TB CARE I is a USAID five year cooperative agreement (2010-2015) that has been awarded to the Tuberculosis Coalition for Technical Assistance (TBCTA) with KNCV Tuberculosis Foundation as the lead partner. TB CARE I is a unique coalition of the major international organizations in TB control: American Thoracic Society (ATS), FHI 360, International Union Against Tuberculosis and Lung Disease (The Union), Japan Anti-Tuberculosis Association (JATA), KNCV Tuberculosis Foundation, Management Sciences for Health (MSH), World Health Organization (WHO).

Celebrating the second Supranational Reference Laboratory in Africa, the National Tuberculosis Reference Laboratory in Kampala, Uganda recently made the grade; here’s the story and what came next...
Background

The WHO/Global Laboratory Initiative (GLI) TB Supranational Reference Laboratory Network was created in 1994 in order to support the WHO-International Union Against Tuberculosis and Lung Disease, Global Project on TB drug resistance surveillance. The objectives of the Global Project are to estimate the magnitude of drug resistance globally, determine trends and provide data to inform WHO policy decisions.

The core principles of the Global Project are to ensure accurate and representative sampling of the populations under study, allow for the differentiation of new and previously treated cases and ensure that laboratory results are quality assured.

The original terms of reference required that each of the Supranational Reference Laboratories had a permanent functional TB laboratory providing quality culture and drug susceptibility testing (DST), with a commitment to support at least two countries with DST proficiency testing, to provide external quality assessment during drug resistance surveys, and to provide training on culture and DST.

Between 1994 and 2013, the network expanded to 30 laboratories, largely driven by regional initiatives and institutional interest in joining the network.

The Criteria

TB SNRLs are expected to meet the following minimum criteria:

1. Officially recognized by the National Health Authority or Ministry of Health acting as National Level TB Reference Laboratory (NRL) supporting a functional national or sub-national network of lower level laboratories.

2. New candidates must have a formal link with an established TB SNRL, which mentors them for at least one year.

3. Technical capacity to perform acid-fast bacilli (AFB) microscopy, culture, identification and DST of *M. tuberculosis* using phenotypic and molecular methods according to current WHO policy guidance.

4. Meet national laboratory regulations and conform to WHO and other international standards for performing TB testing.

5. Proven DST accuracy (participated in at least 2 consecutive rounds of supranational reference laboratory network proficiency testing) with sufficient workload levels to maintain proficiency.

6. Ability to support laboratories in other countries.

7. Established or the capacity to establish working relationships with NRLs in other countries through formal links.

8. Commit to provide the minimum SNRL service requirements, specifically:
   a. Establish formal links with at least two NRLs.
   b. Provide at least three technical assistance visits to countries every two years.
   c. Provide reports to the GLI secretariat on SNRL services provided to countries.
   d. Report at least one activity per country per year.
In January 2007, the United States Agency for International Development (USAID)-funded Tuberculosis Control Assistance Program (TB CAP) organized a meeting in Nairobi, Kenya at which the idea of having a SNRL for TB in East Africa was first proposed. At that point there was only one SNRL in sub-Saharan Africa, which was located in Pretoria, South Africa. The thinking was that a SNRL serving the East-Africa region would facilitate the development of quality TB laboratory networks, which are essential for the diagnosis of TB. During that meeting, the national reference laboratories of various countries, including Uganda, were identified as candidates. After a careful assessment, which included strong political commitment from the Ugandan Ministry of Health, Uganda was selected, and the project to support it got underway.

The project was developed under TB CAP and TB CARE I and funded by USAID, with The Union as lead. They, together with the supranational laboratory at the Tropical Institute in Antwerp, KNCV Tuberculosis Foundation and the Royal Tropical Institute in Amsterdam have worked continuously over the past seven years with the laboratory staff in Uganda.

The strategy was to first strengthen the national TB reference laboratory (NTRL) so it was able to fulfill its role and responsibilities of providing quality services throughout Uganda. Once that was established, the next step was to invest in the resources needed to ensure that the laboratory and its staff could provide international services to other national reference laboratories in the East Africa Region.

Four years later in early 2011, and after a wide range of activities, improvements and interventions had been carried out, an assessment conducted by the WHO, found that the laboratory met the requirements to qualify as a SNRL-candidate. It was given a two year probation period to prove its capacity to help other laboratories in the region.

Two years later, the goal of being a WHO-certified and registered SNRL was reached. The Director of the Stop TB Department, Dr. Mario Raviglione, said that he “recognized the hard work and the commitment made by the Uganda TB laboratory in order to be confirmed for supranational laboratory status” and he called upon other TB laboratories, especially those that are located in Africa, to strive to achieve the same status.

“It’s going to be much easier in terms of disease diagnosis”
Uganda SNRL Director Dr. Moses Joloba

HOW IT HAPPENED
The major milestones in the laboratory's progress towards supernational reference laboratory status.
“With the new diagnostics in hand and new drugs on the horizon, we are at a turning point in global TB control”

TB CARE I Director, Maarten van Cleeff

Workers in the Uganda SNRL (Photo by Tristan Bayly)

WHAT DID IT TAKE?

Investment and Support

In order to reach SNRL status, the laboratory benefited from US Government investments which amounted to around $6 Million.

The three main areas of TB CAP/TB CARE I support were:
1) Technical Assistance & Training
2) Support for staff salaries
3) The procurement of equipment and supplies.

Leadership, Persistence and Determination

Laboratory Director Dr. Moses Joloba, his entire team, all the technical partners and USAID, all remained steadfast in their commitment to making this project a success. It took more time than originally planned and had to overcome many challenges, such as staff retention. The development and approval process for annual workplans was sometimes frustrating, but the team persisted.

A New Mindset

Perhaps the most important part of the undertaking was the introduction of a “quality mindset”. Beginning in 2008 with a course entitled “An Introduction to Quality Management”, this process was by no means straight forward, but gradually the entire team began to understand how quality leads to efficiency.

Team Spirit and Coordination

The Ugandan SNRL is an excellent example of successful partnerships. This achievement would not have been possible without the support of other institutions. Alongside the renovations, the CDC worked on integration into wider public health services, FIND focused on the introduction of GeneXpert, Case Western Reserve University focused on research, and the German Leprosy Relief Association supported supplies and in-country services.

The laboratory management has shown its leadership in coordinating interventions from so many stakeholders.

On 15th April 2013 the NTRL of Uganda became the first TB laboratory in East Africa to achieve SNRL status. A hand-over ceremony of the prestigious SNRL certificate took place during the 5th Annual Global Laboratory Initiative (GLI) meeting in Annecy, France.
Uganda is one of only two countries in Africa to receive this certification from the WHO, and when the SNRL certificate was granted in April 2013 the laboratory became the first in East and Central Africa to attain supranational status.

This certification is a step towards eliminating TB in Uganda and neighboring countries. Currently 22 countries collectively account for about 80 percent of the world’s TB cases (so called high burden countries), Uganda is unfortunately one of these, as are its neighbors, Tanzania, Kenya, Ethiopia and the Democratic Republic of Congo, and approximately 25 percent of the world’s TB cases are in Africa.

To add to the problem, the more deadly form of TB, Multi-drug Resistant TB (MDR-TB), is spreading both in East and Central Africa due to challenges of delivering quality treatment regimens and making sure TB patients take their medication strictly as prescribed. Not taking the full course of drugs or taking them inconsistently can cause the TB bacteria to mutate and become resistant to drugs. These drug resistant and multi-drug resistant strains are far more difficult to diagnose and to treat, which leads to increased transmission and means laboratories such as this one are more important than ever before.

Laboratories throughout Uganda rely on the SNRL to provide quality testing and control, in order to ensure that local laboratories are diagnosing patients correctly and to provide training on new laboratory technology. The ‘Supra’ designation means the laboratory can now accept samples from any laboratory in Africa, which means that thousands more people can now be accurately tested and, if found to have TB, started on treatment. Previously, National TB laboratories in Sub-Saharan Africa had to send their samples to South Africa or to Europe for quality diagnostic testing. Now, with this certification, this laboratory brings affordable diagnostic services to countries across the region. This accomplishment shows it is possible to achieve high TB diagnostic standards in the developing world, at an affordable price.

The annual number of samples received at the laboratory has increased from 153 in 2008 to over 10,000 today. Previously, a sputum sample used to take an average of 17 days to reach the laboratory; the average is now just 48 hours, and once the samples arrive, it usually takes about two hours to carry out a diagnosis, meaning more lives are being saved.

“No one should die of a disease that is preventable or treatable”
American Ambassador to Uganda, Scott H. DeLisi
The East African Public Health Laboratory Networking Project funded by The World Bank aimed to improve 32 laboratories in cross border areas in East Africa (Burundi, Kenya, Uganda, Rwanda and Tanzania). The Uganda SNRL was chosen to lead both the Laboratory Networking and Accreditation Working Group.

The Uganda SNRL pioneered the innovative cost effective peer review mechanism by which the five East African Community member states assess each other’s performance annually using the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) checklist (a WHO standardized checklist to score laboratory elements giving a one-five star rating).

To ensure objectivity and promote cross country learning, assessors are drawn from the cross-country pool of professionals trained and certified by Africa Society for Laboratory Medicine (ASLM). This ensures that assessments are performed using highly qualified personnel and that they produce robust and reliable results.

Participation in the laboratory network has provided a structured and supportive process for making improvements on quality systems. This creates both healthy competition and a sense of solidarity. The main benefits of the network are that it fosters mutual accountability, promotes collaboration, and provides a platform for learning from innovative practices.

Under the leadership of the Uganda SNRL and through the TB CARE I supported East, Central and Southern Africa Health Community (ECSA-HC), the Laboratory Networking and Accreditation Technical Working Group has guided countries, facilitated training and provided technical support.

The first annual assessment in December 2011 revealed that less than 25 percent of the laboratories were at or above the project goal of two stars, and the majority of these were in Uganda.

By the third annual review in 2013, 77 percent of project-supported laboratories scored at least two stars, of which 33 percent scored three stars and 17 percent reached four stars. Since the beginning of the project, facilities in Kenya and Rwanda have made the most progress.

The Uganda NTRL has also won two key awards from the ASLM, the first for best laboratory practice in Africa in 2012 and the second for achieving accreditation as a government institution in 2014.

**Main Achievements:**

1. Over 75% of the laboratories now have more than two stars using the WHO stepwise SLIPTA process
2. Turnaround times have gone from eight weeks to a maximum of two days
3. Specimen referral systems have increased access to services
4. Use of laboratory information management systems.
TB CARE I - Laboratory Tools

This toolbox contains 6 products to support countries in strengthening their laboratory services:
1. A Roadmap for Laboratory Strengthening
2. Standard Operating Procedures (SOPs)
3. Logistics/Supply Management Tool
4. External Quality Assurance Training Package (EQA)
5. Management Information System (MIS)
6. Culture & DST Training Package

Download the laboratory tools.

Laboratory Diagnosis of Tuberculosis by Smear Microscopy (Updated 2013)

This handbook uses simple text and clear illustrations to assist laboratory staff in understanding the important issues involved in conducting sputum smear microscopy for the diagnosis of TB.

Download the publication.

A Practical Handbook for National TB Laboratory Strategic Plan Development

This handbook is designed to help national TB control programs to develop a TB-specific national laboratory strategic plan. It draws upon ‘Guidance for Development of National Laboratory Strategic Plans: Helping to expand sustainable quality testing to improve the care and treatment of people infected with and affected by HIV/AIDS, TB and Malaria’ and from the Global Laboratory Initiative’s ‘Roadmap for ensuring quality tuberculosis diagnostics services within national laboratory strategic plans’.

Download the publication (Zipped Package).

TB Microscopy Network Accreditation

This guidance document is a tool that allows both countries and consultants to objectively evaluate laboratory performance against a set of standards that represent existing WHO guidance and to develop the foundation for a network accreditation program based on WHO-approved guidelines and standards.

Download the publication.

For the full range of TB CARE I Laboratory Tools visit:
http://www.tbcare1.org/publications/toolbox/lab

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