National efforts in biorisk management: Malaysian perspectives

T.S. Saraswathy
Ministry of Health
Malaysia

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Strategic roadmap for Global Health Security

- Each country should strengthen their public health capacity for effective biothreat reduction, preparedness & response and implement effective biorisk programmes

- Every country should collectively contribute and respond towards Global health security

---WHO---
Global Biological Threats

1. Global outbreaks of infectious disease
   - Natural outbreaks in Asia Pacific region represent unpredictable sources of dangerous pathogens: novel, emerging and re-emerging

2. Radical/Terrorist threat
   - Terrorist groups have established intent to do harm; use of BW represents a potential threat

3. Modern technologies technologies

Increasing vulnerability of the bioscience sector for accidental release or intentional misuse
BIOTHREATS: MALAYSIA’S PERSPECTIVES

NATURALLY OCCURRING
- Outbreaks of infectious diseases
- Communicable diseases
- Lab acquired infections
- Importation: migrant labour, travel etc.

PERCEIVED RISK
- Modern Biotechnology
- Synthetic biology
- Dual use / Misuse
- Bioterrorism

BIOSAFETY

BIOSECURITY
- Integrated Biorisk management system

Sustainable National Public Health Security
**Malaysia**

**Natural biothreats**: Infectious disease outbreaks

- 1997 Enterovirus outbreak - Sarawak
  - 42 deaths
- 1998/99 Nipah viral encephalitis outbreak
  - 283 cases/109 deaths; Economic losses
- 2001 Anthrax threat related scare
  - 103 reported suspicious incidents

**Risk of importation of exotic and novel biological agents**

- 1992 Wild poliovirus infection
- 1993 Visceral Leishmaniasis (Kala Azar)
- 1998 Chikungunya viral infection
- 2002 Cholera 0139 in 2002
- 2003 SARS 5 probable cases
- Avian influenza (H5N1) in 2004 No human cases
- 2009/2010 Pandemic H1N1 2009 ~15,000 cases with 88 deaths
BIOTHRATS: MALAYSIA’S PERSPECTIVES

NATURALLY OCCURING

Outbreaks of infect diseases
Communicable diseases
Lab acquired infections
Importation: migrant labour travel etc.

PERCEIVED RISK

Modern Biotechnology
Synthetic biology
Dual use / Misuse
Bioterrorism

BIOSAFETY

BIOSECURITY

Integrated Biorisk management system

Sustainable National Public Health Security
National efforts on biorisk management

- Legislations related to biosafety and biosecurity
- Biorisks and biothreats impact public health: our obligations of IHR, resolution 58.3 (2005) – Legally binding for all 193 WHO Member States, international law
  
  * Strengthen public health capacity for effective biothreat reduction, preparedness & response
  
  * Improve communication on disease surveillance at all levels

- Develop laboratory capabilities / staff competency to deal with disease / Strengthening existing organisations and networks working on infectious diseases;

- Laboratory biosafety / biosecurity culture

- Biosafety review process for research involving high risk pathogens
BIOSAFETY & BIOSECURITY LEGAL FRAMEWORK

National obligations

- Government is committed and is taking effective administrative steps for mitigation of biological risks
- Effective control of biological agents: BWTC Draft Bill is presently in the final phases for Cabinet approval process
- Biosafety Act 2007 for regulation of recombinant DNA technology
- Prevention & Control of Infectious Diseases (Importation & Exportation of Human Remains, Human tissues and pathogenic organisms & Substances) Regulations 2006

International obligations

- State Party Cartagena Protocol on Biosafety
- State Party BWTC
- International Health Regulations (IHR)
PARTIAL LIST OF LEGISLATIONS RELATED TO BIOLOGICAL SAFETY & SECURITY

- BWTC Draft Bill, 2012
- Strategic Trade Act 2010 (Act 708, 2010)
- Malaysian Quarantine and Inspection Services (MAQIS), Act 2011
- Penal Code (Act No. 574) (as amended)
- Prevention and Control of Infectious Diseases Act (Act No. 342, 1988), Regulations, 2006
- Biosafety Act (Act No. 678, 2007)
- Occupational Safety and Health (Notification of Accident, Dangerous Occurrence, Occupational Poisoning and Occupational Disease) Regulations 2004 (P.U.(A) 128/2004
- Destruction of Disease-Bearing Insects Act (Act No. 154, 1975)
- Postal Services Act (Act No. 465, 1991)
- Emergency (Public Order and Prevention of Crime) Ordinance, 1969
- Public Order (Preservation) Act (Act No. 296, 1958)
- Animals Act (Act No. 647, 1953)
- Environmental Quality Act (Act No. 127, 1974)
- Environmental Quality (Prescribed Premises) (Scheduled Wastes Treatment and Disposal Facilities) Regulations 1989 (P.U.(A) 141/89)
- Environmental Quality (Scheduled Wastes) Regulations 2005 (P.U.(A) 294/2005) (as amended)
- Emergency (Essential Powers) Act (Act No. 216, 1979)
- Aviation Offences Act (Act No. 307, 1984)
- Waters Act (Act No. 418, 1920)
- Food Act (Act No. 281, 1983)
PUBLIC HEALTH PREPAREDNESS & RESPONSE

- IHR requires countries to develop, strengthen and maintain the capacity to prevent, detect, assess, notify and report public health emergencies of international concern.

Malaysian strategy for Emerging Diseases

An efficient infectious disease outbreak response in Ministry of Health

A sensitive, infectious disease surveillance programme in man & animals: for rapid detection of communicable disease outbreaks

A practical, logistical emergency response plan
Risk communication programmes; Infection prevention & control procedures; Medical care

Effective communication & networking at all levels with various sectors & collaborative partners, locally and internationally
Rapid Response Network and information dissemination

Case of infectious diseases

Conduct case investigation & initiate control measures

Communicable Disease Control Section, Public Health Dept MOH

District Medical Officer of Health

State Health Office

Reporting Physician
Public sector
Private sector

Laboratories
District Hosp Lab
State Labs
IMR (Ref Lab)
Public Health Lab

Int Ref Labs
eg CDC, Japan, Australia

WHO & other relevant int. agencies (GOARN, GISEN)

Malaysia has been supportive in the efforts by international networks such as WHO, OIE and FAO in strengthening international surveillance and detection of infectious diseases
ASIA-PACIFIC STRATEGY FOR EMERG. DISEASES
BUILDING LABORATORY CAPACITIES FOR OUTBREAK MANAGEMENT.

MYSED WORKING DOCUMENT:
WORKING SAFELY AND SECURELY
Scientists in bioscience laboratories work with living organisms, some of these are highly infectious. Activities include manipulations of these organisms, their products, toxins or genomes.

Self regulation based on international best practices, WHO guidelines and national biorisk management guidelines
Access to pathogens is necessary…
**R & D is important**

- Basic research
- Applied research
- Culture collections
- Pharmaceutical and manufacturing

- Education
- Evaluation
- Internal quality
- External assessment

**Access to knowledge, technologies research and analytical capacity**
Laboratory Biorisk Management

*Best Practices start in the laboratory…*

- **Establish a sustainable laboratory biosafety & biosecurity culture**
- **Implement effective biorisk training programmes: core competencies and awareness-raising of laboratory managers**
- **Development of Malaysian Standards for Biosafety and Biocontainment in Microbiology Laboratories**
Laboratory biosecurity in the Malaysian Laboratory

• Scientists understand importance of lab biosafety **But** Laboratory biosecurity is a relatively new for bioscience laboratories including Malaysia.

• The fact that awareness level of perceived threats about biocrime is not high, suggests that BRM approach should be implemented. **A sensitive approach needed, not to impede research and diagnosis of pathogens.**
DUAL-USE RESEARCH

Modern biotechnology and other advances in S & T enable scientists to create bioengineered pathogens that could be highly contagious and extremely virulent.

Professional groups such as science academies are debating for a protective oversight system for dual-use research.

Different perceptions about dual use concerns. For example pathogen genomes are considered critical to understanding pathogen characteristics; but the genetic information can also be deliberately mis-used to enhance or induce virulence in a non-pathogenic host.

The importance of a research review process is highlighted which offers an independent peer review monitoring of life science research in our public and academic institutions. In Malaysia, Biosafety Regulations 2010, requires research institutions to set up IBCs and strengthen biosafety review of research protocols for adequate biocontainment and oversight.
Biosafety Review Process

Researchers are bound by all legal requirements, (local & international) which regulate their work, particularly **health and safety requirements**, environmental standards.

- A list of National Health Research Priorities
- Research Review Committee, Medical Ethics Comm, Animal Ethics, IBC, GMAC guidelines, Good Clinical Practice Guidelines
- A system for awarding research grants
- A system for monitoring progress and research outputs

Researchers are bound by all legal requirements, including health and safety requirements, environmental standards.
National Approaches

- Effective implementation of legislative measures
- Scientists in Malaysia are bound by all legal requirements, (local & international) which regulate their work, particularly health and safety requirements and environmental standards.

Research Review Committee, Medical Ethics Committee, Animal Ethics Comm, Institutional Biosafety Comm, (Gene Regulation Committee) / Good Clinical Practice Guidelines
Our Govt’s goal for research & diagnostic laboratories

Security through safe laboratory practices

- Creating a biosafety culture in the laboratory at all levels in the organization through a National Code of Practice and training

- Strengthening laboratories through GLP: external QAP/QC and accreditation

Training & Awareness in BRM
Joint efforts with NGOs:
Role of Biosafety associations

- Complement and supplement the efforts of government;
- Acts as a resource for training and research;
- Voluntary manpower, diverse expertise, cross boundary partnerships to achieve common goals;
- Affiliations and Partnerships to Deliver sustainable biosafety programs targeting needy countries/organizations/individuals.
Malaysian Biosafety & Biosecurity Association

- Launched in July 2011 during the International BioSSD Congress in Kuala Lumpur. **Primary mission to complement government efforts to promote a biorisk culture**

A non profit voluntary organization

Membership is multi-sectoral (health, agriculture, academia, defence, corporate)

A neutral platform to promote biosafety and biosecurity
ACHIEVEMENTS OF MBBA

1. Capacity building through awareness raising and advocacy
   i) “ABOT” Train the trainer workshops 2 phases completed
   ii) TB Biorisk management workshop in Jan 2013 ASM/MBBA collaboration

2. Work in partnerships to integrate resources and manpower

3. Website development

4. Partnerships and Collaboration (With local and International agencies eg. Microbiology Society Malaysia, EU pilot projects)

CHALLENGES FOR OUR BRM GOAL

- Adequate allocation of funds for biosafety in research budgets to improve basic biosafety infrastructure, facilities and equipment
- Establish a sustainable laboratory biosafety programme
- Creating a biosafety culture in the laboratory at all levels in the organization
- Authority, scope, responsibilities and implementation of biosafety / biosecurity legislations with different agencies with varying approaches
THANK YOU