Brief history of the development of the Framework on Sharing influenza viruses and access to vaccines and other benefits

The Intergovernmental (IGM) Process

Since the late 1940's, WHO has coordinated a network of influenza public health laboratories (Global Influenza Surveillance and Response System, or GISRS) which has served two principal purposes: 1) to gather representative samples of circulating influenza viruses in order to conduct detailed risk assessment; and 2) to develop vaccine candidate strains and provide them, free of charge, to influenza vaccine manufacturers for vaccine production. Until quite recently, interest in the GISRS was generally limited to industrialized countries whose populations used seasonal vaccines.

The emergence of H5N1 and its potential to trigger an influenza pandemic, changed the level of interest in the GISRS and brought scrutiny on its processes and procedures as they relate to the development of influenza vaccines. As the perceived threat of an H5N1-derived pandemic increased, influenza vaccine manufacturers started to develop and test H5N1 vaccines. The precipitating cause of the Intergovernmental Meeting (IGM) was the difficulty for some developing countries to secure H5N1 vaccine at affordable prices despite having contributed viruses. The need for a more transparent, fair and equitable system for the sharing of viruses as well as the benefits derived from the use of such viruses became pressing. As a result, in May 2007 the 60th World Health Assembly adopted resolution 60.28 which requested the Director-General to, inter alia, convene an IGM with a view to reforming many of the practices and processes of GISRS.

Over the next 4 years, Member States, with Secretariat support, worked through an intergovernmental process to develop a Framework that covers the sharing of influenza viruses with pandemic potential (under the Framework, these are known as "PIP biological materials") on the one hand, and fair and equitable access to benefits derived from the use of such viruses, on the other.

Important outcomes

Some significant areas of consensus were reached:

- **Equal Footing**: During the December 2008 session of the IGM, Member States agreed that they are committed to share, on an equal footing, H5N1 as well as other influenza viruses with human pandemic potential, as well as the benefits, considering these as equally important parts of the collective action for global public health. This principle is reflected in Framework Section 1, paragraph 3.
- **An Advisory Group**, composed of 18 members, based on equitable representation of the six WHO regions and of affected countries was established with the mandate, inter alia, to "monitor, assess and report on how the different functions of the Framework are implemented by its components."
- **An Influenza Virus Traceability Mechanism** was created and launched in 2008 and upgraded in 2010. It provides access to results of analyses carried out with viruses submitted to the GISRS and also permits users to see transfers of the PIP biological materials.
- Adoption of **Guiding Principles for the development of Terms of Reference** for current and prospective GISRS laboratories for H5N1 and other human pandemic influenza viruses.

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1 A detailed Chronology is attached at Annex 1.

Adoption of two **Standard Material Transfer Agreements ("SMTA"):** These SMTAs are binding contracts that provide the conditions under which PIP biological materials may be transferred from one party to the other. They are "standard" because their agreed terms are not negotiable. The two "SMTAs" in the Framework are: "SMTA1" which applies to transfers of materials among members of GISRS; and "SMTA2" which applies to transfers of materials from GISRS to parties outside GISRS.

Establishment of an annual financial **"Partnership Contribution"** to be made by influenza vaccine, diagnostic and pharmaceutical manufacturers who use WHO GISRS. The annual contribution shall be equivalent to 50% of the running costs of WHO GISRS. Contributions shall start in 2012. The funds will be used to improve pandemic preparedness and response.

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1 The Global Influenza Surveillance Network (GISN) was renamed the WHO Global Influenza Surveillance and Response System (GISRS) through the adoption of the PIP Framework at the Sixty-fourth World Health Assembly on 24 May, 2011.
Annex 1

**Chronology of Meetings, Reports & Activities related to the Pandemic Influenza Preparedness: Framework for sharing influenza viruses and access to vaccines and other benefits**

### 2007

**Jan 2007**
EB adopts Resolution 7 containing "Best Practices for Sharing Influenza Viruses and Sequence Data"

**26-27 Mar 2007**
Jakarta High Level Technical Meeting on "Responsible Practices for Sharing Avian Influenza Viruses and Resulting benefits"
- Recommendations for High Level Meeting
- High Level Meeting issues "Jakarta Declaration"

**19-20 Apr 2007**
Technical Working Group Meeting (Geneva)
- Follow-up to the Jakarta High Level Technical Consultation

**14-23 May 2007**
WHA Drafting Group for Resolution 60.28 (Geneva) (Chair, Viroj Tangcharoensathien, Thailand)
- Reaches consensus on resolution 60.28 which provides the blueprint for improving global pandemic influenza preparedness; calls for DG to convene an Intergovernmental Meeting

**31 Jul- 4 Aug 2007**
Interdisciplinary Working Group (IDWG) Singapore (Chair, Viroj Tangcharoensathien, Thailand)

**20-23 Nov 2007**
Intergovernmental Meeting (IGM) (Geneva)
- Elects Chair, Jane Halton (Australia)
- Issues Interim Statement calling on DG to:
  - Urgently develop a virus traceability mechanism; and
  - Establish an Advisory Group

### 2008

**3-4 April 2008**
Open-Ended Working Group of the IGM, Geneva
- Calls on IGM Bureau to develop a Chair’s Text

**May 2008**
IGM Bureau meets to discuss parameters of Chair’s Text (Geneva)

**29 Jun- 27 Jul 2008**
Electronic consultation of Chair’s Text

**29 September 2008**
Publication of Chair’s Text (6 languages)

**21 October 2008**
Advisory Group Meeting, (Geneva) (Chair, Bruno Lina, France)

**8-13 December 2008**
Intergovernmental Meeting (Geneva)
- Developed and adopted Guiding Principles for the development of Terms of Reference for WHO Network laboratories
- Adopted Terms of Reference for the Advisory Group
Achieved considerable progress on the Framework, notably with respect to consensus on MS commitment to share, influenza viruses and benefits on an equal footing.

**2009**

5 March 2009  -  2nd meeting of the Advisory Group (Chair, Bruno Lina, France)
-  WHO Technical Meeting on Options for the Establishment of an International stockpile of H5N1 vaccine (Geneva)

31 Mar - 2 Apr 2009  Informal meetings lead by Norway and the Foreign Policy & Global Health Group (Montreux); followed-up by meetings hosted by Canada

15-16 May 2009  Intergovernmental Meeting (Geneva)
Secretariat issues comprehensive reports on:
-  Influenza virus traceability mechanism;
-  Detailed terms of reference for WHO Network laboratories
-  Revised version of the technical parts of the SMTA
-  Identification of the needs and priorities for each of the benefits listed in section 6 of IGM text, in particular concerning the vaccine stockpile, as well as options for their financing.

16 May 2009  IGM concludes its business without reaching consensus on the Framework text

20 May 2009  WHA 62 - Resolution 62.10: Requests DG to
-  Work with Member States to carry forward agreed parts of the Framework
-  Facilitate a transparent process to finalize remaining elements under the Framework

19-20 Oct 2009  Director-General’s Consultation with Member States (Geneva); Discussion Paper published 18 Sept 2009

**2010**

January 2010  Executive Board notes the outcomes of the Director-General’s Consultation; Agrees to the proposal for negotiations between Member States through an Open-ended Working Group to be convened on 10-12 May 2010.

10-12 May 2010  Pandemic Influenza Preparedness Open-ended working group (PIP OEWG) (Geneva);
-  Elects Co-Chairs, Ambassador Angell-Hansen (Norway) & Ambassador Gomez-Camacho (Mexico).
-  Begins work to finalize Framework text.

13-17 Dec 2010  PIP OEWG (Geneva); Progress made on Framework text; Secretariat presents Preliminary Findings for Technical Studies requested under WHA 63.1

**2011**

11-15 April 2011  PIP OEWG (Geneva). Member States reach consensus on Framework text to be submitted to WHA 64 for adoption. Significant elements include:
- Industry Partnership Contribution
- 2 Standard Material Transfer Agreements (one for transfers within the WHO network and one for transfers outside the Network)
- Recognition of the critical role and responsibility of industry to contribute to pandemic preparedness

24 May 2011 WHA Resolution 64.5 adopts the PIP Framework