World Health Organization

REGIONAL OFFICE FOR Africa

Report on the Status of EDPLN BSL-3 in Select Countries in the African Region

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Abbreviations

ACDP	UK Advisory Committee on Dangerous Pathogens
AFRO	World Health Organization Regional Office for Africa
AFR	African Region
BMBL	US Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological Safety Cabinet
BSL-3	Biological Safety Laboratory, Level 3
CCHF	Crimean-Congo Haemorrhagic Fever
CDC	US Centers for Disease Control and Prevention
EDP	Emerging and Dangerous Pathogens
EDPLN	Emerging and Dangerous Pathogen Laboratory Network
EU	European Union Directive 2000/54
EVD	Ebola Virus Disease
GISRS	Global Influenza Surveillance and Response System
GPLN	Global Polio Laboratory Network
HEPA	High-Efficiency Particulate Air
HVAC	Heating, Ventilation, Air Conditioning
IHR (2005)	International Health Regulations (2005)
JICA	Japan International Cooperation Agency
NICD	National Institute for Communicable Diseases
PEPFAR	The United States President's Emergency Plan for AIDS Relief
PPE	Personal Protective Equipment
RVF	Rift Valley Fever
SOP	Standard Operating Procedures
VHF	Viral Haemorrhagic Fever viruses
WHO	World Health Organization
WHO LBM	World Health Organization Laboratory Biosafety Manual

Executive summary

The African region experiences around 100 public health events annually, of which 80% are caused by infectious diseases. Although only a portion of these public health events are caused by emerging and dangerous pathogens (EDP), recurring outbreaks of diseases such as Ebola Virus Disease (EVD) and Dengue Fever/Dengue Haemorrhagic Fever are a feature of the regional situation.

The WHO Emerging and Dangerous Pathogen Laboratory Network (EDPLN) in Africa aims to provide a diagnostic service for a range of pathogenic agents Due to the dangerous nature of these organisms, a safe laboratory environment, such as a Biosafety Level 3 (BSL-3) laboratory, is required to conduct some diagnostic procedures. This laboratory must be designed to ensure that the staff and surrounding area are protected from the agents handled within and must be able to be run in a sustainable fashion. The presence of a BSL-3 laboratory in a country, whether human or animal, is a valuable resource as it provides diagnostic capacity during outbreaks and in-between outbreaks.

The requirements for such laboratories were originally defined in the WHO Laboratory Biosafety Manual (WHO LBM), which was first published in 1983. Additionally, many countries have established regulatory frameworks to further define these laboratories and produced guidance documents or legislature specifying their design features and requirements. However, these activities have tended to be led by developed countries whose laboratory features include specifications that require a high degree of technical expertise to construct, maintain and re-certify. Although these solutions work well in countries with a developed bio-containment infrastructure, they may be impractical for countries, which have greater financial constraints, and lack infrastructure and trained personnel.

The Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region was created to meet the needs of the WHO AFRO Emerging and Dangerous Pathogen Laboratory Network (AFR EDPLN) and provides information on the design, construction and commissioning of bio-containment laboratories for the diagnosis of a range of emerging viral pathogens. The Assessment Tool document contains a laboratory assessment tool, which provides a framework for the assessment of BSL-3 laboratories.

Following trial assessments in Ghana, Uganda and Kenya, the tool was revised to better fit its purpose. The final version was sent to the remaining AFR EDPLN laboratories to survey the status of BSL-3 laboratories in the Region. This document reports on the status of the 13 AFR EDPLN laboratories.

Background

The International Health Regulations (2005) (IHR (2005)) is a global legally binding document requiring that national, regional and international capacities are in place to manage public health events and emergencies in a collective, coordinated and effective manner.1 The Regulations contain obligations and procedures needed to ensure global health security. The latest revision, the IHR (2005), was adopted by the Fifty-Eighth World Health Assembly on 23rd May, 2005 and entered into force on 15th June, 2007. The IHR (2005) require that State Parties develop, strengthen and maintain core capacities for surveillance and response. One of those core capacities is to provide support through "… laboratory analysis of samples (domestically or through collaborating centres) and logistical assistance (e.g. equipment, supplies and transport)" during a public health response.

The Global Polio Laboratory Network (GPLN) and the Global Influenza Surveillance and Response System (GISRS) were created, in part, to provide laboratory diagnostics for polio identification and monitoring the evolution of influenza viruses, respectively. These networks have allowed countries to establish the necessary laboratory infrastructure and train personnel in diagnostic techniques applicable to any pathogen.

With the increase in the manipulation of emerging and dangerous pathogens (EDP), containment laboratories were constructed to 1) to protect the laboratory worker from a pathogen and 2) to provide safeguards to protect the environment and community from the pathogen by prevention of its escape from the laboratory. Biosafety Level 3 (BSL-3) laboratories are a type of containment laboratory used by institutions working with risk group 2 or 3 biological pathogens where there is a serious risk of infection to humans, animals or plants. The BSL-3 provides safeguards, which minimize the risk of infection to individuals, the community and the environment. The presence of a BSL-3 laboratories in countries, whether human or animal, is/are valuable resources as if well equipped and maintained they provide diagnostic capacity during outbreaks and in-between outbreaks

The requirements for such laboratories were originally defined in the WHO Laboratory Biosafety Manual (WHO LBM) which was first published in 1983.2 Additionally, the United States of America (USA), Canada, European Union, France, Germany, the United Kingdom (UK), and South Africa have established regulatory frameworks to further define these laboratories and produced guidance documents or legislature specifying their design features and requirements.3-13 Some of the key design and operational features that are common among specifications and guidelines from selected countries are outlined in Table 1.

Since these activities have tended to be led by developed countries, laboratory features include specifications that require a high degree of technical expertise to construct, commission, maintain, repair and re-certify. Although these solutions work well in high-income, technologically-advanced countries with a developed bio-containment infrastructure, which may be impractical for countries that have greater financial constraints, and lack infrastructure and trained personnel.

Table 1. Design and operational features among selected BSL-3 documents

Requirement	BSL-3 Guidance Documents			
	WHO LBM[a]	BMBL[b]	UK ACDP[c]	EUd
Separation of the laboratory	Y	Y	Y	R
International biohazard warning symbol and sign displayed on laboratory access doors	Y	Y	Not specified	Y
Anteroom	Y	Y	Not specified	N
Surfaces are impervious to water (bench, floor, walls and ceilings), resistant to chemicals (acid, alkali, solvents) and gaseous agents (bench, floor) and are easy to clean	Y	Y	Y	Y
Sealable for decontamination, including sealed windows and any penetrations in the surface	Y	Y	Y	R
Sealable to prevent the entry and exit of invertebrates and rodents/Pest management system in place	Y	Y	Y	Y
Hand wash sink located in laboratory (hands-free or automated)	Y	Y	Y	N
Inflow of air/laboratory under negative pressure to atmosphere	Y	Y	Y	R
Exhaust air HEPA filtered	Y/N^	Y/N^	Y	Y
Biological Safety cabinets/primary containment equipment	Y	Y	Y[#]	Y[#]
Autoclave in laboratory	Y[β]	Y[β]	Y	Not listed
Using PPE	Y	Y	Y	Y
Access restricted	Y	Y	Y	Y

Y=Yes, N=No, R=Recommended

[a]WHO Laboratory Biosafety Manual (WHO BM), [b]US Biosafety in Microbiological and Biomedical Laboratories (BMBL),[c] UK Advisory Committee on Dangerous Pathogens (UK ACDP) [d]EU: EU Directive 2000/54

1. Introduction

1.1 Laboratory containment in the region

The African region (AFR) experiences around 100 public health events annually, of which 80% are caused by infectious diseases. Although only a portion of these public health events are caused by EDP, recurring outbreaks of diseases such as Ebola Virus Disease (EVD), Marburg Virus Disease, Lassa Fever, Rift Valley fever (RVF), Crimean-Congo Haemorrhagic Fever (CCHF), Lujo Haemorrhagic Fever and Dengue Fever/Dengue Haemorrhagic Fever are a feature of the regional situation.

During the past 10 years, laboratory capacity in the region has progressively improved due to a heightened awareness of the need for laboratory capacity, and the strengthening and expansion of the GPLN and GISRS. However, the Ebola virus disease outbreak (2014-2015) highlighted significant gaps in regional laboratory capacity. In the African region, only a few countries have the capacity, in terms of technical ability and laboratory infrastructure, for the diagnosis of EDP outbreaks, in particular viral haemorrhagic fever viruses (VHF).

To fill this gap, in 2010, the World Health Organisation Regional Office for Africa (AFRO) established an Emerging and Dangerous Pathogens Laboratory Network (AFR EDPLN). AFR EDPLN is a network of high containment diagnostic laboratories able and willing to collaborate and share knowledge, biological materials and experimental research results in real time. The goal of the AFR EDPLN is to improve preparedness and response to EDPs by enhancing diagnostic capabilities and providing better access to a range of tests for EDP, notably VHFs, facilitating a more rapid response and improved outbreak control processes. The network also aims to increase regional capacity by: 1) facilitating the sharing of techniques, samples and strains; 2) moving towards a standardized approach to diagnostic testing; and 3) establishing an External Quality Assessment scheme and a regional biobank.

The network currently is comprised of 14 national EDP reference laboratories (in Algeria, Cameroon, Central African Republic, Côte d'Ivoire, Democratic Republic of Congo, Gabon, Ghana, Kenya, Madagascar, Nigeria, Senegal, Sierra Leone, South Africa and Uganda). (Figure 1). EDP reference laboratories are national institutions designated by Ministries of Health and recognised by the World Health Organization (WHO) for the purpose of participating in the work of the WHO regional EDPLN.

Figure 1. AFR EDPLN Countries

WHO is acting to ensure that a sustainable contribution can be made to the reduction of morbidity and mortality caused by EDPs in Africa, by enhancing the capacity of the AFR EDPLN. Following the outcome of the regional training on laboratory diagnosis of EDPs at the National Institute for Communicable Diseases (NICD), South Africa in September 2012 and the meeting of the Heads of EDP laboratories in Harare in May 2013, a number of documents were developed aimed at providing Member States with guidelines and tools for building laboratory capacity for EDP with a view to joining the EDPLN and in turn building regional capacity. A draft laboratory assessment tool was discussed and revised in Brazzaville in July 2015. Pilot assessments were performed prior to finalizing the tool.

1.2 The need for adequate containment laboratories in the African region

The Region experiences over 80 infectious public health events annually. A robust, reliable and resilient network of laboratories with the capacity to detect EDP is needed so that the Region is better prepared to detect and respond to future threats to regional health security. Currently, there are 14 laboratories that are members of the AFR EDPLN but there is a need to increase this number to further strengthen regional capacity.

The Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region aims to meet the needs of the AFR EDPLN by providing Member States with information on the design, construction and commissioning of bio-containment laboratories for the diagnosis of a range of emerging viral pathogens such as Marburg, Ebola, Lassa fever, Rift Valley fever, Lujo, Crimean-Congo haemorrhagic fever and Dengue viruses. The strength of the document is that it focuses on building containment laboratories in a low resource context and provides guidance on biosafety and biosecurity requirements that can be easily met in a resource-limited environment. The document also contains a laboratory assessment tool to assess the infrastructure of BSL-3 laboratories.

1.3 Challenges to achieving containment laboratories in the African Region

There is a need to increase the number of member laboratories within AFR EDPLN to improve preparedness and response to EDPs. However, significant challenges prevent the expansion of the network. These include absent or poor: policies and regulations; infrastructure (within the laboratory and within the country); reagents and supply chains; and trained personnel.

Most of the laboratory specifications and standards developed are by well-resourced countries with technical advancements to create complex laboratories despite the fact that appropriate containment of dangerous pathogens and worker safety can also be attained using simpler and more economically viable conditions. These requirements would be impractical for countries, which have greater financial constraints, lack infrastructure and trained personnel. The adoption of specifications and standards based on a country's needs assessment and its capacity to fulfill regulations is considered the best approach in any country, especially in middle and low-income countries. The Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region is a starting point for low-resource countries to identify requirements that can be easily met without unsustainable operation and maintenance needs. AFRO conducted surveys of the 11 AFR EDPLN laboratories to determine the status of existing BSL-3 infrastructure.

2. Objectives and expected results

The overarching goal of this this project, the development and implementation of the BSL-3 Assessment Tool, is to contribute to the enhancement of regional capacity to detect emerging and dangerous pathogens and to expand the laboratory network in the African region.

General Objective

The main objective of this work is to provide a comprehensive update on the status of BSL-3 capacity in the region based on the laboratory assessment tool, and to further define the regional laboratory capacity to detect EDP. Additionally, this report and the above mentioned document, The Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region will serve as a comprehensive guide to other countries on strategies and methodologies for improving containment laboratory capacity.

Specific Objectives

- To identify strengths, weaknesses and opportunities for improvement
- To use the data analysis to further refine the assessment tool for future use.
- To make recommendations for improvement of BSL-3 capacity and expansion of the AFR EDPLN.

Table 2. Date and Team Composition of Laboratory Assessment Missions

3. Methodology

3.1 Tool used for the survey

The BSL-3 laboratory assessment tool (Annex 1) contained within the Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region was developed following the regional training on laboratory diagnosis of EDP at the NICD (South Africa, September 2012), the subsequent meeting of the heads of EDP laboratories (Harare, May 2013) and a meeting to review the draft assessment tool and formulate a process for data collection (Brazzaville, July 2015). The laboratory assessment tool aims to evaluate laboratories for their ability to provide a safe environment for the detection of EDP.

The laboratory assessment tool is divided into 12 sections:

1) General laboratory information
2) Standards, regulations and guidelines for laboratory design and construction
3) Oversight mechanisms
4) Existing BSL-3 laboratories in the country
5) Laboratory use and funding
6) Laboratory entry
7) Laboratory finishes, sealability and equipment
8) HVAC systems and BSC
9) Waste and disinfections
10) Documentation and roles
11) Maintenance and certification
12) Availability of expertise in design, construction, commissioning and maintenance of laboratories and key equipment

These sections can be broadly grouped as follows:

1) Laboratory Overview, Including Funding and National BSL-3 Capacity
2) BSL-3 Design, Construction, Certification, Regulation and Standard Operating Procedures
3) Physical Infrastructure and Equipment
4) Work Processes
5) Facility Maintenance

The data will be presented under the five broad components mentioned above. Annex 2 refers to the specific questions grouped under the five broad components.

3.2 Data collection and sample size

The assessment tool document was shared with 13 laboratories within eleven (11) countries (Algeria, Central African Republic, Cameroon, Gabon, Ghana, Kenya, Madagascar, Nigeria, Senegal, South Africa and Uganda) in the AFR for completion. The sample size was 11 if the question related to a national perspective, and 13 if the question related to features of individual laboratories.

Assessment missions were conducted in laboratories in Ghana, Kenya and Uganda by a team consisting of WHO staff and external laboratory experts as indicated below (Table 2).

All other laboratory assessment surveys were completed electronically. Completed surveys were forwarded to AFRO where the data was compiled and analysed.

Country	Laboratory	Assessment Team	Mission date (2015)
Ghana	Noguchi Memorial Institute for Medical Research	Dr Coulibaly Sheick Oumar (WHO, AFRO) Dr Rosemary Sang (KEMRI, Kenya) Dr Julius Lutwama(UVRI, Uganda) Dr Allan Bennet (PHE, UK)	5–9 October
Kenya	Kenya Medical Research Institute (KEMRI)	Dr Jean-Bosco Ndihokubwayo (WHO, AFRO) Professor Janusz Paweska (NICD, South Africa) Professor Nigel Silman (PHE, UK) Professor Sunday Aremu Omilabu (Lagos, Nigeria) Dr Emmanuel Nakouné Yandoko (IPB, Central African Republic)	9-13 November
Uganda	Uganda Virus Research Institute (UVRI)	Heather Sheeley (PHE, UK) Dr Richter Razafindratsimandresy (Institut Pasteur, Madagascar) Dr Richard Njouom (Institut Pasteur, Cameroon) Dr R Kazunobu Kojima (WHO, HQ, Geneva)	19-23 October

3.3 Data quality and analysis

The surveys received from countries were examined for completeness and the data compiled. If gaps in responses were identified, contact was made with the relevant laboratory to complete the parameter if it was blank or to clarify a response if necessary. A descriptive analysis was performed to describe the current status of BSL 3 laboratories in the 11 countries surveyed

4. Outcomes

All 13 laboratories within the 11 countries completed the questionnaire.

4.1 Laboratory overview including funding and National BSL-3 capacity

Names and locations of BSL-3 laboratories that completed the survey are listed in Table 3. Descriptions of the laboratories, as reported, are contained in Annex 3.

Seven countries reported the presence of additional BSL-3 laboratories in their countries. Countries reported a mix of entomological, human and animal laboratories. Five countries reported that additional BSL-3 laboratories are planned or are being constructed, with many to be completed by 2019.

With regards to funding, the majority (9/13) of laboratories indicated more than one funding source. National governments are the major source of funding (10/13) while 62% (8/13) of laboratories also indicated foreign organisations as a source of funding. Three laboratories indicated only one funding source. Of the three laboratories, two are funded by the government and one is solely funded by a foreign organization. Other funding sources for laboratories include the French Ministry of Health, US Centers for Disease Control and Prevention (CDC), Japan International Cooperation Agency (JICA), Institut Pasteur, African Development Bank, Volkswagen Foundation (Germany), The United States President's Emergency Plan for AIDS Relief (PEPFAR) and WHO.

In line with the reported source of funding, the majority (10/13) of laboratories are affiliated with government ministries, in particular the Ministry of Health or its equivalent. Three laboratories have private non-profit partnerships with the Ministry of Health (Table 4). Institutions responsible for the laboratory construction, maintenance and salary of staff varied. Most (7/13) were funded by a mix of national government, private and foreign organisations. Only two laboratories were solely funded by the national governments.
Other entities such as the JICA, PEPFAR, US CDC and Institut Pasteur and independent consultants have been responsible for the laboratory construction and maintenance, and the salary of staff in some countries.

Table 3. Names and locations of laboratories that completed the survey

Country	Name of Laboratory Assessed	Location	Date opened
Algeria	BSL3-laboratory, Virology Department, Institut Pasteur	Algiers, Algeria	2014
Cameroon	Pathogen Level 3 Facility, Centre Pasteur du Cameroun, the National Reference and Public Health Laboratory	Yaounde	2003
Central African Republic	Pathogen Level 3 Facility, Arbovirus, Haemorrhagic fever viruses, Emerging viruses and Zoonoses laboratory, Institut Pasteur	Bangui, Central African Republic	2011
Gabon	Centre International de Recherches Médicales de Franceville	Franceville, Gabon	1997
Ghana	Pathogen Level 3 Facility, Noguchi Memorial Institute for Medical Research (NMIMR), University of Ghana, Legon	Accra, Ghana	1999
Kenya	BSL-3 Laboratory, Centre for Virus Research, Kenya Medical Research Institute (KEMRI)	Nairobi, Kenya	1999
Madagascar	Pathogen Level 3 Facility, Virology Unit, Institut Pasteur de Madagascar,	Antananarivo, Madagascar	2008
Nigeria	BSL-2 with glove box, Virology Research Laboratory, Central Research Laboratory, College of Medicine of the University of Lagos and Lagos University Teaching Hospital.	Lagos, Nigeria	1992
Senegal	Pathogen Level 3 Facility, virology unit, Institut Pasteur, Dakar, ,	Dakar, Senegal	2000
South Africa	1. Centre for TB – BSL-3 Facility (CTB) 2. Centre for Respiratory Diseases and Meningitis – Virology BSL-3 Facility (CRDM) 3. Centre for Emerging and Zoonotic Diseases – Special Bacterial Pathogens Reference Laboratory BSL-3 Facility (CEZD-SBPRL)	Johannesburg, South Africa	2010 2013
Uganda	Highly Pathogenic Viral Diseases Diagnostic Laboratory, Uganda Virus Research Institute (UVRI)	Entebbe, Uganda	2008

Table 4. Source of funding and affiliation of laboratories

Number of laboratories	Sources of funding*			
	Government	Private institution	Foreign organization	Other
	10	4	8	3
	Laboratory affiliation			
	Government		Private institution	
	10		3	

4.2 Design, construction, certification, regulation and standard operating procedures of BSL-3 laboratories

Only one country among the 11 surveyed has developed national standards for the design, operation and construction of BSL-3 laboratories. They have also developed the biosafety and biosecurity aspects of handling hazardous infectious agents and genetically modified organisms.

All laboratories that completed the survey indicated that they use international guidelines for BSL-3 design and construction, and that they follow the WHO Laboratory Biosafety Manual. Six laboratories indicated that they use additional guidelines such as the Canadian Biosafety Standard and Japanese legislation (Table 5).

Table 5. Standards and International Guidelines Used for BSL-3 Design and Construction

Number of laboratories	Are international guidelines for BSL-3 design and construction followed?			
	Yes		No	
	13		0	
	International guidelines followed#			
	WHO LBM^	US BMBL*	UK ACDP**	Other
	13	3	0	6

Individual laboratories may use more than one document for guidance
^ WHO Laboratory Biosafety Manual
* US Biosafety in Microbiological and Biomedical Laboratories (BMBL)
** UK Advisory Committee on Dangerous Pathogens (UK ACDP)

Ten out of 11 countries indicated that they have access to expertise for the design, construction and maintenance of BSL-3 laboratories (Table 6). One country contains a glove box within their BSL-2 facility, therefore this question was not applicable. Of the ten countries, only one reported that they are able to obtain all expertise nationally. The remaining nine countries used a mix of national and international sources for expertise in one or more of the functions. Freelance biosecurity experts as well as the following institutions have provided technical guidance/expertise for the design and construction of laboratories in the region: CDC, Bernard Nocht Institute for Tropical Medicine (Hamburg Germany), University of Hohenheim (Stuttgart, Germany), GermFree (USA), Labover (France), Institute of Immunology (Luxembourg),

Table 6. Source of technical expertise for the design, construction and maintenance of BSL-3 laboratories by number of country*

Expertise	Source of expertise		
	National	National/International	International
HVAC engineers	7	1	2
Safety cabinet testers	5	2	3
Filter testers	5	1	4
Autoclave engineers	5	1	4
Laboratory designer	3	1	6
Specialist architects**	4	1	4

* One country contains a glove box within their BSL-2 facility, therefore this question was not applicable

** Missing data from one country

Table 7 presents the oversight mechanisms reported by the laboratories surveyed. Certification of laboratories to handle high-risk pathogens is recognition that the laboratory can achieve containment of the organism and the appropriate safety measures required for individuals working with the pathogen. Twelve laboratories reported to have a process in place for laboratory certification. One laboratory contains a glove box within their BSL-2 laboratory and therefore questions regarding certification do not apply. Most laboratories (9/12) utilised the services of an external consultant for certification of laboratories. The certification process for one laboratory is driven by the government in conjunction with WHO, and for two laboratories, WHO or their institution drives the process.

Table 7. Oversight mechanisms for BSL-3 laboratories

Number of laboratories	**Is there a process for laboratory approval and certification?***				
	Yes			No	
	12			0	
	Body that approves and certifies the laboratory**				
	Government	External consultant	Funder	International organization	Other
	1	9	1	2	3
	Regular inspection/audit of containment laboratories?				
	Yes			No	
	10			3	
	Body that inspects/audits the laboratory**				
	Government	External consultant	Funder	International organization	Institutional
	0	6	2	2	7
	Periodicity of inspection/audits				
	Six-monthly		Yearly		Other
	0		4		6
	Are there written risk assessments?				
	Yes			No	
	10			3	
	Personnel that approves risk assessments#				
	Laboratory scientist	Principal investigator	Institute/ University biosafety officer	Laboratory management	Regulator
	2	3	4	5	0

* One laboratory contains a glove box within their BSL-2 laboratory and therefore this question and related questions do not apply.
** Individual laboratories may have more than one body that approves/ certifies/inspects the laboratory
# Individual laboratories may have more than one type of personnel that approves risk assessments

For most laboratories (10/13) there are regular audit/inspections of the laboratory. The majority of laboratories employed a combination of sources of experts for laboratory inspections (6/13). The most common combination of experts was an external consultant with an institutional inspector (3/6). No laboratory had a government body inspect/audit their laboratory. The time interval between inspections varied, with 24 months reported as the longest interval. One laboratory indicated that regular inspections did not take place and one indicated that inspections did occur but they were intermittent.

Ten laboratories (10/13) reported that written risk assessments were available. Two laboratories indicated that they are in the process of preparing written risk assessments. Three laboratories used a combination of personnel to approve risk assessments, while others relied on the institutional biosafety officer (2/10), laboratory scientist (1/10), principal investigator

(1/10) or laboratory management (3/10) as the sole approver. No laboratory surveyed reported approval by a regulator. All laboratories reported having standard operating procedures (SOP) or other detailed procedures available.

In regard to certification of equipment, biological safety cabinets (BSC) require regular inspection and certification so that they remain within performance specifications and provide protection to users. There are a number of standards that can be used for certification of safety cabinets. The two most common standards used by the laboratories assessed were the 1) NSF/ANSI49 (7/13) and 2) EN12469:2000 (8/13) (Table 8). Some laboratories used a combination of both standards and one facility relied on an external consultant so the standard that is employed was not known.

Table 8. Standards for Biosafety Cabinet certification*

Number of laboratories	Standards for certification					
	NSF/ANSI49	EN12469:2000	AS 2252	JIS K 3800	Don't Know	Other
	7	8	0	0	0	4

* Individual laboratories may use more than one standard for certification

The majority of laboratories reported having a sign on the external door to the facility indicating the presence of bio-hazardous agents (11/13) and contact details of the laboratory manager/supervisor (9/13). Laboratories that did not have these in place indicated that this would be rectified in the near future. Additionally, all laboratories indicated that entry criteria to the laboratory were specified (Table 9).

Table 9. Laboratory signage in place among laboratories surveyed

Number of laboratories	Biohazard sign on the door of the laboratory?	
	Yes	No
	11	2
	A sign indicating contact details of the laboratory manager/supervisor?*	
	Yes	No
	9	3
	Laboratory entry criteria specified?	
	Yes	No
	13	0

* Missing data from one laboratory

4.3 Physical Infrastructure and equipment

The physical infrastructure of the laboratory relates to all the physical and engineering facets of the laboratory, from the laboratory footprint/floor plan and location to the air system and finishes inside the laboratory. This section can be further divided into Air flow, water, layout and internal features of the laboratory.

Air flow management

The aim of negative pressure or directional air flow is to ensure that any aerosols produced in the laboratory do not escape from the laboratory through the door or walls, even when doors are opened.

All but one laboratory (12/13) indicated that there is directional airflow into the containment facility and that there is a pressure differential between the containment laboratory and the outside environment (Table 10). One laboratory contains a glove box within their BSL-2 facility, therefore this question was not applicable. Various mechanisms of monitoring the pressure and air-flow were described such as pressure gauges and water manometers. All laboratories reported using a heating, ventilation and air conditioning (HVAC) system to achieve directional airflow and that this system was alarmed for positive pressurisation. The one exception was the laboratory that did not have directional airflow or a pressure differential (BSL-2 laboratory with glove box) as it was not applicable.

Considerations of exhaust air from a BSL-3 facility are two-fold. Firstly, the exhaust system must not be located close to air conditioning intake sites and secondly the exhaust air must be safely discharged into the environment, meaning free of any organisms that may cause disease. In this regard, all laboratories reported that the exhaust system did not affect the air-flow balance in the containment area thereby maintaining an undisrupted air flow to BSC and ensuring worker safety.

Regarding the safe discharge of laboratory exhaust air, all laboratories indicated that exhaust air was filtered prior to discharge into the environment. In most cases air was passed through filters of increasing stringency in a series, with the final filter a high-efficiency particulate air (HEPA) or absolute filter. One laboratory indicated that the filters were housed in a bag-in-bag-out change housings with an integral test system.

Table 10. Description of BSL-3 laboratory air flow management *

	Pressure differential between the inside and outside of the laboratory?	
	Yes	No
Number of laboratories	12	0
	Directional airflow into the laboratory?	
	Yes	No
	12	0
	Does the laboratory exhaust air affect the room's air balance?	
	Yes	No
	0	12
	Is laboratory exhaust air HEPA filtered?	
	Yes	No
	12	0
	Is the HVAC system alarmed for positive pressurization?	
	Yes	No
	12	0

* One country contains a glove box within their BSL-2 facility; therefore these questions are not applicable

Laboratory layout and construction features

All but one laboratory (12/13) indicated the presence of an anteroom which are separated from other laboratory activities (Table 11). One laboratory contains a glove box within their BSL-2 facility therefore this question was not applicable. In cases where an anteroom was present, most laboratories (11/12) indicated that the laboratory doors were interlocked. Annex 4 presents an example of a BSL-3 laboratory layout from Institut Pasteur Madagascar.

As a component of the assessment tool the presence of a break out panel/emergency exit is considered. The majority (10/13) of laboratories indicated that they had an emergency egress mechanism (e.g break out panel or emergency button that opened all laboratory doors).

Table 10. Description of BSL-3 laboratory air flow management *

	Is BSL-3 separated from other laboratories?*	
	Yes	No
	12	0
	Is there an anteroom to the BSL-3?*	
	Yes	No
Number of laboratories	12	0
	Are laboratory doors interlocked?*	
	Yes	No
	11	1
	Is there a breakout panel (emergency exit)?	
	Yes	No
	10	3

*One laboratory contains a glove box within their BSL-2 facility; therefore these questions are not applicable

Internal Features

Table 12 presents the internal features of laboratories. All laboratories that completed the assessment tool indicated that benches and floors were water resistant and cleanable. Openings and penetrations, including windows, into the laboratory were sealed, and that the laboratory was sealable for decontamination. One laboratory reported that neither the walls nor the ceiling of the laboratory were water resistant or cleanable.

Table 12. Laboratory finishes and sealability

Number of laboratories	**Surfaces that are water resistant and cleanable**			
	Walls	Floors	Benches	Ceilings
	12	13	13	12
	Openings and penetrations sealed?			
	Yes		No	
	13		0	
	Laboratory sealable for fumigation?			
	Yes		No	
	13		0	
	Are windows sealed, closed and reinforced?			
	Yes		No	
	13		0	

* One country contains a glove box within their BSL-2 facility; therefore these questions are not applicable

Water

The concept of a "dry" BSL-3 laboratory is gaining acceptance, as the engineering controls for water based BSL-3 laboratories are substantive. Of the laboratories that completed the survey, seven were dry laboratories, negating the need for a sink for hand, an effluent decontamination, or backflow prevention within the designated BSL-3 laboratory space.

Nine laboratories indicated that there was a sink for hand washing in the adjacent containment area (laboratory or anteroom) and the remaining four indicated that a sink was in a nearby laboratory. Six laboratories reported having an effluent decontamination system fitted. Some laboratories that do not have such a system indicated that any liquid effluent or waste liquid is inactivated/decontaminated and/or autoclaved before disposal. While backflow prevention for the water supply is a requirement under the WHO LBM and BMBL guidelines, only four laboratories indicated compliance with this requirement (Table 13).

Table 13. Water system description among laboratories surveyed

Number of laboratories	**Is there a sink for hand washing within the surrounding containment area?**	
	Yes	No
	9	4
	Is the laboratory fitted with an effluent decontamination system?	
	Yes	No
	6	7
	Is there sewer backflow prevention?	
	Yes	No
	4	9

Equipment

The survey tool deals with the presence of equipment in the facility in a number of sections. The type(s) of equipment in any facility will be determined by the user, however in relation to a BSL-3 laboratory certain pieces of equipment are required to ensure containment of infectious material, to protect workers and to inactivate infectious agents.

All laboratories reported having BSC and the number in each facility varied from 1 to 3. The type of BSC also varied. However, most laboratories have Class II BSC and 4 laboratories contained Class III BSC. Class II BSC have complex airflows and therefore are subject to more performance problems than Class I or III biosafety cabinets. As a consequence, positioning of a Class II BSC within a laboratory is important so that correct airflows are maintained and the safety of the operator is ensured. All laboratories indicated that BSC were positioned so that air flow to the BSC was not disrupted. As to be expected, the exact location of the BSC in laboratories varied greatly between laboratories and most likely was dependent on space available and the location of other equipment within the laboratory.

Exhaust from a BSC may cause disruption in airflows within the laboratory, particularly if there is limited space. Responses from the survey indicated that a variety of methods were used for the discharge of exhaust air from the BSC. The common methods used were recirculation into the laboratory, hard ducted, and connected to the building exhaust. Only two laboratories indicated the use of a canopy hood. In all cases, exhaust from the BSC was HEPA filtered before discharge into the environment (internal if in lab or external if hard ducted out).

Centrifugation of material is considered a manipulation that can generate aerosols. In this regard, and to prevent worker exposure to potentially harmful substances, it is recommended that centrifuges with sealed buckets and rotors be used in a containment facility. All laboratories completing the assessment tool indicated that centrifuges are used in the containment facility and that buckets and rotors are sealed to prevent release of infectious material.

Finally, considering inactivation and removal of infectious material and waste safely from the BSL-3 laboratory, the presence of an autoclave either within the facility (preferred option) or external to the facility is required. If the autoclave is not within the BSL-3 facility, then provision must be made to safely transport the infectious material to the autoclave. All laboratories reported to have an autoclave with most laboratories (9/13) indicating a double ended

autoclave, and four laboratories with floor standing models (Table 14). All but one laboratory (12/13) reported having an autoclave within the containment area. In the case where the autoclave was outside the containment area, waste was safely transported from the containment area to the autoclave (double bagged in biohazard bags). Additionally, incinerators can be used for waste management as an alternative or complementary option to decontamination of waste. All but two (11/13) laboratories reported having an incinerator.

Table 14. Laboratory waste and disinfection methods

Number of laboratories	**Is there an autoclave?**		
	Yes	No	
	13	0	
	Type of autoclave		
	Floor standing	Bench top	Double ended
	4	0	9
	Is the autoclave within the containment area?		
	Yes	No	
	12	1	
	Is there an incinerator?		
	Yes	No	
	9	4	

4.4 Work Processes

Work processes can be divided according to the occupational health and safety aspects and the functions of the laboratory.

Personnel safety

Laboratory signs, standard operating procedures and risk assessments are key to personnel safety. These laboratory features inform all staff on the nature and risks of the work as well as procedures to mitigate risks with manipulating EDP. As presented previously, standard operating procedures, written risk assessments, biohazard signs, and signs with contact details are present in all or most of the laboratories.

All laboratories indicated that personal protective equipment (PPE) was available for use in the laboratory. The type of PPE provided was common amongst all laboratories and included: lab coats, Tyvek coveralls, solid front to back closing gowns, eye protection-goggles or face shields, overshoes/booties, gumboots, masks (N95, FFP3), and gloves (nitrile/latex). Respiratory protection equipment is provided by nine laboratories and was not standard between labs. However, types of protection provided include: masks (N95, FFP3), PAPR respiratory systems, and positive pressure masks (Getraco). All reported that PPE is only used while in the laboratory and doffed on exit. Disposable PPE is most commonly used and therefore, decontamination is not required after use, nor is it generally autoclaved following use. Items that do require decontamination such as goggles and gumboots are decontaminated as per standard operating procedures.

With regard to personnel safety related to the performance of manipulations with EDP, all laboratories that handle EDP indicated that they are handled in a BSC.

Annex 5 provides an example of a hand washing SOPs for a dry laboratory.

Facility personnel

The health status of personnel who use the laboratory is of paramount importance.

The number of people who handle pathogens in the laboratories ranged from two to 30. However, most laboratories noted that 10 or less people handled pathogens in the laboratories. The one laboratory that reported 30 persons noted that this is the number of persons authorized to handle pathogens; the number that actually work in the facility is less.

Pre-employment medical checks are undertaken by all laboratories, and regular medical assessments of staff are carried out by all but three laboratories (10/13) (Table 15). However, the regularity or time interval for assessments is not provided. Additionally, only two laboratories provided workers with cards to indicate that they work with hazardous infectious agents.

The presence of a biosafety officer is critical for personnel training and safety. All but one laboratory (12/13) reported that they had a biosafety officer. The nature of the position, full time or part time, varied between laboratories as did the level of training. Over 50% (9/13) of laboratories also reported having a biosecurity officer but, as with the biosafety officer, the nature of the position and training varied between laboratories (Table 15).

Table 15. Documentation and roles performed among laboratories surveyed

Number of laboratories	**Are laboratory workers medically assessed?**	
	Yes	No
	13	0
	Is medical assessment performed on a regular basis?	
	Yes	No
	10	3
	Are laboratory workers provided with a card that identifies them as working with hazardous agents?	
	Yes	No
	2	11
	Is there a laboratory biosafety officer?	
	Yes	No
	12	1
	Is there a biosecurity officer?	
	Yes	No
	9	4

Laboratory function

All laboratories surveyed indicated that their primary function was diagnostic, with a majority (11/13) also serving a research function. Only one facility reported having a production function where they are engaged in antigen production for various pathogens (Table 16). Taking into consideration that the laboratories surveyed predominantly deal with human disease conditions or those at the animal human interface, all laboratories indicated that human and/or zoonotic pathogens are received and handled in the laboratories.

Polymerase Chain Reaction is performed in 10 of the laboratories, immunological assays in 8 laboratories, cell culture in 7 and virus isolation in 9 laboratories (Table 16). Other techniques performed in the laboratories included: viral antigen production, whole genome sequencing, drug susceptibility testing, line probe assays, bacterial culture, microscopy, micro-neutralization assays for influenza, MIRU-VNTR 24, Spoligotyping, and IS6110-RFLP.

Table 16. Functions and techniques performed among laboratories surveyed*

Number of laboratories	**Functions**				
	Diagnostic		Research		Production
	13		11		1
	Techniques				
	PCR	Immunological tests	Cell culture	Virus isolation	Other
	10	8	7	9	6

* Individual laboratories may have more than one function and perform more than one technique

Virus isolation is a key tool in outbreak investigations, and while PCR can rapidly identify a pathogen, virus isolation and cultivation is required to amplify or increase the agent so that it may be further characterised. A wide variety of viral agents are handled in the laboratories assessed. Table 17 presents the groups of pathogens isolated. Other viruses that are isolated by a single laboratory (not necessarily the same laboratory) include: Marburg virus, Lassa fever virus, simian immunodeficiency virus (SIV), human T-lymphotropic virus (HTLV), Middle East respiratory syndrome coronavirus (MERS-CoV), and hantaviruses. Only one specialized bacterial laboratory within AFR EDPLN isolates and handles bacterial pathogens, with the exception of another laboratory that specifically isolates mycobacterium. The bacterial pathogens isolated include: Bacillus anthracis, Clostridium botulinum, Yersinia pestis, Bartonella spp., Leptospirosis, Brucella spp and Burkholderia spp.

Table 17. Types of viral agents isolated among laboratories surveyed^

Number of laboratories	Viral Agents				
	VHF*	Other arboviruses**	Human Immunodeficiency Virus (HIV)	Influenza (human and avian)	Other#
	6	7	5	5	4

^ Individual laboratories may isolate more than one agent
* VHF viruses include: Yellow Fever, RVF, CCHF, Ebola and Dengue fever
** Other arboviruses include: WNV, Zika virus, Chikungunya virus, O'nyong-nyong virus and Semliki Forest virus
#Other viruses include: rabies, herpes and measles viruses

There are a greater number of laboratories that handle pathogens compared to those that isolate pathogens. Table 18 presents the groups of pathogens handled by the laboratories surveyed. As with viral isolation, only one laboratory (not necessarily the same laboratory) handles the following viruses: simian immunodeficiency virus (SIV), human T-lymphotropic virus (HTLV), and hantaviruses. Only one specialized bacterial laboratory within AFR EDPLN handles bacterial pathogens, with the exception of another laboratory that specifically handles M. ulcerans and Pneumococcal meningitis. The bacterial pathogens handled include the following: Clostridium botulinum, Yersinia pestis, Bartonella spp., Leptospirosis, Brucella spp and Burkholderia spp.

Additionally, only one laboratory indicated that they have the capability to isolate and handle rare viruses which include Bluetongue and Dakar bat viruses.

Table 18. Types of pathogens handled among laboratories surveyed^

Pathogens handled	Number of laboratories
Viral agents	
VHF*	10
Other arboviruses**	13
Human Immunodeficiency Virus (HIV)	8
Influenza (human and avian)	10
MERS-CoV	3
Monkey pox	2
Other#	8
Bacterial agents&	6

^ Individual laboratories may isolate more than one agent
*VHF viruses include: Yellow Fever, RVF, CCHF, Lasa Fever, Ebola virus, Marburg virus, and Dengue fever
**Other arboviruses include: WNV, Zika virus, Chikungunya virus, O'nyong-nyong virus and Semliki Forest virus
#Other viruses include: rabies, polio, herpes, hepatitis and measles viruses
&Bacterial agents include: M. Tuberculosis and Bacillus anthracis

4.5 Facility maintenance

The ongoing maintenance of a BSL-3 facility is critical for its continued operation.

All laboratories indicated that they have a preventative maintenance plan in place (Table 19). However, who is responsible for facility maintenance varied between laboratories. All but one facility (12/13) indicated they have a staff member responsible for maintenance functions and it was noted that, most often, the person responsible was the facilities manager. Other laboratories indicated that a biomedical engineer, facility engineer or a maintenance team were responsible for maintenance functions. One laboratory utilised the services of an external maintenance company for servicing and repairs.

Predominantly, maintenance functions were carried out "in-house" (10/12) often with the assistance of either national or international contractors (Table 19). For one laboratory, maintenance functions were carried out exclusively by international contractors and for another by national and international contractors. One facility did not provide a response.

Seven laboratories indicated that maintenance is budgeted for centrally, three reported maintenance is funded by external income and one facility indicated that it relied on funds that are centrally budgeted and from external income (Table 19). Four laboratories indicated that there was no specified budget for maintenance of the facility. Instead, a mix of program funding was noted. Government, private and foreign funding were used for the construction and/or operation of the laboratories.

All but one (12/13) laboratory indicated that they have a period where the facility is shut down for maintenance but, the time interval varied between laboratories. Out of the 12 laboratories that have a regular shut down period for maintenance, the majority of laboratories shut down annually (9/12), with one laboratory indicating an interval of 18 months.

Table 19. Laboratory maintenance of surveyed laboratories

Number of laboratories	**Is there a preventive maintenance plan?**			
	Yes		No	
	13		0	
	Is staff member responsible for maintenance?			
	Yes		No	
	12		1	
	Person who carries out laboratory maintenance*#			
	In-house	National contractor	International contractor	Other
	10	6	5	0
	Source of maintenance budget#			
	Centrally	External income	No specific budget	Other
	7	3	4	0
	Is there a regular periodic shut down for maintenance?			
	Yes		No	
	12		1	
	Periodicity of maintenance*			
	Six-monthly	Yearly	Other	None
	1	9	1	0

*Missing data from one laboratory
#Individual laboratories may have more than one person who carries out maintenance functions and more than one source of budget

In regard to maintenance, specialised expertise is usually required to test, repair and maintain certain features of a containment laboratory such as HVAC, safety cabinets, filters and autoclaves. For sustainability and the smooth operation of the facility the availability of this expertise is crucial. The presence of expertise nationally is always preferable as it reduces costs. However, for the specialised nature of BSL-3 laboratories expertise may not be able to be sourced nationally. Most countries are able to do HVAC maintenance without seeking external assistance but, for the other areas of expertise 50% of laboratories must seek international consultants to conduct maintenance functions (Table 20). Ten countries are represented and one country was excluded as they indicated they do not have these services available.

Table 20. Sources of expertise for maintenance

	National	National/International	International
HVAC engineers	7	1	2
Autoclave engineers	5	1	4
Safety Cabinet Testers	5	2	3
Filter testers	5	1	4

5. Conclusions and recommendations

Conclusions

The assessments were carried out in 13 laboratories in 11 countries.

Overall, BSL-3 laboratories within the AFR EDPLN comprise of similar requirements to operate with many functioning as dry laboratories. The majority of, if not all, laboratories surveyed indicated safety processes and procedures in place to protect the health of staff as well as the maintenance of equipment. These results are not surprising given the nature of pathogens that are managed.

Upon further discussion with countries, the guidelines used to design and construct BSL-3 laboratories were only known to the construction company; research staff completing the survey could only infer that the guidelines used were based on the contractor's country of origin. In addition, when external contractors are used for the purpose of certifying BSC or the laboratory itself, it is often not known to what standard the BSC or the lab itself is being measured against. If these processes are donor driven, then the regulations used are often those of the donor country funding the facility.

Common gaps and challenges were also noted from the survey. Only one country surveyed have national regulations for the design and construction of BSL-3 laboratories. In the absence of national regulations, countries should follow the minimal standards needed to design, construct and operate a BSL-3 laboratory. These minimal standards can then be adapted to national needs. The WHO Laboratory Biosafety Manual and Assessment Tool for Key Processes associated with the Design, Construction, Operation, Maintenance and Regulation of BSL-3 Laboratories in the WHO African Region is a great starting point in determining the basic necessities for construction of a BSL-3.

Further gaps and challenges can be broadly grouped under: human resources; financing; timeliness of laboratory supplies and parts; and scheduled audits. Many have noted the difficulties in obtaining, training and sustaining local laboratory staff as well as staff that routinely operate and service the laboratory. Financing is a perennial issue as many laboratories are fully or partially externally funded; ensuring sustainable financing is a continuous work in progress. The long wait times to obtain laboratory supplies and parts due to logistics severely hamper IHR (2005) requirements of rapid assessment and information sharing. Even processes to conduct scheduled laboratory audits and/or inspections were lacking in many countries surveyed.

It was also noted that some questions in the tool were not well defined. These are evidenced by the varied responses between institutions or the lack of clarity within responses, leading to additional contact with the laboratories. For example, with regard to the question on provision of a card for laboratory workers (Question 10e), although only two laboratories indicated that a card was issued to employees identifying them as working with hazardous agents, most laboratories indicated that only appropriately trained and medically checked staff are afforded access to BSL-3 containment laboratories. A list of staff working in BSL-3 is recorded, and regularly updated with the pathogens they may be exposed to as workers in the facility.

Upon discussion with the heads of AFR EDPLN laboratories, a guidance document to provide further clarity in completing the laboratory assessment tool was suggested.

Recommendations

A list of recommendations on the results of the survey as well as from discussion with heads of AFR EDPLN laboratories are below. These are listed as general recommendations and specific recommendations categorized into the five broad groupings.

- Develop a guide to accompany the assessment tool.
- Pilot assessment tool in Francophone countries.
- Sustain AFR EDPLN network by regular meetings and collaborations.
- Review status of BSL-3 capacity in 3 years' time.
- Encourage collaboration within the network in areas such as: training, equipment, expertise etc.

Laboratory overview including funding and BSL-3 capacity

- Ensure sustainable funding mechanisms for operation and maintenance
- Assess workforce training for laboratory use and maintenance and identify gaps

Construction, design, certification, regulation and standard operating procedures

- Consider the site placement when planning BSL-3 laboratory construction to avoid technical issues (altitude/environment, etc.)
- Consider planned activities when designing and constructing a BSL-3 laboratory
- Encourage countries to adapt recognized laboratory regulations to the country context
- Develop a mechanism for regular inspection/audit by peer review (i.e. experts, WHO, other labs) based on existing models (polio, flu, HIV)
- Ensure involvement of all stakeholders in the design and construction of the facility (e.g. Include IT, electricians, end users, etc. in preliminary discussions)
- End users should visit the laboratory during construction and/or an existing and functioning BSL-3 laboratory to ensure the specifications are correct

Physical infrastructure and equipment

- Ensure continuous power to the laboratory, have a backup plan for loss of power from the electrical grid, especially for BSC II
- Ensure controlled, authorized access to laboratory
- Consider the use of CCTVs within the laboratory
- Ensure Class II BSC are connected to an uninterruptable power supply or a reliable back up power supply

Work processes

- Develop SOPs for dry vs wet lab in regard to work processes, in particular hand washing
- Ensure training of non-laboratory staff (i.e maintenance personnel) in safe work practices in containment laboratories

Facility maintenance

- Promote recruitment of expert in the lab or have a (conduct a) maintenance contract
- Utilise regional expertise for maintenance functions and work at training local expertise for these functions.

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7. Annexes

Annex 1: Laboratory Assessment Tool for BSL-3 Laboratories

Laboratory assessment tool for BSL-3 laboratories*

A draft laboratory assessment tool for human BSL-3 laboratories was provided for discussion at the meeting held in WHO Regional Office for Africa in Brazzaville from 27-31 July 2015. After discussion, this tool was revised and submitted for further discussion at the meeting and afterwards, by email. This tool was tested on a series of laboratory visits in Ghana, Uganda and Kenya. Revisions were made after each of the visits and the final assessment tool is shown in the next section. The aim of the checklist is to analyse existing EDPL infrastructure.

Laboratory Assessment Checklist

1	General information on the laboratory

a. Name and location of the laboratory

b. General impression on physical aspects of the laboratory (for example: security, perimeter, age of the building, etc.).

2. Standards, regulations and guidelines for laboratory design and construction

a. Do you have any national standards or guidelines you follow in regards to laboratory design and construction?

☐ Yes ☐ No

If **YES,** please indicate below the national standard you follow

b. Do you follow international guidelines for BSL-3 laboratory design and construction?

☐ Yes ☐ No

If **YES,** identify which international guidelines you follow

- ☐ WHO Biosafety Manual
- ☐ US BMBL
- ☐ UK ACDP
- ☐ Other (please specify below)

c. What standard do you use for safety cabinet certification?

- ☐ NSF/ANSI49
- ☐ EN12469:2000
- ☐ AS 2252
- ☐ JIS K 3800
- ☐ Don't know
- ☐ Other (please specify below)

Any additional comments:

3. Oversight mechanisms

a. Do you have a process for laboratory approval and certification?

☐ Yes ☐ No

If **YES,** please specify

- ☐ Governmental
- ☐ External Consultant
- ☐ Funder
- ☐ International Organisation (e.g. WHO/OIE)
- ☐ Other (please specify below)

b. Is there regular inspection/audit of containment laboratories?

☐ Yes ☐ No

If **YES,** please indicate the body that inspects/audits the laboratory

- ☐ Governmental
- ☐ Institutional
- ☐ External Consultant
- ☐ International Organisation (e.g. WHO/OIE)
- ☐ Funder
- ☐ Other (please specify below)

If **YES,** please indicate how often containment laboratories are inspected/ audited?

- ☐ Six-monthly
- ☐ Yearly
- ☐ Other (please specify below)

c. Do you have written risk assessments?

☐ Yes ☐ No

If **YES,** who approves risk assessments?

- ☐ Laboratory Scientist
- ☐ Laboratory management
- ☐ Principle Investigator
- ☐ Regulator
- ☐ Institute/University Biosafety Officer

Any additional comments:

4. Existing BSL-3 laboratories in the country

a. Are there any other BSL-3 laboratories/facilities in the country?

☐ Yes ☐ No

If **YES,** how many laboratories are there in the country?

List laboratories by human/animal/plant facilities, if known:

b. Are there any other laboratories/facilities under planning or construction?

☐ Yes ☐ No

If **YES,** list planned laboratories/facilities or those under construction.

c. Any additional comments:

5. Laboratory Use and Funding

a. What is the function of this laboratory?

- ☐ Diagnostic (D)
- ☐ Research (R)
- ☐ Production (P)

Indicate the role of the laboratory in regards to sample type: ☐ Human ☐ Animal

b. Are the pathogens handled human, zoonotic, or animal pathogens?

- ☐ Human
- ☐ Zoonotic
- ☐ Animal

c. When did the laboratory open? (indicate year)

d. What are the sources of funding of the laboratory?

	Rank
☐ Government	☐
☐ Private institution	☐
☐ Foreign organisation	☐
☐ Other (please specify below)	☐

If there is more than one source that funds the laboratory, rank them in order of funds provide:

e. What is the affiliation of this laboratory?

☐ Government ☐ Private

If Government, please indicate below which ministry.

f. Who was/is responsible for

- the lab construction?
- salary of staff?
- laboratory maintenance?

Please, indicate below:

g. Which laboratory techniques are carried out in the laboratory?

- ☐ PCR
- ☐ immunological tests
- ☐ cell culture
- ☐ viral isolation
- ☐ other (please specify below)

h. In relation to virus isolation, which pathogens are handled in the laboratory? Please list below:

i. How many people handle pathogens in the facility?

j. List below the agents handled in the facility at present and in the future

k. Any additional comments:

6. Laboratory Entry		
	Questions	**Evidence/Comments**
a.	Is the BSL-3 lab separated from other labs used for normal activities? ☐ Yes ☐ No	
b.	Is there an anteroom to the BSL-3 laboratory? ☐ Yes ☐ No	
c.	Is there a biohazard sign on the door of the laboratory? ☐ Yes ☐ No	
d.	Is there a sign indicating contact details of the laboratory supervisor/manager? ☐ Yes ☐ No	
e.	Are the laboratory entry criteria specified? ☐ Yes ☐ No	
f.	Are the laboratory doors interlocked? ☐ Yes ☐ No	
g.	Is there pressure differential between inside the laboratory and its external environment? ☐ Yes ☐ No	
h.	Is there a breakout panel (emergency exit)? ☐ Yes ☐ No	
i	Is respiratory protection equipment (RPE) available? ☐ Yes ☐ No If **YES,** please indicate what type	
j.	Is PPE provided? ☐ Yes ☐ No If **YES**, please indicate what type?	
k	Is the PPE only used while in the laboratory and doffed in the laboratory? ☐ Yes ☐ No	
l.	Is the PPE decontaminated after use? ☐ Yes ☐ No	

Any additional comments:

7. Laboratory Finishes, Sealability and Equipment		
	Question	**Evidence/Comments**
a.	Are the following surfaces water resistant, and cleanable? Yes No Walls ☐ ☐ Floors ☐ ☐ Benches ☐ ☐ Ceilings ☐ ☐	
b.	Are openings and penetrations sealed? ☐ Yes ☐ No	
c.	Is the laboratory sealable for fumigation? ☐ Yes ☐ No	
d.	Are the windows sealed, closed and reinforced? ☐ Yes ☐ No	
e.	Are centrifuges used? ☐ Yes ☐ No If **YES**, are the buckets and rotors sealed? ☐ Yes ☐ No	
f	Are all manipulations with the EDP carried out in a biological safety cabinet? (Class II or above) ☐ Yes ☐ No	
g.	Is there a sink for hand washing within the containment area i.e. lab or anteroom? ☐ Yes ☐ No If **NO**, indicate the location of sink for hand washing.	
h.	Is the facility fitted with an effluent decontamination system?	

☐ Yes ☐ No	
Any additional comments:	

8. HVAC systems and BSC		
	Question	**Evidence/Comments**
a.	Is there a directional airflow into the laboratory? ☐ Yes ☐ No If **YES**, • How is this achieved (method)? • How is it monitored? Please indicate	
b.	Are there biological safety cabinets in the laboratory? ☐ Yes ☐ No If **YES**, please indicate below how many and the type of BSC in the laboratory	
c.	Where are BSC situated in the laboratory? Please describe.	
d	What happens to laboratory exhaust air? (please indicate)	
e.	Does this affect the room's air balance? ☐ Yes ☐ No	
f.	Is the exhaust air from the biosafety cabinet ☐ recirculated in the lab ☐ hard-ducted ☐ thimble (canopy hood) ☐ connected to the building exhaust?	
g.	Is exhaust air from the laboratory filtered (HEPA)? ☐ Yes ☐ No	

	If **NO**, is air discharged safely?	
h.	How are the filters installed? ☐ Yes ☐ No	
i.	Is the HVAC system alarmed for positive pressurisation? ☐ Yes ☐ No	
Any additional comments:		

9. Waste and Disinfection		
	Question	**Evidence/Comments**
a.	Is there an autoclave for inactivating waste? ☐ Yes ☐ No If **YES,** please indicate what type of autoclave; ☐ floor standing ☐ bench top ☐ double ended	
b.	Is the autoclave within the containment area? ☐ Yes ☐ No	
c.	If the autoclave is located outside, how is waste transported to the autoclave?	
d.	Is there an incinerator? ☐ Yes ☐ No	
e.	Is there sewer backflow prevention? ☐ Yes ☐ No If **YES,** please indicate what type?	

Any additional comments:

10. Documentation and Roles		
	Question	**Evidence/Comments**
a.	Are there SOPS or other detailed procedures available? ☐ Yes ☐ No	
b.	Are there written risk assessments? ☐ Yes ☐ No	
c.	Are laboratory workers medically assessed pre-employment? ☐ Yes ☐ No	
d.	Is medical assessment of laboratory workers carried out on a regular basis? ☐ Yes ☐ No	
e.	Are laboratory workers provided with a card identifying them as working with hazardous agents? ☐ Yes ☐ No	
f.	Does the lab have an appointed **Biosafety** officer? ☐ Yes ☐ No If **YES,** is this a full-time role? What training has she/he received? (please indicate)	
g.	Is there a **Biosecurity** officer? ☐ Yes ☐ No If **YES,** is it a full time role? What training has she/he received?	
Any additional comments:		

11. Maintenance and Certification

a. Is there a preventive maintenance plan?

☐ Yes ☐ No

b. Is a staff member responsible for maintenance?

☐ Yes ☐ No

If **YES**, please indicate staff member responsible e.g. facilities manager/engineer

c. How is this budgeted for?

Centrally ☐

From external income ☐

No specified budget ☐

Other, please define

d. Is there a regular periodic shut down for maintenance?

☐ Yes ☐ No

If **YES,** Please indicate time interval:

Six-monthly ☐

Yearly ☐

None ☐

Other, please specify

e. Who carries out the maintenance of the laboratory? Please indicate

In-house ☐

National contractor ☐

International contractor ☐

Other, please specify

f. Is there a plan for the laboratory to be certified?

☐ Yes ☐ No

If **YES,** indicate re-certification interval:

Annually ☐

Six-monthly ☐

Other, please specify

g. What support (funds, technical expertise) has been received for the construction/ operation of these facilities? Please indicate.

If funds have been received, please indicate source/donor.

12. Availability of expertise in the design, construction, commissioning and maintenance of facility and key equipment

Do you have the following services available for construction/maintenance of BSL-3 facilities?

☐ Yes ☐ No

If **YES**

Please indicate below if the expertise is sourced nationally or internationally?

	Source of Expertise	
	Nationally	**International**
HVAC engineers	☐	☐
Safety cabinet testers	☐	☐
Filter testers	☐	☐
Autoclave engineers	☐	☐
Laboratory designer	☐	☐
Specialist architects	☐	☐

Any additional comments:

Annex 2: Laboratory Assessment Tool Questions Grouped within the 5 broader components

Group Name	Question Number	Question Description
1. Laboratory overview including funding and National BSL-3 capacity	1a	Name and location of the laboratory
	1b	General impression on physical aspects of the laboratory (for example: security, perimeter, age of the building, etc.)
	4a	Are there any other BSL-3 laboratories/facilities in the country?
	4b	Are there any other laboratories/facilities under planning or construction?
	4c	Additional comments
	5c	When did the laboratory open? (indicate year)
	5d	What are the sources of funding of the laboratory?
	5e	What is the affiliation of this laboratory
	5f	Who was/is responsible for • the lab construction? • salary of staff? • laboratory maintenance?
2. BSL-3 Design, Construction, Certification, Regulation and Standard Operating Procedures	2a	Do you have any national standards or guidelines you follow in regards to laboratory design and construction?
	2b	Do you follow international guidelines for BSL-3 laboratory design and construction?
	2c	What standard do you use for safety cabinet certification?
	3a	Do you have a process for laboratory approval and certification?
	3b	Is there regular inspection/audit of containment laboratories?
	3c	Do you have written risk assessments?
	6c	Is there a biohazard sign on the door of the laboratory?
	6d	Is there a sign indicating contact details of the laboratory supervisor/manager?
	6e	Are the laboratory entry criteria specified?
	10a	Are there SOPS or other detailed procedures available?
	10b	Are there written risk assessments?
	11f	Is there a plan for the laboratory to be certified?
	11g	What support (funds, technical expertise) has been received for the construction/ operation of these facilities?
	12	Do you have the following services available for construction/maintenance of BSL-3 facilities?
3.Physical infrastructure	6a	layout
	6b	Is the BSL-3 lab separated from other labs used for normal activities?
	6f	Is there an anteroom to the BSL-3 laboratory?
	6g	Is there pressure differential between inside the

		laboratory and its external environment?
	6h	Is there a breakout panel (emergency exit)?
	7a	Are the following surfaces water resistant, and cleanable?
	7b	Are openings and penetrations sealed?
	7c	Is the laboratory sealable for fumigation?
	7d	Are the windows sealed, closed and reinforced?
	7e	Are centrifuges used?
	7g	Is there a sink for hand washing within the containment area i.e. lab or anteroom?
	7h	Is the facility fitted with an effluent decontamination system?
	8a	Is there a directional airflow into the laboratory?
	8b	Are there biological safety cabinets in the laboratory?
	8c	Where are BSC situated in the laboratory?
	8d	What happens to laboratory exhaust air?
	8e	Does this affect the room's air balance?
	8f	Is the exhaust air from the biosafety cabinet -recirculated in the lab -hard-ducted -thimble (canopy hood) -connected to the building exhaust?
	8g	Is exhaust air from the laboratory filtered (HEPA)?
	8h	How are the filters installed?
	8i	Is the HVAC system alarmed for positive pressurisation?
	9a	Is there an autoclave for inactivating waste?
	9b	Is the autoclave within the containment area?
	9c	If the autoclave is located outside, how is waste transported to the autoclave?
	9d	Is there an incinerator?
	9e	Is there sewer backflow prevention?
4.Work Processes	3c	Do you have written risk assessments?
	5a	What is the function of this laboratory?
	5b	Are the pathogens handled human, zoonotic, or animal pathogens?
	5g	Which laboratory techniques are carried out in the laboratory?
	5h	In relation to virus isolation, which pathogens are handled in the laboratory?
	5i	How many people handle pathogens in the facility?
	5j	List below the agents handled in the facility at present and in the future
	6c	Is there a biohazard sign on the door of the laboratory?
	6d	Is there a sign indicating contact details of the laboratory supervisor/manager?

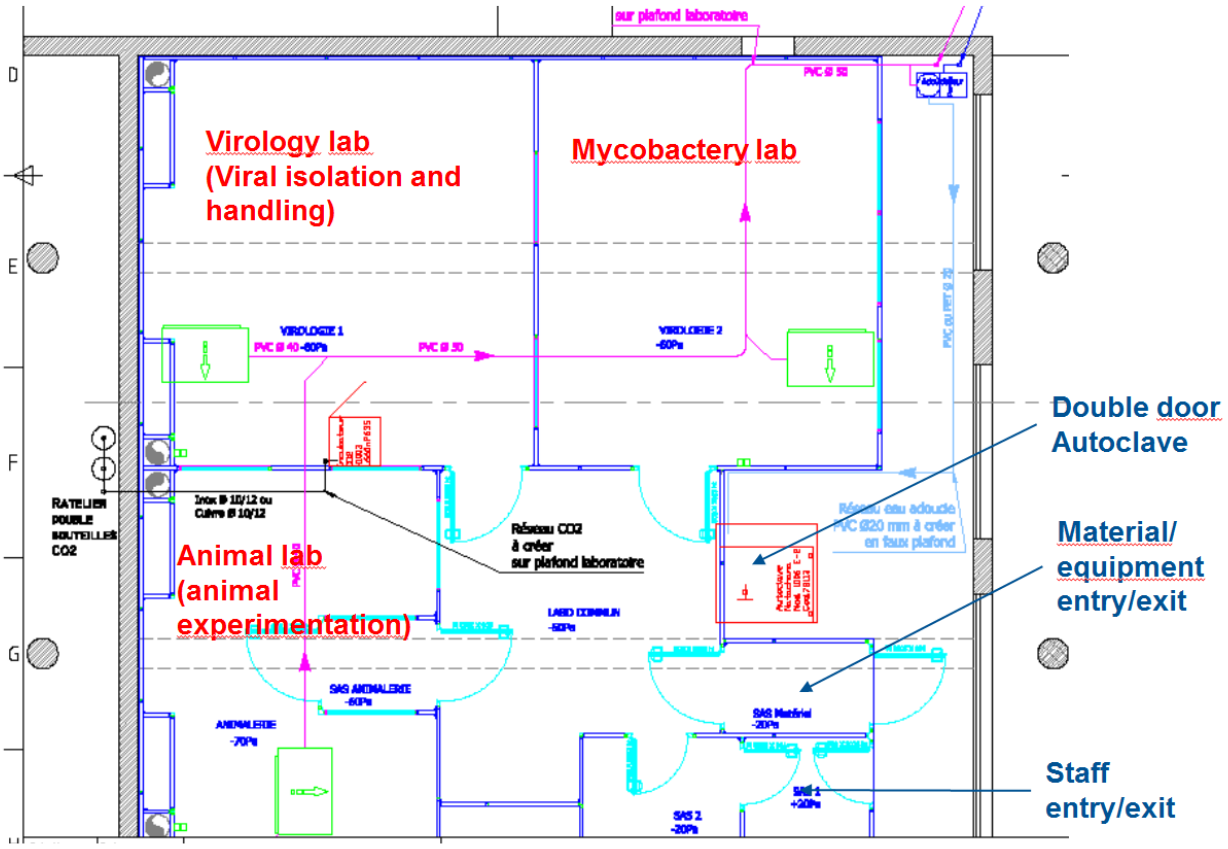
	6i	Is respiratory protection equipment (RPE) available?
	6j	Is PPE provided?
	6k	Is the PPE only used while in the laboratory and doffed in the laboratory?
	6l	Is the PPE decontaminated after use?
	7f	Are all manipulations with the EDP carried out in a biological safety cabinet? (Class II or above)
	10a	Are there SOPS or other detailed procedures available?
	10b	Are there written risk assessments?
	10c	Are laboratory workers medically assessed pre-employment?
	10d	Is medical assessment of laboratory workers carried out on a regular basis?
	10e	Are laboratory workers provided with a card identifying them as working with hazardous agents?
	10f	Does the lab have an appointed Biosafety officer?
	10g	Is there a Biosecurity officer?
5.Facility Maintenance	11a	Is there a preventive maintenance plan?
	11b	Is a staff member responsible for maintenance?
	11c	How is this budgeted for?
	11d	Is there a regular periodic shut down for maintenance?
	11e	Who carries out the maintenance of the laboratory?
	12	Do you have the following services available for construction/maintenance of BSL-3 facilities?

Annex 3: Physical Description of Laboratories Surveyed

Country	Laboratory Description (security, perimeter, building age, area)
Algeria	**BSL3-laboratory, Virology Department, Pasteur Institute** • Inaugurated on Jun 24th, 2014 • Standalone facility with a BSL-3 lab and supporting BSL-2 • Surface area : 40 m^2. • There are multiple security measures in place within and around the laboratory • There is a secure perimeter • Fire alarms and biohazard signs are placed within the laboratory
Cameroon	**Centre Pasteur du Cameroun** • BSL-3 Laboratory established in 2003, renovated in 2007 and 2011 • The laboratory is physically and technically fully functional
Central African Republic	**Arbovirus, Haemorrhagic Fever Viruses, Emerging viruses and Zoonoses laboratory, Institut Pasteur** • Built and inaugurated on February 25th, 2011 • BSL-3 laboratory located in annex building • Laboratory area is 300 m2 • BSL-3 laboratory secured by alarm system
Gabon	**Centre International de Recherches Médicales de Franceville** • Research Centre established in 1979, 40 hectare area • Around 400 m2 of laboratories and offices
Ghana	**Noguchi Memorial Institute for Medical Research** • Building was inaugurated in 2000 • Standalone facility with two BSL-3 labs and supporting BSL-2 • There is an onsite maintenance team • Access restricted to approved personnel
Kenya	**Kenya Medical Research Institute, Centre for Virus Research** • The building was re-opened in 1999 after renovations • There is a secure perimeter around the entire compound • 24hr security for the compound
Madagascar	**Institut Pasteur of Madagascar, Virology Unit** • There is a perimeter wall round the entire institute. • 24hr security personnel guarding the compound. • The building was built in 2008 and has operated since then
Nigeria	**Virology Research Laboratory** • Location is on the ground floor of the old dental building • This is a BSL- 2 laboratory with a glove box • The laboratory is comprised of four main rooms (laboratory sections) located within an umbrella laboratory • The laboratory is well secured with functional biosafety and

	biosecurity measures
Senegal	**Institut Pasteur Dakar** • Laboratory BSL-3 SAS1, SAS2, Handling zone) • Building is 16 years old (BSL-3 activities began in 2000) • Surface area: 30.72 m^2
South Africa	**National Institute for Communicable Diseases Centre (NICD) for Emerging and Zoonotic Diseases (CEZD)–Special Bacterial Pathogens Reference Laboratory (SBPRL)** • The BSL3 Facility comprises of multiple laboratory spaces, equipped with a range of primary containment equipment (e.g. BSC's and centrifuges) • The laboratory is accessed via an anteroom with inter-locking doors. • The facility is served by a double door autoclave installed on one of the perimeter walls of the lab for removal of solid materials
	NICD Centre for TB • The facility is fairly new and was opened in 2010. • The BSL-3 lab area is separate from other lab areas and is accessed via an anteroom. • The BSL-3 Facility comprises of multiple laboratory spaces, equipped with a range of primary containment equipment (e.g. BSC's and centrifuges). • The facility is served by a double door autoclave installed on one of the perimeter walls of the lab for removal of solid materials
	NICD Centre for Respiratory Diseases and Meningitis • The BSL-3 facility is a newly renovated facility within an existing building, located in a secure area. • It comprises of two laboratory spaces, a main laboratory and a hot room (with a Class III glovebox) • It is serviced by a shower, change and ante rooms • The facility is served by a double door autoclave connected to the main laboratory perimeter for removal of solid materials
Uganda	**UVRI Highly Pathogenic Viral Diseases Diagnostic Laboratory** • The physical appearance is very good and well maintained • There is a secure perimeter • Laboratory was recently refurbished

Annex 4: BSL-3 laboratory layout from Institut Pasteur Madagascar



Annex 5: Example of Hand Washing Standard Operating Procedures for a Dry Laboratory

Procedures for hand washing

In laboratories that contain two anterooms, procedures for hand washing are as follows:

1. In the first anteroom, use detergent to clean the first pair of gloves before taking them off and entering the second anteroom
2. In the second anteroom, take off the second pair of gloves and wash your hands using hydro-alcoholic gel
3. Exit the second anteroom
4. Wash your hands with soap after you exit the second anteroom (outside of the containment laboratory)

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