PANCAP GFR9 Project

Medical Laboratories Component

Implemented by Caribbean Med Labs Foundation (CMLF)

October 2015

Strengthening Caribbean Laboratory Networks

Overall Objective:

"A regional network for provision of laboratory testing to support HIV/AIDS, Sexually Transmitted Infections (STIs) and Opportunistic Infections (OIs) (including support for monitoring of Haematology and Biochemical parameters) established in the region".

1.0 THE GFR9 LABORATORY COMPONENT

1.1 LABORATORY COMPONENT OBJECTIVES AND STRATEGIES

A laboratory intervention was included as a key component of the HIV/AIDS Global Fund Round 9 (GFR9), and was implemented by CMLF with the objective of forging a regional network to provide the critical support required from Caribbean medical and public health laboratories if overall programme objectives are to be successful. Increased access to quality, affordable and sustainable laboratory services required to effectively support national HIV treatment and care programmes has been among the key challenges faced by regional Governments over the past two decades.

Project strategies sought to first identify the gaps in national and regional infrastructures that are currently impacting laboratory services and in collaboration with national and regional stakeholders and partners, to identify and support implementation of feasible solutions. Towards this end the GFR9 project strategies included:

- Conducting baseline and repeated annual laboratory surveys in 16 project countries
- Identifying gaps and barriers in national and regional laboratory structures, systems and capacity
- Identifying laboratories that have the potential to provide a national and/or regional reference service and providing support for strengthening their capacity to provide these services
- Facilitating the development of national strategic and action plans to strengthen laboratory networks that will more effectively provide high quality HIV, STI, OI services
- Providing periodic monitoring oversight for implementation of plans
- Upgrading quality management systems and relevant techniques within national networks in collaboration with other regional partners
- Facilitating implementation and/or improvement of laboratory information systems (LIS) to encourage effective sharing of laboratory information across the network
- Providing support for laboratory participation in proficiency testing (PT) programmes for external quality assessment.

- Development of National Laboratory Policy Regional Framework – advocacy for its endorsement and facilitation of its adaptation at national level.

Packages of tests were defined by regional stakeholders (clinicians and laboratory professionals) as the tests that were critical to effective management of HIV/AIDS patients. There was common agreement among regional stakeholders in Project countries about the core lab support needed as follows:

1) ready access to HIV screening and confirmatory testing; viral load and DNA PCR diagnosis and CD4 testing.

2) ready access to a basic complement of tests for evaluating liver and kidney functions and a Complete Blood Count (CBC) analysis.

3) ready access to TB diagnosis and common STIs such as syphilis and GC.

4) a preliminary complement of opportunistic infections (OIs) to be addressed was developed by a multi-stakeholder group but recommendations were that decisions on an appropriate complement would have to be confirmed at the national level.

2.0 MAJOR ACHIEVEMENTS

The major achievements of the laboratory component of the GFR9 grant are outlined below.

Laboratory Services Assessment and Monitoring

1. Collection and analysis of baseline information on the regional situation with respect to laboratory services to support HIV/AIDS programmes was a key aspect of determining the strategies necessary to support the laboratory intervention.
2. CMLF promoted and assisted countries to establish formats for recording sample information and monitoring turnaround times for the defined packages of services. Establishment of systems for ongoing collection and monitoring of laboratory network data was critical – including identification of major packages of service required to support HIV programmes, national structures for quality of laboratory services, and key indicators of laboratory network performance – specifically, turnaround time (TAT), proficiency testing performance and surveillance reporting.

Advocacy and Policy Support for Laboratory Networks

3. Data collected and observations made of laboratory service gaps were used to advocate for the necessary support from key stakeholders including clinicians, laboratory management and staff, Ministers and Ministries of Health and Programme Managers for establishment and sustainability of regional and national laboratory networks.
4. Technical and financial support was provided by CMLF for the annual HIV Laboratory Network meeting as part of the CCAS Annual meeting from 2011 to 2015. In 2011 this resulted in a Declaration being issued by the CCAS meeting for the first time, with respect to important policy issues for laboratory services in the region.
5. Data collected by CMLF in assessing laboratory services and the CCAS Declaration was used to obtain the COHSOD Decision in 2012, committing Ministers of Health support for establishment of national and regional networks, policy and regulatory support for laboratory services and support for the development of transitional plans to ensure sustainability of laboratory quality interventions through a smooth handover of resource responsibilities from donor to national governments.
6. Development of a Regional Model Framework for National Laboratory Policy was undertaken by CMLF in collaboration with a regional group of experts to advance the process of policy formulation. Endorsement and support from Ministers of Health and Chief Medical Officers in 2014, for adaptation and adoption at national level was obtained through advocating at regional meetings and in national fora. The Model Framework, which is based on WHO guidance, and meets the requirements of International Health Regulations that all countries have signed on to meet by 2016, includes requirements for:
    a. Governance and Co-ordination of laboratory services (including establishment of National Focal Point, National Laboratory Advisory Committee, provision of financial resources, competencies of staff)
    b. Quality Management Systems (including legislation for regulation and licensing, and training of laboratories to meet QMS requirements)
    c. Support Systems including Procurement and Inventory, Safety and Biosafety and Maintenance.
    d. Laboratory Information Management – integration with Health Information Systems.

7. Model legislation to support the implementation of the National Laboratory Policy was drafted for sharing with countries.
8. CMLF website was upgraded and regular website and social media updates used to inform stakeholders http://cmedlabsfoundation.net/
9. Publication of semi-annual Caribbean Med Lab News was initiated electronically and in hard copy with the objective of providing stakeholders with updates on issues of importance to laboratory services within the Caribbean region. In particular, the newsletter has highlighted issues challenging sustainability of laboratory services within the region.

Quality of Services

10. CMLF facilitated the development of National Laboratory Policies based on Regional Framework in 13 participating countries.
11. CMLF was included in collaboration with PAHO/WHO, US Centers for Disease Control and Prevention, the CARICOM Regional Organisation for Standards and Quality (CROSQ) and Regional Accreditation Bodies to develop the Laboratory Quality Management Systems - Stepwise Improvement Process (LQMS-SIP). In developing the National Laboratory Policy Regional Framework, Tier 1 of the LQMS-SIP was included as the requirement for licensing of laboratories.
12. Proficiency testing programmes were provided to participating laboratories in 15 countries in the areas of HIV, Haematology and Biochemistry, STI and OI testing. Countries were provided with guidance and models for analyzing and undertaking corrective actions to improve their performance. CMLF also advocated with participating countries to secure the necessary funding to sustain PT programmes.

Laboratory Information Systems

13. Assessments were conducted of laboratory information management systems within participating countries.
14. Based on the outcomes of the baseline assessment in which 11 national laboratories indicated that they managed their data manually, the CMLF Electronic Logbook was designed and developed to facilitate tracking of turnaround times and other key indicators, as well as surveillance reporting by

laboratories without Laboratory Information Management Systems (LIMS). The CMLF Electronic Logbook was piloted in two laboratories in Suriname.

15. CMLF provided Technical Assistance and established a User Group to assist countries with LIMS to better utilize their capabilities and to extract data for surveillance and indicator monitoring.

Access to Services – National and Regional Reference Nodes

16. CMLF facilitated the development of National Laboratory Network Plans in 10 participating countries. These network plans included structuring of the national network to provide access to levels of service – based on the regional model agreed and endorsed at the CCAS meeting of the HIV Laboratory Network, including clinicians and programme managers.
17. Identification of regional reference nodes for provision of reference services for:
    a. Molecular diagnostics – Barbados and Jamaica
    b. Validation of HIV test kits - Jamaica
    c. Proficiency testing and Quality Control models – Belize and Suriname.
18. A QMS Costing framework was developed to guide governments and laboratories in planning and costing their QMS implementation.
19. Support was provided to selected reference laboratories:
    a. Barbados Lady Meade Reference Laboratory to improve efficiency and cost recovery systems with a view to ensuring sustainability and quality of service to OECS countries.
    b. Belize and Suriname for improving and/or establishing national PT and Quality Control programmes.

Sexually Transmitted Infections and Opportunistic Infections

20. Based on gaps identified in baseline assessments, a regional training workshop for Diagnosis of Opportunistic Infections (OIs) and Sexually Transmitted Infections (STIs) was conducted for participants from 15 countries.
21. Standard Operating Procedures for OI and STI testing and a Plan of Action were produced as outputs of the regional training workshop.

3.0 LESSSONS LEARNED

1. Active linkages with Ministries of Health and their laboratories for the conduct of this programme within countries was a critical success factor.
2. The development of a Regional Model Framework for National Laboratory Policy and obtaining of endorsements from Ministers of Health and Chief Medical Officers at their regional meetings, was an effective method for fast-tracking the development of policies at the national level.
3. It was key to ensure that linkages were made between the objectives of the GF R9 laboratory initiatives with CARICOM, PAHO and CDC initiatives for:
    a. Development of the Caribbean Pubic Health Agency (CARPHA)
    b. Integration of HIV into the health sector including policy dialogue
    c. Stepwise process for Quality Management Systems implementation toward Accreditation within the Caribbean.
4. The involvement of PANCAP-CARICOM in this project presented major opportunities for impact on regional policy formulation. Through the linkages with CARICOM and PANCAP access to Regional Meetings of Ministers of Health and annual reports to the Council of Ministers (COHSOD), support for the policy initiative and for appropriate support for laboratories was facilitated.
5. The inclusion of clinicians within the annual CCAS meeting presented a great opportunity to include their input in development of critical aspects of the laboratory network's services e.g. establishment of levels of laboratory services, indicators of success for the network, etc.
6. The supportive and solution-oriented approach of the PR as represented by the PMU within CARICOM served as a major source of guidance and support for the implementation of this project and is a key success factor for the successful implementation of such a project.

4.0 SUSTAINABILITY

The sustainability of this intervention will require **political** support and engagement of **laboratory and administrative managers** at the national level. A critical success factor will be the adoption and implementation of the draft national policies and supporting legislation, which provide overall guidance for the effective and quality assured functioning of laboratory services. The function of the National Laboratory Advisory Committee established for the implementation of the National Laboratory Policy and

National Network Plan developed under this project is a critical component that must be endorsed and made accountable under the Ministry of Health within each country. Support for the necessary legislative adaptation and adoption will also be critical.

At the regional level, CMLF will undertake the development and implementation of a supporting and accountability strategy in collaboration with CARICOM/PANCAP and CARPHA for following up on implementation of the COHSOD decision of 2015 which should be included within regional meetings. At the 2015 COHSOD, Ministers of Health:

(i) **Noted and Congratulated** countries for the progress made in developing national laboratory policies with facilitation by CMLF;

(ii) **Committed** to provide leadership at the national level to support adoption and implementation of the National Laboratory Policy – critical to ensuring reliable and sustainable national laboratory services and to meeting IHR requirements.

(iii) **Recognised** the current operational challenges being faced by national regional laboratories and agreed to **address with urgency,** the allocation of the minimum quantum of human and financial resources required to secure consistent, uninterrupted, reliable testing and information generation by laboratories, given the evidence that while only approximately **5% of the national health budget** in most countries is expended on laboratory services, **laboratory data influences 70% of clinical decisions and a significant percentage of public health decision-making**.

Collection and use of data on network performance must be continued through to ensure continued functioning of the network and to provide the information necessary to secure the political, administrative and technical actions to support and improve the networks.