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Strengthening national laboratory health systems in the Caribbean region

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The President’s Emergency Plan for AIDS Relief (PEPFAR) programme for the Caribbean Region was established in 2008 to address health system challenges, including fragile laboratory services and systems. The laboratory component of this programme consisted of several phases: assessment of laboratory needs of all 12 countries engaged in the programme; addressing gaps identified during the assessment; and monitoring and evaluation of the progress achieved. After one year of PEPFAR collaboration with national governments and other partners, laboratory services and systems greatly improved. Some of the milestones include: (1) the accreditation of a public laboratory; (2) improved access to HIV diagnosis with faster turnaround time; (3) establishment of capacity for platforms for DNA PCR, viral load and HIV drug resistance; (4) development of the laboratory workforce; and (5) establishment of a framework for implementation of sustainable quality management systems for laboratory accreditation. The progress recorded in strengthening laboratory health systems after one year of initiating this collaboration shows that with a rigorous initial assessment, programme design and intervention and strategic partnership, national laboratory health systems can be greatly enhanced to support programme implementation. Continued collaboration and country leadership is critical to create an integrated and sustainable laboratory network in the Caribbean.

Keywords: HIV/AIDS; Caribbean region; laboratory health systems strengthening

Introduction

Over the past 10 years, there has been increased funding from the global community to fight the HIV epidemic. Some examples of this international effort include the President’s Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis (TB) and Malaria (GFATM), the World Bank HIV/AIDS initiatives, the Bill and Melinda Gates Foundation and the Clinton Health Access Initiative (Lieberman et al. 2009, PEPFAR 2010, Kates et al. 2011). Although there

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has been criticism that this funding has created parallel health systems in developing countries (England 2007, Marshal et al. 2009, McCoy et al. 2009), there is substantial evidence that the outcome of this approach has led to overall health systems strengthening, or at least the provision of key policy information to reshape health priority thinking, with positive gains beyond HIV-related programmes (AmfAR 2009, El-Sadr and De Cock 2009, Levine and Oomman 2009, Cohn et al. 2010). The success of the first five years of PEPFAR (PEPFAR I) led to its reauthorisation in July 2008 of the second five years of PEPFAR (PEPFAR II) (Walensky and Kuritzkes 2010). The reauthorisation required US government (USG) agencies that support HIV prevention and control activities to work closely with national, regional and international partners to develop a joint strategic plan, or partnership framework, based on shared goals and objectives, mutual contributions and measurable outcomes, with the goal of country ownership.

Although HIV prevalence among adults in the Caribbean is approximately 1.0%, which is higher than in all other regions outside sub-Saharan Africa (UNAIDS/WHO 2007), bilateral support under PEPFAR I was provided only to Haiti, Guyana and the Dominican Republic. In PEPFAR II, the US–Caribbean Regional Partnership Framework was established to build the capacity of national governments and to strengthen the effectiveness of regional coordinating agencies and non-governmental organisations providing quality, cost-effective national HIV/AIDS programmes to reduce HIV incidence in the Caribbean region. This programme covers activities in 12 countries, including the six countries that make up the Organization of Eastern Caribbean States (OECS); St. Lucia, St. Vincent and the Grenadines, Grenada, Antigua and Barbuda, St. Kitts and Nevis, Dominica, and the six additional countries of Barbados, Trinidad and Tobago, Belize, Suriname, Jamaica and the Bahamas (Figure 1).

Significant challenges to effective implementation of HIV/AIDS activities in the Caribbean include the lack of a trained workforce, inadequate health systems and infrastructure and limited access to quality-assured laboratory services to support scale-up of HIV diagnosis and clinical monitoring of patients receiving treatment (Abayomi and Landis 2008). In particular, the role of laboratory systems and services as part of health care delivery in this region has not been given proper importance. Successful use of current PEPFAR funds by these countries to strengthen their overall health systems, including laboratory health services and systems, will depend on effective collaboration of the governments with PEPFAR and other donor organisations.

This article outlines laboratory challenges faced in the Caribbean region prior to PEPFAR II support, describes progress made within the first year of implementation and provides a framework to ensure sustainability and ownership of the laboratory referral system by national governments.

**Objectives**
The PEPFAR Caribbean Laboratory programme was established with the objectives to: (1) support Caribbean-led organisations to create a sustainable regional laboratory network and (2) assist governments and regional public health agencies to improve the scope and quality of HIV diagnostic and clinical laboratory monitoring services and systems.
Methodology

Laboratory referral system in the Caribbean region prior to 2008

In 1975, the Pan American Health Organization (PAHO) established the Caribbean Epidemiology Centre (CAREC) to support epidemiological research and other health-related services in the region. PAHO also established a special programme on HIV/AIDS and Sexually Transmitted Infections (STIs), including laboratory capacity, to serve as a regional centre of excellence to support several types of testing including molecular testing, confirmation of HIV and TB and proficiency testing programmes for external quality assessment (EQA). The subsequent establishment of the Pan Caribbean Partnership against AIDS (PANCAP), and the proposed Caribbean Public Health Agency (CARPHA) completely revised and streamlined CAREC’s laboratory mission (Caribbean Common Market (CARICOM) and Pan Caribbean Partnership against HIV/AIDS (PANCAP) 2010). The support services that CAREC provided to countries were terminated and individual national laboratories were challenged to assume a greater role in providing more complex, timely, high-quality and reliable diagnostic and clinical laboratory services to meet expanding national HIV prevention, treatment and care programmes.

Figure 1. United States Government Caribbean Regional partnership framework countries.
Laboratory needs assessment conducted by PEPFAR in 2008–2009

Between 2008 and 2009, the Caribbean PEPFAR Laboratory Technical Working Group, comprised of members from the US government interagency team, conducted a laboratory needs assessment of all 12 countries within the current PEPFAR support. The goal of this assessment was to gather data on laboratory capacities within these countries and incorporate this information into the five-year strategic plan of the Caribbean Regional Partnership Framework, the Framework Implementation Plan and the annual Operational Plan. During the assessment visits, meetings were held with key Ministry of Health officials including various laboratory directors or their designees. Initial discussions were centred on the goals and strategies of the PEPFAR II programme and challenges faced by countries in strengthening laboratory services and systems. This was followed by a critical assessment of their laboratories using standardised tools that included questions on the laboratory’s readiness and stage in the implementation of quality management systems (QMSs) and accreditation, presence of national laboratory strategic plan and policy, staffing needs, training and competency assessment, testing platforms, presence of national HIV diagnostic algorithms, plans to roll out HIV rapid testing, quality assurance activities including participation in external quality assessment programmes, equipment maintenance/service contracts, supplies and procurement systems, laboratory informatics system, waste management and biosafety issues. Data were entered and analysed using Microsoft Excel (Microsoft Corporation, Redmond, WA, USA). After analysis of the data, follow-up discussions were held with countries to review outcomes of the assessment and develop collaborative intervention work plans that formed part of the PEPFAR Caribbean Regional Operational Plan (ROP).

Results and discussions

The outcome of this assessment (Figures 2 and 3) and follow-up assessments conducted by PAHO indicated that laboratory services and infrastructure were still very weak throughout the countries. Overall, there was a lack of access to timely, low-cost and high-quality laboratory services, resulting in delayed diagnosis, misdiagnosis and/or inadequate clinical laboratory monitoring to support treatment efforts.

HIV clinical laboratory diagnostic and monitoring services

Laboratory services to support HIV diagnosis within the Caribbean Region were below required standards (Figure 2). Several laboratories in the region were at different levels of national HIV diagnostic algorithm development; the overall process of testing and results reporting was cumbersome; and, there were long turnaround times averaging two to three weeks, and as long as six weeks in some countries. In fact, point-of-care diagnosis involving a combination of HIV rapid tests was new, not well understood, and essentially not used in most of the countries. Dried blood spot (DBS) specimens collected for early infant HIV diagnosis (EID) were shipped to South Africa with support from the Clinton Health Access Initiative. Because of the complexities and the cost of this initiative, only a few infant samples
were analysed by DNA PCR testing. This resulted in fewer infants receiving care and treatment.

Clinical laboratory monitoring, particularly CD4 testing, among the six OECS countries was a challenge. For example, in some of the countries laboratory equipment was discarded, broken or could not be serviced due to lack of proper technical support. Moreover, test kits and reagents were not always available. None of the OECS countries had the capability for molecular testing, including HIV viral load quantification and drug resistance genotyping (Figure 2). The cost per test for specimens referred for testing to countries outside of the region ranged from US$100 to $180 for viral load testing and US$300 for HIV drug resistance testing. As a result of this high cost, monitoring patients on antiretroviral therapy was a challenge in terms of affordability and timeliness. Consequently, very few people in the entire region either knew their HIV status or had access to quality clinical laboratory monitoring.

**HIV clinical laboratory systems**

As of 2008, only nine (5.2%) of the estimated 173 laboratories in the Caribbean region was accredited; six of these were medical laboratories. All accredited laboratories were either private or faith-based health facility laboratories. Thus, although more than 90% of the population used public government laboratories, none of them were accredited (Table 1). Overall quality assurance in Caribbean laboratories was weak or non-existent, and it was common for facilities to focus on providing laboratory services without paying adequate attention to improving systems, making sustainable quality systems unattainable (Nkengasong et al. 2009).

In addition, reagent procurement and equipment maintenance were major barriers to providing quality laboratory services and ensuring sustainable quality systems.
Because of the complexity of the government procurement systems for managing donor funds, procurement of laboratory reagents and equipment and payment of maintenance charges were greatly delayed. Furthermore, some countries lacked the funds to procure reagents and purchase service contracts for the laboratory equipment. Moreover, there was no provision for equipment maintenance or properly laid out procurement contracts (Figure 3). Due to the lack of reagents and/or poorly functioning equipment, laboratories experienced several service interruptions that negatively affected the accuracy of the diagnosis, and the monitoring of patients.

Table 1. Improvement in laboratory services and systems after one year of PEPFAR intervention.

<table>
<thead>
<tr>
<th>Type of laboratory activities</th>
<th>2008–2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of public laboratories accredited</td>
<td>0/12</td>
<td>1/12 (8.3)</td>
</tr>
<tr>
<td>Presence of DNA PCR capacity</td>
<td>0/5</td>
<td>3/5 (60)</td>
</tr>
<tr>
<td>Countries shipping DBS samples abroad for testing</td>
<td>11/12 (92)</td>
<td>1/12 (8.3)</td>
</tr>
<tr>
<td>In-country HIV confirmation</td>
<td>6/12 (50)</td>
<td>12/12 (100)</td>
</tr>
<tr>
<td>Average turnaround time for release of HIV serology test results</td>
<td>1 month</td>
<td>1 week</td>
</tr>
<tr>
<td>Countries with in country capacity for HIV drug resistance testing</td>
<td>0/2</td>
<td>1/2 (50)</td>
</tr>
<tr>
<td>Countries with regular CD4 testing capacity</td>
<td>8/12 (75)</td>
<td>12/12 (100)</td>
</tr>
<tr>
<td>Participation in EQA for viral load and DNA PCR testing</td>
<td>0/5</td>
<td>3/5 (60)</td>
</tr>
</tbody>
</table>

Because of the complexity of the government procurement systems for managing donor funds, procurement of laboratory reagents and equipment and payment of maintenance charges were greatly delayed. Furthermore, some countries lacked the funds to procure reagents and purchase service contracts for the laboratory equipment. Moreover, there was no provision for equipment maintenance or properly laid out procurement contracts (Figure 3). Due to the lack of reagents and/or poorly functioning equipment, laboratories experienced several service interruptions that negatively affected the accuracy of the diagnosis, and the monitoring of patients.

Figure 3. Percentage of countries with different clinical laboratory support systems in the Caribbean Region in 2008.
Finally, paper-based and computerised laboratory information systems were weak, with no standardised data collection and reporting tools in most of the laboratories in the region. This also affected the tracking of data within the laboratory systems as well as accurate reporting of information. Hence, the process of reporting laboratory data to donors and multilateral agencies became unnecessarily burdensome.

While several countries in this region have drafted working documents for an integrated laboratory network, none have developed a national laboratory strategic plan providing for a tiered integrated laboratory network with efficient service delivery across various health systems (Nkengasong et al. 2009, World Health Organization 2011a). Unfortunately, the working documents drafted did not adequately address or present laboratory priorities and goals that could easily guide partners on programme collaboration.

**PEPFAR laboratory achievements from 2009–2010**

The goal of the laboratory strengthening component in the Caribbean PEPFAR II framework was to increase the capacity of national governments and regional organisations to improve the quality and availability of diagnostic and monitoring services and systems for HIV, STIs and opportunistic infections. The key focus areas for the laboratory included: (1) sample referral systems, (2) infrastructure upgrades, (3) staff training and retention, (4) equipment procurement and laboratory reagent inventory and (5) implementation of scalable and sustainable quality systems leading to accreditation.

**Establishment of the Caribbean regional laboratory referral and hub systems**

Regional referral and hub systems were developed as a result of the current state of laboratory services and systems, and the critical need for well-planned and managed regional laboratory coordination. The rationale for establishing these systems is the small populations of the individual countries in the Caribbean region, and the limited human resources in most of them. This makes setting up complex and expensive testing technologies such as molecular testing not feasible, cost effective or sustainable. In most of the countries, particularly the smaller ones, there is only one laboratory providing testing services. Thus, an in-country tiered referral and back-up laboratory system would not be feasible.

In partnership with PAHO, Caribbean Common Market (CARICOM), PANCAP, CARPHA, the Clinton Health Access Initiative and key laboratory stakeholders within the region, the current PEPFAR Caribbean laboratory strengthening programme proposed a new strategy to create a regional reference laboratory (RRL) in Barbados to support OECS countries and sub-regional clinical laboratory hubs located in Jamaica, the Bahamas, Suriname and Trinidad and Tobago. Based on local and national transportation challenges and other logistic considerations, these hubs serve as back-up laboratories for each other and support other Caribbean countries (Figure 4). Currently, sample referral to the RRL and hubs occurs only for molecular testing (viral load, DNA PCR and HIV drug resistance), and EQA support that are not cost effective to be independently carried out in these countries. However, national reference laboratories of each country are being empowered to
perform assays such as CD4, clinical chemistry, haematology, and TB, Opportunistic Infections (OIs), STIs and HIV diagnosis. This system ensures that each country has full capability to provide timely, accurate and high-quality results to support current and future surveillance, detection, care and treatment activities.

Following the realignment of CAREC's laboratory activities, countries in the Caribbean region established CARPHA to oversee core functions, including public health laboratory network and referral systems. This institution is not yet functional as the governments are still addressing issues related to location, staffing and portfolio definition. In accordance with PEPFAR II’s vision of working with governments and regional entities to strengthen their health systems and ensure country ownership, the current regional referral and back-up laboratory systems is in alignment with both the Caribbean Regional Strategic Framework on HIV/AIDS (2008–2012 PANCAP), and the vision of CARPHA. As such, it is anticipated that once the CARPHA structure becomes functional, it will take over, continue and sustain the functions of this system.

**Ladymeade Reference Unit (LRU) laboratory accreditation**

The Caribbean-led regional laboratory strategies, with technical and financial support from the Caribbean Community (CARICOM) and PAHO/CAREC, collaborated with several organisations, including the Caribbean Regional Organization for Standards and Quality /Caribbean Laboratory Accreditation Services, the Caribbean Med Lab Foundation, and other laboratory quality oriented institutions to train over 1000 laboratory personnel in the region on the International Standard Organization 15,189 QMS. This initiative created more awareness among laboratory staff in the region; however, the cumbersome nature of the international accreditation processes and the lack of advocacy from policy-makers were major challenges to implementing QMS and moving these laboratories toward accreditation.
There is evidence to show that careful and well-planned coordinated efforts between host governments and donor institutions have led to tremendous improvement in overall health systems including enhanced laboratory capacity (Abimiku 2009). The PEPFAR II Caribbean Regional Laboratory Strengthening Programme recognised the urgent need to support efforts to accredit one public laboratory, demonstrate best practices and encourage other laboratories to engage in this process. In October 2009, a joint effort between PEPFAR and the government of Barbados led to the accreditation of the LRU laboratory by the College of American Pathologists (Table 1). Key to the accreditation of the LRU laboratory was effective laboratory management with a designated quality assurance officer, motivated laboratory staff and, most importantly, buy-in from the Minister of Health of Barbados. Moreover, the laboratory received additional technical support from Centers for Disease Control and Prevention that included: (1) training on preparing a laboratory for accreditation that included biosafety and biosecurity, (2) provision of laboratory standard operating procedures templates, (3) assistance in pre-assessment internal audit and recommendations and (4) assistance in resolving citations noted during the College of American Pathologists assessment visit.

The excellent collaboration between the national government and a regional partner clearly demonstrates the importance of open dialogue, advocacy and shared responsibilities for effective programme implementation and success. This has completely reshaped regional thinking about accreditation of public laboratories and has stimulated increasing interest from several public laboratories to engage in the accreditation process. Accreditation is the only benchmark that assesses laboratories in accordance with recognised international standards, providing external validation that assures clients that laboratory services are accurate, traceable and reproducible.

Adoption of a step-wise process for implementing QMSs and accreditation

Many laboratory managers in the region have attributed the lack of laboratory staff retention, inadequate support from policy-makers and, most importantly, cumbersome ISO 15189 standards as the reason for not achieving laboratory accreditation. Guided by the newly developed World Health Organization-African Region step-wise accreditation scheme (Gershy-Damet et al. 2010) and the Thailand and Argentine accreditation processes (Mazziotta 2009, Joint WHO-CDC Conference 2011), the PEPFAR II Caribbean Regional Laboratory Strengthening Programme has worked with partners such as PAHO, the Clinton Health Access Initiative and representatives from the government and the private sector to assist the region in adopting the step-wise process for implementing QMS for accreditation. As a result of this initiative, a strategic framework document to guide the implementation of the process is currently being developed.

The concept of the step-wise process is to provide resource-limited laboratories with the opportunity for continuous improvement of quality systems (Assefa et al. 2009). Through this method, laboratory services and systems are strengthened over time and a continuous learning process is established. Moreover, laboratory personnel improve their skills, are engaged in the participatory approach, and ultimately own the entire process. To support the accreditation process, the PEPFAR II laboratory TWG has identified key components such as the role of international
partners and key stakeholders, standards and assessment tools, assessors and assessor training programmes, equipment calibration and biosafety, laboratory management and mentoring training, and proficiency testing programmes that will be integrated for a holistic approach to implementing sustainable QMSs leading to accreditation.

It is expected that by implementing the step-wise process, countries in the Caribbean region will be able to meet the requirements of their national laboratory standards as well as aspiring to meet international standards for accreditation as recommended by the WHO and CDC (Joint WHO-CDC Conference 2011).

**In-country HIV serology testing and confirmation**

One great challenge faced by countries in the region has been to carry out evaluations of HIV diagnostic test kits in order to determine national HIV testing algorithms. Because of low HIV prevalence and small populations within the region, it is challenging to collect the required amount of samples for HIV test kit evaluation, and to develop national testing algorithms as recommended by the WHO (WHO 2011b). International organisations such as the WHO, CDC-US Agency for International Development and US-Food and Drug Administration have evaluated and documented sensitivities, specificities and other selection guidelines for the use of HIV rapid test kits, including peculiarities of resources-limited settings (WHO 2011b, Office of HIV/AIDS 2010). These evaluations involved samples obtained globally with different genetic subtypes and recombinant viruses to ensure their performance in various regions of the world. The PEPFAR II Caribbean Regional Laboratory Strengthening programme used this information in guiding countries to select and validate test kits in-country as well as for proposed national HIV testing algorithms. This has also provided opportunities for additional training of staff and competency assessment and certification with task shifting that allows non-laboratorians to be involved in the testing process. Currently, there is confirmatory diagnosis of HIV in all 12 countries with reduced turnaround time which occurred in only about 50% of the countries, in 2008 (Table 1). Countries are now committed and engaged with the PEPFAR II HIV Prevention working group to develop voluntary counselling and testing sites and to roll out HIV rapid testing, especially among the most at risk populations, which until now has been a huge challenge in the region.

**Molecular testing capacity**

Prior to the PEPFAR II intervention, there was no laboratory in the region capable of carrying out DNA PCR testing to support EID. All DBS samples for EID were subsequently shipped to South Africa for testing with support from the Clinton Health Access Initiative. In collaboration with the Clinton Health Access Initiative and Roche Diagnostics as a public-private partnership, the PEPFAR II Caribbean Regional Laboratory Strengthening programme set up DNA PCR testing platforms in Jamaica and Barbados. Laboratory staffs from these countries were further trained on this technique. Moreover, the molecular testing laboratory in Suriname validated an in-house technique for EID using characterised DBS panels from CDC. These laboratories are currently participating successfully in the proficiency testing programme run by CDC. Through the networks set-up within the regional
laboratory referral and back-up systems (Figure 4), laboratories are currently carrying out testing for EID, and DBS specimens are no longer shipped to South Africa for testing. This has resulted in significant decreases in cost and turnaround time (Table 1).

Prior to PEPFAR II intervention, samples for HIV drug resistance testing from all 12 countries in the region were shipped to Puerto Rico and Martinique for testing. The current PEPFAR proposed regional laboratory referral and hub system includes setting up two HIV drug resistance genotyping platforms and training of laboratory staff in both Barbados and Jamaica (Table 1). Since 2006, the PAHO/WHO office in the region has been working with countries to implement HIV drug resistance prevention strategies focusing primarily on early warning indicators. With the establishment of the HIV drug resistance genotypic platforms in these two countries, the region has agreed to review and create a broader network incorporating both surveillance and clinical laboratory monitoring aspects into this activity. Availability of these platforms will assist countries in quickly generating data on the presence and pattern of HIV drug resistance, and will enable clinicians to make firm and early decisions, particularly on patients failing antiretroviral therapy.

Training
Retention of laboratory staff is a major challenge in the region due to low salaries and lack of career development opportunities. There is an urgent need to strengthen human capacity through technical assistance, recruitment of permanent staff and training in specialised areas such as good clinical laboratory practice, quality assurance and quality control and general laboratory safety. The PEPFAR Caribbean Regional Programme, through its Health Systems Strengthening Technical Working Group, has been involved in several regional and international trainings to enhance staff capability in implementing quality systems and improving the quality of test results being released for HIV prevention, surveillance and overall patient care practices. These include training for TB diagnosis and quality control, DNA and RNA PCR, HIV drug resistance testing, biosafety and biosecurity and national laboratory strategic plan development. PEPFAR II has recruited key laboratory staff, particularly managers and quality assurance coordinators for several laboratories, to ensure effective and timely implementation of QMS. Career development through well-oriented and evidence-based training will lead to effective workforce development, institutional strengthening, and ultimately staff retention, which has been a tremendous challenge in the Caribbean region as described in other regions (Mukanga et al. 2010). This has the potential of improvement and long-term sustainability of current health systems as envisioned by the PEPFAR II.

Strengthening HIV/AIDS services and systems as integrated tools for multiple disease management
The second five years of PEPFAR (PEPFAR II) plans to use current HIV/AIDS resources to strengthen overall weak health systems. PEPFAR-supported laboratory efforts have benefited other disease control efforts. For example, H1N1 PCR testing was easily incorporated into the HIV laboratory in Barbados, supported by PEPFAR funding. This laboratory serves now as the referral laboratory for
pandemic influenza and other emerging infections. Contrary to current misconceptions that HIV/AIDS focused funds have weakened other health services (England 2007, Marshall et al. 2009, McCoy et al. 2009), countries should take advantage of current in-country resources and develop programmes that will strengthen the entire health sector.

Conclusions and recommendations
The Caribbean Regional PEPFAR II Programme has established a Partnership Framework with national governments and regional partners with the vision of strengthening the entire health system to confront the current HIV/AIDS pandemic. Significant progress has been made in strengthening laboratory services and systems within the first year of implementation of this initiative. Continuous collaboration and a holistic approach will be necessary to guarantee long-term sustainability and eventual country and regional ownership of HIV/AIDS programmes as well as overall integrated disease spectrums across the region. Moreover, regional coordination, appropriate networking, consultation, dialogue and understanding will be necessary among countries in the Caribbean region to ensure effective use of current donor funds.

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References


