Pandemic Influenza Preparedness Framework

# Partnership Contribution High-Level Implementation Plan III 2024-2030

World Health Organization

PIP FRAMEWORK

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# Partnership Contribution High-Level Implementation Plan III 2024-2030

World Health Organization

Pandemic Influenza Preparedness Framework: Partnership Contribution High-Level Implementation Plan III 2024-2030

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# Foreword

The COVID-19 pandemic exposed the world to the profound and far-reaching consequences a pandemic can have on health systems, economies and societies when the world is not adequately prepared. The need for sustained investment in pandemic influenza preparedness has become ever more apparent because, as we all know, an influenza pandemic is certain – the only question is when.

This third high-level implementation plan (HLIP III) is one of the mechanisms through which WHO aims to strengthen pandemic *influenza* preparedness, by using partnership contribution preparedness funds. The plan focuses on (i) improving policy and planning; (ii) ensuring capacities to enable WHO's Global Influenza Surveillance and Response System (GISRS) to rapidly identify and share influenza viruses with pandemic potential; (iii) preparing communities to engage and manage infodemics; and (iv) preparing operational plans for equitable access to medical countermeasures, by all countries in need, at the time of the next pandemic.

For maximum effectiveness, pandemic preparedness requires strong, collaborative and interlinked systems that take a whole-of-government and whole-of-society approach. In a highly dynamic and increasingly interconnected world, a collaborative approach is required: the complexities involved are such that neither individual countries nor international organizations can develop the required capabilities on their own. Importantly, Member States are at the heart of the Pandemic Influenza Preparedness (PIP) Framework, having recognized over 10 years ago the importance of equity in pandemic preparedness and response. Implementing HLIP III will contribute to its vision and make the world safer – and more equitable – for all.

History tells us that COVID-19 will not be the last pandemic. Through collaboration under the PIP Framework, we have a unique opportunity to synergize pandemic preparedness efforts and create stronger and more resilient country capacities to minimize the impact of a future influenza pandemic when it arises.

Dr Tedros Adhanom Ghebreyesus
WHO Director-General

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WHO regional offices and representatives from country offices: WHO Regional Office for Africa; WHO Regional Office for the Americas; WHO Regional Office for South-East Asia; WHO Regional Office for Europe; WHO Regional Office for the Eastern Mediterranean; and WHO Regional Office for the Western Pacific.

WHO headquarters departments: Epidemic and Pandemic Preparedness and Prevention (EPP/WPE), including the Global Influenza Programme (GIP) and High Impact Events Preparedness (IEP) units; Country Readiness Strengthening (CRS/WPE); Regulation and Prequalification (RPQ/MHP) including the Regulatory Systems Strengthening (RSS) unit; and Immunization, Vaccines and Biologicals (IVB/UHL).

The process of informing and writing this Plan was supported by ACT-IVD as an external consultant to the WHO PIP Framework Secretariat.

# Abbreviations

| | |
|---|---|
| GISRS | Global Influenza Surveillance and Response System |
| HEPR | health emergency preparedness, response and resilience |
| HLIP | high-level implementation plan |
| IHR | International Health Regulations (2005) |
| NIC | National Influenza Centre |
| NRA | national regulatory authority |
| PC | partnership contribution |
| PCITEM | Partnership Contribution Independent Technical Expert Mechanism |
| PCR | polymerase chain reaction |
| PIP | pandemic influenza preparedness |
| SARS | severe acute respiratory syndrome |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| RCCE | risk communication and community engagement |
| WHA | World Health Assembly |
| WHO | World Health Organization |

# Executive summary

Our global experience of the COVID-19 pandemic has re-emphasized the critical nature of influenza pandemic preparedness and has highlighted areas of global strength and resilience as well as important gaps and opportunities for further improvement. The high-level implementation plan (HLIP) for pandemic influenza preparedness (PIP) is the mechanism through which WHO aims to strengthen pandemic preparedness for influenza specifically and is an essential part of the wider PIP Framework for the sharing of influenza viruses and access to vaccines and other benefits, which was adopted by the World Health Assembly in May 2011. This third implementation plan (HLIP III) details the use of the partnership contribution (PC) preparedness funds for the period 2024–2030.

The aim of HLIP III is to improve global pandemic influenza preparedness and response by focusing on realization of the following outcome:

> **Strengthened pandemic influenza preparedness through a whole-of-government and whole-of-society approach that ensures a more equitable response by building stronger and resilient country capacities.**

HLIP III takes into consideration the lessons learned from the response to the COVID-19 pandemic, the gains made over time, including from previous HLIPs, and the broader programmatic and policy context in order to address gaps in pandemic influenza preparedness. Implementation of HLIP III will strengthen global, regional, and country-level pandemic influenza preparedness, and will be steered throughout its timeframe by the advice and inputs of the PIP Advisory Group and the Partnership Contribution Independent Technical Expert Mechanism (PCITEM).

At the heart of successful pandemic influenza preparedness sits the Global Influenza Surveillance and Response System (GISRS) and the involvement of a rich landscape of stakeholders at country, regional and global levels. This is reflected both in the structure of HLIP III and the processes used to develop it. First, HLIP III is designed in the context of broader global and WHO initiatives to enhance global preparedness, such as the Global Influenza Strategy, the International Health Regulations (2005), the Global Architecture for Health Emergency Preparedness, Response and Resilience, and Universal Health Coverage and Health Systems Strengthening. The perspectives of stakeholders –including Ministries of Health, GISRS institutions, the PIP Advisory Group, PCITEM, industry, civil society organizations, influenza programme development partners and

WHO implementation teams – were essential to HLIP III design. Secondly, HLIP III implementation is contextualized to country needs based on their existing systems and capacities for pandemic preparedness and response. As countries are at the heart of the PIP Framework, HLIP III focuses on advancing countries' needs. Thirdly, HLIP III is designed to operate coherently with other country, regional and global initiatives to strengthen pandemic influenza preparedness. WHO aims to ensure complementarity, efficiency and effectiveness in implementation in order to maximize impact, recognizing that HLIP III is one initiative contributing to collective achievements.

The success of HLIP III relies on the availability of funding through the PC. The PC is a mechanism for financing pandemic preparedness activities funded by the influenza product manufacturers that make annual voluntary cash contributions in return for using GISRS. These are voluntary cash contributions paid annually to WHO. The PC is a key component of the PIP Framework and showcases joint efforts between the public and private sectors to prepare the world for a future influenza pandemic.

HLIP III details four outputs, including deliverables and indicative activities for each, which work synergistically together to achieve the overall outcome. As a guiding document, HLIP III describes activities that can be planned at the global, regional and country levels in line with the outputs, recognizing the available financing each year and the flexibility needed in an ever-changing landscape. The document also explains how progress will be monitored, evaluated and reported on in order to maintain stakeholder awareness and engagement in this body of work.

HLIP III and its associated delivery structure will ensure that PC funds are allocated when and where they can best address global pandemic influenza preparedness needs. By combining the foundations laid by previous HLIPs, the PC funds, and the current global momentum to improve pandemic influenza preparedness, significant progress can be made over the 2024–2030 period. The stronger and more resilient country capacities that will result, will ensure a more equitable, timely and effective response to pandemic influenza viruses. This stands to benefit all of society by minimizing the disruptive consequences of a pandemic.

## **Box 1.** What's new in HLIP III?

- **Emphasis on pandemic influenza preparedness policies and planning** to underpin and drive forward capacity strengthening efforts. HLIP III will help stakeholders make use of multi-source data – including data from health surveillance, burden of disease enumeration and social listening systems – in order to inform the design of policies and plans that address preparedness and response needs equitably.
- **Operationalization of enablers for whole-of-society preparedness and response.** This includes engaging different sectors in planning and exercising pandemic influenza preparedness and response operations (Output 1), strengthening the capacities of scientists, media professionals and multisectoral government officials in knowledge translation (Output 3), and having operational readiness to deploy pandemic response products with procedures that clearly articulate the role of different multisectoral and multilevel stakeholders (Output 4).
- **Increase in the global reach and capacities of GISRS** institutions including through the introduction of approaches and technologies that facilitate early warning, such as streamlined data management systems and capabilities for genomic sequencing.
- **Expansion of new approaches established during the COVID-19 pandemic for social listening and infodemic management**, so that the roll-out of public health and social measures during the next influenza pandemic is designed with community knowledge, attitudes and practice in mind.
- **Support for regulatory functions that are essential for pandemic response**, such as pharmacovigilance. This involves building on the capacities and procedures established during the COVID-19 pandemic that are appropriate to emergencies.
- **Development of multistakeholder operational frameworks for the implementation of Standard Material Transfer Agreements 2**, building on the lessons learned and the new landscape of stakeholders engaged in COVID-19 pandemic product deployment.
- **Provision of technical assistance and policy guidance to countries, including those that are establishing capability for improved vaccine technologies.** This takes into account the rapidly evolving technology landscape and innovations, while emphasizing the need for coherent and sustainable policies at country level.

# 1. Introduction

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits ("the PIP Framework" or "the Framework") is an international arrangement that was adopted by the World Health Assembly in May 2011 in order to:

> **improve pandemic influenza preparedness and response and strengthen the protection against the pandemic influenza by improving and strengthening the WHO Global Influenza Surveillance and Response System (GISRS)** *(1)*.

The PIP Framework is an innovative partnership among Member States, industry, civil society and other stakeholders. Its aims are to improve both the sharing of influenza viruses with pandemic potential (IVPP) and equitable access to the products necessary to respond to pandemic influenza – such as vaccines, antiviral medicines and diagnostic products. Implementation of the PIP Framework strives to build sustainable capacities for preventing, detecting and responding to pandemic influenza.

The PIP partnership contribution high-level implementation plan III (HLIP III) operates within the scope of the PIP Framework and the initiatives and WHO resolutions it refers to. HLIP III will improve global pandemic influenza preparedness by guiding capacity building over the next six years, from 2024–2030. The Outcome that HLIP III is focused on realizing is:

> **Strengthened pandemic influenza preparedness through a whole-of-government and whole-of-society approach that ensures a more equitable response by building stronger and resilient country capacities.**

HLIP III has been designed so that all its Activities, Deliverables and Outputs lead to enhanced global capacities aligned with that one Outcome. That means creating a more equitable response to pandemic influenza by engaging various stakeholders and sectors and by investing in policy, preparedness planning and operational capacities. The initiatives detailed in HLIP III utilize partnership contribution (PC) preparedness funds, which are annual voluntary payments made by the influenza vaccine, diagnostic and pharmaceutical manufacturers that use the WHO GISRS.

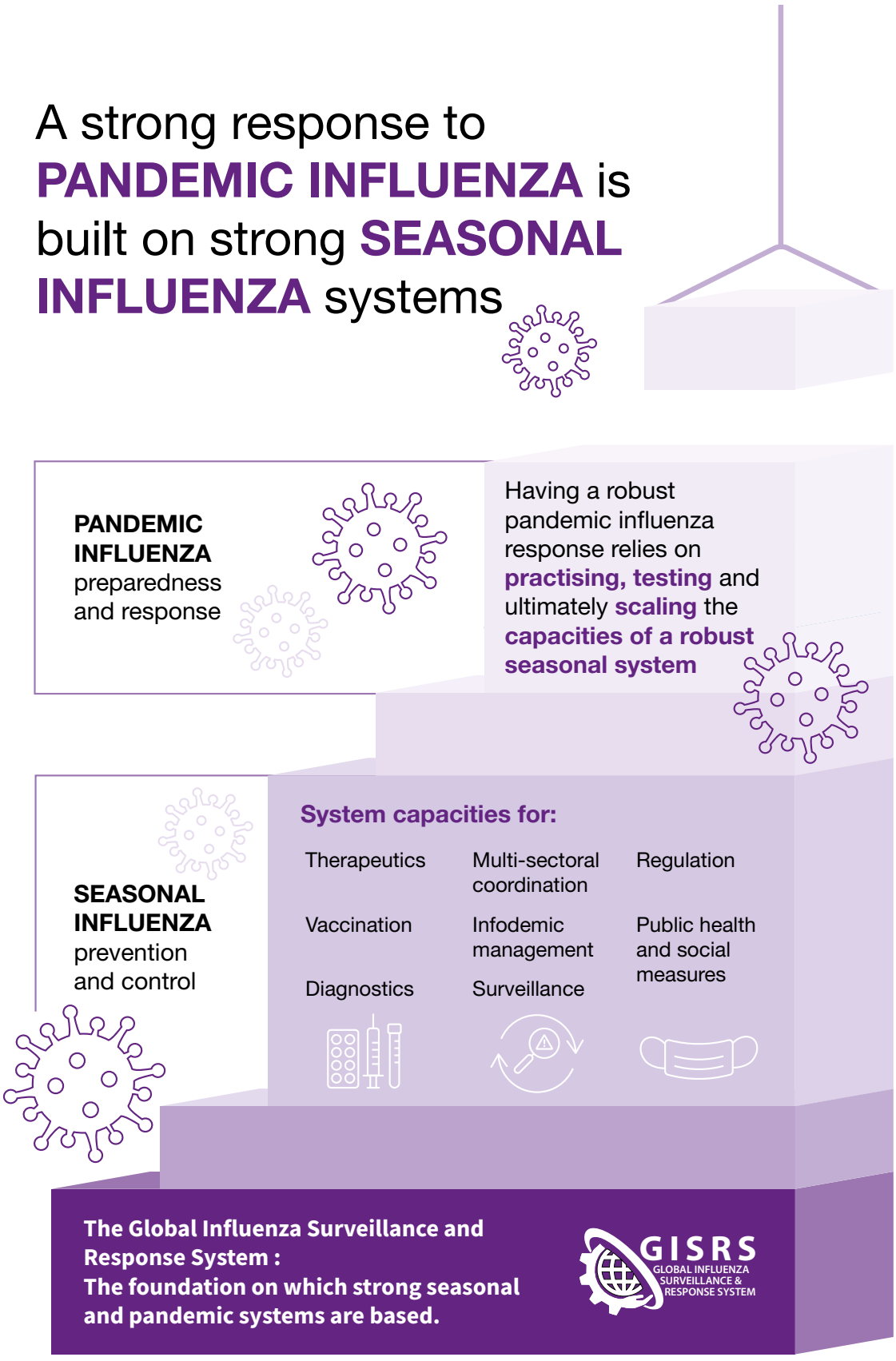
# 1.1 What is pandemic influenza preparedness?

The PIP Framework is focused on improving preparedness specifically for pandemic influenza, while remaining cognizant of the broader landscape and context for public health preparedness (see section 1.5). Preparedness is defined as the knowledge, capacities, and systems that work to reduce vulnerability and enhance resilience *(2,3)*. This is achieved by strengthening country, regional and global capacities to prepare for and respond to pandemic influenza.

Pandemic influenza preparedness involves building capacities by leveraging existing systems and broader capacities, including those for seasonal influenza. This approach enables countries to be efficient in their overarching influenza prevention, control and response programming, and to have in place effective and routinely exercised systems before a pandemic occurs (see Fig. 1). For example, evidence from the A(H1N1) influenza pandemic of 2009 has shown that countries with seasonal influenza vaccination programmes were faster at introducing and deploying pandemic influenza vaccines *(4)*.

Strengthening health system capacities – such as by building and training the health workforce, strengthening surveillance information systems, developing risk communication capacities, and improving access to medical products – are also critical for a robust response to an influenza pandemic. Preparing for an influenza pandemic is a collaborative undertaking that requires a whole-of-government and whole-of-society approach involving a wide range of stakeholders. This philosophy ensures that multiple sectors communicate and work together to achieve better public health outcomes.

**Figure 1. Seasonal influenza systems – the foundation of pandemic influenza preparedness**



# 1.2 Why pandemic influenza preparedness matters

The COVID-19 pandemic has sensitized the world to how profound an impact a pandemic can have on virtually all areas of society. WHO data show that, as of 31 December 2022, over 730 million cases globally had been confirmed as COVID-19, with over 6.6 million deaths *(5)*. Moreover, data from the International Monetary Fund indicate an economic downturn not seen since the Great Depression *(6)*.

Countries were better prepared to rise to the challenges posed by COVID-19 because of their pandemic influenza preparedness (PIP) planning, including gains made as a result of implementation of the PIP PC. The collateral benefits of PIP planning to the COVID-19 response are summarized in Table 1.

## Table 1. Gains supported by PIP PC implementation and the collateral benefits to the COVID-19 response

| | 1 | 2 | 3 |
|---|---|---|---|
| **Objectives**<br>PC objectives 2014–2023: All countries should have... | **well-established core capacities for surveillance, risk assessment and response** | **access to a National Influenza Centre (NIC)** | **a clearer picture of influenza burden of disease** |
| **Gains**<br>In 2014-2021, PC contributed US$ 112 million to: | **131** countries either started or improved their laboratory and surveillance systems for participation in GISRS (FluNet, FluID, seasonal influenza virus/sample sharing) | **13** new NICs designated by countries and recognized by WHO, bringing the global total to 148 in 124 countries | **48** countries (including 33 low- and middle-income countries) published burden of disease estimates.<br><br>The global seasonal influenza-associated respiratory deaths estimate was updated, and hospitalization burden estimate underway |
| **Benefits**<br>Collateral benefits to the COVID-19 response: | **76** countries integrated COVID-19 surveillance into influenza sentinel systems.<br><br>Influenza/GISRS platforms for External Quality Assessment Programme, sample and data sharing are used by countries for COVID-19 | Most (>90%) NICs serve as national COVID-19 reference labs | Expertise built at country level for estimating influenza morbidity and mortality is being used to better understand COVID-19 burden |

## Objectives

PC objectives 2014–2023: All countries should have...

**access to pandemic influenza vaccines and antiviral medicines**

**improved capacities to carry out effective risk communication and community engagement at the time of a pandemic**

## Gains

In 2014-2021, PC contributed US$ 112 million to:

- **37 of 63** PC countries updated influenza pandemic preparedness plans, 15 countries tested plans National deployment and vaccination planning guidance and tools were published and **45** countries trained
- **41 of 48** PC countries developed a regulatory roadmap for timely approval of pandemic influenza products
- **24 of 48** PC countries signatory to Collaborative Registration Procedure to streamline regulatory actions during emergencies

OpenWHO online learning platform with 23 influenza-related courses, over **228 000** users from **193** countries

## Benefits

Collateral benefits to the COVID-19 response:

- **177** countries developed COVID-19 plans based on approaches used in influenza plans; 72 conducted an intra-action review to update their response plans
- Influenza national deployment and vaccination planning guidance adapted; **151** countries used guidance for their COVID-19 national deployment and vaccination plans, including 89 of 92 COVAX Advance Market Commitment countries/economies
- **47 of 48** PC countries authorized ≥1 COVID-19 vaccine; of 45 with timeline data, 87% authorized a product ≤ 15 days of the WHO emergency use listing.
- **9 out of 10** PC countries that did not receive vaccines during the 2009 pandemic authorized ≥1 COVID-19 vaccines, with eight doing so in a timely way (≤ 15 days)

**6.35 million**
enrolments across 42 OpenWHO courses on COVID-19

Although the COVID-19 pandemic identified areas of global strength and resilience, it also highlighted important gaps and opportunities for improvement (see Table 1 above, section 1.8 below, as well as Annex 1). This consequently triggered countries to establish new capacities to better deal with the challenges posed by a pandemic. These enhanced capacities – along with the learnings from COVID-19 – now provide important foundations to further improve pandemic influenza preparedness.

Although it may be SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) that is etched most firmly into our memories, the past 100 years have seen four influenza pandemics. The most severe and deadliest pandemic was the 1918 A(H1N1) influenza pandemic, which infected an estimated one third of the global population and caused an estimated 50 million deaths. The subsequent 1957 A(H2N2) influenza pandemic caused 1–2 million deaths, but could have been far worse: the creation of a vaccine was responsible for saving hundreds of thousands of lives *(7)*. The 1968 A(H3N2) influenza pandemic saw over 500 000 case notifications within weeks of its emergence and circled the globe within a few months; a vaccine was available by the end of 1968, and the outbreaks appeared to be under control the following year. But influenza outbreaks and pandemics recur: most recently, the 2009 A(H1N1) pandemic was first detected in April and spread rapidly across the world, reaching 74 countries by June the same year.

There are two trends observable from these influenza pandemics. First, the increasing speed at which viruses spread globally. Secondly, we can be increasingly confident that – with appropriate intervention and by taking on board the lessons from the past – response capabilities can continue to improve. This means that we have an opportunity to be as well prepared as possible when the next influenza pandemic emerges, in order to minimize its spread and impact; it is this opportunity that HLIP III aims to realize.

## 1.3 Key opportunities in pandemic influenza preparedness

There are multiple opportunities for optimizing pandemic influenza preparedness. First, laying an essential foundation, by generating policies and plans that are institutionalized before the onset of an outbreak. Having appropriate policy and planning in place facilitates early response in order to suppress an influenza outbreak quickly, thus reducing the potentially catastrophic future impacts of an influenza pandemic.

Secondly, adequate preparedness is only effective if interventions can be triggered as soon as a virus with pandemic potential emerges; this requires investment in a strong infrastructure for early detection, based on sufficient laboratory capacity and resilient surveillance systems such as WHO GISRS.

Thirdly, in order to prevent interventions becoming the subjects of conjecture, speculation, poor-quality information and viral misleading content, it is also crucial that any proposed intervention is implemented in a way that considers community sentiment.

Lastly, safe, reliable, effective and affordable countermeasures are essential to enable optimal interventions to be implemented. These countermeasures need to be available in an equitable, timely and predictable manner so that they can be deployed where they are needed most.

Only by interweaving these four elements in a balanced manner can effective pandemic influenza preparedness realize the health and economic benefits of containing an influenza outbreak before it becomes a public health emergency.

Our experience with pandemics has made clear that the global needs for pandemic influenza preparedness are substantial. The financial resources needed to prepare the world for an influenza pandemic therefore far exceed the PC preparedness funds. However, the funds available do make a critical contribution to enhancing and accelerating preparedness. In order to maximize the return on investment of the PC preparedness funds, the application of the funds is informed by important lessons learned from application of the previous HLIPs and from the recent COVID-19 pandemic, and consideration of the broader evolving landscape for pandemic preparedness.

## 1.4 How are PIP PC funds utilized?

The overall objective of the PIP Framework is to improve pandemic influenza preparedness and response and to strengthen protection against pandemic influenza by improving and strengthening GISRS. Additionally, section 6.14.4 of the PIP Framework indicates that the PC funds are to be used for "improving pandemic preparedness and response, inter alia, for conducting burden of disease studies, strengthening laboratory and surveillance capacity, access and effective deployment of pandemic vaccines and antiviral medicines".

The high-level implementation plans specify how the PC funds will be used to achieve these aims. The first high-level implementation plan was developed for and implemented in 2014–2017; the second covered the six-year period of 2018–2023. This third iteration incorporates lessons learned from: implementation of HLIP I and HLIP II; global and country level responses to the COVID-19 pandemic; and programmatic and policy aspects for pandemic preparedness set through the Global Influenza Strategy *(8)*.

HLIP III sets out to incorporate all that we have learned while also ensuring continuity with the previous plans, enabling improvements in capacity over time to be properly assessed and the sustainability of our efforts to be monitored. HLIP III was developed in 2022 through analyses of the literature and through a robust consultation process. Further detail on the development process for HLIP III can be found in Annex 2.

# 1.5 What is the context for PIP implementation?

While PIP investments are focused on strengthening pandemic influenza preparedness specifically, there are broad synergies with global frameworks addressing the underlying health systems and capacities that augment preparedness. Aligning HLIP III with those initiatives ensures that they are complementary and mutually reinforcing. This creates a rich context for the sustainable implementation of pandemic influenza preparedness.

As shown in Fig. 2, key frameworks include the WHO Global Influenza Strategy *(8)*, the International Health Regulations (IHR) (9) , the Global Architecture for Health Emergency Preparedness Response and Resilience *(10)*, Health Systems Strengthening and Universal Health Coverage *(11)*, and the Sustainable Development Goals *(12)*. HLIP III's alignment with each is described below.

## Global Influenza Strategy 2019–2030

The three key goals of the Global Influenza Strategy 2019–2030 are to reduce the burden of seasonal influenza, minimize the risk of zoonotic influenza, and mitigate the impact of pandemic influenza *(8)*. The Global Influenza Strategy positions pandemic planning as being rooted in strong influenza prevention, control and response programmes as part of the wider health system. Seasonal and zoonotic influenza programmes, policies and systems are inherently connected to pandemic influenza preparedness and response and are commonly implemented by similar sets of stakeholders for efficiency and effectiveness. Countries are thus encouraged to consider the systems, capacities and capabilities needed in the continuum of seasonal, zoonotic and pandemic influenza (see Fig. 1).

Strategic Objective 4 of the Global Influenza Strategy sets out to "strengthen pandemic preparedness and response for influenza to make the world safer" *(8)*. The objective focuses on strengthening national, regional, global and multisectoral collaboration in order to ensure that preparedness efforts are better aligned, so that the response to a pandemic can be more timely and more effective. HLIP III will contribute directly to this Strategic Objective. Articulating the HLIP III results hierarchy and aligning it with the Global Influenza Strategy is critical for efficient and effective programme delivery. The common framework of the Strategy enables countries to consider HLIP III support in line with their own pandemic influenza investments and to maximize the coherence of support provided by other partners.

## International Health Regulations (2005)

The IHR (2005) are an instrument of international law that is legally-binding on 196 countries, including the 194 WHO Member States *(9)*. The IHR require 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 III benefits a wide range of country capacities required under the IHR (2005).

## Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience *(10)*

The deficiencies revealed by the COVID-19 pandemic have highlighted the need for a stronger and more inclusive health emergency preparedness, response, and resilience (HEPR) architecture. The proposed architecture for HEPR was presented to the Seventy-fifth World Health Assembly in 2022. The architecture describes emergency coordination, collaborative surveillance, community protection, clinical care and access to countermeasures as the five core subsystems needed to prevent, prepare, detect and respond effectively to health emergencies at country, regional and global levels. Together, the five components are embedded in health system and multisectoral capacities and action, and are underpinned by governance, financing and the three principles of equity, inclusivity and coherence. The global implementation plan for HEPR will be based on this architecture. HLIP III aligns with the overarching HEPR approach by recognizing the need for stronger capacities and whole-of-society engagement for better preparedness and response to future emergencies including pandemic influenza.

## Universal Health Coverage and Health Systems Strengthening

Universal health coverage is defined by WHO as all people having access to the health services they need, when and where they need them, without financial hardship *(11)*. To achieve this, health systems must be strengthened by focusing on six core components: leadership and governance, service delivery, health system financing, health workforce, medical products, vaccines and technologies and health information systems. Global strategies and roadmaps, including for health workforce *(13)* and for access to medicines, vaccines and health products *(14)*, set an important frame for disease-specific capacity strengthening; HLIP III aligns with this approach, whereby implementation will address the foundational system capacities required for an adequate pandemic response.

## Sustainable Development Goals *(12)*

In 2015, the United Nations adopted 17 goals with the aim to eliminate poverty, inequality and ensure a sustainable future for all on the planet. Of relevance to global public health is Goal 3 on Good Health and Well-Being. HLIP III directly contributes to Target 3.d: “Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks” *(12)*.

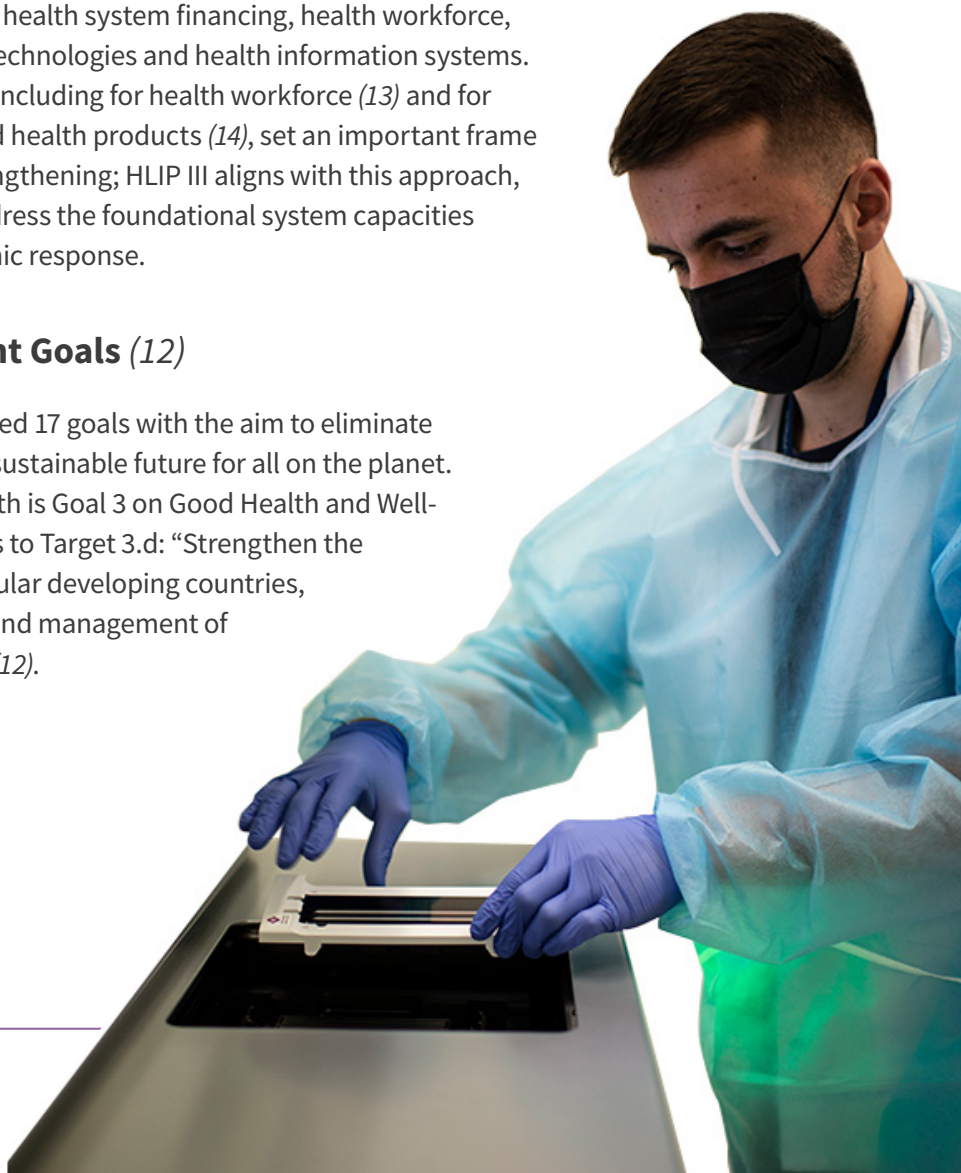
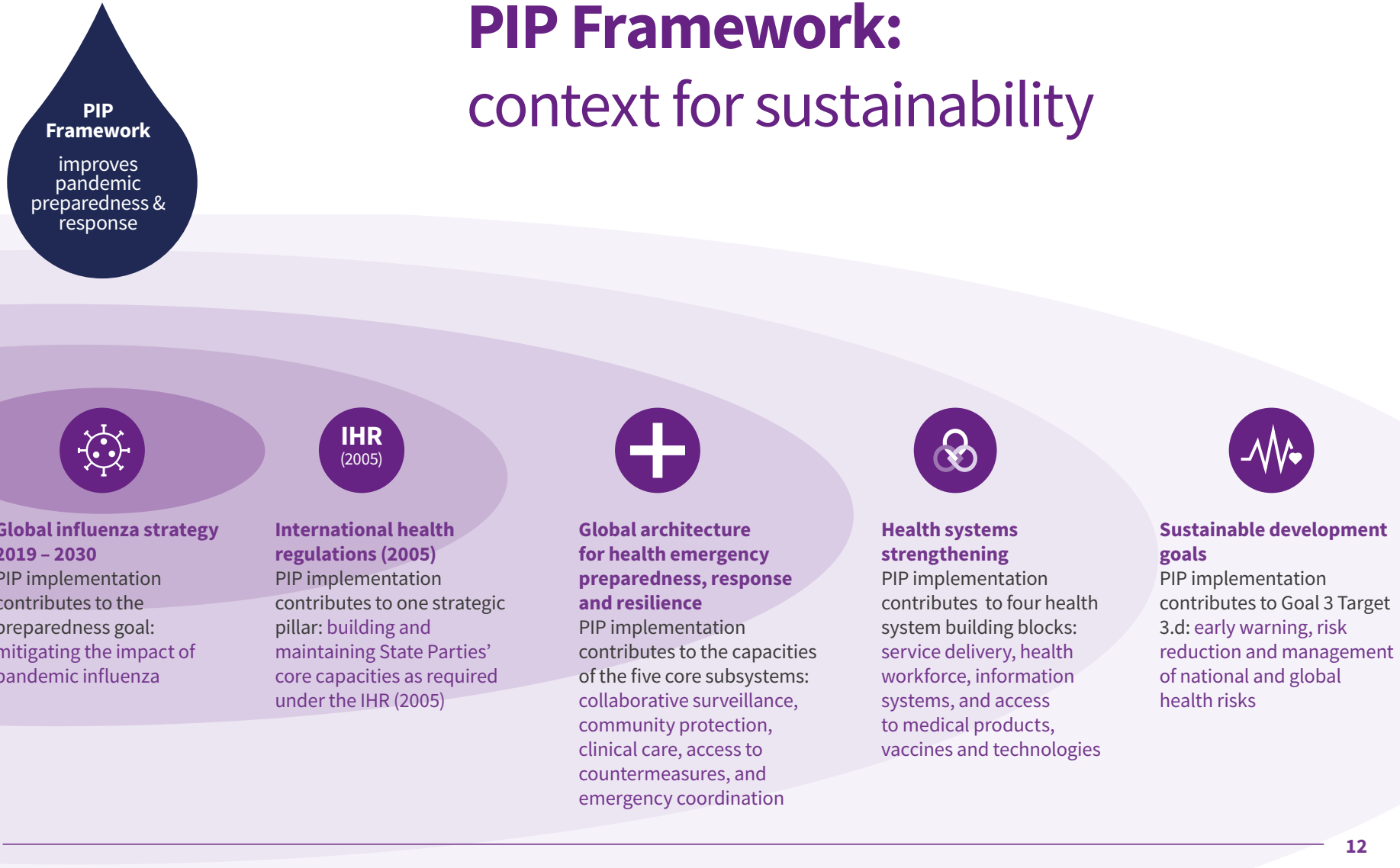


**Figure 2. The collateral benefit and context for sustainable implementation of the PIP Framework**



## 1.6 Stakeholder context

The development and effective implementation of HLIP III happens in a rich stakeholder mosaic which brings together multiple sectors. Key stakeholders involved in realizing the joint outcome of HLIP III are listed below.

- **Countries**, especially Ministries of Health, are key implementers of PIP PC funds and are at the heart of pandemic influenza preparedness.
- **GISRS institutions** include NICs, which are the mainstay of the system for influenza global alert, detection and surveillance and share viruses and other information. WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories provide expert analysis and technical capacity building.
- **Industry** provides the PC funds and the products needed for influenza prevention, control and response.
- **Civil society organizations** ensure that country and community needs are equitably met.
- **Influenza development partners** are engaged in influenza preparedness and response.
- **PCITEM** provides scientific and technical guidance and advice on projects selected for funding under the PIP PC.
- **The PIP Advisory Group** provides regular advice to the WHO Director-General on the use of resources and interacts with stakeholders.

As of December 2022, Member States are negotiating a pandemic accord to strengthen pandemic prevention, preparedness and response. This may change the context for implementation and Member State priorities for pandemic preparedness; in that event, HLIP III would be updated accordingly.

## 1.7 Building on previous PIP gains and lessons from implementation

HLIP III builds on gains made, opportunities identified, and challenges experienced through implementation of HLIP I and HLIP II. Progress in pandemic influenza preparedness was made in line with the five strategic objectives set for HLIP implementation in 2014–2023 (see Table 1 above).[1] GISRS was strengthened and the burden of disease better understood in low- and

1 Unless otherwise indicated, data and figures referenced in this document reflect the programmatic gains made between 2014 and 2022, as reflected in the PIP Framework six-monthly progress reports found on the PIP website: https://www.who.int/initiatives/pandemic-influenza-preparedness-framework/partnership-contribution

middle-income countries to drive pandemic preparedness policies. Operational planning for an influenza pandemic further advanced at country and global levels, including in risk communication and community engagement (RCCE), as well as in health system capacities for regulatory readiness, health workforce and access to medical products. Functional capacities were strengthened so that they are ready to surge during a future influenza pandemic response.

HLIP III was also shaped by several challenges experienced during previous HLIP implementation. In earlier years, there was limited decision-maker attention for preparedness in low-resource settings or in countries that experienced multiple emergencies. This changed over time through the increased availability of surveillance and burden of disease data, the launch of the Global Influenza Strategy in 2019, as well as the COVID-19 pandemic, which highlighted the criticality of preparedness and functional systems. Other challenges that shaped HLIP III included the limited health workforce available at country level to advance operational components such as pandemic product deployment planning and RCCE. HLIP III helps address these challenges by building on the incremental gains made over time as well as by promoting networks and approaches that bring countries together to share experiences and collaborate.

As shown in Table 1 above, the accomplishments achieved under previous HLIPs have collaterally benefited the COVID-19 pandemic response. As identified through the mid-term review of HLIP II, which was conducted one year into the COVID-19 pandemic, PIP implementation enabled countries to rapidly adopt or adapt capacities relevant for the response. In essence, PIP contributed to the systems and capacities that prepared countries for the COVID-19 pandemic. Conversely, the mid-term review identified that the response to COVID-19 catalysed the development and strengthening of capabilities that are in turn relevant for a future influenza pandemic. As the landscape for investing in pandemic influenza preparedness will continue to evolve in the coming years, it is important that investments build upon lessons learned during COVID-19 as they apply to pandemic influenza.

## 1.8 Lessons from the COVID-19 response

The response to the SARS-CoV-2 pandemic has flagged important gaps and considerations for global, regional, and country-level pandemic preparedness. These include:

- the role of public health and social measures;
- whole-of-society and whole-of-government readiness and response;
- the value and challenge of modified diagnostic and clinical care pathways for surveillance; and
- the need to consider and address clinical management capacities and surge infrastructure requirements, among others.

International reviews of the COVID-19 response conducted during the pandemic were used to inform HLIP III design. These included the reports of the Independent Panel for Pandemic Preparedness and Response *(15)*, the Report of the IHR Review Committee on the Functioning of the International Health Regulations (2005) *(16)* and reports from the G7 and G20 *(17,18)*. A total of 300 recommendations from the reports were reviewed *(19)*.

At the country level, intra-action reviews (IARs) were conducted during the COVID-19 response to identify opportunities to further strengthen country emergency preparedness and response capacities and course correct the response as needed. As of 14 April 2022, 120 intra-action reviews had been conducted globally by 73 countries across all six WHO regions.

The international- and country-level reviews illustrated how governments leveraged existing systems and resources, innovated new solutions, and strategized their response. Recurring themes were that the world had not expected a public health crisis of this magnitude and countries did not feel they were adequately prepared for it, as they did not have in place adequate infrastructure, human, material and financial resources to manage the emergency. Linked to this were challenges related to preventing the surge in COVID-19 cases from collapsing the healthcare systems. Lastly, as vaccines became available, countries and partners had to identify ways to get new vaccines produced, approved and rolled out at unprecedented speed.

Many cross-cutting themes emerged regarding country efforts to overcome the COVID-19 pandemic. These included:

- **repurposing existing policies**, strategies, plans, standard operating procedures and human resources to respond rapidly to the crisis;
- **maximizing multisectoral coordination**, public-private partnerships, academic collaboration, and civil society engagement during response operations;
- **ramping up the use of digital innovations** to increase the efficiency of contact tracing, RCCE, monitoring vaccine uptake; and
- **creating inter-operable systems** between different sectors.
- **data- and information-sharing** were key, including through tools originally designed for the management of influenza-related data such as WHO's FluMART for epidemiological and virological data sharing and the Global Initiative on Sharing Avian Influenza Data (GISAID) for genomic data sharing.

These findings provided a rich evidence base for the gaps and needs for future pandemic influenza preparedness, and helped shape the HLIP III results hierarchy described below in Chapter 2.

The following key lessons learned are elaborated on in Annex 1.

- Influenza preparedness helped with the COVID-19 response; the COVID-19 response can now help pandemic influenza preparedness.

- The criticality of building community trust and engaging people in the protective actions needed to effectively respond to a pandemic.
- Understanding the burden of influenza informs preparedness policies and planning.
- Policies and plans need to be flexibly constructed to deploy and equitably distribute pandemic products as technologies evolve.
- One Health thinking enables surveillance systems to rapidly detect, assess and respond to influenza viruses with pandemic potential.
- Pandemic influenza preparedness needs to account for the lessons from COVID-19 to optimize clinical care policies and planning.

## **Box 2.** Building on COVID-19 lessons: future national influenza pandemic preparedness planning, a case study from Islamic Republic of Iran

Since 2018, the PIP PC has been investing in the development, updating and exercising of influenza pandemic preparedness plans so that countries are better prepared to respond at the time of the next pandemic. This involves political commitment, multisectoral engagement and coordination and risk assessment, and ensures that adequate infrastructure, financing, human resources, and equipment are in place *(2)*.

In early 2019, the Iranian Ministry of Health and Medical Education began drafting its national influenza pandemic preparedness plan, using the three-phased approach defined by WHO's essential steps in developing or updating a national pandemic influenza preparedness plan. When the COVID-19 pandemic struck, the Iranian Ministry of Health and Medical Education team continued developing the influenza pandemic preparedness plan and expanded the planning process by analysing the gaps and challenges faced during the response and developing a real-time roadmap and implementation plan. The result was a national influenza pandemic preparedness plan that is comprehensive, multisectoral and multidisciplinary.

Moving forward, the PIP PC will continue to support countries in strengthening systems and capacities for influenza pandemic preparedness and ensuring that effective plans are in place and routinely exercised.

To learn more about Iran's experience, see the full story on the WHO website: https://www.who.int/news/item/14-10-2022-influenza-pandemic-preparedness-planning-in-the-islamic-republic-of-iran

# 2. Implementation plan

The architecture of the HLIP III was developed in accordance with the concepts of the WHO results chain (see Fig. 3). This ensures that PC preparedness funds are invested in activities that contribute to achieving deliverables, which are project-based priorities. This in turn contributes to achieving the broader outputs, outcome and overall impact.

HLIP III has one overall outcome, which contributes to improved global pandemic influenza preparedness:

> **Strengthened pandemic influenza preparedness through a whole-of-government and whole-of-society approach that ensures a more equitable response by building stronger and resilient country capacities.**

This outcome is supported by four outputs.

**Output 1. Policy and plans** that result in health systems prepared for pandemic influenza.

**Output 2. Collaborative surveillance through GISRS** laboratory capacity and resilient surveillance systems maintained and strengthened through GISRS

**Output 3. Community protection** strengthened community engagement, knowledge translation and infodemic management capacities for influenza

**Output 4. Access to countermeasures** strong regulatory systems and a common approach to timely and affordable access, allocation and deployment of pandemic influenza products results in a more equitable response.

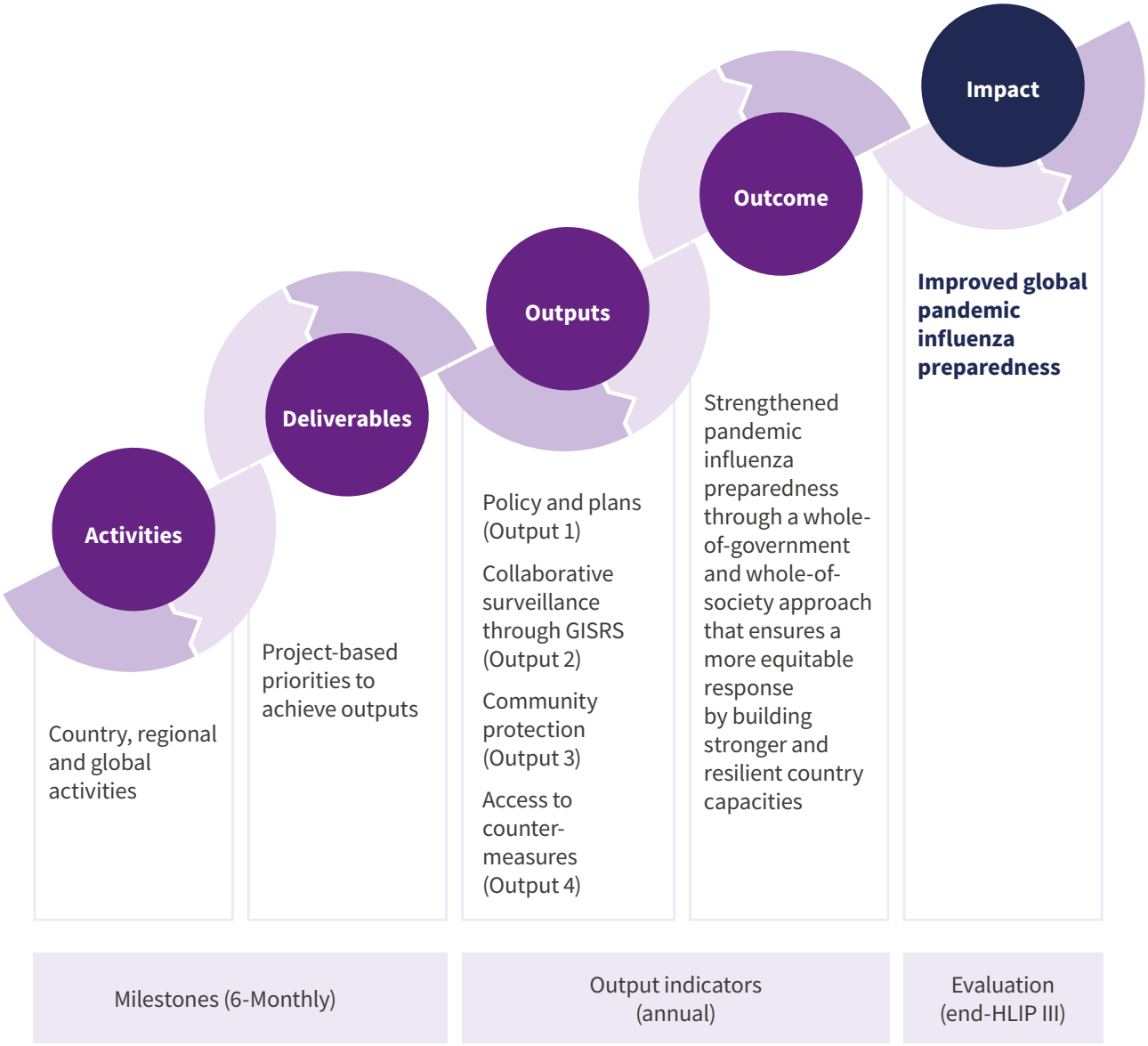
For each output there is a corresponding set of deliverables, which are achieved through implementation of activities. Some activities will directly strengthen capacities in PC recipient countries, while others will benefit all countries through implementation at global or regional level. However, activities will differ depending on the region and country context and needs. The approach to country prioritization is detailed in Chapter 3.

As is illustrated in the WHO Results Chain Overview in Fig. 3, progress towards the implementation of activities and deliverables will be monitored against milestones. Specific indicators will be used to monitor progress towards each output and the overall outcome. The milestones and indicators facilitate monitoring and communication of progress over the six years covered by HLIP III and serve as the basis for reporting. The details for each indicator, including its rationale, 2023 baseline and 2024–2030 target, will be made available in a separate HLIP III Monitoring and Evaluation Framework.

A visual summary of the HLIP III results hierarchy using this results chain is presented in Fig. 4. Details on financing, governance, monitoring, evaluation and reporting are presented in Chapter 3.

The following pages provide detail on each of the four outputs and their corresponding deliverables, indicative activities and indicators.

## Figure 3. WHO Results Chain Overview



## Figure 4. HLIP III 2024–2030 results hierarchy

### 1 Policy & plans

**Policy and plans that result in health systems prepared for pandemic influenza**

a. Health and economic influenza burden of disease informs the development of policy
b. Influenza preparedness policies are strengthened in the context of health systems
c. Pandemic preparedness plans are developed, updated and exercised across sectors
d. Policies are developed for equitable and sustained availability of pandemic influenza vaccines and other products

### 4 Access to countermeasures

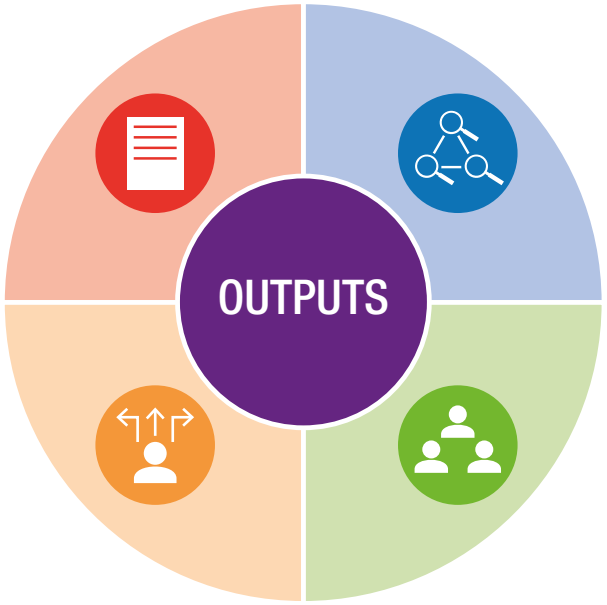
**Strong regulatory systems and a common approach to timely and affordable access, allocation and deployment of pandemic influenza products results in a more equitable response**

a. Regulatory readiness and resilience in countries is enhanced
b. A common approach to managing global access, allocation and deployment of pandemic products including SMTA 2 operationalization is prepared
c. Country capacity to deploy and distribute pandemic products is strengthened

Contributes to the Global Influenza Strategy's Strategic Objective 4: Strengthen pandemic preparedness and response for influenza to make the world safer.

## OUTCOME

Strengthened pandemic influenza preparedness through a whole-of-government and whole-of-society approach that ensures a more equitable response by building stronger and resilient country capacities.




### 2 Collaborative surveillance through GISRS

**Laboratory capacity and resilient surveillance systems are maintained and strengthened through GISRS**

a. Laboratory capacities, including genomics, are strengthened
b. Resilient surveillance systems are improved and maintained in a One Health context

### 3 Community protection

**Strengthened community engagement, knowledge translation and infodemic management capacities for influenza**

a. Country risk communications and community engagement (RCCE) systems and capacities are enhanced and regularly exercised for influenza
b. Knowledge translation capacity is developed and enhanced
c. Effective infodemic management systems in place

# Output 1: Policy and plans

**Policy and plans that result in health systems prepared for pandemic influenza**

Pandemic preparedness and response rests on the foundation of the policies and plans that are institutionalized prior to the onset of the event. Having appropriate policy and planning in place means that authorities can quickly trigger actions that address the event and mitigate its impact until effective preventive countermeasures are developed and rolled out. Appropriate policy and planning for influenza pandemic preparedness should include (i) understanding the burden of disease, (ii) coordinating within wider health system policies, and (iii) engaging multiple sectors to be ready to deliver effective interventions when they are needed.

Important gains in understanding influenza disease burden and impact on society have been made since 2014. Forty-eight countries now have influenza health burden data estimates and four have economic burden estimates. Of 194 countries globally, 144 reported (between 2018 and 2020) having influenza vaccine policies and 102 reported updating policies. Importantly, countries with burden data were more likely to update their policies, as the data provide impetus to refine policies, including to determine which groups are at high risk of severe disease or which groups should be prioritized for countermeasures. This impetus also came following the launch of the Global Influenza Strategy in 2019, which saw increased attention for policy development. It must be recognized however, that attention to influenza prevention and control policies remains uneven, and that more support is needed, especially for low- and middle-income countries, in elaborating the key clinical, public health and social measures needed during the response.

This need is captured in Deliverable A and the associated indicative activities and monitored by determining the number of Member States with published disease burden estimates based on data collected since 2011 as a key indicator, and in Deliverable B by focusing on establishing, updating and implementing influenza prevention, control and preparedness policies.

Influenza pandemic preparedness has played a key role in supporting countries to respond to the COVID-19 pandemic, demonstrating the value of preparedness for a wide range of disease threats, not just influenza. Additionally, the COVID-19 response ignited numerous innovations, including in vaccine platforms, that have the potential to change the landscape and response to an influenza pandemic in the coming years. Maintaining momentum and engagement will make it possible to build on the technological gains and lessons from COVID-19, alongside the successes and gains already made in pandemic influenza preparedness.

A key lesson from COVID-19 is that pandemic preparedness requires continuous investment into updating and exercising of comprehensive plans that are multisectoral and engage the whole of society. Now that multisectoral decision-makers around the world appreciate the gravity and critical nature of pandemic planning, plans should feed into and be referenced in broader national health strategies and emergency response action plans in order to facilitate national level implementation, financing and monitoring as part of sustainable implementation.

Although influenza preparedness planning at country level collaterally benefited the COVID-19 pandemic, some countries continued to face a lack of the resources needed to rapidly put policy and plans in place. Of 63 PC countries supported in 2018–2021, thirty-seven developed influenza pandemic preparedness plans, but these need to be further updated and the remaining ones developed, taking into consideration COVID-19 lessons and updates in WHO guidance.

The importance of equitable pandemic policy and planning is one of the key lessons from COVID-19 pandemic. As a WHO staff member noted, “When it comes to a crisis, if you don’t have a system in place, you can’t have equity”. This echoes HEPR (June 2022) *(10)*, which emphasizes the importance of the principles of equity, inclusivity, and coherence in building a stronger global health security architecture.

Deliverable C reflects this multisectoral approach to pandemic preparedness planning in its indicative activities, such as the integration of relevant public health and social measures.

Further highlighted was the importance of public-private cooperation that can improve both pandemic/emergency surveillance and the capacity to develop, manufacture and deliver medical countermeasures in a pandemic/emergency. A multisectoral approach to pandemic preparedness policy and planning is thus central to ensuring equitable and sustainable access to medical countermeasures in a time of crisis.

Deliverable D focuses on assuring that global policies are developed for equitable and sustained availability of pandemic influenza vaccines and other products which will be monitored by evaluating the number of Member States that have undertaken a national analysis of influenza vaccine procurement or production sustainability (Indicator 1.5). As described in Annex 1, WHO technical assistance and support to countries will facilitate sustainable vaccine policy and delivery systems while accounting for emerging technologies and an ever-changing landscape.

These lessons demonstrate the importance of continuous learning and improvement in health systems. To strengthen pandemic influenza preparedness, there is therefore a need to establish, update and implement influenza prevention, control and preparedness policies (Deliverable B), that are well informed by health and economic influenza burden of disease (Deliverable A). Pandemic preparedness plans should be developed, updated and exercised across sectors (Deliverable C), and should be in line with global policies developed for equitable and sustainable availability of pandemic influenza vaccines and other products (Deliverable D).

Following the COVID-19 pandemic, there is a key opportunity to engage political and senior officials so that they can help shape effective and sustainable country influenza pandemic preparedness policies.

Details of the deliverables, indicative activities and indicators for measuring progress against this Output are set out in Tables 2 and 3.

## **Box 3.** The power of partnerships: estimating seasonal influenza burden

Most low- and middle-income countries with influenza surveillance systems collect and report data on hospitalizations and, sometimes, deaths. However, few distinguish between mild/ moderate non-hospitalized cases and critically ill hospitalized cases. Quantifying the burden of influenza across the disease severity spectrum is important in order to be able to understand and address the full impact of seasonal influenza on health systems and societies.

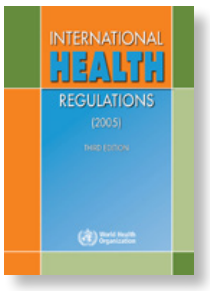
Since the start of PIP PC implementation in 2014, measuring the burden of disease has therefore been a key area of focus. By 2022, 48 countries, including 33 low- and middle-income countries, published their burden estimates, which has additionally contributed to a better understanding of the global burden.

Partnerships are key and have helped WHO to develop guidance, advocacy products and collaboratively build an enabling environment in which countries can enumerate burden and use the findings to strengthen influenza pandemic preparedness and response planning. Most recently, WHO worked with the Johns Hopkins Center for Health Security on a user-friendly webtool to facilitate the estimation of seasonal influenza burden across the disease severity pyramid, from mild/ moderate non-hospitalized cases to influenza-associated deaths, with a focus on medically attended illness. The tool, which is called the Seasonal Influenza Burden of Disease Estimator, uses a multiplier-based approach that allows countries with data on influenza-associated hospitalizations or deaths to estimate seasonal influenza burden at all levels of the disease severity pyramid.

As we look towards the future, continuing investments in this area will be critical for the development of more effective policies, by furthering understanding of the burden across disease severity, the burden averted by influenza vaccination programmes, and the cost-effectiveness of vaccinations or other interventions.

To learn more about the Seasonal Influenza Burden of Disease Estimator webtool, see https://www.who.int/news/item/14-10-2022-estimating-seasonal-influenza-burden-across-the-disease-severity-pyramid and https://www.flutool.org.

## Context of Output 1 with other WHO Programmes (see also section 1.5)




**International Health Regulations (2005)** ***(9)*****.**

Supports countries to improve seven IHR core capacities: Policy, Coordination, Financing, Health emergency management, Health service provision, Infection prevention and control, Point of entry and border health.

**Global Influenza Strategy 2019–2030** ***(8)*****.**

Strengthens national, regional and global planning to enable timely and effective pandemic readiness.

**10 proposals to build a safer world together** ***(10)*****.**

Supports building HEPR capacities in emergency coordination and clinical care.

## Table 2. Output 1: Policy and plans - deliverables and corresponding activities

| Deliverables | | Indicative activities (Output 1) |
|---|---|---|
| A | **Health and economic influenza burden of disease informs the development of policy** | • Provide improved and updated national, regional and global estimates of influenza burden, including additional disease burden endpoints ranging from mild disease to deaths, estimates for subgroups and economic analysis, cost-effectiveness analyses, through the gathering of relevant data and providing training and mentoring.<br>• Develop tools and provide guidance to help communicate health and economic influenza disease burden findings to national and international expert bodies in a format that promotes usage and evidence-based policy decision-making. |
| B | **Influenza preparedness policies are strengthened in the context of health systems** | • Support countries in developing, implementing and strengthening national influenza management policies including for clinical care, appropriate use of therapeutics, and access and benefit sharing.<br>• Ensure countries integrate relevant public health and social measures for the prevention and control of influenza into national programmes.<br>• Assist countries in developing and strengthening national influenza immunization policies to target groups, and monitor uptake, coverage, acceptance and demand. |
| C | **Pandemic preparedness plans are developed, updated and exercised across sectors** | • Support countries in developing or updating plans for pandemic influenza in line with national planning approaches (for example, include as part of an all-hazard, respiratory pathogen, or influenza-specific plan).<br>• Facilitate the elaboration and implementation of preparedness actions across sectors and at different levels as determined by country needs and context, and in light of COVID-19 pandemic lessons learned.<br>• Enable countries to test pandemic preparedness plans including across sectors on a regular basis. |
| D | **Policies are developed for equitable and sustained availability of pandemic influenza vaccines and other products** | • Provide technical assistance and policy guidance to countries, including those that are establishing manufacturing capacity for improved vaccine technologies, to ensure sustainable influenza vaccine procurement, production and distribution.<br>• Coordinate engagement activities with stakeholders (for example, countries, industry and civil society) on influenza vaccine and other product production and implementation issues, including the monitoring of global production capacity and pre-pandemic vaccine development. |

## Table 3. Output 1: Policy and plans - indicators

| Indicator | | Mapped deliverable |
|---|---|---|
| 1.1 | # of Member States with published disease burden estimates based on data collected since 2011 | A |
| 1.2 | # of Member States that developed or updated an influenza vaccination policy | B |
| 1.3 | # of Member States that developed or updated a pandemic preparedness plan inclusive of influenza | C |
| 1.4 | # of Member States that exercised their pandemic preparedness for influenza including across sectors | C |
| 1.5 | # of Member States that have undertaken a national analysis of influenza vaccine procurement or production sustainability | D |
| 1.6 | Global production capacity for pandemic influenza vaccines and antivirals | D |

## **Box 4.** Monitoring global influenza vaccine production capacity

The Global Influenza Strategy called for better global tools, including vaccines, for influenza prevention, preparedness and response. “While research towards developing next-generation” – including universal – “influenza vaccines is ongoing, the current strategy for vaccine supply in a pandemic relies on seasonal influenza vaccine production being switched over to pandemic vaccines. Understanding how much vaccine could be produced, in which regions of the world and in what timeframe is critical to informing influenza pandemic preparedness.” *(20)*

Estimated annual seasonal influenza vaccine production capacity changed little between 2015 and 2019, increasing from 1.47 billion to 1.48 billion doses with potential maximum annual influenza pandemic vaccine production capacity increasing from 6.37 billion to 8.31 billion doses. These figures present a best-case scenario, with several assumptions which may impact supply. A moderate-case scenario shows that 4.15 billion doses of pandemic vaccine could be available in a 12-month period. Continued efforts are needed to ensure the sustainability of this production and to conduct research for vaccines that are faster to produce and more broadly protective taking into account lessons learned from COVID-19 vaccine development. *(20)*

As part of this high-level implementation plan for 2024–2030, WHO will provide technical assistance and policy guidance to countries, including those that are establishing manufacturing capacity for improved technologies, and will continue to monitor production capacity and pre-pandemic vaccine development.

# Output 2: Collaborative surveillance through GISRS

**Laboratory capacity and resilient surveillance systems are maintained and strengthened through GISRS**

Pandemic influenza response requires the ability to detect a disease event and alert the global community early. Building an effective global surveillance system is therefore paramount in order to enable an early and effective response to a virus with pandemic potential. Over 70 years after GISRS was established, its task of monitoring and alerting countries and other stakeholders to an influenza virus of pandemic potential is as important as ever.

Building an effective global surveillance system requires, firstly, that countries have the capacity to detect influenza in their populations. Gains made by GISRS here are a core success, with an additional 13 national institutions being designated National Influenza Centres (NICs) in 2014–2021. This brings the total number of NICs to 148 in 124 countries, with potential to increase this in the coming years.

After detection, countries need to be able to report data on detected influenza, including alerting in the event of influenza viruses of pandemic potential. This capacity has been further strengthened in recent years, with 73% of countries reporting virological data and 68% reporting epidemiological data to WHO. It is imperative, however, that reporting is strengthened further still so that no potential pandemic influenza virus slips through the surveillance net. With this in mind, Deliverable A focuses on further strengthening the laboratory capacities, including genomics, required for adequate surveillance.

There is an important place for novel innovations to strengthen and leverage existing systems to facilitate integrated and resilient surveillance for influenza viruses with pandemic potential. Specifically, the roll-out of genomic surveillance for SARS-CoV-2 presents an opportunity to increase the timeliness of country-level influenza surveillance, where there is a need to emphasize the quality and timeliness of data.

In 2021–2022, a jump from 105 to 131 countries with sequencing capacity used for SARS-CoV-2 indicates the proliferation of this technology. Recently published WHO guidance on end-to-end integrated influenza/SARS-CoV-2 surveillance presents an opportunity for further capacity growth, capitalizing on the gains made during COVID-19 and developing technical capacity at a global scale for pandemic Influenza surveillance *(21)*.

COVID-19 has served as a timely reminder that resilient early detection at a global level can only be realized when surveillance systems are collaborative between countries. The development

of a mosaic of "event-based outbreak detection and One Health response at the animal-human interface, strong clinical networks of sensitized clinicians, and strong laboratory networks" across countries, especially incorporating sentinel influenza surveillance, is paramount in ensuring that surveillance capacities are maintained and integrated into a comprehensive web of virus detection. Deliverable B captures these ambitions.

In addition to this, the increasing impact of environmental degradation and climate change on human health has shown a key need to integrate animal and environmental health into how surveillance systems assess risk. As noted in the Joint Risk Assessment Operational Tool of the Tripartite Zoonoses Guide:

> **bringing together national information and expertise from all relevant sectors for the joint assessment of health risks from zoonotic disease allows all sectors, acting together, to evaluate fully, understand and manage shared risks at the human-animal-environment interface** *(22)***.**

This perspective recognizes the ways in which environment and animal health can spill over into humans through zoonoses, thereby increasing the risk of the emergence of influenza viruses of pandemic potential.

## **Box 5.** "First time" achievements in pandemic influenza preparedness in two regions with high humanitarian and public health vulnerabilities, 2014-2021

The Africa and Eastern Mediterranean regions suffer a large burden of humanitarian vulnerabilities. Between 2014 and 2021, nine of the ten United Nations system-wide scale ups in response to emergencies occurred in these two regions *(24).*

Despite the multiple emergencies, significant gains in pandemic influenza preparedness were made in both regions, thanks to PC investments in laboratory and surveillance capacities. For example:

- Four NICs were newly recognized by WHO in three African countries and one Eastern Mediterranean country, bringing the total number to 33 NICs in 31 countries in these two regions.
- Fifteen countries started sharing influenza viruses or clinical specimens with WHO collaborating centres since 2014, 12 in the African region and 3 in the Eastern Mediterranean region.

These gains represent global solidarity to ensure that populations everywhere, regardless of context, are supported to strengthen their preparedness for a future influenza pandemic. The work operationalizes equity, which is at the heart of the PIP Framework, and WHO's mandate to serve the vulnerable. Building on the success to date, equity will guide delivery of HLIP III.

To learn more about these achievements, see the full story on the WHO website: https://www.who.int/news/item/21-03-2022-first-time-achievements-in-pandemic-influenza-preparedness-in-two-regions-with-high-humanitarian-and-public-health-vulnerabilitie-s-2014-2021

This One Health approach – a view of the health of the environment, animals, and human beings as one – represents a particular opportunity in global surveillance systems. The nature of influenza as a zoonotic disease provides ample opportunity for coordination between animal and human health surveillance sectors as part of a comprehensive web of prevention against influenza viruses of pandemic potential. Collaborative surveillance systems thus mean not only international collaboration, but also multidisciplinary and multisectoral coordination across the environment, animal, and human health nexus *(23)*.

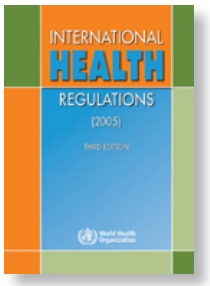
In addition to monitoring for virus emergence, it is also essential to monitor the effectiveness of interventions – both biomedical and public health and social measures. As experiences of

COVID-19 have shown, governments may not have a full understanding of the effectiveness of particular measures in their national context. Surveillance capacity at subnational granularity may therefore also be required to fully understand the effectiveness, and conditions for effectiveness, on a national level.

The importance of global surveillance for influenza pandemic preparedness had been long recognized through GISRS' establishment and activities. In the ten years since the adoption of the PIP Framework, progress on surveillance capacity building across the globe has been one of its biggest successes. However, that does not mean that there are not still gaps and opportunities in global collaborative surveillance across different sectors, the human-animal interface, access to technological advances, and resources for granular surveillance activities. Levelling the surveillance playing field will not only increase national coverage but will also strengthen the entire network and so sustain global pandemic influenza surveillance.

Details of the deliverables, indicative activities and indicators for measuring progress against this Output are presented in Tables 4 and 5.

## Context of Output 2 with other WHO Programmes (see also section 1.5)




**International Health Regulations (2005)** ***(9)*****.**

Supports countries to improve four IHR core capacities: Surveillance, Laboratory, Human resources, One Health/Zoonotic diseases.

**Global Influenza Strategy 2019–2030** ***(8)*****.**

Supports countries to enhance, integrate and expand virological surveillance.

**10 proposals to build a safer world together** ***(10)*****.**

Supports building HEPR capacities for collaborative surveillance.

## Table 4. Output 2: Collaborative surveillance through GISRS - deliverables and corresponding activities

| Deliverables | | Indicative activities (Output 2) |
|---|---|---|
| A | **Laboratory capacities, including genomics, are strengthened** | • Facilitate quality virus detection through training, mentorship and External Quality Assessment Programmes for polymerase chain reaction (PCR) and genomic sequencing.<br>• Assist countries with sharing timely representative influenza samples with WHO Collaborating Centres, including through the WHO shipping fund project.<br>• 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.<br>• Support National Influenza Centres (NICs) with sequencing capacity to establish protocols and systems for influenza virus sequencing.<br>• Routinely update influenza candidate vaccine viruses, virus detection protocols and reagents, and reference materials, and support GISRS to assess and monitor circulating influenza viruses and enable candidate vaccine virus recommendations. |
| B | **Resilient surveillance systems are improved and maintained in a One Health context** | • Provide support to countries on the mosaic of influenza-relevant surveillance systems, especially to strengthen sentinel influenza surveillance and to apply relevant technologies/innovations.<br>• Support surveillance implementation, coordination, and risk assessment at the human-animal interface to inform pandemic risk management.<br>• Assist countries in conducting severity assessments, based on the Pandemic Influenza Severity Assessment (PISA) approach, to inform calibration of public health and social measures.<br>• Work with countries to strengthen systems for influenza data sharing (epidemiological and virological) from national to regional/global platforms and improve data management systems to inform policies and pandemic risk assessments (for example, using the Tool for Influenza Pandemic Risk Assessment).<br>• Establish a network of countries that can rapidly implement standardized Pandemic Special Investigations and Studies (PSS) to characterize key epidemiological parameters during a pandemic. |

## Table 5. Output 2: Collaborative surveillance through GISRS - indicators

| Indicator | | Mapped deliverable |
|---|---|---|
| 2.1 | % of Member States that participated and were 100% correct for non-seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme | A |
| 2.2 | % of Member States that participated and were 100% correct for seasonal influenza virus identification and in the WHO PCR External Quality Assessment Programme | A |
| 2.3 | % of Member States that had timely sharing of influenza virus isolates or clinical specimens with WHO CCs according to WHO guidance | A |
| 2.4 | # of zoonotic influenza viruses, and other influenza viruses with pandemic potential characterized by GISRS | A |
| 2.5 | % of Member States sharing IVPPs with GISRS according to WHO IVPP sharing guidance | A |
| 2.6 | # of global risk assessments published for influenza viruses and at the human-animal interface | B |
| 2.7 | # of global risk assessments conducted using the Tool for Influenza Pandemic Risk Assessment (TIPRA) | B |
| 2.8 | # of Member States reporting influenza severity indicators to WHO | B |
| 2.9 | % of Member States reporting virological surveillance data to the WHO global influenza data platform | B |
| 2.10 | % of Member States reporting epidemiological data to the WHO global influenza data platform | B |
| 2.11 | # of sites participating in the WHO investigations and studies network (Unity Studies) | B |

# Output 3: Community protection

**Strengthened community engagement, knowledge translation and infodemic management capacities for influenza**

It is the community that forms the basis of pandemic preparedness and response: as cases spread and interventions are defined by governments, the uptake of the measures ultimately falls to the community. Examples extend beyond influenza – to the centrality of safe and dignified burials during the 2014 Ebola outbreak, community-level public health needs after the Zika epidemic, and management of social media narratives in COVID-19 within the new environment of a digitized globalized society. Communities should therefore be actively engaged in planning two-way communication and be considered in the creation and implementation of interventions.

In addition to engaging communities in the co-creation of interventions during health emergencies, an emphasis on whole-of-government and multisectoral approaches to public health have become more prominent. Engaging with multiple policy areas and ensuring the trust of local communities is central to the functioning of public health and social measures.

Public health and social measures refers to measures or actions by individuals, institutions, communities, local and national governments and international bodies to slow or stop the spread of disease at the time of the next influenza pandemic. Information about public health and social measures and other response actions need to be provided to communities to facilitate their engagement, contextualization and uptake.

Routine monitoring of community sentiment is an essential part of quality surveillance practices to inform the design of effective interventions. When good-quality information about topics of concern to individuals and populations is lacking, the topics can fast become subjects of conjecture, speculation, poor-quality information and viral misleading content, potentially harming communities. Digital information analysis, triangulation of social listening and other data sources for generating insights have been maturing and used increasingly in various settings and programmes at WHO.

Effective RCCE plans are critical to an effective pandemic response – everything from communicating the latest information, to sharing recommended preventative actions, to managing those infected. So far, 188 countries have developed RCCE plans for COVID-19 based on WHO guidance. And yet in 2021 the average global International Health Regulations (IHR 2005) RCCE capacity score was 64%, which indicates a need to support underlying systems for quality emergency RCCE response. This highlights a need to continue investments in RCCE, and an opportunity to build in capacities for science translation and infodemic management (Deliverable A).

Translation of knowledge and insights from researchers, responders and decision-makers to the wider community is essential for infodemic management. Typically, complex and often rapidly evolving information about infectious disease and policy responses must be delivered in a manner that is appropriate for a wide range of audiences, explains nuance clearly without misleading, and enables members of the community to take reasonable and appropriate actions to protect themselves and others. This requires the involvement of, and deferral to, experts like science communicators, social and political scientists, and anthropologists. Deliverable B sets out to build country capacities in this area.

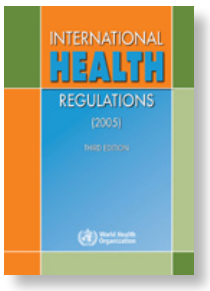
Infodemic management refers to the systematic use of risk- and evidence-based analysis and approaches to manage the overwhelming amount of information and reduce its potentially negative impact on health behaviours during emergencies. As of June 2022, 132 countries have started rolling out systematic approaches for infodemic management. This work can be strengthened and expanded for the purpose of pandemic influenza preparedness (Deliverable C).

In recent years, emphasis has been placed on the need for inclusive and community-focused capacities. However, there remains limited expertise and resources at country level to optimally engage communities and deliver both medical and public health interventions. Some training has already been delivered, with 6.25 million users being enrolled on OpenWHO courses for COVID-19 response, including RCCE.

This area of work is critical for future pandemic preparedness and aims to provide user-friendly tools and guidance that facilitate country and partner uptake.

Details on the deliverables, indicative activities and indicators for measuring progress against this Output are presented in Tables 6 and 7.

## Context of Output 3 with other WHO Programmes (see also section 1.5)




**International Health Regulations (2005)** ***(9)*****.**

Supports countries to improve two IHR core capacities: RCCE, Human resources.

**Global Influenza Strategy 2019–2030** ***(8)*****.**

Supports developing effective influenza communication strategies.

**10 proposals to build a safer world together** ***(10)*****.**

Supports building HEPR capacities in community protection and clinical care.

## **Box 6.** Social digital listening and infodemic management informs effective RCCE: the lesson of COVID-19

In collaboration with research partners, WHO developed an integrated method for collating and analysing infodemic data to generate insights to inform emergency response actions. This 'social digital listening' method was used during the COVID-19 pandemic to routinely analyse social media, traditional media, and other data sources, to create infodemic intelligence reports that inform effective RCCE.

The method also enables data from different sectors to be used, which informs whole of-society response actions *(25)*.

The lessons from COVID-19 are driving the development of global guidance and the adaptation of the method for use during a future influenza pandemic. HLIP III will be at the cutting edge in order to roll this approach out to countries.

## Table 6. Output 3: Community protection - deliverables and corresponding activities

| Deliverables | | Indicative activities (Output 3) |
|---|---|---|
| A | **Country RCCE systems and capacities are enhanced and regularly exercised for influenza** | • Support countries to develop and implement RCCE components (risk communication systems, stakeholder coordination, public communication mechanisms, community engagement, and misinformation management) within pandemic preparedness planning, including the identification of surge resources, exercising capacities and maximising community ownership.<br>• Strengthen networks for country support and surge capacity (for example, social scientists, anthropologists, vaccine communication experts, infodemic managers).<br>• Strengthen the engagement of WHO Information Network for Epidemics (EPI-WIN) communities in pandemic preparedness initiatives, including understanding risk perceptions, for tailored risk communications to high-risk groups. |
| B | **Knowledge translation capacity is developed and enhanced** | • Strengthen the Science Translation Network involving researchers including health scientists, specialists in communication sciences and information technologies for the digital society, media professionals, health professionals and decision-makers by increasing country participation and conducting joint activities on acute respiratory pathogen events.<br>• Provide assistance in knowledge translation capacities and systems to Ministry of Health, intergovernmental and multisectoral stakeholders to facilitate evidence-informed pandemic influenza preparedness policies. |
| C | **Effective infodemic management systems in place** | • Support countries to set up and use digital and other social listening data sources, analytics and tools to monitor infodemics and inform response actions.<br>• Train Ministry of Health staff responsible for community protection in infodemic management including its use during acute respiratory pathogen events such as seasonal influenza. This will prepare public health systems for when an influenza pandemic strikes. |

## Table 7. Output 3: Community protection - indicators

| Indicator | | Mapped deliverable |
|---|---|---|
| 3.1 | % of Member States with mechanisms developed for public communication and/or media relations, including infodemics, and activities are being implemented at the national level | A |
| 3.2 | # of Member States that have included the core components of RCCE in their pandemic preparedness plans | A |
| 3.3 | # of engagements with WHO Information Network for Epidemics (EPI-WIN) communities in pandemic preparedness initiatives | A |
| 3.4 | # of Member States participating in the Science Translation Network | B |
| 3.5 | # of Member States that conduct regular infodemic surveillance and analysis | C |

# Output 4: Access to countermeasures

**Strong regulatory systems and a common approach to timely and affordable access, allocation and deployment of pandemic influenza products results in a more equitable response**

Timely access to countermeasures, including vaccines, therapeutics, personal protective equipment, diagnostic tests and other devices/equipment is central to improving the effectiveness of the response to a future influenza pandemic. Investment in strong regulatory systems and a common approach to timely and affordable access, allocation and deployment of pandemic influenza products is therefore essential to ensure predictable and equitable access to necessary pandemic products. Strengthening access to countermeasures also contributes to core capacities as required under the International Health Regulations (2005) *(9)*.

Sustainable Development Goal 3.8 highlights the need to "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." COVID-19 and other recent emergencies have highlighted gaps in regulatory processes, including pharmacovigilance and management of substandard and falsified products, country preparedness and the supply chains required to achieve this goal, especially in low-income countries. There is a need to address these gaps and strengthen regulatory systems to ensure timely authorization of assured quality pandemic products by focusing on regulatory convergence, regulatory streamlining, reliance, and global and regional collaboration (Deliverable A).

Recently, regulatory pathways in low- and middle-income countries have been strengthened for vaccine approvals through the implementation of institutional development plans and the application of the WHO global benchmarking tool to monitor progress over time. As a result, 41 out of 48 PC countries have roadmaps to develop national regulatory guidelines. However, with only 9 (19%) having finalized and adopted a national guideline there is further room for improvement, especially to reduce use of import permits without application of a recommended regulatory pathway.

Similar efforts are required for diagnostic test kits and devices, especially in low- and middle-income countries, which are least likely to have a regulatory framework in place for diagnostics. In line with this, World Health Assembly Resolution 67.20 specifically calls for "strengthening areas of regulation of health products that are the least developed, such as regulation of medical devices, including diagnostics".

This lack of diagnostic regulation capacity impedes implementation of testing systems, which has harmful health, economic and socioeconomic impacts *(26)* and has wide-reaching impacts in a public health emergency. The COVID-19 pandemic clearly highlighted the critical

importance of accurate diagnostics, especially when it comes to allocating limited therapeutic and preventative resources. However, the widespread scarcity and inequity of access to diagnostic capacity were also highlighted. The momentum behind pandemic preparedness has the potential to improve diagnostic access more generally.

Improving equitable deployment of pandemic products, including through development of procurement mechanisms that promote fair and equitable access, remains a priority area. COVAX demonstrated the imperative of providing fair and equitable procurement and deployment of medical countermeasures, but also the difficulty in doing so through advance market commitments. Promoting not only procurement and deployment of medical countermeasures, but development and production in an equitable and global manner has far more potential to transform influenza pandemic preparedness.

This needs to be complemented by coordinated global and regional initiatives to strengthen national-level deployment capacities for the efficient delivery of vaccines and other pandemic products. Work to operationalize Standard Material Transfer Agreement 2s under the PIP Framework will address many upstream procedures involving international stakeholders, which ultimately impact downstream country procedures for deployment of pandemic products (Deliverable B).

As of June 2022, 34 countries have reviewed their COVID-19 national deployment and vaccination plans, which were developed based on approaches recommended for PIP product deployment. However, supporting countries to develop, revise, test and update their pandemic Influenza national deployment and vaccination plans based on lessons learned from COVID-19 is still essential to strengthen countries capabilities to deploy and distribute pandemic products (Deliverable C).

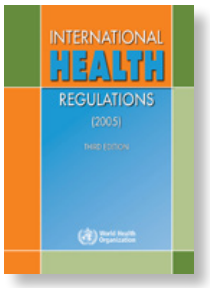
Access to countermeasures and pandemic products is a requirement for preventing, detecting, and responding to pandemic influenza. Access to these countermeasures should be timely and equitable across countries, and countries should have the capacity to regulate and deploy these products.

While significant progress has been made in the regulation and deployment of vaccines, there is still work to do in improving regulation and deployment of diagnostics and therapeutics for pandemic response.

Through the PIP Framework, country capabilities to regulate, access, deploy, and distribute pandemic influenza products can be developed to create global preparedness.

Details of the deliverables, indicative activities and indicators for measuring progress against this Output are set out in Tables 8 and 9.

## Context of Output 4 with other WHO Programmes (see also section 1.5)




**International Health Regulations (2005)** ***(9)*****.**

Supports countries on four IHR core capacities: Policy, Coordination, Health emergency management, Health services provision.

**Global Influenza Strategy 2019–2030** ***(8)*****.**

Supports national regulatory authorities (NRAs) on approval pathways for the next generation of influenza vaccines.

**10 proposals to build a safer world together** ***(10)*****.**

Supports building HEPR capacities in emergency coordination and clinical care.

## Table 8. Output 4: Access to countermeasures - deliverables and corresponding activities

| Deliverables | | Indicative activities (Output 4) |
|---|---|---|
| A | **Regulatory readiness and resilience in countries is enhanced** | • Provide countries with up-to-date guidance on regulatory preparedness and approaches for monitoring regulatory functions/ capacity<br>• Support countries to strengthen national capacities to regulate pandemic influenza products including regulatory system, market authorization and post-market surveillance and pharmacovigilance<br>• Enable countries to implement institutional development plans, benchmark capacity and adopt national guidelines relevant to emergency preparedness and response.<br>• Promote the adoption of facilitated regulatory pathways for timely access to assured quality pandemic influenza products, including vaccines, antivirals, and diagnostics. |
| B | **A common approach to managing global access, allocation and deployment of pandemic products including Standard Material Transfer Agreement 2 operationalization is prepared** | • In collaboration with stakeholders, update global and regional operational plans for the access (including procurement), allocation and deployment of pandemic products including products secured through Standard Material Transfer Agreement 2s to be ready at the time of a pandemic.<br>• Exercise global and regional access, allocation and deployment processes with stakeholders and deployment partners. |
| C | **Country capacity to deploy and distribute pandemic products is strengthened** | • Develop, update, and provide technical guidance and tools to inform national deployment and vaccination plans, as well as plans for receiving and deploying other pandemic response products such as therapeutics (including antivirals).<br>• Support countries to develop, revise, test and update national deployment and vaccination plans.<br>• Assist countries in maintaining coordination between national deployment and vaccination plan stakeholders and other national pandemic preparedness planning actors such as regulatory authorities, immunization bodies and influenza programmes. |

## Table 9. Output 4: Access to countermeasures - indicators

| Indicator | | Mapped deliverable |
|---|---|---|
| 4.1 | # of Member States that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products | A |
| 4.2 | # of Member States which strengthened national regulatory capacity to oversee pandemic influenza products as per WHO benchmarking and institutional development plan implementation | A |
| 4.3 | Stages implemented to develop, elaborate and refine the common approach to managing global access, allocation and deployment of pandemic products | B |
| 4.4 | # of Member States that developed or updated a pandemic influenza national deployment and vaccination plan (since COVID-19 pandemic) | C |
| 4.5 | # of annual global, regional or country simulation exercises conducted to test deployment of pandemic influenza vaccines or other products | C |

## **Box 7.** A collateral benefit to the COVID-19 pandemic response

Since 2014, using PC funds, WHO has used a multi-pronged approach to strengthen regulatory readiness for an influenza pandemic in 48 PIP PC recipient countries, including issuing policy and technical guidance, benchmarking national regulatory authority (NRA) performance, capacity-building to fill gaps, delivering planning workshops and mentoring NRA staff.

To understand if these investments paid off, we looked at how countries fared in 2009 during the influenza pandemic versus during the COVID-19 pandemic:

In 2009, 21 countries (22%) eligible to receive vaccines through WHO did not provide marketing authorization or accept pandemic products.

For COVID-19, by 30 June 2021, 47 out of the 48 PIP PC recipient countries had authorized one or more COVID-19 vaccines.

For the 45 countries with data, 87% provided timely marketing authorization within 15 days of emergency use listing by WHO.

Furthermore, nine of the 10 countries that did not receive pandemic influenza vaccines during the 2009 pandemic have authorized one or more COVID-19 vaccines, with eight doing so in a timely fashion.

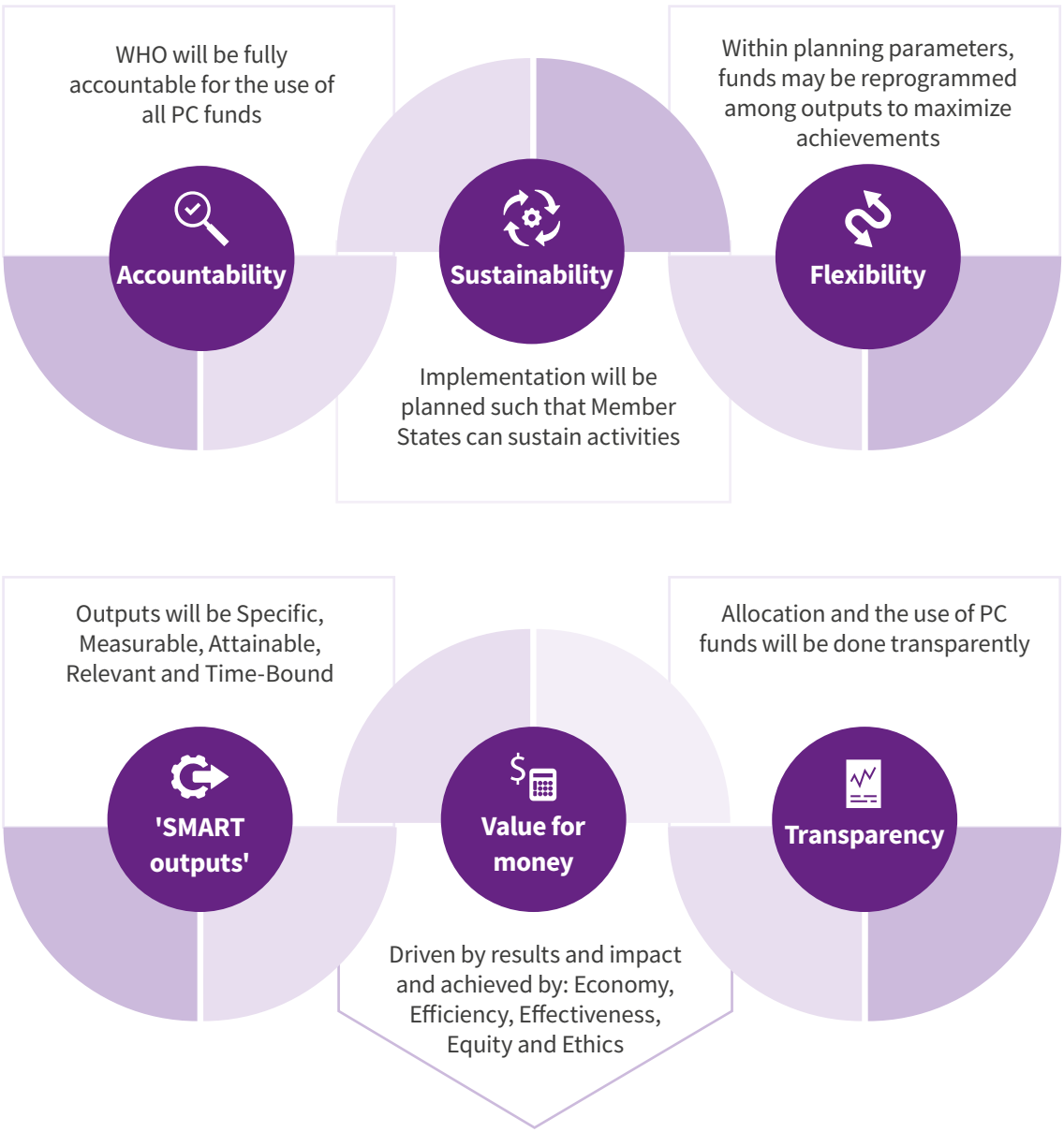
These numbers reflect how WHO technical support, enabled by the PIP PC, contributed to the improvement of NRA performance and the importance of continuing this support. HLIP III investments will enable countries to learn and apply lessons from the COVID-19 pandemic, and to sustain the gains made over time.

To learn more, see the full story on the WHO website: https://www.who.int/news/item/03-02-2022-a-tale-of-two-pandemics-improvements-in-regulatory-performance-between-the-2009-influenza-a(h1n1)-pandemic-to-the-covid-19-pandemic

# 3. HLIP III delivery

To deliver results and impact in line with the PIP Framework expectations, HLIP III delivery is guided by the principles of accountability, sustainability, flexibility, 'SMART outputs', value for money, and transparency (see Fig. 5).

## Figure 5. Planning principles for HLIP III




**Value for Money at WHO is achieved through the 5 E's:**

1. **Economy:** keeping inputs (human and financial resources) as lean as possible
2. **Efficiency:** using those inputs to obtain or "buy" as much output as possible
3. **Effectiveness:** keeping the quality of outputs as high as possible to have the greatest possible impact
4. **Equity:** taking into consideration the extent to which outputs benefit and ensure coverage of the most vulnerable and hard-to-reach populations
5. **Ethics:** ensuring that inputs, outputs and outcomes uphold the fundamental ethical principles of respect, goodwill, justice and not causing harm.

# 3.1 Funding through the PIP partnership contribution

The PC is one element of the Pandemic Influenza Preparedness Framework's benefit sharing system. The PC is a sustainable financing mechanism under which influenza vaccine, antiviral and diagnostic manufacturers that use the WHO GISRS make an annual financial contribution to WHO. PC funds supplement and accelerate existing national, regional and global initiatives for pandemic influenza preparedness and response. As described in the PIP Framework, PC preparedness funds will be used (implemented) "for improving influenza pandemic preparedness and response, inter alia, for conducting disease burden studies, strengthening laboratory and surveillance capacity, access and effective deployment of pandemic vaccines and antiviral medicines "*(1)*. 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. Therefore, the current annual PC to be paid to WHO is US$ 28 million.

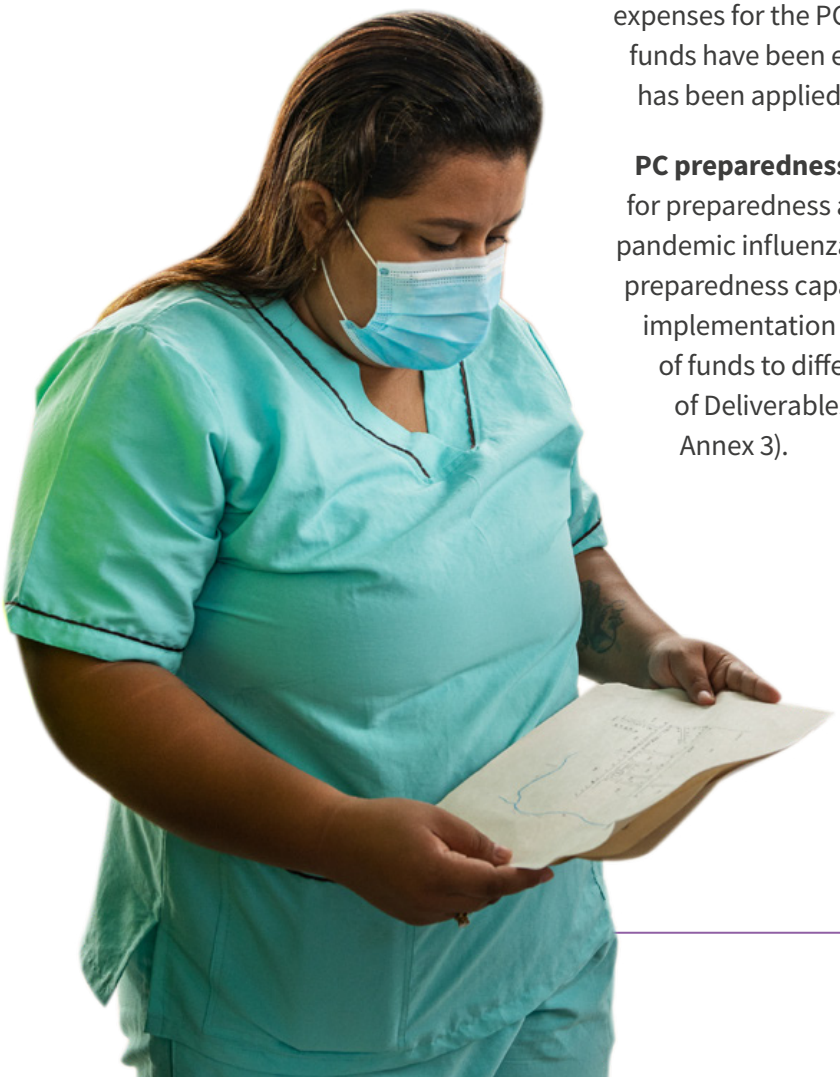
The technical and financial investment of countries and other partners, including GISRS play a critical role in advancing pandemic preparedness alongside PC investments. Collectively, resources are used to strengthen pandemic preparedness systems, knowledge and capacities. The progress made and successes achieved are a result of collaboration on common objectives.

## Proportional division of PIP PC funds

The PIP PC funds are to be used for both pandemic preparedness and response as well as to support the functions of the PIP Secretariat. The proportional division of PC funds has been consistent since the start of the PIP Framework, but it is periodically reviewed and may be adjusted if deemed necessary by the PIP Advisory Group. All funds are subject to WHO Programme Support Costs, 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 *(27)*. PC funds are allocated as follows (see also Fig. 6):

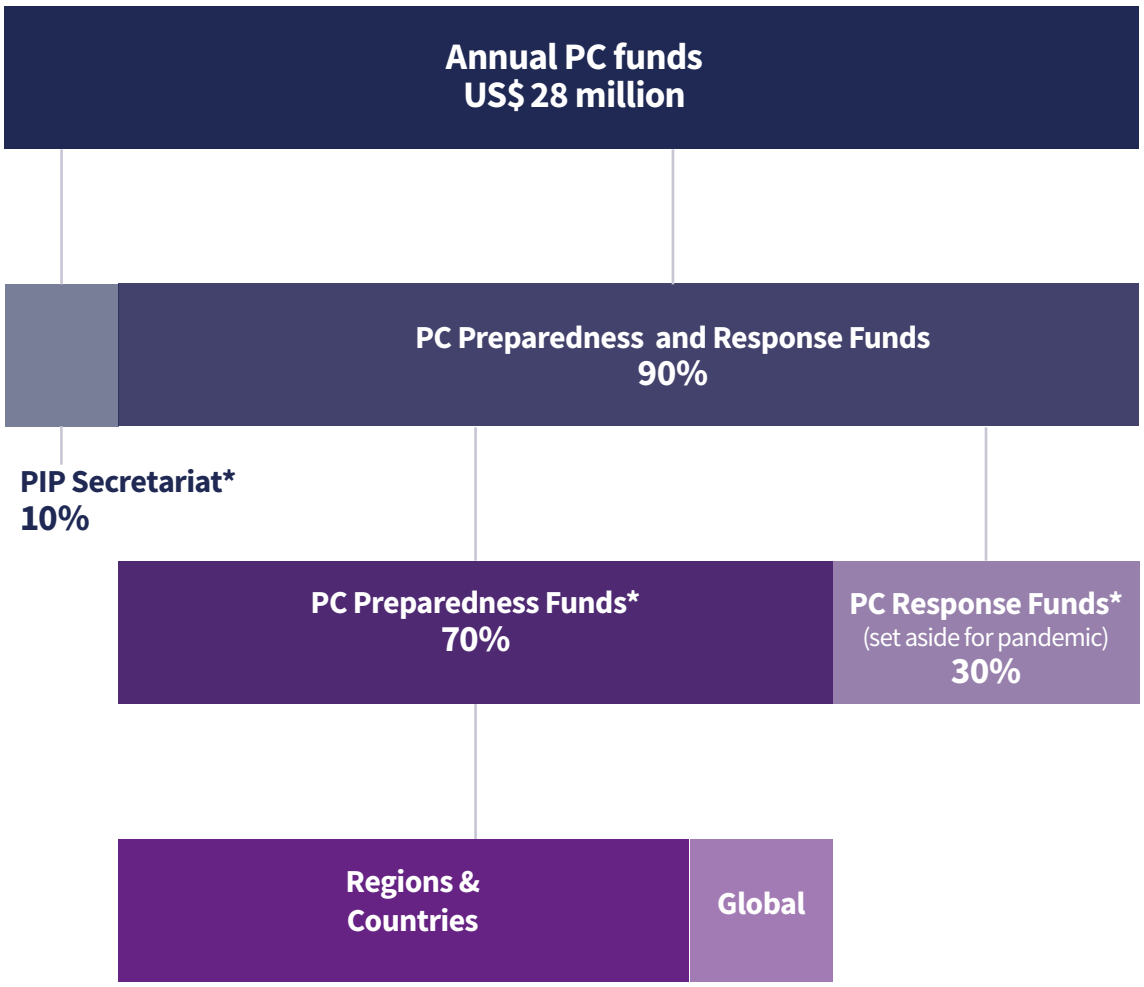
**PIP Secretariat:** Ten percent of PC funds are allocated for the PIP Secretariat. The PIP Secretariat costs cover management and implementation of the full PIP Framework including preparation and convening of PIP Advisory Group meetings, Standard Material Transfer Agreement 2 negotiations, implementing decisions from the World Health Assembly that relate to the PIP Framework, and reporting. WHO applies Programme Support Costs 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 at the time of an influenza pandemic. Interest accrues on these funds with all interest being kept within the Response Fund account. 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 (for example, government donations or response funds from organizations other WHO). WHO applies Programme Support Costs at 7% of direct expenses for the PC Response funds. As no PC Response funds have been expended, no Programme Support Cost has been applied to date.



**PC preparedness funds:** Of the PC funds available for preparedness and response, 70% are used for pandemic influenza preparedness to improve pandemic preparedness capacities according to the high-level implementation plan (see Chapter 2). The allocation of funds to different Outputs is based on the scope of Deliverables and may be adjusted over time (see Annex 3).

**Figure 6. Proportional allocation of annual PC funds**




*WHO's Programme Support Cost are applied as funds are expended

# 3.2 Allocation of PC funds

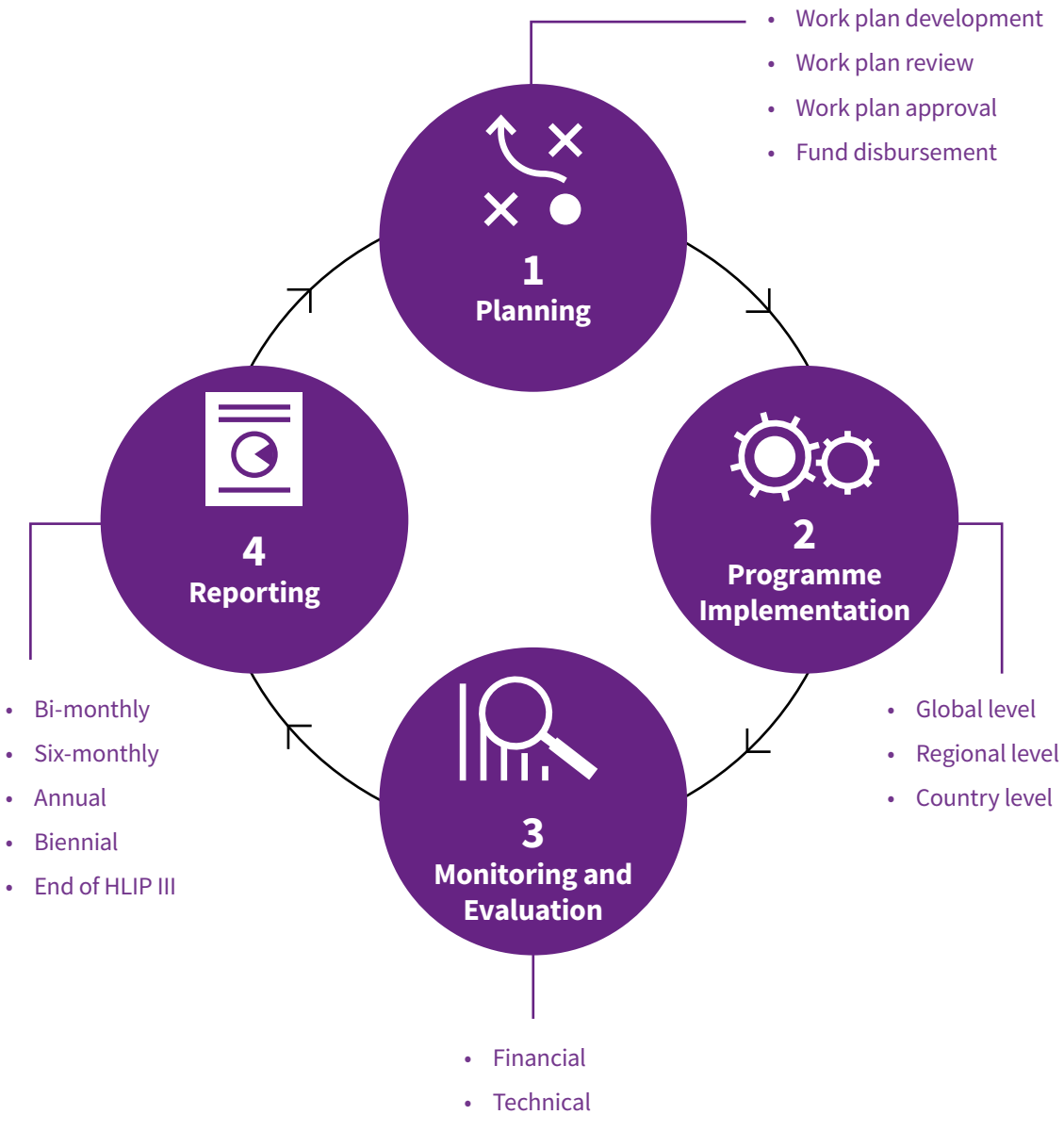
PC funds are used to improve preparedness through global, regional and country-level activities. Some countries will be supported through (a) biennial country-specific work plans, and others through (b) activities implemented by WHO regionally and globally. Funds to implement the biennial work plans are allocated yearly based on progress, continuing needs and availability of funds. Recognizing that PC funds are limited, a three-step process will be applied to identify PC countries and establish country-specific work plans. The process will include understanding the capacities, needs and maturity of each country relative to the Outputs; prioritizing the countries for funding; and confirming the selected countries commitment (for more details on the approach and criteria, see Annex 4). The list of countries funded for each Output will be published on the PIP website. The list will be updated every

two years or as needed to reflect any changes in country level work plan recipients. Changes will be based on work plan implementation, contextual factors affecting implementation and indicator performance.

## 3.3 Project management cycle

As implementation of PC preparedness funds is executed across WHO headquarters, regions and countries, effective project management is key to successful implementation (see Fig. 7). Four key processes of the project management cycle are described below.

**Figure 7. Project management cycle for implementation of PC preparedness funds**



## 3.3.1 Planning

The project management cycle begins with detailed biennial operational planning. This process has four stages:

### Stage 1: Work plan development

Work plans are developed by WHO country, regional and headquarters teams in consultation with stakeholders including Ministries of Health and influenza development partners. The HLIP III results hierarchy (Fig. 4) guides how work plan content is developed to ensure that proposed activities advance progress on the indicators. Budgets are developed for each Output using a project-based approach, based on the Deliverables and needs assessed. Financing of work plans is dependent on the availability of funds.

### Stage 2: Work plan review

Work plans are reviewed in two steps, first internally and second by an independent technical review group, namely the Partnership Contribution 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 WHO regional offices and headquarters. 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 reviews activities for scientific and technical suitability against the deliverables and outputs. PCITEM meets in person once before the start of the work plan biennium. Additional meetings are held as needed. This group provides inputs to WHO technical teams to improve and finalize the work plans. PCITEM then provides its advice to the Director of Epidemic and Pandemic Preparedness and Prevention (EPP).

The internal and external 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 III results hierarchy (Fig. 4).

### Stage 3: Work plan approval

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

**Stage 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.

### 3.3.2 Implementation

Implementation is conducted at a global, regional and country level to achieve the deliverables as described earlier in this report (see Chapter 2), and is a collaborative exercise between Ministries of Health, GISRS and WHO. Further explanation of the roles and responsibilities to implement are described below in section 3.4 and Annex 4.

### 3.3.3 Monitoring and evaluation

Monitoring and evaluation support sound programme management and achievement of results *(28)*. There will be routine technical and financial monitoring in addition to evaluation processes to capture achievements, and to alert managers to implementation issues. In addition to HLIP III implementation monitoring, complementary tools such as the IHR (2005) monitoring and evaluation framework will also monitor progress. Results from the yearly State Party Self-Assessment Annual Report (SPAR) and periodic Joint External Evaluations (JEE) will shed light on country progress and preparedness for future emergencies including pandemic influenza.

The various processes described and summarized in Annex 4 are 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.

HLIP III is considered a living document that is subject to change, as circumstances evolve, including aligning with the legally binding pandemic accord that is under development. 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 effective HLIP III implementation. Potential changes to the HLIP III design will be discussed with the relevant stakeholders prior to implementation. A final HLIP III evaluation and impact assessment will be conducted following the six-year implementation period.

### 3.3.4 Reporting

Regular updates will provide stakeholders with progress on technical and financial implementation and results. This includes through twice yearly progress reports, newsletter stories, and the WHO programme budget portal. Financial reporting will provide breakdown by staff and activities, and implementation rates by output. Certified 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 (see Annex 4 for more details).

### 3.3.5 Risk management

An assessment of risks and their potential effects on HLIP III implementation and mitigation measures are presented in detail in Annex 5. High-level risks identified relate to areas of planning; implementation; and management, accountability, and reporting.

## 3.4 Project implementation roles and responsibilities

Implementation is a combined and coordinated effort of implementing units at WHO, on the one hand, and Ministry of Health, and GISRS institutions (notably, NICs and WHO Collaborating Centres), on the other. Ministries of Health and NICs implement funds in accordance with agreed-upon work plans in order to improve national pandemic influenza preparedness capacities. Additionally, WHO Collaborating Centres 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 III activities. The roles and responsibilities of WHO teams at all three levels of the Organization are outlined in further detail in Annex 4.

## 3.5 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, 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 Ministry of Health of countries 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 countries will be reminded of the expectation to share IVPP in accordance with the PIP Framework. The biennial review of PC 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 measure of ensuring the PIP PC implementation occurs as outlined in this plan, and where necessary corrective actions can be taken. In addition to overseeing implementation based on internal inputs from WHO technical teams and the PIP Secretariat, WHO senior management are also informed by PCITEM, an external set of experts, who provide inputs on the technical suitability and alignment of the biennial work plans in line with the HLIP III results hierarchy and progress made over time.

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# Annexes

# Annex 1. Lessons learned and opportunities for HLIP III

The design of HLIP III was informed by the following six lessons that emerged based on the literature review, stakeholder inputs and previous implementation.

## Influenza preparedness helped with the COVID-19 response; the COVID-19 response can now help pandemic influenza preparedness

An overarching lesson is that influenza preparedness helped countries with their COVID-19 responses and COVID-19 has in turn helped build additional capacities which can now be leveraged for pandemic influenza preparedness.

Stakeholders were emphatic about this complementarity between COVID-19 and pandemic influenza preparedness in multiple areas. First, on preparedness planning, one respondent to the consultation said that "contingency planning at hospital level, especially for influenza… became the template for hospital contingency planning for COVID-19 response." While another noted that "the influenza pandemic plan provided a strong foundation in COVID-19 response that can help with any kind of pandemic such as training, capacity, planning, and coordination among partners." This extended to core capacities, where one individual noted that "without the work that we did through the PIP support for RCCE we would not have been able to ramp it up at the level of the country for RCCE related to COVID-19." This wide area of engagement was often attributed to both COVID-19 and influenza being respiratory pathogens: "COVID-19 has demonstrated that the systems and capacities that PIP has developed are essential for any epidemic and pandemic response caused by a respiratory pathogen."

This relationship has also worked the other way around. For example, the attention to genomic surveillance since the onset of the COVID-19 pandemic, has resulted in a 43% jump (from 105 to 150) in the number of countries with sequencing capacity *(1)*. Now, we can leverage gains made during the COVID-19 pandemic to buttress pandemic influenza preparedness.

Importantly, the findings from our review indicate that the capacities and capabilities strengthened through the PIP Framework for pandemic influenza can have ripple effects with applicability to seasonal influenza, other respiratory pathogens, general pandemic preparedness, and broader health systems. This is why the "context for sustainability" has been

introduced into the framing for HLIP III, showing PIP's broad collateral benefits. By providing complementarity to other initiatives in broader sustainable development, PIP can have a wider impact while also capitalizing on complementarities for influenza preparedness. This is important to decision-makers, especially in limited resource settings where efficiency is paramount.

## Criticality of building community trust and engaging people in the protective actions needed to effectively respond to a pandemic

The importance of effectively engaging members of the public in the response has been a central theme of past epidemics, from SARS in 2003 to West Africa's Ebola outbreak in 2013–2016, and now the COVID-19 pandemic *(2)*. COVID-19, however, saw an unprecedented level of rumours and misinformation, which claimed many lives, and made the role of social listening and fighting the "infodemics" more important than ever before. Quoting the United Nations Secretary General, "as COVID-19 spreads, a tsunami of misinformation, hate, scapegoating and scare-mongering has been unleashed" *(3)*. The infodemic triggered governments and different multi-sectoral stakeholders at country, regional and global levels to roll out campaigns that increase societal resilience against disinformation *(4)*.

More recently, the World Health Assembly noted,

> **the negative impact of misinformation, disinformation and stigmatization on preparedness and response to health emergencies, and on people's physical and mental health, and the need to counter mis- and disinformation and stigmatization in the context of health emergencies, and recognizing that for all stakeholders to be part of the response, they need to have access to timely and accurate information and to be involved in decisions that affect them** *(5)***.**

Member States were urged to,

> **share with their population and the global community reliable and comprehensive information on health emergencies and the public health responses to be taken by local, national, regional and international public health authorities, and take measures to strengthen health literacy and to counter misinformation, disinformation and stigmatization, including by providing access to other sources of fact- and science-based information** *(5)***.**

The central importance of modern risk communication, infodemic management and knowledge translation approaches, through social media strategies, community outreach, and communications training, were strongly emphasized throughout the PIP stakeholder consultations and recommendations review. As noted by a WHO staff member engaged in previous pandemics, "we need to have the tools to listen to the population and to have the network to make sure that we can convey the right information at the right time in the right format."

Implementation of previous HLIPs saw the introduction of innovations such as OpenWHO for knowledge transfer; community engagement through the WHO Information Network for Epidemics (EPI-WIN) on pandemic influenza preparedness, focusing on youth, the world of work and faith-based networks; and systemization of approaches regionally to roll out training packages focusing on (i) risk communications systems (ii) stakeholder coordination (iii) public communication mechanisms (iv) community engagement, and (v) misinformation management. Opportunities identified through previous reviews include the need to shift implementation based on emerging lessons from COVID-19, recognizing the ways that populations receive and act on information, and to better link RCCE to other components of pandemic influenza preparedness.

Therefore, to be prepared for a future influenza pandemic, there is a need to build on the momentum generated by COVID-19. This includes consolidating capacities and standard operating procedures for RCCE, capitalizing on established platforms and networks as modalities for pandemic influenza preparedness (such as knowledge translation) so that they are ready for response, and continually innovating to support countries and communities to deal with the increased demand for tackling misinformation.

## Understanding the burden of influenza informs preparedness policies and planning

The health and socioeconomic burden of a disease can have an impact on both the outcome of interventions and the overall effect of a pandemic. COVID-19 showed this clearly, with aging and comorbidities being significant predictors of worse outcomes. Understanding the distribution of disease within different cultural and economic sections of the population can help guide the best ways in which to arrange testing services, vaccination plans, clinical care and other health system functions. It is therefore also important to understand population dynamics, social structures, and health care system surge/stretch and breaking points to best design and implement interventions.

A good deal of progress has been made in this context over the years. Influenza burden data are now available in 48 countries, and global estimates have been updated. The data are also effecting change: countries with influenza burden data were much more likely to keep their national influenza vaccine policies up to date. The limitations must be recognized however,

as this only represents 25% of countries globally and just four countries have analysed the economic burden associated with influenza. This highlights the room to grow.

Importantly, many countries utilized the methods established for estimating influenza morbidity and mortality to better understand COVID-19 burden. This is important for ministries of health that operate holistic acute respiratory disease control programmes. In turn, COVID-19 provided impetus for WHO, surveillance officials and researchers to elaborate methods to better understand the "pyramid" of disease burden reflecting the proportion of the population infected, medically attended, hospitalized and dying. The full pyramid estimates are important to guide preparedness planning assumptions for when a pandemic strikes. The collateral gains made during the COVID-19 pandemic show how efforts can be galvanized during an emergency to further advance knowledge and capacities.

Reflecting on earlier HLIP implementation, stakeholders noted that burden of disease was decontextualized. Although there was a good deal of emphasis placed on ensuring that burden of disease was known and reported, there was limited uptake and use of the data to inform policy: "COVID-19 has convinced countries much more than any burden of disease studies that it's better to be prepared for respiratory viruses." This highlights that preparedness efforts during "peace time" are at risk of receiving limited attention by decision makers, reinforcing the need to explain the significance of burden of disease estimates to inform pandemic preparedness. Decision makers should be made aware how valuable burden estimates are in understanding vaccine effectiveness and identifying vulnerable groups at the time of a pandemic.

Another respondent noted that,

> **until the emergence of COVID-19, deployment of pandemic response products had been seen as a logistical issue. However, we have seen during COVID-19 that it is not only a logistical issue. It is also about how it is regulated, who is in need, and how it is deployed. Logistics is one part, but it is not the only part.**

Knowing who is at high risk of infection, severe outcomes or negative socioeconomic impact enables Ministries of Health and other stakeholders to plan for different response scenarios and prioritize risk groups for interventions.

As the world transitions from the COVID-19 response, WHO and stakeholders need to find ways to reinforce the added value of burden estimates to inform influenza pandemic preparedness policies and plans. It is important to incorporate burden of disease and socioeconomic impact data into pandemic preparedness planning, in order to be able to make evidence-based decisions on deployment and allocation of pandemic products. We have therefore placed the use of burden data under policy as Deliverable A of Output 1 in order to emphasize the central importance of nationally and locally contextualized pandemic preparedness planning which takes into account accurate and reliable disease and societal burden data.

# Policies and plans need to be flexibly constructed to deploy and equitably distribute pandemic products as technologies evolve

Novel technologies have the potential to transform the way we respond to outbreaks of infectious disease and save lives. However, such technological shifts require:

i. policies to be adapted to incorporate them into response plans
ii. additional investment to develop, approve, and deploy new pandemic products and (
iii. a wide distribution as they are frequently inequitably accessed and distributed on a global scale. As such, it is imperative that policies, plans, and logistics are sufficiently adaptable and supportive to enable access to and uptake of novel pandemic products as technologies evolve over the next six years.

The approval and use of mRNA vaccines during COVID-19 represents one such technological shift and signals an opportunity to augment the tools used for a future pandemic influenza response. Work is already underway, including through WHO's mRNA Technology Transfer Programme, to transfer mRNA vaccine development and production technology and know-how to recipients to strengthen health security *(6)*. This will see a diversification in countries able to produce products at the time of an emergency. Two influenza mRNA vaccines are currently in phase 3 clinical trials, and several other clinical trials are also ongoing to assess the efficacy and validity of the mRNA and other scalable vaccine platforms for both seasonal and pandemic influenza vaccines *(7)*. While these developments are promising and can be a game-changer in the fight against influenza – especially during a pandemic – it is still too early to call it a success. For pandemic planning purposes, we must continue to account for existing technologies, and watch and plan for the introduction of new products.

Consultations echoed this need to keep up with the pace of technological evolution, with one respondent noting that "we will continue to see these developments affecting all areas" and another saying "I think as long as the regulatory pathways continue to innovate along with the technologies themselves, I think that will be critically important." These inputs highlight a need for policy readiness as the evolution of technologies continues, including: building trust in vaccine platforms, deployment planning and logistics, and regulation of novel technologies.

Consultations also highlighted the disparity in access to new technological advances, particularly in reference to COVID-19 vaccines:

> **With COVID we saw all of our fears come true across the vaccine enterprise and supply chain. Despite it being a new disease, the time for vaccine development was fast; however, we had issues with the supply and the time until delivery was quite lengthy. Because we saw**

> **such sustained and prolonged inequity to the supply, we're now seeing that people don't want the vaccine despite the available supply.**

Not only do systems within countries need to have readiness for novel technologies, but global systems need to be prepared to facilitate the equitable access and distribution of pandemic products.

To address the rapid pace of technological evolution, and given PIP's overall scope, HLIP III focuses on building a level of flexibility and adaptability at the policy level to enable responses to be shaped around new pandemic products. Pandemic planning in all areas should maintain coherence across the continuum of response, whilst maintaining resilience to novel technological development. To do so, HLIP III's Outputs 1 and 4 emphasize planning and operational capacity building, respectively.

HLIP III focuses on Standard Material Transfer Agreement 2s and regional/national manufacturing distribution as key indicators of equity, as well as being framed by WHO's Roadmap for access to medicines, vaccines, and health products *(8)*.

## One Health thinking enables surveillance systems to rapidly detect, assess and respond to influenza viruses with pandemic potential

The emergence and re-emergence of pathogens through spillover from animal reservoirs has proven to be the source of many public health emergencies, including avian influenza viruses globally, multiple Ebola virus spillover events in western and central Africa, Nipah virus in Asia, Middle East respiratory syndrome coronavirus (MERS-CoV) in the Middle East, and Hendra virus in Australia. As environmental and climate changes increase the geographical range of some disease vectors and make interactions between human and animal populations more frequent, spillover events are likely to become even more frequent.

The continued detection of emerging pathogens, including most recently SARS-CoV-2, further highlights the need for coordinated surveillance and risk assessment to provide timely and quality information for decision-making and action. Conceptually, this is at the heart of One Health. The report of the COVID-19 International Health Regulations Review Committee noted that,

> **the general difficulty in identifying zoonotic spillover events early also reinforces the need to focus not only on the response side of disease outbreaks, but also on activities that prevent the emergence of new zoonotic diseases in the first place and foster a One Health approach** *(9)***.**

For pandemic influenza preparedness, One Health involves coordinated surveillance and risk assessment at the human-animal interface as it is this interface that gives rise to influenza viruses with pandemic potential. The emergence of A(H5N1), A(H7N9), and A(H9N2) subtypes of influenza A virus and the increased genetic exchange among influenza viruses in wild aquatic birds, commercial and domestic poultry, pigs, and humans pose a continuing threat to humanity.

Findings from the HLIP III development consultations saw an emphasis placed on One Health and the human-animal interface, particularly around the need to be monitoring animal populations for potential spillover influenza viruses. One survey respondent, for example, stated that,

> **Policies that oblige or allow countries to continue surveillance on the emergence of new pathogens, not only human but also in animals (such as new influenza viruses), should be considered, and maintaining this surveillance is key to alertness in what could be a very complex situation.**

The criticality of influenza surveillance in animals was a common theme across the consultations. While animal influenza surveillance is beyond the scope of the PIP Framework, coordinated surveillance such as human and animal health authorities jointly reviewing influenza activity data and assessing risk to inform action can be addressed and strengthened through HLIP III.

Advancing collaborative surveillance is critical for pandemic influenza preparedness. This will build coherently on HLIP II investments to strengthen joint outbreak investigation efforts which had increasing levels of country attention over time. For example, in 2020–21 and based on PIP PC monitoring data, 430 outbreak detection and response trainings were conducted in 61 countries from all six regions. This was a 71% increase in trainings conducted compared to the first biennium of HLIP II implementation (2018–2019).

Collaborative surveillance through GISRS (Output 2) emphasizes that collaboration is needed both (i) within countries so that stakeholders have the relevant data, risk assessments and processes to rapidly trigger action, and (ii) between countries through regionally and globally coordinated GISRS efforts so that influenza viruses with pandemic potential are rapidly characterized and addressed. This requires investments in the laboratory and surveillance capabilities, adaptation to ever-changing platforms for data collection, analysis and reporting, support to make routine joint risk assessments for influenza at the human-animal interface, and inclusion of rapidly evolving technologies such as those for genomic sequencing to speed up the characterization of emerging influenza viruses.

# Pandemic influenza preparedness needs to account for the lessons from COVID-19 to optimize clinical care policies and planning

COVID-19 shed light on a critical health system gap: respiratory clinical care pathways and response operations. Almost half of all hospitals in low- and middle-income countries have an unreliable supply of medical oxygen or lack it entirely. Even fewer primary care facilities have pulse oximeters to help health workers determine if a patient needs oxygen therapy *(10)*. This is compounded by a lack of workforce training on clinical recognition and risk stratification of severe patients, which contributes to worse outcomes. Through WHO pulse surveys during the pandemic, countries commonly cited health workforce limitations as a bottleneck for delivering COVID-19 clinical care. Low workforce morale, insufficient or irregular remuneration, and perceptions of inadequate infection prevention and control in some countries exacerbated the challenges.

The capacity of the health sector, especially hospitals, to respond to and recover from health emergencies is critical to protect individuals' lives and to ensure the continuity of essential health services. Health facilities and clinical management networks must learn to quickly expand or adapt their capacities, including respiratory clinical care, considering at all times the specific needs of at-risk or marginalized groups. This means that the clinical workforce is integral in pandemic influenza preparedness planning.

Clinical care was discussed in multiple HLIP III development consultations with country level stakeholders and through the survey:

> **Tents, patient flow and separation were the most challenging and still are, together with lack of knowledge and awareness about respiratory illnesses, especially influenza. So, clinicians and other health care workers still need to be trained on clinical diagnosis and patient management of influenza and other acute respiratory infections.**

The sharing of best practices for clinical care was also highlighted: "The clinical treatment procedures of the disease should be shared early, and clinicians trained in the management of them."

Inter-pandemic investments in respiratory clinical care are effective. Small investments made at regional level through earlier HLIPs, such as in the Americas, the European and South-East Asian regions, as well as in specific countries such as Armenia, Bolivia, Myanmar, Nepal, and Uzbekistan, collaterally prepared frontline health workers to set up triage and respiratory clinical care protocols during the COVID-19 pandemic response.

The magnitude of the gaps as well as the initial and recurring costs needed to advance clinical care preparedness for a future influenza pandemic mean that this is a task beyond the

scale of the PC preparedness funds alone. Nevertheless, what is within the scale of HLIP III implementation is to support countries in clinical care policy and preparedness planning. WHO can galvanize country health systems and partner networks to strengthen hospital preparedness planning, focusing on risk profiling, response planning, and surge capacity assessments. The work can also support Ministries of Health to enhance the health workforce by developing and embedding respiratory clinical training packages and readiness curriculum for health services in tertiary medical training and continuing education schemes.

These efforts, emphasized through Output 1, Deliverable B, will help countries to be better prepared to manage the influx of pandemic influenza cases, while concurrently advancing multiple health systems and supporting the goal of universal health coverage.

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# Annex 2. HLIP III development process

HLIP III was developed by WHO in a collaborative and iterative manner, whereby a review of the evidence and landscape as well as discussion with key stakeholders were the primary methods used to develop the overall design.

WHO commissioned an external consulting firm to:

- analyse progress from previous PIP PC implementation
- review lessons and themes from the COVID-19 pandemic
- appraise the current landscape for pandemic influenza preparedness, and
- engage PIP Framework stakeholders.

The consultant group took two complementary approaches: evidence review and stakeholder consultation. Stakeholder consultations were undertaken in multiple stages and focused on ensuring that key priorities, gaps and needs would be addressed through the design and roll out of HLIP III. Throughout the process, feedback was gathered through a combination of meetings and online surveys (see Fig. A2.1).

## Evidence review

An extensive document review was done, including of the international- and country-level COVID-19-related assessments, the published literature, PIP progress reports and the HLIP II mid-term review. The aim of the evidence review was to identify major opportunities, gaps, and lessons learned from previous PIP Framework implementation and the COVID-19 pandemic response. It took into consideration the evolving global landscape for pandemic and epidemic preparedness and areas of work that the COVID-19 pandemic brought to prominence to improve pandemic preparedness. A synthesis of this review can be found in Annex 1.

# Consultations

Consultation was an essential part of the development of this plan. At the outset of the HLIP III development process, a broad range of stakeholders and key partners (see section 1.6), in addition to WHO technical implementing units, were consulted on the lessons learned from previous HLIP implementation, lessons learned from the COVID-19 pandemic, and opportunities to further strengthen pandemic influenza preparedness.

Initial consultations, conducted between June and July 2022, took a two-pronged approach:

- **Interviews** were conducted with representatives from PIP PC countries, PCITEM members, GISRS, partnership contributors, and WHO output technical implementing teams at WHO headquarters, regional offices and country offices.
- **An online survey**, designed using the same questions utilized for the interviews, was disseminated to all key stakeholders including those unable to participate in the interviews (that is, civil society and the PIP Advisory Group).

Nineteen group interviews were conducted and over 30 survey responses were received, resulting in a wide range of technical inputs based on differing contexts and broad geographic representation. A summary of the results of the consultation was sent to all who participated in the consultation process, be it through interview or survey.

# HLIP III draft development

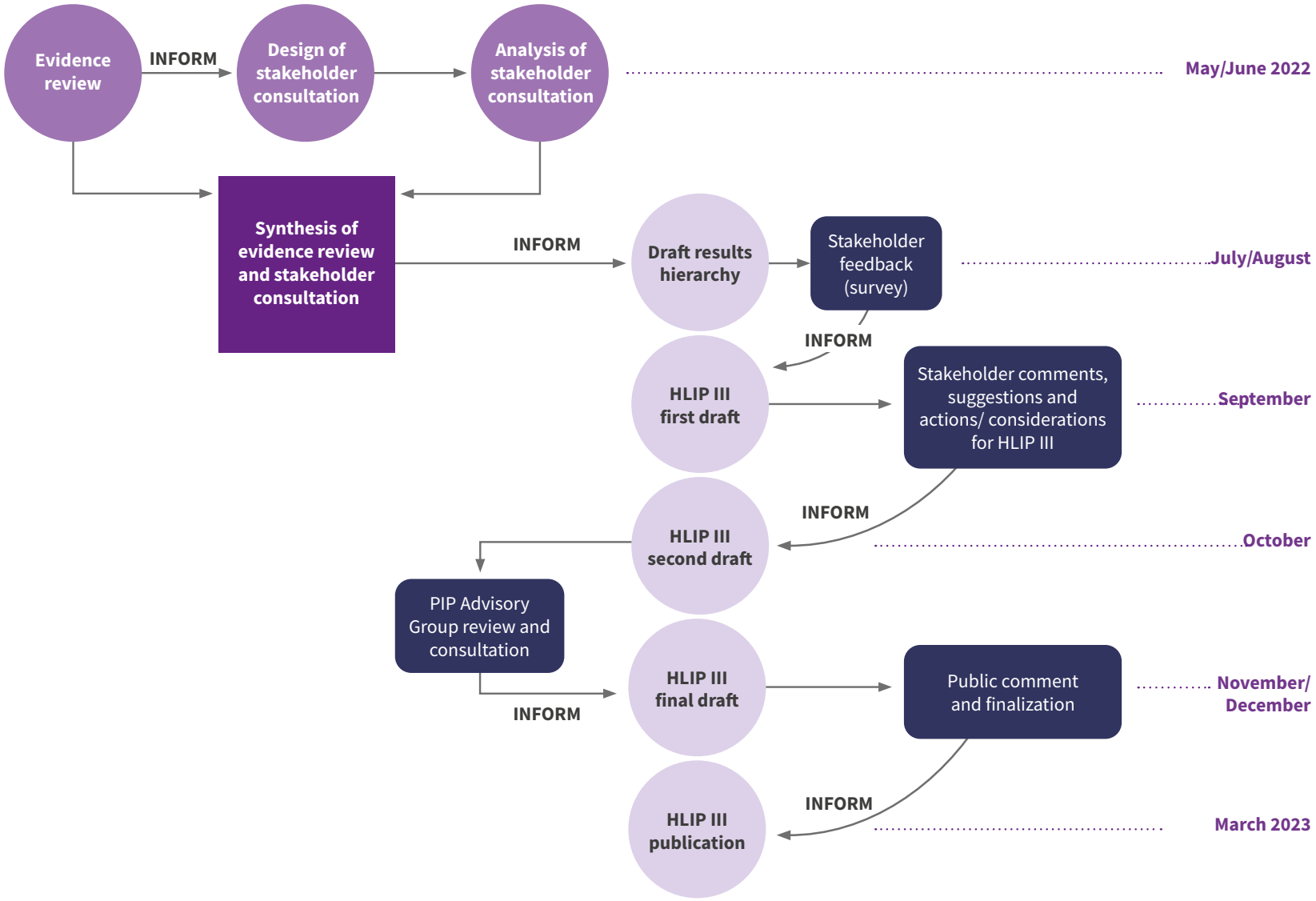
As visualized in Fig. A2.1, the steps taken to develop the design of HLIP III were:

- **Synthesis.** The findings from the stakeholder consultation were consolidated and synthesized, and then merged with the findings from the evidence review. The result of this detailed synthesis led to the development of the first draft of the results hierarchy, which was sent to stakeholders in August 2022.
- **Review of results hierarchy.** Feedback was requested from all stakeholders via an online survey. Fifteen responses with over 80 comments were received. These comments were all carefully reviewed and considered, and they consequently helped to inform the first draft of HLIP III, which was then circulated to stakeholders in September 2022.
- **Review of HLIP III draft.** Feedback was requested from all stakeholders via an online survey. Twenty-two responses and over 110 comments were received. All comments were carefully reviewed and considered. The varying perspectives and inputs were reflected in the document, keeping in mind the relevance of the inputs to improving pandemic influenza preparedness, consideration of the gaps and needs, the gains

made, lessons learned, feasibility of implementation and the evolving landscape. Throughout this process, WHO staff from headquarters, regional and country offices were consulted to ensure the operational feasibility of the evolving design.

- **Submission to the PIP Advisory Group.** An advanced draft of HLIP III was submitted to the PIP Advisory Group and shared with stakeholders in October 2022.
- **Finalization.** All recommendations made by the PIP Advisory Group were incorporated into a final draft for public comment in November 2022. The plan was finalized in early 2023.

## Figure A2.1. A flow chart of iterative consultations with the PIP Framework stakeholders



# Annex 3. Illustrative annual budget

A high-level illustrative annual budget for 2024–2030 is presented below. It is subject to change. Budgets will be refined at the time of work plan development, and will be based on needs of country, regional and global implementation to achieve project deliverables, while also considering funding availability and absorption capacity.

| Preparedness | WHO headquarters | Regional and country levels | Annual |
|---|---|---|---|
| Output 1: Policy and plans | 1 250 000 | 2 500 000 | 3 750 000 |
| Output 2: Collaborative surveillance through GISRS | 1 500 000 | 3 600 000 | 5 100 000 |
| Output 3: Community protection | 1 000 000 | 2 000 000 | 3 000 000 |
| Output 4: Access to countermeasures | 1 250 000 | 2 000 000 | 3 250 000 |
| Subtotal for preparedness | **5 000 000** | **10 100 000** | **15 100 000** |
| Planning contingency[a] | | | 510 619 |
| **Total for Preparedness** | | | **15 610 619** |
| Response[b] | | | 7 065 421 |
| PIP Secretariat | | | 2 477 876 |
| Programme Support Costs[c] | | | 2 846 084 |
| **TOTAL[d]** | | | **28 000 000** |

[a] The planning contingency will be assigned to the outputs based on assessed needs.
[b] Funds reserved by WHO in accordance with PIP Framework section 6.14.5 for use by WHO for pandemic influenza response activities.
[c] WHO Programme Support Cost is calculated at 13% of direct costs for the preparedness and Secretariat components, and 7% of direct costs for the response component.
[d] The current total annual income projection for 2024–2030 is subject to timely receipt of funds from contributors to the partnership contribution.

# Annex 4. Project management

This annex details how the PIP Secretariat plans to select PC countries and how it monitors technical progress and financial implementation and ensures quality reporting. This annex further explains the roles and responsibilities of WHO teams in HLIP III implementation.

## PC country selection

A three-step process will be used to select countries to receive PC funding.

**Step 1. Country profile:** the first step establishes a profile for all low- and middle-income 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 outputs.

**Step 2. Feasibility assessment:** the second step prioritizes countries for funding by using the set of feasibility and operationalization questions described below.

**Step 3. Confirmation of commitment:** the third step confirms PC recipient countries, after ensuring that countries are committed to implementing PC funded activities.

Each step is detailed below, first for Output 2 (Collaborative surveillance through GISRS) and then for Outputs 1, 3 and 4, which focus on the policy, planning and operationalization of capacities needed for pandemic influenza preparedness and response.

## Allocation of PC funds for Output 2

### Step 1. Country profile

In each region, the WHO regional office (in coordination with country offices) will establish a country profile for each country (in line with World Bank classifications of low and middle-income countries) according to the following criteria:

- Presence of influenza-like illness (ILI) or ambulatory respiratory disease surveillance
- Presence of severe acute respiratory infections (SARI) surveillance
- Presence of WHO-recognized NIC
- 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 in the last 3 years?
  - Did the country report timely and consistently to FluID in the last 3 years?
  - Did the country have timely and consistent reporting to FluNet in the last 3 years?
  - Did the country share influenza virus isolates or clinical specimens with WHO Collabrating Centres in the last 3 years?
- Inclusion of the country in the United Nations Global Humanitarian Overview list *(1)*.

## Step 2. Country prioritization criteria

In each region, the regional office will prioritize the countries according to the answers to the following questions, in consultation with WHO Collaborating Centres and relevant units at headquarters. Prioritization among countries will be made by the regional offices.

- From the profile items above, can performance be improved?
- If the country had a country level work plan during HLIP II (2018–2023), will HLIP III funding enable it to meet the output?
- Are funds from other sources available and sufficient to address the output in this country?
- Are there barriers for WHO to support influenza activities in this country? Consider operational and financial barriers including presence of concurrent emergencies that are diverting attention from pandemic influenza preparedness or whether previous PIP PC or influenza-related funds could not be implemented.
- Will PIP support to this country advance subregional, regional or global pandemic preparedness? Consider the country's population size and whether the country's influenza trends represent those for geographically proximate countries.

## Step 3. Confirming PC countries

The PIP Secretariat will inform each WHO regional office about the PC funds available. WHO regional offices 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.

# Allocation of PC funds for Outputs 1, 3 and 4

## Step 1. Country profile

In each region, the WHO regional office (in coordination with country offices) will establish a country profile for each low- and middle-income country according to the following criteria:

- Existence of a pandemic influenza preparedness plan and date of plan
- If plan is available, does the plan account for lessons from the COVID-19 pandemic?
- Country adoption of a national guideline for the emergency market authorization (including legal framework, guideline and written procedures for conducting the process) or presence of a roadmap to develop and endorse a national guideline
- Presence of a pandemic product (at minimum, vaccine) national deployment plan
- Presence of a mechanism for social listening to inform RCCE
- Country participation in WHO's Science Translation Network
- Inclusion of the country in the United Nations Global Humanitarian Overview list *(1)*.

## Step 2. Country prioritization criteria

In each region, the WHO regional office will prioritize the countries according to the answers to the following questions, in consultation with relevant units at headquarters. Prioritization among countries will be made by the regional offices.

- From the country profile (points 1 and 2), does the country have an up-to-date plan?
- Are funds from other sources available and sufficient to address these outputs in this country?
- Are there barriers for WHO to support influenza activities in this country? Consider operational and financial barriers including presence of concurrent emergencies that are diverting attention from pandemic influenza preparedness or whether previous PIP PC or influenza-related funds could not be implemented.

## Step 3: Confirming PC countries

The PIP Secretariat will inform each regional office about the PC funds available. Regional offices 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 these outputs.

# Technical monitoring

To facilitate technical monitoring and to maintain a results-based focus, outcome and output level indicators and deliverable level milestones are used to monitor progress. Within WHO, responsible officers are assigned at the three levels of the Organization to facilitate technical implementation and monitoring. Their monitoring functions include working with the PIP Secretariat, Ministry of Health and other relevant stakeholders to:

- Identify and take corrective actions in response to problems, delays and deviations
- Reprogramme (reschedule, revise or reprioritize products and activities)
- Reallocate and refocus financial and human resources for efficient implementation

Each month the PIP Secretariat holds teleconferences with responsible officers at headquarters and regional offices. 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 responsible officers in WHO headquarters and regional offices to review technical and financial progress and to kick-start processes for the development of future work plans. See Table A4.1 for a summary of technical monitoring methods.

# 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 headquarters departments, regional office divisions and country offices are responsible for monitoring aspects of implementation including implementation of approved work plans (staff and activity), financing, and risks associated with budget management. This is done using the financial tracking system (GSM) and other tools (for example Business Intelligence, which is an internal WHO system).

Additional monitoring and oversight are provided by the PIP Secretariat. Each month, the PIP Secretariat provides all implementing units at headquarters and regional offices as well as the EPP 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 by the technical units at all three levels of the Organization to support short and long-term planning, troubleshooting and risk management in the case that implementation is off-track. It also facilitates reporting to senior management and other stakeholders on progress against work plan targets.

Moreover, 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 in consultation with Ministry of Health or other stakeholders as relevant. Significant course corrections, if required, are escalated to senior management for approval and recorded under standard WHO change control procedures.

In addition to the routine financial monitoring processes, additional measures such as an external audit *(2)* 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.

Table A4.1 presents a summary of financial monitoring methods.

### Table A4.1 Summary of monitoring and evaluation methods

| Type | Frequency | Description |
|---|---|---|
| **Technical monitoring** | Monthly | Monthly calls between headquarters, regional offices and PIP Secretariat. |
| | 6-monthly | Milestone monitoring on deliverables. |
| | Annual | Outcome and output indicator monitoring. |
| | | Yearly global planning meeting between PIP Secretariat, and technical units in headquarters and regional offices. |
| **Financial monitoring** | Monthly | Financial reports on all implementation from the PIP Secretariat. |
| | | Financial monitoring by WHO technical teams at the three levels of the Organization. |
| | 6-monthly | Compliance checks by PIP Secretariat. |
| | Subject to WHA request | External auditor-specific examination *(2)*. |
| **Evaluation** | Mid-HLIP III | Midterm review to assess progress and consider changes in HLIP III. |
| | End-HLIP III | End of HLIP III evaluation and impact assessment. |

# Reporting

Table A4.2 outlines the different reporting methods used for HLIP III implementation and their relative frequency.

## Table A4.2 HLIP III implementation reporting

| Reporting frequency | Product | Description |
|---|---|---|
| **Bi-Monthly** | Newsletter | Presents select country, regional and global achievement(s) in PIP PC implementation as stories from the field in the *influenza@WHO* newsletter. |
| **6-Monthly** | Presentation to PIP Advisory Group and other stakeholders | Provides updates on the implementation status of all deliverables through milestones and financial implementation rate for all outputs. |
| | Progress report | Reported to the Advisory Group and other stakeholders every six months at semi-annual meetings and the report is published on the PIP website. |
| | WHO's Programme Budget Portal | Provides details on financial and technical progress up to the output level and including at country level. Compliant with the International Aid Transparency Initiative (IATI). |
| **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. Published on the PIP website. |
| **Biennial** | Biennial 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. Published on the PIP website. |
| | 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. |

# Roles and responsibilities of WHO teams in HLIP III implementation

All three levels of the WHO are involved in the day-to-day of HLIP III implementation, but each with unique roles (see Table A4.3). The PIP Secretariat leads planning, monitoring and reporting processes, and manages the distribution of funds to implementing units. Technical teams at country, regional and headquarters also support monitoring and reporting processes, and are responsible for developing work plans in consultation with their respective stakeholders. Each regional and headquarters 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, the WHO health emergencies focal points are responsible for coordinating with Ministry of Health and other stakeholders to facilitate implementation of planned activities.

Teams at WHO headquarters work in collaboration with the regional offices to ensure that implementation addresses regional needs and promotes increased preparedness. In turn, regional offices are responsible for liaising and collaborating with country offices to reflect country-level needs and Ministry of Health priorities.

## Table A4.3 Roles and responsibilities of WHO teams in HLIP III, by organizational level

| Role and responsibility | WHO country offices | WHO regional offices | WHO headquarters technical units | PIP Secretariat |
|---|---|---|---|---|
| **Planning** | Support Ministry of Health to develop work plans | Develop regional level work plans<br><br>Collaborate with headquarters teams to align country, regional and global work plans | Develop global work plans<br><br>Collaborate with regional offices to ensure alignment of country, regional and global work plans | Provide work plan templates<br><br>Provide programmatic and budget guidance to country, regional and headquarters teams<br><br>Review all work plans to confirm alignment with the HLIP III results hierarchy<br><br>Prepare all reviewed work plans for senior management approval<br><br>Inform and engage with the PIP Advisory Group, PCITEM and external stakeholders as appropriate |
| **Implementation** | Support Ministry of Health to implement activities at country level | Implement activities at regional level<br><br>Support country level implementation as necessary | Implement activities at global level<br><br>Support regional implementation as necessary | |

| Role and responsibility | WHO country offices | WHO regional offices | WHO headquarters technical units | PIP Secretariat |
|---|---|---|---|---|
| **Monitoring** | Work with Ministry of Health to monitor and record progress on activities (milestones), indicator data and financial implementation<br><br>Trigger work plan changes to regional offices if necessary | Monitor and record progress on activities (milestones), indicator data and financial implementation across the region<br><br>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<br><br>Analyse global level data and request work plan changes to PIP Secretariat if necessary | Provide monitoring and reporting templates<br><br>Monitor and record progress on activities (milestones) and indicator data<br><br>Update baseline work plans as necessary |
| **Reporting** | Monthly, semi-annual and annual progress reports to regional offices | Monthly, semi-annual and annual progress reports to PIP Secretariat | Monthly, semi-annual and annual progress reports to PIP Secretariat | Provide biennial reports to Member States and semi-annual and annual reports to PIP Advisory Group and stakeholders<br><br>Publish updates on implementation in the *influenza@WHO* Newsletter |

# References

1. Global Humanitarian Overview 2022. United Nations Office for the Coordination of Humanitarian Affairs (OCHA). (https://www.unocha.org/2022GHO, accessed 16 December 2022).
2. Basic documents: forty-ninth edition (including amendments adopted up to 31 May 2019). Geneva: World Health Organization; 2020 (https://apps.who.int/gb/bd/, accessed 16 December 2022).

# Annex 5. Risk analysis

This risk analysis presents an overview of high-level risks to PC implementation, and potential mitigation strategies. These risks were identified based on a high-level analysis of the programme, as well as risks identified during prior implementation periods. Mitigation strategies incorporate learnings from both HLIP I and HLIP II.

## Table A5.1 Risk analysis: planning stage

| Stage | Risk | Potential effects | Mitigation strategy |
|---|---|---|---|
| **Planning** | Lack of coherence with, or duplication of other WHO programmes or initiatives | Inefficient use of PC preparedness funds | • Consult with other WHO programmes on HLIP III, and be clear about existing synergies<br>• Communicate with other WHO teams during planning to prevent duplication<br>• 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 | • Apply the transparent country selection criteria and process outlined in HLIP III Annex 4 and communicate to stakeholders<br>• Limit the role of the PIP Advisory Group to providing feedback on the criteria for country selection |
| | Workplans not in line with the HLIP III results hierarchy | • Activities set out in workplans do not deliver on the outputs and deliverables<br>• Reduction in the overall impact of the PC preparedness funds | • Provide implementing teams with a workplan template based on the HLIP III outputs and deliverables<br>• Conduct iterative internal work plan reviews, including a 360-feedback review, to ensure work plans are designed to deliver on the outputs and deliverables and are aligned globally, regionally and nationally<br>• External review of work plans by PCITEM |

## Table A5.2 Risk analysis: implementation stage

| Stage | Risk | Potential effects | Mitigation strategy |
|---|---|---|---|
| **Implementation** | Delayed implementation of projects | • Member State and stakeholder impatience/ dissatisfaction<br>• Member States raise concerns with WHO Director-General | • Develop realistic timeframes and funding estimates<br>• Provide regular implementation updates to WHO Director-General, PIP Advisory Group, industry and other stakeholders, and Member States<br>• Determine cause of delays and address immediately<br>• Ensure appropriate timeline and process for work plan development and approvals including timing of PCITEM<br>• Ensure timely distribution of funds to implementing units to facilitate implementation, taking into consideration annual and biennial closure period (late December) |
| | Delays with PIP PC contributions | Project implementation delayed/stopped/ truncated | • Adhere to PC standards of practice to identify contributors and collect PC funds on time<br>• Develop scalable and modular plans to accommodate available resources<br>• Review and monitor implementation on a regular basis, adjust plans and reprogramme resources, as necessary<br>• Escalate to PIP Advisory Group for guidance |
| | Lack of country recipient commitment | • Outputs not achieved<br>• No progress on indicators, outcomes compromised | • Develop clear criteria for country selection<br>• Require a letter of commitment from the Ministry of Health of recipient countries<br>• Adhere to monitoring processes and encourage progress on indicators<br>• Withdraw PC funds if, after intervention, country is unable to implement the funds or is not committed |

| Stage | Risk | Potential effects | Mitigation strategy |
|---|---|---|---|
| **Implementation** | Projects are not sustainable | Pandemic preparedness is not optimal in the long-term | • Ensure sustainability is integral to project development and a criterion for country selection<br>• Integrate sustainability as a planning principle for all actions taken under HLIP III<br>• Withdraw PC funds if, after intervention, country does not demonstrate ability to sustain projects in the long-term |
| | 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<br>• Staff budget to be reviewed with yearly fund allocation to ensure appropriateness |
| | Pandemic influenza event | Implementation slowed or halted | [Pandemic response begins]<br>• Rapidly evaluate status of implementation and assess potential for resource re-allocation to facilitate pandemic response |
| | Other pandemic event | Implementation slowed or halted | [Pandemic response begins]<br>• Rapidly assess potential for reallocation of funds and identify complementary activities that will facilitate response to the ongoing pandemic response while concurrently building capacity for a future influenza pandemic |

## Table A5.3 Risk analysis: management, accountability and reporting stage

| Stage | Risk | Potential effects | Mitigation strategy |
|---|---|---|---|
| **Management, accountability and reporting** | Deviation from approved work plan | • Products not aligned with intended outputs and deliverables<br>• Inappropriate use of PC preparedness funds<br>• Impacts stakeholder relations and diminishes trust | • Strict use of work plan change control process to confirm suitability of changes requested and coherence with the HLIP III results hierarchy<br>• PIP Secretariat reviews work plans thoroughly, conducts six-monthly compliance checks and engages responsible officers monthly (at headquarters and regional levels) to ensure influenza-specific implementation |
| | Insufficient staff to properly monitor implementation | Projects poorly managed, outputs not delivered, timeframes not met | • Develop realistic staffing plan for all levels of project implementation<br>• Build in flexibility to review processes as needed to ensure that tasks have reasonable expectations while ensuring high quality implementation<br>• Staff budget to be reviewed with yearly fund allocation to ensure appropriateness |
| | Managers do not monitor work plans | Over or under spend of PC preparedness funds | • PIP Secretariat conducts routine compliance checks<br>• Monthly updates from responsible officers on progress and work plan changes needed |

| Stage | Risk | Potential effects | Mitigation strategy |
|---|---|---|---|
| **Management, 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<br>• Provide PIP Advisory Group/ Executive Board/World Health Assembly regular updates on project implementation<br>• Report utilization of PIP funds on the WHO Programme Budget Portal which is compliant with the International Aid Transparency Initiative<br>• External auditor specific examination subject to World Health Assembly request |
| | Insufficient or inadequate implementation reporting | Member States and stakeholders raise concerns about implementation reporting | • Adhere to detailed financial and technical reporting processes based on monitoring and evaluation plan<br>• Include different kinds of monitoring and reporting methods (for example, qualitative stories and quantitative milestones/indicators) at regular time intervals (bi-monthly, semi-annually and annually). |

**World Health Organization**
20, Avenue Appia
1211 Geneva 27
Switzerland

**Email**: pipframework@who.int

**Website**: https://www.who.int/initiatives/pandemic-influenza-preparedness-framework