

OIE Consultation on Sustainable Laboratories

Executive Summary

On 1-2 March 2018 at OIE Headquarters in Paris, France, 50-60 international experts from Africa, Asia, Europe, the Caribbean, and the Americas convened to discuss ways to improve the sustainability of laboratory biosafety and biosecurity in the broader context of sustainable laboratory systems.

The purpose of the meeting was to:

- Engage the animal health sector in the discussion on sustainable laboratories, which has been on-going for approximately five years
- Share country experiences which highlight challenges and solutions to sustainability
- Consider the compatibility of international guidance and policies with sustainable laboratories
- Set in motion a transformative agenda to improve the sustainability of diagnostic laboratories

From the outset, it was highlighted that functional national veterinary diagnostic laboratories contribute to prosperity, stability, and security within countries and beyond their borders.

Sustainability of the laboratory encompasses the maintenance of essential physical and non-physical elements that are required for safe, secure and effective functioning. Although laboratories vary in their complexity, there are core functions which are common to all.

Case presentations from national experts highlighted some of the difficulties in sustaining a functioning laboratory. These challenges aggregate around common themes, including: equipment calibration and maintenance; acquisition and retention of competent personnel; energy and clean water; consumables and procurement; disposal of waste and effluent; lack of political support for the laboratory; and inadequate operating budget. Biological risk management and quality assurance were thought to be lacking from the working culture in many facilities around the world.

In the context of capacity building, a common scenario had been the construction of a facility (with financial assistance from an external partners) without the subsequent implementation of a long term plan for sustainable maintenance of the laboratory. In some cases, the initial design specification of the facility was not adapted to the local situation making it 'unfit for purpose'. In many cases, the operating budget was inadequate for proper maintenance and everyday functioning of the laboratory.

Sustainable laboratories must be fit for purpose and adapted to the local situation and risks. This includes the laboratory design, location, equipment, human resources, work processes and flows, and biological risk and quality management systems. Laboratories require ongoing investment for operational costs and it is essential that a sustainable business model is in place.

It is acknowledged that it may not be practical or necessary to apply the same standards in all settings since the local context (including risks and resources) varies. However, sustainability should not be seen as a means of relaxing or reducing standards. It is reasonable to suggest that unsustainable laboratories pose a greater immediate and future biosafety and biosecurity risk. Sustainability should be associated with improved laboratory biosecurity and biosafety.

Laboratories are safer and more secure with quality management systems in place. In the same context that sustainable laboratories systems are linked to sustainable biosafety and biosecurity, biosafety and biosecurity are essential components of a quality management system. Integrated management systems (biological risks and quality, among others) allow for important gains to be made by veterinary laboratories in the implementation of OIE standards and will safeguard against accidental or intentional release of infectious agents.

There are a wide range of operational, managerial, engineering and design solutions to improve the sustainability of existing facilities and to optimize the sustainability of laboratories to be built in the future. Some of these solutions are low-cost or low resource; others will require investment but are likely to be worthwhile and to yield financial, livelihoods, health, safety and security benefits for the years to come. Cost benefit analysis will help decision makers see the multiple benefits (in net financial terms) of sustainable financial investments in laboratories, including economic, welfare, health, peace and other benefits. This will be a useful tool to gain political support within countries, which in many cases is lacking.

Since both the public and private sectors are beneficiaries of a functioning laboratory, public-private partnerships may provide opportunities for sustainable investments in laboratories.

The greatest results can be realized if all the public and private stakeholders rally around a common and transformative agenda.

Conclusions:

The meeting, Chatham House, the WHO, and the OIE agreed that the sustainability of laboratories must be improved. Solutions will require a multidisciplinary, multi-sectoral, and collaborative approach.

1. A functioning, appropriately resourced laboratory contributes to prosperity, stability and security at a national, regional and global level.
2. Laboratory facilities (including their infrastructure, engineering, and flexibility of design) must be 'fit for purpose' and thus adapted to the local context and risks.
3. Sustainability of laboratory biosafety and biosecurity, quality management, and business continuity are inextricably linked.
4. Political buy-in, governance of laboratories, and empowerment of laboratory staff are key to the sustainability of a laboratory.
5. Sustainability will be improved by networking and sharing of information and best practices at all levels (local, national, regional, and international).
6. The adoption of risk-based and evidence-based approaches will make a positive contribution to sustainable laboratory biosafety and biosecurity.
7. Creative and open-minded thinking and innovation are key to improving laboratory sustainability. This includes reframing the problem, satisfying basic needs, and reasoning around the functions of the laboratory.
8. A sustainability strategy must also consider sustainable approaches to education, training and retention of competencies.

9. Business models for sustainable laboratories and capacity building benefit from utilising private-public-partnership models, which engage private sector users and suppliers.



The Way Forward

The participants of the consultation agreed that now is the time to set in motion a transformative agenda to improve the sustainability of diagnostic laboratories, and the outputs of the working groups will form the basis of the first step in the way forward and will follow. A summary of central themes discussed, the Consultation agenda and the list of participants in can be found in Annexes I, II, and III, respectively.

Annex I: Central themes related to sustainable laboratory biosafety and biosecurity

Challenges and solutions discussed during the meeting aggregate around common themes. The following aims to summarize some of the main points highlighted in the discussion.

Sustainability

The sustainability of laboratory biosafety and biosecurity, quality management systems, and the overall laboratory system are inextricably linked. Diagnostic laboratories are an essential component of the health system and thus provide benefits for health, productivity, and livelihoods. In the context of security, laboratories safeguard dangerous pathogens which might be used for bioweapons development if they were to fall into the wrong hands.

The essential contribution that laboratory biosafety and biosecurity delivers needs to be understood within a political, social and economic context, so that appropriate resourcing decisions are made to guarantee the efficiency and effectiveness of services provided through laboratory facilities. A measure of success would be financing for biosafety and biosecurity through national budgets, as opposed to by external donor organisations.

In addition, governments and the Veterinary Services should be clear and strategic about what they need and want from laboratories. A 'black box' or 'input/output' view of laboratories, or a project-based approach focused heavily on building technical capability are all insufficient in a sustainable laboratory model. A cultural shift towards functional and optimized laboratories and laboratory networks on a path towards the implementation of OIE standards would be a measure of success.

Operational costs

In general terms, the cost of design and construction of containment laboratories is always considered. This usually includes analyzing the design and construction costs to identify opportunities for introducing efficiencies. However, operational costs of these facilities are often neglected or ignored. This is a significant oversight. In terms of sustainability, the operational costs are the single largest expense of any laboratory, excluding labour costs. Operating costs vary depending on the function of the laboratory space and they generally increase with the level of containment. Operating costs vary over the life span of the laboratory and may increase towards the end of life, when significant refits are required. External environmental conditions have a significant impact on the operating costs of a laboratory. Dramatic environmental fluctuations directly impact on heating and cooling costs.

Often there is significant scope to reduce the costs of operating high containment facilities and economic analyses would assist in identifying where the greatest gains can be made.

If operating costs are not fully considered at the planning phase, the facility can become a significant burden on the health service. Solutions (or 'measures of success' if implemented) can include conducting a costing exercise or pre-assessment (e.g., PVS Laboratory Tool and tool being developed by Chatham House) prior to design and construction and/or cost-benefit analysis of any investment by the national government or external donor organisation, (e.g. new construction, refurbishment, or project-based technical capacity building) so that by the time the Veterinary Services (or public-private partnership) will take over management of this investment, knowledge of costs, advocacy, planning and budget allocations can be foreseen to avoid investments from turning into burdens and risk-laden situations for already low resourced Veterinary Services. Consideration should also be

given to whether a high containment facility is actually needed. Proper and safe inactivation of samples may be one way to reduce the need for high containment diagnostic facilities, thus guidance on inactivation of samples can support sustainable laboratories.

Equipment and consumables

Use of poorly installed or maintained equipment may increase the risk of adverse conditions for safety and security.

Proper installation, certification and servicing of biosafety cabinets (including filter replacement) appears to be a common and widespread barrier to sustainable laboratory biosafety and biosecurity. Problems include unavailability of parts (e.g. new HEPA filters), no local equipment certifiers (they are often located considerable distance away), and the costs of servicing the equipment.

The high cost of freezers and efficiencies of use should be part of a sustainable approach including setting necessary operating temperature and effective sustainable cooling of the space in which they are housed. Freezers are needed for storing diagnostic samples for Quality Assurance, however they are fragile and vulnerable to power cuts. It is not only interruptions to power supply which can create problems, but also fluctuations in voltage.

General solutions include:

- simplifying the design of laboratories (based on biorisk management principles) to avoid installation of equipment which cannot be adequately maintained;
- considering alternative evidence-based biosafety options;
- training and empowering local people to service and calibrate critical equipment;
- regional coordination to increase purchasing power and demand a more competitive price for maintenance and consumables;
- using sensing devices to allow equipment at satellite laboratories to be monitored (remotely) or for technology to allow equipment to self-calibrate or diagnose.
- considering alternative power supply (e.g. solar power).

Availability of chemicals and reagents was also cited as a common problem, often further limited by the high cost. Regional strategies (i.e. cooperatives) which demand a more competitive price may provide solutions.

Design

Design must be fit for purpose, adapted to the local context, and consider current and future requirements of the laboratory. The design should be evidence-based, apply biorisk management principles, and use the latest technology. Although design usually accounts for current working practices, it must also account for future transformations, including the increasing automation of diagnostic work, and the availability of new technology, such as mobile (i.e. pen-side) diagnostic testing and remote monitoring of equipment. The pace of technology change is outstripping architectural design and building standards. As a result, it is a challenge for design codes (rules for the design of a new laboratory) to keep up with laboratory trends (e.g. automation, multi-space environments, refits).

Design considerations to ensure that the laboratory meets the required performance are complex. There is a need to meet statutory needs (e.g. laws around fire, health and safety, dangerous pathogen storage etc.) and non-statutory requirements (e.g. infection control, lab design for

workflow etc.) whilst ensuring that the laboratory also complies with relevant bio-risk management needs. In the decision making process, conflicts may arise (e.g. disability access vs. infection control). Design thus requires extensive consultation to de-conflict issues, prioritize requirements, and manage resulting design risks.

Design solutions and best practices can adapt facilities to low resource settings (e.g. flat pack laboratories, modular laboratories).

Bio-risk management

Risks can never be reduced to zero but they can be reduced to what is deemed an acceptable level based on evidence and local risk assessment.

The WHO and OIE guidance on laboratory biosafety and biosecurity has evolved towards a bio-risk management approach and away from a prescriptive (i.e. biosafety level (BSL 1, 2, 3...)) approach. The bio-risk management approach is consistent with sustainability because it adapts procedures to the local setting and risks. This is particularly important for the animal health sector where risks from handling non-zoonotic high-impact animal disease agents (such as foot and mouth disease virus) vary according to the disease status of the country. Bio-risk management can also more easily be implemented in varying resource settings than the prescriptive approach.

The continued use of terminology referring to BSL 'levels' indicates that the appropriate biorisk management approach has not been universally adopted and therefore more effort is needed in this arena.

Biological risk management requires an evidence base to inform risk assessment and to allow prioritization. In terms of sustainability, an evidence base promotes proportionality, avoiding the prescription of unnecessary procedures or overdesign and allowing resource optimization.

The evidence base also identifies areas for improvement or interventions that provide the most benefit. One study¹ suggests that the majority (72%) of laboratory exposures to human pathogens and toxins can be addressed through standard operation procedures, whilst only a minimum (17%) of exposures occurred through equipment failure. This suggests that significant gains in biosafety and biosecurity can be made by promoting good microbiological practices (which may be supported through certification).

Solutions to improve the sustainability of biosafety and biosecurity include promoting a bio-risk management approach, eliminating the dogma around Risk Groups and Biosafety Levels; focusing on good microbiological practices and procedures; and emphasizing competencies and continuing professional development.

Training and retention of competence

Significant investments are made in training laboratory personnel in biosafety and biosecurity. Challenges to sustaining these competencies include targeting the right people for training in the first place, ensuring that training is effective in transferring required competencies, measuring the

¹ Bienek A, Heisz M, Su M. Surveillance of laboratory exposures to human pathogens and toxins: Canada 2016. Volume 43-11, November 2, 2017: Antimicrobial resistance and One Health. <https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2017-43/ccdr-volume-43-11-november-2-2017/surveillance-laboratory-exposures-human-pathogens-toxins-canada-2016.html?wbdisable=true>

competencies, instilling biological risk management from the earliest stages, and avoiding a competency drain (e.g. ensuring retention of staff).

Various approaches have been used, including train the trainer, on-line training, integration of biosafety and biosecurity into other curricula, and certification of biosafety professionals. Examples include OIE guidelines for competencies of veterinary paraprofessionals working in laboratory diagnosis; train the trainer and Master trainer curricula as presented by African Union (AU)-PANVAC; and certification programme for individuals handling biological materials (International Federation of Biosafety Associations (IFBA)). The OIE is currently in the process of developing accompanying curricula for laboratory veterinary paraprofessionals that will provide guidance to countries on the coursework recommended for veterinary paraprofessionals working in the laboratory setting.

Improvements will require ongoing investments and innovation in training techniques, with a focus not only on training, but on secondary and post-secondary education and continuing education. Gains are likely to be incremental in nature.

The role of the private sector and public private partnerships (PPP)

Private sector actors with a stake in laboratories include users (e.g. livestock producers and exporters) who benefit financially from a well-functioning laboratory which supports their industries, and suppliers of equipment, services and consumables who have a vested interest to ensure continuity of their businesses. There are various models for engaging the private sector and for public-private partnerships and it is important to consider the local dynamics and maintain appropriate regulatory oversight.

Privatization of services which support the laboratory (e.g. local servicing, maintenance and certification of equipment), with appropriate oversight, may also provide incentives to train and equip local staff.

Public private partnership may also extend to QMS accreditation and certification bodies where services are delivered through a network or consortium.

By forming regional networks or cooperatives, laboratories may be able to increase their purchasing power for consumables and services, better positioning them to make 'deals' with private sector suppliers.

Innovation

A number of technologies being used every day in the laboratory were developed for use by other sectors. Open Innovation looks outside of the sector for solutions, aiming to overcome silos and secrecy. Open Innovative may provide solutions to fix some of the remaining obstacles to sustainability laboratory systems. To engage other sectors it is useful to reframe the problem so that it appears more familiar to the new sector. Mechanisms include actively searching for specific technologies in non-traditional sectors and/or holding Open Innovation competitions or 'Grand Challenges'.

Innovation is not only restricted to engineering and technologies but also to procedures, training and management.

Annex II: Meeting Agenda

CONSULTATION ON SUSTAINABLE LABORATORY BIOSAFETY AND BIOSECURITY

OIE Headquarters, Paris (France), 1-2 March 2018

• SALON VITTOZ •

MARCH 1		
Session 1	Introduction	
09.00	Welcome	(Stone)
	Objectives of the meeting	(Harper/Hamilton)
Session 2	Perspectives	
09.30	Country perspectives (8 Member Countries, responding to set of questions)	Chair: Harper
	<ul style="list-style-type: none"> ○ Challenges to sustainable laboratory biosafety and biosecurity ○ Challenges to maintaining quality management ○ Challenges to infrastructure and engineering ○ Funding model and challenges related to financial sustainability 	
	Donor perspective: experiences with planning, construction, maintenance and operations	(20 min.) (Smith)
	The Cape Town experience – biosafety and biosecurity in a drought	(20 min.) (Roberts)
	Facilitated panel discussion to tease out the challenges related to sustaining the overall laboratory system	
13.00-14.00	Lunch	
Session 3	Adapting to an evidence-based risk management-approach	
14.00	Biological Risk Management	(15 min.) (El Harrak)
	Evidence base for biosafety and biosecurity procedures	(20 min.) (Kojima)
	Sustainable Laboratories for High-Consequence Pathogens	(15 min.) (Harper)
	Chronology of events in the sustainable laboratories initiative	(10 min.) (Sheeley)
	Discussion (15 minutes)	
15.15-15.45	Coffee	
Session 4	Sustainability models	
15.45	Making sustainability an option	(30 min.) (Davies)
	Costs associated with running high containment laboratories	(20 min.) (Clavijo)
	Assessment of demand for laboratory services: OIE Performance of Veterinary Services Laboratory Tool	(20 min.) (Lasley)
	Facilitated discussion to reflect on the outcomes of Day 1	
MARCH 2		

Session 5	Innovation	Chair: Dieuzu Labaye
9.00	Innovative solutions in the field setting (20 min.)	(Yingst)
	Supporting innovative solutions for sustainability of laboratories in Africa (20 min.)	(Nwankpa)
	The role of Open Innovation (20 min.)	(Ferran)
	Design of Sustainable Laboratory Environments – Trends and Environmental Considerations’ (20 min.)	(Astley)
	Discussion	
10.30	Coffee	
Session 6	Group work	
11.00	Instructions	(Hamilton/Lasley)
	Group 1: Biosafety and biosecurity (Salon Leclainche)	Diaz/Kojima
	How do the OIE standards on biosafety and biosecurity complement Chatham House’s initiative ‘Safe and secure biomaterials’?	
	Are the biosafety and biosecurity procedures in your laboratory or in your experience based on evidence?	
	Give examples of which procedures are evidence-based and which are not	
	How can evidence-driven biosafety and biosecurity measures be applied (identification, assessment, management, communication)?	
	What are some operational solutions to sustainable biosafety and biosecurity implementation in the laboratory setting?	
	What are some engineering solutions to sustainable biosafety and biosecurity implementation in the laboratory setting?	
	Group 2: Sustainability (Salon Blajan)	Davies/Sheeley
	What outcomes can be reached if financial sustainability of the laboratory is achieved?	
	How can a sustainable veterinary laboratory influence the larger Veterinary Services in achieving its goals?	
	What is the relationship between financial sustainability, Quality Management Systems and biosafety and biosecurity in the laboratory?	
	What economies of scale can be made by thinking about the laboratory system (national or regional) in addition to individual laboratories?	
	How can the OIE PVS Laboratory Tool better approach challenges and provide an output that is directly useful for Member Countries, Donors and Partners?	
	Group 3: Operational and engineering solutions to laboratory sustainability (Salon Vittoz)	Cattoli/Astley
	What impact do operational issues (sample flow, procurement, work flow management, etc.) have on laboratory sustainability?	
	What impact do engineering issues (electricity, water, equipment, etc.) have on laboratory sustainability?	
	What solutions and resources already exist to address these issues?	
	How can laboratories take advantage of these solutions?	
	Group 4: Innovation (14er 2eme Etage)	Dieuzu Labaye
	What are the priorities for innovative technology to reduce laboratory costs and overheads and ensure sustainable resources for the laboratory?	
	How could such Research & Development be funded (in the absence of significant commercial benefit for developers from solutions)?	

Do models exist? Give examples of success stories

What arguments can be made for the implementation of new, innovative solutions, if confronted by resistance?

Group 5: Quality Management Systems (14er 1er Etage) Lasley

How can quality management systems contribute to sustainable laboratories and laboratory systems?

What is the relationship between quality management systems and biosafety and biosecurity implementation?

What arguments can be made for the implementation of QMS, if confronted by resistance?

13.30-
14.30

Lunch

Session 7

Facilitated discussion to reflect on the outcomes of Session 6

Lasley/Kojima

14.30

Feedback from group work

Conclusions and next steps

Hamilton/Harper

15.30

Are Chatham House, WHO, OIE aligned in their approaches?

What were the greatest challenges identified in Session 2?

Is there agreement that biosafety and biosecurity is inextricably linked to sustainability of a laboratory, the laboratory system, and the Veterinary Services in a country?

How can approaches to laboratory policies and capacity building be enhanced to improve sustainability?

How can innovative solutions attempt to solve the greatest challenges identified in Session 2?

How to fund research programme for innovation? (Subsidise? R and D blueprint model?)

How can CH, OIE, WHO and other partners stimulate innovation and the uptake of innovative solutions – competition etc.

What is feasible/realistic in terms of capacity building/implementation? How far can this go?

Annex III: List of Participants

CONSULTATION ON SUSTAINABLE LABORATORY BIOSAFETY AND BIOSECURITY

OIE Headquarters, Paris (France), 1-2 March 2018

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