



CASE STUDY

Catalyzing the market for accurate tuberculosis testing in India's extensive private sector through IPAQT

INCREASING ACCESS TO ACCURATE, VALIDATED DIAGNOSTICS IN THE PRIVATE SECTOR IS KEY TO REDUCING INDIA'S HIGH TUBERCULOSIS BURDEN. CHAI FACILITATED A PARTNERSHIP BETWEEN PRIVATE SECTOR LABORATORIES AND MANUFACTURERS TO SUPPORT ADOPTION OF A LOW-PRICE, HIGH-VOLUME MODEL THAT IMPROVES ACCESS TO QUALITY DIAGNOSTICS AND STRENGTHENS LINKAGES IN INDIA'S HEALTHCARE SYSTEM.

OVERVIEW

India accounts for 23% of global tuberculosis (TB) incidence with an estimated 2.2M cases reported in 2014 and a 2.2% rate of multi-drug resistance.¹ While India's Revised National Tuberculosis Control Program (RNTCP) offers a 100% geographic reach,² numerous studies indicate that more than 50% of patients seek care in the largely unregulated private sector^{3 4 5} where poor regulation and complex financial incentives can prevent access to high-quality TB tests.⁶

As in other low- and middle-income countries, reduced public-sector pricing negotiated between the government and global diagnostic manufacturers is not made available to the private sector. Historically, high quality, WHO-endorsed TB tests have been costly and less profitable in the private sector due to their high priced platforms and assays, and the presence of multiple players in the value chain. Because privately owned diagnostic providers (i.e., laboratories) are motivated in part by profits and high returns on investment, their financial model does not necessarily align with the public health objective to provide these quality tests.

Consequently, cheaper, sub-optimal tests with higher margins are widely used in the private sector where approximately half of patients seek care. This can often lead to misdiagnosis and/or delayed diagnosis resulting in increased disease transmission, drug resistance, and mortality. Further, a relative absence of collaboration between sectors means the RNTCP is notified of only a fraction of the positive TB cases detected in the private sector, which limits RNTCP's ability to track the disease and appropriately manage the national response.

To address the supply- and demand-side challenges preventing widespread availability of accurate and affordable TB diagnosis in the private sector, CHAI, in

THEORY OF CHANGE

Improving access to high-quality TB diagnostics reduces morbidity, mortality, and drug resistance rates. In a developing country with a high TB burden and high utilization of private sector laboratories, discounted prices for WHO-endorsed tests in the private sector, combined with increased awareness of test benefits, will result in sustained private sector uptake of high-quality diagnostics at improved patient pricing levels.

IMPACT

CHAI catalyzed the creation of IPAQT, a consortium of accredited private sector laboratories that offer WHO-endorsed tests to patients at or below a ceiling price in exchange for improved pricing from suppliers for test equipment and reagents. Since 2013, IPAQT has generated accurate diagnoses for more than 290,000 individuals suspected of TB at a comparable price to non-WHO-endorsed tests that may not have provided accurate diagnosis. The model also piloted approaches to improve linkage with public sector treatment, facilitating government notification of more than 20,000 confirmed TB patients.

KEY PARTNERS

- Bill & Melinda Gates Foundation
- DFID
- McGill International TB Centre
- Private sector laboratories and manufacturers

collaboration with the McGill International TB Centre, Bill & Melinda Gates Foundation, DFID, and other partners, launched the Initiative for Promoting Affordable and Quality TB Tests (IPAQT) in March 2013.

APPROACH

The IPAQT business model aimed to address key systemic weaknesses in order to boost the uptake of quality TB tests. The cornerstone of the IPAQT strategy was adoption of a low-margin, high-volume mass market model that aligned the interests of test suppliers, private laboratories, and patients. The suppliers and laboratories maintained profit margins once uptake of accurate and validated tests was achieved; in turn, patients and the public health system received better tests and, ultimately, better health outcomes. The model was predicated on three prongs.

Ensure access to high-quality diagnostics at low prices for patients and laboratories

First, CHAI worked with manufacturers of WHO-validated tests to extend negotiated public-sector pricing for quality equipment and reagents to partnering private sector laboratories at 30-50% less than existing commercial rates. CHAI then brought together a consortium of private sector laboratories, called IPAQT, providing them access to the improved supplier pricing on the condition that they pass on the benefit of this pricing to patients. The ceiling price – the maximum price testing centers could charge patients – was determined through analysis of operating costs and negotiations between CHAI and partnering laboratories. This process reduced the average price to patients in the private sector for WHO endorsed TB tests to the level of sub-optimal serological TB tests available in the market:

- GeneXpert – from US\$67 to US\$33
- Hain Line Probe Assay – from US\$58 to US\$27
- MGIT Liquid Culture – from US\$18 to US\$15

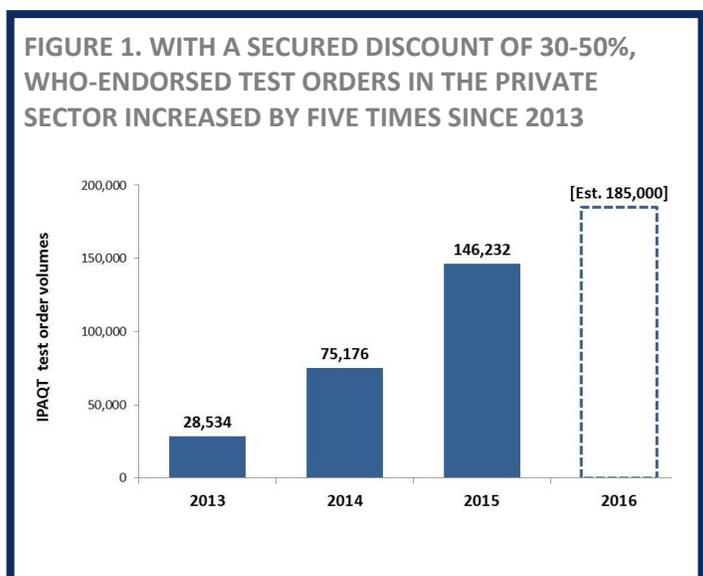
IPAQT membership was open to any privately owned, quality standard accredited laboratory offering TB diagnostic services, provided they agreed to offer tests to patients at or below the negotiated ceiling price. These partners also had to abide by two additional conditions: (i) discontinue use of non-validated and low-quality TB tests in lieu of accurate, WHO-endorsed tests, and (ii) notify government of all positively diagnosed TB cases.

Establish sustainable market pricing by growing procurement volumes

IPAQT was launched in March 2013 with five large private laboratories. However, most private sector doctors were unaware of the benefits and availability of WHO-validated TB tests. CHAI recognized the need for a coordinated medical education effort to increase test demand. CHAI proceeded to conduct medical education seminars in collaboration with private laboratories and

large healthcare providers to promote adoption of WHO-issued diagnostic guidelines. These seminars have reached 8,000 private doctors in more than 40 cities as of April 2016.

Furthermore, rigorous in-clinic sensitizations similar to those used by pharmaceutical representatives were piloted in five cities. An on-the-ground team of representatives educated private doctors and assisted partner laboratories with patient notification. CHAI piloted this approach, called “Demand Generation and Notification Efforts” (DENOTE), in September 2014. The resulting increase in private sector doctors’ awareness of validated TB testing has led to more test prescriptions for IPAQT partner laboratories.



Increase and streamline notification of results between the public and private sector systems

DENOTE representatives also assisted IPAQT partner laboratories in ensuring that the RNTCP is notified of diagnosed patients through an automated internet-based system. This information enables the RNTCP to follow-up on privately diagnosed TB patients who otherwise would be missed by the government program in order to link them to appropriate treatment. In cities where DENOTE field officers are not present, CHAI linked private labs and public sector district TB officers through remote training and support.

IMPACT

IPAQT has transformed the private sector market for validated TB testing in India. Highlights of its impact on patients, partnering laboratories, manufacturers, and India’s greater health system include:



Lower costs and improved access to quality tests for patients – As of May 2016, IPAQT has provided access to accurate and rapid diagnosis for over 290,000 individuals suspected of TB, resulting in substantial out-of-pocket savings. A McGill University analysis of private sector patient pricing for GeneXpert tests in 12 high-burden countries found pricing to be the lowest in IPAQT partner laboratories.⁷ Further, while it is difficult to quantify the degree of improved health outcomes due to issues of patient data confidentiality, many of the estimated 32% of patients diagnosed as TB positive, and 25% of the drug-resistant TB positive, may have gone undiagnosed with nonstandard tests. It can be inferred that improved access to high quality diagnostics has led to improved health outcomes for the 290,000 presumptive cases that accessed IPAQT services.

Fostered access to quality tests in the private sector – IPAQT has built significant inroads in the private sector. Starting with only five partner laboratories in March 2013, the consortium has grown to 121 partner laboratories as of May 2016. These partner labs cater to over 5,500 sample collection centers, which provide coverage to more than 85% of Indian districts. Growth opportunities remain: the private sector consists of approximately 300 to 400 accredited labs, and approximately 100,000 private unaccredited laboratories overall.⁸

Greater health systems impact – Private laboratories' RNTCP notifications for positive TB cases grew from 1,444 cases in 2014 to more than 20,000 cases in the selected five cities within a year of DENOTE's launch. National policy has also been updated to reflect that TB patients diagnosed via a calibrated GeneXpert in the private sector can begin treatment in the public sector without the need for additional confirmatory public-sector testing.

LIMITATIONS AND LESSONS LEARNED

The IPAQT model establishes that existing market dynamics in the private sector can be leveraged to create a sustainable public health impact through innovative approaches to service delivery. With the promise of true point-of-care molecular testing and further reductions in price in the future, such approaches may yield even greater impact.

IPAQT has demonstrated that access pricing in the private sector should be complemented with targeted demand-generation activities to educate doctors and test prescribers. Both DENOTE field officer outreach and

medical education seminars led to increased awareness of quality TB diagnostics within the provider community. However, it should be noted that these interventions are resource-intensive and the continued sustainability of demand-generation activities must be considered.

The IPAQT model does not rely on a direct financial support mechanism for laboratories or patients, which is considered a strength of the approach. However, the underlying costs and economics of other market contexts should be studied carefully before employing the IPAQT model to ensure that it is the right fit.

FUTURE OUTLOOK

To reinforce demand, CHAI is exploring the limited-time offer of vouchers redeemable for free or discounted tests available through IPAQT to select healthcare providers. This initiative will gather data to understand the impact of pricing on prescription behavior change and uptake rates.

CHAI is also exploring the model's applications in other disease areas in India, and globally in other high-burden countries with large private sectors.

¹ World Health Organization *Global Tuberculosis Report, 2015*
http://www.who.int/tb/publications/global_report/en/

² *TB India 2007: RNTCP Status Report*
<http://tbcindia.nic.in/WriteReadData/l892s/8838543515TB%20India%202007.pdf>

³ Kapoor SK, Raman AV, Sachdeva KS, Satyanarayana S (2012) How Did the TB Patients Reach DOTS Services in Delhi? A Study of Patient Treatment Seeking Behavior. *PLoS ONE* 7(8): e42458. doi:10.1371/journal.pone.0042458

⁴ Sreeramareddy CT, Panduru KV, Menten J, Van den Ende J (2009) Time delays in diagnosis of pulmonary tuberculosis: a systematic review of literature. *BMC Infect Dis* 9: 91. 1471-2334-9-91 [pii];10.1186/1471-2334-9-91

⁵ Uplekar MW (2003) Public-private mix for DOTS: demanding, but delay will only hamper TB control. *Int J Tuberc Lung Dis* 7: 1113–1114

⁶ Pai M. Promoting Affordable and Quality Tuberculosis Testing in India. *Journal of Laboratory Physicians*. 2013;5(1):1-4. doi:10.4103/0974-2727.115895.

⁷ Puri L et al. *Lancet Global Health*, 2016

⁸ Chaudhury A. *Manual of Commercial Methods in Clinical Microbiology International Edition* John Wiley & Sons Inc. 2016

About the Clinton Health Access Initiative

In 2002, the Clinton Health Access Initiative (CHAI) began as the Clinton HIV/AIDS Initiative to address the HIV/AIDS crisis in the developing world. Taking the lead from governments and working with partners, CHAI now works to improve markets for lifesaving medicines and diagnostics, lower the costs of treatments, and expand access to life-saving technologies — creating a sustainable model that can be owned and maintained by governments.

To learn more about CHAI, please visit
www.clintonhealthaccess.org

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