BIORISK MANAGEMENT IN A ONE HEALTH WORLD
USDA ARS 3rd INTERNATIONAL BIOSAFETY & BIOCONTAINMENT SYMPOSIUM
5 FEBRUARY 2015
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Malaysia (1998)

Sept
• Severe febrile encephalitis cases reported among pig farmers in Perak
• Investigation notes respiratory disease in pigs

Oct-Nov
• Intensive JEV control measures

Feb
• Human and pig disease cases recognized in other parts of Malaysia

March
• 11 cases of respiratory and encephalitis illnesses in Singapore abattoir workers
• Novel virus confirmed
• Cabinet Task Force Committee chaired by DG-Health
• 24/7 National Operations Room at MOH

April -
• Culling of >1 million pigs

265 cases
105 deaths
K B Chua et al. Science 2000;288:1432-1435

China/Hong Kong (2002-3)

- Nov 2002: First reported case of atypical pneumonia in Guangdong Province
- Feb 2003: Clinician from Guangdong becomes ill while visiting Hong Kong
  - First case of atypical pneumonia in Vietnam
- March 2003: First case of atypical pneumonia in Vietnam
  - WHO issues global alert
- April 2003: SARS virus sequenced
- June 2003: Final naturally transmitted cases reported
Chain of transmission among guests at Hotel M—Hong Kong, 2003

1. **Hotel M Hong Kong**
   - 37 close contacts
   - 99 HCWs (includes 17 medical students)
   - 156 close contacts of HCWs and patients

2. **Hospital 1 Hong Kong**
   - 0 HCWs

3. **Hospital 2 Hong Kong**
   - 4 HCWs*
   - 3 HCWs

4. **Hospital 3 Hong Kong**
   - 28 HCWs
   - 156 close contacts of HCWs and patients

5. **Hospital 4 Hong Kong**
   - 4 other Hong Kong Hospitals
   - 37 HCWs
   - Unknown number close contacts
   - 3 HCWs

6. **Hospital 2 Hong Kong**
   - 4 family members
   - 10 HCWs

7. **Hotel 2 Hong Kong**
   - 2 family members

8. **Hospital 1 Hong Kong**
   - 34 HCWs
   - 37 close contacts
   - 2 family members

9. **Hospital 2 Hong Kong**
   - 4 family members

10. **Hospital 2 Hong Kong**
    - 2 close contacts

11. **Hotel 2 Hong Kong**
    - 2 family members

12. **Hospital 2 Hong Kong**
    - 2 family members

13. **Hospital 2 Hong Kong**
    - 2 family members

14. **Hospital 2 Hong Kong**
    - 2 family members

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*HCWs = Healthcare workers

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**Regions:**
- Canada
- Ireland
- United States
- Germany
- Singapore
- Vietnam
- Hong Kong
- Thailand
- United States
- Ireland

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**Note:**
- "†" indicates HCWs
- "§" indicates family members
- "*" indicates additional HCWs

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**Others:**
- 4 family members
- 10 HCWs
- 2 close contacts
- 2 family members
- 34 HCWs
- 37 close contacts
- 3 family members
- 37 HCWs
- Unknown number close contacts
Figure 2. Schematic Diagram of the Boeing 737-300 Aircraft on Flight 2 from Hong Kong to Beijing.

Two flight attendants and two Chinese officials also reportedly had illness that met the WHO criteria for a probable case of SARS. The flight attendants are shown here as members of the crew. The seat locations of the two Chinese officials are unknown, and they are not included in the diagram.

Adopted by 194 States Parties

Entered into force

2005

2007

2009

2012

2014

States report meeting all core capacity requirements

OR

States report meeting all core capacity requirements

OR

Request extension

OR

Request 2nd extension

States assess core capacities

Plan/implement capacity building

118

27

42

9

Fully implemented

2-year extension obtained (with implementation plan)

2-year extension requested (no implementation plan)

No report
What did States Parties agree to do?

(Articles 4, 5, 13, 44 and Annex 1)

Communications
- Designate a National IHR Focal Point

Core Capacities
- Meet minimum requirements to detect, assess, report, and respond to public health events

Points of Entry
- Support disease detection and control at designated ports and borders

Notification
- Develop a framework for notifying WHO within 24 hours of a potential PHEIC

Minimal interference
- Take evidence-based actions sensitive to impact on trade, travel, and human rights

Evaluate status
- Conduct self-assessments and report to WHO
Annex 1 defines IHR (2005) core capacity requirements

**National**
- Detect unexpected disease or deaths
- Assess reports within 48 hours
- Notify WHO
- Support or implement control measures

**Intermediate**
- Detect unexpected disease or deaths
- Assess and confirm reported events
- Report to national level
- Support or implement control measures

**Local**
- Detect unexpected disease or deaths
- Assess events immediately
- Report essential information to appropriate level
- Implement preliminary control measures

- Provide epidemiological, laboratory, and logistical support
- Approve and implement containment and control measures
- Coordinate with other ministries
- Disseminate information to key actors
- Establish operational national public health emergency response plan
- Develop rapid response teams
Country Reports on IHR Implementation - 2012
Aggregate Score (%)

Legislation 70%
Coordination 80%
Surveillance 80%
Response 80%
Preparedness 70%
Risk Communications 70%
Human Resources 60%
Laboratory 80%
PoE 60%
Zoonotic 80%
Food Safety 80%
Chemical 50%
Radiological 50%
Case Detection (according to case definitions)/Registration → Sample Collection → Laboratory Testing

Verification and Risk Assessment ← Outbreak Investigation ← Reporting of Structured Data

Case Management and Control Measures
Human

- Report of positive specimen
  - Health facility
    - Case management
  - District health office
    - Regional and/or central level – assess in 24 hours
      - Ministry of Health
        - Ministry of Agriculture
        - WHO – Country, Regional, HQ

Animal

- Report of positive specimen
  - Veterinary facility
    - Case management or culling
      - Regional and/or central level - assess and verify
  - District/Regional animal health office
    - Ministry of Agriculture
      - Ministry of Health
      - FAO/OIE
<table>
<thead>
<tr>
<th></th>
<th>ACTION PACKAGES - PREVENT AVOIDABLE EPIDEMICS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Develop an integrated and global package of activities to combat antimicrobial resistance.</td>
</tr>
<tr>
<td></td>
<td>Leading: Canada, Germany, Netherlands, Sweden, United Kingdom</td>
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<tr>
<td></td>
<td>Contributing: Australia, India, Indonesia, Italy, Japan, Norway, Portugal, Switzerland, Thailand, United States</td>
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<tr>
<td></td>
<td>IOs: FAO, OIE, WHO</td>
</tr>
<tr>
<td>2</td>
<td>Adopt behaviors, policies and/or practices that minimize the spillover of zoonotic diseases from lower animals into human populations.</td>
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<tr>
<td></td>
<td>Leading: Indonesia, Vietnam</td>
</tr>
<tr>
<td></td>
<td>Contributing: Georgia, Kenya, Sweden, United Kingdom, United States, Yemen</td>
</tr>
<tr>
<td></td>
<td>IOs: FAO, OIE, WHO</td>
</tr>
<tr>
<td>3</td>
<td>A whole-of-government national biosafety and biosecurity system is in place.</td>
</tr>
<tr>
<td></td>
<td>Leading: Canada, Denmark, Kenya, Peru, Portugal, Spain</td>
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<tr>
<td></td>
<td>Contributing: Azerbaijan, Germany, India (TBC), Jordan, Republic of Korea, United Kingdom, United States</td>
</tr>
<tr>
<td></td>
<td>IOs: FAO, IAEA, INTERPOL, OIE, WHO</td>
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<tr>
<td>4</td>
<td>A functioning national vaccine delivery is in place.</td>
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<tr>
<td></td>
<td>Leading: Italy, Portugal</td>
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<td></td>
<td>Contributing: India, Pakistan, Republic of Korea, Saudi Arabia, United Arab Emirates, Yemen</td>
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<tr>
<td></td>
<td>IOs: FAO, OIE, WHO</td>
</tr>
<tr>
<td>ACTION PACKAGES – DETECT THREATS EARLY</td>
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<td>----------------------------------------</td>
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<tr>
<td><strong>1</strong> Real-time biosurveillance with a national laboratory system and effective modern point-of-care and laboratory-based diagnostics.</td>
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<tr>
<td>Leading: South Africa, Thailand, US Contributing: Canada, China, Ethiopia, Finland, Georgia, Israel, Japan, Malaysia, Mexico, Peru, Switzerland, United Kingdom, Yemen IOs: FAO, OIE, WHO</td>
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</tr>
<tr>
<td><strong>2/3</strong> Strengthen foundational indicator- and event-based surveillance systems that are able to detect events of significance for public health, animal health and health security.</td>
<td></td>
</tr>
<tr>
<td>Leading: Georgia, Norway Contributing: Azerbaijan, Ethiopia, Finland, Indonesia, Israel, Italy, Kenya, Mexico, United Kingdom, United States, Yemen IOs: FAO, OIE, WHO</td>
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<td><strong>4</strong> Timely and accurate disease reporting according to WHO requirements and consistent coordination with FAO and OIE.</td>
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<tr>
<td>Leading: France Contributing: Israel IOs: FAO, OIE, WHO</td>
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<td><strong>5</strong> A workforce (physicians, veterinarians, biostatisticians, laboratory scientists, farming/livestock professionals, and field epidemiologists) who can systematically cooperate to meet relevant IHR and PVS core competencies.</td>
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<tr>
<td>Leading: Jordan, Thailand Contributing: Ethiopia, Finland, Saudi Arabia, United States, Yemen IOs: FAO, OIE, WHO</td>
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<td></td>
<td>ACTION PACKAGES – RESPOND RAPIDLY &amp; EFFECTIVELY</td>
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<td>-----------------------------------------------</td>
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<tr>
<td>1</td>
<td>Every country will have a public health Emergency Operations Center (EOC) functioning according to minimum common standards.</td>
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<tr>
<td>2</td>
<td>In the event of a biological event of suspected or confirmed deliberate origin, a country will be able to conduct a rapid, multi-sectoral response, including the capacity to link public health and law enforcement, and to provide and/or request effective and timely international assistance, including to investigate alleged use events.</td>
</tr>
<tr>
<td>3</td>
<td>A national framework for transferring (sending and receiving) medical countermeasures and public health and medical personnel among international partners during public health emergencies.</td>
</tr>
</tbody>
</table>
Example: Biosafety/Biosecurity Action Package

Five-Year Action Items:

- Develop and implement a strategic plan for biosafety and biosecurity.
- Develop, modernize, enact, and sustain country-specific legislation to support a national program.
- Develop, implement, and sustain a national oversight program for pathogen biosafety and biosecurity that will incorporate biological risk evaluations of the nation’s biological entities; the creation of a legal framework and legal authorities; a multi-sectoral approach; the design and construction of the oversight program; the assessment and establishment of best practices to be put in place in laboratories and facilities; the training of national officials on biological risk evaluation; and existing security arrangements.
- Establish a new (or mandate an existing) government agency to administer and enforce biosafety and biosecurity oversight systems; creation of the country’s list of agents of concern; and development of best practices, information material and tools for government and other entities. Activities should be conducted to ensure that agents are identified, licensed, transported, secured, monitored, and disposed of in a minimum number of facilities with biosafety and biosecurity best practices in place.
- Integrate field investigation and emergency response capability as an important part of the national program.

Number of countries that have completed/Completion of a national framework and comprehensive oversight system for pathogen biosafety and biosecurity, strain collections, containment laboratories and monitoring systems that includes identification and storage of national strain collections in a minimal number of facilities.
# GHSA Action Package Prevent 3: Biosafety and Biosecurity

**GHSA 5-Year National Target**

A whole-of-government national biosafety and biosecurity system is in place, ensuring that especially dangerous pathogens are identified, held, secured and monitored in a minimal number of facilities according to best practices; biological risk management training and educational outreach are conducted to promote a shared culture of responsibility, reduce dual-use biological risks, and ensure safe transfer of biological agents; and country-specific biosecurity legislation, laboratory licensing, and pathogen control measures are in place as appropriate.

As measured by:

- Number of countries who have completed/completion of a national framework and comprehensive oversight system for pathogen biosafety and biosecurity, strain collections, containment laboratories and monitoring systems that includes identification and storage of national strain collections in a minimal number of facilities.

## Human Public Health

<table>
<thead>
<tr>
<th>IHR Monitoring Framework (Core Capacity 4: Response)</th>
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<tbody>
<tr>
<td>▪ Safe disposal policy and procedures for medical and nonmedical waste established. (Framework only)</td>
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<tr>
<th>IHR Monitoring Framework &amp; Questionnaire (Core Capacity 8: Laboratories)</th>
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<tr>
<td>▪ National regulations compatible with international guidelines implemented for the packaging and transport of clinical specimens. (8.1.1.9)</td>
</tr>
<tr>
<td>▪ Staff at national or relevant level trained for the safe shipment of infectious substances according to international standards (ICAO/IATA) (8.1.1.12)</td>
</tr>
<tr>
<td>▪ Processes for shipment of infectious substances when investigating an urgent public health event consistently meet IATA/ICAO standards (8.1.1.13)</td>
</tr>
<tr>
<td>▪ Laboratory biosafety and Laboratory Biosecurity (Biorisk management) practices are in place and implemented (8.2.1.1)*</td>
</tr>
<tr>
<td>▪ Biosafety guidelines are accessible to laboratories. (8.2.1.1)*</td>
</tr>
<tr>
<td>▪ An institution or person responsible for inspection (could include certification of biosafety equipment) of laboratories for compliance with biosafety requirements is identified. (8.2.1.5)*</td>
</tr>
<tr>
<td>▪ Regulations, policies or strategies for laboratory biosafety are available. (8.2.1.2)*</td>
</tr>
<tr>
<td>▪ A responsible entity is designated for laboratory biosafety and laboratory biosecurity (biorisk management). (8.2.1.3)*</td>
</tr>
<tr>
<td>▪ Relevant staff are trained on laboratory biosafety and laboratory biosecurity guidelines. (8.2.1.4)*</td>
</tr>
<tr>
<td>▪ Biorisk assessment is conducted in laboratories to guide and update biosafety regulations, procedures and practices, including for decontamination and management of infectious waste. (8.2.1.6)*</td>
</tr>
</tbody>
</table>

## Animal Public Health

<table>
<thead>
<tr>
<th>OIE Terrestrial Code (Chapters 3.2, 5.6 and 5.8)</th>
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<tbody>
<tr>
<td>▪ Veterinary legislation, regulations and functional capabilities, including: Assessment of the adequacy and implementation of relevant legislation (national and sub-national); assessment of ability of VS to enforce legislation; and animal health controls of the importation, use, and bio-containment of organisms which are aetiological agents of animal diseases, and of pathological material. (3.2.14)*</td>
</tr>
<tr>
<td>▪ Pathogens should be categorized according to the risk they pose to both human and animal health. They are grouped into four risk categories. Detailed information is provided in the Terrestrial Manual. (5.8.3)*</td>
</tr>
<tr>
<td>▪ Importation of animal pathogens: Import licences should contain conditions appropriate to the risk posed by the pathogen and, in relation to air transport, the appropriate standards of IATA concerning the packaging and transport of hazardous substances. (5.8.4)</td>
</tr>
<tr>
<td>▪ Laboratory containment of animal pathogens: Guidance on the laboratory containment of animal pathogens and on the import conditions applicable to animal pathogens is found in Chapter 1.1.2. of the Terrestrial Manual. Additional guidance on human safety is also found in this chapter. (5.8.5)*</td>
</tr>
</tbody>
</table>