

# Pandemic Influenza Preparedness Partnership Contribution - High-Level Implementation Plan 20132016

November 2016 – February 2017

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# List of acronyms

# Overview

AOW	Area of Work	SEARO	WHO Regional Office for South East Asia
AFRO	WHO Regional Office for Africa	WHO	World Health Organization
AMRO	WHO Regional Office for the Americas	WHO CC	WHO Collaborating Centres
CC	Collaborating Centre	WPRO	WHO Regional Office for the Western Pacific
EBS	Event-based surveillance		
EMP	WHO Department for Essential Medicines and Health Products		
EMRO	WHO Regional Office for the Eastern Mediterranean		
EURO	WHO Regional Office for Europe		
GAP	Global Action Plan		
GIP	Global Influenza Program		
GISRS	Global Influenza Surveillance and Response System		
GSM	Global System Management		
HLIP	High-level Implementation Plan		
IHR	International Health Regulations		
ILI	Influenza-like Illness		
IVB	WHO Department for Immunization, Vaccines and Biologicals		
MOOC	Massive Open Online Course		
NIC	National Influenza Centre		
NRA	National Regulatory Authority		
PCR	Polymerase Chain Reaction		
PIP	Pandemic Influenza Preparedness		
SARI	Severe Acute Respiratory Infections		

#### Introduction

## **Background**

Since 1952, WHO has co-ordinated the Global Influenza Surveillance and Response System (GISRS) – a network of laboratories that monitor the evolution of existing influenza viruses and serve as a global alert mechanism for the emergence of new ones. The network comprises of 143 WHO-recognised National Influenza Centres (NICs); six WHO Collaborating Centres (WHO CCs); four WHO Essential Regulatory Laboratories and 13 WHO H5 reference laboratories. GISRS provides information, data and materials to manufacturers of influenza vaccines, antivirals and diagnostics.

In May 2011, WHO Member States unanimously adopted the Pandemic Influenza Preparedness Framework at the sixty-forth World Health Assembly. The PIP Framework is the result of a four-year intergovernmental negotiation process. The Framework aims to improve and strengthen the sharing of influenza viruses with human pandemic potential and to increase the access of developing countries to vaccines and other pandemic supplies. The framework established two mechanisms to facilitate access to the benefits that result from the sharing of viruses with human pandemic potential: the Partnership Contribution (a financial contribution from industry partners), and the Standard Material Transfer Agreement 2 (a contract with industry partners that establishes a structured process for efficient and equitable access to vaccines and influenza products at the time of a pandemic). WHO is responsible for the implementation of the PIP framework.

The Partnership Contribution is an annual contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers (henceforth "industry partners") that use the WHO GISRS network. Each year, the PIP Secretariat requests that industry partners complete a questionnaire to identify all companies that manufacture influenza products and use GISRS. The contribution expected from is based on the average of their annual influenza product sales from the three previous years, plus 2009 - the first year of the last pandemic.

WHO uses the funds provided to strengthen influenza pandemic preparedness and response capacity. Of the funding received through the Partnership Contribution, around 10% is used to fund the Secretariat at WHO HQ, and an additional 10% is taken for the WHO Program Support Cost (PSC). Of the remainder, 70% is allocated to activities that improve pandemic preparedness in countries where preparedness is weak and 30% is allocated to a response fund, and held in reserve for use in relation to activities in the next pandemic.

Funds for pandemic preparedness are allocated between headquarters, regional offices and priority countries in each of the five areas of work. Of the preparedness funds, around 70% are allocated towards developing laboratory and surveillance capacity in 43 PIP priority countries. The remainder of the funds are distributed between the other four areas of work: burden of disease; regulatory capacity building; planning for deployment and risk communications.

#### Context

The PIP Partnership Contribution model is taking a new and innovative approach to private-public partnerships to build pandemic preparedness. It is important to contextualise this evaluation by highlighting that the PIP model is a new initiative within the WHO, including a brand-new team with a brand-new mandate, raising funds in a new way. Furthermore, the PIP framework remains relatively young. This evaluation represents the first opportunity to formally take stock of the progress made to-date, evaluate the key successes and challenges and consolidate the lessons learned to-date.

The PIP framework Secretariat sits within the pandemic and epidemic diseases department of the WHO. The department promotes strategies, initiatives and mechanisms to address epidemic diseases to reduce their impact on vulnerable populations and limit their spread. All WHO departments and offices are required to abide by WHO rules and regulations around financial management and procurement. Some stakeholder perceptions relating to these areas, and captured in this evaluation, are beyond the PIP Secretariat's control.

Dalberg was engaged to assess how PIP Partnership Contribution funded activities have led to outputs, outcomes, and impact, in line with the targets set in the first high-level implementation plan (HLIP 1) 2013-2016, and to identify the lessons learned over this period. The issues highlighted, and resulting recommendations, will contribute to the design of the second high-level implementation plan (HLIP 2). Several other analyses will provide input into HLIP 2, including a second Gaps and Needs Analysis.

Table 1. The PIP Partnership Contribution – areas of work, objectives and priority countries.

Area of work	Objectives	Priority countries
Laboratory and surveillance	Improve national ability to detect, monitor and share novel influenza viruses	Afghanistan, Algeria, Armenia, Bangladesh, Bolivia, Burundi, Cambodia, Cameroon, Chile, Republic of Congo, Costa Rica, Djibouti, Dominican Republic, Ecuador, Egypt, Fiji, Ghana, Haiti, Indonesia, Jordan, Korea DPR, Kyrgyzstan, Lao PDR, Lebanon, Madagascar, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Nicaragua, Sierra Leone, South Africa, Suriname, Tajikistan, The United Republic of Tanzania, Timor-Leste, Turkmenistan, Ukraine, Uzbekistan, Viet Nam, Yemen, Zambia
Burden of disease	Provide training and support for burden of influenza estimates which will contribute to the development of a global burden of influenza estimate	Albania, Armenia, Cambodia, Chile, Costa Rica, Croatia, Egypt, Georgia, Indonesia, Kyrgyzstan, Lao PDR, Madagascar, Republic of Moldova, Mongolia, Nepal, Oman, Senegal, Serbia, Ukraine
Regulatory capacity building	Build national regulatory capacity so that vaccines, diagnostic tests and antiviral medicines for influenza can be deployed quickly	Armenia, Bolivia, Cambodia, Congo (Democratic Republic of), Ethiopia, Georgia, Ghana, Haiti, Kenya, Lao PDR, Nepal, Pakistan, Sri Lanka, Sudan, United Republic of Tanzania, Uganda
Planning for deployment	Plan for efficient and equitable deployment of vital supplies for pandemic influenza	Armenia, Bolivia, Cambodia, Congo (Democratic Republic of), Ethiopia, Georgia, Ghana, Haiti, Kenya, Lao PDR, Nepal, Pakistan, Sri Lanka, Sudan, United Rep. of Tanzania, Uganda
Risk communications	Build national capacity to provide accurate public health information during emergencies	Afghanistan, Barbados, Bangladesh, Bhutan, Burkina Faso, Cambodia, Dominica, Ecuador, Egypt, Honduras, Fiji, Gabon, Indonesia, Kazakhstan, Kenya, Lao PDR, Lebanon, Mauritania, Mexico, Moldova (Republic of), Mongolia, Mozambique, Nepal, Pakistan, Panama, Saint Lucia, Saint Vincent and the Grenadines, Senegal, Seychelles, Sudan, Suriname, Timor-Leste, Turkey, Ukraine, Uzbekistan, Viet Nam, Yemen, Zimbabwe

#### **Evaluation criteria**

This evaluation considered the work funded by the PIP Partnership Contribution against four criteria: relevance, effectiveness, efficiency and impact. Relevance and effectiveness are considered within the context of each area of work (AOW). Efficiency relates mostly to the way in which the PIP Secretariat functions and interacts with external stakeholders, and so is considered at the program level. Impact relates to the broader achievements of the program in global public health.

Table 2. DAC criteria for assessing the Partnership Contribution.

Criteria	Questions posed
Relevance	Were the desired outcomes of each AOW consistent with the objectives of the program?
	Were the activities within each AOW relevant to the desired outcomes?
	Was the country prioritization process well suited to the outcomes of each AOW?
Effectiveness	Were output targets met over the period 2013-2016?
	What were the key successes and challenges in achieving the targets?
Efficiency	How well did stakeholders work together to achieve the program's outcomes?
	What processes were used to achieve the program's outcomes? What worked well, what was challenging, and why?
Impact	What has been the overall impact on global pandemic preparedness?

Within the assessment of program relevance, it was not possible for Dalberg to evaluate if more appropriate priority countries could have been chosen, mostly due to a lack of counterfactual evidence (i.e. would alternative options for priority countries have led to greater achievement of the objectives of the PIP Partnership Contribution?). However, Dalberg did assess whether the prioritisation criteria were clear and applied consistently. Dalberg also captured stakeholders' perspectives on the prioritization process and its outcomes.

Effectiveness was measured by evaluating progress made towards each output indicator's target, within each AOW. Efficiency is evaluated by describing the issues faced by stakeholders, and assessing the effect of each. Impact is challenging to assess this early into the program, and is mainly considered through the perspectives of stakeholders interviewed during the course of this evaluation.

## **Evaluation methodology**

We established the fact base for the evaluation by:

- Drawing on internal WHO documents including (i) workplans; (ii) annual reports; (iii) laboratory and surveillance indicator scores; (iv) financial reports; (v) other documents as shared by WHO.
- Interviewing 40 stakeholders<sup>1</sup> including i) representatives of the PIP Secretariat; (ii) the heads of each AOW; (iii) regional office focal points; (iv) industry partners; (v) WHO CCs); (vi) non-PIP Secretariat WHO staff and (vii) National Influenza Centres (NICs).

#### Interviewee coverage

Contact details for interviewees were obtained from the PIP Secretariat. A summary of interviewees by stakeholder type is shown in *table 3*.

Table 3. Stakeholders interviewed by stakeholder group.

Stakeholder group	Number of interviewees
PIP Secretariat	4
AOW staff in headquarters	6
Regional office PIP focal points	10
Industry partners	7
WHO CCs	4
WHO (non-PIP)	5
National Influenza Centres (NICs)	3
Other	1
Total	40

#### Interview approach

Stakeholder interviews lasted between 45 and 60 minutes. The interviews focussed on the four DAC criteria of the evaluation.

#### Interview data interpretation

Stakeholders occasionally held conflicting perspectives across various aspects of the program, in particular the root causes for specific issues. This report highlights instances where there are divergences of opinion.

<sup>&</sup>lt;sup>1</sup> Forty stakeholders were interviewed. Four of these stakeholders were interviewed twice.

It is worth noting in advance that stakeholders were often resistant to quantifying the overall impact of the PIP Partnership Contribution. The Secretariat noted that impact may be too difficult to assess at such an early stage of the program. There are also no indicators at the impact level (i.e. public health impact, estimated cases averted), which is likely due to the difficulty in quantifying these indicators for pandemic influenza — an inherently probabilistic event. As such, a quantitative assessment is not possible.

#### **Data quality issues**

Laboratory and surveillance indicator data are collected via an online questionnaire sent to country offices. The country office in turn collects these data from the ministries of health through face-to-face discussion and/or document review. The regional office validates this information and cross-checks it with Ministry of Health staff or via email correspondence. Stakeholders note that the validating process may not be sufficiently rigorous to ensure the results are always fully accurate. Stakeholders also note that indicator scores change beyond what would be expected between the biannual scoring rounds, which can be difficult to rationalize. This is likely due to varying level of knowledge among responders around the country's own capacity combined with those individuals' different interpretations of specific questions or associated timelines.

## **Document layout**

This report begins by assessing each AOW against the criteria of relevance and effectiveness. In addition, under the laboratory and surveillance AOW, effectiveness is considered region-by-region.

The report then assesses the broader criteria of efficiency and impact. These criteria are not considered to be AOW-specific as in many cases inefficiencies in one AOW were broadly applicable to other AOWs.

Figure 1. Layout of this document.

# **Section 1: AOW-specific issues**

# Laboratory and Surveillance capacity

Relevance

Effectiveness

AFRO, AMRO, EMRO, EURO, SEARO, WPRO

# Burden of Disease

Relevance

Effectiveness

# Regulatory Capacity Building

Relevance

Effectiveness

# **Planning for Deployment**

Relevance

Effectiveness

# Risk Communication

Relevance

Effectiveness

# **Section 2: Non-AOW-specific issues**

Efficiency

Impact

## **Executive Summary**

In this executive summary, we consider each component of the evaluation framework in turn: relevance; effectiveness; efficiency and impact. We also consider lessons for the logframe design. Within the effectiveness section, we assess progress made within each area of work (AOW) in turn. The other sections cover all AOWs together.

## **Background**

Since 1952, WHO has co-ordinated the Global Influenza Surveillance and Response System (GISRS) — a network of laboratories that monitor the evolution of existing influenza viruses and serve as a global alert mechanism for the emergence of new ones. In May 2011, during the sixty-fourth World Health Assembly, WHO Member States unanimously adopted the Pandemic Influenza Preparedness Framework, which was designed to improve pandemic preparedness at the global level. One component of the PIP framework is the Partnership Contribution: an annual contribution to WHO from industry partners that use the GISRS network. WHO uses the funds provided to strengthen influenza pandemic preparedness and response capacities in priority countries under each of the five areas of work.

Dalberg was engaged to assess the extent to which those activities have led to outputs, outcomes, and impact, in line with the targets set in HLIP 1, 2013-2016.

This report's findings are based on an assessment of i) key documents, including work plans, progress reports (where available), as well as ii) interviews with 40 stakeholders including the PIP Secretariat, WHO Regional Offices, AOW heads at WHO headquarters, WHO CCs, NICs and external experts on pandemic influenza.

#### **Context**

This evaluation covers the first high level implementation plan, initially intended to cover the period from 2013-2016. Delays at the start of the program meant that activity implementation did not start until mid-2014. As a result, HLIP 1 was formally extended to 2017.

The outcomes identified in HLIP 1 are expected to be achieved over a 10-year timeline. This evaluation therefore focuses on progress against the output targets set in HLIP 1, for which the timeline was 2013-2016.

#### Relevance

Between 2014 and 2016, the PIP Partnership Contribution funded activities in areas of work that are important to reach a high level of pandemic influenza preparedness in WHO member states. Activities under each AOW often led to improved preparedness. For example, since the start of the program an additional 20 priority countries have established functional event-based surveillance systems with relevant definitions, protocols and procedures in place.

The process of prioritizing countries for support from the PIP Partnership Contribution, and the determination of whether these countries were the most important and relevant, was a

key issue for many stakeholders. Perspectives varied as to whether the country prioritization methodology was the most appropriate, and whether it was applied consistently across regions. It is difficult for the evaluation team to ascertain whether the most appropriate countries were prioritized. However, multiple stakeholders across regional offices and AOWs noted that the prioritization process was not well communicated to some countries. Interviewees noted that this led stakeholders in some countries to question the fairness of the process, and to ask to be considered for Partnership Contribution funding at a later point. The Secretariat notes that a 'call for application' would not have been suitable for selecting the priority countries that could benefit most from Partnership Contribution support and that it consulted extensively with regional offices prior to priority country selection.

Several stakeholders noted that priority countries were selected without sufficient consultation with countries themselves. Some NICs were not aware of the opportunities presented by funding from the PIP Partnership Contribution. Stakeholders in Collaborating Centres noted that this was true more broadly. The PIP Secretariat prioritised countries for the laboratory and surveillance AOW based on a gaps analysis of existing detection and monitoring capacity, and consultation with regional offices which considered additional secondary factors. The resulting priority countries selected had a range of high and low baseline capacity scores, both within regions themselves and between regions. It is possible that the range of capacity levels in prioritised countries led to stakeholder confusion around approach to country prioritization.

### **Effectiveness and AOW-specific issues**

All AOWs have made progress towards targets and, on-the-whole, stakeholders report that WHO member states are better prepared than they were prior to support from the PIP Partnership Contribution. Several issues hindered progress. In most regions, influenza is not a health priority, limiting overall support for action. However, influenza is becoming a more important issue for governments in some countries following development of burden of disease estimates. Large-scale health emergencies diverted human resources away from influenza in some regional offices, constraining progress towards targets.

#### Laboratory and surveillance.

All regions have made progress towards one or more targets within the laboratory and surveillance AOW, but none have yet achieved them all.

Laboratory and surveillance capacity improved across detection, monitoring and sharing. The number of priority countries considered well-prepared for detection increased from seven to 26; the number able to monitor epidemiological data increased from seven to 17 and the number able to monitor virological data increased from 27 to 33. A total of 30 countries shared influenza viruses with WHO at least once a year in the previous two years. While no target was set for this output, the number of countries sharing at least one shipment of viruses in the first year of indicator collection (September 2013-August 2014) was 25,

compared to 32 in the most recent year of indicator collection (September 2015-August 2016).

## Burden of disease

The burden of disease team provided training for regional office staff and supported the development of burden studies in around 67 countries. Two priority countries have now published burden of disease estimates, falling short of the initial target of 19. However, the burden of disease team provided technical support to 48 non-PIP priority countries, of which six have published burden of disease estimates. A global-level estimate is under development, with completion expected by the end of 2017, one year behind schedule. The AOW reports that progress in activities was hindered by a high administrative burden on technical staff, delays in funding disbursal, and duplication of activities with other donor programs.

#### Regulatory capacity building

Progress was made towards each of the outputs for regulatory capacity building. The regulatory capacity building AOW achieved its target of developing guidelines and is now rolling them out in target countries.

The AOW assessed capacity and developed institutional development plans in 14 out of 16 priority countries. It subsequently ran targeted training sessions on quality management systems in seven priority countries, on product evaluation of influenza vaccines in seven priority countries and on pharmacovigilance in 11 of 16 priority countries. The impact on capacity itself will not be known until the next institutional assessments, potentially in 2017. However, it is expected that tangible capacity improvement will only be reflected in the indicators in three to five years, due to the size of the effort required to improve most regulatory systems.

Progress towards uptake of the collaborative procedure was complicated due to a WHO reorganization which resulted in an expansion of scope from just vaccines to also include diagnostics and medicines. A total of 14 countries out of a targeted 48 have adopted a common regulatory approach. However, it is important to note that this output does not fully reflect the number of countries with accelerated approval mechanisms as there are several alternative methods to achieve this outcome, not captured in the indicators for this output.

Stakeholders in the regulatory capacity building AOW noted that workplan approval delays hampered progress towards achieving the targets set for each output.

#### Planning for deployment

Stakeholders noted that countries are increasingly running self-assessments and round-table simulations for emergency situations. Countries are also beginning to diversify deployment plans that were previously focussed on resource mobilisation, to include aspects such as development of staff rosters for use in health emergencies, and engagement of relevant private sector partners.

Simulation software for pandemic response remains under development. Stakeholders reported that progress had been hindered multiple times due to administrative and financial delays between the AOW and the PIP Secretariat.

Stakeholders reported that some targets were set without the full agreement of AOW staff, who felt that the targets set unrealistic expectations given the resources available. Progress has not yet been reflected by a change in indicator values, which are binary in nature. Use of intermediate indicators would allow greater visibility of progress for this AOW.

#### **Risk Communications**

The risk communications AOW has made considerable progress in developing training material, with a total of five modules accessible on the WHO website. The number of registered users of online material at the end of 2016 was 598, exceeding the initial target of 500. Additionally, web-based risk communications training material is now accessible to all Member States in 18 languages.

With regards to Output 2, a total of 20 priority countries benefitted from the International Health Regulations (IHR) risk communications program, short of the target of 30. This was largely due to competing health priorities, most notably the emergence of Ebola virus in 2014.

The AOW effectively deployed the Emergency Communications Network. One hundred percent of countries requesting risk communication surge support received that support within 72 hours of the request, exceeding the target of 80%.

#### **Efficiency**

The PIP Secretariat is still a relatively new team, is part of a young program, and sits outside of the traditional WHO program budget structure. Partially as a result of these factors, there remain growing-pains, mostly around the ways the Secretariat collects data and distributes funding.

Issues that negatively impact implementation efficiency relate to workplan templates, approval processes, the annual funding cycle, and the program's logframe (discussed separately). These issues have negatively impacted progress across most AOWs. It is possible that process adjustments in these areas could yield significant benefits.

Through consultation with stakeholders and review of documentation, the evaluation team identified the following issues with work planning and approval:

- The work plan template design does not allow for a description of linkages between activities and impact, making it challenging for experts to provide relevant and timely advice during workplan reviews. The work planning process is thereby open to errors, sometimes resulting in submission of poor quality workplans. Workplan approvals can become protracted, with multiple iterations sent between the Secretariat and regional offices or areas of work.
- The annual contribution model contributes to workplan approval delays. Annual contributions generally arrive late in the calendar year, creating uncertainty for the Secretariat around the amount of funding that will be available for disbursal to the regions and AOWs. Workplans can only be approved when sufficient funding is available, and so this often occurs late in the year, and sometimes not until a few months into the year in which the activities should take place.
- Approval delays, in combination with the WHO biennial funding approach, can sometimes mean AOWs must self-finance activities to avoid having under-funded and incomplete workplans. The late approval of workplans and subsequent late disbursal of funding can mean AOWs are not able to fully implement activities before the end of the WHO biennium, at which point remaining funds are withdrawn. (Note that this is WHO policy and does not fall within the Secretariat's control). The impact of this issue depends on each AOW's willingness and ability to access alternative sources of finance whilst PIP Partnership Contribution funding is being prepared. In some cases, activities continue but suppliers go unpaid (e.g. planning for deployment), or, activities continue and AOWs use funds from elsewhere in the interim (e.g. risk communications), or, activities are postponed or cancelled all together (e.g. regulatory capacity building). The Secretariat notes that it is the responsibility of AOWs to follow WHO procurement rules and regulations.

Additional issues related to communication between the PIP Secretariat and external stakeholders, the way the Partnership Contribution is calculated and the portion of Partnership Contribution funds allocated to different areas of work. The following issued were noted:

• The PIP Secretariat currently does not report PIP Partnership Contribution expenditure at the activity level. A majority of the interviewed industry partners and stakeholders from WHO CCs would like to see detailed expenditure reporting in

addition to workplans (which are forward-looking) and Secretariat reports (which focus at the output level).

- A majority of industry partners noted that the Partnership Contribution formula should be updated, as currently: i) the total sum is based on the cost of running the GISRS network rather than the cost of activities required and ii) it includes some weighting on revenue generated in the 2009 pandemic, which is unlikely to be as relevant today as it was when the Partnership Contribution formula was first used. In discussions with the evaluation team, the Secretariat confirmed that it is open to an adjustment of the formula, and would welcome proposals from industry partners.
- There was divergence of opinion around the appropriate portion of PIP Partnership
  Contribution funds allocated to laboratory and surveillance. Two stakeholders
  suggested that PIP Partnership Contribution funds contributed a disproportionately
  large amount towards building laboratory and surveillance capacities. Their
  suggestion was that more of these costs should be borne by non-PIP PC funders.

## **Impact**

Some AOWs are already beginning to positively impact preparedness (risk communications, burden of disease, lab and surveillance), while others will take longer to have impact due to the scale of the change required (planning for deployment and regulatory capacity building).

Several stakeholders noted that the true impact of the program can only be measured after the next pandemic, and in fact, the HLIP 1 2013-2016 did not include impact-specific metrics (see below).

## Log frame design

The logframe's design - which outlines the linkages between activities, outputs and outcomes - is not conducive to fully assessing the level of improved preparedness. Targets were sometimes too ambitious, and did not fully consider the timeline that would be required to achieve the targets. Non-PIP funded activities can also affect indicator scores, especially in countries with existing influenza capacity. Although this is unavoidable, the log frame should acknowledge the impact of these non-PIP activities on the achievement of targets. Furthermore, some indicators are binary in nature, and do not provide sufficient detail to monitor progress effectively, or do not consider alternative and additional activities that could achieve similar impact.

In places, the logframe did not adequately reflect:

- Potential alternative pathways to achieve the same outputs (e.g. regulatory capacity building)
- A sufficiently realistic timeframe for implementation (e.g. laboratory and surveillance, regulatory capacity building, planning for deployment)
- The potential dependencies between outputs (e.g. planning for deployment).

Furthermore, the lograme did not always have sufficient clarity to facilitate monitoring of progress. To be specific, the logframe requires countries to be scored against indicators in a binary way despite there being a spectrum of possible values for the indicator at the country level (e.g. burden of disease, regulatory capacity building). Moreover, the wording of some indicators is too vague (e.g. burden of disease) and in some cases does not provide sufficient information as to the effort required to achieve them (e.g. risk communications).

## **Recommendations**

The recommendations are listed below with the aim of specifically addressing the issues highlighted in the evaluation. They are designed to act as key inputs to the design of HLIP 2.

To develop recommendations, the evaluation team initially identified the key issues facing the program. Each issue, was identified by making observations on data, from sources including (i) stakeholder interviews (ii) existing reports and (iii) data provided by WHO. The tables below provide detail on the specific groups of observations, the issues emanating from each group, and the subsequent recommendations that aim to address each issue.

# **Recommendation 1: Improve logframe design**

Observations	Issue summary	Specific action
Interviewee observations:	Challenging to define	The PIP Secretariat should consider redesigning the logframe with the
<ul> <li>Weak links between activities</li> </ul>	overall progress and	following aims:
and indicators	impact, progress, and	Define impact at the global, regional and country level
<ul> <li>Difficulty in defining impact</li> </ul>	links between activities,	Design and articulate robust linkages between activities, and
<ul> <li>Difficulty in measuring progress</li> </ul>	outputs, and outcomes	achievement of outputs, outcomes, and impact
Desk research:		Provide sufficient modulation in indicators to highlight progress on an
<ul> <li>Logframe includes several</li> </ul>		annual basis
binary indicators, and few		Account for the starting point for various priority countries (i.e. more
progress indicators		might be expected from some countries than others)
Impact: Work planning is more straightforward and more likely to lead to measurable impact		

# **Recommendation 2: Improve reporting granularity**

Observations	Issue summary	Specific action
<ul> <li>All industry partners interviewed noted:         <ul> <li>Insufficient detail over activities provided in reporting</li> </ul> </li> <li>Other interviewee observations:         <ul> <li>Current system does not ensure that funding recipients spend resources on activities as planned, reducing accountability</li> </ul> </li> <li>Desk research:         <ul> <li>Secretariat ceased activity monitoring in 2015</li> </ul> </li> </ul>	Industry partners question program implementation success, in part, due to lack of visibility of detailed expenditure  Limited accountability at activity-level	<ul> <li>Monitoring and reporting financial disbursements down to the activity level         <ul> <li>This would require more detailed, country-level financial reports and retrospective activity reports (including at country and regional office level)</li> <li>This should include all activities of funding recipients and at the Secretariat</li> </ul> </li> <li>Assessing how best to collect laboratory and surveillance data from countries themselves, to ensure an accurate understanding of existing capacities (as well as financial data mentioned above).         <ul> <li>One option is to consider external verification of activities and/or capacities – for example by engaging WHO CCs to monitor progress against specific outputs</li> </ul> </li> <li>Reporting a description of country-specific activities and related challenges and impact</li> </ul>

Impact: Relevant stakeholders are held accountable for expenditure and outputs, and this is shared with contributors

Recommendation 3: Provide clarity on country prioritisation

Observations Issue summary	Specific action
<ul> <li>Many interviewees noted:         <ul> <li>Process did not sufficiently involve countries</li> <li>Criteria were not clearly communicated</li> </ul> </li> <li>Some interviewees noted:         <ul> <li>Prioritization outcomes did not yield most appropriate countries</li> </ul> </li> <li>Desk research:         <ul> <li>Prioritization process (for L&amp;S) applied criteria objectively to all eligible countries² although secondary factors often outweighed the outcome of</li> </ul> </li> </ul>	The PIP Secretariat should consider the following:  Communication of the country prioritization process itself will be critical to ensure support for the process among all member states:  The PIP Secretariat should consider whether responsibility for such communication sits most efficiently within the Secretariat itself, or at regional office level  All eligible countries should be made aware of the opportunity for PIP Partnership Contribution support and of the assessment criteria  Results of the prioritization should be communicated in the same manner  Prioritization criteria should be clear to all relevant stakeholders, including how and when expert opinion will be used as criteria

Impact: All eligible countries understand decisions around future support

<sup>&</sup>lt;sup>2</sup> Dalberg did not assess the suitability of prioritization outcomes

# Recommendation 4: Speed up workplan approvals

Observations	Issue summary	Specific action
<ul> <li>Many interviewees noted:         <ul> <li>Work plan approval process takes longer-than-expected</li> <li>Work plan reviewers often request several detailed iterations before approval</li> <li>Work plan templates do not require sufficient description of rationale for choice of activities</li> </ul> </li> <li>Industry partners noted:         <ul> <li>Variable contributions (by year) create business planning challenges</li> <li>No visibility over work plans before contributions are made, creates internal approval challenges</li> </ul> </li> <li>Some interviewees noted:</li> </ul>	Implementation progress was restricted by work plan approval delays	The PIP Secretariat should consider the following:  Adjusting the workplan templates to enable:  Inclusion of relevant detail and articulation of linkages between activities, outputs, outcomes, and impact  Harmonization with WHO Global Systems Management (GSM) system  Where countries and regions do not complete workplans to an adequate level, the Secretariat should consider investigating the root causes of this and what solutions exist to address them (i.e. additional capacity/support, retraining, etc.)  Moving to a biennial funding cycle:  This could reduce funding disbursement delays (in year 2)  This would enable and require longer-term planning by all actors, including funders and funding recipients  This could also have advantages in aligning the PIP Partnership Contribution with the WHO PB  (This could also at least partially address industry partners' desire to approve work plans before making contributions)

Work plans do not contain		
sufficiently explicit and detailed		
rationale for proposed		
expenditure to warrant		
immediate approval (without		
further discussion)		
Impact: Implementation can proceed with fewer delays.		

# Recommendation 5: Review approach and timeline for industry partner contributions

Observations Issue summar	y Specific action
<ul> <li>Industry partners noted:         <ul> <li>Contribution calculation algorithm is too reliant on 2009 outbreak</li> <li>Basing calculations on cost of running GISRS is not the most relevant approach</li> </ul> </li> <li>Desk research:         <ul> <li>Some industry partners' contributions vary significantly each year</li> </ul> </li> <li>Industry partner question ration contribution a which increase difficulty of objective internal approach</li> <li>Contribution services</li> </ul>	<ul> <li>Discussing the contribution algorithm with industry partners to identify if a more relevant formula exists:         <ul> <li>This applies to the way in which individual contributes are calculated, as well as the total funding envelope</li> </ul> </li> <li>val to cartnership</li> </ul>

## **Laboratory and Surveillance**

#### Relevance

Stakeholders describe laboratory and surveillance capacity as the cornerstone of pandemic influenza preparedness. Most stakeholders agreed that laboratory and surveillance capacity is vital in the development of seasonal influenza vaccines, and in the identification of influenza viruses with pandemic potential. These stakeholders tended to agree that it was appropriate for the majority of PIP Partnership Contribution funding to go towards this AOW. (Two stakeholders noted however that non-influenza disease areas were reaping disproportionately large benefits from PIP Partnership Contribution funds, and allocation towards this AOW should be reduced accordingly<sup>3</sup>.)

Country prioritisation was partly based on each country's baseline detection and monitoring capacity, but secondary criteria were often weighted heavily in the final **determination.** Prior to the selection of priority countries, WHO conducted a gaps assessment of influenza surveillance capacity in each of the WHO regions. The gaps assessment scored countries on their detection and monitoring capacity, in order to group countries based on need. The scoring system for both monitoring and detection was based partly on IHR implementation status of event-based surveillance, presence or absence of a WHOrecognised NIC in the country, and on existing PCR capacity. For detection, the scoring system also the included the country's ability to ship influenza virus samples. For monitoring, the scoring system also included the country's capacity to conduct ILI and SARI surveillance. The PIP Secretariat shared a database of the results of the gaps analysis with regional offices, which included secondary factors of country development status, H5N1 vulnerability and total population size, to help regions to identify priority countries for strengthening laboratory and surveillance capacity. Regions further refined countries by considering additional factors including their political situation, absorptive capacity, geographical location, interest in working in influenza and their ability to build on existing capacities to produce influenza surveillance data that could be shared with neighbouring countries. Finally, the PIP Secretariat required that regions select at least one Output 2 priority country in each transmission zone. Overall, secondary factors weighted strongly during consultations with regional offices and countries were often selected based on their own merits, rather than as a consequence of the scoring itself.

The resulting priority countries selected had a range of high and low baseline capacity scores, both within regions themselves and between regions. This variation makes it difficult to determine precisely how secondary factors were considered and applied within- and between- regions e.g. some priority countries scored highly on detection capacity, whilst others in the same region scored very low. Overall, to select priority countries, secondary factors were combined with primary factors from the gaps analysis in a way that reflected regional experts' judgements on each countries' suitability for prioritization — rather than

<sup>&</sup>lt;sup>3</sup> Dalberg did not attempt to assess the accuracy of this claim.

taking a quantitative scoring approach. It is possible that the variety of existing capacity in prioritised countries led to confusion among stakeholders around the outcomes of the country prioritization process.

Several stakeholders felt that the country prioritization process itself was not communicated to all relevant parties, making it difficult for some to understand how priority countries were chosen. Several stakeholders were unaware of the country selection methodology and did not understand country selection rationale (for example, whether the focus of the laboratory and surveillance AOW was to select countries with no existing capacity, or to select countries with existing-but-weak capacity). Additionally, communication of prioritization results did not always reach all stakeholders, leading to some priority countries not being aware of their status. (This was confirmed during an interview with an NIC of a priority country that had only been aware that it was eligible for Partnership Contribution funding since December 2016).

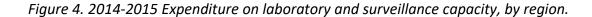
#### **Effectiveness**

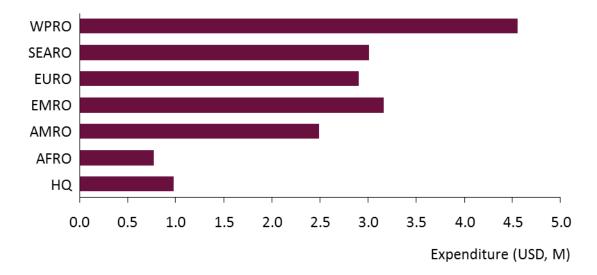
Activities that made important contributions to pandemic influenza preparedness and response included trainings, development of guidelines and distribution of reagents and supplies to NICs. For example, in AMRO, PIP Partnership Contribution funds facilitated trainings in sample submission for over 50 laboratory technicians. In AFRO, the regional office produced guidelines and protocols for investigation of respiratory illness outbreaks. In Nicaragua, the NIC was assessed and reorganized to improve co-ordination, monitoring and reporting, while in Chile six laboratories were verified as competent to carry out influenza detection through real time PCR. These various activities supported the establishment of country-level surveillance response systems in some countries, and the strengthening of response systems in others.

The implementation rate was 80% across 2014 and 2015. Output 1, 2 and 3 had implementation rates<sup>4</sup> of 79%, 79% and 81% respectively across 2014 and 2015. Total expenditure on laboratory and surveillance capacity between 2014 and 2015 was USD 18M, around USD 1M of which was spent at headquarters. Expenditure volumes were relatively high in WPRO, broadly similar in AMRO, EMRO, EURO and SEARO, and lower in AFRO.

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<sup>&</sup>lt;sup>4</sup> Implementation rate is defined as the proportion of funds budgeted that were spent





## Effectiveness - AFRO

Table 4. Status of output indicators in AFRO.

**Output indicators for priority countries:** Algeria, Burundi, Cameroon, Congo, Ghana, Madagascar, Mozambique, Sierra Leone, South Africa, The United Republic of Tanzania and Zambia

	Baseline	Target	Status <sup>5</sup>
Output 1: Detection capacity			
Number of countries with an established and functioning event- based surveillance system	1	11	5
Output 2: Monitoring capacity			
Number of countries able to consistently report and analyse virological data	8	11	8
Number of countries able to consistently report and analyse epidemiological data	1	11	2
Output 3: Sharing capacity			
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	8

Progress towards developing detection capacity accelerated in 2015 and in 2016, with a total of five countries hosting event-based systems in AFRO. However, this falls short of the initial target of 11. At the beginning of the program only Ghana had a functioning event-based system. As of the end of 2016, Algeria, Ghana, Madagascar, South Africa and Zambia had

<sup>&</sup>lt;sup>5</sup> Status uses indicator data as reported for the period Feb-Aug 2016

established functioning event-based systems, and progress towards establishing one had been made in the Republic of the Congo, Mozambique and Sierra Leone. It should be noted however that Algeria, Madagascar, South Africa and Zambia did not receive Partnership Contribution funds between 2013 and 2016. Furthermore, between round three of data collection (August '15- Feb '16) and round four of data collection (Mar'16 – August '16), there was a decrease in the number of countries with an event-based surveillance system from seven countries to five countries, per the indicator scores. This change was due to misreporting of the presence of an EBS in Burundi during round three of data collection. The status of an EBS in Mozambique is unclear and will be clarified by the regional office in the next round of data collection. Inaccuracy in indicator results could be due to different personnel completing the questionnaire within country, or show continued confusion around the questionnaire used to collect indicator data.

There was no improvement in reporting of virological data from the beginning of the program. During the last round of data collection, eight out of 11 countries could consistently report virological data - the same countries as at the start of the program. Of the remaining three, Burundi and the Republic of the Congo remained with the same indicator score as at the start of the program. Sierra Leone's score decreased as it did not report virological data during 2016.

There was a moderate improvement in reporting of epidemiological data. South Africa developed capacity to consistently report epidemiological data - despite not receiving Partnership Contribution funds - making the total number of countries able to report epidemiological data two. The remaining nine countries had no improvement in epidemiological reporting capacity as per their output indicator scores. Progress in the region is short of the target of 11 countries. It is worth noting that that all rounds of indicator collection besides the baseline and round four would have suggested no countries had epidemiological reporting capacity.

The funding for lab and surveillance could not always be fully utilised due to competing health priorities across the region. A total of USD 770,000 was spent on lab and surveillance activities in AFRO across 2014 and 2015. This represents the smallest expenditure across all regions; around one third that spent by the next lowest region (AMRO, USD 2.5M). In 2014 and 2015, PIP Partnership Contribution funds were used in only two of the 11 PIP priority countries for lab and surveillance: Ghana and Tanzania. In 2016, only three countries implemented activities with PIP Partnership Contribution funds (Ghana, Congo and Burundi). The remaining priority countries did not receive country-specific support. The regional implementation rate in AFRO was 13% in 2014 and 59% across the 2014/2015 biennium. Stakeholders noted that implementation rates were negatively impacted partly due to the emergence of Ebola in 2014, which resulted in transfer of human resources away from influenza in both country and regional offices. For example, Ghana - one of the laboratory and surveillance priority countries - became the headquarters of the UN Mission for Ebola Emergency Response (UNMEER). Furthermore, in 2015, countries in the AFRO region were

afflicted by cholera outbreaks, and a particularly severe meningitis season, causing diversion of regional resources and personnel from influenza preparedness. More generally, stakeholders noted that influenza is not considered a top health priority in AFRO, and high-level advocacy would be required to generate more interest in PIP Partnership Contribution participation.

# Effectiveness – AMRO

Table 5. Status of output indicators in AMRO.

**Output indicators for priority countries:** Bolivia (Plurinational State of), Chile, Costa Rica, Dominican Republic, Ecuador, Haiti, Nicaragua and Suriname

	Baseline	Target	Status <sup>6</sup>
Output 1: Detection capacity			
Number of countries with an established and functioning event- based surveillance system	0	8	3
Output 2: Monitoring capacity	•		
Number of countries able to consistently report and analyse virological data	7	8	7
Number of countries able to consistently report and analyse epidemiological data	0	8	3
Output 3: Sharing capacity			
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	6

AMRO made progress towards developing detection capacity, with three countries establishing event-based systems. This fell short of the target of eight countries. Dominican Republic, Ecuador and Nicaragua operationalised event-based surveillance systems during the first high level implementation plan. Bolivia, Chile, Costa Rica, Haiti and Suriname remain without event-based systems, but continue to build functional indicator-based surveillance. In 2014 and the first part of 2015, most funding for strengthening detection capacity in these countries was focussed on improving the SARI and ILI reporting systems.

There was moderate improvement in reporting of epidemiological data. Three countries (Chile, Ecuador and Suriname) started consistently reporting epidemiological data. However, this falls short of the target of eight countries. While Costa Rica and Nicaragua report data on a biweekly basis, they have not yet configured their data systems to report to FluID. Bolivia

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<sup>&</sup>lt;sup>6</sup> Status uses indicator data as reported for the period Feb-Aug 2016

and Dominican Republic have established sentinel sites but have relatively poor epidemiological data collection.

Existing strength in the reporting of virological data was maintained. Seven out of eight priority countries had strong virological reporting capacity since the 2009 influenza pandemic. Stakeholders noted AMRO as a region has particularly strong virological reporting capacity. Virological data reporting was strengthened in Suriname but weakened in Haiti, due to competing health priorities which prevented the receipt and testing of samples in the national laboratory. In addition to virological and epidemiological reporting, the regional office used PIP Partnership Contribution funds to improve human-animal interface surveillance in the region. However, this use of funds is not reflected in the core indicators.

A lack of will to share data from one Ministry of Health restricted visibility of progress in one priority country, whilst competing health priorities limited progress itself in others. Stakeholders noted that one ministry of health was reluctant or slow to share data with the regional office. It is unclear why this was the case. In response, staff from the regional office went on multiple missions to the country office and confirmed that progress had been made, but with less traction than other countries in the region. Another priority country had multiple competing health priorities, severely limiting any progress towards greater influenza pandemic preparedness.

Six countries shared influenza virus samples with WHOCCs, H5 reference laboratories and essential regulatory authorities at least once in the past two years. Bolivia, Chile, Costa Rica, Dominican Republic, Ecuador and Nicaragua all submitted influenza virus samples at least once a year between August 2014 and August 2016. Suriname was unable to ship samples due to a lack of international courier in the country, while Haiti had no samples to ship.

# Effectiveness – EMRO

Table 6. Status of output indicators in EMRO.

Output indicators for priority countries: Afghanistan, Djibouti<sup>7</sup>, Egypt, Jordan, Lebanon, Morocco and Yemen<sup>8</sup> Baseline Status<sup>9</sup> **Target Output 1: Detection capacity** Number of countries with an established and functioning event-7 4 5 based surveillance system **Output 2: Monitoring capacity** Number of countries able to consistently report and analyse 2 7 5 virological data

<sup>&</sup>lt;sup>7</sup> No funds were allocated to Djibouti in 2015 or 2016.

<sup>&</sup>lt;sup>8</sup> The PIP Secretariat did not provide funding for Yemen in 2015 and 2016 owing to its conflict situation.

<sup>&</sup>lt;sup>9</sup> Status uses indicator data as reported for the period Feb-Aug 2016

Number of countries able to consistently report and analyse epidemiological data	1	7	2
Output 3: Sharing capacity			
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	4

Progress has been made in detection capacity in EMRO, with one more country establishing a functioning event-based surveillance system as compared to the start-point. In total, five countries have functioning systems, falling short of the target of seven. Afghanistan, Egypt and Yemen maintained their pre-existing event-based surveillance systems. Lebanon and Jordan established new event-based surveillance systems. The continuity of event-based surveillance systems in Afghanistan and Yemen is particularly promising against a background of regional conflict. Additionally, progress in Lebanon comes against a great influx of refugees that has put more pressure on the health system at large. Morocco's event-based surveillance system dropped relative to the start-point due to diversion of resources to implement alternate activities in 2016, including the development of standard operating procedures.

**Progress has been made in monitoring capacity in EMRO.** Afghanistan and Morocco consistently reported epidemiological data over the period August 2015-August 2016. Furthermore, Afghanistan, Lebanon and Morocco started to consistently report virological data, while Egypt and Jordan maintain pre-existing virological reporting capacity. Thus, the total number countries consistently monitoring virological data increased to five.

Four countries shared influenza virus samples with WHOCCs, H5 reference laboratories and essential regulatory authorities at least once in the past two years. By the end of 2016, Afghanistan, Egypt, Jordan and Morocco had sent at least one shipment a year between August 2014 and August 2016. Lebanon also shared one shipment, up from a start-point of zero.

Stakeholders report an improvement in laboratory and surveillance capacity beyond the four core output indicators for laboratory and surveillance capacity. Stakeholders noted that since the founding of the PIP Partnership Contribution, all priority countries in EMRO can now perform PCR testing on influenza samples. Stakeholders noted that progress has been particularly strong in countries that started from a low base capacity. As such, while progress has been made it has not always been sufficient for the country to score highly enough for it to contribute to the value of the indicator.

Additionally, stakeholders report that influenza is increasingly recognised as a public health issue, and that the build-up of human resources in this area has broader benefits for pandemic preparedness.

Effectiveness - EURO

Table 7. Status of output indicators in EURO.

**Output indicators for priority countries:** Armenia, Kyrgyzstan, Tajikistan, Turkmenistan, Ukraine, Uzbekistan

	Baseline	Target	Status 10
Output 1: Detection capacity			
Number of countries with an established and functioning event- based surveillance system	0	6	011
Output 2: Monitoring capacity	- 1		
Number of countries able to consistently report and analyse virological data	4	6	4
Number of countries able to consistently report and analyse epidemiological data	5	6	5
Output 3: Sharing capacity	- 1		l
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	3

There was confusion in the Euro region as to the specific definition of Output 1, and therefore reporting was submitted with errors. PIP L&S activities contributed to indicator based surveillance but were not used to directly build event-based surveillance. None of the six priority countries have event-based surveillance systems, nor are they in the process of building it.

There has been a slight improvement in monitoring of epidemiological and virological data against a relatively high start-point. At the start-point, all countries apart from Turkmenistan conducted weekly reporting of epidemiological data. While Turkmenistan has improved since the start point, it only reported epidemiological data for eight weeks, so there was no change in indicator value. The regional office noted that this indicator refers to both analysis and reporting. In the Euro region, analytical capability in this regard is low, and the region is implementing a large piece of work to improve data management through training and IT development and support.

**Four countries continued to report virological data.** Tajikistan remains the only country not reporting virological data. Turkmenistan has improved, reporting virological data for eight weeks of the preceding year, but this is not sufficient to change the indicator value. All other

<sup>&</sup>lt;sup>10</sup> Status uses indicator data as reported for the period Feb-Aug 2016

<sup>&</sup>lt;sup>11</sup> Note that this figure was officially reported to the PIP Secretariat at 4, but staff from the region noted that there was confusion as to the specific definition of the output

countries maintained good reporting of virological data from the start-point to the end of 2016.

Progress in this AOW was hindered by civil unrest in one priority country and competing health priorities in others. In EURO priority countries, pandemic influenza remains a low priority. In addition, Ukraine was not able to receive Partnership Contribution funding in 2015 due to localized violence and civil unrest within the country.

Three countries shared influenza virus samples with WHOCCs, H5 reference laboratories and essential regulatory authorities at least once in the past two years. Armenia, Kyrgyzstan and Ukraine all submitted influenza virus samples at least once a year between August 2014 and August 2016. Tajikistan made progress, sending one influenza sample to a WHO CC in 2016.

#### Effectiveness - SEARO

Table 8. Status of output indicators in SEARO.

**Output indicators for priority countries:** Bangladesh, Democratic People's Republic of Korea, Indonesia, Myanmar, Nepal, Timor-Leste

	Baseline	Target	Status 12
Output 1: Detection capacity			
Number of countries with an established and functioning event- based surveillance system	1	6	5
Output 2: Monitoring capacity			
Number of countries able to consistently report and analyse virological data	2	6	4
Number of countries able to consistently report and analyse epidemiological data	0	6	1
Output 3: Sharing capacity	<u> </u>		
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	4

There has been marked improvement in detection capacity in SEARO. Bangladesh, Myanmar, Nepal and Timor-Leste established event-based surveillance systems, while Indonesia maintained its existing event-based system. There was no improvement in the

<sup>&</sup>lt;sup>12</sup> Status uses indicator data as reported for the period Feb-Aug 2016

detection capacity of the Democratic People's Republic of Korea, where there remains no plan to establish an event-based surveillance system.

One country is now able to consistently report epidemiological data, up from a start-point of zero but remaining behind the target of six. At the start of the program, no countries consistently reported epidemiological data. Indonesia has since established weekly epidemiological reporting. Bangladesh also made some improvement, with 29 reporting weeks in the preceding year. Nepal is sharing a weekly epidemiological report with the regional office, and work is ongoing with its sole SARI site to report to FluID. Support for epidemiological surveillance is growing with the country Ministry of Health but the focus to date has been on establishing virological monitoring capacity.

Four countries report virological data weekly, an increase from the starting-point of two, but lower than the target of six. Over the course of HLIP 1, Bangladesh and Myanmar established weekly reporting of virological data, while Nepal and Indonesia maintained pre-existing virological reporting capacity. Staff in Timor-Leste have been trained in virological testing but reagents and other supplies have not yet been received by the country office. DPRK continues not to report virological data.

Four countries shared influenza virus samples with WHOCCs, H5 reference laboratories and essential regulatory authorities at least once in the past two years. Bangladesh, Indonesia, Myanmar and Nepal all submitted influenza virus samples at least once a year between August 2014 and August 2016. Timor-Leste is yet to receive reagents and supplies to enable virus sharing. DPRK continues not to share influenza virus samples.

Of the six countries selected as priority countries for PIP, it was particularly difficult to implement activities in three. Countries experienced several challenges including (i) gaining access to financial capital from the regional office, (ii) low capacity in the country office and (iii) under-staffing of the disease surveillance and epidemiology department of the country office.

The Regional Office reported that country offices often do not prioritise pandemic influenza, but this has been aided recently by work assessing burden of disease. Thailand developed disease burden estimates and found that up to 10% of severe respiratory disease was related to influenza. It remains the only country in the region to have a formal recommendation for the influenza vaccine for high-risk groups.

#### Effectiveness - WPRO

Table 9. Status of output indicators in WPRO.

Output indicators for priority countries: Cambodia, Fiji, Lao, Mongolia and Vietnam

	Baseline	Target	Status 13
Output 1: Detection capacity			
Number of countries with an established and functioning event- based surveillance system	1	5	4
Output 2: Monitoring capacity	1	l	
Number of countries able to consistently report and analyse virological data	4	5	5
Number of countries able to consistently report and analyse epidemiological data	0	5	4
Output 3: Sharing capacity	- 1	l	
Number of countries sharing influenza virus with WHO CCs, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	NA	NA	5

Progress has been made towards establishing detection capacity, with a total of three countries hosting event-based surveillance systems compared to a start-point of one. Fiji, Lao PDR and Mongolia established event-based surveillance systems, while Vietnam maintained its pre-existing system. Cambodia has established an event-based surveillance system but the protocols are currently not consistently implemented. Two non-priority countries received Partnership Contribution funds. Papua New Guinea received funds for PCR procurement and supplies, while China received support for trainings related to early detection of influenza outbreaks, and influenza surveillance.

The region has made strong progress in collecting epidemiological information with four out of five countries now consistently reporting epidemiological data. Cambodia, Fiji, Lao and Mongolia have established epidemiological reporting capacity over the course of HLIP 1. Vietnam has demonstrated the capacity to report and analyse epidemiological data through routine influenza surveillance reports but has not started routinely reporting this data to FluID.

**The target for consistently reporting virological data was achieved.** Fiji began consistently reporting virological data, hence the target for virological data reporting was achieved.

Five countries shared influenza virus samples with WHOCCs, H5 reference laboratories and essential regulatory authorities at least once in the past two years. All five priority countries in WPRO have shared virus samples with Collaborating Centres since the start of the program.

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<sup>&</sup>lt;sup>13</sup> Source: Indicator data as reported for the period Feb-Aug 2016. Updated based on correspondence with regional office.

#### **Burden of Disease**

#### Relevance

The burden of disease AOW is essential for raising the profile of influenza as an important public health issue in countries with competing health priorities. The gaps and needs analysis conducted in advance of HLIP 1 identified that the burden of influenza disease remained unknown in most of the world, with available information deriving from just a few countries located in temperate climates. This lack of data made it difficult to prioritise influenza prevention and control programs against a background of other health problems. In some countries which developed burden of disease estimates, such as Thailand, the Ministry of Health has introduced seasonal influenza vaccination for high-risk groups. Burden of disease estimates also provide a better understanding of the epidemiology and seasonality of influenza and its risk factors to inform development of seasonal vaccination policy.

The current approach to burden of disease studies focusses on the disease burden using influenza surveillance data. The consistency of this approach makes it easier to compare burden of disease estimates between countries and regions in a consistent manner. The AOW would like to rollout an expanded definition of burden of disease estimates, to support national level policy makers. Another output that could be considered is economic burden, which may consider either the direct healthcare costs or the socio-economic burden. A WHO-developed method for assessing economic burden has been piloted in four priority countries and two non-priority countries.

Country prioritization criteria varied by region. In AFRO, countries were prioritised based on their existing capacity for influenza surveillance and their potential to provide accurate data. In AMRO, one country was selected based on previous successful studies of influenza hospitalization burden. In EMRO, the AOW selected one specific country as it was close to developing a vaccine and would benefit from associated burden of disease estimates. In SEARO, country selection was justified based on population size and the high burden of H5N1 within the country. In WPRO countries were selected based on their lack of participation in the GAP (Global Action Plan) technology transfer agreement.

Some of the priority countries selected were already receiving support from other donors, and so funding may have been of more use if alternative countries were targeted. Other organizations providing funds to improve influenza pandemic preparedness included the US Centers for Disease Control and USAID. Stakeholders reported that, in some cases, countries were incentivized to use non-PIP funding because donor policies use current year expenditure to calculate next year's funding. These instances reduced the potential for the AOW to have impact in those countries – and funding may have been better allocated to other countries.

#### **Effectiveness**

Table 10. Status of output indicators for the Burden of Disease AOW.

**Outcome:** National policy-makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources

	Baseline	Target	Status
Output 1: Derive regionally representative influenza disease burden estimates from selected countries  Number of countries supported by the Partnership  Contribution with disease burden estimates by 2016	0	19	2
Output 2: Derive a global estimate of influenza disease burden estimates from selected countries  Global estimate of influenza disease burden derived from national estimates published	0	December 2016	Expected end of 2017

The burden of disease team supported many countries, both priority and non-priority. Of the 19 priority countries and 48 non-priority countries receiving support, two priority countries and six non-priority countries published burden of disease estimates. Of priority countries, Costa Rica and Egypt have published burden of disease estimates, falling short of the target of 19. Seven priority countries (Madagascar, Senegal, Chile, Ukraine, Indonesia, Cambodia and Mongolia) formally presented their results and are expected to publish soon. Of the 48 non-priority countries that were supported, six have published, and ten have formally presented their own burden of disease estimates.

Activities that contributed to the development of burden of disease estimates included development of tools and methodologies to support countries developing burden of disease estimates. The AOW team formed partnerships with academic institutions. For example, EMRO partnered with Imperial College London and the Aga Khan University to train experts from the region on disease burden estimates. To improve the quality of publication, the Burden of Disease AOW provided a training for regional staff on publishing academic papers. In addition to considering the disease burden, in 2015, WHO's economic burden tool was piloted by four PIP priority countries (Chile, Costa Rica, Lao and Indonesia) and two other countries (Colombia and Romania).

**Development of global-level burden of disease estimates remains behind schedule.** The burden of disease AOW is currently developing a global estimate of influenza disease burden. This work began almost one year last, and the outcome is expected at the end of December 2017, one year behind schedule.

Progress towards achieving deliverables was largely hindered by a high administrative burden on technical staff. The AOW noted that significant time was required for administrative tasks. Some of these activities are related to approval processes within PIP itself, such as completing workplans and recruiting new staff, while others relate to WHO-

wide policy such as the need to obtain multiple bids when contracting external service providers.

**Implementation rates varied between 2014 and 2015**<sup>14</sup>. In 2014, no countries received PIP Partnership Contribution funds in the burden of disease AOW. The overall implementation rate was 11% in 2014, with all expenditure on Output 1 related activities. Unspent funds carried over from 2014 were largely spent in 2015. The total expenditure across 2014 and 2015 was USD 630,000 with an associated implementation rate of 76%.

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 $<sup>^{14}</sup>$  Implementation rate is defined as the proportion of budgeted funds that were spent

# **Regulatory Capacity Building**

#### Relevance

The Regulatory Capacity Building AOW is important in improving preparedness. In the Gaps and Needs Analysis of 2013, countries and international experts indicated that national regulatory preparedness for influenza products including vaccines, antivirals and diagnostics should be a priority area for the PIP Partnership Contribution. The lessons learned included a need for a common pathway to facilitate vaccine deployment during influenza pandemics.

Some stakeholders considered the selection criteria for priority countries to be overly complex, and too donor-focussed, at the expense of considering countries based on need. The model for country prioritisation was developed in 2012 and was simple at inception but eventually included ten different criteria including demographic and economic indicators, the countries' interest to other donors, the status and progress of their existing national regulatory authority (NRA), presence of national control laboratories, newly introduced or plans to introduce influenza vaccine production, regulatory history and involvement in the GAP for influenza vaccine. Stakeholders noted that the focus on existing donors meant that some countries were not included despite having the potential to benefit greatly from Partnership Contribution funds.

## The AOW is currently in the process of redesigning and simplifying the prioritisation criteria.

The intention is to reduce the weighting on the presence of other in-country donors. Measures for prioritisation criteria may include transparency and corruption metrics, and the human development index as a proxy for areas where the most sustainable intervention can be made. The new prioritisation criteria will be considered as part of HLIP 2. Existing priority countries will not be removed from the AOW's list.

#### **Effectiveness**

Table 11. Status of output indicators for the Regulatory Capacity Building AOW.

**Outcome:** Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic

	Baseline	Target	Status
Output 1: Develop guidelines on regulatory preparedness for non- vaccine producing countries that enable them to expedite approval of influenza vaccines used in national immunization programs.	0	1	1
Regulatory preparedness guidelines endorsed by the WHO Expert Committee on Biologicals Standardization (ECBS)			

Output 2: NRA capacity to regulate influenza products including vaccines, antivirals and diagnostics is strengthened.  Number of countries which developed regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics in case of a pandemic as per the WHO NRA assessment and IDP elaboration and implementation	0	16	1 <sup>15</sup>
Output 3: Regulatory processes to accelerate approval of influenza vaccines, antivirals and diagnostics during a public health emergency are incorporated into deployment plans for pandemic influenza products.  Number of countries with a common approach for accelerated regulatory approval of influenza products in a public health emergency	0	48	14 <sup>16</sup>

The regulatory capacity building AOW achieved its target of developing guidelines and is now rolling them out in target countries. In 2014, the Regulatory Capacity Building AOW developed the 'Guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries'. The guidelines were subsequently endorsed by the WHO Expert Committee on Biologicals Standardization (ECBS) thereby achieving the target for Output 1. The AOW team will begin implementing said guidelines in 2017.

WHO benchmarked the NRA capacity of 14 of 16 priority countries and identified gaps in regulatory systems. It subsequently ran targeted trainings and workshops. The AOW assessed capacity in 14 out of 16 priority countries, focussed on pharmacovigilance, regulatory systems strength and market authorisation ability. Eight priority countries were below critical capacity in pharmacovigilance, three were below critical capacity in marketing authorization and one was below critical capacity in regulatory systems. The regulatory capacity building AOW developed trainings to address the key weaknesses, which focussed mainly on improved pharmacovigilance. The objective of these trainings was to move countries out of critical capacity and into acceptable capacity. The NRAs of 23 countries, including seven PIP priority countries attended capacity building workshops on Quality Management Systems (QMS). Additionally, seven of 16 PIP countries attended the Global Learning Opportunities course on 'Product Evaluation of Influenza Vaccines'. Finally, NRAs from 11 of 16 PIP priority countries attended in-country and overseas pharmacovigilance trainings. The impact of these trainings will not be known until the next benchmarking.

<sup>&</sup>lt;sup>15</sup> This figure is taken from the 2015 annual report in the absence of an updated figure. A second assessment should be carried out in 2017 to determine progress towards this target

<sup>&</sup>lt;sup>16</sup> This represents the number of countries that have adopted collaborative procedures and may not represent the number that have a common approach.

NRA re-benchmarking is being planned for 2017 to measure the effectiveness of regulatory building capacity activities in strengthening regulatory capacity. It is difficult to assess the progress made against Output 2 by this AOW until a second assessment of regulatory capacity is carried out to compare against the benchmark

The collaborative procedure has been adopted by 14 out of 48 priority countries, though countries may also have used alternative pathways to achieve the same impact. The regulatory building capacity team ran advocacy workshops on the implementation of the collaborative procedure for influenza vaccines in SEARO in 2015 and in EMRO in 2016. Countries can also achieve accelerated national registration through other means, including reliance on the WHO PQ process, reliance on the decision of other NRAs or regional harmonization processes. The indicator is therefore not fully reflective of all options available to accelerate national registration and does not reflect true progress towards achieving the AOW's intended outcome. The achievement of Output 3 was made more challenging due to a WHO reorganization in which the AOW were transferred from the IVB team to the EMP department. This indicator was then expanded to include diagnostics and medicines making the initial target unrealistic.

The implementation rate was 56% across 2014 and 2015<sup>17</sup>. In 2014 the overall implementation rate in the regulatory building capacity AOW was 5%. A total of 1.1M USD was spent across 2014 and 2015, with a corresponding implementation rate of 56%. The proportion of budgeted funds spent for Output 3 was 7%.

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<sup>&</sup>lt;sup>17</sup> Implementation rate is defined as the proportion of funds budgeted that were spent

# **Planning for Deployment**

#### Relevance

The planning for deployment AOW is essential for improving global- and country- level preparedness for pandemic influenza. During the 2009 influenza pandemic, deliveries of influenza vaccine did not start until January 2010. WHO required a letter of intent (indicating desire to receive vaccines), letter of agreement (waiving liability for the donated vaccines) and national deployment plan from countries before vaccines from the scarce supply were released to them. The National Deployment Plan was the most difficult and last of the prerequisites to be completed by countries, requiring significant time, assistance and financial resources. As a result, the development and improvement of National Deployment Plans was considered vital to improve the timeliness of vaccine deployment during pandemic response.

The country selection process was driven by regional offices and stakeholders report that more country-level consultation would be welcomed. Regional offices selected priority countries based on country need, the existing state of regulatory capacity in-country and the presence of funding from other donors in-country. However, the AOW reported that countries were often unaware of the selection process taking place so were unable to indicate their interest in being included in the various areas of work. Stakeholders reported that some countries that were not selected as priority countries asked how they could be included as a priority country going forward.

#### Effectiveness - No feedback received from AOW

Table 12. Status of output indicators for the Planning for Deployment AOW.

Outcome: Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics will be developed and regularly updated AWAITING FIGURES FROM AOW **Baseline Target** Status Output 1: A common approach to manage deployment operations is developed and shared with stakeholders and deployment partners A common deployment approach is developed with multiple 0 1 deployment stakeholder endorsement Number of training and simulation exercises with deployment 0 8 stakeholders Output 2: Country deployment readiness systems are simplified and updated Model country recipient agreement is revised and updated 0 1 Countries and partners accessing web-based planning tools 0 16

A simulation remains under development but was set back multiple times due to funding delays. Contractors were unable to continue work over a period of four months due to the unavailability of funding from the Secretariat. Stakeholders put forward several reasons for these setbacks, including the late disbursal of funding by the Secretariat, late submission of the workplan by the AOW, or sub-optimal management of internal- or external- IT support.

Stakeholders report that countries have increasingly run planning for deployment exercises including self-assessments and round-table simulation. Deployment plans have been diversified from focussing just on resource mobilisation, to also considering components such as developing emergency staff rosters. Countries are increasingly forging agreements with private sector partners that could provide support during an emergency.

The AOW noted that it was not consulted prior to finalization of some indicators (and the indicators themselves were too ambitious). The Secretariat contends that the AOW was consulted, but agreement was not reached. The target for one indicator was to run eight simulations in priority countries. The AOW considered this very challenging given the resources available. Furthermore, the indicator 'model country recipient agreement is revised and updated' is considered highly unlikely, outside of pandemic situations.

The implementation rate was 44% across 2014 and 2015<sup>18</sup>. In 2014 no countries received PIP Partnership Contribution funds and the overall implementation rate was 7%, with implementation rates of 0% and 74% for Output 1 and 2 respectively. Across 2014 and 2015, the implementation rate was 44%, breaking down as 48% and 36% for Output 1 and 2 respectively.

The outputs for planning for deployment are likely to be achieved only in the long term, but the current design does not allow for communication of intermediate progress. Two of the outputs are binary and will remain at 'zero' for several years before switching to 'one' upon completion. Process indicators would be more useful to monitor the progress made by the AOW.

In the future, output indicators should focus on the maturity of country level plans. Indicators should be designed to allow intermediate progress to be shown. For example, indicators could include the number of countries with a logistical distribution plan in place, and the number of countries that have run round-table simulations.

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<sup>&</sup>lt;sup>18</sup> Implementation rate is defined as the proportion of funds budgeted that were spent

#### **Risk Communications**

#### Relevance

Previous health emergencies including the spread of pandemic influenza in 2009, Ebola Virus Disease in 2015 and Zika Virus Infection in 2016, have demonstrated the importance of effective risk communication. Risk communication capacity building has the aim of ensuring countries have policies, procedures and plans in place for communicating to national audiences during public health crises. The aim of effective risk communications is to encourage individuals and communities to make decisions and engage in practices that will minimise the spread of the pandemic. The 2015 Report of the Ebola Interim Assessment Panel highlighted shortcomings in the WHO risk communication response, stating "Communication of risk and promotion of appropriate safe behaviours need to be much more thoroughly researched and documented, so that WHO and other entities engaged in this activity have a better impact in their risk communication efforts to the public". Additionally, the gaps and needs analysis conducted in advance of the HLIP reported that 29% of countries had less than 50% of required risk communications capacity.

Countries were prioritised for support based primarily on existing capacity and work on IHR implementation, commitment from Ministries of Health and risk of disease outbreaks. The AOW also considered countries' likely ability to sustain capacity, regional representation, ability to build in-country collaboration and absorptive capacity. Stakeholders noted that the country selection procedure resulted broadly in the correct countries being prioritised for the risk communication AOW.

#### **Effectiveness**

capacity

Table 13. Status of output indicators for the Burden of Disease AOW.

**Outcome:** Global risk communications capacities are strengthened with a special focus on pandemic influenza communications

	Baseline	Target	Status	
Output 1: Access to risk communications training and platforms is increased enabling all countries to respond more effectively to a potential influenza pandemic				
Tools and web-based risk communications training material accessible to Member States in all language versions by December 2015	0	194	194	
Number of registered users of online material	0	500	598	
Number of trainings completed on IHR risk communications training website	0	200	129	
Output 2: Risk communications capacity is established in priority countries with little or no				

Targeted Member States will have benefited from IHR risk communications programme by end of 2016	0	30	20
Output 3: Global Emergency Communications Network (ECN) operationalized to provide support to countries before, during and after public health emergencies			
Proportion of requests for risk communications surge support responded to within 72 hours by WHO in 2015/2016	0	80%	100%

Activities conducted by the AOW included forging new partnerships, delivering trainings and workshops, and deploying the emergency communications network during public health emergencies. The risk communications AOW initiated partnerships with Harvard School of Public Health and Hong Kong University to create evidence-based measurements of risk communications outcomes. Risk communications materials were developed and promoted at multiple training sessions — reaching 395 participants from 45 countries. Subregional workshops in South East Europe and the Caribbean included simulation exercises of top hazards facing a country including influenza outbreak. National risk communications plans were developed in Viet Nam and Sudan. Work with the media started in Kyrgyzstan and Viet Nam, and at a South-East Asia regional training event for ten countries. Thirty-five emergency communication network members were deployed to over ten countries over the course of 2014.

The risk communications AOW has developed risk-based communication training materials in 18 languages. A total of 598 stakeholders registered to use the online materials, exceeding the target of 500 users initially set. The training materials are available online and are intended to provide WHO Member states with self-use learning material on risk communication for epidemics, pandemics and other health emergencies. The website also provides contact details for the risk communications team for countries that want to organize a national risk communication training workshop.

At least 129 stakeholders completed risk communications trainings online, falling short of the target of 200. This was largely due to the poor functionality of the iLearn platform. Participants from priority countries reported to the AOW that the functionality of the website was poor and it prevented them from completing the courses. In response to this, the AOW made the risk communications material available on the WHO website in a special training page. This format does not allow the AOW to monitor the course completion rate. It is anticipated that this training will move to the OpenWHO platform in the future, to enable monitoring of course completion rates.

Twenty countries were trained in the IHR risk communications program, falling short of the targeted 30. This was largely due to competing health priorities such as Ebola. Furthermore, in some priority countries, fragile security situations prevented non-emergency work from taking place.

Furthermore, the AOW reports that countries favour developing general risk communication plans applicable to multiple public health threats, resulting in plans which are often too vague for a robust influenza communications plan. The risk communication plans that result from these workshops are high-level, as countries want to develop plans which are inclusive of multiple health threats including cholera, meningitis and Ebola, rather than plans tailored specifically to pandemic influenza. In the future, the risk communication AOW would like to collaborate with countries to develop specialised risk communication plans for the top five public health threats within the country, of which pandemic influenza would be one.

For Output 3, the AOW planned and implemented training for 150 risk communications staff who are now on a roster for deployment in emergency situations. The training program includes risk communication theory and a simulation exercise to assess the strengths of each participant. Around 80% of the staff have been deployed to emergency situations. All requests for emergency risk communications support were responded to within 72 hours during 2015/16.

The AOW is developing an online platform to provide training and act as a live-source of information in emergency situations. The platform will host a risk communications massive open online course (MOOC). The platform is also intended to act as a source of live-information and instruction during pandemics. In the future, it is anticipated that training will be more focussed on simulation exercises, with participants having completed the theory section of the course on the platform prior to the training.

The implementation rate was 85% across 2014 and 2015<sup>19</sup>. In 2014, the implementation rate for the risk communications AOW was 42% overall, breaking down as 43%, 55% and 34% for Output 1, 2 and 3 respectively. Across 2014 and 2015, the overall implementation rate was 85%, breaking down as 89%, 91% and 65% for Output 1, 2 and 3 respectively.

The AOW reports that it has benefitted from having four full-time staff, who have ensured continuity and sustainability. The AOW consists of a team of two senior staff and two junior staff. The AOW reports that having staff based at WHO headquarters has facilitated effective relationships with regional- and country focal points, which in turn has supported successful implementation.

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<sup>&</sup>lt;sup>19</sup> Implementation rate is defined as total expenditure as a proportion of budgeted funds

### **Efficiency**

This section provides analysis of the processes and systems, mostly implemented by the PIP Secretariat during its normal functions and engagements with external actors. The PIP Secretariat is still a relatively new unit and sits outside of the traditional WHO program budget structure. Partially as a result of these factors, there remain growing-pains, mostly around the ways the Secretariat collects data and distributes funding. Specific constraining factors including workplan template design, approval processes, the annual funding cycle, and the program's logframe (discussed separately). These issues have negatively impacted progress across most AOWs, but it is possible that process adjustments in these areas could yield significant benefits.

# Efficiency issues specific to laboratory and surveillance capacity

The number of indicators for this AOW increased since the start of the program, although only the original targets are used for external reporting. At the start of the program, the PIP Partnership Contribution used four output indicators under this AOW. However, these were considered too limited to accurately assess progress against this AOW. Additional indicators were added and data are now collected against 21 indicators (four from all member states, the others from priority countries-only). However, only four output indicators are systematically used in external reporting, whilst the others are used by the Secretariat, regional offices, country offices and other staff in headquarters to monitor progress more broadly. Some stakeholders felt it was easy to report on the indicators. Others considered them to be time consuming and burdensome, taking focus away from activity implementation to complete the reporting requirements.

Formerly, priority countries self-scored against indicators. Changing the scoring procedure to a questionnaire set by headquarters produced more reliable results. Data for most indicators are collected twice a year. In the first and second round of scoring, countries were required to directly score themselves against each indicator. However, the PIP Secretariat felt that this approach led to less reliable results as scoring was too open to interpretation. Since the third round of scoring (August 2015-Feburary 2016), countries have completed a questionnaire focusing on specific capabilities. A score is then generated from the responses, and can be consistently interpreted by the Secretariat. Evidence to support the answers in the questionnaire is also required, further improving the reliability of the results.

However, the scoring system remains somewhat open to interpretation such that questionnaire responses, and corresponding scores, often vary beyond what would be expected between adjacent assessments. While use of the questionnaire has reduced subjective interpretation, there can be large variation in scores between adjacent rounds. Inconsistencies in scoring is likely due to different individuals completing the questionnaire between and within countries. Previously, regional offices were asked to corroborate the scores given by each country for each of the indicators. However, the amount of engagement by the regions with the country offices varies substantially, making the corroboration process

less reliable. One regional office noted that it would be more reliable for it to complete the indicator questionnaire on behalf of its priority countries. It is not clear the extent to which other regional offices support this idea. Stakeholders suggested there could be an additional technical review of the scoring given by each country. One WHO CC noted that a more effective way to score countries for this AOW would be to send staff from the nearest Collaborating Centres to the country NIC for in-person inspections. This suggestion would require further elaboration and testing to assess feasibility and value.

#### Delays in workplan approval and funding disbursement

Industry partners are invoiced and funds are collected annually. Payments are often received well beyond the 30 days indicated on the invoice, and often in the following calendar year. The Secretariat invoices industry partners on an annual basis. Between 2013 and 2015, invoices were sent in mid-November of each year. Yet, at the start of the following calendar year there were substantial shortfalls in funding received compared to funding requested. In the early years of the program, activities would continue to receive funding by using unspent funds from the previous year (the first set of invoices were dispatched in 2012). Invoice dates, funds available at the end of the year, and total funds received are shown in the table below.

Table 14. Date invoices were sent, funds available at the end of the calendar year, and total funds received, by year.

Year	Invoices sent	Funds available at the start of the calendar year	Total funds received
2013	12/11/13	USD 15.1 M	USD 27.5 M
2014	13/11/14	USD 15.1 M	USD 27.0 M
2015	19/11/15	USD 11.6 M	USD 25.2 M
2016	05/08/16	USD 19.7 M	pending

The workplan template design does not facilitate efficient interactions between the Secretariat, regional- and country offices. The workplan template does not enable users to input a sufficient level of detail on planned activities, and specifically how each would contribute to the relevant outputs and outcomes. This results in lengthy back-and-forth iterations between headquarters, regional- and country offices to gain understanding of the rationale for including activities and their linkages to outputs and outcomes. As a result, workplan approval can be delayed until several months into the year the activities are planned for, reducing the time available for activity.

The Secretariat reports that regional offices and AOWs submit workplans of vastly differing quality. The Secretariat reports that workplans have previously been submitting requesting

more than twice the amount of funding available from the allocated budget, creating a burden on the Secretariat and the need for an extensive review and iteration process. The Secretariat further notes that it holds semi-annual workshops to plan for development of workplans and to review the template design.

The Secretariat is only able to approve workplans up to the value of funds it has received. Delayed receipt of funds therefore results in delayed workplan approval. To expedite funding disbursement, the Secretariat requested all workplan activities to be categorized as 'high', 'medium' or 'low' priority. Funds are then allocated first to high priority activities. This has helped to address delays somewhat, but stakeholders note that country offices increasingly list activities as 'high' even when this is unwarranted.

Workplan approval is further delayed due to the practice of not approving regional workplans until all regions have submitted workplans. Regional offices that submit workplans early report frustration at having to wait for regions that are delayed in submitting their workplans, or waiting for regions whose workplans require significant iterations before approval.

The release of funding in tranches delays implementation of activities which require significant upfront investment. The Secretariat release funding in tranches rather than as a single transaction. In one region, several countries did not have the reagents required to test influenza specimens for a couple of months as the first tranche of funding released was too small. The influenza centres had to wait until an additional tranche of funding was dispatched before influenza specimens could be tested.

The two-year WHO funding cycle complicates financial administration, particularly when close to the end of the WHO biennium, at which point unspent funding can be revoked. On several occasions, funding was made unavailable to AOWs because expenditure would occur beyond the end of the WHO biennium. Whilst this restricted implementation progress, it important to note that this is a WHO-wide policy is not within the PIP Secretariat's control.

# Impact of disbursement delays

The impact of delayed funding depends on the ability of each AOW to finance its own activities whilst approval is pending. In some cases, AOWs did not receive funding until nine months after the expected date. In the risk communication AOW, activities continued but the AOW used funds from elsewhere to fund ongoing activities. In the regulatory capacity building AOW, activities could not be carried out until funding was received. In the planning for deployment AOW, activities continued where possible, but it was not possible to pay suppliers and contractors on time.

In the regulatory capacity building AOW, funding for 2014 was not received until September, leaving insufficient time to implement planned activities before the end of the year. The AOW team was unable to implement the total funds provided by the end of 2015, so the PIP Secretariat withdrew unspent funds totalling USD 370,000. Late disbursal of funds in 2016 also resulted in insufficient time to implement activities. Owing to the late disbursement of

the third funding tranche, the PIP Secretariat withheld the fourth tranche of USD 643,000 at the end of 2016. This arrangement had been agreed in advance with the EMP director under whom the AOW was managed. The total funds rendered unavailable to the AOW due to delayed disbursement or funding withdrawal was ~USD 1 M.

In the planning for deployment AOW in 2014, many iterations were required before the workplan was finalised<sup>20</sup>. In 2015, stakeholders report that delayed disbursal of funding meant that staff and contractors were not paid for four months. Contractors were unable to continue work without payment, and so software development was also set-back by four months. In the workplan for 2016, the PIP Secretariat did not approve funding for an IT manager who the AOW described as fundamental to the software development process, setting back software development further. The AOW reports that it did not receive sufficient explanation for why this decision was made. Finally, lack of approval of a workplan before the end of a biennium resulted in the AOW not being able to fulfil its contract obligations to an external software development firm. The AOW reports that this could have had legal ramifications for WHO (although that was not the case).

#### Administrative and communication issues

All AOWs reported that a high administrative burden has hindered progress towards achieving deliverables. For example, the burden of disease AOW reported that it was required to find two bidders for a contract to determine burden of disease in Madagascar. The AOW reported that it was known that the first bidder was the most well prepared group to conduct the study in the country. However, this is a WHO-wide policy and unlikely to be within the influence of the PIP Secretariat. The planning for deployment AOW reported that up to 50% of technical staffs' time is spent on administrative tasks, reducing their ability to monitor and advance activities.

Some areas of work reported that progress had been hindered by communication difficulties between the AOWs, country- and regional- offices. Some stakeholders reported that regional and country offices are over-burdened by information requests about activities and indicators from the PIP Secretariat and other donors. It should be noted that the evaluation team was not able to verify the extent to which this is the case. The PIP Secretariat organized monthly meetings with the regions, in which the AOWs participate, to discuss progress made in each AOW. However, some AOWs noted that regions often send staff with expertise in laboratory and surveillance capacity who do not know the status of other areas of work in their regions.

## **Industry partners' perspectives**

Industry partners were concerned about a perceived "lack of financial transparency", particularly around how contributions were being spent in-country. Industry partners noted that a database showing the funding utilised for every activity in every country should be

<sup>&</sup>lt;sup>20</sup> The Dalberg team was not able to verify the precise length of delay

available. Financial data available through the PIP Partnership Contribution portal is not of sufficient granularity to identify what activities were funded at the country-level. Industry partners suggested that activities should be ordered to show the output they are contributing to, and the anticipated impact of completing the activity. Additionally, stakeholders note that it is not clear how the 30% allocated to the response fund would be used in the event of a pandemic. While it is anticipated that these funds would be used for logistical purposes, industry partners have not seen a specific plan of how the reserve fund would be used. Finally, industry partners believe there should be more transparency and granularity around how much of the funding is consumed by the Secretariat, including staff and travel costs. The Secretariat noted that this would require more staff at headquarters. Some industry partners reported concern that Partnership Contribution funds were being used to conduct administrative work at WHO rather than fund activities at country- and regional- level. The evaluation team has not attempted to verify these statements and so cannot comment on their validity.

Industry partners propose that the size of the Partnership Contribution should have been determined by funding needs for improving pandemic preparedness, rather than the running costs of GISRS. Currently, the overall size of the Partnership Contribution is half the cost of running the GISRS laboratory network<sup>21</sup>. Industry partners noted that this does not necessarily correlate well with the funding needed to improve pandemic preparedness. Instead, industry partners would prefer to be invoiced after workplans have been developed, when the amount of funding required is known. It is worth noting that some industry partners consider the size of the contribution they give to be greater than the value they get from use of the GISRS network.

Most, but not all, industry partners noted that the algorithm should be updated to reduce the weighting on revenues from the 2009 influenza pandemic. The current algorithm for determining the Partnership Contribution depends on (i) industry partners' revenues from seasonal vaccine production from the last three years and (ii) industry partner revenues from the 2009 influenza pandemic. Industry partners noted that there has been a substantial change in the influenza vaccine landscape in the intervening period, and that the distribution of revenues from a coming pandemic may no longer reflect the distribution of revenues from the 2009 influenza pandemic. As such, industry partners suggest that revenues from 2009 should be removed from the algorithm. At a time in the future following another pandemic, revenues from the pandemic could be included in the formula for a couple of years after.

Industry partners observe that advisory group meetings are driven heavily by the PIP Secretariat. Industry partners noted that AOW heads and regional focal points should have more opportunity to discuss progress in their AOW or region. The Secretariat contends that all regions and AOWs are invited to every advisory group meeting, and that participation is generally low but improving.

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<sup>&</sup>lt;sup>21</sup> http://www.who.int/influenza/pip/pip\_pcimpplan\_17jan2014.pdf

One industry partner considered the allocation of 70% of preparedness funds to laboratory and surveillance to be too high, and suggested a greater portion should be spent on burden of disease and planning for deployment. One industry partner raised concerns that laboratory and surveillance capacity in countries was being built on the back of Partnership Contribution funds, despite this capacity also benefitting broader health objectives. While it is likely that other donors are providing funding to establish laboratory and surveillance capacity for other public health threats, this should be communicated to stakeholders in an open and transparent way.

Industry partners report frustration that the Partnership Contribution changes year-to-year, as it makes budgeting and forecasting difficult. The process for collecting the Partnership Contribution starts with a questionnaire completed annually by industry that identifies influenza vaccine, diagnostic and pharmaceutical manufacturers using the GISRS network. Industry partners report that the uncertainty around the number of industry partners likely to be included in the Partnership Contribution each year results in significant uncertainty and makes budgeting for the year ahead more challenging. One industry partner noted that it would favour a fixed contribution over the next five years.

# **Impact**

#### Overall

Most stakeholders agreed that since the founding of the Pandemic Influenza Preparedness Partnership Contribution there has been a marked increase in country-level preparedness, and attention given to pandemic influenza. Stakeholders generally feel better equipped than they were during 2009, but find it difficult to quantify the extent to which preparedness has improved.

Stakeholders report that PIP Partnership Contribution-funded activities have complemented IHR capacity building more broadly at the country level, especially in low-income countries. In addition, staff costs covered by the PIP Partnership Contribution funds in the WHO Country Offices enable more efficient follow up with the Member States on IHR programme implementation.

#### Areas of work

In laboratory and surveillance capacity, the number of countries considered well prepared for detection increased from seven to 26; the number able to monitor epidemiological data increased from seven to 17 and the number able to monitor virological data increased from 27 to 33. Furthermore, a total of 30 countries shared influenza viruses with WHO at least once a year in the previous two years. While this progress is undeniably in the right direction, implementation of specific activities outlined in the workplans and implemented using Partnership Contribution funds are not routinely monitored by the PIP Secretariat, making it difficult to attribute improvements thanks to Partnership Contribution funding.

One of the most common issues reported among stakeholders was that influenza is not considered to be a public health priority. Stakeholders reported that burden of disease estimates have helped to raise influenza on the agenda in multiple countries. For example, burden of disease estimates in Thailand (not a priority country) resulted in the country being the first in the region to adopt a formal recommendation for seasonal influenza vaccine in high-risk groups. It is possible that similar outcomes will be seen in other countries as the number to publish burden of disease estimates increases.

It is difficult to assess the impact of the regulatory capacity building AOW in advance of the next regulatory capacity benchmarking, scheduled for 2017.

The impact of the planning for deployment AOW remains relatively limited and difficult to measure while the simulation software remains under development. It is possible that the number of countries prepared to deploy vaccines will increase quickly following finalization of the simulation. Stakeholders also noted that some countries are revising their deployment plans, and holding some round-table simulations.

The risk communications AOW has made significant progress in developing risk communication capacity as reflected in the progress it has made towards all three of its outputs. Twenty priority countries benefitted from IHR risk communications training and an

additional 150 staff are available on a roster for use in emergencies. Stakeholders report that 80% of these staff have already been deployed to emergency situations.

## **Recommendations**

The recommendations are listed below with the aim of specifically addressing the issues highlighted in the evaluation. They are designed to act as key inputs to the design of HLIP 2.

To develop recommendations, the evaluation team initially identified the key issues facing the program. Each issue, was identified by making observations on data, from sources including (i) stakeholder interviews (ii) existing reports and (iii) data provided by WHO. The tables below provide detail on the specific groups of observations, the issues emanating from each group, and the subsequent recommendations that aim to address each issue.

# **Recommendation 1: Improve logframe design**

Observations	Issue summary	Specific action	
Interviewee observations:	Challenging to define	The PIP Secretariat should consider redesigning the logframe with the	
<ul> <li>Weak links between activities</li> </ul>	overall progress and	following aims:	
and indicators	impact, progress, and	Define impact at the global, regional and country level	
<ul> <li>Difficulty in defining impact</li> </ul>	links between activities,	Design and articulate robust linkages between activities, and	
<ul> <li>Difficulty in measuring progress</li> </ul>	outputs, and outcomes	achievement of outputs, outcomes, and impact	
Desk research:		Provide sufficient modulation in indicators to highlight progress on an	
<ul> <li>Logframe includes several</li> </ul>		annual basis	
binary indicators, and few		Account for the starting point for various priority countries (i.e. more	
progress indicators		might be expected from some countries than others)	
Impact: Work planning is more straightforward and more likely to lead to measurable impact			

# **Recommendation 2: Improve reporting granularity**

Observations	Issue summary	Specific action
<ul> <li>All industry partners interviewed noted:         <ul> <li>Insufficient detail over activities provided in reporting</li> </ul> </li> <li>Other interviewee observations:         <ul> <li>Current system does not ensure that funding recipients spend resources on activities as planned, reducing accountability</li> </ul> </li> <li>Desk research:         <ul> <li>Secretariat ceased activity monitoring in 2015</li> </ul> </li> </ul>	Industry partners question program implementation success, in part, due to lack of visibility of detailed expenditure  Limited accountability at activity-level	<ul> <li>Monitoring and reporting financial disbursements down to the activity level         <ul> <li>This would require more detailed, country-level financial reports and retrospective activity reports (including at country and regional office level)</li> <li>This should include all activities of funding recipients and at the Secretariat</li> </ul> </li> <li>Assessing how best to collect laboratory and surveillance data from countries themselves, to ensure an accurate understanding of existing capacities (as well as financial data mentioned above).         <ul> <li>One option is to consider external verification of activities and/or capacities – for example by engaging WHO CCs to monitor progress against specific outputs</li> </ul> </li> <li>Reporting a description of country-specific activities and related challenges and impact</li> </ul>

Impact: Relevant stakeholders are held accountable for expenditure and outputs, and this is shared with contributors

Recommendation 3: Provide clarity on country prioritisation

Observations	Issue summary	Specific action
<ul> <li>Many interviewees noted:         <ul> <li>Process did not sufficiently involve countries</li> <li>Criteria were not clearly communicated</li> </ul> </li> <li>Some interviewees noted:         <ul> <li>Prioritization outcomes did not yield most appropriate countries</li> </ul> </li> <li>Desk research:         <ul> <li>Prioritization process (for L&amp;S) applied criteria objectively to all eligible countries<sup>22</sup> although secondary factors often outweighed the outcome of primary scoring criteria.</li> </ul> </li> </ul>	Country prioritization process is opaque, leading to some misgivings over suitability of prioritization criteria	<ul> <li>The PIP Secretariat should consider the following:</li> <li>Communication of the country prioritization process itself will be critical to ensure support for the process among all member states:         <ul> <li>The PIP Secretariat should consider whether responsibility for such communication sits most efficiently within the Secretariat itself, or at regional office level</li> <li>All eligible countries should be made aware of the opportunity for PIP Partnership Contribution support and of the assessment criteria</li> <li>Results of the prioritization should be communicated in the same manner</li> </ul> </li> <li>Prioritization criteria should be clear to all relevant stakeholders, including how and when expert opinion will be used as criteria</li> </ul>

Impact: All eligible countries understand decisions around future support

<sup>&</sup>lt;sup>22</sup> Dalberg did not assess the suitability of prioritization outcomes

# Recommendation 4: Speed up workplan approvals

<ul> <li>Work plans do not contain</li> </ul>		
sufficiently explicit and detailed		
rationale for proposed		
expenditure to warrant		
immediate approval (without		
further discussion)		
	Impact: Implementation	can proceed with fewer delays.

# Recommendation 5: Review approach and timeline for industry partner contributions

<ul> <li>Contribution calculation</li> <li>question rationale of</li> </ul>	PIP Secretariat should consider the following: Discussing the contribution algorithm with industry partners to identify f a more relevant formula exists:  — This applies to the way in which individual contributes are
running GISRS is not the most relevant approach  • Desk research:  - Some industry partners' contributions vary significantly	calculated, as well as the total funding envelope

# **Appendix 1: Log frame design issues**

### Log frame design

The logframe's design - which outlines the linkages between activities, outputs and outcomes - is not conducive to fully assessing the level of improved preparedness. Targets were sometimes too ambitious, and did not fully consider the timeline that would be required to achieve the targets. Non-PIP funded activities can also affect indicator scores, especially in countries with existing influenza capacity. Although this is unavoidable, procedures should be in place to account for the impact of these non-PIP activities on the achievement of targets. Furthermore, some indicators are binary in nature, and do not provide sufficient detail to monitor progress effectively, or do not consider alternative and additional activities that could achieve similar impact.

In places, the logframe did not adequately reflect:

- Potential alternative pathways to achieve the same outputs (e.g. regulatory capacity building)
- A sufficiently realistic timeframe for implementation (e.g. laboratory and surveillance, regulatory capacity building, planning for deployment)
- The potential dependencies between outputs (e.g. planning for deployment).

Furthermore, the lograme did not always have sufficient clarity to facilitate monitoring of progress. To be specific, the logframe requires countries to be scored against indicators in a binary way despite there being a spectrum of possible values for the indicator at the country level (e.g. burden of disease, regulatory capacity building). Moreover, the wording of some indicators is too vague (e.g. burden of disease) and in some cases does not provide sufficient information as to the effort required to achieve them (e.g. risk communications).

# Laboratory and surveillance

Some stakeholders suggested the PIP Secretariat should develop intermediate progress indicators. Some indicators were representative of long term change and were binary in nature, such as the establishment of an event-based surveillance system. Breaking this indicator down into several smaller sub-indicators could help PIP review progress within countries against the detection output.

#### Burden of disease

It is difficult to assess progress made by this area in some areas of work due to lack of indicator specificity. For example, measuring the progress of burden of disease estimates was complicated by the fact that the quality of publication was not specified in the log frame.

## Regulatory capacity building

The outputs have not been designed well to enable communication of annual progress. The publication of WHO guidelines was measured as an output despite not directly leading to the

desired outcome. This was an example where the dependencies of between outputs were not clearly noted. Furthermore, regulatory capacity builds up over time such that annual progress indicators are not so relevant. Moreover, Output 3 is difficult to define because there are many means through which countries can adopt a common approach for accelerated regulatory approval of influenza products which is difficult to capture.

# **Appendix 2: Invoice payment**

Figure 9. Invoice payment over time, 2013

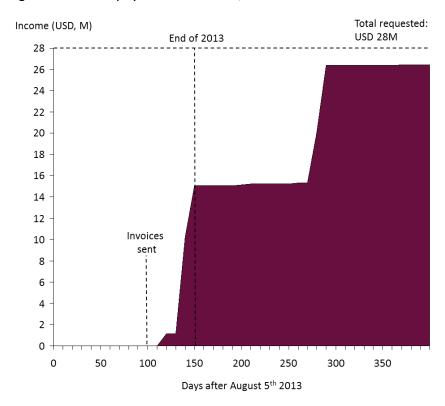


Figure 10. Invoice payment over time, 2014

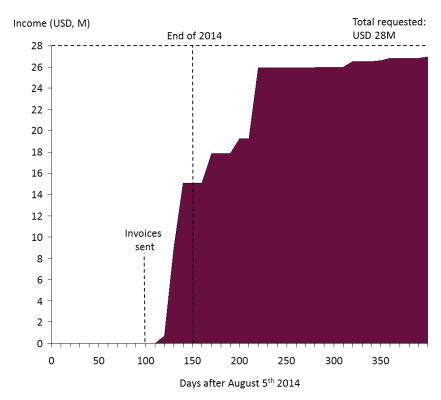


Figure 11. Invoice payment over time, 2015

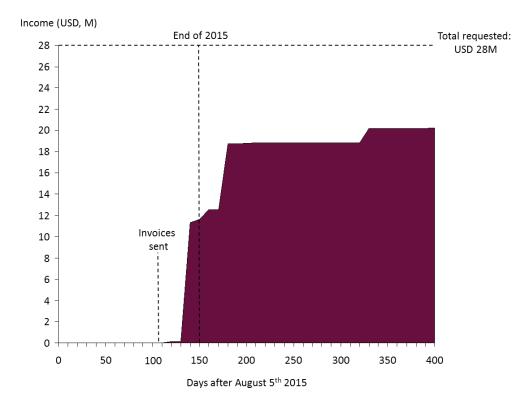
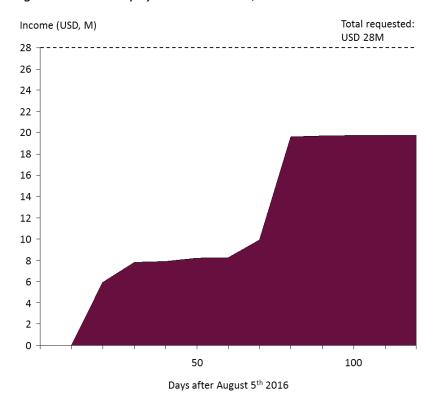


Figure 12. Invoice payment over time, 2016



# Summary

Table 15. Date invoices were sent, funds available at the end of the calendar year, and total funds received, by year.

Year	Invoices sent	Funds available at year end	Total funds received
2013	12/11/13	USD 15.1 M	USD 27.5 M
2014	13/11/14	USD 15.1 M	USD 27.0 M
2015	19/11/15	USD 11.6 M	USD 25.2 M
2016	05/08/16	USD 19.7 M	pending

# **Appendix 3: List of interviewees**

Table 16. List of stakeholders interviewed.

Contact Name	Organization	Stakeholder category	Role / AOW / Region / Unit / Department / Organization
Claudia Alfonso	WHO	AOW	Regulatory capacity building
Lisa Hedman	WHO	AOW	Planning for deployment
Jennifer Barragan	WHO	PIP Secretariat	Laboratory and surveillance
Paul Rogers	WHO	PIP Secretariat	Project manager
Julia Fitzner	WHO	AOW	Burden of disease
Gaya Gemhewageg	WHO	AOW	Risk communications
Katelijn Vandemaelek	WHO	AOW	Laboratory and surveillance
Sandra Jackson	WHO	AOW	Laboratory and surveillance
Kate Strong	WHO	PIP Secretariat	Technical officer, monitoring and evaluation
Anne Marie Huvos	WHO	PIP Secretariat	
Rafe Slattery	WHO	WHO (non-PIP)	Pandemics and epidemics
Catherine Oswald	WHO	WHO (non-PIP)	Pandemics and epidemics
Sylvie Briand	WHO	WHO (non-PIP)	Director, Infectious Hazards Management
Wenqing Zhang	WHO	WHO (non-PIP)	Global Influenza Program
Aditama Tjandra Phil Gould	WHO	Regional	SEARO
Fahmi Sembiring	WHO	Regional	SEARO

Soatiana Rajatonirina	WHO	Regional	AFRO
Rakhee Palekar	WHO	Regional	AMRO
Wasiq Khan	WHO	Regional	EMRO
Caroline Brown	WHO	Regional	EURO, Programme Manager Influenza & Other Respiratory Pathogens program and responsible for PIP implementation
Sarah Hamid Jun Nakagawa Barbatunde Olowokure	WHO	Regional	WPRO
Thedi Ziegler		WHO	Consultant
Ann Moen	US CDC	СС	Associate Director, Extramural Influenza Program
John McCauley	The Francis Crick Institute	СС	Director, WHO CC, Worldwide Influenza Centre
Nancy Cox	US CDC	СС	Former Director, Influenza Division
lan Barr	VIDRL	СС	Deputy Director, VIDRL
Bob Cracknell Beverley Taylor	Seqiris	Industry partner	Technical Services, Influenza Operations
Matthew Downham	MedImmune	Industry partner	Associate Director, Flu Manufacturing Sciences & Technology
Phyllis Arthur	BIO	Industry partner	Managing Director, Infectious Diseases and Diagnostics Policy
Sam Lee Atika Abelin Phil Hosbach	Sanofi	Industry partner	Senior Director, Pandemic & New Influenza Products Director, Global Influenza Policy Vice President, Global Vaccine Public Affairs
Florette Treurnicht Amelia Buys Orienka Helferscee	South Africa, NIC	NIC	
Abdulakhad Safarov	Tajikistan, WHO	WHO	

# Appendix 4: List of documents used

Source	Format				
Background					
Partnership contribution gaps and needs analysis, 2013	Report				
PIP critical paths analysis	Report				
Annual reports					
Partnership contribution annual report 2015	Report				
Partnership contribution annual report 2014	Report				
Workplans					
Areas of work workplans; 2014-2016	Spreadsheet				
Regional workplans; 2014-2016	Spreadsheet				
Indicator data					
Indicator scoring criteria					
Laboratory and surveillance indicator data; August 2013-August 2016	Spreadsheet				
Burden of disease publication progress	Spreadsheet				
Funding					
Funding requested and received, by date and industry partner	Spreadsheet				