Implementation of GeneXpert in South Africa

Overview

- The National department of Health together with the NHLS have been a global leader in rolling-out Xpert MTB/RIF, addressing the country’s high TB incidence rate, frequency of TB/HIV co-infection, and burden of multidrug-resistant TB.
- 287 GeneXpert instruments of varying sizes (GX4: 95; GX16:186; GX48: 1; GX80:5) have been placed in 207 sites – both urban and rural settings, and by the end of September 2013, NHLS had successfully reached 100% completion of the National Implementation Plan. Additional Infinity analysers are in the process of being placed in the highest throughput labs, in order to further increase testing capacity.
- From March 2011 through April 2014, the NHLS has already performed 3,300,544 Xpert MTB/RIF tests in the public sector, accounting for more than 60% of the globally procured cartridges.
- The average national TB positivity rate among suspects was found to be 8% using microscopy but up to 16-18% in the first year, 13-14% in the second and third year and 11-12% in the fourth year, after introduction of Xpert® MTB/RIF assay.
- To date, approximately 7% of TB-positive specimens have had rifampicin resistance.
- Two% of all tests have had error results while invalid results, which likely represent sample problems, have occurred in less than 1%.
- The programme is now being further expanded to a quarter of a million people in special risk populations such as the Correctional Services and peri-mining communities.

Correctional Services

In order to improve TB control in all 242 correctional facilities in South Africa, the NHLS is working in partnership with the Department of Correctional Services (DCS), NDoH, Aurum Institute, TB/HIV Care Association and Right to Care to ensure access to regular HIV- and TB-related screening, testing and treatment of up to 150,000 offenders through various funding mechanisms including the CDC and Global Fund. Xpert MTB/Rif testing is being provided either on-site, or at the nearest referral laboratory. During 2014, Xpert MTB/RIF testing facilities have been established on-site at the following Correctional Facilities:

- Kgoši Mampuru Management Area II
- Barberton Management Area
- Johannesburg Management Area
- Groenpunt Management Area
- Pollsmoor Management Area
- St Albans Management Area
- Durban-Westville Management Area

In order to improve linkages to treatment, both within the correctional facilities and once the patient has been released, NHLS is in the process of implementing its system of SMS printers, providing immediate results reporting from the NHLS.
Peri-mining Communities

NHLS, together with the Aurum Institute, has been appointed by NDoH (under the Global Fund grant) to provide services to implement interventions aimed at improving TB and HIV/AIDS management for vulnerable peri-mining communities (estimated at around 600,000 people) in 6 main mining districts. Six staffed and GeneXpert-equipped mobile TB units will be provided within the communities to undertake Xpert MTB/RIF testing for TB. In addition, persons newly identified as HIV-infected through the clinical partner will be staged for HIV-treatment using CD4 tests provided by the closest NHLS lab in the district. The 6 districts with a high proportion of mines in South Africa that have been identified for focused attention are:

- Lejweleputswa (Free State)
- Dr K K Kaunda & Bojanala Districts (North West)
- West Rand (Gauteng)
- Waterberg & Sekhukhune (Limpopo)

Multi Drug Resistant Tuberculosis (MDR-TB) and Linkage-to-Care

Through funding provided by CDC and Global Fund, a “Linkage-to-Care” initiative is being developed for all MDR-TB cases. This initiative involves the integration of current NDoH electronic TB registers with the NHLS data warehouse as well as to be linked as part of an integrated MDR-TB contact and defaulter tracing system through a mobile health (mHealth) mechanism. It is envisioned that at the initiation of treatment for a new MDR-TB case, an SMS will be triggered and sent to the cell-phone of the appropriate nurse led ward-based team for follow-up. In addition, it is proposed that each district be provided with a tracing coordinator to facilitate the roll out, training and mentorship of ward teams and the introduction of the mHealth system. This is being developed together with the Johns Hopkins University and JHPIEGO.

Other activities

- **Training:** A total of 388 laboratory staff and 3,554 health care workers have been trained from 01 April 2013 to 31 March 2014. In addition, 3 centralized “Advanced training” courses have been conducted. The NPP team has also been working together with FIND to develop on-line web-based GeneXpert clinical training material for healthcare workers.
- **External Quality Assurance:** In order to monitor on-going quality of testing services, all Xpert MTB/RIF testing laboratories are enrolled on an external quality assessment (EQA) program for GeneXpert using dried culture spots (DCS), which was developed through funds provided by the CDC. This program has now been expanded to 19 countries in Africa, USA, South America and Asia and also includes all ACTG sites. In addition, a verification program has been developed through CDC funding which allows for every newly placed GeneXpert analyser to be deemed “fit for purpose” before clinical results can be reported. To date, the DCS verification program has successfully been used to verify >3,500 modules of the GeneXpert instruments.
- **Alternate specimen protocols:** Protocols for testing extra-pulmonary specimen types such as fine needle aspirates, pleural fluids, cerebrospinal fluid, ascites fluid, urine, gastric aspirates and
tissue have been developed in collaboration with the TB referral laboratory in Braamfontein, and through funding from the CDC. A study to evaluate the Xpert MTB/RIF assay on paediatric stool specimens is currently underway.