

# Pandemic Influenza Preparedness Framework

Sharing of influenza viruses &  
access to vaccines and other benefits

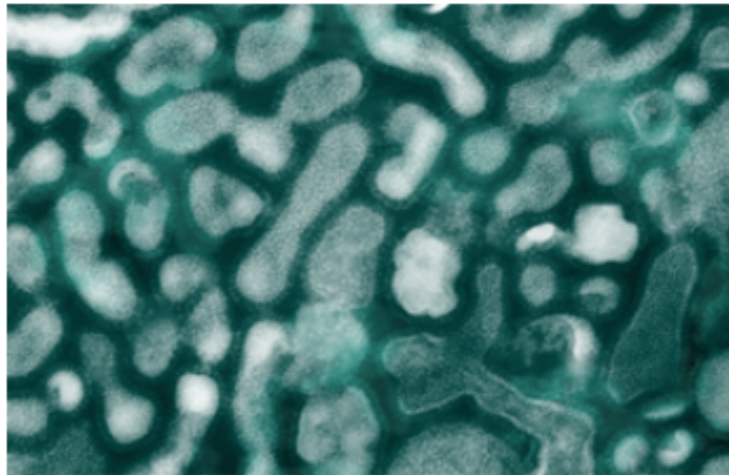
Presentation to World Influenza Conference

8 September 2018

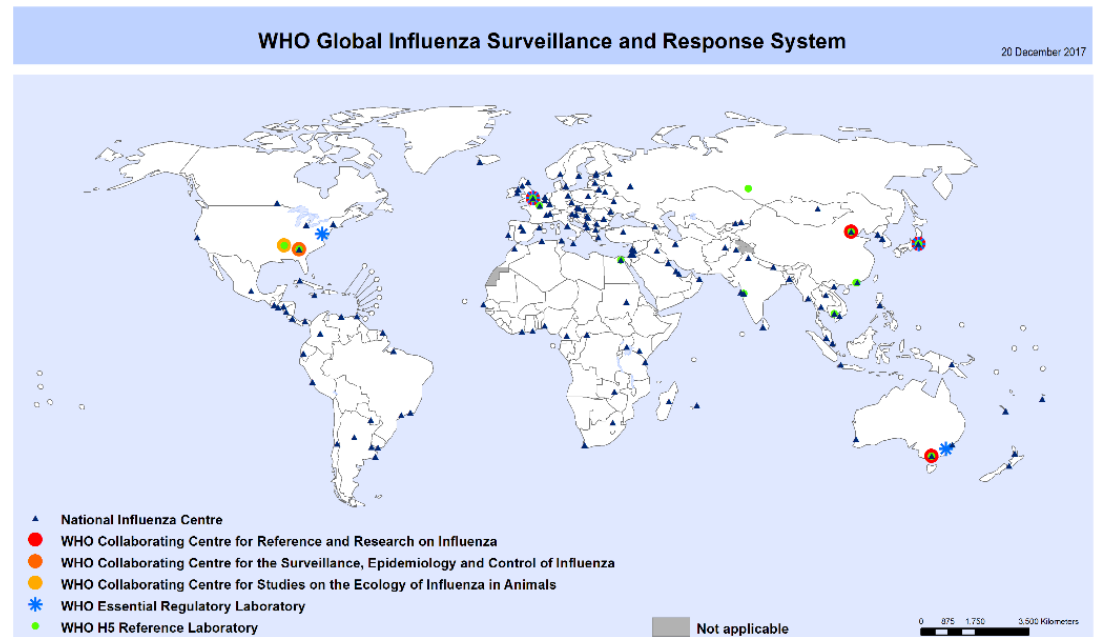


# Influenza

- Unique, highly contagious, infectious disease
- Among few known **pandemic-prone** pathogens
  - Pandemic is question of '*when*' not '*if*'
- 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



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

Data Source: Global Influenza Surveillance and Response System (GISRS), WHO  
Map Production: Global Influenza Programme  
World Health Organization

 World Health Organization  
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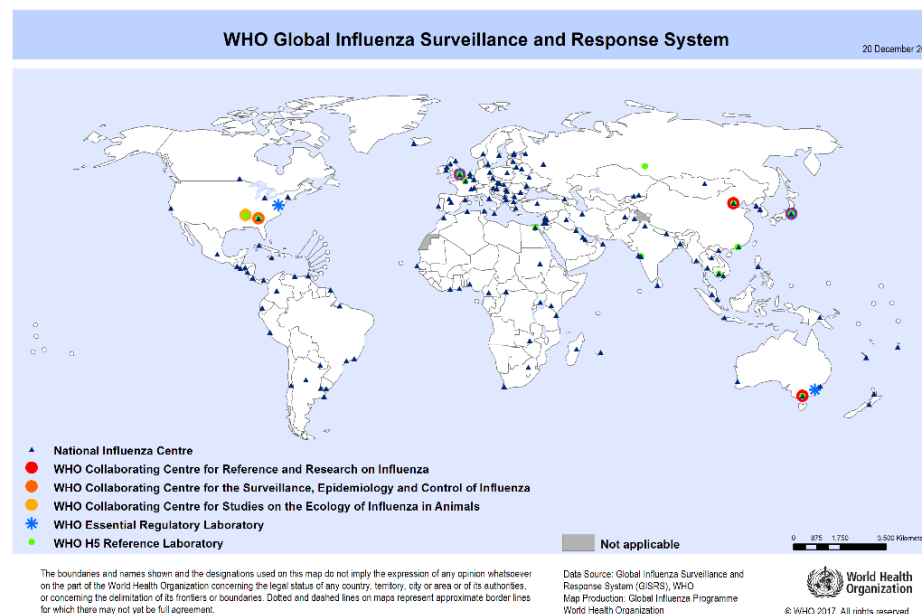
# GISRS – Global Virus Sharing for Public Health Security

→ **66 years of excellence** on the frontlines of influenza virus detection, sharing and risk assessment

- **114** Member States supporting **153** laboratories
- ~ US\$ 56.5

## *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

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- 'Bird Flu' - Re-emergence of A(H5N1) in SE Asia ~ 2003
  - Viruses sent into GISRS (GISN) for characterization, risk assessment and vaccine virus development
- Candidate vaccines developed → limited availability of vaccines at high price



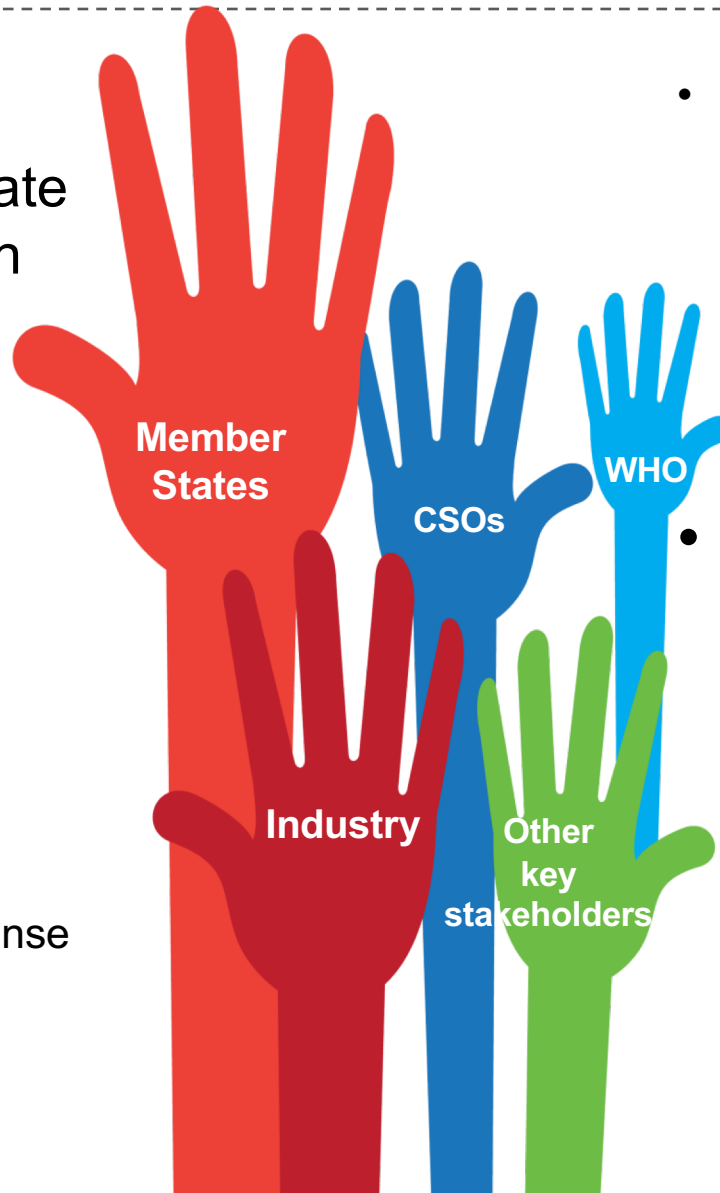
Bird flu virus H5N1 infection in laying Hens.



# Global Discussions on Equitable Access to Vaccines

→ 2007-2011: WHO Member States negotiate an innovative approach to increasing public health security:

- **Share viruses** with pandemic potential 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 brings together Member States, GISRS, industry, CSOs, NGOs, philanthropic organizations, other stakeholders, & WHO

## • Key Guiding Principles:

- Equity
- Transparency
- Partnership

# Benefit Sharing: Two key mechanisms (1)

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## 1) Standard Material Transfer Agreement 2

- Legally binding contracts with manufacturers to provide to WHO, real-time access to pandemic products needed at the time of next pandemic
- SMTA2s establish a predictable and structured access by WHO to specific pandemic response products (e.g. vaccines, antivirals, diagnostics) for countries in need
- Manufacturers select benefit sharing options based on their nature and capacities



# Key achievements – SMTA 2



**>400M doses  
of vaccines**

**25M Syringes**



**10 million  
treatment courses  
of antivirals**

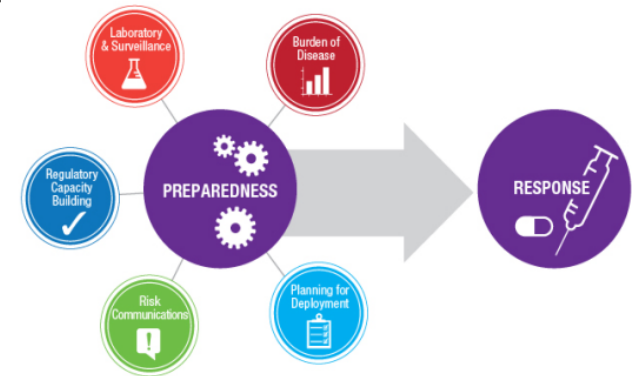


**250,000  
diagnostic kits**

# Benefit Sharing: Two key mechanisms (2)

## 2) Partnership Contribution (PC)

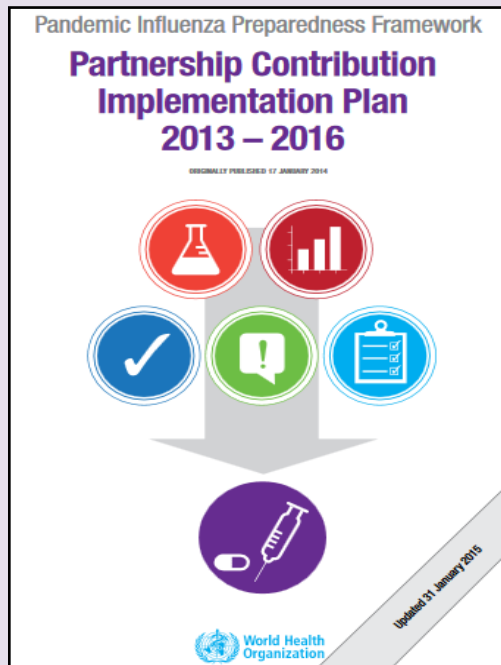
- US\$ 28M/year to WHO from 'influenza vaccine, diagnostic and pharmaceutical manufacturers *that use GISRS*'
- Enables WHO to strengthen key pandemic preparedness and response capacities
- WHO brings together political and technical expertise; aims to ensure long term sustainability and success
- To date, nearly US\$ 145 million received by WHO





# High Level Results 2014-2017

- Five areas of work in 72 countries & globally
- ~400k per country
- \$64 million implemented
- 86% of 21 indicator targets met or exceeded



## L&S



- 42 countries routinely share seasonal influenza viruses with GISRS.
- 36 countries share influenza epidemiological data with WHO through 'FluID.'
- 22 countries share influenza virological data with WHO through 'FluNET.'

## BOD



- New global influenza mortality estimate published in 2017
- 10/19 target countries completed BOD; 6 published results

## REG



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

## DEP



- 'PIPDeploy' launched in 2017: First global simulation portal for pandemic influenza vaccine deployment

## RC



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

# PIP Framework & Genetic Sequence Data (GSD)

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- PIPF covers GSD but GSD is not part of the definition of PIP Biological Materials
  - Therefore, GSD is not covered by benefit sharing or other PIP Framework systems (e.g. virus traceability mechanism)
- Member States request PIP Advisory Group (AG) to provide guidance to Director-General on the best process to handle GSD under the Framework (section 5.2.4)



# AG Work on GSD – 3 Guiding Questions

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AG work started in 2013, guided by 3 questions:

- 1) What should be the benefits from IVPP GSD?
- 2) At which point should benefit sharing be triggered?  
(access? use? commercialization of product?  
other?)
- 3) How can data sharing and benefit sharing be synergistic and mutually supportive?



# Emerging principles

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Four key principles that integrate access and benefit-sharing objectives

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## KEY PRINCIPLES



Rapid sharing of high-quality GSD for timely risk assessment & rapid response

Sustainable, public access to IVPP GSD

Fair and equitable sharing of benefits arising from sharing of GSD

Acknowledgement of data providers & active collaboration between data providers & users

# Governance & Review (1)

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## → 3-pillared oversight mechanism

- World Health Assembly: oversees implementation
- Director-General: promotes implementation
- 18 member Advisory Group (AG):
  - Advises Director-General on the use of the Partnership Contribution
  - Monitors & assesses implementation of Framework
  - Interacts with Industry & other stakeholders

## Governance & Review (2)

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- Full Framework review in 2016 and submission of Report to WHA 70 (May2017)
- Report includes key question:
  - *Should **scope** of PIP Framework be expanded or not to include: a) seasonal viruses; b) GSD in definition of PIP Biological Materials*
- WHA 70 considered Review report and requested DG to conduct comprehensive Analysis of that key question

# Next Steps

- Virus Sharing: Continue to implement guidance on sharing IVPP
- Benefit sharing:
  - SMTA2: Continue to conclude SMTA2
  - PC: Continue to strengthen preparedness through implementation of capacity building activities in 72 countries
- Governance:
  - Publish draft Analysis in mid-September
  - Consult with MS & stakeholders 15-16 Oct
  - Revise Analysis, as necessary, & submit to EB144 (Jan 2019) for discussion and forwarding to WHA 72 (May 2019)

## Step-wise Guidance at a Glance Selection and Shipping of IVPP to WHO CCs of GISRS under PIP Framework



\* More information can be found in the corresponding numbered chapters under the section "Guidance on which and when IVPP samples should be shipped to WHO CC" of the "Operational Guidance on Sharing Influenza Virus of Human Pandemic Potential (IVPP) under the Pandemic Influenza Preparedness (PIP) Framework".  
 Unusual situation of IVPV includes cluster of 3 or more people infected, cluster involving healthcare workers infected, first human infection(s) in a country with a novel subtype which may not exist or infect people in other countries, increasing proportion of cases with no known animal contact, and any other situations as a advised by WHO.  
 Epidemic period: a period of no more than 12 months, e.g. 1 October - 30 September, 1 January - 30 December or another period of 12 months or less depending on seasonal patterns of circulation.  
 Criteria for selection: different age groups, males and females, different geographic locations within the country, different months over the course of outbreak, before and after national treatment, select clinical samples with real-time RT-PCR cycle threshold (CT) value of <30.  
 \*WHO CC of the country's choice (see link: [https://www.who.int/influenza/whoccr\\_laboratory\\_collaborative\\_centres.html](https://www.who.int/influenza/whoccr_laboratory_collaborative_centres.html))

30 June 2017, by GISRS



Partnership Contribution (PC) Preparedness High-Level Implementation Plan II 2018-2023





## Acknowledgements & Thanks

- Member States
- Global Influenza Surveillance & Response System (GISRS)
- Partnership Contributors, civil society, other partners & stakeholders
- WHO HQ, Regional and Country office colleagues

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

*Thank You!*