



The Center for Law & the Public's Health
at Georgetown & Johns Hopkins Universities

*CDC Collaborating Center Promoting Health through Law
WHO/PAHO Collaborating Center on Public Health Law and Human Rights*

Avian Influenza: Preparing for and Responding to a Potential Pandemic

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A Brief Overview

- What are Public Health Laws?
- Medical Countermeasures
 - Vaccines
 - Antiviral Medications
- Public Health Interventions
 - Surveillance
 - Agriculture and Trade Restrictions
 - Community Hygiene and Infection Control
 - Quarantine & Isolation
 - Decreased “Social Mixing”
 - International Travel and Border Control

What is Public Health Law?

The legal powers and duties of government used primarily *to assure the conditions for people to be healthy* (e.g., to identify, prevent, and ameliorate risks to health in the [human] population), and . . .

What is Public Health Law?

the **structural** (e.g. separation of powers, federalism) and **rights-based** (e.g. privacy, liberty, autonomy) **limitations** on the power of the state to act in the interests of the public's health or constrain legally-protected interests of individuals.

What are Public Health Laws?

- Legal provisions at all levels of government, including international law, that allow for and limit powers to protect and promote human health or animal health
- Broad conception of public health laws: laws related to health, immigration, trade, regulation of products, environmental, clinical research, individual rights, professional licensure
- There significant overlap between the health concerns of human and animal populations, but legal frameworks are often different, disparate, and disconnected.

Pandemic Influenza

- Highly pathogenic influenza A (H5N1) has been spreading through avian populations
- Scientists and policy-makers are concerned that this virus will mutate and become transmissible between humans
- What should be done to prevent, prepare for, and respond to a potential influenza pandemic?

Public Health Challenges during a Pandemic



Pandemic Influenza: Current Status

- There is currently no human pandemic, but it is likely that one will occur, if not via H5N1 then through some future virus strain
- A pandemic would have multiple impacts on life, health, economic, and social factors

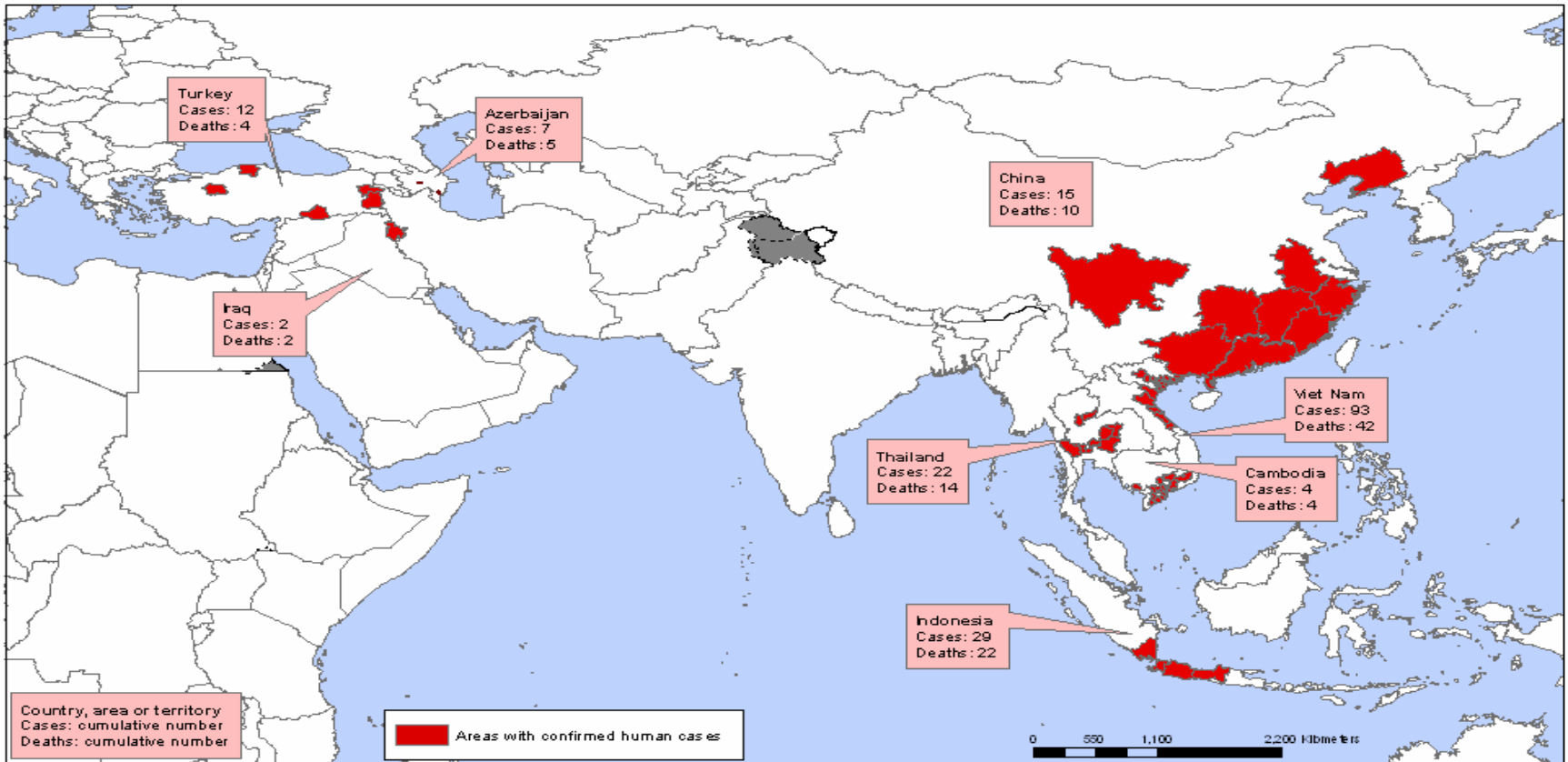
Pandemic Influenza: Law and Policy

- Law is an important tool
- Policy decisions are a vital component of the preparation for and response to an influenza pandemic
- Ethical considerations should inform law and policy decisions related to pandemic influenza

Human Cases of H5N1 since 2003

Affected areas with confirmed human cases of H5N1 avian influenza since 2003

Status as of 21 March 2006

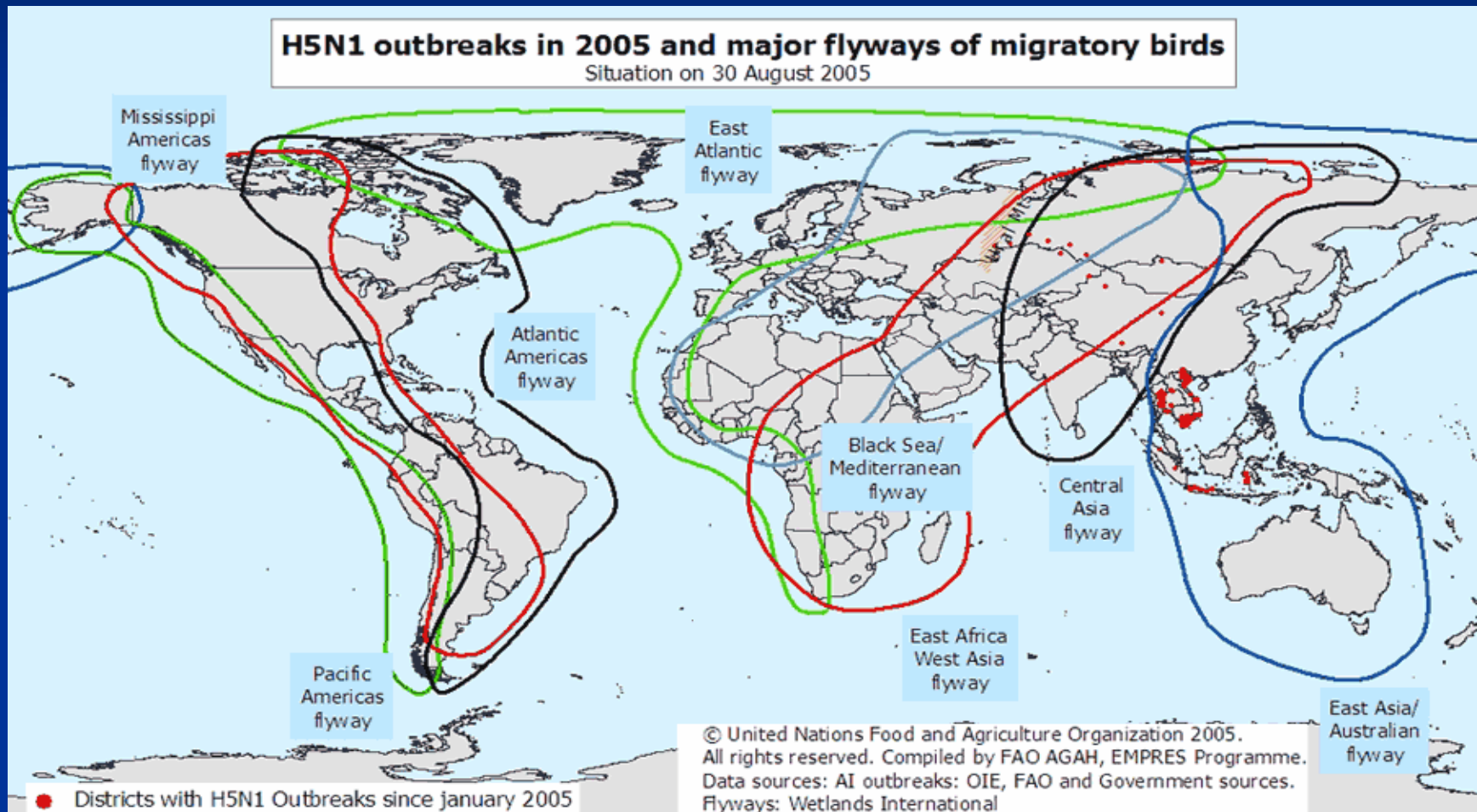


The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers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

Data Source: WHO / Map Production: Public Health Mapping and GIS Communicable Diseases (CDS) World Health Organization

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H5N1 Outbreaks and Bird Flyways



Two Types of Interventions

- Medical Countermeasures
 - Vaccines
 - Antiviral Medications
- Public Health Interventions
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Two Types of Interventions

Each of these potential interventions have scientific, political, and legal components

Medical Countermeasures

- In preparation for a potential pandemic influenza outbreak, three planning barriers must be overcome
 - Adequate supply
 - Efficient distribution
 - Ethically appropriate allocation

Medical Countermeasures: Supply Issues

■ Funding - United States

- The President's influenza preparedness plan calls for \$7 billion in funding
 - Of these funds, approximately \$6 billion is for medical countermeasures
 - \$4.7 billion for cell-based vaccine technology and stockpiling experimental vaccines
 - \$1.4 billion for antiviral medications
- Congress has allocated \$3.8 billion, with about \$3.4 billion devoted to medical countermeasures
- The federal government expects states to pay for a large percentage of medical countermeasures

Medical Countermeasures: Supply Issues

- Funding - International
 - The resources available for pandemic preparedness varies greatly among countries
 - Many countries have allocated funding for avian influenza countermeasures. The Beijing Declaration, signed in January 2006, called for increase cooperation between countries including funding pledges of \$1.9 billion.
 - The Beijing Declaration also envisions a key role for the World Health Organization and the International Health Regulations

Medical Countermeasures: Supply Issues

■ Manufacturers

- Vaccine supply has been inconsistent
- Pharmaceutical manufacturers are increasingly abandoning vaccines
 - In 1967, there were 26 vaccine manufacturers licensed in the US
 - This year, there were only 4

Medical Countermeasures: Supply Issues

- Why are companies abandoning vaccines?
 - Market forces create disincentives that inhibit vaccine development
 - high investment costs
 - limited or variable markets
 - High cost of regulatory compliance
 - Multiple, overlapping regulatory requirements
 - Complaints about FDA manufacturing oversight
 - Fear of liability
 - Overstated concern: In the past 20 years, there have only been 10 reported jury verdicts or judicial decisions relating to influenza vaccines
 - Intellectual Property Issues
 - The threat of compulsory licensing

Medical Countermeasures: Supply Issues

- What can we do to increase supply?
 - Public/private strategies rather than a reliance solely on private markets
 - The government can create incentives for companies to enter the market by:
 - Boosting demand through seasonal vaccine awareness program
 - Issuing purchasing contract
 - Providing price guarantees or subsidies

Medical Countermeasures: Supply Issues

- What can we do to increase supply?
 - Implement more efficient regulatory oversight
 - Ensure timely review of new products
 - Coordinate state, federal, and international regulations
 - Improve transparency and communication in the regulatory process

Medical Countermeasures: Supply Issues

- What can we do to increase supply?
- Two questionable ideas:
 - Liability protections?
 - Such protections might encourage manufacturers to enter the market, but this must be balanced against fair compensation to injured patients
 - Solution: Vaccine Injury Compensation Program
 - Stronger patent protections?
 - The threat of compulsory licensing might inhibit innovation, but we must also ensure sufficient production
 - Hoffman-La Roche holds the patent on Tamiflu
 - They oppose compulsory licensing, even though they have admitted that global demand exceeds their production capacity

Medical Countermeasures: Distribution Issues

- Even if we have sufficient supply, there are significant logistical problems associated with massive medication distribution
 - Time
 - Geography
 - Safety
 - Multiple Doses
- Most plans are silent about these issues
- The key is a plan that focuses on inter-jurisdictional cooperation
 - Establish a chain of command
 - Create procedures that efficiently gets medications from a national stockpile to the state and local areas where it is needed
 - Establish authorization to move these materials across national borders

Medical Countermeasures: Allocation Issues

- Given all of these supply and distribution issues, we must assume that there will be a shortage of medical countermeasures
- How should medical countermeasures be ethically allocated?

Medical Countermeasures: Allocation Issues

- Allocation Criteria
 - Public health/prevention
 - e.g. ring vaccination
 - Scientific/Medical Functioning
 - e.g. vaccine production, medical personnel
 - Social Functioning/Critical Infrastructure
 - e.g. police, firefighters, sanitation, utilities, government
 - Medical Need/Vulnerability
 - Social/Economic Justice
 - Global Justice

Public Health Interventions

- Surveillance
 - Rapid diagnosis, screening, reporting, case-contact investigations, etc.
- Two issues
 - Authority to conduct surveillance and share data
 - Who should conduct surveillance (public, private, or both)?
 - Who should have access to the data? (National Health Agency, WHO, public)
 - Privacy
 - Surveillance involves the transmission of sensitive information
 - The US data protection statute makes exception for surveillance
 - Public health information laws should be enacted to prevent wrongful disclosure

Public Health Interventions

- Animal-Human Interchange
 - Birds are vectors for spreading avian influenza
 - An early prevention strategy is to limit contact that results in animal-human interchange
 - Separation of human and animal populations
 - Health in animal farming
 - Quarantines or culls of exposed and diseased animals
 - These interventions are difficult to carry out in poor countries where laboratories and surveillance personnel are scarce

Public Health Interventions

■ Community Hygiene

- Hand-washing, disinfection, respiratory hygiene, personal protective equipment
- The public must be educated to use these techniques appropriately

■ Hospital Infection Control

- Only 40% of hospital workers are vaccinated annually
- Voluntary measures (education, incentives, peer advocacy, access) can increase this number
- 15 states in the US have mandatory vaccination laws for health care workers, but they are limited in scope and enforceability

Public Health Interventions

- Isolation and Quarantine
 - Legal authority
 - The power should be clearly defined
 - with criteria based on risk
 - and adequate due process procedures
 - Safety issues
 - Safe and hygienic locations
 - Adequate medical care
 - Necessities of life
 - Enforcement/Incentives

Public Health Interventions

- Decreased Social Mixing
 - Closing public places, canceling public events, “flu days”
 - But numerous legal questions must be resolved
 - Who has the power to make these decisions and under what circumstances?
 - How are the decisions enforced?

Public Health Interventions

- International Travel and Border Control
 - Entry and exit screening, disease reporting, health alert notices, collection of passenger information, travel restriction, etc.
 - These techniques have consequences
 - Decreased freedom of movement
 - Transmission of sensitive information
 - Economic costs
 - These burdens are justified only if legitimate public health goals are being met

Summary

- A well developed legal structure can facilitate an effective response to a potential influenza pandemic
- Many of the scientific and logistical challenges have a legal component
- Law should be flexible enough to adapt to novel public health challenges posed by emerging infectious diseases
- Law should incorporate the knowledge and experience of scientists and health professionals to improve decision-making
- Law should clearly authorize powers and limits on these powers

Conclusion

- For more information, please see the *Center for Law and the Public's Health Website* at: www.publichealthlaw.net
- If you have any questions, please contact me at gable1@law.georgetown.edu.
- **The research team for this project includes Lawrence O. Gostin and Benjamin Berkman**

• ***Xie Xie!***