Factors affecting access to quality HIV diagnostic services in Liberia from a laboratory perspective

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A thesis submitted in partial fulfilment of the requirement for the degree of Master of Science in International Health

By

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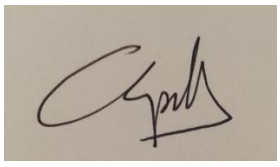

Master in International Health

September 2021

KIT (Royal Tropical Institute) / Vrije Universiteit Amsterdam

Amsterdam, the Netherlands

Organised by:

KIT (Royal Tropical Institute)

Amsterdam, the Netherlands

In cooperation with:

Vrije Universiteit Amsterdam (VU)

Amsterdam, the Netherlands

List of Abbreviations

AIDS	Acquired immune deficiency syndrome
ANC	Antenatal Clinic
ART	Antiretroviral treatment
ARV	Antiretroviral drug
ASLM	African Society for Laboratory Medicine
CCM	Country Coordinating Mechanism
CD4	Cluster of Differentiation 4
CDC	Center for Disease Control
CDO	Country Diagnostic Officer
DBS	Dried Blood Spot
DHIS	District Health Information System
DHS	Demographic and Health Survey
DIC	Drop-In Center
EDTA	Ethylenediaminetetraacetic acid
EID	Early Infant Diagnosis
EQA	External Quality Assessment
EVD	Ebola Virus Disease
GAVI	Global Alliance for Vaccines and Immunization
GF	The Global Fund to fight Aids, Tuberculosis and Malaria
GDP	Gross Domestic Product
HMIS	Health Management Information System
HNSP	HIV National Strategic Plan
HTC	HIV Testing and Counselling
HTS	HIV Testing Services
HIV	Human Immunodeficiency virus
IHR	International Health Regulations
JEE	Joint External Evaluation

LMIS	Logistics Management and Information System
LIMS	Laboratory Information Management System
MOH	Ministry of Health
MSM	Men having Sex with Men
NAC	National Aids Commission
NACP	National Aids Control Program
NBSP	National Blood Safety Program
NDD	National Diagnostic Division
NDU	National Diagnostic Unit
NGO	Non-Governmental Organisation
NHSP	National HIV Strategic Plan
NTCP	National Tuberculosis Control Program
NPHIL	National Public Health Institute of Liberia
NPHRL	National Public Health Reference Laboratory
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
PLHIV	People Living with HIV
PMTCT	Prevention of Mother to Child Transmission
POC	Point-of-Care
RDT	Rapid Diagnostic Test
SARA	Service Availability and Readiness Assessment
SLIPTA	Stepwise Laboratory (Quality) Improvement Process Towards Accreditation
SLMTA	Strengthening Laboratory Management Toward Accreditation
SPNHLSL	Strategic Plan for the National Health Laboratory System of Liberia
SW	Sex Workers
TB	Tuberculosis
USA	United States of America
USAID	United States Agency for International Development
UNAIDS	Joint United Nations Programme on HIV/AIDS

UNDP	United Nations Development Program
VL	Viral Load
WHO	World Health Organization

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Abstract

Background: At the end of 2019, Liberia was still lagging behind the 2020 UNAIDS 90-90-90 target. Meanwhile, the 2014 Ebola epidemic had exposed the country health system weaknesses, in particular regarding its laboratory capacity.

Objectives: Identify factors affecting access to quality HIV diagnostics in Liberia, from a laboratory perspective.

Method: A literature review, using an adapted version of the Conceptual framework for testing process and associated errors in sample processing after Hickner and al and Carraro and Plebani.

Results: Our review highlighted a laboratory system in its initial stage of development, with the recent creation of the National Public Health Institute of Liberia and elaboration of national strategy and policy documents. Yet responsibilities for moving the agenda forward and funding needs are not clearly defined. Stock-out of health products, shortage of laboratory staff, an unoptimized diagnostic network and sample transportation system, with no quality assurance system in place, negatively impact the delivery of quality HIV diagnostic services (analytical phase), which constitutes a barrier to test commissioning by health workers and may reduce clinicians' trust in the results. At health facility level, lack of knowledge, heavy workload and stigma impact offering of services (pre-analytical phase) and may jeopardize adequate use of results, when returned (post-analytical phase). There was limited research identified for Liberia, in particular regarding HTC practice, laboratory procedures, turnaround times and quality assurance activities.

Conclusion: The development of a National Laboratory system in Liberia needs to be accelerated. Supply chain weaknesses and human resources gaps have to be addressed structurally. Implementation of task-shifting, optimization of the diagnostic network and practical quality assurance improvement processes, can already improve access to quality HIV diagnostic services. Operational research needs to be undertaken to fill the knowledge gaps.

Keywords: Diagnostics, HIV, Laboratory, Liberia, Laboratory system

Wordcount: 13 187

1. Background

Geographical context

Liberia is a West African country covering 111,000 square kilometres (see Figure 1-(1). Its Atlantic coastline is 360 mile long and it has borders with Sierra Leone, Guinea-Conakry and Ivory Coast. (2) Liberia is divided into fifteen counties, which are subdivided into 92 second-level administrative divisions called districts. (3)

Figure 1 – Map of Liberia (1)

Political context

Liberia was founded by free people of color and later former slaves, whose emigration from the United States of America was organized by the American Colonization Society. The Republic of Liberia was established on July 26, 1847. Between 1847 and 1980, political and economic power remained in the hands of the black colonists descendants, leaving Liberia indigenous population out. (4) Profound inequalities and ethnic tensions created by this society led to two civil wars between 1989 and 2003, which destroyed infrastructure and led to public services shutdown in large parts of the country. (5)

Since the war ended, significant efforts were undertaken to consolidate peace and stability. In 2018, the peaceful transition of power was a positive signal and set the grounds for further development efforts. (2)

Economic context

Liberia is a low-income country, with reported Gross National Income per capita of US$ 370. Liberia's economy, dominated by agriculture and mining, is slowly transforming, with the emergence of a services sector. (2) Liberia ranked 181st out of 189 in the latest United Nations Development Programme (UNDP) Human Development Index and 155th in the Gender Inequality Index (2019). (6)

Poverty levels remain high, with 72% of the rural population and 32% of the urban population below the poverty rate measured at the national poverty line in 2016. (7) Its population of 4.6 million is very young, result of a high fertility rate (4,3 births per woman in 2018) and a low life expectancy (63,8 years in 2018). (8) The Gini coefficient for Liberia was 35,3 in 2016. (9)

Health situation

Maternal mortality stands at 661 for 100,000 live births in 2017 (down from 1,072 in 2013) and infant mortality at 32,4 per 1,000 live births in 2019, down from 54 in 2013. The under-5 mortality is 84,6 per 1,000 live births. (10) Leading causes of mortality in 2019 are malaria, diarrheal diseases, neonatal disorders, lower respiratory infections, heart disease and HIV/AIDS. (11)

Health system

Civil wars had a dramatic impact on the health system, with major infrastructure destructions, health personnel loss and partial or complete halt of health services depending on the regions. (2) Since they ended, several reforms were implemented to increase access of Liberians to quality healthcare, with the introduction of the Basic Package of Health Services, later upgraded to the Essential Package of Health Services. (12)

Liberia is divided into 5 regions, 15 counties covering 92 health districts. Liberia's health system is structured into three levels of service delivery: primary level with 671 health clinics, secondary level with 58 health centres and county hospitals, and tertiary level consisting of a limited number of regional and referral hospitals (36 hospitals in total). (3)

The laboratory system comprises five public health laboratories (the National Reference Laboratory, four regional laboratories) and 401 clinical laboratories (285 public, 116 private, 1 at the public-private tertiary facility level). Clinical laboratories provide services ranging from Rapid Diagnostic tests ('RDT') to advanced diagnostics, using automated analysers. (13)

In 2017, health expenditure per capita amount to US$ 65 and represent 8% of the GDP. Out of pocket expenditure represent 40% of health expenditures while development assistance for health expenditures represent 42 %. (11)

Partnership landscape

Liberia health sector benefits from strong support from multilateral and bilateral partners (USAID, World Bank, Global Fund, GAVI, etc.). The Ebola outbreak underlined the need to invest in health systems strengthening. (14)

HIV in Liberia

To end the HIV/AIDS epidemic, UNAIDS had globally set three targets to be achieved by the end of 2020: 90% of all people living with HIV should know their HIV status, 90% all people with diagnosed HIV infection should receive sustained antiretroviral therapy and 90% of all people receiving antiretroviral therapy should have viral suppression. (15)

In 2019, it was estimated that 43,000 adult and 3,600 children under 14 lived with HIV in Liberia: 57% knew that they are HIV-positive and, out of those, 56% were on antiretroviral treatment ('ART') while no data was reported regarding viral suppression. Coverage of adult and children on ART overall was 34%. 90% of pregnant women needing ARV for PMTCT were on ART, yet final transmission rate including during breastfeeding was 14,5%. Coverage of early infant diagnosis ('EID') was low at 22%. (16)

HIV-AIDS is the sixth cause of mortality in Liberia: estimated number of deaths due to HIV/AIDS was 1,900 in 2019, a reduction of 45% since 2010. Overall adult prevalence rate is estimated at 1,5% while prevalence rates in key-population ('KP') groups are much higher (see Table 1- (16)). Incidence rate is estimated at 0,74 per 1,000 population and has reduced by 35% since 2010. (11)(16).

Group	Estimated prevalence rate	Estimated n# of PLHIV
Adult aged 15 to 49	1,5%	47 000
Men Having Sex with Men ('MSM')	19,8%	14 771
Sex workers ('SW')	9,8%	15 984
Injecting Drug Users ('IDU')	3,9%	160

Table 1 - Estimated HIV prevalence in 2019 in Liberia

2. Problem statement

In 2019, in Liberia, 57% of the estimated number of people living with HIV knew their status, 56% of them were on antiretroviral treatment ('ART') while no data was reported regarding viral suppression. About one out of 3 adults and children needing ART receives it and 22% only of infants born to HIV+ mothers receives an early infant diagnosis ('EID'). (16) This performance is far from reaching the 90-90-90 targets.

Factors from both the patient side (demand) and the system side (supply) contribute to the low results reached regarding the delivery of HIV diagnostic services (HIV testing, EID, VL) and ensuring viral suppression. From the patient/demand side, factors affecting the decision to seek an HIV test and HIV infection viral load monitoring are the knowledge of HIV, trust in the health system and the health care staff, the presence of fear of HIV-related stigma, the level of self-perceived risk of HIV infection, the costs of accessing those services, the distance to the health facility as well as gender norms affecting the women ability to seek services, including lack of paternal support for early infant diagnosis (17). From the supply side, the structure of service delivery, the existence of guidelines and trained staff, the availability of health products and equipment required as well as the quality and timeliness of communication of test results are factors contributing to reaching the goals. (18)

If laboratory diagnostic services are not available at the scale and quality required, efforts to increase demand cannot lead to the expected results and may actually carry a negative impact (19). Indeed, if patients, incentivized to seek medical care, cannot receive services with the expected quality, their trust in the system will decrease and the provider-patient relationship will be harmed. This may discourage patients to seek HIV testing in the future, for themselves, their partners or children, and may prevent HIV positive patients from seeking adequate care, with the risk of treatment interruption and development of drug resistance.

Therefore, while much remains to be done to ensure all Liberians accept and voluntarily seek HIV testing and that HIV positive patients remain observant of their ART treatment and in demand of viral load monitoring, it is essential, for these interventions to be both impactful and ethical, that all systems are in place for them to access quality HIV diagnostic services and receive appropriate clinical services including ART in order to reach viral suppression. (19)

Since the Maputo Declaration on Strengthening of Laboratory systems in 2008, laboratory services have improved in a number of countries in Sub Saharan Africa, however progress has been uneven and many countries still experience significant challenges: equipment not fully functional due to lack of maintenance; stock-out of laboratory products (tests, reagents, consumables); unavailability of trained human resources; inefficient sample transportation system resulting in delays between testing and results reporting. In 2014, the Ebola epidemic in West and Central Africa underlined the weaknesses of the national health system in Liberia, particularly its laboratory services. (20)

Issues affecting the HIV testing within the laboratory system in Liberia are wide and range from inadequate institutional arrangements, lack of skilled workforce, dysfunctional equipment to insufficient supply chain and information systems. (21) Since the end of the Ebola outbreak, increased attention has been paid to the laboratory system, with the development of national policy and strategy documents and the creation end 2016 of the National Public Health Institute of Liberia ('NPHIL'). (22)(23) The NPHIL Strategic Plan recognizes the limited laboratory capacity to detect, notify and respond to most infectious diseases of public health concern and

underlines the need to develop a bio-surveillance and laboratory diagnostic system. (13) In 2019, an audit of the Liberia portfolio of grants to fight HIV, TB and Malaria undertaken by the GF also highlighted that deficiencies in the supply chain systems and in the laboratory system in particular were contributing to low EID coverage of and under-utilization of viral load ('VL') equipment in the facilities visited, thereby contributing to under-diagnosis of HIV positive infants and insufficient viral suppression. (24)

Justification:

Reaching the 90/90/90 target requires the existence of functional laboratory services delivering quality HIV Diagnostics at scale, both testing services and clinical management such as VL testing and CD4. Without availability of quality HIV testing, RDT or Early Infant Diagnosis, patients may remain undiagnosed, impacting results against the first 90 target, even if they come to request the services. In addition, even when a patient is diagnosed, in the absence of functional laboratories able to timely monitor viral load and CD4 counts, inadequate treatment regimens may be prescribed, leading to increased drug resistance and absence of viral suppression, impacting the third 90 target.

While the demand side, i.e. the patient ability to access and request HIV testing and viral load monitoring services, is also an important factor contributing to achieving these targets, the area of research of this thesis will be the Liberia laboratory system itself, as having a well-functioning system in place is a pre-condition to ensuring the HIV control program can reach its goals.

3. Objectives

The objective of my research will be to identify, from a laboratory perspective, factors influencing access to quality HIV testing and viral load monitoring services in Liberia and issue recommendations to improve access to and quality of such services.

Specific objectives include:

- To analyse the governance, strategy, policy and financing aspects, with regards to the laboratory system and HIV program in Liberia;
- To analyse how the current laboratory systems set-up influences access to quality HIV diagnostic services, both HIV testing services and clinical monitoring diagnostic tests;
- To identify what Liberia can learn from neighbouring countries and countries in Eastern and Southern Africa having achieved high level and quality of HIV testing, Early Infant Diagnosis and Viral Load diagnostic coverage in order to scale up its HIV testing and clinical management diagnostic services;
- To issue recommendations to improve access and quality of the laboratory systems for HIV diagnosis and HIV infection monitoring from the laboratory systems perspective in Liberia to the Ministry of Health ('MOH') of Liberia, the National Public Health Institute of Liberia, the donor community and to health service/ laboratory managers.

4. Methodology

The method followed will be literature research.

4.1 Search strategy

For all objectives, search engines used for and the inclusion criteria are detailed below:

Key Search terms	MESH: 'Laboratory', 'Policy', 'Laboratory personnel', 'Health workforce', 'HIV', 'Diagnosis', 'Diagnostic services', 'Diagnostic errors', 'Laboratory Proficiency Testing', 'Quality assurance Healthcare', 'Health services accessibility', 'Point of care testing', 'Viral Load', 'Sustained virologic response', 'Retention in care', 'Child', 'Vulnerable population', 'Interventions', 'Policy', 'Best practices', 'Eastern Africa', 'Southern Africa', 'Sierra Leone', 'Guinea'. Non-MESH: 'laboratory system', 'laboratory services', 'laboratory supply chain', 'laboratory workforce', 'laboratory financing', 'diagnostics quality assurance', 'governance', 'laboratory strategy', 'HIV program', 'HIV diagnostic', 'HIV testing', 'HIV self-testing', 'access to HIV testing', 'testing', 'access to HIV diagnostics', 'clinical management of HIV', 'CD4 monitoring', 'Viral Load monitoring', 'early infant diagnosis', 'PMTCT', 'ART retention', 'HIV drug resistance', 'Key-populations', 'Sex workers', 'MSM', 'children', 'HIV viral suppression', 'scale up, 'success', 'lessons learnt'. The key-words above will be searched for Liberia specifically and also independently.
Databases used for the Search	Pubmed, Google scholar, Microsoft Academic Search, Refseek
Inclusion criteria	Published in English, French or Spanish Published papers, snowballing article references Published since 2010

Grey literature from the MOH of Liberia, WHO, UNAIDS, GF and other national/international bodies of relevance will be searched and used. As this data is not validated, it is understood that bias may exist, however information available from these sources is interesting and sometimes the only source available. Snowballing was also done on references included in articles and documents. No record was kept of the exact numbers found.

4.2 Conceptual framework

After looking at different frameworks (WHO Building blocks, Lesveque model), I decided to use an adapted version of the Conceptual framework for testing process and associated errors in sample processing after Hickner and al and Carraro and Plebani, because it is based on the three phases of the Diagnostic-Therapeutic loop (Pre-analytical, Analytical and Post-Analytical) and addresses well the specifics of an individual test processing and factors associated with positive patient outcome following the performance of a test. (25)

However, that framework does not allow for the review of several aspects of the laboratory system itself which are important to analyse barriers to access and are well defined in the WHO Building Blocks framework.

I therefore adapted the framework to include aspects linked to governance, strategy and policy, and financing, in an additional phase, called the pre-pre-analytical phase, as shown below.

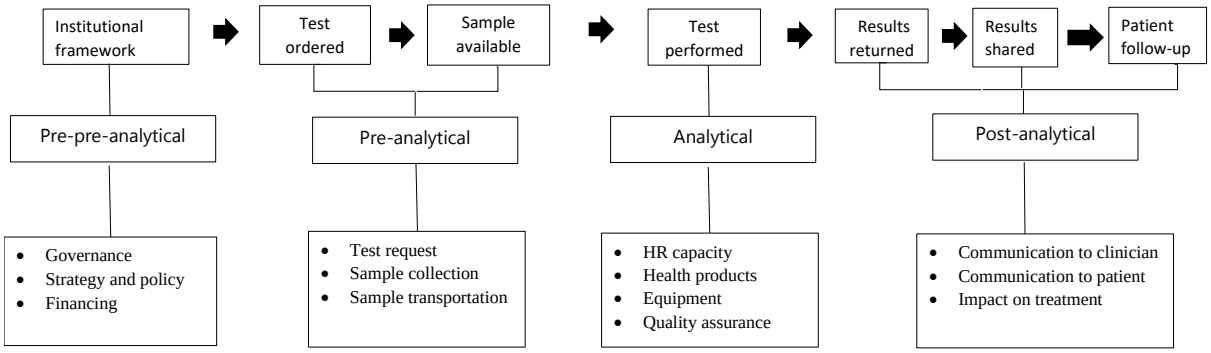


Figure 2 – Adjusted framework based on Conceptual framework for testing process and associated errors in sample processing after Hickner and al and Carraro and Plebani (25)

- Pre-pre analytical phase: governance, strategy, policy and financing, will be reviewed to understand their influence on access to HIV diagnostic services.
- Pre-analytical phase: we will review the test commissioning and sample collection and transportation.
- Analytical phase: we will review the actual test delivery, from the HR capacity, laboratory products, equipment availability and quality assurance perspectives.
- Post-analytical phase: we will review how test results are communicated and whether they lead to appropriate treatment decisions.

Phases are linked in a sequential way: the institutional framework (Pre-pre-analytical) will influence whether there are adequate means and knowledge for tests to be ordered and implemented (Pre-analytical/Analytical). The test can only be performed (Analytical phase) if a quality sample has reached the testing location and all inputs are available to produce reliable results, later communicated for decision-making (Post-Analytical). Phases are also closely linked among themselves as, for example, failure to perform the test due to lack of reagents or to return results to clinician may lower providers' future willingness to commission those tests.

In each of the phase, both HIV testing and clinical monitoring of HIV will be reviewed.

5. Results section

In the Results section, we will analyse, for each phase, how the laboratory system provides access to HIV diagnostic services in Liberia and relations between the different phases.

Developed by author

5.1 Pre-pre analytical phase – Institutional framework for HIV diagnostics

In this section, we will assess how governance, strategy, policy and financing for the laboratory system and the HIV program impact access to quality HIV diagnostic services.

5.1.1 Governance

Governance can be defined as the way organizations are structured and their relationships influence their ability to coordinate actions and share accountability for the results. (26)

Governance for the laboratory system

Before the Ebola epidemic, supervision of medical laboratory operations in Liberia were under the responsibility of the National Diagnostic Division ('NDD'), reporting to the Chief Medical Officer of the MOH. The National Reference Laboratory ('NRL'), created in 2010, was hierarchically located within the MOH, though we could not identify through our research to whom it was reporting exactly. (22)

End 2016, following the Ebola epidemic, the creation of the National Public Health Institute of Liberia ("NPHIL") was enacted. (13) In Liberia, the NPHIL is largely autonomous, with a reporting responsibility only towards the MOH, without however specifying to whom exactly. This autonomy can allow for independence in oversight of health operations through surveillance and in setting strategic goals and priorities for research. Nevertheless, it can also make the collaboration with the different MOH departments more difficult as information and samples related to outbreak alerts

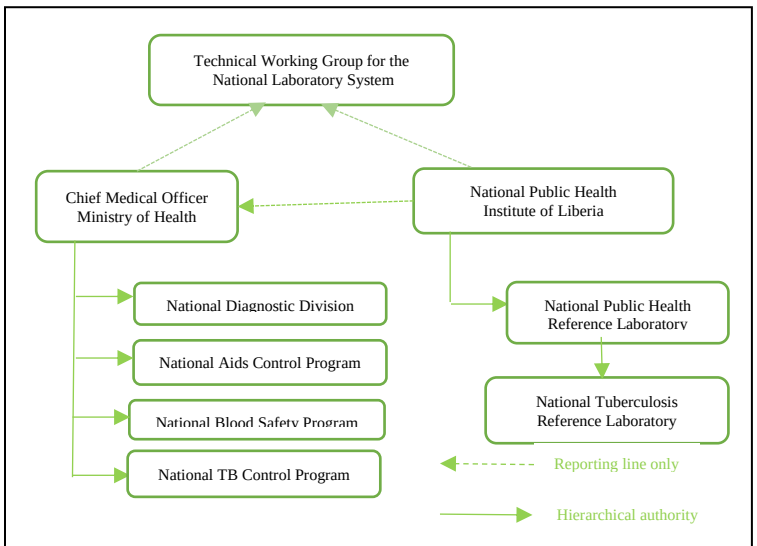


Figure 3 – Organogram of the National Laboratory System of Liberia - Ministry of Health of Liberia. Five-Year Strategic Plan for the National Health Laboratory System of Liberia 2019 - 2024. 2019; October (23)

come from clinical laboratories. Being outside of the MOH, budgetary allocation may also be more difficult to obtain. (27)

The National Public Health Reference Laboratory (“ NPHRL”) is now part of the NPHIL and has the responsibility to strengthen public health diagnostic capacity for diseases of public health concern, perform quality assurance and referral testing as well as training and supervision of public health regional laboratories and of integrated disease surveillance teams at county and district level. (22). (28)

A Technical Working Group for the National Laboratory System is planned in the new organogram to ensure alignment between all stakeholders and coordination between the NPHIL and the different departments within the MOH (including the NDD and the NACP). However, we could not find evidence confirming this Working Group is operational. (23)

In the Maputo declaration on laboratory systems strengthening, the importance of establishing a dedicated department of laboratory systems within the MOH was underlined. (29) A review of the type of laboratory governance adopted in 39 sub-Saharan African countries, from national strategy and policy documents issued until 2010, highlighted the variety of models followed, illustrated below:

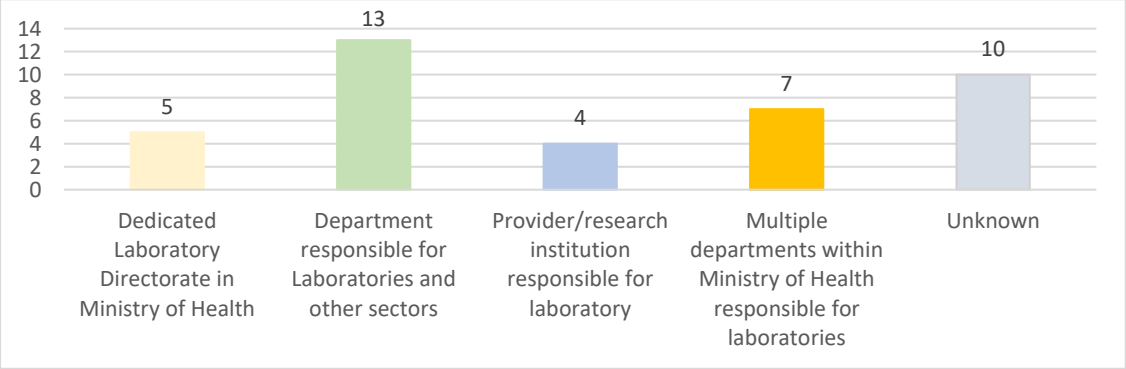


Figure 4 - Type of laboratory governance in 39 Sub-Saharan African countries (30)

The article strongly recommended to pursue efforts for the creation of a Directorate for Laboratory Services to ensure prioritization of the development of regulations, accreditation plans and definition of norms and standards. (30) In that review, Liberia was identified as having multiple departments dedicated to laboratory within the MOH, so was not complying with the recommendation of the Maputo declaration. The National Laboratory System Policy mentions that “some” laboratories fall directly under the responsibility of the NACP, but it was not possible to identify which ones and how the relationship between NACP and NDD is organized. (22)

A joint report of the African Society for Laboratory Medicine (‘ASLM’) and the Africa Centre for Disease Control and Prevention (‘Africa CDC’) of September 2020 identifies weak laboratory governance as a key root cause of dysfunction in laboratory networks and refers in particular to two issues: the inexistence of a directorate of laboratories and unclear definition of administrative versus technical tasks between directorates, national public health institutes and national reference laboratories. (31)

Governance for the HIV response

The National Aids commission ("NAC"), established in 2010, coordinates the decentralized and multi-sectoral HIV response and advocates for funding of the HIV response, while the Country Coordinating Mechanism ("CCM") mandate is to supervise implementation of GF grants and submit request for funding. All sectors/partners involved in the HIV response are represented in the NAC and CCM, with the NAC being also a CCM member. While the CCM mandate is more focused on GF grant processes, overlaps do exist between the bodies' mandates, in terms of coordination of and advocacy for the HIV response. (32)(33)

What is a Country Coordinating Mechanism ('CCM')? (33)

CCMs are mechanisms for public-private partnership in the coordination of national disease programs at country level. CCM members represent the interests of country-level stakeholders in the fight against HIV, TB, and malaria. As individuals, CCM members are accountable to the core constituency and, as a group, the CCM is accountable to the nation (through its identified reporting channels, including i.e., core legislative body).

The NACP oversees the clinical response, including coordinating access to diagnostic and care for targeted population. Non-Governmental Organizations manage HIV community-based prevention activities towards MSM and SW, including provision of HIV testing and counselling services ('HTC') and referral for care. (34)

A 2018 GF audit highlighted that CCMs reviewed were generally duplicating other health coordinating bodies in country or not coordinating enough with them, limiting the ability to address cross-cutting issues. (35) In Liberia, the Health Sector Coordinating Committee, chaired by the Minister of Health, is the Country Multi-stakeholder Platform. (36) A One Health platform was also set-up in 2017 to coordinate health security interventions. (36) (37) We could not find evidence of coordination between these different mechanisms.

5.1.2 Strategy and policy

Strategy and policy for the laboratory system

After a five-year gap following the first plan covering 2011-2015, the second Five Year Strategic Plan for the National Health Laboratory System of Liberia ('SPNHLSL') was finalized in October 2019 for the period 2019-2024. It underlines twelve strategic objectives, covering priority areas for the laboratory system, detailing for each one output and priority actions required, in line with the National Laboratory Policy issued in July 2019. (23)

Key-activities planned in the SPNHLSL, such as development of the organization structure of the National Laboratory System, compilation of an exhaustive listing of all laboratory facilities, definition of a testing menu, show that the development of a harmonized and structured laboratory system is still at a very early stage. In addition, the Strategic Plan does not include any element of cost nor any operational details and we could not locate any such document through our research. The Monitoring Framework defined is basic and only makes reference to high-level outcomes, with no clear accountability framework for targets set. (22)(23)

We compared the content of the SPNHLSL with those of Uganda and Sierra Leone (see table 2). All are low-income Sub-Saharan countries, with Sierra Leone being as Liberia a small West-African post-conflict state with low generalized epidemic, though HIV prevalence is higher in Uganda.

	Liberia	Sierra Leone	Uganda
Organization and management	X	X	X
Laboratory services	X	X	X
Infrastructure, biosafety and biosecurity	X	X	X
Equipment and supplies	X	X	X
Human Resources	X	X	X
Quality Management Systems	X	X	X
Health LIMS	X	X	X
Research and development	X	X	X
Point of Care testing services			X
Partnerships		X	X
Regulatory and Legal Framework	X		X
Monitoring and Evaluation			X
Financing and Accountability	X		X
Community			X

Table 2 – Analysis of areas covered by the Laboratory National Strategic Plans of Liberia, Sierra Leone and Uganda (24) (39) (40)

Strategic areas covered by the SPNHLSL could be found in the other NSP, though in more or less details depending on the country. However, the SPNHLSL did not include sections found in other NSPs related to Point of Care ('POC') testing, Community, Monitoring and Evaluation (Uganda), and Partnerships (Uganda, Sierra Leone), which may be due to Uganda being more advanced due its higher HIV prevalence. (23) (38) (39)

Strategy and policy for HIV response

In the National HIV strategic plan ('NHSP') covering the period 2015-2020, HTC services are to be provided through antenatal care clinics, family planning clinics, health facilities, TB clinics, and through programs managed by civil society organisations (for KP). Clinical care for PLHIV, including CD4 and VL, is managed in ART centres where HIV + patients are referred. Specific outreach activities are planned for KP. (40)

In the HNSP, little information is provided about laboratory-related challenges for the HIV response. The HNSP does not address laboratory-related challenges as a cross-cutting issue, as no laboratory-related issue is mentioned in the section detailing the 5 main Health System Strengthening challenges impacting the HIV program. Laboratory services only appear in the Procurement and Supply chain section, with mention of coordination required between pharmacists and county diagnostic officers and of the need to incorporate laboratory reagents and consumables in the Logistics and Health Management Information Systems. The HNSP does not mention the NDD nor the NPHRL, who were also not represented in the Prevention and Care working groups set up to elaborate the HNSP, questioning the links between them.(40)

5.1.3 Financing

Financing of the laboratory system

In a study performed of strategic documents of 39 sub-Saharan African countries for the period 2010-2012, limited information was available on budget needed and available for laboratory services. (30) This is the case in Liberia where no financial information is disclosed in the National Policy or the SPNHLSL. (22)(23)

In the same review, evidence of a budget line for the laboratory services was identified in 2 countries only. (30) No dedicated budget line for laboratory services exists in Liberia and it is unclear which systems and personnel will be used to conduct fiscal/budgetary planning and accounting for the laboratory system while this was identified as key-issues for other countries. (30)(38)

Financing of the HIV NSP

The HNSP, which serves as basis for donor funding requests, includes an estimated costing per intervention of US$ 189 million for the 2015-2020 period (details on activities' costing or assumptions followed are not available in the document). Based on reported commitments from government and donors in the HNSP, financial resources available were expected to represent US$ 118 million, i.e. 62% of total needs. (40). If realized, this funding would have represented an average of US$ 676 per prevalent case, which is close to the average of US$ 702 estimated to have been spent per prevalent case in Sub-Saharan African countries in 2017. (41) However, 2019 AIDS-related spending reported in the Global Aids monitoring report showed lower amounts, at respectively US$ 11 and 10 million for 2014 and 2015 (no amount was reported for subsequent years), showing a substantial funding gap. (40). This amount seems in line with the yearly funding allocation from GF, of US$ 30 million for HIV-TB for the period 2018-2020, though this amount appears inadequate to meet program needs. (34) (42)

From the Pre-pre Analytical Phase to the Pre-analytical Phase

From an institutional perspective, the laboratory system in Liberia is still in its early stage. As the system is not yet structured, with clear roles, coordination mechanism, and funding, those gaps will impact the quality delivery of HIV diagnostics for each Phase of the Diagnostic-Therapeutic loop .

5.2 Pre-analytical phase – Ordering the test and making the sample available for testing

In this section, we will focus on analysing the steps of the test ordering, sample collection and transportation to the laboratory.

5.2.1 Ordering the HIV diagnostic test

Developed by author

To order an HIV diagnostic test, the commissioner needs to have the knowledge, capacity and willingness to do so, and the tests need to be available from the system perspective.

5.2.1.a Ordering a test to diagnose HIV

In Liberia, the Opt-out Provider-initiated testing and counselling ('PITC') is the preferred strategy for HIV testing, to be implemented as standard of care in Antenatal care ('ANC'), TB and STI clinics, and in-patient wards. HIV RDTs are performed in the facility during the patient visit. (43)

In the Service Availability and Readiness Assessment performed ('SARA') performed in 2018, only 32% of the facilities offering HTC had at least one staff trained over the past two years, which points out to a limited knowledge of health care workers. (3)

Availability of the 5 tracer items tested for HTC in the SARA (Guidelines available, at least 1 staff trained, room with visual and auditory privacy, HIV diagnostic capacity, condoms) decreased even further to 20%, highlighting general lack of capacity to offer such services. (3)

We could not find data related to health care providers' willingness to offer HTC in Liberia. In the UNAIDS 2013 HIV Stigma Index report, 2,5% of PLHIV interviewed reported being denied access to health services due to their HIV status: while this percentage may seem small, it does not include persons which have experienced stigma when accessing health services. (44) UNAIDS 2019 report highlight that 55% of men and 48% of women surveyed in Liberia in 2018 answered No when asked if they would purchase produce from a vendor who was HIV positive, which testifies of a remaining high prevalence of stigma. (46) While this is not specific to the health worker population, such a high level of stigma is likely to translate into some form of discrimination at health facility level.

Health facility density varies from 1,3 per 10,000 inhabitants for the counties of Bong, Nimba and Grand Bassa to 3,6 for Sinoe, which raises concerns over equity of access to services of the Liberian population in 2018. (3) In rural counties, it is estimated 60% (1.2 million people) of the population lives more than 5 km from the nearest health facility. (45)

65% of the 765 health facilities offer HTC services, with lowest coverage found in Margibi and Montserrado counties with respectively 35% and 36% coverage. Only 56% of NGO facilities offered the service against 78% of public facilities offered, and services were more

likely to be available in rural areas than in urban ones, maybe linked to the lowest health facility density there (76% versus 41%). (3)

Though not meeting targets set, results reported for the PMTCT and TB programs in Liberia (in 2018, 74% of HIV+ women knew their HIV status; in 2016, 74% of TB patients had been tested for HIV) seem to indicate that opt-out PITC is implemented by health providers in ANC and TB clinics. (24) (46) For KP, HIV testing by peer counsellors started to be implemented in Liberia in 2016, with the establishment of Drop-In-Centres for referral for confirmatory testing and care and treatment. However the program has been experiencing challenges, with 59% of reactive cases not subject to confirmatory testing. (24)

In 2019, only 22% of infants born to women living with HIV received a virological test for HIV within two months of birth. (16)

In Ivory Coast, a cross-sectional survey implemented in 2018 highlighted a low rate of proposal of HIV testing by health care professionals. For nurses, lack of HIV training was seen as major contributor to the low testing proposition while presence of dedicated HIV testing staff positively influenced the willingness to propose a test. For physicians, lack of awareness and interest in HTC were identified. For all, the absence of an on-site ARV prescription service was considered an obstacle to offering HTC. (47) Ivory Coast is a lower-middle income francophone country and Liberia a low-income anglophone country, yet both are neighbouring West African countries, with HIV prevalence between 1 and 5%, so factors affecting the knowledge, capacity and willingness of health care providers to offer HTC in Ivory Coast may be experienced in Liberia. Additional barriers reported in two studies in Malawi and Tanzania included test kit shortages, inadequate physical space and high workload leading to performing risk assessment before initiating HTC. (48) (49)

Studies undertaken in Malawi and South Africa reported higher level of PITC for ANC and TB clinics, with perceived factors being clearer policy guidelines and providers feeling they have a reason to offer HTC due to the pregnancy and the risks linked to HIV/TB co-infection. (50) (51) While we have not found for Liberia data regarding overall percentage of patients being offered PITC to compare with, testing results reported for the ANC and TB clinics could point to a similar situation. (24) (46)

Regarding EID, studies undertaken in different contexts in Sub-Saharan Africa (Burkina Faso, Kenya and South Africa) have shown that understaffing, insufficient knowledge of HIV testing guidelines and laboratory sample collection techniques as well as poor communication between ANC, delivery and postnatal facilities were barriers to providers initiating EID. (50) (51) (18)

In light of the data available for other countries, it can be expected that the percentage of HIV tests commissioned by health providers be low due to staff shortages and heavy workload, low level of training and stigma associated with HIV.

5.2.1.b Ordering laboratory tests required for the care of a PLHIV

Liberia 2020 National Guidelines for HIV Care and Treatment plan that, once diagnosed, VL monitoring should be done every six months during the first year and then every year thereafter. (52)

In 2018, 32 hospitals (89%), 41 health centres (71%) and 188 health clinics (28%) were providing treatment follow-up services for persons on ART as per the SARA, meaning a need for referral to another facility for patients of 47% of health facilities offering HTC. (3)

While HIV treatment guidelines were available in 83% of facilities providing care to PLHIV, only 42% had one staff trained in ART prescription and management over the past two years, underlining a low level of knowledge. Mean diagnostic capacity of various tests essential in general service provision to clients was assessed at 39% overall. Only 4% of patients had a VL count reported in the record and 12% a CD4 count, highlighting a low implementation of routine HIV diagnostic testing for clinical management. (3) The interruption of availability of the molecular testing capacity during the Ebola outbreak, shortly after the start of its implementation in 2013, may have hampered initial efforts to promote the request for VL testing. (53)

We could not find any study in relation to health provider knowledge, capacity and willingness to provide HIV care in Liberia. In South Africa, a survey highlighted lack of knowledge of nurses and auxiliary staff regarding ART management and HIV complications. (54) The fact insufficient knowledge among nurses was observed in South Africa, despite its higher economic status and magnitude of HIV disease burden, indicates it may also prevail in Liberia. (3)

In a qualitative study done in Malawi regarding VL monitoring implementation, main barriers identified by providers were the workload generated and reporting requirements, while a strong facilitator was the satisfaction to use laboratory results to guide clinical management. (55) Though Malawi and Liberia are different in terms of HIV prevalence and program maturity, they are both low-income countries with shortage of health workers, therefore the negative impact generated by the workload and reporting needs, but also the motivation of improving the quality of patient care may also exist in Liberia.

5.2.2 Specimen collection and transportation

Developed by author

Once the test ordered, a sample needs to be timely collected and transported in the required conditions. (56)

5.2.2.a Specimen collection

To perform an HIV RDT, a sample of blood needs to be drawn from the patient, intravenously of via finger prick. (57) The Liberia 2020 National HIV Testing guidelines plan that, at health facility, health care providers will initiate and perform the testing and counselling, including collecting the sample, while lay providers may collect the sample when performing HTC as screening service in the community. (43) The HIV Treatment Guidelines 2020 detail different sample collection procedures: for CD4, whole blood in Ethylenediaminetetraacetic acid ('EDTA') tube needs to be drawn while, for VL and EID, Dried Blood Spots ('DBS') are being

used. (52) We could not find documented evidence confirming whether the plan laid out in the guidelines is adhered to.

The use of DBS for sample collection has been encouraged to increase access to HIV testing due to its less restrictive conservation requirements. Studies undertaken in South Africa and Malawi highlighted that, when duly trained, lay providers can collect samples with Dried Blood Spots from finger pricks, leading to results with similar accuracy. (58)

Once collected, samples need to be packed to be transported. A National Rapid assessment of the laboratory system in Sierra Leone reported that only 13% of the health facilities surveyed had the ability to pack the specimen as per the appropriate guidelines. (59) As Sierra Leone and Liberia are neighbouring countries, both post-conflict, low-income and English-speaking, with severe health system challenges, the existence of such difficulties in Sierra Leone could point out to similar challenges in Liberia.

5.2.2.b Specimen transportation

For VL and EID, DBS specimens can be transported and stored at 37 degrees in humid conditions for a period of 1 to 2 weeks before having to be used. (52) If well packed, DBS specimens can bear extreme temperatures, representing a significant advantage over other methods of specimen collection (whole blood/plasma) in contexts where transportation systems are weak and cold chain maintenance a challenge. Several surveys comparing VL test results using DBS and plasma have concluded on the strong correlation of ribonucleic acid levels using the two methods. (60) For CD4 testing, at 37 degrees, blood collected in an EDTA tube needs to be used within 6 hours of collection, which represents a significant challenge, particularly for remote health facilities. (61)

Temperature		37 degrees (humid conditions)	15-30 degrees (room temperature)	4 degrees	-20 degrees
Time	Whole Blood Venous EDTA	6 hours	6 hours	Non applicable	Non applicabl
	Plasma	24 hours	24 hours	5 days	1 year
	Dried Blood Spot	1-2 weeks	1-2 weeks	2-52 weeks	3-36 months

Table 3 - Summary of recommendations for time of transport and storage at various conditions for plasma, whole-blood and dried blood spot specimens for HIV viral load testing (62)

Transport conditions in Liberia are difficult, due to limited tarred roads (6%) and weather conditions (heat, humidity, rainy season leading to impracticable roads), making the transportation of Whole blood and Plasma specimens as per the requirements described in Table 3 above extremely challenging in general, particularly for samples collected at remote health facilities. (62)

The 2016 JEE gave however a score of 3 (out of 4) to the specimen referral and transport system, underlining a reasonable performance. This scoring reflected the existence of a partnership with the organization Riders-for-Health, which supports the transport of clinical and public health specimens from health care facilities to regionally or centrally based laboratories. (63)

Started out of the Ebola outbreak in March 2015, the Riders for Health program is based on a "Relay system" and "Hub and spoke" method and includes vehicle fleet management services and implementation of a national sample transport system using 60 couriers picking from 302 pick-up points, connecting health centres to the laboratories at the regional level. The NPHIL reports that, in the first and second half of 2017, laboratory results for public surveillance tests

were received respectively within 7 and 4 days of initial alert. (28) The Riders organization reports that an average of 78% of samples would now arrive at laboratories within 24 hours of collection, versus 25% before (exact period not mentioned), though no research is available to corroborate this. (64)

Entirely funded by USAID, the program sustainability could be challenged, should the financing stop. (64) We could not find documented evidence that the Riders for Health system was actually in use for HIV sample transportation in Liberia.

From the Pre-Analytical Phase to the Analytical Phase

Low level of training of staff, limited availability of tools and products, stigma prevalence, and limited coverage of HTC and ART services constitute barriers to commissioning of HIV diagnostic tests. For CD4, VL and EID tests, specimen collection technicity and transportation constitute challenges, which DBS kits use and implementation of the Riders for Health program for HIV diagnostic could help address. Once the sample has reached the laboratory, starts the actual performance of the test, discussed in the next section: Analytical Phase.

5.3 Analytical phase – Performing an HIV diagnostic test

In this section, we will analyse the availability and quality of the main contributors to the actual performance of the test: human resources, health products, equipment and quality assurance.

Developed by author

5.3.1 Human Resource capacity

The Health Workforce density per 10,000 population was assessed in the SARA as 10,7, i.e. less than 50% of the WHO recommendation of 23/10,000 population and showed significant disparities between counties with Montserrado and Bomi counties having the highest density (14/100,000) and rural counties (Rivercess, Grand Bassa) the smallest at around 7/10,000. Health workforce cadres considered in the assessment were Physicians/doctors, physicians assistants, nurses and midwifes, therefore there is no assessment of the laboratory staff availability. (3)

In its 2011-2021 National Health and Social Welfare Policy, the MOH projected needs for 2021, resulting in a total of 893 laboratory-related staff, e.g. 6% out of the expected total need (see Figure 5). (65)

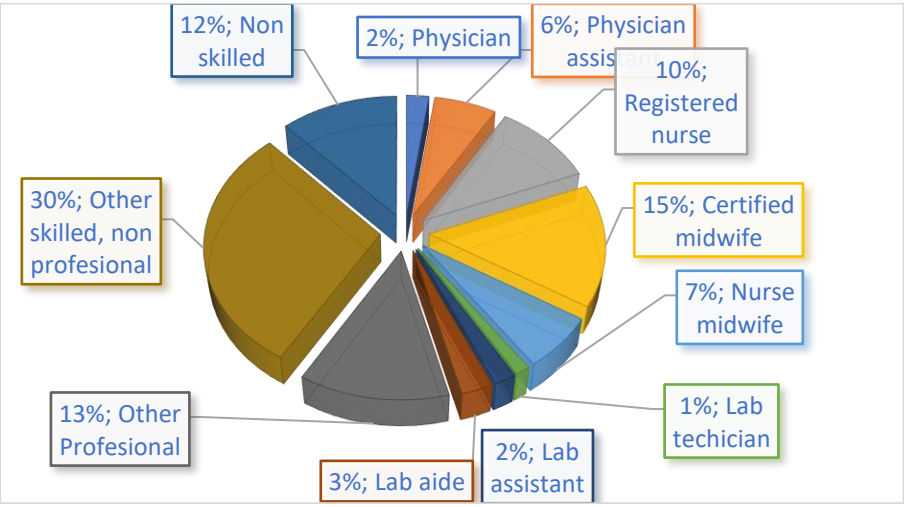


Figure 5 – Repartition of projected needs of health cadres in Liberia in 2021 (65)

The revised implementation plan of the Health Workforce Program issued after the Ebola outbreak for 2015-2021 focuses on five cadres of health professionals other than the laboratory staff and only makes reference once to a goal of expanding laboratory assistants, without giving any more detail. (66)

An analysis of Liberia, Guinea and Sierra Leone HR investment plans post-Ebola, underlines the budgetary challenges the plans' intended growth represent in contexts of limited fiscal space. It highlights areas to be further resolved for such investments to bring the expected outcome: uneven distribution of resources between rural and urban settings, ratios between

health cadres (doctors to nurses, etc) as well as pre-service training, in-service training and motivation. (67)

The only laboratory capacity assessment found for Liberia highlighted that 13% of the 107 TB laboratories enrolled in an onsite TB proficiency testing programme could not participate in the study due to lack of staff member able to perform the test while an additional 33% were relying on laboratory aides using job aides without a formal training. (68)

In Liberia, only two pre-service laboratory institutions offer laboratory training curriculum (two diplomas, one associate and one bachelor degree, number of yearly graduates not known). (23) Staff retention remains challenging, with government workers experiencing low wages, delays in salary payment and difficult conditions in hardship/rural areas, and will be researched further in a planned Health Worker Retention Study. (66)

5.3.2 Availability of test kits, laboratory products and reagents

The supply chain system is an ecosystem of organizations, technology and activities set up to ensure a product is made available at the place and time when it is needed as cost-efficiently as possible. (69)

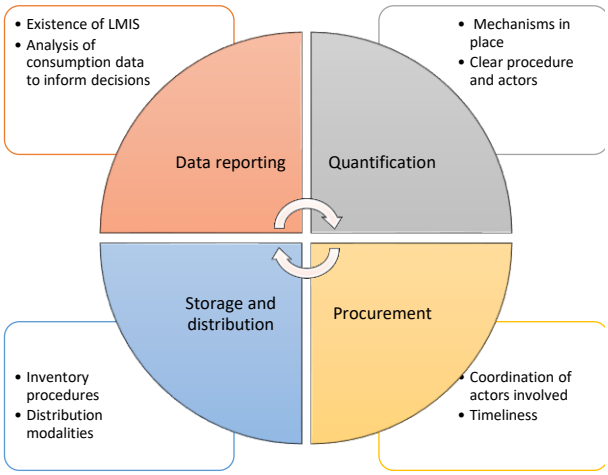


Figure 6 - Supply Chain system pillars (69)

In the strategic plans developed, supply chain weaknesses are referred to as main bottleneck to service delivery, due to frequent stock-out of drugs and health products. (14)(41) A GF audit performed in 2019 reported that 20 out of 25 facilities visited were experiencing stock-out of key-commodities for the three diseases (HIV, TB and Malaria) despite stocks being available at central level. HIV commodities stock-outs were reported in 48% of facilities visited, with an average stock-out period of 68 days while the low utilisation rate of GeneXpert machines (10%) was attributed to cartridges stock-outs at all facilities. (24) No information is provided on which HIV commodities are captured nor on the methodology followed to compute the stock-out, yet findings indicate constant heath products unavailability as a material issue.

Quantification and procurement

No national quantification process for laboratory products was identified in Liberia through our research while a national committee is in charge of quantification for HIV commodities. (25) Procurement of GF-funded HIV laboratory products is done through international procurement agents, with reagent procurement delays reported as main cause of testing unavailability. (35) (53)

Storage and distribution

The National Drug Service is in charge of storing and distributing medicines and health products. In 2019, no inventory procedures, tools or management system were in place during the GF audit at the new central warehouse, raising concerns over its ability to fulfil its function. A parallel supply chain management system, managed vertically by the HIV disease program, was identified for laboratory products. (24)

In 2018, only 62% of facilities had a reliable source of power and not all of them had basic equipment, meaning all health facilities performing HTC may not be able to store RDTs in a well-ventilated storage space, at maximum temperature of 25-30 degrees. (3) A study undertaken in Malawi concluded that excess temperature (37 degrees during 28 days) did not affect HIV RDTs' sensitivity and specificity, though it did not factor humidity factor nor a longer period than 28 days. (70) A systematic review by WHO of rates and causes of HIV misdiagnosis on all continents identified the use of inappropriate, damaged or expired test kits as one of the main contributing factors. (71)

Reagents for Cepheid VL&EID GeneXpert equipment should be stored between 2-28 degrees while reagents for the conventional platform in Monrovia need to be kept at –20 degrees with uninterrupted power. (61) In 2012, all hospitals reported generators as their primary source of power supply, which may ensure appropriate storage conditions provided maintenance and fuel can be constantly available. (72)

Management information system

In 2018, an electronic Logistic Management Information System ('eLMIS') was implemented in Liberia, with USAID support, to ensure availability of real-time information to support inventory management, procurement and distribution decisions. The system should be interoperable with the Health Information System for triangulation of data. (73) However we did not find evidence of results achieved nor of impact on health products availability.

5.3.3 Availability of functional equipment

The choice and placement of instruments required for HIV care need to be carefully thought through to ensure accessibility and cost-effectiveness. (74) Centralized and decentralized models present different advantages and disadvantages (see Table 4): higher throughputs and better control over quality are key-features of centralized models while timely access to diagnostic results is a key advantage of a decentralized system.

	Advantages	Disadvantages
Decentralized	• Patients' timely access to diagnostics and results • Current focus on decentralization • Does not limit growth	• Complexity of quality systems • Complexity of instrument service and support • Infrastructure challenges
Hybrid		
Centralized	• Quality is maintained through less complicated means • High throughput, low cost instrumentation is utilized	• Limits for growth • Specimen or patient transport • Complex information systems

Table 4 - Advantages/disadvantages of centralized and decentralized approaches to VL/EID (74)

For VL and EID, the first molecular testing capacity was established in Monrovia in 2013 with the installation of a Polymerase Chain Reaction ('PCR') machine. Due to the difficulties encountered to implement central testing, the use of the GeneXpert machines, installed at county level for TB and then EVD, was expanded to include VL and EID. (53)

The 2016 JEE concluded that the lack of available functional equipment in the laboratories was a significant challenge in Liberia, with no mechanism in place for maintenance and repair of the equipment. (63) To address that, the MOH created and deployed a new cadre of trained biomedical engineering technician ("BMET") within the county health teams, with responsibility for equipment functionality, though we have not been able to find documented evidence of their impact. (23) (75) For VL&EID equipment, the absence of an in-country authorized service provider able to perform regular calibration of the machines has been mentioned as a challenge to optimal machine utilization. (53)

A review of harmonization efforts of instruments in HIV laboratory systems undertaken by 8 African countries highlighted varying levels of successes and a common set of recurring challenges, with the greatest diversity of manufacturing brands found for chemistry and haematology, while equipment for CD4 and VL/EID appeared less diverse possibly due to WHO pre-qualification requirement imposed by international donors. (76) Instrument downtime due to lack of maintenance or servicing is also recognized as a challenge for VL scale-up in Sub-Saharan Africa, corroborating difficulties faced for the GeneXpert machines. (77)

5.3.4 Quality management system

The 2016 JEE gave Liberia the lowest mark of 1 to the laboratory quality system, with one priority recommendation being to actually develop a quality management system. (63) The NPHRL is responsible for the implementation of the quality assurance system, and for supervision and monitoring of the four regional public health laboratories and referral testing. (23) There is officially a supervision of clinical laboratories in place by County Diagnostic Officers but no information was found to confirm it is in place. (78)

Different factors affect HIV diagnosis accuracy with an HIV RDT: the quality of the HIV RDT, the test selection and algorithm used and the quality of the testing procedure itself. (79) In Liberia, until recently, the testing strategy recommended the result of a third assay to rule-in HIV infection as a tie-breaker test, which did not follow WHO recommendations and was identified as a source of misdiagnosis; this was revised in the June 2020 HTS Guidelines. (79) (43)

Those guidelines plan that internal quality assurance be performed and proficient testing implemented on a national scale for all HTC counsellors under supervision of qualified laboratory personnel. (43) No data was found to ascertain whether this is taking place for the HIV program, and, if so, with which results. For the TB program, used here as a proxy, only 25% of the 80 TB sputum microscopy laboratories participating in external proficiency testing had an acceptable result, with only two facilities scoring 100%. (68)

A systematic review of literature published between 1999 and 2014 to assess the causes and extent of HIV misdiagnosis identified rates of false HIV positive rates ranging from 2,6% to 10,3% in three studies and instance of false HIV negative cases (rate of 2% in South Africa, Zimbabwe, Tanzania) in three other studies, though underlining the limited number of studies available. Factors related to poor HIV testing quality were technical errors such as labelling and recordkeeping, user errors in performing or interpreting the HIV RDT, suboptimal testing strategy and poor management and supervision. (71)

For VL&EID, due to controls built-in and difficulties linked to retesting, external quality assurance is generally done through proficiency testing: data from an External Quality Assurance program for VL&EID by the US CDC highlighted a link between program participation and performance. (79) Nevertheless, we could not find evidence of Liberia participation.

Early 2017, the MOH started implementing the Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA) approach to strengthen its laboratory services. (80) Two cohorts of trainees attended the initial training, with subsequent audits taking place in eight county and two regional hospitals, highlighting major gaps and weaknesses at all level (scores not available). (15) (23) The German cooperation, which supports eight county hospitals in the South East region with mentoring and training, reported that 3 hospitals had reached in 2019 a one-star rating (out of 5), showing progress can be achieved but underlining external support may be needed. (75)

Figure What is the Stepwise Laboratory (Quality) Improvement Process Towards Accreditation (SLIPTA)? (80)

SLIPTA is a comprehensive approach to strengthen national health laboratory services in a stepwise manner by providing graduated levels of performance recognition towards long-term fulfilment of the ISO 15189 standard.

SLIPTA provides a pathway that recognizes conformity over time by breaking down the process into a series of specific implementation-friendly stages.

SLIPTA recognizes laboratories where they are in the process of quality improvement; supports them through audits and technical assistance from an independent evaluating group (IEG); and tracks and rewards progress towards obtaining these accreditation standards.

From Analytical Phase to the Post-Analytical Phase

Human resources gaps, supply chain challenges, absence of functional equipment and lack of systematic quality assurance program can lead to lack of or delays in testing, or to delivery of incorrect results. When available, results need to be communicated to impact patient care.

5.4 Post-analytical phase – How test results are used

In this section, we will review the communication of laboratory test results to clinicians and patients and how they are taken into account for patient care.

5.4.1 Communication of test results

In this section, we will review how HIV diagnostic results are communicated to clinicians and patients.

5.4.1.1 Communication of test results to clinicians

Developed by author

HIV RDT results are available onsite within a short period of time (about 15 minutes) to the person performing the test, hence turnaround time for results to clinicians is not expected to be problematic. (81)

Our research identified limited data related to VL test results communication to clinicians in Liberia. One retrospective study of GeneXpert testing data for HIV VL over the period December 2015 to March 2017 reported a short turnaround time of one day between the moment the sample arrived at the laboratory and the time test results were received by the requesting unit. However, the article does not specify whether samples tested were coming from the facility performing the test or had also been received from other facilities. (53) The absence of data on HIV patients with suppressed VL in Liberia 2019 UNAIDS Factsheet may imply that test results management is inadequate and potentially results not returned. (16)

Riders for Health reports that, in Liberia, test results are communicated by email or text message from the laboratory to the rural community health center. (64) The 2018 SARA highlighted that only 77% of the 36 hospitals, 31% of the 58 health centres and 7% of the 671 health clinics had a computer with internet while availability of communication equipment was higher (respectively 88%, 63% and 51%). (3) It is therefore unclear how rural community health centres receive such communication, though it could be that staff use their private mobile phones, raising potential privacy concerns.

No information was found for Liberia regarding EID turnaround times. Nevertheless, a systematic review of factors associated with accessibility of EID services in sub-Saharan Africa identified the long turnaround time for PCR test results as a barrier to implementation, with median time between sample collection and communication of results to the attending health worker ranging from 1,3 to 7,7 months in the studies performed. (18)

5.4.1.2 Communication of test results to patients

Developed by author

Results from the Demographic and Health Survey 2019-2020 in Liberia highlight that 4,3% of women and 1,7% of men surveyed had been tested for HIV but not received their results. While it means a high percentage of patients received their results, it is also a missed opportunity. (82)

Liberia HIV Treatment Guidelines require to actively communicate to a patient, by phone or through home visit, any detectable VL results as soon as the result is received on site. (52) We were not able to identify data related to communication of results to patients in Liberia: as a proxy, we will consider that patients enrolled in care and lost to follow-up will not be able to receive their VL test results, if they had been requested.

In 2019, an audit done in 25 health facilities reported that 49% of the patients initiated in care during or before 2018 were classified as Lost to Follow-up, which is due to many different factors including issues regarding laboratory results. (24) This seems consistent with 2016 estimates of retention at 12 months of 69,9 % among patients initiated on ART and 24,7% for patients not on ART, with these rates going down to 48.7% and 9,4% at 36 months. (83) Liberia performance is lower than the average 36-months retention rates after ART initiation estimated for the Africa, Asia and Latin America regions in a systematic review covering the period 2008-2013 (respectively 65%, 80% and 64%). (84)

5.4.2 Impact of test results on treatment

Developed by author

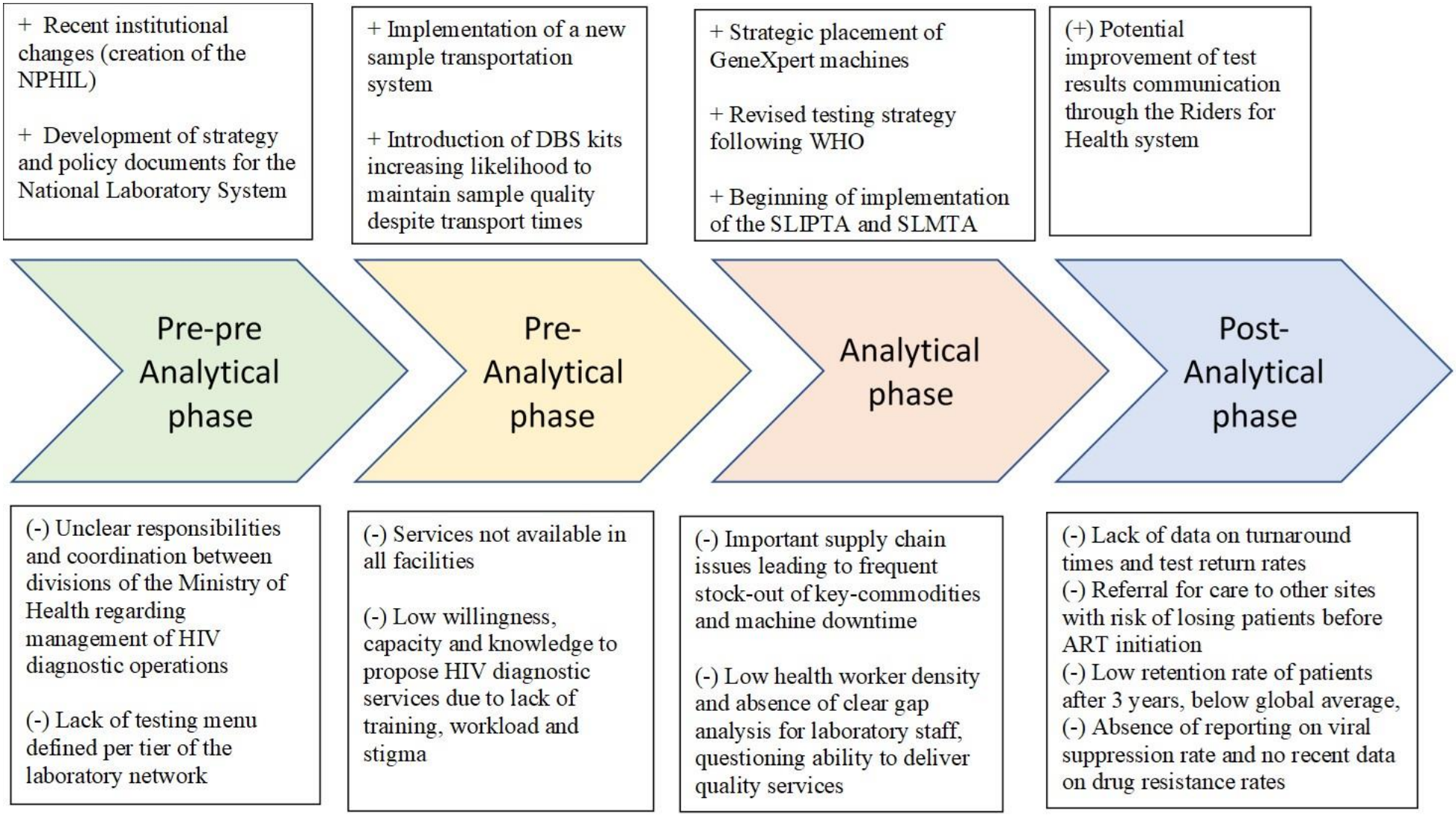
In 2018, patients of 51% of the 495 Liberian facilities offering HTC had to be referred for care to one of 245 ART services after a positive diagnosis. (3) In 2019, 56% of people knowing their HIV status were on ART, highlighting a gap which may be partly due to loss to follow-up during the referral process. (16) A GF audit also found that 41% of HIV-positive confirmed cases among KP were not initiated on ART, highlighting a gap in the treatment cascade. (24)

A study done in 2014 among 116 newly HIV-1-infected patients at one Monrovia hospital in Monrovia assessed the prevalence of Transmitted Drug Resistance in recently diagnosed and untreated patients at 5,9% in 2014 while in Sierra Leone, a study done on 215 patients in November 2017 in one hospital in Freetown reported even higher drug resistance rates of 22.4% for ART-naive patients and 56% for ART-experienced patients. (85)(86) (The differences between the drug resistance rates between the two countries may be due to the fact that the Liberia study was performed pre-Ebola and the Sierra Leone one post-Ebola, with disruption of treatment during the Ebola crisis a potential source of increased drug resistance.

A cross-sectional study performed in 2013 in two hospitals in Monrovia, on patients on ART for more than one year presenting clinical and/or immunological failure, highlighted high prevalence of resistance-associated mutations of 63% and 71% among the tested group. However, this study only included patients with signs of treatment failure and who attended two major hospitals, not representative of health facilities situation in Liberia. (87)

An exploratory study done in 4 health facilities in Tanzania highlighted limited collaboration and communication between clinician and laboratory professionals, with differences in education levels causing clinicians' mistrust in laboratory test results, though sample size was small and interviewees limited to the ones present onsite. (88) Given human resource constraints in Liberia, with limited skilled staff available, as in Tanzania, such collaboration issues may also be happening. In South Africa, a survey across primary health care physicians in 2015 reported difficulties in interpreting test results in 17% of diagnostic encounters and identified interpretive comments from the laboratory as contributing to increased use of the test results. (89)

Figure 7 - Summary of main Findings per Phase – *Developed by author*



6. Best practices

In this section, we will identify best practices related to each phase of the HIV Diagnostic-therapeutic loop.

6.1 Best practices - Pre-pre analytical phase

The ASLM and African CDC refer to Ethiopia and Uganda as having solid laboratory governance. In Ethiopia, oversight of the laboratory system is the responsibility of the Ethiopian Public Health Institute (EPHI), an autonomous institution, while in Uganda, it lies with the Department of National Health Laboratory and Diagnostic Services, part of the MOH, showing different governance choices can be implemented with good results, provided a **clear definition of responsibilities** ensures ownership and accountability for laboratory strengthening activities. Best practices shared by both countries include having updated national policies and strategic plans, dedicated budget lines for the laboratory and clear definition of laboratory clinical and public health functions from the reference level to the community level. While those attributes point to the direction of a clearer institutional framework, the article however does not substantiate it with outcomes (for example increase in budget dedicated to the laboratory system or increase in population coverage of services) nor highlights other contributing factors (leadership, partner support). (90)

In Ethiopia and Malawi, the **rationalization of the test menus** within the laboratory network was triggered by the planned implementation of an LMIS project, while in Zambia it derived from the creation of a Procurement Committee in the Laboratory Working Group. (91)While its need can be identified in different ways, agreeing on what can be expected at which tier of the laboratory system is necessary to define the needs in human resources, procurement and IT system capability, but also to discuss possible integration of services.

6.2 Best practices - Pre-analytical phase

High HIV prevalence countries have created/piloted new positions to address barriers to offering HIV diagnostic services identified by health workers (heavy workload, burden of reporting).

In Malawi, a study examining the implementation of the **new position of HIV Diagnostic Assistant** ("HDA") concluded on the positive impact on HIV testing volume (+35%) and on DNA-PCR at 2 months for EID (+ 75%). However only specific sites with expected high HTC unmet needs were selected, with no control group. The fact an average of 6,4 HDAs were recruited per site also questions the feasibility of this intervention in a lower HIV prevalence country. (92)

In South Africa, implementation of a **VL champion model** (generally a nurse trained in quality management, with 10 hours of weekly time freed) in three facilities (low, medium and high volume) led to an increase of the 12-month VL completion rate from respectively 68%, 54% and 64% pre-implementation to more than 90% post-implementation. However, no control group was defined, making it difficult to attribute results exclusively to the VL champion model, and implementation took place in pilot sites, with no decision yet to integrate that

intervention. Ability to free time of trained nurses may be a barrier for implementation in under-resourced environments. (93)

Studies in Eastern and Southern Africa have documented the feasibility and acceptability of **HIV Self-testing** ('HST') among different delivery models. While one study in DRC has highlighted high acceptability (95%) of HST among adolescent population using a door-to-door approach, only limited research was done in West and Central Africa. (94) In 2018, a program (ATLAS) started in Ivory Coast, Mali and Senegal to assess the feasibility and efficacy of HST interventions in the region, focusing on hard-to-reach population using different delivery channels, with no results for KP yet. (95)

Uganda has used **a hub-and-spoke model** to design its sample referral and result delivery system for VL and EID. The implementation of this system resulted in a decrease from 12 to 7 days of the sample delivery time but also from 12 to 5 days for the result transit time (post-analytical phase). (96) In Zimbabwe, a similar system implemented for CD4, TB and EID increased the number of samples tested by 70% and the ART initiation rate by 76%. (97)

6.3 Best practices - Analytical phase

To address the shortage of healthcare staff, particularly acute in low-resource settings such as Liberia, **task shifting to community health workers** or lay workers has been recommended by WHO. (98) (99) Studies have shown the effectiveness of HIV testing interventions implemented in the community by trained and supervised CHWs. (100) CHWs can also perform sample collection and simple point-of-care testing. (101) However, when defining their scope of responsibilities, challenges reported in studies done in Eastern and Southern Africa, such as inadequate training, poor remuneration, poor recognition, lack of involvement in decision-making process, and insufficient supervision, should be taken into account. (102)

A randomized control trial undertaken in South Africa assessed that **implementation of POC VL testing with task shifting** versus standard laboratory VL testing led to improve the outcome of viral suppression with retention in care from 76 to 90%. However, participants came from the same clinic, were enrolled at their 6-months visit (thereby excluding patient not returning to care after ART initiation) and task shifting was to an enrolled nurse trained for two years versus a registered nurse with a four-year training. South Africa being a high burden country, replicability to other settings with lower prevalence, smaller volumes and different cost implications, would have to be further studied. (103)

In Zimbabwe, a cross-sectional retrospective study on 46 sites on implementation of **POC for EID** reported similar results in terms of internal quality control failure rate and turnaround time between non-laboratory and specialized laboratory-trained operators, hence suggesting task-shifting to nurses can be implemented without compromising testing quality, though the accuracy of test results by both cadres has not been assessed in this study. (104) An observational study covering eight countries in Sub-Saharan Africa concluded on significant improvements of turnaround times with POC EID, with median time from sample collection to infant ART initiation reduced by half. (105) While the evidence of the gain in turnaround time implementation is strong, other factors including cost-effectiveness of the network, training and quality assurance requirements, should be considered when introducing this intervention.

To address commodity stock-outs, Kenya implemented a program called **SMS for Life.** Health workers were prompted to report every week the status of key-commodities by SMS, which was then interfaced with the web application at district level for prompt reaction, leading at the end of the implementation period to a reduction of stock-out of those key-commodities by 38%. (106)

In Zambia, a **Diagnostic Network Optimization** ('DNO') exercise focused on access to Viral Load testing led to a two-fold increase in number of tests performed, though other programmatic interventions may have contributed to the increase. (107) In Uganda, centralization of EID services following a similar exercise led to a decrease of the internal laboratory processing time from 25 to 2 days. (96)

Major global HIV funders (GF, Pepfar) have negotiated **all-inclusive pricing agreements** with global VL/EID manufacturers, which include service, maintenance, data solutions and vendor-managed inventory options. Benefit of these contracts lies in the shifting of responsibility for equipment functionality and product expiration management to manufacturer. (97) (108)

A review of the results of **HIV proficiency testing exercises** in Zambia over a two-year period and in Haiti over a 5-year period highlighted respectively a reduction of incorrect test results from 69 to 31 per 1000 tests and an increase in the number of laboratories reaching a score above 80% from 49 (out of 70 laboratories reporting results, 70%) in 2006 to 145 in 2011 (out of 159, 91%), though participating laboratories were not the same throughout the period in both cases. (109) (110)

A review of the implementation in 302 laboratories in 47 countries worldwide of the **Strengthening Laboratory Management Toward Accreditation (SLMTA) programme** showed an increase in checklist scores (from 39% at baseline to 64% at exit) during the programme time between 2010 and 2013. However data was not yet available for more than half of the 617 laboratories enrolled in the programme which had not yet finished it and sustainability of the progress beyond the program could not be assessed. (111)

6.4 Best practices - Post-analytical phase

Studies done in 8 sub-Saharan countries highlighted that using **short message service (SMS) and general packet radio service (GPRS) printer system** for communication of EID results to health facility led to an average reduction of 2,5 weeks (-25%) compared to routine paper-based courier. (112) While the device is easy to use, it requires electricity and a functional telecommunication network, whose availability may be limited in remote parts of Liberia. (113) **Data connectivity options** offered by most VL/EID equipment, through which data is sent centrally for reporting and management and to health centres (by sms for example) can also lower communication time, with however the same network constraints. (97)

Co-locating HTS and ART services may facilitate linkage to care by minimizing patient movement within the health facility. A systematic review examining association of service co-location with HIV care outcome identified positive association for linkage to care and ART uptake for co-location models associating HIV care and non-HIV specific primary care, though noting the relative weakness of studies design (very few RCTs). (114)

7. Discussion

We will discuss below positive aspects and barriers identified affecting the delivery of HIV diagnostic services for each phase in Liberia from a laboratory system perspective, as well as the applicability of lessons from other countries.

Objective 1: analyse the governance, strategy, policy and financing aspects, with regards to the laboratory system and the HIV program in Liberia

As for objective 1, the pre-pre-analytical phase, positive steps have been noted recently with the creation of the NPHIL end 2016 and the development in 2019 of the National Laboratory Policy and the Five Year Strategic Plan for the National Health Laboratory System. However, while a NSP is available, the **absence of a costed action plan** reduces the chances of a coordinated and prioritized implementation, and makes more difficult request for funding. (23)

Liberia seems also to be experiencing the two main weaknesses highlighted by the joint African CDC – ASLM report, which are the **inexistence of a directorate of laboratories and unclear definition of administrative versus technical tasks** between directorates, national public health institutes and national reference laboratories. The NDD in Liberia could be considered to be a Directorate of Laboratories if it were to have full responsibility for all clinical laboratories in the country, without certain laboratories reporting to other entities within the MoH such as NACP. Additionally, while the NSP for the Laboratory system gives the responsibility of public health laboratories to the NPHIL and the responsibility of clinical laboratories to the NDD, it is unclear how these responsibilities are articulated in practice, in particular regarding training, supervision and quality assurance activities. (23,31) Clear definition of roles and responsibilities seems all the more important as the NPHIL is not located within the MoH, which may represent an obstacle to ensure alignment and prevent duplication.

The **lack of definition of the testing menu at each tier of the laboratory system,** based on needs and on the mapping of existing capacity, does not set a clear framework within which to strengthen HIV diagnostic operations. (23)

Objective 2 - To analyse how the current laboratory system set-up influences access to quality HIV diagnostic services, both HIV testing services and clinical monitoring diagnostic tests;

The different phases are closely interlinked. Nevertheless, given their scale, we consider weaknesses in the analytical phase to be the most critical: without the ability to perform a test, any effort to strengthen the pre-analytical and post-analytical phases would be counter-productive.

In the analytical phase, main issues identified are supply chain issues, shortages of qualified staff and lack of quality assurance. Without health products and functional equipment, staff, whether trained or not, cannot perform the test, nor would there be any quality to check. We identify the **supply chain issues** to be of major importance for implementation of quality HIV diagnostics in Liberia. If stock-out of health products and equipment downtime are frequent, opportunities for testing are missed and health workers' willingness to offer these services is negatively impacted. Satisfaction of the staff performing the tests is also reduced as the quality of samples and therefore of results may be impacted by delays. (19) As the number of laboratories performing VL&EID is lower than the number of health facilities, issues of

reagents stock-outs and equipment downtime may be easier to try and address in the short-term, despite the reagents low shelf-life. Addressing these supply chain systemic issues will require extensive assessment, planning, funding, coordination with health actors, and determined leadership, which the laboratory sector has not had to date. Therefore, while this is a critical issue to tackle, addressing it on a systemic level will take time.

Current location of VL/EID equipment may not be maximizing coverage of services and enabling short turnaround times. As we do not know if the Riders for Health program implemented for public health surveillance is in use for HIV diagnostics, the performance of the current HIV sample transportation system remains to assessed, as it directly impacts all other phases when badly performing (long waiting times before pick-up creating frustration and demotivation at health facility (pre-analytical), risk of sample becoming unusable or of lower quality (analytical), risk of wrong results leading to inappropriate treatment decisions (post-analytical). (53, 63, 64)

Shortage of qualified staff, illustrated by a health workforce density of less than half of the WHO recommendation, affects all phases: it impacts the ability to offer HTC services (pre-analytical phase), the quality of services delivered (analytical phase) and the ability to take appropriate medical decisions (post-analytical). The implementation of task-shifting of HTC to nurses, while allowing expansion of services, has most likely contributed to an increase of their workload, reported as one of the major bottlenecks to HTC offering in Malawi and Tanzania. (3,48,49) In the analytical phase, the absence of consideration of laboratory staff in the 2015-2021 Health Workforce program and lack of assessment of both HR needs and gaps in the laboratory system, testify of the low attention given to date to this health cadre. (66) Building a cadre of health workers requires investment in training and certification institutions, allocation of additional national budgets as well as efforts to make sure trained staff is retained.

Challenges mentioned above highlight **risks related to suboptimal quality of testing performed**. In addition to the harm caused to the patient, a misdiagnosis negatively impacts the relationship between the laboratory and clinical staff using the results (post-analytical). In that context, the lack of evidence of implementation of an EQA program for HIV diagnostics is of concern, though the beginning of implementation of the SLIPTA program in regional and county hospital laboratories is a promising development. (76, 80)

Limited data could be found regarding actual test result return rates and turnaround times in the post-analytical phase. However, the fact only 56% of HIV positive patients are on ART, the low retention rate of patients on ART and the identified transmission of drug resistance in ART-naïve patients, together with the lack of data on viral suppression of people on ART, point out to a system unable to provide adequate, continued and documented care after an HIV positive diagnosis. (24,85,87)

Objective 3 – To identify what Liberia can learn from neighbouring countries and countries in Eastern and Southern Africa having achieved high level and quality of HIV testing, Early Infant Diagnosis and Viral Load diagnostic coverage in order to scale up its HIV testing, and clinical management diagnostic services;

In Uganda and Ethiopia, the leadership required to structure and strengthen the laboratory system derived from the **definition of a clear organizational structure and ownership for the laboratory system**. (90) If Liberia wants to move forward with the structuring of its own laboratory system, this is a critical initial step to ensure accountability for the next steps of implementation of the NSP. The definition of the test menu across the tiered network, which informs other requirements such as definition of HR needs, supply chain requirements and

capabilities of the network, was the starting point of different laboratory strengthening processes in Ethiopia, Malawi and Zambia. (91)

Strengthening the supply chain system will require continued investment, training and supervision efforts to ensure that inventory management is correctly done at all levels (starting from the central level), storage conditions progressively improved and distribution done to health facilities timely to meet their needs. The recent implementation of the eLMIS should enable higher visibility on stock levels, provided quality of data can be ensured. While these strengthening efforts are taking place, Liberia could implement a weekly control/alert system, similar to the SMS for Life, to prevent stock-outs and allow for redistribution between sites when possible. (106)

Implementing in Liberia a **diagnostic network optimization exercise** ('DNO') as was done successfully in Zambia and Uganda for HIV VL, would allow maximizing the coverage of VL&EID and enable designing a sample transportation system aligned with the equipment location and able to deliver turnaround times compatible with sample stability requirements. (96,97) Given the structural issues affecting the supply chain, and need to implement strong quality assurance activities, caution should be exercised during the DNO when considering expansion of sites where VL&EID testing is performed. In particular, the decision to introduce **POC equipment for VL&EID** at decentralized level with task-shifting to nurses in Liberia, as in South Africa and Zimbabwe, would have to take into account needs for training, supervision and quality assurance. (103,104,105) For that reason, we would not anticipate a significant roll-out of POC equipment for VL&EID but rather a targeted use for specific population difficult to reach and retain in care (KP, hard to reach areas).

To prevent downtime of VL&EID equipment and improve stock management, Liberia could benefit from **all-inclusive agreements with VL&EID manufacturers** negotiated by the main global HIV funders. (97,108) Leveraging them would allow Liberia overcome its relatively weak position towards them given its low volume of testing compared to high HIV prevalence countries.

To address the workload issue and allow for HTC uptake in the general population, implementation of **task-shifting for HIV testing to lay workers and community health workers** such as done in Malawi could be explored. (98,99,100) While considering this intervention, attention should be given to ensuring CHWs are adequately trained, supervised and part of a sustainable plan (work cadres, remuneration). (102) Implementation may have to be targeted, for example for those living far from a health center (> 5 kms) or where health staff retention issues are most acute. For KP, a main target group due to their high HIV prevalence, **HIV Self-testing**, assessed as feasible and acceptable in the Eastern and Southern African regions, could be considered, once results of the pilot program currently led in 3 West African countries are known. (94,95)

Creating an **HIV diagnostic-specific position,** such as the Malawi HDA or the South Africa VL Champion, could allow overcoming workload challenges and ensure prioritization of HIV diagnostic across the different phases. As Liberia has a lower HIV prevalence and national budget per capita than Malawi and South Africa, and given existing issues related to staff payment and retention, a new cadre of health worker or carving out time for existing staff on a national scale may not be relevant. Nevertheless, such a position could be envisioned in a limited number of health centers with expected highest unmet HIV diagnostic testing needs,

provided cost-effectiveness is assessed as reasonable and supportive of resource allocation. (92,93)

To embed improvements in its quality assurance program, Liberia could also consider implementing the **SLMTA program** which has been shown to contribute to significant increases in SLIPTA scores. (111)

Limitations

An important limitation of this study is the lack of publicly available data and research done in Liberia, which led me to use proxies and research from other countries from Sub-Saharan Africa. The lack of opportunity to receive information from and validate results with key-informants in country has also been an additional limitation in that context.

The conceptual framework was useful in identifying and analysing determinants for each phase of the diagnostic-therapeutic loop but its use led sometimes to confusion due to the overlaps between the different phases and strong interlinkages which made the analysis at times repetitive. A health systems framework may have been better suited to analyse the cross-cutting areas, particularly for the human resources aspect, yet it may not have addressed the specifics of the laboratory operation.

8. Conclusion

We analysed the factors affecting the delivery of quality HIV diagnostic services in Liberia from a laboratory system perspective using the four different phases of the diagnostic-therapeutic loop.

Main issues can be found in the analytical phase: stock-outs of health products and equipment failure, shortages of staff and lack of evidence of a functional quality assurance program impact the ability of the system to perform quality testing operations and deliver results to inform patient treatment. In the pre-pre-analytical phase, unclear definition of roles and responsibilities, absence of a costed action plan to implement the NSP and absence of definition of the menu of tests across the tiered network are hampering the institutional capacity to respond to systemic issues identified in the analytical phase. Challenges noted in the analytical phase also negatively impact the willingness of the health workers to commission tests (pre-analytical phase), already affected by lack of knowledge and heavy workload. Coverage of services remains unclear as the capacity of the current sample transportation system to meet the needs of the network and minimize turnaround times is not demonstrated. Lack of data regarding the post-analytical phase makes it difficult to conclude on main issues affecting that phase, though low enrolment into ART of HIV positive patients, lack of national data on viral suppression and suspected high level of drug resistance point out to challenges in the communication and use of test results. Scarcity of available literature for Liberia was identified during the review, in particular regarding implementation of PITC, laboratory procedures at facility level (test ordering, documentation, follow-up systems), turnaround times and use of test results by clinicians.

Addressing the cross-cutting issues related to shortages of qualified human resources and weak supply chain system will require long-term plans, which should be supported by strong leadership for the sector, to build and retain cadres of health workers, and strengthen storage, distribution and inventory practices and procedures at all levels. Yet experience from other countries can help find solutions to improve access to quality HIV diagnostic services in the short-term. Implementation of task-shifting to lay workers and CHWs can help increasing offering of HTC while alleviating the burden on health workers, though need for training and supervision have to be addressed. HIV diagnostic-specific positions, introduced in some high-HIV prevalence countries and potentially adaptable to Liberia in different scale and form, led to improve test offering and follow-up throughout the different phases. As task-shifting to non-specialized staff increases, implementation of proficiency testing exercises and practical improvement programs such as SLMTA, addresses concerns over misdiagnosis. For VL and EID, improved service coverages and reduced turnaround times can be achieved through a diagnostic optimization exercise, which allows to define jointly equipment network and the sample transportation system.

9. Recommendations

Policy

- Roles and responsibilities of the NDD, NACP and NPHIL should be clarified in order to ensure ownership and accountability for laboratory strengthening activities;
- A costed and prioritized action plan to operationalize the National Laboratory Strategic Plan should be elaborated, with responsibilities and timelines assigned; definition of the testing menu at each tier of the laboratory system should be prioritized;
- Long-term plans for increasing the availability of qualified laboratory staff should be defined, in coordination with the Ministry of Finance, to ensure training, recruitment and retention are addressed.

Intervention

- A Diagnostic Network Optimization exercise should be undertaken to define the type and location of diagnostic equipment to maximize services coverage (including reviewing the opportunity to implement POC for VL&EID in selected facilities) and adopt a cost-effective sample transportation system, aligned with the equipment network;
- Define and implement an action plan to strengthen storage practices, inventory controls and ensure eLMIS data quality for decision-making; consider a weekly alert system to prevent stock-outs;
- Task-shifting to community health workers for HTC in the general population and self-testing for Key-Population should be considered to increase the offering of HTC;
- Proficiency testing for the HIV programme should be implemented at health facility level and results documented to ascertain rates and sources of errors;
- Negotiations on all-inclusive agreements should be initiated with diagnostic manufacturers to include equipment maintenance, support for stock management and data connectivity;
- The opportunity to pilot the appointment of an HIV diagnostic-focal point position in selected high-volume health facilities should be investigated.

Research

- An Operational Research agenda should be developed and include in order of priority the following issues to be studied: barriers to PITC implementation, laboratory procedures at facility level (test ordering, documentation, result reporting), turnaround times for VL&EID test and use of test results by clinicians.

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