

Editorial

New TB Tools Need to be Affordable in the Private Sector: The Case Study of Xpert MTB/RIF

Of the estimated 10.4 million people who fell ill with tuberculosis (TB) in 2016, only 6.3 million people were detected and officially notified to national TB programmes, leaving a gap of 4.1 million [1]. These 4.1 million people are considered ‘missing.’ Where are they and why are they missing?

A recent 13-country patient pathway analysis shows that about 60% of all TB patients seek care in the formal or informal private health sector [2]. Further, there is a striking correlation between the estimated number of missing patients in each country, and the proportion of care-seeking that is private.

In fact, the private health sector is a major source of health care in 12 countries with the highest TB burden, including India, Pakistan, the Philippines, Bangladesh, Afghanistan, Kenya, Uganda, Vietnam, Indonesia, Myanmar, Nigeria and Cambodia [3]. In these economies, even poor patients with TB seek care from private health care providers, and delayed diagnosis and misdiagnosis are widely recognized problems [4]. Further, patients as well as doctors do not respect public versus private boundaries and often switch between these sectors [5,6].

So, if we want to diagnose TB early and accurately, we need to engage and work with the private health sector [3]. Regardless of where patients seek care, we need to ensure that they have access to high quality, patient-centric TB diagnosis and treatment [7]. This means that we need to make sure that new TB tools are not only scaled-up in the public sector, but are also affordable and accessible in the private health sector [8].

Xpert MTB/RIF (Cepheid Inc, Sunnyvale, USA), a WHO-endorsed rapid TB test, is the best front-line test we have today for TB detection and rapid drug-resistance screening [9]. This test is available at a concessional price of \$9.98 per cartridge. Data from Cepheid show that, as of 31 December 2017, a total of 9449 GeneXpert instruments and 34 million Xpert MTB/RIF cartridges had been procured in the public sector in 130 of the 145 countries eligible for concessional pricing.

Unfortunately, concessional pricing is restricted to the public sector in high burden countries. Private sector hospitals and laboratories are not eligible for concessional pricing, even if they are in highest TB burden countries. What is the impact of these restrictions on prices patients pay for Xpert MTB/RIF?

In 2015, we conducted the first study on pricing of Xpert MTB/RIF in the private sector in 12 highly privatized health markets [10].

As shown in the table below, in 6 of the 12 countries, there was no commercial availability of Xpert in the private sector [10]. In the remaining six countries, the average price charged by private laboratories or hospitals was US \$68.73 (range \$30.26–\$155.44), as compared to a fully loaded cost of \$20–30 per test paid by national TB programmes [10].

In 2017–18, we updated the survey to assess changes over time, using similar methods. Our new findings (Table 1) show that Xpert is now commercially available in the private sector in 7 of 12 countries. In comparison to the average price to the patient of US \$68.73 in 2015, patients now pay US \$84.53 (range \$46.70–\$175.00), which translates to a 23% increase (that cannot be explained by just inflation).

In 2015, the lowest private sector price was in India, via laboratories in a network called the Initiative for Promoting Affordable and Quality TB Tests (IPAQT) [11]. IPAQT, a private sector initiative coordinated by the Clinton Health Access Initiative (CHAI), that has been able to access concessional prices from several manufacturers of WHO-approved diagnostics by agreeing to charge patients no more than agreed upon ceiling prices. Laboratories in IPAQT offered Xpert at a fixed price of INR 2000 (US\$30.26 in 2015), compared with an average of \$52.82 in the rest of the private market in India in 2015. The 2017–18 data show a similar trend, with IPAQT laboratories still offering the lowest price (US \$33.80) among all 12 countries. Interestingly, the gap between IPAQT and market prices in India has narrowed between 2015 and 2018, suggesting that IPAQT might have played a role in increasing affordability in the private sector at large.

IPAQT now includes 200 accredited, private laboratories, and since 2013, these laboratories have conducted nearly 700,000 WHO-endorsed TB tests (including Xpert MTB/RIF, line probe assays, and liquid cultures) at negotiated prices (Harkesh Dabas, CHAI, India, personal communication). Several test manufacturers are now engaged in IPAQT, underscoring their willingness to partner with non-profits and global health agencies.

In addition to IPAQT, there are other approaches to increasing access to new tools. For example, the pediatric TB partnership between India’s Revised National TB Control Programme (RNTCP) and Foundation for Innovative New Diagnostics (FIND), increased high-quality testing for children in the private sector in India, by leveraging public sector GeneXpert facilities for testing pediatric samples referred from the private

Table 1 | Prices paid by private patients for Xpert MTB/RIF in 12 high burden countries in 2015 and 2017–18

Country	Mean price for Xpert MTB/RIF 2015	Mean price for Xpert MTB/RIF 2017–18	Range 2015	Range 2017–18	Labs contacted in 2015 with Xpert testing	Labs contacted in 2017–18 with Xpert testing
Kenya	\$80.60	\$85.36	\$51-\$171	\$58.20- \$149.38	5	5
India						
IPAQT* member laboratories	\$30.26	\$33.80	Fixed Price	Fixed Price	–	–
Rest of Private Sector	\$52.82	\$46.70	\$27.84-\$86.55	\$24.67-\$80.19	13	22
Pakistan	\$37.26	\$47.67	\$25.96-\$58.65	\$25.63-\$66.45	4	7
Philippines	\$155.44	\$152.49	\$128-\$183	\$106.4- \$170	9	8
Bangladesh	\$74.75	\$64.20	\$45.50-\$130	\$42-\$90	4	6
Afghanistan	\$50.00	No Xpert	–	–	1	–
Uganda	No Xpert	No Xpert	–	–	–	–
Vietnam	No Xpert	No Xpert	–	–	–	–
Indonesia	No Xpert	No Xpert	–	–	–	–
Myanmar	No Xpert	\$71.03	–	–	–	1
Nigeria	No Xpert	\$175.00	–	\$115.00–\$235.00	–	2
Cambodia	No Xpert	No Xpert	–	–	–	–

Greater than 50% of all primary health-care visits in the countries listed in this table were to a private healthcare provider [6]. Prices correct at December 2017. *IPAQT refers to the Initiative for Promoting Affordable and Quality TB Tests (www.ipaqt.org), a private sector initiative coordinated by the Clinton Health Access Initiative in New Delhi, which offers WHO-approved diagnostics at concessional prices.

sector [12]. This strategy needs to be scaled-up for both adult and pediatric TB testing, to ensure public GeneXpert facilities, which have excess capacity, are optimally used for greatest impact [13].

Overall, our data show that while Xpert is now available in more countries in the private health sector, it largely remains expensive for patients. It is important to acknowledge that high price is not entirely driven by test manufacturers. In addition to higher commercial prices by the manufacturer, there are other costs such as shipping and import costs, distributor margins, incentives to doctors, and mark-ups by laboratories and hospitals. Cumulatively, these factors result in the high prices reflected in the surveys. Thus, interventions such as import duty waivers for all essential diagnostics, and tighter regulation (e.g. price controls) by governments to prevent price gouging by private hospitals and laboratories are worth considering.

Our data also illustrate the need for novel private sector business models like IPAQT to increase as well as maintain affordability of new tools. The IPAQT model is now being considered in other highly privatized countries, as manufacturers have indicated willingness to collaborate with local private laboratory networks and partners to expand access. Also, IPAQT recently expanded its menu to include quality-assured tests for HIV and hepatitis C [14], underscoring the importance of leveraging such initiatives to go beyond TB, increase affordability and access to a variety of global health products, and optimize the use of multi-disease platform technologies such as GeneXpert [15,16].

In the longer run, we need more affordable multi-disease platform technologies that are designed for low resource settings, that can be used to deliver a variety of tests included in the Essential Diagnostics List that will be released by World Health Organization this year [17]. Novel technologies coming out of countries such as India and China offer a lot of hope, and could potentially reach a larger population than expensive technologies designed for high income markets.

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Nirros Ponnudurai

Faculty of Medicine, McGill University, Montreal, Canada

Claudia M. Denkinge

Foundation for Innovative New Diagnostics, Geneva, Switzerland

Wayne Van Gemert

Global Drug Facility, Stop TB Partnership, Geneva, Switzerland

Madhukar Pai*

McGill International TB Centre, McGill University, Montreal, Canada

Manipal McGill Centre for Infectious Diseases, Manipal Academy of Higher Education, Manipal, India

* Address: McGill University, Dept of Epidemiology & Biostatistics,
1020 Pine Ave West, Montreal, QC H3A 1A2, Canada.

E-mail address: madhukar.pai@mcgill.ca

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