

# BUILDING RESILIENT WORLD-CLASS TB DIAGNOSTIC SYSTEMS IN THE ECSA REGION AND BEYOND



# **POLICY BRIEF**

#### Introduction

Tuberculosis (TB) remains one of the leading causes of morbidly and mortality in the East, Central and Southern Africa (ECSA) region. The countries of the sub-region (with an estimated population of 410 million) had an estimated incidence of 1.07 million TB cases in 2016. The region reported over 154,161 deaths due to TB among HIV negative people, and an additional 142,342 deaths among HIV positive people. Globally, the highest incidence rates of TB for 2015 were recorded in the ECSA sub-region, ranging from 22 to over 800 per 100,000 population. The incidence in South Africa was 834/100,000, followed by Lesotho (788/100,000), Eswatini (565/100,000) and Mozambique (551/100,000).

Every year, ECSA sub-region is 'missing to find' 46% (497,851 TB cases) of estimated incident new TB cases. In 2016, this accounted for 15% of global estimated burden of 'missed to find' TB cases of about 3.7 million cases. Ethiopia and Kenya lead this list of missed to diagnose TB cases in the region. Further, about 25% of all notified new TB cases (clinically diagnosed TB cases) in the region were treated empirically in 2016.

#### Context

While the global strategy for TB has shifted from 'Stop TB' to 'End TB' strategy, the plan to achieve this for lower income countries remains unclear. Successful management and treatment of TB, especially drugresistant TB requires a robust network of TB laboratories with adequate biosafety, modern methods for diagnosis, standard operating procedures and appropriate quality assurance. However, in many countries, the TB laboratory component has historically been chronically underfunded, and at times unprioritized and understaffed. This is characterized by ineffective laboratories systems, poor transportation systems and low investment in health that consequently affect the functionality of the laboratory network, making achievement of quality TB diagnostics harder.

Lack of diagnostic capacity is a barrier preventing an effective response to the challenges of TB, and multi-drug resistant TB. A high-quality TB diagnosis and robust laboratory networks is critical for finding and treating missed people affected with TB. Therefore, service delivery through high quality regional and in-country laboratory networks has a critical role in global efforts for finding missed people affected with TB. This would help achieving the goals of WHO End TB strategy (and associated targets of 90% reduction in TB deaths and an 80% reduction in the TB incidence rate by 2030, compared with 2015) and related Sustainable Development Goals (SDGs) for 2030.

This policy brief, therefore, makes recommendations on how lower income countries can be supported to achieve quality TB diagnostics.

# The Role of Supra-National Tuberculosis Reference Laboratory (NTRL), Uganda in Strengthening TB Lab Systems in the Region

NTRL Uganda received accreditation from the World Health Organization (WHO) in April, 2013, becoming the first Supranational TB Reference Laboratory (SRL) in Sub-Saharan Africa and the second after Algeria in Africa. Consequently, it now serves a dual purpose as NTRL Uganda, and on the other hand, as SRL Uganda, supporting other NTRLs in East, Central and Southern Africa (ECSA) region to improve TB diagnostics.

This policy brief is based on experiences and lessons learned by Uganda Supranational TB Reference National Laboratory (SRL), while implementing a Global Fund supported 'Regional TB Lab Strengthening Project' in partnership with the East, Central and Southern Africa Health Community (ECSA-HC).

The Global Fund project currently supports National TB Reference Laboratories in 21 countries, namely; Angola, Botswana, Burundi, Eritrea, Eswatini, Ethiopia, Kenya, Lesotho, Liberia, Malawi, Mauritius, Mozambique, Namibia, Rwanda, Seychelles, Somalia, South Sudan, Tanzania, Uganda, Zambia and Zimbabwe. In this project, ECSA-HC serves as the principal grant administrator and plays the facilitating and coordinating role; while Uganda SRL runs the lab operations and implements the project through supporting and mentoring the national laboratories of the countries to build robust, resilient and sustainable TB diagnostic systems.

## Achievements by the SRL Project in Uganda

With the support of Global Fund, SRL Uganda has made significant strides in improving TB diagnostic services in the region. The Uganda SRL has over the years served as a demonstration site offering training and peer-to-peer mentorship – both regional training courses and in-country sessions – as well as services in the areas of diagnostic testing, external quality assurance, proficiency testing and quality management systems.

Consequently, these have led to accelerated accreditation of National TB Labs in the region, moving from only one accredited NRL in 2015 (Uganda) to six by 2020.

# The Gaps

Despite the achievements mentioned, significant gaps remain. Countries play a critical role of in strengthening the diagnostic arm of the health system especially at such a time where more importance is being placed on diagnostic services. However, the region's reliance on donor funding mainly the Global Fund, the US Government, the UK government and others has made most TB programs unsustainable. Additionally, many aspects that are out of grant support, such as lower level laboratories and maintenance lag behind.

Out of SRL Uganda's experience in implementing the Regional TB Lab Strengthening Project, the following gaps have been identified:

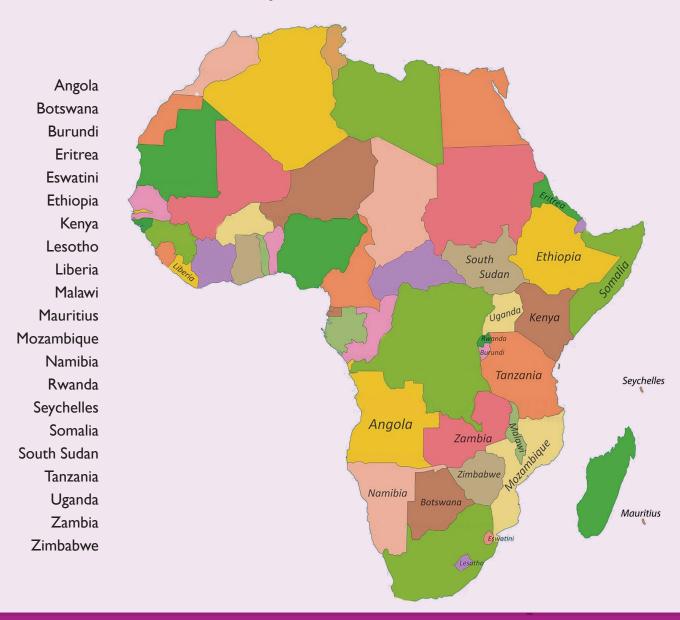
- In most countries, the national TB reference lab is often not part of the National TB program. This greatly affects coordination of programs.
- The National TB reference laboratories do not have specific laboratory strengthening plans and are usually underrepresented in the national TB strategic plans.
- There are no technical guidelines contextualized on the region's disease patterns as well as surveys on prevalence and drug resistance.
- As the countries apply for accreditation, there are no guidelines for implementing the laboratory accreditation process, thus a number of countries get stuck in the application processes.
- There are no well-organized accredited training courses relevant to the region, thus trainings are often outsourced to other SRLs outside Africa and most countries in the region cannot afford to send their laboratory HR to attend the trainings.
- Due to underfunding and poor management of commodities and supplies, the TB laboratories often suffer from commodities stock-outs or expirations.

### Policy Recommendations

To achieve effectiveness of national TB programs, there is need to maximize effects of investments, ensure country ownership, invest and maximize the use of data to improve programming. On a policy level, the following are recommended:

- To strengthen coordination, National TB programs and National TB Reference laboratories need to work together to reinforce TB/DR TB diagnostics services in countries.
- There is need for revision of existing TB strategic plans to factor in a more pronounced laboratory component.
- National TB Reference laboratories need to develop laboratory strengthening plans.
- The region needs contextualized technical guidelines for prevalence and drug resistant surveys.
- There is a need to develop guidelines for implementation of the laboratory accreditation process.
- Countries need to adopt a supply chain portal for management of TB laboratories supplies which gives opportunities to network laboratories and share stocks to reduce stock-outs and expirations.
- With the newer and more efficient technologies, countries need to speed up the process of adoption of the newer technologies like the new rapid molecular diagnostic tests, such as, the Genome Sequencer.

# GLOBAL FUND PROJECT BENEFICIARY COUNTRIES





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