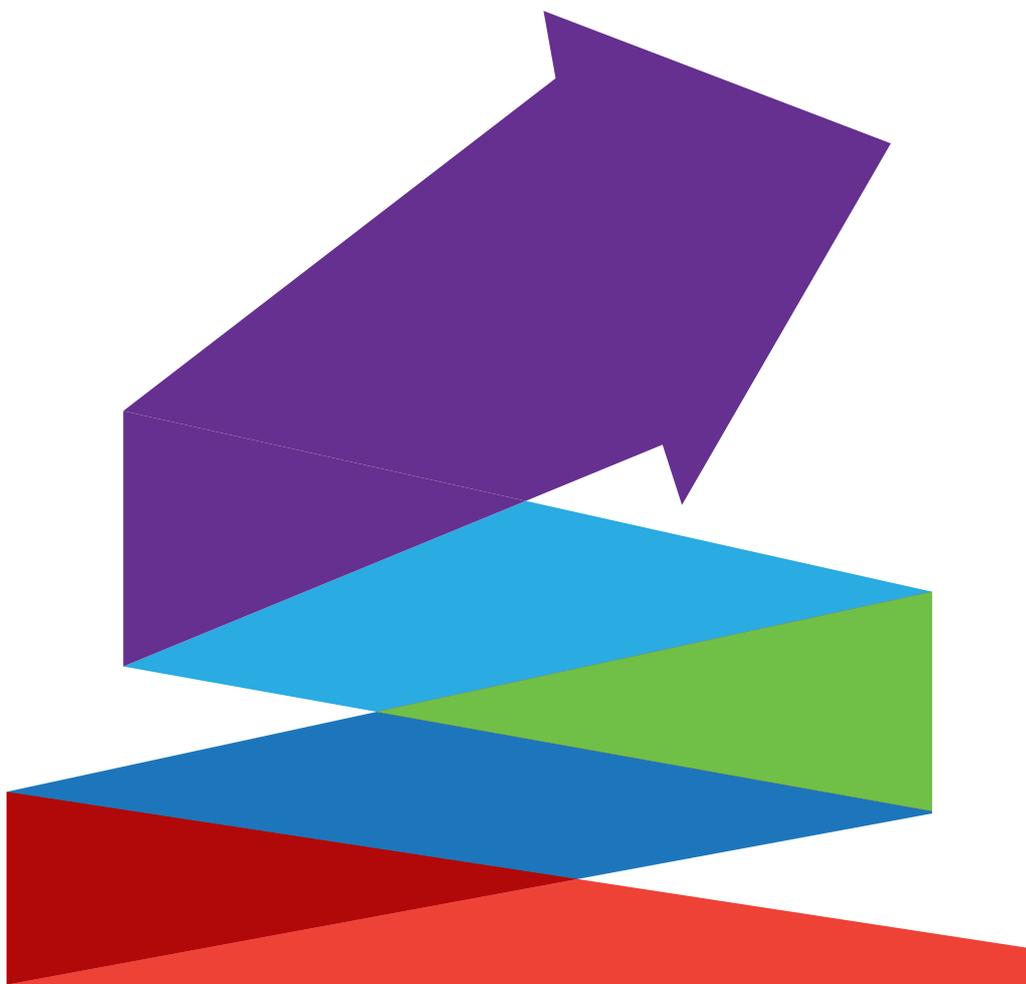


# Pandemic Influenza Preparedness Framework

PARTNERSHIP CONTRIBUTION IMPLEMENTATION PLAN



## **Analysis of Gaps and Needs for the PIP PC Implementation**



World Health  
Organization

© World Health Organization 2017. All rights reserved.

All rights reserved. Publications of the World Health Organization are available on the WHO web site ([www.who.int](http://www.who.int)) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: [bookorders@who.int](mailto:bookorders@who.int)).

Requests for permission to reproduce or translate WHO publications –whether for sale or for non-commercial distribution– should be addressed to WHO Press through the WHO web site ([www.who.int/about/licensing/copyright\\_form/en/index.html](http://www.who.int/about/licensing/copyright_form/en/index.html)).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Published: 31 January 2017

# Pandemic Influenza Preparedness Framework

PARTNERSHIP CONTRIBUTION IMPLEMENTATION PLAN

## **Analysis of Gaps and Needs for the PIP PC Implementation**



# Table of Contents

<b>1.</b>	<b>Introduction</b> .....	<b>02</b>
<b>2.</b>	<b>Value of achievements to date</b> .....	<b>03</b>
<b>3.</b>	<b>AOW Activities</b> .....	<b>04</b>
<b>3.1</b>	<b>Laboratory &amp; Surveillance Capacity Building</b> .....	<b>06</b>
<b>3.2</b>	<b>Burden of Disease</b> .....	<b>06</b>
<b>3.3</b>	<b>Regulatory Capacity Building</b> .....	<b>07</b>
<b>3.4</b>	<b>Risk Communications</b> .....	<b>07</b>
<b>3.5</b>	<b>Planning for Deployment</b> .....	<b>08</b>
<b>3.6</b>	<b>Proposed new directions</b> .....	<b>08</b>
<b>4.</b>	<b>Regional Offices and country-level implementation</b> .....	<b>10</b>
<b>4.1</b>	<b>Regional Offices</b> .....	<b>10</b>
<b>4.2</b>	<b>Country-level implementation</b> .....	<b>10</b>
<b>5.</b>	<b>Enabling factors for improving implementation</b> .....	<b>12</b>
<b>5.1</b>	<b>Implementation process</b> .....	<b>12</b>
<b>5.2</b>	<b>Funding</b> .....	<b>12</b>
<b>6.</b>	<b>Conclusion</b> .....	<b>14</b>
	<b>Appendix 1: Overview of Methodology</b> .....	<b>16</b>
	<b>Appendix 2: Supporting Factors for Implementation of AOW Activities</b> .....	<b>20</b>

# Acronyms & abbreviations

<b>AOW</b>	Area of work
<b>CC</b>	Collaborating Center
<b>CDC</b>	United States Centers for Disease Control and Prevention
<b>CO</b>	Country Office
<b>ERL</b>	Essential regulatory laboratory
<b>GAP</b>	Global Action Plan for Influenza Vaccines
<b>GIP</b>	Global Influenza Programme
<b>GISRS</b>	Global Influenza Surveillance and Response System
<b>HLIP</b>	High level implementation plan
<b>HQ</b>	WHO Headquarters
<b>IHR</b>	International Health Regulations
<b>IPC</b>	Infection, prevention and control
<b>IVR</b>	WHO Initiative for Vaccine Research
<b>L&amp;S</b>	Laboratory & Surveillance
<b>MERS</b>	Middle East Respiratory Syndrome
<b>NIC</b>	National Influenza Centre laboratory
<b>NRA</b>	National regulatory authority
<b>PC</b>	Partnership contribution
<b>PHI</b>	Public Health, Innovation and Intellectual Property
<b>PIP</b>	Pandemic Influenza Preparedness
<b>R&amp;D</b>	Research and development
<b>RO</b>	Regional Office
<b>SWOT</b>	Strengths, weaknesses, opportunities and threats
<b>WHO</b>	World Health Organization

# Acknowledgments

This document benefitted from the input of many people who contributed their time through interviews, workshops, the anonymous survey, or who sent us written comments. WHO would like to acknowledge the following people, who participated in the original SWOT analysis, face-to-face interviews or meetings to identify the gaps and needs for pandemic influenza preparedness presented in this report:

Atika Abelin | Tjandra Aditama | Claudia Alfonso | William Ampofo | Phyllis Arthur | Chris Baggoley | Jarbas Barbosa da Silva Jr | Paula Barbosa | Ian Barr | Jennifer Barragan | Terry Gail Besselaar | Sylvie Briand | Caroline Brown | Mia Brytting | Nancy Cox | Razieh Ostad Ali Dehaghi | Philippe Desmeth | Mamoudou Harouna Djingarey | Matthew Downham | Erica Dueger | Nedret Emirogl | Julia Fitzner | Gaya Manori Gamhewage | Bruce Gellin | Phil Gould | Hamad Ali Hamad El-Turabi | Ruth Harvey | Lisa Hedman | Belinda Herring | Christopher Herz | Didier Houssin | Aeron Hurt | Anne Huvos | Philippe Jacon | Sandra Jackson | Daniel Jernigan | Kerri-Ann Jones | Jaqueline Katz | Wasiq Khan | Raymond Lin Tzer Pin | Miho Maruoka | John McCauley | Fran McGrath | Ziad A. Memish | Janneth Maridadi Mghamba | Cuauhtémoc Mancha Moctezuma | Ann Moen | Hama Issa Moussa | Claudia Nannei | Zsolt Nemeth | Richard Njouom | Takato Odagiri | Rakhee Palekar | Paba Palihawadana | William Perea | Huma Qureshi | Mahmudur Rahman | Paul Rogers | Gina Samaan | Tharini Sathiamoorthy | Tamara Schudel | Sangeeta Shashikant | Nikki Shindo | Yuelong Shu | Steve Solomon | Erin Sparrow | Kate Strong | Oliver Gerd Strucke | Beverly Taylor | Katelijn Vandemaele | P.V. Venugopal | Niteen Wairagkar | Richard Webby | Margarita Xydia-Charmantha | Thedi Ziegler | Wenqing Zhang | Weigong Zhou.

# 1. Introduction

*The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits* (PIP Framework) is an international arrangement adopted by the World Health Assembly in May 2011 to improve global pandemic influenza preparedness and response.<sup>1</sup> The Framework establishes a PIP Benefit Sharing System that includes an annual partnership contribution (PC) to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers that use the WHO Global Influenza Surveillance and Response System (GISRS).<sup>2</sup> The Framework specifies that the PC resources shall be used to improve pandemic preparedness and response by building country capacity to detect, monitor and share novel influenza viruses with human pandemic potential.<sup>3</sup>

This report presents the results of a **Gaps and Needs Analysis** undertaken in 2016 to support development of the next high level Pandemic Influenza Preparedness (PIP) Partnership Contribution (PC) Implementation Plan (HLIP II) that will guide future planning and allocation of preparedness funds under the World Health Organization *Pandemic Influenza Preparedness Framework* (PIP Framework).

The process to develop the HLIP II began in September 2016 and contains two parts:

- 1) An independent, external evaluation to assess the value of achievements under PIP PC implementation from 2013 to 2016; and
- 2) A forward-looking 'Gaps and Needs Analysis' that identifies:
  - Actions that need continued support;
  - Areas of work that do not require further PIP PC fund support; and
  - New areas of work that can promote and strengthen pandemic influenza preparedness in countries.

Both parts of the process were undertaken in consultation with a wide range of PIP Framework stakeholder groups. The stakeholder groups that were engaged for the Gaps & Needs Analysis are as follows:

- PIP Framework Advisory Group
- PIP Secretariat
- WHO Headquarters
- WHO Areas of Work
- WHO Regional Offices
- WHO Country Offices
- External experts in pandemic influenza (from academia, foundations, national institutions and other organizations)
- GISRS Network - National Influenza Centre laboratories, WHO Collaborating Centres, Essential Regulatory Laboratories and H5 Reference Laboratories
- WHO Member States
- UN Partner Agencies
- Civil Society
- Industry

Four activity types were used to gather information: interviews and workshops (47 individuals participated); a SWOT (Strengths, Weaknesses, Opportunities and Threats) exercise (~45 individuals participated); an online survey (120 respondents); and a review of select secondary information (see **Appendix 1**). A detailed methodology for the process to gather information for the Gaps and Needs Analysis is found in **Appendix 1**.

<sup>1</sup> See <http://www.who.int/influenza/pip/en/> to download the Framework.

<sup>2</sup> See PIP Framework Section 6.14.3

<sup>3</sup> See PIP Framework Section 6.14.4

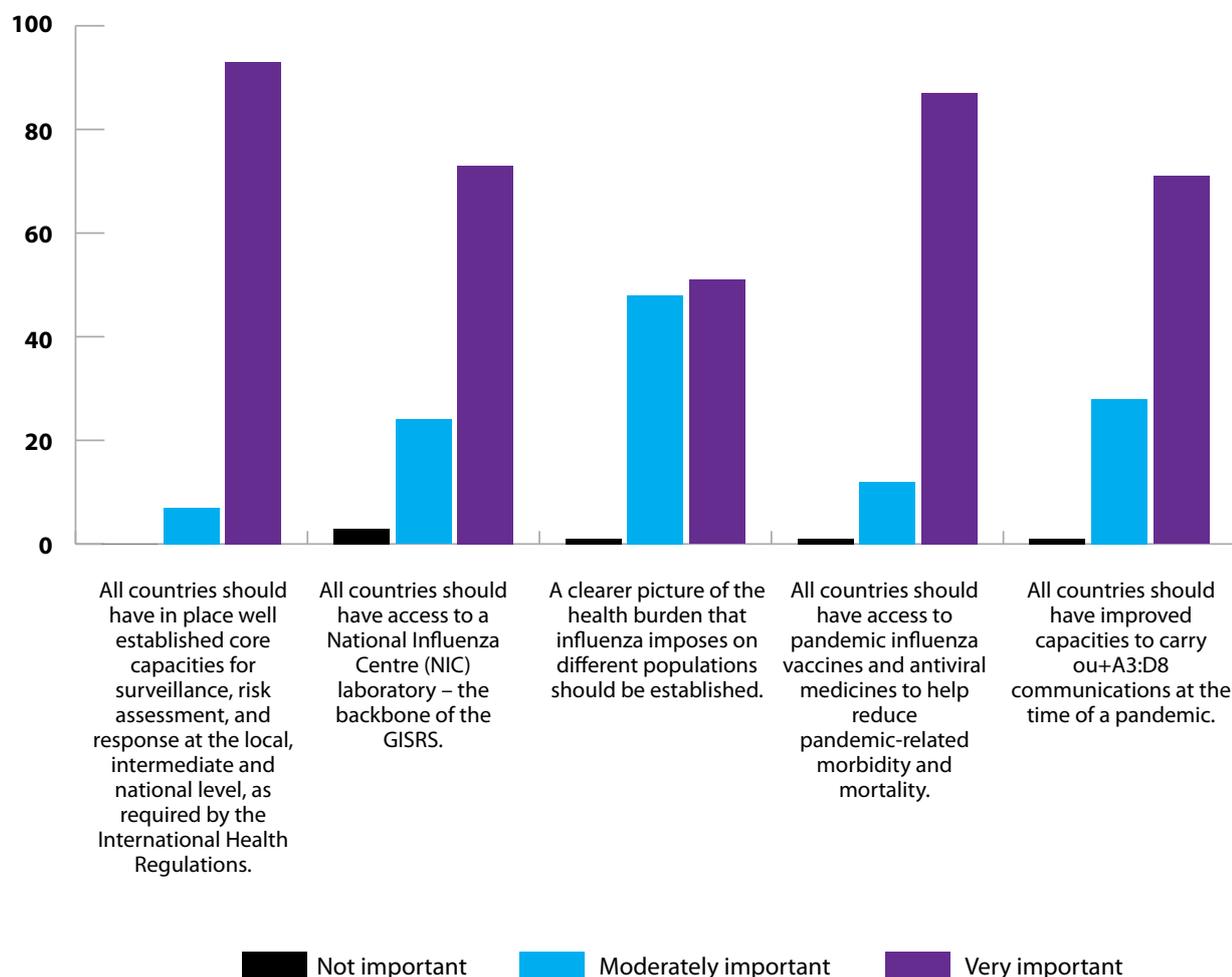
## 2. Value of achievements to date

PIP is widely viewed by stakeholders as an innovative program and partnership that has enabled the development of key aspects of pandemic influenza preparedness and has catalyzed preparedness efforts for many countries.

Many stakeholders noted that the PIP PC implementation plan is ambitious, and draws on health systems, laboratory systems and country capacities that exist outside of the reach of PIP. It will require time for success to be fully realized.

An external, independent evaluation will look at the value of achievements in depth, assessing progress under each AOW to achieve the outputs and outcomes from the HLIP I, and to measure the impact generated by each AOW in terms of how it has helped prepared the global community for pandemic influenza.

**Figure 1: Stakeholder perceptions on pandemic preparedness**



### 3. AOW activities



There are currently five areas of work (AOW) that focus the activities resourced by PIP PC fund implementation. Taken together, the AOWs are intended to strengthen specific capacities that are necessary for countries to be better prepared to respond to pandemic influenza. This is done with the recognition that the PIP Framework PC resources are supplementary and are not sufficient to comprehensively address all gaps; high-value activities, that complement what is being done by other initiatives, and that are likely to result in a substantial improvement in preparedness, must be carefully chosen.<sup>4</sup>

The outcomes, outputs and key activities developed for the AOWs were defined in 2013. Since that time, global preparedness has evolved and lessons have been learned from other outbreaks (e.g., Ebola, Zika, MERS). The Gaps & Needs Analysis revisited the priorities for addressing gaps in global preparedness in light of these changes.

**Figure 2** (page 5) shows the responses to the survey question “Which of the following factors represent gaps in current global pandemic influenza preparedness?” As can be seen in the figure, responses varied considerably among stakeholder groups, reflecting different groups’ priorities. There is no single factor that stood out above all as a critical gap, but the three factors that were considered to be at least a moderately important gap by at least three

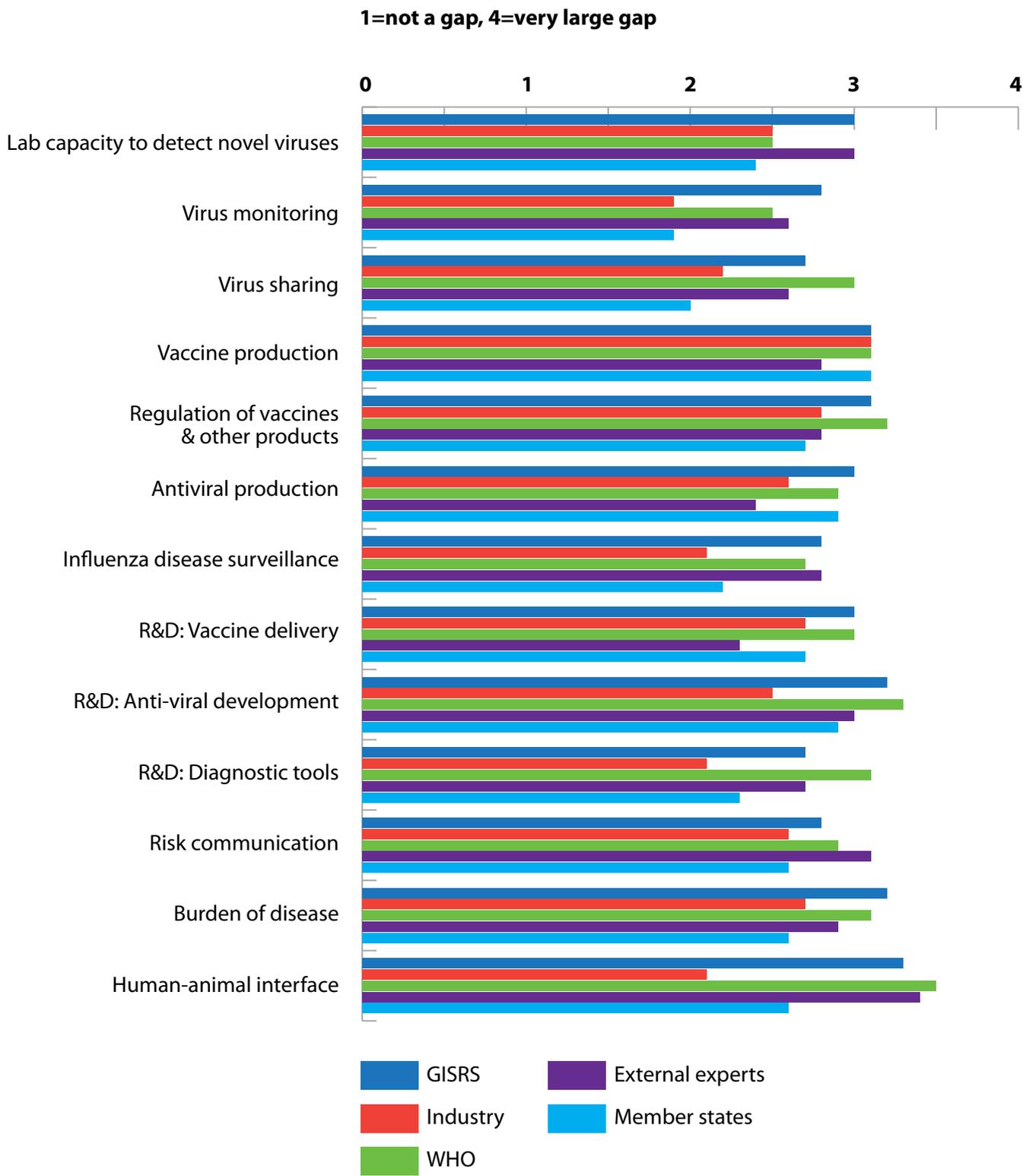
stakeholder groups were vaccine production; R&D on antiviral development; and the human-animal interface.

As the implementation of PIP PC contribution moves into the next phase with the development of HLIP II, choices will need to be made about which activities represent a priority for future funding. Some stakeholders have suggested taking a targeted approach in which fewer AOWs / activities are funded. A more targeted focus may help to more rapidly build capacity in specific areas, but would mean less attention to other areas that are equally important for global preparedness. Ultimately, a decision between a targeted approach versus a broader framework, will require strategic decision making for the HLIP II.

The following subsections describe stakeholders’ perspectives about how each AOW should evolve in order to achieve its outcomes, and what the priority gaps and needs are. This is followed by a discussion of several new potential areas of work that were proposed by respondents to complement the existing AOWs and more fully address preparedness issues.

<sup>4</sup> See [http://www.who.int/influenza/pip/pip\\_cpa\\_2015.pdf](http://www.who.int/influenza/pip/pip_cpa_2015.pdf) for more explanation of this process for selecting activities with the greatest impact.

**Figure 2: Current gaps in global pandemic influenza preparedness**



### 3.1 Laboratory & Surveillance Capacity Building

#### Areas to be discontinued

No areas to be discontinued under this AOW were identified.

#### Areas to be maintained

It was uniformly recommended that all activities currently undertaken in Laboratory and Surveillance should be maintained or enhanced (see below). In particular, continuing to establish and support NICs was identified as a high priority.

#### Areas to be enhanced or added

The following activities were identified, ordered from greatest to least stakeholder support.

- Enhance sustainable laboratory capacity building
  - Set different tiers of support for NICs/countries at different capacities, so that both basic and advanced laboratory skills can be appropriately built and monitored.
  - Align with existing capacity building initiatives not specific to influenza, for example, the capacity building activities under IHR.
- Increase the delivery of training and proficiency programs
  - Tailor trainings for different levels of laboratory capacity, using the WHO CCs to identify and coordinate the level of support required.
  - For basic-level training, encourage NICs to support each other in developing skills and develop a “train-the-trainer” model to increase the pool of available trainers.
  - Ensure that high-performing medium-level laboratories receive sufficient support so that capacity to detect, monitor and share novel influenza viruses does not decline.
  - Host advanced skills trainings at the WHO CCs to minimize loss of staff during the training or training being attempted in in-country laboratories with inadequate equipment.
  - Promote regional trainings including non-PIP countries to build capacities in a wider audience.
- Continue and enhance surveillance and quality measures
  - Extend surveillance activities to zoonotic events,
  - Improve capacity to analyze or interpret the data in-country.
  - Develop consistent and workable data systems to provide information on the severity of a pandemic.

- Improve evidence-based surveillance to detect unusual events.
- Improve risk assessment for GISRS, possibly incorporating elements from TIPRA.
- Extend GISRS to sharing epidemiology information as well as virological information.

- Increase access to reagents, sera, diagnostic tests and other materials. This is an area of high priority for many NICs.
  - Explore the use of joint purchasing agreements to support access to laboratory reagents and other supplies.
  - Develop countries’ ability to procure their own reagents to create a more self-sufficient and sustainable system and set reasonable expectations regarding the length of time PIP can provide support.
- Increase opportunities for collaboration, mentorship and cross-institution research, including additional inter- and intra-regional technical support and mentorship to help build capacity and enhance technical skills.
  - Create opportunities for cross-institutional research studies that achieve two ends: undertaking research to expand understanding of pandemic influenza; and enabling regional or cross-regional collaboration between NICs and other laboratories, which will provide opportunities for staff to build practical skillsets and confidence.
- Increase collaboration between GISRS personnel and PIP Secretariat to further involve GISRS in planning and implementation.
- Enhance support for virus sharing
  - Increase engagement with countries that are reluctant to share viruses.
  - Improve the logistics for virus shipping
  - Provide clarity on the impact of the Nagoya Protocol on virus sharing.
- Provide and train additional Laboratory and Surveillance staff within the WHO.
- Support further vaccine development.

## 3.2 Burden of Disease

### Areas to be discontinued

No areas to be discontinued under this AOW were identified.

### Areas to be maintained

Progress made to date varies substantially across regions. While current activities should be maintained, the nature of those activities will differ depending on where they are being applied. What needs maintaining in some regions needs more development in other regions.

### Areas to be enhanced or added

The following activities were identified, ordered from greatest to least stakeholder support.

- Identify ways to use burden of disease data to support policy development at a national or international level. A range of stakeholders noted that burden of disease data may help policy makers understand why a focus on pandemic influenza is relevant and useful; may create support in-country for PIP PC Implementation; and may create support for vaccination programs and other investments into preparedness.
- Improve country-level sharing of data. Investigate ways to encourage more countries to share raw burden of disease data.
- Improve linkages with surveillance data for seasonal influenza and animal influenza.
- Investigate additional approaches for understanding disease burden. Suggestions for modifications included:
  - Developing estimates for regions or climatic areas instead of country-specific estimates;
  - Investigating burden of disease amongst high-risk or vulnerable groups;
  - Developing methods for capturing the non-respiratory portion of disease burden; and
  - Validating and use hospital-burden data in areas where sentinel sites face limitations.
- Increase collaboration among regional and between WHO and other organizations around burden of disease data.

## 3.3 Regulatory Capacity Building

### Areas to be discontinued

No areas to be discontinued under this AOW were identified.

### Areas to be maintained

All activities currently undertaken in Regulatory Capacity should be maintained or enhanced (see below). Stakeholders noted, however, that it has been difficult to recognize progress made in this AOW for a number of reasons including the fact that regulatory capacity building is less specific to pandemic influenza than the other AOWs and that it is dependent on political and bureaucratic processes outside the control of the AOW, which affects the timeline for delivery of results. Better process indicators (discussed in Section 5.1) may improve the ability to demonstrate progress.

### Areas to be enhanced or added

The following activities were identified, ordered from greatest to least stakeholder support.

- Facilitate pre-qualification of vaccines and antivirals, for example through a fast-track process or through building on previous agreements with Ministries of Health. It is acknowledged that this area has challenges, but also constitutes an important priority.
- Develop regional or sub-regional regulatory harmonization policies. Among other benefits, harmonization would allow manufacturers to make donations if desired, while also reducing the burden of individual NRAs.
- Increase capacity building to strengthen national regulatory systems, pharmacovigilance and market authorization processes.

### 3.4 Risk Communications

#### Areas to be discontinued

No areas to be discontinued under this AOW were identified.

#### Areas to be maintained

Substantial and demonstrable progress has been made in Risk Communications. In addition, in light of the recent Ebola outbreak, stakeholders emphasized the need to maintain or enhance activities in this AOW, as discussed below.

#### Areas to be enhanced or added

The following activities were identified, ordered from greatest to least stakeholder support.

- Develop locally-grounded risk communications approaches in collaboration with ROs, in order to embed risk communication activities in national contexts and to improve public knowledge.
- Facilitate additional research and collaborations with social science disciplines to inform evidence-based development of risk communication strategies. Ensure that existing research from a range of disciplines is also being well-utilized.
- Strengthen outreach and collaboration to all stakeholders, including government sectors, civil society, private sector and other international agencies and actors. This will help to improve capacity building with a range of stakeholders and to align with other organizations.
- Develop methods to improve acceptability of influenza vaccines among the public.
- Increase focus on global systems building and resources for last minute capacity building and knowledge transfer.

### 3.5 Planning for Deployment

#### Areas to be discontinued

No areas to be discontinued under this AOW were identified.

#### Areas to be maintained

All activities currently undertaken in Planning for Deployment should be maintained or enhanced (see below).

#### Areas to be enhanced or added

The following activities were identified, ordered from greatest to least stakeholder support.

- Implement simulation exercises, including both antiviral deployment (planned for 2017) and vaccine deployment scenarios. This has substantial support from all stakeholders as an important priority to understand gaps in preparedness. Specific suggestions include;
  - Running both national and international simulation exercises;
  - Ensuring the simulations have an in-built external evaluation component;
  - Ensuring the simulations involve testing logistical coordination and communication capacities across institutions;
  - Tying the simulations into national preparedness plans and deployment plans, as a way to test plan effectiveness;
  - Greater collaboration across and between regions with WHO HQ in the development of simulation exercises;
  - Linking future simulation exercises with the IHR Monitoring and Evaluation Framework.
- Further enhance development of national vaccine and pandemic product deployment plans, including deployment of in-country vaccine stockpile and roll-out, preparing for sharing global vaccine supplies, and logistical considerations for non-vaccine materials (e.g. antivirals, syringes, needles). It was suggested that improved harmonization with other WHO programs (e.g. Access to Essential Medicines) for deployment of essential pandemic response medicines and products would support deployment. It was suggested by more than one stakeholder group that that to ensure successful deployment of pandemic vaccines, countries need to have seasonal vaccination systems in place.
- Catalyze development of criteria for global vaccine allocation, which relates to developing deployment plans, but may require development of a specific activity area.
- Increase collaboration among implementing partners, for example other WHO programs, other governmental and non-governmental international organizations responsible for emergency response, donors).
- Provide more in-country targeted training.

### 3.6 Proposed new directions

Several new areas have been suggested to operationalize preparedness, as described below. Some of these may be most appropriate to establish as a new AOW; others may be housed under an existing AOW, or span several different areas.

#### **National pandemic preparedness plans**

The development and regular updating of national pandemic preparedness plans was identified as a gap not currently addressed under any of the existing AOWs. While this area had broad support from a range of stakeholder groups, there were multiple—and sometimes conflicting—views as to the approach or elements that pandemic planning should include. These views are summarized below:

- There was disagreement over whether plans should be specific to pandemic influenza, include all severe infectious diseases, or take an all-hazards approach.
- There was acknowledgement that it will be difficult to harmonize plans at a country level, given that some national-level plans describe only how a country will respond at the time of a pandemic outbreak, while others also include capacity building prior to a pandemic.
- Sub-national pandemic plans are also needed for effective preparedness. Because large cities are particularly vulnerable due to global travel, urbanisation and density, they may also need to develop their own plans specific to the local capacity.

Preparedness planning will be a collaborative effort with support needed from a range of experts at different WHO levels (e.g. IHR, experts at WHO HQ) and with different partners and/or coordination with initiatives such as the Global Health Security Agenda (GHSa). Plans may also need support from disciplines such as animal health, risk assessment, IPC and vaccine deployment.

#### **Integration of the animal-human interface (using a “One Health” approach)**

There was strong support for integrating the “One Health” approach to human and animal influenza surveillance, risk assessment, and response. This change would most directly affect the L&S and Burden of Disease AOWs through extending surveillance and reporting to include zoonotic events. However, the approach to all AOWs would likely shift through the consideration of how public

health interacts with animal health, as well as the implications in terms of social, economic and other dimensions.

#### **Strengthening clinical management of pandemic influenza**

A number of stakeholders from WHO ROs and HQ pointed out that clinical management does not seem to be addressed in the current objectives but is also an important component of minimizing adverse effects of an eventual pandemic, especially at the start of a pandemic when vaccine are not yet available. Specific elements of clinical management that are important to address include deployment of antivirals and antiviral stockpile management, training of health care workers to manage cases and use antivirals appropriately, improved infection, prevention and control (IPC) training and practices, improved equipment for clinical management (e.g. ventilator machines, oxygen therapy) at health care facilities, and obtaining personal protective equipment (PPE) for health care workers.

There has been some work already done in this area in some regions, with interest expressed by others. There are several WHO guidance documents on the clinical management of influenza, and there is currently a process to produce a standard document that includes training curricula. If clinical management were to be added, there are a range of supports and existing processes to draw on to ensure that additional work would not be “reinventing the wheel”.

#### **Linkages between effective seasonal influenza vaccine campaigns and pandemic influenza vaccine roll-out**

A diverse group of stakeholders suggested that building capacity for seasonal vaccination should be included within PC implementation, as this capacity would help build the foundation for systems and structures (i.e. processes and resources) that are needed in a pandemic, for example with countries developing vaccine production capacity or establishing access to vaccine. A seasonal vaccination system in-country could also benefit the supply chain for other medicines and resources, such as diagnostic tools and antivirals.

However, other stakeholders noted that a focus on seasonal influenza would attenuate PIP’s pandemic focus. In particular, some industry stakeholders emphasized that PC implementation should retain a pandemic focus, as including seasonal could jeopardize industry commitments.

# 4. Regional offices and country-level implementation

## 4.1 Regional Offices

Due to the many differences across regions, each of the six regional WHO ROs faces unique issues. Regional flexibility is required to take into account countries' differing levels of preparedness and capacity to carry out key activities under each AOW. For example, regulatory capacity is very difficult to implement in the regions where there is no uptake of influenza vaccines, making this AOW an extremely low priority. Additionally, clinical management training has started in some regions that have already strengthened capacities in other AOWs. For these reasons, AOWs should work closely with Regional Offices to set priorities for their work stream according to regional capacities and needs.

Each RO is addressing preparedness in the way most appropriate for regional capacity, and these needs do not necessarily align with one another. This variance is challenging for reporting, as the current suite of indicators and other reporting mechanisms do not necessarily capture the full range of activities in which each region is engaging. Indicators that better represent actual implementation, as well as tailored objectives for different country capacities, will improve reporting accuracy.

Just as the specific activities implemented need to be decided on a regional basis, funding allocation works best with additional regional input. Increased control at a regional level (for example by funneling funds through the RO) will not only align with how other programs at the WHO are managed, but also will allow ROs to better manage implementation and improve accountability.

## 4.2 Country-level implementation

PC implementation funds have played an important role in helping many countries plan for preparedness. However, there remain a number of gaps and needs that must be addressed to promote progress towards pandemic preparedness at the country level.

### Country Selection

A number of stakeholders communicated dissatisfaction with the current procedure for identifying which countries receive PC funding, and expressed hope that the process would be revisited with increased transparency.

Several criteria were suggested in choosing future PIP countries. Among these, criteria with wide support included: burden of disease; capacity and strength of government and social structures (including the health care system) to achieve change; economic status; ability to implement preparedness plans; the country's own funding commitment; pandemic risk (based on zoonoses); a stable political environment; the likelihood that the country could share viruses and develop high-quality data; and the country's readiness to respond.

A number of respondents expressed the desire for PIP funding to support countries at varying levels of development. While countries at low levels of development are obvious candidates, outbreaks such as MERS are a reminder of the vulnerability of high-resource countries.

### Country commitment

A number of stakeholders described the problem of pandemic preparedness not being a sufficient priority within the country. Specific observations regarding prioritization in-country included the following:

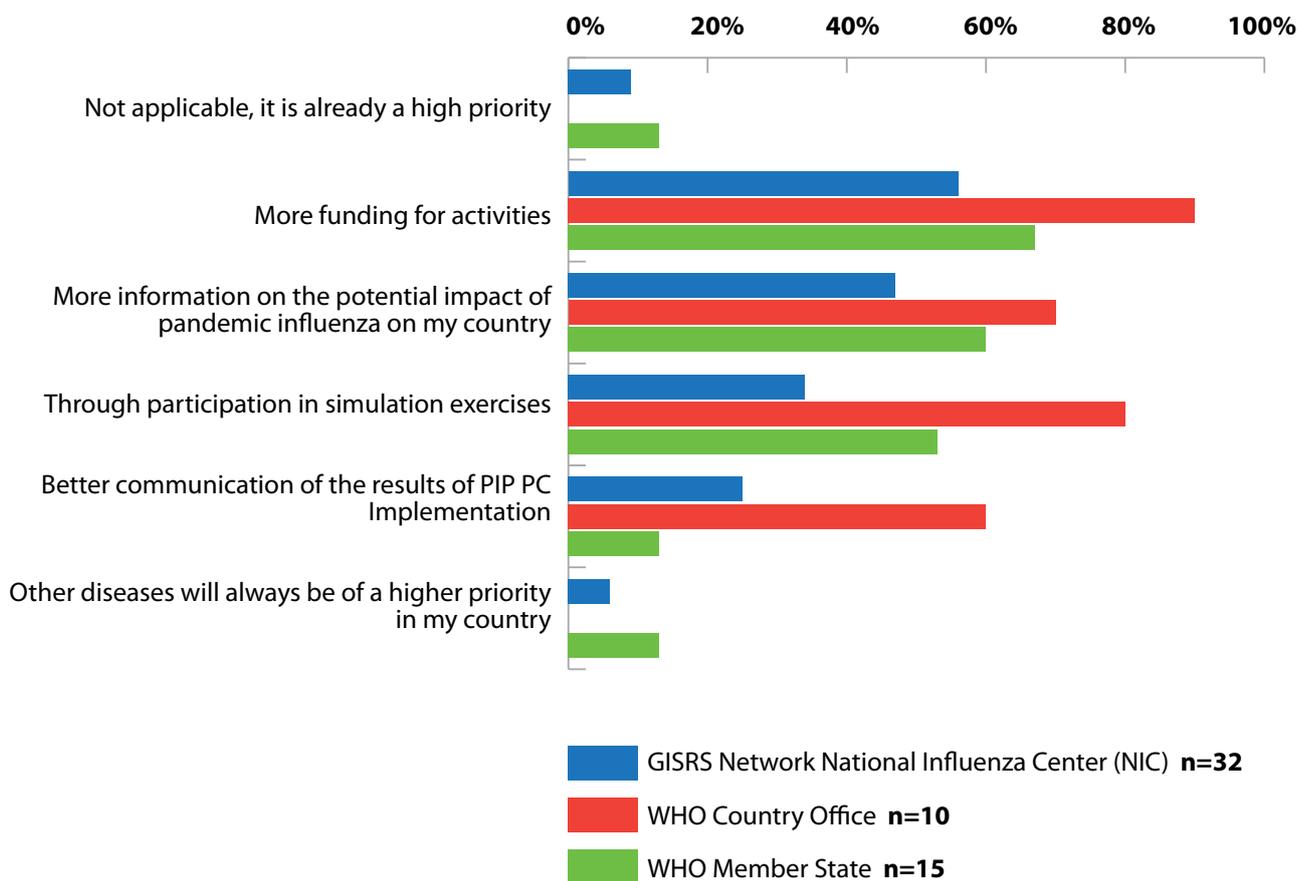
- Countries often don't see pandemic influenza as a national priority.
- There needs to be country-level and ministerial (Ministry of Health) buy-in and engagement for pandemic influenza preparedness.
- Many countries are not aware that PIP exists, or what the project does.
- There are some countries that receive support from PIP but the NICs and Ministry of Health are not aware of it.

Several specific suggestions were made to improve country buy-in before the country is selected to receive PC implementation funds (Figure 3). The most common suggestion was that an agreement should be reached between WHO and the Ministry of Health that ensures the country is a willing partner that will accept support, and will in turn support activities and staff in-country in order to fulfill objectives and provide deliverables. A second suggestion was to provide data to demonstrate the benefit of pandemic influenza preparedness planning, as governments are often very responsive to data. Figure 3 shows the results of NIC, Member State and CO responses to the survey question on factors that could raise the profile of pandemic influenza at the country level.

### Tailoring support at the country level

A wide range of stakeholders emphasized the need to tailor or tier the approach to PC implementation to specific needs and level of experience in a country. This tailoring / tiering approach could consider: the level of support given; outcomes and outputs to be achieved in order to develop realistic goals including for countries that currently have weak or no capacity; and indicators of progress that are tiered in a way that can be appropriate for countries with advance capacity, and countries with limited capacity. It was suggested that any plan for support should developed in partnership with the Ministry of Health.

**Figure 3: Factors that could raise the profile of pandemic influenza preparedness at country level**



## 5. Enabling factors for improving implementation

There are opportunities to improve implementation in order to develop the program and better address the evolving target of pandemic influenza preparedness. This section presents topics that represent gaps, needs and opportunities spanning the entire PC implementation approach.

**Figure 4** shows responses to the survey question “What are the key factors needed to improve the sustainability of preparedness moving into the future?” The responses highlight the fact that the priorities of different stakeholder groups vary considerably.

The following discussion presents in more detail the factors that were described in interviews, workshops and through written feedback as being important for ensuring effective and efficient implementation of the PIP PC funds.

### 5.1 Implementation Process

The factors described below will support preparedness for pandemic influenza by improving the efficiency, effectiveness and reach of the PIP PC implementation processes.

- **Increased visibility** of the PIP Framework and PIP PC Implementation among national governments, other agencies working in influenza, industry and civil society, such that both internal and external stakeholders have a clear understanding of the vision and objective of PIP.
- **Increased communication and collaboration** within WHO and with external stakeholders to ensure clear understanding of roles and responsibilities, to ensure that global efforts have a maximum impact, to build long term and sustainable relationships (e.g. through strengthening industry engagement), and to foster learning and capacity building opportunities. Industry and member states in particular, have been singled out as important partners for engagement.
- **Continued or enhanced alignment with WHO programmes and initiatives** including GIP, IHR, IVR,

and PHI for possible integration of select activities that were previously implemented under the GAP.

- **Enhanced working relationships** with national or international programmes that support pandemic preparedness, e.g. US CDC, to ensure complementary activities and best use of resources.
- **Clarification** of PIP’s role with respect to highly-resourced and initiatives and institutions focussing on pandemic preparedness, such as the GHSA and World Bank.
- **Evidence-based performance measurement** using specific, measureable, achievable, relevant and time-bound (‘SMART’) indicators to monitor the outputs and outcomes (expected change) toward which the PIP PC Implementation is working. Indicators need to be able to recognize progress made across countries of varying capacity.
- **Reporting structure** that meets the expectations of all stakeholders for provision of transparent, timely data and analysis that provides information on how PIP PC Implementation funds are implemented and their impact on global pandemic influenza preparedness.

### 5.2 Funding

The factors described below will support efficient and effective allocation of the limited PC resources in order to best support global pandemic preparedness.

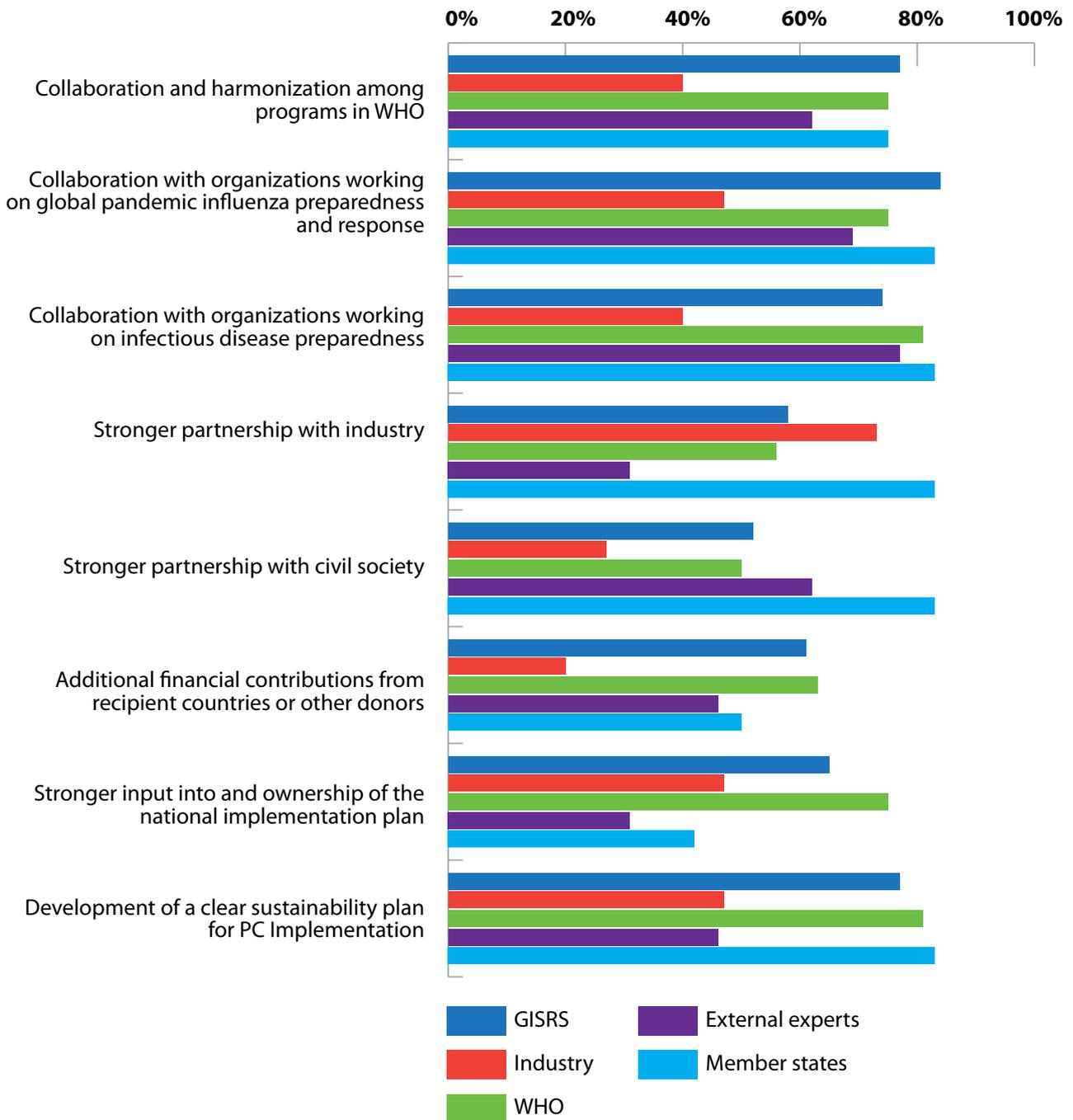
- **Maintaining the current funding splits**, with 70% of funds allocated for preparedness and 30% for response; and among the AOWs, 70% allocated for Laboratory & Surveillance.
- **Increased proportion of funds that may be allocated to staff**, which is likely to result in increased continuity of implementation activities at the country, regional and HQ level. Resources for quality staffing who can devote their attention to PIP was discussed by stakeholders as being a

success factor for effective implementation at all levels of the WHO (i.e. HQ, RO, CO).

- **Improved disbursement efficiency** such that the process of funding disbursement is more streamlined and timely, with better reporting on how PC funds were used for PIP activities. This will help improve the contracting and hiring process, and will lead to more efficiencies and improved outcomes.

- **Ensuring sustainability of PIP funding.** Industry is the source of the partnership contributions that form the financial backbone of PIP, and engaging industry more strongly as a partner was seen as a priority by a wide range of stakeholders. However, industry alone may not represent a sufficient or sustainable funding source and there is a need to investigate alternatives such as member state contributions through a country matching scheme.<sup>5</sup>

**Figure 4: Key factors needed to improve the sustainability of preparedness moving into the future**



<sup>5</sup> For example, in the CDC country-matching model, the CDC selects priority countries. Investments from CDC slowly decrease while country contributions increase, creating local ownership at the end of CDC investment.

## 6. Conclusion

There was strong agreement that the activities supported by PIP PC implementation have provided value in terms of enhancing preparedness for pandemic influenza, particularly in low-resource locations. There is also recognition that current PIP PC-funded activities should be maintained or enhanced, and new directions added in order to improve effectiveness, reporting and sustainability of implementation and better prepare for the next pandemic. This must be done in the context of directing the limited PC funds to complement, and not replace existing funding streams.

The information presented in this report will be used together with the evaluation and the work of complementary initiatives, including IHR and GAP) to produce the next high-level Implementation plan (HLIP II), which will define outcomes and outputs and the allocation of PC funds for the next several years.

# Appendices

# Appendix 1

## Overview of methodology

The Gaps and Needs Analysis was conducted by Habitat Health Impact Consulting (Canada), between September, 2016 and January, 2017.

### Data Gathering

Data was gathered through four activity types, as described below.

- a. Stakeholder interviews.** Interviews were conducted with 34 individuals across many different categories of PIP Framework stakeholders; around 13 additional stakeholders were engaged through workshops or other group activities. In addition, a number of stakeholders provided written submissions.
- b. SWOT exercise.** A SWOT (Strengths, Weaknesses, Opportunities and Threats) exercise was held on October 20, 2016, during the WHO PIP Framework Advisory Group meeting in Geneva. Participants were asked in advance to provide input on strengths, weaknesses, opportunities and threats relevant to each of the five Areas of Work (AOWs) and to pandemic influenza preparedness planning as a whole. These themes were explored and further developed at the in-person meeting, at which approximately 45 people were present.
- c. Online survey.** An online survey was conducted and was broadly advertised to WHO stakeholders through emails and newsletters. A total of 120 respondents participated in the online survey. For those who did not wish to participate in the survey or interviews, or who had additional comments to add, there was also an opportunity to provide written feedback with two written submissions received.

**Table 1** shows the stakeholders groups who participated in each activity type. Appendix 1 describes the methodology for data collection and analysis.

**Table 1: Stakeholders participating in data gathering activities**

Stakeholder group	Interviews & workshops	SWOT exercise	Online survey / written feedback
PIP Framework Advisory Group (AG)	X	X	X
PIP Secretariat	X	X	X
WHO Headquarters	X	X	X
WHO Area of Work (AOW)	X	X	X
WHO Regional Office	X	X	X
WHO Country Office			X
GISRS Network - National Influenza Centre laboratory (NIC)			X
GISRS Network – Collaborating Centre (CC)	X		X
GISRS Network – Essential Regulatory Lab (ERL)			X
GISRS Network – H5 Reference Laboratory			X
WHO Member State			X
UN Partner Agency			X
Civil Society		X	X
Industry		X	X
External experts in pandemic influenza (from academia, foundations, national institutions and other organizations)	X		X

**Table 2** shows the number of survey respondents from each stakeholder group, both as a total and by geographical region. [It should be noted that respondents were able to indicate that they worked in more than one region.] As can be seen in the table and top figure, there was an uneven distribution of stakeholder groups. In order to adjust for this uneven distribution, results in this report have been presented by stakeholder type. As can be seen in, Europe was more strongly represented than other geographic areas, and the African region was particularly under-represented.

**Table 2: Profile of survey respondents**

	TOTAL	AFR	AMR	EMR	EUR	SEAR	WPR	HQ
PIP Framework Advisory Group	0	0	0	0	0	0	0	0
WHO Headquarters	5	0	0	0	0	0	0	5
WHO Regional Office	7	0	1	0	3	0	3	0
WHO Country Office	10	0	3	7	0	0	0	0
GISRS Network - CC	8	1	3	1	3	2	3	1
GISRS Network - ERL	2	1	0	0	1	0	0	0
GISRS Network - H5 Ref Lab	4	0	0	0	0	1	3	0
GISRS Network - NIC	34	2	8	2	17	1	4	0
Member State	15	0	1	6	8	0	0	0
Civil Society	1	1	0	1	0	1	1	0
Industry	20	2	7	4	6	5	6	0
Academic Institution	6	0	1	0	4	0	1	0
UN Partner Agency	0	0	0	0	0	0	0	0
Foundations and other donors	0	0	0	0	0	0	0	0
Other	8	0	2	1	2	2	1	0
		7	26	22	44	12	22	6

AFR: African Region; AMR: Region of the Americas; EMR: Eastern Mediterranean Region; EUR: European Region; SEAR: South-East Asia Region; WPR: Western Pacific Region; HQ: WHO HQ

**d. Secondary Data Analysis.** A number of documents were reviewed, notably:

Department of Immunization, Vaccines and Biologicals and the Department of Epidemic and Pandemic Alert and Response. 2006. *Global pandemic Influenza action plan to Increase vaccine supply*. World Health Organization.

Global Influenza Program. 2012. *Critical care training, severe forms of influenza infection including severe pneumonia, acute respiratory distress syndrome, severe sepsis, and septic shock: Toolkit*. World Health Organization.

IHR (2005) Monitoring and Evaluation Framework. 2016. *Joint External Evaluation Tool, International Health Regulations (2005)*. World Health Organization.

Jean-Giles, L., Hegermann-Lindenchrone, M., Brown, C., Hasin, A., Shaw, Ian. and Nguyen-Van-Tam, J. 2010. *Recommendations for Good Proactive in Pandemic Preparedness: Identified through evaluation of the response to pandemic (H1N1) 2009*. World Health Organization and The University of Nottingham.

PIP Framework Review Group. 2016. *Preliminary Findings*. World Health Organization.

2016 Pandemic Influenza Preparedness Framework Review Group. 2016. *Review of the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*.

## Appendix 1: Methodology, cont.

World Health Organization. 2011. *Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits.*

World Health Organization. 2013. *Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016: Gap Analyses.*

World Health Organization. 2015. *Pandemic Influenza Preparedness Framework Partnership Contribution Implementation Plan 2013 – 2016.*

World Health Organization. 2016. *Implementation of the International Health Regulations (2005), Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, Report by the Director-General.* Sixty-Ninth World Health Assembly.

World Health Organization. 2016. *Pandemic Influenza Preparedness Framework Partnership Contribution Annual Report 2015.*

World Health Organization. 2016. *PIP Framework Advisory Group Reports.* Accessed at [http://www.who.int/influenza/pip/pip\\_meetings\\_consultations/en/](http://www.who.int/influenza/pip/pip_meetings_consultations/en/)

World Health Organization. 2015. *Pandemic Influenza Preparedness (PIP) Framework Critical Path Analysis from Detection to Protection.*

World Health Organization. 2016. *International Health Regulations (2005).* Third Edition.

## Data Analysis

Qualitative data was analyzed using framework analysis, as defined by Ritchie and Spencer (2002).<sup>6</sup> A set of initial themes was created based on the issues and topics that the Gaps & Needs Analysis was intended to address, which was developed into an initial framework used for extracting themes from qualitative data sources as the project progressed. The thematic framework was revisited and refined in an iterative manner as new topics emerged that could not be adequately captured using the initial framework.

Quantitative data from the survey was analyzed using the analytic tools provided through SurveyMonkey, which was the program used to develop and administer the online survey. In order to compensate for the substantial variance between the numbers of respondents from different stakeholder groups, quantitative responses are presented separately for different stakeholder types. An analysis was run to examine whether there appeared to be consistent patterns of responses that aligned with geography or stakeholder type, but no consistent patterns appeared. Where stakeholder groups were pooled, the pooling was therefore done on the basis of shared interest or experience: for example, combining responses across all types of GISRS labs.

## Limitations

The major limitations are as follows:

The analysis was not equally successful in engaging stakeholders from all geographic regions supported by PIP PC funds. The regions of Europe, the Americas, Eastern Mediterranean and the Western Pacific provided much more input to the questionnaire than did those of Africa or South-East Asia. Additionally, the regions of the Americas, Eastern Mediterranean, Europe and South-East Asia participated more in the interview process than the Western Pacific Region and the African Region, although all regions were given an equal opportunity to participate.

The results presented in the report rely on the information that was provided by stakeholders, and reflects the diversity of their views and beliefs. An independent validation of the accuracy of respondents' answers was not conducted.

---

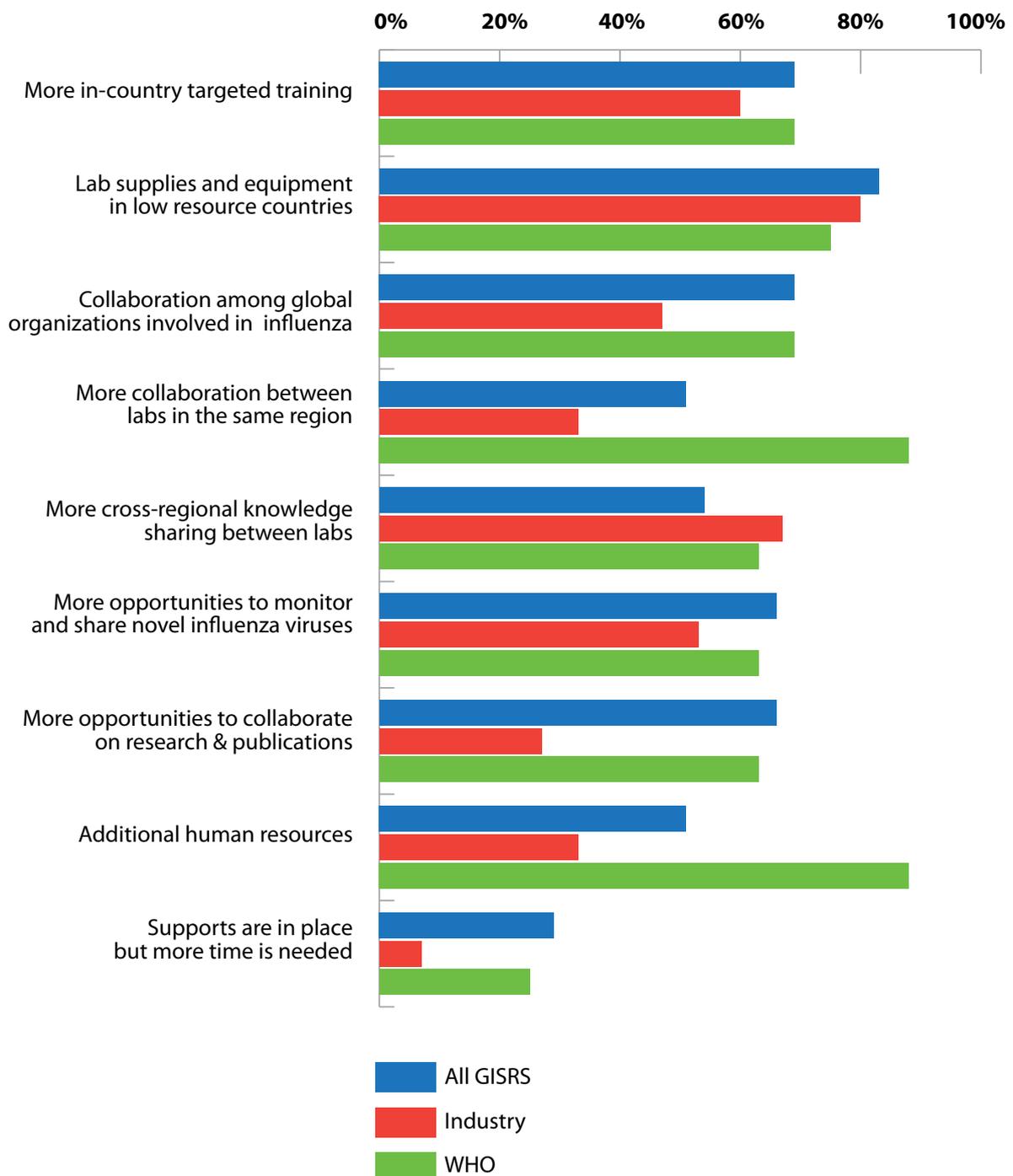
<sup>5</sup> FRitchie, J. & Spencer, L. (2002). *Qualitative Data Analysis for Applied Policy Research*. In: *The Qualitative Researcher's Companion*. Edited by Huberman, A. M. & Miles, M. B.

## Appendix 2

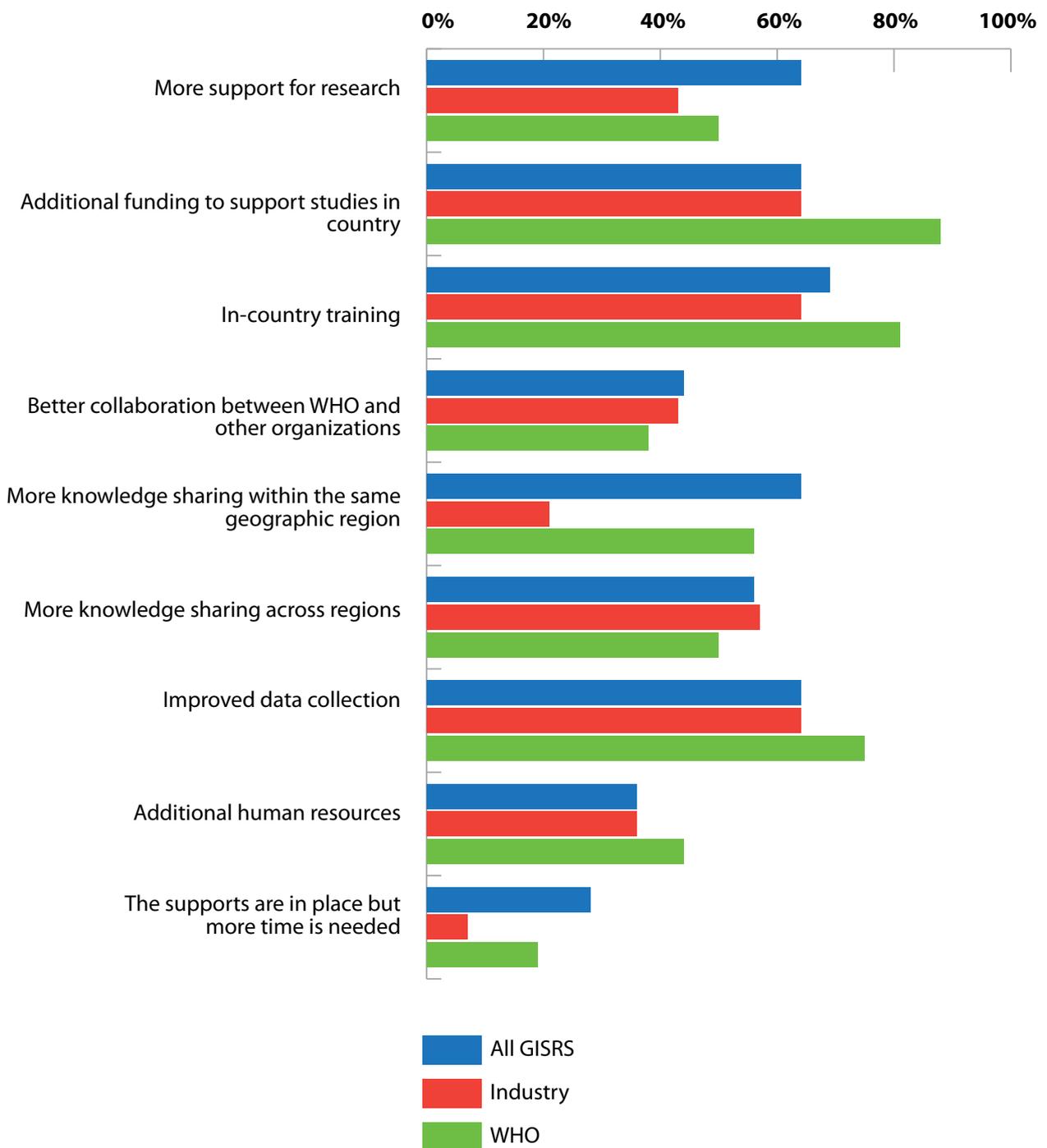
# Supporting factors for implementation of AOW activities

The figures below provide results from the online survey on factors that could further support implementation of each AOW.

**Figure 5: Factors that could further support implementation of Laboratory & Surveillance activities**

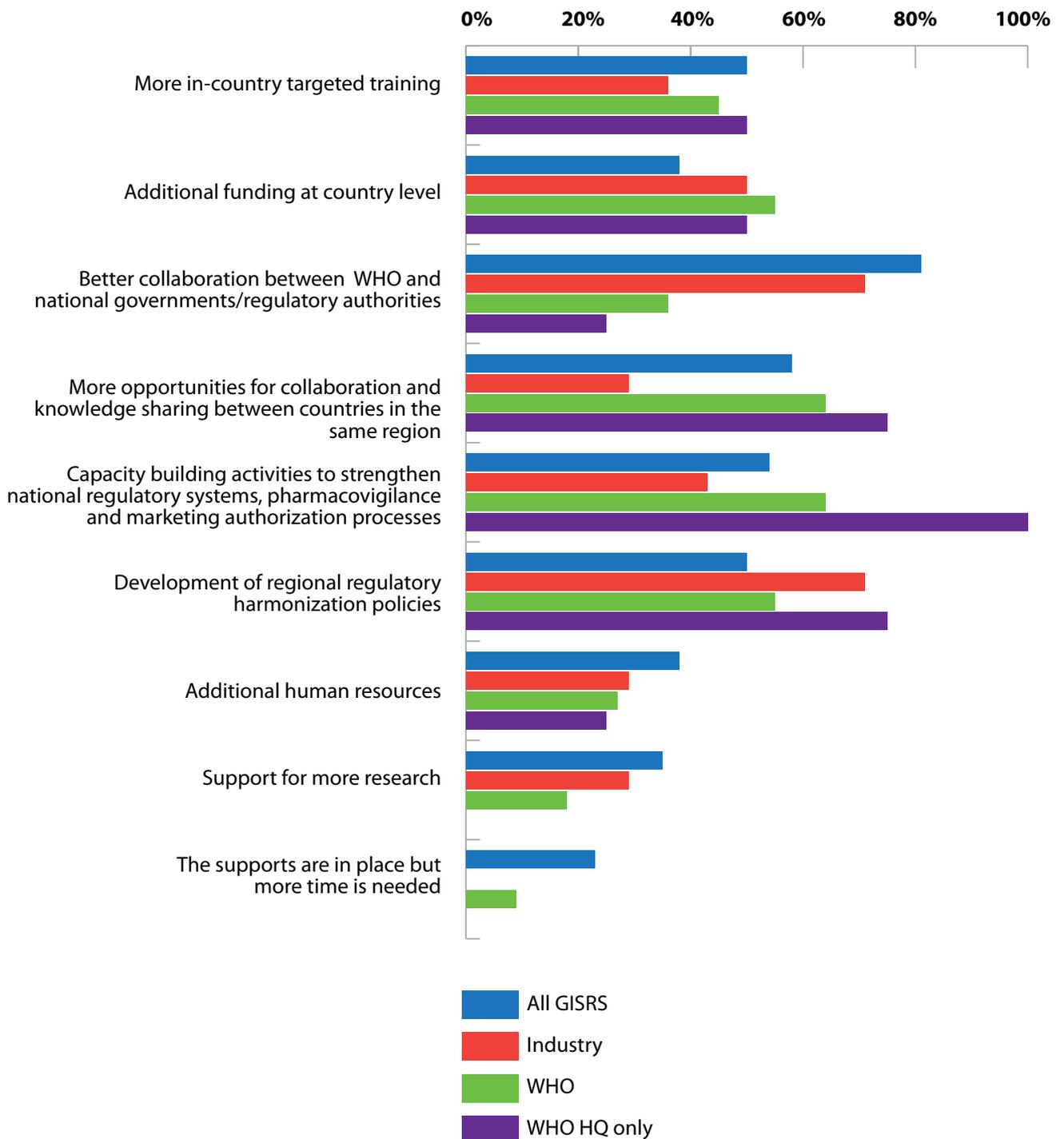


**Figure 6: Factors that could further support implementation of Burden of Disease activities**

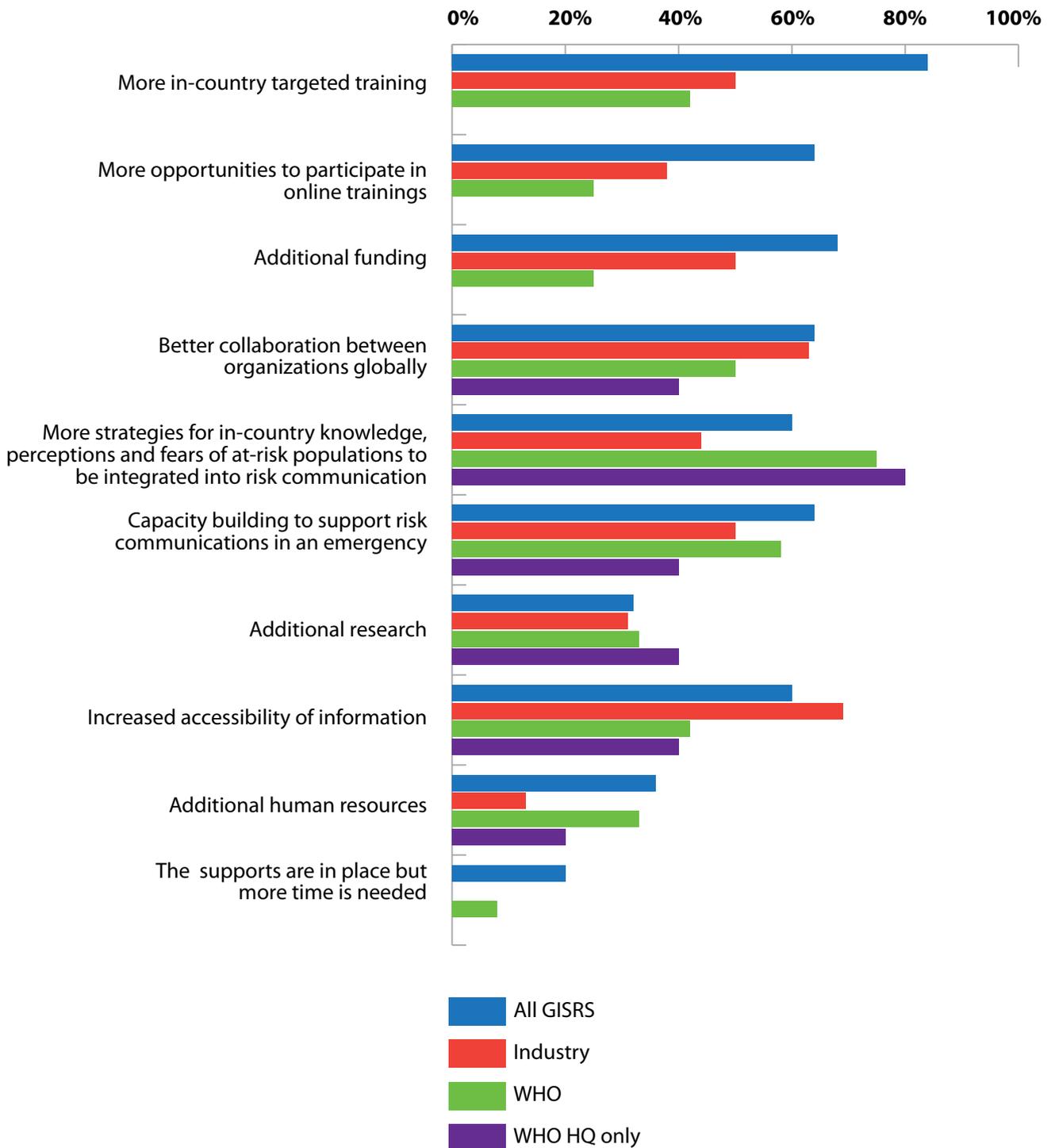


## Appendix 2: Supporting factors for implementation of AOW activities, cont.

**Figure 7: Factors that could further support implementation of Regulatory Capacity Building activities**

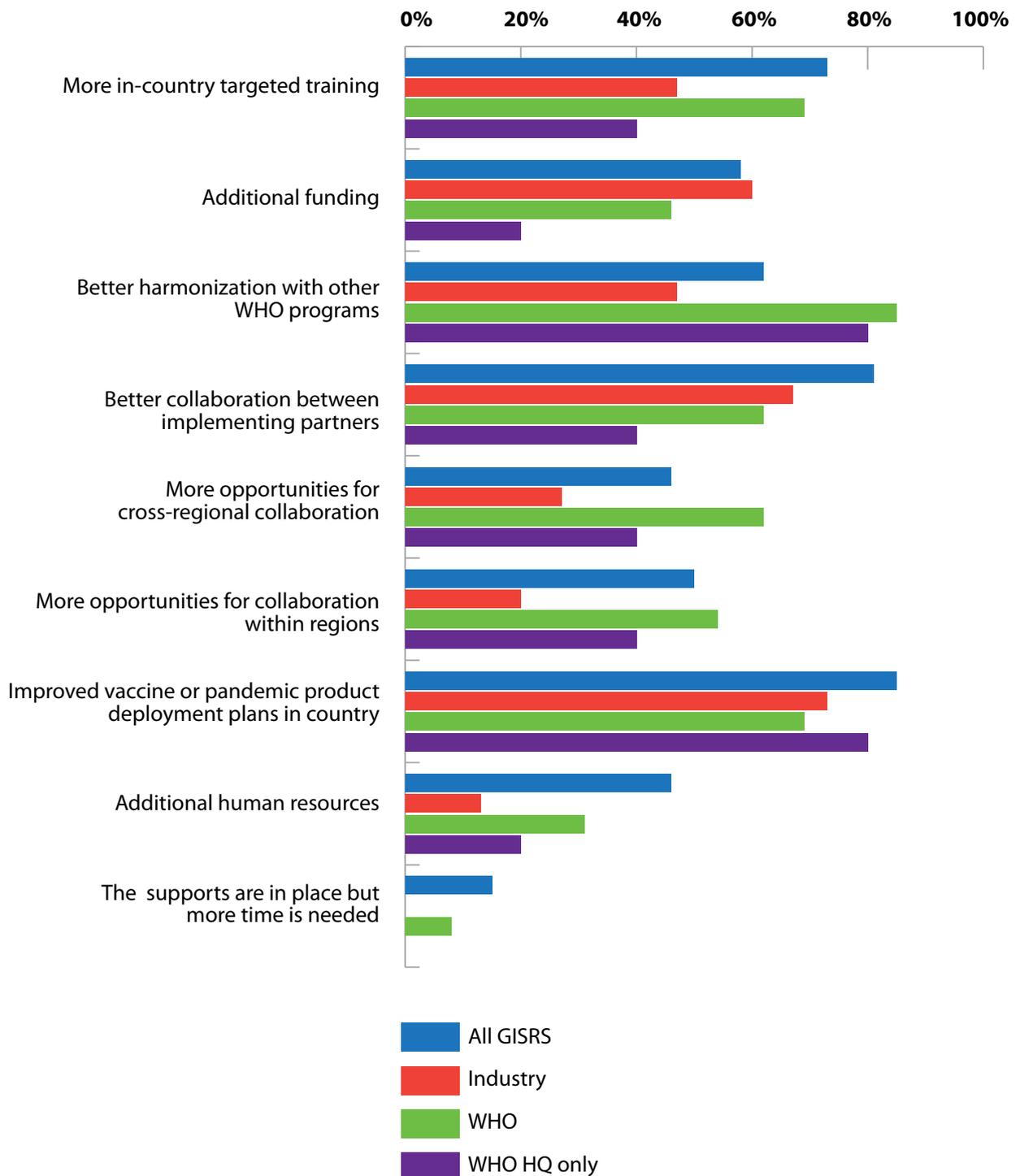


**Figure 8: Factors that could further support the implementation of Risk Communication activities**



## Appendix 2: Supporting factors for implementation of AOW activities, cont.

**Figure 9: Factors that could further support implementation of Planning for Deployment activities**









## **World Health Organization**

20 Avenue Appia  
1211 Geneva 27  
Switzerland

### **PIP Framework Secretariat**

Pandemic and Epidemic Diseases  
Outbreaks and Health Emergencies

**email** [pipframework@who.int](mailto:pipframework@who.int)

<http://www.who.int/influenza/pip/en/>



**World Health  
Organization**