World Health Organization

Pandemic Influenza Preparedness (PIP) Framework

Partnership Contribution (PC) Preparedness High-Level Implementation Plan II 2018-2023

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Executive Summary

Part 1: Context

The ***Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*** **('PIP Framework' or 'Framework')** is an international arrangement adopted by the World Health Assembly (WHA) in May 2011 to improve global pandemic influenza preparedness and response. The Framework establishes a PIP Benefit Sharing System that includes an annual **Partnership Contribution (PC)** to WHO from influenza vaccine, diagnostic, and pharmaceutical manufacturers using the WHO global Influenza Surveillance and Response System (GISRS).

The Framework states that the annual amount to be received by WHO is equivalent to 50% of the running costs of GISRS, which means the annual PC to be paid to WHO is US $28 million. The funds are to be used for improving pandemic influenza preparedness and response. Since 2013, funds received by WHO have been allocated as follows: 10% of PC Funds are allocated for the PIP Secretariat and, of the remainder, 30% are set aside for response during an influenza pandemic and 70% of funds are allocated for preparedness. This **High Level Implementation for 2018-2023 (HLIP II)** outlines the use of PC Preparedness Funds. It builds on the progress made under the first High Level Implementation Plan, which outlined the scope of work from 2013-2017 (HLIP I).[1]

This Plan was designed to complement existing global and WHO initiatives to enhance global preparedness. Several reviews and analyses (i.e. the PIP Framework Review 2016,[2] a Gaps and Needs Analysis,[3] an External Evaluation of HLIP I,[4] and the Critical Path Analysis[5]) guided the development of this document to ensure a strategic focus. There was also substantial input from stakeholders that was vital to the development and finalization of this Plan.

Part 2: The Implementation Plan

The Implementation Plan is the heart of this document and outlines how global preparedness will be improved. The Implementation Plan presents a results hierarchy that consists of six Outputs, each with specific Deliverables and indicative activities. Together, these build towards achieving the intended PC Preparedness Outcome:

> **Influenza surveillance systems, knowledge and capacities for a timely and appropriate response to pandemic influenza are established and strengthened**.

[1] http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1
[2] http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1
[3] http://www.who.int/influenza/pip/benefit_sharing/PIP_GapAnalysis2017.pdf?ua=1
[4] http://who.int/about/evaluation/pip_evaluation_report.pdf?ua=1
[5] http://apps.who.int/iris/bitstream/10665/161368/1/WHO_HSE_PED_GIP_PIP_2015.1_eng.pdf?ua=1&ua=1&ua=1

Progress is monitored using six Outcome indicators. Each Output is also monitored with predefined 'SMART' indicators. Milestones are used to monitor the progress towards achieving Deliverables and completing activities.

The six Outputs are:

Laboratory and Surveillance Capacity Building (L&S, Output 1): National influenza laboratory and surveillance systems contribute to GISRS for timely risk assessment & response measures.

- This Output will support countries to improve their laboratory and surveillance system capacities, and to actively participate in GISRS.
- It is supported by six Output indicators and five Deliverables.

Burden of Disease (BOD, Output 2): Influenza disease burden estimates are used for public health decisions.

- This Output will focus on ensuring that national, regional and global influenza burden estimates are available, and that they are communicated in an effective manner so that they are used by decision-makers.
- It is supported by one Output indicator and two Deliverables.

Regulatory Capacity Building (REG, Output 3): Timely access to quality-assured pandemic influenza products is supported.

- This Output will improve regulatory systems and processes that facilitate timely access to pandemic influenza products including antivirals, diagnostics and vaccines.
- It is supported by one Output indicator and two Deliverables.

Risk Communications and Community Engagement (RCCE, Output 4): Tools and guidance are available for countries to enhance influenza risk communication and community engagement.

- This Output will include social and behavioral science-based risk reduction strategies (including to address vaccine hesitancy), while placing a direct focus on exercising RCCE capacities for seasonal influenza to improve preparedness for pandemic influenza.
- It is supported by two Output indicators and two Deliverables.

Planning for Deployment (DEP, Output 5): Plans for effective and efficient deployment of pandemic supplies are optimized.

- This Output will support the development and periodic review of global and national plans for pandemic product deployment, will work with global stakeholders to improve deployment systems, and will assist countries in developing and sustaining vaccine procurement and production practices.
- It is supported by two Output indicators and three Deliverables.

Influenza Pandemic Preparedness Planning (IPPP, Output 6): National pandemic influenza preparedness and response plans are updated in the context of all-hazards preparedness and global health security.

- This Output will support countries to further develop their pandemic influenza preparedness plans, and will help bring together progress made under the other HLIP II Outputs.
- It is supported by one Output indicator and one Deliverable.

The Implementation Plan also includes **revised country selection criteria** for each Output. The list of countries funded for each Output will be published on the PIP website and in annual reports, and selected countries will be reviewed every two years by regional offices and partners. This list will be updated if necessary.

Part 3: Management

As implementation of PC Preparedness Funds is executed across WHO headquarters, regions and countries, effective project management is key to successful implementation. Management of PIP PC Implementation utilizes four steps:

1. **Planning.** Biennial work plans will be developed at country, regional and global levels. The PIP Secretariat ensures alignment of the work plans with HLIP II Deliverables. There will also be an external review by a technical and independent review body. After reviews and necessary revisions, work plans will be submitted to the Executive Director of the WHO Emergencies Programme through the Director of the Department of Infectious Hazard Management, and PC Funds will be released upon approval.
2. **Implementation.** Implementation is conducted at country, regional and global levels as described in the Implementation Plan.
3. **Monitoring and Evaluation.** This includes financial monitoring, work plan implementation monitoring and a final evaluation.
    a. Financial monitoring complies to WHO's Internal Control Framework, and includes: monthly oversight by the PIP Secretariat; 6-monthly compliance checks; and external audits if requested by the World Health Assembly (WHA).
    b. Work plan monitoring includes: monthly calls between WHO headquarters, regional offices and the PIP Secretariat; 6-monthly milestone monitoring on Deliverables; and annual Outcome and Output indicator monitoring. Monitoring data will be collected from the WHO implementing units by the PIP Secretariat.
    c. A mid-HLIP II review will be conducted in 2020 to assess progress and consider changes where necessary. At the end of HLIP II in 2023, there will be a final external evaluation and impact assessment.
4. **Reporting.** Reporting is conducted at several intervals: bi-monthly through the PIP Newsletter on achievements; 6-monthly through a presentation to the PIP AG and other stakeholders to discuss implementation status; annually through a report that includes progress on indicators; and biennially through a report to the WHA.

There are several mechanisms in place to ensure that implementers are held accountable and remain committed to PC Implementation as outlined in this Plan. These mechanisms include confirming the interest of potential PC recipient countries, biennial review of recipient countries, and regular monitoring and reporting. These mechanisms ensure that all partners remain aware of the expectations of the PIP Framework and of PIP PC Implementation, and that responsible use of funds is maintained to best address global pandemic influenza preparedness needs.

Acronyms & Abbreviations

AFRO	Regional Office for Africa
AG	Advisory Group
AMRO	Regional Office for the Americas
AOW	Area of Work
BOD	Burden of Disease
CC	Collaborating Centre
CO	WHO Country Office
CRA	Country Recipient Agreement
CSO	Civil Society Organization
CVV	Candidate Vaccine Virus
DEP	Planning for Deployment
EMRO	Regional Office for the Eastern Mediterranean
EQAP	External Quality Assessment Programme
ERL	Essential Regulatory Laboratory
ERMH	Emergency Risk Management for Health
EURO	Regional Office for Europe
GAP	Global Action Plan for Influenza Vaccines
GIP	Global Influenza Programme
GISRS	Global Influenza Surveillance and Response System
HLIP	High Level Implementation Plan
HQ	WHO Headquarters
IDP	Institutional development plan
IHM	Infectious Hazard Management
IHR	International Health Regulations (2005)
IPPP	Influenza Pandemic Preparedness Planning
ISST	Infectious substances shipping training
IVPP	Influenza virus with pandemic potential
L&S	Laboratory and Surveillance Capacity Building
MERS	Middle East Respiratory Syndrome
MOH	Ministry of Health
NIC	National Influenza Centre
NITAG	National Immunization Technical Advisory Groups
NRA	National Regulatory Authority
PAHO	Pan-American Health Organization
PC	Partnership Contribution
PCITEM	PC Independent Technical Expert Mechanism
PIP	Pandemic Influenza Preparedness
PIRM	Pandemic Influenza Risk Management
RCCE	Risk Communications and Community Engagement
REG	Regulatory Capacity Building
RO	WHO Regional Office
SAGE	Strategic Advisory Group of Experts (SAGE)
SEARO	Regional Office for South-East Asia
TAG	Technical Advisory Groups
VCM	Vaccine Composition Meeting
WHA	World Health Assembly
WHE	WHO Health Emergencies Programme
WHO	World Health Organization
WPRO	Regional Office for the Western Pacific

Introduction

The *Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits* (the "PIP Framework" or "Framework") is an international arrangement adopted by the World Health Assembly in May 2011 to improve global pandemic influenza preparedness and response.[6]

The PIP Framework is an innovative partnership among Member States, industry, civil society and other stakeholders. It aims to improve the sharing of influenza viruses with pandemic potential (IVPP), on the one hand, and the equitable access to products necessary to respond to pandemic influenza (e.g. vaccines, antiviral medicines and diagnostic products), on the other. Under the Framework, implementation strives to build sustainable capacities for detecting and responding to pandemic influenza.

This document presents the PIP Partnership Contribution (PC) **High-Level Implementation Plan II (HLIP II)**, which will guide capacity building in order to improve global pandemic influenza preparedness over the next six years, from 2018 to 2023. The development of this plan relied on a participatory process that engaged a broad range of stakeholders including: the PIP Advisory Group (AG); WHO Global Influenza Surveillance and Response System (GISRS); industry; and civil society organizations (CSOs).

QUICK LOOK: What's new in HLIP II?

- The Results Hierarchy includes **one Outcome** for implementation of PC Preparedness Funds to improve pandemic influenza preparedness, which is addressed through **six Outputs**.
- Laboratory and Surveillance Capacity Building (L&S, Output 1) will have an increased focus on building national and global capacities for risk and severity assessment of influenza.
- Under Burden of Disease (BOD, Output 2), there is a greater emphasis to use burden of disease estimates to **inform policy decisions.**
- Regulatory Capacity Building (REG, Output 3) will link **regulatory preparedness** to other **components of national pandemic influenza preparedness,** including vaccine deployment.
- Under **Risk Communication and Community Engagement** (RCCE, Output 4), capacities and resources for pandemic influenza preparedness will be built and exercised during seasonal influenza epidemics.
- There is a greater emphasis on **exercising a common approach for deployment** of pandemic influenza products to countries, and with linkages to in-country deployment plans (DEP, Output 5).
- There is enhanced **integration** of all country capacity building under the new Output, **Influenza Pandemic Preparedness Planning** (IPPP, Output 6), with emphasis on developing or revising plans.
- There are improved **Outcome and Output indicators**, as well as defined **milestones** to demonstrate progress and report on fund use.
- Clarity has been provided on how implementation of PC Preparedness Funds will collaterally strengthen national core capacities under the **International Health Regulations** and support implementation of **WHO's Pandemic Influenza Risk Management Guidance**.
- The **country selection criteria** have been revised to increase clarity. In addition, countries selected for support will be consulted to confirm their commitment for implementation.

[6] http://www.who.int/influenza/pip/en/

Part 1: Context

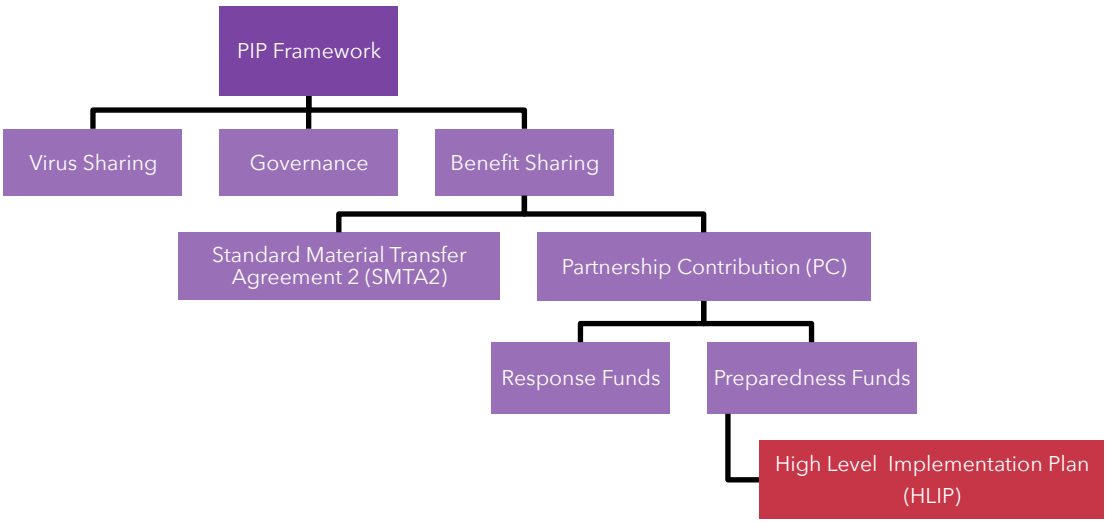
1. About the PIP Framework

The PIP Framework is the result of a four-year intergovernmental process that was sparked by the re-emergence of influenza A(H5N1) in 2004. The aim was to establish a system where access to IVPP was placed on an equal footing with access to benefits such as pandemic vaccines.

The **Partnership Contribution (PC)** is one element of the PIP benefit sharing system (Figure 1).

The PC is an innovative and sustainable financing mechanism under which influenza vaccine, antiviral and diagnostic manufacturers that use the WHO GISRS, make an annual financial contribution to WHO.[7] PC Funds supplement and accelerate existing national, regional and global initiatives for pandemic influenza preparedness and response. PC Preparedness Funds are to be used (implemented) for improving pandemic preparedness activities that include strengthening laboratory and surveillance capacities, conducting influenza disease burden studies, improving national regulatory systems to ensure timely access to pandemic products, improving risk communication and community engagement for pandemic influenza, promoting effective deployment of pandemic vaccines and antiviral medicines, and finally developing, revising, and testing country pandemic influenza preparedness plans.[8]

Figure 1: Overview of the PIP Framework



The Framework states that the annual amount to be received by WHO is equivalent to 50% of the running costs of GISRS, which in 2010 were approximately US $56.5 million.[9] Therefore, the annual PC to be paid to WHO is US $28 million.

The HLIP II describes how the PC Preparedness Funds will be used from 2018 to 2023 to best improve global capacities for detecting and responding to pandemic influenza.

[7] See PIP Framework sections 6.14.1 and 6.14.2
[8] See PIP Framework section 6.14.4
[9] See PIP Framework section 6.14.3 and 6.14.4

1.1 Ten-Year Objectives for Improving Pandemic Influenza Preparedness

Prior to the first HLIP designed in 2013, the PIP AG identified several 10-year objectives for improving pandemic influenza preparedness. These were based on a gap analysis published in November 2013.[10] These objectives remain relevant for the development of HLIP II and informed the design of the HLIP II Results Hierarchy.

1. All countries should have in place well-established core capacities for surveillance, risk assessment, and response at the local, intermediate and national level, as required by the IHR.
2. All countries should have access to a National Influenza Centre (NIC) laboratory – the backbone of the GISRS.
3. A clearer picture of the health burden that influenza imposes on different populations should be established.
4. All countries should have access to pandemic influenza vaccines and antiviral medicines to help reduce pandemic-related morbidity and mortality.
5. All countries should have improved capacities to carry out effective risk communications at the time of a pandemic.

1.2 Progress to Date

Substantial progress has been made since 2011 to implement the PIP Framework. Achievements have improved global preparedness in several areas.

1.2.1 Progress on Access to Pandemic Response Products

Implementation of the Framework has resulted in several significant advances in the global pandemic influenza preparedness landscape.

A. Equitable access to pandemic response products. By concluding Standard Material Transfer Agreements 2 (SMTA2), WHO has secured access to several critical, life-saving pandemic response products that will be made available to it in real-time when the next pandemic strikes, including:

- An estimated **400 million doses of pandemic vaccine.** This represents approximately four times the amount of pandemic vaccine that was available during the 2009 pandemic.
- **10 million antiviral treatment courses** to be used by countries in need. This diversifies the current antiviral stockpile to which WHO has access.
- **250 thousand diagnostic kits**

[10] http://www.who.int/influenza/pip/pip_pc_ga.pdf?ua=1

B. In addition to these in-kind products, WHO has worked with its partners who have contributed upwards of US **$125 million** to strengthen pandemic influenza preparedness and response capacities.

C. The PIP framework has stimulated more countries to share influenza viruses.

D. Finally, as of July 2017, WHO has concluded **63 SMTA2** with **academic and research institutions** and received **25 benefit-sharing offers**. These offers are predominately for L&S.

1.2.2 Progress on PIP PC Implementation

HLIP II builds on the prior High Level Implementation Plan that outlined a programme of work from 2013 to 2017 (HLIP I).[11] It is worth noting the accomplishments that were achieved under HLIP I. These are described below (Figure 2), according to the five Areas of Work (AOWs) that were implemented in that Plan. HLIP I achievements are described in annual reports available online.[12]

Figure 2: Examples of Progress made on Pandemic Influenza Preparedness under HLIP I, as of December 2016

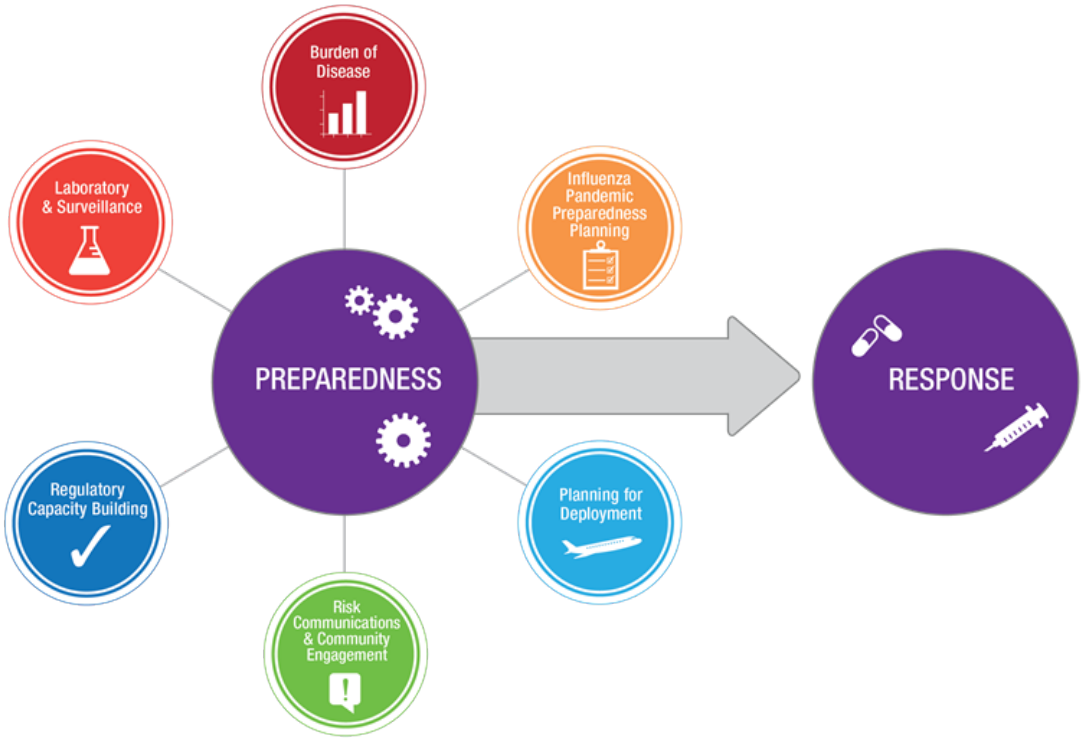
[11] http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1
[12] http://www.who.int/influenza/pip/benefit_sharing/pc_implementation/en/

1.3 Alignment of HLIP I AOWs with HLIP II Outputs

HLIP II carries forward the work under each AOW. However, it has redefined these AOWs as six Outputs to be aligned with the WHO results chain terminology. To ensure clarity and maintain linkages with the five AOWs from HLIP I, these are labeled as follows in **HLIP II** (Figure 3):

- Laboratory and Surveillance Capacity Building (L&S) AOW sits within **L&S (Output 1)**
- Burden of Disease (BOD) AOW sits within **BOD (Output 2)**
- Regulatory Capacity Building (REG) AOW sits within **REG (Output 3)**
- Risk Communications AOW is now labeled Risk Communications and Community Engagement (RCCE), and sits within **RCCE (Output 4)**
- Planning for Deployment (DEP) AOW sits within **DEP (Output 5)**
- Influenza Pandemic Preparedness Planning (IPPP) was previously an activity under L&S in HLIP I. This has been brought forward as a separate Output, namely **IPPP (Output 6)**

Figure 3: Outputs contributing to Pandemic Preparedness' and Response in HLIP II



2. Preparedness Context

2.1 What is Pandemic Preparedness?

Preparedness is defined as the **knowledge**, **capacities**, and **systems** that work to reduce vulnerability and enhance resilience.[13] Pandemic influenza preparedness aims to strengthen country, regional and global capacities to prepare for and respond to pandemic influenza. Preparing for an influenza pandemic is collaborative, and requires a whole-of-government and whole-of-society approach.

2.2 Global Health Security Context

The PIP Framework's preparedness mandate sits within the context of several broader global frameworks and initiatives that address emergency preparedness. PIP PC Implementation aims to align with these frameworks and initiatives to build upon momentum to improve global health. Examples of other initiatives that provide context include the Sustainable Development Goals (SDGs),[14] the International Health Regulations (IHR),[15] the Global Health Security Agenda (GHSA),[16] and the Inter-Agency Standing Committee (IASC) Common Framework for Preparedness.[17] This list is not exhaustive, and there are several other global frameworks that affect emergency preparedness. Relevant global frameworks and priorities have been taken into account in developing HLIP II to ensure that, where appropriate, Outputs collaterally advance global strategies and that PC Preparedness Funds are used effectively.

2.3 Synergies with other WHO Programmes

In addition to global frameworks, individual WHO regions are also guided by regional strategies that address preparedness and disaster risk management:

- AFRO: Integrated Disease Surveillance Response Framework (IDSR)[18] and Disaster Risk Management Strategy[19]
- AMRO/PAHO: Strategic Plan for Disaster Reduction and Response[20]
- EMRO: IHR implementation[21]
- EURO: Health 2020[22]

[13] Adapted from the WHO Strategic Framework for Emergency Preparedness (2017) and the IASC Common Framework for Emergency Preparedness (2013)
[14] https://sustainabledevelopment.un.org/sdgs
[15] http://www.who.int/ihr/publications/9789241596664/en/
[16] https://www.ghsagenda.org/
[17] https://interagencystandingcommittee.org/system/files/final_common_framework_for_preparedness.pdf
[18] https://www.cdc.gov/globalhealth/healthprotection/idsr/index.html
[19] https://www.aho.afro.who.int/en/ahm/issue/18/reports/disaster-risk-management-strategy-health-sector-african-region
[20] http://www.paho.org/disasters/index.php?option=com_content&task=view&id=989&Itemid=1&lang=en
[21] http://www.who.int/ihr/publications/9789241580496/en/
[22] http://www.euro.who.int/en/health-topics/health-policy/health-2020-the-european-policy-for-health-and-well-being/about-health-2020

- SEARO/WPRO: Asia-Pacific Strategy for Emerging Diseases (APSED)[23]

These regional priorities have influenced the strategic directions and presentation of HLIP II, which allows individual regions to use PC Preparedness Funds in synergy with their priorities.

The focus of PC Preparedness Funds also intersects with other WHO programmes and initiatives aimed at strengthening preparedness and response capacities.[24] To enhance impact and minimize duplication, HLIP II is synergized with these programmes. Pandemic preparedness work that strengthens capacities under other frameworks and initiatives are collateral benefits of PIP PC Implementation. However, PC Preparedness Funds are allocated and used in order to directly improve global preparedness for an influenza pandemic as set out in the five 10-year objectives established by the PIP AG in 2013 (Section 1.1).

International Health Regulations (2005): IHR (2005) is a legally-binding international instrument. It requires WHO Member States to build 13 core capacities to detect, assess and report public health events, and to respond promptly and effectively to public health risks and public health emergencies of international concern. By strengthening preparedness and response to pandemic influenza, HLIP II will benefit country capacities required under the IHR. The core capacities that will collaterally benefit from HLIP II implementation are shown below (Table 1).

Table 1: Implementation of IHR Core Capacities and HLIP II Synergies

IHR Core Capacity	HLIP II Output
Surveillance	L&S (Output 1)
Response	L&S (Output 1)
Preparedness	REG (Output 3), DEP (Output 5), & IPPP (Output 6)
Risk communications	RCCE (Output 4)
Human resources	L&S (Output 1) & RCCE (Output 4)
Laboratory	L&S (Output 1)

Pandemic Influenza Risk Management Guidance (PIRM): This WHO guidance presents an approach to inform and harmonize both national and international influenza pandemic preparedness planning. It applies the principles of all-hazards 'emergency risk management for health' (ERMH), which includes six categories of essential components (Table 2). HLIP II will support implementation and roll-out of this guidance to countries.

[23] http://www.wpro.who.int/emerging_diseases/APSED2010/en/
[24] R&D Blueprint http://www.who.int/blueprint/en/ and Contingency Fund for Emergencies http://www.who.int/about/who_reform/emergency-capacities/contingency-fund/en/

Table 2: PIRM and HLIP II Synergies

PIRM Category of Essential Components	HLIP II Output
Information and knowledge management	L&S (Output 1) & RCCE (Output 4)
Policies and resource management	BOD (Output 2)
Health and related services	REG (Output 3)
Community capacities	RCCE (Output 4)
Health infrastructure and logistics	DEP (Output 5)
Planning and coordination	IPPP (Output 6)

Global Action Plan for Influenza Vaccines (GAP): The GAP initiative was launched in 2006 and closed in 2016. GAP was a comprehensive strategy to reduce the global shortage of pandemic influenza vaccines, through increasing seasonal influenza vaccine production and use in developing countries, while also promoting influenza vaccine research. Three areas of synergy between HLIP II and GAP priorities were identified based on the GAP AG report to the WHO Director-General (Table 3).[25] Implementation of HLIP II for pandemic influenza preparedness, particularly vaccine preparedness, will benefit from the momentum and systems established during GAP.

Table 3: GAP and HLIP II Synergies

GAP Priority Issues	HLIP II Output
Continued technical assistance to countries to have sustainable seasonal influenza procurement/ production plans, commitment, availability of funding and a health care system that serves the whole population with a trusted vaccine infrastructure	REG (Output 3) & DEP (Output 5)
Address root causes of vaccine hesitancy	RCCE (Output 4)
Provide evidence on vaccine effectiveness in specific risk groups	BOD (Output 2)

[25] http://www.who.int/influenza_vaccines_plan/news/gap3_Nov16/en/

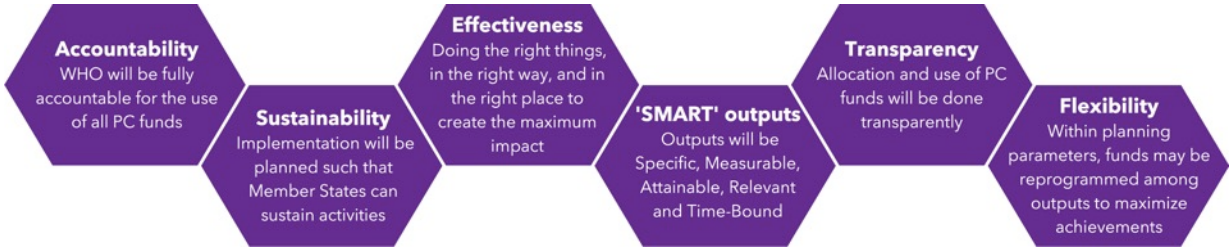
3. Design of the HLIP II

The design and development of HLIP II was informed by a number of principles, assumptions and lessons learnt.

3.1 Planning Principles

The first HLIP was guided by six planning principles that have remained valid and relevant to ensure that PC implementation is effective, efficient and fair, and yields the expected global changes in pandemic preparedness (Figure 4). These planning principles are accountability, sustainability, effectiveness, 'SMART' outputs, transparency and flexibility.[26]

Figure 4: Planning Principles for HLIP II



3.2 Involvement of Multiple Stakeholders in HLIP II Design

Developing HLIP II was a consultative process, which involved and engaged multiple stakeholders, focusing on the common goal of improving pandemic influenza preparedness. Stakeholders consulted include:

- **PIP AG**, which provides regular advice to the WHO Director-General on the use of resources and interact with stakeholders.
- **GISRS**. NICs are the mainstay of the system for influenza global alert, detection and surveillance, and share viruses and other information. WHO Collaborating Centres (CCs), H5 Reference Laboratories and Essential Regulatory Laboratories (ERLs) provide expert analysis and technical capacity building.
- **Industry**, which provides the PC Funds.
- **Civil Society Organizations (CSOs)**, which ensures that Member State and community needs are equitably met.
- **Others,** namely influenza development partners engaged in influenza preparedness and response.

The engagement process including the different stakeholders consulted in HLIP II design is included in Annex 1.

[26] See Introduction, section 4 of HLIP I for descriptions of the planning principles (http://www.who.int/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1)

3.3 Lessons from Reviews, Evaluations and Analyses

Two reviews, the *Report of the 2016 PIP Framework Review Group* (the 'PIP Review 2016') and the *Review Report of the Review Committee on the Functioning of the IHR (2005) and on Pandemic Influenza (H1N1)* (the '2009 IHR After-Action Review'), have provided further context for priority issues that will be addressed through HLIP II. This Plan was also informed by consultative processes, including the *Gaps and Needs Analysis*; and the *External Evaluation of PIP Partnership Contribution High-Level Implementation Plan 2013-2016*. The *Critical Path Analysis* linked the various priorities and provided an architecture for planning.

3.3.1 PIP Review 2016

The PIP Framework was reviewed in 2016 by an independent group of experts to assess achievements and challenges in the implementation of the Framework as well as to identify how implementation has improved preparedness.[27] Five recommendations from the Review informed the development of HLIP II (Table 4).

Table 4: PIP Review Recommendations that Informed HLIP II

Recommendation number	Description	Location within HLIP II
2b	PC implementation measures should be better communicated in regular PIP AG reports and post-meeting briefings to highlight progress	Section 6.2.3 Monitoring and Evaluation, and Section 6.2.4 Reporting
2c	Communication and transparency should be enhanced around issues such as selection of countries for PC funds	Section 5, Selecting PC Recipient Countries
25	Consider including process measures for PC Implementation	6.2.3 Monitoring and Evaluation
34	Consider lessons learned from GAP	BOD (Output 2), REG (Output 3) & DEP (Output 5)
35	Activity under the PIP Framework should be undertaken with the provisions of the IHR (2005) in mind, and capacity building efforts aligned	Section 2.3, Synergies with other WHO Programmes L&S (Output 1), REG (Output 3), RCCE (Output 4), DEP (Output 5), IPPP (Output 6)

3.3.2 2009 IHR After-Action Review

Following the 2009 pandemic, an expert review committee was convened to review the functioning of IHR (2005). It concluded that the world was "ill-prepared" to respond to a severe influenza pandemic.[28] In response to this, several Outputs under HLIP II were informed by recommendations from this review that was published in 2011 (Table 5).

[27] http://apps.who.int/gb/ebwha/pdf_files/EB140/B140_16-en.pdf?ua=1
[28] http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf

Table 5: 2009 IHR After-Action Review Recommendations that Informed HLIP II

Recommendation number	Description	Location within HLIP II
1	Accelerate implementation of IHR core capacities	Part 2: Implementation Plan
8	Develop and apply measure to assess severity	L&S (Output 1)
9	Streamline management of guidance documents	RCCE (Output 4)
10	Develop and implement a strategic, organization-wide communications policy	RCCE (Output 4)
11	Encourage advance agreements for vaccine distribution and delivery	REG (Output 3) & (DEP (Output 5)
14	Reach agreement on sharing of viruses and access to vaccines and other benefits. It was recommended to increase global vaccine production capacity by urging countries to immunize their high-risk populations yearly against seasonal influenza, when consistent with national priorities. This can reduce the burden of disease and can increase experience with local production, distribution and delivery. It will also improve surveillance, communication and professional/public education.	BOD (Output 2), RCCE (Output 4), DEP (Output 5)

3.3.3 Gaps and Needs Analysis (GNA)

The GNA was conducted from September 2016 - January 2017. It addressed the questions of which Outcomes, Outputs and activities funded by PC Preparedness Fund implementation between 2013 and 2016 should be maintained, enhanced or discontinued, and what new AOWs (i.e., Outputs) could be added.

The GNA uncovered technical gaps and needs for PIP PC implementation. Detailed results can be found in the report.[29] Key gaps, and how they have been integrated into HLIP II include:

- **National pandemic preparedness planning was identified as a potential new AOW:** This has been included as IPPP (Output 6).
- **There is a need to use burden of disease data for informed decision-making:** BOD (Output 2) has been revised to make this a Deliverable.
- **Risk communications requires locally-grounded approaches, integration of social science interventions, and should address the anti-vaccination movement:** All of these areas have been included in RCCE (Output 4), with an emphasis on community engagement.
- **Planning for deployment requires more simulation exercises and development of national deployment plans:** Development of deployment plans will be strengthened under DEP (Output 5) and IPPP (Output 6). More exercises will be conducted under DEP (Output 5) to improve planning, coordination and allocation using a simulation application (PIP Deploy), which was developed under HLIP I.

[29] http://www.who.int/influenza/pip/benefit_sharing/PIP_GapAnalysis2017.pdf?ua=1

- **Integration of the human-animal interface** will continue to be strengthened through joint risk assessments under L&S (Output 1).
- **Linkages between seasonal influenza vaccination campaigns and pandemic influenza vaccine preparedness** will be made in RCCE (Output 4) and DEP (Output 5). While seasonal influenza viruses are outside the scope of the PIP Framework, nevertheless seasonal influenza epidemics provide the opportunity to strengthen preparedness and response capacities.

3.3.4 External Evaluation of PIP Partnership Contribution High-Level Implementation Plan 2013-2016

An external evaluation of PIP PC Implementation was conducted from November 2016 - February 2017. The Evaluation assessed progress towards achieving Outputs and Outcomes, measured the short, medium and long-term impact of PC Preparedness Funds, and identified lessons learnt to improve implementation.[30]

The four major recommendations relevant to PC Preparedness Funds implementation and how they have been addressed in HLIP II are described below:

- **Recommendation 1: Improve log frame design.** Outcome and Output indicators have been revised, and milestones will be used to better reflect progress. The WHO results chain was used to build the HLIP II Results Hierarchy.
- **Recommendation 2: Improve reporting granularity.** The monitoring, evaluation and reporting processes outlined in Section 6 of HLIP II will facilitate communication of progress and HLIP II achievements, including linkages between financial and technical implementation.
- **Recommendation 3: Provide clarity on country prioritization.** The country selection criteria have been updated and the process for country selection is explicitly stated for each Output (Section 5) in HLIP II. In order to receive funds, countries will have to express their commitment to the implementation and monitoring processes defined in HLIP II.
- **Recommendation 4: Speed up work plan approvals.** A newly established PC Independent Technical Expert Mechanism (PCITEM) will provide support to ensure technical appropriateness of work plans, while also speeding up the approval process through timely reviews. Planning has also moved to a biennial cycle to be aligned with standard WHO processes and to reduce work plan development iterations.

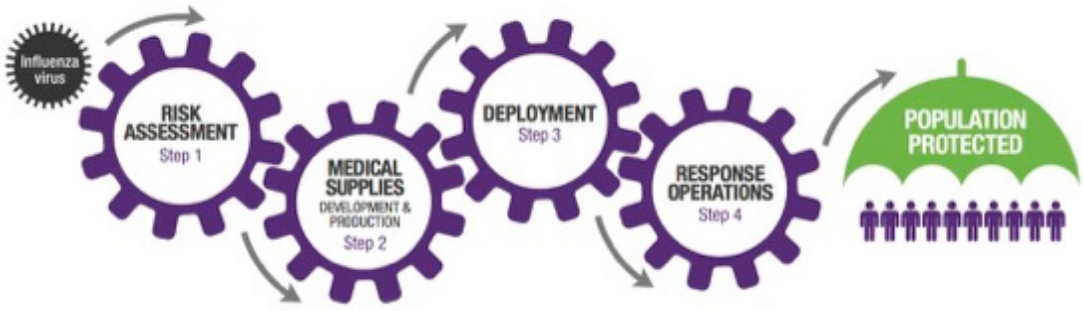
3.3.5 Critical Path Analysis

The Critical Path Analysis (CPA) was developed in 2015 [31] to provide a high-level overview of the complex, multi-sectoral 'path' from detection of a new influenza virus to protection of the global community (Figure 5). It described the priorities for intervention, which were reflected in the five AOWs under HLIP I. Under HLIP II, this pathway continues to provide strategic directions for Outputs One to Five. Furthermore, given the need to better

[30] http://who.int/about/evaluation/pip_evaluation_report.pdf?ua=1
[31] http://www.who.int/influenza/pip/pip_cpa_2015.pdf

harmonize these Outputs at national level, the addition of IPPP (Output 6) brings together each step of the critical path, relying on the capacities developed under the five other Outputs. Under HLIP II, all Outputs form a strategic and cohesive pathway to improve global preparedness.

Figure 5: Illustration of the Critical Path Analysis, From Detection to Protection



3.4 Allocation of PIP PC Funds

Funds are needed for both pandemic preparedness and response (Figure 6). PC Response Funds are set aside to be used in the time of a pandemic. PC Preparedness Funds are used for improving pandemic preparedness according to HLIP II. The proportion of PC Funds allocated to Preparedness and Response may change over time. The allocation of funds to different Outputs is based on the scope of Deliverables, and may be adjusted over time (Annex 2). All funds are subject to WHO Program Support Costs (PSC), which is a charge that is applied to contribute to the broader administration and management functions of WHO based on how the funds are used.[32] The PSC is applied to each component of PC distribution as described below.

PIP Secretariat: Ten percent of PC Funds are allocated for the PIP Secretariat. The PIP Secretariat costs cover management and implementation of the full PIP Framework including preparation and convening of PIP AG meetings, SMTA-2 negotiations, implementing decisions from the World Health Assembly that relate to the PIP Framework, and reporting. WHO applies PSC at 13% of direct expenses for the PIP Secretariat.

PC Response Funds: Of the PC Funds available for preparedness and response, 30% are set aside for emergency response, to be used in the time of an influenza pandemic. The PC Response Funds are a small portion of the resources that would be needed for a pandemic, but are intended to cover initial costs before other funding sources are available (e.g. government donations or response funds from organizations other than WHO). WHO applies PSC at 7% of direct expenses for the PC Response Funds. As no PC Response Funds have been expended, no PSC has been applied to date.

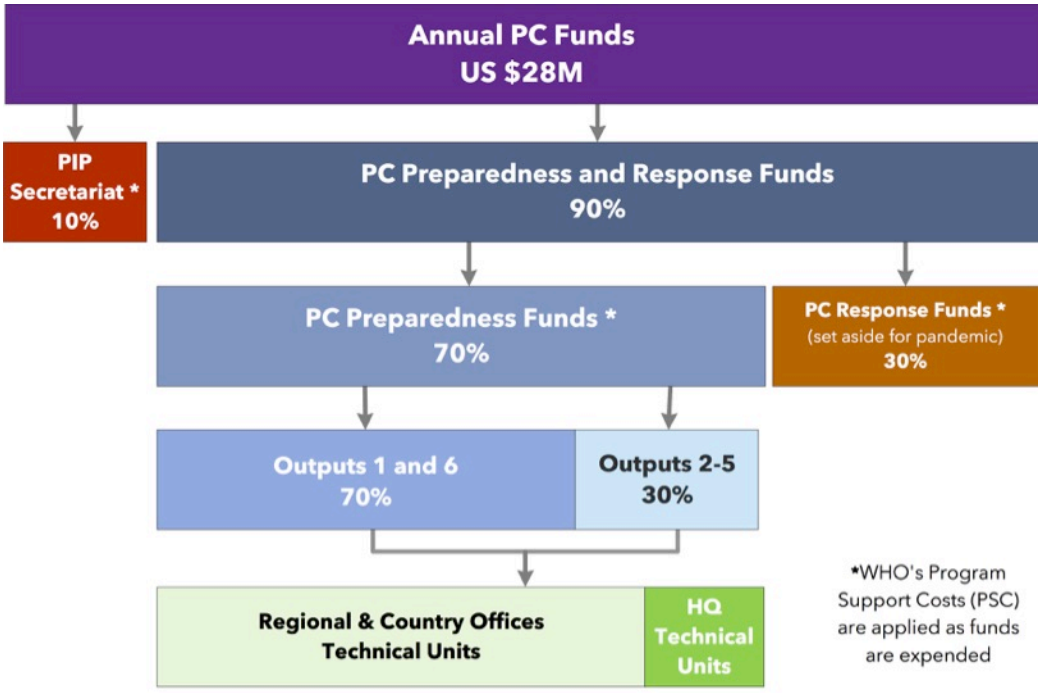
PC Preparedness Funds: Of the PC Funds available for preparedness and response, 70% are used for pandemic influenza preparedness. PC Preparedness Funds are allocated to technical units at WHO HQ (e.g., the Global Influenza Programme), as well as technical units in regions and countries (Annex 2). The global needs for pandemic influenza

[32] WHA34.17 (1981) outlines the application of PSC.

preparedness are substantial, and the financial resources needed to prepare the world for an influenza pandemic are far greater than the PC Preparedness Funds. However, the funds available are a critical contribution to enhancing and accelerating preparedness, and have successfully leveraged other resources and initiatives to enhance preparedness. WHO applies PSC at 13% of direct expenses for the PC Preparedness Funds.

PC Preparedness Funds are allocated using both an equity and a needs-based approach. These Funds are divided across regions in an equitable manner, ensuring that low- and middle-income Member States in all regions can benefit from the resources. Following that division, Funds are allocated to Deliverables and corresponding activities using a needs-based approach. Activities are funded based on the level of priority and technical appropriateness to contribute to the Deliverable, and budgets are developed according to available PC Preparedness Funds.

Figure 6: Proportional Distribution of PC funds



3.5 Assumptions and Limitations

HLIP II is considered a living document that is subject to change, as circumstances evolve. The broad architecture of the Plan will be used to develop biennial work plans under each Output.

Implementation will be contingent on receipt of funds. WHO does not have other funds, independent of the PC Preparedness Funds received, to finance the activities proposed herein. Receipt of funds on a regular and timely basis is needed for the implementation of activities and achievement of the Deliverables outlined in this plan.

Part 2: Implementation Plan

4. Implementation Plan

The architecture of HLIP II has been developed according to the WHO results chain. This ensures that inputs are invested in activities that will contribute to achieving Deliverables, which in turn contribute to broader Outputs, Outcome and overall Impact (Figure 7). HLIP II has one **Preparedness Outcome** that summarizes the five ten-year objectives established by the PIP AG in 2013. The Preparedness Outcome is addressed through **six Outputs.** Each Output is achieved through activities to reach the **Deliverables**, which are project-based priorities that articulate what WHO will deliver. It is understood that each region and country may have different needs according to capacities. Therefore, within the narrative for each Output, a list of **indicative activities** is also provided to highlight the specific activities that work towards the Deliverables.

All activities will improve global pandemic influenza preparedness. Some activities will directly strengthen capacities in PC recipient countries, while other activities will benefit all countries through implementation at global or regional level. Activities will however, differ depending on the country and needs.

As indicated in Figure 7, **Milestones** have been defined for the activities and Deliverables, and **Indicators** have been defined for each Output and the Outcome. These will facilitate monitoring and communication of progress over the six years of HLIP II and be the basis for reporting. A summary of the **HLIP II Results Hierarchy** using this results chain is presented in Figure 8. Details on monitoring, evaluation and reporting are in Section 6 as well as in Annex 3.

Figure 7: Results Chain Overview

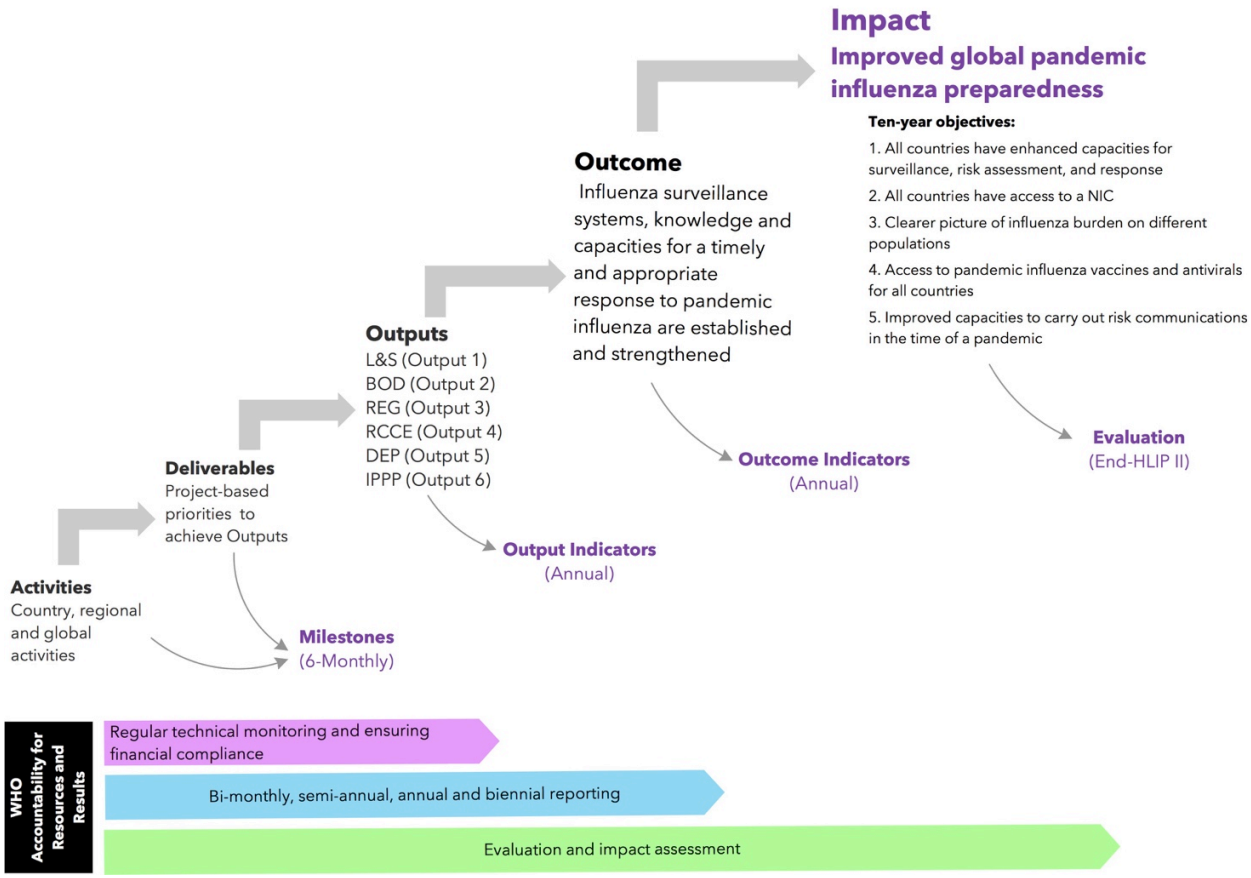


Figure 8: HLIP II Results Hierarchy

PC Outcome and its indicators

Influenza surveillance systems, knowledge and capacities for a timely and appropriate response to pandemic influenza are established and strengthened

- **Outcome Indicator 1:** % of Member States sharing IVPPs with GISRS according to WHO IVPP sharing guidance
- **Outcome Indicator 2:** % of Member States reporting to FluNet
- **Outcome Indicator 3:** % of Member States reporting to FluID
- **Outcome Indicator 4:** % of Member States with burden of disease estimates that have been considered by NITAG or other decision-making bodies
- **Outcome Indicator 5:** # of Member States that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products
- **Outcome Indicator 6:** % of Member States that developed or updated a pandemic influenza preparedness plan

Outputs and their indicators

L&S (Output 1)	BOD (Output 2)	REG (Output 3)	RCCE (Output 4)	DEP (Output 5)	IPPP (Output 6)
National influenza laboratory and surveillance systems contribute to GISRS for timely risk assessment & response measure	**Influenza disease burden estimates are used for public health decisions**	**Timely access to quality-assured pandemic influenza products is supported**	**Tools and guidance are available for countries to enhance influenza risk communication and community engagement**	**Plans for effective & efficient deployment of pandemic supplies are optimized**	**National pandemic influenza preparedness & response plans are updated in the context of all-hazards preparedness and global health security**
1.1 # of risk assessments published for influenza viruses at the human-animal interface following WHO guidance 1.2 # of Member States reporting influenza severity indicators to WHO 1.3 % of Member States that participated and were 100% correct for non-seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP) 1.4 % of Member States that participated and were 100% correct for seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP) 1.5 % of Member States that had timely sharing of influenza virus isolates or clinical specimens with WHO CCs according to WHO guidance 1.6 # of zoonotic influenza viruses and other influenza viruses with pandemic potential characterized by GISRS	2.1 # of Member States with published disease burden estimates based on data collected since 2011	3.1 # of Member States which strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and IDP implementation	4.1 # of users from target audiences who completed learning modules on influenza and related RCCE content on the OpenWHO platform 4.2 # of Member States that utilized RCCE support for influenza preparedness or response	5.1 Annual simulation exercise conducted to test global deployment of pandemic influenza vaccines and other products 5.2 # of Member States that have undergone a national analysis of influenza vaccine procurement or production sustainability	6.1 % of Member States that exercised their pandemic influenza preparedness plan including across sectors

Deliverables

a. Risk and severity of influenza, including at the human-animal interface, are routinely assessed b. Quality influenza virus detection capacity is sustained c. Countries are supported to consistently report influenza data to global platforms d. Countries are supported to share timely representative influenza samples with WHO CCs e. Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated	a. Representative national, regional and global disease burden estimates are available b. Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making	a. National regulatory capacity for pandemic influenza products is strengthened b. Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted	a. Countries and front-line responders have access to resources for influenza risk communication, community engagement and social science-based interventions b. Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement	a. A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners b. National deployment planning process is revised and updated c. Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries	a. Countries are supported to develop, test and update their influenza pandemic preparedness plan

PIP PC Preparedness Outcome: Influenza surveillance systems, knowledge and capacities for a timely and appropriate response to pandemic influenza are established and strengthened

HLIP II has one Outcome that contributes to improved global pandemic influenza preparedness. HLIP II has been designed so that activities, Deliverables and Outputs will all come together to build global capacities under this one Outcome. This Outcome statement summarizes the five broad ten-year objectives established by the PIP AG in 2013 (Section 1.1).

Progress towards the Outcome will be monitored using six indicators. The six indicators were defined to reflect collective progress of the different Outputs. For example, Outcome Indicator 6 will reflect achievements in L&S (Output 1), REG (Output 3), RCCE (Output 4), DEP (Output 5) and IPPP (Output 6). The rationale and details of each indicator are presented in Annex 3.

Importantly, the Outcome indicators defined for HLIP II are intentionally aligned with those used by other initiatives to improve global pandemic influenza preparedness. This will enable all partners and institutions to show and share in the progress and impact achieved to improve global pandemic influenza preparedness and response.[33]

Indicator	Baseline (2017)	Target (2023)
Outcome Indicator 1: % of Member States sharing IVPPs with GISRS according to WHO IVPP sharing guidance	N/A [a]	N/A [b, c]
Outcome Indicator 2: % of Member States reporting to FluNet	86%	90% [d]
Outcome Indicator 3: % of Member States reporting to FluID	54%	80% [d]
Outcome Indicator 4: % of Member States with burden of disease estimates that have been considered by NITAG or other decision-making bodies	N/A	50% [c]
Outcome Indicator 5: # of Member States that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products	0	37 [d]
Outcome Indicator 6: % of Member States that developed or updated a pandemic influenza preparedness plan	25%	85% [d]

[a] The WHO IVPP sharing guidance was published in 2017
[b] This is a monitoring indicator, no target established
[c] Indicator focuses on all Member States
[d] Indicator focuses on PC recipient Member States

[33] Progress on the HLIP II Outcome indicators reflects the investments made through PC Preparedness Funds, whilst also recognizing the contribution made through other Member State, regional and global initiatives.

L&S (Output 1): National influenza laboratory and surveillance systems contribute to GISRS for timely risk assessment & response measures

Effective surveillance is a cornerstone of pandemic influenza preparedness as it provides accurate and timely information that is necessary for risk management. National and global systems for laboratory and epidemiologic surveillance need to be robust in order to capture data that support risk and severity assessment, and to inform response measures including vaccine composition and other public health measures. Linkages in surveillance and risk assessment at the human-animal interface are critical to rapidly identify and respond to emerging potential threats. Surveillance systems rely on strong and sustained capacities in national laboratories for quality influenza virus detection.

L&S (Output 1) supports implementation of:

- **PIP Review Recommendation 35**, to support alignment of capacity building activities under IHR (2005)
- **2009 IHR After-Action Review Recommendations 1 & 8,** to accelerate implementation of IHR core capacities, and to develop and apply measures to assess severity, respectively.

In many countries, influenza-related surveillance systems remain weak. **This Output will support countries to improve their laboratory and surveillance system capacities, and to actively participate in GISRS.** These different actions will enhance virus and information sharing, risk and severity assessment including at the human-animal interface, and will improve response measures. Global pandemic influenza risk management, through strengthening GISRS, will reduce global vulnerabilities. The capacities strengthened through this Output will also help to detect other emerging threats, in line with an all-hazards approach. This reflects a collateral benefit for overall global preparedness, especially for emerging respiratory infectious diseases.

Context of L&S (Output 1) with other WHO Programmes

Supports countries on four IHR core capacities: Surveillance, Response, Human Resources, and Laboratory.

For PIRM, this facilitates WHO's supportive role and national responsibilities to strengthen '*Information and Knowledge Management*'.

Output Indicators

Six indicators will be used to monitor L&S progress towards the Output. The rationale and details of each indicator are presented in Annex 3.

	Indicator	Baseline (2017)	Target (2023) [a]
1.1	# of risk assessments published for influenza viruses at the human-animal interface following WHO guidance	10	70
1.2	# of Member States reporting influenza severity indicators to WHO	13	65
1.3	% of Member States that participated and were 100% correct for non-seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)	89%	95% [b]
1.4	% of Member States that participated and were 100% correct for seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)	96%	95% [c]
1.5	% of Member States that had timely sharing of influenza virus isolates or clinical specimens with WHO CCs according to WHO guidance	34%	42%
1.6	# of zoonotic influenza viruses and other influenza viruses with pandemic potential characterized by GISRS	N/A	N/A [d]

[a] Indicators focus on all Member States

[b] A yearly target has been established to sustain quality influenza virus detection capacity globally. Yearly fluctuations in the proportion of Member States participating and correctly identifying all viruses in the panel are expected. Fluctuations can be due to, but are not limited to, the shipment and logistics of panel distribution as well as panel complexity.

[c] ibid

[d] This is a monitoring indicator, no target established.

Deliverables and Corresponding Activities

Five Deliverables will guide implementation from 2018 to 2023, in order to achieve L&S (Output 1). Several different activities may contribute to L&S (Output 1); however these may vary by country according to capacities and needs.

Deliverables to Achieve L&S (Output 1)		Indicative Activities (Output 1)
Deliverable A	Risk and severity of influenza, including at the human-animal interface, are routinely assessed	• Provide technical support to national authorities to maintain and enhance influenza surveillance as well as coordination at the human-animal interface. • Carry out regular influenza risk assessment and provide guidance and tools for assessing severity of seasonal and pandemic influenza.
Deliverable B	Quality influenza virus detection capacity is sustained	• Continue the WHO EQAP for PCR. • Train NIC staff in quality management and laboratory techniques.
Deliverable C	Countries are supported to consistently report influenza data to global platforms	• Strengthen data and information sharing from national to regional and global platforms and improve data management systems.
Deliverable D	Countries are supported to share timely representative influenza samples with WHO CCs	• Facilitate influenza sample shipment to GISRS by providing necessary consumables and train NIC staff to select and ship quality samples.
Deliverable E	Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated	• Operate, advocate and train in the use of the Influenza Virus Traceability Mechanism (IVTM) in order to track in real time the movement of PIP biological materials. • Support GISRS to assess and monitor circulating influenza viruses to enable CVVs recommendations, as well as to update guidance, materials and protocols.

BOD (Output 2): Influenza disease burden estimates are used for public health decisions

A clear understanding of influenza burden (i.e. morbidity, mortality and economic) in countries, regions and across the globe is necessary to enable appropriate influenza policy-making and intervention planning including for the next pandemic. These estimates help governments and policy makers to make informed evidence-based decisions on influenza policy, understand the economic cost of influenza, generate an understanding of risk within a population, and to inform vaccine policy and programmes. While influenza burden has become better defined in recent years, there is still work to be done to derive estimates for geographic regions and by risk groups, and to ensure that this information can be used by governments and decision-makers.

BOD (Output 2) support implementation of:

- **PIP Review Recommendation 34,** to consider lessons learned from GAP
- **2009 IHR After-Action Review Recommendation 14,** to expand global influenza vaccine production capacity (including countries to immunize their high-risk populations yearly, where indicated).

This Output will focus on ensuring that national, regional and global influenza burden estimates are available, and that they are communicated in an effective manner so that they are used by decision-makers. The tools developed through this body of work will be available to all countries to enable iterative burden estimates as well as progressively build knowledge that can be used by decision-makers globally. This will support continued understanding of global influenza burden since the 2009 pandemic, develop stronger influenza and vaccination policies, assist in identifying appropriate populations to vaccinate including during the next pandemic, and help countries to prioritize influenza when and where burden is high.

Context of BOD (Output 2) with other WHO Programmes

For PIRM, this facilitates WHO's supportive role through strengthening '*policies and resource management',* by providing technical support to document disease burden and economic impact of influenza, and potentially to develop national vaccine policy.

Implements lessons learnt from GAP to continue increasing evidence-based use of influenza vaccines.

Output Indicator

One indicator will be used to monitor BOD progress towards the Output. The rationale and details for this indicator are presented in Annex 3.

	Indicator	Baseline (2017)	Target (2023) [a]
2.1	# of Member States with published disease burden estimates based on data collected since 2011	19	46

[a] Indicator focuses on all Member States

Deliverables and Corresponding Activities

Two Deliverables will guide implementation from 2018 to 2023, in order to achieve BOD (Output 2). Several different activities may contribute to BOD (Output 2); however these may vary by country according to capacities and needs.

Deliverables to Achieve BOD (Output 2)		Indicative Activities (Output 2)
Deliverable A	Representative national, regional and global disease burden estimates are available	• Provide improved and updated national, regional and global estimates of influenza burden (including additional disease burden end-points and estimates for sub-groups), through: 1) gathering relevant data; 2) providing training and mentoring; and 3) supporting the development and application of tools and guidance for estimating burden of disease.
Deliverable B	Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making	• Provide guidance and supportive tools to help increase usage of influenza data for evidence-based decision making, including advocacy to policy makers. • Generate policy relevant information from influenza burden estimates through different stakeholder consultations, meetings and missions. • Conduct a global assessment of influenza and vaccination policy changes resulting from burden findings communicated to expert bodies (in HLIP II year 6).

REG (Output 3): Timely access to quality-assured pandemic influenza products is supported

National requirements and capacities for regulatory oversight of medical products can have a significant impact on the timely deployment, use and administration of pandemic influenza products including vaccines. Early engagement with National Regulatory Authorities (NRAs) to build capacities and develop regulatory pathways for pandemic product approval in the time of an emergency is an essential component of preparedness.

REG (Output 3) supports implementation of:

- **PIP Review Recommendation 34 and 35,** to consider lessons learned from GAP and to support alignment of capacity building activities under IHR (2005)
- **2009 IHR After-Action Review Recommendation 11,** to encourage advance agreement for vaccine distribution and delivery
- **SDG 3.8:** 'Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all'

During the interpandemic phase, WHO promotes regulatory harmonization and reliance, and provides support to strengthen existing regulatory systems. NRAs should review the options[34] available to them during a pandemic and choose the appropriate procedures that ensure timely access to the required products. The emergency procedures should include plans for information management, as well as plans for effective communication and cooperation between different units of the NRA and relevant stakeholders such as public health authorities. Plans for post-marketing surveillance to monitor the safety and efficacy of pandemic influenza products must also be developed. Plans should be linked to national influenza pandemic preparedness plans as well as national deployment plans.

Output 3 will improve regulatory systems and processes that facilitate timely access to pandemic influenza products including antivirals, diagnostics and vaccines. This work encompasses building regulatory capacities at national and regional levels, as well as facilitating countries' adoption of pathways that accelerate approval. It also supports countries with weak or no regulatory capacity to implement the Institutional Development Plans (IDPs) that were established during HLIP I.

[34] http://www.who.int/biologicals/expert_committee/PIP_Non-producer_guide_BS_final-working_version-19102016-clean.pdf

Context of REG (Output 3) with other WHO Programmes

Supports countries on improving one IHR Core Capacity, Preparedness.

For PIRM, this facilitates national responsibilities for '*Health and related services'* through considering policies and needs of an in-country approach to antivirals and vaccinations.

Implements lessons learnt from GAP to continue strengthening expertise in National Regulatory Authorities.

Output Indicator

One indicator will be used to monitor REG progress towards the Output. The rationale and details for this indicator are presented in Annex 3.

	Indicator	Baseline (2017)	Target (2023) [a]
3.1	# of Member States which strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and IDP implementation	1	16

[a] Indicator focuses on PC recipient Member States

Deliverables and Corresponding Activities

Two Deliverables will guide implementation from 2018 to 2023, in order to achieve REG (Output 3). Several different activities may contribute to REG (Output 3); however this will vary by country according to capacities and needs.

Deliverables to Achieve REG (Output 3)		Indicative Activities (Output 3)
Deliverable A	National regulatory capacity for pandemic influenza products is strengthened	• Benchmark capacity, identify gaps, and provide technical support in line with IDPs to strengthen capacity of NRAs in the 16 priority countries to assure the quality, safety and efficacy of pandemic influenza vaccines, antivirals, and diagnostics.
Deliverable B	Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted	• Conduct global learning workshops and provide technical assistance for the implementation of the WHO *Guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine producing countries*. • Promote national, regional and global harmonization of regulatory capacity benchmarking tools and regulatory systems strengthening policies. • Promote the adoption of facilitated regulatory pathways for timely access to assured quality pandemic influenza products, including vaccines, antivirals, and diagnostics.

RCCE (Output 4): Tools and guidance are available for countries to enhance influenza risk communication and community engagement

Effective risk communication is instrumental during a pandemic. In an emergency, information and misinformation spread rapidly and the latter can hinder effective outbreak response. Populations and communities may have cultural or social practices that increase their risk to pandemic influenza, for example through unique beliefs about health and health-practices that lead to misconceptions (e.g. lack of social distancing or rejection of vaccines). Risk communication messages should be channeled effectively to reach those at-risk, while understanding social and cultural beliefs that may contribute to risky behaviours.

RCCE (Output 4) supports implementation of:

- **PIP Review Recommendation 35,** to support alignment of capacity building activities under IHR (2005)
- **2009 IHR After-Action Review Recommendations 9 and 10,** to streamline management of WHO guidance, and to develop and implement a strategic and organization-wide communications policy.

Providing effective risk communications also requires that countries, organizations, and front-line responders are equipped with updated and easy to use tools, information and resources. Integrating RCCE into national pandemic preparedness plans will prepare countries for disseminating well-planned risk communication messages in a pandemic. Furthermore, during a pandemic, a country's risk communication capacities are likely to be overwhelmed and may need additional surge support for RCCE.

The scope of risk communication capacity building under HLIP II increases the focus on community engagement and readiness for seasonal influenza as a proxy for pandemic influenza preparedness. This will be achieved by systematically integrating social and cultural considerations into the planning and implementation of RCCE and decreasing dependence on generic, one-way messages that have been the hallmark of communication in the past. At the same time, capacities of countries and agencies that communicate risk more broadly will continue to be strengthened and surge capacity sustained. **Output 4 will expand to include social and behavioral science-based risk reduction strategies (including to address vaccine hesitancy), while placing a direct focus on exercising RCCE capacities for seasonal influenza to improve preparedness for pandemic influenza.**

Context of RCCE (Output 4) with other WHO Programmes

Supports countries to improve two IHR Core Capacities: Risk Communication and Human Resources.

For PIRM, this facilitates WHO's supportive role and national responsibilities in enhancing communications ('*Information and knowledge management*'), as well as for planning and action that is centred around the local health workforce and community (*'Community ERMH capacities'*).

Addresses recommendation from the closing of GAP to address the root causes of vaccine hesitancy.

Output Indicator

Two indicators will be used to monitor RCCE progress towards the Output. The rationale and details of each indicator are presented in Annex 3.

	Indicator	Baseline (2017)	Target (2023) [a]
4.1	# of users from target audiences who completed learning modules on influenza and related RCCE content on the OpenWHO platform	2,430	40,000
4.2	# of Member States that utilized RCCE support for influenza preparedness or response	0	160

[a] Indicators focus on all Member States

Deliverables and Corresponding Activities

Two Deliverables will guide implementation from 2018 to 2023, in order to achieve RCCE (Output 4). Several different activities may contribute to RCCE (Output 4); however this will vary according to capacities and needs.

Deliverables to Achieve RCCE (Output 4)		Indicative Activities (Output 4)
Deliverable A	Countries and front-line responders have access to resources for influenza risk communication, community engagement and social science-based interventions	• Develop guidance, tools, exercise materials, and online learning for strengthening of national and local capacities for risk communication, community engagement, and other social science-based interventions for seasonal, zoonotic, and pandemic influenza. • Build global partnerships and networks for alignment and coordination of approaches with animal health and other sectors, with community-level development actors and human health sector stakeholders.
Deliverable B	Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement	• Provide hands-on support for developing risk communication components of national seasonal and pandemic influenza preparedness plans and response. • Strengthen networks for relevant RCCE for country support and surge capacity (e.g. social scientists, anthropologists, vaccine communication experts etc.).

DEP (Output 5): Plans for effective and efficient deployment of pandemic supplies are optimized

Advance planning for the deployment of vaccines, antivirals and other pandemic influenza products allows for countries and emergency responders to act efficiently. Many pandemic products are complex to deploy and a global mechanism is needed to ensure that requests and allocations are equitably coordinated and managed, especially in situations of scarce supply. At national level, detailed operational plans are critical in ensuring that products are appropriately distributed to points of care. This includes the use of micro-planning, supply chain technologies, and planning for surge capacity in distribution structures and systems.

DEP (Output 5) supports implementation of:

- **PIP Review Recommendations 34 and 35,** to consider lessons learned from GAP and to support alignment of capacity building activities under IHR (2005)
- **2009 IHR After-Action Review Recommendations 11 and 14,** to encourage advance agreements for vaccine distribution and delivery, and to increase global vaccine production and yearly vaccination

PIP Deploy was developed as a simulation application to improve deployment of pandemic products. It is an online application that engages multiple stakeholders in deployment operations (i.e. manufacturers, country officials, and support agencies). In the inter-pandemic phase, exercises using PIP Deploy prepare stakeholders for various deployment scenarios, to improve capacities to coordinate deployment across their systems, and tests key interactions to reduce bottlenecks. Future development of PIP Deploy will include interoperability with existing deployment systems to use in pandemic responses.

In addition to global deployment systems, countries also need to routinely assess their seasonal influenza vaccine procurement, manufacturing (where relevant) and delivery systems to sustain access to products, including during a pandemic. HLIP II will support countries to assess the sustainability of their vaccine procurement/production practices to help identify and address challenges in policy and health care environments. These steps during the inter-pandemic phase will improve pandemic vaccine preparedness.

This Output will support the development and periodic review of global and national plans for pandemic product deployment, will work with global stakeholders to improve deployment systems, and will assist countries in developing and sustaining vaccine procurement and production practices.

Context of DEP (Output 5) with other WHO Programmes

Supports countries on one IHR Core Capacity, Preparedness.

For PIRM, this facilitates WHO's supporting role and national responsibilities for *'Health infrastructure and logistics'*, by establishing procedures that ensure rapid procurement and deployment and public health supplies.

Applies lessons learnt from GAP to provide technical assistance to countries on sustainable policies and processes for procurement and production of vaccine.

Output Indicators

Two indicators will be used to monitor DEP progress towards the Output. The rationale and details of each indicator are presented in Annex 3.

Indicator	Baseline (2017)	Target (2023) [a]
5.1 Annual simulation exercise conducted to test global deployment of pandemic influenza vaccines and other products	1	7
5.2 # of Member States that have undergone a national analysis of influenza vaccine procurement or production sustainability	6	12

[a] Indicators focus on all Member States

Deliverables and Corresponding Activities

Three Deliverables will guide implementation from 2018 to 2023, in order to achieve DEP (Output 5). Several different activities may contribute to DEP (Output 5); however these may vary according to capacities and needs.

Deliverables to Achieve DEP (Output 5)		Indicative Activities (Output 5)
Deliverable A	A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners	• Further develop and globally exercise PIP Deploy to address gaps in planning, coordination and allocation of pandemic influenza products so that a common approach to global deployment of pandemic supplies is continuously refined. • Identify and address typical cold chain capacities and bottlenecks at global, regional hubs, and national levels through desk reviews, surveys or interviews.
Deliverable B	National deployment planning process is revised and updated	• Provide technical guidance and tools for countries to develop or update their national pandemic product deployment plans.
Deliverable C	Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries	• Provide technical assistance and policy guidance to countries on sustainable seasonal influenza vaccine procurement and production, including delivery systems. • Coordinate engagement with stakeholders, countries, industry and civil society on influenza vaccine production issues, including monitoring global production capacity and pre-pandemic vaccine development.

IPPP (Output 6): National pandemic influenza preparedness and response plans are updated in the context of all-hazards preparedness and global health security

The impact of pandemic influenza on individuals and societies can be reduced by being well prepared. This means having comprehensive plans that are multi-sectoral and that engage the whole-of-society.

IPPP (Output 6) supports implementation of:

- **PIP Review Recommendation 35,** to support alignment of capacity building activities under IHR (2005)

Current WHO guidance on pandemic influenza risk management encourages Member States to develop flexible plans that are based on national risk assessment, and that uncouple country-level risk management decisions from WHO's global risk assessment of pandemic phases.[35] Good-practices[36] and checklists[37] are available to guide countries in pandemic influenza risk management including for developing or updating plans.

While many countries have plans in place, recent events (e.g. 2009 influenza pandemic, MERS and Ebola epidemics), have emphasized the need for regular updating and testing of plans to further strengthen operational readiness. **This Output will support countries to further develop their pandemic influenza preparedness plans, and will help bring together progress made under the other HLIP II Outputs; especially L&S, REG, RCCE and DEP.** This Output will catalyze the political commitment, coordination, risk assessment, infrastructure, financing, human resources, equipment, exercises and knowledge needed for countries to be prepared.[38]

Context of IPPP (Output 6) with other WHO Programmes

Supports countries on one IHR Core Capacity, Preparedness.

For PIRM, this facilitates WHO's supportive role and national responsibilities to have comprehensive plans, especially *'Planning and coordination'*.

[35] http://www.who.int/influenza/preparedness/pandemic/influenza_risk_management_update2017/en/
[36] http://www.euro.who.int/__data/assets/pdf_file/0017/128060/e94534.pdf
[37] This checklist is in the process of being revised, and an updated version may be available. A version from 2005 is available at: http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_4/en/
[38] WHO Strategic Framework for Emergency Preparedness. WHO, 2017 http://apps.who.int/iris/bitstream/10665/254883/1/9789241511827-eng.pdf?ua=1

Output Indicator

One indicator will be used to monitor IPPP progress towards the Output. The rationale and details of the indicator are presented in Annex 3.

	Indicator	Baseline (2017)	Target (2023) [a]
6.1	% of Member States that exercised their pandemic influenza preparedness plan including across sectors	5%	70%

[a] Indicator focuses on PC recipient Member States

Deliverable and Corresponding Activities

One Deliverable will guide implementation from 2018 to 2023, in order to achieve IPPP (Output 6). Several different activities may contribute to IPPP (Output 6); however these may vary by country according to capacities and needs.

Deliverables to Achieve IPPP (Output 6)		Indicative Activities (Output 6)
Deliverable A	Countries are supported to develop, test and update their influenza pandemic preparedness plan	• Provide countries with guidance and technical assistance to develop or revise national preparedness plans for early detection of, and response to, pandemic influenza as well as for integrating influenza-specific plans into broader all-hazards preparedness. • Provide countries with methods and tools to assess and modify recommended preparedness measures and interventions in consultation with appropriate partners including those outside the health-care sector, on the acceptability, effectiveness and feasibility of interventions. • Enable countries to develop, exercise and periodically revise national and subnational pandemic risk management plans in close collaboration with all relevant public and private partners.

5. Selecting PC Recipient Countries

PC funds are used to improve preparedness through global, regional and country-level activities. Some countries will be supported through (a) biennial country-specific work plans, and others through (b) activities implemented by ROs and HQ. Funds to implement the biennial work plans are allocated yearly based on progress, continuing needs and availability of funds.

This country selection process supports the implementation of:

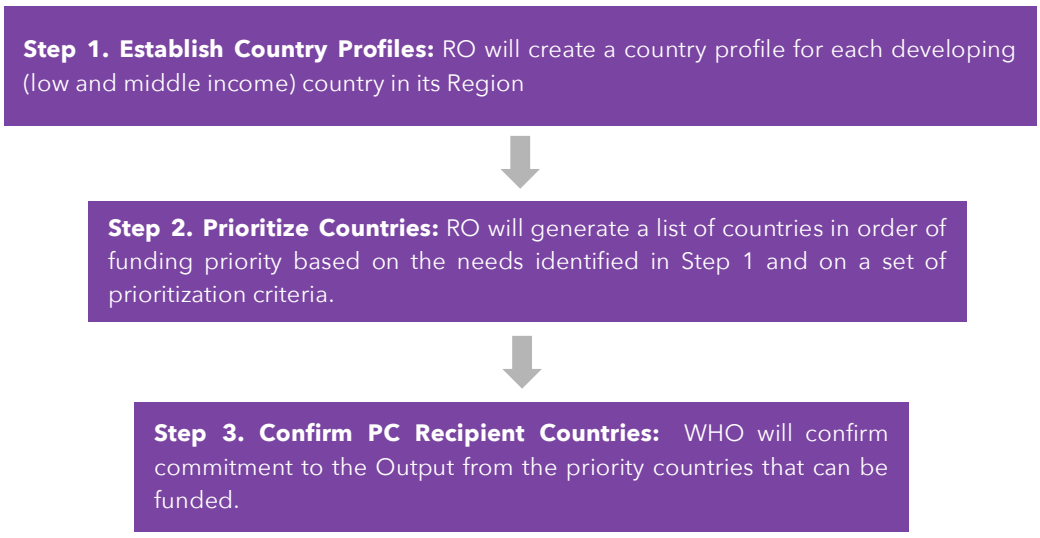
- **PIP Review Recommendation 2c,** to revise the country selection criteria.

This section describes the approach for selecting countries that will have country-specific work plans. Countries will receive funds for the activities and Deliverables that are defined within approved plans. Countries identified for support will be consulted to confirm their agreement and commitment to the activities. The list of countries funded for each Output will be published on the PIP website and in annual reports. The list will be updated every two years to reflect any changes in country recipients. Changes will be based on work plan implementation and indicator performance.

5.1 Selection Criteria for L&S (Output 1) and IPPP (Output 6)

For L&S (Output 1) and IPPP (Output 6), a three-step process will be used to select countries for PC funding (Figure 9). The first step establishes a profile for all developing countries in each region based on pre-defined criteria described further below. This provides an understanding of the capacities, needs and maturity of each country relative to the Output. Using the set of feasibility and operationalization questions described further below, the second step prioritizes countries for funding. The third step confirms PC-fund recipient countries after ensuring that countries are committed to implementing PC funded activities.

Figure 9: HLIP II Process for Selecting Countries for L&S and IPPP PC Preparedness Funding



For L&S (Output 1) and IPPP (Output 6), the criteria for each of the three steps are elaborated further below.

5.1.1 L&S (Output 1)

5.1.1.1 Step 1: Country Profile Criteria

In each Region, the RO (in coordination with CO) will establish a country profile for each developing country according to the following criteria:

1. Gross nation income (GNI) per capita.
2. Population size.
3. Presence of ILI or Ambulatory Respiratory Disease Surveillance.
4. Presence of SARI Surveillance.
5. Presence of WHO recognized NIC.
6. Performance on five laboratory and surveillance system indicators:
    - Did the country participate and score 100% for non-seasonal influenza viruses in the WHO PCR External Quality Assessment Programme (EQAP) last year?
    - Did the country participate and score 100% for seasonal influenza viruses in the WHO PCR External Quality Assessment Programme (EQAP) last year?
    - Did the country report to FluID in the last year?
    - Did the country report to FluNet in the last year?
    - Did the country share influenza virus isolates or clinical specimens with WHO CCs in the last year?
7. Inclusion of the country in the WHE priority country list.[39]

5.1.1.2 Step 2: Country Prioritization Criteria

In each region, the RO will prioritize the countries according to the answers to the following questions, in consultation with WHO CCs and relevant units at HQ. The decision on the order of priority among countries will be made by the RO.

A. From the profile item (6) above, can performance be improved?

B. If the country received PC funds during HLIP I (2013–2017), will HLIP II funding enable it to meet the Output?

C. Are funds from other sources available and sufficient to address the Output in this country?

[39] WHE priority countries are those (a) with ongoing Health cluster (or equivalent) emergency operations (b) that are highly vulnerable to all hazards (defined using the INFORM dimensions, vulnerability and coping capacity), or (c) targeted for enhanced surveillance and preparedness based on regional and country prioritization.

D. Are there barriers for WHO to support influenza activities in this country? Consider operational and financial barriers including whether the country is in a Complex Grade 3 Emergency or whether previous PIP PC or influenza-related funds from WHO could not be implemented.

E. Will PIP support to this country advance sub-regional, regional or global pandemic preparedness? Consider the country's population size and if the country's influenza trends represent those for geographically proximate countries.

5.1.1.3 Step 3: Confirming PC Recipients

HQ will inform each RO about the PC funds available. RO will then determine the number of countries that can be funded and will consult with each country to confirm their interest and commitment to implement PC funded activities for this Output.

5.1.2 IPPP (Output 6)

5.1.2.1 Step 1: Country Profile Criteria

In each region, the RO (in coordination with CO) will establish a country profile for each developing country according to the following criteria:

1. Existence of a pandemic influenza preparedness plan and date of plan.
2. If plan is available, does the plan uncouple national preparedness and response actions from global phases (as recommended in PIRM guidance)?
3. Country population size.
4. UN INFORM Disaster Vulnerability score.
5. UN INFORM Disaster Lack of Coping Capacity score.
6. Inclusion of the country in the WHE priority country list.[40]

5.1.2.2 Step 2: Country Prioritization Criteria

In each region, the RO will prioritize the countries according to the answers to the following questions, in consultation with relevant units at HQ. The decision on the order of priority countries will be made by the RO.

A. From the country profile items (1 and 2), does the country have an up-to-date plan?

B. Based on the UN INFORM scores and WHE prioritization, does the country's status make it particularly vulnerable in the case of an influenza pandemic?

C. Are funds from other sources available and sufficient to address the Output in this country?

D. Are there barriers for WHO to support influenza activities in this country? Consider operational and financial barriers including whether the country is in a Complex

[40] WHE priority countries are those (a) with ongoing Health cluster (or equivalent) emergency operations (b) that are highly vulnerable to all hazards (defined using the INFORM dimensions, vulnerability and coping capacity), or (c) targeted for enhanced surveillance and preparedness based on regional and country prioritization.

Grade 3 Emergency or whether previous PIP PC or influenza-related funds from WHO could not be implemented.

E. If the country has, or is in the process of developing, a national IHR core capacity development and maintenance plan (also known as National Action Plan for Health Security), would PC support for this Output link to their capacity-building priorities in IHR Core Capacity 5 (Preparedness)?

5.1.2.3 Step 3: PC Recipient Countries

HQ will inform each RO about the PC funds available. RO will then determine the number of countries that can be funded and will consult with each country to confirm its interest and commitment to implementing PC funded activities for this Output.

5.2 Selection Process for Remaining Outputs

For the following areas, which are largely implemented through global or regional activities, the methods for selecting countries for funding are described below.

5.2.1 BOD (Output 2)

For selecting countries, the following process will be applied:

- Technical requests from countries or from Surveillance/Research Groups will be submitted to relevant units in HQ and to the appropriate RO.
- Proposals will be jointly evaluated by relevant units in HQ and RO for technical and feasibility criteria:
    - Do the methods in the proposal enable:
        - BOD calculation in a way that will add to the understanding of influenza disease burden in that country, region or globally (Deliverable A)? Or,
        - Communication of findings to expert bodies in a format that promotes evidence-based decision-making (Deliverable B)?
    - Is the proposal feasible and likely to be completed?
    - Is the funding amount requested reasonable and can it be supported by PC funds?
    - Is funding available and sufficient for this proposal from other national or international sources?
    - Is the timeline for the activity in line with the HLIP II Output?
- Will PC funding support increase regional representation so that data are available from various WHO regions?

5.2.2 REG (Output 3)

Through global and regional initiatives, WHO will facilitate all countries to adopt regulatory pathways that accelerate approval for use of pandemic influenza products. In addition, due

to the length of time needed to build regulatory capacity, more intensive capacity building will be implemented in the 16 countries previously selected under REG in HLIP I. This includes strengthening capacity in regulatory systems, market authorization and pharmacovigilance. The criteria applied to prioritize countries during HLIP I are available for review.[41] No new countries will be added in HLIP II.

5.2.3 RCCE (Output 4)

For selecting countries, the following process will be applied:

- Country requests for technical assistance will be submitted to relevant units at HQ and RO.
- Proposals will be jointly evaluated by relevant units at HQ and RO for technical and feasibility criteria:
    - Is the country's risk communication capacity currently assessed to be low?
    - Will the assistance facilitate countries to improve influenza-specific risk communication, community engagement or social science based interventions?
    - Is the funding amount requested reasonable and can it be supported by PIP PC?
    - Is funding available for this proposal from other national or international sources?
    - Is the timeline for the activity in line with the HLIP II Output?
- Will support to this country have further benefit, such as improving global or regional guidance, tools or interactive resources that would then be available to other countries?

5.2.4 DEP (Output 5)

This area of work will be implemented at global level. Countries will be supported to improve their national deployment plans and capacities through IPPP (Output 6). Country requests for technical assistance will be supported by relevant units at RO and HQ.

[41] See page 10 of HLIP I (http://www.who.int/entity/influenza/pip/pip_pcimpplan_update_31jan2015.pdf?ua=1)

Part 3: Management

6. Project Management

6.1 Receipt and Management of Funds

PC Preparedness Funds will be used for the purposes indicated in HLIP II (Annex 2). Funds will be administered in accordance with the financial and administrative rules, regulations, and procedures of WHO. Income and expenditure recorded in respect of contributions received will be identified and kept separately by WHO in relevant accounts.

6.2 Project Management Cycle

As implementation of PC Preparedness Funds is executed across WHO HQ, regions and countries, effective project management is key to successful implementation (Figure 10). Four key processes are described in detail in the sections below.

Figure 10: Project Management Cycle for Implementation of PC Preparedness Funds

6.2.1 Planning

The project management cycle begins with detailed biennial operational planning. This process has four sub-stages, as described below.

6.2.1.1 Work Plan Development

Work plans are developed by COs, ROs, and HQ. The HLIP II Results Hierarchy (Figure 8), including Outcome and Output indicator targets, guides how work plan content is developed to ensure that proposed activities result in improved indicator results. Budgets are developed for each Output using a project-based approach, based on Deliverables and as identified from the needs assessed. Financing of work plans is dependent on the availability of funds.

6.2.1.2 *Work Plan Review*

Work plans are reviewed in two steps, first **internally** and second by an independent technical review group, namely the **PC Independent Technical Expert Mechanism (PCITEM)**.

> **Internal review:** Work plans are reviewed for programmatic and financial soundness by the PIP Secretariat and by relevant technical units in ROs and HQ. This includes: assessing the appropriateness of work plans to contribute to the Outcome and Outputs; ensuring that there will be progress against indicators and Deliverables; and preventing duplication of activities. Teleconferences are held between the different levels of WHO to discuss and ensure work plan coherence.
>
> **External review (PCITEM):** This is an independent review body of eight experts that will review activities for scientific and technical suitability against the Deliverables and Outputs. PCITEM will meet in person once before the start of the work plan biennium. Additional meetings will be held as needed. This group will provide inputs to WHO technical teams to improve and finalize the work plans. PCITEM will then provide its advice to the Director of Infectious Hazard Management (IHM).

The above reviews aim to ensure that activities are focused on achieving results (indicator targets), that expected results are achievable within timelines, and that funds are used efficiently and appropriately. Work plans will be adjusted based on the comments from the reviews. This Outcome and Output indicator-driven approach to work plan development maintains the focus of implementation on improving pandemic influenza preparedness according to the HLIP II Results Hierarchy (Figure 8).

6.2.1.3 *Work Plan Approval*

Once finalized, work plans are submitted for approval to the Executive Director of WHO Health Emergencies Programme (WHE), through the Director of the Department of IHM.

6.2.1.4 *Fund Disbursement*

Upon approval from the Executive Director, WHE, funds are disbursed and recorded in accordance with approved plans and WHO financial rules and regulations.

6.2.2 Implementation

Implementation is conducted at a global, regional and country level to achieve the Deliverables as described earlier in this report (Section 4), and is a collaborative exercise between Ministries of Health, GISRS, WHO COs, ROs and HQ. Further explanation of the roles and responsibilities to implement are described in Section 7.

6.2.3 Monitoring and Evaluation

Monitoring and evaluation support sound programme management and achievement of results.[42] There will be routine financial and work plan monitoring in addition to evaluation processes to capture achievements, and to alert managers to implementation issues. The various processes described below and summarized in

[42] http://apps.who.int/iris/bitstream/10665/96311/1/9789241548687_eng.pdf?ua=1

Table 6 will be forward-looking and aim to reduce risks in implementation, enable efficient and effective implementation of available funds, and promote good relations with stakeholders due to clear tracking of progress towards Deliverables.

Table 6: Summary of Monitoring and Evaluation Stages

	Frequency	Description
Financial Monitoring	Monthly	• Financial reports on all implementation from the PIP Secretariat.
	Monthly	• Financial monitoring by implementers at COs, ROs and HQ.
	6-monthly	• Compliance checks by PIP Secretariat.
	Subject to WHA request	• External auditor-specific examination.[43]
Work Plan Monitoring	Monthly	• Monthly calls between HQ, ROs and PIP Secretariat.
	6-monthly	• Milestone monitoring on Deliverables (Annex 3).
	Annual	• Outcome and Output indicator monitoring (Annex 3).
		• Yearly global planning meeting between PIP Secretariat, and technical units in HQ and ROs.
Evaluation	Mid-HLIP II (2020)	• Midterm review to assess progress and consider changes in HLIP II (Annex 3).
	End-HLIP II (2023)	• End of HLIP II evaluation and impact assessment.

6.2.3.1 Financial Monitoring

WHO has rules regarding expenditure of funds against activity work plans. Compliance is integral to WHO's financial processes. WHO's Internal Control Framework drives compliance with WHO financial rules. Managers at HQ departments, RO divisions and COs are responsible for monitoring aspects of implementation including implementation of approved work plans (staff and activity), financing, and risks associated with budget management.[44] This is done using the financial tracking system (GSM) and other tools (e.g. Business Intelligence, which is an internal WHO system).

Additional monitoring and oversight is provided by the PIP Secretariat. Each month, the PIP Secretariat provides all implementing HQ and RO units as well as the IHM Director with a financial implementation update based on data in GSM. The implementation rate (expenditures and encumbrances) is compared to funds distributed for work plans. Analyses are provided to highlight overall implementation rates, as well as by Output and region. This monthly analysis supplements additional monitoring at HQ, ROs and COs to support short and long-term planning, trouble-shooting and risk management in the case that implementation rates are low. It also facilitates reporting to senior management and other stakeholders on progress against work plan targets.

[43] Section 14.5, WHO Basic Documents, 48th Ed.
[44] Consistent with PRP.SOP.II.003 (internal Budget Monitoring document)

Twice yearly, the PIP Secretariat conducts compliance checks of all work plans to ensure that funds distributed and budgeted against Deliverables are done according to approved work plans, and that fund expenditure is compliant with approved work plans.

Based on findings from the above processes, corrective actions are taken; significant course corrections, if necessary, are escalated to senior management for approval and recorded under change control procedures.

In addition to the above routine financial monitoring processes, additional measures such as an external audit[45] may be undertaken to confirm that the WHO financial regulations have been appropriately applied in the use of the PC Preparedness Funds, and that the reported financial information is accurate and reliable.

6.2.3.2 Work Plan Monitoring

To facilitate work plan monitoring and to maintain a results-based focus, Outcome and Output level indicators and Deliverable level milestones are used to monitor progress (Annex 3). Responsible Officers are assigned for work plans at HQ, ROs and COs to oversee technical implementation and monitoring. Their monitoring functions include working with the PIP Secretariat to:

- Identify and take corrective actions in response to problems, delays and deviations
- Re-programme (re-schedule, revise or re-prioritize products and activities)
- Re-allocate and re-focus financial and human resources for efficient implementation

Each month, the PIP Secretariat holds meetings/teleconferences with Responsible Officers at HQ and ROs. This provides a forum for updates on progress, to discuss operational and administrative information, and to identify and trouble-shoot implementation issues. Records of the meetings are shared with implementing officers and are also used to report progress to senior management.

The PIP Secretariat participates in regional workshops involving PC recipient countries to discuss implementation and to ensure alignment of plans with the Results Hierarchy. To monitor progress on an *ad hoc* basis, the PIP Secretariat also leverages opportunities to engage with beneficiaries during activities conducted by technical units.

Yearly, the PIP Secretariat holds a global planning meeting for HQ and RO Responsible Officers to review technical and financial progress and discuss plans for future work plans.

6.2.3.3 Evaluation

A midterm review will be conducted to assess progress, consider changes in the landscape for global pandemic influenza preparedness and discuss potential 'mid-course adjustments' needed for future HLIP II implementation (Annex 3). These will be discussed with various stakeholders and beneficiaries before confirming changes to the HLIP II design.

A final HLIP II evaluation and impact assessment will be conducted following the six-year

[45] Subject to Health Assembly request for external auditor specific examination (Section 14.5, WHO Basic Documents, 48th Ed.)

implementation period (Annex 3). This will reflect on the five objectives set by the AG in 2013 (Section 1.1) for improving pandemic influenza preparedness.

6.2.4 Reporting

Regular technical and financial reports will provide updates on implementation progress and results (

Table 7 and Annex 3).

Table 7: Reporting Process in the PC Implementation Cycle

Reporting Frequency	Product	Description
Bi-Monthly	Newsletter	• Presents select country, regional and global achievement(s) in PIP PC Implementation. • Reported in the PIP E-Newsletter as stories from the field.
6-Monthly	Presentation to PIP AG and other stakeholders	• Provides updates on the implementation status of all Deliverables through milestones and financial implementation rate for all Outputs. • Reported to the AG and other stakeholders every six months at semi-annual meetings
Annual	Annual report	• Presents progress on the Outcome and Output indicators. • Links programmatic and financial implementation through reporting on expenditures at Deliverable level. A certified financial statement is included. • Reported publicly through the PIP PC Annual Report.
Biennial	Report to WHA	• In accordance with the Framework, the Director-General will inform the World Health Assembly (WHA), through the Executive Board, on the status of and progress on implementation of the PIP Framework, including the use of PC.[46]

Financial reporting will also provide breakdown by staff and activities, and implementation rates by Output. Statements of total PC Preparedness Funds received, committed, and remaining (balances) will be provided annually.

In addition to formal reporting measures, there may also be *ad hoc* reporting when required through both written statements and presentations to keep stakeholders informed and to provide the basis for strategic assessment and decision-making.

[46] See PIP Framework Section 7.4.1(iv)

6.2.5 Increased Visibility

As recommended in the PIP Review 2016, there is a need to increase the visibility of PIP Framework implementation and make clear its achievements. In addition to existing reporting mechanisms, the PIP Secretariat will regularly search for *ad hoc* or new reporting mechanisms and forums to share progress and achievements from HLIP II implementation. Teams implementing HLIP II work plans will also be encouraged to acknowledge use of PC Preparedness Funds in their activities, presentations, and reports.

6.2.6 Risk Management

A number of high-level risks were identified in different areas of planning, implementation, management and accountability/reporting. An assessment of their potential effects on HLIP II implementation and mitigation measures are presented (Annex 4).

7. Project Implementation Roles and Responsibilities

Implementation is a combined and coordinated effort of implementing units at WHO HQ, ROs and COs, on the one hand, and Ministry of Health (MOH), and GISRS institutions (notably, NICs and WHO CCs), on the other. Each has a critical role that guides the success of PC Implementation. While teams at WHO HQ, ROs and COs are directly involved in planning and directing implementation, external stakeholders also play critical roles.

MOH and NICs are directly involved in implementing funds in accordance with agreed-upon work plans in order to improve national pandemic influenza preparedness capacities. Additionally, WHO CCs provide technical support and advice to the WHO on laboratory and surveillance, and may be called upon for technical assistance for implementation, training, and guidance on other relevant HLIP II activities. The roles of WHO HQ (i.e. technical units and the PIP Secretariat), ROs and COs are outlined in Section 7.1 in further detail.

7.1 Roles and Responsibilities of Internal WHO Implementers

All three levels of the WHO are directly involved in the day-to-day implementation process, but each with unique roles (Table 8). The PIP Secretariat leads planning, monitoring and reporting processes, and manages the distribution of funds to implementing units. Technical teams at HQ, ROs and COs also support monitoring and reporting processes, and are responsible for developing their respective work plans. Each technical RO and HQ team has Responsible Officers who are accountable for the management of resources and delivery of results and who must ensure that funds are spent in accordance with work plans. In-country, COs are responsible for implementing planned activities that improve national pandemic influenza preparedness.

Teams at WHO HQ work in collaboration with ROs to ensure that implementation addresses regional needs and promotes increased preparedness. ROs are responsible for liaising and collaborating with COs to reflect country-level needs.

Table 8: WHO implementing unit Roles and Responsibilities at the three levels of the organization

	Country Offices (COs)	Regional Offices (ROs)	Headquarters (HQ) Technical Units	PIP Secretariat
Planning	• Develop country work plans	• Review country work plans • Develop RO work plans • Collaborate with HQ to ensure alignment of country, regional and global work plans	• Develop global work plans • Collaborate with ROs to ensure alignment of regional and global work plans	• Provide work plan templates • Provide programmatic and budget guidance to RO and HQ units • Review all CO, RO and HQ work plans • Prepare all reviewed work plans for WHE Executive Director approval, through IHM Director • Engage with PIP AG, PCITEM and external stakeholders as appropriate throughout planning process
Implementation	• Implement activities at country level	• Implement activities at regional level • Support and coordinate CO implementation as necessary	• Implement activities at global level • Support RO implementation as necessary	
Monitoring	• Monitor and record progress on activities (milestones), indicator data and financial implementation at country level • Analyse country level data and progress and request work plan changes to RO if necessary	• Monitor and record progress on activities (milestones), indicator data and financial implementation across the region • Analyse regional level data and request work plan changes to PIP Secretariat if necessary	• Monitor and record progress on activities (milestones), indicator data and financial implementation at global level • Analyse global level data and request work plan changes to PIP Secretariat if necessary	• Provide monitoring and reporting templates • Monitor and record progress on activities (milestones) and indicator data • Request changes to IHM Director if necessary • Update baseline work plans as necessary
Reporting	• Monthly, semi-annual and annual progress reports to RO	• Monthly, semi-annual and annual progress reports to PIP Secretariat	• Monthly, semi-annual and annual progress reports to PIP Secretariat	• Biennial reports to Member States • Semi-annual and annual reports to PIP AG and stakeholders • PIP Newsletter

7.2 Accountability

There are several mechanisms in place to ensure that implementers are held accountable and remain committed to PC Implementation as outlined in this Plan. Within WHO, regular monitoring and reporting processes (Sections 6.2.3 and 6.2.4), and consistent consultation with stakeholders ensure accountability of all three WHO levels.

There are additional measures to hold external stakeholders accountable. As a part of the country selection process, the MOH of any Member State receiving PC Preparedness Fund support will be requested to confirm willingness to work on the intended Outputs and agree to report on progress measures in reports made publicly available. All PIP PC recipient countries will be reminded of the expectation to share IVPP in accordance with the PIP Framework.[47] The biennial review of PC recipient countries is also a mechanism to review country commitment and implementation progress.

Project governance and oversight is provided by WHO senior management. This acts as a final measure of ensuring the PIP PC Implementation occurs as outlined in this Plan, and where necessary corrective actions can be taken.

[47] See PIP Framework Section 1, Principle 3.

Annexes

Annex 1: HLIP II Development Processes

HLIP II was developed by WHO through intensive collaboration among the three levels of the Organization, as well as through broad and intensive consultations (e.g. meetings, electronic consultations for input and feedback) with a broad range of stakeholders and key partners as shown below.

HLIP II Consultation Process: September 2016 to November 2017					
HLIP II Product	**PIP AG**	**GISRS**	**Industry**	**CSO**	**Other [c]**
Gaps and Needs Analysis	√	√[a]	√	√	√
PIP AG discusses 1st draft Results Hierarchy	√	√[b]	√	√	
PIP PC Implementation (2013-2016) Independent external evaluation		√[a]	√		
HLIP II conceptual framework	√	√[b]	√	√	√
1st Draft HLIP II sent for comment	√	√[a]	√	√	√
2nd Draft HLIP II sent for comment	√	√[a]	√	√	√
Near-final HLIP II draft sent for review	√	√[a]	√	√	√
Near-final HLIP II draft presented at PIP AG meeting	√	√[b]	√	√	
HLIP II submitted to WHO DG for approval (December 2017)					

[a] All GISRS institutions (NICs, WHO CCs, ERLs, H5 Reference Laboratories)

[b] GISRS institutions (WHO CCs and ERLs)

[c] Includes influenza development partners (intergovernmental agencies and private and public donor agencies)

Annex 2: Budget

The high-level Budget for 2018-2023 is presented below. Budgets for each Output will be refined and finalized based on the needs presented in the HQ, RO and CO work plans.

Outcomes and Outputs	USD	
Preparedness	**Annual**	**Entire Period**
L&S (Output 1) & IPPP (Output 6)		
AFRO	1,600,000	9,600,000
AMRO	1,600,000	9,600,000
EMRO	1,600,000	9,600,000
EURO	1,600,000	9,600,000
SEARO	1,600,000	9,600,000
WPRO	1,600,000	9,600,000
Headquarters	1,500,000	9,000,000
Sub-total	**11,100,000**	**66,600,000**
BOD (Output 2)		
Headquarters and Regional Offices as required	1,000,000	6,000,000
Sub-total	**1,000,000**	**6,000,000**
REG (Output 3)		
Headquarters and Regional Offices as required	1,000,000	6,000,000
Sub-total	**1,000,000**	**6,000,000**
RCCE (Output 4)		
Headquarters and Regional Offices as required	1,000,000	6,000,000
Sub-total	**1,000,000**	**6,000,000**
DEP (Output 5)		
Headquarters and Regional Offices as required	1,000,000	6,000,000
Sub-total	**1,000,000**	**6,000,000**
Preparedness	15,100,000	90,600,000
Planning Contingency [a]	510,619	3,063,717
Total for Preparedness	**15,610,619**	**93,663,717**
Response	7,065,421	42,392,523
PIP Secretariat	2,477,876	14,867,257
PSC [b]	2,846,084	17,076,503
TOTAL [c]	**28,000,000**	**168,000,000**

[a] The Planning Contingency will be assigned to the Outputs based on assessed needs.

[b] WHO Program Support Cost (PSC) is calculated at 13% of direct costs for the Preparedness and Secretariat components, and 7% of direct costs for the Response component.

[c] The total income projection for 2018-2023 is subject to receipt of funds from contributors.

Annex 3: Monitoring, Evaluation and Reporting

Contents of Annex 3

A. Overview of Monitoring, Reporting and Evaluation in HLIP II

The overall purpose of monitoring and evaluation is to ensure that project inputs flow through to achieving the Outcome, and to provide a method for measuring progress against the Outcome/Outputs. In HLIP II, there are multiple components to measure progress and performance over time.

Highlights from the Field

- **Function**: Monitoring
- **Frequency**: Bi-monthly reporting
- **Reporting**: PIP Newsletter

Milestones

- **Function**: Monitoring and evaluation
- **Frequency**: Six-monthly reporting
- **Reporting**: During PIP AG meetings

Outcome & Output Indicators

- **Function**: Monitoring and evaluation
- **Frequency**: Annual reporting
- **Reporting**: PIP PC Annual Reports

Mid-term Review & Adjustments

- **Function**: Evaluation
- **Frequency**: After first biennum (covering 2018 and 2019)
- **Reporting**: During PIP AG meeting

HLIP II Evaluation & Impact Assessment

- **Function**: Evaluation
- **Frequency**: After 6 years (covering 2018 to 2023)
- **Reporting**: PIP website

B. Glossary of Terms for the Annex 3: Monitoring Evaluation and Reporting

The definitions in this glossary are extracted from WHO's Programme Management Glossary of Terms.[48] These definitions apply to the monitoring, evaluation and reporting processes within HLIP II.

Achievement	1. Actual change as a result of delivering a programme or in implementing an intervention. 2. Actual value of a performance indicator measured at any point of time.
Activity	Activities are a set of interrelated actions necessary to deliver a product or a service.
Baseline	Characteristic of the situation at the beginning of a planning period. Value of an indicator measured at (or close to) the beginning of a planning period.
Deliverable	A description of the contributions to the output of each of the levels of the Organization. It reflects the division of labour of the three levels of the Organization.
Impact	Sustainable change in the health of populations to which the Secretariat and countries contribute.
Indicator	Characteristic of a result that is measurable or objectively verifiable Indicators support judgment on performance
Milestone	An activity or event that marks a significant progress in delivering a product or service.
Monitoring	Continuous follow-up of activities and assessment of the programme delivery to ensure implementers are proceeding according to plan and that the results are likely to be achieved.
Outcome	Change in countries in terms of service coverage and access, or reduction of risk factors, to which the work of the Secretariat is expected to contribute.
Output	Change in countries in terms of policies or institutional capacities, that the Secretariat is committed to influence directly, or achievement of the Secretariat in relation to normative work. The outputs define what the Secretariat will be held accountable for and determine activities during the project.
Product	Final and observable result of an activity or combination of activities.
Result	A describable or measurable change that is derived from a cause-and-effect relationship. There are three types of such changes – outputs, outcomes and impact – which can be set in motion by a development intervention.

[48] WHO Programme Management Glossary of Terms, Version June 2017 (internal document)

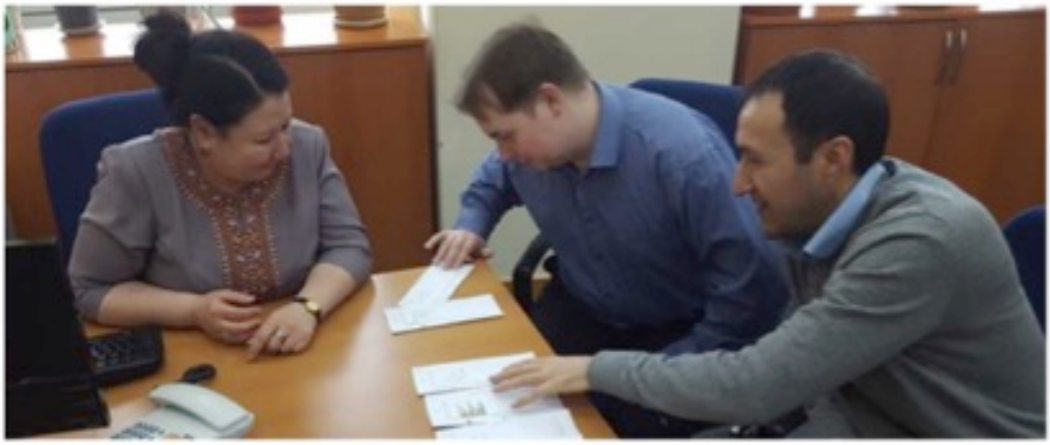
Service	On-going and identifiable result of an activity or combination of activities. The term has been introduced to reflect the intangible nature of many of the actions delivered by the Secretariat.
Target	Expected value of an indicator at the end of a planning period.

C. Highlights from the Field

Highlights, at global, regional or country level, will be reported on a bi-monthly basis through the PIP Newsletter. This will include one to two highlights per Newsletter. The PIP Newsletter is available online.[49] These highlights will each include (where relevant):

- Background/Context
- Date of event
- Regions and countries involved
- Relevant Output and Deliverable(s)
- Activities leading to the achievements
- Contribution to pandemic influenza preparedness
- Photos
- Next steps

Example: PIP Newsletter (March 2017)



Strengthening capacity for influenza surveillance in Turkmenistan: an important milestone reached

Since 2014, PIP Partnership Contribution funds have been used to strengthen influenza surveillance and control in Turkmenistan. Building a sustainable framework that provides Turkmenistan ministry officials with timely, high quality data in an easily understandable format is essential to improved influenza prevention and control.

PIP activities in Turkmenistan were built around improving data quality and data management practices. First, evaluations were carried out to assess what surveillance systems are in place, and what are their strengths and limitations. Based on mission recommendations, sentinel and virological surveillance capacities were significantly strengthened.

In the second phase, implementation of tools to improve data management and analysis have become the focus. In 2016, a new influenza data management software was developed, installed and training was provided, replacing an existing paper based reporting system. During the most recent mission, a WHO team updated the software to incorporate sentinel surveillance data management. Now, the data management system combines data from universal, sentinel and virological surveillance to produce weekly influenza reports. Next phases will focus on further improving the quality of surveillance data and expanding sentinel sites.□

[49] http://www.who.int/influenza/pip/pip_newsletter/en/

D. Milestones

Milestones are activities or events that mark significant progress in achieving the Deliverables for each Output. HQ and RO implementing units will report on milestones to the PIP Secretariat. The milestones will be measured every six months and progress on milestones will be reported during the semi-annual PIP AG meetings to the PIP AG and other stakeholders in attendance. The milestones for each Deliverable are included in the following section, organized by each Output.

L&S (Output 1): National influenza laboratory and surveillance systems contribute to GISRS for timely risk assessment and response measures

Deliverables	Milestones	Details for milestone reporting	Offices reporting to PIP Secretariat
Risk and severity of influenza, including at the human-animal interface, are routinely assessed	PISA trainings completed	• Number of trainings completed • Place and date • Number and list of participating countries	HQ RO
	Outbreak detection and response trainings completed (e.g. Rapid Response Trainings)	• Number of trainings completed • Place and date • Number and list of participating countries	RO
	Human-animal interface strengthened through meetings, workshops, joint investigations or risk assessments	• Number of meetings, workshops, joint investigations or risk assessments conducted • Place and date • Number and list of participating countries	HQ RO
Quality influenza virus detection capacity is sustained	Laboratory trainings and technical support missions/visits provided to countries	• Number of trainings/missions/visits completed • Organizer or supporter (e.g. WHO, GISRS) • Place and date • Number and list of countries involved	HQ RO
	EQAP status	Select between: 1. EQAP contract signed (HQ) 2. EQAP sent out (HQ) 3. EQAP results received (HQ) 4. EQAP results published in the Weekly	HQ RO

		Epidemiological Record (WER) (HQ) 5. Results shared with participating laboratories (RO)	
Countries are supported to consistently report influenza data to global platforms	Regional influenza meetings (e.g. NIC meeting) held to improve global influenza surveillance system strengthening	• Number of meetings completed • Place and date • Number and list of participating countries	RO
	Technical assistance and support for surveillance provided to countries (e.g. for sentinel sites, data management)	• Type of technical assistance or support provided (trainings/missions, support to evaluations/assessments) • Place and date • Number and list of countries involved	HQ RO
	Regional bulletins published	• Region name(s) • Number of bulletins published • Type of content published • Relevant links	RO
Countries are supported to share timely representative influenza samples with WHO CCs	Infectious Substance Shipping Training (ISST) provided	• Number of ISST provided • Date • Number and list of countries involved	RO
	Shipments made using Shipping Fund Project *(Global level only)*	• Number of shipments	HQ
Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated	Protocols or guidance reviewed *(Global level only)*	• Document name • Summary of content • Date	HQ
	Vaccine Composition Meeting (VCM) consultations completed *(Global level only)*	• Summary of VCM recommendations showing CVVs from WHO website	HQ

BOD (Output 2): Influenza disease burden estimates are used for public health decisions

Deliverables	Milestones	Details for milestone reporting	Offices reporting to PIP Secretariat
Representative national, regional and global disease burden estimates are available	Burden of disease estimates development stage	For each country involved, select between: 1. Country contacted 2. Implementation plan established 3. Field work started 4. Denominator estimated 5. Rate calculated (disease burden estimate completed) 6. Disease burden findings shared (made available to stakeholders) 7. Disease burden findings published (in peer-review journal) 8. Burden of disease estimates used in regional or global estimates	HQ RO
Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making	Communication process of disease burden findings	Select between: 1. NITAG/TAG or other decision-making bodies focal points contacted 2. Influenza put on NITAG/ TAG or other decision-making bodies agenda 3. Burden of disease findings discussions/ recommendations documented	HQ RO

REG (Output 3): Timely access to quality assured pandemic influenza products is supported

Deliverables	Milestones	Details for milestone reporting	Offices reporting to PIP Secretariat
National regulatory capacity for pandemic influenza products is strengthened	Tool refinement for supporting regulatory preparedness for pandemic influenza	• Types of refinement(s) completed • Purpose of the refinement(s) • Place and dates	HQ
	Benchmarking and IDP follow-up missions	• Number and list of countries benchmarked or IDP followed up • IDP component • Place and date	HQ
Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted	Translation of the PIP regulatory guidelines into Spanish, French, and Russian	• Number of UN languages in which the guidelines are available • Place and date of translation	HQ
	Implementation of the PIP regulatory guidelines linking national influenza pandemic preparedness plans (IPPP) and national deployment and vaccination plan (NDVP) for pandemic influenza vaccines	• Number of regional workshops conducted • Number and list of participating countries • Place and date	HQ

RCCE (Output 4): Tools and guidance are available for countries to enhance influenza risk communication and community engagement

Deliverables	Milestones	Details for milestone reporting	Offices reporting to PIP Secretariat
Countries and front-line responders have access to resources for influenza risk communication, community engagement and social science-based interventions	WHO Guideline on engaging communities for epidemics and pandemics, and module(s) developed or updated, and uploaded on OpenWHO	• Details of product uploaded (guidance type, content, intended audience, purpose) • Date	HQ
	Advocacy and marketing completed to promote use of OpenWHO influenza-relevant modules	• Type of advocacy/marketing event • Number and list of countries involved • Audience • Place and date	HQ
	Intelligence mapped for risk and socio-economic factors, behavioural patterns, cultural values, languages, etc. in priority countries	• Document name • Summary of content • Date • Number and list of countries involved	HQ
Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement	Technical support provided to countries	• Type of technical assistance provided (trainings/missions/ visits/deployment of experts) • Number and list of countries involved • Place and date	HQ
	Global partnerships and networks for alignment and coordination for effective RCCE capacity	Select between: 1. Partners identified/contacted 2. Plan of action developed 3. Evidence of approach alignment available (Memorandum of Understanding, joint guidance, joint missions or trainings)	HQ

DEP (Output 5): Plans for effective and efficient deployment of pandemic supplies are optimized

Deliverables	Milestones	Details for milestone reporting	Offices reporting to PIP Secretariat
A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners	PIP Deploy refined to facilitate planning, allocation and coordination	• Types of refinement(s) completed • Purpose of the refinement(s) • Date	HQ
	Common approach advocated to Member States and other stakeholders through workshops, exercises and trainings	• Number of workshops/exercises/ trainings completed • Place and date • Number and list of participating countries/stakeholders	HQ
National deployment planning process is revised and updated	Global guidance revised	• Details of product updated (document/tool type, intended users, purpose) • Date	HQ
	Technical support provided to countries to update their national deployment plan as part of their influenza pandemic preparedness plan	• Type of technical support provided (trainings/missions/ visits/etc.) • Number and list of countries involved • Place and date	HQ
Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries	Sustainability assessment process	For each country involved, select between: 1. Country engagement & concurrence 2. Kick-off meeting completed 3. Draft report completed 4. Stakeholders workshop held 5. Final sustainability assessment report available	HQ
	Technical assistance provided	• Type of technical assistance provided (trainings/missions/ visits/etc.) • Number and list of countries involved • Place and date	HQ

IPPP (Output 6): National pandemic influenza preparedness and response plans are updated in the context of all-hazards preparedness and global health security

Deliverable	Milestone	Details for milestone reporting	Offices reporting to PIP Secretariat
Countries are supported to develop, test and update their pandemic influenza preparedness plan	IPPP development/ revision stage in cycle	For each country involved, select between: 1. Planning meeting held/ workshop completed (type, who was involved, when) 2. IPPP written or revised (when) 3. IPPP exercised (when) 4. IPPP adjusted after exercise if needed (when) 5. IPPP endorsed (when)	RO

E. Outcome and Output Indicators

Progress on Outcome and Output indicators will be reported yearly through the PC Annual Report. This section breaks down each indicator to provide additional details on a rationale for the indicator, measurement details including data disaggregation, and method for data collection and reporting. This is organized by Outcome indicators, followed by indicators for each Output.

PC Preparedness Outcome: Influenza surveillance systems, knowledge and capacities for a timely and appropriate response to pandemic influenza are established and strengthened

Outcome Indicator 1: IVPPs shared with GISRS

Indicator	Proportion (%) of Member States sharing IVPPs with GISRS according to WHO IVPP sharing guidance
Rationale for use	Provision of IVPPs in line with guidance will enable timely risk assessment and response measures
Relevant output(s)/ deliverable(s)	**Output 1 - Deliverable D:** Countries are supported to share timely representative influenza samples with WHO CCs
Definition of key terms	**IVPP:** Influenza Viruses with Human Pandemic Potential **WHO IVPP sharing guidance:** The WHO Operational Guidance for Sharing Influenza Viruses with Human Pandemic Potential provides guidance on which and when IVPP samples should be shipped to WHO Collaborating Centres (WHO CCs)
MEASUREMENT	
Numerator	Number of Member States sharing IVPPs with WHO CCs according to WHO IVPP sharing guidance
Denominator	Number of Member States which reported zoonotic influenza infections through IHR (publicly available DON notification)
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme Influenza Virus Traceability Mechanism (IVTM) and Vaccine Composition Meeting / IHR notifications
Period covered	From 1 September to 31 August
Reporting frequency	Updated once annually

Outcome Indicator 2: Reporting of virological influenza data to FluNet

Indicator	Proportion (%) of Member States reporting to FluNet
Rationale for use	More Member States participating consistently in virological data reporting will facilitate risk assessment and response measures. The timeliness of the information reported to FluNet will improve timeliness of risk assessments and response measures
Relevant output(s)/ deliverable(s)	**Output 1 - Deliverable C:** Countries are supported to consistently report influenza data to global platforms
Definition of key terms	**Consistently:** Member States reporting at least 60% of the weeks of during the influenza season For Northern Hemisphere: Member States reporting 20 or more weeks during the season (week 40 to week 20) (ILI or ARI, SARI) For Southern Hemisphere: Member States reporting 13 or more weeks during the season (week 18 to week 40) (ILI or ARI, SARI) For countries with year-round surveillance: Member States reporting 32 or more weeks (week 40 to week 39) (ILI or ARI, SARI) **Timely:** Reports have to be submitted no later than 1 week after the epidemiological week as per WHO requirements (by Thursday 12 am UTC Time)
MEASUREMENT	
Numerator	Number of Member States reporting to FluNet
Denominator	Total number of Member States
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region By stage - Member States reporting to FluNet: a - Consistently and timely b - Consistently only c - Inconsistently/ sporadic reporting d - Not reporting
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme FluNet
Period covered	For the Northern Hemisphere season: period from week 40 to week 20 For the Southern Hemisphere season: period from week 18 to week 40 For countries with year-round surveillance: period from week 40 to week 39
Reporting frequency	Updated once annually

Outcome Indicator 3: Reporting of epidemiological influenza data to FluID

Indicator	Proportion (%) of Member States reporting to FluID
Rationale for use	More Member States participating consistently in epidemiological data reporting will facilitate risk assessment and response measures. The timeliness of the information reported to FluID will improve timeliness of risk assessments and response measures
Relevant output(s)/ deliverable(s)	**Output 1 - Deliverable C:** Countries are supported to consistently report influenza data to global platforms
Definition of key terms	**Consistently:** Member States reporting at least 60% of the weeks during the influenza season For Northern Hemisphere: Member States reporting 20 or more weeks during the season (week 40 to week 20) For Southern Hemisphere: Member States reporting 13 or more weeks during the season (week 18 to week 40) For countries with year-round surveillance: Member States reporting 32 or more weeks (week 40 to week 39) **Timely:** Reports have to be submitted no later than 1 week after the epidemiological week as per WHO requirements (by Thursday 12 am UTC Time)
MEASUREMENT	
Numerator	Number of Member States reporting to FluID
Denominator	Total number of Member States
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region By stage - Member States reporting to FluID: a - Consistently and timely b - Consistently only c - Inconsistently / sporadic reporting d - Not reporting
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme FluID
Period covered	For the Northern Hemisphere season: period from week 40 to week 20 For the Southern Hemisphere season: period from week 18 to week 40 For countries with year-round surveillance: period from week 40 to week 39
Reporting frequency	Updated once annually

Outcome Indicator 4: Sharing of disease burden estimates

Indicator	Proportion (%) of Member States with burden of disease estimates that have been considered by NITAG or other decision-making bodies
Rationale for use	Presenting influenza morbidity, mortality and economic burden to NITAGs/TAGs will enable these committees to assess the need for introducing or updating public health measures including vaccination
Relevant output(s)/ deliverable(s)	**Output 2** - **Deliverable B:** Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making
Definition of key terms	**Estimates available:** estimates are known **Estimates published:** estimates published in peer-reviewed journal **Decision-making bodies:** can include pandemic planning, clinical care or emergency management groups
MEASUREMENT	
Numerator	Number of Member States with burden of disease estimates that have been considered by NITAG or other decision-making bodies
Denominator	Number of Member States with published burden of disease estimates or with estimates available
Disaggregation by	By Member State (global) By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme and Regional Offices NITAG/TAG or other decision-making bodies reports
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

Outcome Indicator 5: Regulatory approach for timely approval for use of pandemic influenza products

Indicator	Number of Member States that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products
Rationale for use	A country with a defined regulatory approach will be able to receive and use pandemic influenza products during a pandemic
Relevant output(s)/ deliverable(s)	**Output 3 - Deliverable B:** Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted
Definition of key terms	**Regulatory approach:** WHO Guidelines on Regulatory Preparedness for Non-Vaccine Producing Countries in Response to Pandemic Influenza Emergency provides a set of regulatory pathways/approaches that can be considered by NRAs. They can be accessed here: http://www.who.int/biologicals/expert_committee/PIP_Non-producer_guide_BS_final-working_version-19102016-clean.pdf **Timely:** Timely approval means the regulatory body's approval for use of a product is done in opportune time to facilitate access to the product **Implementation** includes: • having a functional defined regulatory pathway available and, • linkages established for national pandemic preparedness plan (participation in WHO sponsored workshops on incorporating regulatory aspects in national pandemic preparedness plan)
MEASUREMENT	
Numerator	Number of PC recipient Member States that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products
Denominator	N/A
Disaggregation by	By PC recipient Member State By WHO Region Numerator further described according to the regulatory approach selected
DATA COLLECTION & REPORTING	
Data source/means of verification	Regulation of Medicines and Other Health Technologies (RHT) Unit Surveys from workshops and benchmarking
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

Outcome Indicator 6: National pandemic influenza preparedness plans

Indicator	Proportion (%) of Member States that developed or updated a pandemic influenza preparedness plan
Rationale for use	Advance planning and preparedness are critical to help mitigate the impact of a pandemic. A country with a pandemic plan will have better knowledge and capacities for timely response to a pandemic (IHR Core Capacity 5). Since the publication of PIRM, countries should develop or update their plans. This latest WHO guidance encourages countries to uncouple national actions from global phases (key change/guiding principle)
Relevant output(s)/ deliverable(s)	**Output 4 - Deliverable B:** Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement **Output 5 - Deliverable B:** National deployment planning process is revised and updated **Output 6 - Deliverable A:** Countries are supported to develop, test and update their influenza pandemic preparedness plan
Definition of key terms	**Member States which developed a plan:** Member States without a publically available national pandemic influenza preparedness plan that have developed a plan since the publication of WHO PIRM guiding principle (i.e. starting in 2014) **Member States which updated their plan**: Member States with a pandemic influenza preparedness plan that have updated their plan since the publication of WHO PIRM guiding principle (i.e. starting in 2014)
MEASUREMENT	
Numerator	Number of PC recipient Member States that developed or updated a pandemic influenza preparedness plan since 2014
Denominator	Total number of PC recipient Member States
Disaggregation by	By PC recipient Member State By WHO Region Analyses may be presented, where relevant, by stage of development/update: Stage 1 - Planning and organizing Stage 2 - Writing Stage 3 - Exercising Stage 4 - Adjusting Stage 5 - Endorsement (plan is finalized and nationally signed-off)
DATA COLLECTION & REPORTING	
Data source/means of verification	Global Influenza Programme and Regional Offices Pandemic influenza preparedness plans from PC recipient Member States / Strategic Partnership Portal
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

L&S (Output 1): National influenza laboratory and surveillance systems contribute to GISRS for timely risk assessment and response measures

L&S Indicator 1.1

Routine risk assessments of circulating influenza viruses at the human-animal interface

Indicator	Number of risk assessments published for influenza viruses at the human-animal interface following WHO guidance
Rationale for use	This indicator reflects the capacity to gather, collate, analyse cross-sectoral data and to then undertake and share regular risk assessments on zoonotic influenza viruses
Relevant deliverable(s)	**Deliverable A:** Risk and severity of influenza, including at the human-animal interface, are routinely assessed
Definition of key terms	**Risk assessment:** process to review the likelihood and impact of an event **Routine:** at least 10 risk assessments per year **Human-animal interface:** humans can be infected with animal influenza viruses. Since human infections are primarily acquired through direct contact with infected animals or contaminated environments, outbreak investigation at these sources will inform risk assessment
MEASUREMENT	
Numerator	Number of WHO risk assessments published for influenza viruses at the human-animal interface following WHO guidance
Denominator	N/A
Disaggregation by	Analyses may be presented, where relevant, on risk assessments conducted for events including the first documented case/s of human infection with a non-seasonal or animal influenza virus. Information presented may include the time from receipt of IHR notification to risk assessment publication and institutions involved (e.g. World Organisation for Animal Health, Food and Agriculture Organization)
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme website
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

L&S Indicator 1.2

Reporting on influenza severity to WHO

Indicator	Number of Member States reporting influenza severity indicators to WHO
Rationale for use	Participating in severity assessment using the global tool will enable timely severity assessment and associated response recommendations
Relevant deliverable(s)	**Deliverable A:** Risk and severity of influenza, including at the human-animal interface, are routinely assessed
Definition of key terms	**Reporting:** reports have to be submitted at least twice in a season (mid and end of season)
MEASUREMENT	
Numerator	Number of Member States reporting at least one severity indicator to global WHO PISA platform
Denominator	N/A
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme FluMART PISA dashboard
Period covered	For the Northern Hemisphere season: period from week 40 to week 20 For the Southern Hemisphere season: period from week 18 to week 40 For countries with year-round surveillance: period from week 40 to week 39
Reporting frequency	Updated once annually

L&S Indicator 1.3

PCR quality for non-seasonal influenza viruses

Indicator	Proportion (%) of Member States that participated and were 100% correct for non-seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)
Rationale for use	This indicator measures the quality of the PCR testing to detect non-seasonal influenza viruses with pandemic potential based on the performance in the most-recent panel of the WHO Influenza PCR EQAP
Relevant deliverable(s)	**Deliverable B:** Quality influenza virus detection capacity is sustained
Definition of key terms	**Participate in PCR EQAP:** at least one laboratory in the Member State was enrolled, received the panel and returned the results
MEASUREMENT	
Numerator	Number of Member States with at least one national laboratory that participated and was 100% correct for non-seasonal virus identification in the most recent WHO influenza PCR EQAP
Denominator	Number of Member States that participated in PCR EQAP
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region Some Member States have more than one laboratory participating in EQAP. Analyses may be presented, where relevant, by the number of laboratories and by National Influenza Centre status
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme EQAP database
Period covered	From 1 April to 30 October
Reporting frequency	Updated once annually

L&S Indicator 1.4

PCR quality for seasonal influenza viruses

Indicator	Proportion (%) of Member States that participated and were 100% correct for seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)
Rationale for use	This indicator measures the quality of the PCR testing to detect seasonal circulating viruses based on the performance in the most recent panel of the WHO Influenza PCR EQAP
Relevant deliverable(s)	**Deliverable B:** Quality influenza virus detection capacity is sustained
Definition of key terms	**Participate in PCR EQAP:** at least one laboratory in the Member State was enrolled, received the panel and returned the results
MEASUREMENT	
Numerator	Number of Member States with at least one national laboratory that participated and was 100% correct for seasonal virus identification in the most-recent WHO influenza PCR EQAP
Denominator	Number of Member States that participated in EQAP
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region Some Member States have more than one laboratory participating in EQAP. Analyses may be presented, where relevant, by the number of laboratories and by National Influenza Centre status
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme EQAP database
Period covered	From 1 April to 30 October
Reporting frequency	Updated once annually

L&S Indicator 1.5

Influenza virus sharing

Indicator	Proportion (%) of Member States that had timely sharing of influenza virus isolates or clinical specimens with WHO CCs according to WHO guidance
Rationale for use	Timely sharing of samples will enable timely risk assessment and response measures including preparation of pre-pandemic candidate vaccine viruses
Relevant deliverable(s)	**Deliverable D:** Countries are supported to share timely representative influenza samples with WHO CCs
Definition of key terms	**Timely:** To enable influenza viruses to be analysed in time for updated vaccine composition recommendations twice every year, shipments should be sent four to eight weeks prior to the two WHO consultations, i.e.: • Between December to mid-January (latest), • Between July and mid-August (latest), and • April-May for later northern hemisphere (NH) or early southern hemisphere (SH) season samples, • September-October for later SH or early NH samples
MEASUREMENT	
Numerator	Number of Member States that have sent at least two timely shipments of virus isolates or clinical specimens to WHO CCs (seasonal or IVPP) according to WHO guidance
Denominator	Total number of Member States
Disaggregation by	By Member State (global) By PC recipient Member State By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme Vaccine Composition Meeting and Shipping Fund Project
Period covered	From 1 September to 31 August
Reporting frequency	Updated once annually

L&S Indicator 1.6

Characterization of zoonotic influenza viruses and other influenza viruses with pandemic potential

Indicator	Number of zoonotic influenza viruses and other influenza viruses with pandemic potential characterized by GISRS
Rationale for use	This indicator relates to GISRS' monitoring capacity to inform vaccine virus development and pandemic risk assessment
Relevant deliverable(s)	**Deliverable E:** Influenza CVVs, virus detection protocols and reference materials are routinely updated
Definition of key terms	**Characterization:** description of antigenic and/or genotypic characteristics of the influenza virus **Zoonotic influenza viruses:** animal influenza viruses that have infected humans through direct or indirect contact
MEASUREMENT	
Numerator	Number of zoonotic influenza viruses and other influenza viruses with pandemic potential characterized by WHO CCs
Denominator	N/A
Disaggregation by	By originating Member State (global) By influenza subtype (including a specific table on number of zoonotic CVVs)
DATA COLLECTION & REPORTING	
Data source/means of verification	Vaccine Composition Meeting data packages (September and February) WHO Collaborating Centres and WHO Global Influenza Programme
Period covered	From 1 September to 31 August
Reporting frequency	Updated once annually

BOD (Output 2): Influenza disease burden estimates are used for public health decisions

BOD Indicator 2.1
Publication of disease burden estimates

Indicator	Number of Member States with published disease burden estimates based on data collected since 2011
Rationale for use	Availability of morbidity, mortality and economic disease burden estimates will facilitate decision-makers 'evidence based policy development. Inclusion of recent data from 2011 onwards (i.e. post-2009 pandemic) would be most useful for decision makers
Relevant deliverable(s)	**Deliverable A:** Representative national, regional and global disease burden estimates are available
Definition of key terms	**Published:** estimates published in peer-reviewed journal
MEASUREMENT	
Numerator	Number of Member States with published disease burden estimates based on data collected since 2011
Denominator	N/A
Disaggregation by	By Member State (global) By WHO Region By end point (e.g. mortality, hospitalization, economic analysis) or risk group
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme Published reports or reports submitted to WHO
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

REG (Output 3): Timely access to quality-assured pandemic influenza products is supported

REG Indicator 3.1
National regulatory capacity strengthening

Indicator	Number of Member States which strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and IDP implementation
Rationale for use	Countries with improved regulatory capacity will be better prepared to facilitate timely access to quality-assured medical products. This can be measured/ monitored through maturity level achieved over time in key regulatory functions as per NRA benchmarking and IDP implementation (focusing on regulatory systems, marketing authorization and pharmacovigilance)
Relevant deliverable(s)	**Deliverable A:** National regulatory capacity for pandemic influenza products is strengthened
Definition of key terms	**Strengthened**: at least one maturity level increase from baseline in regulatory system and targeted regulatory functions that are sustained and/or improved for three to five years
MEASUREMENT	
Numerator	Number of PC recipient Member States which strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and IDP implementation
Denominator	N/A
Disaggregation by	By PC recipient Member State By WHO Region Numerator further described according to the three areas of regulatory capacity building (Quality Management System, Market Authorization and Pharmacovigilance)
DATA COLLECTION & REPORTING	
Data source/means of verification	Regulation of Medicines and Other Health Technologies (RHT) Unit Benchmarking reports and IDP follow up visits
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

RCCE (Output 4): Tools and guidance are available for countries to enhance influenza risk communication and community engagement

RCCE Indicator 4.1
Use of OpenWHO resources

Indicator	Number of users from target audiences who completed learning modules on influenza and related RCCE content on the OpenWHO platform
Rationale for use	Influenza resources for RCCE need to be up-to-date, easily accessible and available to many users in different languages and formats. Users of the OpenWHO platform can play a role in cascading information, knowledge, skills and have a multiplier effect for capacity-building. Institutionalizing the use of OpenWHO as the platform for emergencies now will be beneficial for reaching global audiences rapidly during a pandemic
Relevant deliverable(s)	**Deliverable A:** Member States and frontline responders have access to resources for influenza risk communication, community engagement and social science-based interventions
Definition of key terms	**Target audiences:** Public health officials & experts, Emergency personnel, front-line responders & decision-makers, health care workers and volunteers
MEASUREMENT	
Numerator	Number of users from target audience who completed learning modules on influenza and related RCCE content on the OpenWHO platform
Denominator	N/A
Disaggregation by	By Member State (global) By WHO Region By user type By module By week
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Experts Networks & Interventions Unit OpenWHO.org traffic monitoring reports on numbers, geographical location, and other demographic data
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

RCCE Indicator 4.2

Use of RCCE technical support

Indicator	Number of Member States that utilized RCCE support for influenza preparedness or response
Rationale for use	In many countries, standing capacity for RCCE is limited (based on IHR indicator data, 2017). To build RCCE capacities for pandemic influenza and to exercise them during seasonal influenza epidemics, WHO need to provide technical assistance and mentorship to Ministries of Health and other partners
Relevant deliverable(s)	**Deliverable B:** Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement
Definition of key terms	**Utilized:** take action upon the support provided for (a) preparedness (e.g. planning, Knowledge, Attitude and Practices surveys, intelligence mapping, RCCE material developed or disseminated), or (b) response measures (e.g. outbreak investigation, campaigns, RCCE material developed or disseminated) **Support:** includes trainings/workshops, missions, deployments, webinars, or provision of targeted/adapted resources for that event
MEASUREMENT	
Numerator	Number of Member States that utilized RCCE support for influenza preparedness or response
Denominator	N/A
Disaggregation by	By Member State (global) By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Experts Networks & Interventions Unit Plans or Standard Operating Procedures available, mission reports, workshop reports, links to webinars, adapted resources provided to country
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

DEP (Output 5): Plans for effective and efficient deployment of pandemic supplies are optimized

DEP Indicator 5.1
PIP Deploy testing

Indicator	Annual simulation exercise conducted to test global deployment of pandemic influenza vaccines and other products
Rationale for use	Tests enable stakeholders to optimize their deployment plans and to remain engaged in the key operational interactions needed for distribution of products to countries during an emergency
Relevant deliverable(s)	**Deliverable A:** A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners
Definition of key terms	**Exercise:** form of practice, training, monitoring or evaluation of capabilities, involving the description or simulation of an emergency to which a described or simulated response is made **Deployment:** steps include product allocation, acceptance, changes, regulatory authorization and shipment to a country's point of entry **PIP Deploy:** online simulation application which enables different stakeholders (e.g. manufacturers, countries, freight forwarder, WHO and other support agencies) to allocate, plan and coordinate product deployment
MEASUREMENT	
Numerator	Annual simulation exercise conducted using PIP Deploy to test global deployment of pandemic influenza vaccines and other products
Denominator	N/A
Disaggregation by	By participant (manufacturer, Member State, support agency, etc.)
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Experts Networks & Interventions Unit PIP Deploy simulation exercise and the application's monitoring reports
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

DEP Indicator 5.2

Sustainability of influenza vaccine procurement and production for pandemic preparedness

Indicator	Number of Member States that have undergone a national analysis of influenza vaccine procurement or production sustainability
Rationale for use	Addressing sustainability of production and procurement creates the conditions for vaccine security in the event of a pandemic. Countries undergoing a sustainability assessment using the WHO sustainability checklist demonstrate attention to preparedness and vaccine security The assessment (checklist) considers seven key areas: Policy environment and health care system, policy other than health, influenza-surveillance, early detection and evidence, product development and manufacturing, influenza vaccine procurement, product approval and regulations, communication for influenza vaccination
Relevant deliverable(s)	**Deliverable C:** Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to Member States
Definition of key terms	_
MEASUREMENT	
Numerator	Number of Member States that have undergone a national analysis of influenza vaccine procurement or production sustainability
Denominator	N/A
Disaggregation by	By Member State (global) By WHO Region By countries producing By countries procuring By developed countries By developing countries
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Essential Medicines and Health Products Department Published reports of assessment (http://www.who.int/influenza_vaccines_plan/objectives/Sustainability_production_flu_vaccines/en/)
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

IPPP (Output 6): National pandemic influenza preparedness and response plans are updated in the context of all-hazards preparedness and global health security

IPPP Indicator 6.1
Exercise national pandemic influenza preparedness plans

Indicator	Proportion (%) of Member States that exercised their pandemic influenza preparedness plan including across sectors
Rationale for use	Exercising plans help develop, assess and test the functional capabilities of systems, procedures and mechanisms to respond to a pandemic. Exercises play an important role in identifying strengths and gaps in the development and implementation of preparedness measures
Relevant deliverable(s)	**Output 4 - Deliverable B:** Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement **Output 5 - Deliverable B:** National deployment planning process is revised and updated **Output 6 - Deliverable A:** Countries are supported to develop, test and update their influenza pandemic preparedness plan
Definition of key terms	**Exercise:** form of practice, training, monitoring or evaluation of capabilities, involving the description or simulation of an emergency to which a described or simulated response is made **Sectors:** include Ministry of Health and other agencies involved in pandemic preparedness (e.g. Ministry of Agriculture, animal laboratory services)
MEASUREMENT	
Numerator	Number of PC recipient Member States that exercised their pandemic influenza preparedness plan including across sectors
Denominator	Total number of PC recipient Member States
Disaggregation by	By PC recipient Member State By WHO Region
DATA COLLECTION & REPORTING	
Data source/means of verification	WHO Global Influenza Programme and Regional Offices Reports on exercises conducted, draft plans from PC recipient Member States
Period covered	From 1 January to 31 December
Reporting frequency	Updated once annually

F. Mid-Term Review

A review will be completed to determine if a mid-course adjustment is needed to improve the design and implementation of HLIP II. The review will not assess performance of individual implementers or activities, but rather it will focus on the broader Results Hierarchy. The review will address three questions:

1. Is there evidence that the current HLIP II design is making a difference to improve global pandemic influenza preparedness?
2. What is helping or hindering implementation to achieve the desired outputs?
3. Is there evidence of synergy with other initiatives/programmes relevant to pandemic influenza preparedness?

The review will be led by the PIP Secretariat and will engage a variety of stakeholders including HQ and RO technical units responsible for implementing the Deliverables, representatives from recipient countries, the PIP AG, GISRS (notably WHO CCs), industry and CSO. Findings and recommendations arising from the review will inform if the Results Hierarchy or implementation process needs to be updated or adjusted.

G. End-of-Project Evaluation

An external evaluation will be completed to assess HLIP II's effectiveness (impact). This is defined as:

1. Progress against the Outcome by achieving the Outputs.
2. Progress against the 10-year objectives for pandemic influenza preparedness that were established in 2013 (as described in Section 1.1 of HLIP II).

The evaluation will also review:

- Efficiency: Is there evidence of value for money?
- Sustainability: Has sustainable capacity been built to improve pandemic influenza preparedness?

The lessons learnt will support future designs and investments in pandemic influenza preparedness.

Annex 4: Risk Analysis

This risk analysis provides an overview of high-level risks to PC Implementation, as well as potential mitigation strategies to be used in the case these risks come to fruition. These risks are developed based on a high-level analysis of the program, as well as risks that came to light from the HLIP I implementation period. Mitigation strategies incorporate learnings from HLIP I.

Risk	Potential Effects	Mitigation Strategy
Planning		
Industry or other stakeholders do not endorse the detailed implementation plan	• Delayed start of implementation	• Communicate implementation plan approval process • Engage with throughout planning process and integrate feedback • Share draft plans
Lack of coherence with, or duplication of other WHO programs or initiatives	• Inefficient use of PC Preparedness Funds	• Consult with other WHO programs in HLIP II, and be clear about existing synergies • Communicate with other WHO teams during planning to prevent duplication • Build in flexibility to update the plan during implementation if duplications become clear
Real or perceived conflict of interest in the development of recommended country recipients	• Member States and stakeholders raise concerns	• Develop a transparent country selection criteria and process that is communicated to stakeholders • Limit the role of the PIP AG to providing feedback on the criteria for country selection
Implementation		
Delayed implementation of projects	• Member State and stakeholder impatience / dissatisfaction • Member States raise concerns with DG	• Develop realistic timeframes and funding estimates • Provide regular implementation updates to DG, AG, Industry and other stakeholders, and Member States • Determine cause of delays & address immediately • Ensure appropriate timeline and process for work plan development and approvals including timing of PCITEM • Ensure appropriate disbursement mechanism to facilitate access to funds for implementation taking into consideration annual and biennial closure period (late December)
Industry withholds or delays PC payments	• Project implementation delayed / stopped / truncated	• Adhere to PC Standards of Practice to identify contributors and collect PC funds on time • Develop scalable and modular plans to accommodate available resources • Review and monitor implementation on a regular basis, adjust plans and reprogramme resources, as necessary
Lack of country recipient commitment	• Outputs not achieved; no progress on indicators outcomes compromised	• Develop clear criteria for country selection • Require a letter of commitment from MOH of recipient countries • Adhere to monitoring processes and encourage progress on indicators

Projects are not sustainable	• Key elements of PIP Framework benefit sharing system questioned	• Ensure sustainability is integral to project development and a criterion for country selection • Integrate sustainability as a planning principle for all actions taken under HLIP II
Implementation staff becomes overburdened	• Delayed implementation	• Build in flexibility to review processes as needed to ensure that tasks have reasonable expectations while ensuring high quality implementation • Staff budget to be reviewed with yearly fund allocation to ensure appropriateness
Pandemic influenza event	• Implementation slowed or halted	[Pandemic response begins] • Rapidly evaluate status of implementation and assess potential for resource re-allocation to facilitate pandemic response
Management		
Resources used for activities outside approved work plan	• Inappropriate use of PC Preparedness Funds	• PIP Secretariat review work plans thoroughly, conduct six-monthly compliance checks and engage Responsible Officers monthly (at HQ and RO level) to ensure influenza-specific implementation
Insufficient staff (HQ, RO, CO) to properly monitor implementation	• Projects poorly managed, outputs not delivered, timeframes not met	• Develop realistic staffing plan for all levels of project implementation
Accountability and Reporting		
PC Funds not sufficiently distinguishable from other Organization resources	• Member States and stakeholders raise concerns about implementation	• Establish separate financial accounts, work plans and budgets, in accordance with WHO financial rules and regulations • Provide AG/EB/WHA regular updates on project implementation • External auditor specific examination subject to Health Assembly request[50]
Insufficient or inadequate implementation reporting	• Member States and stakeholders raise concerns about implementation reporting	• Adhere to detailed financial and narrative reporting processes based on monitoring and evaluation plan • Include regular monitoring of varying intensity at different (e.g. highlights, milestones, Output and Outcome indicators), and at regular time intervals (e.g. bi-monthly, 6-monthly, and annual)
Managers do not monitor work plans	• Over or under spend of PC Preparedness Funds	• PIP Secretariat conducts routine compliance checks • Monthly updates from Responsible Officers on progress and work plan changes needed
Deviation from approved work plan	• Products not aligned with intended Deliverables, impacts relations with stakeholders	• PIP Secretariat compliance checks • Strict use of work plan change control process to confirm suitability of changes requested and coherence with Results Hierarchy

[50] Subject to Health Assembly request for external auditor specific examination (Section 14.5, WHO Basic Documents, 48th Ed.)