Initiative for Promoting Affordable Quality TB Tests (IPAQT)

30 August 2013
Agenda

The need for a private sector focused initiative

IPAQT – The structure and the story thus far

Challenges and the future ahead
The need for a private sector focused initiative

IPAQT – The structure and the story thus far

Challenges and the future ahead
India has ~3 Million patients\(^1\) and a very successful National TB Programme

**India suffers from the highest TB burden in the world**

<table>
<thead>
<tr>
<th>Breakdown of TB cases(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>India</td>
</tr>
<tr>
<td>25%</td>
</tr>
<tr>
<td>Rest of the World</td>
</tr>
<tr>
<td>75%</td>
</tr>
</tbody>
</table>

**The National TB program (RNTCP) has been doing a stellar job in addressing the disease**

**Distance (km) between patient residence and the health facility\(^2\)**

- Urban
- Rural

**National Strategic Plan achievements & targets (millions)\(^3\)**

- Suspects Examined
- Put on Treatment

**DOTS (TB)**
- 2007-2012: 2
- 2012-2017: 6

**ACT (Malaria)**
- 2007-2012: 6
- 2012-2017: 47

**ARV (HIV/AIDS)**
- 2007-2012: 28
- 2012-2017: 48

RNTCP is one of India’s largest and greatest public health achievements:

- 13000 District Microscopy Centers (DMCs)
- 23000 Primary Healthcare centers (PHCs)
- 3.5% annual decline in TB since 2002 onwards
- Prevalence rate down to 250/100,000 from 583 in 1990

SOURCE: 1. RNTCP TB India Report 2013: Annual TB Incidence (India) is 2.3 million, prevalence is 3.1 million; 2. Survey done under the framework of the AMASA project (Access to Medicines in Africa and South Asia) in 2012; 3. National Strategic Plan 2012
However, India’s large, unregulated private sector plays a key role in healthcare management…

The private sector in India has a dominant presence in all areas of healthcare…

…especially in TB, where a significant number of patients start their treatment pathway in private sector

Share of Private Sector in Indian Healthcare Market

- Doctors: 80%
- Outpatient Care: 80%
- Hospitalised Care: 57%

India has the one of the largest private healthcare sectors in the world. Implications include:

- 72% of healthcare expenditure is out of pocket
- Total mean costs incurred by patients with pulmonary tuberculosis was $562.66 in 2009; this represents ~193% of the estimated monthly income of a manual laborer
- Debilitating effects on the poor – liquidation of assets; indebtedness (40% of hospitalized & 2% in the country every year end up BPL

….although it has several infirmities (Slide 1 of 2)

<table>
<thead>
<tr>
<th>Poor Practices at Laboratories/ No Regulation</th>
<th>High cost of quality tests and poor access</th>
<th>Insufficient engagement with NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Few accredited labs and weak quality assurance</td>
<td></td>
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<tr>
<td>- Only 400 labs (out of 40-100K) have accreditation</td>
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<td></td>
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<tr>
<td>- Variations in quality across labs (very few perform EQA)</td>
<td></td>
<td></td>
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<tr>
<td>- Widespread availability and use of bad tests, inappropriate samples, off-label use of products</td>
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<tr>
<td>- Growing use of IGRAs for active TB; high reliance on blood tests</td>
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<td></td>
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<tr>
<td>- High cost of WHO-endorsed tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Import duties, many intermediaries, distributor mark-ups, referral fees/kickbacks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Exclusion of private sector from negotiated pricing agreements; manufacturers’ assumption that private sector is made up of affluent TB patients (resulting in premium pricing)</td>
<td></td>
<td></td>
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<tr>
<td>- FIND agreements/buy-downs do not apply to private sector</td>
<td></td>
<td></td>
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<tr>
<td>- Lack of programmatic links; poor case notification</td>
<td></td>
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<tr>
<td>- Private providers prefer to retain cases (and not refer them to NTP, even if TB treatment is free in the public sector);</td>
<td></td>
<td></td>
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<tr>
<td>- Disincentives for private providers to notify</td>
<td></td>
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</table>

SOURCE: 1. Dr. Madhukar Pai UNITAID2013 TB Market Forum; 2. Please see appendix for details
Demand Side Shortcomings

Provider behaviour and adherence to guidelines

- Poor adherence to standards and guidelines and low quality of care
  - ISTC and national guidelines not followed for diagnosis
  - Suboptimal treatment (e.g. irrational drug regimens and high MDR-TB prevalence)

- Perverse incentives to use inappropriate tests/samples

Patient behavior and choices

- Despite free diagnosis in the public sector, patients still prefer private care
  - Patients are not able to separate good from bad tests in the private market
  - Patients delay seeking care and/or move from one provider to another
  - Even poor patients prefer private care; patients pay a lot for suboptimal care
Higher commercial incentives on poor tests

Intermediary margins for TB tests\(^1\)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Lab Margins</th>
<th>Network Margins</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sputum smear</td>
<td>$0.8</td>
<td>$0.6</td>
</tr>
<tr>
<td>Serology</td>
<td>$5.5</td>
<td>$4.6</td>
</tr>
<tr>
<td>In-house PCR</td>
<td>$7.0</td>
<td></td>
</tr>
</tbody>
</table>

Too many intermediaries in the value chain

Ex-factory price (x)

Taxes & transport charges (1.3x)

Distributor margins (1.9x)

Reference lab margins (2.5x)

Franchisee lab margins (2.9x)

Provider margins (3.3x)

Patient price

WHO-approved diagnostics are expensive

Price of WHO-approved tests in private sector\(^1\)

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Average</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Smear</td>
<td>$2</td>
<td>$52</td>
</tr>
<tr>
<td>Hain</td>
<td>$58</td>
<td></td>
</tr>
<tr>
<td>GeneXpert</td>
<td>$64</td>
<td></td>
</tr>
<tr>
<td>MGIT + DST</td>
<td>$73</td>
<td></td>
</tr>
</tbody>
</table>

Average monthly Household income of TB patients\(^2\)

Breakdown of TB tests in the private sector (2011)\(^2\)

- **Serology**, 52%
- **Smear microscopy**, 26%
- **TB-Gold**, 2%
- **Culture**, 10%
- **PCR**, 10%

Annual TB tests in the private sector (2011) = 11.5 million*

*Does not include TST and Chest X-ray

SOURCE: 1. Discussions with manufacturers (Cepheid), distributors (LabIndia, Biomerieux) and labs; 2.CHAI and IIMB student analysis
For manufacturers of WHO-approved tests, potential profits from the premium model are high, but volumes are limited.

Charging high prices for WHO-approved tests gave access to a small fraction of the total market...

### Monthly household incomes of the TB patients in the non-RNTCP segment

<table>
<thead>
<tr>
<th>Household income</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;$201</td>
<td>0.7%</td>
</tr>
<tr>
<td>$161-200</td>
<td>3.0%</td>
</tr>
<tr>
<td>$80-160</td>
<td>8.2%</td>
</tr>
<tr>
<td>&lt;$80</td>
<td>88.1%</td>
</tr>
</tbody>
</table>

Assuming a patient is willing to pay up to half a month’s household income for a TB test; at the **premium price of $64**, only **3.7% of market would be available**

…and although profit margins were high, the volumes were small

### GeneXpert MTB/ RIF

<table>
<thead>
<tr>
<th>Manufacturer's profit (‘000)</th>
<th>Reagent volumes (‘000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0</td>
<td>0</td>
</tr>
<tr>
<td>$3,000</td>
<td>0</td>
</tr>
<tr>
<td>$6,000</td>
<td>500</td>
</tr>
<tr>
<td>$9,000</td>
<td>1,000</td>
</tr>
<tr>
<td>$12,000</td>
<td>1,500</td>
</tr>
<tr>
<td>$15,000</td>
<td>2,000</td>
</tr>
<tr>
<td>$18,000</td>
<td>439</td>
</tr>
</tbody>
</table>

| Ex-factory premium pricing ($19) | |
|----------------------------------| |
| Maximum (12% premium market)     | 439                    |
| Base case (4% premium market)    | 5,284                  |
| Minimum (0.7% premium market)    | 0                      |

**SOURCE:** 1. Community-based survey conducted across 30 districts on ‘From Where Are Tuberculosis Patients Accessing Treatment in India?'; 2. CHAI analysis
IPAQT emerged as a result of recent developments that presented an opportunity for various stakeholders.

Government ban on serological tests provided a chance for the public health community, diagnostics manufacturers and private sector labs to facilitate change.

... a partnership was set up to replace serology with appropriate and optimal tests.

Breakdown of TB tests in private sector:

- **Smear microscopy**: 26%
- **TB-Gold**: 2%
- **Culture**: 10%
- **PCR**: 10%
- **Serology**: 52%
- **ELISA**: 25%
- **Lateral flow assay**: 75%

**Diagnostic manufacturers**
- Huge revenue potential to capture a significant share of the serology market

**Private labs**
- Need to replace serology volumes of with alternative tests in similar price range

**Price of alternative tests to be comparable to serological tests (ELISA ~$20)**

**Annual TB tests in the private sector (2011) = 11.5 million**

*SOURCE: 1. Discussions with manufacturers (Cepheid), distributors (LabIndia, Biomerieux) and labs; 2. CHAI and IIMB student analysis; NOTE: *Excludes X-rays and TST
Agenda

The need for a private sector focused initiative

IPAQT – The structure and the story thus far

Challenges and the future ahead
The initiative was set up as a partnership of laboratories – and created a win-win-win partnership for all stakeholders

**Diagnostic manufacturers**
- Higher volumes
- Lower transaction costs

**National TB Programme**
- Ability to track positive cases in the private sector for treatment follow-up

**Patient in the Private Sector**
- Access to affordable quality diagnostics
- Faster diagnosis, shortened time to proper treatment

**NGOs and Academia**
- Controlled patient price of quality TB tests
- Opportunity to influence diagnosis practices in the private sector through guiding principles
- Opportunity to ensure case notification transparency and quality

**Private laboratories**
- Access to quality assured TB tests at lower prices
- Gain market share by offering better tests

**Key guiding principles of IPAQT – to be followed by all IPAQT labs**

- Use of only high-quality TB tests
  - Only WHO/ RNTCP-approved tests to be included in IPAQT
  - All member labs to undergo periodic EQA
  - Only accredited labs to join

- Affordable price to patients
  - Partner labs to charge the patients below a ceiling price

- Linking diagnosis to treatment
  - Partner labs to notify all the positive cases to RNTCP
All stakeholders in the value chain agreed to drop their margins - translating into lower prices for the TB patient

**Xpert MTB/ RIF**

- Pricing in the private sector
- Pricing through IPAQT

<table>
<thead>
<tr>
<th></th>
<th>Ex-factory price</th>
<th>Transport + taxes¹</th>
<th>Distributor margins</th>
<th>Reference lab margins*</th>
<th>Franchisee lab margins**</th>
<th>Provider incentives**</th>
<th>Patient price</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Distributor price</strong></td>
<td>$19.1</td>
<td>$10.2 (53%)</td>
<td>$6.4 (64%)</td>
<td>$8.0 (27%)</td>
<td>$10.3 (21%)</td>
<td>$8.0 (12%)</td>
<td>$63.6</td>
</tr>
<tr>
<td><strong>Patient price</strong></td>
<td>$10.0</td>
<td>$1.3 (8%)</td>
<td>$6.0 (25%)</td>
<td>$1.3 (8%)</td>
<td>$6.0 (25%)</td>
<td>$3.6 (12%)</td>
<td>$30.9</td>
</tr>
<tr>
<td><strong>Hain Genotype</strong></td>
<td>$24.2</td>
<td>$1.8 (7%)</td>
<td>$6.9 (34%)</td>
<td>$8.7 (15%)</td>
<td>$8.7 (15%)</td>
<td>$3.6 (12%)</td>
<td>$58.2</td>
</tr>
<tr>
<td><strong>Distributor price</strong></td>
<td>$12.2</td>
<td>$1.0 (8%)</td>
<td>$3.6 (13%)</td>
<td>$3.6 (13%)</td>
<td>$3.6 (12%)</td>
<td>$8.7 (15%)</td>
<td>$27.3</td>
</tr>
</tbody>
</table>

**Although the per unit returns are lower, all the players could make higher aggregate returns on basis of higher volumes**

**NOTE:**
1. New price calculation accounts for a 5% error rate and assumes 80% utilization, advance payment and an outright equipment purchase model; *Calculated as a percentage of patient price minus franchisee lab margins and provider incentives; ** Calculated as percentage of patient price.
IPAQT has made satisfactory progress in the first quarter of its inception

50 member labs

..with over 3500 franchisee labs and collection centers

..and nearly 40 installed bases

<table>
<thead>
<tr>
<th></th>
<th>GX</th>
<th>Hain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of labs offering tests</td>
<td>30</td>
<td>9</td>
</tr>
<tr>
<td>Lowest price offered</td>
<td>1700</td>
<td>1600</td>
</tr>
<tr>
<td>Volume of tests (as of July end)</td>
<td>6420</td>
<td>2500</td>
</tr>
</tbody>
</table>

Member labs include—
- 5 of the 6 national lab chains
- 12 Hospitals
- 21 Regional chains
- 9 Stand-alone labs

(+ 32 prospective labs)

Number of districts covered so far: 390 (60% of total)

Number of GeneXpert tests in Indian Private Sector

<table>
<thead>
<tr>
<th></th>
<th>Entire 2012 (approx)</th>
<th>2013 (first quarter)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>500</td>
<td>6,000</td>
</tr>
</tbody>
</table>
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The need for a private sector focused initiative

IPAQT – The structure and the story thus far

Challenges and the future ahead
There are several challenges in managing the varied, often competing, interests of the different stakeholders.

### Demand Side Challenges

**Limited awareness about the ban on serology**

- **Total serology testing market**:
  - Lateral Flow Assay, 75% (Small, standalone labs will continue serology)
  - ELISA, 25% (Large labs may discontinue serology)

- **Current small universe of labs performing WHO-approved tests**, due to -
  - Unequal Incentives – higher margins for IGRA based tests/in-house PCRs
  - Lack of awareness – about test value and availability

### Supply Side Challenges

**Higher margins on in-house PCR tests and IGRAs**

- **Current small universe of labs performing WHO-approved tests**, due to -
  - Higher margins on non-validated tests
  - Payment structure – High capex; advance payments; lower margins
  - Preference for blood as a sample

Further progress will be in the face of stiff market dynamics; the key is to find a balance between affordability and access and seed the market to a point where WHO-approved tests become the de-facto choice in the private sector diagnostics market.
Thank You

Please visit www.ipaqt.org for more information
Appendix
Appendix 2: Sub-optimal tests have higher margins compared to quality tests, making them economically more attractive to labs and providers.

Laboratories, collection centers and providers tend to favor tests like TB Gold and in-house PCR as they have higher margins as compared to the WHO-approved tests.
...that are highly exposed to the actual size of the premium market

Mass market strategy can yield significantly higher volumes and profit than a premium strategy...

...even when key assumptions are adjusted

**GeneXpert MTB/ RIF**

<table>
<thead>
<tr>
<th></th>
<th>Ex-factory premium pricing ($19)</th>
<th>Ex-factory mass market pricing ($10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagent volumes</td>
<td>$35,367,335</td>
<td>$5,284,114</td>
</tr>
<tr>
<td>Installed bases</td>
<td>11,812,737</td>
<td>439,135</td>
</tr>
<tr>
<td>Manufacturer's profit</td>
<td>3,155</td>
<td>117</td>
</tr>
</tbody>
</table>

**Relative profits varying by size of the premium market**

- Ex-factory premium pricing ($19)
- Ex-factory mass market pricing ($10)

If the premium market as % of total market is <25%, then mass-market pricing would generate higher returns.

**GeneXpert MTB/ RIF**

| Source: CHAI analysis |

**NOTE:** Assumess uptake rates of 100% of potential customers in the premium market and a premium market of 4% of total TB patient population.