PIP Framework Review Group 2016

Preliminary Findings

19 August 2016

Contents

Overarching findings

An innovative approach to improving pandemic preparedness

Finding 1: The Pandemic Influenza Preparedness (PIP) Framework is valued as a bold and innovative tool for pandemic preparedness and is a model for meaningful public-private partnerships. The implementation of the Framework has demonstrated that an agreement that balances virus sharing and benefit sharing on an equal footing can be successfully implemented. In doing so, the PIP Framework Secretariat has established trusted and transparent relationships with key stakeholders including industry and civil society, working in partnership with Member States.

Finding 2: The Framework has improved global influenza pandemic preparedness through implementation of the benefit sharing mechanisms that have enabled WHO to successfully: secure, via standard material transfer agreements:access to vaccines and antivirals in the event of an influenza pandemic; funding of capacity building in priority countries with limited or no national ability to detect, monitor and share novel influenza viruses; and establishment of a reserve fund for response. Through these activities, there is an increase in confidence and greater predictability in the global capacity to respond to an influenza pandemic as well as more equity of that response.

Finding 3: The benefits of the PIP Framework extend beyond SMTA 2s and implementation of the PC funds. The ongoing risk assessment by GISRS on seasonal influenza viruses and periodic risk assessment on other influenza viruses to ascertain pandemic potential provide key benefits for countries by strengthening core capacities for seasonal influenza response and pandemic preparedness. PIP PC investment in building and supporting capacity for surveillance and laboratory detection of novel influenza viruses, contributes significantly to the functioning of GISRS, which benefits all countries in pandemic preparedness, core IHR capacity building, and overall health system strengthening.

Finding 4: While there are indices for progress in specific areas such as PC implementation, there are no overarching indicators to measure the progress in implementing the Framework as a whole. This Review has identified that key outcomes must be measured to determine overall progress and these should be standardised to enable continuous future monitoring.

Finding 5: Contributions made to the Framework could be given more visible recognition and acknowledgement, including the significant annual investment by Member States of at least $56.5 million to support the running costs of GISRS, other in-kind contributions, as well as the contributions of all participating entities to Partnership Contribution funds. Such recognition should build on the Secretariat's existing practice of formally acknowledging PC contributors.

Ensuring the relevance of the PIP Framework

Finding 1: Maintaining the currency of the PIP Framework, and communicating the collateral benefits that flow from pandemic preparedness is especially important as countries with several competing health priorities usually focus their attention on current diseases and therefore will be unprepared for an influenza pandemic. The continued relevance of the Framework will be critical for ensuring the ongoing commitment of all stakeholders for influenza preparedness.

Finding 2: The PIP principles of placing virus sharing and benefit sharing on an equal footing remain as relevant today as five years ago; finding ways to ensure continued

fulfilment of those principles will be a continuing challenge, despite the good progress to date.

Finding 3: To ensure the continued relevance and optimal impact of the Framework, regular review of the scope and functioning of the Framework is needed.

Finding 4: Currently, the Framework does not specify the period for subsequent reviews. There is a need for Member States to indicate when the Framework should next be reviewed and how often future reviews should take place.

Finding 5: An increasingly urgent concern among stakeholders and Member States has been how to address the impact of new technology, particularly that relating to genetic sequence data and new methods of vaccine production, under the Framework (see section 3.xx).

Expanding the Framework to seasonal influenza

Finding: Expansion of the Framework to include seasonal influenza would eliminate the current disconnect between the handling of seasonal and pandemic influenza viruses under the Framework. It would also contribute to the recognition of the PIP Framework as a specialized international access and benefit-sharing instrument for all human influenza viruses that is consistent with the objectives of the Convention on Biological Diversity and the Nagoya Protocol. Such recognition would be beneficial to public health by advancing efforts to ensure the rapid sharing of all influenza viruses and the consequential benefits. However, the significant workload implications for GISRS laboratories should be avoided, for example, by ensuring that the IVTM remains limited to tracking PIP biological materials with possible expansion to include seasonal CVVs. Consultation with Member States, industry and civil society would be needed to address the challenges of ensuring the adequacy of benefit sharing for the inclusion of seasonal influenza viruses.

Improved communication about the Framework

Finding: Some stakeholders do not clearly understand key aspects of the Framework, including priority country selection for PC implementation and the progress that is being achieved in PC-funded projects. While WHO and the Advisory Group engage in regular, transparent communication with stakeholders, these gaps need to be addressed by publicising more widely the Framework and its implementation and achievements.

Using the PIP Framework as a model for other pathogens

Finding 1: The success of the PIP Framework in ensuring better and more equitable access to vaccines and antivirals, particularly to priority countries, has led some stakeholders to propose the application of the principles of the Framework to other infectious diseases. However, expanding the current Framework to pathogens other than influenza would be a very complicated process and seriously threaten its viability.

Finding 2: The sharing of pathogens other than influenza viruses could be encouraged through a broader interpretation of IHR Article 6[1] on sharing information.

[1] For the full text of Article 6 on Notification, see p12 of http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410_eng.pdf

Virus Sharing

Overview

Finding 1: The GISRS virus sharing system generally works well, although there is a serious risk to the system due to the inadequate sharing of recent H5N1 viruses from some countries. At an operational level, there are platforms for the rapid exchange of information and strong interactions between different organizations. Thus, so far, there is no evidence that GISRS laboratories have not complied with their SMTA1 obligations. In terms of logistics, the WHO Shipping Fund Project has increased laboratories' ability to share viruses. Separately, there are also enduring links, in place for more than 40 years, with non-GISRS laboratories, especially from the animal sector, that develop and donate CVVs for pandemic vaccines to GISRS.

Finding 2: Sharing of recent H5N1 viruses from some countries in EMRO, SEARO and WPRO has been rather unsatisfactory and should be encouraged, in light of the Framework establishment to promote benefit sharing hand in hand with virus sharing.

Finding 3: GISRS now has 143 laboratories and the recently completed self-assessment in September 2014 showed that the response to the emergence of the H7N9 strain was generally prompt and comprehensive.[2] Moreover, the laboratory capacity developed for influenza appears to have had collateral benefits for other pathogens, such as MERS-CoV.[3] However, the self-assessment also revealed weaknesses, such as gaps in geographic coverage (particularly in Africa and the Middle East) along with insufficient national funding and a lack of prioritization of influenza.[4]

Finding 4: GISRS also provides several benefits, including conducting critical risk assessment, and providing diagnostic kits, reagents, reference viruses, expertise, training and capacity building at no cost to Member States. Other collateral benefits include increased collaborative scientific publications such as those explaining how WHO makes vaccines virus recommendations, specialist informal consultation on the improvement of vaccine virus selection and guidance on switching from seasonal to pandemic vaccine production.

Finding 5: Collaboration with the animal sector has been of critical importance to risk assessment and the development of CVVs. GISRS collaborates closely with the Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE), and the OFFLU (the joint OIE-FAO network of animal influenza experts) to conduct important virological characterization of zoonotic influenza viruses and develop candidate vaccine viruses for pandemic preparedness. In some cases, where viruses from human infections are not shared—or their sharing is delayed—due to export controls, political hesitancy, or other reasons, animal viruses have served as partial substitutes, allowing risk assessment and CVV development to take place.

Finding 6: In case of an influenza pandemic, GISRS will face a surge of samples to process, and concerns have been raised that the network could become overwhelmed. WHO has provided guidance to prepare for this contingency, including prioritisation of

[2] http://www.who.int/influenza/pip/virus_sharing/gisrs_self_assessment.pdf, Section 4.1.
[3] http://www.who.int/influenza/pip/virus_sharing/gisrs_self_assessment.pdf, Section 4.1.
[4] http://www.who.int/influenza/pip/virus_sharing/gisrs_self_assessment.pdf, Section 4.2.

virus samples to be forwarded to WHO CCs for further analysis and development of CVVs.[5] This guidance proved valuable during the 2009 A(H1N1) pandemic. It should be maintained, improved as necessary, and continue to be made publicly available emphasizing the need for sharing of physical viruses and sequence data.

Influenza Virus Traceability Mechanism

Finding 1: Consistent use of the IVTM among GISRS laboratories is vital to ensuring transparency and advancing the PIP benefit goal of equitable benefit sharing.

Finding 2: IVTM recordkeeping is sporadic amongst NICs because many deal primarily and routinely with seasonal influenza, and the IVTM is used specifically for specimens with pandemic potential. Many NICs therefore have had little exposure to this tool in day-to-day operations. While CCs tend to use the tool consistently, NICs generally fail to enter shipments of PIP biological materials. This appears to stem from a lack of knowledge, and training on the use of the IVTM could help address this.

Virus-sharing metrics

Finding 1: While the sharing of PIP biological materials initially increased after adoption of the PIP Framework, a steady decline has been noted over the past 2 years. This decline is a serious threat to the sustainability of the Framework. The reasons for this decline vary but this clearly needs to be addressed urgently. One reason may be due to the adoption of the initial molecular testing of influenza specimens rather than virus isolation and therefore might include the sharing of GSD instead of physical samples. There may also be a lack of understanding of the requirement and reasons for sharing all PIP material via the IVTM. While IVPP GSD can be an invaluable resource for preliminary risk assessment and other activities, it cannot yet substitute for the physical virus sample. Therefore, while sharing GSD – particularly in the interim while physical samples are being prepared and shipped – is valuable, it alone does not fulfil a laboratory's responsibilities under the PIP Framework (Section 5.1.1).

Finding 2: NICs' lack of familiarity onvirus sharing via the IVTM system is a risk to the Framework. As IVPPs have arisen in only a handful of countries, not all NICS may fully understand their obligations under the PIP Framework. In addition, the specific requirements for import and export licenses for pathogens that are the responsibility of different departments can cause confusion for laboratories that have never dealt with IVPP.

[5] WHO checklist for influenza pandemic preparedness planning. WHO/CDS/CSR/GIP/2005.4. *Pandemic contingency planning checklist for NICs and other national flu labs.* August 2009

Genetic Sequence Data

Finding 1: Many IVPP sequences are already being shared. Technological developments mean that GSD can increasingly provide critical supplementary information, and in some cases, substitute for physical samples for pandemic risk assessment and the development of commercial products. Therefore, clarity is required on the handling of GSD under the Framework to ensure that it is guided by the same principles as the sharing of PIP materials.

Finding 2: A key challenge has been the lack of agreement on what should be traced. Options could include tracking of access to GSD or commercial products developed using GSD. Issues relate to transparency in both the sharing and traceability of GSD, in order to identify any resulting benefit that should be shared. Progress has been made by the Advisory Group into examining possible approaches to handling GSD under the PIP Framework as requested by Member States in section 5.2.4.

Finding 3: In the view of this Review Group, based on the evidence contained in the work undertaken by the AG, monitoring all access to GSD may not be feasible given the many public and private ways of sharing and accessing GSD. Indeed, given that GSD can be shared easily through private means that are not recorded anywhere (e.g. email), if GSD benefit sharing is to be based on tracking of access to GSD, it would not be feasible to ensure fairness and equity in benefit sharing; concerns over free-riders simply could not be addressed. In addition, monitoring all access to GSD would have significant consequences in terms of workload for the WHO PIP Framework Secretariat, without necessarily leading to a substantial increase in benefit sharing. Monitoring use in commercial end-products, however, would be feasible, using an appropriate search engine. Tracking commercial products, rather than access to GSD, would be practicable, achievable and cost-effective, to best achieve the goals of access and benefit-sharing.

Finding 4: Capturing benefit sharing on commercial products developed using GSD may provide a model for the sharing of other pathogens should a similar model be established for other infectious diseases.

Finding 5: How the Framework should address the handling of GSD is complex. Changing the definition of PIP Biological Materials to include GSD would require substantive amendments to the existing text, since GSD cannot always be substituted for physical materials. One approach could be development of an Annex for PIP Framework Article 6 to include GSD. This may be a more feasible approach and could allow taking into account the specificities of GSD.

Benefit Sharing

Standard Material Transfer Agreement 2 (SMTA2)

Finding 1: Four SMTA2s have been signed to date with vaccine manufacturers, one with a diagnostic manufacturer, and 45 with academic institutions. Despite some SMTA2s remain outstanding as negotiations are yet to be completed, the Review Group considers that progress has not been slow and that good progress in the circumstances has been achieved. The Secretariat has focused on addressing those which offer the biggest gains - these agreements signed to date have already significantly improved WHO's future access to pandemic vaccine doses, antivirals and other products for distribution to countries in need should a pandemic occur.

Finding 2: The regularity and high quality of communication between the Secretariat and industry and other stakeholders has helped to facilitate the conclusion of SMTA2s. On the occasions when negotiations have been complicated or have stalled, the Secretariat has successfully implemented the stepwise approach recommended by the Advisory Group to progress towards an agreement in a timely manner. There is nevertheless a perception that some eligible entities are not signing SMTA2s. In practice, a delicate balance needs to be maintained with the companies that are not facilitating completion of the negotiations; if these manufacturers are denied access to PIP biological materials because of failing to sign an SMTA2, this could be detrimental to public health. Member States assistance could be sought to enable conclusion of such agreements.

Finding 3: Although SMTA2s were designed to be broad enough to accommodate a range of commitments, no companies to date have agreed to provide technology transfer. This reluctance to enter into technology transfer agreements may be for intellectual property reasons or because not all eligible manufacturers have influenza-relevant technologies that could be made available for licence through WHO.

Finding 4: The good progress on securing prequalified vaccines and antivirals has been achieved through the PIP Secretariat's clear strategic approach of prioritizing agreements with multinational companies before moving on to negotiations with medium to small companies. Some Member States have queried whether the labour-intensive process of signing SMTA2s with small and medium companies is worth the resources required given the relatively modest additional volume of vaccines or other products secured. However, the PIP Framework's principle of fairness and equity in benefit sharing – which results in signing SMTA2s with all parties that receive PIP biological materials – is valued and the Secretariat recognizes the importance of maintaining that goal despite the diminishing returns in terms of additional products secured. Manufacturers should be treated equitably and it would be unfair to focus only on signing agreements with large producers. The Secretariat has already made considerable effort to familiarise small and medium companies with the collateral benefits that are available, such as increased understanding of requirements for WHO prequalification status. The Review Group is of the opinion that the Secretariat with support from the Advisory Group, should continue to take steps to better prepare companies for the SMTA2 negotiation procedure.

Finding 5: Where new vaccine manufacturers are still in the process of establishing themselves (initiated via the GAP programme), PIP Framework Partnership Contribution funds could be used to strengthen their progress to achieve sustainable seasonal and pandemic vaccine production capacity, for example through a training programme that could

continue the support currently provided by the influenza GAP programme which will end in 2016. Such a proposal would benefit from discussions with established manufacturers to build support and collaboration. The SMTA2 mechanism could be leveraged to fund such training if there were flexibility over the SMTA2 options for come categories of participants, such as diagnostic companies and Category C entities. Along these lines, the Secretariat is assessing the introduction of laboratory and surveillance training that Category C SMTA2 contributors could support in order to complement PC Preparedness investment.

Finding 6: In November 2013, at the request of WHO, the Strategic Advisory Group of Experts (SAGE) on Immunization reviewed its 2007 recommended policies for the establishment and use of influenza A(H5N1) vaccine stockpiles during a pandemic. Recognizing the immediate access to pandemic vaccine production secured by the SMTA 2 agreements under the PIP Framework and the unchanged global epidemiology of influenza A(H5N1) amongst other factors, SAGE recommended that WHO should no longer create a stockpile of influenza A(H5N1) vaccine. Instead, WHO should ensure immediate access to pandemic vaccines under the PIP Framework[6,7]. This decision is not reflected in the PIP Framework (Section 6.9).

Finding 7: Member States with in-country influenza vaccine production capacity need to include the SMTA requirements of the manufacturer(s) into their pandemic influenza response plans. It is essential that Member States ensure that the manufacturers can fulfil their SMTA2 commitments to provide WHO with real time access to pandemic vaccines and allow the export of these vaccines to other countries.

Partnership Contribution collection

Finding 1: The involvement of industry in the collaborative development[8] of the Partnership Contribution formula has achieved their strong buy-in, and has resulted in early contribution payments being made in 2012, and the collection of 96% of the funds due for each of 2013 and 2014.

Finding 2: Collection of PC is a continuing challenge, however, as not all companies pay their contributions by the expected deadline, and a few have not paid in full. This is of concern since the PC mechanism relies on all stakeholders fulfilling their obligations. Unlike a contractual SMTA 2, the Partnership Contribution system is not legally binding and there are no enforcement mechanisms available to WHO beyond skilful negotiation and the potential embarrassment for a company of public exposure. However, Member States have signed up to the Framework and can hold their companies to account to fulfil these obligations.

Finding 3: Issues of concern that could adversely affect the Partnership Contribution process were identified. Some civil society organizations and industry representatives consider that not all entities qualifying to make contributions actually do so in practice, resulting in a perception of inequity. Some companies (mostly manufacturers of diagnostic products) that

[6] PIP AG 2014 annual report, section 3.5. http://www.who.int/influenza/pip/ag_annual_report_2014.pdf?ua=1

[7] Meeting of the Strategic Advisory Group of Experts on immunization, November 2013 – conclusions and recommendations. Weekly Epidemiological Record 2014;89:1-20 Strategic Advisory Group of Experts (SAGE) Working Group on Influenza Vaccines and Immunizations. http://www.who.int/wer/2014/wer8901.pdf?ua=1 Page 10

[8] http://www.who.int/influenza/pip/benefit_sharing/pc_collection_sop.pdf?ua=1, Annex 2, page 1

make infrequent use of GISRS, perceive unfairness in the requirement to make annual contributions, even though their product sales continue to benefit from past access to the network.

Finding 4: Several industry representatives have complained that the fluctuation in the amount of PC they are asked to pay each year poses budgetary challenges, and they would prefer to pay a set amount. Industry has begun a consultative process to review the PC formula, working with all relevant industry sectors (vaccine, diagnostics and pharmaceuticals) and the PIP Secretariat. This is consistent with the recommendation of the PIP Advisory Group in April 2016. A review of GISRS running costs is also underway and the results will enable an assessment of whether the 2010 estimate needs updating.

Partnership Contribution implementation

Finding 1: Since funds began to be distributed in 2014, the implementation of the Partnership Contribution benefit sharing mechanism has been transparent and well-aligned with the Partnership Contribution Implementation Plan 2013-2016.

Finding 2: These PC resources have allowed countries to develop multi-year plans and have fostered sustained and meaningful capacity building.

Finding 3: Expenditure does not always keep pace with collection, leading to an erroneous perception among some stakeholders that either additional Preparedness funds are not needed or that work plans are failing to be implemented according to planned timeframes. This risks an erosion of support among the entities making Partnership Contributions and an unwillingness to make further contributions.

Finding 4: The Secretariat communicates regularly about the achievements and challenges of PC implementation. Nevertheless, stakeholders regularly raise specific issues with WHO concerning: (1) Dissatisfaction that PC funds continue to be collected while the Response fund is left untouched, which seemingly indicates a lack of understanding that this is a contingency fund to enable rapid response at the start of a pandemic; (2) the basis on which recipient Priority Countries are selected, even though the criteria and process for selection have been published,[9] though this could indicate the desire of certain countries to be put on this list; and (3) a lack of appreciation of how PC funds are building capacity in countries to increase preparedness for pandemic influenza.

Finding 5: Industry and Member States (particularly at the regional level) remain highly interested in understanding the decision-making process for implementing PC funds, and providing input as appropriate. Regions, too, have requested opportunities for PIP PC implementers to discuss lessons learned, and would like to be more engaged in planning, implementation and monitoring. However, it should be noted that WHO Regional offices are invited to participate in all AG meetings and staff turnover may account for these offices not to be fully abreast of PIP discussions and implementation policies.

Finding 6: PC implementation Areas of Work, especially Burden of Disease studies, Regulatory Capacity and Planning for Deployment, are fundamental for the introduction of seasonal influenza vaccine programmes, which in turn provides the critical foundations for the operation of the PIP Framework and pandemic preparedness.

[9] http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1, Page 10

Finding 7: However, in four out of 12 H5-affected countries that received PC funds, virus sharing is not increasing despite an increase in resources being provided.

Finding 8: The timing of the first pandemic wave of a virus for some countries may occur long after the virus has established itself as a seasonal virus in other countries e.g. Fiji did not experience the first wave of pandemic H1N1 2009 virus until 2016. Fiji requested access to pandemic support from the WHO but the PIP Framework does not provide response support for a pandemic virus that is now classified as a seasonal virus.

Finding 9: Several regional offices raised the issue of the limited PIP funding that is available for funding PIP staff involved in implementation of PIP activities . There is worry over the approach set by HQ senior management that WHO must be conservative in using PIP PC funds to support WHO staff; while recognizing that some funds must be dedicated to support staff who have full time responsibility for implementing PIP activities. The current operating principle is that the percentage used for WHO staff should be kept as low as possible to ensure that the maximum amount of PIP PC funds goes to activities implemented by countries. Other sources of funds may be appropriate to assist with staffing costs, and the Framework Section 6.14.3.1 does encourage other donors generally to provide additional funds.

Governance

Finding 1: Although it is relatively new (adolescent is a term used), the PIP Framework is an example of a successful and innovative public private partnership (PPP) with a well-functioning governance structure that oversees how the Framework is operationalized. It has benefited from strong commitment at each of WHO's three levels: Headquarters, including the PIP Secretariat and Global Influenza Programme (GIP); Regional Offices; and Country Offices.

Finding 2: The Advisory Group performs well and plays a key role in effective governance by providing impartial, competent, committed, strategic, and pragmatic oversight and guidance.

Finding 3: The intended composition of the Advisory Group has been achieved in practice, with a good balance of skills and representation of the regions. The engagement of WHO Regional Offices in Advisory Group meetings has benefited all participants – and Regions should be encouraged to increase their participation. Where expert evidence and situational analysis has been required, the Advisory Group has successfully initiated the establishment by the Director-General of technical and expert working groups on genetic sequence data (GSD).

Finding 4: The value of the Advisory Group has been enhanced by members' familiarity with the issues and the expertise that has developed over time. However, the fixed three year term for Advisory Group members, with extensions only for a further full three year term, means that the membership of the Advisory Group will be completely renewed every three years. This regular turnover brings benefits in terms of fresh inputs from new members but also risks the loss of institutional memory with the exit of experienced members.

Finding 5: Based on evidence provided to the Review Group, since 2011, Advisory Group recommendations to the PIP Secretariat and the Director-General have been acted upon. The Advisory Group's Annual Reports and the Director-General's biennial reports have been completed and delivered on time and made available as publications on the PIP Framework website. The Director-General has reported each year on the PIP Framework to the Executive Board and the World Health Assembly; therefore, Member States are well apprised of its actions and progress. However, harmonising the prescribed content of the Advisory Group Annual Reports and the Director-General's biennial reports would improve efficiency.

Finding 6: The regularity and transparency of communication and engagement between the Advisory Group and Member States, industry and civil society organizations was recognized and appreciated by a number of key informants interviewed by the Review Group. That said, only a relatively small number of civil society organisations engage consistently with the Secretariat; this may be because others are unclearr about the relevance of the PIP Framework for their work. The Secretariat could reach out to a wider community of civil society groups in order to broaden and deepen engagement, which would bring new perspectives that could benefit the Framework.

Finding 7: Some GISRS members, notably WHO Collaborating Centres, feel there should be greater interaction between themselves, the Advisory Group, and the PIP Secretariat, such as the regular, direct contact that occurs between the Advisory Group and industry/civil society groups.

Finding 8: The Review Group has greatly benefited from the inclusion of two former members of the Advisory Group who have provided guidance and a historical perspective on the PIP Framework and its implementation.

Finding 9: The PIP Framework calls on the Director-General to make available the necessary human and financial resources to support the work of the Advisory Group and the Secretariat (Annex 3, section 5). Those resources are stretched and it is important that they are enhanced to implement the increasing activities and Recommendations in this Review.

Linkages with other instruments and WHO programmes

Global Action Plan for Influenza Vaccines (GAP)[10]

Finding: There are important synergies between the PIP Framework and GAP programme.[11] This includes encouraging technology transfers and building capacity for burden of disease studies, regulatory authorities and risk communications. However, as mentioned in Section 3.4.1. (SMTA 2s), technology transfer agreements are currently not being obtained, perhaps in part because the private sector is reluctant to nurture potential competition. The closing of the GAP programme at the end of 2016 may result in the end of these synergistic activities and could impact on the benefit sharing aspects of the PIP Framework.

International Health Regulations (2005)[12]

Finding: PIP Framework PC funds may have collateral benefits in improving IHR core capacities, especially in the areas of laboratory and surveillance capacity. However, since PC funds began to be distributed in 2014, data on the relationship between PC funds and IHR core capacities are not yet available. An analysis of PC funds' impact on IHR core capacities should be undertaken in the next review of the PIP Framework.

Nagoya Protocol to the Convention on Biological Diversity[13]

Finding 1[14]: The PIP Framework is an access and benefit-sharing sharing agreement that appears to be consistent with the objectives of the Nagoya Protocol. As such, it should be considered a specialized international access and benefit-sharing instrument for pandemic influenza. Acknowledgement by the Health Assembly of the status of the PIP Framework with respect to Nagoya would facilitate global understanding and fulfilment of the Framework's objectives.

Finding 2: Awareness of the Nagoya Protocol, especially in sectors other than the environment is limited, and its potential implications for public health are not widely understood. While the WHO Secretariat is producing a report to clarify these implications, better knowledge and understanding of the Protocol is required in the public health sector especially in Member States.

Finding 3: Countries and manufacturers sharing seasonal influenza viruses may be facing increasing legal uncertainty as the Nagoya Protocol is implemented. Acknowledgement of the PIP Framework in its current form as a specialized instrument would only cover pandemic influenza viruses (see Finding 1). However, by expanding the scope of the PIPF to cover

[10] http://www.who.int/influenza_vaccines_plan/

[11] The objectives of the GAP programme centre around increasing influenza vaccine manufacturing capacity for developing countries, and include an increase in the manufacture and use of seasonal vaccine, an increase in vaccine production capacity for pandemic vaccine and relevant research and development. The GAP was developed by WHO together with public health and academic experts, vaccine manufacturers and funding agencies from developed and developing countries. The third and final GAP consultation will take place in November 2016.

[12] http://www.who.int/ihr/

[13] http://www.cbd.int/

[14] In January 2016, the WHO Executive Board requested the Director-General to undertake a study on the public health implications of implementation of the Nagoya Protocol. The Review Group's findings have benefited from updates and data from that process.

seasonal influenza viruses, it could become the specialised instrument for all influenza viruses. Becoming such an instrument covering all influenza viruses would require ensuring the sufficiency, adequacy and practicability of access and benefit sharing arrangements for this class of pathogens as a whole.

Finding 4: (Placeholder for potential finding from the WHO study on the implications of the Nagoya Protocol).

List of Acronyms for the PIP Framework[15]

AFRO	WHO Regional Office for Africa
AG	PIP Framework Advisory Group
AMRO/PAHO	WHO Regional Office for the Americas/Pan-American Health Organization
AOW	Area of work
BOD	Burden of disease
BSF	Band Selection Form (under Partnership Contribution)
CC	WHO Collaborating Centre for Influenza
CPA	Critical Path Analysis
CVV	Candidate vaccine virus
EB	Executive Board
EID	Emerging infectious disease
EMRO	WHO Regional Office for the Eastern Mediterranean
EQAP	External Quality Assessment Project
ERL	WHO Essential Regulatory Laboratory
EURO	WHO Regional Office for Europe
FAO	Food and Agriculture Organization of the United Nations
GAP	Global Action Plan for Influenza Vaccines
GIP	WHO Global Influenza Programme
GISRS	Global Influenza Surveillance and Response System
GSD	Genetic sequence data
H5RL	WHO H5 Reference Laboratory
IHR	International Health Regulations (2005)
ILI	Influenza-like illness
IVPP	Influenza virus with human pandemic potential
IVTM	Influenza Virus Traceability Mechanism
L&S	Laboratory and surveillance
MERS-CoV	Middle East respiratory syndrome coronavirus
MOH	Ministry of Health
MS	WHO Member State
NIC	WHO National Influenza Centre
OIE	World Organisation for Animal Health
PC	Partnership Contribution
PHEIC	Public health emergency of international concern
PIP	Pandemic influenza preparedness
PIP BM	PIP Biological Materials
PIP Framework	Pandemic Influenza Preparedness Framework
PPP	Public-private partnership
PQ	Prequalification
PSC	WHO Programme Support Costs

[15] This list includes acronyms commonly used in discussion of the PIP Framework. Not all acronyms appear in the circulated documents.

RO	Regional Office
SAGE	Strategic Advisory Group of Experts on Immunization
SARI	Severe Acute Respiratory Infection
SEARO	WHO South-East Asia Regional Office
SMTA	Standard Material Transfer Agreement
RSV	Respiratory Syncytial Virus
WHA	World Health Assembly
WHO	World Health Organization
WPRO	WHO Regional Office for the Western Pacific