Introduction:

With its renewed focus on health systems strengthening and on global public goods, the World Bank has taken a leadership role in proposing a regional investment in laboratory strengthening and control of infectious diseases in Africa. This approach aims to promote coordinated and harmonized strategies and activities at the regional level. The World Bank is well suited to lead a regional approach to health sector strengthening because (i) there are critical regional gaps (e.g. laboratory capacity) that the World Bank could fill that are not adequately addressed by others; (ii) the World Bank has the capabilities and resources to be effective, as it has a growing body of experience with regional investments; (iii) the World Bank’s financial support would be combined with technical expertise from partners, such as the World Health Organization and others, and may leverage financing from other partners; and (iv) the World Bank can provide flexible financing to assist countries to address both national public health priorities and to tackle the regional challenges of TB control, thereby maximizing the impact of these investments across the continent.

The World Bank Regional Health Systems Strengthening and Tuberculosis (TB) Support Project will use TB as a pathfinder to strengthen the regional response to global public goods issues in health. That is, although TB laboratory strengthening would play a central role, the overriding goal is to ensure that a broader health systems approach to laboratory strengthening is adopted to maximize the impact and sustainability of these investments. Given the public good nature of these investments, a regional financing instrument is proposed, whereby countries which are willing to use part of their IDA country allocation (i.e. one-third of the total amount of the IDA credit) would benefit from additional regional resources (i.e. two-thirds of the IDA credit). In other words, one-third of the amount would come from the fixed pot of money which is available at the World Bank and two-thirds would be over and above that amount. The World Bank’s collaboration in the expanded UNITAID/FIND/WHO project will help to leverage additional grant resources for drugs and modern diagnostics for countries participating in the regional project.

It is well-recognized that a key bottleneck in health service delivery is weak laboratory capacity which hinders patient management and disease surveillance. Laboratory and diagnostic capacities have not been a priority of many governments or donors until recently. The gross underfunding of laboratories coupled with inadequate numbers of skilled staff has resulted in unreliable and inaccurate testing and misdiagnosis, which in turn leads to higher costs and compromised patient care. In many countries in Africa, diagnosis based on clinical symptoms alone can lead to misdiagnosis, inappropriate treatment, missed cases, lost opportunities to prevent transmission, increased morbidity, unnecessary loss of life, and wasted resources. Building laboratory capacity to provide rapid, accurate, affordable, and reliable diagnostic tests
will enable health care workers to find more cases, deliver more effective treatment, enhance efficiency in use of resources, and improve quality of care. The call to strengthen public health laboratories in Africa was recently reinforced at the 58th African Ministers of Health Regional Committee in Yaoundé.

The World Bank regional project aims to improve access, quality, and efficiency of TB diagnostic services using an integrated approach to laboratory strengthening. The specific objectives would be to: (i) establish additional Supranational Reference Laboratories in strategic locations to provide quality assurance, training, technical assistance, and capacity building; (ii) develop a network of well-functioning national reference laboratories and regional centers of excellence to provide quality diagnostic services throughout the region; (iii) introduce modern diagnostic techniques, increasing capacity for drug-resistance surveillance, and ensuring compliance with biosafety and infection control standards in public health laboratories in priority countries; and (iv) develop and test alternative service delivery models to promote private sector involvement. The project would also facilitate learning and knowledge sharing across the network of participating laboratories and countries. In this way a coordinated regional approach to issues such as the spread of multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB can move forward.

All high burden countries will be eligible to take advantage of the US$140 million regional project. Countries to participate in this project will be selected and prioritized based on: (i) epidemiological situation (e.g. burden of TB, HIV, and drug-resistant TB); (ii) existing laboratory capacity to address HIV-related and drug-resistant TB and clear plans for laboratory improvement; (iii) presence of other partners and agencies and projected funding gaps; and (iv) country interest to participate in this regional operation and willingness to contribute one-third to the total cost from the respective IDA country allocations. Based on a preliminary analysis of the countries with respect to TB burden, country preparedness, and existing capacity, the tentative list of countries includes Benin, Burkina Faso, Cameroon, Democratic Republic of Congo, Kenya, Madagascar, Malawi, Mali, Mozambique, Nigeria, Rwanda, Tanzania, Uganda, and Zambia. This group of target countries accounts for more than 52 percent of the total population of Africa and 51 percent of the continent’s preventable deaths due to TB. To date, the World Bank has commitments for the required IDA country allocations from the Country Management Units responsible for Kenya, Tanzania and Uganda as well as agreements from the respective task teams and cluster leaders working on health in these countries. As such, the initial project development activities will focus on these three countries.

The preparation and design of the proposed project is being conducted in close collaboration with key partners to take advantage of existing expertise and country knowledge and to identify opportunities for complementary support. The World Bank team is comprised of experts from the US Centers for Disease Control and Prevention, KNCV Tuberculosis Foundation, Management Sciences for Health, World Health Organization, and USAID. This coordinated approach will ensure that the World Bank’s comparative advantage in providing flexible financing will be coupled with the technical know-how from the Stop TB partnership and other experts and organizations.
A scoping and identification mission for the World Bank-funded Regional Health Systems Strengthening and TB Support Project took place in Uganda from March 29 to April 4, 2009. The mission was led by Miriam Schneidman (Senior Health Specialist, Africa Region, World Bank) and included Peter Okwero (Senior Health Specialist, World Bank Country Office), Thomas M. Shinnick (Associate Director for Global Laboratory Activities, Division of Tuberculosis Elimination, CDC), Linda M. Parsons (Team Lead, Clinical and Opportunistic Infection Team, International Laboratory Branch, Global AIDS Program, CDC), Catherine Mundy (Principal Program Associate for Laboratory Services, Management Sciences for Health, USAID supported), and Jeroen van Gorkam (Deputy-Director Project Management Unit, TB CAP, USAID supported, KNCV Tuberculosis Foundation). The main objectives of the mission were to: (i) review laboratory capacity and main challenges; (ii) identify key areas which might be supported under the project, and (iii) agree on the next steps for Uganda to participate in the regional project.

**Background on Uganda:**

With consistent economic growth for the last several years, Uganda’s per capita income has slowly risen and is approaching $400; though, the country has fallen in the Human Development Index to 157. Uganda is in an epidemiological transition, but communicable diseases still dominate. Estimates show that more than 75% of life years lost due to premature deaths are from ten preventable diseases, including tuberculosis and HIV/AIDS. In Fiscal Year 2006/07, 11% of the Government of Uganda’s fiscal budget was allocated to health with a per capita expenditure of $19.67; though, that includes donor financing. TB control is primarily donor dependent.

The 2008 WHO Global TB Report ranked Uganda 15th among the 22 TB high burden countries with an estimated incidence of 355/100,000 and 106,037 new cases in 2006. The overwhelming majority of new infectious cases are in the economically productive and sexually active age group of 15 to 54 years resulting in both negative economic impacts and an HIV-fueled epidemic. Indeed, HIV remains the leading risk factor for TB. Case detection is problematic in Uganda as the country continues to have difficulty implementing the needed components to adequately find and diagnose infected individuals. Limited access to diagnostic services, especially in rural areas, and the non-prioritization of sputum-smear microscopy for identifying infectious cases further hinder anti-TB efforts.

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<th>Facts at a glance (2006):</th>
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<tr>
<td>TB incidence: 355/100,000</td>
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<tr>
<td>TB mortality: 84/100,000</td>
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<tr>
<td>Case detection rate: 44%</td>
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<tr>
<td>Treatment success rate: 73%</td>
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<tr>
<td>Estimated adult (15-49) HIV prevalence: 5.4% (2007)</td>
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<td>TB patients tested for HIV who were HIV+: 59%</td>
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Figure 1 shows the case notification trend in Uganda from 1974 - 2005. Up to 1989 the small numbers of cases reported were due to a collapsed health system. There was a steep rise in reported cases in the early 1990s as the reporting system was reactivated. It is not until 1995 that reporting starts to reflect the actual epidemiologic situation.
The scale up of universal access to antiretroviral treatment has reduced AIDS related morbidity and mortality leading to stabilization in HIV prevalence; but HIV/AIDS continues to pose public health and development challenges in Uganda. UNAIDS estimated that the prevalence of HIV infection was 5.4% in adults (15-49) in 2007, that there were 940,000 individuals living with HIV/AIDS in Uganda, and that 77,000 persons died from AIDS or AIDS-related conditions that same year. On average, more than half of the new TB patients in Uganda are co-infected with HIV compared to 8% globally. The confluence of the HIV and TB epidemics is leading to larger numbers of TB cases in younger, economically productive members of society, especially girls and young women.

Primarily because of a low case detection rate, only 32 out of every 100 infectious cases of TB in Uganda are found and treated successfully. Obviously, this needs to be remedied. Prior TB program and laboratory assessments have highlighted the need to strengthen diagnostic services, including access to these services, and to provide resources for laboratories to perform quality-assured sputum smear microscopy. While Uganda has made progress in addressing these issues, additional assistance is needed.

**Main health sector issues in Uganda:**

Despite wide coverage of DOTS, case detection and treatment success indicators remain low. This sub-optimal performance is at least partly attributable to following factors:

**Inadequate financing:** In 2008, only 36% of Uganda’s National Tuberculosis and Leprosy Program (NTLP) budget was being funded leading to a shortfall of nearly $8.5 million, according to the World Health Organization. Laboratory supplies and equipment constituted approximate 14% of the NTLP’s budget in that same year. While additional funds are being made available through Global Fund grants, the flow of funds to and within districts is often slow.

**Human resources:** Although Uganda is one of the six countries implementing the Intensified Support Action Country Initiative (ISAC) to address human resource shortages in TB control
programs, there has been an on-going need to strengthen management capacity at all levels within the program. As such, the NTLP has lobbied for the improvement of the staff, including the appointment of a full-time Director for the National TB Reference Laboratory (NRL) and the strengthening of district level supervisors. In addition, at the technical level, there has also been a particular concern related to the understaffing of laboratories and the need for initial and refresher training for laboratory personnel.

**Infrastructure (laboratories and diagnostics):** While progress has occurred in this area, such as limited rehabilitation of some laboratory infrastructure and the strengthening of External Quality Assurance (EQA), in general, laboratories and their associated diagnostic testing remain the weakest segment in Uganda’s anti-TB efforts. An ambitious plan for the National TB Reference Laboratory has been developed which will include its functioning as a national supervisory laboratory by supporting supervision, quality assurance, training, drug-resistance surveillance and serving as a reference center for problematic cases. However, numerous challenges will need to be overcome to implement this plan. For example, at the central level key stakeholders have not been able to effectively advocate for increased resources for laboratory services. Indicative of this is a limited access to quality smear microscopy, an EQA system which does not cover the whole country, a lack of routine culture to facilitate diagnosis of smear negative pulmonary and extrapulmonary TB, and very limited drug susceptibility testing. In short, diagnostic testing and microscopy have been the weakest arms of the DOTS strategy in Uganda and needs critical strengthening. One assessment team found that non-functional microscopes ranged from 10% in some districts to 30% in others and that only 38% of units within the primary health care system provided TB microscopy and treatment.

Other assessments have been equally concerned about the urgent need to improve the laboratory situation in Uganda citing, among other issues: an inadequate recognition that accurate diagnosis is essential to cost-effective and efficient prevention and management of TB; a limited prioritized allocation of resources to the laboratory sector; a lack of targeted investment to maintain or improve infrastructure of laboratories, equipment, human resources, and to strengthen systems, leadership and management; a fragmented approach to strengthening laboratories; a weak guiding national policy, strategic plan and national dedicated budget for laboratory services; and a general lack of coordination among partners. While the Round 6 Global Fund grant is intended to address some of these issues through the procurement of equipment, establishing better referral systems, and strengthening the supervision of district level laboratories, there are many critical gaps that remain outstanding.

**Procurement and supply chain weaknesses:** The DELIVER Project supported the establishment of computerized pull consumption delivery system in 2004 to reduce stock outs by strengthening drug tracking. However, the capacity of peripheral health workers to use it is still weak in a number of districts. Other assessments have noted a lack of a multi-year procurement plan, no committed drug procurement budget, and a general lack of routine resources. As such, Uganda continues to experience disruptions in drug supplies.

**Slow and uncoordinated health information systems:** District-level TB Registers in Uganda are used to compile case findings, treatment outcomes, and program management data which are verified before submission to the NTLP. However, there are gaps in completeness and
consistency of data as well as a weak system to follow up treatment interrupters and transfer outs. Other weaknesses in the system include poor quality supervision at all levels, inadequate feedback, and weak program management, monitoring and evaluation in general.

**Limited private sector involvement:** The quality of TB care offered by private health care providers is often uncertain and uneven. These weak linkages between the public and private sectors also hamper the ability of the reporting system to accurately capture information of the patients who go to private providers. It is, thus, recognized by the NTLP that TB control targets will not be met unless private care providers become actively involved in DOTS implementation.

**Government of Uganda’s response for TB prevention and control:**

The Ugandan NTLP attained full district coverage of DOTS in 1995 and DOTS forms the core of its current strategy. Despite universal geographic access, the actual population coverage remains low. Other challenges in the NTLP’s DOTS implementation program include: weak political commitment, reliance on radiology rather than sputum smear microscopy for diagnosis, ruptures in drug supplies, and a weak reporting system.

TB case detection is integrated into the general health units as part of primary health care system. Case detection is based on sputum smear microscopy for smear acid fast bacilli using Ziehl-Neelson staining. The use of fluorescence microscopy is limited to busy units. Culture facilities are primarily available at the National TB Reference Laboratory with only a few other facilities able to perform culture or drug-susceptibility testing. The Ugandan government and Foundation for Innovative New Diagnostics (FIND) in 2008 opened a laboratory in Wandegeya, Uganda, that can diagnose MDR-TB tuberculosis and XDR-TB within one day using rapid molecular tests for drug resistance (line-probe assays). Uganda is the second country in Africa, after South Africa, to open a laboratory with these capabilities. The new laboratory also will be used to research and evaluate new TB testing techniques before they are introduced into the national TB program. In addition, the laboratory will begin training laboratory technicians from neighboring countries early next year.

As a sub-goal within its TB strategy, the NTLP recognized that it needed to increase access to quality-assured bacteriology for TB care. As such the NTLP began working with districts to review the current distribution of microscopy centers, in order to procure binocular microscopes and fluorescence microscopes for busy units along with reagents and supplies, and a general strengthening of internal quality control and EQA. Further, the TB NRL is introducing culture for diagnosing smear-negative extra-pulmonary TB and investigating new diagnostic tools. In order to accomplish these goals, the NTLP aims to improve the human resource at the NRL, strengthen the capacity of the NRL to supervise and monitor TB microscopy services, procure and distribute additional laboratory equipment and reagents, establish a referral system for culture and drug-susceptibility testing, conduct supervision and monitoring visits to laboratories at all levels, and conduct refresher training courses on bacteriology.

**Key policy and institutional reforms supported by the project:** This project will significantly assist the Government of Uganda by further linking the NTLP with the National HIV/AIDS Program by supporting the integration of TB and HIV/AIDS prevention, control, and treatment efforts. It will further strengthen the capacity of these government units to coordinate their
efforts at all levels and will ensure that both the design and implementation of this program are broadly participatory and include the private sector, civil society, and affected communities.

**TB laboratory capacities and challenges:**

The World Bank mission had the opportunity to carry out several field visits and to hold discussions with a wide range of stakeholders involved in laboratory strengthening in the public and non-profit private sector. The team visited Mulago Hospital, Nsamba Hospital (supported by the Italian Association for Solidarity among People), Entebbe General Hospital, Ndejje Health Center, Mpigi Health Center, and Gombe District Hospital. The visits highlighted some of the major challenges on the ground: (i) severe space constraints; (ii) inappropriate or outdated microscopes and equipment; (iii) chronic problems with stock outs of supplies and reagents; (iv) serious understaffing; (v) poor use of laboratory services in clinical care; (vi) weaknesses in maintaining registers; and (vii) lack of means for following up defaulters. Summaries of the site visits are attached as appendices.

However, for the most part, the World Bank team relied on the existing reports of recent assessments, evaluations, and reviews of the TB laboratory services in Uganda conducted by the World Health Organization, Management Sciences for Health, TBCAP, International Union Against Tuberculosis and Lung Diseases, International Organization for Migration, PATH, USAID, and other partners for information on current capacities, needs, and challenges. Key findings from the prior assessments and teams discussions are summarized below.

**Relationship with the National TB and Leprosy Program (NTLP):** There is a well established and excellent relationship between the NRL and the NTLP. The national TB program policy and the strategic plan recognize the importance of laboratory services and include specific laboratory plans and activities. The head of the NRL is considered a staff member of the NTLP, attends NTLP meetings, and advises NTLP on issues concerning TB laboratory services. At the district and peripheral levels the TB program and laboratory are also tightly linked.

**Linkages with National Research Organizations and Universities:** TB services are provided by both government and non-governmental health facilities. For example, about one-third of the microscopy centers in Uganda are run by private, not-for-profit organizations, or non-governmental organizations. The NTLP and NRL work closely with research organizations, medical schools, and non-governmental organizations and provide policy and guidelines on TB research. The Joint Clinical Research Center (JCRC) laboratory, MRC-Entebbe laboratory, FIND laboratory, and the NRL are the only laboratories performing culture and drug susceptibility testing and assist each other with external quality control. JCRC works closely with NRL in terms of staff exchange and strengthening the NRL.

**Organization of the TB laboratory network:** TB services are organized into nine zones (regions) which are subdivided into several districts each (total of 80 districts). The populations within the districts are served by the health centers which include a total of 783 laboratories. The TB laboratory network is organized in parallel and has five levels: Health Center III laboratories, Health Center IV laboratories (most private and non-governmental laboratories are at this level), District laboratories, Regional laboratories, and the National Reference Laboratory (NRL). In
general, the TB laboratory services are integrated with other laboratory services. That is, no stand-alone laboratories for TB exist with the exception of the NRL. At present, only the national laboratory and some non-governmental, research-oriented laboratories have culture capacity. The rest are microscopy centers

**Quality Assurance and Supervision of the Microscopy Network:** The NRL conducts an extensive external assurance (EQA) program for the microscopy laboratories through supervisory visits and blinded rechecking. There is regular supervision to all zones (but not all laboratories), and rechecking of routine smears for about 80% of microscopy laboratories (617 of 783 laboratories). Refresher training for microscopy is held in a recently refurbished training center and more that 500 persons have been through the refresher course during the past four years. EQA by rechecking has become very well known and accepted by peripheral laboratories and programs because of funds for reporting and for regular zonal laboratory meetings. Despite the strong EQA program, there is a danger of excessive decentralization of the TB smear microscopy services which risks making control of network equipment, supplies and EQA difficult. Although it is preferable to bring a microscopy services nearer to the community, a healthy balance between decentralisation and quality is required.

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<tr>
<th>Uganda National EQA Coverage for AFB Smear Microscopy</th>
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<td><strong>Zones (out of 9)</strong></td>
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<tr>
<td><strong>Districts (out of 80)</strong></td>
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<tr>
<td><strong>Lab units (out of 726)</strong></td>
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<td><strong>Total slides rechecked</strong></td>
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<th>On-site Supervision – microscopes checked</th>
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<tr>
<td><strong>Total Number of microscopes</strong></td>
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<tr>
<td><strong>Working microscopes (good, fair)</strong></td>
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<td>(87 monocular; 7 non functional)</td>
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**Laboratory Challenges:** The TB laboratory network faces a number of interrelated challenges to becoming a fully functional network and providing the quality laboratory services needed for the diagnosis and treatment of TB. Overall, these challenges compromise the quality of services and have led to loss of trust in the laboratory by both clinicians and patients.

**Institutional framework:** Within the Ministry of Health, there is no single coordinating body or office for laboratory services.

**Coordination:** Multiple entities (both national and international) are working on overlapping pieces of laboratory strengthening without central coordination, resulting in duplication of effort and lack of a unified approach.
**Funding:** Laboratory services are under-funded. The national budget does not contain a line item dedicated for laboratory services. External funding is often disease specific. Funding for critical NRL positions relies on external funding which is not stable.

**Human resources:** Human resource availability continues to be a challenge, particularly in respect to the lack of sufficient numbers of well-trained laboratory technicians. There is a lack of training capacity to develop laboratory workers in Uganda; existing laboratory training institutions cannot keep up with the demand for trained personnel. Also, there are challenges with recruitment, deployment, and retention of trained laboratory staff, especially in the rural areas. For example, well-trained laboratory workers tend to gravitate toward urban centers, exacerbating the shortages in isolated, rural areas.

**Quality management system.** A fully functional the laboratory network must be built on quality management principles. Training on quality management systems is available in Uganda, but laboratorians in Uganda have not generally had access or exposure to this training.

**Laboratory facilities and equipment:** The building housing the NRL in Wandegeya Kampala was built in 1927 and is in need of refurbishment or replacement. Laboratory facilities and infrastructure including utilities are generally very poor in most parts of the country. Some laboratories at Health Center IV level and above have been renovated or constructed under the national laboratory strengthening program, but much remains to be done. Other common problems include shortages of power, water, and space. Many laboratories lack appropriate equipment. There are too many different brands of microscopes and some do not meet required standards. Poor maintenance practices are frequent. A high proportion of laboratories lack biosafety equipment to protect staff while handling specimens.

**Integration of Uganda regional centers in TB laboratory services:** Although there are nine regional laboratories listed as part of the national network, these labs are not supporting the district or health center microscopy laboratories as would be required in an efficient laboratory network. They do not provide adequate quality assurance or other support to the laboratories in their regions.

**Specimen referral and transport:** Within a network of laboratories, referring specimens or isolates to other laboratories for testing is common, and indeed, necessary to provide efficiently more sophisticated laboratory services such as drug susceptibility testing. Delays in referring specimens and reporting information can lead to delays in diagnosis, disease treatment and control, and surveillance activities. An effective referral system is not yet available in Uganda, although the use of Poste Uganda to transport high priority samples to the NRL for testing has been useful in some situations.

**Supply chain and logistics:** The procurement and distribution of all laboratory supplies and reagents has been mandated to the Central Public Health Laboratory (CPHL) National Medical Stores. However, the TB NRL is not represented at the CPHL procurement committee which defines the specifications of reagents. Also, the TB NRL is not involved in quality control of the procured reagents and supplies. The quality of reagents procured is variable and not known. Transport to distribute supplies from the district stores to the peripheral is a concern. The shift in responsibilities for procurement, from NRL to CPHL has resulted in shortages of supplies and poor quality reagents.

**Recording and reporting:** The poor quality of recording and reporting requires improvement. The importance of the recording and reporting system is still not well understood by
laboratorians or TB control officials, and hence, not well integrated into the health system. Registries and information systems are not used as tools to improve program performance. The cross-checking of laboratory and program registries is weak. There are errors in completion and accuracy of information. Modern laboratory information management systems are lacking.

**Key Gaps in TB Diagnosis:** The challenges noted above also affect Uganda’s ability to provide equitable and accessible TB laboratory services for diagnosis and follow-up. It is well recognized in the country that the effective response for TB case detection and management remains constrained by systemic health systems weaknesses which also affect other laboratory services. Key barriers include human resources, financing, supply chain management, information, and logistic systems. The need to strengthen diagnostic services and to provide resources for laboratories is well recognized and a number of important initiatives are underway. Human resources capacity is a particularly serious issue, as numbers are far below critical mass, and there is inadequate pay, lack of structured career paths, and non-recognition of the importance of diagnostic services. Given the highly infectious nature of TB, other gaps related to the need to step up efforts to protect Ugandan health workers and laboratory technicians from being infected.

The current TB control strategy relies on radiology and sputum smear microscopy for diagnosis. Culture to isolate *Mycobacterium tuberculosis* bacteria is not routinely done, and there are only a few laboratories capable of culturing *M. tuberculosis* bacteria. This greatly limits the ability to detect extrapulmonary TB and smear-negative pulmonary TB which is common in HIV-infected TB cases. In addition, drug-susceptibility testing of *M. tuberculosis* isolates is not routinely performed. This is of particular concern because the potential emergence of drug-resistant forms of TB threatens to compromise the significant progress Uganda has made in both TB control and HIV/AIDS treatment (i.e. as PLWHA are more susceptible to develop drug-resistant TB and have poorer outcomes). Uganda needs to avoid the development and spread of drug-resistant TB which fuels higher health costs, as treatment for MDR-TB is more expensive and lengthier, treatment failure is high, and outcomes are poor. A major investment in strengthening laboratories in a comprehensive manner would enable Ugandan health care workers to deliver more effective treatment, enhance efficiency in use of resources, and improve quality of care. Also, a major investment in strengthening infection control procedures and facilities in hospitals would enable Ugandan health care workers to safely deliver treatment to MDR-TB patients and prevent the nosocomial spread of MDR-TB. Ensuring an adequate supply of drugs for treating drug-resistant forms of TB is equally critical to avoid transmission and minimize patient suffering. Currently, the availability of drugs for these patients is problematic, resulting in long waiting lists.

**Potential Areas for Bank Support:**

While many partners are intervening in laboratory strengthening and a number of innovative programs are underway, gaps persist and additional resources are needed, particularly flexible financing which promotes a comprehensive health systems approach to laboratory strengthening. The proposed World Bank regional project offers a unique opportunity for Uganda to scale up existing programs, foster partnerships, and play a pivotal leadership role in the region. The
World Bank team discussed with key stakeholders the challenges noted above and areas of potential support were identified.

**Coordination and Leadership:** A major challenge to any effort to increase laboratory capacity in Uganda will be to ensure coordination of all involved partners and efficient use of resources for sustainable laboratory improvements. A coordinating or steering group is needed and should work to ensure that activities are coordinated, partners are not duplicating efforts, TB laboratory services are harmonized or integrated with laboratory services for other diseases of public health importance, and standardized data are collected and analyzed to assess the effectiveness of laboratory strengthening interventions.

In the long run, the viability of a public health laboratory network relies on resources and commitments from the Ugandan government. A strategy that was endorsed in the Maputo Declaration to ensure that laboratory issues are adequately represented at the highest levels of government is have a focal person in the Ministry of Health who is responsible for public health laboratory issues. Such an office would be responsible for national policies and strategies for public health laboratories as well as address cross-cutting issues in laboratory strengthening. Technical expertise for disease-specific issues would be available at the appropriate NRL.

**Strengthen the Public Health Laboratory Network using a Systems Approach:** A potential major area of support could include support to establish a network of public health laboratories that can provide reliable, high quality testing to improve health and combat infectious diseases. Strengthening of regional centers and national laboratories has the potential to impact disease control in Uganda and in neighboring countries. Development of such a network requires efforts integrated across disease programs and based on quality management principles. Any successful laboratory strengthening effort involves assessment and understanding of the structure, performance, and cost of the network of laboratory service providers and users; development of a referral and information network to ensure reliable testing and prompt flow of specimens and information; and use of quality-improvement principles to continually evaluate and improve the performance of the laboratory service network.

The laboratory testing needed for diagnosis and care of a patient often depends on a network of laboratories providing testing for diagnosis, treatment, and monitoring of therapy outcomes. Within a network of laboratories, referring specimens or isolates to other laboratories for testing is common and can involve both the private and public sectors. To optimize diagnostic, treatment, and control activities, the flow of specimens and information among laboratorians, clinicians, and public health officials should be efficient and well-coordinated. Indeed, operation of a modern laboratory requires incorporating an integrated information management system into the majority of laboratory activities, including inventory management, specimen tracking, test-result reporting, and information sharing with clinicians and public health officials. State-of-the-art laboratory information management systems diseases are available that can improve the quality and organization of laboratory data and speed the flow of information to those who have a need to know. Importantly, the availability of such information management systems strengthens the laboratory’s capabilities for all laboratory testing for all diseases. World Bank financing could promote development and installation of modern, integrated, compatible, electronic information systems.
World Bank financing could promote a systems approach to optimize laboratory testing and information exchange and to ensure that appropriate services are available in every program. This would imply support for (i) establishing lines of communication among laboratorians, clinicians, and public health officials at different levels in the health system; (ii) expediting reporting of laboratory results, which can avoid delayed or inappropriate treatment and missed opportunities to prevent transmission; (iii) developing evidence-based recommendations for use of new laboratory technologies; (iv) maintaining staff proficiency in light of increasing numbers of specimens to test, workforce shortages, and loss of laboratory expertise; (v) supporting internal and external quality assurance systems; and (vi) upgrading laboratory information systems and connecting all partners in order to improve the quality and organization of laboratory data and speed the flow of information for all laboratory testing for all diseases.

World Bank financing might also promote the use of quality management principles and accreditation of public health laboratories. For example, standardized training in quality management systems, such as the courses available through the Infectious Diseases Institute (IDI) at Makerere University, could be provided routinely to laboratorians at all levels of the health system. A system for accrediting laboratories helps ensure that laboratories meet performance standards and engenders confidence in laboratory results. National reference laboratories should strive towards accreditation by international standards such as ISO15189. For lower levels of the laboratory network, it is essential that laboratory services be matched with the available clinical care and that the accreditation requirements for each level of laboratory be matched with the services offered and performance criteria. Such tiered accreditation system should be aligned with tiered accreditation systems being developed by international organizations such as the World Health Organization.

**Build Laboratory Capacity with a Focus on TB:** Access to the diagnostic services needed to diagnosis and treat TB requires a network of laboratories that includes local health centers, district health centers (general hospitals), regional centers, and national laboratories. Strengthening of the local, district, and general centers is usually considered in the province of national programs and is addressed in another World Bank project (described below). On the other hand, strengthening of national reference laboratories and regional (zonal) laboratories have the potential to impact disease control in Uganda and in neighboring countries and hence would be suitable for support from an East Africa regional program.

**Establish a Laboratory Center of Excellence in Uganda and East Africa:** One potential area of support would be to assist Uganda to play a key regional role by becoming a center of excellence in East Africa for the diagnosis and treatment of TB and other infectious diseases. The country is well qualified to play such a leadership role. The National Tuberculosis Reference Laboratory of Uganda is among the better laboratories in the region and is known for its technical capabilities and its expertise in training TB laboratory specialists and in quality assurance systems. The laboratory is poised to become a national and international resource for strengthening TB laboratory services. With adequate laboratory space and staff, the NRL could introduce into the Ugandan TB control program modern techniques for the diagnosis of TB, and in particular MDR-TB, increase TB case detection rates, and establish capacity for detecting drug-resistant tuberculosis. A strong, well-functioning, state-of-the-art Ugandan NRL could play
a leadership role in laboratory strengthening in the East Africa region by becoming a supranational reference laboratory. A supranational reference laboratory located in East Africa is a critical resource needed to improve TB laboratory services in Uganda and neighboring countries. The World Bank financing could facilitate this process and leverage additional resources from other partners once there is a national and regional consensus that Uganda would be willing and able to play such a role.

**Establish Centers of Excellence in Regional (Zonal) Hospitals in Uganda:** Establishing centers of excellence at the regional hospitals will require improvements in infrastructure including human resources, infection control, information services, computer support, back-up power generators; implementation of sustainable external quality assurance and proficiency; institution of a quality management system; and training in laboratory and supply chain management. Such centers of excellence would also strengthen laboratory testing and patient care at general hospitals and health centers. For example, decentralization of laboratory services and introduction of modern diagnostics at regional hospitals will result in reduced diagnostic delays, improved patient outcomes, reduced transmission, and lower rates of drug resistance. Also, the centers could serve as a source of expertise and resources to conduct external quality assurance, perform supervision, provide consultation, train local technicians, and offer advanced testing for lower level laboratories.

Ideally, the centers of excellence for laboratories would be paired with centers of excellence for treatment, especially treatment of MDR-TB. In this case, a major investment in strengthening infection control procedures and facilities in the regional hospitals would be needed to enable Ugandan health care workers to safely deliver treatment to MDR-TB patients and prevent the nosocomial spread of MDR-TB.

Establishing state-of-the-art laboratories at regional hospitals has several other potential benefits. It offers the country the opportunity to develop centers of excellence for treatment and patient care, especially if such centers of excellence for TB are integrated with centers of excellence for HIV/AIDS, malaria, and clinical care. In this case, coordinating TB capacity building with capacity building efforts of JCRC (HIV/AIDS), IDI (malaria) and other partners will be essential. A potential synergy here is that molecular tests for HIV (PCR for detecting HIV infections in infants) and molecular tests for MDR-TB (PCR-based line-probe assays) could be integrated into an activity with shared space, reagents, and technicians. Judicious choice of which regional hospitals to strengthen in an initial phase offers the opportunity to address TB issues in the East Africa sub-region by providing diagnostic services and care in areas in which a large number of TB cases are in persons who are migrants or refugees from neighboring countries as well as reducing the export of TB cases to neighboring countries by virtue of the quality of care available at the Ugandan center of excellence. To evaluate the impact of the centers on TB in East Africa, it would be important to track performance measures such as the number of persons from neighboring countries diagnosed and treated for TB in the centers and the number of medical or laboratory consultations or trainings provided across borders.
To optimize the value of a well-developed tier of laboratories at the country regional (zonal) level to the East Africa sub-region, it would be necessary to strengthen in parallel the region-level laboratories in other countries of the East Africa sub-region. A multi-pronged strengthening would be greatly enhanced by developing an East Africa sub-regional strategy and a sub-regional steering group or technical committee to guide the process. The technical committee, which would include the supranational reference laboratory, would be a vehicle to ensure consistent, complementary approaches to laboratory strengthening; share best practices and lessons learned; and facilitate training, monitoring, and evaluation activities. Furthermore, the national regional laboratories and centers of excellence for treatment and patient care could work in partnership to develop evidence-based approaches for the diagnosis and treatment of multidrug-resistant tuberculosis and other priority public health issues. Such centers of excellence for the diagnosis and treatment of multidrug-resistant TB are essential to combating this growing challenge to TB control and could serve all of East Africa by taking advantage of advances in telemedicine and abilities to provide medical consultations from regional centers.

Another strength of coordinated laboratory and clinical networks in the East Africa sub-region is the opportunity to conduct research projects that address region-wide issues. Opportunities exist for operational, translational, implementation, and evaluation research to investigate drug resistance, diagnostic testing algorithms, impact of new rapid diagnostic methods on treatment outcomes, laboratory performance measures, treatment regimens, specimen referral systems, information flow and reporting systems, and other issues.
**Improve Harmonization and Integration of Laboratory Services:** To optimize patient care and the functioning of the public health laboratory network and to ensure integration and harmonization of activities the Ugandan disease-specific national reference laboratories (e.g., TB NRL, HIV/AIDS NRL, malaria NRL, etc) could be located in a single location. This would foster a more efficient and cost-effective operation of the laboratory network as network activities cut across disease lines. For example, cross-cutting activities that are critical for any public health laboratory network include quality assurance programs, quality management systems, accreditation, biosafety, procurement, logistics, specimen referral processes, information technology, reporting systems, monitoring, supervision, evaluation, and training. One could envisage designated officials in an integrated public health system that could ensure that all public health laboratories follow the essential elements of a quality management system, are accredited, participate in quality assurance programs, have safe work environments, etc. Co-localization might foster programs to cross-train TB, HIV/AIDS, and malaria laboratory staff and clinicians to provide integrated counselling and testing and care and treatment services and to cross-train supervisory staff to provide quality assurance for all programs.

This co-localization process could be gradual and progressive, perhaps starting with the National TB Reference Laboratory and the Central Public Health Laboratory which are both in the process of designing and constructing or renovating laboratory space. It would be of benefit to both laboratories if a new building was constructed that could provide sufficient designated independent laboratory space for each NRL as well as space for shared activities which would improve the efficiencies of each laboratory. The NTLR would require sufficient space to house its responsibilities as a NRL as well as dedicated space for its planned work as a supranational reference laboratory and programmatically relevant research activities. The CPHL would require sufficient space for laboratory activities associated with its diagnostic, surveillance and outbreak investigation activities as well as its administrative responsibilities. Shared activities, which would improve the efficiencies of each laboratory, might include designated staff persons to address the cross-cutting issues described above. It should be noted that the two laboratories (NTRL, CPHL) are currently independent programs; incorporation of these programs into an integrated national public health laboratory organization will have to be done carefully to avoid any disruption in the functioning or strengthening of either laboratory.

Overall, the World Bank regional project could provide financing for: (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 which the Bank is collaborating in; (ii) providing training and capacity building (iii) strengthening and putting in place quality management systems and linking the network of laboratories; (iv) assisting with operational and logistical costs; (v) providing technical assistance; and (vi) supporting public/private partnerships to scale up innovative programs. The activities eligible for financing would include both those focused on TB control as well as systemic health systems dimensions necessary for building sustainable public health laboratory capacity in Uganda and in neighboring countries.

**Potential Synergies between the Uganda Health Infrastructure and Systems Support Project and the World Bank Regional Health Systems Strengthening and TB Support Project:** A World Bank-funded Uganda Health Infrastructure and Systems Support Project is under
preparation on a track parallel to the regional project. The Infrastructure and Systems project will be focused on the broad strengthening of the performance of Health Center III and IV facilities, general hospitals, and upgrading of 2 general hospitals to regional hospitals. At these hospitals and health centers, general laboratory facilities will be renovated and re-equipped as required, management systems will be strengthened and human resource issues will receive a high priority. Complementing these efforts, the World Bank regional project will focus on strengthening laboratory capacity at the national level, with a primary focus on the TB NRL, but with the vision of supporting the creation of a National Public Health Laboratory System in which all NRLs for the major endemic diseases work together closely, under the direction of the Ministry of Health. Also, the TB NRL will provide support to five regional TB laboratories, which are housed in five of the regional hospitals. These laboratories will again provide support to general hospital laboratories, which support the operations of laboratories in Health Centers 4 and 3 in their district — the targets of the Infrastructure and Systems project.

The synergies arise because the projects address different tiers of the laboratory system while at the same time emphasizing building integrated laboratory services, which greatly facilitates the overall care of patients, and using a systems approach based on quality laboratory management principles. That is, while the Infrastructure and Systems Project has its main focus on tackling human resources issues and strengthening the broad functions of selected health facilities at the decentralized level, the regional project will focus on the specific laboratory component at national and regional level, and the development of a well functioning network of quality laboratories from the national level to the health Center level. This provides a unique opportunity to put in place appropriate laboratory capacity (physical and human) in the decentralized facilities and to link them to the regional treatment and diagnostic centers of excellence.

In addition, the financing from the regional project would reinforce support to be provided under the US$100 million Bank-funded health operation which is under preparation, to the extent that laboratory and diagnostic capacities would be reinforced at different levels of the health system with upgrading of infrastructure and diagnostic capacity and introduction of infection control measures, and strengthening of human resources at participating district hospitals.

**Policy Context:**

The proposed World Bank East African regional initiative for laboratory strengthening is in line with and supports global, regional and national health goals and priorities.

**Global Policy Context:** The Millennium Development Goals aim at eradicating poverty and improving health. Three of the goals are specifically aimed at health improvement through reduction of child mortality; improvement of maternal health; and the fight against HIV/AIDS, malaria and other diseases, including TB. More specifically, this initiative supports the objectives outlined in the Stop TB Strategy to achieve universal access to high quality diagnosis and patient centered treatment and protect poor and vulnerable populations from TB, TB/HIV, and multidrug resistant TB.

**Regional Policy Context:** Uganda is committed to all regional efforts aimed at improving health and development in East Africa and in Africa as a whole. More specifically, the 2008 Maputo
Declaration on Strengthening of Laboratory Systems in Africa recognizes the challenges limiting the scale-up of services for TB, malaria and HIV. It calls on national governments, donors, and partners to join their efforts in integrating support and improving laboratory systems.

Uganda National Policy Context: In line with the Maputo declaration and national health plans and policies, the Ministry of Health (MOH) has been working on preparing a National Health Laboratory Policy since March 2008, in line with the National Health Policy (NHP) and the Health Sector Strategic Plan II (HSSPII). The NHP advocates “the attainment of a good standard of health for all people in Uganda, in order to promote a healthy and productive life”. It focuses on the implementation of the Uganda National Minimum Health Care Package (UNMHCP), which emphasizes the principles of primary health care, equity, good quality services, and strengthening of collaboration and partnerships with all stakeholders both public and private. The HSSPII recognizes the laboratory services as one of the major support services needed for the effective and efficient delivery of the UNMHCP. However, it identifies the laboratory services as one of the areas needing improvement in order to improve the general functioning and effectiveness of the health system.

The National Health Laboratory Policy (NHLP):
Development of the NHLP: The process was led jointly by the MOH Assistant Commissioners for Communicable Diseases and Clinical Services (Hospitals), with external technical assistance from FIND. MOH engaged a broad range of stakeholders in an extensive consultative process over several months. This included the review and analysis of several policy documents dealing with health issues in Uganda, identification of the challenges for Uganda’s laboratory services, and the development and review of policy drafts to obtain a consensus. The interactive workshops and meetings were attended by heads of department and divisions of the Ministry of Health, directors of major hospitals in the public and private sector, proprietors and managers of public and private laboratories, academia, laboratory practitioners from various levels of the health system, and a number of development partners. In August 2008, the draft policy document was submitted for the required internal review processes within the Ministry of Health. This is almost complete and the policy is expected to be ready in April 2009 for launch and dissemination.

Aims and Content of the NHLP: The policy aims to provide a framework and guidance for ensuring that health laboratory services in Uganda are strengthened to support the effective and efficient delivery of the UNMHCP to all people in Uganda. The overall objectives of the policy are four-fold:

1) to put in place an organizational and management structure for coordinating laboratory services,
2) to develop, deploy, motivate, and retain adequate numbers of laboratory staff,
3) to mobilize financial and logistical resources required to support the delivery of quality laboratory services, and
4) to establish a system for monitoring and evaluation of laboratory services.

The specific policy objectives and strategies for achieving these are intended to address the major challenges for laboratory services and therefore cover the following areas:

- Management and organization
- Laboratory services
The policy is intended as a true ‘national’ policy and is applicable at all levels of the health system to both public and private sectors. Of particular interest for the World Bank, is the promotion of partnerships between public and private laboratories in order to improve equity and access to quality laboratory services.

**The National Health Laboratory Strategic Plan (NHLSP):** Currently the MOH with its partners is in the process of developing a National Health Laboratory Strategic Plan (NHLSP) which is aligned directly with the laboratory policy objectives and strategies. In reality, this is a plan for effective implementation of the laboratory policy. It will spell out the activities, deliverables, indicators on the progress of the implementation, timelines for the specified activities, as well as persons, institutions and organization or partners responsible for the different activities in the implementation process. Following initial consultations, the Laboratory Technical Committee, chaired by the Assistant Commissioner for Communicable Diseases and composed of representatives from the public and private sectors, is responsible for the practical development of the NHLSP. The plan is expected to be completed during 2009.

**Target beneficiaries and additional positive effects**

TB and HIV infected patients, their families, health care providers, the national and district health systems, and even whole communities will all benefit from this project. In turn, the country will gain socio-economically as the burden of disease is decreased in the economically active population and the costs of seeking care are reduced.

**Individuals (infected, at-risk, families/friends, communities):** Strengthening and expanding the laboratory network in Uganda will benefit those individuals in rural areas who are currently underserved in addition to those with more ready access in urban centers. The ability to better diagnose cases, both TB and MDR-TB, will reduce current and future morbidity and mortality due to TB, but will also complement activities done through the HIV/AIDS control program. This collaborative approach will allow more individuals to access both ART and CB-DOTS.

**Health Workers:** The supplying of laboratory and diagnostic equipment and subsequent training along with supportive supervision will enhance the skills of health workers, particularly those employed within the laboratory network. This will have further benefits as most laboratory personnel are responsible for more than just identifying TB. Infection control measures will
reduce the high attrition and morbidity amongst TB health workers and, perhaps, lead to greater staff retention.

Health Systems Strengthened: Some of the potential benefits of this project include: the strengthening of human resources through new and refresher training leading to personnel better able to carry out anti-TB efforts; a stronger capacity to manage TB, HIV, and co-infected individuals; an improvement in the provision of services both geographically and demographically; and overall program management and monitoring, including the management of the supply chain. Further, the HMIS would be strengthened through the linking of laboratory results at all levels, collaboration between programs would be increased, and service delivery would, thus, be of better quality and more comprehensive.

Economic Benefits: The World Bank published a paper "The Economic Benefit of TB Control" (Policy Research Working Paper 4295, 2007) that identified a benefit to cost ratio of 9:1 for investments made in TB control in populations with a high prevalence of HIV infection in Africa. With an estimated 561/100,000 Ugandans infected with TB in 2006, and those infected mainly in their most economically productive years, the economic benefits of addressing TB become that much more compelling.

Regional Benefits: There is a strong possibility that Uganda will be a site for a Supranational Reference Laboratory or Center of Excellence which will result in a number of additional benefits for the region including: additional, coordinated, and standardized training opportunities; strengthened and regionally led quality assurance programs; and more readily available first-line and second-line drug-susceptibility testing for surrounding countries. An increase in the availability of drug-susceptibility testing would be expected to reduce diagnostic delay for patients suffering with MDR and XDR-TB. Additionally, as improvements are made at both the regional and country level this will necessitate that collaborative efforts are strengthened between participating countries. Finally, with periodic migration and goods and services routinely traded between countries, the prevention and control of TB in one country will indirectly benefit neighboring countries.

Sustainability and Risks:

Sustainability: The Ugandan NTLP has shown itself to be committed to fighting TB and TB/HIV through its long-standing use of DOTS, its seeking out of additional sources of funding for TB treatment and control efforts, and its consistent collaborative efforts in developing its programs. Because all activities will be derived from the NTLP’s strategic plan along with other pre-existing programs, sustainability will be better assured through government and partner support. Further, the Ugandan NTLP has already identified its low case detection rate as an area in need of strengthening and support. Additional resources to address this issue will strategically targeted at those activities which will yield the greatest benefit for the lowest cost, with an emphasis on reducing recurrent expenses that may be a result of capacity building and infrastructure upgrades.

Risks and Controversial Aspects: Because this project is both country-specific and regional in nature, the potential for a lessening of political commitment or disagreements amongst participating countries is great. However, both the design and implementation phases of the
regional project will include not only the Government of Uganda, but also targeted regional institutions such as the East African Community and South African Development Community and, thus, promoting ownership in the political process.

Sustainable financing will remain a risk in terms of the recurrent and on-going costs associated with the laboratory network. Assurances will be built into project agreements that will help sustain the needed recurrent financing either through government or other donor commitments. Furthermore, careful planning and forecasting will be utilized to ensure that funds are used to rationally target technical and geographical areas of need. Participants will be trained in the necessary financial management tools to adequately ensure the economic viability of the laboratories. Because of the amount of funding now available for both TB and HIV efforts in Uganda, there is also the additional risk of duplicating efforts, poor coordination, and subsequent failure to deliver on project promises. However, all of these risks are mitigated by involving all relevant stakeholders during the project’s design, development, and implementation and establishing a coordinating or steering committee.

The World Bank regional project will also ensure that any controversial aspects related to its implementation in Uganda are mitigated. For example, the geographical distribution of diagnostic and treatment units is severely skewed with some having population ratios as low as 1:20,000 while others are as high as 1:190,000; the majority of health units are in urban areas. This may conversely lead to a “not in my backyard” attitude among those living near current or possible sites. The project will also work with its partners to ensure that there is an adequate geographic distribution of facilities within the laboratory network along with informing resident populations of the nature of the facilities and their work, and mitigating any potential environmental hazards. Thus, the project will not only increase equity in the availability and accessibility of services, but will also mitigate stigma and discrimination associated with TB and TB prevention and control efforts.
St. Raphael of St. Francis Nsambya Hospital, supported by the Italian Association for Solidarity among People (AISPO). This hospital is a Health Center 6. The WB team was escorted by Dr. Francesco Aloi from AISPO. The laboratory of Nsambya Hospital has a full service laboratory providing the following tests:

- AFB smear microscopy
- Malaria smears
- Microbiology
- Parasitology
- Clinical monitoring for patients on ART – CD4, viral loads, chemistry, hematology
- Cryptococcal antigen (CrAg) test performed on CSF – (There are many meningitis cases, especially in children. It was reported that there is a need to heat fix CSF from children to eliminate large amounts of protein that will cause false-positive agglutination.)

The laboratory space was small and crowded, but a new facility including space for BSL 2 and BSL 3 laboratories is under construction. TB culture will then be performed on site.

The laboratory staff also provides site supervision for laboratories performing AFB smear microscopy and serves as the 1st controller for re-reading AFB smears for EQA for Kampala, and 2nd controller for the Central Zone. Two booklets were received from Dr. Aloi:

- AISPO STOP-TB Project Activities, based at St. Raphael of St. Francis Nsambya Hospital Laboratory in Partnership with Uganda National TB and Leprosy Programme (NTLP), 4th Quarter, October – December, 2008
- 2nd Laboratory Assessment for Kampala and Central Zone, October 2008

The following questions were asked during the lab assessments.

1. How long have you been working in this place?
2. How many people work in the lab?
3. Are you available at this lab all the time?
4. How often does the DTLS visit this laboratory?
5. Number of working/non-working monocular scopes?
6. Number of working/non-working binocular scopes?
7. Where do you take the faulty microscopes for servicing?
8. How long does the servicing take (in days)?
9. Do you have an NTLP register?
10. If no, where do you register results?
11. How long does it take to return results to patients (in days)?
12. Are TB smears kept in order?
13. Does the lab have the required reagents to do TB tests?
14. Who is the supplier for these reagents?
15. Have you ever received expired reagents from this supplier?
16. How do the reagents get to the lab?
17. Have you ever run out of stock?
18. If yes, why did you run out of stock?
19. Are gloves available in the lab?
20. Is there a sink with running water?
21. Is the airflow adequate?
22. Is there a method for infectious waste disposal?
23. Are lab coats available in the lab?
24. Is there sufficient storage space?
25. Have staff participated in previous assessments and workshops?

Entebbe Hospital, Mpanga Robert, Hospital Administrator. This is a Health Center 4. It provides only minimal laboratory services, but has an operating theater which elevates the facility from a HC 3 to a HC 4. The World Bank team was escorted by Roy, the laboratory supervisor. The main laboratory is very small, with several staff and students. AFB smear microscopy is performed in a small section of the laboratory, along with rapid methods for syphilis, HIV, malaria smears, and typing for blood transfusions. Other simple methods are also performed. A poster indicating the appropriate way to discard waste had been received in the laboratory describing how different types of waste should be discarded in bins of different colors. The laboratory was not able to read any smears because the electricity had been off for the last 24 hours.

The team also visited the isolation ward for TB patients – this ward was located in what was a previously a remote area, but now is surrounded by homes and businesses. Although the health care worker had received a Certificate of Merit for her work, she expressed feelings of being overwhelmed with the many tasks expected of her – dispensing of TB drugs, following-up with many clients on therapy, and performing AFB smear microscopy for follow-up cases. A positive smear was read by the team (power was on here), although focusing of the microscope was not ideal. There was a critical need for TB reagents and slides that are close to stock outs, and expiry. The system for ordering reagents through the National Medical Stores is difficult, with the need for the order to go through the District Laboratory Focal Persons, with delivery to the District site rather than directly to the laboratory in need.

Ndejie Health Center, is located in a community between Entebbe and Kampala. The team was hosted by Omusawo Womusaayi, laboratory technician. This HC4 facility was very difficult to reach because of its location on a steep hill in the middle of a highly populated area accessible only on very rough dirt roads. It appeared that most of the testing being performed was AFB smear microscopy, HIV rapid testing, and malaria smears. There was a small theatre where cesarean sections, appendectomies, hernia repairs and other emergency operations could be performed. A binocular microscope was functioning but was kept locked up to ensure that it would not be stolen. A monocular scope with a mirror light source was also available. The NTLP register was in use and used appropriately. As in the other laboratories visited today, no control slides were prepared and stained either daily or with each batch of slides. A hand-crank four-tube centrifuge was used to spin down bloods and urines. Unlike the stock-out situation seen in Entebbe, this laboratory had a large quantity of stains. Because of the light workload in this facility, some likely will expire before use. It appears that the uneven distribution of supplies is fairly common. There was an ample supply of slides, however the slides did not have a frosted end needed to label with a pencil, so the technician was forced to look for and purchase a diamond pencil.
Report of field visits on 1 April 2009
Visiting team: Miriam Schneidman, Catherine Mundy, Jeroen van Gorkom, Fred Kangave (NRL), Mpigi District TB/L Coordinator

Mpigi district
The district North-West of Kampala has a population of 420,000, which is served by 2 hospitals (1 MOH, 1 FBO), 2 Health Centers 4, 62 Health Centers 3. We were able to meet the Chief Administrative Officer (Mr. Henry Makombe) and the District Medical Officer of Health. Main health problems cited by CAO were sanitation and hygiene, malaria, HIV/AIDS; and lack of human resources to address these problems in an effective manner. Although the devolution to district level enables the district to recruit staff directly, remuneration packages (money and housing) are not successful in attracting sufficient staff. Administrative procedures are tedious and time consuming, and the salary scales are fixed and identical per staff category in all parts of the country. His budget is inadequate to meet the needs of the district, earmarked for specific activities and does not allow for any improvisation.

TB treatment success of new ss+ patients in the district is low at XX%, due to a default rate of 25%. The district does not have a CB-DOTS program, ensuring that patients complete their treatment. (2007 cohort). TB/HIV activities are well implemented, with 92% of TB patients having an HIV test result, 66% being HIV+, 80% being on CPT. 15% of registered HIV+ TB patients are reported to also receive ART during TB treatment. DTLC says this is under-reported due to problems in proper recording.

Mpigi Health Centre (4)
We were met by one of the Clinical Officers working in the HC (Mr. Amos Sijambo). The HC is offering the following clinical services: MCH and ANC; mental care; immunization; PMTCT; laboratory (mostly doing malaria blood smear, HIV tests, TB smear examination, and some others like Hb, stool, urine, bloodbank/transfusion; maternity facility (14 beds); general admission ward (31 beds); surgery (mostly cesarean section, emergency surgery, some elective operations); dental services. At the compound JCRC has constructed a new building for the ART clinic, staffed by HC staff complemented by 1 – 2 JCRC staff (data management officer). The HC has 2 medical officers, 6 clinical officers(?).

Laboratory: The lab is staffed by 1 technician (absent), 1 assistant technician (for 6 years), and 1 volunteer (1 ½ years working there without salary, secondary school leaver, does all lab work, which he learned on the job). The lab is quite small, but adequate for the work that is mostly on malaria BS, HIV testing, and AFB examination. The microscope is of poor cheap quality, not really suitable for malaria BS and AFB. The TB laboratory register is well recorded. In the first quarter the lab examined 40 patients, 10 of which were found with sputum positive. The burden of sputum smear examinations is this almost equivalent to 1 patient per day, quite a low burden. It is noticed that the register does not indicate whether the ss+ patients are also on TB treatment – as is advised by NTLP. EQA: All sputum smears are kept in 4 smear boxes, for EQA. Smears are selected during supervision by the DTLC who brings them to the District Lab Focal Person for re-reading under the TB NRL EQA program.
TB: The TB Register is overall well recorded, but is not up-to-date. For several patients there are no records of attendance over the past months. The District TB/L Coordinator explains that this is due to the fact that the many HIV+ patients (about 60% of TB patients are HIV+) are mostly on ART at the ART clinic operated under JCRC, where they receive their TB treatment during a one-stop-shop consultation. Their attendance is recorded in the ART electronic register and patient card, not in the Facility TB Register. The DTLC is the one collecting all the information from the patient cards when he comes to the HC to collect the data for the quarterly report. The HC does not have a dedicated or focal person for TB.

Gombe (district) hospital - MOH
We meet with the MO in charge and the laboratory technologist. The hospital has 6 medical officers, of whom several are generally absent for training on shorter or longer courses.

The laboratory is housed in a spacious and light room (of 6 x 6 meters and 2 adjacent rooms) with benches along the walls and one in the middle, at the OPD. The lab has only 2 staff, one technologist and a laboratory assistant. The lab technician is also the District Lab Focal person who is responsible for supervising 23 labs in the district. In general he manages to visit each lab once per year, due to competing clinical priorities, while it should be quarterly. He has a checklist to assist him, but time is often limited allowing only a quick running-off of the checklist. He carries stained and non-stained sputum smears to check on proficiency in reading and staining. He also does blind re-reading of smears, on average 50 smears for each laboratory. He may use a vehicle or motorcycle for this supervision work. Funds for supervisions are a problem (@ USh 150,000 or approx U$60). He generally uses a motorcycle for the supervision.

Most of the lab work is on HIV testing, TB smears, malaria BS and hemoglobin. It has one good binocular microscope (Olympus) provided by NTLP. TB smear lab turn-around-time is cited as 8-12 hours. Patients need to bring 3 specimens still (not 2 as is the most recent policy). On the second day when patients bring 2 additional specimens (early morning and spot) they wait for the results.

Supply management is an issue, because funding is limited. The laboratory mostly has no running water, as the general hospital. Power cuts are a common problem, paralyzing lab operations.

The hospital does not have a special TB ward. Admitted TB patients are separated in one corner of the ward. TB Infection measures are virtually absent beyond the practice of separation.

Community involvement in TB control is not much developed. The district has >3,000 Village Health Teams in the district, which are involved in prevention and health education, guided by Gombe district hospital staff.