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Managing dangerous pathogens: challenges in the wake of the recent West African Ebola outbreak

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ABSTRACT

In the aftermath of the 2014–2016 West Africa Ebola outbreak, there are a multitude of Ebola samples that are unaccounted for as well as virus samples stored in facilities that do not have an appropriate level of biosecurity and biosafety, creating serious threats to public health and security. In this article, we review the existing global governance mechanisms for addressing this biosafety and biosecurity concern. We also describe an ongoing effort to support the Government of Sierra Leone to find and secure Ebola samples as foreign labs are shut down, and institute systems for biosafety and biosecurity. We describe the challenges of tracking all Ebola samples and their associated data, and efforts to place these samples in suitable inventoried repositories by local health authorities. We recommend that governments around the world ensure that plans, procedures and regulations are in place prior to the chaos of an emergency in order to ensure that dangerous pathogens are handled in safe and secure manners, that data are preserved for research, and appropriate practices are utilised for consent.

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Introduction

The twentieth century has seen accidental release and the use of biological and chemical agents by groups or individuals committing heinous crimes against humanity. Many disease-causing pathogens are suitable for weaponisation, but of particular concern are the category 'A' pathogens which are easily transmissible, have a high morbidity and mortality, cause widespread panic and civil unrest and for which there is no known effective therapy (National Institutes of Allergy and Infectious Disease [NIAID], n.d.). Ebola virus disease falls into this category of pathogens. In the aftermath of the 2014–2016 West Africa Ebola outbreak, there are a multitude of Ebola biological samples that are unaccounted for as well as virus samples stored in facilities that do not have an appropriate level of biosecurity and biosafety, creating serious threats to public health and security. In this article, we review the existing global governance mechanisms for addressing this biosafety and biosecurity concern, ranging from international conventions to national measures to ensure biomedical samples are handled in a safe and ethical manner. We also discuss

ongoing efforts to secure samples in Sierra Leone and recommendations for future action.

Background

The West African outbreak Ebola outbreak is thought to have started in December 2013 in Guinea and eventually spread to Sierra Leone, Liberia, Mali, Nigeria and Senegal, in addition to a few sporadic cases in Europe and the United States (Breakwell et al., 2016). The global community, including humanitarian NGOs, responded in the most heavily affected countries, creating a multitude of Ebola holding or quarantine units, coupled with isolation units or Ebola Treatment Units (ETUs; Bell et al., 2016). In the process of screening thousands of patients for the confirmatory Ebola test, biomedical samples were collected and sent to one of many rapidly established laboratories, created to deal with the sudden volume of testing, including mobile laboratories donated by partner nations. These laboratories were established by a variety of partners who were responding to the crisis, including Belgium, Canada,

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China, The Netherlands, France, Germany, Italy, Nigeria, South Africa, Spain, the United Kingdom and the United States (United Nations, 2014; World Health Organization [WHO], 2015a). Additionally, there was an influx of academic research interests as well as commercial clinical research organisations conducting trials, all with access to biomedical Ebola samples.

Over the course of the outbreak, Ebola samples were subjected to one of the following: destruction, export out of the affected country through an official government agreement, export out of the affected country without an agreement or continued storage in country. The samples that remained in the region were often stored in facilities without adequate biosafety or biosecurity, that is, 'protection, control and accountability measures implemented to prevent the loss, theft, misuse, diversion or intentional release of biological agents and toxins and related resources as well as unauthorised access to, retention or transfer of such material' (Biological Weapons Reader [BWPP], 2009). Common practice for safe and secure handling of Ebola when conducting research is to operate within a Biosafety Level 4 (BSL4) laboratory. There are, however, only two BSL4 facilities in Africa, located in Gabon and South Africa (National Academy of Sciences [NAS], 2011).

As the outbreak concludes, labs established by international partners are closing down and samples are being held on behalf of the governments in the affected countries in temporary consolidated storage facilities. There is an effort on the part of the governments that did not already have systems in place to consolidate the remaining samples and data into professionally managed and inventoried biobanks with adequate biosafety and biosecurity standards. Several external entities are working with these governments to build overall laboratory capacity, including the European Union CBRN Centers of Excellence, the U.S. Centers for Disease Control and Prevention, and Expertise France, in addition to the efforts described in this paper. West African Governments are raising questions, however, about not only the safety and security of the Ebola samples, but also the ethical standards that should be applied in relation to the patients who provided the samples and the interests of foreign entities that have expressed interest in using the samples for research (Dakar Declaration, 2015).

International governance and ethical challenges

The West Africa Ebola crisis raised a number of questions about the strength and comprehensiveness of the legal and regulatory systems in place in the affected countries

for emergency health response and public health security. The International Health Regulations (IHR), adopted in 2005, were intended to '... prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade' (WHO, 2008). It was recognised, however, during the *Technical Consultation on monitoring and evaluation of functional core capacity for implementing the International Health Regulations (2005)*, which took place from 20 to 22 October 2015, that '... national capacities were not able to keep pace with national needs to manage these emergencies efficiently and effectively' and that '... assessments of the recent Ebola outbreak had confirmed this situation' (WHO/HSE, 2015c). This consultation, along with a multitude of other review panels and committees are examining how to strengthen global governance of disease, response capacities and how to build appropriate national capacities to implement the IHR (Commission on a Global Health Risk Framework for the Future [GHRFF], 2016; Moon et al., 2015; United Nations, 2016; WHO, 2015b). The IHR themselves and none of these consultations, however, have anything to say about the biosecurity of the Ebola samples. Nor do they have anything to say about sovereign control over Ebola samples and their use or transfer out of the affected countries (WHO, 2008).

The Global Health Security Agenda (GHSA), launched in February 2014, was a response to the need to strengthen global capacity to prevent, detect and respond to infectious disease threats, and in recognition that most countries were unable to successfully implement IHR core capacities (Global Health Security Agenda [GHSA], n.d.). GHSA aims to marshal resources to countries through a series of 11 Action Packages, designed to build and measure capacity around prevention, detection and response. GHSA's Biosafety and Biosecurity Action Package (Prevent-3) and, especially Prevent-3's National Action Item 5 calls upon participating countries to strengthen their biosafety and biosecurity legislation in order to address risks arising from activities involving dangerous pathogens such as Ebola, including '... possessing, handling, using, producing, storing, permitting access to, transferring, importing, exporting, and releasing or otherwise abandoning' (Global Health Security Agenda [GHSA] Action Packages, n.d.). GHSA, however, is not legally binding agreement, as it is solely a consortium of nations committed to building global capacity to fight infectious diseases.

The objectives of the GHSA, however, are well aligned with initiatives going back several years, that support strengthening the Biological and Toxin Weapons

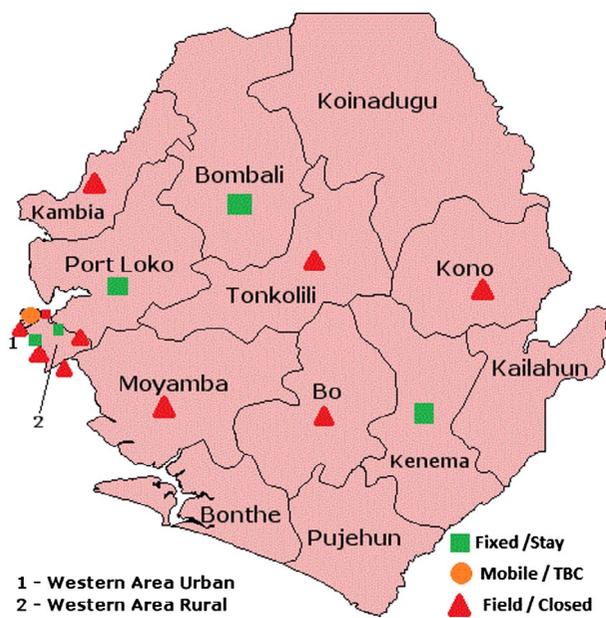


Figure 1. Map showing the location and status of laboratories able to conduct diagnostic testing on Ebola in Sierra Leone. Source: Created by authors, with data adapted and updated from map provided by the Sierra Leone Laboratory Technical Working Group, 2015.

Convention (BWC) and the related provisions of UN Security Council Resolution 1540 (2004) (UNSCR 1540) through regulatory measures. These international regimes hold lessons for how to secure the remaining Ebola samples in West Africa and ensure that any activities involving them are legitimate and properly regulated. The Seventh Review Conference of the BWC agreed that countries must prevent and punish biological weapons activities while also ensuring ‘... the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorised access to and removal of such agents or toxins’ (Biological and Toxin Weapons Convention [BWC], 2011). UNSCR 1540 requires countries to develop and maintain effective measures to account for and secure biological materials (e.g. pathogen samples); to ensure their physical protection; to enhance border control and law enforcement to prevent their illicit trafficking; and for export control over these materials (UNSCR, 2004). Accordingly, sovereign efforts to assert control over activities involving pathogens such as Ebola, through legal and regulatory measures, support the objectives of the GHSA Prevent-3 Action Package, the BWC and the related provisions of UNSCR 1540. At the same time, these efforts strengthen national and global public health and health security as well as response capability.

To achieve the objective of sovereign control over activities involving Ebola samples and other pathogens in the affected countries, there are several steps ahead. First, a comprehensive analysis of existing national legislation must be undertaken to highlight the gaps and areas that require strengthening in their regulatory systems for biosecurity and dangerous pathogen management. Second, governments should consider drafting and adopting legislation which criminalises misuse of dangerous pathogens, while encouraging their safe and secure use for peaceful activities such as research. For example, VERTIC’s ‘Sample Act for National Implementation of the 1972 BWC and Related Requirements of UN Security Council Resolution 1540’ is an example of a comprehensive legal instrument that could be considered by the government in Sierra Leone. Such an act would address regulatory matters with relevant definitions; prohibitions and penalties; control lists for biological agents and toxins, equipment and technology; measures for licensing, transfer control (taking into consideration, for example, the Australia Group Common Control Lists) and transportation; and enforcement measures, including inspections and international legal co-operation and assistance (VERTIC, n.d.).

In addition to addressing the affected countries’ concerns about the security of the Ebola samples and their use, the international norms and ethics of storage, the global community and national governments must also consider the conduct of primary and secondary research and the movement of samples and associated data without adequate ethical considerations and consent.

Biosecurity in practice: the case of Sierra Leone

Ebola samples left over from the 2014–2016 outbreak are widely dispersed across the affected West African nations, and Sierra Leone in particular. The international partners that sponsored the setting up of these laboratories are closing them down, and these samples are most times left in the field laboratories where they were tested during the outbreak, although it is not clear if all of the samples still remain in these laboratories. Aside from the biosecurity implications, this situation also creates challenges to the conduct of research. The cryo-preservation conditions in these structures crafted for emergency response to an outbreak are sub optimal for maintaining bio-material in a fit state for future research. This is especially so now that the emergency situation has waned, causing both funding and attention to be diverted by other priorities (Box 1).

Box 1. What happened to the Ebola samples in Sierra Leone?

Spring 2014–January 2015: Phase of insufficient capacity

In this phase, the Kenema Viral Haemorrhagic Fever Laboratory in the far east of the country was the only laboratory with the ability to diagnose Ebola. All samples were sent to this one lab for diagnosis. Samples from this period held at the Kenema lab may or may not have been accompanied with their demographic data. The backlog of samples led to delays between arrival of samples and actual testing. The documentation in this phase is poor, as one would expect, given the enormity of the outbreak. Results were lost or misassigned. The infrastructure at Kenema was not designed for the volume of samples arising from the expanding outbreak situation. However, this was eventually rectified by nationwide training on sample management, rigid protocol on sample assignment and increasing laboratory facilities across the country through international collaborators.

December 2014–August 2015: Phase of sufficient or at least distributed capacity

This phase was reached progressively, as treatment centres and laboratories sprung up in the wake of the advancing disease. During this phase, the assignment of samples to labs was based on a nationwide matrix to deliver best turnaround time (TAT), which all labs had to report daily to the National Ebola Response Centre (NERC). Samples were sent to the nearest lab with the shortest TAT. Assignment followed a process that is now too complicated to be reconstructed. As partners with differing languages and documentation protocols multiplied across a wider geographical area to stem a growing epidemic, a consistent and homogeneous standard of sample data management became more and more difficult to adhere to. All labs were required to send their daily results back to NERC, although this daily return of results back to NERC was not fully implemented until 22 January 2015.

September 2015–present: The post Ebola recovery period

Due to the diminishing numbers of Ebola cases, partners are closing down their labs from 16 to 8 currently, and anticipated to be reduced to 6 by the end of July 2016 (see Figure 1). Despite no agreed protocol accounting for handing over or disposal of samples, labs run by international partners have closed with samples either transferred abroad, destroyed or moved to other labs in-country.

The Ministry of Health and Sanitation (MOHS) in Sierra Leone centrally captured some of the Ebola sample information in a database. However, this data collection only commenced on 22 January 2015, and the information that does exist on the samples requires individual verification.

There is as yet no agreed protocol for closing the international labs stood up during the outbreak, handing over the samples or cataloguing their data. As labs continue to close, they either export the positive samples, or transfer them to other facilities with a closing date further out in time. Often these transferred samples are found without proper monitoring, files, data or chain of custody records in secluded areas of the secondary or even tertiary labs. Every time they are moved, the chance is increased that sample and data can be separated in an irreconcilable manner, or that samples may be lost.

In Sierra Leone, regulating the export of samples is the domain of the Pharmacy Board. However, in the midst of the Ebola outbreak, numerous other institutions, official and unofficial, became involved with authorising the export of biomedical Ebola samples. The Pharmacy Board itself is an institution that is authorised to regulate the inward distribution and regulation of drugs. It is still developing capacity to deal with small amounts of research-based requests for export of biomedical samples. The Ebola outbreak brought a rush of international institutions aiming to assist in stopping the outbreak, and in the middle of the devastating outbreak, the Government had difficulty monitoring and keeping track of all of the actors and their actions. This was made even more complicated by the absence of any national biosafety/biosecurity legal or regulatory framework to guide the process of sample safety and security or the ethics of sample sharing. This lack of existing legal and regulatory infrastructure, combined with the number of actors operating in the country as part of the outbreak response, and the chaos of the outbreak itself, resulted in a situation in which it became and remains impossible to track what happened to all of the biomedical samples of Ebola. Box 2 explains what happened to biomedical samples of Ebola taken from the affected population in Sierra Leone at the height of the Ebola outbreak.

As the outbreak decreased in intensity, global organisations, including the World Health Organization, took steps to better understand the biosafety/biosecurity implications of the Ebola sample. The Global Emerging Pathogens Treatment Consortium (GET), an Africa-based consortium of experts focusing on Emerging Infectious Diseases, worked with the government in Sierra Leone to provide a series of services focused on five key areas to build national capacity to support research capacity on dangerous pathogens:

Box 2. Biomedical sample and data chain of custody during the Ebola outbreak in Sierra Leone

Patient presents or is referred to a holding center and gives blood or other biological tissue for routine diagnosis with or without consent

- (1) Patients may be enrolled in subsequent research study or clinical trial with or without consent.
- (2) Regarding biomedical sample used for diagnostic procedure and other research related activity, remnant is stored in existing form or in a processed form along with sample-related data (with and without consent).
- (3) Clinical and research data accrue at the laboratories, holding centers, ETUs and other clinical locations.
- (4) Sample is exported out of the country for further analysis or for 'safe keeping' with or without Material Transfer Agreements and export permits.
- (5) Further data are generated from exported samples or transferred to commercial concerns and subject to academic enquiry or knowledge derivation economy.
- (6) Some samples are destroyed with or without consent of patients or the custodial governments.
- (7) Some samples are subjected to further experimentation including injection into primates without consent.

- *Infrastructure:* Bringing partners renovate the National Blood Bank of Sierra Leone with full plasmapheresis capacity;
- *Manpower:* Provision of local capacity building programmes to upskill technicians to levels proficiency to handle dangerous pathogens;
- *Knowledge support:* Providing technical support to enable the government to engage in fair contract negotiations for clinical trials, discussions on biobanking capability, drafting policy related to biosecurity and biosafety, and assisting in proposal writing;
- *Funding support:* Identifying and bringing onboard appropriate funding partners to support biosafety/biosecurity capacity building in the country;

- *Implementation support:* Assisting with manpower and international quality assurance support to ensure that research projects on pathogens performed within the country conform to global standards.

The chaos of the outbreak, coupled with non-mature public health infrastructure, incomplete legal and regulatory systems, and the desperate need for rapid international assistance created an environment that enabled weak accountability. While the international community will always face an urgency to gain access to samples to advance the understanding of a disease and provide solutions that could assist with containment strategies, it is essential that clear global governance and specificity that adjudicates over the rights to and movements of biomedical material be developed and clarified. Nations – particularly developing nations – must focus on the creation of national legislation to address the movement and authority over samples, particularly those that pose a threat to biosafety and biosecurity.

Conclusion

It is the responsibility of the global health community, which includes international and regional organisations, governments (across their ministries), emergency response and medical assistance NGOs, first responders, police and intelligence officials, to ensure that dangerous pathogens such as Ebola, when acquired during disease outbreaks, are properly secured and sequestered in a manner that is in keeping with international obligations (BWC, UNSCR 1540), voluntary international standards (GHSA) and accepted ethical norms for the patients from whom the samples have been taken. The global health community must also ensure that these samples, and research on them in laboratories do not pose a threat to health care workers or to the public through accidental release (a biosafety issue), and that opportunities do not arise for theft or intentional misuse (a biosecurity issue). The objectives of biosecurity and biosafety cannot be achieved unless the principles are inculcated into the culture and practice of the populace generally and the laboratory/medical personnel specifically, with known repositories for safe deposit of the samples.

In view of this, it is incumbent that in the aftermath of the recent outbreak of the Ebola virus in West Africa that all Ebola samples and their associated data are accounted for either by planned destruction or placed in suitable inventoried repositories by the local health authority or representatives thereof in whose jurisdiction the outbreak has occurred. Access to biological samples and their data should be decided by clearly defined

governance mechanisms and adjudicated over by principles that serve the global community while ensuring there is beneficence and due ethical consideration for the patients and communities from whom the samples were taken.

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Brian Conton is the owner and Clinical Director of the Physio-Fitness rehabilitation Centre in Freetown. He has worked on convalescent whole blood and serum studies for managing Ebola patients. He is currently the project lead for establishing a secure biobank to store samples left over from the 2014–2015 Ebola outbreak in Sierra Leone. He is a member of the GET Consortium.

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