Pandemic Influenza Preparedness Framework

Advisory Group Annual Report to the Director-General

2020
1. INTRODUCTION

1. The Advisory Group (AG) is a group of 18 independent technical experts who monitor the PIP Framework and advise the WHO Director-General on its functioning. Each year, as part of its terms of reference\(^1\), the AG submits to the Director-General of the World Health Organization a report on its evaluation of progress in the implementation of the Pandemic Influenza Preparedness Framework (“PIP Framework”). Previous reports can be found here. This report covers the period 1 January through 31 December 2020.

2. The key goals of the PIP Framework include to improve and strengthen the sharing of influenza viruses with human pandemic potential through the WHO Global Influenza Surveillance and Response System (GISRS), and to increase the access of developing countries to vaccines and other pandemic response supplies. The Framework (Section 7.2.5) specifies that the AG’s Annual Report should evaluate seven technical areas:

    i. Necessary technical capacities of GISRS and sharing of influenza viruses (Virus sharing);
    ii. Operational functioning of GISRS;
    iii. GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building, burden of disease studies);
    iv. Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential;
    v. The Influenza Virus Traceability Mechanism;
    vi. The sharing of influenza viruses and access to vaccines and other benefits (benefit sharing);
    vii. Use of financial and non-financial contributions.

3. Meetings of the Advisory Group are convened typically twice a year. Due to the COVID-19 pandemic, the March 2020 meeting was not convened. The AG held its first virtual meeting from 12-16 October 2020, preceded by three technical briefings on: (1) strengthening engagement with the diagnostics sector and outcomes of the World Health Assembly, (2) COVID-19 and influenza virus sharing and (3) the ACT-Accelerator.

4. The response to COVID-19 overshadowed implementation of all PIP-related activities. A central, recurring theme has been the invaluable global asset that GISRS represents for the global response. The targeted capacity-strengthening activities supported by PIP have also been recognized, and despite slow-downs, some notable results and impact have been achieved, as reflected in this report. Care was exercised at all times to ensure that PIP Partnership Contribution (PC) funds were used to implement influenza specific capacity-strengthening activities. Thus, for instance, in April 2020, using PC, WHO started supporting activities that had benefits for both pandemic influenza preparedness and response and COVID-19. This included strengthening data sharing systems to facilitate holistic data and information management on acute respiratory infections, and technical support to execute the regulatory approval processes of pandemic response products. Periodic risk assessments were done to manage and, to the extent possible, minimize the impact of COVID-19 on implementation of the PIP Partnership Contribution (PC).

5. The Annual Report draws on progress reports published by the Secretariat as well as data and information that the AG received at its biannual meetings. These sources include:

\(^1\) Available here: [https://www.who.int/influenza/pip/advisory_group/PIP_AG_Terms_of_Reference.pdf?ua=1](https://www.who.int/influenza/pip/advisory_group/PIP_AG_Terms_of_Reference.pdf?ua=1)
a. Pandemic influenza preparedness framework: annual progress report, 1 January - 31 December 2020
b. Briefings which the AG received from the PIP Secretariat, the WHO Global Influenza Programme (GIP) and GISRS, including reports, information and data on the sharing of influenza viruses, both seasonal virus and Influenza Viruses with Human Pandemic Potential (IVPP).

6. Each AG meeting includes consultation with stakeholders and discussion with GISRS representatives during relevant technical sessions.

2. SUMMARY

7. Overall, it is the view of the AG that the PIP Framework continues to function well, and implementation has been sustained during this challenging year, with the ongoing COVID-19 pandemic. It is a model partnership between WHO, Member States, industry and civil society. Based on the negotiated agreement among Member States, it is functioning as a transparent systematic approach to access and benefit sharing related to influenza viruses of pandemic potential.

8. The High-Level Implementation Plan II (HLIPII) made progress in its six output areas albeit far more slowly than expected due to the COVID-19 pandemic. The risk of COVID-19 hindering influenza surveillance and HLIP II implementation was monitored throughout 2020. WHO undertook a series of measures including mission briefings, meetings with GISRS institutions, circulars to Member States, and advocacy through all relevant WHO offices to mitigate the risk of the COVID-19 pandemic on influenza preparedness. For 11 indicators considered at risk of not progressing due to the pandemic, 4 nevertheless made gains. The overall implementation of the HLIP II is advancing, but more slowly than originally planned with programmatic expenditures reduced.

9. Having reviewed GIP’s regular reporting on virus sharing and discussed the overall functioning of the GISRS with WHO Collaborating Centre representatives, the AG notes that GISRS is currently operating well and proved its critical role in responding to the pandemic. Its work supported the annual Vaccine Composition Meetings (VCM) and its work with Influenza Viruses with Pandemic Potential (IVPP) resulted in the development of three new Candidate Vaccine Viruses (CVVs).

10. However, the COVID-19 pandemic has also hindered pandemic influenza preparedness with the disruption of travel and supply chains, as well as by overburdening national health systems’ and WHO’s human resources. The disruptions caused by the pandemic and a sharp drop in influenza activity resulted in reduced sample sharing in 2020.

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2 Available here: [https://www.who.int/publications/i/item/9789240024205](https://www.who.int/publications/i/item/9789240024205)


11. The work done by GISRS and the capacity strengthening projects under HLIP II has also had a significant impact on the global response to the COVID-19 pandemic. The HLIP II’s comprehensive approach to pandemic influenza preparedness and response served as an important foundation for responses to the COVID-19 pandemic – e.g., PIP’s work on the expediting regulatory approval for vaccines served as a model for development of an expedited regulatory approach for COVID-19 vaccines. Likewise, GISRS developed and provided guidance on sentinel surveillance for COVID-19, and COVID-19 training courses were developed on Open WHO, a platform which received support from the PIP Framework.

12. At the close of 2020, the partnership contribution (PC) collected from industry was 53% of the expected total (US$ 28M) for the calendar year, reflecting a slow collection rate and this continues to be an issue for discussion with the AG, industry and the Secretariat. However, the overall collection rate, which is a result of the Secretariat’s and industry’s ongoing efforts, is 97% for the period 2013-2019.

13. The AG commends the PIP Secretariat, GIP, GISRS and regional offices for their tireless efforts this year as they were called upon to continue their work to strengthen global influenza pandemic preparedness in the midst of the emerging and ongoing COVID-19 pandemic. The team adapted and demonstrated the importance of their ongoing work on pandemic influenza preparedness planning and capacity building.

14. Pandemic influenza and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are both respiratory viruses. The synergies between the work done through GIP, GISRS, and the PIP Framework to prepare and respond to an influenza pandemic and what was needed on the ground this year as the COVID-19 pandemic developed and spread globally will provide essential information for future programmes. The HLIP II mid-term review in 2021 is expected to highlight the immediate adjustments needed to improve HLIP II as well as the medium-longer term shifts in programmatic implementation needed to strengthen pandemic influenza preparedness in light of the COVID-19 context. Hopefully, the lessons from this ongoing devastating respiratory pandemic will help us to better prepare the world for the next one.

3. SEVEN TOPIC AREAS

15. Illustrative examples of achievements and challenges follow for each of the seven topic areas covered in the AG Annual Report (sections 3.1-3.7).

3.1 Necessary technical capacities of GISRS and sharing of influenza viruses (Virus sharing)

16. The WHO operational guidance on sharing Influenza Viruses with Human Pandemic Potential (IVPP) continues to be the key guidance in assisting National Influenza Centres (NICs), H5 Reference Laboratories and other Nationally Authorized Laboratories to select and ship IVPP to GISRS Collaborating Centres. The GIP and GISRS have continued to proactively promote and clarify processes and reinforce the importance of timely sharing of IVPP.

17. 75% (3/4) of the countries that reported zoonotic influenza cases to WHO timely shared IVPPs with GISRS, an improvement from last year (71%).

5 Available here: https://apps.who.int/iris/handle/10665/259402
18. However disruptions caused by the COVID-19 pandemic and the sharp drop in influenza activity in 2020 resulted in overall reduced influenza sample sharing.

19. In 2020, a total of 124 (64%) countries shared influenza viruses/clinical specimens at least once with WHO CCs. The proportion of countries sharing two timely shipments with WHO CCs (in line with WHO guidance) decreased in 2020 (31%) compared to the 2019 baseline (44%).

20. Using the Shipping Fund Project (SFP), 88 countries from all 6 WHO regions made 154 shipments to WHO CCs in 2020. This is compared to 252 shipments made by 109 countries in 2019.

21. As a platform, the SFP was rapidly adapted to support the COVID-19 response so that countries could share their specimens with COVID-19 reference laboratories for further characterization and to validate their results.

22. The GISAID Initiative⁶ has played an important role in the sharing of data on all influenza viruses and the coronavirus causing COVID-19 among the WHO Collaborating Centers and National Influenza Centers. This includes the bi-annual influenza vaccine virus recommendations made by GISRS.

3.2 Operational functioning of GISRS

23. GISRS continues to operate well. It is a strong system built on Member States’ commitments to national facilities as defined in the WHO Terms of Reference and experienced, well-trained and committed staff at institutions and centers across the globe, and at WHO headquarters and regional offices. The GIP oversees the network and has worked consistently to strengthen the systems, addressing delays in sharing and clarifying processes.

24. A total of 1105 zoonotic influenza viruses and other influenza viruses with pandemic potential were characterized by GISRS in 2020, a 28% rise from last year (864). The viruses were of 10 influenza A subtypes and originated from 13 countries. Through the two Vaccine Composition Meetings, characterization led to the development of 3 new Candidate Vaccine Viruses (H1N1v, H9N2, H5N1) for pandemic influenza preparedness.

25. As the recent (2021) issue related to the use of a seasonal influenza candidate vaccine virus shows, there are growing concerns over the implementation of national access and benefit sharing laws, including those to implement the Nagoya Protocol and the implications for systems such as GISRS.

3.3 GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building, burden of disease studies)

26. The PIP Framework Annual Progress Report for 2020 presents a range of data demonstrating progress in capacity building for pandemic preparedness and response. Highlights include:

- The NIC in Suriname (a PC recipient country) was newly recognized by WHO bringing the total number of NICs globally to 147 in 123 countries. NICs are playing a critical role in the COVID-19 pandemic with most serving as national reference laboratories.

⁶ Accessed here: https://www.gisaid.org/
• All 40 2018-19 PC recipient countries developed a COVID-19 response plan in 2020, where most developed their plans based on their IPPP\(^7\) and within 4 months after the declaration of the PHEIC (n=36, 90%). PIP investments facilitated countries to develop their COVID-19 response plans.
• Four additional countries published their Burden of Disease (BOD) estimates and 4 updated their previous findings bringing the total to 43 countries with BOD estimates globally. Of the 43 countries, 67% (29) are LMICs. The progress made has already exceeded the 2021 biennial indicator target. In addition, 57 countries have either already calculated or established a plan to calculate their national BOD estimates.
• WHO is developing an influenza disease burden pyramid tool to help countries with limited data to comprehensively estimate their burden of disease. The tool was used to inform the COVID-19 disease burden pyramid tool and will be adjusted based on experience gained.
• Ghana became the second country in Africa to attain WHO Maturity Level 3 (ML3) for their regulatory system, which is a major achievement supported by PIP. ML3 indicates the presence of a stable, well-functioning, and integrated system of oversight for medical products.
• Exceeding the biennial target of 23 countries, 27 countries developed country roadmaps and follow-up plans for the implementation of pathways required for timely approval of products.
• Building on PIP, a section on regulatory preparedness for the expedited approval of COVID-19 vaccines was developed under the NDVP guidance published in November 2020.
• OpenWHO continues to grow as a forum for knowledge exchange. In 2020, over 152,000 users completed influenza-related RCCE trainings.
• In 2020, WHO established infodemic management and lessons learnt will support RCCE implementation for future pandemic influenza preparedness.
• Over 1,700 participants from all six WHO regions participated in global webinars to strengthen national RCCE capacities relevant to COVID-19 and pandemic influenza with on average more than 90 countries participating in each webinar.
• The FoRCCE network was developed with PIP PC support in 2019 and proved to be instrumental during the COVID-19 response. This network enabled the tracking and sharing of social listening data, sentiment analysis, tailored risk communication materials, rumor monitoring strategies, behavioral insights survey tools, and country and community focused capacity building products.
• In September 2020, an influenza vaccination toolbox was launched. This included tools and guidance related to influenza vaccine programme development and strengthening for MOH Officials, WHO staff, vaccinators, health workers, researchers, and other key stakeholders.
• Of the 63 IPPP PC recipient countries in the 2020-21 biennium, 35 (56%) now have a plan based on WHO's Pandemic Influenza Risk Management guidance. This is an increase of 2 PC recipient countries with an up-to-date plan since 2019.
• In 2018-19, PIP supported the development of the Pandemic Special Studies to outline the key questions, protocols and tools needed at the time of a pandemic to rapidly characterize the seroepidemiological characteristics of a new virus. For COVID-19, the PSS were rapidly adapted and became the “Unity Studies”.
• The three reports requested under Decision WHA72(12)10 were concluded and uploaded to the PIP Framework webpage, along with comments received from stakeholders. In addition, the Director-General provided two reports to WHA73 on: (1) influenza preparedness and (2) harmonizing the approach to reporting on PIP Framework implementation.

\(^{7}\) See Pandemic Influenza Preparedness Framework: progress report, 1 January - 30 June 2020
3.4 Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential

27. WHO integrated the reporting of COVID-19 community transmission surveillance data into influenza platforms to increase efficiency and facilitate monitoring of respiratory disease activity holistically.

28. Globally, 150 (77%) countries reported virological data to FluNet and 131 (68%) epidemiological data to FluID. Most of these (respectively 83% and 81%) reported consistently during the influenza season. In 2020, 2 countries started reporting for the first time to FluNet. Of the 41 PC L&S recipient countries, the proportion reporting to FluNet (88%) and FluID (73%) exceeded the annual indicator targets despite the COVID-19 pandemic.

29. In 2020, 47 countries from 6 regions benefited from laboratory trainings activities. WHO ROs continue to follow up with low performing laboratories through implementation of laboratory quality management systems to ensure consistent quality results of influenza detection. Although 110 countries that participated in influenza EQAP in 2020, this was 26 fewer compared to 2019 likely due to COVID-19 disruptions. All 147 NICs participated in the COVID-19 EQAP highlighting the commitment to assuring laboratory services during a public health emergency.

30. A total of 6 WHO risk assessments of human infections with non-seasonal or animal influenza viruses were published.

3.5 The Influenza Virus Traceability Mechanism (IVTM)

31. IVTM is working as a transparent tracking system. A new version of the IVTM (IVTM 2.0)8 was launched in June 2020 with positive feedback from users about the performance of the new version.

32. In early 2020, WHO updated 4 molecular detection protocols9, published guidance on the use of next-generation sequencing for genetic characterization of influenza viruses, and guidance to support countries in using GISRS for COVID-19 surveillance and response. An e-consultation was conducted in October 2020 to review lessons learnt and assess further opportunities to use GISRS to support countries in their COVID-19 pandemic response and beyond.

3.6 The sharing of influenza viruses and access to vaccines and other benefits (Benefit Sharing)

33. Virus sharing and access to benefits are at the center of the PIP framework. Virus sharing has been previously addressed (see Sections 3.1). Benefit sharing is covered through two benefit sharing mechanisms: the annual Partnership Contribution (PC)10 and the Standard Material Transfer Agreement 2 (SMTA 2). The Secretariat diligently manages the collection of the Partnership Contribution as well as the negotiation and review of SMTA2s. Work initiated in 2020 is ongoing to better understand the use of PIP biological material by the diagnostic sector is an example the Secretariat’s diligent approach.

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8 Accessed here: https://extranet.who.int/ivtm2
9 Available here: WHO information for molecular diagnosis of influenza virus - update
10 The PIP PC funding model is described in HLIP II, Section 6
34. The PC is collected as an annual cash contribution from influenza vaccine, diagnostic, and pharmaceutical manufacturers that use GISRS. Funds are allocated for: (a) pandemic preparedness capacity building; (b) response activities during the time of an influenza pandemic; and (c) PIP Secretariat for the management and implementation of the Framework. As mentioned earlier, collection of the PC in the year it is invoiced continues to be a challenge despite overall collection continuing to be very satisfactory.

35. SMTA2: Fourteen agreements have been signed with large, medium, and small vaccine manufacturers since 2013—including 1 in 2020, securing access by WHO to 10% of future production of pandemic vaccines, in real time; this translates to over 400 million vaccine doses using current technologies. The agreements have also included the supply of over 10 million treatment courses of antivirals, 250 000 diagnostic test kits, and 25 million syringes. A further 73 SMTA2 agreements have been signed with academic and research institutions—including 3 that were signed in 2020. These agreements have led to 29 offers of benefit-sharing from academic & research institutions.

36. To implement the WHA’s 2019 amendment to the PIP Framework (Decision WHA72(12) OP2), a process has been developed and is being implemented to amend the 84 SMTA2s signed prior to the Decision to add a new reporting obligations for indirect use of PIP BM.

37. Initiated in November 2020, a series of meetings were held to discuss pandemic vaccine deployment activities with a view towards operationalizing the SMTA2 supply commitments.

3.7 The use of financial and non-financial contributions

38. The technical and financial investments of countries and other partners, including GISRS, play a critical role in advancing pandemic influenza preparedness alongside PC investments. Collectively, resources are used to strengthen pandemic preparedness systems, knowledge and capacities.

39. The overall implementation of the Biennium budget has moved slowly this year, no doubt due the impacts of the COVID-19 pandemic. However, it is important to note programmes adapted to new conditions, e.g. no travel, stretched human resources working to maintain progress, and the use of newly developed capacities to respond to the pandemic.

40. The PIP PC Preparedness budget for the 2020-2021 biennium was USD 31.4 million, and as of 31 December 2020 USD 16.7 million (53%) had been funded and USD 6.6 million (21%) had been implemented. The WHO Programme Budget Portal\(^{11}\) provides updated, detailed and transparent information on PIP contributions, budget allocations, technical and financial implementation, and progress across three level of the organization against specific objectives across the six output s of the High-Level Implementation Plan II 2018-2023.

41. As of 31 December 2020, total collection for PIP PC stood at US$ 227.70 million. Of this, a total of US$ 126.93 million was allocated to preparedness (net funds available for implementation) and US$ 61.48 million was allocated to the Response Fund (inclusive of programme support costs). An additional amount of $3.58 million, representing accrued interest on the response fund for the 2018,2019 and 2020, was added to response funds.

\(^{11}\) Accessed here: [https://open.who.int/2020-21/our-work/category/14/programme/14.003/about/about](https://open.who.int/2020-21/our-work/category/14/programme/14.003/about/about)
42. Overall, the AG believes that the funding allocations are well managed and monitored. The accounts are reviewed on an annual basis by the WHO financial department and Certified Financial Statement are issued each year and included in PIP Framework annual and biennial progress reports.