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USAID TB PROGRAM SOUTH AFRICA: TB DIAGNOSTICS TECHNICAL BRIEF

Lack of diagnostic capacity has been a significant barrier in preventing an effective response to the tuberculosis (TB) epidemic worldwide. According to the World Health Organization (WHO)'s Global Tuberculosis Report 2012, "a high-quality laboratory system that uses modern diagnostics is a prerequisite for early, rapid and accurate detection of TB". Inadequacies in laboratory capacity in many low and middle income countries have been cited as part of the reason why only 66% of the estimated 8.7 million TB cases in 2011 were diagnosed and notified by national TB control programs. South Africa has nearly half a million incident cases of TB each year, as well as high burdens of multidrug-resistant TB (MDR-TB) and TB/HIV co-infection. Funded by the United States Agency for International Development (USAID), the TB Program South Africa (2009–2014) is supporting the South Africa National Department of Health to expand access to rapid, high-quality diagnostics so that TB patients are initiated on treatment sooner, raising their chance of being cured and reducing their chance of spreading TB to others.

Mapping and Identifying Gaps in Laboratory Systems

The USAID TB Program South Africa undertook a desk survey in 2010 to identify preliminary challenges with the country's laboratory system. Identified challenges included prolonged sputum turn-around time, problems in cold chain maintenance during the transportation of specimens and insufficient access to laboratories by the clinics and screening sites. The next year, in partnership with the National Health Laboratory Service, the program mapped all the TB microscopy diagnostic centers in the country to determine the coverage of TB laboratory services. The program also developed a facility diagnostic information collection (FDIC) tool and a laboratory diagnostic information collection tool (LDIC) to collect information on bacteriological diagnosis of TB and document whether appropriate procedures were in place. Using these tools, the program can investigate laboratory challenges, share the findings with facility and district staff, develop interventions, and monitor progress through follow-up site visits.

Rapid Assessment

In 2011, the TB Program South Africa used the FDIC and LDIC tools to conduct a rapid appraisal of 22 facilities in Mafikeng district and 10 facilities in Ventersdorp district of Northwest Province in response to the poor performance of the province's TB program. The assessment revealed a lack of TB registers in some facilities and poor recording and updating of results in others. These results informed the development of tailored interventions to help the facilities address their diagnostic challenges.

Roll Out of GeneXpert Rapid TB Testing

Early diagnosis is essential to achieving significant reductions in death and disability as a result of TB and HIV. One of the key objectives of TB Program South Africa is to foster early diagnosis through expanded access to new and effective diagnostic technologies.

In December 2010, WHO endorsed Xpert MTB/RIF (GeneXpert), a rapid testing machine that can simultaneously diagnose TB and detect resistance to rifampicin, one of the most important anti-TB drugs, in less than 24 hours - and has the potential to greatly reduce the delay between sputum sample collection and treatment initiation for patients with suspected MDR TB. This test can also diagnose up to 72% of smear negative pulmonary TB. In an effort to improve the diagnostic capacity for drug susceptible and drug resistant TB, South Africa was among the first countries to adopt and implement GeneXpert as a replacement of smear microscopy for all people presenting with TB symptoms. The TB Program South Africa partnered

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closely with the National Department of Health to facilitate GeneXpert roll out beginning in March 2011. Thanks to strong government investment, South Africa now has 289 GeneXpert machines placed throughout the country (the project itself initiated the purchase and placement of 11 GeneXpert machines in project-supported districts). Since 2011, 3.2 million TB tests have been conducted and nearly 400,000 cases of TB have been diagnosed thanks to GeneXpert. The number of MDR-TB (RIF-resistant) cases identified has risen from 2,467 in 2011 to 13,817 in 2013.

Capacity Building of Laboratory and Clinical Staff

The TB Program South Africa worked with the Department of Health to develop and incorporate a diagnostic algorithm for GeneXpert into the National TB Treatment Guidelines. Previously, patients with suspected DR TB had to wait for confirmation of drug-susceptibility testing before starting on second-line treatment, and new and treatment TB cases were treated using separate diagnostic algorithms. Now, health care workers are able to treat all TB suspects using one revised algorithm. Through a lab-based training program, the TB Program South Africa has trained 916 technical and 3968 clinical staff on the use of the GeneXpert machines. The project is continuing to monitor GeneXpert roll out, working with districts and laboratories to improve compliance with the diagnostic algorithm and ensure accurate reporting. Adherence to the algorithm is continuing to improve over time.

National TB Diagnostics Summit

On November 18-19, 2013, the project facilitated a National TB Diagnostics Summit, which brought together key stakeholders to review and discuss the state of TB diagnostics in South Africa and to create a roadmap for improving laboratory diagnosis of TB throughout the country. A total of 100 local and international participants attended, including representatives from the National Department of Health, the Department of Science and Technology, USAID, public and private laboratory service providers, diagnostic product manufacturers, funders, academics and researchers, and implementing partners.

Participants at the National TB Diagnostics Summit in November 2013

Key recommendations resulting from the summit include:

1. Develop of a generic national implementation framework for review and roll out of new diagnostic tests;
2. Establish of a multi-stakeholder national task team of experts to provide ongoing guidance on the introduction of new tests/diagnostic procedures;
3. Host of annual meetings to follow up on implementation.

The USAID TB Program South Africa is continuing to work with the National Department of Health and other partners throughout South Africa to ensure that scale-up of more sensitive diagnostic tests is accompanied by wider health systems strengthening efforts, so that increased diagnostic capacity increases TB treatment initiation and decreases mortality among TB patients.

Key Topics of the National TB Diagnostics Summit

Introduction of new tests

- How were currently available tests introduced in SA (culture, LPA, GXP)?
- What was the rationale?
- What lessons have been learnt?
- How are the algorithms being used?
- What is the role of private sector?

Linking communities to services

- Interface between community and Diagnostics
- Access to TB Screening and HIV testing
- Early Diagnosis of TB and MDR TB
- Linking patients to treatment services

Challenges in implementing the technologies

- Challenges related to reaching all levels of the Health System?
  - QA challenges
  - Clinical challenges
  - Operational challenges
- Diagnosis of TB in children

Key role players in diagnostics

- What is on the horizon for TB diagnostics- globally and in South Africa?
- What are the roles of the public, private and the research sectors?