Opportunities & Challenges in Global Cooperation: Influenza Virus Sharing, Intellectual Property and Access to Vaccines and other Benefits

Seminar on Biological Weapons Convention
Supporting Global Health

Oslo, 19 June 2009

Global Influenza Programme
World Health Organization

What was the Intergovernmental Meeting (IGM)?

- In the context of pandemic influenza preparedness, the IGM was a **Member State-lead** process to improve WHO's 50+ year old system for influenza risk assessment and response by increasing its **transparency** and promoting **fairness and equity** of access to benefits derived

Background

Avian & Pandemic Influenza
Serious Global Threats

Credit: US National Museum of Health and Medicine

World Health Organization

Influenza surveillance

- **Pandemic Influenza:** a new influenza virus against which the human population has no or little immunity, resulting in several, simultaneous epidemics worldwide can cause serious disease and death with concomitant social and economic disruptions.

- **Surveillance** – at the national and global levels – is the best defence against emergence of pandemic influenza viruses; enables public health systems to **detect** and **assess** viral changes early and rapidly trigger **response** measures

Risk assessment & response: Essential tools for pandemic influenza preparedness

Risk Assessment

- Timely sharing
- Access to critical information
  - Epidemiology, viruses...
- Scientific research

Risk Response

- Reduced human exposure
- Preparedness planning
  - Rapid containment operations
- Interventions & access
  - Communications, vaccine, antiviral drugs, other ….

International Health Regulations

Global Influenza Surveillance Network

World Health Organization

What happened? (1)

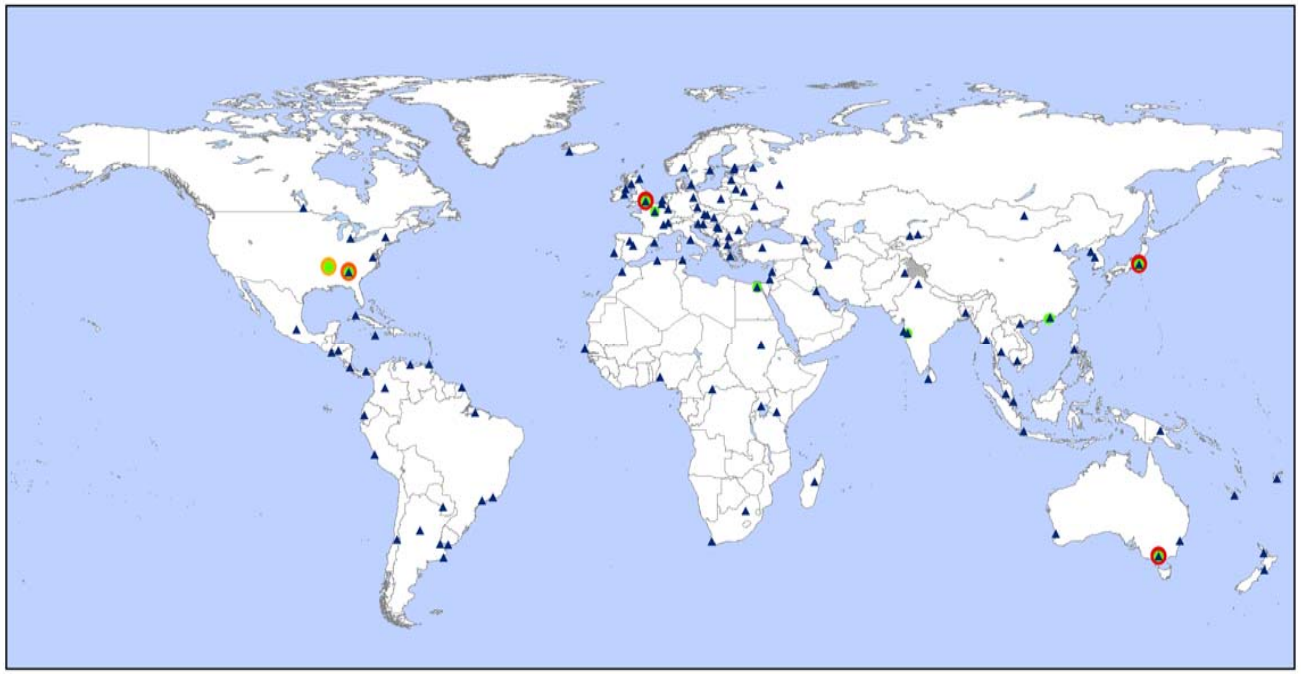
- Until H5N1, influenza was primarily a focus for developed countries that produce and use most seasonal influenza vaccine
- **Emergence of H5N1** put a spotlight on the risks of avian and pandemic influenza
- Highlighted influenza as a **priority** for developing & developed countries alike and underscored the **global insufficiency** of influenza vaccine manufacturing capacity

What happened? (2)

- Virus contributing developing countries questioned the WHO system for influenza virus sharing : **Why contribute if there are no benefits**
- Developing countries lost **trust** in WHO
- Developing countries called for improvements in the WHO Global Influenza Surveillance Network

WHO global influenza surveillance network: collective action to assess and manage risks

The WHO Global Influenza Surveillance Network (GISN), July 2008



25 July 2008

- National Influenza Centres
- H5 Reference Laboratories
- WHO Collaborating Centre for Studies on the Ecology of Influenza in Animals
- WHO Collaborating Centre for the Surveillance, Epidemiology and Control of Influenza
- WHO Collaborating Centres for Reference and Research on Influenza

World Health Organization

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Data Source: WHO FluNet, GISN
Map Production:
HSE/EPR/GIP, HSE/EPR/GIS
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What is GISN? (1)

- The Global Influenza Surveillance Network (GISN) is an international network of laboratories that **voluntarily** collaborate year-round to **detect** – as rapidly as possible – the **emergence of new and potentially pandemic influenza viruses**
- Network laboratories **share influenza viruses/specimens** and related information with each other and monitor the evolution and spread of influenza in the world
- Under WHO's coordination, GISN works to strengthen national influenza surveillance capacity in all countries

What is GISN? (2)

- GISN is a **global partnership** that includes:
  - 126 National Influenza Centres ("NICs") in 97 countries,
  - 5 specialized influenza Collaborating Centres (CCs")
  - 3 national regulatory laboratories
  - 4 H5 Reference Labs
- Expansion of Network is ongoing with new laboratory designations underway

What does GISN do? (1)

- Conducts epidemic/pandemic influenza **risk assessment**
  - Routinely track viruses to detect & identify new influenza viruses
  - Carry out genetic & antigenic characterization
  - Test viruses for resistance to antiviral drugs
  - Provide up-to-date information to partners and WHO
  - Provide diagnostic materials and reagents to laboratories that require them
  - CC's provide advice and training to NICs on the most up-to-date laboratory methods to diagnose influenza
- NICs process >200,000 clinical specimens a year to diagnose influenza

What does GISN do? (2)

- Develops key component of influenza **risk response**
  - CC's **select & develop candidate vaccine viruses** necessary for vaccine development and production
  - CC's provide **candidate vaccine viruses to any qualified vaccine producer**
- GISN laboratories provide all services at no charge – Member States underwrite the costs of laboratory staff, maintenance and training programs

The IGM

Mandated by WHA Resolution 60.28 (May 2007)

Goals of WHA 60.28

- **Increase transparency** of activities of WHO CC, H5 Reference laboratory, and associated laboratories
- Increase Member State participation in & control over **use of viruses** by third parties notably through adoption a **standard material transfer agreement (SMTA)**
- **Strengthen MS participation** in the surveillance network
- Develop international framework/guidelines for sharing of benefits, including:
    - H5N1 vaccine stockpile
    - Capacity building/ training,
    - Technology transfer
    - Mechanism to ensure developing country access to pandemic vaccines

WHA 60.28

- Raised **two major questions**
  - Under what conditions will countries share influenza viruses?
  - How can developing countries gain fair and equitable access to affordable pandemic influenza vaccines?

IGM Issues

Broad, multisectoral, **technical & political** issues including:

- How to balance **public health security** with the **exercise of state sovereignty** over biological materials
- **Multilateral vs. bilateral** approaches to sharing viruses & benefits
- How to **sustain benefits** over time
- How to ensure greater **fairness and equity of access** to benefits, notably vaccines
- How to **increase transparency** in the virus sharing system
- How to secure continued **rapid & timely sharing of viruses**

The IGM Process

- Many meetings & consultations – formal and informal
- Tense discussions among MS notably on:
  - **Mandatory vs. voluntary sharing of benefits**
  - **Bilateral vs. multilateral** paradigm
  - Rights of virus recipients to conduct **research and file patent** applications over inventions derived from use of viruses
- Framework for sharing influenza viruses and access to benefits was developed and negotiated

What was achieved

- **MS commitment to share** virus & benefits **on an equal footing**; consensus many parts of the Framework, notably the list of benefits

- Trust in WHO strengthened through **increased transparency**:
  - Guiding Principles for development of GISN laboratory Terms of Reference (ToRs) adopted
  - All GISN laboratory ToRs revised & in some cases created
  - Advisory Group established
  - Influenza Virus Traceability Mechanism put in place
  - Progress to establish an H5N1 vaccine stockpile

Outstanding issues

- How to achieve **fair & equitable** access to affordable pandemic vaccines
- **Sustainability** of the system
- The **conditions for virus sharing** - What should be included in a Standard Material Transfer Agreement (SMTA)?
- How should the Framework and/or the SMTA deal with **research & intellectual property rights**
- **WHA 62.10** (May 2009) requests the DG to carry forward agreed parts, facilitate finalization of the Framework, including the SMTA & report the EB 126 (January 2010)

Fair and equitable access to affordable pandemic influenza vaccines

- No easy or quick solutions. Requirements include:
- **Increasing global influenza vaccine production capacity**:
  - Assessing influenza disease burden – is there justification to expand or build new plants
  - Transferring technology to developing countries, including through implementation of WHO's Global Action plan to Increase Vaccine Supply
  - Developing new vaccine technologies
- **Increasing access to affordable vaccines**:
  - Advance donation/purchase agreements for real-time access
  - Tiered pricing arrangements

Sustainability of the system

- 13 different benefits were agreed ranging from very **broad** (pandemic influenza risk assessment and response) to very **specific** (provision of diagnostic reagents and test kits) to **technical** (capacity building for surveillance and regulatory issues)
- WHO is assessing **options & approaches** to support the system's long-term ability to provide benefits

SMTA & Conditions for sharing viruses

- MS recognize the necessity to share viruses but do not yet agree on how this will be done
- Basic issue is **defining the limits on use** of viruses by different recipients, for instance:
  - What does "pandemic risk assessment and response" include
  - What goes beyond that and constitutes "research"
  - How can developing country scientists be involved in research projects and fully participate in scientific journal publications
  - What are recipient rights with respect to patenting inventions

The issue of patents

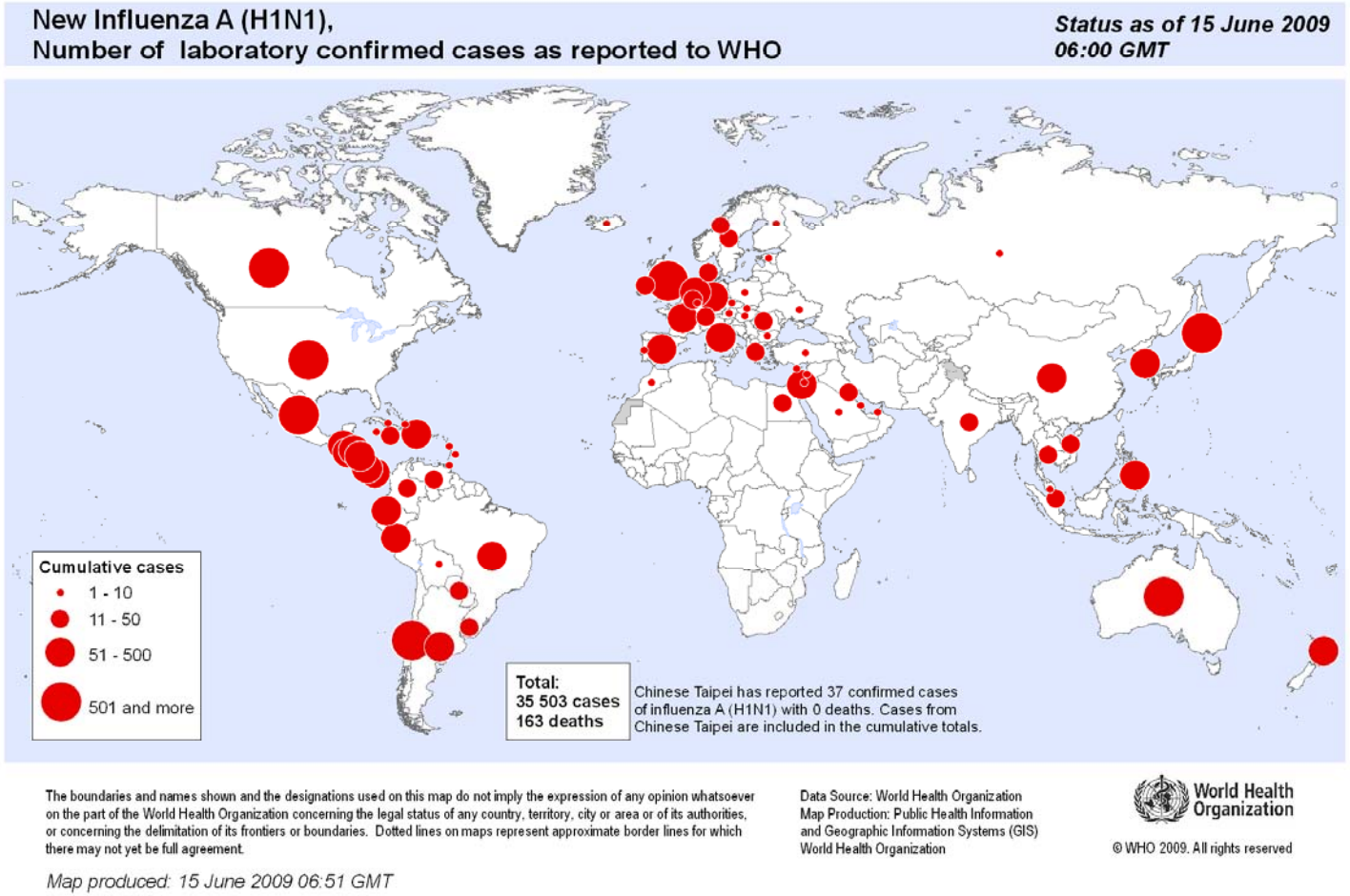
- Very complex issue with 3 MS positions: **allow** vs. **restrict** vs. **prohibit** virus recipients from seeking patent protection for inventions developed with the virus
- Many facets to consider, for instance:
  - What is behind MS positions: Access to research projects? Access to technology? Access to royalties?
  - Would restricting or prohibiting patenting jeopardize incentives to innovate in public health
  - Can patenting be allowed while maintaining the principle of fair and equitable sharing of benefits
  - Would the issue be better addressed elsewhere (WTO, WIPO)
- No answers as of yet

WIPO Patent Report

- WHA 60.28 requests DG to commission an expert study on patent issues related to influenza viruses and its genes
- Report and Annex on Patent landscape for the H5 virus produced by WIPO can be found at:
- http://www.who.int/csr/disease/avian_influenza/wipo_ipdoc/en/index.html
- WIPO has indicated it will update the report with an H1 landscape

Reflections on A(H1N1) response

Pandemic Phase 6
(map of spread 15 June 2009)



World Health Organization

Sovereignty

- Countries **responsibly exercised sovereignty**
- **Complied with IHR**
- Countries balanced their rights with their obligations and **placed public health at the forefront of actions**

Virus Sharing

- **H1N1 viruses/specimens**, and related information, including sequence data - **freely and timely shared** by countries with WHO Network & with all sectors (public, private, academic, non-profit)
- Viruses/specimens shared **without delays, conditions or use of legal instruments - no MTAs** used for the sharing of H1N1 wild-type viruses
- The global public goods of surveillance and risk assessment were “produced” due to timely and unconditional sharing of viruses

Access to Genetic Sequence Data

- Genetic sequence data was **publicly released** on GenBank as soon as available

Intellectual Property Rights

- To date:
  - No known claims of IP over H1N1 viruses
  - No known constraints to research and development due to IP
  - No known IP claims over products produced
- WIPO has offered to extend its patent landscape to H1N1

Transparency & Traceability

- WHO Influenza Virus Traceability Mechanism (IVTM) is not being used
- Laboratories lacked time and staff resources to enter the required data into the system

WHO Network Capacity

- Demonstrated its ability to respond to the significant stress of the emergency situation
- Highlighted need for flexibility in prioritizing actions at different pandemic phases

Benefits being provided

- **Risk assessment**: timely, transparent, evidence based
- **Candidate vaccine viruses**; **diagnostic reagents & test kits**; **reference reagents** for vaccine potency determination
- **Antivirals** deployed from stockpiles
- **WHO negotiating** with manufacturers to secure **real-time access to pandemic vaccines**
- WHO working with **regulatory agencies** for expedited approval of antivirals and vaccines

Conclusions

- IGM presented **complex, global, multisectoral issues**
- **Substantive issues remain** despite notable achievements
- Test brought by H1N1 demonstrates that the system functions; completing consensus on the Framework will require sustained MS trust in each other and WHO
- **Implications for public health and emerging infectious diseases are ever-present**

Thank you