

## Xpert MTB/RIF for tuberculosis testing: access and price in highly privatised health markets

Xpert MTB/RIF (Cepheid, Sunnyvale, CA, USA) is the biggest recent advance in tuberculosis diagnosis, and since 2010 more than 15 million cartridges have been procured through concessional pricing (\$9.98 per cartridge in 2015).<sup>1</sup> However, even in countries with a high tuberculosis burden, the private sector is not eligible for concessional pricing for Xpert, nor for other WHO-endorsed tests such as line probe assays (LPA) and liquid cultures. Manufacturers set higher prices for reagents and instruments for private laboratories and institutions than for the public sector, and there are additional costs (such as import duties), and margins imposed by distributors, intermediaries, and laboratories.

Why does private sector pricing and access matter? The private sector is a major source of health care in 12 of the 22 countries with the highest tuberculosis burden, including India, Pakistan, the Philippines, Bangladesh, Afghanistan, Kenya, Uganda, Vietnam, Indonesia, Myanmar, Nigeria, and Cambodia.<sup>2,3</sup> In these economies, even poor patients with tuberculosis seek care from private health-care providers, and delayed diagnosis and misdiagnosis are important problems.<sup>2</sup>

Little is known about how exclusion from concessional pricing programmes affects access to the Xpert test, nor the price for patients in the private sector. We contacted tuberculosis experts in 12 countries and asked them to check commercial availability of Xpert in their country, and collect price data from private laboratories that offer Xpert testing. We had at least two respondents from each of the 12 countries, and they included national tuberculosis

programme staff, tuberculosis researchers and clinicians, and agencies such as the Foundation for Innovative New Diagnostics (FIND) and the Clinton Health Access Initiative (CHAI).

As shown in the table, in six of the 12 countries, there is no commercial availability of Xpert in the private sector. Patients, however, can access the test via the public sector and special public-private mix projects. In the remaining six countries, the average price charged by private laboratories was US\$68.73 (range \$30.26–\$155.44). While the exact cost breakdown is unknown, the final price paid by patients included cost of reagents and instruments, shipping, import duties, distributor margins, laboratory profit margins, and, in some settings, incentives for doctors who order the test. By comparison, the public sector in each of these countries offers testing with Xpert at no cost to patients. The fully loaded cost of Xpert for the public sector has been estimated to be about \$20–30 per test, depending on whether machines are used at maximum capacity and other operational factors (H Sohn, personal communication).

In the countries we surveyed, the highest price for patients paying for Xpert testing was in the Philippines, while the lowest average price was offered in India, via laboratories in a network called the Initiative for Promoting Affordable and Quality TB Tests (IPAQT).<sup>4</sup> IPAQT, a private sector initiative, offers WHO-approved diagnostics at concessional prices. Laboratories in IPAQT offer Xpert at a fixed price of INR 2000 (\$30.26), compared with an average of \$52.82 in the rest of the private sector in India. By January, 2016, IPAQT had consolidated 110 accredited private laboratories that receive concessional pricing for Xpert, LPA, and liquid cultures. In exchange for access to the public sector concessional pricing for reagents and equipment, member laboratories must agree to pass on price reductions to patients, by charging no more than a transparently agreed ceiling price, notifying tuberculosis cases to the public sector, and participating in quality assurance programmes.<sup>5</sup> Since its launch in 2013, more than 200 000 tuberculosis tests have been done by IPAQT laboratories (H Dabas, personal communication).



	Mean price for Xpert MTB/RIF	Range	Private laboratories offering Xpert MTB/RIF (N)	Laboratories contacted for price information (N)
Kenya	\$80.60	\$51–\$171	5	5
India				
IPAQT member laboratories	\$30.26	Fixed Price	76	..
Rest of private sector	\$52.82	\$27.84–\$86.55	60	13
Pakistan	\$37.26	\$25.96–\$58.65	4	4
Philippines	\$155.44	\$128–\$183	11	9
Bangladesh	\$74.75	\$45.50–\$130	4	4
Afghanistan	\$50.00	..	1	1
Uganda	No Xpert	..	0	..
Vietnam	No Xpert	..	0	..
Indonesia	No Xpert	..	0	..
Myanmar	No Xpert	..	0	..
Nigeria	No Xpert	..	0	..
Cambodia	No Xpert	..	0	..

More than 50% of primary health-care visits were to a private health-care provider in the countries shown.<sup>4</sup> Prices correct at September, 2015. IPAQT=Initiative for Promoting Access to Quality TB Tests.

**Table: Price paid by private patients for Xpert MTB/RIF in 12 high burden countries with high rates of private health-care use**

Our findings suggest that commercial sale of Xpert seem to be limited, and, with some exceptions, patients in the private sector pay a lot for this test. These factors could result in low levels of access to quality tests and blunt the benefits of new diagnostic tools.<sup>6</sup> However, since we were unable to access data for the numbers of tests done in public facilities versus the private providers, our results are only suggestive. However, our data do underscore the need for a private sector access strategy to ensure that quality diagnostics reach all patients with suspected tuberculosis. The strategy will need to draw on various approaches, such as the inclusion of the private sector in current and future pricing agreements, replication of IPAQT-like models in other economies, consolidation of private laboratories by intermediary agencies, public-private mix projects to allow privately managed patients to be tested in public facilities, use of subsidies and vouchers by private provider interface agencies, and social businesses to cross-subsidise tuberculosis tests against more profitable tests. Product manufacturers will need to realise that most patients with tuberculosis in countries with a high burden of the disease have limited means, and a mass-market (that is, a low margin, but high volume) rather than premium (high margin, but low volume) pricing model may be more appropriate for tuberculosis tests in these countries. The IPAQT experience supports this theory. Lastly, access to good diagnostic tests will not necessarily improve tuberculosis outcomes in the private sector. This will require a comprehensive public-private model that offers patient centric, quality care.<sup>2,7</sup>

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- 1 WHO. WHO monitoring of Xpert MTB/RIF roll-out. <http://www.who.int/tb/laboratory/mtbrifrollout/en/index.html> (accessed Oct 6, 2015).
- 2 Wells WA, Uplekar M, Pai M. Achieving systemic and scalable private sector engagement in tuberculosis care and prevention in Asia. *PLoS Med* 2015; **12**: e1001842.
- 3 Global Health Group at UCSF. Private healthcare in developing countries. <http://ps4h.org/globalhealthdata.html> (accessed Jan 6, 2016).
- 4 IPAQT. Initiative for promoting affordable & quality TB tests. <http://www.ipaqt.org> (accessed Oct 6, 2015).
- 5 Pai M. Promoting affordable and quality tuberculosis testing in India. *J Lab Physicians* 2013; **5**: 1–4.
- 6 Salje H, Andrews JR, Deo S, et al. The importance of implementation strategy in scaling up Xpert MTB/RIF for diagnosis of tuberculosis in the Indian health-care system: a transmission model. *PLoS Med* 2014; **11**: e1001674.
- 7 Pai M, Yadav P, Anupindi R. Tuberculosis control needs a complete and patient-centric solution. *Lancet Glob Health* 2014; **2**: e189–90.