STRENGTHENING OF MEDICAL LABORATORY SERVICES IN THE CARIBBEAN

END OF PROJECT REPORT

Project Implementation Unit

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EDF VIII
ABBREVIATIONS AND ACCRONYMS

CAREC Caribbean Epidemiology Center
CARICOM Caribbean Community
CARIFORUM Caribbean Forum
CASMET Caribbean Association of Medical Technologists
CDC US Centers for Disease Control and Prevention
CHRC Caribbean Health Research Council
CIDA Canadian International Development Agency
CMC CAREC Member Countries
CMO Chief Medical Officer
CPA Clinical Pathology Association (UK) Ltd
CPHA Canadian Public Health Association
CRIP Caribbean Regional Indicative Programme
CROSQ CARICOM’s Regional Office for Standards & Quality
DFID United Kingdom Division for International Development
DRAO Deputy Regional Authorizing Officer
EDF European Development Fund
EU European Union
IAC Insurance Association of the Caribbean
IAAC Inter-American Accreditation Corporation
ISO International Standard
IS Information System
JEC Joint Executive Committee
JICA Japanese International Cooperation Agency
MLT Medical Laboratory Technologist
NCCLS National Commission for Clinical Laboratory Standards (USA)
NGO Non-governmental organisation
OCT Overseas Countries and Territories
OECS Organisation of Eastern Caribbean Countries
PAHO Pan-American Health Organization
PMU Project Management Unit
PS Permanent Secretary
PT Proficiency Testing
QA Quality Assurance
SPSTI Special Programme on Sexually Transmitted Infections
SWEDAC Swedish Board for Accreditation and Conformity Assessment
TTBS Trinidad and Tobago, Trinidad and Tobago Bureau of Standards
TTLAS Trinidad and Tobago Laboratory Accreditation Scheme
UKOT United Kingdom Overseas Territories
UWI University of the West Indies
VCT Voluntary Counseling and Testing
WHO World Health Organization
**FINANCIAL & TECHNICAL GLOSSARY**

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<td>Budget Line</td>
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<td>FA</td>
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<td>Objectively Verifiable Indicators</td>
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1. The Project

1.1 Context

Health laboratories in large measure, underpin the success of disease control, elimination and prevention efforts, often being the first site of detection and confirmation of disease outbreaks. However, the quality of both public and private sector laboratory output varies widely and no regional mechanism existed before this project, for standardizing, monitoring and controlling the quality of medical laboratory output. Delays in the detection and investigation of outbreaks have led to the loss of millions of dollars in cancelled visitor arrivals and increased expenditures on local health services. Additionally, the failure to provide accurate and early diagnosis of high-impact diseases such as cancer, AIDS and diabetes has often resulted in preventable loss of life.

On the wider front, this project supported developments in trade, tourism and economic growth within participating countries. The negative impact of diseases on public well-being and on tourism markets in the Caribbean has reinforced the recognition that disease prevention and control are critical to sustainable development in this region. Without a doubt, reduction in disease outbreaks that threaten personal health and the tourism industry, a major source of economic growth, employment and foreign currency, is dependent on strong and viable health systems. Over the past three decades, the tourism industry has become an increasingly important part of the diversification strategy of Caribbean economies and represented an overall turnover of some $20 billion US for CAREC member countries in 2000. Revenues from tourism often represent a significant percentage of GNPs – from as high as 75% in Anguilla to 25% in Jamaica (Source: Caribbean Tourism Organisation (CTO)).

The project was developed in the context of the growing realisation in the Caribbean region that medical laboratory error had reached unacceptably high levels. Such error undermines the quality of patient management, epidemiological surveillance and public health interventions. The Caribbean Epidemiology Centre (CAREC) was mandated by Caribbean countries to play a lead role in the reform of medical laboratories within the region.

CAREC used operational research to inform and promote appropriate laboratory policies and strategies, to encourage governments to allocate adequate resources and introduce new systems and to train laboratory managers on laboratory service quality assurance (QA) methods\(^1\) both within the public and private sectors. CAREC’s advocacy efforts have convinced governments to initiate the reform of both public and private laboratories within a wider health sector reform framework.

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\(^1\) QA covers all aspects of laboratory activities: policy and programme objectives, confidentiality of patient data, lab design, safety features, personnel management, procurement, equipment calibration & maintenance, standard operating procedures, method selection & evaluation, documentation and processing of testing results, reference standards, intra- and inter-lab testing programmes & results, control of samples and records, internal audits, reports to management, corrective action, formats (methods, reports, certificates etc), programme revision & update, and financial management.
The range of problems varied between countries in the CARIFORUM region. All countries accepted that their laboratory networks were in need of improvement but some of the countries were more advanced than others in reforming them. In addition, the range of problems faced by public laboratories was different from those faced by private laboratories. The main problems faced by medical laboratories in the region and in varying degrees were:

**Legislation and Accreditation**
- Registration of laboratory staff and facilities as well as regulatory legislation, standards, and the accreditation of medical laboratories and laboratory staff were non-existent.

**Human Resource Development**
- The training of staff of public and private laboratories in all aspects of medical laboratory QA was in need of review and upgrading.
- The working environment (in terms of human resource management, physical environment and the availability of the tools of the trade) of public laboratories did not always facilitate high standards of professional work. Hence the morale of public laboratory staff about the importance of their work was low. In addition, staff commitment to quality standards and services varied across laboratories.

**Laboratory Management**
- Skills in laboratory and quality management were not evident in many laboratories.
- In public laboratories there were regular shortages of reagents and the maintenance of equipment and air-conditioners.
- The rate of use of quality control (QC) checks and proficiency testing in laboratories varied but in general failed to meet the demands of best practice.
- Safety standards were poor.
- In public laboratories the time taken to produce laboratory results was often too long to adequately meet patient management requirements.
- There was insufficient laboratory strategic planning and implementation of Quality Assurance programmes.
- Resource utilization in laboratories was frequently poor.

**Regional Coordination**
- Laboratory information systems and their linkage with epidemiological services were either non-existent or incomplete.
- There was absence of laboratory networks facilitating the sharing of expertise, best practices, services and information.
Operational Research

- There was a lack of regional-based model-solutions based on applied and operational research

The project also addressed the Caribbean Co-operation in Health (CCH) II targets for Health Systems improvement and the Caribbean Single Market and Economy objectives for harmonizing standards, accreditation and training to facilitate free movement of goods, services and professionals within the region.

It was envisaged that the project would result in the establishment of standards for medical laboratories and an accreditation mechanism that would monitor the implementation and maintenance of standards, thus providing support for health sector reform initiatives. The project also addressed the improvements in training curricula and human resource capacity to ensure that standards could be met and maintained. It sought to improve the laboratory support for disease surveillance and control, thus increasing the capacity of countries to respond to public health emergencies and to meet the requirements of the revised International Health Regulations which came into effect in January 2005.

The primary beneficiaries of this project were the following:

- Ministries of Health
  
  **Benefits:** The upgrading of skills among laboratory staff and managers within both public and private sector through the training provided by the project. In addition, Ministries of Health gained through improvements in planning and organisation of their laboratory services at a national level and now have agreed standards for medical laboratories which, with their co-operation in enacting the model legislation provided by the project, can provide a mechanism for registering and regulating medical laboratories.

- Medical technologists, Laboratory Managers, Laboratory Medical Specialists (e.g. Pathologists, Haematologists, etc.), Medical Technologist Associations
  
  **Benefits:** Gained from the upgrading of skills in quality management and the institution of standards and upgrading the professional status of medical technologists in the region.

- Health care providers, patients, Medical Associations, Insurance companies
  
  **Benefits:** Better quality of laboratory services provided to support care and management and disease prevention and control; and now have a method for determining laboratories that meet quality standards through licensing and accreditation
• Standards Organisations (national and regional)
  **Benefits:** Have collaborated in adopting standards, developing guidance documents and mechanisms for monitoring of medical laboratory quality

• Medical technologist training institutions
  **Benefits:** Upgrading and standardizing of their curricula to meet regional and international standards of practice.

The 15 participating CARIFORUM countries (the beneficiaries) were Antigua and Barbuda, the Bahamas, Barbados, Belize, Dominica, Dominican Republic, Grenada, Guyana, Haiti, Jamaica, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Suriname and Trinidad and Tobago.

1.2 **Project Description**

1.2.1 **Project Goal and Purpose**

The overall goal of the project was to improve national and regional medical laboratory information in CARIFORUM countries, resulting in improved patient management, disease prevention and control. The higher-level objective was to improve the health status of Caribbean populations.

The project purpose was that improved management of, and co-ordination between, public and private laboratories in the CARIFORUM region leads to increased availability of high quality laboratory information.

The principal activities were training of existing staff in laboratory management and quality assurance, training of laboratory and quality managers to improve the management of laboratory services, inclusion of these aspects within curricula of training institutions, development of standards and a regional accreditation system for medical laboratories, improvement of laboratory information systems, improvement of co-ordination of laboratory services at the national level, and conduct of operational research in aspects of laboratory support to disease prevention and control initiatives.

**Expected Results**

The project results were:

**Legislation and accreditation** (output 1)

Regional medical laboratory standards and accreditation mechanism and national legislation and registration scheme established;

**Human resource development** (output 2)
Training capacity at the national and regional levels in the field of medical laboratory QA enhanced;

Public and private sector laboratory staff trained in medical laboratory QA in the 15 CARIFORUM countries;

**Laboratory management (output 3)**

Public and private laboratory management improved through implementation of the Quality Assurance Programme;

**Regional co-ordination (output 4)**

Greater regional co-ordination and integration through the establishment of laboratory networks to facilitate sharing of expertise, services and information;

**Operational research (output 5)**

Operational research findings utilised and influencing laboratory management and public health policy, decision-making, and action.

2. Major Achievements

**2.1 Legislation and Accreditation**

At the start of this project, with respect to standards, legislation and accreditation, there was no agreed or common standard for medical laboratory services within the region. Furthermore, the majority of countries had no requirement for registration of laboratories nor legislation requiring the licensing of laboratories. Sixty-eight percent (68%) of laboratories participating in a 2003 survey conducted by the project responded that there were no regulations for control of laboratory services within the 23 countries surveyed and 75% indicated that there was no requirement for registration of laboratories. There was also no regional mechanism for accreditation of medical laboratories.

**Achievements of Component**

The overall goal of the **legislation and accreditation** component was to establish regional medical laboratory standards and an **accreditation** mechanism and national legislation and registration schemes.

The strategy outlined in the project financing agreement to accomplish the establishment of a regional medical laboratory standards and accreditation mechanism and national legislation and registration schemes, was that the project would assist the CARICOM Regional Organisation for Standards and Quality (CROSQ) in collaboration with National Bureaux of Standards to establish a regional accreditation and monitoring body for
medical laboratory Quality Assurance. On-going work in regulatory legislation in the region would generate a regional model for national registration and control of laboratory practices.

The major outputs of this project component have therefore been:

- Agreement on a common standard – ISO 15189 - for medical laboratories within the region. The project has developed guidance documents in English, French, Spanish and Dutch to assist laboratories with the implementation of the standard.
- Development of model legislation for registration and licensing of laboratories.
- Development of an accreditation mechanism to facilitate accreditation of laboratories within the region. The Caribbean Laboratory Accreditation Scheme (CLAS) will coordinate the regional development of accreditation of laboratories, in a manner that leverages regional capacity and harmonises processes and procedures. CLAS was proposed by the Project and approved by the CROSQ Council.
- Advocacy for implementation of the standard, legislation and accreditation through a marketing campaign to promote CLAS.
- A cadre of 50 persons was trained as Lead and/or Technical Assessors to support the CLAS Accreditation Scheme. National Accreditation Focal Points were also trained to serve countries without Accreditation Bodies in the development of the regional accreditation mechanism and at the national level, to serve as part of the monitoring system for medical laboratories.

2.2 Human Resource Development

Medical laboratory evaluations conducted by the Caribbean Epidemiology Centre (CAREC) as far back as the 1990s and repeated in 2003 in CAREC member countries, Haiti and the Dominican Republic, identified major gaps in laboratory operations in both the public and private medical laboratory sectors. Weak laboratory management, limited compliance with requirements of globally recognized laboratory standards and lack of efficient and effective laboratory quality management systems were identified. Assessments further pinpointed a lack of laboratory management skills, limited knowledge of the appropriate medical laboratory benchmarks and standards, limited understanding of laboratory quality management systems (QMS) and some resistance to changing inappropriate laboratory practices widely used by Caribbean medical laboratory staff for many years. A common gap was the lack of functioning networks at the national and regional levels.

In 2003, assessments of the curricula used by the training institutions in Project countries to prepare medical laboratory practitioners (MLTs) for the workplace also identified significant gaps. Curricula used by the different institutions varied considerably, were in the main content-based, were focused on knowledge gain and were not primarily focused on ensuring that technologists were competent to practice as required on entry
to the medical laboratory environment. Training in laboratory quality management systems was limited or nonexistent and neither faculty nor students were familiar with the global standard or benchmark for medical laboratory operations. Curricula therefore were not structured around nor took cognizance of the requirements with which graduating technologists would be expected to comply on entry to the workplace. Additionally, while the agreed benchmark for laboratory operations in the region, the ISO 15189:2003 standard for medical laboratories required MLTs to maintain competency through periodic upgrading, there was limited access, in the region, to continuing education opportunities.

**Achievements of Component**

The overall achievements of this component thus included:

- Increased laboratory management capacity through extensive training of laboratory managers and/or senior medical laboratory personnel. A 30-month blended training programme for 56 Laboratory and Quality Managers drawn from 21 countries in the region, was completed in 2006. Forty senior laboratory staff graduated and received a post-graduate certificate in Laboratory and Quality Management - jointly issued by Michener Institute in Canada and CAREC.
- Increased knowledge about laboratory quality management systems and the recognised benchmarks or standard for laboratory operations through training of laboratory staff. Over 250 laboratory staff in 9 countries were sensitized to laboratory quality management systems, the ISO 15189:2003 standard, and laboratory accreditation through on-site training workshops.
- Improved quality practices in medical laboratories through application of knowledge by laboratory staff as measured by in-country post-training assessments
- Increased collaboration among regional laboratory staff as evidenced by the networks established through the project’s interventions
- Development of a new harmonised performance or competency-based curriculum for MLT training in the region. This new curriculum will be piloted by four of the MLT training institutions in 2007. This revised curriculum is based on the Caribbean Regional Competency Profile (CRCP), expanded from seven competency areas to fourteen for basic medical technologist training, in agreement with curriculum officers from nine training institutions in 8 Project countries that currently prepare medical laboratory technologists (MLTs) for the workplace. The CRCP has been translated into French, Spanish and Dutch.
- Improved capacity in the Caribbean for the provision of distance and continuing education for MLTs. Three competency-based pilot courses have been developed for MLTs to be delivered through a distance modality by a joint team involving key persons from Barbados Community College; UWIDEC and University of Technology, Jamaica; Michener University, Canada and CAREC in collaboration with the Caribbean Knowledge Learning Network (CKLN) in 2007.
- Videos, paper-based, CD-ROM and DVD materials containing training information on laboratory quality management systems, standards, and
accreditation were produced and distributed. A web-based programme was completed and will be displayed on the CAREC website and the Project’s web portal. A multimedia website was developed as a repository for training material that will be accessed by regional MLT trainers. The 8-module “How-To” manuals on laboratory management were translated into French, Spanish and Dutch.

2.3 Laboratory Management

In this component, the implementation of quality management systems, establishment of quality targets according to good laboratory practice and/or the requirements of a recognised laboratory standard, were given priority. Project targets included laboratory equipment maintenance and procurement, quality management systems and microbiology diagnostic capacity. Advocating for the designation of a focal point person to oversee and lead each laboratory’s quality effort was also a key strategy. Very critical also was the strategy to involve as wide a multisectoral stakeholder group as was feasible at the national level. The Project strongly advised that National Laboratory Advisory Committees should be appointed and strategic plans be developed to guide and support laboratory service improvements.

Achievements of Component

Some of the specific results achieved by this component were:

- An agreed procurement model for the region that
  - is feasible and compatible with national/regional policies structures and realities
  - facilitates the timely and efficient acquisition of equipment and supplies
  - optimizes administrative, technical and operational efficiency of laboratories

- A maintenance system that
  - ensures the upkeep of medical laboratory equipment
  - facilitates the availability of an adequate number of trained and competent biomedical technicians/engineers
  - improves the skills of laboratory staff to maintain laboratory equipment

A professional group of biomedical engineers/technicians, also known as BiPAC (Biomedical Professional Association of the Caribbean) was formed to build a regional network for maintaining equipment as well as forming linkages with health professionals who use their expertise. The group has developed their constitution, mission statement, logo, set the level of membership and relevant fees.
• An interactive data base that
  o allows for monitoring of key quality performance indicators within the laboratory
  o facilitates the assessment of the effectiveness of interventions
  o is available to and used by relevant stakeholders

A trained group of health care providers competent in the use of the essential elements of a Quality System that improves the outputs of the medical laboratories in the region.

Several cytoscreeners across the region were trained from eleven cytology laboratories across the region. The project also initiated a regional cytology programme, using regional material. A pilot of this programme using glass and digital slide images was conducted in Jamaica.

The Project also initiated the:

1. Establishment of Quality Managers in participating national laboratories

2. Establishment of National Laboratory Advisory Committees (NLAC) in 20 of the 23 participating countries. Strategic Plans (facilitated by the project) for improved co-ordination and delivery of services by medical and public health laboratories were developed in 12 of the 15 participating CARIFORUM countries and 3 of the 7 OCTs.

The strategies and delivery mechanisms for achieving these results included the participation of the use of advisory committees; regional and international consultants; visits to countries for training of relevant persons; advocacy to decision makers at available fora; gathering of data and dissemination of information; and provision of tools and services to empower laboratory staff, biomedical engineers/technicians, physicians, nurses, pharmacists, procurement officers, and other stakeholders.

2.3.1 Microbiology

The overall goals of the Microbiology component were to:

• Improve operations of regional and national microbiology operations to provide high quality laboratory information leading to improved patient management and treatment.

• Provide guidelines to countries to assist in the determination of the level of service required by the region, and the specific countries within the region.


**Achievements of Component**

The interventions conducted under this component focused on:

- Assessment of the current situation within microbiology laboratories within the region
- Development of standard methods to guide improved functioning of these laboratories.

Data collected during the course of the Project indicated that methodologies being used within the Caribbean region were outdated, varied from laboratory to laboratory, were wasteful in terms of resources and were likely to be producing incorrect results. This was manifested by the poor performance in the EQA (External Quality Assessment) scheme by all but a very few participating laboratories. In addition, audits of microbiology laboratories revealed that there was very little quality control of media, tests or reagents, and an inability to interpret results in the light of clinical data.

Existing training courses were focused on content rather than on competencies. This lack of appropriate initial and ongoing training, coupled with poor and/or little supervision, and lack of accountability and support led to the poor situation reflected in the microbiology laboratories of the Caribbean region.

In order to harmonize microbiology methods within the region, to ensure best practice and the level of service required from each laboratory, to be cost-effective, and to give a high quality, accurate and appropriate service, the Project initiated a Standard Methods Drafting Group. This regional group achieved the following:

- Developed 17 Microbiology Technical Standard Methods which cover the most commonly used methods, critical methods, and the most recent methods for detecting emerging antibiotic resistance in micro-organisms.
- Developed 4 Microbiology Standard Methods to support the 17 technical methods. These support methods include:
  - Safety in the Microbiology Department
  - Media and Media Quality Control
  - Test and Reagent Quality Control
  - Propagation and Maintenance of Quality Control Organisms

A framework to guide the levels of microbiology service at national and regional levels was also developed and is scheduled for discussion at the regional meeting of Laboratory Directors in 2007.

**2.4 Regional Coordination**

The overall goal of the *regional co-ordination* component was to improve regional co-ordination and integration of Caribbean laboratories through the establishment of laboratory networks to facilitate sharing of expertise, services and information.
The strategies outlined in the financing agreement for achieving this component included a wide range of initiatives. Regional coordination and integration were intended to be strengthened through the development of databases on all aspects of laboratory services, development of information management systems to support improved networking and the sharing of timely information on new developments in laboratory science, development of an expanded regional proficiency testing programme, and establishing a network of regional reference nodes.

**Achievements of Component**

The CAREC-CNPHI Collaboration

Through collaboration with The Canadian Network for Public Health Intelligence (CNPHI), accounts have been created for national Laboratory Directors, Epidemiologists, and Information Management teams. The collaboration centres for these groups have been created and the process registration continues. CNPHI tools include on-line meeting organisers, discussion forum and contacts/ distribution lists, as well as hyperlink and document management tools. The platform was designed for managing public health-related interactions, and participation by CAREC stakeholders facilitates interaction with a wider stakeholder community in Public health.

The SMLS Portal

This facility supports the institutional memory of the SMLS Project, the Laboratory Infrastructure database and access to accreditation and continuing education resources. It also presents an orientation to the Caribbean region and countries from a health perspective, and a conceptual framework for the Caribbean Integrated Health Network, providing detailed orientation to its many components.

Data for Action interventions were a key strategy to improve the management of laboratory information. Subregional and in-country workshops were conducted to

- plan and implement with the laboratory and its stakeholders, the information management processes required to collect the minimum data set in order to meet the objectives of public health surveillance and health situation analysis,
- plan and implement, within the laboratory, the information management processes required to consistently monitor turnaround times, customer satisfaction and quality control procedures
- map the examination process including pre- and post-analytical phases in the laboratory to facilitate optimization of the process in meeting the agreed information requirements, as well as to support the use of a software costing tool for laboratory investigations.

An assessment of the regional IT infrastructure in laboratories was conducted through a combination of laboratory visits and the administration of a questionnaire. The data were
Strengthening of Medical Laboratory Services in the Caribbean

compiled and analysed and showed that fewer than 30% of laboratories had any form of electronic information management systems, a significant proportion of the equipment in place was outdated or non-functional, and the majority of staff in laboratories was never exposed to any formal training in the use of computers. The outline of an implementation plan for the laboratory network was developed as well as a conceptual framework for an integrated health information network. A strategy for creating and accessible, affordable LIMS solution that would meet the complex needs of Caribbean Laboratories was developed and initiated.

Regional Proficiency Testing Programme

The External Quality Assessment (EQAS) programme at CAREC for the 23 countries involves acquisition and distribution of material and individual reports, as well as, receipt of summary reports. Due to restricted resources there is limited intervention to support the laboratories whose results are discordant. However interventions have been provided both by the CAREC laboratory and the SMLS project staff for Chemistry, Parasitology, Bacteriology, and Mycobacteriology. The opportunity was used during the Project to have physicians participate as facilitators to emphasize the impact laboratory reports have on patient diagnosis and care, as well as the cost of health care.

A Quality Assurance laboratory was built by the Project at CAREC to facilitate the expanded EQAS programme. Arrangements for provision of cost-effective panels for all aspects of laboratory services were initiated through discussions with Canadian CEQAL and Randox as potential partners with CAREC in future.

Regional Reference Nodes

The establishment of reference nodes, given the starting point and the many issues to be resolved in establishing these nodes has not been fully achieved during the course of this project. The Barbados Lady Meade Reference Laboratory is working towards accreditation and is one of the laboratories included under the Proinvest Project currently being developed in collaboration with that already existing EU-funded project. The Jamaica National Public Health Laboratory has also indicated interest in becoming a regional reference node and is actively working towards accreditation with support from their continuing SWEDAC Project and support already provided by this Project.

Discussions have also been initiated in Martinique with respect to potential participation of French OCTs who have expert capacity and may be interested in becoming part of the regional reference nodes. A possible project in collaboration with the French Technical Co-operation has being initiated.
Twinning Initiatives

Twinning programmes were established in two ways. Laboratories were encouraged to apply to the WHO twinning programme. Guyana has been officially ‘twinned’ with the American Society for Clinical Pathologists (ASCP) who will initiate a visit to the country in March, 2007. The Barbados Public Health Laboratory was twinned through the Association of Public Health Laboratories in the USA with a State Public Health Laboratory.

The LABS initiative was established by the Project to facilitate the continued functioning of regional and national laboratory networks. A ‘Buddy’ is a resource that a laboratory can count on for advice, guidance, encouragement, sharing of strategies, best practices, expertise and new learnings. The expectation is that the networked laboratories will foster the spirit of collaboration and common goals among their staff, have a better appreciation for the diversity of views and experiences across the region, be more self-confident and empowered, pool resources to offer more cost-effective service, building a momentum for high quality medical laboratory services over time and collectively driving medical laboratories in the Caribbean towards accreditation.

Figure 1: Diagrammatic representation of the ‘Buddy’ network
2.5 Operational Research

The Project used two strategies to encourage and foster a climate of evidence-based decision-making. The first was the requirement for the Project’s management trainees to conduct a simple gap analysis or error study targeting some aspect of their Quality Management System - proposing and implementing corrective action. The second was to develop a research agenda for the Project through collaboration and discussion with medical laboratory stakeholders.

A number of preliminary research questions were developed by the PIU for stakeholder consideration and studies addressing the following major questions were selected for further development and implementation.

1. The occurrence of error in Caribbean medical laboratories
2. Factors impacting on the recruitment and retention of medical technologists in the Caribbean
3. Post-training readiness of graduate MLTs for the workplace
4. Criteria used by clinicians for determining the quality of a laboratory service.
5. Manpower (workload) study
6. The Effect of Staff Attitudes on Quality in Microbiology Laboratories

The results of these studies have already been used in presentations at various fora and will be formally communicated to decision-makers to assist in policy decisions and published as appropriate.

Annex 1 provides a report against the project logframe with respect to deliverables under the project.

Annex 2 provides a matrix of project activities by country with respect to both regional and national implementation.

Annex 3 includes a summary report with respect to project impact in countries.

3. Project Implementation

The Project was approved on 24 May, 2000 under the 8th European Development Fund (EDF) Caribbean Regional Indicative Programme (CRIP). The Financing Agreement for the four-year project was signed by the Secretariat of the CARIFORUM and by the European Commission in August, 2000, based on a project proposal initially developed by CAREC.

CAREC is the implementing agency for the project and staff is hired with project funds for staffing a Project Implementation Unit (PIU) which has responsibility for technical execution of the project. Technical supervision and support for the project are provided...
through the CAREC. Finances for the execution of approved work programme activities and costs are managed by a CARIFORUM Project Management Unit (PMU). An imprest account is established for that purpose.

The Start-up Work Programme was signed between CAREC/PAHO and CARIFORUM in August 2001, marking the starting point of the project. The Project Manager was hired in August 2002 and the Work Programme for Year 1 officially started on November 1st, 2002.

*Work Programmes (WP):*

- Start-up WP Start date: October 1st, 2001. End date: October 31st, 2002

The project work programme is reviewed and approved annually by a Steering Committee. The Steering Committee Terms of Reference and membership are included as Annex 4 of this document. A system of Technical Advisory Committees is operated by the project to facilitate ownership and expert technical input (from within and external to the region) for decision-making on the various aspects of the project. The Project now had three Advisory Committees with working Sub-Committees as follows:

- Standards, Legislation and Accreditation Committee
  - Standards Advisory Sub-Committee
  - Legislation and Accreditation Advisory Sub-Committee;
- Human Resource Development Committee
  - Curriculum Advisory Sub-Committee
  - Distance Education Advisory Sub-Committee
- Laboratory Management, Systems Development and Research Committee
  - Procurement Advisory Sub-Committee
  - Maintenance Advisory Sub-Committee
  - Microbiology Advisory Sub-Committee
  - Microbiology Standard Methods Working Group
  - Research Advisory Sub-Committee
  - Laboratory Information Management Sub-Committee

This mechanism of Committees and Sub-Committees was approved by the Project Steering Committee and allowed for a wide involvement of key stakeholders, facilitated ownership of project outcomes, and were a valuable strategy for obtaining technical expertise, inputs and opinions in support of project implementation. They were also critical to ensuring that a realistic view of issues was presented, and relevant solutions
formulated and applied, that would support sustainability of project outcomes. The list of Advisory Committees and their Terms of Reference are included as Annex 5.

3.1 Administrative Arrangements – Major Highlights

Two Memoranda of Understanding were signed for the operation of this project. The first applied only to the start-up and first year of project implementation. The second MOU was signed in 2004 and is the MOU which governed the operation of the project from 2004 till the end of the project. A no-cost extension of the Project, based on the results and recommendation of the Mid-Term Review and requests from the Project Steering Committee and CARIFORUM, was approved by the EU Brussels in September 2005. The project was therefore been extended to March 2007.

During the Start-up WP and WP1, the project operated under the MOU derived from the EU/WHO agreement in which funds were managed within the PAHO financial system and PAHO rules applied. All staff hired for the project was engaged on CAREC contracts. At the end of WP1, the project was threatened with closure, due to differing financial requirements between PAHO and the EU with respect to the conduct of the audit. As a result, negotiations were again undertaken between PAHO, the EU and CARIFORUM to agree on new administrative and financial arrangements.

From WP 2, at the start of 2004, the project moved to a new mode of operation based on the new MOU agreed between PAHO and CARIFORUM. A CARIFORUM Unit (PMU), staffed by persons hired by CARIFORUM, was established to handle the finances of the project according to EDF rules, while the technical aspects of project execution remained under the supervision of the CAREC Director and were executed by CAREC staff (PIU).

The final change in administrative arrangements for the project arose for the final work programme, PE 4 which started in March 2006. Due to the difficulties being experienced in hiring additional training staff and a Monitoring and Evaluation Specialist, given the limitations of CAREC salary and benefit packages, and with the expectation that changes in CAREC compensation to meet the CARICOM comparator would be undertaken by CAREC in 2006, the technical staff of the Project were all moved to CARIFORUM contracts but still remained under the technical direction of the CAREC Director.

The major challenges with respect to the administrative arrangements related to the changes in financial rules, regulations and processes occasioned by the changes from PAHO to EDF rules and within the EDF system, to changes in personnel at the EU Delegations which resulted in variations in interpretation of EDF rules. In addition, the volume of transactions conducted by the project, along with the requirements under EDF rules created a major burden for both the PMU and the responsible EU Delegations.
In 2005, after operating for one year under EDF rules, and achieving justifications through the submission of financial reports only, on submission for reimbursement of January to May 2005 expenditures, the PMU was informed of the need to provide boarding passes for all travel that had occurred within the first 5 months of 2005. This resulted in a major delay in submission of justifications for WP3, as such documents were difficult in some cases, and impossible in others, to obtain after a delay of several months. The resulting attempts to find alternative solutions with EU Brussels were never concluded, and the outstanding justifications became a major impediment to the execution of PE4, when further advances on PE4 were held by the EU, in November 2006, pending the submission of all justifications for WP3, which were by then overdue. This resulted in major cashflow and thus implementation challenges towards the end of PE4.

Some of the justifications submitted under WP3 were queried by the EU. They are within the following three categories:

1. Justifications for travel for which boarding passes are missing. This was a particular problem with the first 5 months of WP3 as noted above.
2. Payments made on the basis of copies. These were payments facilitated by CAREC/PAHO, early in WP3 (in keeping with previous practice) when PAHO offices in countries where workshops were being conducted, provided per diem, and payments to hotels, etc. and retained the original invoices.
3. Use of laboratories and universities within North America for provision of proficiency testing material. This resulted from the use of suppliers who had an ongoing relationship with CAREC, for many years preceding the Project. Some of these suppliers had actually created products suitable for use by the Caribbean as a result of the ongoing relationship with CAREC. In the interest of providing comparable proficiency testing (PT) results that would allow for trend analysis over the years, and to ensure the sustainability of this programme when CAREC resumes the handling of the PT programme after the end of the Project, this was the most feasible alternative.

The European Delegation has confirmed that on review of all the documentation for WP 3 that there has been no mismanagement of funds. However substantial expenses have not been accepted because of the three reasons outlined above. The issue with respect to reimbursement for any payments not accepted by the EU will need to be handled with CARIFORUM and the Secretariat has already been alerted. The process will involve engagement of Brussels to make a final determination on the acceptance or rejection of the expenses and will take some time.

4. Sustainability

The major CARIFORUM project comes to an end in March, 2007. All funded activities ended in December, 2006. The project to support the British and Dutch OCTs ends in September 2007, with funded activities ending in June 2007. Arrangements have
already been made to transfer the critical technical and administrative staff that will be necessary to facilitate the completion of the OCT work programme as of January, 2007. However, the majority of the technical staff, except those required for closing the work programme, will not be employed beyond June, 2007.

A number of critical initiatives have begun under this project and will need to be continued to achieve long-term impact. Critical to the achievement of the vision for this project, institutional and country responsibilities will need to be sustained and strengthened, and funding opportunities must be sought to continue progress. Identified institutional and country responsibilities are listed below as well as suggested areas for funding.

4.1 Institutional Responsibilities:

a. CLAS and National Accreditation Focal Points and National Accreditation Bodies – mechanism for monitoring standards implementation and moving towards accreditation. CROSQ has accepted a lead role in continuing this aspect.

b. Standards Bureaux, CROSQ, CAREC – continue with standards adoption and adaptation in future

c. Distance education – continuing education – Medical Lab Technology (MLT) schools, CAREC, CASMET (Caribbean Association of Medical Technologists). The goal is to forge a joint collaborative mechanism for the development and delivery of MLT continuing education. Joint institutional mechanism does not currently exist in the region (issues of ownership/responsibility for final award etc.) Caribbean Knowledge Learning Network (CKLN) will pilot this intervention in 2007.

d. Curriculum changes in MLT schools – Implementation of the four year BSc curriculum. This is already underway at University of Technology (UTECH) in Jamaica, Barbados Community College (BCC) and University of Belize. CAREC should continue to explore, encourage, forge and/or support key international and regional partnerships in relation to the delivery of MLT courses. There also needs to be continued provision for the Laboratory and Quality Management Training post-graduate training programme, in collaboration with the MLT schools.

e. Microbiology follow up project – CAREC

f. Proficiency testing support – CAREC to undertake on fee for service basis

g. Information technology infrastructure and systems – CAREC to provide support for continuation.

h. CARICOM - needs to play a functional role in continued oversight of the strengthening/lab accreditation initiative

i. CAREC should continue to conduct and/or support operational research that informs the ongoing strengthening of medical laboratory management and operations (i.e. not just technical research).
Note:
At a recent meeting of Laboratory Directors, several recommendations were made for the continuation of activities of the Medical Laboratory Strengthening project, to be carried out through CAREC. Lab directors requested that CAREC examine mechanisms and seek resources for sustaining the gains made by the current project and addressing country needs for improved infrastructure. The following initiatives were suggested to be continued as core functions of CAREC:
- EQAS and information management
- Advocacy regionally and locally
- Development and evaluation of standard methods (Microbiology)
- Sustainability of distance learning

4.2 Country Responsibilities:

a. Adoption and enforcement of legislation for licensing of labs
b. Continued functioning of National Laboratory Advisory Committees and implementation of national laboratory strategic plans
c. Provision of resources to public laboratories for implementation of standards

4.3 Areas requiring additional funding for sustainability

In order to secure the future of the project gains, a number of areas will require funding. The following initiatives are already underway:

a. Capacity Building:
An informal approach has been made to CARIFORUM, under the umbrella of the 10th EDF to include within the Regional Indicative Programme, a human resource capacity building initiative. This initiative would support CAREC’s regional surveillance and epidemiology programs, which in turn, would build on and extend the impact of the SMLS project to include laboratory and epidemiology capacity building within the region under a contributory agreement with PAHO/CAREC.

b. Sustainability of the accreditation initiative: CLAS
A business plan has been developed for the operation of CLAS. This plan outlines the funding required for the next five years to support the CLAS Secretariat and to harmonize and build the regional accreditation initiative. For 2007, CROSQ has already initiated action to secure funding for CLAS for the first four years. The business plan has already been used to approach the German Metrology organization (PTB) and UNIDO for funding.

Furthermore, approaches have already been made to PROINVEST, an existing EDF-funded regional project (operating in Trinidad) to support 7 countries (Trinidad & Tobago, Barbados, Guyana, Dominican Republic, Jamaica, St. Lucia and The Bahamas) with technical assistance. Through consultancies, support is planned for selected labs (1-2 public and 7-10 private labs per country) to meet accreditation requirements over a
period of one year. The negotiations for this funding should be concluded within a short timeframe (3-6 months) and funding should be acquired on or before the end of the SMLS OCT project.

c. **External Quality Assessment (EQA)**
EQA should continue to reside within CAREC’s laboratory. However, resources are required to support the following:

1. Three staff positions: Programme Co-ordinator (a position already created at CAREC); Administrative Assistant; Technical Officer
2. Space – a laboratory is being constructed and equipped by the existing SMLS project
3. Ongoing costs of panel purchase, shipping, etc. (For national public laboratories this would amount to approximately $40,000 US annually)
4. Costs for additional labs – to be covered by fee for service
5. Communication and other overhead costs (to be assessed)

For 2007 (and possibly beyond) financing for panels, shipping and communication costs will be provided through CAREC’s HIV/AIDS PANCAP Project.

d. **Microbiology Development**
The development of the Microbiology component is a key core CAREC function which the project has undertaken and which will need to revert to the CAREC laboratory as the project comes to an end. In order to continue the development that has been undertaken in this area, the SMLS project is undertaking the development of a microbiology proposal. It is estimated that the proposal will require the following staff for implementation: a Technical Co-ordinator; Technical Officer; Administrative Assistant. It is important to bear in mind, that the SMLS project undertook the financing and functioning of the Microbiology Laboratory Advisor position (equivalent to Technical Co-ordinator listed above) which was previously within the CAREC laboratory. The project proposal includes estimates of the cost for continued functioning of this key area.

e. **Training & Curriculum Development**
1. Efforts to transform one of the management training modules - People Management - into a course that can be piloted by distance is important in making the entire programme accessible to regional laboratory managers. This pilot will be undertaken in collaboration with CKLN in 2007.
2. Creation of opportunities to access training tools, materials and information on multimedia or other types of websites and portals will support country efforts to provide ongoing training for laboratory staff.
3. Obtaining buy-in and readiness to accept and implement a performance-based curriculum is key to ensuring appropriate preparation of new MLT graduates and thus to changing the quality cultures in medical laboratories.
f. **Portals and Databases**

CAREC member countries have re-iterated the need for support from CAREC in the development, deployment and maintenance of ICT solutions for surveillance and health services delivery. The project has amassed a great deal of very useful and unique regional information relative to trained individuals, skill sets, areas of expertise, laboratory infrastructure, and quality management systems, etc. CAREC needs to identify a clear responsibility and structure for the management of portals and databases that will support the sustainability of these networks. CAREC should also encourage sharing of best practices and consistency of operations and practice among laboratories and laboratory stakeholders. CAREC’s ability to deploy tools towards improved internal and external collaborations requires the ability of the staff that supports the IT infrastructure to configure the hardware, software and operating systems as required. This requires CAREC to maintain a sub-network separate and apart from the PAHO network.


g. **Laboratory evaluations and support for QMS implementation**

The SMLS project has built extensive experience in the conduct of laboratory evaluations against the new ISO 15189 standards. CAREC should identify a responsibility and structure for the continued assistance to countries to develop and/or strengthen their Quality Management Systems. This could be done in collaboration with CLAS.

h. **Reference Nodes**

Criteria for regional reference nodes established by Lab Directors and Epidemiologists in 2004, was shared with Permanent Secretaries and Chief Medical Officers within Ministries of Health of participating countries, and countries with potential to provide services as regional reference nodes were surveyed and invited to indicate their interest. Discussions have been initiated in Martinique with respect to potential participation of French OCTs who have expert capacity and may be interested in becoming part of the regional reference nodes. A project with the French Technical Cooperation is being planned to support this area.

Recommendations for sustainability of the Project interventions were made by the Project’s fifth Steering Committee and are included as Annex 6 of this report.

Previous approaches for further funding included an approach to the Japanese (JICA), through CARICOM, for a project to strengthen laboratory infrastructure (equipment stock) and biomedical engineering services. This effort was not successful as the major JICA inputs within the region are through bilateral rather than regional mechanisms.
5. Limitations and Challenges

The major challenges in the implementation of this project were:

1. Co-ordination across a wide range of countries with different capacities, orientations, norms, cultures, languages. This required country strategies that were different (as reflected within strategic plans facilitated by the project), determination of approaches and interventions based on technical staff knowledge of individual country realities.

2. Ensuring required policy level support – policy level support was critical to ensuring the success of many of the project interventions. This required ongoing dialogue and information sharing with policy makers – at regional fora, in-country visits, correspondence, and through in-country advocates.

3. The major political, governance and other issues impacting on the Haitian interventions were a major challenge. The changes in Haiti during Project implementation included political unrest, changes in government, general instability resulting in difficulties with gaining approvals for travel for Project staff and country participants. Absorptive capacity was also a key issue – Haiti did not respond to several invitations to join in regional activities. Lack of a public health/national lab at the start of the project, and generally low level of MLT training were others. In addition, there were major losses of key personnel – the Director of the Laboratory Network, Dr. Yolette Vergin, a member of the Project’s Steering Committee and Laboratory and Quality Management Training Programme was killed at the end of 2003. Mr. Frantz LaMothe, Director of the National Public Health Lab, died in 2006. Despite these challenges, Haiti was one of the first countries to complete its strategic plan with support from the Project in 2003, and achieved one of the major objectives of that plan i.e. to develop a national public health lab (funding support provided by US Centers for Disease Control), during the course of the Project.

4. A major challenge in the execution has been in finding and ensuring an adequate pool of technical staff and consultants. Hiring of technical staff caused major delay in the start-up of key components of the project. For the first year of execution, only the Training Manager and Project Manager were on staff for the majority of the year. The Lab Technical Expert was hired two years into the project, despite wide advertising of all posts regionally and internationally. In hiring consultants, it was not always possible to obtain three offers during the required bidding process and this delayed the execution in a number of instances. This included instances in which the EU framework contracting procedure was utilized.

5. Changes in project management - from PAHO to EU and changes within EU were already outlined within the Project Implementation section. These resulted in challenges in ensuring adequate cash flow which resulted in delays in execution. In addition, these administrative arrangements along with changes in CAREC administration and Laboratory Management led to some loss of ownership of the Project by CAREC and hampered agreements on follow-up.
absorption of Project activities by CAREC, despite the fact that many of the Project functions were core to CAREC’s functions.

6. In the process of executing the legislation and accreditation component, it was important to design the process for licensing and its interface with the accreditation system, and to gain consensus on the model before attempting to draft the model legislation. However, the consensus on the model and interest of policy makers in adopting such legislation at the national level was achieved with commitment by several countries to adoption of legislation.

7. It is very important that the marketing component of the project, which has been delayed significantly by the tendering process, be executed and resources to accomplish this are being sourced through partnerships with interested stakeholders such as insurance companies.
6. Lessons Learnt – Critical Success Factors

There are a number of important lessons learnt and critical success factors that were important in the process of execution of this project. They include the following:

1. In order to ensure project success, the project’s philosophy was one of:
   o Inclusiveness, involvement & ownership
   o Joint decision-making
   o Partnership & networking
   o Facilitation
   o Advocacy
   o Communities and teams
   o Empowerment
   o Sustainability
   o One health service/One laboratory service
   o Public and private participation

Greater than 1000 stakeholders were engaged.

2. The most critical strategy utilized in all components was working with existing regional and national institutions which have the mandate for standards adoption, accreditation, medical technology training, etc. This approach ensured the involvement and ownership of such institutions in the execution and sustainability of the project gains.

3. Creation of in-country Champions through both the management training programme and training institution interventions was viewed as key to sustaining effective training and implementation efforts. During the Project, the Laboratory and Quality Management trainees, as part of the requirements of their training programme, conducted in-country training for other personnel in-country during their training programme. In this way, the reach of the Project’s training was facilitated well beyond the in-country training actually conducted by the Project itself.

4. Facilitating the creation of a collaborative and joint inter-institutional approach to production and delivery of MLT distance and continuing education courses is the basis for sustaining a reliable, cost-effective capacity within the region.

5. The success of the project was facilitated by the fact that it was implemented by CAREC, a regional institution that has traditional and strong co-operation history and linkages with countries in the region. Despite the challenges this posed to the administrative issues, the technical and political strength brought by CAREC’s involvement in the project is an important success factor, which would have been increased significantly had there been more acceptable solutions to the administrative issues. Any future arrangement for financing of CAREC projects or programmes with EC funding must include provision for much improved administrative arrangements.

6. The process of ensuring consensus requires the wide engagement of stakeholders and may take additional time but it greatly reduces the time for execution of the final agreement. The process of wide consultation at regional
level and in-country discussions has resulted in the agreement on the major outcomes of the project. The consensus process was facilitated at the regional level by the system of Advisory Committees utilized by the project to agree on adoption of policies, implementation strategies, etc.

7. The importance of support from policy and decision makers is critical. As policy makers change it is important to ensure that new persons are adequately briefed and brought on board to ensure continuing support.

8. The implementation of this project required in-country capacity for planning, monitoring and implementation, in an environment and culture where such systems are not traditional. This therefore required major interventions, at political, managerial and technical levels to encourage and ensure the development of such a culture. Interventions included the Laboratory and Quality Management training curriculum, strategic and action plan workshops and other interventions e.g. Data for Action Workshops, at national level, development of plans and implementation reports by participating countries and by various stakeholders involved with implementation. In this regard, National Laboratory Advisory Committees were critical components of the project implementation and sustainability strategy.

9. It was clear that countries which had most benefit from the project were those which
   o Established National Advisory Committee
   o Developed a Strategic Plan for laboratory services
   o Implemented a system for monitoring and following up on execution of the plan
   o Encouraged and facilitated active and wide stakeholder involvement
   o Ministry of Health provided active support
   o Maximum use was made of resources and interventions e.g. other donor funds
   o Personal commitment – proactive leadership especially from major stakeholders – Laboratory and Quality Management trainees

The overall success of the project was based on the following factors:
   a. Compelling vision – the project addressed a common regional goal
   b. Advocacy and partnerships to ensure support for vision
      • Regional (Council of Ministers, CARICOM, CROSQ, CARIFORUM, CAREC, CASMET)
      • National (Ministries of Health, Trade, Finance, Tourism), laboratory personnel (public and private), standards bureaus, training institutions, users/clients - (health care providers, general public, insurance companies, etc.), suppliers
      • Encouraging representation from insurance companies on both the Project’s Steering Committee and NLAC has been a strategy to sensitisise them to the importance of laboratory
standards. Further approaches have been made to foster support from this very influential stakeholder group and to collaborate in the conduct of research studies and marketing initiatives.

- Policy and legislative changes – standards adaptation/adopter, model legislation
- Training – leadership and management, technical training, curriculum changes, continuing education
- Supportive environment and structures – National Laboratory Advisory Committees (NLAC), Biomedical Professional Association of the Caribbean (BIPAC), etc.

The success of this project intervention was based on the collective work, passion and enthusiasm of a wide range of stakeholders throughout the region – stakeholders who were able to buy-in and see their role in supporting the vision of medical laboratories within the Caribbean aspiring to international standards and having systems and the required personnel and resources in place to achieve them.

7. Financial Report

The total budget set out in the Financing Agreement No 6296/REG between the Commission of European Communities and the Member States of the CARIFORUM is €9,755,000; €7,500,000 from EDF funds and €2,255,000 as countries’ counterpart contributions. Below is a summary table of the financial report of the Project.

**Statement of Expenditure & Commitments - Direct Labour Component as at January 31, 2007**

<table>
<thead>
<tr>
<th></th>
<th>Expenditure</th>
<th></th>
<th>% Utilisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actual</td>
<td>Budgeted</td>
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<td>Start up Work Programme</td>
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<td>Work Programme No 3</td>
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<td>Work Programme No 4</td>
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<tr>
<td>Amounts Decommitted to WP 2</td>
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Budgeted amounts do not take account of amounts decommitted at the end of the budgetary period but where budgets revisions have been approved during the budget period, the figures utilised are that of the last approved revision.

**Country Counterpart Contributions Reported as at January 31, 2007**

<table>
<thead>
<tr>
<th>Country</th>
<th>Reported Contribution</th>
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<tbody>
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<td>Antigua &amp; Barbuda</td>
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<td>Bahamas</td>
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<td>Belize</td>
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<td>Guyana</td>
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<td>St. Vincent &amp; the Grenadines</td>
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<td>Suriname</td>
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<td>Trinidad &amp; Tobago</td>
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<td>Total</td>
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## Projected Expenditures to Closure, March 31, 2007
as at January 31, 2007

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<tr>
<th>Expenditure by Outputs/Categories</th>
<th>SWP</th>
<th>WP1</th>
<th>WP 2</th>
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The above figures are inclusive of commitments and other expenditures projected to the end of the project.