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Investigating Diagnostics in Global Health

Working paper

Laboratory strengthening in public health emergencies: perspectives from Sierra Leone

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Executive summary

The 2020 COVID-19 outbreak has dramatically highlighted the vital role laboratory systems play in effective epidemic response, with medical testing widely recognised as essential to immediate containment and ongoing surveillance. In under-resourced settings with weak and fragmented laboratory infrastructure, public health experts are rightly concerned about the potential for the virus to spread through communities undetected. This is not the first time that weaknesses in laboratory infrastructure have been thrown into sharp relief by an infectious disease outbreak: efforts to contain the 2014-2016 Ebola virus disease (EVD) outbreak in West Africa were similarly impeded by testing limitations, prompting massive international investment in laboratory strengthening in the region. It is important to reflect on the lessons learned from laboratory-focused interventions during the Ebola crisis and, in particular, on how those interventions were received and experienced on the ground, in order to inform current strategies for COVID-19 emergency response and health system building.

This working paper examines the impact of international efforts to strengthen laboratory systems during and after the Ebola outbreak in Sierra Leone. Sierra Leone was the country most severely affected by the Ebola outbreak and is currently preparing for a predicted rise in COVID-19 cases. Adopting an anthropological approach, we focus our analysis specifically on the impact of emergency laboratory interventions on health system staff. In particular, we propose that the perspectives and experiences of laboratory experts in Sierra Leone are fundamental to improving scientific and policy understandings of how laboratory systems work and where international assistance might be most effectively directed. Despite its importance, we argue, this knowledge is often forgotten or neglected by researchers and policymakers in the aftermath of an emergency.

The paper draws on a scholarly and grey literature review of laboratory system building during the Ebola outbreak and its aftermath, in addition to 8 months of anthropological fieldwork, including observations of 12 laboratories in Sierra Leone and 48 interviews with local laboratory staff, national-level policymakers, and international laboratory scientists involved in the Ebola outbreak in Sierra Leone. The first section of the working paper provides a brief historical overview of the development of laboratories during British colonialism (1808-1961) up to the Ebola outbreak in 2014. The second section discusses qualitative insights regarding investments made in three key areas of laboratory capacity building: governance, material infrastructure and training, and post-Ebola laboratory capacity building in government and healthcare institutions. The final section highlights local priorities for laboratory capacity building and provides recommendations to best enable future emergency laboratory strengthening efforts to have lasting impact on the ground.

We argue that, whilst the Ebola epidemic significantly improved the molecular diagnostic capacity of the country, sustained investments are needed in the areas of regulatory capacity, material infrastructure, and training to address current gaps in quality assurance, supply chain management, specimen transportation, maintenance systems and waste disposal. Drawing on three case studies of laboratory capacity building in three different healthcare institutions, we show how international organisations differ in their approaches, ranging from supporting government hospitals with point-of-

care diagnostics and generalised laboratory capacity to creating exemplary institutions and reference laboratories with donor-dependent laboratory procurement and distribution systems. We argue that every organisation struggled to connect their work to existing government laboratory systems (including supply chain management, specimen transport, and surveillance systems), and that these failures to connect affected the sustainability of investments within the national laboratory network. Point-of-care diagnostics (including cartridge-based bench-top devices and rapid diagnostic tests) were used by all three organisations as temporary solutions to address gaps in the government's diagnostic system, but are often difficult to integrate within national procurement and distribution systems. Future interventions should be encouraged to incorporate sustainability measures, such as maintenance contracts, during the design phase of each project. Similarly, training of laboratory personnel and material support should be standardised in order for emergency laboratory-strengthening efforts to have lasting impact on the health system.

1. Introduction

The West Africa outbreak of Ebola virus disease was unprecedented in terms of magnitude and caused major public health and socio-economic crises in the region. Between December 2013 and July 2016, an estimated 28,616 people were infected and 11,310 people died across Guinea, Sierra Leone, and Liberia, the three worst-affected countries (WHO 2016a). Sierra Leone had the highest number of cases, with 14,122 estimated infections, of which 8704 were laboratory-confirmed (Ibid.). Healthcare workers were among the people most severely affected by the outbreak, with an estimated 295 infected and 221 deaths, representing 21 percent of Sierra Leone's health workforce (GoSL 2015). In Sierra Leone, laboratory workers had the second-highest number of occupational infections, after nurses (WHO 2015).

The Ebola outbreak exposed significant gaps in Sierra Leone's laboratory system. The scarcity of diagnostic devices in the early weeks of the outbreak left patients waiting for days in isolation centres for laboratory results (Paweska et al. 2017). The lack of a unified national sample transport system to enable transportation between the rural health centres and Ebola diagnostic facilities hampered a timely and coordinated response (Sesay 2016), while delays in laboratory confirmation impeded control and prevention efforts, allowing the epidemic to spread undetected within and across borders (Nkengasong and Skaggs 2015).

Investment in diagnostics and laboratory systems has long been a neglected component of health system strengthening efforts in low- and middle-income countries (Ondoa et al. 2017). The Ebola outbreak prompted a wide range of international assistance in terms of laboratory support and emergency preparedness, varying from the provision of mobile laboratories meant to upscale the Ebola diagnostic capacity in-country, to technical assistance in the development of national-level laboratory and surveillance systems and policy frameworks, to the establishment of entirely new laboratories, hospitals, and training programmes.

While many international laboratory teams have published accounts of their diagnostic achievements and laboratory support during the outbreak (Bailey et al. 2017; Boisen et al. 2016; Paweska et al. 2017; ZeLiang et al. 2015; Mesman et al. 2019; Reusken et al. 2016; Arias et al. 2016; Logue et al. 2017), less is known about the long-term impacts of these interventions. Additionally, a policy review of the UK government's response to the outbreak concluded that there has been inadequate systematic reflection to meaningfully assess the effectiveness of supported interventions (ICAI 2018). The perspectives of Sierra Leonean laboratory workers and policymakers regarding the international laboratory response and future epidemic preparedness efforts are a notable absence in this literature, but are fundamental to understanding what worked, what didn't, and what lessons must be widely learned to improve future epidemic responses, especially in resource-poor health systems.

Social scientists (McMahon et al. 2016; Park 2016; Raven, Wurie, and Witter et al. 2018) have documented health workers' experiences of and responses to the outbreak, which included stigmatisation, institutional humiliation, depression, stress, isolation, and economic hardship. Furthermore, the outbreak exacerbated a weak sense of trust within and across health facilities,

providers, communities, and households (Richards et al. 2019). There has, however, been a notable absence of social science research exploring the perspectives and experiences of Sierra Leonean laboratory staff working during the Ebola outbreak, which itself mirrors the lack of attention that laboratory workers received in media coverage of the epidemic relative to other health professionals. This is despite the essential role played by laboratory staff in bringing the epidemic to an end. Such absences risk reinforcing the broader neglect of laboratory services in global health priority settings.

This working paper draws on a scholarly and grey literature review of laboratory system building during the Ebola outbreak and its aftermath, in addition to anthropological fieldwork including observations and interviews at 12 laboratories in Sierra Leone. Qualitative data collection was conducted over a period of 15 months (September 2018–December 2019), during which 48 interviews were conducted with laboratory staff (#15), health workers (#12), and key informants (#21) including (inter)national-level policymakers and international laboratory scientists working in response to the Ebola outbreak in Sierra Leone.

The first section of the working paper provides a brief historical overview of the development of laboratories during British colonialism (1808-1961) to the Ebola outbreak. This is followed by a section discussing qualitative insights from interviews and literature review regarding diagnostic interventions during the 2014-2016 West Africa Ebola outbreak in three key areas of laboratory capacity building: material infrastructure, governance, and training. We then describe three examples of how international organisations contributed to the long-term laboratory capacity building of health institutions, using insights derived from observations and interview data. The final concluding section offers recommendations to ensure emergency laboratory-strengthening efforts have longer-lasting effects. These recommendations have the potential to inform the international response to the current COVID-19 outbreak and improve the future epidemic preparedness of Sierra Leone.

2. Laboratory system prior to the Ebola outbreak

The fragmented and under-resourced laboratory system with which Sierra Leone was forced to respond to Ebola in 2014 was a direct legacy of the neglect of medical testing infrastructure by colonial and postcolonial regimes. The first laboratories were established by British colonial authorities in Sierra Leone in the early 1900s, born out of a desire to gather knowledge about the causes and control of malaria and other tropical diseases, which had killed many of the first European settlers and gave the country its reputation as the 'White Man's Grave' (Bockarie, Gbakima, and Barnish 1999). The British government focused its laboratory investigations on the Freetown peninsula, which was made a Crown Colony in 1808. Few investigations were undertaken in the 'provinces', the interior land over which Britain declared a protectorate in 1896, and laboratory services, like other medical services, were largely inaccessible for Sierra Leoneans.

In the 1950s, various epidemiological surveys undertaken in the provinces by WHO resulted in the establishment of two serological laboratories, one of which was located in Bo District in Southern Province (WHO 1962), but there were no comprehensive efforts to establish integrated, country-wide laboratory and disease surveillance services (Manton and Gorsky 2018). At independence in 1961, laboratory services therefore remained concentrated in international research laboratories and a handful of government colonial hospitals or mission hospitals.

In the 1960s, WHO supported newly independent countries with health system planning, and Sierra Leone's first National Health Plan mentions the plan to establish a national laboratory service (MoHS 1965, in Manton and Gorsky 2018). But these plans were impeded initially by the absence of a trained national workforce (Manton and Gorsky 2018), and were all but abandoned in the 1970s with the financial restrictions that followed the world oil crisis and growing political unrest in the country (Shakow, Yates, and Keshavjee 2018). New international research laboratories were established in Sierra Leone by international agencies, such as the United States Centers for Disease Control and Prevention (US CDC). But clinical laboratory services remained fragmented and limited to central government hospitals and a few private laboratories that began to spring up in commercial centres (MacCormak 1984).

The civil war (1991–2002) crippled the health system and led to an outflux of the international agencies that had been supporting laboratories, including the US CDC and the WHO. After the war, efforts to rebuild the health system were dictated by debt relief conditions and focused on decentralisation, community financing, and support for a private sector that had grown substantially during the war when public services were closed. Little investment was made in the training, transportation systems or referral infrastructure required for a national laboratory system.

In 2008, laboratory experts from sub-Saharan Africa countries and major global health donors in the field of malaria, TB, and HIV/AIDS met in Maputo, Mozambique, resulting in the Maputo Declaration on strengthening of laboratory systems (WHO 2008a). The Maputo Declaration outlined three crucial elements of a functional laboratory network: 1) human capacity with competent staff and effective supervision; 2) infrastructure, including uninterrupted power supply, access to distilled water,

functioning laboratory equipment, and supply chain management system to provide diagnostics, reagents, and consumables; and 3) the management of quality assurance systems (WHO 2008b). In Sierra Leone, the Declaration prompted numerous policy initiatives, including the publication of first national medical laboratory policy in 2009, the establishment of the Laboratory Medicine/Science undergraduate degree course at the University of Sierra Leone's College of Medicine and Allied Health Sciences (COMAHS), and the inclusion of laboratory services in the 2010 and 2015 Basic Package of Essential Health Services (MOHS 2010, 2015).

The growth in international, donor-funded disease programmes for HIV, Malaria and Tuberculosis in the 2000s led to investments in training, quality assurance and infrastructure for disease-specific laboratory testing programmes. The Central Public Health Reference Laboratory (CPHRL), established in 2011, for instance, was funded by the US CDC through The President's Emergency Plan for AIDS Relief (PEPFAR) to provide quality assurance and post-market validation of diagnostic tests for HIV, and carry out testing for epidemic-prone diseases such as influenza, yellow fever, measles, and cholera. But donor-driven initiatives were uncoordinated and limited in scope (Barr et al. 2019), while national level planning for laboratory systems remained, for the most part, unimplemented (Njuguna et al. 2019). The lack of system-wide investments and funding left significant gaps in basic laboratory services, including the lack of an effective sample transportation system (MoHS 2015), an absence of laboratory testing at community and district levels, and a dearth of investment in systems for waste management, maintenance or quality assurance. This was the state of the laboratory system when the first cases of Ebola were detected in March 2014.

3. Diagnostic interventions during Ebola

This section describes the main diagnostic interventions during Ebola in the three areas highlighted as crucial elements of a functional laboratory network: 1) material infrastructure (including diagnostic laboratories and equipment, as well as specimen transportation methods); 2) governance (national coordination and policymaking, as well as international emergency regulation mechanisms); and 3) training (human capacity building in molecular diagnostics). These three areas were outlined by interviewees as core areas where major improvements were made during the Ebola epidemic. In this section we discuss each of these areas in turn, focusing on the kinds of interventions made, the actors involved, and perceptions of their long-term impact on the health system by laboratory experts in Sierra Leone.

In Sierra Leone, the first positive Ebola sample was identified inside the Viral Haemorrhagic Fever Consortium (VHFC) research laboratory at Kenema Government Hospital on 25 May 2014 (Gire et al. 2014). The city of Kenema, situated in Eastern Province, is endemic to Lassa fever, another type of haemorrhagic fever, and houses the only Lassa treatment centre and isolation ward in the country (Shaffer 2019). The VHFC laboratory was constructed in 2005 on the grounds of the hospital as part of the Manu River Union Lassa Fever Network[1], and focused on the research and development of diagnostics, primarily for Lassa fever (Wilkinson 2013).

During the Ebola outbreak, Kenema's research laboratory was also used by the American epidemiological data company Metabiota, Inc., set up by the 'virus hunter' Dr. Nathan Wolfe, whose core business was using surveillance data to predict new outbreaks and who had been conducting research on viral haemorrhagic fevers in Sierra Leone since 2009 (Lachenal 2015). When the Ebola outbreak began in Guinea, Metabiota, Inc. was contracted by the US Department of Defence to assist Sierra Leone's government with setting up Ebola screening and contact tracing to enable the early detection of cases and prevent further transmission (Wauquier et al. 2015).

In the early months of the epidemic, most Ebola infections occurred in Kenema's neighbouring district, Kailahun. Kenema's district medical officer requested the VHFC staff (consisting of surveillance officers, phlebotomists, and a laboratory technician experienced in working with Lassa fever) to train Kailahun's district health management team (DHMT), which had no experience of handling haemorrhagic fevers. Because of the under-resourced national specimen transportation system, in the early months of the outbreak a VHFC vehicle was used to transport specimens from Kailahun to Kenema. Other samples were transported by the DHMT's surveillance vehicles, ambulances, motorbikes, and even public buses early on in the outbreak (Walsh and Johnson 2018).

Besides the samples, suspected Ebola patients travelled to Kenema, where the hospital's 25-bed Lassa ward was turned into an Ebola ward, which soon ran out of resources, including protective gear. In June 2014, the doctor in charge of the Lassa ward and the country's only virologist, Dr. Sheik

1. A multi-country consortium including the World Health Organization, United Nations, the United States' Office of Foreign Disaster Assistance (OFDA), the US Army Medical Research Institute of Infectious Diseases (USAMRIID) and Tulane University (Khan et al. 2008).

Humarr Khan, was reported to be managing 80 Ebola patients by himself (Hayden 2014). Inside Kenema's laboratory, Metabiota, Inc. and VHFC laboratory staff were analysing suspected Ebola samples using reverse transcription polymerase chain reaction (RT-PCR) molecular techniques, which are considered the gold standard[2] for Ebola diagnosis. RT-PCR methodology requires laboratory infrastructure (e.g., electricity, temperature-sensitive reagents, equipment maintenance, and technical expertise in molecular biology) and usually takes between four and six hours to produce results (Broadhurst, Brooks, and Pollock 2016). At the start of the outbreak, this kind of laboratory infrastructure and molecular expertise was not available in any other government laboratory in the country.

As the virus spread across the country, the VHFC laboratory struggled to deal with the rapidly increasing number of samples sent to them. At the time, the VHFC research laboratory employed only three Sierra Leonean laboratory staff (two laboratory scientists and one laboratory technician), all of whom soon became overwhelmed by the volume of work and who, during interviews, described being sleep deprived:

> At times, we got a minimum of 500 people per day. So we had to analyse all those samples. At the end of the day it was very tiring because we had to work flat out. It was really, really tiring (laboratory staff #47).

Kenema's laboratory and Ebola ward could not cope with the number of samples and patients, and many health workers (including laboratory staff, nurses, and doctors, including Dr. Khan) lost their lives due to occupational infections (Goba et al. 2016).

In August 2014, as the epidemic reached hundreds of cases per week in Liberia, Guinea and Sierra Leone, the WHO announced a Public Health Emergency of International Concern (PHEIC). The delay in the WHO's declaration was attributed to poor political mobilisation and insufficient surveillance and laboratory capacity in West Africa, which hampered early detection and led to an underestimation of the scale of the epidemic (Hoffman and Silverberg 2018). The announcement of the PHEIC galvanised international agencies and governments, helping to mobilise resources to improve laboratory testing across the region. Additionally, it activated WHO's central mechanism for responding to public health emergencies: the Global Outbreak Alert and Response Network (GOARN). Through GOARN, a wide range of international laboratory support was deployed, including public health agencies (the Public Health Agency of Canada, the US CDC, the Chinese Center for Disease Control and Prevention, and South Africa's National Institute for Communicable Diseases), research institutes (the *Institut Pasteur* and *Bernhard-Nocht-Institut*), UN agencies, the UK's DFID, and the EU Mobile Laboratory.

3.1. Material infrastructure

The first international laboratory team deployed through GOARN was Canada's Public Health Agency (in mid-July), which set up the first mobile laboratory in a *Médecins Sans Frontières* (MSF) treatment

2. Other diagnostic techniques used to detect Ebola include viral culture tests, serological tests, and antigen ELISA tests, none of which were available in Sierra Leone at the onset of the outbreak.

centre in Kenema's neighbouring district, Kailahun. MSF reported not receiving contact lists from confirmed Ebola-positive cases from Kenema's laboratory and raised the alarm that the epidemic was 'out of control' (MSF 2015). The Canadian team of laboratory scientists began checking the Ebola samples from Metabiota, Inc. and VHFC laboratories and alerted the WHO, the US CDC, and the Sierra Leone Ministry of Health and Sanitation, reporting false-positive tests and discrepancies between test outcomes by Metabiota, Inc. and VHFC laboratories[3]. In August 2014, an international laboratory team from the US CDC deployed through GOARN and 'took over' Ebola screening from the VHFC and Metabiota, Inc. (Wauquier et al. 2015: 4). As the epidemic spread to the west of the country and the need to improve testing infrastructure became increasingly urgent, a growing number of international laboratories were established across the country.

During the outbreak, a total of 18 international laboratories supported the diagnosis of Ebola in Sierra Leone[4]. Eleven laboratory teams worked in mobile laboratories, also referred to as *modular* laboratories, which come in different forms, including inflatable tents, shipping containers, converted trucks, and portable negative-pressure biological containment systems set up in fixed structures (Wölfel et al. 2015; Haaskjold et al. 2016; Reusken et al. 2016; ZeLiang et al. 2015; Paweska et al. 2017). Mobile laboratories were deployed by the European Mobile Laboratory Project (EMLab), Public Health England (PHE), the Dutch Ministry of Foreign Affairs, the African Union and the Chinese Military, among others.

3. **https://www.cbsnews.com/news/american-company-metabiota-problems-during-ebola-outbreak/** (accessed 6 August 2019)

4. See **"Table 1" on page 43** for an overview of the Ebola diagnostic laboratories during the outbreak.

Image 1: The mobile laboratory used during Ebola outbreak supported by the Dutch government was left at the Princess Christian Maternity Hospital in Freetown. Photo by Olivia Acland, August 2019.

Field laboratories were also used. In some cases equipment was installed inside fixed structures at hospitals or Ebola treatment units, as was done by US CDC (Flint et al. 2016). In other cases new structures were built from scratch. For instance, Public Health England/DFID funded the construction of fixed laboratories by the British military in Makeni, Port Loko, Kerry Town, and at Emergency Hospital in Freetown (Bailey et al. 2017; Colavita et al. 2016). Most of these laboratories were temporarily used during Ebola, and its equipment was later transported to newly build or refurbished laboratories located in more conveniently located places inside government hospitals, as some of the Ebola field laboratories were located outside towns, and thus more difficult to reach.

Image 2: Remains from PHE-run laboratory located at former Ebola treatment unit outside Makeni town. Photo by Oliva Acland, August 2019.

Whilst the majority of international agencies focused on increasing Sierra Leone's diagnostic capacity for Ebola specifically, the African Union, besides running an Ebola-focused mobile laboratory, also supported non-Ebola clinical laboratories. The African Union sent a total of 844 health workers to Sierra Leone, Guinea, and Liberia to support critical health services, including laboratory staff, who supported non-Ebola government hospital laboratories by developing quality manuals and working to improve laboratory safety standards (AAEST 2016).

Besides the diagnostic assistance provided by international laboratory teams, transportation of specimens from holding centres to Ebola diagnostic laboratories was supported by the British military from October 2014. As part of the UK's aim to enable a 'swifter' Ebola response, the British military provided a helicopter for sample transport, which significantly improved the turnaround times of test results (Walsh and Johnson 2018). Furthermore, the UK's DFID funding was used to employ Sierra Leonean health workers as 'laboratory liaison officers' in Ebola laboratories, who immediately phoned laboratory results to clinicians, and 'specimen courier supervisors' to oversee specimen transport (Options 2015). These additional staff formed a crucial part of the diagnostic infrastructure during Ebola (the positions were closed post-Ebola), as they communicated and cross-checked patients' test results (for which knowledge of local languages and spelling was important). One laboratory staff member who was employed through this scheme in a South Africa-supported Ebola laboratory explained:

> The South Africans came every five or six weeks. They bring in a new set of experts, yes, so we normally worked with them because, the thing is, they cannot pronounce some of their local

> names, how to spell [when] collecting data, putting it into the system, and sending out results (laboratory staff #45).

Much of the emergency laboratory infrastructure that entered the country as part of the emergency response was repatriated when the epidemic ended along with the international laboratory workers who had staffed them. But some field and mobile laboratories were donated to the MOHS, including the Chinese military mobile laboratory which was donated to 34th Military Hospital, and the mobile laboratory funded by the US Defense Threat Reduction Agency which became stationed at the CPHRL lab in Lakka.

Image 3: Donated mobile laboratory run by MRI Global during the outbreak in Moyamba, currently located at the CPHRL compound in Lakka. Photo by Eva Vernooij, February 2019.

Both the Chinese military and PHE closed the emergency field laboratories they had established during the outbreak, but built new hospital laboratories nearby. The Chinese military built a new infectious disease unit at the 34th Military Hospital in Freetown, including a laboratory which mainly specialises in HIV and hepatitis B infections. PHE established new 'legacy laboratories', refurbishing the government's hospital laboratory in Makeni, and at Connaught Government Hospital in Freetown, as well as the construction of an entire new laboratory structure at Bo Government Hospital (Logue et al. 2017, Peña-Fernandez and Choi 2016). The China CDC and PHE post-Ebola laboratory projects became a part of a range of post-Ebola institution building efforts by a range of international agencies and NGOs, which are discussed in more detail in the next section. In many cases the equipment that had been used in field laboratories was transferred to the new permanent hospital laboratories. For example PHE transferred the GeneXpert automated PCR machines it had used in the later stages of the epidemic to its legacy laboratories in Bo and Makeni.

Image 4: Makeni government legacy laboratory build by PHE during Ebola. Photo by Olivia Acland, August 2019.

Image 5: Lab technician uses the GeneXpert machine for HIV viral load testing, 34th Military Hospital Freetown. Photo by Olivia Acland, August 2019.

Towards the end of the outbreak, automated RT-PCR machines had become widely used across the international laboratory network. Many of these machines supported assays for multiple diseases, and their donation to hospital laboratories at the end of the outbreak contributed to increased in-country PCR testing capacity. Interviewees described increased molecular diagnostics laboratory capacity as one of the primary lasting impacts of the emergency laboratory response:

> Honestly, this [Ebola] has improved the laboratory network. Today you go to most of our laboratories, people know something about molecular science; they know how to process samples because we have the equipment and we have the individuals that have been trained to do that (laboratory staff, #45).

In order to sustain the material infrastructure investments made in the laboratories where Ebola diagnostic testing took place during the outbreak, there is a need to expand the biomedical engineering unit and negotiate maintenance contracts with diagnostic companies to train and build local capacity in preventative maintenance. Our interviewees shared different stories of laboratory equipment such as centrifuges, freezers, and PCR equipment break downs for which they waited weeks or months before it was repaired. There are only a few biomedical equipment engineers in-country, one of them works at the largest hospital in Freetown, and explained that one of his main problems is accessing spare parts for fixing or replacing broken equipment, often donated by partner agencies. He explains:

> There was one centrifuge that was brought in there by Public Health England about 12,000 reps per minute, it was having problems with the rotor. We didn't have a rotor in the country. The problem was there was a long screw that fits underneath the rotor. That was broken, and for you to access it was very, very difficult. So that piece of equipment had to be in the workshop for over three weeks. So we diagnosed the problem, but even if you do where can you get those particular screws? You have to go to the black market to see how we can improvise to get the screw. We fixed it onto the centrifuge and now they are using it (key informant, #48)

At the time of the field visits in 2019, there were twelve laboratories where molecular diagnostic testing was done during Ebola and where PCR equipment was available (though few laboratories had the necessary reagents to conduct Ebola testing), of which seven are located in public government hospitals, three were research laboratories and two reference laboratories[5]. However, as we discuss below, outstanding challenges in integrating this PCR testing infrastructure, which had been built up around one specific disease, with a national laboratory system meant this capacity was, in many instances, unrealised.

5. See **"Table 2: PCR-equipped laboratories where molecular capacity was build during Ebola" on page 43** for an overview of PCR-equipped laboratories.

3.2. Governance

Coordinating the various international laboratories and the transportation of samples were described by one prominent laboratory expert in Sierra Leone as challenging because of an ill-defined leadership plan, which resulted in most laboratories operating independently (Wurie 2016). During the first months of the outbreak, coordination of the Ebola response was led by the Ministry of Health and Sanitation through the establishment of the National Ebola Task Force, chaired by the Minister of Health, with representatives from other government departments, UN agencies (WHO, UNFPA, UNICEF, WFP), and other smaller donors and NGOs (Ross 2017). The task force was later substituted by an Emergency Operations Centre (EOC), which was initially run out of the WHO's office and later moved next to the headquarters of the Republic of Sierra Leone Armed Forces in Freetown (Walsh and Johnson 2018). Both governance mechanisms were critiqued for lacking strategic planning, and political tensions between different directorates hampered the response (Ross 2017). In October 2014, the Sierra Leone president restructured the governance structure and appointed the Sierra Leone Minister of Defence as the new national Ebola coordinator in charge of the National Ebola Response Centre (NERC) and District Ebola Response Centres (DERCs), which operated separately from the existing Ministry of Health and Sanitation (MoHS) DHMTs.

A laboratory technical working group (LTWG) was established in 2014, consisting of national and international laboratory scientists and acting as an expert advisory body for the MoHS. After the changes in Ebola governance, the MoHS and LTWG continued to be involved in the coordination of laboratory system improvements and, working with the WHO and US CDC, developed a manual for specimen collection, packaging, and dispatching (Zhang et al. 2015).

During Ebola, the US CDC, the WHO, and DFID were the primary technical advisors for laboratory-strengthening activities. The work of technical advisors consisted of providing advice to MoHS in working groups on epidemiology and surveillance, case investigation, laboratory capacity, sample transportation, infection control, community engagement, and safe burials (Dahl et al. 2016). Whilst the US CDC's work focused mostly on improving surveillance systems informed by the Global Health Security Agenda (GHSA), the UK's DFID's focused on providing 'problem solving support' to improve specimen transport coordination by designing a standardised data reporting system, (DFID 2016). Additionally, DFID funded a national assessment of laboratory systems for the MoHS, which was used to develop a national laboratory strategic plan.

The WHO provided technical advice during the outbreak by deploying staff to help national government ministries formulate Ebola response plans. In the early months of the epidemic, the WHO accelerated the research and development of Ebola rapid point-of-care tests for use in decentralised healthcare facilities and issued target product profiles (TPPs) for Ebola diagnostics in countries with limited laboratory infrastructure. Furthermore, the WHO established an emergency use authorisation listing (EUAL) mechanism to review the submissions of new diagnostic devices (Raftery et al. 2018). In Sierra Leone, several rapid Ebola diagnostic tests and one point-of-care automated RT-PCR device

(Cepheid's GeneXpert Ebola assay), were validated in small-scale validation studies[6]. Alongside diagnostic manufacturers, NGOs, and research organisations, the WHO was conducting its own clinical validation study of rapid diagnostic tests (RDTs) and newly developed PCR-based assays in several international laboratories in Sierra Leone.

The EUAL mechanism was criticised by the health workers, policymakers, and laboratory workers we interviewed. One criticism was related to the WHO's assumed role of diagnostic evaluator. Local authorities in Kenema decided to use an Ebola RDT in December 2014 developed by the VHFC consortium while the WHO was still undertaking a separate evaluation of the RDT. The District Management Officer decided to ignore WHO's orders and felt the RDT could be of use to help protect health workers by using it as a triage tool to separate people who tested positive, who were classified as probable cases, from the people who tested negative (classified as improbable cases). The results of the RDTs were not given to patients, but were shared with the health workers, who then took extra care when treating the probable Ebola patients while awaiting laboratory confirmation of the diagnosis. An interviewed laboratory technician reported having used the RDT to test sick children admitted to the paediatric ward, which helped prevent the mixing of probable Ebola patients with other sick children in the ward. He argued:

> They [the WHO] were like, 'Oh no, this—you are going against the ethics. This kit is not approved.' But I was not looking for what was approved, what not approved at that point. I was looking [to save a] life at that particular point (key informant #20).

Another issue was that, while emergency regulatory mechanisms focused on point-of-care tests for Ebola, this did little to improve basic laboratory capacity for diagnosis and management of endemic diseases in Sierra Leone. Even in the midst of the outbreak, some health workers saw international actors' focus on Ebola diagnostics at the expense of other basic laboratory tests as an oversight. They argued that when it comes to caring for Ebola patients, tests such as liver function or electrolytes were crucial to monitor and save lives during the outbreak, but received far less attention than Ebola diagnostics, and depend on well-equipped microbiology, haematology and biochemistry departments, which received little investment from international agencies (Ansumana et al 2020).

6. See **"Table 3: Ebola rapid diagnostic tests validated/used in Sierra Leone" on page 45** for an overview of the Ebola rapid diagnostic tests used in Sierra Leone.

Image 6: Makeni government hospital microbiology/haematology/biochemistry laboratory (which received little investments during and post-Ebola). Photo by Olivia Acland, August 2019

One possible success story in terms of the EUAL's contribution to longer-term health system strengthening efforts is provided by the Cepheid GeneXpert machine. In March 2015, the GeneXpert Ebola assay received emergency use authorisation (WHO 2016c). The assay provided results in 90 minutes, required less molecular expertise and human resources to operate and was more specific and sensitive than serological tests. As the GeneXpert diagnostic platform also supported tests for MDR-TB and viral load testing for HIV, it had the potential to contribute to broader PCR-based diagnostic capacity after the end of the outbreak.

In the summer of 2015, following the EUAL listing of the GeneXpert assay and with a view to the platform's potential for broader system-strengthening, PHE, with WHO support, brought several GeneXpert machines into the country. However, the Sierra Leone Pharmacy Board, which reviews the quality of medicines and diagnostic devices, did not feel they were properly consulted in this process. The people who approached them for registration seemed to assume that ethical approval for the original research study on which the WHO's EUAL listing was based, immediately conferred approval for product registration. Yet, as was explained by a key informant, any diagnostics that is being tested for the purpose of market authorisation (rather than research) should inform the Sierra Leone Pharmacy Board prior to commencing the validation trial:

> This lady from WHO came, a British lady, brought the application, so we asked for data to inform the registration, and they said they did the study in Sierra Leone. Sierra Leone? We have not approved any such study . . . People just come in country and do what they want to do and then they disappear (key informant #44).

This event fed into a sense, widely articulated by civil servants and laboratory workers in Sierra Leone, that international systems of governance and regulation by-passed national systems and needs and failed to respect national sovereignty.

3.3. Training

Whilst many of the international laboratories responding to the Ebola outbreak provided some kind of in-house training to local staff, few laboratories incorporated national laboratory staff into daily operations of performing PCR testing and analysis during the peak phase of the epidemic. Yet towards the end of the epidemic, different training courses on molecular diagnostics were provided in-country for laboratory staff through (inter)national universities and government agencies. Interviewed laboratory staff perceived the investments in molecular diagnostic training as highly valuable with regards to building human resource capacity in Sierra Leone and for their personal development.

The South African-supported Ebola diagnostic laboratory in Lakka was the primary site where national staff were trained in molecular diagnostics during the peak of the outbreak. Often the requests for training came from the individual workers themselves, who had to convince the LTWG and international agencies to be allowed to work inside the laboratory. One laboratory technician who worked in Lakka during the outbreak mentioned:

> It was great, because I had the opportunity to learn a lot, I had the opportunity to be exposed to the work, and it allowed me to gain more experience. Even when the South Africans went away, the lab was handed over to MoHS and we were still there working. And the work was done by us independently without their supervision (laboratory staff #42).

For international laboratory scientists used to working in laboratories with higher biocontainment and biosafety standards, the safety risks, not the capacity building of local staff, were of highest concern:

> When we started, the first day we opened was horrific. We got a bag just with blood vials in it and the whole bag was just bloody. It was really unsafe. It was really difficult . . . I used to work in the containment level four (key informant #27).

Towards the end of the outbreak in December 2015, the LTWG coordinated a three-month course in molecular diagnostics for 25 national laboratory scientists and technicians working in public hospital laboratories so as to provide more training opportunities in molecular diagnostics. This course was accredited by COMAHS and included practical work in those international Ebola laboratories still present in-country, which used varied PCR equipment, biocontainment procedures, and reagents, helping the laboratory scientists widen their skill sets. Different international laboratory scientists and

leads of lab teams from the WHO, US CDC, PHE, and PIH provided lectures for the course. Besides the skills and knowledge gained, the course exposed laboratory staff to research and provided access to a network of international laboratory scientists.

Several other organisations and universities organised training courses for laboratory workers during Ebola. For example the private University of Makeni (UNIMAK[7]), ran a three month training for 10 students from the School of Public Health at UNIMAK and 10 technicians from the Holy Spirit Hospital and the Makeni Government Hospital in molecular biology and immunology. Additionally, a project entitled 'Emergency Preparedness Against Ebola and Other Infectious Diseases' funded by the Dutch government trained 10 laboratory workers to conduct molecular diagnosis of five high-priority infectious zoonotic viral diseases; Ebola, Lassa, Rifft Valley fever (RVF), rabies, and avian influenza virus (Koroma et al. 2017). Yet another training was provided by the organisation MRIGlobal and the US CDC conducted a six-week training for 26 national rapid response team laboratory staff on conducting molecular diagnosis and topics such as quality assurance, quality control, and biosafety training inside a mobile container laboratory used in Moyamba district funded by the US Defense Threat Reduction Agency (Presser 2020). Finally, the Chinese CDC provided short-term training to 12 Sierra Leonean laboratory staff in their laboratory in Western Area Rural and three of them received scholarships for master's or doctoral programs in China (Wang et al. 2020).

Image 7: University of Makeni's Molecular Research Laboratory. Photo by Olivia Acland, August 2019

7. The UNIMAK laboratory was established with DFID funding post-Ebola and inherited PCR equipment from PHE, subsequently used by surveillance research projects PREDICT and PREEMPT funded by UNAIDS and the Defense Advanced Research Project Agency.

After the outbreak ended, several international agencies (such as South Africa's National Institute for Communicable Diseases and PHE) kept supporting the laboratories for some time with supplies of reagents, ad-hoc telecommunications and financial assistance, and the repairing of air conditioners and water supply systems (Paweska et al. 2017). This allowed the national team lead of Lakka's TB reference laboratory to train an additional 27 Sierra Leonean laboratory workers in PCR techniques. Similarly, PHE trained Sierra Leonean laboratory technicians in molecular diagnostics, who continued working in the molecular laboratories and operating the GeneXpert machine and assisted with new research projects post-outbreak.

Image 8: Laboratory staff performing multidrug resistant TB testing in newly constructed TB reference laboratory in Lakka, photo by Olivia Acland, August 2019.

For laboratory workers who received PCR training during the outbreak and who are still working in the health system in Sierra Leone, the experience was hugely important in terms of skill building, career opportunities, and a sense of pride of being able to conduct sophisticated molecular techniques which are useful for the country. However, in order to sustain knowledge and skills in molecular diagnostics, it is necessary to continue running PCR tests and analysis. This has become challenging since the outbreak ended since reagents used by important PCR machines are not available through the national supply system. One way laboratory staff tried to keep up their knowledge was by watching animated YouTube videos of PCR analysis during breaks. This shows that training is seen as a priority by laboratory experts in Sierra Leone and one of the areas where emergency response has the capacity to contribute to longer term systems-building. But this potential can only be realised when training is integrated with other system-building activities, including support for supply and procurement systems.

Interviewees mentioned several priorities for future trainings in areas in which emergency training efforts fell short. One area where local laboratory staff experienced a training gap was regarding the (preventative) maintenance of diagnostic technologies brought in by international partners. Another priority mentioned was to provide stock management training to all laboratory workers and to streamline the communication channels between laboratories, hospital management, and the central medical stores so as to improve supply chain management. Finally, laboratory staff were keen to receive training in research design and research proposal development to allow them to become more involved in academic diagnostic-related projects.

In conclusion, this section made clear that the emergency laboratory investments improved material infrastructure, governance and training of laboratory personnel, primarily in the area of molecular diagnostic capacity. The material infrastructure needed to keep the newly set up (mobile) laboratories running related to electricity (in the form of generators because of the unreliable electric grid), maintenance of diagnostic PCR equipment, and specimen transportation of suspected Ebola samples from holding centres to diagnostic laboratories, was largely donor-funded. Whilst most of the molecular testing was performed by international laboratory staff, local laboratory technicians were working in newly created positions to improve the specimen transport between laboratories and holding centers. When the epidemic came to an end, much of the donor-funded material infrastructure and human resource support ended, and limited local capacity was built in (preventative) maintenance in molecular diagnostic equipment, which hampered the sustainability of investments made.

4. Laboratory capacity building post-Ebola

Whilst the national government's role in governing the laboratory response during the outbreak was limited, post-Ebola the government is trying to more effectively coordinate laboratory-strengthening activities led by international organisations. This was evinced by an observed meeting of the laboratory technical working group (LTWG) in January 2019 at the Emergency Operating Centre in Freetown, where all 'partners' were asked to present their planned laboratory activities for the coming year. The meeting was chaired by a laboratory manager from the Ministry of Health, who stressed that he did 'not want to police'; rather, the Ministry wished to be aware of and involved in the laboratory activities of international organisations. The Ministry also presented the national training work plan for laboratory staff and urged partners to send in their training plans to best align agendas and avoid duplication.

Representatives from nine organisations involved in laboratory capacity building were present at the meeting, which can be divided into three groups: 1) 'technical advice' givers (the World Health Organization [WHO], World Bank, and US Center for Disease Control and Prevention [US CDC]); 2) 'implementing partners' (ICAP, the Association of Public Health Laboratories [APHL], and Solthis); and 3) 'institution-building' organisations (Partners in Health [PIH], the Chinese Center for Disease Control and Prevention [China CDC], and King's Sierra Leone Partnership). The next two sections discuss the main activities of both the technical advice givers and the institution-building organisations[8]. Implementing partners activities are not discussed as either their involvement has ended (APHL) or they are primarily involved in disease-specific projects or research projects; laboratory capacity building is not the main aim (ICAP and Solthis). By exploring the ways in which the organisations interact with national governance structures—including the government's specimen transport, surveillance, and supply systems—we highlight the ongoing challenges of the Sierra Leone government to integrate international donors' diagnostic interventions.

4.1. Capacity building of governance institutions

> 'The thing about [the] laboratory, nothing is achieved overnight. Sustainability is the keyword. There is not a single partner that comes in with a 50-year plan'. - Key informant #34

In the aftermath of the Ebola outbreak, there have been 20 new plans, policies, and strategies developed to improve the country's healthcare system, which include laboratory-related policies on supply chains, waste management, health information, and a proposed public health agency (MoHS 2017). The 2016–2020 National Health Laboratory Strategic Plan is the main guiding document outlining the national priorities in terms of laboratory capacity building, and was developed towards the end of the Ebola outbreak by the LTWG in collaboration with key donor agencies: the US CDC, Department for International Development (DFID), PHE, the Global Fund, the World Bank, and the Chinese CDC (MoHS 2016).

8. This paper focuses particularly on interventions and agencies, whose main work is focused on laboratory capacity building. There might be other health system preparedness- and surveillance-strengthening initiatives that include laboratory components, but these are not discussed.

Post-Ebola, key improvements have been made in terms of the governance and coordination of laboratory services, which was an area highlighted in the national strategic plan. The national-level governance of the laboratory system is now divided between two directorates of the Ministry of Health and Sanitation: the Directorate of Emergency and Disease Surveillance, which oversees surveillance activities and public health laboratories (including the Central Public Health Reference Laboratory [CPHRL] and laboratories at the primary healthcare level), and the Directorate of Laboratory Services, which is responsible for the management of hospital laboratories at secondary and tertiary care levels. Both national-level laboratory managers operate from the Emergency Operation Center (EOC) in Freetown, established during Ebola.

The EOC was perceived by interviewees as a key investment in terms of governance, coordination, and epidemic preparedness. When in 2018 the research project PREDICT discovered a Marburg virus in bats[9], the EOC served as the hub for coordinating the laboratory response:

> We saw that when there was a Marburg scare, everyone descended [on] the EOC, conversations were had, and it's at that point the technical people start to talk diagnostics. That is when they have the debates, so if there was another outbreak, we all descend [on] the EOC and someone [says], 'I want us to use RDTs,' another technical scientist would say, 'But this is my argument for not using RDTs.' At the end of that debate, we will have a common ground and that becomes the hymn sheet, so all 27 partners will have to agree to use the RDT or to use the PCR, or, if the consensus is 'let's use both,' x number of partners will use the RDT or will use both. But the agreement will be made, and everyone will be singing from the same hymn sheet (key informant #19).

Now, the involvement of the US CDC and the WHO in laboratory strengthening is similar to their involvement pre-Ebola, wherein they provide technical advice to the Ministry of Health regarding policy development, seek funding to implement the strategic plan's activities, and procure diagnostic reagents for the CPHRL. The WHO does not have internal funding for its work in Sierra Leone post-Ebola, and receives funding only through the US CDC and DFID. Funding from DFID was used by the WHO to procure GeneXpert Ebola reagents. Post-Ebola, WHO's integrated disease surveillance and response programme (IDSR) was heavily invested in by the World Bank's Regional Disease Surveillance Systems Enhancement (REDISSE) programme.

The REDISSE programme has a laboratory capacity component which focuses activities on key areas of governance, infrastructure, and training (De Geyndt 2018). The World Bank achieves this by seconding laboratory experts from other African countries to the Sierra Leone government to assist with the procurement of reagents and laboratory equipment, assess gaps in laboratory capacity, and improve quality assurance systems. The World Bank staff are attached to different government facilities and help laboratory leads improve quality systems and standard operating procedures in the laboratories. Additionally, they teach in the undergraduate laboratory medicine course at COMAHS.

9. **https://www.the-scientist.com/news-opinion/bats-in-sierra-leone-carry-marburg-virus-65271** (visited 30.07.2020)

A new national governance body established post-Ebola is the creation of a biobanking facility in Sierra Leone where Ebola samples can be stored and used for research and development. Due to the lack of such facilities and of biosafety/biosecurity policies during Ebola, many of the international laboratory teams transferred Ebola samples to biobanking facilities overseas (Hannigan et al. 2019). This spurred the development of the Global Emerging Pathogens Treatment Consortium (GET), which has been providing technical advice (by, for example, conducting workshops) for the Sierra Leone government so as to facilitate the development of biobanking and biosecurity policies which in turn enable local research capacity (Abayomi et al. 2016).

4.2 Capacity building of health institutions

In the aftermath of the Ebola outbreak, international organisations took different approaches to longer-term laboratory capacity building in health institutions, which ranged from supporting the implementation of both point-of-care diagnostics and generalised laboratory capacity to creating exemplary health institutions and new reference laboratories. By exploring the ways in which three international organisations interact with national governance structures (including the government's specimen transport, surveillance, and supply systems), we highlight ongoing challenges faced by the Sierra Leone government to integrate international donors' diagnostic interventions and the roles point-of-care diagnostics play in laboratory strengthening initiatives.

Partners in Health in Koidu government hospital

Partners in Health is an American global health organisation which provides health care to poor and marginalised communities by creating and managing medical institutions (hospitals and health centres) and networks of community health workers in various countries. PIH started working in Sierra Leone in October 2014, where they provided emergency care in 17 health facilities across four districts, including a large Ebola treatment unit at Port Loko District (Cancedda et al. 2018). PIH did not manage Ebola laboratories themselves but provided logistical support to two mobile diagnostic laboratories operated and funded by the Dutch government and stationed at facilities in Freetown and Kono District. Additionally, PIH conducted research into an Ebola rapid diagnostic test [RDT] (Broadhurst et al. 2015).

Post-Ebola, PIH shifted focus to provide long-term support at the Koidu Government District Hospital in Kono District and the private Wellbody Clinic, located close to the hospital[10]. PIH's health system strengthening model—also referred to as 'staff, stuff, space, and systems'—was also applied to their laboratory capacity building programme (Mesman et al. 2019). Without the staff (laboratory workforce), stuff (equipment and supplies), and space (physical infrastructure) in place, PIH argues that few laboratories would be capable of considering or assessing the importance of systems related to improving quality, biosafety, standardisation, maintenance, and accurate recording and reporting,

10. A discussion of other work done by PIH (e.g., supporting mental health care in Kissy Psychiatric Hospital and multi-resistant TB care in Lakka Government Hospital) is beyond the scope of this paper.

which they argue are crucial elements for a well-functioning laboratory (Orozco et al. 2017). In Koidu Government Hospital's laboratory, the space was therefore upgraded, and 24-hour electricity (a rarity in government laboratories) and a water supply were installed and financed.

In terms of *staff*, PIH hired several staff members who work alongside the government's laboratory staff in Koidu Hospital's laboratory (which PIH refers to as 'accompaniment'). The PIH employed staff work on quality management by developing standard operating procedures, conducting regular training, and overseeing supply and maintenance elements rather than performing laboratory bench work. In 2019, over 450 PIH staff worked in facilities and communities in Kono district as well as in the wider Freetown area (PIH 2019).

Regarding *stuff*, a laboratory PIH staff member explained during a site visit to Koidu Government Hospital that PIH buys an estimated 98 percent of the diagnostic supplies utilised, while the government merely supplies syringes and gloves. The laboratory equipment consists of a mix of automated haematology and biochemistry machines, microscopes (used for urine and stool analysis and malaria), and point-of-care machines and RDTs for specific infections (e.g., HIV, TB, typhoid, and STIs). *System* elements—related to supply, the procurement of laboratory equipment, quality control, maintenance, and information management systems—are presently all financed and managed by PIH.

Image 9: Four generators supplying Koidu government hospital with 24 hour electricity (requiring 10.000-13.000 litres of fuel per month, estimated to costs ~7500 GBP). Photo by Eva Vernooij, March 2019.

One of the challenges experienced by PIH when working with the government's specimen referral system was the delay in receiving back results for HIV viral load testing, which took place in the CPHRL at Lakka, about 200 miles from Koidu Government Hospital. It sometimes took two months to

receive results, which PIH found unconducive to patients' care. This eventually led them to find a solution by advocating for point-of-care viral load testing using GeneXpert machines in district hospitals. Reflecting on this process, a key informant working for PIH stated:

> It was not easy, because at that time Global Fund brought their machines for viral load in Lakka, and they were very interested in using those machines and not creating a new system with GeneXpert. But, in the end, we were able to get some cartridges, and we started doing it (key informant #41).

Point-of-care diagnostics were thus used to plug the gaps in, rather than improve, the specimen referral system. Point-of-care tests were furthermore used in Koidu Government Hospital as a temporary solution when other laboratory equipment broke down (for example, a broken biochemistry analyser was replaced by a point-of-care i-STAT machine).

Another challenge described by a key informant is how to navigate the push by diagnostic developers to promote new (and expensive) automated molecular equipment, for example the gastrointestinal RT-PCR platform by BioFire FilmArray, which costs $155.00 per test which is higher than the minimum monthly wage in Sierra Leone (Ansumana et al. 2020). PIH received an offer from a diagnostic company to test the new machine for two years as part of a research validation study, after which they would need to start paying for the reagents themselves. The Sierra Leone's PIH team tried to convince the PIH directorate in the US that they would rather invest in training laboratory workers to conduct culture and sensitivity testing using Gram staining to detect bacterial and fungal infections, but had not yet been able to do so:

> I strongly believe that in Sierra Leone, I don't say that those array machines are not amazing, they are. But you are not creating the structures of learning basic microbiology. Going from having nothing to having one machine that tells you what is the bacteria and everything, it sounds like a super big jump. And also you wouldn't be able to– The problem with these machines is the contamination factor. You end up having a result that maybe nosocomial infections or even just contamination from bad transportation of the samples or processing of the samples and everything. So what happens when the funding from that research finishes? How do you fund that? The government is not going to be able to do it. And most of our lab technicians are not even able to do a simple gram. It's so frustrating (key informant #41).

PIH's approach to laboratory strengthening could be described as aiming to create exemplary institutions for the government to aspire to take over when financially ready. Yet, interviewees stated that the organisation does not have an "exit-plan", and therefore a future challenge for the government will be to align and integrate PIH supported laboratory systems within their national system.

King's Sierra Leone partnership (KSLP) in Connaught Government Hospital

A different kind of model for health system strengthening with a similar focus on supporting government medical institutions can be seen in the work done by the King's College London's Sierra Leone partnership (KSLP). KSLP was established in 2011 as a multi-actor arrangement between King's

Health Partners (King's College London, Guy's and St. Thomas', King's College Hospital, and the South London and Maudsley NHS Foundation Trusts) and three Sierra Leonean partner institutions: Connaught Hospital, the COMAHS, and the Sierra Leone Ministry of Health and Sanitation (MoHS) (Herrick and Brooks 2018).

In early 2013, KSLP established an office in Freetown consisting initially of four British junior doctors working as volunteers to strengthen research capabilities and support clinical engagement at Connaught, curriculum development at COMAHS, human resources for health at the MoHS (KSLP 2016). Between 2013 and 2016, 87 international volunteers and staff were sent to work in Connaught Hospital, the country's principal adult referral hospital, to develop capacity in critical care and anaesthetics, mental health, emergency medicine, internal medicine, pharmacy and physiotherapy, as well as responding to the Ebola response (Brooks and Herrick 2019). During Ebola, the resuscitation area and medical observation rooms in the emergency department were transformed into an Ebola holding unit managed by KSLP.

At the end of the outbreak, KSLP implemented infrastructural improvements in Connaught Hospital using DFID funding which focused on improving infection prevention control and water, sanitation, and hygiene, and constructed a new infectious disease unit and oxygen plant. In terms of diagnostic interventions KSLP used funding from research and implementation projects to introduce various point-of-care tests in the hospital, including HemoCue, Malaria RDT, and CRAQ RDT to diagnose Cryptococcal meningitis, with the aim of improving clinical care decision-making (KSLP 2016). Furthermore, through the placement of short-term international laboratory technicians, doctors, and scientists, KSLP provides mentorship, professional development training, and human resource capacity to COMAHS students and lecturers, furthering local research capacity. Finally, KSLP organises training for the maintenance department in Connaught Hospital, which includes training on how to service laboratory equipment. An important aspect of KSLP's approach is to 'minimise dependency'; as such, they don't finance national laboratory staff or provide core funding to the laboratory beyond a starter pack of laboratory reagents for diagnostic tests they helped introduce in the hospital (Ibid.).

Post-Ebola Connaught's main laboratory was refurbished by PHE as part of the UK government's Resilient Zero programme, which entailed reconstruction of the laboratory space with most material infrastructure investments made in the molecular department. Some interviewees expressed disappointment with the limited investments made to improve routine laboratory capacity in the microbiology, haematology and biochemistry departments, which was only done later in response to the severe floods and mudslide in Freetown in 2017. By that time, PHE supported the deployment of the UK Public Health Rapid Support Team which facilitated cholera preparedness in Connaught laboratory by purchasing equipment, reagents and training laboratory staff to conduct cholera testing. The limited expertise in microbiology of the local laboratory staff was perceived by a key informant interviewed as a barrier for training them to do culture testing, and instead more experienced World Bank supported staff were trained which possessed the "baseline" skills to work from. In the end, Connaught laboratory never received any suspected cholera samples, as all samples were send to

Ola During Children's Hospital, which at the time was the primary laboratory conducting cholera culture testing.

At the time of data collection in Connaught in 2019, some local laboratory technicians were being trained by World Bank staff to conduct culture and sensitivity testing as part of a technician's bachelor thesis project (studying laboratory medicine at COMAHS), using left-over materials from PHE's cholera preparedness work. Whilst PHE's cholera preparedness was an emergency laboratory project, it was still able to have a longer-lasting effect because of the actions of the laboratory lead in ordering long-lasting laboratory reagents:

> If you buy a bottle of media, the powder, it will last for two years. If you buy a bottle of stain, it can last for five. So if you bear that in mind, sustainability-wise. I wouldn't say that it's by direction, because the UK government are probably more interested in, "You need to provide a cholera lab now, what do you need now?" Rather than, if I do it this way, I'll have it for ages (key informant #27).

Whilst these supplies and the supervisory support of World Bank supported laboratory staff helped to build capacity in culture and sensitivity testing, it was not yet widely available to the hospital's patients yet. This requires sustained material infrastructural investments such as reliable electricity for growing cell cultures in an incubator, consistent supply chains of laboratory supplies such as petri dishes, and additional training of laboratory personnel besides the bachelor student.

Image 10. Connaught laboratory, microbiology department, Photo by Olivia Acland, August 2019.

One of the challenges KSLP faced when integrating their laboratory work within government systems had to do with handing over their diagnostic interventions to the hospital management and integrating with national procurement and supply systems. A key informant working with KSLP explained this in relation to the introduction of the HemoCue, a point-of-care device which enables the measurement of haemoglobin at the patient's bedside within 10 minutes, rather than taking the sample to the laboratory which increases the waiting time for results to at least 24 hours:

> We bought the machine [. . .] and then said, 'If you manage to do this amount of tests and keep the revenue, you will keep the system going.' So that's how HemoCue started. And it's been successfully handed over . . . We did the same with buying the reagents for the biochemistry and the haematology machines. Unfortunately, that business case has failed, largely because we've got a high free healthcare population and the proportion of paying individuals to free healthcare population is a lot less. I think when your centralised system is not working then having modular systems is easier. And I think that's one of the issues that we're facing at the moment. HemoCue is modular and handled by the laboratory staff. Larger plans which require a national supply chain are less modular (key informant #1).

However, six months later the hospital ran out of stock of HemoCue microcuvettes, in addition to reagents for the haematology machine, hence the laboratory staff went back to performing a less accurate test known as haematocrit or PCV to diagnose anaemia inside the laboratory. In these situations KSLP tries to work with the hospital management to help solve problems of supply chain management, but refrains from direct procurement of new reagents so as not to create dependency, in which they differ from PIH.

China CDC in the National Reference Laboratory for Viral Haemorrhagic Fevers

Towards the end of the epidemic, the China CDC financed the construction of a new fixed Biosafety level (BSL) 3 laboratory in the Jui Hospital compound, where both research and surveillance for Ebola takes place (Yang et al. 2016, Wang et al. 2016). The laboratory was renamed the National Reference Laboratory for Viral Haemorrhagic Fevers, and is currently considered the main site for the surveillance testing of Ebola and other haemorrhagic fevers. The entire laboratory, infrastructure, staff salaries, and reagents are financed by the Chinese Ministry of Commerce and managed by China CDC. Their surveillance system is based on sentinel surveillance, whereby samples are collected from patients with fever or diarrhoea from 10 hospitals across Sierra Leone. Samples are transported to the China CDC laboratory and tested for Ebola and other infectious diseases[11] using PCR-based testing. Additionally, river water from Western Area Rural is tested for pathogens. The China CDC surveillance system is operating independently from the national IDSR surveillance system, and has a separate transportation system.

The Chinese CDC also organised training on biosafety and molecular diagnostics for government laboratory staff in their training centre located inside Jui Government Hospital. During a site visit to the

11. Yellow fever, Lassa fever, dengue, Rift Valley fever, Marburg, chikungunya, malaria, Vibrio cholerae, salmonella (typhi and non-typhi), E. coli, and shigella.

Chinese CDC laboratory, the manager explained that he thinks 'training is more important than surveillance'; nonetheless, the majority of laboratory staff working inside the BSL-3 molecular department are from China. There are eight local staff members, of which only one was trained to work in the BSL-3 laboratory. Culture testing is conducted inside Jui government hospital laboratory. Local staff perform malaria testing using RDTs, a remarkable choice as microscopy is considered the gold standard for malaria diagnosis in endemic countries. This quirk was attributed to a gap in the expertise of the Chinese CDC's available staff. Hence, in this instance RDTs fill a gap in human resource capacity from international laboratory staff.

Image 11: BSL-3 laboratory China CDC Laboratory, Jui. Photo by Eva Vernooij, March 2019.

One of the challenges the China CDC and the Sierra Leone government face is the integration of their surveillance activities with clinical information systems. International agencies supporting the sentinel sites reported to be unaware of the ways in which patients' samples are collected by the China CDC and claimed not to be informed by the results. At the same time, laboratory staff working in the China CDC complained of receiving too few samples from hospital laboratories. International organisations supporting the government were also unaware of the longer-term goal of the Chinese CDC, as was mentioned by a key informant:

> We had a meeting once—the US CDC, WHO, and China CDC—that we specifically asked for because nobody knew what they were doing. A number of people asked in a number of different ways, "What is the objective of this project?" We didn't even say, "Is it research?" or "What is it?" They were like, "It's just surveillance [so] the Ministry [can] have this surveillance data," but that doesn't sit with everybody. There has to be a higher objective or a goal that somehow they get

> something out of it, but we don't understand what that is. I did ask, "Are you going to publish this data? Is it a research project?" And they said, "No" (key informant #19).

The Chinese government's investments in Sierra Leone range much further than supporting surveillance and training of laboratory staff, and consists of supporting major infrastructural projects in power, water, roads, agriculture, mineral reserves, ports, and telecommunications (Klyton et al. 2019). Whilst current funding for the China CDC laboratory lasts until extend until 2023, key informants were uncertain about the ability of the Sierra Leone government to finance the running costs of the new reference laboratory. One of the main problems they foresaw are the electricity costs, as explained by a laboratory scientist working in a government hospital laboratory;

> Once the national grid is off, the generators are there, but no fuel. They ask partners to bring big generators that can take a drum or two drums of fuel in two hours… Once these partners go, who can fuel a hospital with five drums, over a thousand litres? It's not easy. The electricity is a big problem (laboratory staff #10).

Another challenge for the government of Sierra Leone is to align the parallel systems for sample transportation and surveillance systems, one supported through the national reference laboratory at CPHRL in Lakka, and the other through the China CDC laboratory. Laboratory staff mentioned they experienced challenges with regards to receiving back results from reference laboratories, caused by challenges in logistical capacity the district health management team's (DHMT's) surveillance officer and laboratory technician, who reported to be often without fuel to pick up and deliver samples, as well as the absence of a national laboratory information system.

This section described different laboratory capacity building activities in three key healthcare institutions in Sierra Leone; a refurbished laboratory in the country's largest government referral hospital, a new Ebola reference laboratory, and a revamped district government hospital in a remote district severely affected by the Ebola outbreak. The organisations differed in their approach to laboratory system building in the ways in which they aligned their activities with government systems, whereby PIH build a rather independently working laboratory system, and China CDC created a supplementary surveillance system and viral haemorrhagic reference laboratory, whilst KSLP tried to build up the existing government system. Furthermore, the organisations differed in the ways they conducted training of local staff during and post-emergencies ranging from long-term accompaniment (PIH), to short-term mentoring (KSLP) to overseas academic training (China CDC). A commonality was the way in which point-of-care diagnostics were used as temporary solutions to address gaps in the government's diagnostic system, but appeared difficult to integrate within national procurement and distribution systems.

5. Conclusion and recommendations

The Ebola outbreak has led to major investments in the strengthening of laboratory systems in Sierra Leone. This working paper highlights some of the difficulties of sustaining these investments and integrating them into a single nation-wide laboratory network. We showed that whilst the Ebola epidemic significantly improved the molecular diagnostic capacity of the country, sustained investments are needed in the areas of regulatory capacity, material infrastructure, and training to address current gaps in quality assurance, supply chain management, specimen transportation, maintenance systems and waste disposal.

The positive effect of Ebola-related investments in molecular capacity in various laboratories in Sierra Leone is evident in the current response to the COVID-19 outbreak. The six PCR-equipped laboratories which are currently conducting COVID-19 testing (Connaught hospital, China CDC laboratory, CPHRL, 34th Military hospital, Kenema's VHFC research laboratory and Makeni government hospital), are able to do so because of the molecular equipment and expertise build in response to the Ebola outbreak. Whilst Connaught's laboratory and China CDC were able to set up COVID-19 testing by March 2020, it took more than six months to initiate testing in Makeni government hospital. To improve countrywide access to COVID-19 testing a strong specimen transportation systems as well as coordinated procurement and distribution management are required, two areas which this working paper highlighted as in need of urgent investment. Furthermore, the COVID-19 response will benefit from a centralised training programme in order to facilitate partner integration and prevent adhoc duplication in training programs.

Finally, we offer some recommendations for international agencies and the Sierra Leone government to enable emergency laboratory strengthening efforts to have lasting impact beyond the timeframe of a disease outbreak and improve the country's diagnostic system.

Recommendations for international agencies:

- Material Infrastructure: Increase investment in microbiology, haematology, and biochemistry departments (and particularly in culture and sensitivity testing) in moments when there is no emergency to improve generalised laboratory capacity.
- Governance: Include national laboratory experts in the development of international regulatory frameworks which guide research and development for diagnostics, such as the World Health Organization (WHO)'s target product profiles (TPPs), so as to ameliorate the alignment of countries' diagnostic priorities and regulatory capacities. In this way, quality can be better monitored.
- Governance: Incorporate laboratory experts from epidemic affected countries into international mechanisms of regulation to improve alignment in the review and regulation of diagnostic devices.
- Training: Researchers investigating or evaluating devices could be required to contribute a certain percentage of their research budget to laboratory system capacity building as outlined by in-country healthcare institutions and government bodies.

Recommendations for national government:

- Material Infrastructure: Review the logistical capacity of the DHMT to carry out specimen transport for integrated disease surveillance and response (IDSR) systems and implement specimen referral systems for community health centres without onsite laboratories.
- Material Infrastructure: Negotiate maintenance contracts with diagnostic companies so as to train and build local capacity in preventative maintenance and provide spares to replace broken equipment, and better include laboratory experts in discussions of the service agreements of laboratory equipment.
- Governance: To develop guidance regarding the national priorities of desired diagnostic platforms (e.g., automated devices, GeneXpert devices, and/or other molecular methods) to improve the integration of partner-supported diagnostic platforms.
- Training: Develop sustainable training regimes for laboratory staff to safeguard quality and provide professional development. Harmonise donor-supporting training initiatives, possibly through the centralisation of all training regimes via one training institute invested in curriculum development and professional development opportunities (for example the University of Sierra Leone).
- Training: Laboratory personnel should be considered a crucial part of outbreak response. National priorities for the capacity building of laboratory personnel should be established and available for review by international agencies, so as to integrate capacity building of local laboratory staff during outbreaks.

Acronyms

APHL	Association of Public Health Laboratories
CDC	Centers for Disease Control and Prevention
CHAI	Clinton Health Access Initiative
CHC	Community Health Centre
CHP	Community Health Post
COMAHS	College of Medicine and Allied Health Sciences
COVID-19	Corona Viral Disease
CPHRL	Central Public Health Reference Laboratory
DERC	District Ebola Response Centres
DFID	Department for International Development
DHMT	District health management teams
DHS	Demographic Health Service
DSTL	Defence Science and Technology Laboratory
EMLab	European Mobile Laboratory Project
EOC	Emergency Operations Centre
EU	European Union
EUAL	Emergency Use Authorisation Listing
EUL	Emergency Use Listing
EVD	Ebola Virus Disease
FHCI	Free Health Care Initiative
GET	Global Emerging Pathogens Treatment Consortium
GHSA	Global Health Security Agenda
GOARN	Global Outbreak Alert and Response Network
IDSR	Integrated Disease Surveillance and Response
KSLP	King's College London's Sierra Leone Partnership
LTWG	Laboratory Technical Working Group
MCHP	Maternal and Child Health Post
MOHS	Ministry of Health and Sanitation
MRC	Medical Research Council
MSF	Médecins Sans Frontières
NERC	National Ebola Response Centre
NHSSP	National Health Sector Strategic Plan
NMSA	National Medical Supplies Agency
NPPU	National Pharmaceutical Procurement Unit
ODCH	Ola During Children's Hospital
PCMH	Princess Christian Maternity Hospital
PEPFAR	President's Emergency Plan for AIDS Relief
PHE	Public Health England
PHEIC	Public Health Emergency of International Concern
PHU	Peripheral Health Unit
PIH	Partners in Health
RDT	Rapid Diagnostic Test
REDISSE	Regional Disease Surveillance Systems Enhancement
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SLBPEHS	Sierra Leone Basic Package of Essential Health Services
TPP	Target Product Profiles
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNIMAK	University of Makeni
VHFC	Viral Haemorrhagic Fever Consortium
WHO	World Health Organization

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Table 1

Name of laboratory where Ebola testing was done	Laboratory location	Type of laboratory	Starting date of testing operational at laboratory	Reference
VHFC laboratory	Kenema gov. hospital, Eastern Province	Hospital lab	Mar-14	Boisen et al. 2016; Goba et al. 2016
Metabiota Inc	Kenema gov. hospital, Eastern Province	Hospital lab	Mar-14	Wauquier et al. 2015
Public Health Agency Canada (PHAC) Lab	Kailahun, Eastern Province/ Freetown	Mobile (this lab was later moved to Prince of Wales ETU in Freetown)	02-Jul-14	Polinquin et al. 2016; Fitzpatrick et al. 2015
US CDC	Kenema, Eastern Province/ Bo, Southern Province	Field laboratory at Kenema hospital (moved to Bo at MSF ETU late September 2014)	22-Aug-14	Flint et al. 2015, Erickson et al. 2016
NICD South Afric a	Lakka Gov. hospital, Western Area Rural	Mobile (modular) - tent inside fixed structure of TB hospital lab.	25-Aug-14	Paweska et al. 2017
China CDC laboratory	Jui, Western Area Rural	Mobile laboratory inside Jui hospital	28-Sep-14	Lu et al. 2016, ZeLiang et al. 2015
PHE lab Kerry town	Kerry town, Western Area Rural	Existing structure at ETU, redesigned by British Military	27-Oct-14	Bailey et al. 2017
PHE lab Port Loko	Port Loko, North West Province	New laboratory build by British Military at ETU	05-Nov-14	Bailey et al. 2017
PHE lab Makeni	Makeni, Northern Province	New laboratory build by British Military at ETU	08-Nov-14	Arias et al. 2016, Bailey et al. 2017
Emergency Hospital	Godrich, Western Area Urban	New laboratory build by British Military at ETU	14-Dec-14	Colavita et al. 2016
EMLab	Kingtom, Freetown / Kambia, Northern Province	Mobile lab at ETU (moved to Kambia later in the outbreak)	14-Dec-14	Wölfel et al. 2015
EMLab	Hastings, Western Area Rural	Mobile lab at ETU	22-Dec-14	Wölfel et al. 2015
Public Health Agency Canada (PHAC) Lab	Magburaka,, Northern Province	Mobile lab at ETU	Dec-14	Theocharopoulos et al. 2017
US Defense Threat Reduction Agency laboratory	Moyamba district, Southern Province	Mobile (container) after outbreak the container was moved to the CPHRL in Lakka	13-Jan-15	Haaskjold et al. 2016
Dutch lab Kono	Kono, Eastern Province	mobile (container) on site of PIH well body clinic, near ETU	13-Jan-15	Reusken et al. 2016
Dutch lab PCMH	Freetown	mobile (container) at the PCMH hospital	17-Feb-15	Reusken et al. 2016
PHE /University of Cambridge	Makeni, Northern Province	Mobile (Tent) set-up next to fixed PHE laboratory, sequencing of ebola samples	16-Apr-15	Arias et al. 2016
PHE lab Kenema	Kenema	Mobile lab at Kenema government hospital	Oct-15	Logue et al. 2017

Table 2: PCR-equipped laboratories where molecular capacity was build during Ebola[12]

Name of laboratory and location	Funder	Diagnostic platform(s) used	Possible to do Ebola testing at time of field visit?
Research Lab: VHF lab at Kenema Government Hospital	VHFC consortium	ReEBOV RDT, PCR	Yes
Research Lab: Mercy research laboratory at Mercy hospital, Bo	American Naval Research Group	PCR	Yes
Research Lab: University of Makeni, Makeni	University of Cambridge, Wellcome trust	miniPCR13	Yes (PCR used for research studies)
Reference Lab: Jui China CDC, Western Area Rural District	China CDC	PCR	Yes
Reference Lab: CPHRL, Lakka	MRI global (during Ebola)	PCR	No (no reagents for Ebola)
Clinical government lab: Makeni government hospital, Makeni	PHE	GeneXpert	Yes (borrowed reagents from EboVAC in Kambia)
Clinical government lab:			
34th Military, Freetown	Chinese military/PHE (?)	Unknown – mobile lab stored at 34th military	No (awaiting regulatory approval of diagnostics)
Clinical government lab: Connaught hospital, Freetown	PHE	GeneXpert	No (no reagents)
Clinical government lab: Bo government hospital, Bo	PHE	GeneXpert	No (no reagent)
Clinical government lab: Lakka TB hospital, Lakka	South African National Institute for Communicable Diseases (NICD) (during Ebola)	PCR	No (no reagents)
Clinical government lab: Princes Christian Maternity Hospital	Dutch ministry of foreign affairs via PIH	PCR	No (no reagents)
Clinical government lab: Kono government hospital (and Well body clinic)	PIH	PCR	GeneXpert used for TB/HIV, no testing done for Ebola

12. Laboratories were visited between December 2018 – September 2019

13. **https://www.labmate-online.com/news/laboratory-products/3/cambio/new-pcr-thermal-cycler-fits-in-the-palm-of-your-hand/36326** (accessed 15 August 2019)

Table 3: Ebola rapid diagnostic tests validated/used in Sierra Leone

Ebola rapid diagnostic tests in Sierra Leone	Locations were Ebola Rapid Diagnostic Tests were used	Purpose: Validation/clinical diagnosis/surveillance	Time period
DSTL test (Walker et al. 2015)	Connaught hospital, Macaulay, Government Hospital, Rokupa Government Hospital and Newtown CHC, Freetown and Western Area District	Validation only	22-Jan-15 -16 February 2016
ReEBOV Corgenix (Boisen et al. 2016)	Kenema Government Laboratory, Makeni PHE laboratory, Connaught hospital, Lakka TB Hospital	Validation and used for presumptive diagnosis	December 2014 – February 2015
OraQuick (cadaveric oral fluid) **WHO EUAL public report**	Validated in Kambia, by WHO using archives samples from European Union and African Union field laboratories at Kambia, archived Ebola positive and negative specimens.	Validation Used by surveillance officers for presumptive diagnosis of corpses	01-Mar-16
OraQuick (whole blood) **WHO EUAL public report**	Validated in CDC laboratory in USA with 75 archived samples from Sierra Leone	Validation	?
SD Biosensor - SD Q Line Ebola Zaire Ag **WHO EUAL public report**	PHE Makeni lab for fresh blood samples, and retrospective samples from: EU Mobile Lab (Hastings), Nigeria Mobile Laboratory (Kambia), PHE Laboratories (Kerry town, Port Loko, Makeni).	Validated by WHO	?
EBOLA Ag K-SeT (Coris BioConcept) (Colavita et al. 2018)	Emergency hospital, Goderich, Western area urban	Validation study using stored blood sample from outbreak	*Post outbreak* April-May 2016
Xprt Ebola Semper et al. 2016	Port Loko, PHE supported laboratory		*April – July 2015*

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