MINISTRY OF HEALTH AND SANITATION

SIERRA LEONE

NATIONAL RAPID ASSESSMENT OF LABORATORY CAPACITY AND SYSTEMS

Sub-Report

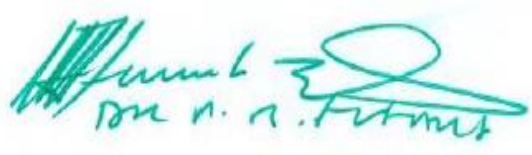
JULY 2015

Foreword

Sierra Leone is just emerging from one of the most challenging public health epidemics in its history with the outbreak of the Ebola epidemic. It has stretched our medical and social services to the limit. A strong, responsive and functional health system is crucial to detect, control and prevent future public health outbreaks. Medical laboratories are essential in the health system and the delivery of services to the people of Sierra Leone. The provision of quality medical laboratory services that provide accurate, timely and reliable diagnostic tests facilitates the effective treatment of patients, early detection of conditions and effective prevention of potential outbreaks. Medical laboratories can play a crucial part in the more efficient use of scarce resources.

Cognisant of the need to strengthen Sierra Leone's medical diagnostic laboratory services, the Ministry of Health and Sanitation (MoHS) has initiated a review of the National Laboratory Strategic Plan (2011–2015), which will provide a framework for strengthening laboratory services in the country. To ensure that the laboratory review is informed by current evidence and the prevailing context in Sierra Leone, a Rapid Assessment of Laboratory Capacity and Systems was undertaken by the Directorate of Hospitals and Laboratory Services, with technical support from Options Consultancy Services Ltd and funded through the UK Department for International Development (DFID). The findings contained in this report will provide insight into existing laboratory capacity in the country, and factors that need to be addressed for the long-term improvement of the laboratory system. This report will contribute to our continued aim of building a more resilient health system in Sierra Leone.

This Ministry wishes to commend leadership provided by the Directorate of Hospital and Laboratory Services and would like to thank all partners that supported the development of this document. We are confident that this document will prove to be an essential resource in developing a National Laboratory Strategic Plan which, when implemented, will benefit the health and well-being of people in Sierra Leone.



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Freetown, Sierra Leone
July 2016

Remarks

It is critical for the Sierra Leone health system to be able to provide services to those that need them most. Medical laboratories are an essential part of the health system, playing key roles in the diagnosis and treatment of patients. The medical laboratory system in the country has however faced significant challenges including financial, human resources and the availability of reagents. The need to strengthen medical laboratory services was demonstrated by the recent Ebola outbreak. Our laboratory system was stretched and unable to make timely diagnosis to enable us defeat this terrible disease.

It is therefore crucial for us to continue making improvements in the medical laboratory system in order to strengthen our health system. We need to use the lessons we have learned from the Ebola epidemic to continue improving the lives of Sierra Leoneans. It is with this in mind that the Ministry of Health and Sanitation has decided to evaluate the current laboratory capacity and systems. We will use this to develop a roadmap towards a well-functioning medical laboratory system that is responsive to the needs of Sierra Leone.

We are grateful to the Directorate of Hospital and Laboratory Services of the Ministry of Health and Sanitation for taking the leadership in finalising this evaluation, and we also thank our development partners, particularly The UK Department of International Development (DFID) for their timely support. We look forward to continually improving health services in Sierra Leone in general and the provision of high quality medical laboratory services in particular.

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Acknowledgements

This Rapid Assessment of Laboratory Capacity and Services would not have been possible without the commitment of a wide range of national and international stakeholders and partners. In particular, we would like to thank DFID for providing funding and technical support through Options Consultancy Services Ltd.

Key advisory support was provided through the Laboratory Technical Working Group (LTWG), the World Health Organization (WHO), and selected national laboratory experts. The National Emergency Response Centre (NERC) was essential in ensuring that logistics were provided to enable data collectors to cross difficult terrains to reach health facilities. Other agencies that have provided invaluable contributions to this assessment are Public Health England (PHE) and the United States Centers for Disease Control and Prevention (CDC).

Finally, but most importantly, we are grateful to all health facilities that took the time to provide vital information that informed this assessment. We encourage all stakeholders to make sure that their valuable insights are used to improve medical diagnostic services at facilities.

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Background

This report presents the findings from the National Rapid Assessment of Laboratory Capacity and Systems that was led by Ministry of Health and Sanitation (MoHS), with support from Options Consultancy Services, and funded through the UK Department for International Development (DFID). Other agencies that have made invaluable contributions to performing this assessment are the National Emergency Response Centre (NERC), the Laboratory Technical Working Group (LTWG) and the World Health Organization (WHO), with key input from Public Health England (PHE) and the United States Centers for Disease Control and Prevention (CDC).

The National Rapid Assessment was conducted between June and July 2015, and covered all 14 districts in Sierra Leone.

The findings from the assessment will contribute to a clear understanding of the current capacities and limitations of laboratories at district level. The report will provide the MoHS and stakeholders with factual data that will inform the imminent review of the National Laboratory Strategic Plan and development of an action plan to strengthen laboratory services.

Methodology

The data gained for the assessment were mainly collected through a quantitative assessment survey, allowing some space for qualitative explanatory notes. The tool comprised 14 sections, and was partially modelled on the WHO identification of key elements in a laboratory system:

1. Laboratory Profile
2. Human Resources
3. Infrastructure
4. Transport and Referral
5. Management of Consumables and Stock
6. Maintenance of Equipment
7. Testing Performance
8. Specimen Management
9. Biosafety
10. Public Health Functions
11. Organisation and Management
12. Data Management
13. Supplies of Consumables and Equipment
14. Basic Testing Capability

In addition, a qualitative facility observation report was provided to each data collection team. A focus group discussion was held with a select number of key stakeholders, consisting of 10 laboratory representatives from all regions of the country. The resulting qualitative data were used to triangulate data and to add contextual information to the quantitative data.

There are an estimated 1,200 laboratory facilities across Sierra Leone. Our sampling frame focused on laboratories that provide basic laboratory testing in line with the Basic Package of Essential Health Services (BPEHS). It excluded any reference laboratories and laboratories focusing solely on Ebola diagnosis. The assessment thus includes a total of 315 laboratories (non-Ebola laboratories) in the sampling framework, which represents 26% of all public health facilities in the country.

A total of 315 facilities were sampled, with between 22–24 facilities per district. Of those, 131 (42%) facilities do not have a laboratory staff member or Tuberculosis (TB)/Directly Observed Therapy (DOT) worker or laboratory facility. Laboratory capacity was assessed among 184 facilities that have either a dedicated laboratory or TB/DOT worker.

Key Findings

Human Resources

- There are inadequate numbers of appropriately trained laboratorians. Of the 181 Community Health Centres (CHCs) sampled, nearly one-third (30%) did not have a single laboratory worker. The two districts with the highest proportions of facilities without laboratory staff were Bonthe (68%) and Pujehun (55%).
- There is no formal, clear scheme of service for laboratory workers, which hampers motivation and career progression.
- Many laboratory workers are performing tasks for which there is inadequate evidence of standardised training/qualifications.
- For one-third (33%) of laboratory workers, the highest form of education achieved is secondary-level (or lower). Almost half of all laboratory workers have a level of education lower than a diploma, and those working in CHCs and Community Health Posts (CHPs) are working in relative isolation, limiting the potential for mentorship and Continuous Professional Development (CPD) from more experienced colleagues.
- Following support provided through the Global Fund National TB Control Programme, 125 facilities (40%) were staffed with laboratory workers who conduct microscopy for TB, but without a formal mandate to perform other clinical laboratory diagnostics.
- The capacity of higher education institutions to provide skilled laboratory workers is hampered by poor resources and a lack of standardised curricula.
- Around half (51%) of the 452 laboratory staff documented as part of this assessment had obtained a diploma. Four members of staff had a graduate degree, and three a postgraduate degree.
- Many laboratory workers reported that remuneration for their laboratory work was either late or unsatisfactory.. In some cases people had not been paid for up to 14 months.

Laboratory Testing

- Laboratory testing is available at CHCs (primary health care level); testing services are therefore relatively accessible for communities.
- Twenty-four facilities were able to readily deliver a selected number of eight essential tests: blood glucose, faecal microscopy, glucosuria, haemoglobin, Human Chorionic Gonadotrophin (hCG) pregnancy test, malaria microscopy/Rapid Diagnostic Test (RDT), proteinuria determination and urine microscopy/dipstick testing.
- The most common tests performed are: sputum for Acid-fast Bacilli (AFB), haemoglobin estimation, blood for malaria parasite, and urinalysis.
- There is an overreliance on manual methods of estimating lab tests. Very few automated methods are used. Automated methods were more common in hospitals.

Transport and Referral

- Hospitals are the facilities most likely to receive specimens from other facilities.
- Around a quarter (26%) of all CHCs and CHPs refer specimens to a higher-level facility.
- The main samples referred are: blood, serum or plasma samples of highly contagious diseases; TB smear samples; biopsies; pap smears; and dried blood spots.
- Over four-fifths (83%) of all facilities did not have guidelines on how to transport specimens.
- Very few facilities (13%) were able to provide appropriate packaging for specimen transportation.
- Over four-fifths (82%) of all facilities did not have a designated transport means, and relied on private vehicles for transporting specimens.

Infrastructure

- Two-thirds (65%) of all laboratories (including more than half of government hospitals) did not have a dedicated water supply, with no running water available.
- A quarter (27%) of all CHCs had no source of electricity, hampering their ability to provide 24-hour curative services, as laid out in the BPEHS.
- Laboratories at five government hospitals lack a refrigerator; those at four hospitals lack a freezer.
- Many laboratories lack adequate workspace to enable proper organisation of equipment and testing, and are of an inadequate standard of hygiene, posing a risk to biosafety and quality of diagnostic results.

Reagents and Equipment Procurement and Supply Systems

- Laboratory supply chains are inadequate, leading to delays in supply and frequent stock-outs. This is compounded by the lack of adequate stock management in many facilities, and the weakness of those systems that are in place.
- The vast majority of facilities do not have the capacity to purify or distil water: 82% of facilities lack a water distillation unit and 80% lack chemicals or a filter to purify water.
- Key items of test kits, laboratory reagents, and consumables and equipment are missing from many government facilities with laboratories.
- Laboratories lack adequate equipment inventories and maintenance and repair plans, while many facilities, particularly those based in rural settings, have inadequate local maintenance and repair capacities. These failings were more prevalent in government facilities, although some private facilities also suffered gaps in these areas.

Quality Management

- The vast majority of public and private labs in Sierra Leone have no established Standard Operating Procedures (SOPs), although some facilities could provide procedures for a selected number of tests.
- External Quality Assurance (EQA) and Internal Quality Control (IQC) mechanisms are in place at some facilities for basic tests, including Malaria RDT, and TB, pregnancy and HIV testing.
- Around three-tenths (29%) of facilities reported having an organisational structure in place that defined the lines of authority and responsibility for key laboratory staff.

Information Management Systems

- Although the Global Fund TB Control Programme and MoHS surveillance processes provide some standardised data reporting relating to TB and DPC, there is no overall Laboratory Information Management System (LIMS). Such a system would need to be linked to the national Health Information Management (HMIS) and Integrated Disease Surveillance Response (IDSR) Systems.
- There are no national standardised laboratory forms or reporting mechanisms. The absence of forms that capture essential clinical and patient data is likely to impact on the quality of laboratory services.
- The absence from laboratories of designated phones and computers with access to the Internet will need to be addressed to facilitate improved data reporting.

Biorisk Management

- One-ninth (11%) of facilities have health and safety protocols in place that define and document roles and responsibilities related to health and safety.
- Half (51%) the facilities (including seven hospitals and seven CHCs) reported having received a visit during the last year from someone to assess health and safety at the facility.
- Staff at 40% of facilities had staff in place trained on health and safety. One-quarter (27%) of facilities had laboratory staff who had received training in 2015.
- Over half (54%, *n*=100) of facilities could provide evidence of waste management procedures being in place.
- Shortages in supplies of essential biosafety and waste disposal equipment exist at all facility levels.

Laboratory Governance

- There are insufficient guidelines that outline minimum requirements, standardisation and national systems to enable improved laboratory governance.
- No laboratory accreditation, registration and licensing systems are currently in place for laboratories; their establishment is an important condition for improving laboratory service quality.
- Laboratories receive insufficient priority. Laboratory leads need to be given the opportunity to input into district, regional and national planning processes. Laboratory government budgets have not been ringfenced.
- Laboratories and TB/DOT centres are funded through a mix of different sources, requiring strong coordination between government and donors.

SWOT Analysis

Strengths

Country-wide coverage: The availability of clinical diagnostic laboratories in all district hospitals and many CHCs has ensured that diagnostic testing services are available across the country.

Testing services available at primary facilities: Ensuring that laboratories are available not only at hospitals but also at CHCs has brought clinical diagnostic services closer to (and therefore relatively accessible for) people in communities.

Laboratory policy and strategy: The MoHS launched the National Health Policy (NHP) in October 2002, which was revised in 2009. The NHP sets out the broad direction of the health sector and aims to maintain and improve the health of all Sierra Leoneans resident within the country.

Strong national laboratory policy and strategy: A national Laboratory Policy was developed in 2010. The policy provided a platform for the development of a strong National Laboratory Strategic Plan (2011–2015). These documents provide a robust base for the development of a new National Laboratory Strategic Plan.

Laboratory management structures in place: Laboratory services are managed by the Directorate of Hospitals and Laboratory Services, under the MoHS. Laboratory technical assistance and advice is provided through the LTWG.

Training institutions: Sierra Leone has institutions in place that provide education in the Biological Sciences to degree level, basic training in Medical Laboratory Science to diploma level, and training for laboratory technologists for roles in both medical and science teaching laboratories.

Weaknesses

Shortage of qualified laboratory personnel: There is an acute shortage of qualified laboratory personnel. The quantity of trained personnel, particularly of laboratory scientists and technicians, is insufficient to meet the country's clinical diagnostic testing needs.

Training/education**:** The graduates from the courses offered by existing Sierra Leonean training institutions and standards achieved are not sufficient to meet the country's need for skilled laboratory staff. In the absence of a scheme of service, professional titles given to laboratory staff often do not reflect skills and education levels, or staff responsibilities in the laboratory. In addition, there are no systems for CPD or progression of career and remuneration, which negatively impacts staff motivation.

Weak laboratory infrastructure, power and water supply, waste disposal facilities: Laboratory workspace is often too small or not designed to serve laboratory purposes. Electricity supply is often unreliable. For many laboratories water is not always available and often of poor quality. Waste disposal is often a challenge, with proper waste management procedures rarely in place or implemented. Incineration equipment is often lacking, and proper drainage for waste water absent. In some cases, these conditions pose a risk to laboratory staff and the community and the environment in which the laboratory is situated.

Weak laboratory regulatory processes and standardisation: There is a need for an authoritative body that sets minimum standards and regulates laboratories. Current systems for laboratory registration and licensing procedures are weak. Service and equipment standards and SOPs are required to ensure minimum quality standards. A regulatory body would be essential to making sure these are enforced.

Unavailability of testing services against the basic package: Though some basic testing services, such as those for TB, are often available as a result of Global Fund support, few facilities visited by this assessment were able to offer services as per the BPEHS. Availability of such testing services is often affected by irregular funding streams, delays in supply of equipment and reagents, and availability of skilled staff at the facility. In addition, weak quality-monitoring systems and inadequate supervision of staff affect the quality of services and laboratory performance against the basic package.

Laboratory service quality: Few laboratories employ consistent internal quality control in their analysis. Only the TB and HIV reference laboratories employ IQC and EQA schemes. SOPs are not in place at most laboratories, as there are no national laboratory standards. Services are negatively impacted by the low education levels of staff.

Weak transport and referral: Specimens are often not referred to higher-level facilities for further testing. Reasons for this include: laboratories not knowing the correct facility for referral; the absence of a well-coordinated transport system; the shortage of safe transport means; the lack of equipment that would safely store samples during transport; and the absence of dedicated and trained transport personnel.

Insufficient resourcing of laboratories: Laboratories need to be afforded greater priority by decision-makers at every level of the health system, and allocated budgets for laboratories need to be ringfenced. Resources should be directed efficiently to address key laboratory needs, informed by existing evidence and advice a dedicated laboratory professional nominated by the Directorate of Hospital and Laboratory Services. Procurement of laboratory equipment and allocation of laboratory funds are often performed with minimal input from laboratory experts.

Intermittent supply of equipment and reagents: Delays in supply of equipment reagents and consumables are affecting availability of testing services against the BPEHS. Laboratory supply chains need strengthening at every stage: procurement, allocation, distribution, receipt, storage and maintenance. As a result of poor specifications, inappropriate supplies are sometimes procured, leading to wastage. There is inadequate local technical support for regular (preventive) equipment maintenance and calibration.

Absence of Laboratory Information Management Systems: The collection, analysis, reporting and utilisation of laboratory data are weak. The absence of standardised laboratory data reporting could affect treatment of patients and their effective referral to higher levels of care. It prevents effective surveillance and monitoring of diseases, posing public health risks. In addition, decisions on laboratory investments are often made without being informed by a solid evidence base.

Opportunities

Development of scheme of service: The government is currently developing a scheme of service that will provide laboratory staff with officially recognised professional status and will enable career progression. This creates an opportunity to improve human resource systems, positively affecting staff morale and retention.

Upgrading existing training institutions: With support from government and donors, courses at existing training institutions could be restructured and facilities could be upgraded to produce more and better skilled laboratory graduates. A Medical Laboratory Scientist (MLS) curriculum is already available. The government is currently in the process of developing Medical Laboratory Technician (MLT) and Medical Laboratory Assistant (MLA) training curricula and has developed key SOPs, which are about to be distributed. These are efforts that partners could leverage.

Strengthening of referral systems and transportation: If referral systems were to be improved, the many CHCs, CHPs and Maternal and Child Health Posts (MCHPs) in the country could serve as effective entry points to more advanced testing services. Existing resources at hospitals and CHCs with strong laboratories could therefore be used more effectively, without the resource-intensive establishment of many additional laboratories.

Strengthening existing laboratory supply chain: Existing procurement systems at the National Pharmacy Procurement Unit (NPPU) and at district levels can be strengthened with improved quantification, standardised specification, procurement, distribution and storage. Input from laboratory professionals, appointed by the Directorate of Hospitals and Laboratory Services, on equipment specifications and needs would reduce wastage of allocated resources.

Leverage existing skills and knowledge: Sierra Leone has many graduates from affiliated sciences, such as Biology or Chemistry who, if given additional opportunities for professional development, could be trained to become laboratory staff.

Increased donor attention: During the past years, laboratories have received important disease-focused support from donors such as the Global Fund to Fight AIDS, TB and Malaria, and the German Leprosy and TB Relief Association (GLRA). In addition, the Ebola epidemic has drawn donors' attention to the urgent need to address overall systemic challenges, and has brought about a realisation that weak health systems in Sierra Leone could impact public health on an international scale. It is important to galvanise current interest from donors and gain their support to fund the implementation of the National Strategic Laboratory Plan.

Threats

Reliability of laboratory testing: If health facilities are unable to provide reliable laboratory testing services (e.g. because staff are insufficiently trained or reagents are of poor quality) there is a risk that patients will be incorrectly diagnosed and therefore not provided with the treatment that they need. This affects both the treatment of the patient and disease control and could lead to wastage of resources.

Reduced health system performance: Provision of efficient laboratory services is an essential part of a functioning healthcare system. Medical laboratories provide confirmation of clinical diagnoses, facilitate improved management of diseases, generate essential public health information, and with adequate government funding, they can facilitate disease surveillance at the grassroots[1].

Laboratories will play an important role in reducing the burden on Sierra Leone's health system, which has been significantly weakened following the Ebola outbreak. Enabling appropriate prioritisation of patients with other essential health needs is fundamental to the optimal management of limited resources: early diagnosis will reduce the length of treatment and therefore the use of resources.

Outbreak of epidemics: If Sierra Leone's Laboratory Systems are not strengthened, they will not be able to help prevent the outbreak of epidemics, such as HIV, Ebola, Lassa fever, measles, dysentery and diarrhoea. This could have a significant impact on people's health at local, national and international levels.

Inefficient allocation of resources: The Ebola epidemic has brought about a realisation that there is an urgent need to strengthen Sierra Leone's health system, and particularly its laboratory system. As Sierra Leone's laboratory system is resourced through different funding streams, coordination and prioritisation of investments is of vital importance. The National Laboratory Strategic Plan will be an essential tool for facilitating this and will outline key priorities in strengthening the country's laboratory system as set by MoHS. It is important that all those supporting MoHS align to these priority areas and form part of a coherent response, coordinated by the Directorate of Hospitals and Laboratory Services.

Biosafety and biosecurity: Insufficient availability and implementation of biosafety procedures and absence of proper drainage and waste disposal equipment can pose a threat to the health and safety of laboratory staff and the community and environment in which the laboratory is situated.

Retention: It is important that weaknesses in the current human resource system for laboratory personnel, such as scheme of service, remuneration and CPD, are addressed before or alongside provision of training. If not, there is a high risk that, once trained, graduates will become demotivated or leave to work elsewhere in search of better remuneration and professional opportunities.

Recommendations

Recommendations: Key priority areas for strengthening the laboratory system

1. Human resource systems for laboratory personnel need to be strengthened, including the provision of high-quality training programmes for all levels of laboratory staff, to enable Sierra Leone to become self-sufficient in generating laboratory personnel at all levels.

2. Biosafety policies and procedures should be established and laboratories should be enabled to comply with these, to ensure the safety of medical laboratory personnel, the communities and environment surrounding the laboratory.

3. Infrastructure at key laboratories needs to be upgraded, with priority given to government hospitals and CHCs to enable them to provide safe and comprehensive testing services. Priority should be given to addressing power shortages, water supplies, cold storage and biosafety facilities.

4. To increase access to testing services, referral networks needs to be established and supported by safe specimen transport means.

5. The laboratory supply chain system needs strengthening, to prevent interruption of services as a result of insufficient equipment or reagents.

6. A Laboratory Information Management System needs to be established to ensure improved availability and use of laboratory data.

7. High-quality management systems need to be strengthened with the introduction of accreditation mechanisms and implementation of EQA schemes.

8. Essential laboratory practice, biosafety, quality, service, and equipment standards need to be agreed. Current laboratory governance structures needs to be supported by a regulatory agency with the authority to implement and enforce these laboratory standards.

9. Laboratory funding mechanisms need to be strengthened and coordinated, and investment decisions informed by and channelled to priority needs.

Next Steps

Next Steps in view of the review of the National Laboratory Strategic Plan

- Clear milestones that are easily trackable should be included in the national strategy. This will ensure that the strategy goes beyond setting policy and can have a sustained impact on the improvement of laboratory services.
- The laboratory strategy should be incorporated at the highest level, mainstreamed through the Presidential Delivery Unit, with implementation led by the Directorate of Hospitals and Laboratory Services.
- Frequent updates on the attainment of the strategy should be made available to the Minister of Health and the Chief Medical Officer.
- A group of laboratory experts should be appointed that will support the MoHS in reviewing progress in attainment of the National Laboratory Strategic Plan, provide suggested improvement and make necessary changes to the strategy to ensure it reaches its objectives.
- The national strategy should be considered as a live policy document that can respond to the fluid situation on the ground and aid utilisation of all available resources.
- The strategy and its enactment should be disseminated to all the district medical officers, District Health Management Boards (DHMTs), and hospital and laboratory leads. This will ensure that the strategy is followed up at local level.