IPAQT*: Shaping Private Sector Diagnostics Market - *Lessons learnt*

**Initiative for Promoting Affordable and Quality TB Tests*
www.ipaqt.org

McGill University
June, 2017

CLINTON HEALTH ACCESS INITIATIVE

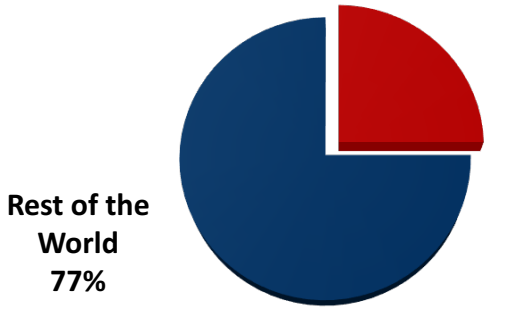
Agenda

- **IPAQT: Background**
- IPAQT: Overview
- Key Achievements
- Lessons Learnt and Way Forward

India has the world's largest TB burden; more than half are diagnosed in the private sector

India has the world's highest TB burden

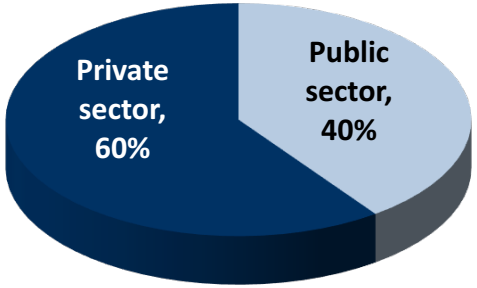
Breakdown of TB cases[1]



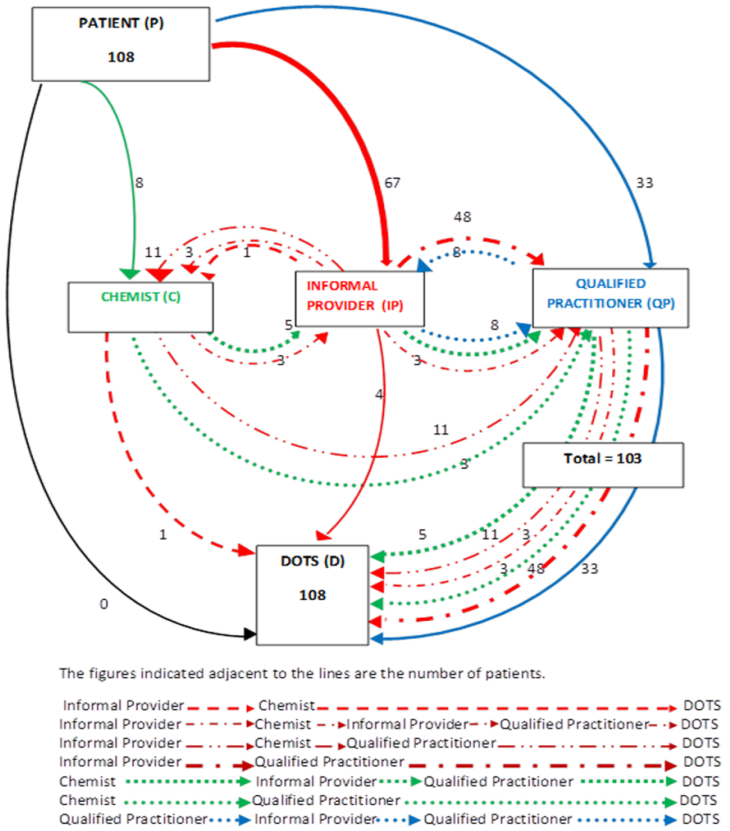
Total TB patients in the world (2012) = 12 million

More than half the patients are managed in the private sector

Break-up of presumptive TB patients by sectors[2]



Most of the people with presumptive TB begin seeking care in the private sector [3]

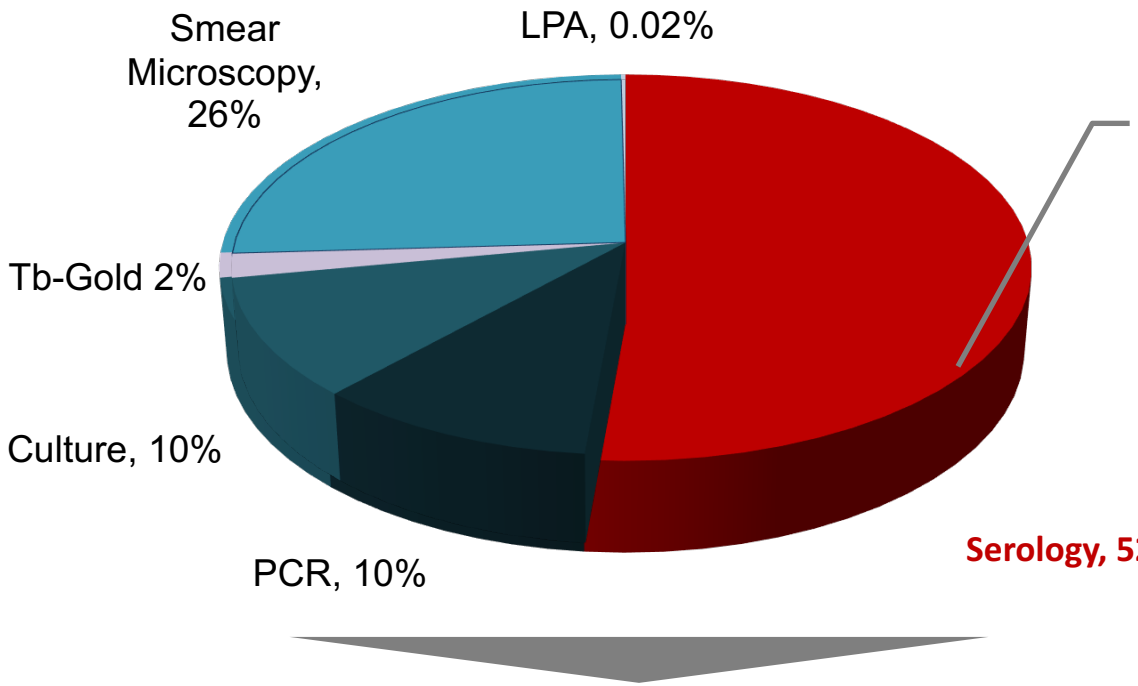


SOURCE: 1. 2013 WHO report: Annual TB prevalence is 2.8 million; global TB prevalence 12 mn; 2.National Strategic Plan 2012; 3. Kapoor SK et al. PLoS ONE 2012

In 2011, there was widespread availability and usage of sub-optimal tests in the private sector

Pre IPAQT private sector TB diagnostics distribution[1]

Annual TB tests in the private sector (2011) = 10.9 million*



In June 2012, the Government of India banned serological tests in the country

This created an opportunity to promote WHO endorsed tests in Indian private sector

SOURCE 1: McGill, CHAI and IIMB student analysis; NOTE: *Does not include TST and Chest X-ray :
http://www.teachepi.org/documents/courses/tbdiagrx2/day3/TB_Diagnostics_Market_Analysis__July16_2012_FINAL.pdf

Key barriers to uptake of WHO-endorsed technologies

Major barriers to accessibility and affordability…

High cost of the equipment & reagents to the lab

Globally negotiated HBDC[1] pricing was available only to public and NGO sector. Thus, only few labs across India invested in these technologies

High cost of WHO endorsed molecular TB test to the patients

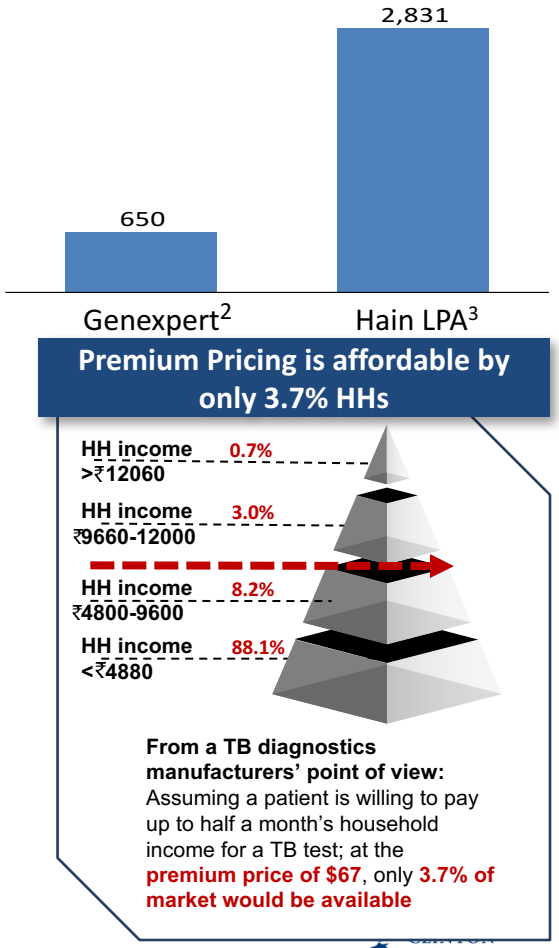
The market price of WHO endorsed molecular tests was higher than the average monthly HH income of a TB patient

Limited awareness among physicians

Majority of the doctors, in both rural and urban area, were not aware about the availability and significance of WHO endorsed molecular tests

…resulting in low uptake of quality tests

Pre IPAQT (est.) Test Volumes for Molecular TB tests



SOURCE:
1. High burden developing countries
Approx data 2 : 2012 data; 3 2011 data

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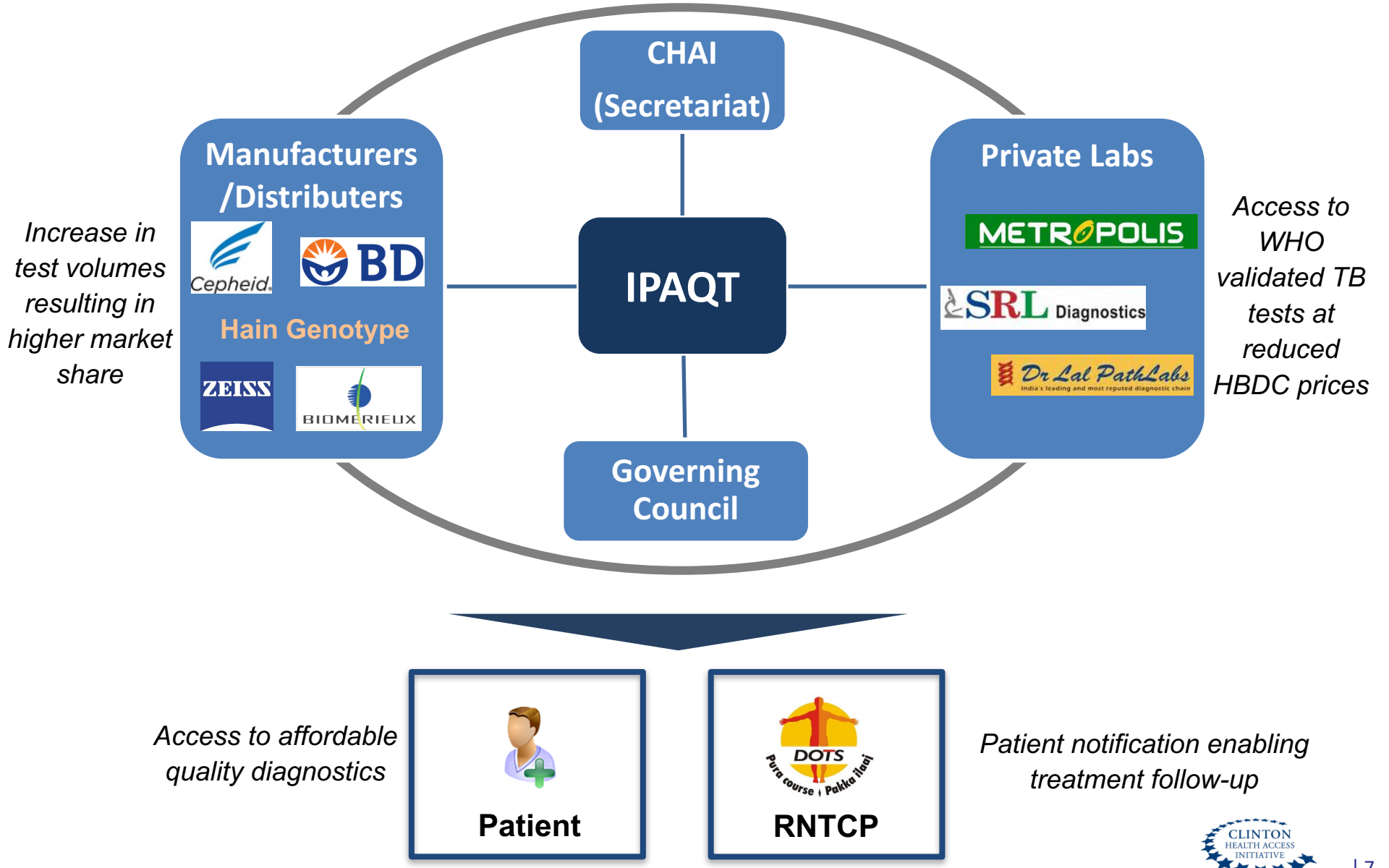
IPAQT provided a framework to align motivations of multiple stakeholders…



…to address major barriers in rapid adoption of quality TB tests, creating a "win-win-win" platform for all stakeholders

High cost of the equipment & reagents to the lab

Proposed solution

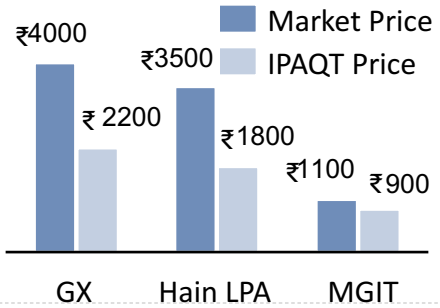
IPAQT model enabled private sector labs to access the HBDC pricing which is 50% less than the commercial sector pricing

Instrument	Pre-IPAQT ($/Unit)	IPAQT ($/Unit)
Capital Investment	₹30,00,000	₹15,00,000
Cartridges	₹2300	₹1150

High cost of WHO endorsed molecular TB test to the patients

To access this HBDC pricing ,IPAQT labs agreed to certain guiding principles

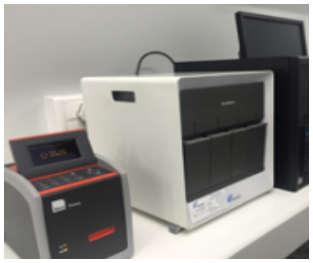
- Low, transparent 'Ceiling Price' to patients
- Use of only validated/endorsed, high-quality TB tests
- Notification of TB cases to RNTCP



Limited awareness among physicians

IPAQT executed demand generation strategies to address the poor awareness through established mass market initiatives (CMEs) as well pilot initiatives for targeted interventions (in-clinic visits through field officers)

IPAQT's current portfolio provides access to four high quality WHO endorsed tests with a provision of adding latest tech when available in the market

	Hain	GeneXpert	MGIT	Bact/Alert
				
Test type	▪ Line Probe Assay	▪ CBNAAT	▪ Liquid culture	▪ Liquid culture
Point of Contact	▪ Biomerieux (Distributor)	▪ Cepheid (Manufacturer)	▪ BD (Manufacturer)	▪ Biomerieux (Manufacturer)
Resistance	▪ Yes (INH and Rif resistance)	▪ Yes (only Rif resistance)	▪ Yes (both first line and second line)	▪ Yes (both first line and second line)
Reporting Time	▪ Within 2-3 days	▪ Within 1 day	▪ Within 15-42 days	▪ Within 15-42 days

Upcoming tests for TB Diagnostics

- Second Line DST – Line Probe Assay
- GeneXpert OMNI
- *Current GeneXpert cartridges would be replaced by Ultra post market launch*

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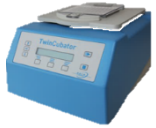
There exist four key requirements for a lab to become a part of IPAQT network

Prerequisite requirement

1 **Within IPAQT, labs with NABL, NABH, NACL, CAP or RNTCP accreditations can perform tests**

Guiding principles of IPAQT

2 Adherence to low & transparent 'Ceiling Price' to patients



Hain LPA
₹1800

GeneXpert
₹2200

MGIT
₹900

BacTAlert
₹1600

3 Use of only validated/endorsed, high-quality TB tests & not perform banned serological tests

✗ **IGRA**

IgG

IgM

✓ **Approved by**

World Health Organization

DOTS – Pura tourse | Pakka ilaaj

- IPAQT labs **agree to discontinue serological tests and PCR on blood samples**
- All member labs to undergo **periodic external quality assurance (EQA)**
- Only accredited labs can join

4 Notification of TB positive cases to RNTCP

+ve

DOTS – Pura tourse | Pakka ilaaj

RNTCP

- In May 2012, notification of all positive TB cases was made mandatory by the government
- **IPAQT labs notify all positive cases to National TB Program to enable free treatment follow-up**

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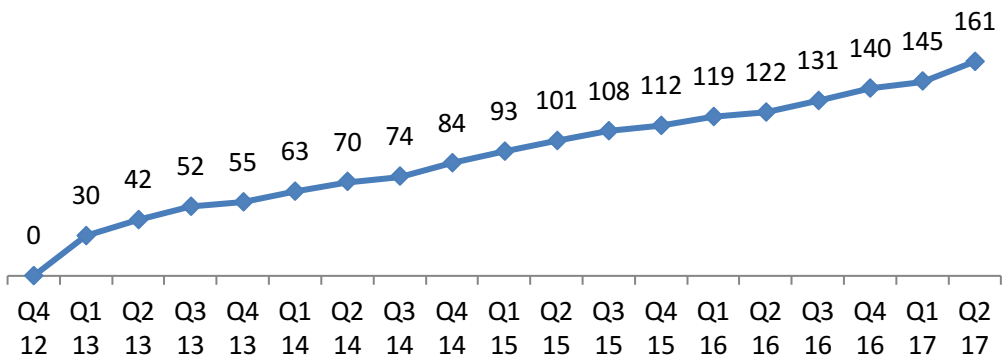
Since 2013, IPAQT network has seen a growth of 8 additional labs per quarter resulting in rapid uptake of WHO endorsed tests in the private sector

Starting with 5 labs, IPAQT now has 161 labs with 5300+ collection centers…

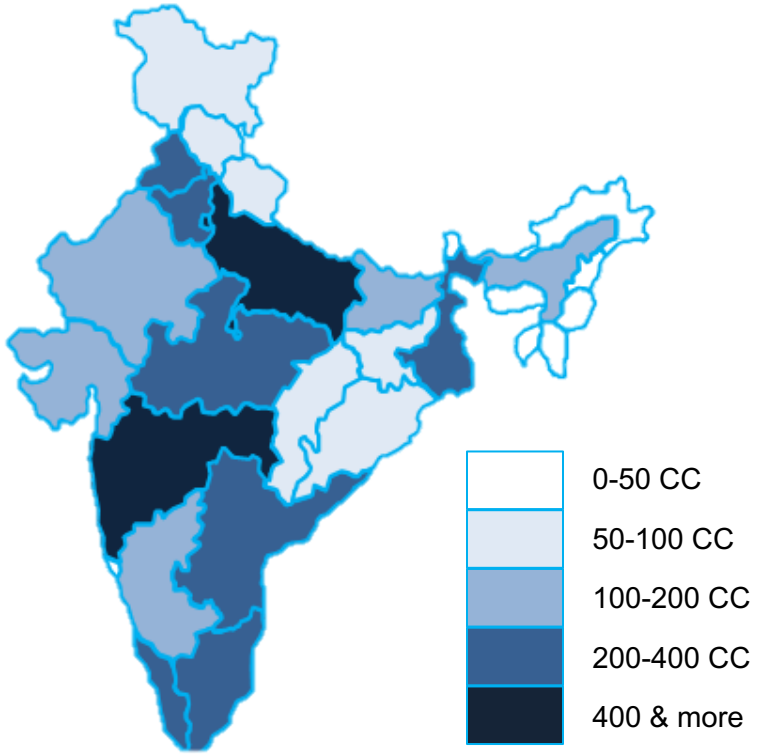
QoQ IPAQT Lab Numbers



Member labs include–

- *6 National lab chains*
- *55 Hospitals*
- *29 Regional chains*
- *71 Stand-alone labs*

…providing a geographic coverage of >85% of Indian districts



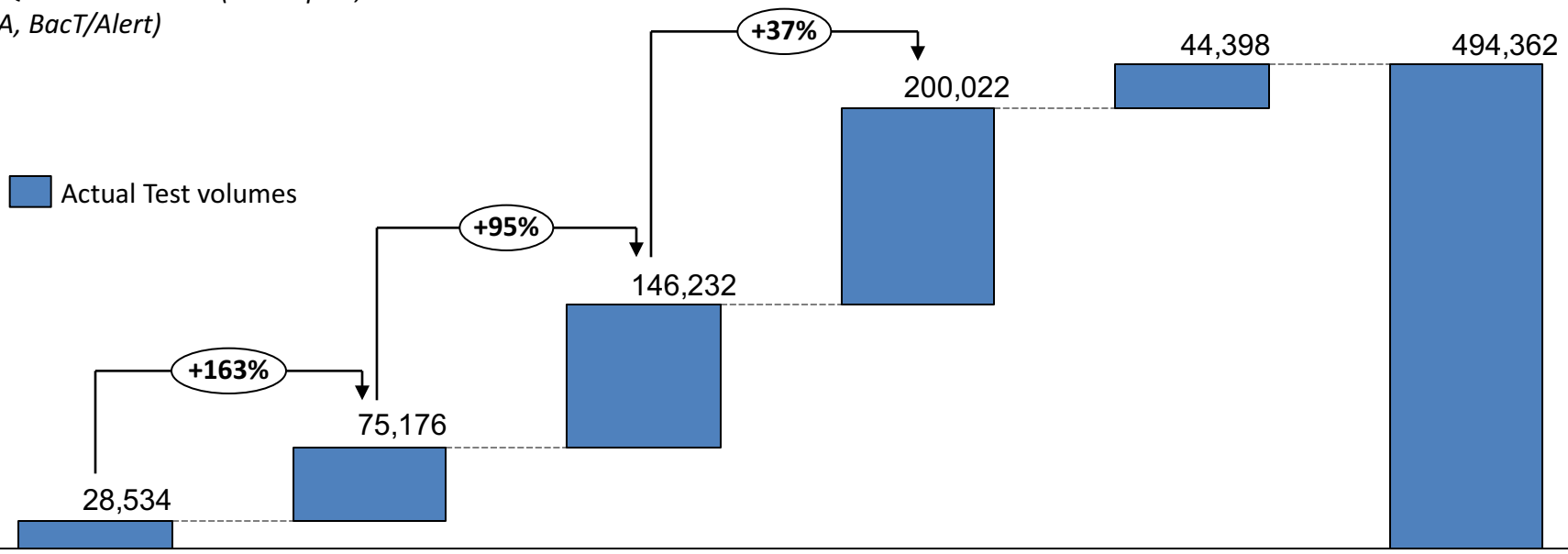
	No. installed bases 2015	No. installed bases 2016
GX	104	137
Hain LPA	39	41
Liquid Culture	23	24

IPAQT operations have resulted in almost 500,000 WHO-endorsed tests conducted in the Indian private sector at subsidized prices

Observed growth in YOY test volumes

- About 500,000 presumptive TB cases tested till Q1-2017
- IPAQT labs have performed on an average 15,000 TB tests per month from 2015 to 2016
- IPAQT represents ~87% of total private sector market share for GeneXpert (2015)

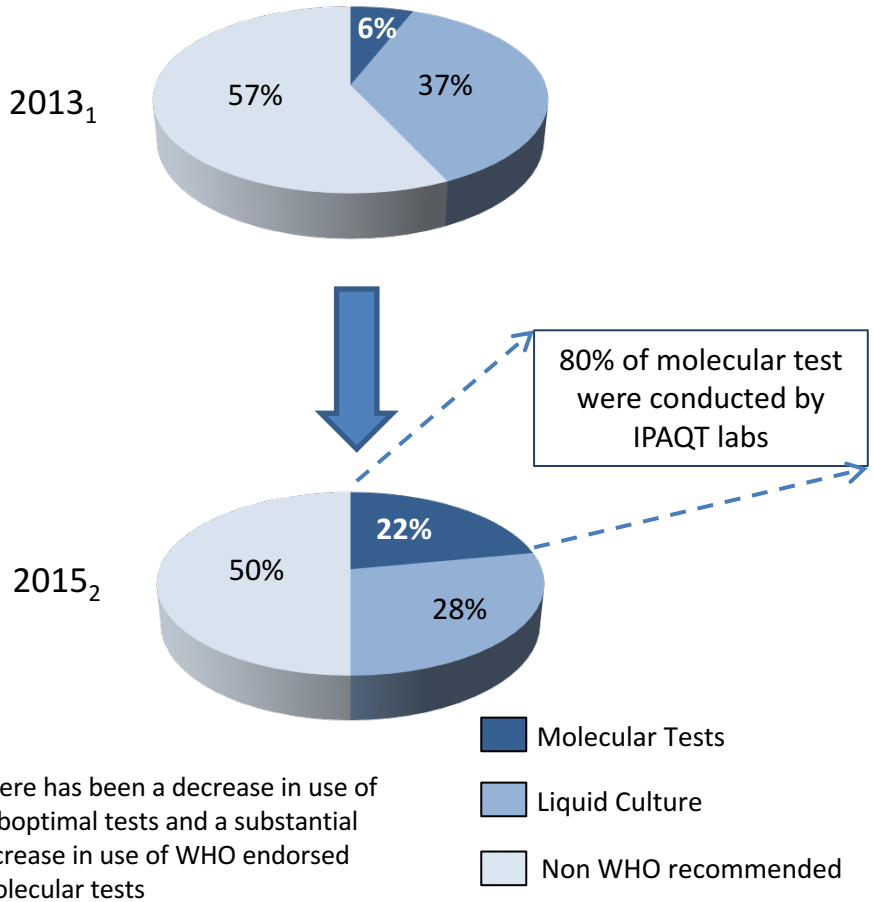
YoY IPAQT Test Volumes *Σ(GeneXpert, Hain LPA, BacT/Alert)*



Avg Tests per Month	2013	2014	2015	2016
	2,378	6,286	12,188	16,668

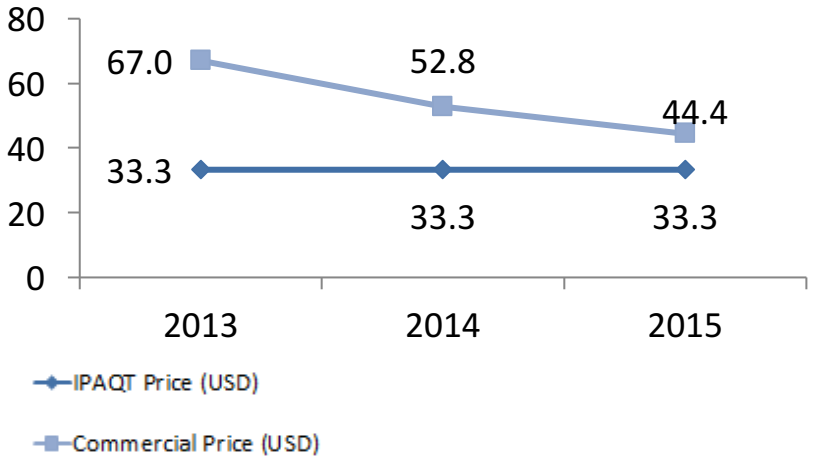
IPAQT has been successful in shaping the private sector molecular TB diagnostics market in India

Change in "similarly priced" diagnostic market from 2013 to 2015



There has been a decrease in use of suboptimal tests and a substantial increase in use of WHO endorsed molecular tests

IPAQT currently contribute majority of total GX volumes in the private sector which has created a negative pressure in the commercial GX pricing



YoY GeneXpert pricing trends in the private sector suggest that IPAQT has been successful in driving down the commercial GX price

Commercial Pricing Source: 2013 & 2016 – Mystery Calling; 2015 - Puri L et al. Lancet Global Health (2016); 2015 – Average pricing for 2013 and 2015;
This pricing analysis may change due to external factors such as introduction of new technologies, input pricing for devices and cartridges etc.

IPAQT complemented the supply side interventions with demand generation activities to sensitize private providers

1

CONTINUED MEDICAL SEMINARS

Conducted regular CMEs to create awareness on accurate diagnostics and treatment on TB

2

IN-CLINIC VISITS/ DENOTE

To address demand side barriers and increase notification from private sector

3

E-NEWSLETTERS

Timely newsletters to update providers on new innovations and technologies in TB

4

IPAQT WEBSITE

IPAQT website serves as a perfect platform for any information related to TB

5

IPAQT CASE STUDY

IPAQT case study was widely disseminated through various platforms

6

IPAQT COVERAGE

IPAQT was mentioned as one of the successful partnership programmes by the RNTCP

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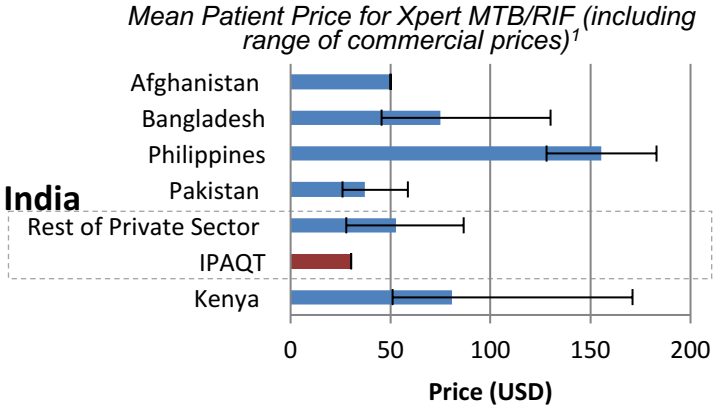
An IPAQT-like model could effectively support the TB control efforts of other major private healthcare economies

1. Increasing access to WHO endorsed technologies



- In 12 out of 22 HBDCs, private sector is major source of healthcare
- IPAQT labs offer the lowest price for GeneXpert (INR 2,200) among all the high burden countries where GeneXpert is commercially available
- An IPAQT-like model can be explored in other countries to access concessional pricing in private sector from selected manufacturers

2. Engaging with private providers

- Medical seminars conducted in collaboration with private sector labs supplement their marketing efforts for their existing private provider network, thereby, leading to more effective engagement model
- DENOTE private provider engagement model is an effective mechanism to mobilize field resources to generate maximum impact
- Engaging physicians digitally may provide greater reach at a lower cost?

3. Strengthening notification and surveillance mechanism

- Laboratories provide the majority of diagnostic support in the private sector thereby, acting as a major source of information for epidemiological surveillance and case notification
- Their ability to absorb technological innovation to automate data reporting processes, complemented with on field support for data completion, makes them a strong potential partner for the national TB program

[1]Puri L et al. Lancet Global Health, 2016

Snapshot of challenges addressed by IPAQT

	Key Challenges	Addressed by IPAQT
Demand	Weak provider knowledge	✓
	Unaffordability of current pricing by patients	≈
	Cultivated a list of Key Opinion Leaders involved in TB control to influence TB treating physicians	✓
Supply	Large and fragmented market due to weak regulatory pathway for diagnostics	✓
	Non-availability of validation and test efficacy data for newer technologies for promoting the tests	✓
	Weak financing mechanisms of tier II & III labs to invest in rapid WHO endorsed tests	✗

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A comprehensive strategy has been designed to support "on-ground" efforts through pan-India digital campaign to drive demand for quality TB tests

Digital Intervention to Generate Insights on behaviour Transformation (among private physicians)

Goal & Objective

- Inducing greater uptake of WHO-endorsed rapid molecular tests in the Indian private sector
- Understanding whether digital communication modes are capable of inducing behaviour transformation amongst Indian private providers towards TB best practices

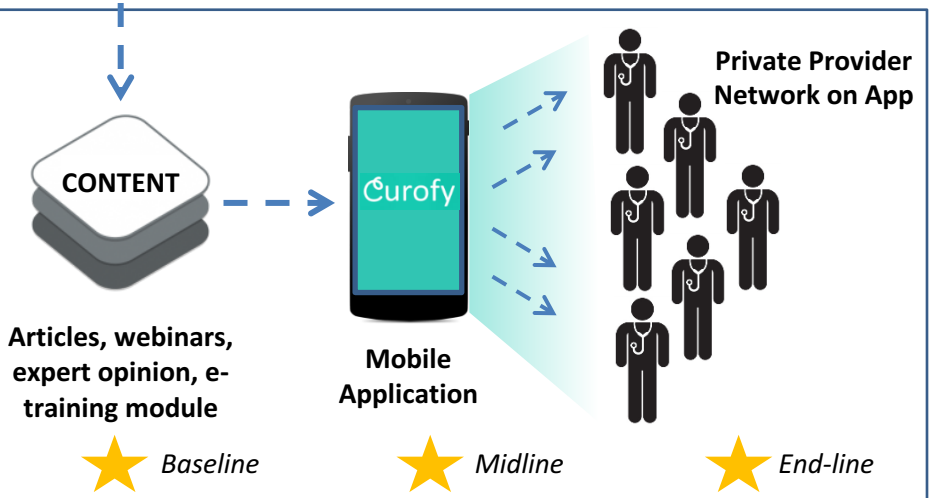
Identify Knowledge Gaps

Levers for Road to Behaviour Change

1 Awareness	2 Interest	3 Action	4 Advocacy
Inform the physician of a need gap; Address it by offering a solution	*Physician acknowledges current gap and there is a need that will be fulfilled through proposed solution*	*Physicians begins to prescribe and prescription materializes into test sales*	*Engage the physicians through ongoing activities to influence their long term behaviour*

Campaign Design to fill the Gaps and Evaluate Impact

- Eight month long campaign including multiple activities has been designed in partnership with "Curofy "– a doctor to doctor networking application to implement this exercise
- Designed a detailed monitoring framework to evaluate the impact of the campaign



Note: Aware about latest quality diagnostic tests (sub-set of WHO endorsed TB tests); Abreast with test comparison details like specificity, sensitivity, MDR-TB detection, strengths, limitations, running time, positioning, etc.; Capable to prescribe most suitable quality test to confirm TB in a presumptive TB case and eventually, become an advocate

Key challenges with digital strategy are identified and steps to mitigate them will be taken up during implementation

	Key Challenges	Addressing Feasibility	Mitigation Steps
Information Overload	• There exists no "one stop shop" for information	≈	• 6-8 month long digital campaign will cover critical elements in TB space
Trust Issues	• Inability to trust digital sources and apply learning from there in their practice	✓	• Approval stamp from various societies and eminent KOLs to build trust
Content	• Content is not very pointed or relevant • Audio visual mode is not effectively utilized, presentation is complex	✓	• Audio-visual content to be promoted with very focused targeting
Extent of engagement	• No incentive to be actively engaged and responsive on digital platforms	≈	• Accreditations / high engagement elements to be used as incentive
Response time	• Need immediate response; hence, prefer opinion from peers	≈	• Partner to establish a response unit to reduce the response time; CHAI to provide FAQs, trainings, etc.
Patient Confidentiality	• Uncomfortable sharing pictures / patient details due to patient confidentiality	✓	• Medical team from partner will screen all information before publishing

All the above mentioned factors might lead to low a response rate on digital platform – appropriate mitigation measures to be conducted with implementation partners

Sources: Primary research through telephonic interviews (N=5), secondary research : http://www.telegraph.co.uk/technology/news/10488778/Digital-doctors-how-mobile-apps-are-changing-healthcare.html

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Thank you for listening. Any questions?