Operations Research within the Indian National TB Programme

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About India
Overview of TB situation in India

• Highest TB burden in the world
• Incidence ~2.2 million cases (25%)
• ~100,000 MDR-TB cases every year
• HIV positivity among TB patients is ~5%

• Revised National TB Control Programme since 1997 (based on DOTS strategy)
• ~1.5 million TB patients notified annually
• ~85% treatment success rate
Overall aim of the TB Control Programme

Identify TB patients

Cure them
Key Challenges for TB control in India

• Maintaining/improving quality and reach of DOTS
  – Improving programme performance in underperforming areas

• Scaling up of MDR-TB management and maintaining the quality of services

• Engaging all care providers

• Promoting community involvement and ownership

• Further strengthening TB-HIV collaborative activities

• Introduction of newer diagnostics and treatment modalities
  – Eg., introduction of latest tests in Programme accredited labs

Source: Central TB Division, MoHFW, GoI
Operations research within RNTCP

• Research agenda
  – Priority topics
  – Concept notes
  – Type of institutions who can undertake OR

• Operations research guidelines
  – Application process
  – Review committees
  – Funding mechanisms

• Challenge: Time consuming & slow

• Additional Approach: Programme based rapid operations research studies
  – Rapid, single research question based operations research studies
Examples
Trend in the notification of different Types of re-treatment TB cases in India (2005-2009)*

<table>
<thead>
<tr>
<th>Year</th>
<th>Total number of retreatment cases notified</th>
<th>Total number of relapse cases notified**</th>
<th>Total number of Treatment After Default cases notified**</th>
<th>Total number of 'failure' cases notified under retreatment cases**</th>
<th>Total number of 'others' notified**</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>224,569</td>
<td>75,054 (33)</td>
<td>72,021 (32%)</td>
<td>17,710 (8)</td>
<td>59,845 (27)</td>
</tr>
<tr>
<td>2006</td>
<td>260,618</td>
<td>90,153 (35)</td>
<td>76,699 (29%)</td>
<td>19,496 (7)</td>
<td>74,270 (28)</td>
</tr>
<tr>
<td>2007</td>
<td>276,936</td>
<td>96,781 (35)</td>
<td>77,397 (28%)</td>
<td>19,012 (7)</td>
<td>83,746 (30)</td>
</tr>
<tr>
<td>2008</td>
<td>289,222</td>
<td>104,210 (36)</td>
<td>76,583 (26%)</td>
<td>18,434 (6)</td>
<td>89,995 (31)</td>
</tr>
<tr>
<td>2009</td>
<td>289,756</td>
<td>108,708 (37)</td>
<td>73,812 (25%)</td>
<td>18,952 (6)</td>
<td>88,284 (30)</td>
</tr>
</tbody>
</table>

*Source: RNTCP Annual Reports for the year 2006-10; **Percentages in brackets are as a proportion of total re-treatment cases
Re-treatment Tuberculosis

• TB Patients previously treated with anti-TB drugs for at least a month

• Mostly as a result of inadequate and improper treatment of the new-TB
Re-treatment TB notifications (2009)

Globally,

– TB notifications - 6 million,
– Re-treatment TB notification: 0.6 million (~10%)

India,

– TB Notifications- 1.5 million
– Re-treatment TB notification: 0.3 million (~19%)

TB Diagnostic and Treatment services in India

• Revised National Tuberculosis Control Programme
  – Services are available through the public health system
  – Good recording and reporting system

• Large private sector health care providers
  – No regulation for treatment of TB
  – No recording and reporting system
Rationale

The information on what proportion of TB cases were previously treated from NTP or outside the NTP in the private sector was not known.

Objective

• To assess the source of previous treatment for re-treatment TB patients registered under India’s NTP

(Whether it was from NTP or outside NTP)
Methods

• Nationally representative cross sectional survey

• Sample size
  – A representative sample size of 880 patients
    • assuming 50% history of previous treatment from RNTCP,
    • a precision of ±5%,
    • considering a 10% non-response rate
    • a design effect of 2 to account for cluster sampling

• 36 districts out of 650 districts selected by population proportionate to size sampling
36 districts selected for the Study
Methods contd..

Survey participants

• All consecutively registered patients in a 15 day window period were included in the study

Data collected at the time of registration

• 10% data was later cross verified by District TB Officers and Medical Consultants

Data variables (6 variables only)

– Name of the district, TB registration number, Age, Sex, Type of retreatment TB, Most recent source of previous treatment; whether it was ‘from RNTCP’ or from ‘non-RNTCP’,
Methods contd..

• Patients were considered to be previously treated under NTP if,
  – they could recollect that they were treated from a ‘patient wise box’ by visiting a DOT Provider thrice weekly or
  – if they possessed a ‘patient identity card’ provided by RNTCP or
  – if the ‘treatment supervisors’ were able to identify a TB registration number by cross-verifying the program records or by reviewing the medical records.

• In the absence of this information, or if the patients had medical records about the previous treatment from the Private sector, patients were considered to be treated outside NTP
Methods contd..

• Ethical considerations
  – The protocol was reviewed and approved by Central TB Division, Ministry of Health and Family Welfare, Government of India
  – Considered routine evaluation of programme

• Data analysis
  – Data were entered in the field by the districts in a structured format, compiled at the National level and then analyzed
  – In order to calculate the statistics, complex sample analysis was done in Epi-Info [to account for cluster sampling methodology with districts as the primary sampling units]
Results

• The data was collected during a 15 day period 16th May-31st May, 2010, in all the 36 selected districts

• A total of 1712 re-treatment patients were registered and all 1712 were enrolled
Results contd..

- The distribution of Age, sex and type of TB were comparable to the distribution in the national notifications.

- Information from:
  - 595 (35%) ‘relapse’ cases,
  - 105 (6%) ‘failure’ cases,
  - 437 (25%) ‘treatment after default (TAD)’ cases and
  - 575 (34%) ‘re-treatment others’ cases.
### Results

- **784** [44% (95% CI: 38-50)] out of 1712 patients
  Previously treated outside NTP

- **958** [56% (95% CI: 50-62)]
  Previously treated under NTP

<table>
<thead>
<tr>
<th>Type of TB</th>
<th>Non-NTP</th>
<th>NTP</th>
<th>Total</th>
<th>Chi square</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N  (%)</td>
<td>N  (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relapse</td>
<td>133 (22)</td>
<td>462 (78)</td>
<td>595</td>
<td>Referent</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Failure</td>
<td>6 (6)</td>
<td>99 (94)</td>
<td>105</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>TAD</td>
<td>278 (64)</td>
<td>159 (36)</td>
<td>437</td>
<td></td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Others</td>
<td>337 (59)</td>
<td>238 (41)</td>
<td>575</td>
<td></td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Limitations

- Represents patients registered under NTP only

- We chose a 15 day period for data collection based on operational feasibility and not randomly
  - If there are seasonal changes in seeking health care from NTP, then this may affect the profile of patients

- Lastly, study based on patient recall and in many cases, records of previous treatment could not be verified
Implications of the study

• First, nearly half of re-treatment TB patients were previously treated outside NTP

• Second, reduction in re-treatment cases in India can be brought about by both
  – strengthening programme processes and reaching out to huge private sector
Implications....

- Third, identify and address risk factors recurrence
  - irregular drug intake/ default
  - tobacco usage
  - diabetes
  - HIV infection
Source of Previous Treatment for Re-Treatment TB Cases Registered under the National TB Control Programme, India, 2010

Kuldeep Singh Sachdeva¹, Srinath Satyanarayana¹,²*, Puneet Kumar Dewan³, Sreenivas Achuthan Nair², Raveendra Reddy³, Debasish Kundu³, Sarabjit Singh Chadha², Ajay Kumar Madhugiri Venkatachalaiaih¹,³, Malik Parmar¹,³, Lakhbir Singh Chauhan¹

¹Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, New Delhi, India, ²South East Asia Regional Office, International Union Against Tuberculosis and Lung Diseases (The Union), New Delhi, India, ³Office of the World Health Organisation (WHO) Representative in India, WHO Country Office, New Delhi, India
The Problem

• ~ 40,000 (16%) of 259,059 ‘re-treatment TB patients’ did not complete treatment!
• Reasons largely unknown (Global and Indian Context)

Research questions

• Who are these patients?
• Why do they not complete treatment?
Study findings:

- Males
- Patients previously treated in the private sector
- Patients who had to travel for treatment to health facilities or receiving treatment in hospitals
- Two thirds of the patients were defaulting from treatment within 2 months
- Weak efforts to trace patients
- Migration was the most common factor for default

Risk Factors for Treatment Default among Re-Treatment Tuberculosis Patients in India, 2006

Ugra Mohan Jha¹, Srinath Satyanarayana²*, Puneet K. Dewan³, Sarabjit Chadha³, Fraser Wares³, Suvanand Sahu³, Devesh Gupta¹, L. S. Chauhan¹

¹Central Tuberculosis Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, New Delhi, India, ²Centre for Operational Research, International Union Against Tuberculosis and Lung Diseases (The Union), New Delhi, India, ³Office of the WHO Representative to India, New Delhi, India
Programme implications

- Monitoring of treatment outcomes of re-treatment TB cases has become a part of routine programme reviews and meetings

- Initiated activities for promoting community-based treatment / Awareness
Other related and follow-up studies

Tuberculosis ‘retreatment others’: profile and treatment outcomes in the state of Andhra Pradesh, India

S. Srinath,*† B. Sharath,‡ K. Santosha,§ S. S. Chadha,‡ S. Roopa,¶ K. Chander,‖ F. Wares,‡
L. S. Chauhan, ** N. C. Wilson, † A. D. Harries*

* Center for Operations Research, International Union Against Tuberculosis and Lung Disease (The Union), Paris, France; † The Union, South-East Asia Regional Office, New Delhi, ‡ Office of the World Health Organization Representative in India, New Delhi, § Impact Health Solutions, Hyderabad, Andhra Pradesh, ¶ Centre for Community Medicine, All India Institute of Medical Sciences, New Delhi, ‖ State TB Office, Directorate of Health, Government of Andhra Pradesh, Hyderabad, ** Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, New Delhi, India

From Where Are Tuberculosis Patients Accessing Treatment in India? Results from a Cross-Sectional Community Based Survey of 30 Districts

Srinath Satyanarayana¹.²*, Sreenivas Achutan Nair¹, Sarabjit Singh Chadha¹, Roopa Shivashankar³, Geetanjali Sharma¹, Subhash Yadav¹, Subrat Mohanty¹, Vishnuvardhan Kamineni¹, Nevin Charles Wilson¹, Anthony David Harries².⁴, Puneet Kumar Dewan⁵
Programme and policy implications

• Regular monitoring of trends in the notification and treatment outcomes of retreatment cases

• Government of India made TB notification in the private sector mandatory

• Efforts to engage private health care providers got intensified

• Operations research has become the mainstay for decision making within the national programme
Other important ORs done within the programme

- Screening of TB suspects for HIV Infection
- Screening of TB patients for Diabetes
- Strengthening Isoniazid preventive therapy among children
- Follow-up sputum smear examination
- Pre-treatment loss to follow-up

- ~ 60 studies between 2009-2013
Lessons learnt

• Selection of research questions very important
  – Make operations research programmatically relevant and useful

• Engage programme managers in the design, implementation and interpretation of the study findings

• Keep the research questions simple

• One-two related research questions at a time

• Big budget not required
Thank you