OIE standards, guidelines and activities for biosafety and biosecurity in veterinary laboratories and animal facilities with a focus on South East Asia

Alex Bouchot, OIE Sub-Regional Representation for South East Asia
World Organisation for Animal Health (OIE)

- An intergovernmental organisation, founded in 1924
- 178 Members (In January 2011)
- Headquarters in Paris, France
  - 5 Regional offices
  - 6 Regional sub offices
Biosecurity / Biosafety

- OIE activities at global level
The OIE’s objectives

**Animal Health Information**
- To ensure **transparency** in the global animal disease and zoonoses situation
- To collect, analyse and disseminate scientific veterinary **information**

**International Standards**
- Within its WTO SPS mandate, to safeguard world trade by publishing health **standards for international trade** in animals and animal products
- To provide a better guarantee of the safety of **food** of animal origin, and to promote animal **welfare**, through a science-based approach

**Activities of Veterinary Services**
- To provide expertise and encourage international solidarity in the **control of animal diseases**
- To improve the legal framework and resources of national **Veterinary Services**
OIE International Standards

**Terrestrial Animal Health Code** – mammals, birds and bees

**Aquatic Animal Health Code** – fish, molluscs and crustaceans

**Manual of Diagnostic Tests and Vaccines for Terrestrial Animals**

**Manual of Diagnostic Tests for Aquatic Animals**

**OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases**

Available in 3 languages and on the OIE website
The OIE’s scientific network

**Reference Laboratories**

- Develop, perform and validate diagnostic tests
- Store and distribute reference reagents
- Organise laboratory proficiency testing of other Members’ laboratories
- Coordinate scientific and technical studies

**Expert centres for animal diseases**

- Provide scientific and technical training to Members
- Are under the responsibility of an expert of reference
- The list of Reference Laboratories is validated by the World Assembly of Delegates annually
Global network of OIE Reference Laboratories

187 OIE Reference Laboratories in 2009 covering 100 diseases
The OIE’s scientific network 3/4

Collaborating Centres 1/2

Centres of excellence on horizontal topics

• Assist in the development of procedures to update and promote international standards and guidelines on animal health and welfare

• Coordinate scientific studies

• Organise training seminars

• Organise and host technical meetings in collaboration with the OIE
Global network of OIE Collaborating Centres

35 Collaborating Centres covering 33 topics
OIE Standards and guidelines for biosafety and biosecurity

To protect health of staff, the general public, animal populations, the environment, and the pathogen
Chapter 1.1.2 on biosafety and biosecurity in veterinary laboratories
General Process for developing Chapter for the *Terrestrial Manual*

1. **Biological Standards Commission (BSC)/Consultant Editor**
   - Authors (Experts)
   - Consultant Editor
   - Review by the BSC with the help of the editorial team

2. **DELEGATES & Relevant Reference Laboratories and other peer reviewers**

- Assembly
- Inclusion on the next edition of the *Manual/OIE website*
- Adoption of the Chapter

Comments
OIE ad hoc group on biosafety/biocontainment

- OIE ad hoc groups examine specific technical issues and provide outputs
- Small groups (<6) of recognised experts from across the world
- To review and update OIE Diagnostic Manual
- Input from public health sector (WHO)
Purpose

To reduce risks to lab workers and reduce risk of spread to animals and the environment through a combination of laboratory practices, construction, and equipment

• Standardisation
• A basis for
  – Good laboratory practices
  – Regulations
  – Legislation
  – Training
Risk based approach

Guidance on risk assessments for pathogens to...

- Determine the risk to human or animal health
- Determine the appropriate containment level (based on proposed nature of lab work)
- Made in context of country situation (animal pathogens)
- Pathogens grouped 1-4 (4 being the most severe risk)
Risk assessments considerations

- Known occurrence of infection with organism, severity of disease, history of lab acquired infection, infective dose
- Amount of pathogen to be handled
- Origin of sample (wildlife)
- Possibility of aerosol formation during procedures
- The threat to food producing animals – economics, trade etc
- Physical state of workers
- Presence of vectors, intermediate host or correct environmental conditions to support transmission of pathogen
- Whether pathogen is enzootic or exotic
- Whether treatment or prophylaxis is available
Grouping by human (or animal) health risk

- **Group 1** – unlikely to cause disease (human or animal), enzootic and no official control
- **Group 2** – may cause disease, unlikely to spread in population (human or animal), treatment/prophylaxis available
  - Animal influenza (apart from Notifiable AI), orf, listeria, salmonella
- **Group 3** – can cause severe disease, may spread in population, treatment/prophylaxis available
  - Rabies, *Bacillus anthracis*, *Mycobacterium bovis*
- **Group 4** – can cause severe disease, high risk of spread in population, often no treatment/prophylaxis available
  - Hendra virus, Nipah virus
Diagnostic specimens

• **Unknown potential**

• Initially treat as *group 2* pathogen unless suspicious that they contain agents in higher risk group (as below)

• Prevent percutaneous and mucous membrane exposure (esp. inhalation and ingestion)

• Once identified refer to procedures for specific risk group

• If aerosol - safety cabinet

Dr Andrew Breed – bat scientist
• **Special risks**

• **Considerations**
  - Infected laboratory animals can generate large amounts of infectious material
  - They kick, scratch, bite, spit and lick (avoid injury or self inoculation)
  - Containment of the animals or vectors
  - Welfare (OIE standards for laboratory animals are under development)
Collection and shipment of diagnostic specimens

Chapter 1.1.1

• Approval to ship
  Lab ready to receive sample/ import license
• Transportation
  Fastest possible way – so it arrives in good condition
  Refrigeration
  Packaging – follow IATA Dangerous Goods Regulations (DGR) for air
• Shipping forms – in line with DGR
Chapter 5.8 – deals with measures to reduce the risks from pathogens, specimens, pathological samples, and of accidental release from the laboratory

Measures at:
- National borders – import licence
- Within national boundaries – containment facilities/handling and competence; and licensing of laboratories

• Importation of animal pathogen permitted only under import license (issued by competent authority)

• Considerations for importation (license)
  • Nature of material
  • Animal of origin (e.g. species, domestic vs. wildlife)
  • Susceptibility of that animal to various diseases
  • Animal health situation of country of origin
  • Pretreatment of samples
  • If air – IATA standards for packaging and shipment

• Requirements for recipient laboratory (3 and 4 (?2))
  • Appropriate containment facilities (satisfy authorities – licensing and regular inspection)
  • Import license only granted if receiving lab meets appropriate containment
Animal disease surveillance and control

*Primum non nocere*

- An effective disease surveillance programme will detect accidental or deliberate release of important animal pathogens (including zoonoses) into animal populations.

- Early detection facilitates a rapid response (containment and control); was it as a result of laboratory release?

- General guidelines for animal health surveillance in the *OIE Code for Terrestrial Animals*.

- Zoning and compartmentalisation, 2 useful concepts.
Aquatic Animals

• No specific recommendations for Laboratories but general recommendations on disinfection in Aquaculture establishment

• Manual of Diagnostic Tests and Vaccines for Aquatic Animals, 2006
  • [http://www.oie.int/eng/normes/fmanual/A_summry.htm](http://www.oie.int/eng/normes/fmanual/A_summry.htm)

• Aquatic Animals Health Code, 2009
  • [http://www.oie.int/eng/normes/fcode/A_summry.htm](http://www.oie.int/eng/normes/fcode/A_summry.htm)
OIE Quality Standard and Guidelines for Veterinary Laboratories, 2008

• Specific interpretation for veterinary laboratories of the ISO/IEC 17025 quality standard for testing laboratory

• Quality management and quality assurance

• To maintain accurate, reliable and safe diagnostic testing (maintain confidence in procedures and test results)
Other related activities
The OIE-PVS Tool and Gap Analyses: the PVS Pathway

Evaluate and improve the Performance of Veterinary Services

based on 46 core competencies

Improve compliance with OIE Standards

Follow-up:
• PVS monitoring
• Gap analyses
• Assistance with legislation
The OIE PVS Pathway

« Treatment »

Specific Activities, Projects and Programs

- Veterinary Legislation
- Public / Private Partnerships
- Veterinary Education
- Laboratories
- PVS Pathway Follow-Up Missions
- PVS Gap Analysis
- PVS Evaluation

incl. VS Strategic Priorities

The OIE collaborates with governments, stakeholders and donors.
The compartmentalisation critical competency

IV-8 Compartmentalisation

The authority and capability of the VS to establish and maintain disease free compartments as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Levels of advancement

1. The VS cannot establish disease free compartments.

2. As necessary, the VS can identify animal sub-populations with a distinct health status suitable for compartmentalisation.

3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free compartments for selected animals and animal products, as necessary.

4. The VS collaborate with their stakeholders to define responsibilities and execute actions that enable it to establish and maintain disease free compartments for selected animals and animal products, as necessary.

5. The VS can demonstrate the scientific basis for any disease free compartments and can gain recognition by other countries that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

Terrestrial Code reference(s):

Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
Chapter 4.3. on Zoning and compartmentalisation.
Chapter 4.4. on Application of compartmentalisation.
Capacity building with OIE Laboratory Twinning

- Sustainable laboratory capacity building to create a better global distribution of laboratory capacity and expertise

- Is a link between an OIE Reference Laboratory or Collaborating Centre (Parent) and a National Laboratory (Candidate) for disease or topic

- To provide support for diseases and topics that are a priority in a region and improve geographical distribution of expertise

- Aims to improve expertise and diagnostic capacity to meet OIE standards

- Supports expertise but not laboratory equipment or construction of laboratory facilities
Guidelines:

Practical minimum biosafety requirements for handling avian influenza viruses in veterinary laboratories


Practical guidance aimed at handling pandemic H1N1 in veterinary laboratories


Aimed at developing country laboratories

www.offlu.net
Collaboration - animal and human health sectors

The FAO/OIE/WHO collaboration: sharing responsibilities and coordinating global activities to address health risks at the animal-human-ecosystems interfaces:

• Build on and secure what has been achieved

• Continue and further develop common training and approaches to guidance

• Develop a common language (biosafety, biocontainment, biosecurity, biorisk)

• Develop common laboratory standards and principles (where appropriate)

• Continue to ensure efficient and safe transport of infectious substances
Collaboration in bioterrorism - animal and human health sectors

Animal disease agents, including those transmissible to humans (zoonoses), have the potential to be used as biological weapons because they have wide economic and social ranging impacts and are readily available.

In addition to its other activities, the OIE continuously cooperates on these matters relating to biological threat reduction, and biosafety with international partners including:

- The Biological and Toxin Weapons Convention (BTWC) and the UN Office for Disarmament Affairs,
- The World Health Organisation,
- The Food and Agriculture Organisation
- The IATA
Eradication of rinderpest

- Destruction of infected animals, traceability, isolation of infected premises, disposal of infective material, disinfection

- VACCINATION

- POLITICAL WILL - internationally concerted efforts

- Official declaration of official global disease freedom expected May 2011

- Risk of reoccurrence?
Beyond rinderpest

- OIE - FAO resolution

- Rinderpest sequestration
  - International oversight by OIE and FAO
  - Contingency plans
    - Approval of minimum no. of repositories
    - Plans for vaccine production, vaccine banks and deployment in case of emergency
    - Biosafety and biosecurity standards
Biosecurity / Biosafety

- OIE activities at regional level
Overview of the SRR activities linked with biosafety and biosecurity

- Work with ASEAN on the Asean Regional Animal Health Information System
- SEACFMD campaign: outbreak investigation training, epinet and labnet, operationalisation of vaccine bank
- PSVS & Identify: focus on lab networking and capacity building
- HPED: training of focal points on OIE standards: notably aquatic animal diseases, animal diseases notification, wildlife, animal production food safety, and coming soon laboratories
- PSVS: added value to the PVS pathway
ARAHIS – OIE ASEAN Regional Animal Health Information System

- Focus on surveillance of endemic diseases,
- Need for greater than 6 monthly reporting as required by OIE for endemics
- Relevant diseases include FMD, CSF and rabies.
- Integrated with SE Asian programs such as FMD as part of monitoring progress.
- Information on countries' capacities including laboratories
<table>
<thead>
<tr>
<th>Country</th>
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<th>Disease</th>
<th>Test</th>
<th>Contact</th>
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<td>Sandwich ELISA</td>
<td>Head Unit Rokiah Omar (Head of Laboratory)</td>
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OIE/AusAID PSVS
HPAI Laboratory Component

PSVS funded by AusAID, main activity supports the PVS Pathway.
HPAI lab component has two parts;
1. Individual visits (sub-contracted to AAHL) and
2. Laboratory networking (funded direct from OIE SRR, technical support from AAHL. Co-hosted with FAO and other partners)
Laboratory Visits

One practical QA training visit and one PT round per national HPAI lab (8) annually by AAHL:

Focus on individual lab gap identification, QA & PT

Simple and sustainable solutions for lab biosecurity advocated (i.e. options with modified BSL2, rather than BSL3)

QA systems early stages for most countries (Vietnam, Thailand have seen good gains, others progressing), PT rounds have provided useful benchmarking for labs, problems have been identified.

Opportunity for more contact through partner activity

Final round of visits have now finished.
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<tr>
<th><strong>Gap Analysis</strong></th>
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**Comment**

- Some Power Problems
- Waste Disposal Disinfection & Sterilisation Spills Bio-safety Guidelines Needed
- LIMS or better excel system needed
- Need for training & budget
- BSCII, PCR & ELISA
- Budget needed for disease investigation
- Training in Trouble shooting & Test analysis
- Need for more staff & experienced staff
- Need training, budget & staff
- Better link between field & lab LIMS Report all results
- Plan needed for outbreak Lab activities

1. Best Practise
2. Some support required (Advice: training, lab workflow & design)
3. Needs support: Training or Budget or Staff
4. Needs support: Staff, Budget and Training Support
5. Needs support: Facilities, Staff, Budget and Training Support
HPAI Laboratory Networking

Co-hosted with FAO, meeting in Sept 09 in Bangkok, last meeting in Ipoh Oct 2010

Developed framework of AI lab support to harmonise activity of partners incl OIE/FAO/USDA.

Practical training session in NIAH, Bangkok

Shipping training

Provided some ad hoc additional support (FAO molecular/H1N1, Asia Pacific Biosafety)
FAO/OIE output: 
Strategic Framework for HPAI labs

Based on assessments
Developed in 2009 and endorsed at HPAI Labnet in Bangkok in September 2009
Good basis for coordinating efforts in HPAI laboratory capacity building – addresses common criticisms
Revisited, updated and tentative planning undertaken at HPAI Labnet Partners in Bangkok on 20-22 July 2010
Has to be followed up for HPAI
Method can serve as a basis for some other disease-based networks.
Way forward under the Identify project of the EPT programme
Conclusions

• Increasing threats
• Importance of standards
• Importance of systems from education to resources
• Importance of coordination between sectors
• Importance of regionally tailor-made approaches
Organisation Mondiale de la Santé Animale
World Organisation for Animal Health
Organización Mundial de Sanidad Animal