2017. The objective of this study is to assess and prioritize potential modifications to the IVTM to improve its user-interface and overall functionality. Participating IVTM users from GISRS (including CCs, ERLs and NICs) will complete their evaluation in November 2017. The findings will guide subsequent IT solutions to ensure that the IVTM is sufficiently robust to fulfil its objectives.

Virus sharing

18. From 1 September 2016 to 31 August 2017, 177 IVPP from 10 countries, Areas and Territories (Annex 2) were shared with WHO CCs compared to 87 IVPPs from four countries in the same period last year. In addition, to improve sharing of IVPP, GIP developed operational guidance for NICs and other national authorized laboratories which has been in effect as from 1 July 2017.

26. To improve sharing of IVPP, GIP, in collaboration with WHO CCs, developed an operational guidance on selecting and sharing IVPP with WHO CCs to operationalize relevant articles in the PIP Framework. The guidance has been in effect since 1 July 2017 and will be piloted for a year.

27. Although challenges remain regarding the logistics and national administrative process of virus sharing, to date 25 different IVPP subtypes including 14 subtypes from human cases have been shared with WHO CCs from 10 countries and territories. The sharing of IVPP with GISRS from confirmed human cases is shown in Figure 1.

Candidate Vaccine Viruses development and sharing

28. Zoonotic influenza viruses continue to be identified and constantly evolve over time. Changes in the genetic and antigenic characteristics of these viruses relative to existing CVVs, and their potential risks to public health, justify the need for ongoing sharing, selection and development of new CVVs. The development of CVVs coordinated by WHO remains an essential component of the overall global strategy for pandemic preparedness and is the first step towards timely vaccine production.

29. The number of CVVs made available by WHO CCs has steadily increased (Figure 2). CVVs shared by WHO CCs with GISRS and non-GISRS laboratories during this reporting period included:

26 PIP Framework, Section 4.1, footnote 1 provides that materials shared with GISRS or other laboratories specifically for non-commercial public health uses including surveillance activities, diagnostic applications, and quality assurance, are not handled as PIP BM.
one influenza A(H1N1)v, 24 influenza A(H5N1), two influenza A(H5N6), two influenza A(H5N8), six influenza A(H7N9) and three influenza A(H9N2) viruses.

Figure 1. Confirmed human cases of influenza H5, H6, H7, H9 and H10 by calendar year of onset of illness and number of viruses shared with GISRS*

* does not include variant viruses; year refers to onset of illness of the human cases and refer to the calendar year

Figure 2. Number of CVVs made available by WHO CCs for vaccine development by calendar year
2.3 Handling genetic sequence data under the PIP Framework

30. Recognizing that further work would be needed to resolve the handling of GSD under the Framework, Member States requested under PIP Framework section 5.2.4 that the Director-General consult with the PIP Advisory Group “on the best process for further discussion and resolution of issues relating to the handling of [IVPP GSD] as part of the PIP Framework.”

31. The PIP Advisory Group has been working on the matter since 2013. To support its work, the Advisory Group established two technical working groups, and developed several documents on the handling of GSD under the Framework. These documents have provided the bases for several recommendations to the Director-General.

32. In its March 2017 meeting, the Advisory Group recommended to the Director-General that it continue its work under section 5.2.4 by developing guidance on an approach to operationalize the handling of IVPP GSD under the PIP Framework for both data sharing and benefit sharing. The Director-General accepted this recommendation. At its next meeting in November 2017, the Advisory Group will discuss GSD in light of decision WHA 70(10), the analysis underway by the Director-General and considering the discussions and outcomes of a consultation on 6-7 November with Member States, GISRS and stakeholders.

3. BENEFIT SHARING

3.1 Status of agreements entered into with industry and academic / research institutions

Category A: Vaccine and antiviral manufacturers

27 Relevant documents produced in the course of the Advisory Group’s work on GSD include: the Report of the Technical Expert Working Group (TEWG) on GSD, established in October 2013 to assess the scientific, technical, operational and intellectual property implications of using GSD to develop vaccines, diagnostic and pharmaceutical products; the Report of the Technical Working Group (TWG) on sharing influenza GSD, established in 2015 to identify the optimal characteristics and best practices of a GSD sharing system that best meets the objectives of the Framework; a paper on “Options to monitor the use of genetic sequence data from influenza viruses with human pandemic potential (IVPP GSD) in end-products”; and, a survey of data providers and data users on the “Sharing of Genetic Sequence Data of Influenza Viruses with Human Pandemic Potential”. These documents are available at http://www.who.int/influenza/pip/advisory_group/gsd/en/. See also, GSD Timeline July 2017, available at http://www.who.int/influenza/pip/advisory_group/GSD_timeline.pdf.


33. WHO has concluded 11 Standard Material Transfer Agreements 2 (SMTAs 2) with vaccine and antiviral manufacturers, including with all the large multinational companies and six of seven companies with a prequalified influenza vaccine which vary in size from large multinationals to medium sized companies. WHO estimates that, subject to a number of factors, the commitments under these agreements will provide WHO with access to approximately 400 million doses of pandemic vaccine that will be made available to countries in need at the time of the next pandemic. This is four times the amount of vaccine that was available to WHO in 2009.

34. WHO will continue working towards concluding SMTAs 2 with the approximately 22 remaining medium- and smaller-sized companies, keeping in mind the nature and capacity of these companies. Most of the remaining companies do not have export experience or prequalified vaccines.

Category B: Diagnostics and other pandemic products

35. The Secretariat has concluded one agreement with a large diagnostic manufacturer. Although no additional SMTAs 2 were concluded during this reporting period, negotiations are underway with some companies. Restructuring in the diagnostics industry has impacted the pace of negotiations. The Secretariat is reviewing how to engage smaller manufacturers and determine appropriate benefit sharing contributions from this subset of companies.

Category C: Research and academic institutions and biotechnology companies

36. A total of 65 agreements have been concluded. Although this category of recipient is asked, but not required, to offer a benefit contribution in exchange for using PIP BM, 29 institutions have made benefit-sharing offers. Most of these offers are focused on laboratory and surveillance capacity building/training.

37. To facilitate implementation of these offers, the PIP Secretariat, working closely with GIP and the WHO CCs, will organize a five-day WHO training programme on laboratory management that could be held in the spring/summer of 2018. The University of Siena, an SMTA 2 signatory, has offered to host the WHO training programme as its contribution under the agreement. The programme will focus on building the skills of laboratory professionals in developing countries and will offer a certificate of completion. WHO plans to seek contributions from Category C signatories to help support the training program and associated costs.

Veterinary Standard Material Transfer Agreements 2

38. In response to the Advisory Group’s March 2017 recommendation, the Secretariat is developing an approach to conclude SMTAs 2 with commercial veterinary manufacturers that use PIP BM to produce veterinary vaccines. Guidance from the Advisory Group will be sought during its November 2017 meeting to allow the Secretariat to move forward.

3.2 Partnership Contribution collection

Summary of Partnership Contribution collection results

39. The PIP Secretariat has completed the process of identifying contributors for the 2017 PC. Based on a thorough review of the history of contributors in the four previous contribution years, as well as the responses received on the 2017 Questionnaire and the Band Selection Form, invoices were sent to 43 companies in mid-August 2017.

40. Collection results for 2012-2017 are summarized in Table 4. Since 2014, the number of entities contacted and the number of contributors identified has remained about the same. Challenges in collecting payments in a full and timely manner include late response rates, accuracy of band self-
assessment, partial payments and non-payment. One large manufacturer has a portion of their payment outstanding for 2015, WHO is following up on this payment. One large 2016 payment was received in June 2017. A list of contributors and the amount of PC collected is included in the PC Annual Report.

Table 3: Summary of Partnership Contribution Collection, 2012-2017, as of 31 August 2017

<table>
<thead>
<tr>
<th>Questionnaire year</th>
<th>No. of entities contacted</th>
<th>No. of questionnaire responses</th>
<th>No. of contributors identified and invoiced</th>
<th>No. of contributors that paid</th>
<th>Amount received in US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>NA&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td>7</td>
<td>18 121 000</td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>194</td>
<td>89</td>
<td>32</td>
<td>30</td>
<td>27 538 586</td>
</tr>
<tr>
<td>2014</td>
<td>250</td>
<td>102</td>
<td>42</td>
<td>38</td>
<td>26 964 063</td>
</tr>
<tr>
<td>2015</td>
<td>256</td>
<td>90</td>
<td>39</td>
<td>32</td>
<td>25 266 711</td>
</tr>
<tr>
<td>2016</td>
<td>249</td>
<td>82</td>
<td>40</td>
<td>27</td>
<td>27 155 942</td>
</tr>
<tr>
<td>2017</td>
<td>250&lt;sup&gt;c&lt;/sup&gt;</td>
<td>19</td>
<td>43</td>
<td>11</td>
<td>7 775 263&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>132 821 565</td>
</tr>
</tbody>
</table>

<sup>a</sup>Partnership Contribution questionnaires were initiated in 2013.

<sup>b</sup>Amount received through 31 August 2017. PC collection for 2017 is in process.

<sup>c</sup>Number of entities contacted is estimated for 2017.

Possible revision of the Partnership Contribution formula

41. An industry-led process to review and potentially revise the PC formula is still underway.

3.3 Partnership Contribution implementation

Proportional division of the Partnership Contribution

42. Since 2012, 70% of PC resources have been allocated to pandemic preparedness and 30% to response based on the Advisory Group’s recommendation and Executive Board decision 131/4. In March 2013, the Advisory Group recommended that a portion of PC funds, not exceeding 10%, averaged over the next 4 years (2013-2016), be used by the PIP Secretariat. Financial details on these allocations can be found on the PIP PC Portal.


43. The WHO Executive Board at its 140th session decided to extend all decisions on the PC until 28 February 2018 and requested submission of a new proposal for its 142nd session in January 2018. This extension has allowed for the development of a new multi-year PC implementation plan (see HLIP below).

44. At its March 2017 meeting, the Advisory Group considered the adequacy and criteria for 30% of PC funds to be set aside for pandemic response and requested that the Secretariat undertake work to determine what might constitute sufficient response funds. The outcomes of this work will be discussed in November 2017.

45. The Advisory Group recommended in March 2017 that all interest accrued on the Response Funds be retained in the Response Fund account. Interest accrued will be retained in Response Fund account from January 2018.

Pandemic preparedness activities: implementation and assessment

46. The 2016 PIP PC Annual Report was posted on the WHO website in August 2017 and provides technical and financial information concerning progress to implement activities outlined in the PC Implementation Plan. The Advisory Group recommended in March 2017 that more detailed information regarding the expenditure of PC funds and the results/impact be published annually to improve clarity and transparency. The 2016 PC Annual Report used a different format from previous years to better illustrate the linkages between expenditures, progress and impact.

47. The total PC funds spent on preparedness since 2014 is approximately US$ 43.8 million, including approximately US$ 17.1 million spent in 2016. These funds have been used to support activities across five different Areas of Work, each of which includes targets designed to measure annual improvement in global preparedness for pandemic influenza. In all five areas, progress towards those targets is on track (Table 4). Funds have been used in 73 countries.

Table 4: Implementation of PC funds: a snapshot of progress in the five areas of work

<table>
<thead>
<tr>
<th>Area of work</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory and surveillance</td>
<td>79% of 43 PIP priority countries have improved their capacity, including the ability to detect new influenza virus subtypes</td>
</tr>
<tr>
<td>Burden of disease</td>
<td>74% of 19 PIP priority countries, across all regions, now have disease burden estimates</td>
</tr>
<tr>
<td>Regulatory capacity building</td>
<td>88% of 16 PIP priority countries have institutional development plans that improve regulatory capacity to oversee</td>
</tr>
</tbody>
</table>


and accelerate approval of pandemic influenza products

**Risk communication**

80% of 30 targeted PIP priority countries received direct support to establish risk communications, and 161 trainings were completed through an online platform

**Planning for deployment**

1st ever global simulation tool was developed for pandemic influenza vaccine deployment

### Development of the Partnership Contribution High Level Implementation Plan II

48. In 2013, WHO issued the first PC High Level Partnership Implementation Plan 2013-2016 (HLIP I) which defined a program of work in five areas. The second plan will cover 2018-2023 and will build on achievements and lessons learnt from the HLIP I. Development of the HLIP II has been completed through a highly collaborative process involving all levels of WHO and external stakeholders, including Member States, GISRS laboratories, industry and civil society organizations (CSOs). A final draft will be discussed at the November 2017 Advisory Group meeting.

49. Preparatory work has included:

- SWOT (Strengths, Weaknesses, Opportunities and Threats) exercise in October 2016
- Gaps and Needs Analysis published in January 2017
- An independent external evaluation of PC-funded activities completed in April 2017 to assess progress towards HLIP I outcomes and outputs; to measure the short-, medium- and long-term impact of PC funds in supporting influenza preparedness; and to identify lessons learnt that could inform the next implementation plan and the management response
- Consultation on the first full draft HLIP II in July 2017 with representatives from the PIP Advisory Group, WHO CCs, NICs, and technical units at WHO headquarters (HQ) and regional offices (RO) during which valuable feedback was received about the plan’s indicators, milestones and deliverables.
- A workshop on HLP II plan development and project management in July 2017 during which representatives from HQ and RO technical units discussed country selection and indicative activities for each HLIP II output.
- Formation of the PC Independent Technical Expert Mechanism (PC ITEM) comprised of eight experts who will review activities for scientific and technical suitability against the HLIP II deliverables and outputs, and provide guidance and advice to support, improve and finalize the work plans.

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Independent financial audit

50. Following the Advisory Group’s March 2017 recommendation and WHA Decision 70(10)(e) “to request the Director-General to request the External Auditor to perform an audit of PIP Partnership Contribution funds in line with the Review Group’s recommendation to provide: (1) assurances that the WHO financial regulations have been appropriately applied in the use of funds and that the financial information reported is accurate and reliable; and (2) recommendations to further increase the transparency of reporting on the linkages between expenditure and technical impact,” an external audit will begin in September 2017.

3.4 Global influenza vaccine production capacity

51. The Global Action Plan for Influenza Vaccines (GAP) closed in 2016. In its final report the GAP Advisory Group noted: the increasing number of countries with seasonal influenza vaccination policies; a quadrupling of potential pandemic influenza vaccine production capacity to 6.4 billion doses, based on established production capacity for seasonal vaccines; and the advances in improved vaccines and vaccine production technologies. Despite such progress, global vaccine production is still insufficient and there are challenges to maintaining current production capacity. This is of concern because production of a pandemic vaccine will require several months and it is likely that each person will require two doses of the vaccine. The work to secure adequate influenza vaccine production capacity must be carried forward in a coordinated manner by WHO and influenza stakeholders.

52. The PIP Review Group recommended that the PIP Advisory Group consider lessons learnt from the GAP and identify any aspects that would support implementation of the PIP Framework. Implementation of HLIP II will benefit from the momentum and systems established during GAP. Technical assistance to countries on sustainable policies and processes for procurement/production of influenza vaccine will be supported through HLIP II.

4. GOVERNANCE

The 2016 PIP Framework Review and decision WHA70(10)

53. The Advisory Group is committed to providing its expertise and experience to assist the Director-General in taking forward decision WHA70(10). The decision specifically cites the role of the PIP Advisory Group in paragraph (8)(b) regarding the analysis of issues raised in connection with the PIP Framework Review Group’s recommendations concerning seasonal influenza and GSD. Carrying out the overall recommendations of the Review Group, the WHA Decision paragraph (8a) also identifies several other roles for the AG.

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Interactions with stakeholders and communications

54. Several of the PIP Review Group’s recommendations touched on the importance of expanding and strengthening effective communications with Members States, GISRS laboratories, industry, civil society, and other stakeholders. Section 2.1 in our Report details plans for enhanced engagement with GISRS and the Advisory Group, and Section 3.3 outlines the extensive consultative process undertaken by the Secretariat to develop the HLIP II.

55. In response to the PIP Review Group’s recommendation that the Secretariat and Advisory Group broaden and deepen engagement with civil society to a greater number of participating organizations, the PIP Secretariat invited over 200 CSOs to a virtual information session on the PIP Framework in February 2017 which resulted in one CSO joining the regular bi-monthly calls with CSOs.

Harmonized reporting/comprehensive evaluation model

56. The 2016 PIP Review Group recommended that WHO should develop a comprehensive evaluation model (CEM), including overall success metrics for the PIP Framework for annual reporting and an infographic to illustrate the status of overall progress in implementing the PIP Framework. The Advisory Group noted during its March 2017 meeting that synthesizing existing information which draws on current indicators and making it more accessible was preferable to developing new systems. Areas not currently addressed could be incorporated into the existing system with the addition of new indicators. The Advisory Group welcomed the Review Group’s suggestion to develop an infographic as a communication tool and noted that it should keep a narrow focus on the work of WHO.

57. Several new communication products were rolled out in the last year including an updated PIP Framework webpage, an infographic and SMTA 2 poster, and publication of the PIP Q&As in French and Spanish. The PIP Newsletter continues to provide regular (seven issues in this reporting period) updates.

Linkages and synergies of PIP Framework with other agreements and activities

58. The 2016 PIP Review Group Report included recommendations to support and maximize synergies between the PIP Framework, the International Health Regulations (2005) and GAP. HLIP II

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will promote synergies between the PIP Framework, the International Health Regulations (2005) and the experience and lessons learned from the Global Action Plan for Influenza Vaccines.

59. The Review Group observed that “the PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.”

Having noted this and the summary of the Secretariat’s report on the public health implications of the implementation of the Nagoya Protocol, the Executive Board in January 2017 requested, **inter alia**, the Director-General to continue consultations with the secretariat of the Convention on Biological Diversity and with other relevant international organizations, as appropriate, in the context of existing international commitments, on access to pathogens and fair and equitable sharing of benefits, in the interest of public health.

Since January 2017, the WHO Secretariat and the Convention on Biological Diversity Secretariat have held several teleconferences and one face-to-face meeting to share information on relevant work being conducted by both bodies, to identify areas for future collaboration, and to agree on a mechanism for the latter. WHA70(10)8(f) recommended that these consultations continue.

New members and meetings of the Advisory Group

60. Following the completion of Dr Jarbas Barbosa da Silva's term as Chair, the Advisory Group selected as its new Chair Professor Mahmudur Rahman (Bangladesh). Professor John Watson (England) continued as the Vice Chair. The Group welcomed six new members at the March 2017 meeting.

61. Based on the findings of the 2016 PIP Review and in accordance with section 3.2 of the Advisory Group Terms of Reference, the Director-General decided to offer a consecutive second term to each member of the Advisory Group following the completion of their first term. The Advisory Group agreed that the duration of the second term could be of flexible duration, up to three years, to enhance the institutional memory and stability of the Advisory Group.

62. Consultations with industry and other stakeholders occurred during each of the Advisory Group’s meetings in October 2016 and March 2017. Information Sessions for the Permanent Missions in Geneva, led by the Advisory Group Chair, were held following each meeting.

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53 A complete listing of Advisory Group members can be found at http://www.who.int/influenza/pip/advisory_group/members/en/.
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<th>Location in report</th>
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<tr>
<td>2. Operational functioning of WHO GISRS</td>
<td>Section 2.1 Annex 2</td>
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</tr>
<tr>
<td>7. Use of financial and non-financial contributions</td>
<td>Section 3.2 Section 3.3 Section 4</td>
</tr>
</tbody>
</table>

1 See PIP Framework, Section 7.2 5 and Annex 3, Section 2 for the seven areas to be covered by the annual report.
ANNEX 2

TECHNICAL CAPACITIES AND OPERATIONAL FUNCTIONING
OF THE WHO GLOBAL INFLUENZA SURVEILLANCE AND RESPONSE SYSTEM

Table 5: Number and subtype of IVPP obtained from humans, characterized by WHO Collaborating Centres, (1 August 2016 -31 July 2017)*

<table>
<thead>
<tr>
<th>Influenza virus</th>
<th>No. of viruses characterized</th>
<th>Originating country/areas/territory providing viruses from human cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Influenza A(H5N1)</td>
<td>8</td>
<td>Egypt</td>
</tr>
<tr>
<td>Influenza A(H5N6)</td>
<td>15</td>
<td>China</td>
</tr>
<tr>
<td>Influenza A(H7N9)</td>
<td>107</td>
<td>China, China, Hong Kong SAR and China, Province of Taiwan</td>
</tr>
<tr>
<td>Influenza A(H7N2)</td>
<td>1</td>
<td>USA</td>
</tr>
<tr>
<td>Influenza A(H9N2)</td>
<td>19</td>
<td>China, Bangladesh, Egypt</td>
</tr>
<tr>
<td>Influenza A(H1N1)v</td>
<td>3</td>
<td>Italy, Netherlands, Switzerland</td>
</tr>
<tr>
<td>Influenza A(H1N2)v</td>
<td>5</td>
<td>USA, Brazil</td>
</tr>
<tr>
<td>Influenza A(H3N2)v</td>
<td>19</td>
<td>Canada, USA</td>
</tr>
</tbody>
</table>

* Source of information: the WHO Consultation on the Composition of Influenza Vaccines, February 2017 (data packages prepared by WHO CCs on zoonotic influenza viruses). Definition; “Characterized” is defined as description of antigenic and/or genotypic characteristics of the influenza virus completed.

In addition, 426 environmental and avian IVPP from 19 countries were characterized by WHO Collaborating Centres from 1 August 2016 to 31 July 2017.
Table 6: Assessment of PCR testing performance by laboratories participating in the WHO external quality assessment programme (EQAP), panel 16 (2017)

<table>
<thead>
<tr>
<th>No. of correct results (10 samples tested)</th>
<th>No. (%) of laboratories (N= 160 participating laboratories)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 samples correct</td>
<td>139 (86.9)</td>
</tr>
<tr>
<td>9 samples correct</td>
<td>12 (7.5)</td>
</tr>
<tr>
<td>6-8 samples correct</td>
<td>8 (5.0)</td>
</tr>
<tr>
<td>&lt;6 samples correct</td>
<td>1 (0.6)</td>
</tr>
</tbody>
</table>

*Results provided for only those laboratories which returned results on time

Figure 3. Performance of laboratories participating in the WHO external quality assessment programme (EQAP) for detection of influenza A and B viruses, panels 1-16, 2007-2017
Table 7: Number of PIPBM recorded in IVTM, by influenza virus subtype, 1 September 2016-31 August 2017

<table>
<thead>
<tr>
<th>Influenza virus subtype</th>
<th>PIP BM</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (H10N7)</td>
<td>1</td>
</tr>
<tr>
<td>A (H10N8)</td>
<td>2</td>
</tr>
<tr>
<td>A (H13N6)</td>
<td>1</td>
</tr>
<tr>
<td>A (H1N1)v</td>
<td>6</td>
</tr>
<tr>
<td>A (H1N2)v</td>
<td>2</td>
</tr>
<tr>
<td>A (H3N2)v</td>
<td>9</td>
</tr>
<tr>
<td>A (H3N8)</td>
<td>1</td>
</tr>
<tr>
<td>A (H5N1)</td>
<td>17</td>
</tr>
<tr>
<td>A (H5N3)</td>
<td>1</td>
</tr>
<tr>
<td>A (H5N6)</td>
<td>10</td>
</tr>
<tr>
<td>A (H5N8)</td>
<td>19</td>
</tr>
<tr>
<td>A (H6N1)</td>
<td>4</td>
</tr>
<tr>
<td>A (H7N2)</td>
<td>2</td>
</tr>
<tr>
<td>A (H7N9)</td>
<td>155</td>
</tr>
<tr>
<td>A (H9N2)</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>235</strong></td>
</tr>
</tbody>
</table>