CARICOM Endorses Urgent Action on Medical Laboratory Crisis

CARICOM Ministers meeting in St Lucia have endorsed recommendations for reversing the crisis in medical laboratories after hearing startling information about the quality of medical laboratory services in the region. The Caribbean Med Labs Foundation (CMLF) had requested PANCAP to include the regional issues affecting laboratory services on the agenda of the 16th meeting of the CARICOM Council for Human and Social Development (COHSOD). Continued...
A medical laboratory result is only useful if it is produced from a quality assured laboratory process; otherwise it is at best unreliable, and at worst, dangerous.

When the Caribbean Med Labs Foundation (CMLF) was established in June 2008, it was out of recognition by key regional health-policy makers that such an organization was necessary if the region were to continue the excellent progress made under the previous “Strengthening of Medical Laboratory Services (SMLS)” Project (2002-2007) funded by the EU and implemented by CAREC.

The Founders recognised that maintaining momentum and the high levels of awareness and sustaining the gains made towards the vision of universal access to high quality Caribbean laboratory services would be challenging. They fully embraced the idea that since laboratory services influence at least 70% of medical decisions, Caribbean public health needed an effective mechanism to advance regional medical laboratory services.

CMLF proposes to continue to promote and support the achievement of quality laboratory services in accordance with appropriate standards, through advocacy, resource mobilisation, collaboration, research and education. A major priority for CMLF is to partner with regional Governments and institutions and international agencies to promote and establish creative approaches and systems for achieving laboratory accreditation. So far these efforts have led to visibly increased levels of ‘buy-in’ by key stakeholders.

The quality of laboratory testing is of critical importance to the public because it is estimated that 70% to 80% of critical medical decisions are influenced by laboratory results. In the Caribbean, snapshots of testing reliability indicate that a high frequency of unreliable results may be occurring.

Among other things, clinicians use laboratory results to decide if someone has diabetes; to determine if someone is at risk for heart attack or has had a heart attack; to determine if someone is HIV positive or has cancer; and to decide on hospital discharge.

Director of CMLF, Valerie Wilson, in a presentation to the COHSOD meeting held in April 2012, disclosed that among CARICOM countries, only Barbados, The Bahamas, Belize and Guyana have established regulations making it mandatory for medical laboratories to be licensed and their operations monitored. However, compliance with regulations may not always be optimal. In contrast, most CARICOM governments have already implemented regulations and monitoring systems for food establishments and vendors, pharmaceuticals and other health professionals. In the wider region, Bermuda has implemented mandatory legislation requiring laboratories to become accredited.

More challenging has been CMLF’s thrust to continue to nurture and encourage the functioning of the region-wide Caribbean laboratory network, recognised as one of the valuable outputs of the SMLS Project. In our view this speaks to the need to genuinely empower our Caribbean laboratories to build resilience and self-reliance.

We wish to thank all institutions, agencies and persons that have supported our work. We wish to particularly recognise the support and confidence that we have received from CARICOM, PANCAP and the Global Fund. We salute and appreciate our primary stakeholders – the laboratories and laboratory professionals.

As chairman of CMLF I would like to express my gratitude to fellow board members and to especially recognize the pillars of our organisation: Ms. Valerie Wilson, Ms. Wendy Kitson-Piggott and Ms Louise Mathura. There is no doubt that CMLF has overcome many challenges in the four years of our existence. Some of these challenges were expected whereas others were not. Yet we continue on the course that we have set ourselves.

There is much at stake here. Health is crucial to development, and it is only through the empowerment of our indigenous institutions that we will be able to claim genuine development.

The Ministers endorsed key policy recommendations for laboratory services and agreed to support development of national and regional laboratory networks. They agreed to establish national regulations and ensure development and implementation of strategic plans for national laboratory services; to allocate the necessary resources to ensure continuous laboratory support; and to transition from resources provided by regional partners to national support.

In August 2011, delegates at a meeting supported by the Caribbean HIV/AIDS Regional Training Network (CHART), Caribbean Cytometry and Analytical Society (CCAS), the US Centers for Disease Control and Prevention (CDC) and the CMLF had issued a Declaration calling for establishment of a Caribbean Laboratory Network.

The CMLF Director emphasised that “Clinicians depend on laboratories to manage patients and when they don’t trust laboratory results they often have to rely only on their clinical judgement in managing their patients. Worldwide, direct and indirect costs of laboratory error can run into millions of dollars.”

Ms Wilson, in her presentation to COHSOD, held out hope for the region to move forward on medical laboratory standards. She listed a number of strengths that would facilitate regional and national action, an important one being that countries themselves are backing the move for licensing and accreditation of laboratories.

The Trinidad and Tobago-based CMLF has been working in partnership with Ministries of Health, PANCAP, PAHO-WHO and CDC-PEPFAR to assess laboratories in the region with the aim ofremedying the situation.
In January 2011, CMLF began work as the recognized PANCAP partner on the laboratory component of the Global Fund Round 9 Project (GFR9) under a Memorandum of Understanding with CARICOM. The project will result in organized networks of quality assured laboratories to support HIV, STI, and Opportunistic Infection (OI) testing, including services to monitor patients on treatment. With these networks, the public will benefit from an improved range of and access to testing services in-country. In addition, the project will facilitate arrangements for referral sites within the region.

**>> Beyond HIV**

Most importantly, since the intervention will take a health systems strengthening approach, it focuses on improving overall laboratory services and not merely those related directly to HIV/AIDS.

**Project activities include:**
- Conducting baseline and repeated annual laboratory surveys
- Identifying gaps and barriers in national and regional laboratory structures, systems and capacity
- Providing support for strengthening laboratories identified as having the potential to provide a national and/or regional reference service
- Establishing criteria for defining success of the regional and national networks
- Facilitating the process for developing national strategic and action plans to strengthen laboratory networks

**>> Major Advances**

CMLF has made major advances in assessing and analyzing the current needs and situation with laboratory services within the region. We have identified potential regional reference node laboratories and facilitated development of national plans for implementing a laboratory network. Further, we have identified criteria for regional network performance. Systems for monitoring network performance will be discussed at the second network meeting coinciding with the August 2012 regional meeting of the Caribbean Cytometry Association (CCAS). CCAS has partnered with CMLF for implementation of this project.

CMLF’s work in the policy arena, using this assessment data, with PANCAP and CARICOM’s support, has produced major results with the recent COHSOD decision on laboratory services within the region (see lead article in this issue). The project is clearly fulfilling a major regional need for strengthening laboratory services and relies on the strong support of Ministries of Health and collaboration with other partners such as CDC and PAHO to ensure success and to sustain improvements.

### CMLF Activities Update

CMLF’s activities extend beyond its current work as laboratory strengthening partner for PANCAP’s GFR9 project. Some of the other activities include:

- Working with the International Federation of Biosafety Associations to establish a Caribbean Biosafety Association (CABSA).
- Collaborating with a regional training institution to introduce a post-graduate programme for Laboratory and Quality Management in 2013.
- Developing a Laboratory Quality Management Systems – Stepwise Implementation Process (LQMS-SIP) with PAHO and CDC.
- Volunteering with the USA’s Clinical Laboratory Standards Institute to strengthen laboratory operations in Africa and on CLSI Expert Committees for quality improvement.
- Developing indicators for performance of TB laboratories with the Royal Tropical Institute (KIT) in The Netherlands.

### The CMLF Board Members:

**Dr. Stephen King, Chairman**  
Independent Senator, Laboratory Director and former Chief Medical Officer, St. Lucia.

**Mr. Lawford Dupres, Deputy Chairman**  
Former Director, Trinidad and Tobago Bureau of Standards and former Director, CARICOM Regional Organisation for Standards and Quality.

**Ms. Ingrid Lashley, Treasurer**  
Director, Trinidad and Tobago Mortgage Finance Co. Ltd.

**Mrs. Marvo Harper, Secretary**  
Legal Practitioner, Trinidad and Tobago.

**Dr. David Picou**  
Former Director, Caribbean Health Research Council.

**Dr. Farley Cleghorn**  
Senior Vice President and Chief Technical Officer, Futures Group, USA.

**Dr. Paula Burns**  
Provost and Vice President (Academic), Northern Alberta Institute of Technology, Canada.

**Mr. Jones P. Madeira**  
Manager of the Information and Protocol Division of the Judiciary of Trinidad and Tobago.

**Dr. Sonia Roache**  
Caribbean College of Family Physicians, Private Practitioner, Trinidad and Tobago.
New Directions for HIV Testing?

>> Test and Treat

At the International AIDS Conference held in Washington D.C. in July 2012, significant focus was placed on exciting new research that may call for a review of current Caribbean HIV/AIDS testing strategies. Research, aimed at reducing transmission rates, for example, explored the effectiveness of ‘Early Treatment’, ‘Treatment as Prevention’ and ‘Test and Treat’ strategies for the elimination of HIV in high endemic countries, promoting the use of pre-exposure prophylaxis for HIV uninfected persons with high risk behaviours, as well as testing of entire populations followed by immediate treatment of those found to be HIV infected (Granich, et al, 2009; Grinsztejn et al., 2012; Kretzschmar et al and Hontelez et al).

>> Global HIV Testing Crisis

There is an acknowledged global HIV testing crisis. Too few infected persons know their status and fail to access available care. The call for scaling up of HIV testing came from many quarters at the AIDS conference (Hirnschall, 2012). There were many Advocates for the use of ‘Home Testing’ and in some environments ‘Door to Door’ testing aimed at expanding the reach of HIV testing services, especially for the most at risk populations (MARPS). Research presented suggested that use of the FDA approved OraSure Technologies oral fluid home test – OraQuick - could increase knowledge of status and positively impact risk practices as well (Carballo-Diéguez, 2012).

>> Caribbean Needs to Act

A pilot study to address quality and other expressed concerns about ‘Home Testing’ will be launched in 2013 and will include the integration of online pre-and post-test counselling into online purchase of HIV home-test kits and will, as well, provide referrals to appropriate care facilities (van der Helm et al, 2012).

The Caribbean must begin to assess the implications of these discussions for regional HIV/AIDS control and prevention efforts and determine whether adjustments need to be made to current testing strategies to more effectively address our epidemic.

References

Grinsztejn, B. et al. (2012). IAC 2012; Abstract THLB05.

Vision
The regional champion for best practice in Medical Laboratory Services

Mission
Promote and support the achievement of quality laboratory services in accordance with appropriate standards, through advocacy, resource mobilisation, collaboration, research and education.

The broad objectives of the CMLF include:

- Continued development of the supportive environment for the rapid expansion of high quality regional laboratory services
- Advocacy at the highest levels for the implementation of relevant laws, regulation and accreditation of regional laboratories
- Mobilisation of resources for laboratory strengthening efforts
- Mapping of a regional coordinating strategy to ensure sustained laboratory strengthening efforts.

Ms Valerie Wilson
Director

Wendy Kitson-Piggott
Laboratory and Quality Systems Specialist

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Administrative/Finance Assistant

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