

## ADDRESSING BIOSECURITY THREATS FROM INCREASING MOLECULAR LABORATORIES IN AFRICA

### Background

The recently concluded COVID-19 summit in Abuja, Nigeria emphasized the urgent need for increase in diagnostic Laboratories to contain the frequent infectious disease outbreaks in Africa. The continent has witnessed surge in the number of infectious diseases in the last few decades, which has also resulted in increase of both public and private diagnostic Laboratories. The Laboratories has contributed in no small means to controlling infectious diseases outbreaks through: prompt diagnosis, surveillance capacity and epidemiology studies. Despite the beneficial contribution of the Laboratories, there are also some biosecurity concerns such as: Waste Disposal Management Practice, Samples and Data Management and Research activities coordination, which are not properly managed in some of these laboratories. Healthcare establishments HCEs such as primary, secondary and tertiary hospitals, research institutions and diagnostic laboratories analyze, generate, handle, treat and dispose of biomedical wastes of various types including pathogenic microorganisms. Disposal of these biomedical wastes if not carefully and properly managed could pose a grave human and environmental health implication.

Owing to some happenings in research Laboratories in the last few decades, ranging from poorly trained Laboratory personnel, denial of responsibilities, inappropriate accountability, incomplete record-keeping, suboptimal facility infrastructure, refusal to acknowledge ethical considerations, lack of (or lack of respect for) codes of conduct that has triggered clearly catalogued laboratory-acquired infections, loss of material and inappropriate manipulations, or even possibly intentional misbehaviour. There is an urgent need for effective monitoring and supervision of emerging diagnostic and molecular laboratories in Africa to prevent any form of biosecurity threat to the environment. There is need for robust guidelines and regulations that will oversee the practices and activities of diagnostic and molecular laboratories. Laboratory induced-Biosecurity threats such as Laboratory wastes disposal, research activities and competency, samples and data management, are some of the major

challenges that need close monitoring, supervision and enforcement. Countries across the globe including some low-income countries signed to an agreement ISO 35001 that clearly stipulates strict adherence to its guidelines and regulations for established diagnostic Laboratories.

Considering the importance of ensuring biosecurity and biosafety in laboratories in Africa, the Global Emerging Pathogens Treatment Consortium (GET) organized a webinar with experts and stakeholders drawn from various fields of biosecurity and biosafety on 19<sup>th</sup> January 2022. The consortium, a biosecurity thin tank organization attempts to educate the public on the importance of reducing biosecurity threat induced by inadequately regulated diagnostic Laboratories and suggest few panacea and managements strategies. The objectives of the webinar include:

1. Discuss establishment of standard and protocols for Research activities in Laboratories in Africa
2. Understanding ethics for Samples collection, storage and data management
3. Understand standard of practice for waste disposal for research and diagnostic Laboratories
4. Review the existing policies that govern the Laboratories activities.

### **Factors that may Induce Biosecurity Threats in Laboratories**

Most Africa countries operate a very fragile healthcare system as well as vague regulatory framework for establishing diagnostic Laboratory making them especially vulnerable to compromised Laboratories practices. The following concepts of diagnostic Laboratory need critical evaluation.

### **Samples collection and processing**

Samples both biospecimen and waste generated from the Laboratory need a clear regulation on utilization, storage and disposal. Generated specimen sample should be well acquired, protected and stored to maximize research benefits from it and prevent intentional or unintentional escape biological materials from the laboratory. Biospecimen management which involves collections, processing and storage, is critical to derivation of maximum information from the samples without actually flouting ethics of samples management.

Poorly designed sample management protocol could limit the extent of research to be performed on the collected samples and otherwise could invalidate derived data.

Disposal of wastes from the Laboratories is equally a major concern as the improperly managed waste could induce an outbreak. This is particularly worrisome for most African countries that are lacking institutional policy regulating research Laboratories operations as well as its fragile healthcare institutions that cannot adequately respond to emergency outbreaks.

### **Research Activities in the laboratories**

It would be imperative to really understand ongoing research activities in Laboratories in Africa. The research activities are majorly influenced by the motives and competency of the personnel. Increasing radicalization and terrorism within Africa could invade our Laboratory samples and engage in nefarious research activities if there are no excellent supervision and monitoring. Standard practices of Laboratories identify research concepts such as ‘dual use of biospecimen-where one and the same piece of scientific research sometimes has the potential to be used for harm as well as for good, and gain of function- extension of microbe’s capacity beyond its natural ability. Typically, the research activities on gain of function might intends no harm, however some malevolent non-researchers might steal dangerous biological agents produced by the researchers or alternatively, *other* researchers—or at least their governments or leadership—might use the results of the original researcher’s work for malevolent purposes. The malevolent purposes may include bioterrorism, biowarfare and blackmail for financial gain. This further emphasized the critical role of government agency on strict supervision and monitory of laboratories activities.

### **Data generation and management**

Data generation is crucial for policy making and national development. Medical laboratories process and store sensitive data during four major phases: arrival of patients in the laboratory premises and registration of their data, pre-analytical, analytical and post-analytical phases. Data generated from laboratories should be adequately regulated and protected. Data protection rules and regulations should be strictly followed to prevent data escaping to the wrong hands including of non-state actors that might use data for personal gain or negative intentions.

## **Panaceas to Mitigating Biological Risks from Research Laboratories in Africa**

1. Development and implementation of national governance structures that will enforce, regulate and promote biosecurity and responsible conduct in the life sciences in African countries
2. Enforcement of established legislative laws, policies and regulations that governs biosafety and biosecurity in research Laboratories in Africa. Most countries in Africa lack effective legislative policies that govern biosafety and biorisks of Laboratory in their country. Enforcement of policies and regulations is weak in other countries in Africa.
3. Establishing and enforcing standard and protocols that guide research and diagnostics activities in Laboratories especially genomics Laboratories in Africa.
4. Enforcement of strict adherence to Ethics of samples and data management (Dual use of samples and Gain of function) in the laboratories. The government should ensure that laboratories follow established guideline for sample collection and use, data management.
5. Developing and enforcing standard protocols for Laboratories waste disposal management. Proper management of wastes will minimize the risk to employees and members of the public, reduce the risk of release of hazardous material to the environment and enable the community to better manage the costs of disposal
6. Coordinated collaboration and communication of research activities within regions. Regional bodies such as West Africa Health Organisation (WAHO) should monitor research activities in member countries and coordinate biosecurity and biosafety activities in the their region.
7. Increase and continuous training and capacity building of laboratory personnel on ethics, biosafety and biosecurity concept.

### **About GET**

*Global Emerging Pathogens Treatment Consortium (GET) was established in 2014 as a direct response to the 2014-16 Ebola virus disease outbreak in West Africa and ongoing outbreaks of Lassa Fever, Meningitis, Multidrug resistance (MDR) enteric fevers and Yellow Fever across the sub region. There was clearly a need to create an African-led multidisciplinary forum of experts capable of working together with international partners to strengthen Africa's preparedness and resilience in tackling such infectious disease outbreaks caused by emerging pathogens, public health emergencies and pandemics.*

*GET found the understanding of biosecurity to be a very underdeveloped area on the continent with clear opportunities for using biosecurity to dramatically improve on capacity for prevention and medical countermeasures during public health crises. GET now operates firmly in the African Biosecurity and pandemic preparedness, space and functions as a think tank, providing high level advocacy and operational and necessary expertise to support Countries and communities achieve improved resources to combat outbreaks and other public health emergencies that can threaten stability, peace and security thereby undermining economic growth and well being. The consortium is working with international collaborators with a goal of providing strategic recommendations and establishing infrastructure and research capacity to respond to highly infectious emerging Pathogens such Ebola, ongoing COVID-19 Pandemic.*

*The Consortium creates a rapid informed response strategy and provides advice and guidance to African countries, and a point of reference for international funding and aid agencies.*