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THE INCREMENTAL COST OF INTRODUCING XPERT® MTB/RIF INTO THE SOUTH AFRICAN NATIONAL TUBERCULOSIS PROGRAMME

Background

South Africa bears a large share of the global burden of HIV/tuberculosis co-infection. The Cepheid GeneXpert System using the Xpert MTB/RIF assay (http://www.cepheid.com/systems-and-software/genexpert-system/), a cassette-based cartridge, has provided the possibility of a rapid, point-of-care diagnosis of tuberculosis (TB) and, simultaneously, a rapid screen for rifampicin (RIF) resistance. The assay is highly sensitive and specific for *M. tuberculosis* (MTB) infection and received a strong recommendation from the World Health Organization (WHO) in December 2010 as the initial test in individuals suspected of multi-drug resistant (MDR) tuberculosis and those with HIV co-infection.

Building on a successful pilot (Phase 1), the South African Department of Health requested the National Health Laboratory System (NHLS) to roll out Xpert technology in a phased manner. In Phase 2A, existing Xpert-enabled laboratories are to be upgraded to allow complete migration from smear microscopy for diagnosis of new patients. During Phase 2B, remaining laboratories in designated high TB caseload districts are to be Xpert-enabled over a 2-3 month period. In Phase 3, all other NHLS laboratories performing smear microscopy will become Xpert-enabled, fully replacing smear microscopy for the diagnosis of TB in South Africa, though microscopy will still retain a role in TB treatment monitoring.

In May 2011, the Health Economics and Epidemiology Office of the University of the Witwatersrand was asked to estimate the incremental cost of the Xpert diagnostic algorithm in diagnosing pulmonary TB over and above the cost of the current diagnostic guidelines.

Methods

The **National TB Cost Model (NTCM)** is an Excel-based population-level decision model developed for this analysis. It represents the diagnostic process leading from TB suspects to TB cases and on to treatment. For South Africa, the model was parameterised using data from a 7.5% sample of the national-level NHLS TB database (n= 1,329,664) and a 34.8% sample of the national-level Electronic TB Register (n= 286,741) as well as data from existing South African Xpert implementation studies. The model follows quarterly cohorts of suspects through a baseline scenario (current diagnostic guidelines only) or an Xpert scenario, in which all three phases of the Xpert® rollout are completed either by the end of 2012 (accelerated scale-up) or by the end of 2013 (gradual scale-up).

The number of suspects (patients or contacts of TB cases with a positive TB symptom screen) was calculated based on data on the general population aged 15 years and above from the Actuarial Society of South Africa AIDS (ASSA) Model (http://aids.actuarialsociety.org.za), with an assumption of a prevalence of TB symptoms of 5.5%. The percentage of TB suspects increases by 10% per year, in line with the targets for South Africa's ongoing Intensified Case Finding campaign. Alternative rates of growth of suspects of 0% and 6.5%, consistent with the WHO "Planning and Budgeting for TB Control" model for South Africa, were also considered. The smear-positivity rate of suspects was set at 10% at baseline and decreases as the number of suspects grow in all scenarios in order to model a stable epidemic.

Unit costs were estimated from the government perspective, including 2010/11 NHLS charges for all laboratory costs except the Xpert test, public-sector salaries and expert opinion on the duration of visits, and public-sector drug costs and standard treatment algorithms for the antibiotic trial. The per-test cost of the Xpert technology was calculated from information on implementation cost, the planned number and size of machines from the NHLS, and assumptions about when the global volumes allowing discounts on the price of cartridges will be reached. As a result, the

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per-test cost of Xpert fluctuates between USD 26 and USD 36 due to timing of capital expenditures for additional machines, module replacement according to an expected useful life of 4 years, and expected global price reductions for cartridges.

Results

Results of the modelling exercise for the baseline scenario and the Xpert accelerated scale-up scenario are summarised in the table below.

Results of the National TB Cost Model for South Africa

Value in 2013/14 (full Xpert coverage)	Baseline scenario	Xpert scenario (accelerated scale-up)	Difference in Xpert scenario
Number of suspects requiring TB diagnosis/year	In all scenarios, the number of suspects requiring diagnosis increases from approximately 1.9 million to 3.2 million, due to the 10% annual increase in suspects built into the model and, to a much lesser extent, population growth.		
Number of patients diagnosed with TB	335,762	437,185	30% more patients diagnosed
Number of patients diagnosed with MDR-TB	12,041	21,250	76% more patients diagnosed
Number of patients initiated on treatment	255,060	354,975	39% more patients initiated on treatment
Method of diagnosis for those diagnosed	46% by smear microscopy, 49% by culture, and 6% clinically	87% by Xpert, 0.05% by smear microscopy, 11% by culture, and 2% clinically.	Far fewer patients diagnosed by smear microscopy, culture, or clinically
Timing of diagnosis	46% of patients are diagnosed by visit 2 (3-5 days after first visit) and 40% by visit 3 (4-6 weeks after visit 2)	83% of patients are diagnosed by visit 2 and 89% by visit 3	37% more patients diagnosed after first clinic visit
Ongoing need for sputum smear microscopy	4.1 million smears (69% for diagnosis and 31% for treatment monitoring)	1.5 million (3% for diagnosis and 97% for treatment monitoring)	63% fewer smears performed
Ongoing need for TB diagnostic cultures	1.4 million	1.1 million	21% fewer cultures performed
Cost per case diagnosed	$312	$367	17% increase
Average cost per case diagnosed and treated	$835	$912	9% increase

The scale-up will require the placement of 65 GX4, 169 GX16, and 4 GX48 (“Infinity”) instruments, with a total national test capacity at full Xpert coverage in 2013 of 11,248 tests per day. Total capital cost (including instruments, additional space, security, and training) between 2011/12 and 2016/17 will be 32 million USD. Total incremental recurrent cost (including cartridges, staff, transport, and quality assurance) will range from 343 million USD (accelerated scale-up) to 301 million USD (gradual scale-up). This recurrent cost is the amount that has to be budgeted over and above the cost of the current diagnostic guidelines. Capital cost does not differ between scale-up scenarios, but recurrent costs for the gradual scale-up scenario are much lower, especially for the first three years of operations, owing to the lower number of machines placed and overall lower testing capacity. The resulting additional annual budget requirement to cover the recurrent costs only will be 34-79 million USD (accelerated scale-up) or 32-67 million USD (gradual scale-up).

One of the outstanding operational questions is whether to place many small instruments in clinics (decentralised option) or fewer larger instruments in laboratories (centralised option).

In our analysis, placing Xpert technology in clinics and hospitals rather than in laboratories will increase the cost of the roll-out by 70% due to a 7-fold increase in capital cost. This is the result of the requirement for many more small instruments (i.e., GX4) which have a higher per-module cost than larger instruments, and the need to equip the clinics with a safe, air-conditioned laboratory space to house the technology.

These results do not take into account a reduction of transmission and, hence, new TB cases (including MDR-TB cases) as a result of earlier identification of TB and initiation on appropriate treatment. The analysis presented here is restricted to the full and incremental cost of the new diagnostic algorithm only and as such does not fully capture the benefits or opportunity cost of the Xpert technology.

Policy relevance

South Africa began its pilot phase of utilising Xpert MTB/RIF technology in March 2011 with the placement of 30 instruments in public-sector laboratories in high case-load districts. In his budget speech in May 2011, the South African Minister of Health announced the roll-out of Xpert technology to one laboratory in each of the country’s 50 health districts by the end of 2011, and the capacitation of all remaining facilities by the end of 2012 (the accelerated scale-up scenario used in this analysis). The analysis presented here is being used by the government to plan and budget for this endeavour and will provide the tools needed to understand the cost implications of different scale-up strategies.