PANDEMIC INFLUENZA PREPAREDNESS (PIP) FRAMEWORK

Critical Path Analysis

From Detection to Protection

World Health Organization

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January 2015

Introduction

What is the CPA?

This Critical Path Analysis provides a high level overview of the complex, multi-sectoral 'path' that starts at the time of the detection of a new influenza virus and culminates with the protection of the global community. The CPA aims to succinctly and clearly:

- Show the extent of the work to be undertaken to strengthen global capacities from detection to protection,
- Highlight areas that are weakest and need strengthening
- Validate and provide the context and rationale for the specific interventions chosen by WHO (including costs) for the period 2013-2016;
- Provide the expected impact of the funds in improving global preparedness.

The CPA will serve as the roadmap for current and next phases of work, enabling all stakeholders to:

- Share a common understanding on the process steps;
- Highlight priorities for intervention;
- Engage in strategic discussions and long-term planning with a view to better preparing the world for the next pandemic influenza.
- Ensure that, in time, all elements of the path are addressed.

Note:
This document will be shared with Member States and posted on the PIP web page.

This document is a companion piece to *Gap Analyses* and *Partnership Contribution Implementation Plan (2013-2016)*, both published in January 2014, and which identify gaps and needs to improve global pandemic readiness and identify priority areas of work (AOW) for 2013-2016.

Background

PIP Framework: The Beginning

The roots of the discussions that lead to the adoption of the PIP Framework by the 194 Member States of WHO in May 2011 start with the re-emergence of H5N1 in 2003. By 2006, the virus had entrenched itself in the agricultural sector of several south-east Asian countries and there were increasing numbers of sporadic human infections. Manufacturers began to develop appropriate vaccines in 2006 using candidate vaccine viruses developed with viruses provided to the WHO coordinated Global Influenza Surveillance Network (which became the Global Influenza Surveillance and Response System under the PIP Framework). The high cost of these vaccines as well as the anticipated limited supply was cause for great concern by developing countries that queried why they should share viruses with a system that provided nothing in return.

The practices of the WHO coordinated network also came under scrutiny. A consequence of the devastating 1918 pandemic, the surveillance network informally started in the late 1940's and comprised a few public health laboratories specialized in influenza working together in a collaborative and informal manner. The objective was to gain knowledge about influenza, conduct regular surveillance, and ensure that timely information was shared about emerging viruses. As an informal network, there were no written rules or regulations for the activities conducted by the members. While this informal approach was sufficient for the mid-20th century this was no longer so in the 21st century. Thus, one of the outcomes of the PIP process was the development of terms and conditions to the sharing of viruses – both within the network and with parties outside it.

In January 2007, Indonesia championed the cause of developing countries' access to vaccines by declaring that it would withhold further sharing of its strains of A(H5N1) viruses with the WHO network until a more fair, equitable and transparent system was developed. Two intergovernmental processes ensued and over four years later, the World Health Assembly unanimously adopted the PIP Framework.

What is the PIP Framework?

The Framework is an ambitious and innovative, Member State driven approach to, increase global pandemic influenza preparedness and response, including more equitable access to pandemic vaccines. In so doing, it recognizes the role of industry as an important contributor to addressing the challenges of pandemic preparedness and response.[1]

Through the Framework, Member States affirmed the fundamental principle that virus sharing and benefit sharing are "equally important parts of collective action of global public health". As such:

- States should exercise their sovereignty by sharing their influenza viruses with human pandemic potential with WHO's network - and be made available for use by any interested entity (with appropriate bio-safety/security)

- Users of these materials and information should comply with the benefit sharing mechanisms established in the PIP Framework, notably to conclude benefits sharing agreements with WHO (known as "Standard Material Transfer Agreements 2" or " SMTA 2") and contribute to the annual Partnership Contribution[2].

What is the Partnership Contribution?

One of the key benefit sharing mechanisms of the Framework, the Partnership Contribution is an innovative approach to improve the world's readiness for pandemic influenza, and its ability to launch a robust response. The Partnership Contribution is paid to WHO every year by influenza vaccine, diagnostic and pharmaceutical manufacturers that use the WHO GISRS, for example, by receiving virus materials. The total yearly amount that WHO is to receive is US$ 28 million which is based on the estimated costs to run the WHO GISRS[3].

The Director-General decides how the funds should be used, based on advice and consultation with the Advisory Group[4], as well as interaction with industry and civil society[5]. The WHO Executive Board also plays a central role, deciding on how much is allocated to preparedness on the one hand, and response on the other[6].

For the period 2012-2016, the Executive Board decided on the following division of PC funds: approximately 70% to preparedness measures and 30% response activities, recognizing the need and usefulness of flexibility in allocating funds[7].

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[1] WHA64.5, PP4

[2] See PIP Framework Annex 2 for the SMTA 2 template and section 6.14.3 for the Partnership Contribution.

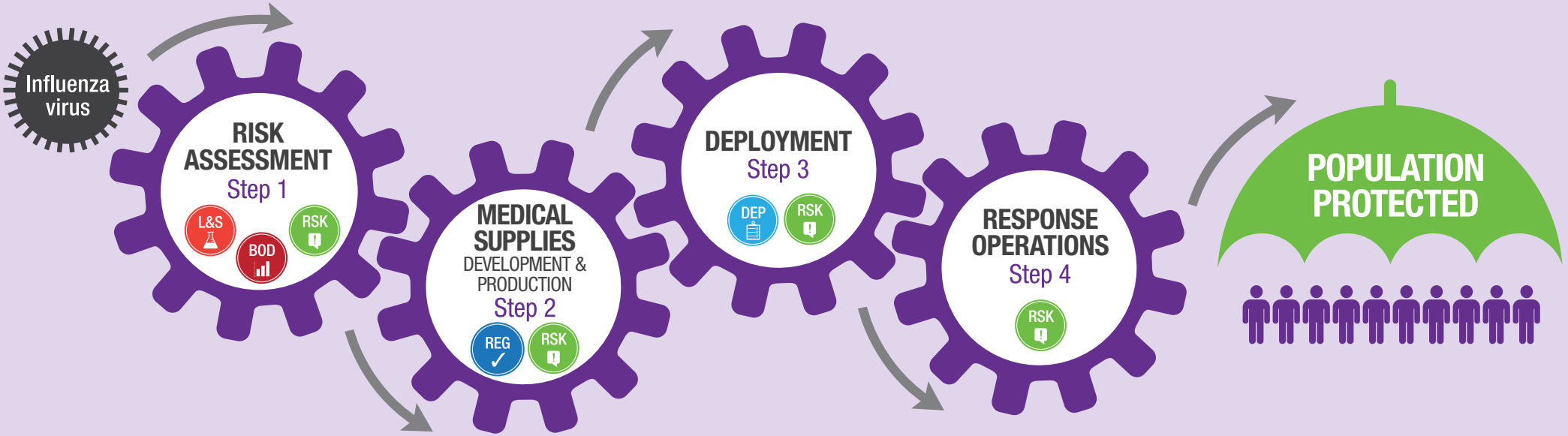
[3] See PIP Framework section 6.14.3 Footnote 1 which establishes that the reference index for the Partnership Contribution will be the running costs of GISRS which, in 2010 were estimated to be US$ 56.5 million. The Partnership Contribution was set at 50% of those running costs which may change over time.

[4] The Advisory Group is an independent group of 18 experts that provide advice and recommendations to the Director-General on the implementation of the Framework. See Section 7.2 and Annex 3 of the PIP Framework for more information.

[5] See PIP Framework section 6.14. 6.

[6] See PIP Framework section 6.14.5.

[7] See EB 131/4 *http://apps.who.int/gb/ebwha/pdf_files/EB131/B131_4-en.pdf*


Influenza virus
RISK ASSESSMENT
Step 1
L&S
BOD
RSK
MEDICAL SUPPLIES
DEVELOPMENT & PRODUCTION
Step 2
REG
RSK
DEPLOYMENT
Step 3
DEP
RSK
RESPONSE OPERATIONS
Step 4
RSK
POPULATION PROTECTED

The Four Steps of the Critical Path: From Detection to Protection

The Path has 4 steps which each have several elements within them. The remainder of this document provides details on each of these steps. Each step is accompanied by an illustration. Within those illustrations, where possible and relevant, references have been provided to specific elements of work in the *PIP PC Implementation Plan 2013-2016*. With respect to each illustration, the following applies:

- Boxes in bold colours reflect activities that have been selected as priorities in the in the *PIP PC Implementation Plan 2013-2016*.

  - Below each **bold** box, there is a code (e.g. **L&S O1K1**) which refers to the following in the *PIP PC Implementation Plan 2013-2016*:

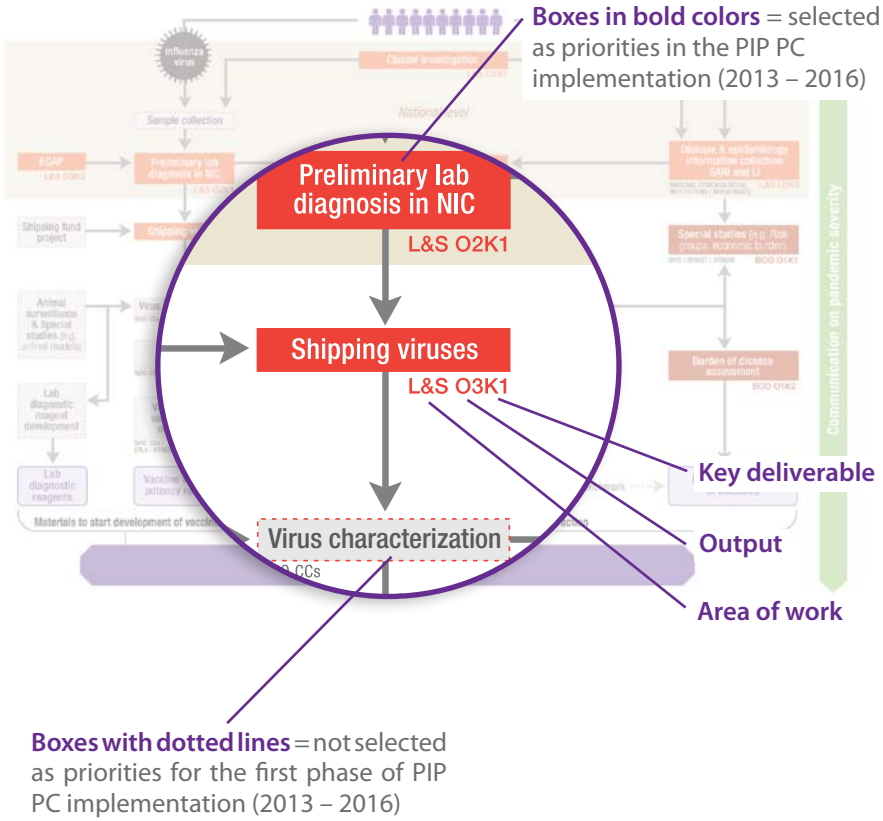
    The first 3 capitalized letters refer to the Area of Work as follows:

    L&S: Laboratory & Surveillance;
    BOD: Burden of Disease;
    REG: Regulatory Capacity building;
    DEP: Planning for Deployment

    The next letter and number (e.g. **O1**) refer to the Output in that Area of Work and the last letter and number refer to the Key Deliverable (e.g. **K1**) in that Output.

Further information on the activities being implemented, as well as financial details, are found in the PIP PC Implementation Portal. (To access the Portal click on the following link: *https://extranet.who.int/pip-pc-implementation/*).

- Boxes with dotted outlines are elements of the Critical Path which are in need of strengthening but were not selected as priorities for the first phase of PIP PC implementation (2013 – 2016). Subject to their continued relevance and the availability of funds, they could be addressed in the next phase(s) of implementation (2017 and beyond).



Step 1: **Pandemic risk assessment**