The World Bank Regional Health Systems Strengthening TB and Laboratory Support Project:

Report of the Scoping and Identification Mission to Tanzania, April 6-11, 2009

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PREFACE

The World Bank is proposing a regional East Africa investment in laboratory
strengthening, especially as it relates to tuberculosis prevention and control, but to
include the possibility of crosscutting laboratory improvement. In order to initiate an
investigation into the feasibility of the involvement of Tanzania in this project, a mission
was organized and conducted April 6-11, 2009. The primary objectives of the mission
were to:

- Assess laboratory capacity and the main challenges or gaps in laboratory support;
- Identify key areas which might be supported under the project
- Identify policy and programmatic issues that need to be addressed
- Evaluate institutional capacities of prospective national and regional partners
- Look for opportunities to promote public-private partnerships
- Propose the next steps that would be required for Tanzania to participate in a
  regional project.

The mission team for this project consisted of:

- Miriam Schneidman, Senior Health Specialist, Africa Region, World Bank, team
  leader
- Emmanuel Malangalila, Senior Health Specialist, World Bank Country Office
- Robert Martin, Laboratory Science Officer, Coordinating Office for Global
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- Carlyn Collins, Pathologist Laboratory Advisor, Division of Laboratory Systems,
  CDC
- Kimberly McCarthy, Microbiologist, Division of TB Elimination, National Center
  for HIV, Hepatitis, Sexually-Transmitted Infections, and Tuberculosis Prevention,
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- Linda M. Parsons, Team Lead of Clinical and Opportunistic Infection Team,
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- Jeremiah Chakaya, Tuberculosis Specialist
- Francois Boillot, Consultant, Health Systems Specialist
INTRODUCTION

The World Bank, as a part of its global goal of strengthening health systems, has proposed a regional investment in East Africa to advance the capacity and capability of health laboratories so that they can provide the essential services needed to support the control of infectious diseases. Because of the growing problems with prevention and control of tuberculosis, exacerbated by the global AIDS epidemic and the emergence of multidrug-resistant organisms, this project has focused on examining laboratory issues related to TB control. However, laboratories serve broad public health and clinical needs; therefore this regional project would also look for opportunities to strengthen laboratories in a way that would ensure benefit to the overall health system.

Laboratories and the services they provide are clearly a vital link in the overall health system. Accurate laboratory testing is essential for disease diagnosis, for appropriate treatment and management of disease, and for public health programs including surveillance and prevention activities. However, in Africa laboratory services have often been a neglected part of the health care system. There is generally a severe underfunding of laboratories, resulting in poor infrastructure, inadequate or poor quality reagents, supplies, and equipment. Low salaries and lack of strong pre-service training programs have resulted in inadequate numbers of skilled staff.

Because of the essential nature of good quality laboratory services and the relative neglect of this area of the health care system in Africa, the World Bank regional project proposes to focus on these services. Specifically, the project aims to improve access, quality, and efficiency of TB diagnostic services using an integrated approach to laboratory strengthening.

An essential component of the World Bank project will be the close collaboration with many key partners who are already at work in East Africa, providing programs to strengthen laboratories. Working in partnership with these groups and organizations will allow the World Bank to take advantage of local knowledge and technical expertise, as well as look for opportunities for complementary support.

The initial approach for this regional project is to conduct missions in three countries – Kenya, Uganda, and Tanzania. This report, prepared by the Tanzania mission team, examines laboratory issues in Tanzania with the project objectives in mind. The report is based on talks with key persons in Tanzania, a set of visits to laboratories at the national and district levels, and a review of a number of earlier assessment visits carried out by the International Union Against Tuberculosis and Lung Disease, the World Health Organization, the American Society for Microbiology, and others.
Background - Tanzania

Tanzania remains one of the poorest countries in the world, although in recent years it has had considerable economic growth. Average life expectancy has, however, declined. In 2003, the total annual expenditure on health per person based on purchasing power parity was approximately $29 for Tanzania, compared with an average of $92 for Sub-Saharan Africa (WHO, World Health Report 2006). TB is among the major causes of morbidity and mortality, and much of the increase is due to the HIV/AIDS epidemic. TB case detection has been estimated at between 46-55%, in contrast to the WHO target of 70%. Multiple drug resistance is still low; statistics from an MDR survey performed in collaboration with WHO and IUATLD in 2007 suggest that the rate of MDR is 1.2% among new cases, and 3.1% among retreatment cases.

Tanzania has a country-wide response to TB control. Guidelines for diagnosis, treatment, and follow-up are consistent among the provinces on the mainland as well as in Zanzibar. While WHO considers Tanzania a low burden country for MDRTB, the country remains one of the 22 high-burden countries (#14) as designated by WHO. It should be noted that although this country is a low burden country for MDRTB, Tanzania remains at risk for an increase in MDRTB due to a lack of experience in the appropriate management of MDRTB patients which may increase the risk of transmission, inadequate first-line drug sensitivity testing due to inadequate physical laboratory infrastructure and personnel shortages. Tanzania is also at risk of spread of MDRTB from other areas in Africa; for example, frequent flights between Tanzania and South Africa, where MDRTB is more problematic, may increase the risk of transmission.
1. Structural and functional profile of the laboratory network

The laboratory network in Tanzania is organized under the Ministries of Health and Social Welfare (MOHSW) for Tanzania mainland and Zanzibar. The two Ministries of Health and Social Welfare are independent, but work in close cooperation to manage health matters for both the mainland and Zanzibar. The Ministries of Health respectively oversee laboratory services at referral and national levels while the ministries of Local Government oversee laboratory services at regional, district and health center levels.

Within the mainland MOHSW, the primary responsibility for laboratory oversight rests in the Diagnostic Services Section (DSS). The DSS is a part of the Hospital Services group, and is responsible to the Director of Hospital Services. The DSS has two sub-sections: Health Care Technical Services and Laboratory Services. Although the MOHSW only has direct oversight for national and referral hospitals, the DSS provides considerable support and assistance to laboratories at other levels. With support from the President’s Emergency Plan for AIDS Relief (PEPFAR) and with collaboration with CDC-Tanzania, the Laboratory Services group has programs for laboratory training, quality management systems implementation, laboratory information systems development. The Laboratory Services group has undertaken management of the National Health Laboratory Quality Assurance and Training Center (NHLQATC) in a new facility developed with PEPFAR funds.

The overall structure of the government laboratories, which provide both clinical and public health services, is as follows:

- A Central Pathology Laboratory (CPL) located at Muhimbili Hospital in Dar es Salaam. This laboratory serves as the National Reference Laboratory, and physically includes the Central Tuberculosis Reference Laboratory (CTRL).
- Five Zonal Referral Laboratories, all of which are hospital-associated. These include the CPL at Muhimbili Hospital, Bugando Medical Center, Kilimanjaro Christian Medical Center (KCMC), Mbeya Referral Hospital Laboratory, and MNazi Mmoja Hospital Referral Laboratory in Zanzibar. The new laboratory at Kibong’oto National TB Hospital will also serve as a referral laboratory.
- Each zone includes several Regional Hospital Laboratories, which form the next level in the network. There are 23 of these regional hospital laboratories.
- District Hospital Laboratories comprise the next level, and generally provide more basic laboratory services. There are 133 district laboratories located in mainland Tanzania.
- Health Centers, dispensaries, and specimen collection points are the most peripheral layer in the structure. Some large health centers have laboratories. Quick diagnostic procedures that do not require laboratory personnel are performed at dispensaries.
A department in the MOHSW, Central Medical Stores, is responsible for the procurement, storage, and distribution of medical supplies. This department purchases using tender processes, and provides areas for dispensing of supplies and reagents in several locations throughout the country.

MOHSW developed a five year national laboratory strategic plan to guide the laboratory infrastructure and capacity building activities through FY 2009. This was developed and completed in consultation with the National Tuberculosis and Leprosy Program and the Malaria Control Program which works closely with the USG Presidential Malaria Initiative Program. The 5 year strategic plan has incorporated laboratory activities for strengthening identification and quality assurance of opportunistic infections, malaria and tuberculosis.

TB Laboratory Network

Heading the national TB laboratory network is the Central Tuberculosis Reference Laboratory, which is physically located in the CPL at Muhimbili Hospital. This laboratory performs AFB smears, Lowenstein-Jenson cultures, and drug susceptibility testing (DST). Currently the only other laboratory in the country performing AFB cultures is Bugando Referral Hospital Laboratory. Although KCMC has in the past performed cultures, a recent loss of critical laboratory staff has made it impossible for this to continue. The Kibong’oto Hospital, which is the only national TB hospital, has recently upgraded its laboratory, and expects to be able to perform cultures as well as some molecular tests in the near future. In addition to these hospital laboratories, there are approximately 700 diagnostic centers in Tanzania that perform AFB smear microscopy.

National TB Reference Laboratory or CTRL

The CTRL is responsible for maintaining acid-fast bacilli (AFB) smear microscopy quality assurance, coordinating, training, conducting drug resistance surveillance, and conducting operational research.

The CTRL is located at MNH. It is managed by the MOHSW (NTLP) and the National Institute for Medical Research (NIMR). It is staffed by nine laboratory technologists (three for MOHSW, six for NIMR). It is the only public laboratory in the country conducting drug sensitivity testing (DST). The laboratory recently completed its first TB drug resistance survey (DRS) with WHO.

TB culture and DST are performed on relapse cases, smear positive return after default, treatment failures, and 25% of new smear positive cases. The laboratory staff estimate that they are seeing less than 50% of MDR TB cases in the country. Referred specimens are delivered by EMS, courier, or post office mail at ambient temperature. Transport routinely takes seven to fourteen days, although this was shorter during their drug resistance survey. Contamination rate is approximately 1.5%.
National TB Referral Hospital – Kibong’oto Hospital

The Kibong’oto hospital is the only national referral TB hospital. It is located in Arusha in northeastern Tanzania. This hospital was established in 1926 as a TB sanatorium under the direction of a British physician, the late Dr. Henry Norman Davies. It became a national TB referral hospital in October 1952. In 2006, the facility began TB/HIV care services, and there are plans to begin MDRTB clinic services starting late 2009 or in 2010. The hospital has 250 beds, solely for TB patients, and usually averages occupancy of 100-120 TB in-patients. Approximately 45% of these patients are TB/HIV co-infected. The hospital staff consists of 205 personnel; with four technologists dedicated to the mycobacteriology laboratory.

The hospital cares for two TB patient populations; those that are referred from other health care facilities and new TB patients. Patients are also seen for retreatment of TB. Sputum specimens are collected from these patients, referred to the laboratory, and if AFB+, the patients are admitted. Specimens are also received from neighboring health centers.

Kibong’oto evaluated a total of 2,911 suspects in 2008. Of the total number of TB suspects, 2,038 were new patients, 873 were follow up. The smear positivity rate reported for these groups is consistent with previously reported smear positivity rates; approximately 16% in the new cases, and 10% in the follow up cases. Similar to the findings at the CTRL, a significant percentage of patients submitted one specimen (spot collection), and did not submit the second.

According to the lead technologist in the TB laboratory, the workload is approximately 25-30 specimens per day. Previously, the laboratory provided culture services, and referred positive isolates to CTRL for DST. Currently, the laboratory is not able to offer culture services due to challenges with receiving reagents and supplies for media preparation.

An MDRTB complex has recently been constructed on the grounds of the hospital. This complex includes a ward (for isolation and recovery), a recreation area, and a BSLIII laboratory. Once the construction is complete, the laboratory will offer the following services: AFB smear, culture and DST (liquid and solid), and PCR. Capacity to perform DST is greatly needed in this region, as the laboratory reported a 4-6 month turnaround time for DST results when using the CTRL.
2. Testing processes – procedures used and equipment available, maintenance of equipment

**TB testing processes**

In the National TB Reference Laboratory, TB culture is performed using LJ and the modified Petroff method. The proportion method is employed for DST for first-line drugs. PNB and TCH are used for identification. LJ slopes are made on site by media staff – two technicians (junior/senior) on a six month rotation. Due to the labor involved with solid culture and the slow turnaround time, the CTRL is planning to implement TB liquid culture and DST using the BD MGIT 960. The CTRL would like to perform second-line DST and the Hain assay, as staff and facilities become sufficiently able to accommodate these procedures.

Second-line testing is performed by a WHO Supranational Reference Laboratory (SRL) in Antwerp, Belgium. The following challenges have been noted with this arrangement: (i) delays and costs in shipping isolates to Antwerp, and (ii) receiving timely results.

There are plans to expand the use of the BD MGIT 960 in Tanzania, so as to increase availability of TB culture. Other sites which plan to add this technology include Kibong’oto National TB Hospital Laboratory and Mbeya Referral Hospital Laboratory.

Throughout the country, case detection is primarily though AFB microscopy using Ziehl-Nielson brightfield microscopy. This is performed in approximately 700-750 diagnostic centers throughout the country. A few laboratories have fluorescent microscopes available for smear microscopy.

At present, case detection does not meet the WHO established target of 70%; currently, case detection is 46%. Most TB patients in Tanzania are AFB sputum smear (-), and approximately 50% of confirmed TB cases are co-infected with HIV. To address this challenge, Tanzania has adopted the WHO guidelines for diagnosing TB in HIV patients that are smear (-). In a recent assessment by IUAT, the laboratories visited were generally noted to be functioning well, with one staff person doing AFB microscopy per week on a rotation basis. Laboratory staff interviewed demonstrated knowledge of national guidelines, procedures and basic information on tuberculosis.

3. Quality and Accreditation

**TB Laboratory Quality Assurance**

The CTRL is currently responsible for quality assurance for Tanzania’s approximately 750 testing sites. A program that was being conducted by the CTRL for AFB microscopy EQA consisted of supervisory visits and blinded rechecking. In an assessment by IUAT in 2009, of all the laboratories visited, there was evidence of all positive slides and a subset of negative slides being kept until the supervisory visit. However, for the past twelve months there were no or very few visits done and even among those visited no performance reports were found on site. For example in 2006-7, only 50 out of 700
laboratories (7.1%) were visited. The CTRL has indicated that the program is being re-evaluated and a new system is being piloted. It is clear that there is insufficient staff at the CTRL to conduct the program as originally planned.

Discussions with the African Medical and Research Foundation (AMREF) revealed that for the past year this organization, working with the MOHSW, has been piloting an AFB proficiency testing scheme in which AFB slides are provided to laboratories for reading. The program is being conducted in East Africa and is managed from Nairobi. Approximately 20 Tanzania laboratories have participated in the pilot; no data was presented, but it was indicated that performance had been poor.

**General Laboratory Quality Assurance**

The Tanzania MOHSW has undertaken a major effort to improve laboratory performance in the past several years. The primary impetus for this effort has been the HIV/AIDS epidemic, and the need to develop laboratory support to meet the needs of prevention services as well as treatment and care. With PEPFAR support and the assistance of many partners, the MOHSW has begun implementation of quality management systems in the laboratories, and has begun work to provide EQA for basic testing.

A new facility that includes laboratories for training and for preparation of EQA material has been completed and equipped, supported with PEPFAR funds. This National Health Laboratory Quality Assurance and Training Center is just becoming operational, but has the potential to provide broad support for quality assurance procedures and for national EQA programs for many laboratory areas in the future. In FY09 the NHLQATC will implement a national EQA scheme, procure and distribute EQA material thereby bringing all the EQA programs under one roof thereby reducing the individual laboratories expenditure and provide comparability at a national level. Chemistry, hematology and opportunistic infection EQA will be instituted in FY 2009. CD4 external quality assessment (EQA) proficiency testing panels for 81 laboratories enrolled in the CD4 EQA were distributed from the NHLQATC, the data collected and analyzed. Eighty of these laboratories performed well. In collaboration with AMREF, MOHSW trained 40 HIV rapid HIV testing supervisors who perform on site monitoring and administer the proficiency panels. NHLQATC supplied proficiency panels for rapid HIV testing using locally produced EQA material for 417 facilities which constitute 20% of all rapid testing sites. Rapid HIV proficiency panels complement the on site monitoring provided by quality assurance officers and rapid testing supervisors. In FY 2009, the NHLQATC will roll out rapid HIV testing EQA to 60% of the facilities and provide EQA panels for HIV Enzyme Linked Immunosorbent Assay (ELISA) serological testing.

**Accreditation efforts and status**

The MOHSW has also set a goal to have the five zonal referral laboratories achieve accreditation to ISO 15189. An activity to begin quality management system implementation in the zonal laboratories, and thus to work toward ISO accreditation, is
being carried out with the Clinical Laboratory Standards Institute (CLSI). For the past two years, a series of assessments followed by the placing of mentors in these laboratories has been carried out. This table indicates the activities that have been included in the CLSI/MOHSW assessment and mentoring efforts:

**Assessment against 15189 includes a broad scope of activities**

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<thead>
<tr>
<th>Organization</th>
<th>Examination Procedures Laboratory</th>
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<tr>
<td>Quality Management System</td>
<td>Equipment</td>
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<tr>
<td>Personnel</td>
<td>Examination Quality Control</td>
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<td>Accommodation and Environment</td>
<td>Non-conformities</td>
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<td>Document Preparation and</td>
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<td>Document Control</td>
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<td>Pre-Examination</td>
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<td>Post-Examination (Waste)</td>
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<td>Post-Examination (Reporting)</td>
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The tables below indicate the changes and improvements that were made by the five participating zonal referral laboratories from the assessment conducted in 2007, to that conducted in 2008. During the intervening period, mentors worked in each of the labs to help local staff implement quality management system policies and activities.

The MOHSW has indicated a plan for accreditation for all national reference and zonal laboratories in the country. The TB NRL has indicated that it will develop plans to follow this MOHSW plan.
4. Laboratory Infrastructure

The CTRL is physically located in the Muhimbili Hospital complex, within the Central Pathology Laboratory. This building was fairly recently renovated and the working space has been considerably improved. However, the CTRL still has many problems with infrastructure that limit the ability of the staff to do necessary work. The actual workspace is limited in size, making it difficult to fully engage the needed numbers of personnel. There is no BSL-III capability, and no adequate space for performing molecular or other new techniques. The current laboratory has no room for expansion and therefore future services will be limited unless this problem is solved. The room where identification and DST is performed does not meet BSL-3 standards required for liquid culture.

Other key laboratories in the TB network have the following infrastructure issues:

1. The laboratory at Kilimanjaro Christian Medical Center has in the past performed TB cultures. However, the laboratory space used for this activity is totally inadequate in size. In addition, recent problems with leakage in the roof which cannot be corrected has made it impossible to use this space. This, combined with loss of staff, has caused the KCMC facility to discontinue performing TB cultures.

2. The new laboratory at Kibong’oto Hospital is almost ready to begin service. There are some issues in getting the laboratory arranged properly for good functioning and for safety. Laboratory personnel should seek the advice from facility design experts, as on the day of the site visit there was discussion of placing one safety cabinet close to the main entry of the laboratory, which would negatively impact the performance of the cabinet.

3. TB cultures are being conducted at Bugando Medical Center, and although the TB laboratory is in an older building, facilities are currently adequate for the work being performed. A new TB laboratory at Mbeya Referral Hospital is under construction and will soon be available for use as a culturing site.

A recent IUAT inspection reviewed a number of more peripheral laboratories and observed that the designs of all visited laboratories were adequate with separate locations for specimen receipt, smear preparation and an area for microscopy. Nevertheless, while the smear preparation areas had a sink, running tap water and open window, the control of air direction depends on the design of the building in such that it is sometime impossible to have the air current flow from the room to outside without the aid of the extractor fan. Power and water supply was available in all visited laboratories although power outage was fairly common in most facilities.

At present, the primary infrastructure issues that need to be addressed concern the TB National Reference Laboratory.
5. Laboratory safety

Many biosafety issues relate to infrastructure and equipment limitations, and these have been discussed in those sections. It is important to further note that, as in many resource-limited countries, laboratory safety training is an important element to be included in the development of country laboratory infrastructure and improvement efforts.

6. Human resources development

According to the MOHSW, inadequate numbers and skill level of laboratorians poses the largest barrier to provision of quality laboratory services. A number of steps have been taken to address this problem, however the need for improvement in this area will continue.

Pre-service training efforts

The current educational system is as follows:

- Medical Degree; five years
- Health Laboratory Scientists: holders of BS in Health Laboratory Science subjects; new three year degree; create career path in second year
- Specialized Health Laboratory Technologists: holders of Advanced Diploma specializing in one discipline of Health Laboratory Technology; two years (under School of Medicine Lab) - one year of coursework, second year practical
- Health Laboratory Technologists: holders of Diploma; three years
- Health Laboratory Assistant: holders of certificate; two years

Schools for training in laboratory technology are located at Muhimbili University, Bugando Medical Center, Kilimanjaro Christian Medical Center, and in Zanzibar; in addition, there are one or two other training sites. These schools are in need of modern instruments for training, additional skilled faculty as well as in-service training for faculty.

In recent years, several steps have been taken to increase opportunities for pre-service training at both local and international institutions. There is a program to allow laboratory assistants to take an 18 month course in laboratory science to upgrade these staff to diploma level (more than 50% of the technical laboratory work force in Tanzania is composed of laboratory assistants). Other staff are also being sponsored for upgrade education, and it is planned that this will lead to an increase in the number of technicians and technologists available in the country with higher levels of education and skills, thereby also raising the number of laboratories managed by appropriately trained personnel from the current 43% to 60%.
In spite of these efforts, laboratories continue to have inadequate numbers of trained staff for carrying out the necessary functions.

**In-service training**

A strong effort to provide critical in-service training has been undertaken in the past several years, primarily as a part of the program for addressing the HIV/AIDS epidemic. From FY 2006 to FY 2008, MOHSW trained national trainers in rapid HIV testing, HIV rapid testing supervisors, early infant diagnosis, quality assurance, standard of care tests, laboratory management, laboratory information systems and equipment management.

In FY 2008 five regional laboratories received mentorship. It is intended to increase this to all 23 regional laboratories in FY 2009. This will be achieved through development of 25 in-country mentors drawn from the existing technical work force thereby building sustainable mentoring capacity in the country. The in country mentorship program will further strengthen the knowledge and skill base of the existing workforce.

The NHLQATC will provide leadership and serve as a focal point for laboratory training and quality systems implementation, and will support and promote operational research. In FY2008, 75 technologists were trained in CD4, Chemistry and Hematology testing and 4 laboratory technologists in DNA PCR proficiency panel production and quality assurance principles at the NHLQATC. The NHLQATC is gaining experience in providing essential in-service training for laboratory staff in Tanzania. The facility is well equipped for training, with adequate laboratories and equipment for a broad range of testing procedures.

**7. Procurement and distribution of supplies and equipment**

The responsibility for procurement and distribution of reagents, supplies, and equipment rests with the department of Central Medical Stores within the MOHSW. The CMS has distribution points around the country, but no direct delivery service.

Many laboratories, especially those outside the immediate vicinity of Dar es Salaam, describe considerable difficulty in obtaining needed supplies and reagents. Although the CMS indicates that they request information regarding projected needs from the laboratories, the laboratories report frequent outages of reagents with resultant long periods of time during which testing cannot take place.

In response to the HIV/AIDS epidemic, a considerable investment has been made to purchase new equipment for laboratory testing. Many laboratories have received small analyzers for chemistry and hematology testing. In addition, systems for performing CD4 counts have been purchased and distributed. Challenges have been in training staff to properly operate the equipment, obtaining the needed reagents, and getting help with repairs and maintenance.
8. Data Management

Electronic Laboratory Information Management Systems (LIMS) have become key components of clinical and public health laboratory infrastructure in developed countries. As health management information systems (HMIS) are developed and as they mature, laboratory data are viewed as key elements of health records.

In resource-limited settings, laboratory data are largely managed by paper-based systems for single purpose use of data. Electronic LIMS are at the earliest stages of development. However, increasingly, laboratories in many countries are viewed as obvious candidates for implementing information and communication technology (ICT) to improve public health outcomes. The need for effective LIMS is increasingly being recognized as important for improving diagnosis, treatment, care, and support for people living with infectious diseases.

While there is this perceived need by countries and by international organizations, and while there have been guidance documents developed and standards addressed, there are many barriers to introduction in resource-limited settings. LIMS that are developed by incorporating best practices of health metrics and standards will strengthen larger public health systems and will help assure the use of those data for better public health outcomes.

PARTNERSHIPS

The Tanzania MOHSW has many partners in its efforts to strengthen and improve laboratory services. The mission team met with a number of these partners to understand their programs, and the laboratory needs that they have identified. The following is a summary of activities and findings from some of the MOHSW partners.

USG

The U. S. Government funds the MOHSW directly and provides technical assistance through US-based laboratory and care and treatment implementing (ART) partners. The primary USG agencies that are based in-country and help to manage this funding and assistance include the U.S. Centers for Disease Control and the U.S. Agency for International Development.

The USG has prioritized implementation of the laboratory quality management systems and strengthening the public health laboratory functions of the National Health Laboratory Quality Assurance and Training Center (NHLQATC). Improving the numbers and skill levels of laboratory technicians as well as defining staff recognition, motivation and retention mechanisms based on quality performance will be a key activity in FY 2009
to be achieved in collaboration with the Human Resources for Health program. USG will strengthen the utilization of laboratory information systems to inform the prevention and care and treatment programs and collaborate with the National Malaria and Tuberculosis and Leprosy programs in the provision of technical assistance in the diagnosis and quality assurance for tuberculosis and malaria. Scale up of infant diagnosis, improvement of laboratory supplies logistics management and equipment maintenance will also be addressed as a priorities in FY 2009. USG has addressed human resource needs in a variety of ways, including support for in-service training as well as working to strengthen the pre-service training through providing support to the schools of medical technology.

Key USG partners include: the American Society for Clinical Pathology (ASCP) which provides assistance with training, the Clinical Laboratory Standards Institute (CLSI) provides assistance with the implementation of laboratory quality systems, the Association of Public Health Laboratories (APHL) with management training and implementation of Laboratory Information Systems (LIS) and the American International Health Alliance (AIHA) provides mentoring opportunities between US-based and Tanzanian institutions and professionals. The USG also provides direct funding to the African Medical research Foundation (AMREF) to support the training activities for the MOHSW and Columbia University which assists with implementation of the Early HIV Infant Diagnosis program.

USG activities complement those of other development partners such as the World Health Organization (WHO), AXIOS, The Abbot Foundation, the Japanese International Cooperation Agency (JICA), Clinton Foundation, the Global Fund and the German Development Cooperation (GTZ) who provide technical and financial assistance to MOHSW. Several of these development partners contribute to the Sector Wide Approach (SWAP) Basket Fund. USG is guided by the National Laboratory Operational Plan in Support of HIV/AIDS care and treatment, the National Laboratory Standard Guidelines and the National Laboratory Quality Assurance Framework in providing laboratory infrastructure and capacity building support to MOHSW. USG liaises with all the laboratory stakeholders through a regular laboratory development partners meeting chaired by the MOHSW.

With USG support, MOHSW developed a five year national laboratory strategic plan to guide the laboratory infrastructure and capacity building activities through FY 2009. This was developed and completed in consultation with the National Tuberculosis and Leprosy Program and the Malaria Control Program which works closely with the USG Presidential Malaria Initiative Program. The 5 year strategic plan has incorporated laboratory activities for strengthening identification and quality assurance of opportunistic infections, malaria and tuberculosis. country, such as genetic sub-typing, HIV drug resistance testing, HIV-1 incidence, and other specialized microbiological assays.
**NIMR**

The National Institute for Medical Research (NIMR) is a part of the Ministry of Health and Social Welfare of Tanzania. It has a national mandate to coordinate and participate in all health-related research in Tanzania, and to ensure that this research is directly related to the work in the field. NIMR is also responsible for ethical conduct and quality of the research in the country.

NIMR has six research centers located throughout Tanzania, which enables the organization to address quality of laboratory services, as well as research needs and gaps in the zonal areas and at the national level. The research activities of NIMR are not isolated, clinical research is based in the hospital, which also complements the routine work of the hospital. NIMR noted the following challenges to their research initiatives in this region: (i) utilization of the labs needs to be broader, and there is a need to develop a network of hospital labs across disciplines, (ii) there is a lack of collaboration between labs (the current approach to capacity building is vertical), (iii) the lab quality needs to be standardized, (iv) sustainability of standards and quality can be difficult once research projects are completed.

The East African Health Research Commission is being established through NIMR. NIMR is also establishing centers of excellence for clinical research within existing institutions in Tanzania.

**PATH**

In 2005, PATH established a TB/HIV project through an MOU with the TB/Leprosy program within the MOHSW. Through this project, PATH has committed to provide assistance with laboratory strengthening efforts in the areas of recruitment and training of personnel, as well as establishing programs to address infection control in health care facilities (laboratories included) in several regions on the mainland of Tanzania as well as Zanzibar. To date, PATH has coordinated training of laboratory personnel in AFB smear microscopy. PATH has also agreed to assist in the expansion of TB laboratory services, through the implementation of the Hain molecular assay, and establishing a QA program for AFB microscopy. PATH has noted the following as challenges to their laboratory strengthening efforts in the region: (i) human resource constraints, lab technicians have a general background and are not trained in TB specifically, (ii) technical assistance for TB as well as specific TB labs are generally not available at the district level, (iii) space constraints in the available laboratories, (iv) a lack of involvement by the private sector.
CLINTON FOUNDATION

The Clinton Foundation is currently working in Tanzania to expand rural care for HIV/AIDS. To this end, a pilot study has been implemented in two districts. The challenges to the Clinton Foundation efforts in this region include: (i) major infrastructure constraints, (ii) human resources and training issues; training needed in laboratory procedures and areas of procurement, specifically those personnel assigned to working in the MSDS, (iii) supply shortages, (iv) difficulty in maintenance of equipment, (v) need for monitoring and regulating new laboratory products to assure quality and reliability.

AMREF

The African Medical and Research Foundation (AMREF) is a regional, East Africa organization that is community focused. In Tanzania, many activities are carried out in coordination and cooperation with the MOHSW. The organization has programs to address safe water, youth problems, and malaria. There are also extensive programs related to HIV/AIDS. To date, the laboratory support provided by this organization has been through training both non-laboratory personnel and laboratory staff in HIV/AIDS related testing, as well as laboratory management, and implementation of EQA. AMREF is also involved in EQA in 4 countries. A center in each country contributes proficiency testing materials for either parasitology, TB, HIV, or hemoglobin; these materials are then shipped to Nairobi. From Nairobi, the proficiency panels are then re-shipped to 10 labs, and reference values are determined. The materials are re-packaged and sent to the participating sites. Clinical questions are also attached to these proficiency panels. Currently, proficiency testing panels are being provided to 60 laboratories in Tanzania, in cooperation with the MOHSW. According to the results of the latest proficiency panel, TB was identified as an area of weakness for Tanzania, as approximately 55% of these panels were missed at the dispensary level. Panel II is being prepared currently. Future plans include increasing the number of participating laboratories, and expanding testing to include syphilis and some chemistry tests. According to AMREF, the challenges to their efforts in this region include: (i) human resource constraints; the number of qualified personnel is insufficient, the available personnel are not appropriately trained, (ii) supplies are not quality assured (for example, staining reagents used for AFB microscopy), (iii) infrastructure constraints (available laboratory space is too small).

MSH

Management Science for Health, or MSH, has its major focus on primary health care centers. In Tanzania, it is providing support in district hospitals and health centers where an area of concern is HIV/TB co-infection. It was noted that there is almost no integration of services for HIV and TB in Tanzania. To date, MSH has worked with these facilities to improve the quality of microscopy, as the current case detection rates in the country are low. MSH is also engaged in providing laboratory management training at
the local level. MSH has noted the following challenges to improving case detection through AFB microscopy: (i) constant lack of supplies, and supplies that are available are not quality assured (this may be due to rigid procurement regulations), (ii) lack of maintenance of equipment, specifically microscopes, (iii) transport system for specimens is weak, (iv) information systems need to be updated, as these systems do not capture relevant patient information (ex. treatment failures), (v) training programs are generally weak, (vi) relationships with key partners such as Becton-Dickinson, FIND and Hain LifeScience need to be strengthened.

There are many partners, both public and private, that provide services or support to laboratories in Tanzania. Each of the partners offers specific technical skills that are important to the laboratory improvement effort, and there are many potential opportunities for working with both public and private partners to achieve laboratory strengthening for TB support, as well as for general public health support.
SUMMARY OF MAJOR FINDINGS AND CONSTRAINTS TO GOOD LABORATORY PERFORMANCE

The World Bank Tanzania team visited several laboratories at different levels in the laboratory system and in different geographic locations. Using the information gathered from these visits, as well as review of earlier assessments by others (WHO, IUAT, CLSI), and from discussions with partners who are working in the effort to improve laboratory services, a common set of gaps or challenges can be recognized. These include:

1. **An inadequate number of skilled laboratory workers.** As an example, at the Kilimanjaro Christian Medical Center in Moshi, which is one of the zonal referral hospitals in Tanzania, there has been a functioning TB laboratory performing cultures for several years. However, within the last year five key staff have left the laboratory for work in other locations, and there is no one in the laboratory capable of doing TB cultures. This laboratory was one of only three in the entire country performing these cultures, and this capability has been lost. In general, human resources in the country are far below critical mass, and there is inadequate pay, lack of structured career paths, and poor morale due to lack of recognition of the importance of diagnostic services.

2. **Inadequate training opportunities** both in terms of the production of clinical pathologists, medical technicians and technologists through pre-service training (i.e. ranging from two to three years for general laboratory skills, with additional study for laboratory specialties) and in-service training in order to refresh knowledge and learn new procedures as new technologies are rolled out.

3. **Lack of a national public health laboratory.** Tanzania has several national reference laboratories which are not co-located. The MOHSW has recognized the need for a national public health facility to allow for coordination and integration of public health policy, surveillance, and to provide laboratory support for all public health activities. The lack of such a focal point significantly hinders efforts at public health laboratory programs.

4. **Limitations of the physical space in key areas.** The result is that there is insufficient space to add new technology, as well as ensure safety when working with pathogens; this is especially noted in the National TB Reference Laboratory, although other key referral laboratories have similar problems. There is no BSL3 laboratory in the national laboratory network, although a new BSL3 laboratory will be opening soon at Kibong’oto Hospital. Additional BSL3 capacity is badly needed, especially at the National TB Reference Laboratory.

5. **Difficulty in maintaining and repairing equipment.** Many laboratories in Tanzania have been provided with new instruments for testing, funded by PEPFAR and other partners. However, the in-country mechanisms for providing ongoing maintenance and repair are not adequate to the challenge. In addition, the skills within the laboratory to maintain, and sometimes even to properly operate the equipment are lacking.

6. **An inadequate supply chain.** Maintaining a continuous flow of needed test kits and other supplies and reagents is very difficult. The Medical Stores Department,
which is part of the MOHSW, is the primary source for these supplies; outages are very common and testing is often delayed or not possible because of lack of availability of these essential supplies.

7. **Lack of a well defined and functioning transport mechanism for specimens.** As only two laboratories in the country are currently performing TB cultures, the shipment of specimens for this purpose is necessary. However, because of inadequate transport mechanisms, these specimens are often not sent for culture. As evidence for this, many of the specimens cultured in the National TB Reference Laboratory come from the physically adjacent Muhimbili Hospital.

8. **Inadequate quality management systems within the laboratories.** Tanzania has made much progress in raising awareness about quality management systems, through training and mentoring projects that have been conducted over the last several years. In some laboratories, there is clear evidence that quality system concepts are being implemented; however in others there is a need for much greater attention to quality assurance practices.

9. **Lack of a sustained EQA program for general laboratory testing.** Tanzania is attempting to provide this important service for the national laboratory system. The new NHLQATC has excellent facilities for preparation of EQA materials, and there are plans to implement a national EQA program that would cover the major laboratory disciplines of chemistry, hematology, microbiology, immunology/serology. However, at present only a program for CD4 testing EQA has actually been implemented.

10. **A lack of information management systems in most laboratories.** Almost all laboratories rely on manual information systems which, unless carefully designed and managed, are not always sufficiently effective for decision making in clinical care. In addition, a national-level information management system would be essential to implement the needed laboratory-based surveillance system for infectious diseases.

11. **General loss of trust in the laboratory by both clinicians and patients.** Producing inaccurate or unreliable data as a result of structural and management problems results in loss of confidence in the laboratory. This is a problem that can be difficult to correct. An unfortunate consequence may be poor use of laboratory services in clinical care.

12. **Some need for infrastructure improvement.** Although considerable effort by the USG and many other partners has seen much new laboratory construction and rehabilitation, there remain many areas where more improvement is needed.

Challenges that relate specifically to TB laboratory testing processes include:

1. **Lack of sufficient capacity to meet Tanzania’s TB culture and DST needs in order to adequately diagnose and treat HIV-related TB and drug resistant disease.** Currently, only two labs in Tanzania perform culture testing (i.e. solid culture only and not liquid culture which has a higher turnaround time), and only the laboratory located within the Muhimbili Hospital performs drug susceptibility testing, serving as the country’s National TB Reference Laboratory. DST for second line drugs is not available in country.
2. The use of conventional brightfield microscopy for AFB smears as a primary diagnostic tool, rather than employing newer technology. The result is that case detection rates are too low. Implementing LED (fluorescence) microscopy will not only improve the sensitivity of microscopy, it will also reduce the number of man hours dedicated to this procedure.

3. Lack of a national, broad EQA program for AFB smear microscopy. The National TB Reference Laboratory has in the past operated an EQA program for re-checking and site supervision of laboratories performing AFB microscopy. This program has not been implemented in the past year or 18 months, due primarily to personnel constraints. AMREF, in cooperation with the MOHSW, has conducted a pilot proficiency testing program, providing slides to be read and evaluating the results. A program that meets IUAT/WHO standards - onsite evaluations, blinded re-checking (unbiased, random sampling of positive and negative slides); and panel testing - and that engages all sites that are performing AFB microscopy should be given high priority.

4. CTRL is currently using conventional methods for culture, identification, and drug susceptibilities. This should be evaluated. Liquid culture should be used as an adjunct to solid media; molecular assays such as line probes should be used as a screen for smear positives to confirm MTBC and to determine drug resistance immediately. Antigen detection assays such as Capilia TB and SD Bioline should be implemented and used in conjunction with liquid culture. It should be noted that the performance, feasibility, and cost effectiveness of these methods should be validated.

5. Simple, cost effective point-of-care tests are needed to allow for more on-site testing. Evaluation of point of care assays will be required to determine what procedures would be effective in Tanzania.
RECOMMENDATIONS

Based on the observed challenges and gaps in laboratory services needed to support strong TB programs, and in order to improve the overall capacity and capability of laboratories in Tanzania, the mission team recommends the following:

1. The development of an East African regional laboratory training center, located in Dar es Salaam, Tanzania

Tanzania has an existing National Health Laboratory Quality Assurance and Training Center, located in Dar es Salaam in close proximity to a NIMR facility and to the U.S. CDC facility. The physical structure is recently completed and is fully equipped. The Center has excellent laboratories specifically designed for training groups of students, as well as lecture rooms and a reference center. It would provide an ideal venue for a regional training center for the East Africa Community, and could provide up-to-date training in:

- **Laboratory technical skills** required for working in a clinical mycobacteriology laboratory and for adapting to the roll out of novel diagnostics, including: specimen processing and culture (solid and liquid culture), identification and validation of new methods (molecular as well as antigen detection), and drug susceptibility testing (molecular and conventional). It could also provide laboratory technical skills in a wide range of testing to support treatment programs as well as other public health areas.

- **Laboratory management tools and systems** designed to train managers in the daily operations of a clinical laboratory, with an emphasis on developing quality assurance programs, and quality management systems. The implementation of quality management systems for TB laboratories is essential, but all laboratories need this focus.

- **Regional External Quality Assessment** training to ensure that countries develop and implement EQA systems according to international standards. Training can be provided in preparation of proficiency panels, management of a distribution system, and analysis of data.

- **Biomedical engineering/equipment maintenance** training for biomedical engineers and technicians to ensure that equipment is well maintained and that safety is ensured.

In addition, the training center could build strong relationships to schools of medical technology in the region, in order to help ensure the provision of adequate numbers of qualified technicians and lab specialists. Some key areas which may need additional support would include: (i) reviewing and/or revising the curriculum to address rapidly changing technological and laboratory quality management needs; (ii) providing modern and appropriate equipment for training in new technologies; and (iii) conducting training for trainers in the network to update skills, in order to maintain a high quality pool of regional trainers.
The Quality Assurance and Training Center would serve as a regional resource, initially providing service to the three countries in the proposed regional network (Tanzania, Uganda, Kenya). The services could be expanded to serve more countries as the network expands.

Tanzania is in a position of strength in this area of developing a regional training center. It already has an excellent facility. It has experience with the delivery of in-service training, and has an established relationship with several partners who have considerable expertise in training in medical technology (the American Society of Clinical Pathology, the Association of Public Health Laboratories, and AMREF, as examples). The development of this existing facility to serve as a regional center of excellence for laboratory training would be of great benefit to all of the East African partners.

2. Establishment of a National Public Health Laboratory and Support to Regional Diagnostic Centers

At present, the MOHSW has considered the possibility of locating some public health laboratory functions using the new NHLQATC facility. This plan has drawbacks, as the facility was developed for use as a quality assurance and training center, and not as a working public health laboratory. The space is not adequate for all public health laboratory needs, particularly as there is no provision for a BSL3 laboratory at the facility and the modifications needed to create this space would be difficult, and would encroach on the space planned for training. Given its optimal location and its outstanding design as a training facility, it may be easier to render this facility operational by taking advantage of its excellent layout as a training center, and developing it into a regional center, making its services available to neighboring countries.

If the MOHSW decides to develop the NHLQATC as a dedicated regional training center there will be a need to establish a public health laboratory. It is the recommendation of this group that constructing a new national public health laboratory be undertaken.

A new national public health laboratory would provide many advantages. The much-needed space for the National TB Reference laboratory could be a part of a new structure, and this would allow for planning a facility that completely meets the needs of the TB program. In addition, the country’s broader public health laboratory needs could be addressed. Locating all of the national public health laboratory functions in one place would greatly aid the effort at integration and strengthening of performance and service.

The current National TB Reference Laboratory, located at Muhimbili Hospital, is in dire need of expansion, so that liquid culture and molecular techniques can be quickly rolled out. This would necessitate a BSL3 laboratory which currently does not exist, and would have broader benefits for microbiology. In order to consolidate public health functions and minimize fragmentation of investments the MOHSW could construct a new national public health laboratory to accommodate the needs of the tuberculosis program and to provide the full range of services essential to good public health practice. This approach would provide a means for all the national reference laboratories for relevant infectious
diseases to be brought together in one place, improving the ability to integrate public health laboratory functions.

The Tanzanian public health laboratory would be part of a *regional network of laboratories* supported under the project with a common goal of enhancing quality of laboratory services and controlling or eliminating communicable diseases in the sub-region. World Bank funding would assist participating countries to: (i) strengthen *integrated surveillance activities*, to provide early warning signals of health risks of regional and international concern; (ii) participate in investigations of *disease outbreaks* in collaboration with public health laboratories in neighboring countries for cross border public health issues; (iii) provide *reference and specialized testing* and conduct *supervision and quality assurance* to laboratories at lower levels of the health system; (iv) establish and maintain an *integrated data management system* to facilitate sharing of relevant data within the country and across the sub-region; and (v) engage in joint *operational research* to evaluate the roll out of new technologies and laboratory methods.

The regional project provides a unique opportunity to revitalize the *East African Integrated Disease Surveillance Network* (EAIDSNet) which is a joint effort of the National Institutes for Medical Research and the Ministries of Health of Kenya, Uganda, and Tanzania, aims to foster cross-country and cross-institutional collaboration, exchange and disseminate timely information, promote regional harmonization, and foster exchange of expertise and best practices. The project would also provide an opportunity to build on the current regional arrangement, as agreed by the East Africa Community and the three countries, whereby Uganda has taken a lead on HIV/AIDS research, Tanzania on TB control, and Kenya on malaria research. The Tanzanian National Institute for Medical Research (NIMR) is well placed to conduct and/or coordinate such operational research in collaboration with its counterpart organizations in Kenya and Uganda. NIMR benefits from support of several partners (CDC, PEPFAR), and has a long standing track record of supporting research to enhance disease management, prevention, and control.

3. **Additional specific recommendations to help improve TB testing networks and procedures**

Within Tanzania, the strengthening of the existing referral centers, making them true *centers of excellence* would help to provide reliable, high quality testing to improve health and address the needs of people with TB, TB/HIV co-infection and drug resistant TB as well as other diagnostic requirements. For example, Kibong’ oto Hospital is slated to become a center of excellence for the management of MDR-TB, and this has the potential to impact disease control efforts in Tanzania and in neighboring countries. The referral centers could serve as a source of expertise and resource to conduct external quality assurance, perform supervision, provide consultation, and offer advanced testing for lower level laboratories. : (i) upgrading, rehabilitation, and/or construction of laboratories, ensuring biosafety and infection control; (ii) providing drugs and equipment, as needed to complement grant financing from UNITAID under the expanded FIND/UNITAID/WHO collaborative arrangement in which the Bank is collaborating;
(iii) providing training and capacity building (iv) strengthening and putting in place quality management systems and linking the network of laboratories; (v) assisting with operational and logistical costs; (vi) providing technical assistance; and (vii) supporting public/private partnerships to scale up innovative programs. TB control as well as systemic health systems are dimensions necessary for building sustainable public health laboratory capacity in Tanzania and in neighboring countries.

The following steps to improve the TB testing processes are recommended:

- Strengthening the network of microscopy centers through improved access to fluorescent or LED microscopes and reagents, and providing training of laboratory personnel
- Improving the current approach to diagnosis by strengthening and improving the availability of EQA to all laboratories performing AFB smear microscopy
- Re-evaluating current laboratory workflow and algorithms, implementing automated systems for culture, and considering simple identification methods.
- Evaluation of point-of-care assays, possibly with help from key partners.
The World Bank is proposing a regional East Africa investment in laboratory strengthening, especially as it relates to tuberculosis prevention and control, and to include the possibility of crosscutting laboratory improvement. In order to look into the feasibility of the involvement of Tanzania in this project, a mission was conducted to assess capacity, identify areas where support is needed, look for opportunities to promote public-private partnerships and propose next steps that would be required for Tanzania to participate in a regional project. This report, prepared by the Tanzania mission team, examines these laboratory issues in Tanzania with the project objectives in mind.