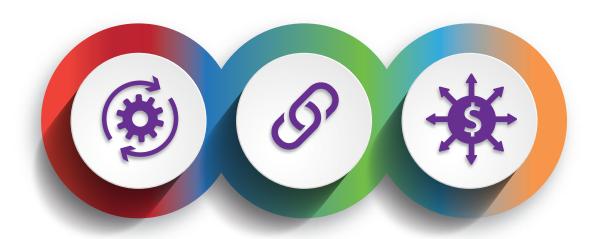
Pandemic Influenza Preparedness Framework

PROGRESS REPORT

1 January - 30 June 2018





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INTRODUCTION

The Pandemic Influenza Preparedness (PIP) Framework is an innovative public health instrument that brings together Member States, industry, other stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. The key goals include: to improve and strengthen the sharing of influenza viruses with human pandemic potential; and to increase the access of developing countries to vaccines and other pandemic response supplies.

The Framework includes a benefit-sharing mechanism called the Partnership Contribution (PC). The PC is collected as an annual cash contribution from influenza vaccine, diagnostic, and pharmaceutical manufacturers that use the WHO Global Influenza Surveillance and Response System (GISRS). Funds are allocated for: (a) pandemic preparedness capacity building; (b) response activities during the time of a pandemic; and (c) PIP Secretariat for the management and implementation of the Framework.

For pandemic preparedness capacity building, activities are implemented according to six outputs under one outcome in the High Level Implementation Plan (HLIP) II 2018-2023. The technical and financial investments 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. We thank countries and partners for their important role and contribution. The progress made and successes achieved are a result of joint collaboration on common objectives.

This report addresses the recommendation from the 2016 PIP Review that WHO develop a progress report that presents overall success metrics and infographics to illustrate progress in PIP Framework implementation. This is the first such report which will be updated every six-months. Technical and financial implementation for HLIP II and the PIP Secretariat are presented. Progress against milestones measured every six months and indicators measured yearly are presented cumulatively from 1 January 2018.

For financial implementation, progress is reported against the biennial workplan allocation. Figures presented exclude WHO Programme Support Costs (PSC) unless otherwise stated. For the mid-year reports, income, expenditures and encumbrances are presented, and are based on WHO's financial tracking system (GSM). For annual reports, income and expenditures are presented, in line with the yearly WHO Interim Certified Financial Statement (ICFS).

Many staff across WHO Clusters and Departments in all Major Offices support the implementation of the PIP Framework. Without their work, dedication and collaboration, there would be no progress to report on. We extend our sincere thanks to these staff for their invaluable input.

The report is structured as a series of infographics as follows:

- PIP Framework implementation overview (pages 6 7)
- Technical and financial implementation progress (pages 8 17)
- Financial annex including ICFS (reported annually only)

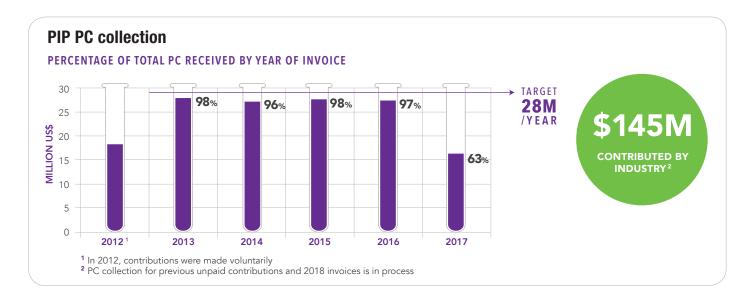
ACRONYMS & ABBREVIATIONS

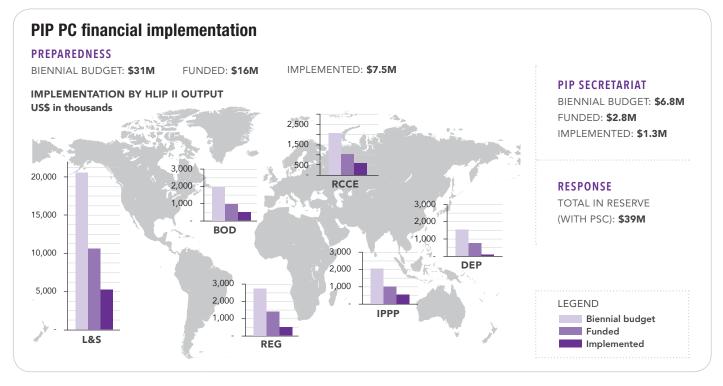
AFR WHO African Region **NITAG** National Immunization Technical Advisory AG Advisory Group **NRA** National Regulatory Authority **AMR** WHO Region of the Americas **NVDP** National Vaccine Deployment Plan BM Biological Material PC Partnership Contribution **BOD** Burden of Disease **PCR** Polymerase Chain Reaction CC Collaborating Centre PIP Pandemic Influenza Preparedness **CRP** Collaborative Registration Procedure **PIRM** Pandemic Influenza Risk Management **CVV** Candidate Vaccine Virus **PISA** Pandemic Influenza Severity Assessment **DFID** Department for International Development (United Kingdom) PQ Prequalification DG Director-General **PSC** Programme Support Costs EB **Executive Board QMS** Quality Management Systems **RCCE FMR** WHO Eastern Mediterranean Region Risk Communications and Community Engagement DEP Planning for Deployment **REG** Regulatory Capacity Building **EQAP** External Quality Assessment Programme RO Regional Office **EUR** WHO European Region **RRT** Rapid Response Teams GIP Global Influenza Programme **SAGE** Strategic Advisory Group of Experts **GISRS** Global Influenza Surveillance and Response System SARI Severe Acute Respiratory Infection **GSD** Genetic Sequence Data **SEAR** WHO South-East Asia Region **SFP** HAI Human Animal Interface Shipping Fund Project HLIP High-Level Implementation Plan SMTA2 Standard Material Transfer Agreement 2 **ICFS** Interim Certified Financial Statement **TAG** Technical Advisory Group IDP Institutional Development Plan **TOR** Terms of Reference Influenza-like Illness UNICEF United Nations Children's Fund ILI **IPPP** Influenza Pandemic Preparedness Planning **US CDC** United States Centers for Disease Control and Prevention ISID International Society for Infectious Diseases **US HHS** United States Department of Health and ISST Infectious Substances Shipping Training **Human Services IVPP** Influenza Virus with Pandemic Potential **VCM** Vaccine Composition Meeting **IVTM** Influenza Virus Traceability Mechanism **WER** Weekly Epidemiological Record L&S Laboratory and Surveillance Capacity Building **WHA** World Health Assembly **LMIC** Low and Middle Income Countries **WPR** WHO Western Pacific Region MS Member State **WHO** World Health Organization

NIC

National Influenza Centre

IMPLEMENTATION OVERVIEW





PIP Framework outcome indicators

OUTCOME

Improved global pandemic influenza preparedness and response through the implementation of the PIP Framework

Indicator	2017 Baseline	Status	2019 Target
% of Member States sharing IVPPs with GISRS according to WHO IVPP sharing guidance	N/A	annually	N/A
% of Member States reporting to FluNet (sustainability indicator)	86%		≥85%
% of Member States reporting to FluID	54%	updated	60%
% of Member States with BoD estimates considered by NITAG	N/A		30%
No. of Member States that have implemented regulatory approach	0 25%	g – Indicators	10
% of Member States that developed or updated a pandemic influenza preparedness plan			60%
% of companies reached to negotiate that signed an SMTA2	34%	Pending	50%
% of Partnership Contributions received in the year of invoice	N/A	<u>Р</u>	100%

PIP Biological Materials* shared

PIP BMs RECORDED IN IVTM





* For definition of 'PIP Biological Materials', see PIP Framework Section 4.1

SMTA2

SMTA2 WITH VACCINE & ANTIVIRAL MANUFACTURERS

Large / multi-national manufacturers

>75M

pandemic production



Medium-sized manufacturers

>5M and <75M

pandemic production



Small manufacturers

<5M

pandemic production



>400M

DOSES SECURED

SMTA2 WITH DIAGNOSTIC MANUFACTURERS & ACADEMIC AND RESEARCH INSTITUTIONS









65 SMTA2 WITH ACADEMIC & RESEARCH INSTITUTIONS



29BENEFIT-SHARING OFFERS ACADEMIC & RESEARCH INSTITUTIONS

PIP Framework governance

On 11-13 April 2018, the Secretariat held the 14th PIP Advisory Group meeting in Geneva, which included an afternoon of consultation with industry and other PIP Framework stakeholders.

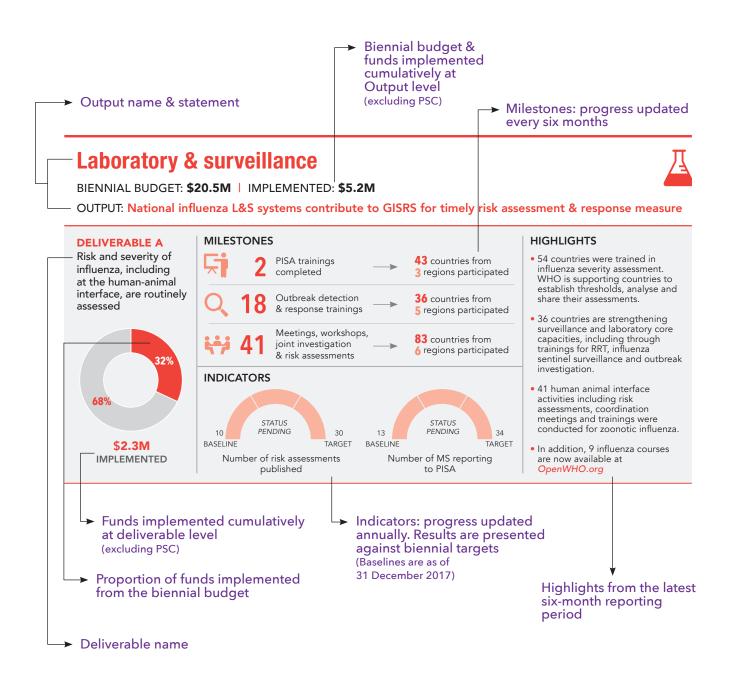


On 10 April 2018, the Secretariat held an Information Session on GISRS and the PIP Framework. The session was attended by more than 40 Member States and a wide range of stakeholders. The webcast from the session can be found at: http://www.who.int/influenza/pip/10_April_Info_Session/en/

In September 2018, the Secretariat will circulate the first draft of the Analysis on the scope of the PIP Framework as requested by the World Health Assembly in Decision 70(10)". This draft will be discussed by Member States and stakeholders at the 15-16 October 2018 consultations on the implementation of Decision WHA70(10)8b.

IMPLEMENTATION PROGRESS

OUTPUT READING GUIDE



Laboratory & surveillance



10

BASFLINE

MILESTONES

published

Proportion of MS that were

100% correct for non-seasonal

virus identification

MILESTONES



OUTPUT: National influenza L&S systems contribute to GISRS for timely risk assessment & response measure



Risk and severity of influenza, including at the human-animal interface, are routinely assessed



IMPLEMENTED

MILESTONES PISA trainings 43 countries from completed 3 regions participated Outbreak detection **36** countries from & response trainings 5 regions participated Meetings, workshops, 83 countries from joint investigation 6 regions participated & risk assessments **INDICATORS** STATUS STATUS

PENDING

30

13

PENDING

34

LINE

TARGET

BASELINE

TARGET

Number of risk assessments

Number of MS reporting

to PISA

Proportion of MS that were

100% correct for seasonal virus

identification

HIGHLIGHTS

- 54 countries were trained in influenza severity assessment.
 WHO is supporting countries to establish thresholds, analyse and share their assessments.
- 36 countries are strengthening surveillance and laboratory core capacities, including through trainings for RRT, influenza sentinel surveillance and outbreak investigation.
- 41 human animal interface activities including risk assessments, coordination meetings and trainings were conducted for zoonotic influenza.
- In addition, 9 influenza courses are now available at OpenWHO.org

DELIVERABLE B

Quality influenza virus detection capacity is sustained



\$1.1M IMPLEMENTED

72 countries from Laboratory trainings, missions and visits 6 regions participated completed **EQAP** status EQAP Results Results shared Results Contract with participating signed sent out received published in WER laboratories **INDICATORS** BASELINE BASELINE 96% 89% ANNUAL TARGET = 90% ANNUAL TARGET = 95%

HIGHLIGHTS

- Laboratory strengthening activities such as laboratory assessments, QMS capacity-building missions, and trainings in diagnostic methods and specimen handling were conducted in 72 countries.
- WHO coordinates yearly PCR EQAP for GISRS and other national influenza laboratories.
 The 2018 panel was sent out and results are pending. WHO and GISRS will support laboratories to improve performance as needed.

DELIVERABLE C

Countries are supported to consistently report influenza data to global platforms



IMPLEMENTED

Regional meetings held 116 countries from to improve global 4 regions participated surveillance systems Trainings, missions & **90** countries from other types of support 6 regions participated for surveillance provided Regional bulletins 4 regions involved published **INDICATORS BASELINE** BASELINE 86% 54% TARGET ≥ 85% TARGET = 60% Proportion of MS reporting Proportion of MS reporting to FluNet to FluID

- 5 regional meetings were held to discuss influenza trends and improve surveillance practices. This involved countries, GISRS institutions and other partners.
- WHO supported 83 countries on surveillance data management to streamline reporting to regional/ global platforms. This was done through remote technical support, regional and country meetings.
- Regional influenza bulletins are used by countries for monitoring influenza activity and to support decision-making. Countries are encouraged to produce national bulletins.



Laboratory & surveillance

DELIVERABLE D

Countries are supported to share timely representative influenza samples with WHO CCs



IMPLEMENTED

MILESTONES

Trainings on infectious substance shipping provided

27 countries from 2 regions involved



INDICATORS STATUS STATUS PENDING PENDING 37% N/A N/A 34% BASELINE TARGET **BASELINE** TARGET Proportion of MS sharing virus Proportion of MS sharing IVPPs with GISRS isolates/clinical specimens

HIGHLIGHTS

- Influenza virus sharing enables GISRS global monitoring, risk assessment and response.
- To ship infectious substances, laboratory staff must be certified.
 4 ISST were held in 2 regions to certify staff.
- WHO's Shipping Fund Project provides funds to enable countries to share influenza viruses up to four times per year. This facilitates the timeliness of viruses characterized by GISRS. In this reporting period, 155 shipments were made.

DELIVERABLE E

Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated



MILESTONES

Protocols and guidance reviewed, including translations

نبئ

1 Vaccine Composition Meeting consultations completed

new A(H5N6) CVV proposed

with CCs

INDICATORS



Number of zoonotic viruses & other IVPPs characterized by GISRS

- WHO IVPP sharing guidance, Seasonal influenza virus sharing guidance, and the updated NIC TOR were disseminated in all Regions in relevant languages to facilitate country utilization of these documents.
- GISRS closely monitors zoonotic influenza viruses for genetic and antigenic evolution to select additional CVVs required. During the VCM held in February 2018, 1 new A(H5N6) CVV was proposed.

Burden of Disease

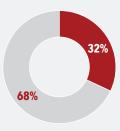
BIENNIAL BUDGET: \$2M | IMPLEMENTED: \$534K



OUTPUT: Influenza disease burden estimates are used for public health decisions

DELIVERABLE A

Representative national, regional and global disease burden estimates are available

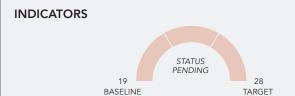


\$296K IMPLEMENTED

MILESTONE

Number of countries in each burden of disease estimate development stage





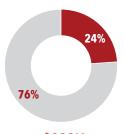
Number of MS with published disease burden estimates based on data collected since 2011

HIGHLIGHTS

- Influenza disease burden estimates are valuable to guide influenza policy development, and implementation of preventive measures. Globally, 23% of countries have estimated or published their national/ sub-national BOD estimates using data. 36 countries have established a plan to estimate BOD.
- Developing regional and global BOD estimates inform both national and international decision-making bodies on influenza preventive measures.
 To date, 53 countries have shared disease burden data for use in regional or global estimates.
- In addition, 2 online courses are now available at *OpenWHO.org* to assist countries in BOD calculation: (1) Estimating the disease burden associated with seasonal influenza, and (2) Estimating economic impact of seasonal influenza.

DELIVERABLE B

Disease burden findings are communicated to national and international expert bodies in a format that promotes evidencebased decision making



\$238K IMPLEMENTED

MILESTONE

2 countries

Shared/communicated BoD estimates to decision-making bodies

INDICATORS



Proportion of MS with burden of disease estimates that have been considered by NITAG or other decision-making bodies

- Calculating the proportion of countries with influenza burden estimates that have been considered by decision-making bodies is challenging. Progress reported here is based on country/regional self-report since the policy development process and impact on policy is rarely published.
- WHO is trying to identify a more systematic approach to monitor progress on this Deliverable. In discussion with the BOD steering committee and WHO regional offices on the benefits and challenges, a periodic country survey is under consideration.

Regulatory capacity building





OUTPUT: Timely access to quality-assured influenza pandemic products is supported

DELIVERABLE A

National regulatory capacity for pandemic influenza products is strengthened



IMPLEMENTED

MILESTONES

Refinements made to WHO Global benchmarking tool



Country benchmarked



6 IDP follow-up visits and implementation activities



INDICATOR



Number of MS which strengthened national regulatory capacity to oversee pandemic influenza products

HIGHLIGHTS

- WHO's global benchmarking tool was revised through public consultation to strengthen national regulatory capacity development and global harmonization.
- In 6 of the 16 PIP recipient countries, regulatory capacity strengthening activities including self-benchmarking and IDP implementation were conducted. Six countries also attended WHO CC pharmacovigilance training workshops.
- Challenges for national IDP implementation include political instability, NRA restructure and public health emergencies (e.g. Ebola). To sustain IDP implementation, WHO teams routinely followed up and technically supported affected countries.

DELIVERABLE B

Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted



\$357K IMPLEMENTED

MILESTONES



PIP regulatory guidelines translated to 5





Workshops/trainings conducted to implement the PIP regulatory guidelines linking national IPPP & NVDP for pandemic influenza vaccines



INDICATOR



Number of MS that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products

- Regulatory pathways to accelerate approval of products during emergencies include PQ and CRP. 38 countries were supported to participate in a WHO meeting on CRP and/or in an annual PQ assessment training.
- Country follow-up to advance adoption of regulatory pathways is critical. To enable this, nine global facilitators were trained through 'Global Learning Opportunities' courses on facilitation skills. This will improve the delivery and transfer of technical knowledge and skills to countries.

Risk Communications & Community Engagement



BIENNIAL BUDGET: \$2M | IMPLEMENTED: \$584K

OUTPUT: Tools and guidance are available for countries to enhance influenza risk communication and community engagement

DELIVERABLE A

Countries and frontline responders have access to resources for influenza risk communication, community engagement and social science-based interventions



\$366K IMPLEMENTED

MILESTONES



3 Guidance/modules available on OpenWHO



13 OpenWHO advocacy & marketing events



2 RCCE factors mapped in

priority country

INDICATORS



Number of users who completed OpenWHO influenza modules

HIGHLIGHTS

- OpenWHO.org has learning resources for pandemic influenza preparedness. PIP funds are used to maintain and promote the platform, develop RCCE specific courses as well as support the production process for other materials uploaded.
- Socio-cultural factors can impact disease spread and are important to consider in the design and delivery of public health interventions. Factors for pandemic influenza were identified and different processes to gather information defined. Two pilot countries are planning to map RCCE factors, one of which has already mapped two factors (language and religious leader networks).

DELIVERABLE B

Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement



\$218K
IMPLEMENTED

MILESTONES



4 Tr

Trainings, missions and other type of technical support provided involving

3 countries from3 regions

Implementation of global partnerships & networks for effective RCCE capacity $\label{eq:cce} % \begin{array}{c} \text{RCCE} & \text{RCCE} \\ \text{RCCE} \\ \text{RCCE} & \text{RCCE} \\ \text{RCCE} & \text{RCCE} \\ \text{RCCE} & \text{RCCE} \\ \text{RCCE} \\ \text{RCCE} & \text{RCCE} \\ \text{RCCE} \\ \text{RCCE} & \text{RCCE} \\ \text{RC$



INDICATORS

STATUS
PENDING
100
BASELINE TARGET

Number of MS that utilized RCCE support for influenza preparedness or response

- RCCE plans were developed in 3 countries, and a regional plan was developed in one region.
- WHO's SocialNet is a global surge capacity of anthropologists and social scientists equipped to support emergency response operations. Experts from SocialNet were deployed to three non-influenza outbreaks (Ebola, Listeriosis and Lassa fever) to sustain skills and capacities (non-PIP funded).
- Collaborations ongoing to leverage resources and capacities with UNICEF, CORE Group, Johns Hopkins University, iNSIST project, University of Dakar, Wellcome Trust, DFID, and ISID.

Planning for Deployment

BIENNIAL BUDGET: \$1.5M | IMPLEMENTED: \$126K



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DELIVERABLE A

A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partners



MILESTONES



PIP Deploy refinements to facilitate planning, allocation and coordination



Advocacy meeting for a common approach completed

INDICATOR



Annual simulation exercise conducted to test global deployment of pandemic influenza vaccines and other products

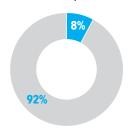
HIGHLIGHTS

- PIP Deploy is a simulation portal that enables stakeholders (countries, manufacturers, etc.) to test vaccine allocation, coordination and distribution. Next steps from the November 2017 global simulation include (a) formative work with stakeholders on plans/ procedures for deploying vaccines, and (b) refinement of the PIP Deploy application. Progress in January-June was limited due to delays in staff recruitment. Staff are now on board and activities will scale-up from July onwards.
- An internal WHO landscape analysis involving 35 staff from 13 units was held to identify preparedness gaps in vaccine deployment. An action plan is under development.

DELIVERABLE B

National deployment planning process is revised and updated

IMPLEMENTED



\$50K IMPLEMENTED

MILESTONES



Global guidance revised



Training, mission, visit and other type of technical support provided to update NVDP

HIGHLIGHTS

- Based on analyses conducted during HLIP I and in consultation with WHO country and regional offices, WHO deployment guidance (2012) remains relevant for countries to develop plans. Supportive tools including infographics and training package are under development to facilitate country use and application of the guidance.
- Questions about national deployment readiness were included in WHO's global IPPP survey. Responses will help define country support needs and technical assistance required.

DELIVERABLE C

Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries

MILESTONES

Number of countries in each phase of the sustainability assessment process



Ş

Training, mission, visit and other type of technical support provided

Deliverable C activities are supported by US HHS through Cooperative Agreement GH14-1420 between US CDC and WHO. PIP funds were not used to date.

STATUS PENDING 8 BASELINE TARGET

Number of MS that have undergone a national analysis of influenza vaccine procurement or production sustainability

- Sustainability assessments allow countries to sustain local production (where applicable) and encourage national procurement of seasonal influenza vaccines with the goal of increasing pandemic preparedness.
- Since the assessments started in 2014, 7 have been completed. In this reporting period, one country agreed to undertake an assessment, one started with a kick-off meeting, and 2 finalized and published their assessment reports.
- The assessment provides a platform for multiple sectors, including health, industrial and economic, to identify opportunities for better coherence and coordination among policies and programmes that would enable sustainable production/procurement of influenza vaccines.

Influenza Pandemic Preparedness Planning



BIENNIAL BUDGET: \$2.3M | IMPLEMENTED: \$475K

OUTPUT: National pandemic influenza preparedness & response plans are updated in the context of all-hazards preparedness and global health security

DELIVERABLE A

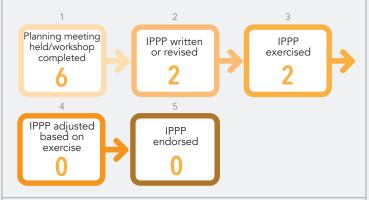
Countries are supported to develop, test and update their pandemic influenza preparedness plan



\$475K IMPLEMENTED

MILESTONES

Number of countries in each phase of the IPPP development/revision process



INDICATORS



Proportion of MS that developed or updated a pandemic influenza preparedness plan

Proportion of MS that exercised their pandemic influenza preparedness plan

30%

TARGET

- WHO advises countries to develop pandemic influenza risk management plans that are multisectoral and that engage whole-ofsociety. Plans should be regularly tested and updated to maximize operational readiness.
- 10 countries from 4 regions undertook activities to develop, update or exercise their plans.
- Leveraging other resources, WHO published guidance including essential steps and a checklist for pandemic planning. Training materials and a simulation exercise guide are also being developed. These resources will increase the efficiency of implementation at regional and country level.
- In addition, WHO is conducting (1) a global IPPP survey to assess national pandemic planning needs and (2) an analysis of influenza preparedness plans in the context of other national disease response plans. Findings from the survey and the analysis will inform future support in the context of IHR (2005) core capacities and all-hazard preparedness.

PIP Framework Secretariat

BIENNIAL BUDGET: \$6.8M | IMPLEMENTED: \$1.3M

OUTPUT: The PIP Secretariat leads, manages and supports implementation of the PIP Framework



DELIVERABLE A

Promote the effective implementation of the PIP Framework in a changing environment



IMPLEMENTED

MILESTONES



Meetings held and reports submitted to WHO DG or governing bodies to support implementation of section 7 of the PIP Framework



Status of the Analysis requested by WHA 70(10)



consulted

Analysis submitted to and discussed by EB

Analysis submitted to and discussed at WHA





Advocacy materials/events completed to promote the PIP Framework to stakeholders

HIGHLIGHTS

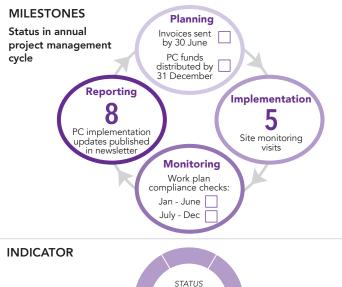
- WHO developed 7 Fact Sheets that concisely present basic information about specific topics related to the Analysis such as Biosafety & biosecurity, GSD and Databases, and New Technologies. For more information see http://www.who. int/influenza/pip/Documents_ WHA70108b/en/
- WHO worked closely with the PIP AG and WHO CCs to develop the draft Analysis on the scope of the PIP Framework.
- Several talks and presentations on PIP were provided to Member States, Academic Institutions, technical gatherings and other fora.

DELIVERABLE B

Collect, implement, monitor and report on the Partnership Contribution



\$432K **IMPLEMENTED**



PENDING 100% (\$28 M) **BASELINE** TARGET

Proportion of Partnership Contributions received in year of invoice

HIGHLIGHTS

- Delays expected in the issuance of 2018 invoices due to revision of documentation and reconciliation of unpaid contributions.
- Monitoring visits were conducted to AFR, AMR, EMR, SEAR and WPR to discuss timely and quality implementation of activities.
- Financial and technical implementation was monitored through monthly coordination calls and financial monitoring reports. The mid-year compliance check to ensure that fund distribution, budgeting and expenditures are compliant with approved workplans will be completed by August 2018.
- "Highlights from the Field" on preparedness and capacity-building activities are published in the online PIP newsletter. See: http://www.who.int/ influenza/pip/pip_newsletter/en/

DELIVERABLE C

Negotiate and plan to operationalize the Standard Material Transfer Agreements 2 (SMTA2)



MILESTONES

Number of SMTA2s in negotiation

With manufacturers With manufacturers With academic of vaccines and/or of other pandemic & research antivirals related products institutions

INDICATOR STATUS PENDING 34% 50% BASFLINE TARGET Proportion of companies reached to negotiate that signed an SMTA2

- 2 SMTA2s were concluded with manufacturers between January and June 2018: one with influenza vaccine manufacturer Takeda (8% donation and 2% reserved pricing) and one with influenza diagnostics manufacturer Becton Dickinson (25 million syringe donation).
- For more information on the agreements signed to date and related benefits http://www.who. int/influenza/pip/benefit_sharing/ smta2_signed/en/



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