Pandemic Influenza Preparedness Framework

Advisory Group 2019 Annual Report to the Director-General

(PIP Framework Section 7.2.5)
I INTRODUCTION

1. Each year the PIP Advisory Group (AG) submits to the Director-General of the World Health Organization (WHO) a report on its evaluation of progress in the implementation of the Pandemic Influenza Preparedness Framework (“PIP Framework”).

2. The Framework specifies that the AG’s Annual Report should cover seven technical areas (PIP Framework section 7.2.5). This year’s report covers the period 1 January through 31 December 2019. This report is being finalized in 2020, as the world is confronting the COVID-19 pandemic.

3. The AG did not convene for its March 2020 meeting due to the COVID-19 pandemic. Pandemic influenza preparedness will be affected by this current crisis. We anticipate that next year’s influenza preparedness could be significantly affected by the stresses placed on health care systems around the world by COVID-19. The AG will be addressing this topic at its upcoming discussions.

4. Over the past year, the AG continued work that was recommended in the 2016 PIP Framework Review specifically regarding the estimate of the GISRS running cost and the level of the Partnership Contribution. These efforts were described in the AG’s meeting reports and are ongoing.

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:
   a. PIP Biennial Progress report for 2018-2019 and the web-based corporate WHO Programme Budget (PB) Portal. Both of these reports are prepared by the PIP Secretariat. These detailed reports track and report on specific metrics and provide infographics for seven outputs: six outputs under the PIP Partnership Contribution and one output for the PIP Secretariat.
   b. Briefings which the AG received from the PIP Secretariat, the WHO Global Influenza Program (GIP) and the WHO Global Influenza Surveillance and Response System (GISRS) including reports, information and data on the sharing of influenza viruses, both seasonal virus and those with human pandemic potential (IVPP).

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

II SUMMARY ASSESSMENT

7. Overall, it is the view of the AG that the PIP Framework continues to function well. It is a model partnership between WHO, Member States, industry and civil society. Based on the negotiated agreement among Member States (MS), it is functioning as a transparent systematic approach to access and benefit sharing related to IVPP. At the close of 2019, the partnership contribution (PC) from industry was 58% of the expected total (US$ 28m) for the calendar year, reflecting the slow collection rate of the contribution in the year it is assessed. This continues to be an issue for discussion with the AG, industry and the Secretariat. The overall collection rate, which is a result of the Secretariat’s and industry’s ongoing efforts, is 97% for the period 2013-2018.

8. The High Level Implementation Plan II (HLIP II) moved forward against its objectives and made significant progress in its six output areas. The HLIP II met or achieved 13 of 17 of its targets for the biennium 2018-2019. The program is moving forward on the complex challenge of strengthening
preparedness broadly – including laboratory, surveillance, regulatory, communication and deployment capacities. The important issue of sustaining these improvements is receiving increased attention. (This will be a critical issue in the wake of the COVID-19 crisis.)

9. Having reviewed GIP’s regular reporting on virus sharing and discussed the overall functioning of the GISRS with WHO Collaborating Centre (CC) representatives who have attended meetings, the AG notes that GISRS is currently operating well but there are some concerns. In 2019 there was a decrease in overall sharing of IVPP influenza in absolute number. This reduction corresponded with the reduction in reported cases. However, the percentage of countries with zoonotic influenza cases that shared IVPPs according to the WHO IVPP guidance regarding timely sharing of samples was only 57% (4 out of 7 countries).

10. There are ongoing concerns about IVPP sharing delays related to increasingly complex national and international procedures for the movement of biological IVPP, from biosafety and biosecurity perspectives. Given the tie between influenza pandemic preparedness and seasonal influenza, the AG was briefed on the delayed sharing of seasonal influenza related to the emergence of procedures or confusion connected with the implementation of the Nagoya protocol. Decision WHA72(12) (2019) identified several actions related to the sharing of influenza virus that the Secretariat is now implementing.

3. ANNUAL REPORT: TOPIC AREAS


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

12. The WHO operational guidance on sharing IVPP (the “Guidance”) continues to play an important role in timely sharing. GIP and GISRS have continued to proactively promote and clarify processes and reinforce the importance of timely sharing of IVPP. This will be an ongoing priority.

13. As mentioned above the percentage of Member States with zoonotic influenza cases sharing IVPPs was 57%. This number reflects the need for ongoing discussions regarding the IVPP Sharing Guidance as well as the challenges to timely sharing that result from issues that require involvement of ministries in addition to the health ministry – e.g. biosafety, biosecurity and import/export regulations and procedures.

14. In addition, when looking at seasonal and IVPP, while 142 MS (73%) shared influenza viruses/clinical samples with WHO CCs at least once, only 86 of MS countries (44%) shared viruses/clinical samples according to the 2017 WHO guidance (requiring two timely shipments). In 2018, the numbers were 132 MS (68%) shared influenza viruses/clinical samples, and 84 MS (43%) shared according to the 2017 WHO guidance.

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15. In 2019, 252 shipments of influenza virus materials were funded through the Shipping Fund Project. This compares with 268 such shipments in 2018.

3.2 Operational functioning of WHO GISRS

16. 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 Global Influenza Program (GIP) oversees the network and has worked consistently to strengthen the systems, addressing delays in sharing and clarifying processes.

17. During 2019, GISRS characterized 864 IVPP. Vaccine Composition Meetings were held and candidate vaccine viruses identified.

18. Potential challenges facing GISRS include the uncertainty surrounding the implementation of the Nagoya Protocol and the potential impact this might have on influenza virus sharing. WHO is reviewing this issue through the implementation of WHA 72(12) and more broadly (related to all pathogens) in connection with implementation of decision WHA72(13).

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

19. The 2018-2019 PIP Framework Biennial Annual Progress Report presents a range of data demonstrating progress in capacity building for pandemic preparedness and response. Highlights include:

- Of the 40 countries that received support for Influenza Pandemic Preparedness Planning support, 8 countries exercised their plan in 2019, compared to 2 in 2018.
- A cadre of 15 trainers was established to scale up the number of mentors who can assist countries in National Vaccine Deployment Planning (NVDP)
- Three MS strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and Institutional Development Plan (IDP) benchmarking
- The number of Burden of Disease (BOD) estimates published by MS continued to increase. In 2019, 4 Member States who had never previously published, published BOD estimates. This compares to 18 BOD estimates published in 2018. This combined increase (2018/2019) exceeded the biennial target.
- During the biennium, 11% of published BOD estimates were considered by MS National Technical Advisory Groups or decision-makers, i.e. using their estimates to update national initiatives.

3.4 Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential

20. The proportion of PC laboratory and surveillance recipient countries reporting to FluNet (virological data) (97%) and to FluID (epidemiological data) (81%) increased during 2019. These results exceeded the HLIP II biennial targets (FluNet - ≥ 85% and FluID - 60%).
21. The PIP Framework Biennial Progress Report described an increase in Member State participation in the External Quality Assessment Program (EQAP) with high percentages of correct results for both seasonal and non-seasonal influenza. In addition, the number of countries reporting Pandemic Influenza Severity Assessment (PISA) indicators also increased in 2019.


3.5 The Influenza Virus Traceability Mechanism

23. IVTM is working as a transparent tracking system. A total of 1,940 PIP biological materials have been recorded in the system since its inception. In 2019 preparation for the launching of IVTM 2.0 progressed according to schedule.

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

24. 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) and the Standard Material Transfer Agreement 2 (SMTA 2).

25. Partnership Contribution: As mentioned earlier, collection of the PC in the year it is invoiced continues to be a challenge. The overall collection rate, which is a result of the Secretariat’s and industry’s ongoing efforts, is 97% for the period 2013-2018.

26. SMTA 2: Five additional agreements were signed in 2019, one with a medium-sized vaccine manufacturer and four category C agreements with academic institutions. Progress on SMTA2 negotiations with several other entities continued and work commenced on amending 85 agreements affected by Decision WHA72(12). In addition, review work continued on Category A and B SMTA2 agreements concluded several years ago, as per the provision in these agreements requiring that they be reviewed at a minimum every four years.

27. In 2019, the AG responded to a request from an Informal Member State consultation in March of that year regarding clarification of some earlier advice. The AG’s response and earlier work served as background information for Decisions WHA72(12) and WHA72(13). The AG continues to track implementation of Decision WHA72(12) which is specifically related to influenza and stays informed of the progress of WHA72(13) and its broader work related to the Nagoya Protocol. Decision WHA72(12), operative paragraph 2, addressed an area of an indirect use of IVPP biological material where benefit sharing could have been missed.

3.7 The use of financial and non-financial contributions

28. The 2018-2019 PIP Framework Biennial Progress Report tracks the allocations and spending according to the six outputs of the HLIP II and the output for the PIP Secretariat. As of December 2019, 92% of the total 2018-2019 budget has been spent. In addition, the WHO Programme Budget Portal provides detailed and transparent information on budget allocations, technical and financial implementation, and progress against specific objectives across the seven output areas.
29. As of 31 December 2019, 58% of the total US$ 28M invoiced in 2019 had been received. Of this US $ 9,090,321 was allocated to preparedness (net of programme support costs). US$ 4,402,312 was allocated to the Response Fund (inclusive of programme support costs) and US$ 1,442,908 (net of programme support costs) was allocated to the PIP Secretariat. An additional amount of US $1,547,974, representing accrued interest on the response fund, was also added.

30. 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 resulting in the Interim Certified Financial Statement which is included in the PIP Framework annual and biennial progress reports.
## Cross-reference: PIP Framework Section 7.2.5 and PIP Framework Biennial Report 2018-2019

|------------|---------------------------------------------------------------------------------------------------------------|
| a. Necessary technical capacities of WHO GISRS | - L&S Milestone on PISA trainings (Deliverable A, p10)  
- L&S Output Indicator on PISA (Deliverable A, p10)  
- Size/expansion of GISRS (Highlights Deliverable B, p10)  
- L&S Outcome Indicator on IVPP sharing (Deliverable D, p11)  
- L&S Output Indicator on zoonotic viruses characterized (Deliverable E, p11) |
| b. Operational functioning of WHO GISRS | - L&S Milestone on lab trainings (Deliverable B, p10)  
- L&S Output Indicators on EQAP (Deliverable B, p10)  
- L&S Output Indicators on FluNet (Deliverable C, p10)  
- L&S Milestone on shipments made using SFP (Deliverable D, p11)  
- L&S Output Indicator on virus shipments (Deliverable D, p11)  
- L&S Milestone on VCM CVVs proposed (Deliverable D, p11) |
| c. WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building) | - L&S Milestone on shipping ISST training (Deliverable D, p11)  
- L&S Milestone on protocols/guidance (Deliverable E, p11)  
- L&S Milestone on VCM CVVs proposed (Deliverable E, p11)  
- BOD Output Indicator on countries with estimates (Deliverable A, p12)  
- BOD Outcome Indicator on countries that used estimates (Deliverable B, p12)  
- REG Outcome Indicator on countries with accelerated pathway (Deliverable B, p13)  
- RCCE Output Indicator on countries utilizing WHO support (Deliverable B, p14)  
- DEP Output Indicator on vaccine sustainability assessments (Deliverable C, p15)  
- IPPP Outcome Indicator on countries with plans (Deliverable A, p16)  
- IPPP Output Indicator on countries with simex (Deliverable A, p16)  
- IPPP protocols/guidance (Highlights Deliverable A, p16)  
- SMTA 2 categories A, B & C (p7)  
- SMTA 2 indicator companies that signed an SMTA 2 (Deliverable C, p17) |
| d. Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential | - L&S Milestone on outbreak response training (Deliverable A, p10)  
- L&S Output Indicator on HAI risk assessments (Deliverable A, p10)  
- L&S Milestone on surveillance coordination meetings (Deliverable C, p10)  
- L&S Milestone on surveillance trainings (Deliverable C, p10)  
- L&S Output Indicator on FluiD (Deliverable C, p10) |
| e. The Influenza Virus Tracking Mechanism | - New PIP BM records in IVTM in a one-year period (p7)  
- Cumulative PIP BM records in IVTM (p7) |
| f. The sharing of influenza viruses and access to vaccines and other benefits | - L&S Milestone on shipping ISST training (Deliverable D, p11)  
- L&S Output Indicator on IVPP shared (Deliverable D, p11)  
- L&S Output Indicator on timely virus/specimen shipments (Deliverable D, p11)  
- L&S Milestone on VCM CVVs proposed (Deliverable E, p11)  
- SMTA 2 vaccine and other benefits total/volume (p7)  
- PC collected (p6) |
| g. Use of financial and non-financial contributions | - Financial implementation graphs by HLIP II Output, Secretariat, Response (p6)  
- Financial graphs (donuts) per PIP Deliverable (pp 10-17)  
- Financial report in annual report including ICFS and detailed table (pp 31-36) |