The use of decentralized GeneXpert by trained non-laboratory technicians in rural clinics in South Africa

The GeneXpert automated molecular assay, that can diagnose TB in 2 h, was endorsed by the World Health Organization both for identifying TB and rifampicin resistance [5]. South Africa was one of the first few countries to implement GeneXpert [5] however GeneXpert units were located mostly within the National Health Laboratory Services (NHLS) and not at point of care [4]. Placing it at the point of care is possible, as it requires uncomplicated processing that can be done by persons with basic computer skills [5]. There is limited data on the use of this test in rural settings, as well as its use by non-laboratory technicians. This correspondence reports on the outcomes of the use of GeneXpert by lay counselors in Dr Kenneth Kaunda sub-district in the Matlosana Municipality, North West Province, South Africa. The study received local ethics approvals from the University of Witwatersrand, regional hospital’s and Provincial research committees.

The Dr Kenneth Kaunda sub-district has one hospital and 16 clinics and an estimated TB incidence of 750/100,000 in 2011 [2]. Rooms at four primary care clinics were renovated to accommodate the four-cartridge GeneXpert machines. Prior to this project all TB samples were sent to the central laboratory for testing.

Six lay counselors with basic computer skills received two weeks training on basic infection control measures, sample preparation and processing on an open bench. A trained technician from NHLS conducted a monthly external quality assurance at each clinic. Samples for testing were received from: contacts of TB patients and TB suspects presenting at the clinic. Procurement and renovation challenges resulted in two clinics starting four months later.

GeneXpert testing was operational for ten months, and a total of 2196 specimens were tested, from 2181 participants (15 tests had to be repeated). The average number of specimens tested per day increased from 2 to 3 in the first month to a maximum of about 7 specimens by month three (Figure 1). Of 2181 sputum specimens that completed the testing, 538 were of contacts from 203 households, and 1643 from TB suspects. 9% (197/2181) of cases had MTB on GeneXpert testing, 1.5% (8/538) among household contacts and 11.5% (189/1643) in TB suspects. In the newly diagnosed TB cases, 7% (13/197) had rifampicin resistance. The overall error rate was 2.6% (57/2196). The error rate in the first month was 10.2% and this improved to 7.9% by month 2, and 3.9% by month 3. The lowest error rate achieved was 1.3%. Error rates reports were available on 44 specimens as follows: 21 signal loss in amplification; 10 syringe pressure reading high; 9 probe check failure, 3 cartridge integrity test failure and 1 temperature not within acceptable limit. Interventions to reduce error rates included additional training and quality assurance by the NHLS and operators with minimal error rates were paired to work with those with high error rates. All the GeneXpert Machines were fully functional throughout the study and did not need any repairs.

This data review shows that GeneXpert can be operated outside of laboratories by non-technicians with minimal error rates. However, the costs of testing could increase if each clinic was to be equipped with GeneXpert and technicians [4]. Yet placing the assays in central laboratories increases the turnaround time for releasing the results to the patients especially if the laboratory is far. The use of non-laboratory technicians minimizes costs of
personnel and logistics for transporting specimens and results. The recurrent costs of personnel and logistics are estimated at US Dollars 5 per test [4]. A detailed costing would be necessary to assess if low-salary lay-technicians, doing several tests at the point of care in various clinics, is more affordable when compared to a qualified, high-salary technician in a central laboratory. However many clinics in rural areas do not have a laboratory in close proximity. The error rates with TB culture results are about 3% [1]. The error rates with the implementation of GeneXpert in central laboratories within the NHLS are estimated at 3–5% [3]; The error rate of 2.6% is comparable to other error rates reported in Laboratories for both GeneXpert and TB culture.

GeneXpert testing for MTB and Rif resistance can be completed in 2 h by a person with minimum computer skills. Non-laboratory technicians can be trained to use GeneXpert and perform tests at the point of care and reduce the costs of logistics for specimens and results. Error rates are minimal and improve with practice. There is a need for a hybrid of models, centralized and decentralized for different settings and according to proximity to a central laboratory to increase access to GeneXpert.

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References


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