Tuberculosis Screening and IPT: Experience from India

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The 17th Core Group Meeting of the TB/HIV Working Group
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This talk will cover

- TB/HIV scenario in India
- Status of implementation of TB/HIV collaborative activities in India
- Experience of expansion of Intensified TB case Finding (ICF) activities at HIV diagnosis and Treatment centres in India
- Issues in adoption of Isoniazid Preventive Therapy (IPT)
Burden of HIV and TB in India

• HIV: Concentrated
  – 0.3% adult prevalence
  – 2.4 million persons
  – 3rd Highest in numbers
  – Heterogeneous distribution
  – NACP (National AIDS Control Programme)

• TB: Everywhere
  – About 2.3 m incident TB cases/yr
  – Highest burden (26%), though 18th in incidence
  – 5% (110,000) HIV-infected with high mortality
  – RNTCP (Revised National TB Control Programme)
National TB/HIV Policy

1. 2001– First TB/HIV “Joint Action Plan” /Policy document developed


4. Framework includes policy guidelines for
   – Establish the mechanisms for coordination
   – Decrease the burden of TB among PLHIV
   – Decrease the impact of HIV in TB patients
National TB/HIV Policy Framework

• **Objectives:**
  
  • To strengthen the mechanisms for coordination between RNTCP and NACP at National, State and District levels.
  
  • To decrease morbidity and mortality due to tuberculosis among persons living with HIV/AIDS.
  
  • To decrease the impact of HIV in tuberculosis patients and provide access to HIV related care and support to HIV- infected TB patients.
TB/HIV activities under National TB/HIV policy framework

- **To decrease burden of HIV in TB patients**
  
  **Intensified TB/HIV Package**
  
  » Routine offer of HIV testing to TB patients
  
  » Decentralized provision of CPT and
  
  » Linkage to ART services

- **To decrease burden of TB in PLHIV**

  **Intensified TB Case Finding at**

  **ICTC and ART Centres**

- **To prevent TB among PLHIV**

  IPT – operational study initiated

  TB infection control in HIV care settings
Standard TB/HIV Training Modules

Training Manual on Intensified TB/HIV Package
for NACP & RNTCP Programme Managers
at State and District level

Training Manual on Intensified TB/HIV Package
for ART Centre Staff

Training Manual on Intensified TB/HIV Package
for Medical Officers

TB/HIV Module
for ART Centre Staff

Training Manual on Intensified TB/HIV Package
for Pharmacists

Training Manual on Intensified TB/HIV Package
for IITC Counsellors

Prepared Jointly by NACP and RNTCP

Available at www.nacoonline.org
Implementation-Commitment at highest Level

Letters issued by both National programmes for smooth implementation
## Co-ordination Mechanisms

<table>
<thead>
<tr>
<th>Level</th>
<th>Chair</th>
<th>Mechanism</th>
<th>Frequency of meeting</th>
<th>Mandate</th>
</tr>
</thead>
<tbody>
<tr>
<td>National</td>
<td>DDG TB / DDG BSD NACO</td>
<td>National technical working Group (NTWG)</td>
<td>Quarterly Meeting</td>
<td>Policy decisions, review</td>
</tr>
<tr>
<td>National</td>
<td>DG NACO/JS RNTCP</td>
<td>Annual Review of TB/HIV Collaborative activities at National and State level</td>
<td></td>
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</tr>
<tr>
<td>State</td>
<td>Principal Secretary Health</td>
<td>State Coordination Committee (SCC)</td>
<td>Bi-annual</td>
<td>Policy decisions at state level</td>
</tr>
<tr>
<td>State</td>
<td>PD-SACS / STO</td>
<td>State technical working Group (SWG)</td>
<td>Quarterly</td>
<td>Review</td>
</tr>
<tr>
<td>District</td>
<td>District collector/DM</td>
<td>District Coordination Committee (DCC)</td>
<td>Quarterly</td>
<td>Review</td>
</tr>
<tr>
<td>District</td>
<td>DTO-DAPCU / HIV Nodal officer</td>
<td>HIV-TB coordination meeting</td>
<td>Monthly</td>
<td>Review</td>
</tr>
</tbody>
</table>
TB suspects referred from ICTC to RNTCP:

- The symptomatic patients attending ICTC suspected to have TB are being referred to RNTCP for Sputum smear Microscopy, irrespective of their HIV status, as a part of **Intensified HIV- TB package**. Over the last five years, there is a significant increase in the referrals to RNTCP for TB case detection.

![Graph showing TB suspects referred from ICTC for evaluation, 2005-2009:](image)

> 10 fold increase in referrals in the last 5 years
Process-Intensified TB Case Finding at HIV care settings – Joint Reporting

ICTC

ART centre

TB Suspect Screening

Line-List

Monthly TB/HIV report

State AIDS Control Society

Standard reporting format

ICTC counselor / ART centre Nurse + RNTCP STS

Validation of reports and line-list in monthly HIV/TB meeting

State AIDS Control Society

NACO

Central TB Division
Process--Intensified TB/HIV package (TB programme) -reporting

- Documentation of HIV status on TB Treatment Card
  - Patient history of HIV test
  - Result of HIV test brought by patients (ICTC referral form)
  - Informed by counselor - "Shared confidentiality"

Provider at PHI

RNTCP TB register

Quarterly reports

Central TB division

NACO
Process--TB Documentation at ART centre on Patient White Card

- **Baseline screening during Pre ART registration**
- **Symptom based screening on every visit to ART centre for any reason**
- **Patients referred from Tb programme**

Documentation of TB status on ART Treatment Card

Provider at ART centre

ART register

PLHA software

CMIS, NACO
Intensified TB case finding (ICF)

• ICF activity at HIV diagnostic centres (ICTC) across the country since 2008
• ICF at ART Centres with standardized R&R introduced and Rapidly expanded in 2010
How ICF works in India? (1)

- Counselors (ART centre staff nurse) expected to ask all clients about TB symptoms, cough of 2 weeks duration and others.

- Clients (PLHIV at ART centres) with symptoms, cough of any duration, referred to Microscopy Center using sputum referral form.
How ICF works in India? (2)

• All the referrals are recorded on a line-list, which is shared with TB programme supervisor.

• TB programme supervisor check his record and completes details on:
  – Status of referral
  – Diagnostic outcome
  – TB treatment initiation

• Monthly VCT report prepared jointly.
ICF at ICTC - referral of clients for TB diagnostic evaluation, 2006–2010

Number referred

% of all clients referred

2006
2007
2008
2009
2010
Outcomes of ICTC Clients Referred for TB Screening, 2010

- Referred: 485,526
- Diagnosed Active TB: 51,502 (11%)
- Started DOTS: 40,263 (78%)
Contribution of ICF at ICTC to TB Case Notification, 7 high HIV states of India
Progress--Reporting of Intensified TB case Finding (ICF) at HIV testing centres (ICTC) and ART centres in India (2010-11)

Close monitoring by the team of officers in SACS and regional coordinators and NACO helped improvement in reporting.

- N=29 states
- N=313 ART centres
Outcomes of ART patient Referred for TB Screening

- Total Number of TB suspects referred: 41,840 (2010), 64,322 (2011)
- Total number found TB: 12,191 (29%), 17,016 (26%)
- Total on DOTS: 10,042 (82%), 14,411 (85%)

2010 & 2011 comparison graph.
Challenges

• Ensuring implementation and reporting by all ICTC and ART centres

• Ensuring Quality reporting –enhanced monitoring
Way Ahead

• Sputum smear microscopy has low sensitivity - adoption of rapid TB diagnostics for PLHIV
• Expansion of definition of “TB suspect” to widen net of eligible patients for early detection
• Expansion of ICF to other HIV care settings – TI projects for HRG, Community Care Centres and Link-ART centres etc.
• Strengthen implementation of Airborne Infection Control in HIV care settings
• Adoption and expansion of IPT – based on OR
Isoniazid Preventive Therapy
Concerns around adoption of IPT for national scale-up

- Exclusion of active TB challenging
  - Limited access to culture and DST for complete evaluation for ruling out TB
- Fear of Drug resistance: Emergence and “Breakthrough TB”
  - Questions around efficacy of IPT given early initiation of ART (<350)
  - Questions around optimum duration of IPT - 6 months Vs. extended
  - Evidence supporting use of IPT among Tuberculin skin test positives only
  - Lack of availability of standardized Tuberculin & its Strength (TU)
  - Immunosuppression issues in use of TST
  - Non-standardized tuberculin Induration size in Indian conditions
- Poor adherence to IPT is expected in a person who is largely asymptomatic (for TB)
Concerns around adoption of IPT for national scale-up ...(1)

- Challenges in operationalization-
  - workload at ART centres
  - Feasibility of decentralized delivery of IPT
  - Monitoring of adherence to IPT specially among those on pre-ART
Evidence reviewed by National Technical Working Group for TB/HIV -international

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Studies</th>
<th>Patients</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probable, confirmed or possible TB</td>
<td>8</td>
<td>4136</td>
<td>0.67 (0.51,0.87)</td>
</tr>
<tr>
<td>- TST positive</td>
<td>4</td>
<td>1311</td>
<td>0.36 (0.22,0.61)</td>
</tr>
<tr>
<td>- TST negative</td>
<td>7</td>
<td>2490</td>
<td>0.86 (0.59,1.26)</td>
</tr>
<tr>
<td>- TST unknown</td>
<td>2</td>
<td>335</td>
<td>0.86 (0.48,1.52)</td>
</tr>
<tr>
<td>Confirmed TB</td>
<td>4</td>
<td>2063</td>
<td>0.72 (0.47,1.11)</td>
</tr>
<tr>
<td>- TST positive</td>
<td>1</td>
<td>112</td>
<td>0.13 (0.01, 2.32)</td>
</tr>
<tr>
<td>- TST negative</td>
<td>3</td>
<td>1021</td>
<td>0.76 (0.36,1.61)</td>
</tr>
<tr>
<td>- TST unknown</td>
<td>2</td>
<td>930</td>
<td>0.79 (0.46,1.36)</td>
</tr>
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(Akollo et al 2010 Cochrane Review)

Preventive chemotherapy (IPT) reduces overall risk of developing TB by upto 33%
Evidence reviewed by National Technical Working Group for TB/HIV: Efficacy as compared to ART alone

<table>
<thead>
<tr>
<th>Study</th>
<th>Total cases / total person-years</th>
<th>Setting</th>
<th>Incidence Per 100 person-yrs</th>
<th>Naive</th>
<th>ART</th>
<th>IPT</th>
<th>IPT+ART</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golub, AIDS 2007</td>
<td>391/17140</td>
<td>Brazil</td>
<td>In</td>
<td>4.0 (3.4-4.7)</td>
<td>1.9 (1.6-2.2)</td>
<td>1.3 (0.4-2.9)</td>
<td>0.8 (0.4-1.7)</td>
</tr>
<tr>
<td>Golub, AIDS 2009</td>
<td>267/4287</td>
<td>South Africa</td>
<td>Inc</td>
<td>7.1 (6.2-8.2)</td>
<td>4.6 (3.4-7.8)</td>
<td>5.2 (0.2-0.8)</td>
<td>1.1 (0.2-0.8)</td>
</tr>
</tbody>
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Evidence reviewed by
National Technical Working Group for TB/HIV -India

<table>
<thead>
<tr>
<th>Cohort</th>
<th>TB incidence rate per 100 PY</th>
</tr>
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<tbody>
<tr>
<td>Control cohort</td>
<td>6.9 per 100 PY</td>
</tr>
<tr>
<td>6 EH cohort</td>
<td>2.4 per 100 PY</td>
</tr>
<tr>
<td>36 H cohort</td>
<td>1.5 per 100 PY</td>
</tr>
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Comparison of TB incidence rate per 100 person years

*(Swaminathan et al, CROI 2010)*
IPT operational feasibility cum efficacy study - Ongoing

OBJECTIVES

• To assess the effectiveness of simple algorithms to exclude active TB prior to IPT initiation

• To assess the feasibility of providing IPT for PLHIV attending ART centres in India.

• To assess the effectiveness of IPT in PLHIV (at different CD4 counts and both pre-ART and on ART) initiated on IPT in India

• To measure number needed to screen (NNS) and number needed to treat (NNT) to prevent one case of TB

Study design: Prospective cohort study

Mid-term review: June 2012, decisions on expansion
Measures to prevent TB among PLHIV

• **Early Initiation of ART**: The NACO has taken decision to initiate ART at CD4 count <350 irrespective of clinical stage and at any CD count in clinical stage III and IV

• **All TB patients to be initiated on ART irrespective of CD count**

• **Isoniazid Preventive Treatment (IPT)**: An feasibility cum efficacy study has been approved by NACO at 12 ART centres across the country

• **Measures for Airborne Infection control**:
  
  – Basic activities like fast tracking of patients with cough, promotion of cough hygiene measures, use of mask and hand washing being implemented at ART Centres
  
  – Structural changes are being advocated with general health system
Tuberculosis in antiretroviral treatment services in resource-limited settings: addressing the challenges of screening and diagnosis
Lawn SD, Wood R; Journal of Infectious Diseases 204 Suppl 4 S1159-67 (Nov 2011)

• ....... Screening and diagnosis of TB in this clinical setting is difficult. However, progress has been made in defining a high-sensitivity, standardized symptom screening tool that assesses a combination of symptoms, rather than relying on report of cough alone. Moreover, newly emerging diagnostic tools show great promise in providing more rapid diagnosis of TB, which is predominantly sputum smear-negative. Further development and implementation of these tools is vital to permit rapid and effective screening for TB in ART services, which is an essential component of patient care
Thank you