Mid-term review of the High-Level Implementation Plan II of the Pandemic Influenza Preparedness Framework

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Executive summary

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

The Framework establishes a Pandemic Influenza Preparedness (PIP) Benefit Sharing System that includes an annual Partnership Contribution (PC) of US$28 million to WHO from influenza vaccine, diagnostic, and pharmaceutical manufacturers using the WHO Global Influenza Surveillance and Response System (GISRS). The funds are to be used for improving pandemic influenza preparedness and response and are allocated against priorities and activities outlined in the **High-Level Implementation Plan II (HLIP II) which runs from 2018 to 2023**. The HLIP II sets out activities according to six outputs: 1) Laboratory and Surveillance (L&S); 2) Burden of Disease (BOD); 3) Regulatory Capacity Building (REG); 4) Risk Communication and Community Engagement (RCCE); 5) Planning for Deployment (DEP); and 6) Influenza Pandemic Preparedness Planning (IPPP)). These build on progress made under the first High Level Implementation Plan, which outlined the scope of work from 2013-2017 (HLIP I).

The Mid-Term Review (MTR) covers the period January 2018 to December 2020 and, in line with the advice and steer given by the PIP Advisory Group (AG) at the October 2020 meeting, focuses on: A) hinderances to implementation and necessary mid-course adjustments; and B) implementation of HLIP II during the ongoing COVID-19 pandemic highlighting operational gaps and opportunities to catalyze pandemic preparedness and response. The MTR brings together the views of a range of important stakeholders from external expert groups, industry, civil society and WHO staff from headquarters, the regions and country offices involved in implementation of the HLIP II.

The MTR found strong progress was made against objectives during the first three years of HLIP II. This included: designation and recognition of nine new National Influenza Centres; publication of 43 country BOD estimates; strengthening of regulatory capacities in seven countries with two in sub-Saharan Africa achieving maturity level 3; scale up and mainstreaming of the OpenWHO platform; and acceleration of support to countries to develop Influenza Pandemic Preparedness Plans.

Most of this progress was made during the first two years (2018-2019) with Implementation during 2020, heavily affected by the ongoing pandemic of COVID-19. This led to redeployment of skills, technology and infrastructure critical in supporting and scaling up the global response. This allowed adaptation of the FluMart platform for COVID-19, roll out of multiplex testing for both SARS-CoV-2 and influenza, scale up and decentralisation of sentinel systems, roll out of genetic sequencing capacities, adaptation of IPPPs and National Vaccine Deployment Plans to COVID-19, use of RCCE networks to share and disseminate learning and use of regional regulatory platforms to expedite approvals for COVID-19.

The response to the SARS-CoV-2 pandemic flagged important gaps and considerations for global, regional and country level pandemic preparedness. These include the role of non-pharmaceutical interventions, whole-of-society and whole-of-government readiness and

response, the value and challenge of modified diagnostic and clinical care pathways for surveillance, the need to consider and address clinical management capacities and surge infrastructure requirements among others. The review notes the time it takes to build national capacities and the need to consider regional or global approaches to preparedness in the interim. The review also flagged the need to consider how the HLIP II can take into account other respiratory pathogens such as SARS-CoV-2 whilst also improving preparedness for influenza.

Finally, the MTR recognised that the landscape for investing in pandemic influenza preparedness is likely to change in the coming years and it is important that future investments in further iterations of the HLIP build upon lessons learned during COVID-19 whilst also maintaining a focus on strengthening country, regional and global capacities for influenza pandemic preparedness.

The MTR concludes with six recommendations made in line with the two objectives as recommended by the AG:

A) **Hinderances and necessary mid-course adjustments:**

1. **Review indicators or milestones that are no longer fit for purpose** and to do this potentially through discussion with the PCITEM.

2. **Consider ways of better capturing and measuring regional activities**.

3. **Regularly inform stakeholders about information available on resource allocation and financial implementation** including when milestones are or are not met, or when shifts are required in financial support.

B) **Opportunities to catalyse pandemic preparedness in light of COVID-19:**

4. **Monitor the current pandemic landscape, capture lessons from COVID-19** including identifying options and alternate ways of responding to a pandemic e.g considering regional or global mechanisms, and **consider inclusion of additional areas of work** as part of HLIP in the coming years.

5. **Consider ways of linking to independent reviews of preparedness** to provide an overview of country and regional preparedness.

6. **Consider ways of mapping PC investments for pandemic influenza preparedness** in the context of the broader preparedness landscape.

Introduction

The *Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits* **('PIP Framework' or 'Framework')** is an international arrangement adopted by the World Health Assembly (WHA) in May 2011 to improve global pandemic influenza preparedness and response[6]. The PIP Framework is an innovative partnership among Member States, industry, civil society and other stakeholders. It aims to improve the sharing of influenza viruses with pandemic potential (IVPP), and support equitable access to products necessary to respond to pandemic influenza (e.g. vaccines, antiviral medicines and diagnostic products). Under the Framework, implementation strives to build sustainable capacities for detecting and responding to pandemic influenza.

Section 6.14.3 of the Framework establishes a PIP Benefit Sharing System that includes the annual **Partnership Contribution (PC),** a novel sustainable financing mechanism whereby influenza vaccine, diagnostic, and pharmaceutical manufacturers that use the WHO global Influenza Surveillance and Response System (GISRS) make an annual financial contribution of $28 million to WHO each year[7]. Most funds are used to strengthen pandemic influenza preparedness, through global, regional and country level activities. They are allocated against priorities and activities outlined in the **High-Level Implementation Plan II (HLIP II) which runs from 2018 to 2023**. The Plan and its results hierarchy was developed through a participatory process that engaged a broad range of stakeholders including: the PIP Advisory Group (AG); GISRS; industry; and civil society organizations (CSOs).

The HLIP II is designed to complement existing global and WHO initiatives to enhance global preparedness. All activities contribute to the five 10-year objectives for improving Pandemic Influenza Preparedness as laid out at inception by the PIP Advisory Group. Countries can receive support directly against a biennial work plan or via regional and headquarter led activities. The criteria and process for prioritising and selecting countries for workplan based support is outlined in section 5 of the HLIP II.

HLIP II consists of six Outputs: 1) Laboratory and Surveillance (L&S), 2) Burden of Disease (BOD); 3) Regulatory Capacity Building (REG); 4) Risk Communication and Community Engagement (RCCE); 5) Planning for Deployment (DEP); and 6) Influenza Pandemic Preparedness Planning (IPPP). Each output area has specific Deliverables against which are indicative milestones and activities. Together, these help build towards the intended PC Preparedness Outcome:

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

Mid-term review:
The mid-term review (MTR) of HLIP II implementation covers the period January 2018 to December 2020. The PIP Advisory Group (AG) provided guidance in the October 2020 meeting, that the review should focus on A) hinderances to implementation and necessary mid-course adjustments; and B) implementation of HLIP II during the ongoing COVID-19

pandemic highlighting operational gaps and opportunities to catalyze pandemic preparedness and response.

The review does not include other aspects of the PIP Framework such as PC collection, governance or standard material transfer agreements 2 (SMTA2). It focuses on implementation of the six outputs outlined in the HLIP II. Inputs received will inform immediate term changes needed to address hinderances to implementation of HLIP II and will also serve as considerations for the medium term such as the design and development of HLIP III or other complementary projects.

Methods:
The review used mixed methods to gather information as follows:
1) Document review of key policy documents including but not limited to:
    i) WHO Global Influenza Strategy (GIS)
    ii) HLIP six-year plan (2018-2023)
    iii) PIP PC six monthly Progress Reports (quarterly through the biennium), regional reports and stories from the field
    iv) PIP Advisory Group Meeting (AGM) Reports and presentations

2) Attendance at the AG and stakeholder meetings in March 2021.

3) Key informant interviews using semi structured interviews (Annex A and B) conducted between 25 March - 30 April 2021. These are divided into the following groups (Annex C):
    i) WHO staff:
        (a) PIP Secretariat,
        (b) WHO HQ and Regional Technical Focal Points (FP) and Programme Officers (PO).
        (c) Country technical staff currently involved in HLIP II implementation. One or two countries implementing at least two of the six output areas from each region were selected for interview/ or to provide written feedback by Regional Offices. Interviews were conducted with Armenia, Bolivia (written), Egypt, Indonesia, Haiti (written), Mongolia, Nigeria and Yemen.
    ii) External stakeholders
        (a) Current members of the AG in post since January 2018 to date. The PIP AG monitors implementation of the PIP Framework and providing evidence-based reporting, assessment and recommendations regarding its functioning interacting with industry and other stakeholders and providing advice to the Director General (DG) on use of the PC.
        (b) Current members of the Partnership Contribution Independent Technical Expert Mechanism (PCITEM) which provides technical and scientific guidance and advice to WHO and advice to support, improve and finalise workplans for selected projects
        (c) Representatives of the four different Manufacturers and Industry Associations (Bio, IFPMA, DCVMN, AdvaMedDx) of which three associations participated.

(d) CSOs that have participated in a minimum of three out of six AGMs held between January 2018 and April 2021 (based on meeting reports published on the website).

(e) GISRS representatives who attended any of the PIP AGMs since January 2018 still in active service as of April 2021.

External stakeholders (as per criteria outlined above) were sent an email containing a short semi-structured questionnaire and an invitation to participate in a focus group discussion. Each group was asked to collate the views of their network and to limit the attendance at the focus group to four. If unable to attend the focus group times, they were given the opportunity to return collated written responses to the questionnaire.

Inputs from key informants were de-identified and referred to by stakeholder group (e.g. PC contributors, Industry representative, CSO representative, PIP AG member, PCITEM member etc) as appropriate. Findings were analyzed qualitatively to identify themes and quantitively to measure progress against project targets. Findings are presented in the report, and recommendations made to inform immediate course corrections and to inform considerations for the next iteration of the HLIP. Further detail on individual outcome and output areas can be found in Annex F where explanation is given for any measures that are off track.

Findings:
The PIP Framework is unique in bringing together industry, civil society, technical partners and WHO to work together around the shared outcome of strengthening pandemic influenza preparedness and response. Since investments in preparedness started in 2014, substantial progress has been made through HLIP I 2014-2017 and in the first 3 years of HLIP II 2018-2020 in implementing the objectives set by the PIP AG (Box 1).

Box 1: Achievements from investments made in HLIP 1 and the first three years of HLIP II (2014-2020)

Achievements: 2014-2020:
- 131 countries started or improved laboratory and surveillance systems for participation in GISRS
- 11 new National Influenza Centres designated and recognised.
- 43 countries (including 29 low and middle income countries) published burden of disease estimates.
- Publication of updates of global seasonal influenza associated respiratory deaths estimates.
- 35 countries update Influenza Pandemic Preparedness Plans and 14 countries test them
- Establishment of the OpenWHO online learning platform with 22 influenza related courses reaching over 192,000 users
- WHO guidelines on regulatory preparedness for provision of marketing authorization of human pandemic influenza vaccines in non-vaccine-producing countries were published.
- 27 countries developed a regulatory roadmap for timely approval of pandemic influenza products based on WHO guidelines.
- Two country National Regulatory Authorities reach maturity level 3 'stable and well-functioning regulatory system'
- Publication of a Global Operational Framework for access, allocation and deployment of pandemic influenza vaccine.

Within the first three years of HLIP II, clear progress was made in all output areas as summarized below and elaborated in Annex F.

L&S: This is the output area with the greatest level of investment and there is continued good progress against most of the deliverables in this output. Nine new National Influenza Centres were designated by countries and recognized by WHO, further helping to strengthen the GISRS network. Additionally, nine countries reported virological data to WHO FluNet and 22 countries reported epidemiological data to FluID for the first time further strengthening global influenza surveillance coverage and its use in informing risk assessment and response measures. For virus sharing, the proportion of Member States sharing influenza samples with WHO Collaborating Centres according to WHO guidance met the 2018-2019 target, but declined in 2020 due to the COVID-19 pandemic and the associated decrease in influenza activity. Whilst training on the Pandemic Influenza Severity Assessment (PISA) Tool has been rolled out, its use has lagged behind, in part due to the type of information required, that may be harder to access in some contexts and due to the impact of the ongoing pandemic.

COVID-19 had a major impact on this area of work, with redeployment of human resources and infrastructure. Internal and external stakeholders unanimously recognised the importance of this infrastructure and network in responding quickly and appropriately to COVID-19 including adaptation of data sharing platforms such as FluMart and roll out of PCR testing. Importantly, COVID-19 has led to a rapid change in landscape with the widespread use of community-based testing, expansion of sentinel surveillance and use of novel technology including genomic sequencing and multiplex testing. There is a need to ensure

this area of work is now able to capture and apply this learning in time for application in future pandemic preparedness planning. This includes a review of the PISA tool.

BOD: This output is important in allowing comparisons of BOD and severity between seasonal and pandemic influenza and to drive evidence-based policy. The last three years have seen marked progress under this output area in particular the number of countries with published BOD estimates. It was felt that countries understand how and where to find tools and how to seek advice as needed. The importance of the networks formed under this output were strongly recognised both inside and outside of WHO including their use comparing and contrasting estimates including on hospitalisation and mortality to understand differences and discrepancies. Use of BOD estimates for policy continues to be hard to capture, but there are discussions ongoing to identify proxy measures. Work from this area was used to inform the design of a COVID-19 BOD pyramid tool which will now be further adapted for influenza. Going forward this area will need to consider updating benchmarks with data and scenarios found during COVID-19.

REG: Regulatory processes take a long time to develop, up to five to ten years in some contexts and progress, as with all output areas, depends on political commitment, resource and support from multiple partners including WHO. The last three years have seen continued steady progress in the strengthening of regulatory systems at national level. Most significantly national regulatory authorities in two African countries reached maturity level 3 indicating the presence of a stable and well-functioning regulatory system. COVID-19 has highlighted the importance of this area of work, and has shown the role and need for regional systems, or agreements between countries in expediting approval processes during an emergency for vaccines and other commodities. Given the time it takes to build national regulatory capacity, there was a general sense that in light of the COVID-19 pandemic, this area of work needed a proper review, to consider how best to achieve preparedness for the next pandemic. This includes the balance of efforts to build and sustain national systems whilst mitigating risk through the use and development of regional or other emergency approval. This should build upon regional harmonisation approaches.

RCCE: At its inception, HLIP II efforts primarily focused on learning through web training and technical support to countries from a central pool of experts. Following the initial success of the OpenWHO.org platform, work under this output area has evolved to include the building of regional expert capacity and communities of practice through the Fundamentals of RCCE (FoRCCE) training network e.g social net training. This now needs to be reflected in the indicators to allow the work being done under this area to be captured appropriately. Given the experience of COVID-19, this area of work, initially built around the five IHR core capacity components for RCCE, warrants review and the focus of implementation shifted based on emerging lessons. This may include consideration of the relative role of infodemic management, which was an important component of the response to COVID-19, and links between PIP investments and other programmes of work in this area.

DEP: The focus of the deployment team has shifted away from global simulations to more localised training, workshops and publications aimed at raising awareness. There was a sense that prior to the COVID-19 pandemic, interest and energy in this output was low. That said tools such as the template for National Vaccine Deployment Plans (NVDP) for pandemic

influenza have been adapted by WHO and used at national and international levels as the basis for planning the deployment of vaccines against SARS-CoV-2. COVID-19 has highlighted the importance of this area of work, not just for vaccines but for diagnostics, personal protective equipment, oxygen, respiratory support infrastructure, and for emerging new technologies etc and the need to strengthen and further develop equitable global systems for deployment.

This area of work needs review, in light of COVID-19, and in view of the emerging global architecture aimed at supporting deployment of commodities and products including proposed initiatives established by the World Bank and the Global Fund. WHO is working with partners to develop a supply chain playbook to articulate the roles of agencies within this space. Further work is also needed to better understand how best to assess priority and deploy scare resources accordingly.

IPPP: This area of work was new for HLIP II and the last three years have seen a steady increase in the number of countries developing IPPPs. The approach used to support countries differs across the regions, with some focusing only on priority countries, and others using regional meetings as an opportunity to support a broader range of countries in developing plans. However few countries were able to test plans, mainly as they were still developing or updating them. A significant number of those countries with IPPPs were able to adapt and redeploy these plans for COVID-19. Additional priorities for consideration were also flagged such as whole-of-society and whole-of-government approaches. Feedback highlighted the importance of and need for plans to be operational including addressing questions such as around stockpiling, pre-pandemic training, capacity to train staff rapidly in the event of a pandemic, and the role of different government counterparts in decision making and financing.

Reporting has improved markedly for HLIP II: An external evaluation of HLIP I provided recommendations to improve the logframe design and reporting granularity of HLIP II. Feedback from external and internal stakeholders on reporting and programme management of HLIP II was extremely positive. The programme reports and presentations to the PIP AG and PCITEM were found to be well organised, clearly structured and transparent. The web portal provides information on budgeting including allocations to countries and regions by output area per biennium. There was general consensus that indicators, milestones, outputs and outcomes were easier to follow however countries and regions noted the reporting burden associated with this approach. External stakeholders are well engaged in HLIP II implementation through attendance at the AG, PCITEM and stakeholder meetings. Whilst the role of each actor was commonly understood, some stakeholders expressed the desire for more communication on financing, particularly where shifts in allocation are needed due to completion of projects, achievement of milestones or where expected progress is off track or where absorption is low.

The responsiveness of the secretariat was well noted as was their willingness to support regional and country implementing teams as needed. Country and regional focal points were proactive in working with government counterparts, engaging regularly to support and monitor implementation. Potential priority countries are now involved early in the programme and encouraged to join workshops to ensure awareness and to maximise their

ability to comply with programme requirements as per country selection criteria set out in the HLIP II section 5. Anecdotally this has helped improve commitment and reporting by countries.

COVID-19 had a major impact on implementation of the HLIP II during 2020 and will continue to influence the architectural and funding landscape for pandemic preparedness: The pandemic did, at its early stages, significantly affect implementation of HLIP II across all output areas. Human resources were reassigned to support the response to COVID-19, platforms for sentinel surveillance modified, capacity building moved online and supply chains disrupted through travel restrictions and lockdowns. This is reflected in the markedly reduced absorption of funds (Annex D) and limited or no progress against nine out of the 19 indicators over the course of 2020. Plans now need to account for this decline in absorption, including those activities that rely on in person interaction versus those that can continue online. Further detail on the impact of COVID-19 on each output area can be found in Annex F.

That said, whilst COVID-19 significantly affected implementation of the HLIP II, there was consensus amongst stakeholders that investment in HLIP I and II was critical in supporting the global response to the SARS-CoV-2 pandemic. This includes through adaptation of infrastructure and technology platforms and use of pre-existing global networks to share and disseminate information and learning rapidly. A list of activities of dual benefit for both influenza pandemic preparedness and for COVID-19 was shared with countries allowing some adjustment of HLIP II workplans and funding. Redeployment of skilled personnel at all levels of the programme not only benefitted the response but provided those involved with first-hand exposure of a pandemic caused by a respiratory pathogen.

The SARS-CoV-2 pandemic flagged critical gaps in and considerations for global, regional and country level response systems. This includes the role of non-pharmaceutical interventions, whole-of-society and whole of government readiness and response (ie working beyond the health sector), modified diagnostic and clinical care pathways, clinical management capacities and surge infrastructure requirements among others as well as looking at how the global system can ensure and promote equity as a core component of health security architecture. It also includes the need to consider how preparedness capacities are built up not only for influenza but other respiratory pathogens of pandemic potential, including analysis of where there might be blockages in the redeployment of resource between pathogens in the event of a pandemic.

The landscape for investing in pandemic influenza preparedness has already and will further evolve over the coming months and years and it is critical that HLIP II is able to evolve and leverage assets including finance, knowledge, innovation and capacities from COVID-19 in order to continue the development and strengthening of country, regional and global systems for pandemic influenza preparedness.

Recommendations:

A) Hinderances and necessary mid-course adjustments:

1. **Review indicators or milestones that are no longer fit for purpose:** The MTR found that several indicators and milestones need changing. Some would have benefited from earlier review e.g. RCCE indicators on OpenWHO.org or indicators on deployment. A careful balance is needed to ensure the stability of measures used to monitor performance over time while also making updates on an exceptional basis to maximize their relevance and timeliness. Previously, PCITEM has provided inputs to WHO on updating indicators or their disaggregation to better monitor implementation. Going forward PCITEM could be more actively engaged in the periodic assessment of indicators on an exceptional basis. Options might be reviewing indicators in a time bound manner, or where indicators are off track or milestones have been achieved early.

2. **Consider ways of better capturing and measuring regional activities:** As noted earlier, many countries benefit from regional workshops, networks, training and support e.g. regional networks for RCCE, regional workshops for countries for IPPP, or regional models for regulatory approvals. These activities are not well captured by the current reporting structure which focuses primarily either on global (all-country) or priority countries. This approach also potentially limits thinking to country systems, which whilst critical may take time to develop. Given the learning from COVID-19 which highlighted the value of regional and global mechanisms it may be worth looking at ways to better capture and consider regional work within HLIP II.

3. **Regularly inform stakeholders about information available on resource allocation and financial implementation** including when changes are made or where progress is off track. The WHO Programme Budget Portal, the PIP Progress Reports and the PCITEM Project Narratives provide detailed information on the financial management. The secretariat should continue to use opportunities to provide stakeholders with financial analyses. This might include when milestones are met or sub-projects completed potentially necessitating a shifts in financial support to stabilize newly established capacities or when projects need to be adjusted due to evolving contexts or technologies or in light of poor progress against milestones where future approaches need discussion. This can also include discussion of appropriate levers that might be used to trigger action and progress against set milestones.

B) **Opportunities to catalyse pandemic preparedness in light of COVID-19:**

4. **Monitor the current pandemic landscape, capture lessons from COVID-19 including identifying options and alternate ways of responding to a pandemic e.g considering regional or global mechanisms and consider inclusion of additional areas of work as part of HLIP in the coming years:** As noted above, COVID-19 has highlighted a number of potential gaps and opportunities in current systems for preparedness. These include clinical case management of severe acute respiratory infections, whole-of-society and whole-of-government readiness, the role of non-pharmaceutical interventions during an influenza pandemic, and broader regulatory preparedness, commodity production and capacity to equitably deploy these. Considering the magnitude of COVID-19 investments, the evolving pandemic landscape and the timelines needed to scope new activities or a new HLIP III, WHO may consider

implementation of 'demonstration' or 'pilot' projects such as the expansion of the remit of GISRS or IPPP work with political leaders whilst simultaneously beginning scoping for the design of HLIP III building upon the lessons emerging from COVID-19.

5. **Consider ways of linking to independent reviews of preparedness:** The focus on specific HLIP II outputs can make it hard to see whether progress is being made in improving preparedness holistically ie across all output areas. Some stakeholders recommended potentially using or linking to independent processes of review. As the 74th World Health Assembly will consider mechanisms to rigorously and inclusively assess International Health Regulations core capacities and gaps in preparedness, this presents an opportunity to incorporate reviews of pandemic influenza preparedness and specific gains and contributions targeted through the HLIP II within a broader framework.

6. **Consider ways of mapping PC investments for pandemic influenza preparedness in the context of the broader preparedness landscape:** COVID-19 is and will likely continue to drive additional investments in global, regional and country preparedness systems. As these resources get mapped through other initiatives such as the COVID-19 Partners Platform or the Strategic Partnership for Health Security and Emergency Preparedness Portal, explore options to reflect the complementarity and efficiency with investments made through the PC and other relevant programmes of work. This, if considered beyond the scope of HLIP II, could be implemented through the Global Influenza Strategy or other programmes in order to ensure it is able to reflect the broader preparedness and disease control programme.

Conclusion:

The last three years have seen continued progress towards the overall outcome measure '**Influenza surveillance systems, knowledge and capacities for a timely and appropriate response to pandemic influenza are established and strengthened'** in priority countries, regionally and globally. This was despite widespread disruption to influenza activities as a result of the ongoing pandemic of SARS CoV-2 which provided an opportunity to look at what gains have been made through PIP PC implementation and emerging gaps and challenges. The six recommendations provide opportunities to address current implementation hindrances and ways to catalyse pandemic preparedness in light of the current context.

Annex A: Semi structured questionnaire – WHO PIP staff

Introduction:
Name
What is your role? What is your remit/ interest with regards to the HLIP II?
Check they understand the remit of the MTR.

How long have you been involved in the PIP and in the HLIP II.
What is your understanding of the main differences between HLIP II and HLIP I?
How has implementation and oversight of HLIP II evolved over time?
How do you monitor progress against the milestones in the HLIP II?
Overall, how well do you feel implementation of the HLIP II is going? Could you summarise how progress is going in your area of interest/focus?

Achievements/strengths of the approach:
What do you think is working well with regards to implementation of the HLIP II?
How has progress been against key deliverables in your area?
Have there been any particular successes you can tell me about?
Could you talk through why you have chosen these and your thoughts on why they have been such a success?

Non-COVID-19 related challenges or barriers to implementation?
Could you tell me about any non COVID-19 related challenges in implementation of the HLIP II? [If focusing on a particular output area then go through indicators where progress is not as expected]
Why do you think progress was not made as planned? [prompt if needed -implementation challenges, challenges with indicator or measurement]
What would you change with regards to this issue in order to make progress against it? [prompt if needed - change milestone, indicator, area, focus etc]

COVID-19
How has COVID-19 affected implementation of the HLIP II (in your area of work)?
Have there been any co-benefits from your work on implementation of the HLIP II and the COVID-19 response? Why?
Do you feel the HLIP II remains relevant in its current form today given the impact of the pandemic?
Would you change anything both immediate and longer term? If so why? If not, why?
What lessons have you taken from the COVID-19 pandemic that you believe should be considered during this next phase of implementation of the HLIP II? What about into the future?

Annex B: Semi structured questionnaire – External Stakeholders

Introduction:
Name
What is your role? What is your remit/ interest with regards to the HLIP II?
Check they understand the remit of the MTR.

How long have you been involved in the PIP and in the HLIP II.
Overall, how well do you feel implementation of the HLIP II is going? Could you summarise how progress is going in your area of interest/focus?

Achievements/strengths of the approach:
What do you think is working well with regards to implementation of the HLIP II?
Have there been any particular successes you can tell me about?
Could you talk through why you have chosen these and your thoughts on why they have been such a success?

Non-COVID-19 related challenges or barriers to implementation:
Could you tell me about any non-COVID-19 related challenges in implementation of the HLIP II?
Why do you think progress was not made as planned?
What would you change with regards to this issue in order to make progress against it?

The impact of COVID-19 on implementation:
How has COVID-19 affected implementation of the HLIP II?
Have there been any co-benefits from COVID-19 to implementation of the HLIP II in your area of interest? Why?
Do you feel the HLIP II remains relevant in its current form today given the impact of the pandemic?
What lessons have you taken from the COVID-19 pandemic that you believe should be considered during this next phase of implementation of the HLIP II? What about into the future?

Future:
Would you make any changes to the HLIP in the immediate term ie for the next three year period? Are there any longer-term changes to the HLIP II you would recommend? If so why? If not, why?

Any other comments?

Annex C: Interview list

Group	
WHO Headquarters	Director: 1 Chief: 1 Secretariat: 4 L&S: 4 BOD: 2 REG: 2 RCCE: 1 DEP: 2 IPPP: 1
WHO Regions	AFRO: 1 AMRO: 2 EURO: 2 EMRO: 1 SEARO: 1 WPRO: 1
WHO Countries	Armenia Bolivia (written feedback) Egypt Haiti (written feedback) Indonesia Mongolia Nigeria Yemen
Member State Ministry of Health counterpart	Nigeria
PIPAG members	Five members
PCITEM	Six members
GISRS	Six members
Industry groups*	Bio – three participants DCVMX – three participants IFPMA – three participants
Civil Society	Two participants

*AdvaMedDx was invited to provide inputs as a key informant but were unable to participate.

Annex D: Allocation of funds

Table 1 provides information on HLIP II biennial budget and expenditure by area of work and WHO Major Office for the 2018-2019 biennium.

Table 2 provides the same overview for the year 2020 alone, noting that a Public Health Emergency of International Concern (PHEIC) was determined by WHO under the International Health Regulations (2005) on 30 January 2020. The figures show the impact of COVID-19 on PIP Framework activities and expenditures.

Table 3 provides expenditures by expenditure type for the 3 years, highlighting a major decrease observed in travel costs, staff costs and contractual services for 2020 due to the pandemic. Approximately $1.3M of staff time costs were repurposed for the COVID-19 response in 2020.

Table 1: HLIP II biennial budget and expenditure by area of work and WHO major office, 2018-2019

Major Office	L&S Budget	L&S Expenditure	BOD Budget	BOD Expenditure	REG Budget	REG Expenditure	RCCE Budget	RCCE Expenditure	DEP Budget	DEP Expenditure	IPPP Budget	IPPP Expenditure
AFR	2,587,000	1,787,818		-		-		-		-	525,000	578,021
AMR	3,586,672	3,373,942	112,246	112,246		-		-	50,000	50,000	31,000	15,894
EMR	3,744,085	3,230,790		-	-	-	121,000	122,330		-	220,500	189,168
EUR	3,714,950	3,368,757		-		-	150,000	204,207		-	360,000	234,945
SEAR	2,631,260	2,316,989		-		-		-		-	456,500	324,650
WPR	2,649,533	2,065,739	-	-	105,101	105,101		-	-	-	523,822	523,822
HQ	1,975,584	2,369,455	1,682,505	1,512,254	2,626,399	2,106,812	1,988,643	1,327,963	1,481,700	979,116	826,309	500,161
Total	20,889,084	18,513,490	1,794,751	1,624,500	2,731,500	2,211,913	2,259,643	1,654,500	1,531,700	1,029,116	2,943,131	2,366,661
% Expenditure		89%		91%		81%		73%		67%		80%

Table 2: HLIP II annual budget and expenditure by area of work and WHO major office, 2020 (COVID-19 declared a PHEIC on 30 January 2020)

Major Office	L&S		BOD		REG		RCCE		DEP		IPPP	
	Budget	Expenditure	Budget	Expenditure	Budget	Expenditure	Budget	Expenditure	Budget	Expenditure	Budget	Expenditure
AFR	1,436,067	449,770					10,000	-			469,320	104,025
AMR	1,648,240	708,738			152,100	44,914	52,000	4,087			173,000	5,651
EMR	1,572,738	848,676				(23,086)	102,000	20,226			232,750	22,551
EUR	1,744,850	845,122				-	65,000	20,821			155,000	74,795
SEAR	1,588,200	915,446				-	50,000				199,750	25,520
WPR	1,091,050	695,305			162,800	50,805	115,000	402			352,000	201,034
HQ	1,413,650	413,924	991,600	275,944	1,277,725	536,537	806,000	119,693	692,100	143,104	203,000	73,208
Total	10,494,795	4,876,981	991,600	275,944	1,592,625	609,170	1,200,000	165,229	692,100	143,104	1,784,820	506,784
% Expenditure		46%		28%		38%		14%		21%		28%

Table 3: HLIP II expenditures by expense type, 2018-2020

Expense Type	2018	2019	2020
Staff Costs*	3,825,140	4,282,320	3,032,152
Medical Supplies and Materials	587,985	815,149	648,339
Equipment, Vehicles and Furniture	23,943	48,414	20,173
Contractual Services*	3,429,879	5,430,369	1,711,467
Travel*	1,939,951	3,103,512	191,637
Transfers and Grants	1,122,163	1,758,654	846,416
General Operating Costs	426,189	606,514	127,027
Total	**11,355,250**	**16,044,932**	**6,577,211**

Annex E: Progress against outcome measures

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

Outcome indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Outcome indicator 1: % of MS sharing IVPPs with GISRS according to WHO IVPP sharing guidance	N/A	N/A	75% (3/4) * 71% (5/7) 75% (3/4)
Outcome indicator 2: % of PC recipient MS reporting to FluNet	84%	85% 85% 90%	89% (33/37) 97% (36/37) 88% (36/41)
Outcome indicator 3: % of PC recipient MS reporting to FluID	51%	60% 70% 80%	73% (27/37) 81% (30/37) 73% (30/41)
Outcome indicator 4: % of MS with burden of disease estimates that have been considered by NITAG or other decision making bodies	n/a	30% 40% 50%	16% (3/19) 11% (4/38) 0% (0/11)
Outcome indicator 5: # of MS that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products	0	10 23 37	6 22 27
Outcome indicator 6: % of PC recipient MS that developed or updated a pandemic influenza preparedness plan since 2014 (N=40)	30% (12/40)	60% 75% 85%	35% (14/40) 65% (26/40) 56% (35/63)

* Of the 4 countries that did not share IVPPs with GISRS according to WHO guidance, 2 had no specimen left or available to share. The other two shared but not according to IVPP guidance.

Overall progress against indicators with set targets is good with only one off-track indicator. This indicator has been assessed in further detail under the section on burden of disease.

Annex F: Progress against output areas

Output area progress: Laboratory and surveillance

Output Title	National influenza L&S systems contribute to GISRS for timely risk assessment & response measures		
Output number per LF	1	**Priority countries**	2019-2020: 37 2020-2021: 41
Approved Budget (%):	2018-19: $20.9M 2020-21: $ 20M	Expenditure :	2018-19: $18.5 m 2020: $4.9m

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: Risk and Severity of influenza including at the human animal interface are routinely assessed	Output indicator 1.1: # of risk assessments published for influenza viruses at the human-animal interface following WHO guidance.	10	30 50 70	17 24 30
	Output indicator 1.2 # of Member States (MS) reporting influenza severity indicators to WHO	13	34 51 65	12 27 14
Deliverable B: Quality influenza virus detection capacity is sustained	Output indicator 1.3: % of MS that participated and were 100% correct for non-seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)	89%	90% 90% 95%	85% 93% 83%
	Output indicator 1.4: % of MS that participated and were 100% correct for seasonal influenza virus identification in the WHO PCR External Quality Assessment Programme (EQAP)	96%	95% 95% 95%	94% 95% 95%
Deliverable C: Countries are supported to consistently report influenza data to global platforms	Outcome indicator 2: % of PC recipient MS reporting to FluNet	84%	85% 85% 90%	89% 97% 88%
	Outcome indicator 3: % of PC recipient MS reporting to FluID	51%	60% 70% 80%	73% 81% 73%
Deliverable D; Countries are supported to share timely representative influenza samples with WHO CCs	Output indicator 1.5: % of MS that had timely sharing of influenza virus isolates or clinical specimens with WHO CCs according to WHO guidance	36%	44% 46% 50%	43% 44% 31%
	Outcome indicator 1: % of MS sharing IVPPs with GISRS according to WHO IVPP sharing guidance	N/A	N/A	75% (3/4) 71% (5/7) 75% (n=4)
Deliverable E: Influenza CVVs, virus detection protocols and reagents, and reference materials are routinely updated.	Output indicator 1.6: # of zoonotic influenza viruses and other influenza viruses with pandemic potential characterized by GISRS	N/A	N/A	605 1469 1105

Background
This output area forms the bulk of activities conducted under the HLIP II accounting for over half the available budget. This output area aims to support countries to improve their laboratory and surveillance system capacities and to actively participate in the GISRS with the aim of enhancing virus and information sharing, risk and severity assessment and improve response measures with the aim of reducing vulnerabilities.

Summary of activities
Good progress has been made against most indicators in this output (see below for output 1.2). This output area is well established and there is a general sense that that activity under this output area is improving year on year with modest increases in the numbers of laboratories participating and, in the number and quality of influenza samples coming in. Close collaboration with the regional offices on a common workplan has helped move work in this area forward and the importance of the network of laboratories was strongly highlighted.

Output Indicator 1.2: The Pandemic Influenza Severity Assessment (PISA) tool was launched in 2017. Since then, over 100 countries from all six regions have participated in training. During the first biennium 27 countries including seven priority countries reported assessments to WHO. In 2020 the number reporting has decreased to 14 presumably due to disruption of influenza due to the ongoing COVID-19 pandemic and sharp decline in influenza activity in 2020. The PISA tool uses a mix of different data sources according to season, but feedback suggests its use varied greatly by region and there were questions over its structure and appropriateness in different contexts. Discussion suggests this indicator may need reviewed, to look or add in other severity tools, including through hospital or other networks.

Impact of COVID-19
There was consensus amongst all stakeholders that investment in output 1 and the GISRS network were critical in setting up systems for COVID-19. Anecdotal reports from regions state that priority countries receiving direct investment for this output area were able to set up laboratory and surveillance systems for COVID-19 much faster than countries receiving less investment or support. It was generally felt that Investment under PIP allowed the response to be more systematic in country, supported the development and scale up of sentinel systems and adaptation of projects such as the EQA project and Shipping Fund Project. Further examples follow:

- Dramatic scale up in testing capacity including decentralisation and expansion of sentinel systems and oversight by NICs including newly accredited NICs.
- Sampling, molecular testing and genetic sequencing through the GISRS system.
- Support for use and scale up of multiplex testing for both COVID-19 and Influenza where possible.
- FluMart which provides the platform for FluNet and FluID was quickly adapted to allow reporting for COVID-19.
- Adaptation of PAHO Flu for COVID-19 allowing automated sharing of data from national to regional to global level.
- EQA schemes and PISA were adapted and used for COVID-19.
- Widespread online dissemination of training materials including on adapting testing systems for COVID-19.

Whilst there is no doubt that PIP was useful for COVID-19 there were challenges maintaining influenza surveillance. Most planned activities stopped including in some countries laboratory testing of samples for influenza in part due to prioritisation of COVID-19 with in some cases National guidance recommending cessation of all non COVID-19 activities, redeployment of capacity to COVID-19 and the knock-on effect of measures including lockdowns and restrictions on international travel resulting in shortages of reagents and other commodities. COVID-19 also led to changes in patient pathways and testing strategies (sentinel versus

diagnostic), disrupting or stopping influenza sentinel surveillance, or leading to mass scale up of decentralised testing with subsequent challenges around data capture. Whilst some training could be conducted online, practical laboratory training and assessments/ accreditations including NIC recognitions had to stop. There were also concerns that the focus on genetic sequencing might lead to a decrease in virus sharing which would be a challenge for influenza.

COVID-19 provides an important opportunity to review current approaches for testing strategies during a pandemic; early detection of non influenza respiratory viruses of pandemic potential if below sentinel surveillance thresholds; the use of impact indicators for PISA with some countries using all hospital confirmed influenza cases now using hospital confirmed COVID-19 cases rather than just sentinel sites. It will be important to review surveillance thresholds in light of COVID-19 given the figures are much worse than the worst influenza season.

Output area progress: Burden of disease

Output Title	Influenza disease burden estimates are used for public health decisions		
Output number per LF	2	Priority Countries	Not predefined, countries apply for support based on set criteria
Approved Budget (%):	2018-19: $1.8m 2020-21: $ 2M	Expenditure	2018- 2019: $1.6M 2020: $275K

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: Representative national, regional and global disease burden estimates are available	Output indicator 2.1: # of MS with published disease burden estimates based on data collected since 2011 (N=194)	21	28 36 46	35 39 43
Deliverable B: Disease burden findings are communicated to national and international expert bodies in a format that promotes evidence-based decision making.	Outcome 4: % of MS with burden of disease estimates that have been considered by NITAG or other decision-making bodies	n/a	30% 40% 50%	16% (3/19) 11% (4/38) 0% (0/11)

Background:
The intention of this output is to ensure availability of national, regional and global influenza burden estimates for evidence-based decision making for both seasonal and pandemic influenza. Estimates provide governments and policy makers with an understanding of population risk allowing them to assess the economic cost of influenza, enabling better informed decisions on influenza policy and vaccine policy and programming.

This output has a global group with representatives from each region. The group meets monthly, providing technical advice, guidance and support as needed including advice regarding funding allocations. There is no set list for support to countries on BOD but decisions are based on need/ opportunity identified through the regions and primarily based on HLIP II country selection criteria. Funding is then allocated accordingly. Technical assistance may be provided to any MS including those not receiving funding.

Summary of progress:
The last three years have seen marked progress under this output area in particular the number of MS with published BOD estimates. It was felt that countries understand how and where to find tools and how to seek advice as needed. The importance of the networks formed under this output were strongly recognised both inside and outside of WHO including their use comparing and contrasting estimates including on hospitalisation and mortality in order to understand differences and discrepancies.

69 countries including 23 LMICs shared data in 2020 for use in regional and global BOD estimates. This will help develop and update global and national prevention and control measures e.g. vaccine and clinical management strategies. The regions commented that significant progress has been made using BOD data to look at vaccine effectiveness with investment in this output through the HLIP II allowing vaccine effectiveness studies to be conducted at country level.

Progress against outcome indicator 4 has fallen short of the target each year since the start of the programme. The intention of Outcome indicator 4 is to show that estimates are being used to guide decision making as per recommendation from the GAP report. In part this is due to a measurement challenge, with colleagues noting the challenge in proving that estimates are used for policy. The team is currently considering whether they can match countries with estimates against countries reporting on influenza using the Joint Reporting Form, which whilst not causal would give some indication of countries with a BOD estimate that has fed into vaccination policy. Another explanation given as to why this indicator remains challenging to report on/ achieve is the predominant skill mix of those working on BOD. It was felt there may be value in expanding the network to include greater participation from policy makers. Efforts are ongoing to expand participation to include more policy makers.

Impact of COVID-19

Whilst a lot of work stalled during COVID-19, teams are now working trying to get back on track. Many countries interested in doing COVID-19 burden estimates are keen to combine with influenza and this presents an opportunity to rethink some of the country level work. WHO has been developing a pyramid tool to help countries with limited data estimate their BOD. The tool was used to inform development of the COVID-19 disease burden pyramid tool which will now need to be adjusted for Influenza based on implementation experience gained through COVID-19 including a refresh of the baseline comparators, whilst recognising the additional complexities of influenza including impact on younger people, variations in impact across geography, and relative paucity of data in comparison with COVID-19.

There is a need to consider whether a specific output on BOD is still needed in this form, or whether it should be adapted now that progress has been made on output indicator 2.1. This may include consideration as to whether this indicator be incorporated into output area 1 or 6? And whether this area of work should evolve to focus more on provision of support to countries to have stronger approaches and tools to use in a pandemic.

Output area progress: Regulatory capacity building

Output Title	Timely access to quality-assured influenza pandemic products is supported		
Output number	3	Priority countries	Output 3.1: 16 Outcome 5: 48
Approved Budget (%):	2018-19: $2.7M 2020-21: $2.8M	Absorption per biennium	2018-19: $2.2M 2020: $609K

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: National regulatory capacity for pandemic influenza products is strengthened	Output indicator 3.1: # of PC recipient MS which strengthened national regulatory capacity to oversee pandemic influenza products	1	4 8 16	3 6 7
Deliverable B: Adoption of regulatory pathways that accelerate approval for use of pandemic influenza products is promoted	Outcome indicator 5: # of PC recipient MS that have implemented a defined regulatory approach that enables timely approval for use of pandemic influenza products.	0	10 23 37	6 22 27

Background

Output 3 aims to improve regulatory systems and processes to facilitate timely access to pandemic influenza products including antivirals, diagnostics and vaccines by building national and regional regulatory capacity and facilitating country adoption of pathways that accelerate approval. It aims to do so through a benchmarking process that identifies and addresses gaps through technical support and training and by supporting countries to adopt regulatory pathways through the conduct of global workshop and provision of technical assistance.

Priority countries were selected at the start of HLIP I and due to the length of time it takes to make progress with regulatory work these have remained the same throughout. There are focal points in the regions with calls monthly to share updates.

Summary of activities

The last three years have seen continued steady progress in the strengthening of regulatory systems at national level. Regulatory processes can take between 5 to 10 years to develop fully and are often not prioritised sufficiently with progress dependent on political commitment, resource and support from a wide range of partners including WHO. Whilst it was recognised that progress under HLIP II output 3 is on track, stakeholders expressed concerns about the focus on the 48 recipient countries, including the need to evolve the support to countries that have reached ML3 or those with low responsiveness.

Impact of COVID-19

COVID-19 has helped galvanise political commitment to strengthen regulatory systems for future pandemics by highlighting the need to prioritize regulatory system strengthening which is often otherwise overlooked during priority setting. A section on regulatory preparedness for expedited approval of COVID-19 was developed under the NDVP guidance and published in 2020. 90% of countries receiving support through PIP were able to approve the COVID-19 vaccine within the set 15-day timeframe.

COVID-19 has however had quite a major impact on regulatory work, with workplans developed being based on travel for technical assistance. The team have tried to adapt to continue working virtually and there has been growing acceptance by countries on the use of webinars including remote work with regulators and regional offices to share updates on regulatory preparedness and country readiness for expedited approval of COVID-19 vaccines and conduct of assessments of country systems. Whilst much can be achieved through remote work, the need for face to face engagement for the assessment of national regulatory systems was emphasised for this output area.

COVID-19 has also raised questions on the approach taken with regards to regulatory work with the use of regional systems for the approval of products for the pandemic. There is a need to review lessons emerging through COVID-19 including the role and utility of regional approaches to approve and regulate products (including products using new technologies such as mRNA vaccines, or multiplex tools) which might be of value to pandemic influenza in the future whilst continuing work to strengthen national capacities.

Output area progress: Risk communications and community engagement

Output Title	Tools and guidance are available for countries to enhance influenza risk communication and community engagement		
Output number per LF	4	Priority countries	Not predefined, countries apply for support based on set criteria
Approved Budget (%):	2018-19: $2.3M 2020-21: $2.3M	Expenditure:	2018-2019: $1.6M 2020: $165K

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: Countries and front- line responders have access to resources for influenza risk communication, community engagement and social science-based interventions	Output indicator 4.1: # of users who completed Open-WHO influenza modules	3475	12500 25000 40000	9922 39734 192111
Deliverable B: Technical assistance is provided to countries to plan and exercise influenza risk communication and community engagement	Output indicator 4.2: # of MS that utilised RCCE support for influenza preparedness and response.	0	100 130 160	10 51 51

Background

The risk communication and community engagement (RCCE) output aims to increase focus on community engagement and readiness for pandemic influenza. The aim is to achieve this by systematically integrating social and cultural considerations into planning and implementation of RCCE. In addition, this area works to strengthen capacities of countries and agencies to communicate risk more broadly and sustain surge capacity through integration of RCCE into national pandemic preparedness plans and ensuring access to updated easy to use tools, information and resources. There is no set list for support to countries on RCCE but decisions are based on need/ opportunity identified through the regions. Funding is then allocated accordingly. Technical assistance may be provided to any country including those not receiving funding.

Summary of activities

This output area initially focused on learning and support for risk communication and community engagement (RCCE). Following the initial success of the OpenWHO.org platform, work under this output area has evolved to include the development of training packages and creation of networks of RCCE focal points across regions. This now needs to be reflected in the indicators to allow the work being done under this area to be captured appropriately.

In addition to the OpenWHO.org platform during 2020 over 90 countries and 1700 participants from across all six WHO regions participated in global webinars aimed at strengthening RCCE activities relevant to COVID-19 and pandemic influenza. The RCCE team are now trying to provide more focused training and support to regional RCCE focal points. One example is the development of the FoRCCE training package which focuses on the five risk communications areas of the International Health Regulations: (1) risk communications systems, (2) stakeholder coordination, (3) public communication mechanisms, (4) community engagement,

and (5) misinformation management. Regional RCCE focal points and HQ leads were brought in to help field test the package in 2019. The plan had been to refine the training and launch but this was delayed due to COVID-19. Instead, the network formed through initial training for FoRCCE was quickly repurposed to support the COVID-19 response.

Most technical assistance is provided through regional activities, and few countries have applied or received funding support to directly implement country-level activities. The shift in program emphasis now needs to be reflected in the indicators to allow the work being done under this area to be captured appropriately.

Output 4.2: Progress against this indicator has been slow and is off track. Goals set were ambitious and open to interpretation. A definition of what is meant by 'support' is needed to aid interpretation of this indicator e.g. are webinars with global reach considered support if not targeting individual countries.

Impact of COVID-19
COVID-19 has greatly increased the use of the online tools such as OpenWHO.org platform or through global webinar trainings as tools to support information sharing and remote training.

As noted, the regional network formed through the FoRCCE training package was repurposed to provide support to the COVID-19 response by allowing them to develop tools and share information and learning emerging from the pandemic. This includes helping track and share social listening data, sentiment analysis, tailored risk communication materials, rumour monitoring strategies, behavioural insights survey tools, country and community focused capacity building products and sharing approaches to managing pandemic fatigue, support social cohesion and enable translation of rapidly evolving science. It is felt that this helped ensure consistency in the response and reduced duplication thus saving time in the response.

In addition, it was felt that the pandemic helped encourage countries to either develop or strengthen response plans including for Influenza. 188 countries developed RCCE plans for COVID-19 in 2020. These experiences will help preparations for future events including pandemic influenza. The group now meets weekly (pre-COVID-19 they met every 2-4 weeks) to share learning and approaches to the pandemic.

Going forward the RCCE team are keen to conduct assessments with countries in each region on what worked and what didn't to inform what capacity building work may be needed in future. There is also a need to look at ways of better integrating surveillance information and data for risk communications. It may also be worth considering whether RCCE benefits from being a stand-alone area, or whether integration into L&S or IPPP should be considered. Finally, given then challenge of mis and dis information, and the evolution of initiatives around infodemiology, it is worth considering how focal points are and can further linkages with these areas of work to share lessons emerging through this output area.

Output area progress: Planning for Deployment

Output Title	Plans for effective & efficient deployment of pandemic supplies are optimized		
Output number per LF	5	Priority Countries	
Approved Budget:	2018-19: $1.5M 2020-21: $1.3M	Absorption	2018-2019: $1M 2020: $143K

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: A common approach to manage global deployment operations is developed and regularly tested with stakeholders and deployment partner	Output indicator 5.1: # of simulation exercises conducted to test global deployment of pandemic influenza vaccines and other products	1	3 5 7	1 6 6
Deliverable B: National deployment planning process is revised and updated				
Deliverable C: Technical assistance to develop policies for sustainable influenza vaccine procurement and production is provided to countries.	Output indicator 5.2: # of MS that have undergone a national analysis of influenza vaccine procurement or production sustainability	6	8 10 12	8 8 8

Background

The deployment output aims to ensure that requests and allocations for deployment of pandemic products are equitably managed. This includes development of national deployment plans that support distribution to points of care. Initially the focus was on an online global simulation application that engages stakeholders involved in deployment (including manufacturers, country officials and support agencies) in order to test systems, prepare stakeholders and improve capacity. Deliverable A focuses on developing a common understanding to global deployment with focus on PIP Deploy, the global simulation tool developed during HLIP I; Deliverable B focuses on national support and capacity building through development of guidance and tools and Deliverable C focuses on technical assistance for policies to allow sustainable vaccine procurement and production.

Summary of activities

Following change over in personnel the focus of the deployment team has shifted away from global simulations to more localised training, workshops and publications aimed at raising awareness.

Impact of COVID-19

The deployment team have had to adapt activities to support in deployment of COVID-19 related commodities. This includes adapting pandemic influenza guidance on National Vaccine Deployment Plans for COVID-19 and uptake of OpenWHO.org, use of infographics developed for influenza, and country and regions have translated and used table-top simulations for COVID-19. At global level the operational framework has been adapted for COVID-19.

COVID-19 has raised awareness of the importance of the deployment output in particular as part of output areas one and six. Distribbution delays, in part due to restrictive travel measures led to shortages in reagents and diagnostics resulting in challenges with global testing capacity for both COVID-19 and Influenza. There were global shortages of personal protective equipment, respirators/ ventilators, oxygen, as well as issues with the equitable distribution of vaccine including through COVAX.

It was felt critical to learn lessons from COVID-19 regarding this output including its primary focus on vaccines. Feedback from interviews raised the need to consider this output at global level and to reconsider the focus of this output area on country simulations and workshops. This included the need to review the remit of this output and whether it continues to primarily focus on vaccines or whether it should expand to consider other commodities. In addition, there were questions around the vaccine production aspect and whether this too should be considered given the current context of COVID-19. This will have to be considered in the context of a changing global landscape for investment in pandemic preparedness and considering the remit of PIP and the financial limitations of the HLIP II.

Output area progress: Influenza Pandemic Preparedness Planning

Output Title	National pandemic influenza preparedness & response plans are updated in the context of all-hazards preparedness and global health security		
Output number per LF	6	**Priority Countries**	2018-19: 40 2020: 63
Approved Budget (%):	2018-19: $2.9M 2020-21: $2.9M	Absorption	2018-19: $2.4M 2020: $506K

Deliverable	Relevant outcome/ output Indicator	Baseline	Target 2019 2021 2023	Progress 2018 2019 2020
Deliverable A: Countries are supported to develop, test and update their pandemic influenza preparedness plan	Outcome indicator 6: % of PC recipient MS that developed or updated a pandemic influenza preparedness plan since 2014	**30% (12/40)**	60% 75% 85%	35% (14/40) 65% (26/40) 56% (35/63)
	Output indicator 6.1: % of PC recipient MS that exercised their pandemic influenza preparedness plan	**5% (2/40)**	30% 50% 70%	10% (4/40) 30% (12/40) 3% (2/63)

Background
This output was introduced at the start of the HLIP II in 2018. It aims to support countries to develop their pandemic influenza preparedness plans and help to bring progress made under the other outputs together at country level. It aims to help build political commitment, coordination, risk assessment capacity, infrastructure, financing, human resource, equipment, simulation exercises and knowledge required for countries to be prepared. The main deliverable focuses on providing guidance and technical assistance to develop national plans, methods and tools to assess and modify interventions and a process by which to test and adapt plans.

Summary of activities
Outcome indicator 6: Of the 63 priority countries, 35 have developed a National Pandemic Plan based on WHOs Pandemic Influenza Risk Management Guidance. 16 more are in the process of developing or updating their plans. Different regions are implementing according to their context. In the African region the focal point brought priority and non-priority countries together to a training of trainers' workshop with follow up workshops in country to review plans. Around half of countries in attendance were able to use the plans they had developed for COVID-19 however many of these countries will not be captured in reporting as they are not priority countries.

Output indicator 6.1: This indicator remains off track. In total 13 of the 63 priority countries have exercised their plans (one country conducted a simulation in both biennia). Several stakeholders interviewed emphasised the importance of readiness rather than planning alone, and that testing and operationalizing plans were of critical importance.

Additional activities:
WHO Europe regional office have included an additional component of work on clinical management. This covers basic standards of care of the SARI patient and is adapted from the SARI course. This was found to be

helpful during COVID-19. Several regions expressed interest in this becoming a core area of focus depending on their context.

Impact of COVID-19
COVID-19 has shown the importance of relationships formed through PIP. A number of those interviewed at country and regional level have emphasised the role PIP has played in brokering and forging relationships with relevant parts of the Ministry of Health accelerating initial work to respond to COVID-19. That said, a number of those interviewed in country or at regional level highlighted the political nature of COVID-19, reflecting on the need to engage and work proactively on preparedness with other parts of Government outside of the Ministry of Health particularly as governance and oversight of the COVID-19 response has fallen to other parts of government in a number of countries.

COVID-19 led to the repurposing of staff to work on pandemic influenza preparedness. Whilst an opportunity for those involved to work through a pandemic caused by a respiratory pathogen, it has affected the ability of countries to continue influenza surveillance. In many countries' influenza preparedness relies on a single person or a small team. There is limited surplus capacity within the system, so if repurposed to other emergencies influenza preparedness suffers.

Anecdotally there was a general sense that work on IPPPs was of benefit to COVID-19. Reports suggest that of the 40 priority countries that developed IPPP during the first biennium, most used these to guide development of COVID-19 response plans in 2020. 36 did so within four months of declaration of a Public Health Emergency of International Concern (PHEIC). As noted above in output 6.1 testing rates are much lower and this was flagged by a number of stakeholders to be an important priority going forward. COVID-19 emphasised the need of both having plans and testing plans or as stated by one interviewee 'the difference between preparedness versus readiness to respond.' COVID-19 has shown that whilst countries have plans not all are ready.

COVID-19 has also flagged the need to consider inclusion of additional components into national plans. These include clinical management and non-pharmaceutical interventions which have become widespread during COVID-19 as well as plans for surging systems like laboratory diagnostics and health systems capacities.

COVID-19 is very much seen as an opportunity to raise awareness of the risk of pandemic influenza and to galvanise political interest and commitment. However, a substantial number of those interviewed at country and regional level felt that the IPPP should be adapted to include a broader range of respiratory viruses.