DiaDev

Investigating Diagnostics in Global Health

Research Report

Investigating the Design and Use of Diagnostic Devices in Global Health

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COMAHS

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Executive summary

This report describes the key findings and recommendations from the DiaDev research project (Investigating the Design and Use of Diagnostic Devices in Global Health). In Sierra Leone, the DiaDev research project has explored the legacy of (inter)national efforts to deploy point-of-care diagnostics and strengthen laboratory systems during the Ebola outbreak and its aftermath. The project aims to inform researchers, funders, policy-makers, governments, and users about whether (and, if so, how) point-of-care tests can strengthen health systems in resource-limited settings and what the local priorities are for improving diagnostic systems in Sierra Leone. By combining qualitative and quantitative data collection methodologies from anthropology and health system research, we have developed a methodological toolkit for studying the life cycle of diagnostic devices as they move through contexts of regulation, use, maintenance, and disposal. Data collection was carried out in Sierra Leone between October 2018 and December 2019 by an interdisciplinary team of social scientists, laboratory experts, and clinicians.

Key insights about the regulatory and procurement processes for point-of-care diagnostics include the limited inclusion of national regulatory agencies when assessing incoming diagnostic products during Ebola. Post-Ebola, gaps in regulatory capacity and the inconsistent government supply of diagnostics enable the use of unregistered diagnostic products from private sellers in government institutions. Regarding the use of diagnostics, our findings showed diagnostics had limited impact on diagnosis and treatment decisions, of which health workers' distrust (of test results and laboratory workers) and the insufficient supply of diagnostics were key contributing factors. Furthermore, maintenance and waste disposal were largely ignored as methods of laboratory system strengthening, both during and post-Ebola. The lack of waste segregation as well as poor maintenance of incinerators represented severe health risks to cleaners and waste handlers (who were often uncontracted staff) during the Ebola outbreak, and this continues to be a problem. The disposal of liquid waste and point-of-care cartridges is but one area in which limited guidance is available to waste handlers. Even now, some diagnostic waste ends up at dumping sites and drainage points in the city, presenting risks to the environment and the general public.

Recommendations

The following recommendations are suggestions to improve the regulation, use, maintenance and waste management of diagnostics in Sierra Leone:

International agencies supporting laboratory system strengthening

- Regulation: 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 (TPP), so as to improve alignment diagnostic priorities and regulatory capacities. In this way, quality can be better monitored.
- Use: Increase investments in routine laboratory capacity in microbiology, haematology, and biochemistry departments, particularly in culture and sensitivity testing, to help curb antimicrobial

resistance.

- Maintenance: Negotiate maintenance contracts with diagnostic companies so as to train and build local capacity in preventative maintenance and better include laboratory experts in discussions of the service agreements of laboratory equipment.
- Waste: Highlight the importance of waste management in international regulatory mechanisms (for example, WHO's target product profile) and stimulate diagnostic manufacturers to design diagnostic products using materials which are safe for use in resource-limited countries.

Sierra Leone government

- Regulation: Incorporate laboratory experts in the Sierra Leone Pharmacy Board to improve review and regulation of diagnostic devices as well as post-market regulatory control by the Central Public Health Reference Laboratory.
- Regulation: 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.
- Regulation: Develop a biomedical research institution or department for the accreditation of laboratory personnel and laboratories within country.
- Use: Review the logistical capacity of the DHMT to carry out specimen transport for IDSR surveillance systems and implement specimen referral systems for CHCs without onsite laboratories.
- Use: (Re)build trust in government laboratory services by improving supply chains, enabling the maintenance of laboratory equipment, and providing training and professional development for laboratory workers, as these factors undermine trust in diagnostics.
- Use: Develop a policy for all laboratory personnel to be accredited before been employed to fully participate in the day to day management and handling of patient samples.
- Waste: Improve the working conditions of cleaners and waste handlers and conduct refresher training on the importance of waste segregation for health workers.

1. Introduction

The DiaDev research project, funded by the European Research Council, investigates the design and use of diagnostic devices in global health (www.diadev.eu). The project explores the role that diagnostic devices are playing in the transformation of health systems in resource-limited settings. Drawing on novel conceptual and methodological tools from social anthropology and health systems research, it investigates the social, cultural, and technical processes involved in developing, deploying, and using diagnostic devices in global health. Through the mapping of diagnostic infrastructures, in-depth qualitative research, and collaborations with stakeholders, DiaDev seeks to identify lessons that can be drawn from the successes and failures of particular diagnostic devices in the places where they are developed and deployed.

In Sierra Leone, research focused on the challenges and opportunities presented by diagnostic devices in a time of intensive epidemic preparedness and laboratory strengthening. The 2014–2016 Ebola Virus Disease (EVD) outbreak in West Africa threw the limitations of Sierra Leone's laboratory infrastructure into sharp relief and mobilised international efforts to develop and deploy new EVD diagnostic tools and laboratory systems within an emergency timeframe. The DiaDev project examines the legacy of (inter)national efforts to strengthen laboratory infrastructure in Sierra Leone post-Ebola and assesses how these changes have been experienced and perceived by policymakers, laboratory staff, and health workers.

The DiaDev research team carried out research in Sierra Leone between October 2018 and December 2019. Drawing on methods including structured observations, semi-structured interviews, and surveys, the researchers developed a methodological toolkit for mapping the life cycles of diagnostic devices, assessing the roles of diagnostic devices in diagnosing fever-based illnesses at different levels of the healthcare system, and mapping the accessibility and usability of point-of-care devices.

The Sierra Leone Ethics and Scientific Review Committee (SLESRC) and the University of Edinburgh's Research Ethics and Integrity Committee granted ethical approval for the project in September 2018. The project involved a collaboration between the Ministries of Health and Defence, the Western Area Urban and Rural District Health Management Team, the College of Medicine & Allied Health Sciences (COMAHS), the University of Edinburgh, King's College London, and King's Sierra Leone Partnership.

In a series of interlinked work packages, the project researchers followed the life cycles of diagnostics to build up an in-depth understanding of their everyday interactions with other elements of the health system (biosafety, infection prevention and control, maintenance, waste disposal, logistics, information sharing, and surveillance). The inter-linked work packages focused on:

Work package one. Regulation: This work package focused retrospectively on lessons learned from point-of-care diagnostics and laboratory-strengthening interventions during and post-Ebola, and examined regulatory and procurement processes for point-of-care devices in use in Sierra Leone.

Work package two. Use: This work package explored how, when, and where patients access and use diagnostic devices and how samples, materials, and information travel between different levels of the

healthcare system.

Work package three. Disposal: This work package examined maintenance and diagnostic waste management and disposal practices for diagnostic devices at the primary, secondary, and tertiary levels of the health system.

Work package four. Capacity building: This work package contributed to the training of Sierra Leone students, researchers, and collaborators through qualitative health research workshops at COMAHS and the 34th Military Hospital and stakeholder workshops, where preliminary findings were shared.

This report provides an overview of the data collected and its preliminary findings, capacity-building activities, and planned outputs.

2. Data collection

This DiaDev research project drew together traditional anthropological research methods (including structured and unstructured observations, semi-structured interviews, focus group discussions) and health system mapping techniques (including participatory mapping, process mapping, and service availability mapping) to examine the life cycles of diagnostic devices in Sierra Leone. Additionally, we conducted a scholarly and grey literature review of laboratory system building during the Ebola outbreak and its aftermath. Below, we summarise the types of data collected at different study sites.

2.1 Qualitative data collection

The initial stage of data collection entailed a focus on clinical diagnostic processes through observation of doctor-patient interactions in triage, consultation, and laboratories at three health facilities providing secondary care: Connaught Hospital, 34th Military Hospital, and Waterloo Community Health Centre (Waterloo CHC was upgraded to a district hospital post-fieldwork). These insights enabled us to design a structured observation tool to systematically document diagnostic pathways for individual patients; to assess whether tests were requested and, if so, when and by whom; and the impact, if any, of test results on treatment prescriptions and patient outcomes.

We collected 52 structured observations of patients presenting with fever across three health facilities. These 52 patients were randomly selected in triage. Patients over the age of 18 were enrolled on the basis of presenting with fever, either self-reported or measured by a thermometer (>38.0 degrees).

The patient population differed slightly between study sites. For example, Connaught Hospital, being the country's largest referral hospital, receives severely sick patients for whom the hospital is often the 'last resort'. Out of the 15 patients we followed in Connaught, 10 were admitted and nine died, and their diagnostic pathways were more complex than the patients followed in Waterloo CHC and 34th Military, the vast majority of which were out-patients.

Research at secondary care facilities was followed by research at a community health post in Western Area Rural into how diagnostic processes differ in health facilities without a laboratory. We selected Lumpa CHP purposively because it was within the catchment area of Waterloo CHC, and we were aiming to understand referral processes between the facilities. However, no patients were followed in Lumpa CHP as the majority presenting at the facilities were under 18 years old. We used the observation data from the facilities to produce process maps consisting of photographs and narrative descriptions of the diagnostic pathways in each facility.

Besides observations, semi-structured interviews were conducted with different groups:

i. Health workers (#45), including a range of cadres such as consultants, junior doctors, community health officers, nurses, environmental health officers, and cleaners/hygienists. Interviews focused on their experiences of the diagnostic systems in question and their perspectives on how the

diagnostic capacity for fever-based illnesses in Sierra Leone might be improved.

ii. Laboratory staff (#20). We conducted 19 individual interviews with Sierra Leonean laboratory workers and one focus group discussion so as to better understand interviewees' experiences of laboratory system strengthening during and post-Ebola as well as the current priorities for improving the national laboratory system.

iii. Key informants (#18), including national-level policymakers and international laboratory scientists supporting the Ebola outbreak in Sierra Leone. Interviews were held to improve our understanding of interviewees' perspectives regarding post-Ebola laboratory system strengthening. Twelve laboratories where Ebola testing took place during the EVD outbreak in Sierra Leone were visited.

iv. Patients (#27) or patients' relatives (in the case of deceased patients), including 18 female and nine male patients who presented with fever in Connaught Hospital, 34th Military Hospital, and Waterloo CHC. Interviews were held so we could understand their diagnostic experiences.

Besides our research in health facilities, we conducted participatory mapping with 10 households from the Bulima community in Western Area Rural. The community study focused on the diagnostic pathways of patients living in rural areas where formal health services are relatively easy to access. We therefore selected a community which was located at about two miles from the CHP which had a high density of drugstores, pharmacies, and alternative healers, who make up other actors in the diagnostic space. Ten households were randomly selected using a cardboard and pencil spinner with an arrow drawn on it. Over a period of two months, the households were visited four times, with researchers enquiring about self-reported fever within the past 24-hour period. Three patients reported a fever-based illness during this period, and patients were accompanied to both informal and formal health workers, where the resultant diagnostic processes were documented. Table 1 provides a schematic overview of the qualitative data collection by study site:

Study site / Data collection method	Health worker interviews	Laboratory staff interviews	Key informant interviews	Patient (or relative) interviews	Structured observations	Household participatory mapping
Connaught Hospital, Freetown	23	6	3	12	15	
34th Military Hospital, Freetown	8	8		8	29	
Waterloo CHC, Western Area Rural	9	5		7	7	
Bo Government Hospital, Bo		1 focus group discussion (n=6)				
Lumpa CHP/ Community, Western Area Rural	5		3			10
National-level laboratory system (country-wide)			12			
Total	45	20	18	27	51	10

2.2 Quantitative data collection

Between February 2019 and September 2019, we conducted a diagnostic mapping survey in all 40 CHCs in Western Area District. The survey tool was adapted from a tool developed by Dr. Pai, McGill Global Health Programs, a laboratory expert and advisor on the World Health Organization's Essential Diagnostic List team. In May 2018, WHO published the first Essential Diagnostics List (EDL) and declared its commitment to give equal importance to diagnostic tests and essential medicines. The survey aims to provide input regarding the needs and local priorities of communities in Sierra Leone in relation to WHO's Essential Diagnostics List.

The survey was designed to provide valuable data about the availability, accessibility, and usability of the diagnostic tests outlined in the Sierra Leone Basic Package of Essential Health Services 2015–2020. Beyond capturing diagnostic technologies, the survey inquired about laboratory infrastructures to generate information about the underlying reasons for non-use or non-availability by including questions about supply chain management, reagents, consumables, equipment, maintenance of equipment, human resources, specimen transport, electricity and water, and waste management and disposal.

The tool was developed in consultation with the directorate of the National Laboratory Services Ministry of Health and Sanitation and the laboratory manager of several public health laboratories, as well as the district health management team (DHMT) of Western Area Urban and Rural. The DHMT

provided up-to-date lists of available CHCs, which were used to contact all CHCs[1] in Western Area District (including 15 in Western Area Rural and 25 in Western Area Urban) to request approval for a site visit.

The data was entered by a researcher during the site visit to the CHC on a hard copy and later transferred to an Excel database. The DiaDev study project provided logistical support to the DHMT laboratory technician on each site visit, as per the request of the DHMT. This enabled the DHMT laboratory technician to gather valuable up-to-date information about laboratory services in the district, a rare opportunity given frequent fuel shortages. For each of the diagnostics assessed, we requested that we see the physical test or equipment in order to verify reported availability.

1. CHCs included in Western Area Rural: Waterloo CHC, Newton CHC, Fourah Bay College CHC, Grafton CHC, Hastings CHC, Benguma CHC, Songo CHC, Kissi Town CHC, Regent CHC, Goderich CHC, Tombo CHC, Fogbo CHC, Christ the King CHC, York CHC, Ogoo Farm CHC. In Western Urban, included CHCs are; Wilberforce CHC, Hill Station CHC, George Brook CHC, St. Anthony CHC, Calaba Town CHC, Al-Khatab CHC, Koya Town CHC, Wellington CHC, Allen Town CHC, Ross Road CHC, Jenneh Wright CHC, Mabella CHC, Ginger Hall CHC, Moyiba CHC, Murray Town CHC, Approved School CHC, Awake CHP, Sierra Leone Red Cross CHC, St. Joseph CHC, Kissy CHC, Susan's Bay CHC, Kuntorlo CHC, Gray Bush CHC, House of Parliament CHC, and Konikay CHC.

3. Preliminary findings

Below, we present some of the key insights gleaned from our research in relation to the different work packages. For all field sites, transcription of interviews and data analysis are still ongoing; as such, the findings presented here provide only preliminary insights.

3.1. Work package 1: regulation and laboratory system strengthening post-Ebola

The Ebola outbreak prompted a wide range of international assistance in terms of laboratory support and emergency preparedness, and included the provision of mobile laboratories; the scaling up of Ebola diagnostic capacity in-country; technical assistance for the development of national-level laboratory and surveillance systems and policy frameworks; and the establishment of entirely new laboratories, hospitals, and training programmes. Key insights from our interviews with laboratory workers during site visits to twelve laboratories where Ebola testing was conducted during the outbreak highlighted the need for further investments in capacity building, particularly relating to governance in the area of regulatory capacity.

Effective use of point-of-care diagnostic devices depends on the existence of regulatory capacity to safeguard the quality of point-of-care devices. Several months into the Ebola outbreak, WHO launched a TPP for Ebola diagnostics, which were desired to be rapid point-of-care tests without extensive biosafety requirements that could be used outside of decentralised healthcare facilities. In addition to the TPP, WHO created an Emergency Use Assessment and Listing (EUAL) mechanism to allow for rapid validation and performance evaluation, after which diagnostics could be procured by UN agencies. Any diagnostic product which is being evaluated for the purpose of market authorisation in Sierra Leone also requires national regulatory approval by the Sierra Leone Pharmacy Board before the validation study can commence. During the Ebola outbreak, six[2] rapid Ebola diagnostic tests were validated in small-scale validation studies in Sierra Leone along with one point-of-care molecular test (Cepheid's GeneXpert Ebola Assay), which was registered with the Pharmacy Board only after the validation study was completed. The Ebola outbreak thus showed the limited inclusion of national regulatory agencies in assessing and monitoring incoming diagnostic products. Additionally, the inclusion of in-country laboratories or regulatory experts in the development of the Ebola TPP could have helped improve the alignment of international and national regulatory frameworks. Another gap in the Ebola TPP was that there were no requirements made regarding diagnostic waste disposal, which turned out to be one of the key factors hampering the use of Ebola diagnostics in decentralised settings.

Our research on the post-Ebola diagnostic system revealed that there is a private unregulated space for diagnostics procurement and supply, and that there are gaps in capacity to deal with that space,

2. UK's Defence Science and Technology Laboratory (DSTL) rapid Ebola test, Corgenix's ReEBOV, Orasure's Oraquick RDT for whole blood and oral fluid RDT, Standard Diagnostics' Q Line, Coris BioConcept RDT, and Cepheid's Xpert Assay.

whether in an emergency or in routine circumstances. By May 2019, five different manufacturers[3] had registered RDTs for 14 different illnesses with the Sierra Leone Pharmacy Board. Our findings from the diagnostic availability mapping across 40 CHCs showed a variety of rapid diagnostic tests from 16 different manufacturers[4] which had not been registered with the Pharmacy Board. According to qualitative interviews with laboratory experts, some of the unregistered tests come from private diagnostic companies; however, there are also many donor-funded unregistered diagnostics, which a key informant explained could be caused by the government not wanting to 'bother' donor agencies with registration processes for donated products. Our qualitative research in different facilities furthermore revealed that gaps in regulatory approval and inconsistent government diagnostic supply systems enable the flourishing of a private supply chain for tests and reagents, which often deliver on the basis of 'just-in-time' supply, whereby small amounts of diagnostics are requested to fill gaps until the government supply arrives. Additionally, at one government CHC, the laboratory does not receive any government supplies and instead functions as a private laboratory. Resultantly, in some facilities laboratory staff apply flexible pricing to diagnostics, as they try to create a return on their investments after buying diagnostic products from private sellers.

Besides the Pharmacy Board, the Central Public Health Reference Laboratory in Lakka is mandated with overseeing quality assurance and the post-market validation of diagnostic tests for specific diseases, such as HIV. Discussions in the expert meeting that DiaDev organised (further discussed in section 4) in March 2019 in Freetown revealed the need to expand quality assurance systems for all diagnostics, especially those that target national priority pathogens. One current priority for the Central Public Health Reference Laboratory is to improve post-market regulatory control by reintroducing lot verification testing of diagnostic devices before and after they are distributed to clinical settings. Enhancing these systems, and aligning the role of CPHRL with the Pharmacy Board's responsibilities in overseeing regulatory approvals, will curtail the supply of low-quality tests and also empower national clinical and public health systems to demand more rigorously tested and, arguably, superior products from international vendors.

Since the Ebola outbreak, there have been improvements in terms of international regulatory mechanisms, including WHO's renamed Emergency Use Listing (EUL) procedures, which place greater emphasis on the role of national regulatory authorities. But increased resources for strengthening governance mechanisms are required if lasting improvements to health systems are to be achieved. Improving the quality of diagnostic devices is essential both for ensuring that clinicians and laboratory workers can trust tests and for improving public trust in the health system.

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3. 1) **Standard Diagnostics** (HIV I/II, syphilis, typhoid salmonella, influenza, H pylori, onchocerciasis, dengue, cholera, malaria, hepatitis B, HIV/Syphilis Duo test); 2) **Alere Medical Co.** (syphilis, hepatitis B, CD4, determine HIV I/II); 3) **Access Bio** (Malaria CareStart RDT); 4) **Cepheid** (Xpert Ebola point-of-care); and 5) **Orasure Technologies, Inc.** (HIV self test).

4. Fortress Diagnostics; Cypress Diagnostics; Machery-Nagel MN; Orchid Biomedical Systems; Nantong Egens Biotechnology Co., Ltd.; Copack; GCC Diagnostics; YD Diagnostics; Guilin Zhonghui Technology Co., Ltd.; Arkray, Inc.; Randox Laboratory, Bionime Corporation; Sysmex; Medipharm; HemoCue; and Bio-Check.

Recommendations

International agencies:

- Include national laboratory experts in the development of international regulatory frameworks, such as WHO's target product profiles (TPP), to guide research and development for diagnostics, thus ameliorating the alignment of countries' diagnostic priorities and regulatory capacities to monitor quality.

Sierra Leone government:

- Incorporate laboratory experts in the Sierra Leone Pharmacy Board to improve review and regulation of diagnostic devices as well as post-market regulatory control by the Central Public Health Reference Laboratory.
- 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.
- Develop a Biomedical Research institution or department for the accreditation of laboratory personnel and laboratories within country.

3.2. Work package 2: use of diagnostics

Diagnostic availability mapping:

Key findings from the diagnostic mapping survey are presented below. Data-cleaning processes and analyses are still ongoing; as such, the presented results are preliminary. Out of the 40 CHCs surveyed, only 24 CHCs had a designated laboratory space. In Western Area Rural, there were three CHCs without a laboratory, whilst in Western Area Urban, there were 21 CHCs without a laboratory. However, all 40 CHCs—including those without designated laboratory spaces—conducted some rapid diagnostic tests, primarily for malaria and HIV. The following table shows the availability of diagnostic tests based on the mapping survey.

Rapid Diagnostic Tests	Availability n/N (%)	Other tests	Availability n/N (%)
Malaria	39/40 (98%)	Widal test (typhoid—not listed in the basic package)	15/40 (38%)
HIV/Syphilis Duo	37/40 (93%)	TB sputum	14/40 (35%)
HIV I/II	33/40 (83%)	Biological specimen routine analysis (stool/urine)	14/40 (35%)
Pregnancy	26/40 (65%)	Malaria microscopy	11/40 (28%)
Random blood sugar	19/40 (48%)	Skin snip	10/40 (25%)
Urine glucose	16/40 (40%)	Blood grouping	8/40 (20%)
HB (including HemoCue)	15/40 (38%)	Blood microscopy (trypanosomiasis, filariasis)	2/40 (5%)
Urinalysis multi-stick	15/40 (38%)	Yeast/mould identification	2/40 (5%)
Cholera (not listed in the basic package)	15/40 (38%)	CD4 count	1/40 (3%)
Hepatitis B	9/40 (23 %)	White blood cell (WBC) count	1/40 (3%)
Hepatitis C	7/40 (18%)	Leishmania	0/40 (0%)
H pylori	5/40 (13%)	Prostate monitoring	0/40 (0%)
VDRL (syphilis)	2/34 (6%)		
Faecal occult blood	2/40 (5%)		
Haemoglobin glycated	2/40 (5%)		
Hepatitis B profile	1/40 (3%)		

The table shows that the majority of the available tests are rapid diagnostic tests, primarily supplied by the National Malaria Control Programme and the National AIDS Control Programme. After the Malaria RDT, HIV RDT, and the HIV/Syphilis Duo RDT, the pregnancy test was the most frequently available test (65%), followed by tests for diabetes, including random blood sugar (48%) and urine glucose (40%). Our qualitative research in one CHC showed that the most requested tests for patients presenting with fever were the Widal test, malaria microscopy, and urine analysis, for which availability was 38%, 28%, and 38% respectively, showing significant gaps in availability. It is remarkable that the Widal test (used for diagnosis of typhoid) was the most commonly available (38%) of the non-rapid tests, despite it not being included in the Basic Package of Essential Health Services. Our qualitative research

revealed that laboratory workers were not always aware of the limited sensitivity and specificity the Widal test, and they saw it as a key test because of the perceived high prevalence of typhoid. Yet, most doctors expressed a lack of trust in the Widal test results, and some doctors preferred to buy typhoid RDTs from private suppliers rather than use the Widal test. This shows the urgent need to further improve the availability of alternative diagnostics of typhoid (e.g., culture and sensitivity testing is considered the gold standard but, during the time of data collection, this was only available in two of the twelve laboratories visited: Jui China CDC and Ola During Children's Hospital. Two other laboratories in Kono Government Hospital and Connaught Hospital were in the process of implementing it).

To assess whether an available diagnostic device is also accessible and useable, laboratories need reagents (e.g., the Giemsa stain for malaria microscopy), consumables (e.g, microscopy slides, urine containers), equipment such as refrigerators (to store reagents) and microscopes, and consumables. Whilst urine multi-sticks were available in 15 out of 40 CHCs, urine containers were available at only 10 CHCs. Deficiencies in government supply systems resulted in the procurement and supply of reagents via private companies. For instance, in all 40 CHCs, sodium reagent for sickling and grouping sera for blood grouping were bought via private suppliers. Some consumables are also supplied via the private supply system. For instance, coverslips used for microscopy tests and cuvettes for haemoglobin testing using the HemoCue point-of-care device were only supplied through private suppliers. Our survey found that 20 laboratories had access to a microscope (of which two were not working) and 26 CHCs had a refrigerator on-site (of which two were not working). The lack of refrigerators (and cold chain provisions) affect the quality of diagnostic tests and reagents, and some staff reported that, in order to preserve quality, they stored diagnostic reagents in a fridge in one of the staff houses at the CHC compound. The (perceived) lack of cold chain provisions also influenced the trust laboratory workers had in the quality of diagnostics bought from private companies.

The usability of a test is affected by the presence of qualified laboratory staff. According to the Sierra Leone Basic Package of Essential Health Services, each CHC should have one laboratory technician and one laboratory assistant as staff. We found that, in 18 out of 40 CHCs (45%), there were no laboratory technicians or laboratory assistants available. In 15 CHCs, there was a laboratory technician on staff, and 19 CHCs had a laboratory assistant. Staff safety was compromised in some settings as only 9 CHCs reported having laboratory coats; furthermore, in 13 CHCs, laboratory staff did not have disposable gloves.

Finally, we found significant differences in available infrastructure, with some CHCs being staffed by several laboratory technicians and laboratory assistants equipped with basic laboratory equipment, and other laboratory spaces merely consisting of a room without electricity, water, equipment, or storage facilities. As such, further research/review is necessary to invest in improving laboratory infrastructure and/or specimen transport services for CHCs, which do not have the equipment necessary to carry out the tests.

Besides the surveillance of epidemic-prone diseases (organised via the DHMT) and China CDC-supported surveillance in Jui Hospital, there were no specimen transport mechanisms to send

specimens for further investigation for routine clinical diagnosis at referral hospitals in place in any of the 40 CHCs. In one CHC without access to a microscope, the laboratory staff used public transport to transport blood samples to another CHC to conduct sample analysis in order to prevent the patient from travelling to a different facility. In general, however, CHCs referred patients to district or referral hospitals, where they may have been required to repeat several diagnostic tests already done at the CHC. This is discussed in the next section, which presents qualitative research findings regarding the role and use of diagnostics in diagnosing fever-based illnesses.

Our research findings illustrated limited investments made in diagnostic waste management and disposal systems. In the diagnostic mapping survey, we found that only one of the 40 CHCs had a waste management standard operation procedure (SOP). Seventy per cent of CHCs have an incinerator, but only 15% were in working condition. Staff reported challenges such as no fuel to burn, no roofing to protect from rain, cracks in walls due to poor construction, and waiting for handover from donors as reasons for unused incinerators. Twenty-eight per cent of the CHCs had a burning pit. All CHCs, however, had a sharps box, and all but one had a dustbin in the laboratory.

Qualitative research: key insights on the use of diagnostics

Based on our preliminary analysis of structured observations across two hospitals, one community health centre, and one community health post, we found that diagnostics had limited impact on diagnosis and treatment decisions predominantly due to health workers' lack of trust in laboratories and the inadequate supply of diagnostics. In the two hospitals, diagnostic tests were requested at the same time as medication was being prescribed. For most observed patients, a pre-lab treatment regimen included antimalarial drugs, a painkiller, one or two broad-spectrum antibiotics, and multivitamins. There were few cases where laboratory results changed the pre-lab treatment plan. Reasons for the limited capacity of diagnostic tests to impact on diagnosis and treatment decisions included patients being unable to pay for tests; the unavailability and stockouts of tests; the long turnaround times of laboratory tests and clinicians' distrust of laboratory tests and RDTs. Our observations also revealed that, despite ordering laboratory tests, clinicians sometimes used their clinical judgement to override tests results. For admitted patients, broad-spectrum antibiotics were often continued because the hospital lacked culture and sensitivity testing, which could be used to tailor and adjust treatment plans. Often, a lack of consistency in the availability of tests and (perceptions of) low quality lead clinicians to direct patients to private labs. This results in laboratory workers feeling that their contributions to the diagnostic process were under-valued.

The concept of (dis)trust emerged as a key theme across all research sites. Distrust of both test results and laboratory workers impacted the uptake of diagnostics and the valuation of laboratory work. From our interviews with laboratory workers, we found that the laboratory is frequently experienced as a neglected space. There were limited meetings between clinicians and laboratory workers, and many felt the lab was not to be considered a vital component of the hospital.

From our literature review about laboratory investments during and post-Ebola, we found that most material investments have been in molecular diagnostics, while limited investments were made in

routine clinical diagnostics in the microbiology, haematology, and biochemistry departments. During Ebola, for example, to provide adequate care for Ebola patients, tests such as liver function tests and electrolyte tests, which depend on a generalised laboratory capacity, are as important as Ebola diagnostics. Post-Ebola, laboratory workers expressed the need to sustain their knowledge and skills in molecular diagnostics through in-house refresher training courses and professional development opportunities, including greater involvement in academic diagnostic-related research projects.

One key insight from interviews with clinicians was that junior doctors learn to distrust hospital laboratories from their seniors. The distrust of test results by clinicians led to distrust spreading across the diagnostic system, and also impacted on patients' distrust in laboratory tests and the health system more generally. From our interviews with patients, we found that, whilst patients were sometimes asked to invest large amounts of money in lab tests, the clinical value of those tests was rarely explained. Additionally, at times, patients were asked to undergo multiple tests in different laboratories, which generated uncertainty and fed the lack of trust. However, our observations of patient diagnostic pathways also revealed that patients often made significant efforts to find treatment and were willing to pay substantial funds for diagnostic tests (for admitted patients, the total cost for tests was often around 500,000 Leones, close to the minimum monthly wage, but sometimes could be as high as 1,000,000 Leones). Generally, patients wanted to know their diagnoses and continued seeking help at different public and private institutions when their illnesses continued.

Our research showed that diagnostics are just one part of the diagnostic process. The responsibility for diagnosis is distributed across different people (patients, patients' relatives, nurses, clinicians, laboratory workers, people involved in the procurement of diagnostic devices, and record keepers) and different spaces (e.g., triages, consultations, hospital laboratories, private laboratories, wards, specialist outpatient department, HIV clinics, TB clinics, and medical records). Furthermore, diagnosis is not a singular event; rather, it emerges over time. Often, patients were reported by health workers as 'being managed' for the initial diagnosis, and received treatment until tests could be done to allow for a differential diagnosis. For admitted patients, this process could take several weeks when tests were unavailable, either because of stockouts of tests or limited funds from patients. The majority of admitted patients and their relatives claimed they had not been informed about test results or diagnoses.

In our community-level research in Western Area Rural, we found that the malaria RDT, pregnancy RDT, and HIV RDT were the only diagnostics readily available (at times). Whilst malaria RDTs are supplied by the National Malaria Programme, the supply varies and sometimes facility staff from CHCs in Western Area Rural use their own money to go to the DHMT to obtain diagnostics, or they buy RDT from private sellers visiting their facilities. Lack of stock resulted in health workers rationing their use of malaria RDTs for severely sick children. A standard treatment regimen was given to feverish children, which included malaria tablets, paracetamol, vitamin B, and antibiotic injections. Health workers were still inclined to provide malaria tablets even when the malaria RDT was negative, and explained to the children's caregivers that the test could not reliably detect malaria. When the malaria RDT was positive, children were often still provided with antibiotics because health workers felt like the children's

caregivers expected injections and IV drips, and feared that, if they did not provide them, they might lose them as customers.

Recommendations

International agencies:

- Increase investments in routine laboratory capacities in microbiology, haematology, and biochemistry departments, particularly in culture and sensitivity testing, to help curb antimicrobial resistance.

Sierra Leone government:

- Review the logistical capacity of the DHMT to carry out specimen transport for IDSR surveillance systems and implement specimen referral systems for CHCs without onsite laboratories.
- (Re)build trust in government laboratory services by improving supply chains, enabling the maintenance of laboratory equipment, and providing training and professional development for laboratory workers, as these factors undermine trust in diagnostics.
- Develop a policy for all laboratory personnel to be accredited before been employed to fully participate in the day to day management and handling of patient samples.

3.3. Work package 3: diagnostic waste management

Diagnostic waste (e.g., disposable plastic rapid test kits, syringes, reagents, cartridges, and collection tubes) and liquid waste (blood, urine) can be harmful to the environment and pose a danger to patients, health workers, and the general public if improperly treated. The open burning and incineration of diagnostic waste, such as empty diagnostic reagents containing chemicals and plastics, can result in the emission of dangerous fumes and particles. For example, cyanide, a chemical used in some point-of-care cartridges, can be potentially dangerous if not burned at high temperatures.

During the Ebola outbreak, one of the reasons why Ebola RDTs were never widely employed was because of the lack of biosafety and waste management systems in decentralised settings. In recent years, there have been several guidelines and strategic plans developed in the areas of infection prevention and waste management. Whilst important, there still seems to be a lack of specific guidance for handling laboratory waste. Our research reveals some priority areas regarding laboratory waste which could inform new guidance on diagnostic waste management.

Our diagnostic availability mapping illustrated the continuous gaps in diagnostic waste management in CHCs in Western Area, particularly highlighting maintenance problems for incinerators and the unavailability of standard operation procedures. Whilst at times waste, general, and infectious refuse were segregated at the point of collection, it was often combined during the burning process or when picked up by waste handlers. In several CHCs, waste was collected by keke drivers or people using wheelbarrows (often combining general and infectious waste), who transported it to public dumping sites or city drains leading to the sea, posing public health risks for scavengers conducting recycling activities.

Our qualitative research in Connaught Hospital on waste management and disposal revealed that lack of waste segregation was a particular problem to the incinerator handlers. Incinerator handlers needed to handpick medical liquid waste (blood bags, urine catheters) from infectious waste before emptying them in wet pits and incinerating. The hospital produced 15 bags of infectious waste per day, but the incinerator was small and could barely fit one bag of waste. The infectious waste that was burned often included general waste, including plastics, which can generate dangerous fumes for incinerator handlers, health workers, and patients. In laboratories across the country, there was little guidance available about where to dispose of liquid waste (including blood), and laboratory workers often did not have any other option than to pour it down the sink, which transported the waste untreated through drainage systems and into the sea.

Our interviews with laboratory cleaners and incinerator handlers revealed that they experienced the work as risky, with particular concerns about accidental needle pricks and the daily inhalation of possibly dangerous fumes. These interviewed laboratory cleaners and incinerator handlers had been working for several years as uncontracted staff, receiving only a monthly stipend of 200,000 Leones from hospital management. After the hospital outsourced waste disposal to a cleaning company, three of the former 13 uncontracted staff were now contracted, yet, at the time of the interviews, many had not been paid for three months, even as the workload had increased tremendously.

Another challenge for hospitals and reference laboratories is disposing of broken laboratory equipment, such as analysers, centrifuges, and refrigerators, which often lie piled up in corners and cupboards. Due to the investment during and post-Ebola, at least 12 laboratories have RT-PCR equipment available (as compared to one before Ebola), which requires additional maintenance and dedicated bioengineering units. Servicing and maintenance of such equipment are often only provided in the first few years following installation, as qualified bioengineers are not available in-country. More training on preventive maintenance for laboratory workers is desired to increase the lifetime of these products.

Recommendations

International agencies:

- Negotiate maintenance contracts with diagnostic companies so as to train and build local capacity in preventative maintenance and better include laboratory experts in discussions of the service agreements of laboratory equipment.
- Highlight the importance of waste management in international regulatory mechanisms (for example, WHO's target product profile) and stimulate diagnostic manufacturers to design diagnostic products using materials which are safe for use in resource-limited countries.

Sierra Leone government:

- Improve working conditions for cleaners and waste handlers, and conduct refresher training on the importance of waste segregation for health workers.

4. Capacity-building activities

- Research proposal development workshop, part of the Sierra Leone Health and Biomedical Research Group (HBIOMED-SL) conference, Hill Valley Hotel, 18 October 2018. DiaDev's research coordinator participated as the facilitator of the preconference, which was attended by 40 biomedicine students from Njala University and COMAHS, who received assistance with their research proposals.
- Qualitative research training for the undergraduate programme in laboratory science and medicine and student engagement sessions at the College of Medicine and Allied Health Sciences (COMAHS), October 2018. The two lectures were conducted by DiaDev's research coordinator and were attended by 25 people. One student engagement session was held for a smaller group of six medical students.
- Expert meeting—'Laboratory Futures: the role of point-of-care devices in Sierra Leone', 4 March 2019, at Hill Valley Hotel, Freetown. The expert meeting was attended by 25 people and featured a keynote by Dr. Isatta Wurie, head of laboratory medicine at COMAHS, short presentations, and a panel discussion with Sierra Leonean laboratory scientists (including Doris Harding, James Rogers, and Mambu Momoh) and health workers (Dr. Boie Jalloh and Fatmata Koroma), who shared their first-hand experiences of using rapid diagnostic tests during the Ebola outbreak. DiaDev co-investigators facilitated the meeting and presented their ongoing research.
- Extensive training and mentoring in qualitative health research methodologies (including ethnographic research, structured observations, and participatory mapping), ethnographic writing and analysis, and presentation skill building for KSLP-based co-investigators.
- Data analysis and academic writing workshop, 23–24 September 2019, at 34th Military Hospital, Freetown. The workshop was attended by all in-country DiaDev investigators and facilitated by DiaDev's PI and research coordinator. The workshop included presentations on academic writing for qualitative research and the thematic analysis of research data, an introduction to NVivo software for qualitative data analysis, and assistance with preparing presentations for dissemination.
- Capacity-building workshop for international research partnerships, 24 September 2019, 34th Military hospital, Freetown. The workshop was attended by 15 researchers from 34th Military Hospital and was facilitated by DiaDev's PI and research administrator. The workshop provided insights about different kinds of research grants, the funding landscape for global health research, grant management and administration, and historical issues and changing expectations in partnerships and capacity building.
- Dissemination and Consultation Workshop, 26 September 2019, at the Hub Hotel, Freetown. The workshop was attended by 35 people and included representatives from the Sierra Leone Laboratory Working Group and Health System Strengthening (HSS), district medical officers from Western Area Rural and Urban District, and laboratory scientists and health workers from included field sites. DiaDev's PI and in-country co-investigators presented results from their ongoing research.

5. Outputs

Academic publications

- Ansumana, R.; Bah, F.; Biao, K.; Harding, D.; Jalloh, M.; Kelly, A.; Koker, F.; Koroma, Z.; Momoh, M.; Rogers, M.; Rogers, J.; Street, A.; Vernooij, E.; Wurie, I. 2020. 'Building Diagnostic Systems in Sierra Leone: the Role of Point-of-Care Devices in Laboratory Strengthening'. African Journal of Laboratory Medicine.
  https://ajlmonline.org/index.php/ajlm/article/view/1029/1470
- 'Research Protocol'. Planned submission to Social Science Protocols, September 2020.
- 'Patient Experiences of the Diagnostic Pathways at a Community Health Centre.' Planned submission to Medicine Anthropology Theory, September 2020.
- 'Architectures of Preparedness: Hope and Hidden Infrastructures of Vaccine Development and Laboratory Strengthening in Sierra Leone'. Planned submission to International Journal of Environmental Research and Public Health, September 2020.
- 'Order and Performativity in Diagnostic Pathways: Anthropological Engagements With Health Systems Research in Sierra Leone'. Planned submission to Social Science & Medicine, December 2020.
- 'Laboratory Strengthening Post-Ebola: Perspectives from Sierra Leone'. Planned submission date: December 2020.
- 'Diagnostic Waste Disposal in Sierra Leone'. Planned submission date: January 2021.
- 'Mapping Survey: Assessing Availability, Accessibility and Usability of Essential Diagnostic Test in 40 CHCs in Western Area Rural and Urban'. Planned submission date: February 2021.
- 'Diagnostic Economies: Valuing Practices of Diagnostics in Sierra Leone'. Planned submission date: March 2021.

Working paper

- Laboratory Strengthening in Public Health Emergencies: Perspectives from Sierra Leone'. To be made available via the DiaDev website in September 2020.

Blogposts

- Kelly, A.; Street, A.; & Vernooij, E. 2020. 'Preparing Africa for Covid-19: Learning Lessons from the Ebola Outbreak'. **https://www.kcl.ac.uk/preparing-africa-for-covid-19-learning-lessons-from-the-ebola-outbreak**
- Kelly, A.; Vernooij, E.; & Street, A. 2020. 'Covid-19 Laboratory Preparedness in Africa: Lessons Can Be Learned from the Ebola Outbreak'. **https://blogs.ed.ac.uk/covid19perspectives/2020/04/09/covid-19-laboratory-preparedness-in-africa-lessons-can-be-learned-from-the-ebola-outbreak**
- Vernooij, E. 2019. 'Ebola Afterlives'. Somatosphere. **http://somatosphere.net/2019/ebola-afterlives.html/**
- Bevan, I.; Street, A.; & Kelly, A. 2018. 'At the Epicentre: the ReEBOV Rapid Diagnostic Test for Ebola'. **https://sway.office.com/OEEELu7zlc4LpKmg**

- Diagnostic mapping case studies, to be published on the DiaDev website: February 2021

Tools

- **Checklist** for assessing diagnostics availability and usability at Community Health Centres. The checklist is available on the DiaDev website: **www.diadev.eu**. The checklist and a database with mapping data have also been made available to the Sierra Leone Ministry of Health and Sanitation and the Directorate of Laboratory Services.
- **Checklist** for assessing diagnostics availability and usability at hospitals. The checklist is available on the DiaDev website: **www.diadev.eu**. The checklist and a database with mapping data have also been made available to the Sierra Leone Ministry of Health and Sanitation and the Directorate of Laboratory Services.
- **Diagnostic mapping handbook**, to be made available via the DiaDev website in March 2021 (**www.diadev.eu**).

Acronyms

CHC	Community Health Centre
CHP	Community Health Post
COMAHS	College of Medicine and Allied Health Sciences
CPHRL	Central Public Health Research Laboratory
DHMT	District Health Management Team
KSLP	King's Sierra Leone Partnership
EDL	Essential Diagnostics List
EUAL	Emergency Use Authorisation Listing
EUL	Emergency Use Listing
EVD	Ebola Virus Disease
HBIOMED-SL	Sierra Leone Health and Biomedical Research Group
HIV	Human Immunodeficiency Viruses
HSS	Health System Strengthening
RDT	Rapid Diagnostic Test
SLBPEHS	Sierra Leone Basic Package of Essential Health Services
SLESRC	Sierra Leone Ethics and Scientific Review Committee
SOP	Standard Operating Procedure
TB	Tuberculosis
TPP	Target Product Profiles
WHO	World Health Organization

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