Pandemic Influenza Preparedness Framework

Sharing of influenza viruses &
access to vaccines and other benefits

Consultation on WHA decision 70(10)8(b)

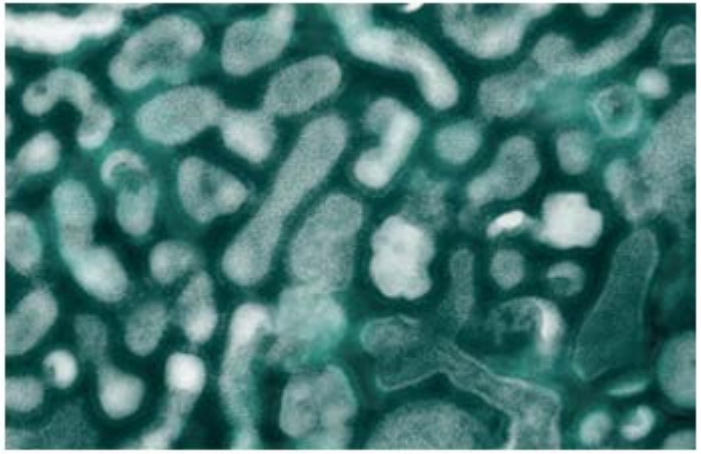
Overview

15-16 October 2018

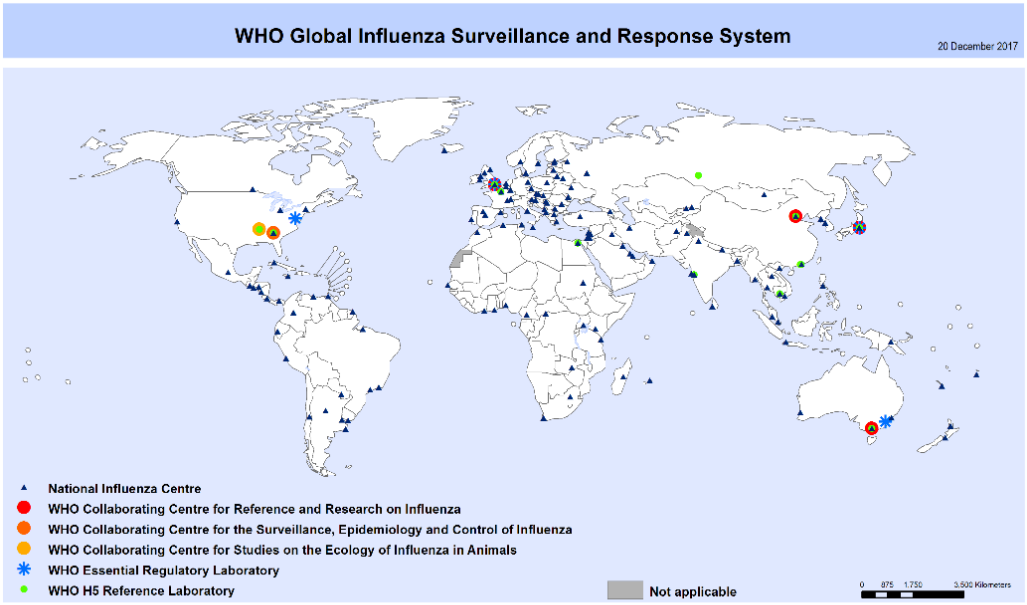
World Health Organization

Influenza

- Unique, highly contagious, infectious disease
- Among few known **pandemic-prone** pathogens
- Global surveillance mechanism coordinated by WHO: **Global Influenza Surveillance and Response System (GISRS)**



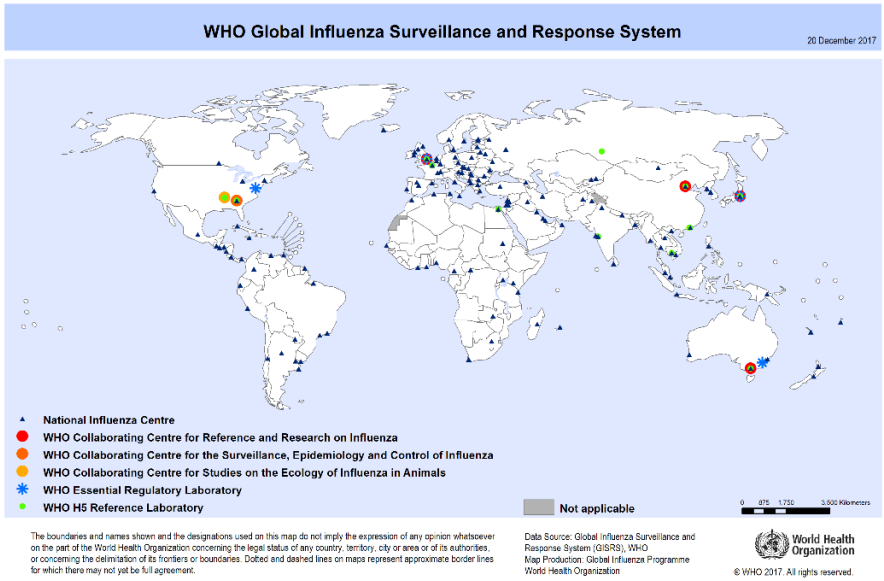
Courtesy of WHO Collaborating Center for Studies on the Ecology of Influenza in Animals, Memphis, USA



World Health Organization

GISRS – Global Virus Sharing for Public Health Security

- **66 years of excellence** on the frontlines of influenza
- **Year-round continuous** virus detection, sharing, risk assessment, and pandemic & epidemic response
  - Network of Public Health Laboratories
  - **114** Member States supporting **153** laboratories under WHO *Terms of Reference*



GISRS
GLOBAL INFLUENZA SURVEILLANCE & RESPONSE SYSTEM
Uniting the world in the fight against influenza

Zoonotic influenza

Seasonal influenza

Pandemic influenza

Annual resources over US$ 84.5 M

US$ 56.5M (Running costs) + US $28M (PIP PC manufacturers) + WHO coordination (in-kind)

GISRS provides to all Member States:

1) Laboratory testing, analyzing & monitoring
- e.g. specimen testing, characterization

2) Risk assessment & mitigation

3) Reagents and viruses
- e.g. free laboratory reagent kits, reference viruses, candidate vaccine viruses (CVVs)

4) Information and knowledge
- e.g. GSD, situation updates

5) Capacity – national and global
- e.g. EQA panels, laboratory protocols, guidance, mentoring

GISRS in 2017 alone .....

~ 3,500,000 specimens tested;
~ 40,000 virus specimens shared with CCs from more than 110 countries;
~ 10,000 viruses characterized by CCs;
~ 45 candidate vaccine viruses developed;
- 138 countries report surveillance findings to FluNet;
- 145 countries demonstrated high quality capacity of virus detection.

PIP Framework Background

- ‘Bird Flu’ - Re-emergence of A(H5N1) in SE Asia ~ 2004
  - Viruses sent into GISRS (GISN) for characterization, risk assessment and vaccine virus development
- Candidate vaccines developed → limited availability of vaccines at high price

Bird flu virus H5N1 infection in laying Hens.

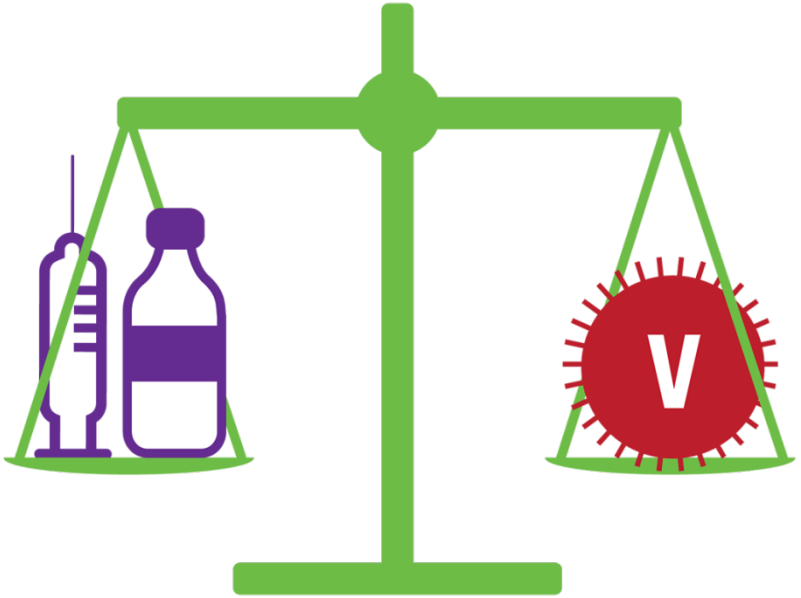
Global Discussions on pandemic influenza preparedness & response

- 2007-2011: WHO Member States negotiate and adopt an innovative approach to increase public health security:
  - **Share influenza viruses with pandemic potential (IVPP)** with WHO/GISRS
  - Ensure all countries are **prepared** for pandemic response
  - Establish mechanisms to ensure greater **equity** of access to pandemic vaccines and other response products

PIP Framework objectives & scope

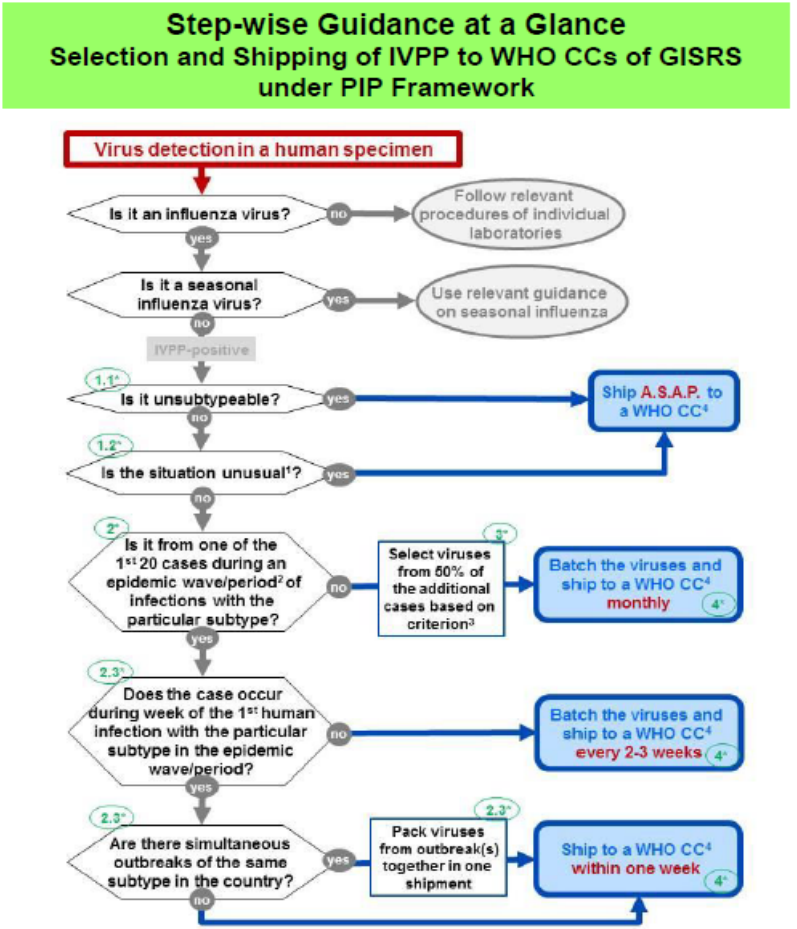
➔ Two objectives to be pursued **on an equal footing**:

- **Virus sharing** - Improve sharing of influenza viruses with the potential to cause a pandemic among humans
- **Benefit sharing** - Achieve more predictable, efficient, and equitable access to benefits arising from the sharing of viruses, notably vaccines and antiviral medicines

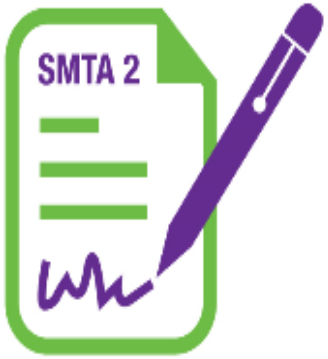


Virus Sharing

- Member States share IVPP with GISRS
- WHO & GISRS work together to develop Guidance to clarify virus sharing expectations under PIPF section 5.1 "*MS…should… provide PIPBM from all cases…. as feasible*."
- Bottlenecks being identified and work is ongoing to consider how to streamline certain processes



Benefit Sharing



Two key mechanisms

➔**SMTA2** (**STANDARD MATERIAL TRANSFER AGREEMENT 2**): Legally binding contracts to secure **advance access to real-time production** of pandemic response products, notably vaccines & antivirals

➔**PC** (**PARTNERSHIP CONTRIBUTION**): **Annual cash contribution to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers that use GISRS** to strengthen pandemic preparedness capacities where they are weak & build response fund

World Health Organization

SMTA2 - Key achievements to date

>400M vaccine doses

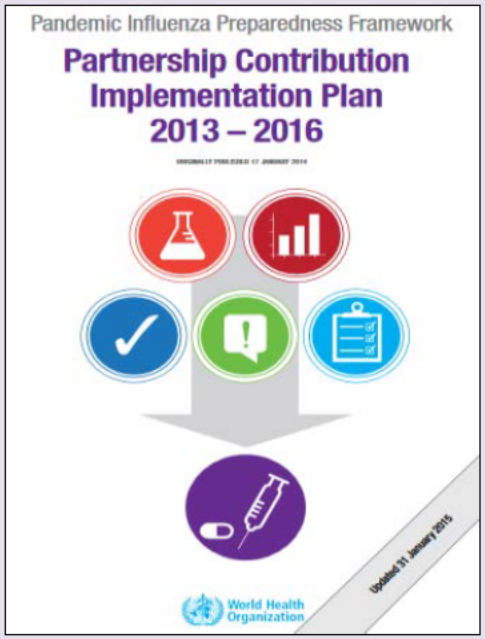
25M Syringes

10 million treatment courses of antivirals

250,000 diagnostic kits

PC High Level Results 2014-2017 (HLIP I)

- Five areas of work in 72 countries & globally
- ~$660k per L&S country
- $64 million implemented
- 81% of 21 indicator targets met (i.e. >85% achieved) or exceeded



Laboratory & Surveillance

L&S

- → **90 →132** countries routinely share influenza viruses with GISRS
- → **55 →91** countries share influenza epidemiological data through 'FluID.'
- → **108→130** countries share influenza virological data through 'FluNET.'

Burden of Disease

BOD

- → **New** global influenza mortality estimate published in 2017
- → **+8** target countries completed BOD and 3 published

Regulatory Capacity Building

REG

- → **+48 countries** have adopted an approach to facilitate timely approval of pandemic influenza products during an emergency

Planning for Deployment

DEP

- → 'PIPDeploy' - World's **first global simulation portal** for pandemic influenza vaccine deployment, launched in 2017

Risk Communications

RC

- → **Online knowledge-transfer platform 'OpenWHO'** launched in 2017, with 8 influenza-related courses. Over **7,500 registered users from 191 countries**.

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PIP FRAMEWORK

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A World Better Prepared for a more Equitable Pandemic Response

Virus Sharing

Benefit sharing

2016 PIP Framework Review

- Comprehensive, independent review after 5 years of implementation to propose revisions *reflecting developments*
- Two important developments in the global context since 2011:
  - **Increasing use of Genetic Sequence Data**
  - **Entry into force of Nagoya Protocol**

Increasing use of Genetic Sequence Data (GSD)

- ➔ Manufacturers increasingly use GSD to manufacture products such as vaccines
- ➔ *SMTA2 is based on receipt of PIPBM (physical material)*
- ➔ **IN THE FUTURE**, vaccines and other pandemic response products may be made **WITHOUT USING** PIP BM
- ➔ WHO would not have access to pandemic vaccines or other product manufactured with **GSD only**

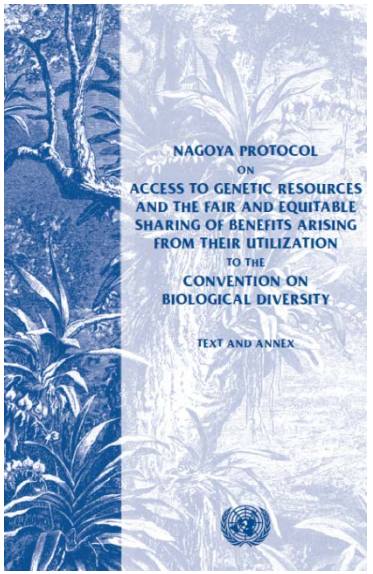
Entry into Force of Nagoya Protocol (NP)

➔What it is

- Environmental treaty under UN Convention on Biological Diversity (CBD)
- 107 Parties
- **Objective:** Ensure genetic resources under CBD are **accessed** with permission of provider countries and that **benefits** are shared with provider countries in a fair and equitable manner.
- Implemented by Parties through domestic legislation

➔What it covers

- **Genetic resources:** Any genetic material (material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value (see CBD Art 2)



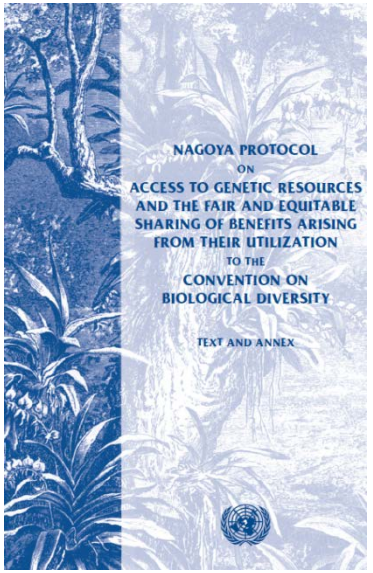
2016 WHO Study on Public Health & NP

In 2016, WHO prepared a study on how implementation of the NP might affect the sharing of pathogens, and the potential PH implications. Conclusions include:

➔ *In time*, implementation of NP may improve access to affordable treatments and help developing countries build capacities for, e.g., disease surveillance and R&D

➔ *Until then*, there are concerns that implementation could:

- slow or limit virus (or broader pathogen) sharing
- impact comprehensiveness and speed of risk assessment and timely development of effective vaccines, diagnostics and medicines



NP & Seasonal Influenza

- **Genetic Resources** fall under NP unless they are covered by a *specialized international instrument (SII)* that is consistent with and does not run counter to NP
- **2016 Review brought to D-G's attention that seasonal influenza viruses would** fall under **NP & national ABS laws** unless covered by an SII
  - Hamper GISRS **seasonal influenza work to carry out** risk assessment, vaccine development and other critical functions
- 2016 Review noted that EU legislation recognized PIP Framework as an SII for IVPP & recommended looking at whether it should be expanded

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Nagoya Protocol and GISRS

- To date, 124 countries:
  - are Nagoya Parties
  - have ratified the Protocol or
  - have national ABS or compliance legislative, administrative or policy measures
- Of those, 79 countries have a GISRS laboratory (including 3 WHO CCs)

Afghanistan	Cameroon	Egypt	Hungary	Luxembourg	Pakistan	Sierra Leone	Vanuatu
Albania	Central African Republic*	Estonia**	India	Madagascar	Palau	Slovakia	Venezuela (Bolivarian Republic of)*
Angola	Chad	eSwatini	Indonesia	Malawi	Panama	Slovenia**	Viet Nam
Antigua and Barbuda	China	Ethiopia	Ireland**	Mali	Peru	South Africa	Zambia
Argentina	Comoros	European Union	Italy**	Malta	Philippines	Spain	Zimbabwe
Austria*	Congo	Fiji	Japan	Marshall Islands	Poland**	Sudan	
Belarus	Costa Rica**	Finland	Jordan	Mauritania	Portugal	Sweden	
Belgium	Côte d'Ivoire	France	Kazakhstan	Mauritius	Qatar	Switzerland	
Benin	Croatia	Gabon	Kenya	Mexico	Republic of Korea	Syrian Arab Republic	
Bhutan	Cyprus**	Gambia (the)	Kuwait	Micronesia (Federated States of)	Republic of Moldova	Tajikistan	
Bolivia (Plurinational State of)	Cuba	Germany	Kyrgyzstan	Mongolia	Romania**	Togo	
Botswana	Czechia	Greece**	Lao People's Democratic Republic	Mozambique	Rwanda	Tuvalu*	
Brazil**	Democratic Republic of the Congo	Guatemala	Latvia**	Myanmar	Saint Kitts and Nevis*	Uganda	
Bulgaria	Denmark	Guinea	Lebanon	Namibia	Samoa	United Arab Emirates	
Burkina Faso	Djibouti	Guinea-Bissau	Lesotho	Netherlands	Sao Tome and Principe	United Kingdom of Great Britain and Northern Ireland	
Burundi	Dominican Republic	Guyana	Liberia	Niger	Senegal	United Republic of Tanzania	
Cambodia	Ecuador	Honduras	Lithuania**	Norway	Seychelles	Uruguay	

* Country has recently ratified
** Country has ABS or compliance measures

Nagoya Party, ABS legislation or recently ratified **with GISRS lab**

Nagoya Party - **no GISRS lab**

As of 12 Oct 2018. Data from https://absch.cbd.int/countries and http://www.who.int/influenza/gisrs_laboratory/national_influenza_centres/en/

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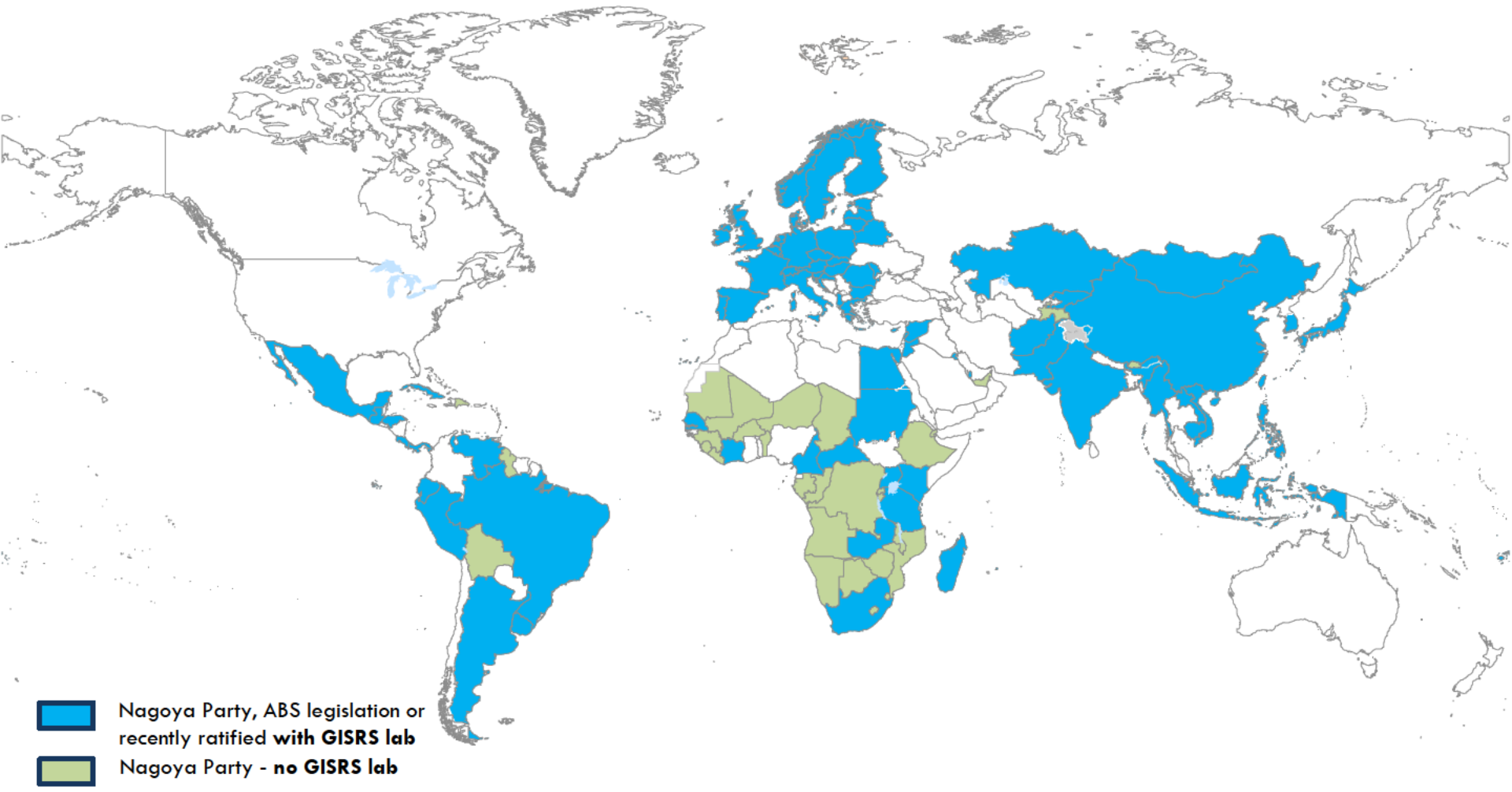
Nagoya Protocol and GISRS (map view)



As of 12 Oct 2018

Data Source: World Health Organization/Convention on Biological Diversity

WHA Requests to Director-General

- ➔WHA 70 (2017) requests WHO to develop an **Analysis of the implications of possible approaches to seasonal influenza and GSD under the PIP Framework**
- ➔WHA 71 requests submission of final text of Analysis to WHA 72 through EB 144

Process to develop *Analysis* – Decision WHA70(10)8(b)

WHA70(10)(8)(b) Implementation Timeline

As of 21 August 2018

WHA 70
Decision WHA70(10)
May 2017

MS & Stakeholder Consultation on Implementation of WHA70(10)8(b)
Click here for more information
6 – 7 Nov 2017

EB 142
Jan 2018

Information Session
Click here for more information
10 Apr 2018

WHA 71
Decision WHA71(11)
May 2018

WHO Workshop *"Facilitating Access and Benefit Sharing for Pathogens to Support Public Health"*
Click here for more information
11 – 12 June 2018

Draft Analysis posted online:
The document will be posted here
17 Sept 2018

MS & Stakeholder Consultation on Implementation of WHA70(10)8(b)
15 – 16 Oct 2018

WHA 72
20 – 28 May 2019

EB 144
24 Jan – 1 Feb 2019

2017 | 2018 | 2019

CBD Ad Hoc Technical Expert Group (AHTEG) on Digital Sequence information (DSI)
Report of the AHTEG
13 – 16 Feb 2018

CBD Meeting of Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)
Recommendation 22/1
2 – 7 July 2018

CBD Meeting of Subsidiary Body on Implementation
Recommendation 2/5
9 – 13 July 2018

CBD COP 14 Nagoya COP-MOP 2
Click here for more information
17 – 29 Nov 2018

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Draft *Analysis* – Overview

➔Analyzes implications (opportunities and challenges) associated with different approaches to seasonal influenza and GSD in the context of the PIP Framework

Draft *Analysis* - Overview

- ➔Matters with Overarching Implications
- ➔Part 1: Potential approaches to seasonal influenza
  1. Maintain current PIP FW scope
  2. Expand PIP FW scope to include seasonal influenza viruses (two possibilities)
  3. Adapt GISRS
  4. Develop a new international ABS instrument to cover all pathogens
- ➔Part 2: Potential approaches to GSD
  1. Maintain current definition of PIP BM
  2. Amend definition of PIP BM
  3. Address benefit-sharing through another mechanism

Consultation Objectives & Expected Outcomes

Objectives

- Discuss draft *Analysis*
- Identify potential points of convergence/divergence
- Identify potential next steps

Expected outcomes

- Inform final text of Analysis for consideration by EB 144
- Contribute to the Director-General's Report to EB144

➢ Objective is <u>not</u> to develop recommendations or make a decision

Documents and additional information

WHO Documents

- Draft Analysis, fact sheets and other supporting documents: http://www.who.int/influenza/pip/ConsultWHA70108b-Oct18/en/
- Study on *Implementation of the Nagoya Protocol and pathogens sharing: public health implications* (6 UN languages): http://www.who.int/un-collaboration/partners/UNCBD/en/
- Q&A - *Implementation of the Nagoya Protocol in the context of human and animal health, and food safety:* http://www.who.int/influenza/pip/QA_NP_Public_Health.pdf
- WHO Comments on DSI: http://www.who.int/un-collaboration/partners/whocommentscbddsi.pdf
- Report from Workshop *Facilitating Access and Benefit Sharing for Pathogens to Support Public Health*: http://www.who.int/influenza/ABSworkshop_June2018/en/
- Other documents related to the *Analysis:* *http://www.who.int/influenza/pip/Documents_WHA70108b/en/*

Documents and additional information

CBD/Nagoya Documents

- ➔ Discussions on SII:
  - Executive Summary, *Study into criteria to identify a specialized international access and benefit-sharing instrument, and a possible process for its recognition*: https://www.cbd.int/doc/c/9376/a644/1bed20a1837af8e3d1edc5f9/sbi-02-inf-17-en.pdf
  - SBI, Recommendation adopted on 13 July, CBD/SBI/REC/2/5, https://www.cbd.int/doc/recommendations/sbi-02/sbi-02-rec-05-en.pdf
- ➔ Discussions on digital sequence information (DSI):
  - SBSTTA, CBD/SBSTTA/REC/22/1, Recommendation adopted on 7 July 2018, https://www.cbd.int/conferences/sbstta-sbi/sbstta-22/documents
  - Report of the Ad Hoc Technical Expert Group on DSI: https://www.cbd.int/doc/c/4f53/a660/20273cadac313787b058a7b6/dsi-ahteg-2018-01-04-en.pdf
  - CBD Fact-Finding and Scoping Study on DSI: https://www.cbd.int/doc/c/e95a/4ddd/4baea2ec772be28edcd10358/dsi-ahteg-2018-01-03-en.pdf
  - Synthesis of views and information on DSI: https://www.cbd.int/doc/c/06dc/df41/cbbe0ff3d861dc4e45953973/dsi-ahteg-2018-01-02-en.pdf

Session I: Discussion - Seasonal Influenza

WHO Consultation WHA 70(10)(8(b)

Member States and Stakeholders

15 October 2018

PIP FRAMEWORK

World Health Organization

Discussion – Draft Analysis Part I: Seasonal Influenza

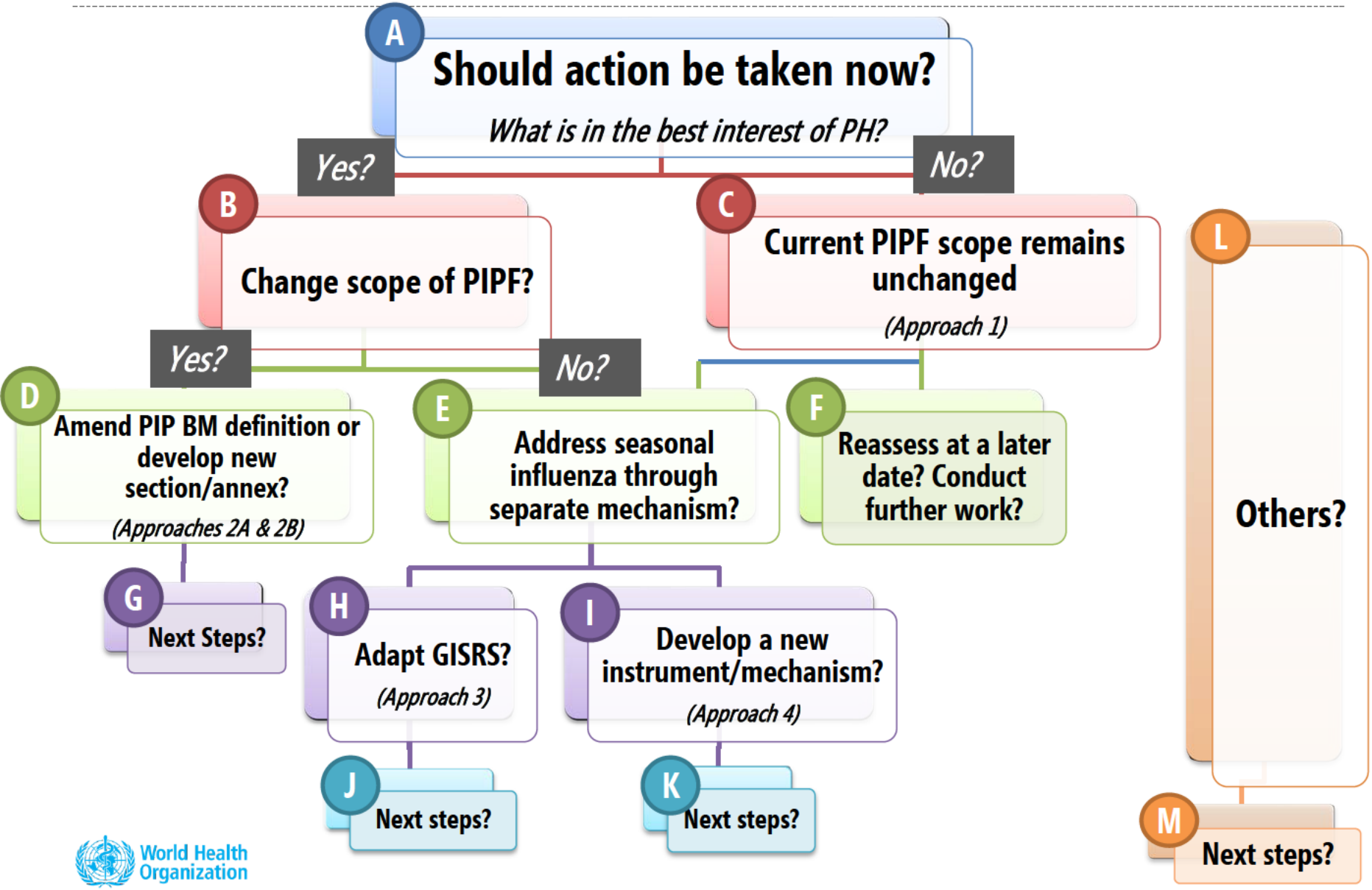
Overarching views

- ➔What are your thoughts on the draft *Analysis Part I: Approaches to seasonal influenza under the PIP Framework*?
- ➔Are there key approaches missing?

Consideration of Approaches to Seasonal Influenza under PIPF

How do we move forward in the best interest of public health?

Seasonal influenza under the PIP Framework



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Session III: Discussion - Genetic Sequence Data (GSD)

Member States and Stakeholders

WHO Consultation WHA 70(10)(8(b)

16 October 2018

PIP FRAMEWORK

World Health Organization

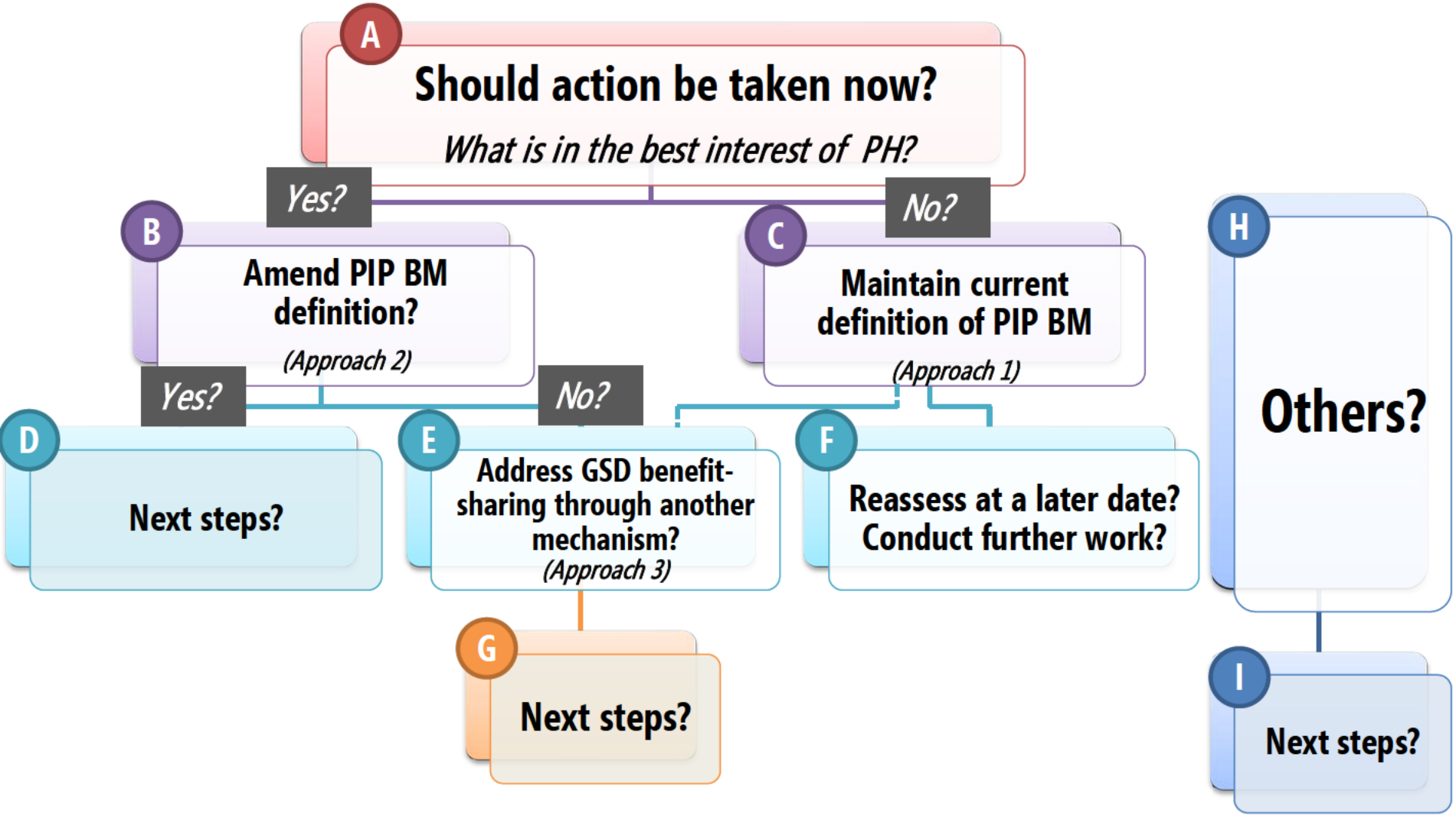
Discussion – Draft Analysis Part II: Genetic Sequence Data (GSD)

- What are your thoughts on the draft *Analysis Part II: Approaches to Genetic Sequence Data under the PIP Framework*?
- Are there key approaches missing?

Consideration of approaches to GSD under PIPF

How do we move forward in the best interest of public health?

GSD under the PIP Framework



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