

# THE LAB

# DIGEST



THE REPUBLIC OF UGANDA

NEWSLETTER

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MINISTRY OF HEALTH

ISSUE 2

## REGIONAL LABORATORY SYSTEMS STRENGTHENING MEETING CONVENED TO SCALE UP VIRAL LOAD AND EARLY INFANT DIAGNOSIS SERVICES



**1<sup>st</sup> Deputy Katikkiro of Buganda, Owek. Hajji Dr. Twaha Kigongo Kaawaase hands over Sickle Cell kits procured with proceeds from the Kabaka Birthday Run, 2019**



**UGANDA HOLDS THE FIRST AFRICAN HEPATITIS SUMMIT.**

**EVOLUTION OF LAB SERVICES IN UGANDA**



# Editor's Note

Esteemed reader,

The second issue of the Lab Digest is here!

This issue takes you through the evolution of the Central Public Health Laboratory from a one room provisional space to the magnificent home in Butabika. Did you know that this great institution/ department started off with one specialist? Catch this and more in our one on one with the Commissioner, National Health Laboratories and Diagnostic Services, Dr. Susan Nabadda.

In here you'll find a mixture of news, features and insights on a wide range of lab-related topics. We take you to the different regions where construction of state of the art laboratories is ongoing, community outreaches to enhance access to quality lab services, and lots more.

We also cast a light on the lab accreditation process, who is eligible and the vital role it plays in enhancing access to quality laboratory services.

I can't emphasize more the very critical role played by the Health Service providers, specifically laboratory specialists who without a doubt form the very backbone of our existence. Your selfless services are greatly appreciated.

Allow me thank the committed team that have worked tirelessly to make this issue a success.

And to you our esteemed readers, I hope you enjoy this issue and please do let us know if there are any topics you'd like to see covered in the future.

With warmest thanks,

**Vivian Nakaliika Serwanjja**

Public Relations Officer/Comms Specialist  
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# National Health Laboratory and Diagnostics Services (NHLDS)

Commonly known as Central Public Health Laboratories, NHLDS is a department in the Ministry of Health mandated to provide stewardship and management of laboratory services in Uganda and provide laboratory support for disease surveillance through investigation and confirmation of disease outbreaks and feeding into the HMIS database at the Ministry of Health resource centre.

## NHLDS LEADERSHIP

# NHLDS

### Our Vision

Quality health laboratory services available to all people in Uganda.

### Our Mission

Provide quality, cost effective and sustainable health laboratory services to support the delivery of the Uganda National Minimum Health Care Package at all levels.



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# EVOLUTION OF LAB SERVICES IN UGANDA

quick and accurate  
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## ONE ON ONE WITH COMMISSIONER NHLDS,



**Dr. Susan Nabadda**  
*Commissioner NHLDS*

### Give us a brief history of Laboratory and diagnostic services in Uganda.

In 1970, the Government of Uganda, after experiencing an outbreak of Cholera and Meningitis, decided to set up a lab called Central Public Health Laboratories (CPHL) to be able to curb that particular outbreak.

But as time went on, in 1980, the political instability in the country led to an upsurge in communicable diseases. A lab was set up to help in diagnosis of the different diseases that affected the population. The World Health Organization and UNICEF came in shortly thereafter and supported the full establishment of the Central Public Health Lab in one room at the present day school of public health, between 1983 and 2005, limping on with the few available resources, then.

It started with one senior technologist, Mr. Guma, the former head of this institution, but by 2005, there were around 4 technical persons.

The main turning point for CPHL was in 2006, when, because of the HIV scourge, CDC and PEPFAR came out to support the establishment of a complete, proper lab, to be able to diagnose the different conditions, especially HIV.

They supported relocation of this lab from the one room at the school of public health to a four-storied space along Buganda road, with additional support in human resource, equipment, and other infrastructure.

Through this, we were able to do beyond what the initial lab was able to do between 2006 and 2016.

In 2016, CPHL relocated from Buganda road to our magnificent home in Butabika, constructed with funding support from PEPFAR, CDC and the Government of Uganda, through Ministry of Health. All this was happening as CPHL was a unit under the department of National Disease Control at the Ministry of Health.

Laboratory services are a vital part of public health. It is important for detection of disease in individuals and populations. Effective use of basic laboratory tests at primary health care level significantly improves diagnosis and treatment outcomes.

In this issue of the Lab Digest, the Commissioner National Health Laboratory and Diagnostic Services Department of the Ministry of Health walks us through the journey of the establishment and growth of this great service in Uganda's healthcare system.

In 2018, we were officially elevated to department level, and our department is called the National Health Laboratory and Diagnostic Services Department, mandated to coordinate laboratory services across the network but at the same time also do specialized reference testing.

## What is the current standing of lab services in Uganda?

Currently we have what we call a laboratory network, for all the labs at the different service levels. Laboratories begin from Health Centre III, Health Centre IV, district (general) hospitals, Regional Referral Hospitals to National Referrals and to the reference labs.

We have around 1280 Health Centre IIIs, and 86% of these have labs.

We have about 197 Health Centre IVs, at the constituency level, and all these have laboratories.

We have 144 general hospitals, 14 regional referral hospitals, and the 4 national referral hospitals all have laboratories.

Outside the network in the public sector, are national reference laboratories that offer specialized services. These include ourselves, CPHL, the National TB reference Lab/Supranational lab, UVRI, we also work with reference labs in academic and research institutions like Makerere, JCRC; so we are in a network of labs at different levels.

We also have the mandate to monitor public not-for-profit labs.

## How many LABS are housed at the CPHL? (And their respective lines of diagnosis)

CPHL has two mandates; Coordination and Reference testing.

Under reference testing, we have labs that operate at a specialized level;

**a) EID Lab:** mainly looks at testing for children who have been exposed to HIV by their mothers, to see if they actually have the virus.

**b) HIV Viral Lab:** tests for HIV Viral Load for patients who test positive to HIV.

**c) The Hepatitis B Viral Lab;** specifically testing for Hepatitis B viral load for patients who have tested positive for Hepatitis B.

**d) The Sickle Cell Testing Laboratory;** this is usually used to screen newborn babies for sickle cell. We have a program for newborn screening, so this lab supports that program. However, ever since we started receiving test kits particularly from Buganda

kingdom, we screen out and confirm from this lab, all samples that are positive from the field. This is also a reference lab for cases that may not have where exactly to have their testing done but we try to decentralize this testing to different hospitals.

**e) National Microbiology Reference lab;** mainly responsible for disease outbreaks and surveillance as well as routine microbiology testing as a programmatic approach for hospitals that may not be able to do the normal routine microbiology. It also handles reference microbiology testing that cannot be done at the lower levels.

**f) We also house the national TB reference Lab/Supranational reference lab:** This is responsible for testing samples that are suspected to be Multi – Drug Resistant (MDR) or those that are supposed to have sensitivity for different drugs, but also offering an oversight role for all TB testing sites across the network. The Supranational reference TB lab receives samples from over 22 countries across Africa, so it is a regional centre of excellence, receiving samples for reference testing, also offering capacity building to the others.

**g) We also have the Malaria reference lab** that is tentatively doing testing for immunological studies, and tests for drug resistance. It is not yet fully developed but we have started. To beef it up we have established a medical entomology insectic to help it build up the national malaria reference lab. They work hand in hand, one supports the other.

**h) We recently established the National Haematopathology Lab** that is responsible for testing mainly blood cancers – Leukemias and Lymphomas -for patients that have blood cancers, to specifically tell them what type of blood cancer they have so that they are able to receive the right treatment. So we receive samples from across the network and we do these tests.

**i) The other that we take as an independent lab** is the calibration centre that receives different equipment for calibration from across the network.

**j) The last one we have is the bio- repository** where we store remnant samples for future research. We store samples from all the different labs, as mentioned above.

## Which one is the busiest? And why?

All our labs are busy, depending on the disease prevalence. Some diseases have a very high burden while others have a low burden. But if you go by the current statistics, on average, we receive around 110 samples at the HIV viral load laboratory per month, the EID lab receives about 3000 samples per month. For the Hepatitis B lab, we receive about 4000 samples per month, so that will make it very busy, but when you look at microbiology, the numbers may not be as high but they are also very busy. If it is an outbreak season the numbers will go up, and when its normal, the numbers will be low. For example, for microbiology, the normal routine samples are around 215 per month, for outbreak samples they are around 31, so it depends on what is on ground at that particular time. For the bacteriology eg Cholera, Ebola, for example in June this year we received around 178, then for NTRL, those that are referred here are around 654 for confirmation of MDR.

## Why would one choose CPHL?

One cannot directly choose CPHL as we stand today. We are a referral lab and when you look at the different labs that I have mentioned, tests are just referred, we do not receive patients at CPHL. We set up reference labs, many of which are accredited with very good quality equipment, capacity in terms of human resource and through different programs because of cost effectiveness, MOH saw it right that these should be done here. So through the system, samples are referred. So one cannot walk in here to for example have an HIV viral load test even if we have a viral load laboratory. You have to go through your clinician, who knows that it is your time to have a viral load and through the system, a sample is taken off and is transported here.

## Can one just walk into the CPHL and have the required tests done? What's the procedure?

CPHL only has reference testing labs and reference means that your sample must be referred for a reason. So most of our samples come through the system, depending on the program. For example, for Hep B viral load, you must have had a positive Hepatitis B test by your clinician or lab that sees it right for you to have a Hep





B viral load done.

There is a procedure that we follow; a form is filed in by your clinician or your facility and then a sample is transported through our robust national transport system to our centre.

So, UNHLS does not have walk in patients to have their tests done. It is a reference testing service.

**Since its establishment the CPHL has achieved immense success, take us through some of the major milestones registered.**

The major milestone has been to officially get recognition as a department under the Ministry of Health, in 2018, with a mandate to coordinate lab services in the country. Previously we were a unit under National Disease Control, with no mandate, much as we were doing the work. Today, lab services are being recognized as an entity so it gives us the mileage to be able to control the services, look for resources, take charge of our human resource.

Accrediting public laboratories; which means that we are assured that the tests that come out of these labs are at the same international level as tests done outside Uganda. This had never been dreamt of.

Accreditation was far from our lab services but currently we have 9 public hospitals that are accredited, both at regional, national and some district hospitals. Another 3 have been recommended for accreditation, while about 11 others are soon applying for accreditation. So we are proud that the lab services we are offering now are of great quality. Additionally, over 100 labs are undergoing quality management improvement programs to ensure that they suit the required standard for quality testing, even before accreditation

We also boast of a robust national sample transport system, where we link the whole country to be able to access quality and timely lab services. This system transports samples from the lower health facility that is not able to do a particular test, to the next facility in hierarchy, until proven that that test cannot be done anywhere and it is brought to the centre, and then results are taken back either electronically or reverse logistics for the requesting facility to be able to receive these results.



***National Health Laboratory and Diagnostics Services (NHLDS) in Butabika, Kampala***

Different samples are transported; HIV samples, Hepatitis, Pathology samples, outbreak samples, animal samples, so that is a very big milestone, and this has increased access to lab services to our people.

A vibrant viral load EID program that actually won a practice award in 2016. How we have managed to make sure that at least 80% of the people in Uganda access a viral load test despite of being very far away from diagnostic services. In Uganda we centrally do HIV viral load testing from CPHL, which means that someone in the remotest area will receive the same quality service as those in the city.

In the same vein, we have established the newborn screening program to screen our patients and babies for sickle cell disease, as an intervention to control the disease because if a person gets to know their status early, then they can be able to determine who to marry.

In the lab, we have been experiencing challenges around equipment maintenance and calibration, but now we have established an equipment calibration centre to assist our labs where calibration and maintenance needs arise. Equipment can be taken from across the network, brought here, calibrated and then taken back. Calibration is very important in the achievement of a good quality test.

The most recent achievement is that we have been pre-qualified by WHO to do pre-qualification for molecular diagnostic tests. This gives us very big mileage as manufacturers can now send us their kits for us to check if they are suitable to be used on the market.

### What are some of the challenges and how have you been able to overcome them?

Funding has been a major challenge. However, the Ministry of Health is working in collaboration with different partners, like PEPFAR, CDC, Global Fund, and USAID has tried to cover up the funding gap that we have. It is important to note that laboratory services are very expensive.

The other challenge, especially in the public sector, has been human resource where people who have upgraded in education are limited by the set structure which only considers diploma holders. But the good news, this past year, the scheme of service was passed to accommodate all the new cadres that are coming up. So we have started on the restructuring process to see how best to fit them in, because we need this human resource across

the whole lab network. It is a process that takes some time, but at least it has started and there is hope to overcome the challenge.

### Where do you see CPHL in the next five years?

In the next five years, under the CPHL arm of reference testing, we want to be a fully-fledged reference testing facility, looking at all areas where reference testing should be done, for example, cancer and other Non-Communicable Diseases, virology, immunology, among many other areas. We have been a bit restricted because of funding, equipment, human resource and other challenges, but we want to overcome all that and have a fully-fledged reference testing service including all the different disciplines in lab so that we are able to serve as a proper national reference lab. I really want to see this happening so that if we talk of reference testing, they don't bring here a sample and we say we are not able to work on it, and refer it abroad. In fact, the main reason to this is to reduce the referrals abroad, for samples that are usually sent abroad.

We also want to see a major improvement in the access of lab services across the network. Out of all the labs that I have mentioned from Health Centre III up to the





national referral level, -they are over 100 – but because of quality, accessibility, we decided to come up with 100 lab hubs that we have fully equipped, with infrastructures and human resource, so that they are able to offer a quality service to the nearby laboratories that cannot do some of the tests. But when you look at our country, those are only 100. So in the next five years I want to see how we can increase access to the lowest levels of care through different technologies that have come up, like Point of Care testing. With funding support, we intend to bring

services even closer to the people, instead of having everything centrally done. So we would like to increase access to a quality lab test at all levels.

We would also love to see our scheme of service well implemented at different levels as it is supposed to be. I know it takes time but I think by the next five years we should be able to achieve it. It comes with wage, restructuring across all levels of care.

I would like to see CPHL become a regional training centre of excellence, starting

with the East Central South African (ECSA) community. Because of the milestones achieved, we believe we can be a benchmark training facility for the ECSA region in the laboratory systems strengthening.

We shall also continue coming up with policies and guidelines for the lab sector, which is another important mandate of the CPHL.

With more collaborations and partnerships, we hope to have increased funding, from both the Government of Uganda as well as our donors and partners.

## FOUR REGIONAL STATE OF THE ART LABORATORIES CONSTRUCTED TO ENHANCE LAB SERVICES

By Dr. Simon Kalyesubula and the EAPHLNP team

In May 2011, the Parliament of Uganda approved a USD 10.1M loan facility from World Bank/International Funding Agency, under the East Africa Public Health Laboratory Networking Project (EAPHLNP). 30% of this saw the construction of a state of the art National Tuberculosis Reference Laboratory (NTRL) at Butabika along with other

achievements. Using this achievement as a spring board, the August House approved an additional financing loan to the tune of USD 15M in December 2015. This additional financing facility is focusing 60% of the loan on civil works for another set of four state of the art laboratories in Mbale, Mbarara, Arua and Lacor-

Gulu, and three Isolation facilities at Mulago, Moroto and Entebbe, for managing case of extremely dangerous pathogens like Ebola and Multi-Drug Resistant TB.

While the quality of health care is heavily influenced by the capacity of diagnostic systems and the quality of the test results that are accurate,

reliable and reproducible, the implementation of quality standards in the laboratory has a threefold effect; build confidence in the use of the laboratory tests and results, build confidence of the service providers at accredited laboratories and enhancing cost-effectiveness and sustainability of public health programs. This is effected through laboratory system strengthening and accreditation programs that follow acceptable national, regional and international standards of quality and competence.

Laboratory accreditation has been recognized as an

important tool for enhancing culture of quality in medical laboratory services. Laboratories implementing continuous quality improvement, will reduce testing errors, facilitate appropriate treatment of patients and rational use of medicines as well as responding appropriately to threats of public health concern.

The NTRL has exceeded its billing and is currently one of the three Supra National TB Reference Laboratories and providing services to 23 countries in Sub-Saharan Africa. Going by the way the country has contained

the Ebola outbreak in neighboring DR Congo from spreading across its border, Uganda is evolving into a model in management and containment of epidemics and events of public health importance.

Beyond commissioning of the NTRL/SRL in November 2017, civil works under EAPHLNP at the Ministry of Health is in various stages of completion for the seven sites in Uganda;

At Mbarara civil works on a one-storied laboratory is at 65% completion with fabrications underway, reinforcing ring beam is 85% complete and plaster of walls on ground floor 60% complete.

## Construction of a state of the art Laboratory space at Mbale Regional Referral Hospital. Inspection and signing off of services installation before casting of the slab works at about 50% done.



Construction of a one storied Laboratory space at Arua Regional Referral Hospital with the ground floor for testing expanded area and first floor for both human resource space and training and conferencing facilities. Excavations and over site concrete 100% done and foundations and plinth walls 80%, hardcore filling 60% done.



## **Remodeling the current Laboratory space at Gulu-Lacor St. Mary's Hospital- in line with the ISO 15189 requirements for Bio Safety and Bio Security.**

Demolition done in June 2019, works with partition blocks done in July 2019 plastering of interior walls and fitting utilities (plumbing and electrical) ongoing in August 2019 to prepare finishing in aSeptember, installation of the equipment in October and finally commissioning of completed works before Christmas of 2019.

St. Mary's Hospital at Lacor- Gulu, having

been established in 1960s as a Missionary health facility, has grown over time to become a hive of health services and care. Over time growing into a Medical, Nursing and Laboratory medicine teaching institution and currently a University teaching hospital. It remains a major player in provision of health care in Northern Uganda and Southern Sudan.





Having recovered from the devastating experience of managing the first ever Ebola epidemic in Uganda in early 2000s. Remodeling the Laboratory at Lacor-Gulu is setting the stage for the planned enrollment for ISO: 15189 international accreditation following several of implementing strengthening laboratory management towards accreditation (SLMTA) and stepwise laboratory improvement process towards accreditation (SLIPTA). This laboratory is the second private sector facility among the 42 facilities enrolled under the regional laboratory networking project in the five member states of the East African Community and the eight sites under the EAPHLNP in Uganda.

Establishing these infrastructures under EAPHLNP is intended for enhancing national and regional efforts at strategically located health facilities in the proximity to borders in East Africa. These facilities will enhance the resilience and effectiveness of laboratories that meets the required quality standards to support patients care and contribute to building strong Disease Surveillance and Response (DSR) systems.

Leveling and securing the site for Multi-Drug Resistant TB Isolation facility at Moroto Regional Referral Hospital.

These developments are emerging opportunities for scaling up the innovations beyond diagnosis and control of communicable diseases to non-communicable diseases especially cancer screening for early signs and risk factors to map planned interventions. Ministry of Health is working in partnerships with global expertise to leverage and ensure coordinated support that are key for sustaining and scaling up these gains.

# LABORATORY ACCREDITATION IMPROVES THE QUALITY OF PATIENT CARE AND MANAGEMENT IN UGANDA

By Patrick Ogwok

Uganda has achieved significant milestones in Laboratory quality management systems since it launched the first National Health Laboratory policy in the year 2009. The policy launch came with a number of changes which were implemented during the 2010-2015 strategic period, and now 2016-2020 strategic period.

One such change was the adoption and implementation of the World Health Organization's (WHO) Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) initiative since 2010. To date, more than 100 Laboratories have implemented SLIPTA, 11 of which have been accredited internationally to ISO 15189 Standards, while many others are on track to attaining accreditation.

The accredited Laboratories include the National Tuberculosis Reference Laboratory (NTRL), the HIV EID/Viral Load Laboratory at CPHL, and Mildmay Uganda Laboratory, which is also national backup Laboratory for EID/Viral Load. Others are Hospital Laboratories of Nsambya, Kayunga, Kiryandongo, Fort Portal, Kilembe, Atatur, Tororo and the Joint Clinical Research Centre.

The Uganda Blood Transfusion Services (UBTS) also attained International Accreditation.

At the beginning it was not easy, to the extent that only one Laboratory - the National Tuberculosis Reference Laboratory that implemented SLIPTA got accredited between 2010 and 2015. Behavioural change was not easy to attain to the level of achieving accreditation, and majority of the Laboratory personnel considered the documentations required in implementing SLIPTA and quality management system as undesirable extra burden. This view has since totally changed, resulting to 10 Laboratories that implemented SLIPTA getting accredited between 2016 and 2019, and many are on course to achieving the same. Many Laboratory personnel in the country now demand for support to take their Laboratories to International Accreditation.

Some of the key success factors included planning for accreditation of up to 25 Laboratories by the year 2020, which is part of the 2016-2020 strategic plan for the Uganda Laboratory Sub-sector; funding support from PEPFAR through Centres for Disease Control and Prevention (CDC) and other Partners, and

technical support from the African Society for Laboratory Medicine (ASLM), A Global Healthcare Public Foundation (AGHPF), and a host of other local and international Partners.

Others include the administrative and political support from the Ministry of Health Top Management which even declared a special day for celebrating achievements in the Laboratory sub-sector on a monthly basis.

At one such function organized to celebrate achievements of Laboratory Accreditation, the Permanent Secretary of the Ministry of Health, Dr. Diana Atwine, stated that Government of Uganda recognizes the fact that more than 70% of decisions made for patient management and disease prevention/control depend on laboratory results, further indicating that this is why the Government has made the laboratory sub-sector a priority.

**“ International accreditation means the results produced at these Laboratories are accurate and credible, and can be trusted by the doctors in the treatment of patients”, she said.**



The 2020 goal of the Uganda Ministry of Health is for up to 25 of the 100 sub-national laboratories currently implementing SLIPTA to be accredited to international standards. "This will promote evidence-based medical practice, and reduce the cost of healthcare", the PS said.

To date, there is a race in which all Hospital Directors and Medical Superintendents are working hard to have their Laboratories accredited to International Standards as this has been proven to improve responsiveness of the healthcare workers, and quality of patient care.



*Ministry of Health Permanent Secretary, Dr Diana Atwine, addresses the media during a special event organized to celebrate achievement of International Accreditation for some of the Laboratories in Uganda.*

## UGANDA NATIONAL HEALTH LABORATORY SERVICES RESEARCH AND ETHICS COMMITTEE ESTABLISHED





In both the National Laboratory policy and the UNHLS strategic plan, the Government committed to undertake research of public health importance for laboratory services. One of the key objectives was to establish a research and ethics committee.

The Uganda National Health Laboratory Services Research and Ethics Committee (UNHLSREC) was accredited on the 5th March 2019, to undertake research of public health importance according to the research priorities of the National Health sector.

The UNHLSREC committee is mandated to:

- Conduct initial and continuing review of any research activities involving human research participants.
- Determine which studies need full committee or expedited review or those that need to be exempted
- Ensure prompt reporting of changes in research activities, unanticipated problems or protocol violations that may cause increased

risk to the research participants or others

- Approve changes in research activities that happen after initial approval.
- Review and ensure adequacy of the informed consent document and process
- Suspend or terminate the research or revoke approval of any research under its review

## REC composition

UNHLSREC is composed of a team of qualified and experienced scientists, academicians and health program experts. Members are appointed by the head UNHLS and they serve for a minimum of 3 years but can renew appointments up to a maximum of 6 years. UNHLSREC review protocols within (14) days from date of submission. Initial reviews and amendments should be submitted 2 weeks prior to REC scheduled meeting. The outcome is communicated within 2 days from the date of the meeting.

UNHLSREC submission requirements

## DOCUMENTS TO BE SUBMITTED

1. A Cover letter (A request letter to UNHLSREC to review the protocol or proposal)
2. Ethical approval from other collaborating Institutions (where applicable)
3. Commitment and support letters from collaborators (where applicable)
4. CVs of Principal investigator not exceeding 4 pages but highlighting core competencies in the intended area of study.
5. Guidelines for writing protocols from the parent institution/university (where applicable).
6. A complete Protocol document including:
  - a. Full proposal
  - b. Consent and assent forms (where applicable) with translations in local languages for the study participants
  - c. Final data collection instruments

## Protocol Submission Procedure

7. a. All applications for reviews should be submitted 10 working days prior to regularly scheduled meetings which are held every last Thursday of the month.
- b. All application documents are accepted after payments to UNHLSREC account, using the following details:

**Bank: Centenary/Najjanankumbi Branch**

**Account Name: Uganda National Health Laboratories Services (REC)**

**Account Number: 3100064563**

### 8. Application fee:

- 8.a. Special studies: 300 USD
- 8.b. PhD studies; 300 USD
- 8.c. Masters studies; 50 USD
- 8.d. Bachelor and Diploma studies 50 USD
8. e Expedited Review adds another cost of 100 USD in addition to the above
8. f Continuing review; 100 USD (**Requirements for continuing Review:**
- A cover letter requesting continuing review should be submitted to UNHLSREC office.
  - Investigators are required to submit a progress report (3 copies) (Use UNHLSREC template).
  - Previously approved protocol should be submitted together with the request.

### UNHLSREC Contact Details

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## ESTABLISHING A SCALABLE IT LANDSCAPE FOR AN INTEGRATED NATIONAL EID AND VIRAL LOAD TESTING PROGRAM: THE UGANDA EXPERIENCE

By Prossy Mbabazi

### Growth of the business process domains in the national EID-VL program

Unlike all other countries in Africa, Uganda uses a centralized testing strategy for Viral Load (VL) and early infant diagnosis (EID). This basically means that one national laboratory handles all the testing for over three thousand health facilities across the country. The EID testing began as early as 2008 while viral load testing started in 2014. The national laboratory in Uganda is called the Uganda National Health Laboratory Services (UNHLS) but is known by its old name; the Central Public Health Laboratories (CPHL).

Uganda has seen an increase in the coverage of EID testing over the years from 21,000 tests in 2008 to 146,000 tests in 2018. For viral load testing, the volumes increased from a little over 100,000 viral load tests between August 2014 and June 2015 (10 months) to over 1,300,000 tests between January and December 2018. The main samples received

from the country were dry blood spots while nearby health facilities sent plasma samples.

This testing program begun with five analyzers (Roche and Abbot platforms) with a combined optimum VL testing capacity of 25,872 tests / month, and an extended capacity (staff working in two shifts.) of 40,000 tests /month. Currently, the laboratory employs 12 analyzers with a testing capacity of 175,188 VL tests per month (2,102,250 tests per annum) for an eight-hour shift. These machines can carry out both EID & VL tests using dried blood spots or plasma with a high dependence on IT systems for managing patient results.

The samples for EID and VL testing are collected by health workers from eligible patients who attend health services from various public and privately owned health facilities across the country. These samples, with their paper request forms, are collected by bike riders from higher level health facilities (hubs) and then referred to CPHL primarily through medical courier vehicles or through the post office. This

same transport system is used to deliver the sample collection materials that the health workers use to collect the samples from CPHL.

The number of hubs in the country rose from eight (08) in 2008 to 100 hubs by 2016 with primary investment in their laboratory capacity. The increased laboratory testing capacity at the hubs triggered the integration of other services at the hubs such as testing for TB, CD4, chemistry and hematology.

The staff in these hubs were trained in various laboratory disciplines such as biosafety, laboratory quality management and logistics management. Following these trainings, the staff were used as trainers for lower facilities and used their facilities for training thus requiring international laboratory accreditation for their services. To easily achieve and maintain their accreditation status, the use of laboratory information systems (LIS) was a vital resource for adoption at these hubs.

### IT - Business integration in the laboratory domains

Following the above developments in the Ugandan laboratory sector, various opportunities presented in key laboratory domains for IT integration



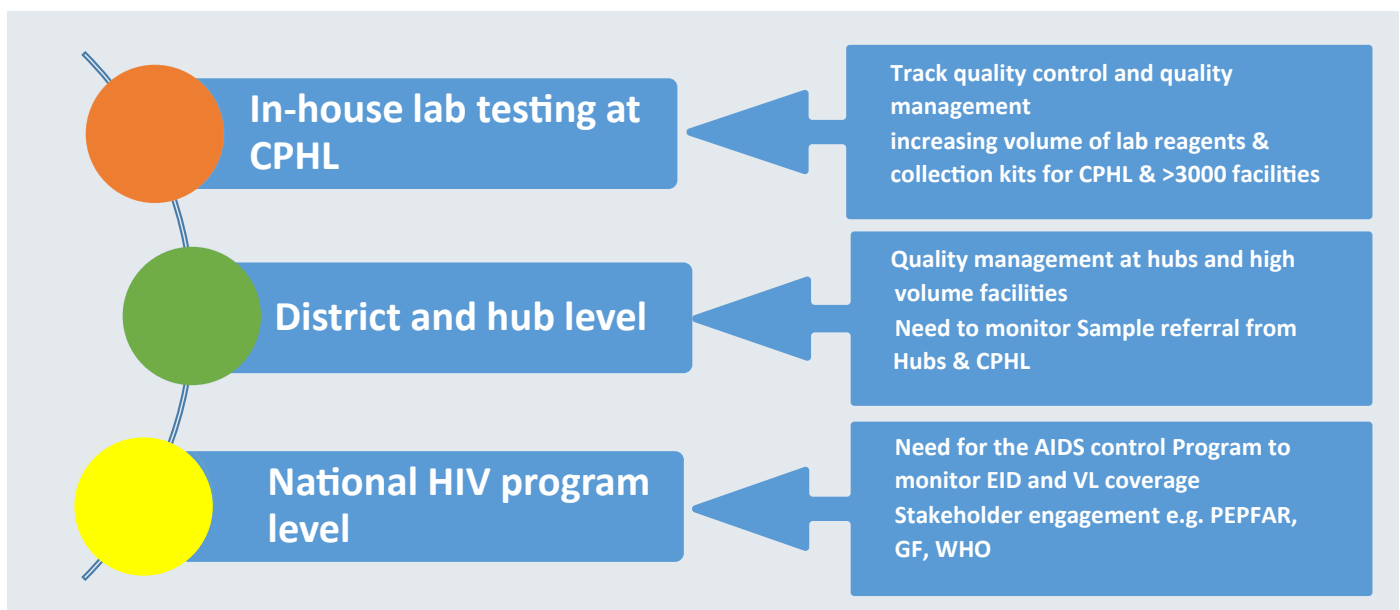
as a key enabler. The main strategies in which the needs were identified included brainstorming, benchmarking and recommendation from

strategic stakeholders. While the business and data needs collection were done in a consultative manner with the laboratory stakeholders,

the strategies for technology and application selection were often left to the IT development teams.

The Figure 1 here below illustrates the domains and their respective business needs that elicited the capability of IT.

## FIGURE 1: NEEDS ASSEMENT IN MAJOR DOMAINS OF LABORATORY SERVICES IN UGANDA



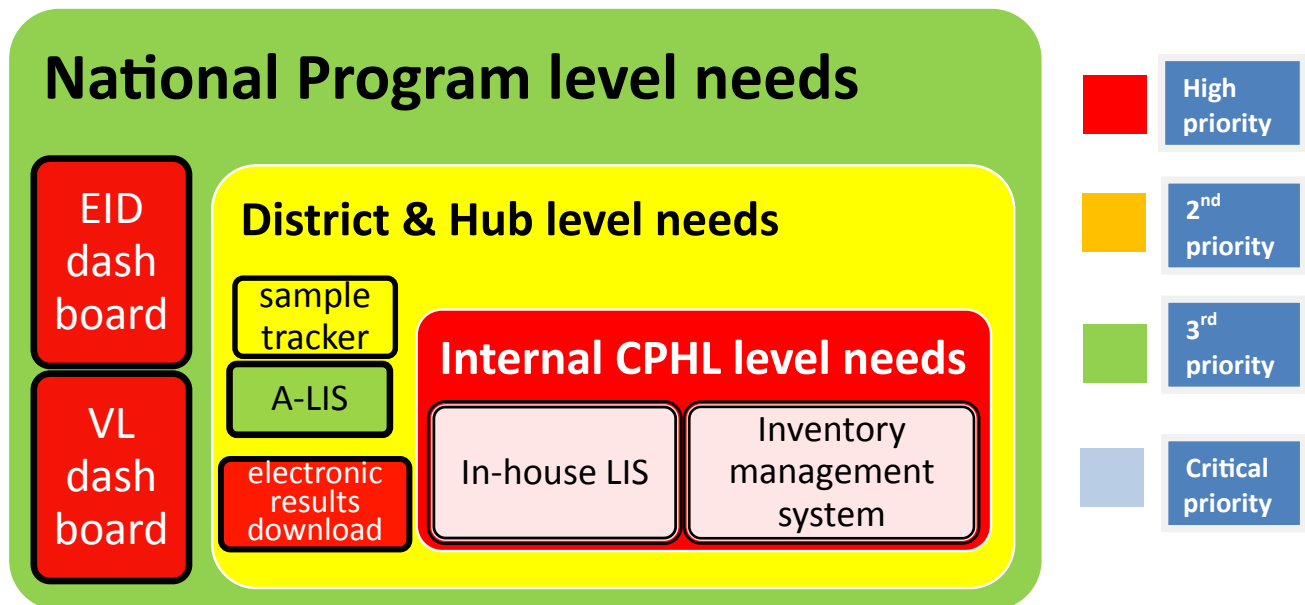
***Key consideration for implementing the IT systems in the business domains Prioritization of needs***

In light of the different stakeholder levels and their unique information system needs, there was need to focus the limited planning resources to areas of most pressing needs. In 2013, the leadership of CPHL appointed a Laboratory Information Management Systems Technical Working Group (LIMS TWG). From the deliberations of the LIMS TWG, the priorities for systems development were developed as illustrated in Figure 2.

The main focus of the LIMS TWG was on the development of an enterprise architecture, called the LIMS master plan, for the laboratory sector. This LIMS master plan would provide a guide to the expansion of IT systems across the country in a logical and efficient manner. While the LIMS TWG met on bi-weekly basis to discuss district/hub level needs using the LIMS master plan, the in-house IT team focussed on creation and upgrading an in-house laboratory information system (LIS).

The choice of a custom built LIS was mainly driven by the fast evolving testing needs in the laboratory as capacity and HR numbers increased, availability of technical capacity to develop software, availability of implementing partner support in terms of software development and ironically lack of financial resources to procure a commercial off the shelf (COTS) system.

**FIGURE 2: PRIORITIZATION OF THE INFORMATION SYSTEMS THAT WERE DEVELOPED IN THE DIFFERENT DOMAINS OF THE LABORATORY SECTOR**



## Unexpected opportunities

While focusing on expanding the capacity of the In-house LIS, it was noted that development of an outward facing national program level dashboard was within quick technological reach. With benchmarks from the Kenya NASCOP dashboard, the CPHL team embarked on developing a viral load dashboard in 2016. Its aim was to enable the national HIV program to pursue an aggressive scale up of viral load testing from about 200,000 tests to 800,000 tests in one year and subsequently, 1,000,000 tests in two years.

This viral load dashboard tool was an instant success and it was the primary monitoring tool used in the monthly demand creation

meetings held by MOH with invitation of district health teams and their supporting implementing partners. It had views of the total testing outputs of the country broken down to the granular levels of the district and health facilities. It had optional filters for age-sex alongside regimens, pregnancy status, time frames and other clinical data that was of key interest to program teams.

Another opportunity that arose from the in-house development was the ability to generate laboratory reports for individual patients. This coupled with establishment of a country-wide hub system for the 100 hubs with increased capacity led to the development of the electronic results download (e-RD) module from within the dashboards.

The e-RD was completed by November 2016 and was launched in February 2017. It was aggressively scaled up from two (02) facilities to 80 hubs within three months. Key to its success was its ease of use, availability of infrastructure at the hubs and minimum additional requirements to set it up. The monthly stakeholder meetings and interest shown development partners were key catalysts for the rapid adoption of the system.

Building on the EID-VL system, the national health laboratory services initiated Sickle Cells testing and Hepatitis B testing programs for the whole country. The EID dashboard was further customized to enable relay of results to facilities in a manner similar to the EID and VL results.

## The hard nuts to crack

While the LIMS TWG took the enterprise architecture route to strategic-cum-operational planning for IT investment, it was not certain how the dreams stipulated would evolve. Insufficient knowledge in the administration of this planning strategy caused delays in the process alongside budget constraints for stakeholder consultations. The budget reductions had severe impact on the HR retention during this planning phase thus high attrition rates.

A two-year pilot of the facility based LIS called ALIS was rolled out at 12 hubs in the country. The goal of the pilot was to prove operational feasibility of LIS in public laboratories with little or no incentives. Two of the sites were disqualified in the first year due to repeated vandalism of hardware. Management of consultancy contracts for customizing the LIS proved challenging and consumed more than seven months without a product. The customization of the LIS took significant shape after the consultancy was concluded and the efforts of in-house software developers focused on it.

A major challenge in the customization of the LIS was the interfacing it with various laboratory analyzers such as

hematology, chemistry, CD4 and Genexpert machines. This need stood out significantly as a number one priority for the end users compared to the increased work load of double transcription into computers alongside paper based tools. Success was achieved through collaboration with development teams in Ghana who had implemented the same system as early as 2012. A key use-case of this facility LIS interfacing initiative arose when the MOH introduced Point of Care (POC) testing for EID. There was a need to maintain data connectivity with the central testing laboratory for diverse brands of POCs. This called for the use of a single system to interface the POCs for relay of results.

## Planning for the future

With the established capabilities in the health sector, the laboratory sector is looking forward to consolidating the technology gains through value addition and interoperability with other strategic level and primary level information systems. The use of enterprise architecture and other IT strategic planning methodology are essential in building the business vision and defining the value streams for proposed investments.

Technological convergence strategies such as cloud computing, software as a service and block chain are fast evolving and will no doubted affect the health sector. Key challenges experienced in the implementation of the technology artifacts included poor internet connectivity and infrastructure maintenance. The emergence of 5G internet and expansion of the national fibre backbone infrastructure present great opportunities.

Uganda has made significant strides in development of ICT policies and the laboratory subsector has been swift in establishing ICT guidelines and SOPs for the laboratory sector to adopt these high level guidances. These guidelines once extended to health workers in simple terms will create more awareness of IT management for non-IT practitioners in the health sector. This will catalyze the adoption of information technology in a sustainable and scalable manner.

As the saying goes, the future is not written in stone but in sand and changes with the tide; IT in the health sector needs to be attentive to the changing tide of both technology innovation and health sector strategy in order to provide value to its eager customers.



## ENHANCING ACCESS TO QUALITY LAB SERVICES THROUGH COMMUNITY OUTREACHES

*By Annet Nabaggala Ssenkibirwa*

The National Health Laboratory and Diagnostic Services (NHLDS/CPHL) houses a Comprehensive Community Laboratory Program headed by Pathologists. It offers Cooperate Social Responsibility (CSR) to the community through medical camps so as to sensitize the community about the relevancy of timely and accurate disease diagnosis coupled with seeking medical services by linking positives to care and treatment.

Initially, there was a very low level of awareness in communities about medical laboratory services where by many people on the official opening of this Laboratory thought the Government was targeting to spread deadly pathogens to them. Also, many people did not know about the many medical laboratory tests available within the country, yet, many are given free of charge by the Government.

Through these camps, people are tested for various diseases that include HIV, Hepatitis B, Sickle cell, Malaria, Syphilis, Blood sugar levels, breast and cervical cancer, along with massive sensitization through health talks for all diseases that emphasise the preventive, diagnosis and linkage to care.

People are informed about all the programs available at NHLDS/CPHL and how best the services can be offered to them in accordance with the Ministry of Health standards.

All the people who test positive to the various diseases are linked to care in the respective health facilities for proper management, care and treatment.



*Clients being triaged by a member of the community outreach team*

NHLDS implements community outreaches (medical camps) in various parts of Uganda in Partnership with both public and private health facilities, NGOs, Community Based Organizations (CBOs), Faith Based Organizations (FBOs), Schools, Rotary clubs, Cultural institutions, and other organizations or institutions to deliver quality community services to all people in Uganda.



*Students being sensitized during an outreach*



*Laboratory team in the community*

In turn this has increased the uptake of laboratory testing services like in HIV, sickle cell, cancer and Hepatitis B where many positive clients have accessed the free viral load services, sickle cell testing and timely treatment from facilities in their proximity. For individuals screened for breast cancer, once lumps are detected, they are attached to Naguru Regional Referral Hospital for Final Needle Aspiration procedure (FNAC) and Mulago National Referral Hospital.

Screen and treat approach in Cervical Cancer management is utilized for all the VIA and Papsmeas that are confirmed

positive. Cryotherapy is immediately used to treat the lesions after attachment to Mulago- Kawempe Hospital and Uganda cancer Institute respectively for further management.

The sickle cell rapid test we use in the outreaches can detect individuals with a sickle cell trait and those with normal hemoglobin (without a trait for sickle cell). All people with a trait are encouraged to access a confirmatory test and reactive children are immediately availed a free confirmatory test from Central Public Health Laboratories.

Through these outreaches, mentorship for health facilities, medical institutions

and individuals is also done during the process of working together with medical teams that we find with in communities, so that quality delivery of services is maintained to include quality service delivery, Customer care, Professionalism as well as observing ethics.

Medical facilities are encouraged to enroll patients for quality care by establishing Infectious

Diseases clinic, Cancer clinics, Sickle cell clinics on top of others, thus various trainings are offered by the community outreach team with respect to viral load testing for HIV and Hepatitis

B plus training in Monitoring and evaluation for quality.

Strengths observed during community outreaches

A number of positive cases are turning up with intention of accessing quality disease confirmation tests, counseling and linkage to care.

The community is very happy and anxious to access and receive quality medical services without trekking distances to health facilities.

Many couples access the outreach to freely know their HIV and Sickle Cell status.



*Laboratory testing process*

In conclusion, community outreaches are very vital in addressing health in communities since the community local systems take full ownership thus mobilizing, encouraging and motivating them to access the health services.

## RESEARCH AND DEVELOPMENT

**By Chris Okiira**

Operational research is the foundation for improving processes in any system. While the laboratories continually generate data, very few laboratory personnel are actively engaged in research. The underlying principle of solving public health problems is through applied research. Research innovations have the potential of delivering cost effective, reliable, accurate and quality diagnostic services.

Applied research and implementation science in the national health laboratory network Uganda is limited. There was no coordinated mechanism to prioritize research and development due to inadequate funding,

training, coordination and management of research. Efforts are underway to promote research across the country by streamlining data collection on routine laboratory practice using the national health laboratory management information system (HLIMS). These efforts also include the newly introduced point of care testing whose governance mechanism by Ministry of Health is in its nascent stages.

UNHLS through its operation research forum generates priority areas for research that are thought to be grey areas for influencing laboratory performance. The generated priority areas have become the draft research agenda being proposed to guide

UNHLS and its partners on areas that require research support. UNHLS conducts research to inform policy and practice in the country.

UNHLS has got the Research and Development Subcommittee. The Research and Development Subcommittee was established to promote operational research within health care laboratories as well as spearhead the development of guidelines for approval of in-vitro diagnostic tests for use in the country. The committee also advises the Laboratory Technical Committee on strategies to promote operational research that informs laboratory policies. One area that research could contribute to is the evaluation of new diagnostic technologies before they are approved for use in the country.



## The scope of functions of the Research and Development Subcommittee includes:

1. Develop a national laboratory based research agenda to be approved by the LTC
2. Advise the LTC on issues pertaining to operational research for laboratory services
3. Spearhead the development of guidelines for adoption of new in-vitro diagnostics into the country's public health system
4. Devise strategies for encouraging laboratories to participate in operational research

UNHLS has accredited research and ethical committee (REC) the Uganda National Council for Science and Technology (UNCST). The UNHLS REC was established in March 2019 to support operational research activities. The REC reviews the research protocols and approves them in line with the Uganda National Council for Science and Technology guidelines.

The research department and individual researchers develops research protocols and submits to the UNHLS REC for review and approvals. UNHLS also has got draft research agenda which guides researchers and partners on the priority areas to conduct the research on. The operational research is conducted at UNHLS as well as in the laboratories across the country.



*Team from UNCST and UNHLS Research Ethics Committee (REC) team.*

## A LOCALLY DRIVEN NATIONAL BIOSAFETY CABINET MAINTENANCE AND CERTIFICATION PROGRAM

### By Abdul Mutaka

As part of laboratory safety, Biological Safety Cabinets (BSCs) protect The Lab personnel, products, and the environment from exposure to biohazards and cross-contamination during routine procedures

This can only be achieved if BSCs are certified, maintained, and used as recommended by international standards. Historically, across all

resource limited countries, there has been limited capacity within the public sector to manage Biosafety cabinets. Their calibration and certification have always been outsourced at a very high cost, there has been limited capacities to advise countries MoH on their infrastructure requirements and specifications, there has also been limited technical capacity to verify the works being done by the outsourced service providers.

In 2015 the Uganda ministry of Health with support from the United States' Centers for Disease Control and Prevention (CDC) implemented one year long comprehensive BSC Certification training in partnership with the Eagleson Institute (USA) and also procured and calibration four BSC certification toolkits to be used in the program.

## In this program, Four Biomedical Engineers were trained on:

- How BSCs are constructed and function
- BSC type and exhausted requirements
- How to use BSC effectively
- How to follow NSF 49 and EN 12469 testing procedures for BSC certification
- Developing a testing grid for BSCs
- Performing inflow and down flow airflow test
- Evaluating BSC airflow using smoke pattern test
- Performing HEPA Filter leak testing
- Determining when and how to decontaminate a BSC
- Troubleshooting BSCs
- Balancing BSC airflows
- Repairing Leaks in HEPA filters
- Changing HEPA filters
- Training users to use BSCs effectively

After the course, the trained Engineers have been able to Develop/Update national BSC inventory in government facilities and drawn up maintenance schedules.

Since the training was conducted, no service contracts have ever been signed in any government facility. IPs and Health facilities are currently arranging for only transport and per diems for the team to go and certify the BSCs in their catchment areas.

The trained resource is also benefiting sister ministries like ministry of Agriculture and other ministries which require the services of BSCs





1<sup>st</sup> Deputy Katikkiro of Buganda, Owek. Hajji Dr. Twaha Kigongo Kaawaase handing over Sickle Cell kits procured with proceeds from the Kabaka Birthday run, 2019, to the Minister of Health Dr. Aceng Jane Ruth.



# THE AFRICAN HEPATITIS SUMMIT.

The first of its kind on the African continent was held at the Commonwealth Resort, Munyonyo, under the theme: **ELIMINATING VIRAL HEPATITIS IN AFRICA; IMPLEMENTING THE VIRAL HEPATITIS STRATEGY.**



On 19th June 2019, Uganda hosted the first ever African Hepatitis Summit. The summit was aimed at rallying partners and countries to eliminate Viral Hepatitis in Africa. **The theme for the summit was, "Eliminating Viral Hepatitis in Africa; Implementing the Viral Hepatitis Strategy".** The event brought together participants from over 25 countries, to provide an

opportunity for countries to develop and work towards implementing action plans, sharing best practices and lessons learnt from each other in the fight against Viral Hepatitis.

The summit was presided over by the Vice President of Uganda His Excellency Edward Ssekandi, who represented the President of Uganda

The Minister of Health, Dr Jane Ruth Aceng, informed the delegates that the Government of Uganda adopted the World Health Assembly (WHA) resolutions of 2010 and 2014 on viral hepatitis that recognize the disease as a public health problem.

# Current efforts to tackle Hepatitis C

Hepatitis C virus (HCV) is a major health problem worldwide. In 2015, the global prevalence of HCV infection was 1.0%, with the highest prevalence in the Eastern Mediterranean Region (2.3%) followed by the European region (1.5%). In Africa, Egypt has had the highest prevalence of 14.7% from a national survey in 2008 followed by Rwanda with 3.1% prevalence within the general population. The annual mortality due to HCV related complications is estimated to be approximately 700,000 deaths. In Uganda the prevalence of Hepatitis C has not been well profiled with data from Blood bank being the closest information about HCV prevalence which approximates it to 1.5%. However, this may be an underestimate because usually blood bank opts for the healthy individuals. It's on this back ground and building on the success strides by the Hepatitis B control program that Uganda has come out to tackle Hepatitis C and a priority disease

The government of Uganda is committed to this cause and the first lady has prepared a fertile ground for management and treatment of HCV. A memorandum of understanding between Uganda and Egypt was signed which saw Egypt commit one million doses of HCV treatment for treating all HCV patients in Africa. This commitment set the ball rolling for Uganda and has already developed her own guidelines for testing and treatment of HCV patients. The initial testing for HCV will be done at all health centers and building on the highly centralized and robust HIV program and National Sample

transport Network, Uganda has now developed HCV diagnostic capacities by using existing HIV testing platforms. Confirmatory tests and post treatment monitoring tests for all HCV positive patients shall be done at NHLDS.

UNHLS is therefore in the process of getting herself ready to handle HCV samples and so far, sample requisition forms for HCV have been designed and the available technologies are in the process of being evaluated to deem them fit for HCV confirmation and monitoring.



*Ag. Commissioner NHLDS, Dr Susan Nabadda receiving an award for her tireless efforts in the fight against Viral Hepatitis in Uganda during the 1st African summit.*



**NATIONAL HEALTH LABORATORY AND DIAGNOSTICS SERVICES (NHLDS)**

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