TRANSFORMING THE MEDICAL LABORATORY LANDSCAPE

A GENERIC CARIBBEAN NATIONAL LABORATORY POLICY FRAMEWORK

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1. FOREWORD

This Generic National Laboratory Policy Framework has been developed to continually improve laboratory services in the Caribbean region. It seeks to provide a blueprint for the development of strong and sustainable national laboratory services by identifying and defining key responsibilities at governance and operational levels.

Governments determine the regulatory environment and the standards regime in which public and private sector laboratories operate. It is the Governments' responsibility to determine who will be allowed to operate a laboratory and the attendant quality monitoring and accountability structures. Governments are also responsible for adequately funding public sector laboratory services to ensure optimal service quality, coverage and access.

2. INTRODUCTION

This national policy framework is intended to define the conditions for the stronger laboratory performance in the Caribbean. It is the prelude to the formulation of national legislation, a 3-5 year laboratory strategic plan and annual or biennial operational plans. Customers of the laboratory - residents, visitors, policymakers, health practitioners, programme managers and clinicians – can be assured that their medical and health data and information needs will be met in an organized and expeditious manner. Similarly, the policy will also inform the intentions of laboratory champions, and investments of development partners and donors.

This framework has been developed by a wide cross-section of regional experts drawn from health policy and practice environments within the public and private sectors. The policy has taken cognizance of the World Health Organisation's (WHO) Health Systems Building Blocks (Service Provision, Health Workforce, Information, Medical Technologies, Financing and Leadership and Governance) and is in alignment with WHO Guidance for Development of National Health Laboratory Policy as well as with ongoing regional laboratory network strengthening initiatives.

By providing overall direction for the establishment and operation of laboratory services, a robust national policy represents a government's commitment and support for organizational and management effectiveness and efficiency. Chief among the deliverables are national standards for laboratory operations and active encouragement of evidence-informed decision-making and quality improvement.

3. BACKGROUND

Caribbean Heads of Governments are committed to their people attaining the highest possible level of health (The Right to Health). The associated duty to care includes the provision of an empowering and enabling set of high quality health services. The major constraint is the cost of health services.

Non-Communicable Diseases (NCDs) represent the most significant driver of health care inflation. NCD risk factors, personal outcomes and population impacts are well-known. Through the POS Declaration and their influence on the UN High Level Meeting on NCDs, Caribbean leaders continue to lead the global agenda of NCD prevention and control. The essential interventions include research; epidemiologic surveillance; policy advocacy; and expert programme-based management of care, treatment and support services. Their effectiveness is wholly dependent on the analysis of laboratory data, since it has been estimated that **80%** of medical decisions are influenced by laboratory results.

The importance of laboratory data and information is amplified by the fact that prevention and control of NCDs (and other burdens) is a development issue recognized as such by CARICOM Heads of Government in the 2001 'Nassau Declaration on Health'. For example, according to the World Bank, the direct cost of diabetes and hypertension as a percentage of total public health expenditure ranges from 17.6% in the Bahamas to 211.3% in Guyana. In St Lucia it is estimated that NCD patients spend 36% of annual household expenditures on out-of-pocket healthcare costs and in Jamaica, 3% of the GDP is expended on NCDs[1].

As the most tourism dependent region in the world, Caribbean economies are very fragile and easily impacted negatively by "breaking news" and social media reports of disease outbreaks. A key and critical role of regional laboratories is the identification of disease outbreaks e.g. foodborne, Legionella, dengue, etc., in order to facilitate rapid and effective public health action. This is critical to protecting the region's tourism market and maintaining regional GDPs.

A case in point includes the rapid intervention subsequent to identification of an outbreak of Legionnaire's disease in one Caribbean hotel in the late 1900s, which prevented what could have been a national economic disaster. Several international tour operators suspended tours for about a month until the issue was resolved. In another Caribbean country, a class action suit due to a disease outbreak resulted in one hotel losing millions of dollars. Indeed, delays in outbreak detection have led and can lead to millions of dollars in cancelled visitor arrivals and increased expenditure at local health levels.

Medico-legal issues have become a regional reality as both local and visiting populations become increasingly litigious. Nothing is more inimical to a vacation in paradise than medical

[1] Source: Dr. Shiyan Chao, Senior Health Economist, LAC Region, World Bank, *Economic Impact of Non-communicable Disease in the Caribbean*, presentation at Caribbean Health Financing Conference, Jamaica, November 12-14, 2013, www.nhf.org.jm/cchfi/index.php/presentations

error, which can arise due to errors in laboratory results contributing to possible treatment error or failure. Potential fallouts include major financial payouts and calamitous reviews in social media, with unfavourable travel advisories posted on government websites of source countries.

The historical view of laboratories as "factories" of test results has to change because it simply no longer serves a useful purpose. The Caribbean is straining under the burdens of severe economic and fiscal challenges, prevalent health risks and disorders. New thinking is needed in order to forge and sustain excellence in health care services.

The immediate imperative is maximizing user satisfaction and minimizing healthcare costs through high levels of reliability, effectiveness and efficiency. Contributing factors to these health system strengthening tasks include adequate and predictable financing; well-trained and motivated staff; well-stocked inventory of equipment and reagents; a robust electronic architecture of data and information processing, reporting and networking; appropriate test algorithms and general laboratory procedures; expert onsite management; and competent governance oversight.

4. HEALTHCARE TRANSFORMATION, INTEGRATION, EXCELLENCE: ROLE OF THE LABORATORY IN THE 21st CENTURY

The health of the Caribbean region is its wealth. This is not cliché; health is a pre-requisite of personal happiness and wellbeing and economic growth and development. The latter half of the 20th century witnessed significant improvements in health status through rational levels of public sector investment in health services. People living longer and productive lives are more likely to contribute to expanding the GDP. There are threats to productivity and longevity notably non-communicable disorders, addictions, injuries, health effects of climate change and new and re-emerging infections.

Investment in health service development must be sustained given the enormity of these health challenges. Investment emphasis should focus on laboratories because they play an indispensable role in the pursuit of excellence in the integrated management of population health and personal medical care. National health commitments under International Health Regulations (IHR) and Millennium Development Goals (MDGs) also demand efficient, reliable and quality-assured laboratory services.

Fundamental to the strengthening of healthcare services in the Caribbean is a culture of evidence-informed decision-making and a business-orientation. In so doing, implementation of this policy will provide the necessary steerage to excellence in laboratory operations. Principles and elements include transparency and accountability; continuous quality improvement; forecasting, strategic and operations planning; smooth and rapid data and information processing and dissemination; costing of services and cost recovery; supply chain and inventory management; utilization review; laboratory networks; occupational health and safety; and competency-based personnel recruitment and assignment.

Once the policies and plans are in place, the next step is adequate resource mobilization and allocation. In the short- to medium-term, the return on investment will be the consistent production of relevant, timely and accurate data and information for clinical, programme and policy decision-making. The potential benefit of this to healthcare services from a revenue standpoint will be a reduction in the frequency and cost of patient interactions as increased relevance, speed and accuracy of laboratory diagnoses allow for a reduction in hospital stays. A reduction in losses due to a reduction in excessive and unnecessary laboratory requests and poor utilization of laboratory results will also translate into revenue gains.

5. DEVELOPING A NATIONAL HEALTH LABORATORY POLICY

5.1 SITUATION ANALYSIS, MISSION & VISION

In spite of the significant investment in Caribbean laboratory development made by Governments and donors for over two decades, regional laboratories have struggled to achieve and sustain the delivery of cost-effective, reliable and timely services. Laboratories have been, in the main, incapable of meeting the objectives established in national health plans that speak to equity, affordability, accessibility and high quality. Access to services continues to be a roller coaster experience in many countries with a service that is available today but not accessible tomorrow because of a lack of supplies, dysfunctional equipment or loss of human resource.
At the root of this dysfunction is a lack of policy direction, planning and sustained financing.

A key first step to developing a national laboratory policy is the conduct of a detailed situational analysis critical to determining the current status of health laboratory services in a country. This should be a highly participatory activity, involving a wide range of stakeholders drawn from the public and private sector and including policy & decision-makers, service providers, development partners, relevant professionals, technical experts etc.

An appropriate national vision and mission should be agreed by stakeholders. An example of a Mission:

"The National Laboratory Network will support essential public health functions through delivery of relevant, equitable and client-focused services of uncompromising quality"

5.2 ESSENTIAL ELEMENTS OF THE NATIONAL POLICY FRAMEWORK

The national laboratory policy should include the following essential elements:

1. **Laboratory Governance and Network Structure** which includes national policy, regulatory legislation and implementation and monitoring structures.
2. **Quality Management Systems** to ensure the quality of laboratory services provided.
3. **Laboratory Support Systems** including procurement and inventory management, equipment management and laboratory safety.
4. **Information and Data Management** to facilitate improved use of data for action.

5.2.1 LABORATORY GOVERNANCE AND NETWORK STRUCTURE

POLICY STATEMENT

There shall be a National Laboratory Network (NLN) that operates on a well-defined structure based on principles of good governance, sustainable financing and efficient use of the resources, of which monitoring and evaluation is a key component.

A comprehensive national framework for health laboratory services includes a well-organized and managed laboratory governance and network structure that addresses the following components:

a. A National Health Policy & Strategy
b. Legislation & Regulation
c. National Structure
d. Financing
e. Human Resource
f. Partnerships & Networking
g. Monitoring & Evaluation
h. Sustainability

a. National Health Policy and Strategy

A National Health Policy should be established to support the National Health Strategic Plan. The National Laboratory Policy and Strategic plan shall be anchored in the **National Health Policy and Strategic Plan.**

b. Legislation and Regulation

Legislation and regulations shall be developed and implemented which clearly define roles, responsibilities and authority, including for point of care testing. The National Laboratory Advisory Committee, the Regulatory Authority and the National Standards Bureau should craft legislation and regulations.

c. National Structure

A National Laboratory Services Focal Point/Coordinator, reporting directly to the Chief Medical Officer or Director of Health Services, shall be assigned within the Ministry of Health to chair the National Laboratory Advisory Committee (NLAC)), and be responsible for the development of strategic information and for co-ordination and oversight of activities related to the national laboratory network.

The NLAC shall be appointed by the Minister of Health to reflect the multisectoral and multidisciplinary stakeholder groups that impact or benefit from effective and high quality laboratory operations. NLAC will assist the Ministry of Health (MOH) and other key stakeholders to develop and monitor implementation of the national laboratory policy and clear 3-5 year strategic plans and operational plans for the functioning of the national laboratory network.

A National Regulatory Authority, with the required competencies, shall be appointed (or assigned from within the existing national or regional structure), which monitors laboratory standards, licensing & registration, inclusive of ethical considerations, facility infrastructure, and laboratory personnel qualifications and maintains a database of **ALL** private and public sector testing facilities.

The Regulatory Board shall be completely separate from the Ministry of Health's (MOH) management including the Advisory Committee.

The National Laboratory Service (MOH) shall be a separate programme within the MOH and have a dedicated budget, with mechanisms to support the efficient utilisation of the laboratory services network.

The National Laboratory Services Focal Point/Coordinator shall engage key stakeholders to establish appropriate infrastructure requirements and essential tests & techniques to be provided at varying levels of health facilities in accordance with the national health service policies and structures.

d. Financing

Effective financing and accountability mechanisms shall be put in place centrally and at local government levels to ensure availability and accessibility of adequate resources for quality and reliable laboratory services. This will require:

- Development of dedicated budgets for national laboratory services within national health budgets.
- Laboratory Health Accounts System as part of the National Health Accounts to provide costing and continuous monitoring of laboratory services income and expenditure.
- Training of laboratory managers in developing and managing annual plans and budgets and in use of data to plan and forecast.

e. Human Resources

The National Laboratory Strategic Plan shall include a Human Resources Management Plan to ensure the appropriate skills mix and competencies of staff to adequately serve this network. This plan must consider HR for ALL laboratories and ALL levels in the network, including a structured system for effective supervision of performance and quality. At a minimum, the skills mix should include specific technical competencies and competencies for laboratory management, co-ordination of laboratory quality and safety, plant and infrastructure upkeep, procurement and laboratory inventory, equipment maintenance, forecasting and budgeting, business and information management and monitoring and evaluation.

The 'Development' component of the Laboratory Network Human Resource Management Plan must include the collaboration with all stakeholders including the training institutions and professional associations, and must include facilitation of re-certification.

f. Partnerships/Networking

Networking between public and private laboratories shall be promoted to improve access and equity of laboratory services.

g. Monitoring and Evaluation

Mechanisms shall be in place for monitoring and evaluating the implementation of this laboratory policy by NLAC with reports to the MOH. Mechanisms shall include the identification of key performance indicators within strategic and operational plans, structured data collection, analysis and reporting with defined timelines and responsibilities and a defined policy and procedure for corrective actions.

h. Sustainability

- The strategies for national laboratory operations shall be integrated into the national health plan as well as into other related stakeholder plans.
- Responsibility for **implementation** of the national laboratory strategic plan shall be clearly identified in the plan.
- A Monitoring and Evaluation Plan must accompany the Strategic Plan.
- The National Laboratory Policy and Strategic Plan must inform the development of a plan for sustainable financing in view of the rapidly decreasing foreign funding – a post donor funding sustainability plan.
- Human Resource retention strategies must be established and implemented including accreditation of training, incentives, a competency-based HR system and career mobility tracks to ensure stability of the human resource pool.
- The network system can be utilised to form a buffer to programmes no longer funded by donor agencies including use of public/private partnerships.
- A ceiling percentage should be established for donor funding.
- Alternative financing should be developed in collaboration with other sectors e.g. Tourism and Agriculture.
- Reduced costs for procurement of supplies will be facilitated through negotiated prices based on pooled regional procurement needs.
- Mechanisms to reduce wastage in the laboratory must be implemented.
- Clinical and public health protocols will be developed for rational use of laboratory services.

5.2.2 QUALITY MANAGEMENT SYSTEMS

POLICY STATEMENT

There shall be a national laboratory quality management framework to ensure that laboratories maintain quality management systems in accordance with a national standard and in keeping with the Ministry of Health's overall quality policy.

There shall be legislation supported by regulations to ensure that laboratories comply with the requirements of the national standard.

There shall be a national laboratory standard that at a minimum shall align with the regional LQMS-SIP (derived from ISO 15189) for medical laboratories and with the accepted International Standard (ISO 17025) for non-medical laboratories.

A comprehensive national framework for health laboratory services includes the establishment and maintenance of a quality management system for all aspects of laboratory services. This should include the conduct of ongoing staff training, continuous monitoring, continuous quality improvement and ongoing corrective actions. A quality-managed laboratory service addresses the following components:

a. A Regulatory System
b. A Network Quality Monitoring and Evaluation System
c. Training and Continuing Education
d. Community & Customer Service
e. Research & Development

a. Regulatory System

- All laboratories shall be required to be registered and licensed in order to provide service
- Sanctions will be imposed if stipulated requirements are not met
- A phased approach to implementation of the prescribed standard shall be adopted in accordance with the regional LQMS-SIP for medical laboratories, and as agreed for other public health laboratories.
- An already existing (national or regional) or new Regulatory Authority with the required competencies shall be given responsibility for monitoring of compliance of laboratory services with the regulatory system.

b. Network Quality Monitoring and Evaluation System

- A network of quality managers from the various laboratories shall be established by the national laboratory focal point to coordinate all activities relating to the national quality management framework.
- The network monitoring system shall include organisation of appropriate external quality assessment schemes (EQAS) for each level of laboratory service, and ensuring mandatory participation with feedback and remediation.

- Network laboratory performance shall be assessed through conduct of on-site assessments.
- Standardised quality indicators shall be developed for network laboratories and used to consistently monitor, evaluate and continuously improve laboratory performance.

c. Training and Continuing Education

- There shall be a structured plan to ensure the initial training and timely updating of staff competencies for both the technical and quality aspects of their duties.

d. Community and Customer service

- Laboratory services shall be an integral part of the health services responsiveness to the community needs and shall adhere to ethical standards.

e. Research and Development

- Laboratories shall be encouraged to participate in relevant health research to improve patient management, laboratory performance and disease prevention and control.

5.2.3 LABORATORY SUPPORT SYSTEMS

POLICY STATEMENT

There shall be a system (legislation and management) to ensure that laboratory operations are cost effective, environmentally friendly and safe.

A comprehensive national framework for health laboratory services should include the standardization of laboratory equipment, supplies and reagents based on the menu of tests being provided at all levels of the laboratory network. Standardisation can benefit from economies of scale, promote cost-efficiencies in procurement, inventory control, storage and distribution. A national laboratory support system should address the following components:

a. Procurement & Supplies
b. Equipment Management
c. Safety and Biosafety

a. Procurement and Supplies Management

- There shall be national guidelines for procurement and inventory management including recommended standard software for inventory management. These guidelines shall include guidance on acceptance and receiving of donations, guidance to prevent uninformed and unapproved switching of supplies and guidance for evaluation of suppliers.
- Appropriate national storage facilities and means of distribution shall be maintained.
- Data shall be utilised for forecasting to ensure evidence-based procurement.

- There shall be an established national (or regional) system for validation of kits and algorithms.

b. Equipment Management

- There shall be national guidelines for the acquisition, use, and maintenance of equipment that supports a robust supply management chain. These guidelines will include guidance on acceptance and receiving of donations and disposal of obsolete equipment.
- Standardisation of equipment, reagents and supplies shall be promoted.
- All major equipment shall be installed with training provided by the supplier and shall be covered by equipment maintenance contracts
- Public Private Partnerships (PPP) shall be explored to facilitate cost effectiveness (pooling of resources) for equipment maintenance.
- Evaluation and verification of equipment and methods shall be conducted according to standard guidelines.
- A national database of laboratory equipment and biomedical engineers shall be maintained.
- Training of Biomedical Engineers and Technicians shall be pursued as a priority.

c. Safety and Biosafety

- The International Standard for Laboratory Safety (ISO 15190) shall be used as a guideline for national laboratory safety.
- There shall be national guidelines for waste management (chemical, biological and radioactive)
- Each laboratory shall have an individual assigned responsibility for overseeing safety.
- The infrastructure of every laboratory should support a safe environment for staff and visitors
- Protocols shall be established to deal with adverse occurrences such as needle stick injury requiring post-exposure prophylaxis (PEP) and other occupationally acquired diseases.
- Protection from blood borne illnesses shall be in place e.g immunisation against Hepatitis B.

5.2.4 INFORMATION AND DATA MANAGEMENT

POLICY STATEMENT

There shall be a national information management framework that includes industry-established standards and guidelines for ensuring connectivity, consistency and confidentiality in information exchange among the various components of the health system

The national health information management framework shall ensure that the laboratories and testing sites have information management systems (manual or

electronic) with the capacity to facilitate laboratory operations and management and to provide high quality information for decision-making at all levels of the health system, bearing in mind that laboratory information management systems (LIMS) are distinct from but are an integral part of health information systems.

Laboratories shall be supported in their effort to optimise the impact of their data in the context the national health information management framework.

The laboratory's main business is the provision of reliable and timely **information** to support health policy development and planning and health service delivery. A comprehensive national framework for health laboratory services must therefore include an efficient and effective system for managing data – i.e. collecting, collating, analysisng and packaging laboratory information. This may be electronic or paper-based. A national laboratory support system should address the following components:

a. Laboratory Information Management Structures
b. Provision of Appropriate Data
c. Public Communication

a. Laboratory Information Management (LIMS) Structures

LIMS structures shall require

- Establishment of standard record keeping systems to rationalise data collection and ensure compatibility with the national health information system.
- Provision of adequate resources – trained human resource and adequate facilities (connectivity and architecture) to facilitate data and information management.
- Establishment of reporting procedures for data/information from the laboratory network to authorised sites on a weekly, monthly or quarterly basis for relevant disease control programmes to support surveillance and disease control. Reporting shall be mandatory and included in the regulatory legislation for laboratory services.
- Training and guidance for data analysis to ensure that laboratory data can be analysed at every level of the health service to guide and support clinical services and public health, including planning of procurement and supplies, human resource allocations, business planning and quality monitoring.

b. Provision of Appropriate Data

- Dedicated studies for establishing reference ranges should be conducted or existing data should be utilised to develop baseline reference ranges to ensure appropriateness for local populations.
- Guidelines for procurement and inventory management, including validation of kits and algorithms, shall be developed and implemented.

c. Public Communication

- A Communication strategy and protocols should be developed to ensure proactive communication of trend data to specific stakeholders.

6. GLOSSARY

Medical Laboratory
Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of diseases or the assessment of the health of, human beings, and which may provide a consultant advisory services covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

NOTE: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms.

Point of Care Testing (POCT)
Testing performed near or at the site of a patient, with the result leading to possible change in the care of the patient

Quality Management System
Management system to direct and control and organisation with regard to quality (relates to the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement).