



# **GHAIN LABORATORY**

## **END OF PROJECT MONOGRAPH**

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## TABLE OF CONTENTS

1. Introduction and program rationale	1
2. Description of Service delivery strategy	2
3. Program achievements/Results	4
4. Discussion	7
5. Conclusion	10
6. References	11

**1****INTRODUCTION AND  
PROGRAM RATIONALE**

Laboratory services are an essential component in diagnosis and treatment of persons infected with HIV, malaria, tuberculosis (TB), sexually transmitted infections (STI) and other diseases. Strong laboratory services translate to accurate and reliable results thereby improving clinical decision-making and overall patient care. Despite overwhelming evidence that laboratory services are absolutely critical for healthcare delivery, they remain one of the most neglected components of health systems in Africa. Prior to considerable efforts devoted to strengthening laboratory systems as evidenced under Global HIV/AIDS Initiative in Nigeria (GHAIN), provision of clinical laboratory services was a major issue in Nigeria. Most hospital laboratories faced major challenges including poor infrastructure, inadequately trained personnel and lack of standardized operating documents that could potentially compromise quality of services to patients.

Since the launch of GHAIN in 2004, significant improvements in laboratory service delivery have been made by strengthening the existing network of public sector laboratories at primary, secondary, and tertiary health facilities throughout Nigeria. The improved capacity of the laboratories enabled the provision of HIV services to meet the accelerated roll out of HIV prevention, care and treatment services in the country. GHAIN supported the upgrading of hospital laboratories to enable them to provide laboratory services necessary for diagnosis and monitoring treatment for HIV/AIDS, TB and other opportunistic infections (OIs). Infrastructure upgrades included: structural renovation and repairs to the laboratory buildings; provision of basic amenities to ensure reliable water and power supply such as water, stand-by generators and power inverters; and the provision of equipment necessary for efficient laboratory service delivery to people living with HIV (PLHIV), including state-of-art automated equipment. In many laboratories, improvements in work and patient flow and safety were accomplished by creating separate sample collection and patient waiting areas.

## 2

## DESCRIPTION OF SERVICE DELIVERY STRATEGY

In 2004, GHAIN's initial focus was to address the infrastructural challenges of secondary health facilities including lack of equipment, inconsistent power supply, capacity building for laboratory personnel in performing diagnosis/monitoring tests. The Institute of Human Virology (University of Maryland) provided GHAIN with technical support from 2004 to early 2006 to establish six laboratories. Thereafter GHAIN was responsible for expanding the network to the current 125 laboratories. GHAIN provided standard equipment for hematology, clinical chemistry, and CD4 measurement, supply of laboratory commodities and training of personnel.

The laboratories were strengthened to provide baseline laboratory tests for HIV positive clients, which include clinical chemistry tests (SGOT, SGPT, serum creatinine, potassium, and blood glucose), hematology (full blood count), CD4 count, hepatitis B surface antigen test and pregnancy tests as needed. GHAIN provided generic standard operating procedures (SOPs), bench top references and job aids to ensure quality service in all the laboratories. Most of the supported laboratories were enrolled into one or more proficiency programs with National Health Laboratories Services (NHLS), South Africa for proficiency testing (PT) program for CD4, hematology, chemistry and HIV serology. Some facilities participated in the Medical Laboratory Science Council of Nigeria's PT program for CD4 count and HIV serology. These enrollments formed part of GHAIN's quality assurance strategy. GHAIN also supported the development of a specimen referral system within its laboratory networks to ensure uninterrupted service delivery even during equipment breakdown and long downtimes.

GHAIN laboratory officers regularly performed visits to the sites for on-site supervision and monitoring thereby ensuring adherence to best practices. All laboratories had standard laboratory registers for patient data in place and maintained good records which were mainly paper-based. GHAIN supported some laboratories with desktop

computers linking them to Lafiya Management Information System (LAMIS) an electronic medical record and Logistic Management Information System (LMIS). Laboratory staff were trained on post exposure prophylaxis and facilities equipped with basic safety equipment including fire extinguishers. In addition, laboratory waste management training was conducted for laboratory staff to allow for safe waste segregation and disposal.

Technical assistance was provided to assist facilities in developing a reliable mechanism for supply of commodities, inventory management and use of logistic tools to capture facility utilization and proper commodity inventory management. GHAIN conducted monthly onsite visits using standardized checklists to assess the quality of laboratory services. Reports that highlighted non-conformities were generated and followed by plans on how to address them. The capacity of laboratory professionals in government and faith based facilities was also developed. Specific training for laboratory scientists and technicians was provided, which included Good Laboratory Practice, safety, quality control, quality assurance and equipment maintenance. Additionally TB microscopy (Ziehl Nielsen and fluorescence), culture, HAIN line probe assay and DNA PCR for early infant diagnosis (EID) of HIV trainings were provided appropriately both locally and internationally through collaboration with the National Health Laboratory Service (NHLS) in South Africa.

# 3

## PROGRAM ACHIEVEMENTS/ RESULTS

In collaboration with Federal Ministry of Health (FMoH), GHAIN developed guidelines and protocols for appropriate laboratory tests required for eligibility for ART and monitoring at all levels of the healthcare delivery system. With its nationwide coverage, GHAIN contributed significantly to laboratory services for HIV testing, CD4 enumeration, clinical chemistry, hematology, EID and TB diagnostics. In health system strengthening, GHAIN established 125 laboratories with capacity to perform clinical laboratory tests exceeding its targets of 112 laboratories. Cumulatively since inception to date GHAIN exceeded its target of 3,485,263 for clinical tests at supported laboratories by conducting, 4,300,467 tests comprising: 2,311,289 HIV disease monitoring tests (hematology, CD4 count and clinical chemistry), 1,918,398, rapid HIV and 10,377 syphilis tests. Within the same period 1,538 laboratory professionals were trained against a target of 945. To date, a total of 125 GHAIN supported laboratories are operational in all the states plus the Federal Capital Territory for HIV diagnosis and ART monitoring, TB microscopy and screening for opportunistic infections.

### Laboratory Equipment

During the project, approximately 428 major equipments were procured and installed; an in-house equipment maintenance strategy (planned preventive maintenance) was implemented to ensure optimal utilization. The equipment maintenance model called for establishing a pool of cross trained equipment maintenance engineers with the responsibility of installation, preventive maintenance and repair of the laboratory equipment in facilities. A team of engineers received training to become certified on various platforms used in laboratories. Through step-down training and mentoring, some engineers at government hospitals acquired the skills and expertise necessary to maintain and service their laboratory equipment. Additionally, an automated database was installed for tracking maintenance activities such as repairs, inventory of serviceable parts and stock management.

### **Jalingo Early Infant Diagnosis laboratory**

GHAIN supported the establishment of a high-tech molecular laboratory for the early diagnosis of HIV infection in HIV-exposed infants (EID), in FMC Jalingo. This facility was the first polymerase chain reaction (PCR) laboratory in the North-Eastern geo-political region of Nigeria with molecular diagnostic capability. A unique collaboration between GHAIN and Adamawa and Taraba states supported the development of the Jalingo EID laboratory based on the GoN EID scale-up plan. The unique ownership of the network pilot capitalized on existing state structures. It was facilitated by joint funding of specimen transport and results dispatch; therefore linking satellite sites to the laboratory. This joint alliance and collaboration has seen an improvement in the turnaround time of test results from over 6 weeks to less than three weeks.

A 2010 integration audit by the National EID Laboratory Team assessed the laboratory quality management systems and received an excellent rating of 95% on a standardized national integration tool. Performance in external quality assessment both local and international proficiency testing program has shown a sustained quality improvement in the laboratory with a performance of 100% for the past two years. The laboratory is in the process of implementing a laboratory quality system in order to guarantee provision of reliable results. Currently capacity is being built for additional molecular testing including viral load for optimal monitoring of PLHIV.

### **Calabar MDR TB culture and molecular diagnostic laboratory**

GHAIN in collaboration with the National Tuberculosis and Leprosy Control Program and Cross River State MoH, established Microbiological Reference Laboratory, a biosafety level 3 Tuberculosis laboratory at Dr. Lawrence Henshaw Memorial Hospital, Calabar with funding from United States President's Emergency Plan for AIDS Relief (PEPFAR) through United States Agency for International Development (USAID). The laboratory was commissioned in April, 2009 as the first phase of a plan to enhance capacity at Dr.



Lawrence Henshaw Memorial Specialist Hospital and Research Center for testing and treatment of TB. The second phase was the establishment of molecular biology laboratory which was completed April, 2010.

The technologies available in the laboratory include use of BACTEC MGIT 960 (liquid culture) for drug susceptibility testing, Lowenstein Jensen media (solid culture), Zeihl-Nelsen microscopy, and Fluorescence Microscopy and molecular diagnosis of MDR TB using line probe assay e.g. HAIN. To enhance competencies in the diagnosis and management of MDR-TB, GHAIN facilitated the training of health workers from Dr. Lawrence Henshaw Memorial Hospital, on the identification and management of MDR-TB cases in line with the Stop TB strategy. This strategy recognizes the need to provide all patients affected by both drug susceptible and drug resistant TB with appropriate care. The laboratory is currently implementing a quality system management under the Strengthening Laboratory Management Towards Accreditation (SLMTA) in Nigeria for WHO Africa regional office (AFRO) accreditation.

### **National and WHO-AFRO Accreditation**

In order to strengthen Nigeria's network of laboratories, GHAIN, in collaboration with other implementing partners and the GON and with the leadership of MLSCN, adopted the WHO -AFRO accreditation system. As part of this nationally coordinated process, GHAIN supported piloting the implementation of WHO AFRO accreditation in six facility laboratories and a further 13 laboratories for national accreditation. Generic quality systems management (QSM) documents were developed and presented formally to the hospital managements of the facilities for adoption and utilization. This approach was designed to help FMOH and SMoH institutionalize laboratory best practices that meet international standards. To ensure its success, GHAIN laboratory services supported building institutional capacity covering a wide range of laboratory practice and continuous improvement of laboratory services. The selected facilities in the pilot for WHO-AFRO accreditation underwent gap analysis through a baseline assessment which highlighted areas requiring improvement.

## 4 DISCUSSIONS

Laboratory services remain one of the cornerstones of successful HIV/AIDS programs. Diagnosing and monitoring prevalent infectious and communicable diseases such as HIV/AIDS, TB and malaria in resource limited settings require significant laboratory support. GHAIN exceeded its PEPFAR targets for the number of laboratories with the capacity to perform clinical tests as well as targets for diagnostic and monitoring tests. GHAIN successfully supported the establishment of two high technology laboratories for early infant diagnosis (EID) and TB culture/drug resistant testing. An innovation with many opportunities for lesson learning and institutionalization of best practice is the capacity building of site staff to implement quality laboratory systems management, and fully transitioning laboratory management responsibilities of this high-tech laboratory. Though GHAIN did not provide viral load assays for clients on treatment when clinically indicated either directly or through sample referrals to other USG partners, this will be addressed with expansion of capacity at the PCR laboratory in Jalingo to include viral load assays.

By then end of the project, GHAIN will have supported the establishment of a national laboratory training center at the Federal Medical Centre (FMC) Owerri for pre- and in-service medical laboratory personnel in Nigeria. The training center will be self-sustaining with the FMC Owerri hospital management, Imo State University Owerri, University Teaching Hospital and MLSCN taking a significant role. This approach was designed to help FMOH and SMOH institutionalize laboratory capacity building.

GHAIN was challenged by lack of laboratory space (physical space), dilapidated infrastructures, and unavailability of basic amenities such as water and electricity. As a result, GHAIN had to provide the essential amenities and engage in significant infrastructural upgrades before service delivery could begin. Whereas laboratory infrastructural upgrades performed at all the facilities were considerable, maintenance of the infrastructural support and work-flow/patient flow improvements were not

systematically maintained by GHAIN or the hospital management. Advocacy to SMOH and state facilities by GHAIN was not always successful in tackling laboratory related activities and needs. GHAIN provided training for SMOH quality supervisors to enable them provide quality service delivery monitoring to facilities within their domain.

However, there was no apparent monitoring and supervision of quality of service delivery provided by State Ministries of Health. The role of state quality officers in laboratories was not clearly articulated with little or no indication that these trained SMOH staff provided supervisory visits.

Staff transfers, attrition, and insufficient number of staff were also major challenges in most of the sites. In many instances, it compromised service delivery especially when trained laboratory personnel left facilities. It must be acknowledged that the majority of the laboratory staff were dedicated to their work despite the workload complaints. The inevitable shifting of key laboratory management responsibilities to lower cadres of laboratory staff could potentially impact negatively on the overall laboratory quality service delivery. This insufficient skills mix varied from site to site, between federal and state facilities, and even among geopolitical regions of the country.

Additionally, the shortage of HIV test kits and laboratory reagents impeded quality laboratory services, and was encountered due to weaknesses in GON procurement and distribution systems. The approval process for reagents also created delays increasing the lead in time. The incessant stock out of reagents and equipment breakdown made it difficult to implement and monitor quality system essential indicators in the laboratories. Inability to measure and monitor an operational quality system affects the documentation of various indicators such as internal quality control thereby compromising efforts of continuous improvement. In terms of process control, GHAIN laboratory services introduced an institutionalized internal quality control strategy but its implementation was weak due to poor internal quality control processes in most facilities. FMC Jalingo is an exception, as in this facility a system was put in place for testing and re-testing “control samples” and documentation of the results. External

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quality assessment was generally successful in GHAIN-supported facilities, most of which sustained a satisfactory performance in proficiency testing results.

Lastly, the separation of HIV service laboratories and routine hospital laboratories posed a challenge in volume of work and service quality disparity. The laboratories differ significantly in infrastructure, equipment, quality processes and procedures. This vertical structure worked against systems strengthening and program sustainability approach. Efforts have since been put in place to address this challenge through integration of laboratory structures in selected sites and implementation of an integrated approach moving forward in order to enhance ownership and sustainability.

## 5 CONCLUSIONS

GHAIN's efforts in laboratory systems strengthening led to establishing a network of 125 laboratories in secondary and tertiary facilities with the capacity to provide HIV diagnosis and treatment monitoring. The project built the capacity of laboratory personnel and improved the infrastructure of laboratories. The laboratories are spread throughout Nigeria and have made a significant contribution to building the laboratory capacity required for scale up in the national HIV care and treatment program. Additionally, improvements in laboratory work- and patients'-flow, safety, training and retraining of laboratory personnel in good laboratory practice, safety, commodity logistics, testing procedures and equipment operations have been accomplished. GHAIN succeeded in leveraging resources to not only establish ART laboratories but also high technology facilities for complex testing of HIV and TB pathogens.

## 6 REFERENCES

1. GHAIN Laboratory Brochure 2010.
2. GHAIN end of project evaluation final report January 2011.
3. WHOAFRO Laboratory Accreditation Checklist for Clinical and Public Health Laboratories Guidance for Development of National Laboratory Strategic Plans, 2008.





Funded by the President's Emergency Plan for AIDS Relief through U.S. Agency for International Development