



Ministry of Health
& Family Welfare
Government of India



World Health
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COUNTRY OFFICE FOR

India



Joint Monitoring Mission

Revised National Tuberculosis Control
Programme (RNTCP), India

21 – 31 August 2012





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Preface

I am pleased to introduce the Report of the 2012 Joint Monitoring Mission (JMM). The Report has made far-reaching recommendations and suggestions; it also provides an action blueprint for TB control efforts in the country. At the request of the Government of India (GOI), the WHO Country Office for India, along with the technical, developmental and implementing partners of the Revised National Tuberculosis Control Programme, has been organizing a JMM every three years to coordinate and guide policies and planning for more effective TB control efforts.

The 2012 JMM came at an opportune moment as it has been able to provide inputs on strategic approaches and innovative mechanisms for achieving the key targets of the 12th Five Year Plan. It has reviewed the progress, challenges and plans for India's TB control initiatives and programmes, and advised the GoI and its partners on the path to be followed for achieving universal access to TB care. It has also reviewed and endorsed the ambitious National Strategic Plan (NSP) for TB Control (2012-2017).

Some of the key recommendations of JMM include: engaging all care providers to achieve universal access to TB care and prevent drug resistance; extending case-finding activities and deploying improved diagnostics and diagnostic strategies; and strengthening health systems.

The JMM has appreciated the government's TB control programme. However, it has cautioned that further successful implementation requires an urgent and emphatic expansion in the prioritization, development, financing and deployment of innovative activities to rapidly detect and correctly treat TB cases, irrespective of public or private sector provision of care. We strongly urge the government and all the partners to take on board the suggestions of the JMM and accord priority to areas that need to be strengthened.

Looking ahead, the roadmap must include: greater urgency and stronger efforts to prevent and address TB; recognition that both, controlling drug sensitive TB and drug resistant TB cannot be done through the public sector alone; the need to turn off the tap of generation of new drug-resistance; thinking innovatively and committing to working with both, the formal and non-formal private sector; accepting that prevention alone is insufficient and must in parallel put in place systems for diagnosis and treatment; and recognizing that partnerships are crucial for success because no one can do it alone.

We welcome and applaud the leadership for investing more in health. As the country becomes an economic superpower, developmental assistance will come less to India, and increasingly come from India. In TB, India has taught the world how to structure a basic control programme, how to prepare a patient-wise box, and how to organize and deliver programme services at scale. There is no doubt in my mind that India can and will continue to be the leader in TB control globally.

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FOREWORD

The Revised National TB Control Programme (RNTCP) has entered the 16th year of its implementation in the country. While the programme has been extremely successful, new challenges requiring our urgent attention have also emerged over the years.

The Joint Monitoring Mission (JMM) was conducted with clearly defined objectives of 'reviewing the country's progress towards the TB-related Millennium Development Goals (MDGs), challenges and plans for TB control efforts, and to advise Government of India and partners on the pathway towards achieving Universal Access to TB care'. The JMM also provided inputs on strategic approaches and innovative mechanisms for achieving the key targets of the 12th Five Year Plan. The JMM has comprehensively drafted their recommendations presented through this report. It is in this context that we take note of the report of the 5th Joint Monitoring Mission (JMM) undertaken in August 2012 by WHO Country Office for India along with a number of other stakeholders and partners.

The Government of India is committed towards the long term vision of TB free India. We must provide for quick and accessible means of quality diagnosis and treatment. The ambit of RNTCP must be expanded to cover or provide for the patients currently being treated outside the programme. Adherence to full and complete treatment needs to be emphasized. We must gear up for the larger case detection of drug resistant TB expected with the rapid expansion of programmatic management of drug resistant TB in India undertaken in the last few years.

We trust that the TB programme managers, both in the Central and State governments, along with all the other stakeholders will carefully study the findings and recommendations of the JMM and make sure fresh approaches are brought for the new and emerging challenges.

(Keshav Desiraju)

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Abbreviations and acronyms

ACSM	advocacy, communication and social mobilization
AIC	airborne infection control
ANM	auxiliary nurse midwife
ART	antiretroviral therapy
ASHA	Accredited Social Health Activist
C/DST	culture and drug susceptibility testing
CBCI-CARD	Catholic Bishops' Conference of India–Coalition for AIDS and Related Diseases
CBNAAT	cartridge-based nucleic acid amplification test
CBO	community-based organization
CCT	conditional cash transfer
CDR	case detection rate
CLHIV	children living with HIV/AIDS
CPT	co-trimoxazole preventive therapy
CSO	civil society organization
CTD	Central Tuberculosis Division
DALY	disability-adjusted life year
DCGI	Drugs Controller General of India
DFID	Department for International Development
DMC	designated microscopy centre
DOT	directly observed treatment
DOTS	directly observed treatment, short-course
DRS	drug resistance surveillance
DR-TB	drug-resistant TB
DST	drug susceptibility testing
DTO	district TB officer
DTU	district tuberculosis unit
EQA	external quality assurance
FAQs	frequently asked questions
FDC	fixed-dose combination
FIND	Foundation for Innovative Diagnostics
FLD	first-line drug
FM	fluorescent microscopy
GDF	Global TB Drug Facility

GF	Global Fund
GoI	Government of India
HRD	human resource development
IAP	Indian Academy of Paediatrics
ICDS	Integrated Child Development Services
ICT	information and communications technology
ICTC	integrated counselling and testing centre
IEC	information, education and communication
IGRA	interferon-gamma release assay
IMA	Indian Medical Association
IMNCI	Integrated Management of Neonatal and Childhood Illness
INH	isoniazid
IPC	interpersonal communication
IPT	isoniazid preventive therapy
IRL	intermediate reference laboratory
JALMA	National JALMA Institute of Leprosy and other Myobacterial Diseases
JMM	Joint Monitoring Mission
KAP	knowledge, attitude and practice
LED-FM	light-emitting diode-based fluorescence microscopy
LIMS	laboratory information management system
LPA	line probe assay
LRS	Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases
MCH	maternal and child health
MCI	Medical Council of India
MDG	Millennium Development Goal
MDR	multidrug resistance
MO	medical officer
MoHFW	Ministry of Health & Family Welfare
MPW	multipurpose worker
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NCDC	National Centre for Disease Control
NEP	new extrapulmonary (TB)
NGO	non-governmental organization
NIFHW	National Institute of Health and Family Welfare
NIRT	National Institute for Research in Tuberculosis
NRHM	National Rural Health Mission

NRL	national reference laboratory
NSN	new smear-negative
NSP	National Strategic Plan
NTI	National Tuberculosis Institute
NTWG	National Technical Working Group
OTC	over the counter
PHI	peripheral health institution
PI	protease inhibitor
PLHIV	people living with HIV/AIDS
PMDT	programmatic management of drug-resistant TB
PP	private health-care provider
PPD	purified protein derivative
PPIA	private provider interface agencies
PPM	public–private mix
PPP	public–private partnership
PWB	patient-wise box
QA	quality assurance
RNTCP	Revised National Tuberculosis Control Programme
RSBY	Rashtriya Swasthya BimaYojana
SACS	state AIDS control society
SHG	self-help group
SLD	second-line drug
SL-DST	second-line drug susceptibility testing
STC	state tuberculosis cell
STDC	state TB training and demonstration centre
STLS	senior tuberculosis laboratory supervisor
STS	senior TB treatment supervisor
STO	state tuberculosis officer
TB	tuberculosis
TBHV	tuberculosis health visitor
TSG	technical support group
TST	tuberculin skin test
TU	tuberculosis unit
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNITAID	International facility for the purchase of drugs to treat HIV/AIDS, malaria and TB
USAID	United States Agency for International Development
WCO	WHO Country Office
WHO	World Health Organization
XDR	extensively drug-resistant

Executive summary

(including main recommendations)

Context

India has the world's highest burden of tuberculosis. TB kills one person every two minutes in India and 750 people every day. Global TB control is unattainable without the control of TB in India. This report reflects the findings, conclusions, and recommendations of the fifth Joint Monitoring Mission (JMM) of the Revised National Tuberculosis Control Programme (RNTCP). The JMM brought together national experts, affiliated departments from the Ministry of Health, civil society, implementing partners, technical and developmental agencies to review the progress, challenges and plans for India's TB control efforts. The JMM was an opportunity to advise the Ministry of Health & Family Welfare (MoHFW) and partners on key challenges, opportunities and recommendations towards achieving their stated goal of Universal Access to TB care.

Achievements

Set up in 1997, India's RNTCP is a cause for great national pride. Over the last five years, the RNTCP has examined more than 36 million persons through sputum-smear microscopy and treated more than 7.5 million TB patients, saving more than one million lives. The RNTCP has firmly established decentralized diagnosis through 13 000 quality-assured microscopy centers embedded in the health system and has expanded community-based treatment to a network of more than 600 000 community treatment providers. On an average day, RNTCP examines 31 500 patients by sputum microscopy and initiates treatment for 6000 TB patients. The quality of programme management, monitoring, and

supervision systems are notable. The RNTCP has intensively upgraded the response to multidrug-resistant TB, rapidly established 43 specialized laboratories and ensured basic services to diagnose and treat multidrug-resistant cases, covering half of the districts in the country. The majority of TB patients treated under the RNTCP are now screened for HIV, and an increasing proportion is linked to antiretroviral treatment. The programme has consistently delivered high level of expenditure, exceeding budget outlay. Over the past year, laudable political and administrative commitment has been demonstrated by major increase in the TB budget, a ban of inaccurate serological tests for TB, a national order for mandatory TB notification and initiation of a national web-based patient tracking system. At the high-level meeting on the Prevention and Management of Multidrug-Resistant TB chaired by the Minister of Health & Family Welfare on 30 August 2012, a commitment was made by the minister for all the resources needed to fight TB in India, and a strong request was made to the Programme and partners to be bold.

Challenges

Despite these achievements and effective programme implementation in most of the public health settings, TB case finding has reached a plateau. Approximately one million TB cases per year are not reported to the programme, and may remain either undiagnosed or ineffectively treated. Delays in diagnosis or ineffective treatment leading to ongoing transmission can spread the disease and propagate the TB epidemic. Patients diagnosed in the private sector remain outside the awareness and reach of the programme, and patients bear high costs for diagnosis and are provided unsupervised treatment with no systems for public health support and hence frequently fall far short of national and international standards. Poor treatment practices drive the development of drug resistance, which endangers patients and creates a costly public health threat for the future. The national vision of TB control will be best achieved with innovative engagement of the private sector.

While budgets are growing, the health system will need to comparably increase its capacity to procure, manage and staff for quality service delivery in order to meet expectations.

The shortage of public sector physicians, nurses, paramedical staff, and programme officers challenge the quality and effectiveness of basic services. The ongoing reliance on short-term contractual workers to fill long-term service needs has created an accumulating administrative challenge.

Implementation of the laudable policies of recent months, e.g. banning TB serology and mandating TB notification poses a daunting challenge. The private market for TB diagnostics remains chaotic and centered on inappropriate blood tests, and capacity needs to be built in the country for

evaluation and approval of new technologies. Despite clear regulations around the sale and dispensation of anti-TB drugs in India, over-the-counter dispensation remains rampant.

Opportunities

TB control in India is at a critical juncture. Strengthening systems is necessary to cement the remarkable progress made over the last decade. Innovative solutions are needed to go beyond current gains and address the challenges of private sector engagement and drug-resistant TB, and leverage the potential of the private sector to help achieve Universal Access. Commendably, the MoHFW has developed an ambitious National Strategic Plan for TB Control (2012-2017), which has set the goal of universal access to early diagnosis and effective treatment, and proposes a four-fold increase in resources and dramatic increase in domestic funding. If implemented, this Plan can save 750 000 lives over the next five years. The National Rural Health Mission (NRHM) has dramatically expanded health budgets and public health management capacity. The NRHM has improved service delivery infrastructure from the hospital to the village level, and has developed an army of community health workers and volunteers that can be leveraged to promptly detect symptomatic persons who suffer from TB. The programme has striking potential to absorb and utilize markedly increased future funding.

New high-sensitivity, rapid diagnostic tests can simplify and speed TB diagnosis. New opportunities have been created by the information technology revolution with mobile connectivity reaching nearly every Indian. The electronic case-based tracking system developed by the MoHFW and National Informatics Centre provides an unprecedented opportunity to support all sectors in providing high quality care, to facilitate financial transactions, and accurately measure the burden of the disease.

Recommendations

The Mission endorses the National Strategic Plan with its vision of Universal Access. The Mission also recommends complete financing and encourages bold/ambitious annual implementation planning of proposed activities. For early detection and appropriate treatment of all TB patients, irrespective of care in public or private sectors, RNTCP as a priority will have to strengthen supervision and management systems, extend case-finding to the community level, engage the private sector, and support innovation at all levels.

- **Engage all care providers to achieve universal access to TB care and prevent drug resistance:** Complete engagement with the private sector is critical for prompt, accurate diagnosis and appropriate care. The MoHFW has already demonstrated the capacity to incentivize non-government providers and outsource services. These strategies need to be refined and expanded nationwide.

- Encourage and fund large-scale state-level innovations and experimentation in private sector engagement such as demand-side financing and social franchising; if found effective, these innovations should be rolled-out nationally.
 - Rapidly implement mandatory notification with a user-friendly notification system and incentives for reporting; use laboratory notifications to detect and address non-reporting providers.
 - Ensure treatment support and ascertain treatment outcomes of all TB cases, irrespective of the source of treatment.
 - Pursue the necessary consultative process to develop Indian standards of TB care applicable in all sectors.
 - Consider transition to daily-dose treatment regimens to address concerns about regimen effectiveness in patients with HIV-infection or initial isoniazid resistance.
 - Pursue and support implementation of regulatory measures for stopping uncontrolled availability of anti-TB drugs. On priority, restrict the availability of impending new anti-TB drugs to authorized outlets, with stringent and accountable distribution controls.
 - Collaborate with social marketing organizations, chemists, and partners for branded anti-TB drug kits for subsidized sale in the private sector, linked to notification and programme-provided treatment support, to ensure quality-assured drugs for TB patients who choose to seek anti TB treatment in the private sector.
- **Extend case-finding activities and deploy improved diagnostics and diagnostic strategies:**
 - Enhance case-finding activities to the community level, through ASHAs, informal providers, and community volunteers sufficiently incentivized for referrals.
 - Improve the existing “patient-initiated pathway”, and introduce the "provider-initiated screening pathway", focusing on clinical risk groups and socially vulnerable groups.
 - Ensure prompt case-finding and diagnosis among children and persons living with HIV.
 - Enhance engagement and mobilization of civil society and affected communities for TB care and control.
 - Prioritize revision of diagnostic algorithms to include new technologies and approaches, with an objective to promptly detect all cases on the initial visit, with upfront application of the best available tests.
 - Notify and register all cases at the time of diagnosis from the public and private sector.
 - Accelerate the development and deployment of the necessary laboratory capacity to conduct quality-assured rapid DST. DST guided treatment is the ultimate goal, and all attempts should be made to move towards achieving universal DST by end of the current plan period.

- **Leverage strengthened health systems for improved programme management, supervision, and services:** RNTCP management systems are being integrated with NRHM structures. In view of the increasing budget, enhancing the NRHM's absorptive capacity at state and district level is thus critical for the effective use of funds for the implementation of TB control activities.
 - Promote ownership and regular prioritized review of RNTCP within the NRHM framework, from State Mission Director level down to the ANM and ASHA level.
 - Provide flexible funds to states and districts for need-based utilization.
 - Prioritize programme support for high-burden or low-capacity states.
 - The Mission endorses decentralization of management units to block level and integration with NRHM structures and recommends RNTCP to ensure adequate capacity development of supervising Block Medical Officers and STS to maintain intensive, high quality supportive supervision.
 - Take advantage of NRHM staff and resources and better utilize nurses and multi-purpose workers to supervise the expanding community DOT cadre.
 - Take advantage of advances in technology to make DOT more patient-friendly; develop and deploy alternate approaches for monitoring treatment adherence.
 - Use automated electronic micro-payments for referrals and treatment support, to preclude delays or failed payment.
 - Develop a medium-term comprehensive human resource development plan to implement NSP strategies and address identified staffing, competency and training gaps.
 - Augment CTD and NTI staff to ensure human resource development strategy implementation, and engage technical support agencies to assist CTD and NTI to carry out HRD.
 - Given the enormity of the challenge to develop and scale-up new activities, invest in national technical assistance, and strengthen technical assistance provided by World Health Organization (WHO) and partners through 2015.
 - Learn from the experiences from Urban TB response in Mumbai and Delhi, and adapt and roll-out an Urban TB model to all large urban areas.

Introduction

India has more new tuberculosis (TB) cases annually than any other country. In 2011, out of the estimated global annual incidence of 9 million TB cases, 2.3 million were estimated to have occurred in India.

According to World Health Organization (WHO) estimates, mortality from TB in India was 320 000 (210 000–470 000) in 2010. More than 80% of the burden of TB is due to premature death, as measured in terms of disability-adjusted life years (DALYs) lost. The problem of TB in the country is further compounded by the emergence of drug-resistant TB (DR-TB), HIV-associated TB and several socioeconomic factors that promote the transmission of the infection.

India's Revised National Tuberculosis Control Programme (RNTCP) is the world's largest TB control programme. Over 1.5 million TB patients are diagnosed and treated under it each year. While the performance of the programme varies widely across districts and states, on most counts, the RNTCP has largely achieved its targets, including complete geographical coverage in March 2006. Since 2008, the RNTCP has consistently succeeded in detecting more than 70% of the estimated new sputum smear-positive cases of TB and cured more than 85% of these. In the process of consolidation, the RNTCP has established systems for quality assurance of sputum microscopy, promoted collaboration between the TB

and HIV programmes, engaged non-governmental organizations (NGOs) and community-based organizations (CBOs) in the care of TB patients, and undertaken rigorous surveillance and monitoring of the programme. In addition, locally feasible and community-based systems for the diagnosis and treatment of DR-TB have been developed, and access is being scaled up rapidly.

The RNTCP has entered the third phase of implementation and the ambitious National Strategic Plan (NSP 2012–2017) has been drawn up as part of the country's 12th Five-Year Plan. The theme of the NSP 2012–2017 is “Universal access for quality diagnosis and treatment for all TB patients in the community” and its target is “Reaching the unreached”. The major focus is on the early and complete detection of all cases of TB, including DR-TB and HIV-associated TB, with greater engagement of the private sector in improving care for all TB patients. The NSP is backed by the commitment of the Government of India (GoI) to substantially increase the investment for TB control, with a four-fold increase in budgetary allocation being considered.

In keeping with the request by GoI, the WHO Country Office (WCO) for India, along with the technical, developmental and implementing partners of the RNTCP, has been organizing a Joint Monitoring Mission (JMM) every three years. The JMM recommendations are used by the RNTCP and its partners to coordinate and guide policies and planning for more effective TB control efforts. In 2012, the JMM was conducted from 21-31 August in New Delhi, with the objective of reviewing the country's progress towards the TB-related Millennium Development Goals (MDGs), taking stock of the challenges and plans for TB control efforts, and advising GoI and its partners on the path to be followed for achieving universal access to TB care. The mission was expected to provide inputs on strategic approaches and innovative mechanisms for achieving the key targets of the 12th Five-Year Plan. The timing of this JMM was appropriate, considering that the RNTCP has developed the ambitious goal of providing universal access to quality care for TB, articulated strategic approaches in the NSP, and sought expert guidance on how to develop, prioritize and deploy these approaches.

General objectives of the JMM 2012

The general objectives of the JMM 2012 were to review the progress, challenges and plans for India's TB control efforts, and to advise GoI and its partners on the path to be followed for achieving universal access to TB care.

Specific objectives

1. To review India's progress towards the TB-related MDGs, Stop TB Partnership and national TB control targets.
2. To review NSP and provide recommendations on plans, pathways and operational approaches, with special focus on:
 - a. Early diagnosis and treatment of TB
 - b. Implementation of TB notification and improvement of surveillance systems
 - c. Innovative strategies to engage the private sector for achieving universal access
 - d. Scaling up and sustaining high-quality programmatic management of drug-resistant tuberculosis (PMDT) services
 - e. Provision of medium- and long-term technical assistance and coordination of TB control in India, including WHO transition planning of technical assistance.
3. To advocate for resource mobilization, domestic and developmental, to achieve the objectives of the NSP and maintain progress towards the larger global goal of elimination of TB by 2050.

Participants

The participants in the JMM included experts from technical agencies, developmental agencies, national institutes, medical colleges and the civil society. The list of participants is given in Annex 1.

The JMM started its work on 21 August 2012 with a briefing session by the national programme manager on all aspects of the programme. The JMM team later visited six states and conducted field visits in 12 districts.

The following states and districts were visited by the JMM:

States	Districts
Bihar	Darbhanga
	Patna
Karnataka	Bagalkot
	Mysore
Maharashtra	Mumbai
	Aurangabad
Punjab	Gurdaspur
	Patiala
Uttar Pradesh	Lucknow
	Varanasi
West Bengal	24 North Parganas
	Kolkata

The states and districts were purposively selected on the basis of their potential to inform deliberations on specific thematic areas, as well as the feasibility/safety of travel to the locations. Each state team was divided into two groups, each of which visited one of the two districts identified to review the RNTCP services. The team visited key institutions, including medical colleges, intermediate reference laboratories, DR-TB centres, district TB centres, tuberculosis units (TUs), designated microscopy centres (DMCs) and directly observed treatment (DOT) centres. The team also visited private healthcare centres, including laboratories, private hospitals and practitioners. Various stakeholders, including patients and community members, were interviewed. Each state team prepared a report on the field visit. This report described in brief the achievements, challenges and possible solutions, and assessed the feasibility and prospects of expanding the new strategies envisaged in the NSP. The state teams conducted a debriefing meeting with the state officials once the field visits were over.

The teams discussed the findings of the field visits at a general debriefing meeting in New Delhi on 26 August 2012. This was followed by in-depth discussions focusing on a number of thematic areas, with experts from each thematic area making an important contribution. Each thematic group then made a presentation to the whole group, incorporated the notable points made in the discussion and prepared a report on the thematic area concerned. The thematic areas included case-finding, diagnostics, treatment, monitoring and evaluation, DR-TB and PMDT, TB-HIV, paediatric TB, public-private mix (PPM), advocacy, communication and social mobilization (ACSM), human resource development, programme financing, research and technical assistance. The summary findings and recommendations were developed and presented to the GoI on 31 August 2012.

This report contains the detailed findings and recommendations of the JMM 2012.

1. Case detection

Background

The number of TB cases detected by the RNTCP rose with increasing DOTS (directly observed treatment, short course) coverage from 1997 to 2005. After nationwide DOTS coverage was achieved in 2006, the case detection per unit population has remained stable and even shown a minor decline in recent years; particularly in new smear-negative (NSN) cases (figure 1).

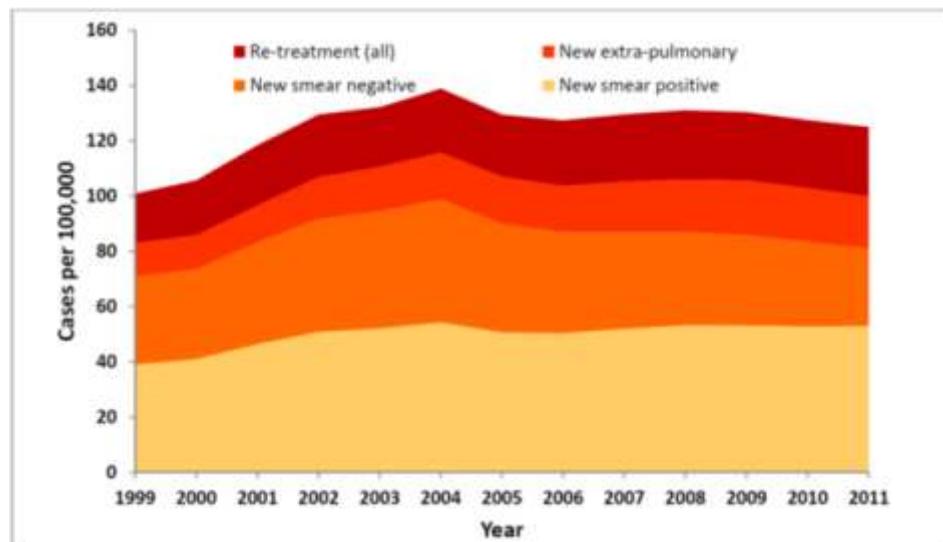


Figure 1. TB case detection rate per 100 000 population, 1990–2011

The RNTCP measures the effort to detect smear-positive TB cases by monitoring the number of patients with symptoms of TB who are tested with sputum smear microscopy per unit population. There has been a steady increase in this indicator, which reflects a continued effort to detect TB cases. In the past, case detection under the RNTCP relied heavily on the number of patients with symptoms reporting to care providers.

Earlier, the programme's objective was to detect at least 70% of new smear positive pulmonary TB cases. The new NSP 2012–2017 aims at universal access, defined as “early detection of 90% of all TB cases”.

Achievements

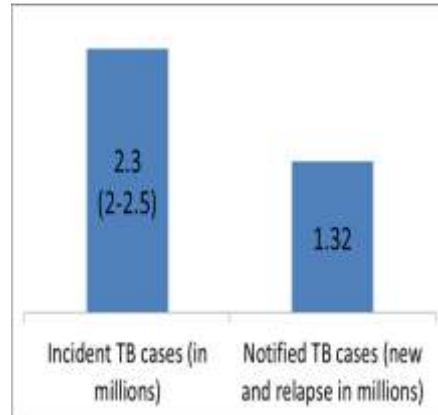
The RNTCP is the largest TB programme in the world in terms of the number of patients treated per annum. In 2011, DOTS treatment was initiated for 1.5 million people with TB.

Over 13 000 peripheral laboratories with smear microscopy services have been established under the programme. Over the past five years alone, more than 36 million persons have been examined through sputum smear microscopy under the RNTCP and more than 7.5 million TB cases have been detected. Every day, approximately 31 500 persons with chest symptoms are examined for TB, more than 3 500 smear-positive TB cases detected, and more than 6000 cases of TB of all forms registered and started on treatment.

Challenges

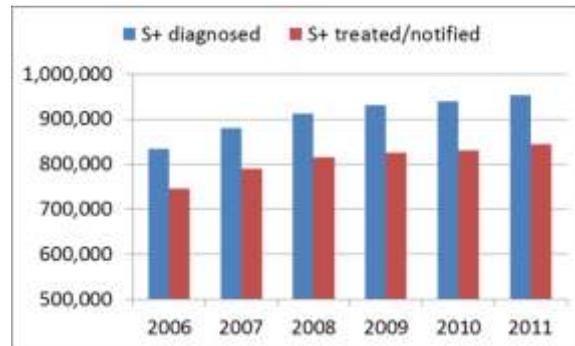
Of the estimated 8.8 million (range 8.5–9.2 million) incident TB cases in the world, 2.3 million (range 2–2.5 million) occur in India. Over the past few years, India has been reporting about 1.5 million TB cases annually and of these, a little over 1.3 million are incident TB cases (new and relapse cases). The latest WHO estimates of the incidence of TB in India and the new figures of incident cases notified annually are shown in Figure 2. The gap between the two shows that about one million people with TB either do not receive care or receive care under suboptimal conditions, with unknown treatment outcomes. Patients diagnosed in the private sector are not reported to the programme and are beyond its reach. They bear high costs to get their condition diagnosed and treated, and the treatment is often unsupervised and unsupported. Moreover, the diagnostic practices and treatment regimen are frequently not consistent with national and international standards. This is a major challenge in the fight against TB in India.

Figure 2. Estimated TB incidence and notified cases in India



In addition, the gap between the smear-positive TB cases diagnosed and those that are treated and notified is about 100 000 per year (figure 3). A good rate of case notification also does not necessarily mean early diagnosis of TB. Delays in the detection of cases could allow the infection to spread in the community before such cases are detected.

Figure 3. Diagnosed and notified smear-positive TB cases, 2006–2011



One of the factors hampering India's efforts to control TB is that though there are large numbers of care providers in the public and private sectors, many of them have not been linked to the RNTCP so far. Also, to achieve universal access, it is clear that the case detection strategy under the RNTCP needs to be revised.

Recommendations

The JMM commends the RNTCP on its ambitious objective of achieving universal access, defined in the NSP as “early detection of 90% of all TB cases”. Keeping this objective in view and considering the current levels of case detection, the following recommendations have been made:

- The Mission fully supports the interventions proposed in the NSP for early and enhanced case detection. The proposed interventions are directed both towards improving the “patient-initiated pathway” of TB

case detection that is currently in place, as well as the introduction of the “screening pathway” for early detection among clinical and social risk groups. Both sets of interventions are clearly needed to reach the targets proposed in the NSP.

- Recognizing the potential of the recent policy requiring mandatory notification of TB in India, the Mission recommends that this policy be rapidly translated into action through the development of a notification system that is user-friendly (e.g. electronic notification via Mile phones), and through the creation of incentives for reporting of confirmed cases by care providers as well as patients.
- To address the gap between the number of diagnosed cases and treated cases (more than 100 000 cases per annum), a change is required in the current policy, under which TB cases that are treated must be registered and notified. Instead, all diagnosed cases should be registered in the TB register at the time of diagnosis and included in the notifications in the quarterly case-finding forms. A laboratory-based notification system is needed for bacteriologically positive cases. For other cases, notification should be done at the point of care where the diagnosis of TB is made (both public and private sector). The web-based, case-based electronic surveillance system (Nikshay) should be used to address duplication of case registration. Mobile phones and the Aadhaar Unique Identification (UID) system can be used to track patients with symptoms of TB and TB patients to deal with those who are lost to follow up for diagnosis or on treatment.
- There is a need for greater focus on care providers in the private sector. Care providers in the private sector should be encouraged to use the system to notify cases, provide treatment support and report treatment outcomes for all cases managed by them, irrespective of the treatment regimen and source of drugs, as long as the diagnostic practices and regimen are consistent with Indian/international standards of TB care. Further recommendations on the private sector are covered under the section on public–private partnerships (PPPs).
- For the introduction of active screening of clinical risk groups, the JMM recommends the following:
 - Among the risk groups, include at least people living with HIV/AIDS (PLHIV), contacts of TB patients, people with diabetes, malnourished people, smokers, and previous patients of TB, people with silicosis and other dust-related lung disorders, and drug abusers.
 - Locally (at the state and district levels), identify and focus on the clinics/care centres serving these groups. These clinics should include the outreach clinics of maternal and child health (MCH) services.

- The following pertain to the active screening of socially vulnerable groups:
 - Set broad national-level guidelines, but identify vulnerable groups and act at local levels (district and block/TU levels/urban wards).
 - Include at least slum-dwellers, migrant workers, prisoners, children, the elderly, tribal and indigenous populations, miners and the populations of notified economically backward districts.
 - Using community resources such as Accredited Social Health Activists (ASHA), panchayats, self-help groups (SHGs) and informal care providers, undertake screening for symptoms in the community, followed by sputum collection from persons with symptoms.
 - Consider the provision of incentives and conditional cash transfer (CCT) to community outreach volunteers engaged in this activity. It would be useful to learn from the CCT models already in place under the National Rural Health Mission (NRHM) for MCH activities.
 - Develop synergies with other health programmes for expanding outreach (e.g. polio supplementary immunization campaigns).
- Scale up the collection of sputum specimens and the systems for their transportation to achieve full coverage by proactively arranging for sputum collection and transportation from all public and private health facilities where patients with symptoms of TB seek care, and at the community level for all communities that do not have a health facility in the village/urban ward. For this purpose, engage the services of NGOs, anganwadis and ASHAs, and also utilize the private sector systems for the transport of laboratory specimens.
- Scale up light-emitting diode (LED)-based fluorescence microscopy (LED-FM), as planned in the NSP and on the basis of the experiences of the Union TB Reach project covering 200 medical colleges. Considering the fact that smear microscopy is not enough to reach the target of detecting at least 90% of all TB cases, rapidly scale up the currently available molecular test (i.e. Xpert MTB-RIF) and develop systems to quickly introduce and scale up tests that may be recommended by WHO in the future.
- Modify the diagnostic algorithm for adult, paediatric and HIV-associated TB to include appropriate diagnostic modalities and molecular tests with the objective of detecting cases early, as far as possible on a single visit by the patient, thus preventing drop-out from diagnostic pathways. The diagnostic algorithm should have the best available test applied upfront. Different diagnostic algorithms may be

required for different health-care settings. The algorithm would depend on the availability of smear and molecular tests and X-ray facilities, as well as the scope for the referral of patients and transport of specimens. Address the role of X-rays in the diagnostic algorithm keeping in mind that X-rays, which are widely used in urban areas, have considerable potential as a screening tool (as shown in prevalence surveys) to select people who will require diagnostic molecular tests.

- In view of the NSP's objective to achieve “early” case detection, consider changing the definition of TB symptomatic to make it more sensitive. For this, include other symptoms and rely less on the duration of symptoms. A symptom complex similar to that considered in the case of PLHIV is suggested. It is also important to recognize and fast track patients with serious symptoms or associated co-morbidity to prevent early mortality.
- In line with the international recommendations and WHO TB treatment guidelines India needs to consider changing the RNTCP regimen to a daily regimen including the feasibility to using fixed-dose combination (FDC) for harmonizing the national TB treatment policy.
- Add to the activities in the workplace programmes proposed in the NSP. Prioritize workplaces that are human resource-intensive, those employing migrant labourers, mining industry and other dust generating workplaces.
- For the detection of extrapulmonary TB, invest in the relevant diagnostic tests through the health system.
- Build a body of evidence on the cost-effectiveness of different approaches and tools for active and early detection of TB cases to justify investments.
- Empower district TB officers (DTOs) to develop creative plans, adapted to the local context, to enhance the detection of TB cases. This will require flexibility in the operational and financial norms and guidelines of the RNTCP.
- As a measure of case-finding efforts, continue to monitor patients with symptoms of TB who are examined with a laboratory test.
- Since engagement of the community and the involvement of the general health system, human resources and outreach workers are of key importance to the implementation of the interventions proposed in the NSP, they need to be addressed. These issues are covered in other sections.

2. Diagnosis

Background

As highlighted in the NSP 2012–2017, early case detection is fundamental to interrupting the transmission of the disease and to the control of TB. According to the highest priority to early diagnosis, the NSP sets an ambitious objective for case-finding—“early detection of 90% of all TB cases”. To achieve this objective by 2017, the RNTCP will need to put innovative mechanisms in place so that the detection of incident cases increases annually by 600 000 and these cases are detected early in the course of the disease.

In addition to dramatically improving case detection, the NSP envisions the creation of mechanisms “for ensuring drug-susceptibility testing (DST)-driven treatment for all TB patients”, starting with those at the highest risk for multidrug resistance (MDR).

These goals have important implications for the manner in which persons suspected to have TB are identified and recruited for testing; the way in which case-finding and notification are carried out; and the diagnostic technologies and services are to be put in place. It is unlikely that the RNTCP can meet its ambitious goals in the areas of case detection and disease control unless there is an improvement both in the speed and breadth of the referral of persons suspected to have TB, and unless more

sensitive technologies are put in place. The goal of achieving an improvement in the cure rates through ensuring DST-driven treatment will require strengthening of the reference laboratory network, as well as decentralization of screening for MDR. This section reviews the current status of diagnostic services at the different levels of the national laboratory network, examines the challenges to and constraints in the achievement of the programme's objectives, and makes a number of specific recommendations.

Current status

India has put in place the world's largest laboratory network for the detection of TB, with nearly 13 000 facilities, including DMCs, TUs and district TB centres, offering diagnostic services. Direct sputum smear microscopy by Ziehl–Neelsen acid-fast staining is the primary tool for case detection under the RNTCP, and is supported by an external programme for quality assurance.

Over the past few years, there has been a slow but steady increase in the number of suspected TB cases examined by microscopy per 100 000 population. However, this has not been accompanied by any significant rise in the rate of cases detected, which has remained stable at 80/100 000 for the past five years.

Culture and Anti-TB Drug Susceptibility Testing (C & DST) services are currently available at 43 Laboratories with various DST technologies such as Solid, Liquid and Molecular (Line Probe Assays). MDR-TB is diagnosed by offering Culture and DST to patients as per the criteria laid down by the programme. As on August 2012, 29 laboratories (4 NRLs, 16 IRLs, 6 Medical College, 3 NGO/Private) are providing LPA services for the PMDT. The programme has also certified six laboratories for the Liquid Culture and DST (MGIT-960).

Newer tools for rapid diagnosis: A systematic feasibility study under guidance and monitoring of a national steering committee on CB-NAAT has been initiated in India in March 2012 in 18 sites across the country. CBNAAT is also used as a DST tool in 10 sites under Expand TB Programme.

Challenges and constraints

Human resources

- The number of trained staff providing laboratory services is inadequate at all levels. Many existing posts remain vacant. The processes of advertisement and recruitment have been slow, and there is a relatively high turnover, due in part to disparities in remuneration. These issues were highlighted in the previous JMM report.
- The need for human resources has become more critical as the workload has increased with the drive towards universal access, as well as the extension of programmatic support to the management of drug resistance. This increased demand on an already weakened workforce is threatening the quality of microscopy supervision.

Infrastructure/logistics

- The quality of the physical infrastructure of some laboratories requires upgrading. In addition, as national reference laboratories (NRLs) and intermediate reference laboratories (IRLs) are called upon to perform a variety of new assays, they need to overcome limitations of space for the installation of instruments and storage of consumables.
- The implementation of new technologies, such as line probe assay (LPA), liquid culture and cartridge-based nucleic acid amplification test (CBNAAT), will place increasing demands on the mechanisms for the management of logistics. At the national level, it is necessary to coordinate customs clearance and transport of materials to states to ensure the availability of tests, test systems and associated consumables. Regulations concerning international procurement on a named-source basis hamper the upgradation of laboratories.

Technology

- Most cases are still detected with conventional microscopy, which has limited sensitivity, as demonstrated by the superior performance of LED-FM and the molecular approaches.
- Until now, LED-FM has reached only a limited number of sites (mostly medical colleges), limiting the benefit of this technology.
- The relatively higher sensitivity of LED-FM has resulted in an improvement in case-finding, but the lack of familiarity of new users with the technique gives rise to uncertainty about the results. The latter problem is confounded by the incomplete implementation of standardized local quality assurance (QA) and external quality assurance (EQA).
- The advantages of rapid testing are lost if the results are not quickly reported so that treatment can be initiated. In the case of testing with

referred specimens, or testing that will not be carried out while the patient is physically available to be informed about the results, the results often do not reach the patient or his primary care provider, resulting in a delay in the initiation of appropriate treatment or a missed opportunity for treatment.

- A recent governmental ban on serological testing to detect anti-TB antibodies has thus far had only a limited impact, with many private providers still offering these tests.
- In many places, interferon-gamma release assays (IGRAs), intended as a test for latent infection, have replaced serological testing. However, IGRA testing for persons suspected to have TB generates confusion and unhelpful results, other than being costly.
- The dropout rate for repeat microscopy examination among smear-negative suspects is high, with many patients not returning for the second examination.
- Pilot studies have shown that CBNAAT results in significant improvements in the speed and sensitivity of case detection and MDR screening, compared to the other existing methods. Issues of physical support (power supply, security, operating temperature), however, pose a challenge.
- Power outages are frequent across India. This has implications for all electrical technologies, including microscopy.
- Though the unit cost for the purchase of CBNAAT cartridges has fallen significantly, a number of additive costs incurred before the disposables reach the testing site make the use of this method much more expensive than microscopy. However, cost-effectiveness modeling is necessary to assess whether the added cost is offset by higher case detection and reduced TB transmission.
- New technologies use instrumentation that requires maintenance and occasional servicing. Service contracts, which do not automatically come with the purchase of the equipment, are not being secured in many cases.
- Emerging test methods, including newer versions of molecular tests, may play an important role in the detection of cases in the public or private sector in India. However, a rigorous evaluation will need to be made of tests that have not yet been endorsed by WHO to examine their performance or operational utility in the Indian context. No clear mechanism for such evaluation is in place in the RNTCP.

Laboratory capacity

- As laboratories in the national network begin implementing culture methods that biologically amplify the pathogen, the health risks for

personnel increase. Biosafety and medical waste management practices are variable and often inadequate. Though biosafety training is available, the staff in the laboratories remains inadequately trained due to the high turnover of staff and lack of annual biosafety certification.

- There is inadequate biomedical technical support to referral laboratories implementing assays that are complex to perform and that rely on sophisticated reagents or equipment.
- Services for the transport of sputum are irregular and their availability incomplete, making it difficult to access any testing besides that available at DMCs or in the private sector.
- The number and throughput of reference laboratories for DST and the monitoring of MDR treatment are inadequate, with some states having no reference DST capacity.

Recommendations

Human resources

- Expedite the process of filling the vacant positions for laboratory staff.
- Examine ways to harmonize the salary structure across programmes related to different diseases, provide training opportunities to motivate the staff, and incentivize quality staff to accept and remain in positions within the programme.
- Increase staffing at the NRLs to support the testing of proficiency, EQA, and the evaluation and possible pilot implementation of new technologies.

Infrastructure/logistics

- Budgetary allocations should be made for the maintenance of the physical infrastructure of the laboratory network at all levels.
- The sourcing of equipment and reagents needs to be handled in such a way that quality is not compromised in the effort to minimize costs. It is recommended that the National Laboratory Committee (i) ensure that detailed specifications are available for materials to be procured, and (ii) liaise with the government procurement agency and identify appropriate experts to give advice on the technical adequacy of tender bids.
- Centralized logistic support, such as that currently available for drug supplies, needs to be put in place for diagnostic equipment and consumables.

Technology

- LED microscopy should be phased in by replacing standard microscopes with high-quality fluorescent microscopes and by equipping new centres with such microscopes.
- Standard operating procedures for QA and EQA of fluorescent microscopy (FM) should be implemented in all laboratories utilizing FM, as should internal laboratory auditing.
- Wherever possible, instrumented systems should be equipped with, or linked to, systems capable of reporting cases directly to the national programme to meet the notification goals, and also electronic reporting to the referring health unit and/or directly to the patient.
- Nikshay should be adapted to include a laboratory information management system (LIMS) that captures testing of persons suspected to have TB, as well as newly diagnosed cases. This would effectively serve as an electronic laboratory register.
- The ban on serological testing should be more widely publicized in the private sector (e.g. via newspaper advertisements and frequently asked questions (FAQs)), and then enforced via the Drugs Controller General of India (DCGI) and state drug controller offices and DTOs.
- The RNTCP should explicitly acknowledge that IGRA testing is inappropriate for the diagnosis of active TB. It should explore ways to discourage the private sector from employing any of the blood-based methods currently in use for testing and should steer it towards sputum-based testing. This should be incorporated into the Indian Standards of TB Care. A list of the RTNCP recommended/approved TB tests should be made publicly available.
- Rapid molecular methods (including CBNAAT), the operation of which has been found to be feasible in decentralized settings (outside of reference laboratories), which have been endorsed after rigorous evaluation and which have led to adequate increases in case detection, should be scaled up to help meet the target for case detection. As stated in the NSP, priority should be given to such testing among populations at risk for TB-HIV, MDR-TB, paediatric TB and extrapulmonary TB.
- While purchasing any equipment, consideration must be given to the power supply necessary to support it and the options for battery back-up (for brief and frequent outages); and alternative sources of energy, such as wind and solar power (for areas with a chronic lack of electric supply) and generator back-up (to power more centralized facilities, especially those running biosafety cabinets).
- The RNTCP should support efforts to decrease the overall costs of

CBNAAT testing both in the private and public sectors. This could be done, for example, through innovative PPM contractual mechanisms, the waiver of import tariffs on WHO-endorsed technologies, and streamlined logistical management of cartridge stocks.

- Annual maintenance contracts should be in place for all equipment, including biosafety cabinets. Air handling systems and other equipment that has an impact on biosafety (e.g. centrifuges) needs to be certified by a competent external agency.
- An integrated mechanism for the evaluation of new technology should be put in place to allow for the timely assessment of potentially appropriate technologies. This would help to determine their operational performance and ease of use. The mechanism should be established under the leadership of the Laboratory Committee and may require the creation of networks of accredited trial sites, specimen and strain banks, and project management capacity.
- The RNTCP should articulate evidence and performance standards required for national adoption and scale-up of new diagnostic tools in the programme. A national mechanism and validation process, supported by National TB Institutes (NTIs), should be put together to generate such evidence.

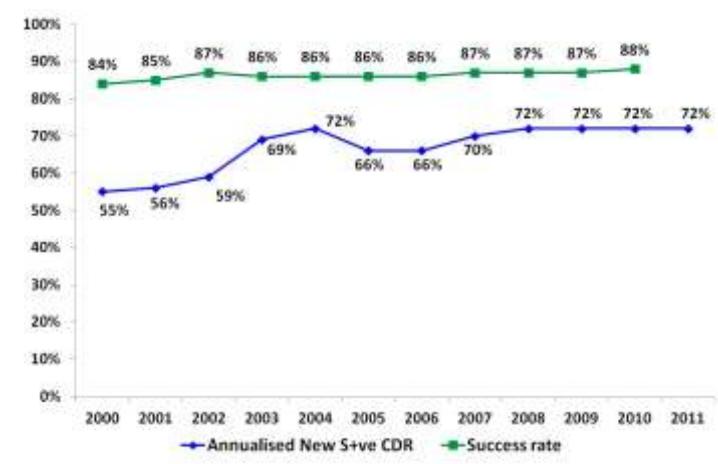
Laboratory capacity

- A system should be established for the annual certification of laboratory staff in biosafety procedures.
- The states need to ensure that biomedical engineers are available to support laboratories using complex testing methods (e.g. culture, LPA), especially those with implications for biosafety.
- Materials should be available and systems in place for the transport of sputum to allow for access to IRL and other laboratories performing LPA, CBNAAT and other molecular tests.
- As the number of referral laboratories increases to meet the target of 1 per 10 million population, new structures will need to be built to specification to meet the requirements of testing under the technologies in use for DST and treatment monitoring.
- Considering that the demands on reference laboratories are many, activities should be prioritized so that the quality of the existing services does not diminish as new activities are initiated, and so that priority is given to testing procedures with the highest clinical impact.

3. TB treatment

The RNTCP achieved complete national coverage in 2006. Since then, the programme has succeeded in consistently achieving a treatment success rate of more than 85% among new smear-positive pulmonary TB cases (figure 4).

Figure 4. New smear-positive case detection rate (CDR) and treatment outcome under the RNTCP, 2000–2011



However, the success has not been uniform across the country and almost one-third of the districts have been performing well below expectation. Also, the treatment outcomes among re-treatment cases are not satisfactory, with the success rate being only 70% (table 1). This represents a major challenge to the RNTCP.

Table 1. Treatment outcomes among notified re-treatment smear-positive TB cases, 1999–2010

Year	Total smear +ve re-treatment cases			
	Success	Death	Failure	Default
1999	68%	7%	6%	18%
2000	69%	7%	6%	16%
2001	71%	7%	6%	15%
2002	72%	7%	6%	14%
2003	70%	8%	6%	15%
2004	71%	7%	6%	16%
2005	69%	7%	6%	17%
2006	69%	8%	6%	16%
2007	70%	8%	5%	15%
2008	71%	8%	5%	14%
2009	71%	8%	6%	14%
2010	71%	8%	6%	14%

The overall default rate of approximately 15% among smear-positive re-treatment cases has remained constant over the past decade and suggests continuing inadequate case-holding. The poor outcome in re-treatment cases treated with the RNTCP's "standardized regimen" could be due to high rates of drug resistance, including monoresistance, polyresistance and MDR-TB. This standardized re-treatment regimen often means the addition of a single drug, which violates the basic principle underlying drug treatment, i.e. that of not adding a single drug to a failing regimen. Thus, there is an urgent need to carry out early DST in re-treatment cases and start appropriate treatment. This will also help in the early identification of MDR-TB cases and prompt initiation of MDR-TB treatment, which is being rapidly scaled up in the country.

Observations from several districts showed that in 2010, DOT practices were followed strictly in only 77% of patients in the intensive phase of treatment, and in fewer patients in the continuation phase. There is a strong need to improve DOT practices in the country; otherwise the outcome of treatment will be unfavourable.

The system for the delivery of treatment is being increasingly decentralized, with the help of more than 0.65 million DOT providers. This has resulted in an improvement in the quality of DOT services. However, there is still a need for further innovations to improve the delivery of DOT, so that patients may receive it at a time and a place that are convenient to them. Funding and staff from the NRHM have been increasingly used by the programme for the delivery of treatment services at the peripheral level. However, low salaries, disparities between the salary structures of the RNTCP and NRHM, as well as increasing work responsibilities, have resulted in attrition, a high turnover, and lack of motivation among the contractual and regular staff.

Private health-care providers (PPs) in India include private practitioners, public health staff and even doctors working in government hospitals and medical colleges who also practise in the private sector as well. The involvement of these PPs in the RNTCP is poor, although a significant proportion of TB patients continue to receive treatment from them. The programme uses thrice-weekly intermittent regimens for treatment and FDCs are not being used at present. PPs mostly do not follow the programme's guidelines on the diagnosis and treatment of TB. They lack faith in the treatment regimens used in the programme and prefer daily treatment regimens using FDCs. The quality of drugs prescribed by PPs is not known and they often use non-standardized treatment regimens.

Medical colleges have been involved in providing RNTCP services for over a decade and more than 300 are actively involved in the programme across the country. These medical colleges account for approximately 20% of all new smear-positive TB patients who are provided with treatment under the RNTCP. The Medical Council of India (MCI) has made it mandatory for every medical college to have RNTCP services, including a DMC and a DOT centre, in order to have its status recognized.

The integration of diagnosis and treatment delivery for TB and HIV is being scaled up in the entire country. However, the appropriateness of the use of the intermittent treatment regimen in patients co-infected with HIV and TB is increasingly being questioned by public as well as private practitioners. Practitioners and patients have also questioned the RNTCP's insistence on direct observation of treatment for TB, but not for antiretroviral therapy (ART) in co-infected patients.

Even though most of the drugs being used by the RNTCP are regularly available, streptomycin injection and rifampicin capsules (150 mg) are often not available for long periods of time. This obviously hampers the institution of appropriate treatment.

Despite the fact that anti-TB drugs fall under Schedule H of the Drug Regulation Act, first-line drugs (FLDs) and second-line drugs (SLDs) are easily available for purchase over the counter (OTC) and are being used indiscriminately, especially by private practitioners. Such unrestricted, irrational use has contributed significantly to the emergence of MDR-TB/extensively drug-resistant (XDR)-TB cases in India. There is an urgent need to ensure the rational use of anti-TB drugs, including newer drugs that are expected to be available in the market in the coming year or two.

The capacity for clinical and operational research in India, especially in medical colleges, has been found to be lacking. There is an urgent need to enhance the capacity for focused research to evaluate newer anti-TB drugs and treatment regimens to improve the programme.

Achievements

- The RNTCP has emerged as the world's largest DOTS programme. It is the programme that expanded DOTS at the fastest rate, and to date more than 15 million TB patients have been treated under it.
- Treatment under the RNTCP has been integrated with PMDT services in terms of staff involvement, procurement and storage of drugs, recording and reporting, and ACSM activities.
- Currently, the RNTCP is using thrice-weekly intermittent DOT and the drugs administered are of assured quality. The programme has achieved a treatment success rate of over 85% among new smear-positive patients in the past five years.
- Well-defined procedures are in place for the procurement and storage of drugs.
- Treatment under the programme has been decentralized and more than 0.65 million DOT providers have been engaged to provide patient-friendly DOT services.
- More than 300 medical colleges provide RNTCP services and contribute approximately 20% of all new smear-positive TB patients who are treated under the programme.

Constraints

- With the current re-treatment regimen, the rate of treatment success is low (approximately 70%), and rates of treatment failure and default are high.
- The regimen being used for cases of re-treatment is not guided by early DST. Thus, inappropriate regimens may be used, and the current regimens being used are frequently questioned by practicing doctors.
- There are insufficient DST facilities for the diagnosis of MDR-TB. This results in delays in the initiation of treatment for MDR-TB treatment, leading to high rates of transmission of infection, mortality and default.
- The institution of appropriate treatment is being hindered by the non-availability of streptomycin injection and rifampicin capsules (150 mg).
- Observations from the field suggest that DOT practices were followed strictly in only 77% of patients in the intensive phase of the treatment programme and in fewer patients in the continuation phase. A significant proportion of TB patients continue to receive treatment from PPs outside the purview of the RNTCP, including private practitioners, public health staff, and even doctors working in government hospitals and medical colleges and who practice in the private sector as well. Direct observation of treatment is virtually non-existent in the case of patients treated by private practitioners.
- PPs are not following the RNTCP guidelines on diagnosis and treatment, and their involvement in the programme is poor.
- PPs have expressed their lack of faith in the thrice-weekly intermittent regimen used by the programme.
- Drugs prescribed outside the purview of the RNTCP are of unknown quality, and the treatment regimens used by private practitioners are often non-standardized.
- As noted earlier in the recommendations of the JMM 2009, the market for first- and second-line anti-TB drugs is unregulated and the volume of the commercial market is by far larger than the volume of drug procurement by the RNTCP.
- Increasing responsibilities, low salary levels, and disparities between the RNTCP and NRHM salary structures have resulted in attrition, a high turnover, and lack of motivation among the contractual and regular staff.

Recommendations

Quality of delivery of treatment

- While promoting the decentralization of treatment, which should be patient-friendly, take advantage of the staff and resources of the NRHM. Also, make better use of mid-level field staff (auxiliary nurse midwives [ANMs], multipurpose workers [MPWs] and tuberculosis health visitors [TBHVs]) to supervise the expanding cadre for DOT at the community level.
- With the increase in programmatic activities (e.g. tackling TB-HIV, PMDT) and workload in terms of the supervision of treatment, ensure that the capacity both of the senior TB treatment supervisor (STS) and supervising block medical officers (MOs) is developed adequately so as to maintain a high level and quality of supervision.
- Take advantage of advances in technology to improve monitoring of adherence to treatment. These include electronic reminders and dosing minders, other innovations and call-centre support.
- Enhance the incentives given to those involved in the supervision of treatment.
- Opt for automated electronic micro-payments to DOT providers so as to preclude delays/non-payment.
- Take advantage of case-based notification at the time of the diagnosis of TB to ensure the timely initiation of treatment, as well as for the monitoring and supervision of treatment, irrespective of whether the patient is receiving care under the public or private sector.

Prompt appropriate treatment

- Given the concerns regarding the appropriateness of the use of the current RNTCP regimens for certain subgroups of patients (including HIV-infected TB patients, patients with non-MDR drug resistance and children), consider shifting to a daily regimen. Seek to retain the simplicity and operational feasibility that has made decentralized treatment under the RNTCP effective.
- Consider the value of a uniform treatment standard, whether it is to be used in the public or private sector, in the path towards the provision of universal access.
- Consider the use of more than one weight band in the treatment of patients who weigh between 30 and 60 kg.
- Consider the use of FDCs under the programme.
- Ensure the availability of quality-assured DST early in the course of the treatment of all TB patients so that they may be given appropriate treatment.

- Make provision for the availability of non-hepatotoxic drugs for patients who develop hepatotoxicity induced by anti-TB drugs.

Rational use of drugs of assured quality

- Strengthen the mechanisms for the procurement of drugs, and prepare for a transition from outsourced procurement and logistics support units to in-sourced procurement and logistics specialists. The first- and second-line anti-TB drugs procured should be of the highest quality. Remain vigilant about the quality of drugs at all levels.
- Institute regulatory measures to check the uncontrolled availability of OTC Schedule H drugs. These include controlling drug distribution through distribution channels dedicated to the public sector, authorized outlets and prescription-based sale of Schedule H anti-TB drugs
- Work with the DCGI to restrict the availability of new anti-TB drugs to authorized outlets, while ensuring accountability and stringent distribution controls.
- New drugs are expected to come into the market in 2013. It is important to involve the DCGI from the beginning (drug registration) in order to regulate the distribution of these drugs and ensure that they are used rationally.

Management of TB with co-morbid conditions

- Screen all TB patients for diabetes. Those suffering from diabetes should be linked to facilities where their condition can be managed appropriately.
- Encourage all health facilities to promote smoking cessation, emphasizing the link between smoking and TB. Establish TB and alcohol de-addiction clinics.

Clinical research

- Invest in clinical research and the expansion of the capacity for clinical research in India to evaluate newer anti-TB drugs and treatment regimens.
- Collect evidence on the optimal regimen for isoniazid (INH) resistance and non-MDR polydrug resistance.

4. Programmatic management of drug-resistant TB (PMDT)

Background

India has a high burden of MDR-TB. In 2010, an estimated 64 000 of the notified cases of pulmonary TB were cases of MDR-TB (WHO 2011 Global TB Report). The estimated number of such cases emerging annually in the country is 99 000.

Population-based drug resistance surveillance (DRS) surveys carried out in the three states of Andhra Pradesh (2008–09), Gujarat (2005–06) and Maharashtra (2005–06) found that the prevalence of MDR-TB among new TB cases was 1.8%–2.7% and among previously treated TB cases, 11.8%–17.4%. The DRS survey in Gujarat found that of the detected MDR-TB cases among the previously treated cases, 4% were cases of XDR-TB. While the extent and magnitude of the prevalence of XDR-TB in India is yet to be determined, it is estimated that a minimum of 2000 such cases emerge annually.

The RNTCP initiated PMDT services in Gujarat and Maharashtra in August/September 2007. After a relatively modest scale-up in services, in late 2010 the RNTCP developed a national PMDT scale-up plan for 2011–2012. The plan was developed by consolidating state-wise microplans for PMDT, through the use of a participatory approach in which all states and union territories were involved. The participants determined the strategies to be used and suggested a broad range of activities to

rapidly scale up PMDT services across the nation. The states set timelines for the scaling up of services in the districts (geographical expansion), as well as for the gradual expansion of criteria for the detection of persons suspected to have MDR-TB (towards achieving universal access in various districts by phases). Careful consideration was given to all preparatory activities, such as upgrading civil works, appointment, appraisal and training of staff, procurement, sample collection, transport and the management of drug logistics.

By August 2012, all the states and union territories have had PMDT services in place, with 18 states having achieved state-wide coverage. A population of 802 million (65% of the country's total population) currently has access to PMDT services across 435 districts. There are plans to achieve nationwide coverage by the end of 2012. Twenty-nine of the planned 43 culture and drug-susceptibility testing (C/DST) laboratories are now established, with an additional 13 laboratories accredited in the public and private sectors. This brings the number of C/DST laboratories accredited by the programme to 42. New technologies, such as LPA, have been introduced in these laboratories. Thirty-four laboratories have been accredited for solid culture, 10 for liquid culture and 29 for LPA. Sixty-seven DR-TB treatment centres are now functional.

The programme's strategy entails initially testing those patients who have a very high risk of MDR-TB, using DST. With the expansion in laboratory and treatment capacity, the RNTCP has widened the criteria for suspects who should be tested in order to move towards achieving universal access to quality-assured DST. The criteria for the referral of a specimen for DST necessarily differed among the districts. The graded criteria for suspecting MDR-TB are as follows:

Criteria A

- All new TB cases who fail an initial FLD treatment
- Smear-positive, previously treated patients who remain smear-positive at the fourth month or later
- All pulmonary TB patients who are contacts of a known MDR-TB case

Criteria B (in addition to Criteria A)

- All smear-positive, previously treated cases of pulmonary TB at the time of diagnosis
- Any smear-positive follow-up result in new or previously treated cases

Criteria C (in addition to Criteria B)

- All smear-negative, previously treated cases of pulmonary TB at the time of diagnosis
- Cases of HIV-TB co-infection at the time of diagnosis

It was planned that by the end of 2012, all districts will be using criteria B to identify persons suspected to have MDR-TB. Keeping in mind the rapidly expanding capacity of laboratories, which are now capable of using a range of tests to diagnose MDR-TB, the RNTCP has amended the algorithm for the use of the various diagnostic tests. The amended algorithm is as follows.

- 1st choice: Molecular DST (e.g. LPA DST or CBNAAT)
- 2nd choice: Liquid culture isolation and LPA DST
- 3rd choice: Solid culture isolation and LPA DST
- 4th choice: Liquid culture isolation and liquid DST
- 5th choice: Solid culture isolation and DST

A field demonstration study is being carried out at 18 sites across the country to determine the operational feasibility and cost-effectiveness of rapid automated CBNAAT. The study's findings will inform the development of policy in respect to the wider adoption and implementation (at the district and tertiary levels) of rapid automated TB and DR-TB diagnostics, e.g. CBNAAT.

The requirements that need to be fulfilled in the areas of training and appraisal for PMDT at the national level in order to facilitate the scale-up plan for the states have also been determined. The Central Tuberculosis Division (CTD) has developed a clear strategy to meet these demands. While national training is conducted periodically at five national PMDT training centres, a core team of experts and consultants from national institutes and experienced states has been formed to support the CTD in meeting the training and appraisal needs as per the scale-up microplan. The RNTCP's central PMDT appraisal tool has been updated, is being utilized as a systematic guide on all aspects of preparation and for identifying gaps in preparedness at the state and district levels. Permission to roll out PMDT services is granted only after a satisfactory "action taken" report is obtained from the appraised state. In 2011, over 140 districts in 31 states were appraised, and in 2012, over 230 districts have been appraised till August 2012.

The treatment of DR-TB patients is based on the DST results for INH and rifampicin. Once the DR-TB Centre Committee decides that the patient should be treated, s/he is advised initial hospitalization in a DR-TB centre for a pre-evaluation work-up and the initiation of Category IV treatment. If the patient's condition is stable one week after the initiation of treatment, s/he is discharged and advised to continue treatment on an ambulatory

basis. If the patient is unable or unwilling to be admitted in the DR-TB centre, the DTO is responsible for arranging for the pre-evaluation work-up to be performed within the district. Once the DR-TB centre that has been approached decides to treat the patient, the DTO should initiate Category IV treatment on a completely ambulatory basis. The RNTCP uses a standardized Category IV treatment regimen. This daily DOT regimen comprises 6–9 months of kanamycin, levofloxacin, cycloserine, ethionamide, pyrazinamide and ethambutol, followed by 18 months of levofloxacin, cycloserine, ethionamide and ethambutol. If the baseline DST for SLDs reveals resistance to ofloxacin, then levofloxacin is replaced by moxifloxacin and sodium PAS.

A standardized treatment regimen is also used for XDR-TB cases. This daily DOT regimen comprises 6–12 months of capreomycin, sodium PAS, moxifloxacin, high-dose INH, clofazimine, linezolid and amoxicillin-clavulanate, followed by 18 months of sodium PAS, moxifloxacin, high-dose INH, clofazimine, linezolid and amoxicillin-clavulanate.

Category IV drugs are procured either via the Global TB Drug Facility (GDF), if supported by the Global Fund (GF) grant, or by the GoI through international competitive bidding procedures, if procured using World Bank credit funds. As for drugs belonging to the Category V regimen, the states have been procuring these locally, adhering to the technical specifications made by the CTD.

Since August 2007, the cumulative number of MDR-TB suspects tested is 76 833, MDR-TB cases detected 17 294, and MDR-TB patients started on treatment 12 114. As a result of the intensive activities in the past 12 months, of the cumulative total of suspects tested and MDR-TB patients started on treatment, 38 162 (50%) and 5126 (42%) were tested and started on treatment respectively in the first six months of 2012. As for the outcomes of treatment in the first nine cohorts (Q3 2007 to Q2 2009) of 967 patients, the treatment was successful in 51% (493) of patients, failed in 8% (74), 18% (175) died and 20% (197) defaulted.

NSP 2012–2017: PMDT component

Vision

- To promptly diagnose and effectively treat all (90%)patients with DR-TB through decentralized DST and PMDT services, integrated into the RNTCP. Given the complexity, scale and cost of this task, a phased approach, under which the initial focus will be on those most likely to have DR-TB, has been developed.

- The RNTCP plans to treat about 160 000 cases of MDR-TB, of which 40 000 are expected to be treated in 2017 itself, and 4100 cases of XDR-TB over the next five years (2012–2017). It is planned that by 2015, all smear-positive TB (new and re-treatment) cases registered under the RNTCP, early during the course of their treatment, should have access to diagnostic and treatment facilities for MDR-TB.

Strategies

- Prevention of drug resistance through sustained implementation of high-quality directly observed treatment, short-course (DOTS)
- Improvement in laboratory capacity for the diagnosis of DR-TB
- Effective treatment of M/XDR-TB patients
 - Improved and wider provision of PMDT services by the RNTCP
 - Promotion of the rational use of anti-TB drugs in the country
- Implementation of measures to control infection

Activities

A wide range of activities are planned under the NSP 2012–2017. The major activities include the following:

Establishment and upgradation of reference diagnostic facilities

- The proposed 43 laboratories will be established and accredited by 2013, and an additional 30 C/DST laboratories accredited by 2015.
- Following the demonstration of operational feasibility and cost-effectiveness, 950 laboratories at the district and tertiary levels will be equipped with rapid automated TB and DR-TB diagnostics, e.g. CBNAAT and 33 (NRLs and accredited C/DST laboratories) to perform second-line DST (SL-DST) by 2015.

Establishment of DR-TB centres

One DR-TB centre will be set up per 10 million population (i.e. a total of 120 centres). The centres will have upgraded airborne infection control (AIC) measures in place.

Improvement of drug storage conditions and capacity

Drug storage conditions and capacity shall be improved at the state and district levels. SLDs should be stored as per the guidelines.

Restructuring of human resources

Significant provision will be made for engaging additional staff, which will include a counsellor at each DR-TB site.

Procurement of drugs

Steps will be taken to ensure central procurement of Category V (both Group 4 and 5) drugs for cases of XDR-TB.

Improvement of treatment outcomes

It is planned to improve the outcomes of treatment by accelerating the shift to earlier diagnosis of MDR-TB (switch from Criteria A to B to C) and using rapid diagnostics (LPA, liquid culture).

Improvement of drug regulatory controls

Regulatory controls against the inappropriate and irrational use of anti-TB drugs will be strengthened.

Management of SLD resistance

Baseline SL-DST at the time of diagnosis will be used to guide the management of resistance to SLDs, as laid out in the guidelines.

Online data management system for M/XDR-TB

Electronic web-based information systems to be piloted and scaled up to all states.

Drug resistance surveys

Drug resistance surveys will be carried out in Madhya Pradesh, Rajasthan and West Bengal. Attempts will be made to effect a gradual switch to routine surveillance as laboratory capacity allows for a switch to Criteria B.

Challenges/constraints/gaps

- There is a risk that the other activities of the RNTCP will suffer if too much focus is placed on PMDT during the phase of expansion of PMDT services.
- Planned laboratory capacity, including the capacity for SL-DST, is still insufficient for the achievement of universal access to diagnosis for all MDR-TB cases.
- An immense number of human resource development (HRD)-related issues, including hiring a large number of staff and meeting training requirements, needs to be tackled.
- Case definitions and definitions of treatment outcomes are lacking when it comes to paediatric cases of MDR-TB.
- A mismatch has been observed between diagnostic capacity and the capacity for the management of treatment during field visits.
- There is a dearth of counseling services and a lack of support for patients.
- The storage space for SLDs is often inadequate and storage conditions are not ideal.
- There is a lack of paediatric formulations for children with MDR-TB.
- There is no clear guidance on the management of contacts, particularly children, of known cases of MDR-TB.

- The engagement of the private sector in the implementation of DOTS and PMDT continues to be limited.
- Regulations to address the availability and irrational use of FLDs and SLDs in the private sector are either not enforced or are too weak.
- The implementation of infection control measures leaves much to be desired, both in terms of the quality and coverage at different levels.
- The targets set by the NSP for 2015 are well below those of the Global Plan to Stop TB, 2011–2015 (Table 2). Further, the 2017 target of treating 40 000 MDR-TB patients falls short of the universal access vision, i.e. 90% of MDR-TB cases.

Table 2. Global Plan to Stop TB, 2011–2015 (NSP targets for 2015)

% of new bacteriologically positive TB patients tested for resistance to FLDs	20%(7%)
% of previously treated TB patients tested for resistance to FLDs	100%(75%)
% of confirmed MDR-TB patients who had a SL-DST	100%(NA)
% of cases with confirmed MDR-TB started on treatment	100%(NA)
Treatment success rate among patients with confirmed MDR-TB	75%(56%)

Recommendations

- While expanding services to diagnose and treat MDR-TB cases, the RNTCP needs to continue focusing on the prevention of M/XDR-TB and activities of the “basic” programme.
- The existing regulations related to anti-TB drugs need to be enforced strictly, with a possible extension of the regulations to further protect these drugs and stop their irrational use.
- Full support of all stakeholders is necessary for the proposed massive scale-up of innovative activities to be undertaken by engaging and partnering with the private sector, and for management activities related to all forms of TB. The use of the private sector in services for the management of DR-TB should be included in the “package”.
- The dictum “Know your epidemiology” should be used to guide further development of policy and operational interventions:
 - Conduct the proposed national DRS survey, including in the private sector, for paediatric cases, and to cover FLDs and SLDs.
 - Consider conducting a separate DRS survey in Mumbai to gain an understanding of the local epidemiology and guide further interventions. If, however, Mumbai is ready for routine DST in all new TB cases, there may not be a need for the survey.

- Accelerate the development of laboratory capacity so that it can meet the requirement for conducting rapid DST of assured quality (for FLDs and SLDs) for all TB patients at diagnosis, including paediatric cases. This will help to guide appropriate treatment of M/XDR-TB cases and will also help the country move closer to its goal of achieving the provision of universal access to MDR-TB cases by 2017 (Criteria D).
- Ensure the alignment of diagnostics, drugs and treatment management services for MDR- and XDR-TB patients, particularly during the current phase of rapid expansion of PMDT services:
 - An integrated, comprehensive electronic information system, which links laboratories, treatment sites, drugs stores and programme managers, should be put in place.
 - The operational plans for the scale-up of laboratories and DR-TB services should be updated annually and the costing revised. The transition from Criteria B to C to D should be guided by an analysis of the laboratory capacity for the diagnosis and follow-up of cases; the available stocks of SLDs; the number of DR-TB centres and TUs; and an assessment of the management services at the field level.
 - Intensive monitoring is necessary, particularly during the transition from Criteria A to B to D.
 - It is essential to build capacity, including in the area of clinical management, to promote decentralization.
- Appropriate case definitions and definitions of treatment outcomes need to be developed for paediatric cases.
- Lack of sufficient in-patient facilities must not become a bottleneck to the initiation of treatment and the creation of “waiting lists” of MDR-TB patients for the initiation of treatment should not occur. The existing programme guidelines on the option of completely ambulatory care should be heeded.
- Continue to ensure that all SLDs procured are of assured quality. Centrally procured Category V (both Group 4 and 5) drugs for XDR-TB cases should be made available.
- Consider the recommendations of the WHO 2011 PMDT guidelines regarding the duration of the intensive phase of treatment (at least eight months) and of the total duration of treatment (at least 20 months).
- Consider the option of performing one culture during each follow-up examination instead of the current practice of performing two.
- Review and update the guidelines for the management of the contacts, adult and paediatric, of known MDR-TB cases.
- Besides “protecting” the existing anti-TB drugs, plan ahead to facilitate the introduction of new drugs and make them available (e.g. and

delamanid for MDR-TB, and moxifloxacin for DS-TB). Plan in such a way that these drugs are used rationally and “protected”.

- Considering its capacity, India needs to play a leading role in the promotion of research and development (R&D) for new tools; in engaging in international trials of new TB drugs and regimens; and in formulating the right policies for the introduction of drugs of the future.

Infection control

- Update the AIC guidelines on the basis of evidence that emerged from the pilot and publish the findings of the study so that they can be shared with the global community.
- Coordinate with and extend technical support to the National AIDS Control Organization (NACO), NRHM, National Centre for Disease Control and the National Institute of Health and Family Welfare to extend the implementation of the guidelines beyond the setting of HIV care and DR-TB centres and laboratories, and into the wider general health system.
- Collaborate with the Hospital Services Consultancy Corporation at the central and state levels, as well as the MCI, for the integration of the AIC guidelines into the Indian Public Health Standards and MCI requisitions for the recognition of medical colleges.

Research

- Research needs to be conducted to improve the management of INH mono-resistance and polydrug-resistant cases.
- The use of high-dose INH in the treatment of MDR-TB cases is another area that requires research.

5. TB-HIV

Background

TB and HIV act in deadly synergy. HIV infection increases the risk of exposure to TB, progression from latent to active TB and death if HIV and TB are not treated in a timely manner. Further, the risk of recurrence is greater even if the patient is successfully treated. Similarly, TB is the most common opportunistic infection and cause of mortality among PLHIV. It is difficult to diagnose and treat owing to challenges related to co-morbidity, the pill burden, co-toxicity and drug interactions. Though only 5% of TB patients in India are HIV-infected, in absolute terms this means that there are more than 100 000 cases annually. India has the second highest number of HIV-associated TB cases in the world and accounts for about 10% of the global burden. This, coupled with the heterogeneous distribution of such cases in the country, poses a challenge to the delivery of services. Since the start of collaborative efforts between the RNTCP and National AIDS Control Programme (NACP) in India in 2001 and the intensification of efforts to deal with TB-HIV in 2008, activities to tackle TB-HIV have evolved to cover most of the WHO policy recommendations.

Despite these achievements and the scale-up, several challenges remain. Nearly 40% of TB patients still do not know their HIV status, especially in districts with a low prevalence of HIV. Of those identified as HIV-positive, only two-thirds are linked to ART as the majority are poor and unable to reach centralized ART centres.

The WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have envisioned the achievement of “Zero new HIV infections, zero discrimination and zero HIV/AIDS deaths” by 2015. This has been reinforced by the 2012 World TB Day theme, which emphasizes “Zero TB deaths”. In order to achieve these goals, the RNTCP and NACP plan to provide universal access to TB-HIV care in the next five years through the implementation of the National TB Strategic Plan (2012–2017) and the NACP IV (2012–2017).

Achievements and observations

- With the visionary leadership provided by the RNTCP and NACP and the excellent coordination between them, and through the efficient National TB-HIV Technical Working Group, a nationwide implementation of the intensified TB-HIV package was achieved by June 2012.
- The progress and quality of the nationwide scale-up were regularly monitored by the National Technical Working Group (NTWG).
- Review meetings and joint supervisory visits of the State Tuberculosis Cell (STC) and State AIDS Control Societies (SACS), particularly to states with a high prevalence of HIV, have helped to expedite the scale-up of activities at the state and district levels. They provide an example of the smooth collaboration that has helped achieve the scale-up.
- The number of TB patients tested for HIV has increased six-fold, from 34 225 in Q4 2008 to 2 01 642 in Q1 2012. The number of HIV-infected TB patients diagnosed and linked to ART care increased from 2693 in Q4 2008 to 7517 in Q1 2011. More than 90% of TB patients living with HIV have received cotrimoxazole preventive therapy (CPT) over the past two years.
- All the recommendations of the JMM 2009, except those on infection control, isoniazid preventive therapy (IPT) and the involvement of PLHIV networks, have been implemented.
- The expedited nationwide implementation of collaborative TB-HIV activities in India has been guided mostly by operational research.
- An effective monitoring and evaluation system, which ensures the systematic capturing of important indicators to assess the performance of the programme and to monitor it, is in place.
- Operational research was carried out before commencing HIV testing for those suspected to have TB. This makes the early diagnosis of HIV among TB patients easier.
- There is a wealth of experience in the implementation of collaborative

TB-HIV activities, particularly in states with a high prevalence of HIV. This experience could be used to improve and scale up collaborative TB-HIV activities, particularly in states with a low prevalence of HIV.

Challenges and constraints

- The absence of functional district coordination committees and a nodal HIV officer have reduced the effectiveness of the implementation of collaborative TB-HIV activities.
- Although attempts have been made to expand the decentralization of ART services, particularly to districts with a high prevalence of HIV, services remain centralized in most districts. This has invariably resulted in poor linkage of TB patients to ART services.
- Despite the issuance of the national AIC guidelines in 2010 and the strong recommendations of the JMM 2009, measures for TB infection control are poorly implemented in many HIV settings.
- Though efforts have been made to institute IPT following feasibility studies, IPT is not being implemented in India yet.
- The engagement of PLHIV and other community networks, including the broader HIV civil society, in TB-HIV activities is very limited at all levels.
- It was noted that recurrent disruptions in the supply of HIV commodities, particularly HIV testing kits, affected the smooth implementation of activities.

Recommendations

- Enhance the leadership of STC and SACS, and promote regular joint supervisory visits and periodic reviews in all states, especially those with a low prevalence of HIV.
- The DTO should be designated the nodal HIV officer, and should be invested with administrative and financial authority by the SACS in districts where no district AIDS prevention and control unit is present.
- Organize more experience-sharing visits by TB and HIV staff from the states and districts performing poorly to those performing the best to catalyze them and improve the quality of implementation.
- Expedite the co-location of facilities for HIV testing in all DMCs and accelerate the provision of facilities for HIV testing in peripheral health institutions (PHIs) without DMCs in states with a high prevalence of HIV.
- Extend HIV testing to cover cases of presumptive TB, as well as family contacts (adults and children) of HIV-positive TB patients and outpatients in states with a high prevalence of HIV.

- Urgently revise the diagnostic algorithm for TB for PLHIV (without inclusion of antibiotic trial) to expedite the diagnosis of smear-negative pulmonary and extrapulmonary TB.
- Implement the WHO's four-symptom algorithm for TB screening (current cough, fever, weight loss and night sweats), and make IPT available at all ART and link-ART centres.
- Prioritize the provision of molecular testing (CBNAAT) in all health facilities with ART centres and in co-located DMCs/integrated counselling and testing centres (ICTCs) in districts with a high prevalence of HIV to ensure the diagnosis of smear-negative pulmonary and extrapulmonary TB.
- Initiate ART among TB patients immediately after they are diagnosed with HIV, while they are undergoing baseline ART evaluation. Counselling on adherence to treatment should be started promptly along with the treatment.
- Make it a priority to provide PLHIV with rifampicin-based daily TB treatment, both in the intensive and continuation phases.
- Ensure the availability of rifabutin for TB patients who have been started on boosted protease inhibitor (PI)-based ART.
- NACO and the CTD should strengthen TB case-finding under targeted HIV intervention projects.
- Accelerate the implementation of the national AIC guidelines and ensure that at least administrative measures are instituted in all co-located DMCs/ICTCs and ART facilities as a minimum standard.
- Make TB infection control one of the key components of the terms of reference of NACO and SACS supervisors.
- Revise the targets in the NSP and include quantitative indicators for TB case-finding in ART and ICTC settings.
- Revise the 2009 National Framework for Joint TB/HIV Collaborative Activities on the basis of up-to-date evidence, the recommendations of the JMM, and the decisions of NACO–CTD and the NTWG.
- Engage networks of PLHIV, community groups and members of the broader HIV civil society in activities related to TB-HIV.
- Continue conducting targeted operational research to address the major challenges to implementation, focusing particularly on the best algorithm for TB case-finding among PLHIV; the outcomes of and adherence to IPT; the impact of Xpert on how promptly cases are detected and on the outcomes; the impact of HIV on the risk for M/XDR-TB and the outcomes of such cases; and the identification of factors associated with higher mortality among PLHIV with TB.

6. Paediatric tuberculosis

Background

Children are highly susceptible to TB and the risk of progression of the disease is also high when they are infected at a young age. Childhood TB, therefore, can account for 10%–15% of all TB cases in high-incidence settings. The risk of a child getting TB is the highest between one and four years of age and during adolescence. In India, children under the age of 14 years are approximately 440 million, constituting about 36% of the total population¹. Though the extent of childhood TB in the country is unknown, it is estimated to be 10.2% of the total adult incidence².

Recognizing the public health importance of TB in children, the RNTCP has made focused efforts to facilitate its diagnosis and treatment.

The diagnosis of paediatric TB is difficult due to (i) the lack of a sensitive, simple point-of-care test, (ii) poor sensitivity of the core test used under the programme, i.e. bacillary diagnosis, and (iii) the fact that children have the highest proportion of severe disseminated and extrapulmonary disease, which require more diagnostic rigour than do all other forms of TB. In common practice, the diagnosis of TB is often based on clinical features; smear examination of body specimens such as the sputum/gastric aspirate (where this is feasible), a positive history of exposure, tuberculin skin test (TST), chest radiography and histopathological examination, as appropriate.

Achievements

In an effort to improve the diagnostics for childhood TB, the RNTCP, in association with the Indian Academy of Paediatrics (IAP), had developed a diagnostic algorithm for pulmonary cases a few years ago³. This algorithm has recently been revised to widen its scope and include more details to cover the diagnosis and treatment of many forms of paediatric TB. The criteria for suspecting TB among children are described, and there are separate algorithms for diagnosing pulmonary TB and peripheral TB lymphadenitis. In addition, a strategy has been set out for the treatment and monitoring of patients who are on treatment. To facilitate diagnosis at the community level, as well as to encourage appropriate referral to higher institutions, the algorithm describes the range of diagnostic tests available from the level of PHIs to those at a higher level.

In consultation with experts, the RNTCP has agreed to use different child-specific case definitions, as the earlier practice of using the adult-oriented, smear-based case definitions for children was confusing, besides being difficult to use.

An uninterrupted supply of good-quality anti-TB drugs through "ready-to-use" patient-wise boxes (PWBs), which contain the patient's complete course of anti-TB drugs, have been made available to every registered TB patient, in accordance with the programme's guidelines. It is to be noted that India is the first country to introduce paediatric PWBs. The fact that the use of paediatric PWBs was lower than expected in the past could have been, in part, due to concerns among the treating fraternity about the adequacy of the doses, particularly for those at the upper end of the weight band⁴. In 2010, on the basis of newer scientific data, WHO recommended doses higher than the currently accepted doses in cases of paediatric TB. In consultation with experts on the subject, the RNTCP agreed to revise the dosages for children with TB. It also agreed to split the existing four pre-treatment weight bands to six to address all the concerns regarding dosing. The number of paediatric TB cases registered under the RNTCP has shown an increasing trend in the past five years and in 2011, about a total of 88 353 cases were notified. These accounted for 6% of all cases⁵. However; the registration of paediatric TB cases under the RNTCP varies widely from state to state, ranging from 5% in the smaller states to 14% in the larger ones. This may be due to variations in the intensity of the disease in different populations, under-diagnosis, under-reporting and inadequacy of the programme's efforts to detect paediatric cases.

One of the simple and effective methods of improving paediatric case-finding is by ensuring that proper surveys are undertaken to identify children with TB symptoms among the household contacts of smear-positive cases. Asymptomatic contacts under six years of age are given IPT. Of late, the programme has been making efforts to see to it that the surveys of the household contacts of infectious cases are more complete.

The RNTCP is currently expanding the capacity for programmatic management of DR-TB and has created a new weight band (<16 kg) to include children. These are early steps which need to be consolidated to address the wider issue of MDR-TB among children, as discussed later.

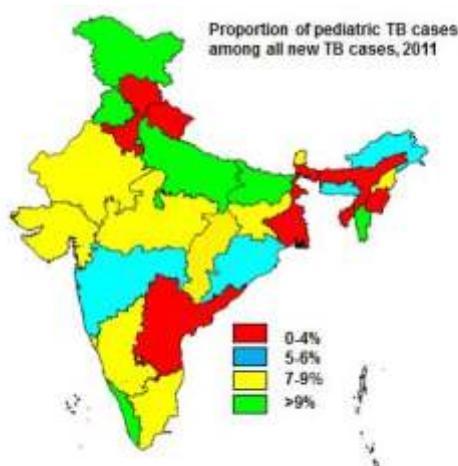


Table 3. Paediatric TB cases registered in India, 2011⁵

Type of case	No. of paediatric TB cases	No. of total TB cases	Proportion of paediatric TB
New smear-positive	12 981	642 32	12%
New smear-negative (NSN)	36 673	340 203	11%
New extrapulmonary (NEP)	34 026	226 965	15%
New others	384	1952	20%
Relapse	1024	112 50	81%
Treatment after failure	249	17 30	41%
Treatment after default	453	72 78	71%
Re-treatment others	2563	101 83	23%
Total new cases	84 064	1 211 44	17%
Total re-treatment cases	4289	304 431	1%
Total TB cases	88 3531	515 872	6%

Challenges

There is a poor understanding of the true magnitude of paediatric TB. The difficulties inherent in establishing simple case definitions for paediatric TB have resulted in the non-inclusion of children in most community surveys on the burden of disease. The process of gathering data on case-finding in the area of paediatric TB is confounded by the inability of many field providers to recognize the disease in time. On the other hand, many others tend to over-diagnose TB on the basis of little evidence.

Despite the availability of a diagnostic algorithm and paediatric PWBs, the number of children who have TB and are being treated under the programme continues to be low. One of the factors contributing to the low proportion of notified paediatric cases is that hardly any cases are diagnosed at the PHIs due to a lack of diagnostic capacity and skills. Children with TB continue to be diagnosed and treated outside the purview of the programme (not necessarily outside the public sector) and hence, are not reported to the RNTCP.

Though the programme has made efforts to bring out national guidelines on the diagnosis and treatment of paediatric TB, in consultation with the IAP, and has made provision for free drugs of high quality in PWBs for different weight bands of the paediatric population, it has not been able to attract many cases to its fold. The major areas of concern and challenges to be addressed are as follows:

- There is a need to strengthen the inadequate capacity and infrastructure for the diagnosis of cases of paediatric TB at primary and secondary care centres in the public sector. Currently, there is not much scope for the investigation of children at almost all TB facilities, which lack either the equipment needed or the skill or personnel required to diagnose various forms of paediatric TB.
- The programme's efforts to engage with paediatricians, in general have been very limited. This has led to a feeling of lack of ownership among the primary care providers for children. Due to the poor involvement of paediatricians and the ensuing deficit in trust, not many children diagnosed in the public sector are treated under the RNTCP.
- Even the TB specialists managing the programme are reluctant to look after children, particularly young children, due to a lack of skills. The current training system and format of the programme are oriented in favour of adults and smear-based diagnosis. Therefore, most of the functionaries of the programme try to retrofit paediatric cases into the same thinking gestalt, which creates a gulf between the paediatricians and the programme.

- Not only are few children being referred to the RNTCP, but the programme is also failing to identify cases among a very captive group, which it can easily reach. Children living with cases of TB are an important group of individuals who are likely to develop TB. The programme's current efforts to screen these contacts for the presence of the disease (and hence to start treatment early) or to prevent the occurrence of the disease by targeted preventive therapy are far from adequate.
- There is an urgent need to train the MOs and staff nurses of the PHIs so that they can identify children suspected to have TB. Since the diagnosis of childhood TB often requires supportive evidence from the TST, radiology and other investigations, it is necessary to improve the skills of the frontline MOs and paediatricians so that patients are diagnosed not only at larger facilities, but also at health institutions closer to their homes.
- The paediatricians in the private sector are not fully aware of the guidelines for the diagnosis and treatment of paediatric TB.
- Many private paediatricians who refer cases to the RNTCP are concerned about certain issues. These include the following:
 - Their diagnosis is not honoured
 - They lose patients who are referred by them due to the fact that the care of patients is not shared
 - Children may not get other drugs (non-TB) that they require in addition to TB drugs
 - It becomes difficult to manage activities, such as immunization or nutrition-related issues. in an integrated fashion.
- Paediatricians have expressed the concern that the drugs to be administered at the extremes of the weight bands may be inadequate, and are also dissatisfied that children continue to receive the same dosages even when they have gained weight while on treatment. In addition, many have concerns about the use of intermittent therapy for managing TB. These are possibly some of the reasons for the lack of support to the RNTCP regimen by paediatricians.
- The research being conducted on paediatric TB, whether under the programme or outside it, is sparse.
- The programme has not made any effort to introduce newer diagnostic tests with a paediatric focus.

Recommendations

The RNTCP has implemented many of the JMM 2009 recommendations, but they need to be implemented consistently, and meticulous monitoring is required if the programme is to have a meaningful impact. The following are the JMM 2012 recommendations:

Case-finding

- Case-finding efforts need to be intensified to detect and treat children with TB, particularly children among vulnerable groups such as those in contact with TB cases at home and children living with HIV/AIDS (CLHIV).
 - There is a need to strengthen the existing activities for TB care, such as training of staff, supervision, monitoring and reporting of age-disaggregated data, with an added focus on childhood TB.
 - The large public sector should be utilized optimally and the programme should effectively build the capacity of MOs at the level of the PHIs for the diagnosis of paediatric TB. The provision of training in the use of purified protein derivative (PPD), TST and radiology has to be given priority, at least in places where radiology facilities are available.
 - An effective strategy should be developed for the dissemination of the paediatric TB guidelines among and their implementation by paediatricians working, both in the public and private sectors.
 - Paediatricians, especially those in the private sector, should be adequately sensitized to the issue of paediatric TB and trained in its diagnosis and the provision of high-quality treatment. Customized training modules that suit the training needs of paediatricians have to be developed, and mechanisms to effectively disseminate knowledge and sensitize and train paediatricians must be built into the system.
 - Mechanisms need to be developed to involve MCH and immunization services in the identification of children suspected to have TB and early referral of such children. The immense opportunities available to liaise with other health departments and programmes covering the population of children should be utilized. These programmes include the Integrated Management of Neonatal and Childhood Illness (IMNCI), Integrated Child Development Services (ICDS) and the polio programme.
- The capacity for the diagnosis and treatment of children with TB needs to be strengthened at all levels and across all sectors. Further, diagnosis and treatment must be standardized.

- A referral linkage system from the peripheral care level to the secondary or tertiary care level must be established for the diagnosis of children suspected to have TB.
- There is a need to engage a pool of trained/programme-accredited paediatricians and radiologists in the private sector for the delivery of diagnostic and treatment services in the districts.
- The useful and validated newer technologies approved by the RNTCP must be utilized, especially among children suspected to have extrapulmonary TB and those co-infected with HIV.
- Effective public–public and public–private collaborative mechanisms need to be developed for quality diagnosis and delivery of treatment.
- There is a need for a programme to develop exclusive ACSM packages targeting the paediatric population.
 - Communities should be sensitized and involved in the identification of children who might have TB. There is a need to facilitate care-seeking among them. It might be useful to involve families/individuals who have actually had TB.

Treatment and management

- A programme should be started to explore the scope for child-friendly regimens, which decrease the pill burden and consist of dispersible tablets.
- There is a need to evaluate home-based DOT for children, with parents as the DOT providers.
- Paediatric TB patients should be monitored closely and facilities should be developed to provide them with support and care during adverse events.
- There is a need to strengthen the provision of IPT to children to increase its coverage and completeness.
- The management of children with suspected/diagnosed DR-TB needs to be strengthened. In this context, mechanisms should be developed to involve child care institutions.

Drug-resistant TB

- A new definition is required for paediatric MDR-TB, as are guidelines for the management of paediatric contacts of people with DR-TB.
- Paediatricians need to be included in the management of DR-TB committees at the district and state levels.

Research

- Surveys assessing the burden of DR-TB should cover children as well.
 - Identify, support and develop centres of excellence for research in paediatric TB.
 - Newer diagnostics and treatment options being tested for or incorporated into the programme should necessarily take children into account.

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7. Engaging private providers and public–private partnerships

Introduction

The NSP aims to extend the umbrella of quality care for TB and TB control to include the private health sector. A transformation in the relationship between the RNTCP and the private health sector is critical for the achievement of all the major objectives of the NSP (universal access, early diagnosis, interruption of transmission, prevention or management of MDR-TB). The programme deserves to be congratulated for acknowledging the need for this change and showing a willingness to move towards a fundamentally new approach.

While very few of the recommendations of the JMM 2009 were implemented, the past three years have seen several positive developments. For example, national consultations have been held, the National Technical Working Group (NTWG) on PPM has been established, serological testing has been banned and TB has been made a notifiable disease. Expenditures under PPM schemes have increased threefold. Strategic opportunities are presented by several key developments in India, such as the availability of new diagnostic technologies, the introduction of the Rashtriya Swasthya Bima Yojana (RSBY) and Aadhaar, and advances in Mobile phone applications.

In recognition of the fact that the approaches used thus far have failed to meet the expectations, the NSP articulates a significantly more open and

ambitious approach. The programme is willing to consider a wider range of appropriate regimens and understands the need to shift from fragmented schemes to a more strategic approach to purchasing services from private providers, notably through demand-side financing.

The plan to engage a PPM technical support group, together with private provider interface agencies (PPIA) in eight states, is excellent and should come into effect within nine months. PPIA contracts should be designed to encourage the rapid development, testing and adoption of innovative approaches to the notification of private cases, the deployment of demand-side financing and the creation of performance-based incentives (with prompt payments), with the aim of ensuring adherence to the Indian Standards for Tuberculosis Care and compliance with the RNTCP's reporting needs. While outsourcing these functions, it is important that the RNTCP should retain ownership of the process and develop the strength and capacity of its staff to ensure that it can exercise its essential role of stewardship.

While the openness of the NSP to new approaches is laudable, we must be clear about the fact that the resources allocated to and the management attention given to these issues (both around 5%) are still not commensurate with the scale of the need and opportunity to involve the private sector (PPs cater to 50%–75% of the TB cases in India).

Context

India has millions of PPs, including qualified and unqualified health practitioners, pharmacies and laboratories. They account for roughly 80% of the first contact of patients (from all socioeconomic groups) with health-care providers, and at least half of those treated for TB in India¹. Given the dominant role played by the private sector in providing health care to all sections of the Indian population, effective engagement with PPs is essential for the achievement of the NSP goals, notably early and universal case detection and rational use of drugs and diagnostics². Studies conducted since the 1990s have documented the extent to which TB is diagnosed and treated in the private sector, as well as the prevalence of largely inappropriate diagnostic and treatment practices³⁻⁵. Most people with active TB visit more than one PP (mostly local informal providers and chemists) and take antibiotics or other treatments, even if most of them eventually register with the RNTCP⁶. PPs rarely request sputum microscopy and rely excessively on chest X-rays and inappropriate tests such as TB serology, which has recently been banned by the GoI⁵. Despite

the ban, serological tests continue to be performed in some laboratories, while other laboratories have replaced these with tests such as IGRA, which are not indicated for active TB. If patients do start on anti-TB drugs, they can rarely afford the full treatment and usually stop taking them as soon as they feel better. TB drugs are freely available OTC, and prescription audits have shown that irrational prescription of TB drugs is a widespread practice, which might partially explain the emergence of MDR and XDR-TB in India^{3,4}. Patients from low-income households lose several months of their income in the process of paying for inappropriate diagnostics and treatments before starting therapy under the RNTCP⁷.

Challenges

Many small pilot projects have been undertaken in India to engage PPs in quality-assured TB care, as specified by the national guidelines⁸. Most of these have been conducted at a very small scale, and the best business model for engaging with the private sector remains elusive⁹. PPs are the first point of care for the vast majority of TB cases and yet, it is estimated that they contribute just 2%–3% of case-finding and less than 1% of case management under the RNTCP. The following challenges make it difficult to achieve a meaningful engagement of PPs, on a scale commensurate with their role in the health-care market.

- The relationship between the PPs and the state is often characterized by a deep mutual mistrust.
- It is not easy for the state to engage with large numbers of independent PPs. Though some PPs are associated with the RNTCP, their numbers are insufficient to reach the scale required.
- The existing PPM schemes have had a very limited impact because of delayed payments, unfulfilled obligations and underutilization of the funds earmarked for PPM/NGO activities.
- Market forces are often powerful impediments to the adherence of PPs to government protocols. PPs very often make considerably more profit from practices that are not in the best public health interest than from practices recommended by the RNTCP. These irrational practices are supported by the concerted marketing efforts of pharmaceutical and diagnostic companies, and often conform to the client's expectations of what constitutes quality care.
- The state's regulatory enforcement mechanisms are too weak to control the private market, considering its size and fragmentation.

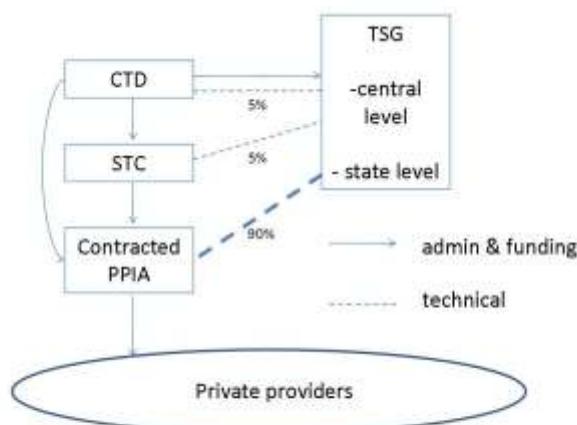
Achievements since the last JMM

There have been several positive developments in the past three years. National consultations have been held on private sector engagement and the NTWG has been established. Serological testing for TB has been banned and TB has been made a notifiable disease, with the Nikshay system being developed for the notification of cases. Analyses of the private TB drug and diagnostics market have also been conducted^{10,11}. Expenditures under PPM schemes have increased threefold and the existing schemes are being revised. Strategic opportunities are presented by several key developments, such as the emergence of new diagnostic technologies, the introduction of the RSBY and Aadhaar, and advances in mobile phone penetration and applications.

Future plans under NSP

The NSP prescribes the development and deployment of engagement models that will overcome the barriers of mutual mistrust, conflicting market forces and fragmentation, so that the TB care provided by the private sector can be improved and encompassed within the programme. The NTWG on PPM will meet regularly to review and analyse data and advise the RNTCP on opportunities to enhance the involvement of the private health sector. At the national and state levels, a technical support group (TSG), which will focus on effective contract management and other partnership-strengthening functions, will be established within the RNTCP. PPIAs will be contracted in the states to manage the activities required for engaging the private sector to a scale commensurate with its presence. The organizational structure envisaged to enhance the engagement with PPs is shown in Figure 6.

Figure 6.



The other measures set forth in the NSP include:

- Greater acceptance by the RNTCP of internationally approved diagnostic and treatment protocols; this is relevant to reaching an agreement on the Indian Standards of TB care that will be acceptable to both, public and private sectors;
- Reliance on market forces rather than normative exhortation;
- Increased use of accreditation and contracting;
- Further outreach to private laboratories (e.g. by supporting consortia of private labs that will offer affordable, quality-assured TB tests);
- Increased control of TB drugs to reduce irrational TB drug use in the private market;
- Innovative use of information and communication technologies, especially for adherence monitoring and notification of cases in the private sector;
- Engagement of corporate hospitals and institutions involved in DNB/PG training.

The NSP's approach to PPM has several strengths. It clearly acknowledges that the current approaches and schemes are inadequate. There is a clear commitment to doing things differently and to scale, and to support this with an increased budgetary allocation. There is a commitment to outsource TSGs and to employ PPIAs for the engagement of PPs at a larger scale. There is a willingness to be flexible in accepting the diagnostic and treatment approaches to be included in the Indian Standards of TB Care (to be developed in consultation with the private sector). There is an implied acknowledgement of the need for flexibility with regard to the strategies and business models used by PPIAs in different states/cities.

Weaknesses and pitfalls of the strategy on PPM

The main weakness of the strategy is that the resources currently envisioned for the implementation of the new approach to the engagement of PPs appear inadequate, given the scale of the task. This suggests that while the need to engage PPs has been acknowledged, it may not have been given sufficient priority. The indicative budget for the TSGs and PPIAs represents just 1.2% of the total NSP budget. The new Composite Index for monitoring performance within the RNTCP assigns only 10 points out of a total 250 (4%) to efforts to improve engagement of NGOs and PPs. The main impediments to the successful execution of the strategy include the lack of capacity within the programme in areas such as cost analysis and contract design, and protracted procurement processes. The

persistent mistrust of the private sector, both in the context of the programme as well as in the broader political and administrative context, may lead to a lack of commitment to the new strategy in some states and districts. The success of the strategy is to some extent dependent on developments outside the TB programme, such as the strengthening of regulatory processes (e.g. regulation of private health care via Clinical Establishments Act) and the development of IT systems. Strong leadership will be of the utmost importance in tackling the possible pitfalls. A new spirit of genuine partnership will be needed, sufficient resources will have to be allocated and accountability will have to be established.

Recommendations

The overall recommendation is that the RNTCP should dedicate sufficient resources and devote enough attention to the implementation of the new approach to strategic partnership with PPs as outlined in the NSP. In particular, the TSG should be established in 2012, four PPIAs should be contracted by the end of 2013, and these should be scaled up to at least eight states by 2017.

The specific recommendations are as follows:

- Increase the funds available for PPIAs, perhaps by shifting from the budget allocated to PPM schemes.
- Finalize the contracts for TSG by November 2012 and the first PPIAs by April 2013.
- Develop and publish the Indian Standards of TB Care within 12 months, in consultation with all the relevant associations (including private TB and chest specialists).
- Appoint full-time PPP coordinators in the STCs participating in the PPIA pilots by April 2013.
- Develop a plan to build the capacity of the state and district staff in matters related to PPM. Provide them with training on the relevant issues.
- During the current revision of schemes, include new schemes that are specifically tailored for PPs of all kinds.
- Involve schemes such as the RSBY at the state and central levels to establish diagnosis and treatment packages for MDR-TB, together with procedures for TB care in pilot projects for outpatients.
- Expedite the signing of memoranda of understanding with corporate hospitals and DNB and postgraduate institutes to involve them in the notification, management and reporting of cases.
- Develop a composite indicator of district and state performance in the

sphere of PPP. This should be included as a distinct thematic area in the next version of the overall RNTCP composite indicator, and be given a weightage that is proportionate to the importance of PPP in the NSP.

- The Indian Medical Association project (IMA-GFATM-RNTCP-PPM Project) should focus on sensitizing PPs on the need to notify cases and on the ban on serological tests. High-performing providers should be given recognition.
- In addition to the other functions of PPIAs listed in the NSP, the terms of reference and the provisions of the contracts of PPIAs should encourage them to develop, test and adapt innovative approaches to:
 - The management of payments to PPs ensuring they are prompt;
 - Appropriate participation in the PMDT by PPs;
 - The use of new diagnostic technologies (to be reported to the programme) by private laboratories;
 - Demand-side financing to reduce financial barriers to adherence among private patients;
 - Electronic payment to PPs and patients, where appropriate;
 - Restricting the sale of anti-TB drugs to accredited chemists, ensuring that only appropriate prescriptions are filled and reporting to the RNTCP of TB cases started on anti-TB treatment; and
 - Engaging “nodal providers” at the local level.

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8. Surveillance, monitoring, evaluation and impact measurement

Introduction

A key element of successful control of TB is the ability to implement a robust surveillance system for the prompt collection and analysis of information on all TB patients receiving care within the population. Surveillance is often described as “information for action”, without a successful surveillance system; public health action will likely be ineffective and inefficient. Surveillance systems are the pillar of routine evaluation and monitoring of public health programmes. The data generated from these systems form the principal evidence-base for appropriate resource allocation, improving programme implementation, and informing current and future planning and policy. Effective supervision, monitoring and evaluation of a programme requires the timely and systematic collection, recording and reporting of data at district, state and national levels. Surveillance data flow is hierarchical, that is district-level data is reported to the state, and state-level data is reported to the national level. Timely analysis and dissemination of the findings at all levels are necessary to translate these data into public health action, and inform policy.

Achievements

The RNCTP has developed a national strategy for monitoring all aspects of implementing TB prevention and care activities in India. This strategic plan

has well-defined roles and responsibilities for all personnel at all levels of implementation, from the peripheral level to the national level. A well-defined reporting and recording system forms the backbone of the strategy. It was observed in this review that the reporting and recording system continues to be functional and strong. With a few exceptions, data collection was complete and valid and TB registers were maintained at the district and state levels. It should be noted, however, that the system accounts only for patients reported by the RNTCP. This system captures only a minority of cases who are diagnosed and treated in the public sector (e.g. NGOs and PPs). An unknown proportion of incident TB cases remain entirely outside the reach of the existing surveillance system. Hence, the current approach relied on indirect and imprecise measures to estimate the national TB burden in India.

Challenges

Under the current paper-based system, recording and reporting takes between 7 and 30 days after the initiation of TB treatment. Importantly, monitoring treatment adherence and completion was confined to the local level, and these key programme indicators were not readily available to higher-level programme managers. However, it was noted that data entry into Epi-Centre, which was used to compile TU-based aggregated information on case-finding, sputum smear conversion and treatment outcomes, appears to be timely and comprehensive. Aggregated data from Epi-Centre were reported via e-mail for feedback and action. While this system was functional at the national level, it must be ensured that these data are used to improve the performance of the programme at the local level and timely action is taken. As observed by the JMM 2009, the full potential of the surveillance data was not fully realized, particularly at the district level. The supervisory discussions on monitoring contained neither relevant, nor instructive evidence-based communications. Moreover, the mechanisms for documenting progress or initiating corrective action to ensure accountability needs improvement.

Like many national TB programmes, the RNCTP has focused primarily on two internationally recognized indicators to monitor performance: a new sputum smear-positive case detection rate of 70%, and a treatment success rate of 85% for new sputum smear-positive cases (i.e. 70/85 target). This approach, while useful for international country-level comparison, may not be appropriate for subnational assessment and suffers from many weaknesses. First, the true national incidence remains largely unmeasured without a case-based reporting and population-based

surveillance system. The case detection rate remains a national-level indicator, and may not be an accurate or valid indicator at district and state levels. Focusing on these two specific output targets may lead to the manipulation of data, with even a small variation resulting in a difference of large numbers. Second, this approach does not emphasize management processes, especially at the local level where implementation takes place. The RNCTP has taken an innovative step to improve the monitoring and evaluation of the programme by trying to go beyond the 70/85 target with the development of a composite indicator that measures performance on the basis of input variables, processes and outcome variables. The composite indicator is a weighted score of an agglomeration of 15 indicators across five thematic areas. The selection criteria for these 15 indicators were chosen carefully, with extensive input from local officers, so as to make them replicable in all districts using the existing routinely collected data by an automated process through reports of Epi-Centre. Weighted scores are not purely cross-sectional, but also take past performance into consideration.

Recently, the GoI took an unprecedented and progressive step towards improving TB surveillance by making the notification of TB mandatory for all clinicians, laboratories and institutions diagnosing and treating TB in India. This executive order was an essential step towards the promotion of national case-based surveillance. However, national guidelines to define reportable, verified cases of TB (both diagnosed and put on treatment) and standardize the mechanism for reporting were still in the process of being drafted at the time of this report. Another measure to improve nationwide surveillance of TB was the development of a new, case-based, online information management system, "Nikshay". However, this platform was in a very early stage of implementation. While this system is poised to substantially improve the timeliness of reporting and recording nationally, it is yet to be seen whether it will help to translate the routine collection of surveillance data into improved programme performance.

It should be noted that the NSP substantially augments the reach and quality of routinely collected information on all incident TB as well as DR-TB cases. The fundamental approach to assessing the disease burden will change from "guesstimating" the approximate estimates of disease to a more accurate counting of the number of TB cases and TB-related deaths. A strengthened routine, case-based reporting and surveillance system, which includes patients diagnosed and treated in the private sector, should be used to improve the management of cases, local monitoring of the

programme, and estimation of the disease burden. As such, the RNCTP was making progress towards eliminating complex, expensive, and imprecise disease-specific surveys, which were the norm in the past.

Recommendations

- Develop national guidelines, in consultation with all public and private (for profit and non-profit) stakeholders, to define reportable, verified cases of TB (both diagnosed and put on treatment) and standardize the mechanism for reporting. Provide technical and operational support to all stakeholders, and empower district- and state-level officers to effectively implement the notification of TB.
- While the development of a composite indicator to measure the performance of the programme was an innovative and progressive step, this tool should be implemented with the help of additional support to the districts/states, as well as continual training on the appropriate use and interpretation of the weighted scores. It is also important to remember that the composite indicator can be useful as a monitoring tool only if it is aligned with the NSP. Operational research is needed to evaluate the validity of the composite indicator against local experience and implementation. Upon completion of this validation, the programme should consider eliminating use of new sputum smear-positive case detection rate as a subnational indicator.
- The RNTCP should monitor progress in the implementation of the NSP by conducting biannual reviews.
- The release and endorsement of the NSP provided an impetus for conducting epidemiological studies to validly document nationally representative estimates of the incidence and prevalence of TB, TB-related mortality, and anti-TB drug resistance. These estimates are needed urgently to ensure the appropriate allocation of resources, improve the implementation and planning of current and future programmes, and inform policy decisions.
- It is recognized that it will take several years for the implementation of TB notification and for the case-based surveillance system to mature enough to be able to provide accurate and informative data for the estimation of the burden of disease in India. In the meantime, inventory studies should be considered to measure the number of TB cases that are detected by non-RNTCP providers and that are not captured in the routine surveillance (i.e. under-reporting). This, along with the estimate of the extent of under diagnosis, when added to the number of notified cases under the RNTCP, may provide a measure of TB incidence.

- The programme should consider developing and implementing standard methods for monitoring trends in TB mortality.
- Drug resistance has emerged as a major threat to the effective control of TB in India. However, attempts to measure the true prevalence of MDR/XDR-TB have been limited to state-level surveys, and there is no accurate estimate of anti-TB drug resistance in the private sector. The RNTCP should consider conducting periodic nationally representative anti-TB drug resistance surveys. These survey must be a nationally representative sample from laboratories both in the public and private sectors, and should include new and re-treatment cases.
- Conducting a national-level TB prevalence survey should be considered a low priority. Prevalence surveys are both resource and time intensive. Given the enormous population size in India, population density and many urban areas, there will be no doubt a diversion of skilled manpower, which could be utilized for other priority areas, such as operational research. Before embarking on such a labour-intensive exercise, one must examine how useful the “return on investment” this kind of survey would be in improving the performance of the programme.
- Further investment (administrative, technical and political) is needed to expand the national information technology platform (Nikshay). Online reporting from all clinicians (both public and private), laboratories and institutes diagnosing and treating TB should be supported. There is a need to address operational issues, such as lack of Internet connectivity in the field, and alternatives should be sought to deal with such problems.
- Continued supervision is of paramount importance. As set out in the NSP, the programme needs to ensure that effective supervision within the TUs is not disrupted when the RNTCP structures align with the general health system (at the block level). The block MOs need to be systematically trained to do supportive supervision of the programme.

9. Human resource development

Achievements

The RNCTP has established a successful staffing and supervision structure, with a committed health workforce. The structure for CTD stewardship and leadership in national capacity-building, provided by the National Tuberculosis Institute (NTI), Lala Ram Sarup Institute of Tuberculosis and Respiratory Diseases (LRS) and equivalent state and district structures, is characterized by clear lines of responsibility and communication. The past five years have seen increased integration between the RNTCP and the NRHM, and further integration is planned in the current NSP. The plan to decentralize the management and supervision of TB to the block level is ambitious and will contribute to an improvement in the quality of the delivery of TB services.

The programme has developed a national training strategy, which promotes an integrated approach to training. The strategy is based on a cascade model, with the aim of ensuring that training is decentralized to the lowest levels. More than 15 training curricula and numerous exercise books and checklists have been developed to orient the staff involved in the management, supervision and delivery of services to their TB-related tasks. The materials developed include modules on the management of TB, provision of DOTS, C/DST, supervision of treatment and laboratories, and management of drug stores. As part of the scale-up of the MDR-TB component of the programme, the PMDT guidelines were recently revised

and the staff was trained in the appropriate diagnosis and treatment of MDR-TB. Thousands of management and supervisory staff members have been trained in the management and supervision of the programme, as well as specific technical interventions, while hundreds of thousands of paramedical staff and community providers have been trained in the provision of DOT.

Currently, 80% of the trained supervisory staff has been deployed, contributing to the rapid scale-up of the programme. To increase the level of motivation among its staff members, the RNTCP encourages the recognition of their work on occasions such as World TB Day and at other TB events. The RNTCP has also requested the states and districts to avoid the rapid transfer of State Tuberculosis Officers (STOs) and DTOs to improve the quality and continuity of the management of the TB programme.

Challenges

While the RNTCP's strides in the sphere of HRD are notable, the programme also faces a number of challenges in this regard. Many of the recommendations of the JMM 2009 – such as developing performance-based reward systems, coordinating with NRHM for training, strengthening packages for staff retention and motivation in remote and rural areas, and improving training quality, quantity and management among others – have not been heeded. The fact that India has a systemic shortage of human resources for health presents a serious challenge to the successful provision of high-quality services for the prevention, care and treatment of TB. Slow recruitment and deployment of staff, as well as inequalities in the terms for hiring staff and the remuneration paid, have contributed to gaps in the workforce and dissatisfaction. The content of the training and capacity-building efforts does not fully meet the requirements of those who are to work as managers, supervisors, providers or community workers; nor is such training and capacity-building always available. Many programme managers hold additional charges and, as a result, do not have adequate time to manage the TB programme. Finally, although terms of reference have been developed for all major staff categories under the RNTCP, most staff members do not have copies of their job descriptions, including their main roles and responsibilities.

The RNTCP is embarking on an ambitious strategy to achieve universal access, which entails a significant expansion of the TB health workforce. Its plan to decentralize the management and supervision of TB to the block level will require a threefold increase in the number of senior treatment

supervisors. Further, the management of the TB programme will have to be coordinated with the existing structure of responsibilities of the block MOs. MDR-TB services are to be scaled up, and the laboratory network will be expanded and enhanced with new diagnostic technologies. These changes have significant implications for the deployment, training and capacity-building of staff. As the NSP recognizes, serious commitment, coordination and investment will be required at the highest levels to be able to effectively manage these HRD issues.

The achievement of the NSP's objectives will also require extensive coordination and collaboration among the RNTCP and NRHM in the area of HRD policy and planning. The human resources available to manage and coordinate HRD technical oversight and capacity-building at the CTD, NTI and NRLs will need to be augmented if the objectives of the NSP are to be achieved.

Key challenges

- The rapid expansion of the RNTCP has compromised central and state capacity to effectively manage and implement the programme; the additional expansion outlined in the NSP will further strain the management systems, unless they are reinforced with additional staff.
- The CTD needs support to develop comprehensive human resource strategies and plans, and to provide leadership for national HRD for the RNTCP. The states and districts also lack the HRD capacity required to ensure adequate staffing and capacity-building.
- Shortages of staff throughout the health sector present a significant challenge to the provision and quality of TB services. In some states, a significant number of posts for RNTCP supervisory staff are vacant (20%). These need to be filled urgently if universal access is to be achieved.
- A comprehensive strategic plan for all aspects of HRD is required, especially in the light of the new NSP.
- Persistent inequalities in the terms and conditions of the RNTCP contractual staff, unlike those of equivalent cadres engaged by the NRHM, are giving rise to frustration and must be addressed if the RNTCP is to have a motivated workforce.
- State and district level training has fallen short of expectations and has failed to meet the requirements. The training needs have not been assessed and the quality of training is not evaluated. Refresher training is hardly provided, with many staff members having undergone no training in the past five years.

- Some of the staff providing TB services, such as AYUSH doctors, do not have the requisite training or qualifications for the services they are asked to provide.
- The appraisal of performance has been introduced in some states recently for regular staff, but there is no such appraisal for the contractual staff of the RNTCP.

NSP 2012–2017: Key HRD strategies

The NSP's vision for HRD, i.e. “Every person in India has access to a motivated and supportive health-care worker who is skilled in TB control,” reflects the RNTCP's overall aim to achieve universal access. The NSP outlines four key HRD strategies and a number of activities. These strategies are enumerated below and the activities emphasized by the NSP are echoed in the recommendations that follow.

- Align more effectively with the health system under the NRHM.
- Leverage the NRHM staff effectively.
- Build the staff capacity to handle multiple new services.
- Improve the management and technical capacity of the programme support cells at the state and district levels to better guide the programme staff to effectively implement the TB programme.

Recommendations

The JMM team made a number of recommendations that will need to be heeded if the RNTCP is to achieve the NSP's objectives. Many of these recommendations are similar to those made by the JMM 2009.

1. *Strengthen HRD planning and coordination*

- Ensure effective coordination and collaboration among the RNTCP and the NRHM with regard to issues pertaining to the management of human resources.
- Convene a high-level working group to guide planning on the management of human resources, establish guidelines, lead research activities and oversee the RNTCP.
- Develop comprehensive, medium and long term HRD plans to implement the NSP strategies and address the gaps that have been identified in competency and training.
 - As part of the planning process, review the workload, staffing norms, job descriptions and key indicators of performance at all levels of the RNTCP hierarchy.

- Augment the skilled staff for HRD management at the CTD to ensure the implementation of the HRD strategy, and engage technical support agencies to assist the CTD in carrying out its HRD plans. Strengthen the training competency for the programme.
- Develop the capacity of state and district programme managers in the management of human resources; consider engaging management institutes or institutes of public administration to achieve this aim.
- Arrange for additional RNTCP supervisory and management staffing at STCs in large states.

2. Clarify roles and responsibilities

- Revise the terms of reference or develop new job descriptions to address the changing roles of the staff. Ensure that all staff members are oriented to their roles and tasks and are provided copies of their terms of reference or job descriptions.
- The qualifications required by different programmes (RNTCP, NACO, NRHM) for hiring laboratory technicians should be uniform so as to encourage the integration of staff responsibilities at the peripheral level.

3. Reinforce and expand structures/systems for development of staff capacity

- Develop a comprehensive training plan to guide the expansion of training required over the next three to five years.
- While developing the plan, assess the training needs as well as the capacity for imparting training, taking into account the fact that the RNTCP needs to expand its TB workforce, the delivery of TB services and diagnostic capability over the next five years.
- While developing the training plan, consider strategies for the assessment of the quality of training.
- Use private and public sector training resources to develop the technical and managerial competence of RNTCP-NRHM staff. The use of state-of-the-art training and distance learning approaches, such as m-health, video training and online courses, is recommended.
- Ensure that core training programmes include field practicums, with training observation and feedback or peer support and review (learn, practice, do).
- Build the capacity of the districts and blocks to train and support community cadres in the identification of people suspected to have TB, referral of cases, and dissemination of information on TB and DOT.

4. *Improve compensation policies and systems*

- Take steps to ensure parity in the service rules (remuneration, incentives, leave, allowances) of the NRHM and RNTCP contractual staff. Contracts should be renewed in a timely manner.
- Delink the payment of salaries/ honoraria from the release of funds for the NRHM/RNTCP by the Centre. The states must set aside funds in advance for the payment of salaries (to be adjusted against the NRHM funds released later). The electronic transfer of payments should be promoted, where possible.

5. *Establish strategies to improve retention and performance of staff*

- Establish opportunities for the career advancement for STS, senior tuberculosis laboratory supervisor (STLS) and other cadres. Give preference to contractual staff while filling vacant, sanctioned posts.
- Institutionalize systems for the assessment of performance and link these to promotion systems.
- Pilot-test team-based recognition and reward systems to emphasize the critical importance of staff working together, within or across levels (community, facility, block, district), to achieve effective TB control.
- Strengthen supportive supervision skills to ensure that the quality of the TB services provided is reinforced by supervisors and that record-keeping, data collection, and reporting are also reviewed and strengthened by them.

10. Advocacy, communication and social mobilization

Background

The control of TB has long been recognized as a complex task, requiring the successful interplay of many factors. Increasing the level of awareness, engaging communities and addressing the social determinants through community-based solutions are emerging as the essential components of any intervention. Therefore, ACSM efforts are vital and integral to all aspects of TB control.

The following observations and recommendations are the product of a synthesis of the findings of field visits, the NSP's review of the status of ACSM, and an assessment both of the achievements of and constraints faced by the RNTCP in the implementation of ACSM activities.

Achievements

- The NSP's approach to ACSM reflects great vision, openness and inclusiveness. It captures the major issues and the components of ACSM are well laid out. There is a clear commitment to promote ACSM, which occupies a central position in the strategic plan.
- State-level information, education and communication (IEC) officers are in place. The Union has provided technical support through ACSM consultants to six states under Axshya, a project supported by The Global Fund (TGF).

- Agencies dedicated to the management of the media have been engaged in developing mass media campaigns and tools, such as television and radio spots. The programme's website has a dedicated IEC resource centre with relevant communication materials, which are available in various languages, for local use.
- Training workshops to build capacity for ACSM have been held at the state and district levels. Reporting of ACSM activities on a quarterly basis is now mandatory.
- During their visits to the states, the JMM's teams found that IEC materials were displayed at the health-care facilities at the peripheral level.
- Support groups for ACSM are being formed at the state level.
- The JMM's teams reported that the presence of Axshya could be felt at the state and district levels. Certain unique interventions have been undertaken under Axshya. These include training of rural health-care providers; the sensitization of village health, sanitation and nutrition committees; and empowerment of the affected community through the creation and sustenance of district TB patients' forums, and the promotion of the "Patient Charter" of rights and responsibilities. The training of the health staff in soft skills to strengthen the patient-provider relationship has been well received. One of the commendable efforts of Axshya has been the innovative "Bulgam Bhai" campaign.

Constraints and challenges

To quote the NSP: "Though modest achievements have been made in TB ACSM, the full potential of the initiative remains to be explored." Another of the observations made in the NSP is: "The visibility and the gravity of the TB epidemic is not grasped beyond the RNTCP." These statements reflect the need to accord ACSM a high priority in the programme.

Even after more than a decade of the implementation of the RNTCP, ACSM continues to be misunderstood as IEC and communication alone, with little focus on the components of advocacy and social mobilization. This is particularly the case at the state and district levels.

- The interpretation of the JMM 2009 recommendations leaves much to be desired and the action taken on them has been weak. Therefore, although strategies and plans for ACSM exist, these are programmed efforts that do not incorporate adequate professional or NGO input.
- The NSP does not put forward adequate strategies to deal with specific groups, such as people with MDR-TB or TB-HIV, children or women, marginalized populations and populations vulnerable to TB, especially migrants. The plan also fails to give enough attention to issues relating to stigma and discrimination.

- Though ACSM has been projected as an integral part of the RNTCP's strategy, there is a lack of emphasis on its operationalization and the aspects of human resources and the budget. Monitoring and evaluation, as well as assessment of impact, have not been addressed in the context of the strategic design.
- While there is a state-level ACSM plan, planning for ACSM remains weak at the district level, where such plans are synonymous with IEC plans. Further, the visiting teams reported that there was a lack of innovation in any of the plans. There is little or no data available to measure the impact of the ACSM activities.
- The integration of ACSM activities for TB into the general health system and the utilization of the communication capability and resources available under the NRHM remain a challenge.
- According to the observations made during the state visits, though the communication facilitator programme is in place, it has yet to show results.
- The programme does not have much visibility at the community level.
- All the teams observed that most of the material found to be in circulation during the field visits was only for the literate population and restricted to banners, handbills and posters. The community did not recall any sustained and visible mass media campaign against TB, with the exception of “Bulgam Bhai”, which in any case has been discontinued due to lack of funds.
- Field observations revealed that the association of TB with the DOTS logo was not very strong in the minds of the people.

Community engagement and social mobilization

Systematic involvement of civil society organizations (CSOs) is limited, although there are a few instances in which SHGs, Panchayati Raj institutions, cooperatives, the youth, CBOs, faith leaders, etc. have been involved. Not much emphasis is placed on community-based monitoring and patient-centred approaches, such as interpersonal communication (IPC) and counselling.

Project Axshya

- Systems to facilitate coordination and collaboration with the Axshya project need to be strengthened at the state and district levels.
- The design of the project allows for limited geographical coverage and also restricts the frequency of the activities carried out under it. This may restrict the impact of the project.
- The current framework for activity-based results is weak and needs to be reviewed.

- Some states have reported that the “Bulgam Bhai” campaign needs to be adapted to the local and cultural context.

Recommendations

General recommendations

- Segment ACSM into advocacy, communication and community mobilization to ensure that emphasis is placed on each component in the NSP. The strategic plan for ACSM needs to be revised to reflect this segmentation. Each component should be addressed separately.
- Develop a comprehensive operational plan to translate the well-conceived strategic plan into action. This operational plan should be based on an assessment of needs and include evidence-based innovative interventions which are locally relevant and address key areas. These areas include MDR-TB, paediatric TB, and TB among vulnerable and marginalized sections of the population, especially migrants, tribals and women.
- Monitoring and evaluation, as well as the assessment of impact on the basis of qualitative and quantitative indicators, should be included in the operational plan. The expectations of the impact of ACSM should go beyond numbers and include qualitative indicators.
- ASCM working groups, in which all stakeholders are represented, should be formed at the district level to improve planning and implementation. Extend the state-level quality ACSM support groups to all districts and states. Identify specialized cadres within the programme to work with the IEC officer. These cadres should have the capability to carry out ACSM-related activities.

Planning and capacity-building

- All plans should be supported by an adequate specified budget and human resources. Monitoring and evaluation activities are a must.
- The constitution of the national task force on ACSM should be expedited. The task force should comprise experts on advocacy, communication and the engagement of the community, each of which should be dealt with separately by different experts. The dedicated technical support in ACSM being given to some states needs to be extended. The pool of master trainers and ACSM experts outside the RNTCP must be tapped to strengthen IEC and capacity-building.
- Review the available evidence, such as the knowledge, attitude and practice (KAP) study done by The Union, Social Assessment Study done by RNTCP etc. and link it to planning and necessary funding.

Uptake of NGO schemes

- Review the NGO schemes and address the reasons for the low uptake of these schemes. The reasons include a lack of funding and flexibility, the failure to adapt to the local context and administrative delays.
- Work through intermediaries/interface agencies to outsource components of ACSM, e.g. communication to appropriate professional agencies and engagement of the community to CSOs. The accountability of these intermediaries/agencies must be ensured.

Project Axshya

- Strengthen coordination at the state and district levels.
- Make a plan to scale up and sustain the project, and extend the effective interventions and models to districts not covered by Axshya.
- Support the extension and customization of innovative campaigns such as “Bulgam Bhai”.
- Axshya must review its activities to assess their impact and should realign them accordingly.

Advocacy

Within the public system

- Develop an advocacy plan with SMART objectives to engage general health departments. The plan should set a specific timeline.
- Involve the district and local administration (district magistrates, Panchayati Raj institutions) in a systematic manner. Advocate with the departments of education at the state and district levels to integrate the existing ACSM activities with school health programmes and other health programmes.
- Advocate for inclusiveness and social support (e.g. in the areas of nutrition, transport and livelihood) with the departments of social welfare, women, tribal welfare and rural development.

With other stakeholders

- Facilitate the advocacy efforts of CSOs by providing data, resources and technical inputs.
- Develop innovative advocacy plans to engage private providers. The plans should include appropriate incentives and deterrents.
- Involve the corporate sector to facilitate the mobilization of resources and create a sense of ownership and accountability.
- It is necessary to engage the media. Set up a dedicated press relations outfit, appoint publicity officers and see to it that there is consistent communication, including communication on the risk of TB and troubleshooting.

Communication

Specific focus areas

- Develop communication plans for specific groups. The plans should address preventive aspects such as appropriate cough hygiene and disposal of sputum, as well as infection control.
- Adopt a targeted approach to the control of factors which increase the risk of TB, such as diabetes, smoking and poverty.
- Formulate an innovative communication strategy which adopts a targeted approach to different stakeholders and the general public for the prevention of DR-TB.
- Foster innovations in the use of information and communications technology (ICT). Encourage the use of mobile phone technology and social media for IEC activities and dissemination follow-up; establish helplines.
- Launch mass campaigns using multiple media to focus on the prevention (early detection) of TB.
- Utilize the RNTCP's experience to tune IEC to the needs of different audiences (doctors, health staff, community workers, patients, families) with respect to information on case-finding, treatment, follow-up and infection control.
- Develop a media plan, inclusive of measures for media buying, for the dissemination of information. The plan should be allocated an adequate budget and resources. Initiate impact studies to evaluate the existing communication material and modify/develop new material on the basis of the evidence.
- A nuanced approach should be adopted while developing the communication plans, ensuring appropriate segmentation. The plans must be customized to address local factors, such as language, dialect and culture, as well as literacy levels and socio-demographic factors.
- Facilitate the development of communication materials at the state level instead of adapting central level materials for the states.
- Review the IEC resource centre and address the reasons for the underutilization of resources. Find means to integrate the communication resources developed outside the programme into the IEC resource pool.

Social mobilization

Engagement and strengthening of the community

- In partnership with CSOs, create an enabling environment to effectively engage the affected communities.
- Identify and build the capacity of capable and willing cured TB patients to serve as advocates as well as local civil society partners, for example, in the district TB forums that have been created under the Axshya project.
- Involve the civil society in drawing up the district-level TB action plan. The civil society at the national level should be represented in all working groups and consultations. Document and recognize the contribution of the civil society.
- Facilitate community-based monitoring/patient surveys.
- Establish grievance cells at the state/DTO levels.

11. Programme financing and integration with health systems

Observations

Programme financing

The RNTCP's 2012–2017 NSP envisages the revision of financial norms and provides for detailed budgeting as the basis for proposed funding levels during the 12th Five-Year Plan. The Central government's plans for funding for the RNTCP (see figure 7) have two major features: (i) a large increase in funding during the next five years (i.e. the 12th Plan); and (ii) a large increase in the proportion of funding from domestic sources.

In recent years, the plateau in the number of cases put on treatment (around 1.5 million since 2008–2009) has been mirrored by a gradual increase in annual funding, which rose from around US\$ 65 million in 2007–2008 to US\$ 85 million in 2011–2012. The NSP proposes a substantial increase in the level of funding, the aim being to reach around US\$ 260 million annually by 2016–2017, in line with the growth in the number of TB patients put on treatment (a target of around 1.75 million patients by 2016–2017).

The increase in RNTCP funding in absolute terms is in line with the dramatic increase planned in the overall health spending of the central government in the 12th Five-Year Plan (see table 4). The proportion allocated to the RNTCP will also increase, from 1.5% of the total during the

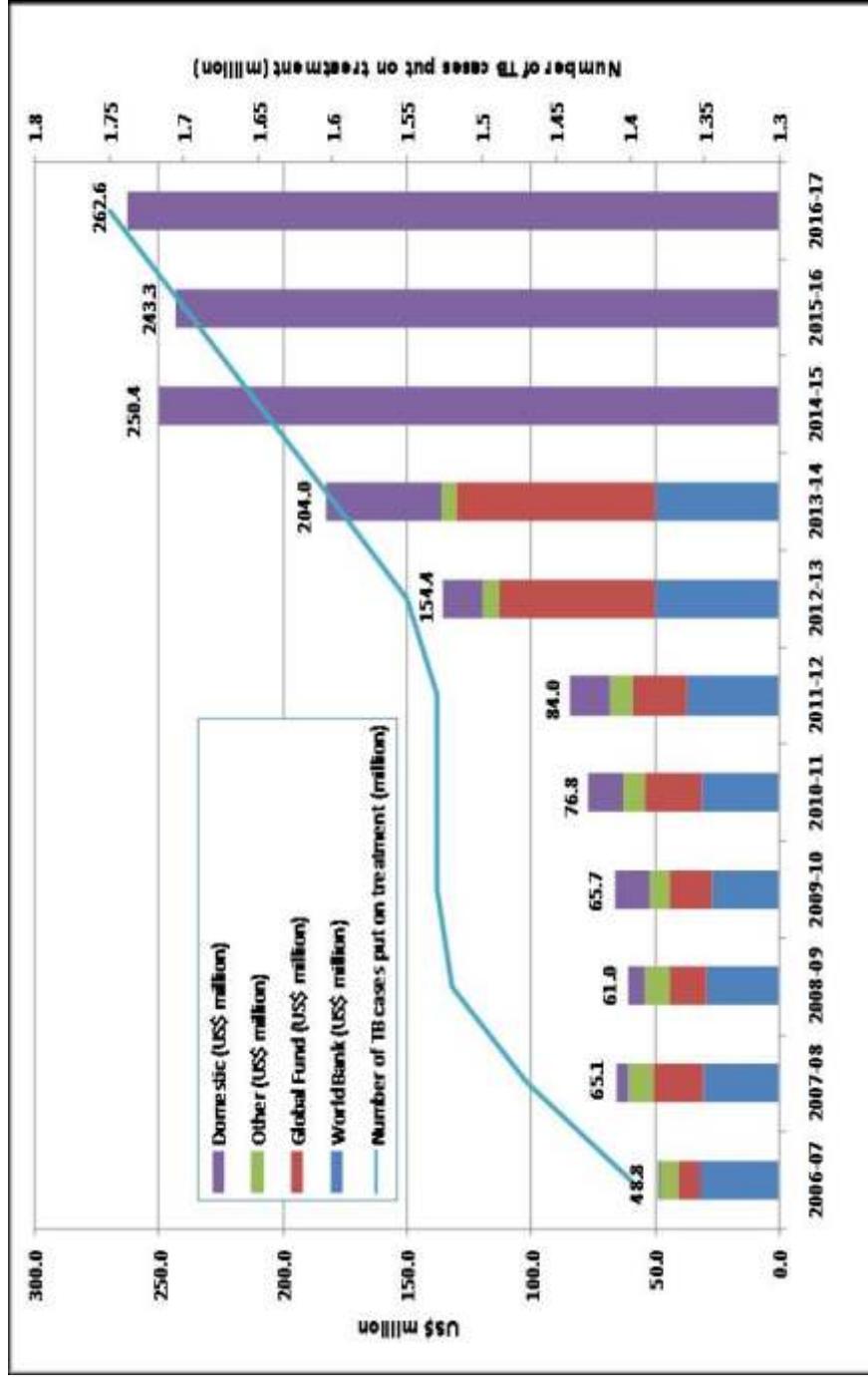
11th Plan to a proposed 1.9% in the 12th Plan. This proportion, however, can perhaps be compared to the burden of TB, as the disease causes an estimated 2.8% of all deaths in India and 6.4% of deaths among the age group of 15–49 years. In per capita terms, during the 12th Plan, the Central government's average annual spending on the control of TB is proposed to be about US\$ 0.18, which is triple the average amount spent, in absolute terms, during the 11th Plan.

Table 4. Central government health spending and RNTCP funding - 10th, 11th and 12th Five Year Plan

		US\$ million			US\$ per capita per year	
		Total Central government health spending	RNTCP	RNTCP as % of total	Total Central government health spending	RNTCP
10th Plan	2002–2007	13 093	168	1.3%	2.38	0.03
11th Plan	2007–2012	24 076	358	1.5%	4.01	0.06
12th Plan*	2012–2017	63 400	1183	1.9%	9.75	0.18

* Proposed amount

Figure 4. Evolution of RNTCP (Central level) funding, 2006–2007 to 2016–2017



Note: (i) 2012–2013 to 2016–2017 amounts are proposed (ii) World Bank financing for 2012–2013 and 2013–2014 is not confirmed (iii) Due to exchange rate assumptions, these figures may not be entirely consistent with those presented elsewhere.

Table 5. International comparisons in TB programme funding

Population (million)	Estimated TB mortality	Estimated annual new TB cases	Notified cases, 2010	Established MDR-TB cases among notified cases, 2010	TB programme budget, 2012 (US\$ million)	TB programme budget per capita, 2012 (US\$)	TB programme budget per new case, 2012 (US\$)	TB programme budget per notified case, 2012 (US\$)	GDP per capita, 2012 (US\$)	TB programme budget per new case as % of GDP per capita
Brazil	5000	85 000	81 946	1140	74	0.38	871	903	9792	9%
Russia	26000	150 000	162 553	31 000	1204	8.42	8027	7407	12 240	66%
India	320 000	2 000 300	1229 175	64 000	136	0.11	59	110	1263	5%
China	54 000	1 000 000	923 308	63 000	319	0.24	319	345	4817	7%
South Africa	25 000	490 000	396 554	9100	218	4.35	445	550	6186	7%
BRICS total	430 000	4 025 000	2 793 536	167 100						
Global	1 100 000	8 800 000	6 200 000	290 000						
% of global	39%	46%	45%	58%						

Sources: WHO, RNTCP and IMF

International comparisons of the level of resources expended on the control of TB may be made to put India's situation in perspective. It has long been the case that compared to the programmes of other countries, India's programme provides services to TB patients at a very low unit cost. This trend is likely to continue over the next five years as well. Table 5 indicates that India's budget for its TB programme is low, both in absolute and per capita terms, in comparison with other middle-income countries. For example, the RNTCP's 2011–2012 budget for each estimated new case is around US\$ 60. This compares poorly with the figure of around US\$ 320 in the case of China. Although this low budget is understandable considering that the per capita GDP of the countries with which comparisons have been made is higher, India's budget for its TB programme is lower even in relation to the GDP (i.e. the amount allocated to each new case as a proportion of the per capita GDP). The comparisons with other countries suggest that, as impressive as the proposed increases in funding under the 12th Plan may be, there is scope for even greater allocation of resources, particularly in view of the scale of the epidemic in India.

In 2006–2007, very little of the approximately US\$ 50 million of the Central-level funding came from domestic sources (see figure 7), although the state government health systems contributed a significant amount of resources (i.e. infrastructure) to TB services. In 2011–2012, funding from domestic sources represented around 20% of the total. By 2016–2017, all the Central government funding for the programme may come from domestic sources. Thus, rapid strides would have been made in the space of less than a decade, speaking of a significant commitment to the control of TB on the part of the national government. Exclusive domestic funding for the programme would require an increase in absorptive capacity as it would mean the exclusive use of national systems, e.g. for the procurement of drugs. Thus, there is a clear need to give priority to the development of the capacity of the various systems required to absorb the planned increases in domestic funding. The planned reduction in international financing for the programme also raises the question of the role that India's international partners would be expected to play in the future. It seems clear that technical engagement (as opposed to, for example, administrative “monitoring”) will become even more of a focus of dialogue between the government and its international partners.

Integration with health systems

A large part of the increase in the health spending of the Central government is accounted for by the NRHM, which was launched in 2005 and in which RNTCP is embedded. In recent years, NRHM's initiatives to bolster the primary health-care system in rural areas have met with a good degree of success, although the progress has been greater in some states than others. NRHM's efforts have resulted in significant improvements in the capacity of the primary health-care system, including administration, infrastructure, equipment and human resources. A network of over 800 000 ASHAs has been created, providing a mechanism for the extension of TB services to the village level. The past few years have seen an increasing level of integration of RNTCP planning, budgeting and management with NRHM processes at the district, state and national levels. The JMM 2006 encouraged the RNTCP to leverage NRHM investments and resources as much as possible. Over the next five years, the government intends to further integrate the RNTCP, along with other programmes, into a single administrative structure.

The NSP 2012–2017 calls for further integration of the RNTCP with the state health system and NRHM structures, notably through the alignment of TUs with the health administration at the block level. Full integration of the TB programme staff with the block-level health administration would increase the number of TUs (with a consequent increase in the requirement of human resources), bringing the average population covered by a TU from around 500 000 to around 200 000.

It was observed during the field missions to the states and districts that several challenges are likely to be faced when attempting to integrate the RNTCP with the general health system, particularly as the programme becomes less independent with regard to human resource management and financial management. In many cases, posts are not filled and there is a high turnover of staff. The administrative staff is overburdened, as the TB programme is often just one of the many charges assigned to a single official. Although the programme, as a whole, has executed more than its available budget, it is evident that there are bottlenecks in the flow of funds in a number of instances. Approved budgets are often not released until a few months after the start of the fiscal year. In some cases, the payment of salaries is delayed, while payments under PPM schemes can be delayed for even a year or longer. Overall, it appears that the TB programme is often not considered a priority by administrators because it represents only around 3% of NRHM funding.

The JMM 2006 recommended that the RNTCP go all out to take planned initiatives to improve urban health services. Over the past year, Mumbai has provided an example of the improvement of urban health services, in terms of scaling up the administrative capacity of the programme, as well as investing in the delivery of services. Although an urban health mission has not been created, it is evident that part of the planned increase in health spending laid down in the 12th Plan will be used to support health services in urban areas. Along with improving the government health service delivery systems in urban areas, it will be necessary to take further steps to engage the private sector, given its preponderant role in the delivery of primary healthcare services in urban India.

It should also be noted that as both central and state government funding for health continue to grow in the next few years, the state governments will have to play an increasingly important role in planning, budgetary and technical decisions. Although support to the health sector under the 12th Plan is likely to continue largely along the lines of the NRHM, it is evident that over time, the Central government is likely to become less directive in the use of fiscal transfers to the states.

Recommendations

Programme financing

1. The JMM commends the government's strong commitment to effectively address the TB epidemic, as evidenced by the increase in domestic funding for the RNTCP during the 12th Plan, possibly to over triple the funding available during the entire 11th Plan.
2. The government and the mission agree that the increase both in overall funding and domestic funding will make significant demands on the national systems. Bottlenecks in human resources and the flow of funds are in evidence even at the current level of financing, and these will need to be addressed if the planned increase in resources is to be effectively translated into services.
3. Reduced international funding for the programme raises the question of what role is to be played by the international partners. The government has indicated that technical assistance will continue to be required, particularly in new areas of programme development and implementation (i.e. scaling up public-private engagement). As for the JMMs, they have provided a highly productive forum for technical engagement and it is recommended that this process be continued in the future.

4. The Director of the NRHM has indicated that substantial domestic funding is available for TB control and is of the view that the programme should thus adopt bold strategies and implementation processes. The JMM encourages the programme to make full use of the current opportunity, possibly by proposing strategies that have hitherto not been advanced (i.e. larger-scale deployment of rapid molecular testing) due to assumed budgetary constraints. Overall, while the planned increases in funding over the next five years can be expected to result in significant progress, it must be kept in mind that funding levels in India remain lower than in other high-burden middle-income countries, and the scale of the epidemic will demand sustained and higher commitments as the government's fiscal capacity continues to grow in the coming years.

Integration with health systems

1. The JMM strongly endorses the NSP's proposal for further integration of the RNTCP with the state/NRHM health administrative structures, particularly the alignment of TUs with block-level health administration.
2. As the programme becomes fully, or almost fully, reliant on the national systems (i.e. for technical assistance and procurement), and as it becomes more integrated with the state health systems, limitations in those systems will need to be addressed. A number of bottlenecks, for example, in the areas of financial and human resource management, have already been identified and should be corrected. Integration with the health system need not be synonymous with centralization of management and a reduction in flexibility. On the contrary, it is evident that the large increase planned in public spending can best be translated into improved health services through greater decentralization/autonomy of management. This would include decentralization to the state, district and block level staff, which is responsible for particular programmes such as the RNTCP.
3. A specific recommendation in this area is that an empowered working group should be constituted to examine and address administrative problems and bottlenecks, as well as obstacles in human resource management and financial management. This group could work on the following issues, as identified by the mission: delays in the flow of funds, audit delays, the role of TB programme managers in financial decision-making, gaps in human resources, inequities in salaries and benefits, the use of NRHM flexible funding and other resources to support TB control efforts, and the problems related to the 75/25 Central–state funding formula.

4. It is important for the RNTCP to formulate appropriate strategies for the control of TB in urban areas. This will necessarily involve both strengthening the administration of the government health system and services, as well as effectively engaging private health-care providers. A first step could be to develop, make resources available for and implement city-specific strategies in selected high-priority urban areas.
5. Along with leveraging the resources of the state health systems and the overall Central government health sector development programme, the RNTCP should seek to collaborate with other programmes in a number of areas, particularly in the areas of the control of noncommunicable diseases (i.e. referral from diabetes screening), and government financed health insurance schemes (i.e. RSBY).
6. Finally, as it integrates itself with the overall health system, the TB control programme can also act as a pathfinder, coming up with innovations and new strategies in areas such as ICT, public-private engagement, urban health and the adoption of new technologies.

12. Research to improve TB care and control

While the fundamental biology of tuberculosis remains unchanged, the evolving nature of the epidemic and shifts in the demographic, economic and health system in which it occurs raise important research questions. In fact, the suitably ambitious goals of the National Strategic Plan for TB Control – 2012-17 cannot be met in the absence of knowledge that can only arise from appropriate research. The money saved by focusing TB control on impactful interventions will more than offset the comparatively small cost of the research required to define and refine such interventions.

Research to improve TB care and control falls broadly into three groups defined by its intended users. Operational research is predominantly of use to health care providers, implementation research is mostly of use to managers of programs scaling up innovation and health systems research is largely of use to those who manage or set policy for those systems. In this context, the JMM has expanded the scope of the review beyond operations research to all research that will be needed to achieve the goals of the NSP.

Historically, Indian research has generated many of the core strategies used in global TB control today, including home-based outpatient treatment, short course chemotherapy with rifampicin-based regimens, and decentralized diagnostic and treatment services. In the past five years, by prioritizing and centrally commissioning research the RNTCP

has successfully completed some of the projects specified in the Project Implementation Plan for 2006–2011. This included disease burden studies for measurement of TB transmission (one nationwide survey and two state surveys), limited district disease prevalence surveys (8), state TB mortality surveys (2), and state anti TB drug resistance surveys (3).

India has also begun to make progress in research capacity development. These efforts were negligible from 2006–2010, but have increased dramatically in 2010–2011. Notable efforts have been made by the Union, WHO, NTI in collaboration with USCDC, to organize a mentored year-long capacity development project oriented around programme requirements. Additional research capacity development workshops in India have been organized by PHFI. For improving RNTCP performance, medical colleges are increasingly important partners. The colleges are required to conduct prioritized and decentralized research projects of both local and national interest, as well as engage new professionals by supporting postgraduate research.

However, implementation of the 2008 RNTCP OR guidelines was been limited in practice. Review of the revised 2008 RNTCP Priority Operational Research Agenda showed that relatively few of the proposed priority research questions were successfully addressed in any form. Most of what was completed was either (a) commissioned by CTD from national institutes or led directly by national or international partners, (b) included in the TRCF-WHO MDP project and driven by a separate research funding and promotion process, (c) driven by partners of RNTCP as part of project implementation, or (d) completed as part of operational research training projects. Research from medical colleges was oriented towards relatively low-impact clinical research questions, such as duration of treatment for specific forms of extra-pulmonary TB. Furthermore, translation of research into policy has been largely ad hoc, driven by the availability of research or changes in global guidelines and not systematically driven by the potential health impact of the issue.

Because of the enormous scope of potential research topics it will be critical to rigorously prioritize efforts according to their relative ability to enable achieving the goals of the National Strategic Plan. To achieve relevance this prioritization process must be driven by the RNTCP itself in partnership with the scientists who are capable of its execution. This process has made progress in the past few years with the elucidation of over 110 research topics. However, this list must be revisited in light of the

NSP and the findings of this JMM. Ideally, this prioritization would include rigorous quantitative analysis of the potential impact of the research results to decrease India's TB burden. The high-level challenges that must be addressed are: (i) extending essential services to patients diagnosed and managed in the private sector, (ii) improving early case-finding, particularly among the HIV-infected and vulnerable, (iii) improving surveillance systems, and (iv) reducing TB morbidity and mortality, including putting patients on the correct treatment from the outset of therapy.

Successfully meeting these needs will require augmentation of the current research efforts with an increasingly dynamic process. For a plethora of potential interventions, the effort must go beyond small pilots to determine their impact to projects that implement for a million people, rapidly evaluating that effort, and stopping what is not working while scaling-up what works to 10 million, then repeating this cycle with a hundred million, and finally a billion. This rapid iteration of “innovation, evaluation and scale-up” is the core work of implementation research. Incorporating this scale up into the dynamic Indian landscape is the work of health systems research.

The JMM fully endorses the plans articulated in the NSP to establish a National Research Cell. The cell will develop normative guidance, commission relevant and priority research, synthesize evidence, review and recommend approval of research proposals, fund research institutions, manage and monitor research activities and conduct research dissemination and capacity building. In order to accomplish this, a dedicated research officer at CTD will be needed to manage a process whereby the programme's research needs are prioritized, addressed and incorporated into policy. Doing so will also require an increasingly coordinated effort to foster research capacity.

Furthermore, India must also tap into its innovative scientific and technical capacity at every level in the scientific process, from the most basic to applied. While it is not the responsibility of the RNTCP to coordinate this, it can play a critical role in broader government efforts that define, connect and fund research at all relevant agencies such as CSIR and ICMR. These efforts must be forward looking and incorporate the development and deployment of new diagnostic tests, drugs and vaccines.

Specific recommendations

- The goals of the National Strategic Plan will not be achieved without knowledge that can only be gained through a spectrum of research activities.

- There is a well-established mechanism for operations research that is critical for learning from local programmatic data. The established national research mechanism continues to be responsible for operation research.
- This needs to be augmented by a National Research Cell for normative guidance, commission priority research, synthesize evidence, fund research institutions, manage and monitor research activities, and conduct research dissemination and capacity building. This cell needs to be promptly staffed by a senior researcher, technical officers, a statistician and accountants as detailed in the National Strategic Plan.
- Given the challenge of universal access, the National Research Cell must rigorously prioritize the research agenda in order to meet the needs of CTD. The current long and comprehensive lists of possible research must be reduced to a short list of questions prioritized by their potential to achieve the goals of the National Strategic Plan.
- There needs to be increasing attention to implementation research involving a rapid cycle of piloting innovation, evaluation, optimization and expansion to scale - enabled by rapid review and funding mechanisms.
- There has been commendable progress in building capacity through efforts such as the OR mentorship programme by CTD, WHO, The Union, CDC, and NTI. However, efforts are needed to increase the scope and scale of capacity training, including increased involvement of medical colleges.
- The RNTCP needs to promote partnerships for the clinical and applied research in the country. This need to include engaging more deeply with the full spectrum of Indian research expertise including DBT, ICMR, CSIR and the private sector. This needs to include coordinated calls for jointly funded proposals on prioritized topics.

13. Technical support

Introduction

Technical support from a variety of sources, both at the national and state/district levels has played a major part in making the RNTCP's achievements possible over the past decade. This JMM chose to address technical support as an independent topic, on the premise that the provision of comprehensive, coordinated technical support will continue to be a valuable component of the RNTCP's activities in the NSP 2012–2017.

Context

In broad terms, according to the JMM discussion group's working definition of technical support, the latter consists of inputs from various parties to support RNTCP policy, planning, implementation, evaluation and advocacy. Technical support includes activities supported by national resources, as well as activities supported by bilateral or multilateral development agencies. Technical support has been provided by diverse agencies and on different thematic areas. However, despite the complexity and diversity of the parties and providers involved, the CTD has done a commendable job in terms of coordination. As for support from national sources, the technical arm of the CTD is the NTI, Bangalore. The other key sources of technical support at the national level include the LRS Institute, National Institute for Research in Tuberculosis (NIRT), JALMA Institute, and Medical College Task Force.

Under agreements with the Ministry of Health and Family Welfare (MoHFW), the partner technical agencies, WHO (funded by USAID and the Department for International Development [DFID]) and the Union (funded by the GF), have placed consultants in the CTD; these operate under the direct supervision of the CTD but with the help of technical guidance from the WHO Country Office (WCO) India. The technical unit of the WCO India works closely with the CTD and provides comprehensive support. FIND-India provides focused, extensive technical support for laboratory services. Its funding sources include the GF and UNITAID. The partners have contracted agencies to implement specific tasks related to technical support, e.g. the USAID-supported agency, PATH, has contracted Initiatives Inc to carry out human resource studies and analysis. It has also supported workshops on the AIC, besides sharing of experiences in the laboratory. To generate evidence that can help guide the RNTCP, key research and demonstration projects have been launched with the support of the partners. These include the demonstration of new diagnostics (LPA, CBNAAT), studies on the reach of services to marginalized populations, and an extensive operational and clinical research portfolio through the USAID-supported NIRT Model DOTS Project. Teams of consultants for the Indian Medical Association (IMA) (GF-funded), Project Axshya (GF-funded) and the Catholic Bishops Conference of India—Coalition for AIDS and Related Diseases (CBCI-CARD) (GF-funded) also support the implementation of specific projects.

At the state level, the State TB Training and Demonstration Centres (STDCs) have assigned staff which could provide local technical support. In addition, the STCs have a few contractual staff members who, in theory, should be able to provide technical support to the districts. WHO-RNTCP medical consultants provide support as part of state or regional teams. Developed originally to facilitate the expansion of DOTS, this network has been retained and given a new focus, i.e. supporting state and district level planning, developing the capacity of state and district officials, and coordinating new initiatives/policies and translating them into programme practice.

The major achievements made largely due to the availability of technical support include laboratory scale-up, EQA, coordination of the TB and HIV programmes, and expansion of MDR-TB services. Since the last JMM, the number of WHO-RNTCP consultants has decreased in the states that are performing well, and as a result, the total number contracted has fallen from 85 to 75.

Challenges

Simply put, given the lofty aspirations articulated in the NSP, the supply of technical support is likely to prove inadequate and it is doubtful whether it can serve to meet our future needs. Whereas in the past, technical support focused primarily on the public sector challenges of quality, services and new activities, those required for the future will have to be of a markedly different nature. Most importantly, the challenge of engaging the private sector, at scale, looms large. This is an area for which we have no good roadmaps. Until now, technical support for the engagement of the private sector has been neither sufficient, nor sustained. Even within the public sector, the pending transition of the health systems and their re-alignment with the NRHM management structures will require comprehensive restructuring of the programme, as well as a large-scale effort to develop the capacity of several thousands of supervisors and block Mos.

The nationwide scale-up of MDR-TB diagnostic and treatment services is an organizational and management challenge that should not be underestimated; despite the successes achieved so far. In reality, less than 5% of the estimated MDR-TB cases are being diagnosed and treated today. The deployment on a large scale of decentralized clinical and laboratory services for this complex clinical condition have not been attempted previously. The only comparable effort was the nationwide scale-up of ART services. This scale-up, however, was vertical and limited, and did not aim at the upfront integration decentralization and extensive coverage being envisioned by the RNTCP for MDR-TB. The development of the national case-based electronic surveillance system will require complete retooling and a transition to a new approach to the daily management of patients, monitoring, supervision and reporting. The scale of the implementation of comprehensive ICT applications, particularly those utilizing mobile data linkages and those for automated reimbursements for health workers/beneficiaries, is still nowhere near the required level.

While the needs have increased, the supply of technical support available appears to be dwindling. The NSP envisages measures for relatively modest strengthening of the human resources of national sources of technical support, such as the national institutes and STDCs. These measures include increasing the number of technical officers in the CTD and having more coordinators for various staff in the STCs. The current plans do not meet the need, and no clear plans have been made for the development of the capacity of the staff to address the challenges that may arise in the future.

The projects supported by the GF have included technical support, but their duration is limited and there are no current plans to sustain those activities. DFID has been a key underwriter for WHO's technical support to the RNTCP. Approximately half of the existing network of consultants and the CTD-embedded drug procurement and logistics support unit that have been deployed are based on this funding stream. With the planned departure of DFID, there is going to be a major shortfall of resources, which should have been met through a planned transition to GF support over 2015.

The priorities and planning of the WCO have been revised in the light of a new and broader Country Cooperation Strategy. While USAID's support for the provision of technical support by WHO has been remarkably consistent and unwavering for the past decade, there is increasing pressure that the parties concerned justify and define the end-point of the ongoing investment. The key problem facing WHO and the supporting partners is mapping out the transition from state-level technical support to indigenous provision of technical support.

Opportunities

In some states, the STDCs are already playing a major role in providing technical support to the STCs. Two examples are Karnataka and Gujarat. Medical colleges have consistently declared their willingness to assist and have made their faculties available, though the RNTCP has not always facilitated their participation, with difficulties arising especially with respect to travel arrangements and reimbursements.

The NSP has proposed strengthening of human resources both in the CTD and STCs, as well as in the NRLs and IRLs.

Recognizing the key role played by WHO, the Mission reacted positively to the proposition that the responsibility for the provision of technical support at the state level for the duration of this NSP could be borne by the states. The Mission issued a strong statement in favour of the continuation of WHO support to the RNTCP, both at the national and state levels, with an acknowledgement that this support should increasingly focus on the capacity-building of technical support resources, particularly in the STCs, STDCs and national institutes. The international community at large, including both technical and developmental agencies, recognizes the central role that India has played in the global fight against TB and is highly committed to helping India achieve the ambitions articulated in the NSP. India remains a point of focus not only because of the high burden of

disease in the country, but also because of its commitment to TB control and the opportunity it offers to learn how to intensify TB control measures in other nations with emerging economies.

Recommendations

For RNTCP

- Strengthen national investment in technical support through the NRHM annual action plans. The following areas of investment should be considered:
 - A proposed cadre of technical officers in the CTD
 - Development of national institutes and capacity-building of the staff of NRLs
 - Contractual consultants (NRHM)
 - STC coordinators and STDC staff
- In the light of the expanding need for technical support, map the needs which are not being met by the existing expertise and those which are unlikely to be met by expertise that would be available in the near future.
- Engage technical partners to help with the development of appropriate proposals to be presented to developmental agencies for their support in fulfilling the needs identified in the area of capacity-building.

For WHO and developmental partners

- Secure the resources necessary to sustain technical support for the RNTCP at the national and state levels through the duration of this NSP, particularly by garnering the GF grant support available.
- Increase the focus on helping the CTD to successfully implement the national case-based electronic surveillance system, on drug distribution controls and implementation research aimed for improving case finding and capacity development. Greater emphasis should be placed on creating a public policy and programme environment that facilitates the engagement of the private sector at a large scale.

Annexes

Annex 1 - List of participants

Joint Monitoring Mission, RNTCP 21-31 August 2012

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Annex 2 - List of team members for field visits

Joint Monitoring Mission, RNTCP 21-25 August 2012

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		State	District(s)
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		State	District(s)
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Annex 3 - State reports

Summaries of findings and recommendations

Bihar

The team visited Patna and Darbhanga. The facilities visited were:

Patna

- Patna Medical College
- DTC TU
- Fatua TU
- RMRI Patna
- STDC and IRL, DOTS Plus site and SDS
- Holy Family Hospital
- Doyens and Sen Laboratory (private)
- IMA building
- Project Axshya office

Darbhanga

- Darbhanga Medical College
- STDC, Darbhanga
- Biraul TU
- Keoti TU
- RB Memorial Hospital (private), Sharma Laboratory (private), Geetha Laboratory (private)

Political and administrative commitment to universal access to TB care

Achievements

- There has been increasing support from the state administration and NRHM in terms of:
 - Renovations (at the SDS, Patna STDC and Patna IRL)
 - Extra procurements (refrigerators, tuberculin)
 - Financing (NRHM additionalities)
 - Regional PMDT review (organized and funded by the state)

Constraints and gaps

- Financial flows are weak. There is under-spending, with only 53% of the allocated RNTCP budget being spent.

- There are chronic gaps in key positions (31 out of 38 DTO posts have been established; only one out of 38 DTOs works full time; 20% of STS and STLS posts have not been created).
- The STDCs are non-functional.
- The district general health systems' sense of ownership of the RNTCP is poor.
 - The involvement of the CS and block medical officer (BMO) in the programme is minimal, even if the BMO is designated the MOTC.
 - ANMs are not involved in case-finding or supervision of case-holding.

Recommendations

- Funding flows must be improved.
- The STDCs need to be made functional.
- There is a need to establish ownership:
 - The NRHM and the general health system must have a sense of ownership of the RNTCP.
 - The monthly meeting of civil surgeons at the state level should be utilized to strengthen RNTCP systems.
 - The ownership of TB services should be cascaded to the field level.
- Organize district BMO meetings, fortnightly block-level ANM meetings and monthly ASHA meetings.
 - There is a need to develop the capacity of the civil surgeons to monitor programme services (with the support of the NTI).

Case-finding activities

Observations

- The health system is still developing. It is functional only down to the block level. However, OPD attendance is improving.
- The number of TB suspects being examined is increasing.
- The overall case notification rate (CNR) is low (72 vs 125), and is falling.
- There is no situational awareness of the underlying burden.

Recommendations

- Activate the general health system to improve case-finding and public referral.
 - ANM and ASHA facilitators should be encouraged, and incentivized, to support case-finding activities (i.e. detect and mobilize chest symptomatics).

- Optimize the functioning of DMCs, but only where OPDs are functional.
- Develop the capacity of medical staff (mostly AYUSH at PHCs) to handle smear-negative TB Dx, e.g. by conducting chest X-rays.

The above must be done, but the potential is modest, given the limited reach and capacity of the public health system.

- Strengthen notification from the formal private sector to get an idea of the burden on it.
- Engage health providers beyond the public sector, formal and informal.

Diagnostics and laboratories

Achievements

- The DMC network is expanding.
- Progress is being made in establishing capacity for LPA, solid and liquid culture and DST in-state.
 - The LPA accreditation process is under way at the IRL. There are plans to introduce solid and liquid culture and DST in 2013.
 - Solid culture is being used at the Rajendra Memorial Research Institute of Medical Sciences (RMRIMS) to monitor the treatment of MDR-TB patients. The DST accreditation process is under way.
 - It is planned to set up a BSL-3/C+DST LPA laboratory in Darbhanga TBDC, in collaboration with the Damien Foundation India Trust.
- The Bihar Indian Medical Association has been spreading awareness regarding the ban on serodiagnostics.

Constraints and gaps

- Mostly contractual laboratory technicians are being used for microscopy. There is minimal or no use of laboratory technicians from the general health system. Hence, 349 of the 680 (50%) posts of laboratory technicians are vacant.
- The number of DMCs is far below the population norm, but almost every block PHC and above has a DMC.
- 35 of the 181 posts for STLs are vacant, which means that quality of lab supervision is being compromised.
- Currently, there is not enough capacity for DST in the state.
- The IRL does not have a generator and cannot operate properly (the freezers get defrosted and the LPA primers ruined).
- Stock-outs have been reported in microscopy laboratory reagents.

Recommendations

- The functioning of the microscopy network requires strengthening.
 - There is an urgent need to fill the sanctioned posts (see section on HR).
 - The quality of microscopy should be assured.
 - Lack of STLS and/or vehicles suggest EQA (on-site evaluation [OSE], PT, RBRC) of DMCs is not being conducted in conformity with the standards.
 - Procurement mechanisms should be improved to prevent shortages of laboratory reagents in districts (see section on drugs and supplies).
- There is a need to increase the capacity for culture and DST to meet the targets for the scale-up of DOT Plus services.
 - Trained microbiologists and a reliable power supply are required at the IRL to start services. In the meantime, partner laboratories (RMRIMS, private) should be engaged.
 - There is a need for certification. Private-sector laboratories are wary of collaborating with any state service due to a history of delay and default in payments.
- The supervisory role of the Bihar IRL requires strengthening.
 - The posts of microbiologists in the IRL should be filled according to the criteria and vehicles should be provided as this will help ensure that OSE in the districts and PT of STLS are conducted as per the standards.
 - OSE should be conducted on an annual basis and regular communication should be established with the NRL.
- If approved by the RNTCP, CBNAAT and other low-touch, field-friendly DST technologies should be deployed in Bihar, as follows:
 - At district laboratories, medical colleges and tertiary hospitals that are functioning well, to be used for MDR-TB suspects, in order to reduce the time taken to initiate MDR-TB treatment, as well as the load of diagnostic culture and DST at central laboratories
 - At selected partner NGO/private laboratories which have certification, in order to increase case-finding and reduce the time for the initiation of treatment

Treatment and treatment support

Achievements

- The indicators for case-holding are satisfactory.
- The involvement of community DOT providers is high (67% of all notified cases).

Constraints and gaps

- There is a stock-out of streptomycin injection and rifampicin (150 mg).
- The buffer stock of drugs of the standard regimen has become dangerously low state-wide.

Recommendations

- ANMs should be employed for the supervision of community DOT providers, instead of only senior treatment supervisors (STS).
- Reporting on adherence needs to be simplified. Besides, the failure to simplify reporting will hamper PPM efforts and hinder case-finding.

Programmatic management of DR-TB

Achievements

- PMDT (criteria A) had been initiated in six districts by April 2012.
- 46 patients have been registered for treatment.
- One patient is being treated by an NGO.
- Training in PMDT has been conducted in all six districts.
- Five more districts have been appraised for the introduction of PMDT.
- According to the providers, the implementation of PMDT is feasible.

Constraints

- There is no accredited DST laboratory in the state.
- No plans have been made to strengthen the capacity of DST laboratories.
- The staff at the DST laboratories is inadequate and the reporting structures are dysfunctional. The existing staff does not have the appropriate qualifications and requires proper training.
- There is a mismatch between diagnostic capacity and the stock of drugs. The diagnostic capacity is too low for the utilization of the drugs in the state store.

Recommendations

- Systems management should be improved to coordinate the identification of those suspected to have DR-TB, diagnosis and treatment.
- The capacity of DST laboratories should be strengthened (see section on laboratories).
- There is a need to expedite the establishment of accredited laboratories and DOTS Plus sites.

TB care in private sector and PPM

Achievements

All are in agreement that it is critical to achieve the NSP goals. Policy is conducive for PPM with many schemes under RNTCP.

- There are ongoing efforts to involve the private sector, e.g. Axshya has conducted 200 workshops to sensitize NGOs.

Constraints and gaps

The results up till now have been unimpressive.

- Funds
 - Only 4% of the state's allocation is for PPM.
 - Only one-third of this is actually being spent.
- There are either delays in payments or the payments are insufficient (no DOTS provider has been paid for 2 years).
- The private sector accounts for less than 1% of the cases notified.

Recommendations

PPM needs to be prioritized.

- Funding should be increased and the flow of funds improved.
- There is a need for innovation, and not just more schemes, in keeping with the vision of the NSP.
- Laboratory services should be outsourced.
- Nikshay should be used for close monitoring.

TB-HIV

Achievements

- State-level coordination is satisfactory.
- The TB-HIV package was rolled out from February 2012.
- State-level training has been conducted, while sensitization at the district level is ongoing.
- DMC laboratory technicians under contract with the RNTCP have been sent to the Bihar State AIDS Control Society (BSACS) for training in testing for HIV.

Constraints and gaps

- The activities in this area are just starting. The ICTC is half non-functional due to HR issues.
- The quality of recording and patient referral is uneven or poor, and additional monitoring and supervision are required in this area.

Recommendations

- The capacity for appropriate referral and documentation must be strengthened.
- DMCs should occupy a central place in the roll-out of whole-blood screening for HIV.

Paediatric TB

Achievements

- Tuberculin is available.
- The block PHC has been supplied with a refrigerator by the NRHM.

Constraints and gaps

- There is a lack of situational awareness of the extent of paediatric TB.
- Normative guidance on the diagnosis of paediatric TB is weak.
- There is no link between the demand and supply of tuberculin.
- The tuberculin supplied to the district had only 7 months of shelf-life remaining.

Recommendations

- Train paediatricians and medical officers in the policy of diagnosis and treatment of paediatric TB.
- Link users to the supply of PPD and syringes.

Human resource development

Achievements

- Peripheral RNTCP staff members are working hard to implement the programme according to the guidelines.
- Bihar has trained all ASHAs as DOT providers, expanding access to all communities. However, there is no standard curriculum of training.
- State-wide, Bihar has increased its staff at all levels in the last two years. Most of these staff is contractual.

Constraints

- Despite the gains, Bihar still faces a major crisis with respect to human resources.
- The public sector accounts for only 0.5 doctor/10 000 population.
- Only one DTO has a dedicated full-time post. In the case of the others (37), the responsibility is just an additional charge, and in seven districts, the post of DTO has not been sanctioned.
- Twenty per cent of the positions of contractual supervisors funded by the RNTCP remain unfilled.

- Only 50% of the positions of laboratory technician have been filled.
- There are frequent delays in the payment of salaries, incentives and allowances to the staff, as well as in the renewal of contracts. Of the honorarium budget, only 49% has been spent.
- There are disparities between the salaries of the contractual staff hired by different programmes and between those of the contractual staff and regular staff.
- Many staff members do not have the qualifications or skills required to perform their roles in the RNTCP programme. The training provided is inadequate or not standardized.
- The standards of the training being provided are still far from what is expected. The level of training at the STDC in Patna is below par, while the STDC in Darbhanga is non-functional. Only 24% of the RNTCP training budget has been spent.
- The DTOs have technical training but lack the training materials and skills required to provide skills-based, quality training to community-based cadres.

Recommendations

- All posts of DTO should be sanctioned.
- The vacant RNTCP staff positions must be filled.
- A clear policy is needed for the harmonization of the salaries of the contractual staff.
- Systems must be established to ensure the timely payment of salaries and honoraria, as well as timely renewal of contracts.
- Technical assistance should be sought to strengthen the capacity of the STDC to conduct appropriate skills-based training, and to provide supervision and technical oversight.
- A state-wise training plan needs to be developed, as do standards for training. The progress of training should be monitored against these standards.
- Oversight of the STDC should be improved to enhance the quality of training and ensure compliance with the standards. There is a need for standardization of the training methods used and the content of training imparted at the district level.

Epidemiology, M&E, notification

Achievements

- Some IE has been conducted in the state.
- Increasing attention is being paid to the quality of data (there is less target-based monitoring and review and less fudging).

Constraints and gaps

- Training for Nikshay is pending.
- The state lacks the capacity for the supervision of M&E activities, besides WHO consultants.
- The STDC is more or less defunct.

Recommendations

- Capacity of the STDC should be strengthened.
- Private and laboratory notification should be pursued aggressively. Notification should be linked to new incentive-based approaches, where possible.

Drugs and supplies

Achievements

- There is an uninterrupted supply of key FLDs and SLDs in the six districts where PMDT has been rolled out.
- The SDS is functioning well. Among other things, it has sufficient storage space and equipment, as well as an air conditioner for SLDs.
- The supply chain from the SDS to the district pharmacies is functional.
- Less than 2% of the drugs in the SDS have reached their expiry date.

Constraints and gaps

- Inadequate stock of FLDs will lead to shortages by 2013.
- Streptomycin has not been available for the past one year and patients are compelled to purchase it.
- The district drug store does not have an air conditioner.
- There is no back-up power supply in the SDS.
- Mechanism for the procurement of laboratory supplies is inefficient.
- Shortages in supplies of reagents.

Recommendations

- Streptomycin should be made available immediately.
- FLD orders should be filled with all requisite information.
- Back-up power supply must be installed in the SDS.
- It is advisable to return to a rate contract system for essential TB laboratory consumables (like the arrangement in force till 2008).
- Outsourced PHC services (power, cleaning) and supply services should be extended to the RNTCP units, which should also receive support from the general health system.
- District drug stores need to be equipped with air conditioners.

Programme financing and strengthening of health system

Achievements

- The basic functions and activities are being carried out, but to varying degrees.

Constraints and gaps

- The programme's expenditure is inadequate.
- The management is weak and the standards of management are poor.
- Key processes and activities are not being monitored and the gaps are not being addressed.

Recommendations

- Expenditure should be increased.
- Technical assistance should be provided to build the capacity of senior programme managers to manage the programme's activities and expenditures and ensure effective implementation.
- Clear management standards and processes need to be developed, along with systems for monitoring the programme's activities.

ACSM

Achievements

- The presence of Axshya can be felt at the state and district levels.

Constraints and gaps

- There are fundamental limitations in the design of Axshya; 'drop in a bucket' e.g. 1 training/year of 30 RMP; but there are >1000 RMP in the district.
- The current framework, which relies on activity-based results, is weak.
- The state and districts rely heavily on Axshya and are not doing much in terms of ACSM.

Recommendations

- The monitoring framework should be expanded to allow for the mobilization of local resources.
- The state and districts should recognize that ACSM is not outsourced to Axshya, but supplementary to RNTCP-owned activities.

Karnataka

State profile

- Capital: Bengaluru
- Districts: 30 + 1 (Bengaluru City)
- Area: 191,976 km²
- Population: 61,130,704 (2011 census)
- Literacy rate: 75.6%
- All districts covered by RNTCP since 2004
- Total number of TB cases notified in 2011: 70,596
- New smear-positive (NSP) case notification rate in 2011: 47%
- Treatment success rate for NSP cases in 2010: 82%

District profiles

Mysore (10 facilities visited)

- Population: 3 million
- 40 PHCs
- 794 private facilities
- 6 TUs
- 32 DMCs
- 26 co-located DMCs/ICTCs
- TB-HIV co-infection (2011): 9%
- Total number of TB cases notified (2011): 4144
 - NSP cases: 36%
 - SNP cases: 20%
 - Extrapulmonary (EP) TB cases: 22%
 - Retreatment cases: 17%
- Paediatric TB cases: 6%

Bagalkot (12 facilities visited)

- Population: 1.9 million
- 60 PHCs
- 632 private facilities
- 4 TUs
- 20 DMCs
- 19 co-located DMCs/ICTCs

- Cases of TB-HIV co-infection (2011): 13%
- Total number of TB cases notified (2011): 2176
 - NSP cases : 39%
 - SNP cases: 32%
 - EP cases: 11%
 - Retreatment cases: 18%

Political and administrative commitment to universal access to TB care

Achievements

- The district administration is supportive and regular reviews are conducted, including during NRHM meetings.
- Regular interdepartmental meetings (revenue, social welfare, etc.) are held to enhance the coordination of activities.

Constraints and gaps

- Files related to the appointment of some contractual staff are pending.

Recommendation

- There is a need to fill certain posts, especially those related to DR-TB.

Diagnostics and laboratories

Achievements

- The number of DMCs is adequate. They have trained staff and the required logistics.
- EQA and data capturing activities are being conducted in the DMCs visited.
- There is sharing of functions between the DMCs and ICTC.

Constraints and gaps

- The implementation of practices for infection control was seen to be poor in most facilities.
- Repeat sputum examinations are rarely carried out.

Recommendation

- The implementation of practices for infection control must be prioritized.

Treatment and treatment support

Achievements

- DOT, as per the RNTCP, is being implemented and is adequately decentralized.
- RNTCP regimens are being followed.

Constraints and gaps

- Despite the implementation of DOT, the default rate is high, especially among retreatment cases.

Recommendation

- Attempts to provide counselling to patients should be stepped up. The counselling should cover alcohol-related and other problems.

Programmatic management DR-TB

Achievements

- LPA services are in place at the state level.
- The IRL is in the process of obtaining certification for solid CDST.

Constraints and gaps

- The scale-up of PMDT services, including the training of staff, is proceeding at a slow pace.
- The district drug stores do not have sufficient space to stock SLDs.

Recommendation

- The implementation of PMDT services should be expedited; ensuring that quality is maintained at the same time.

TB care in private sector and PPM

Achievements

- Line listing of PPs has been done and some TBHVs visit private for-profit providers.
- The Karnataka Private Medical Establishment (KPME) Act is being implemented to ensure that PPs report TB cases to the government.

Constraints and gaps

- The level of involvement of PPs is very low and their treatment practices are poor.
- PPs are not aware of the importance of notifying cases of TB.
- Serological TB tests are still being used by PPs.

- There is no plan to systematically involve the private for-profit sector at any level.
- The contribution of the newer private medical colleges is too low, despite the investments made by the RNTCP.

Recommendations

- Plans should be made to involve the private sector at all levels.
- The state and district authorities should broker the engagement of PPs in the RNTCP and see to it that they participate actively.
- The KPME Act needs to be enforced more effectively.

TB-HIV

Achievements

- The model of DMC–ICTC integration is excellent.
- The coverage of services is high (above 90%), with that of ART being nearly 80%.
- There is excellent coordination and collaboration between SACS and STOs at all levels. SACS has displayed leadership at the state level.
- Doctors involved in ART are very knowledgeable about the treatment of TB. Patients are started on ART regardless of the CD4 count.

Constraints and gaps

- Despite the fact that the programme has good linkages with the provision of CPT and ART, the death rate among HIV-infected TB patients is still 10%–15%.
- Delay in the diagnosis of TB among PLHIV remains a problem, and ART is not introduced early in most cases. In general, TB infection control measures are very weak.

Recommendations

- Focused plans should be made for the early diagnosis of HIV. ICTCs should be set up in sites without a DMC.
- Measures are required to link PLHIV to ART services, which should be offered in good time.
- TB infection control measures should be stepped up in all ART centres.

Paediatric TB

Achievements

- All the key staff members are trained in the guidelines for paediatric TB.
- The drugs for paediatric TB are available.

Constraints and gaps

- Paediatric patients constitute less than 10% of all TB cases.
- Private paediatricians use different regimens.

Recommendation

- There is a need to increase the number of cases of paediatric TB being diagnosed.

Human resource development

Achievements

- Regular training of the staff has been conducted at all levels.
- Level of motivation and commitment of the staff is high.

Constraints and gaps

- There are several vacancies, particularly in Mysore.
- There are five vacancies for the post of DTO at the state level.

Recommendations

- The process of filling up of vacancies should be expedited.
- There is a need to explore alternatives to make the post of DTO attractive.

Epidemiology, M&E, notification

Achievements

- There is good communication between the STO and administrators at the state and district levels regarding TB notification.
- The M&E system is functional and documentation is satisfactory.

Constraints and gaps

- Wider publicity of the TB notification is needed.
- Supervision is being affected by delays in the release of funds.

Recommendation

- Supervision by STS and STLS needs to be strengthened.

Drugs and supplies

Achievements

- The supply of most drugs is regular.
- The facilities and drug stores visited had a satisfactory system for monitoring the supply of drugs.

- PLHIV on second-line ART drugs are being supplied with rifabutin by the state.

Constraints and gaps

- There is a shortage of rifampicin (150 mg), streptomycin and loose INH for prophylaxis.
- The drug stores in both districts have too little space to stock supplies.

Recommendation

- Problems with drug stores to be addressed especially in anticipation of arrival of second line TB drugs.

Programme financing and strengthening of health system

Achievements

- Annual action plans have been drawn up by the state and districts.
- Statement of expenditure is available.

Constraints and gaps

- There are delays in the release of funds for contractual staff—salaries have not been paid for 4–6 months.
- The contractual staff are dissatisfied with the remuneration.

Recommendations

- Find ways to deal with the delay in the release of funds.
- Like the NRHM staff, the RNTCP contractual staff should be provided with mobile SIM cards.

Advocacy and communication

Achievements

- IEC materials on TB are being displayed at several sites, including ART centres.
- Activities are being undertaken to raise awareness, including in schools.

Constraints and gaps

- No data are available to measure the impact of the activities under the programme.
- There are no clear plans on how to do follow up on the ACSM activities.

Recommendation

- There is a need for regular follow-up, especially by community-based workers, of the impact of activities for the generation of awareness.

Engagement of community

Achievements

- ASHAs, anganwadi workers, ANMs, TBHVs and MPWs have been involved in the RNTCP, particularly to help with treatment support.
- The ASHAs are generally well-informed about the RNTCP, even though there is no training scheme in place.
- Work done by the TBHVs in urban areas, particularly in Bagalkot, is excellent.

Constraints and gaps

- The involvement of NGOs is limited and scattered.
- The community workers have not been involved in active case-finding.
- The contribution of community workers is not being documented systematically.

Recommendations

- It is necessary to increase the involvement of community workers, particularly ASHAs and TBHVs, in case-finding at the community level.
- Improvements are required in the monitoring of the contribution of community workers, at least in the areas of case-finding/referral and successful treatment outcome.
- Attempts should be made to strengthen the engagement of NGOs to assist community workers whenever needed.

Maharashtra

State profile

Population: 113.9 million

Administrative set-up: 35 districts, 60 RNTCP districts/reporting units, 279 TUs, 1381 DMCs, 3124 PHIs and 62221 DOT providers/community volunteers.

Full state coverage under RNTCP achieved in 2003, PMDT services initiated in Nagpur division in 2007 with full state coverage achieved in August 2012.

Key programme indicators: Annual (2011) new smear-positive pulmonary TB (PTB) case notification rate 47 per 100000 (59% case detection rate); treatment success rate of new smear-positive PTB cases 85.8% (2010).

Districts visited by JMM: Aurangabad Municipal Corporation, Aurangabad Rural and Mumbai Municipal Corporation (Baiganwadi Urban Health Post, Dharavi Urban Health Centre and Laboratory, GS Medical College and KEM City Council Hospital, District TB Office in South Mumbai, Group TB Hospital, District TB Office for wards A, B, C, Mumbai, Lilavati Hospital).

Key observations

Services have been scaled up in Mumbai and across the state of Maharashtra. In Mumbai, 24 DTCs are being established and there are full-time, trained DTOs in place.

- The number of TUs and DMCs has increased with decentralization in Maharashtra.
- There has been a reduction in the number of vacancies of key staff, particularly medical officers, across the state.
- The attitude and commitment of TB-related staff were observed to be positive.
- TB notification and NIKSHAY are in the early stages of implementation.

- An increasing number of people suspected of TB are being examined across the state. However, the trend is variable across districts.
- As per the guidelines, activities related to contact tracing and IPT in children are being partially implemented.
- All patients interviewed were receiving free treatment, and the level of treatment success in new and previously treated smear-positive cases has been maintained.
- All districts have been covered under PMDT since August 2012.
 - Five C/DST laboratories have been certified by the RNTCP (two in the private sector) and four more are in the process of being certified. Two Gene Xpert pilot sites are functional.
 - Nine DR-TB centres have been established and two more are in the process of being established.
 - There is an increasing trend in the detection of MDR-TB cases, as well as in the initiation of these cases on treatment.
 - Category V drugs for XDR-TB cases are being made available through local procurement of drugs, as per the guidelines.
- TB-HIV activities are being scaled up across the state.
 - The mechanism of TB-HIV coordination, documentation and reporting is being implemented in the whole state.
 - Of the DMCs, 60% of them are co-located with the ICTCs.
 - There is an increasing trend in the number of TB patients with known HIV status.
 - Of the registered TB patients in 2011, >80% of them were aware of their HIV status.
 - Eight per cent of TB patients are HIV-positive—98% are on CPT and 71% on ART.
 - Referral of persons suspected to have TB to the RNTCP from the ICTCs is 9-10%, and from ART 3-4%.
 - There are 1510 ICTCs, 58 ART centres and 146 link ART centres.
- PPD and PWBs are available for children.
- All 41 medical colleges are participating in the RNTCP, contributing around 25% to case finding.
- Total of 6700 PPs and 306 NGOs are participating in schemes and there is TGF-supported IMA project across the state.
- Two state drug stores (SDS) are in place and a third is proposed in Mumbai. The district drug stores have been upgraded for the storage of SLDs.
- In 2011-2012, the expenditure amounted to 88% of the funds available. Many activities of the RNTCP, including the upgradation of infrastructure, are being supported by NRHM additionalities.

- The expenditure is 78% of the approved ACSM budget.
- All community facilitators are in place.
- The policy of making all ASHAs DOT providers for improved decentralization of services with community participation is being implemented.
- The TGF-supported Axshya project is being implemented in the state. Community organizations, including the Catholic Health Association of India (CHAI), Catholic Bishops' Conference of India (CBCI) and Population Services International (PSI), have been involved.
- Pharmacists have been engaged.

Constraints

- The superannuation of the STO and STDC Director, Nagpur is due in the near future.
- The post of City TB Officer has not been created in 20 out of 22 of the cities of Maharashtra, and a number of DTO posts are lying vacant, e.g. in Aurangabad rural district.
- The implementation of the TB notification order is likely to pose many challenges.
- The rate of case detection is falling at the state level and in many districts.
- It was observed that the quality of some microscopy services was suboptimal.
- The programme review mechanisms at the state level are suboptimal. The systems for programme management, supervision and monitoring are weak at the Mumbai city level, and the Aurangabad rural district and Municipal Corporation.
- Additional TU staff is yet to be appointed and trained in Mumbai.
- With 24 DTCs and more than 50 TUs proposed to be set up in Mumbai, the workload of the Pune STDC will need to be redistributed.
- The observed TB case detection rate in Mumbai (82%) probably does not represent the reality and there may be many more cases that do not access RNTCP services, considering the concentrated population with a high probability of transmission and the lack of involvement of the huge private sector.
- Of the total of 29 212 cases registered in Mumbai annually, 8666 (25%) are retreatment cases. In Gene Xpert pilot sites, 16 out of 53 (29%) rifampicin-resistant cases were misclassified as new. In Mumbai, >1800 MDR-TB cases have been already detected in spite of consistent achievement of >90% smear conversion rates and > 85% treatment success rates over the past few years.

- The true burden and epidemiology of M/XDR-TB transmission, particularly in Mumbai, needs to be better understood.
- Over 1800 MDR-TB cases have been detected in Mumbai since January 2012, which poses a challenge to the state's current capacity for the initiation of treatment.
- The local capacity for second-line DST in the state is inadequate.
- Around 70% of the confirmed MDR-TB cases in Maharashtra have been initiated on treatment.
- The DR-TB centre of Nagpur has stopped functioning due to administrative issues.
- Patients do not have a good knowledge of treatment, though the knowledge of Category IV patients is very good.
- It was observed that HIV testing kits were out of stock off and on.
- Services for the initiation of ART treatment are available only at the district level.
- Contact tracing is not yet universal and is inadequate. There is no monitoring of IPT.
- The distribution and use of PPD remain challenging.
- Bonded medical officers (posted for a year) in rural areas get only limited information on the RNTCP during their induction training and are not fully aware of/trained in the details of the RNTCP.
- The morale of the contractual staff is adversely affected by:
 - The terms and conditions and the fact that their status remains contractual;
 - The fact that their salary/POL is yet to be revised despite inflation; and
 - Health insurance and Provident Fund issues.
- Measuring the contribution of the private sector is a challenge.
- The success and/or impact of PPM activities have been limited so far.
 - There is minimal referral from the private sector and other sectors.
 - There is a lack of awareness of the RNTCP guidelines, particularly for paediatric cases.
 - There is a deficit in trust. For example, regimen, lack of feedback, acceptance of “our” diagnosis, DOT, etc.
 - Well-to-do patients do not want to go to a DOTS facility due to inconvenience, stigma and clash with school/work timings.
 - The management capacity of RNTCP officers for liaising with numerous partners at the state and district levels is limited. Districts were found to have a shortage of streptomycin, as well as low stocks of category II PWBs. There were inadequate stocks of category IV drugs, and drugs due to expire shortly were stored (loose Cs and Na PAS, and PWBs), in the districts visited.SLDs

were widely available in private pharmacies. Availability of funds at the state and district levels, and the processing of funds remain issues of concern

- The accountant for the RNTCP at the district level is part-time. ACSM activities in the field were found to be suboptimal. Most of the material found in the field was for the literate population. Systems for measuring the processes and impact of ACSM were lacking. Involvement of Panchayati Raj institutions (PRI) was below the desired level.

Key recommendations

Greater attention needs to be paid to the quality of RNTCP services for drug-sensitive TB cases to curb the ongoing transmission of TB and the development of MDR-TB cases. Efforts must be made to scale up services further and sustain them to manage the high levels of drug-resistant TB in the community.

Political and administrative commitment to universal access to TB care

- Replacements must be found for the STO and STDC Director, Nagpur at the earliest to avoid gaps in leadership at this critical juncture in the programme.
- Permanent posts for 20 of the 22 city TB officers need to be created through the urban development department to strengthen urban TB control. All the vacant positions of DTOs should be filled as soon as possible.
- Periodic Health Secretary-level reviews of performance should be conducted, involving:
 - The Regional Deputy Directors and Chief MOs of the rural districts of Maharashtra;
 - The MOs and health officers of the urban cities of Maharashtra; and
 - State task force of all 41 medical colleges in Maharashtra.
- Mechanisms for TB notification should be developed and implemented, and the implementation of NIKSHAY should be strengthened.
 - Systematic guidance and training of staff are necessary to ensure the effective implementation of TB notification.
- New permanent positions, supplemented by technical staff, should be created in Mumbai. There is a need to invest in improving the capacity for the effective management of RNTCP services. This includes:

- Developing the capacity and skills of the existing staff and private providers at all levels;
- Strengthening the Mumbai TB cell for the overall management, supervision and monitoring of the programme, which may be sustained through the Mumbai Municipal Corporation;
- Investing in the GTB Hospital to develop a centre of excellence in tuberculosis, and developing a State TB Training and Demonstration Centre in Mumbai as a technical institute with infrastructure upgradation, human resources, mobility support to the Mumbai TB cell
- Increasing the number of pharmacists, counselors and drug stores at the district level, and developing peer counselors from among the existing patients; and
- Posting additional supervisors/health visitors in slums and ensuring optimal engagement of general health staff in the delivery of services at the level of urban health posts.

Case-finding activities and engaging all providers in TB care

- Balanced attention to the quality of RNTCP services for drug-sensitive TB cases to prevent emergence of M/XDR-TB, along with simultaneously scaling up PMDT services to prevent transmission.
- Mumbai should develop a clear plan to involve corporate and private hospitals, as well as PPs, in TB control activities with the help of the following steps:
 - A technical advisory committee can be formed on the private sector, with representation of eminent chest physicians, the Indian Medical Association (IMA), Association of Physicians of India (API), Indian Academy of Pediatrics (IAP) and opinion leaders among private providers. This can be subsequently extended to other cities of Maharashtra.
 - All clinical establishments can be asked to notify TB cases and provide enhanced services to deal with these cases under the programme. This will also improve the data available for decision-making.
 - Local incentives may be offered to PPs who refer a case that is diagnosed and successfully treated under the RNTCP.
 - It is necessary to use more responsible diagnostics and prescription practices, which accord with the ISTC, if not the RNTCP.
- At the village level, PRIs should be involved to strengthen efforts at case detection.

Diagnostics and laboratories

- Laboratory technicians and senior tuberculosis laboratory supervisors (STLSs) should be retrained.
- Supportive supervision of the existing staff should be strengthened.
- An IRL should be established at the Group of TB Hospitals as part of the proposed STDC in Mumbai.
- The Director of Medical Education and Research should expedite the approval process for the upgradation of the C/DST laboratory at Aurangabad Government Medical College, and review the involvement of the medical colleges.
- There is a need to build the capacity of the existing C/DST laboratories to conduct second-line DST. The support of the NRL can be taken for this. The results should be used to inform future revisions of treatment regimens for M/XDR-TB to see to it that they are optimal.

Treatment and treatment support

- There is a need to improve counselling and health education for the patients and family members.
- Patient support groups could initially be formed by training peer educators drawn from patients who have successfully completed MDR-TB treatment.

Programmatic management of DR-TB

- Staff at all levels requires complete retraining to be brought up-to-date with the May 2012 version of the RNTCP guidelines for PMDT.
- Activities related to patient and family support and education need to be strengthened.
- At the state level, close monitoring of PMDT services is required during the phase of rapid expansion and the introduction of molecular diagnostic techniques.
- Administrative issues need to be resolved at the DR-TB centre in Nagpur so that it can become functional once again. Resident nursing staff and ward attendants, as well as the ancillary drugs required, should be made available by the state government at all DR-TB centres to ensure sustainable services.
- There is need to strengthen coordination between the districts, laboratories, DR-TB centres and SDS.
- Paediatricians must be involved in the management of paediatric DR-TB cases.
- Category V drugs for XDR-TB cases should be centrally procured to ensure an uninterrupted supply of drugs of assured quality.

- Dispensing of SLDs should be regulated with availability duplicate prescriptions, with one prescription being retained by the dispensing pharmacy.
- If DRS cannot be implemented soon, it is advisable to consider conducting a Mumbai-specific DRS survey, including the private sector, on FLDs and SLDs to learn more about the epidemiology of M/XDR-TB and guide further interventions.
- Services for DR-TB in Mumbai should be strengthened further in the following ways:
 - Decentralize DR-TB centres, e.g. in institutes such as JJ Hospital, GT Hospital, St George Hospital and private hospitals, to increase the bed strength further to be able to manage MDR-TB cases.
 - Enhance laboratory capacity further, e.g. equip the GTB Hospital laboratory for liquid culture and LPA, and the JJ Hospital laboratory for liquid culture and second-line DST.
 - Submit a proposal to TB Reach (Stop TB Partnership) for the improvement of case-finding through the utilization of Gene Xpert machines and for the test to be offered, both in the public and private sectors, to those suspected of having TB.

TB-HIV

- HIV testing services should be available at all DMCs.
- NACO should ensure an uninterrupted supply and buffer stock of HIV testing kits.
- Further decentralization of ART services is a priority.

Paediatric TB

- Dissemination of the new RNTCP /IAP paediatric TB guidelines is necessary.
- Mechanism for the diagnosis of childhood TB should be decentralized down to at least the rural and block level facilities where a paediatrician is available.
- Mechanisms for the distribution and use of PPDs need to be closely monitored for effective utilization that ensures decentralization.
- There is a need to encourage the involvement of paediatricians in the RNTCP by increasing their representation in technical groups and state and zonal task forces and DR-TB committees.

Human resource development

- A plan should be drawn up to ensure that all “bonded” medical officers are trained in the RNTCP.
- The terms and conditions of service of the RNTCP contractual staff must be reviewed.
- An attempt should be made to identify career paths for health officers to facilitate recruitment and retention of capable professionals.

Drugs and supplies

- District drug stores should be set up in the 24 districts and the third state drug store to be established in Mumbai.
- Drug supplies need to be streamlined, and there should be provision for emergency drug procurement at the district or state level.
- There is a need to involve the Commissioner, DGCI to ensure stringent enforcement of the prescription of Schedule H and H1 drugs to restrict OTC sale of anti-TB drugs on a sustainable basis.

Programme financing and strengthening of health system

- Sufficient funds need to be made available for utilization at regular intervals.
- Provision should be made to hire a full-time accountant to oversee the financial management at the district level.

Research

- Computerized training modules should be developed for the RNTCP for web-based distant learning.
- There is a need for further decentralization of operational research decision-making for approval to the state level.
- Plans should be made for the dissemination of research findings from and within the programme.
- Efforts need to be made to promote capacity-building and the involvement of medical colleges in research.

Advocacy and communication

- Norms to ensure the availability of sufficient funds for ACSM must be strengthened.
- ACSM should be integrated into the RNTCP training modules at every level.

Engagement of the community

- Smooth transition must be ensured from the project mode to the programme mode.
- Mechanisms for planning, budgeting and implementation should be integrated into the programme.

Punjab

Districts visited: Gurdaspur and Patiala

Facilities visited:

Gurdaspur: The facilities visited included the DTC, district drug store, DMCs (DTC, Pathankot, Gharota), ICTC and ART centre (Pathankot), DOT centres (DTC, Pathankot, Gharota, Sujampur), various chemists' shops, a private laboratory, patients' residences and the local chemists' association. We also visited a rural healthcare provider and IMA consultant, and assessed ACSM activities in a slum (Batala).

Patiala: The state-level facilities visited were the state TB cell, SDS, STDC, IRL and DR-TB centre. Those visited at the district level were the DTC, district drug store, Rajpura TU, DMCs (DTC, TB Hospital, Rajpura Civil Hospital), Patiala Medical College, two ICTCs, an ART centre, two DOT centres, two private clinics, the local branch of the IMA, residence of two patients and two chemists' shops. To assess community involvement, we visited the Truck Colony in Patiala and a village covered by the Nabha TU.

Political and administrative commitment to universal access to TB care

Observations

- There is a very high level of political and administrative commitment to the provision of universal access to TB care.
- Proper reviews are conducted at the state and district levels.
- Additional funding support is being provided by the NRHM.
- Level of participation of the rural health department is low.
- There are delays in addressing key issues related to HR.

Recommendations

- There is a need to improve coordination between the state health department and the rural health department.
- Administrators must pay greater attention to HR issues.

Case-finding activities

Observations

- Rate of referral of chest symptomatics by the rural health department is low.
- Efforts at case-finding leave much to be desired (the number of patients examined per smear-positive case is only eight).
- Of the 96 smear-positive cases diagnosed per 100 000 population annually, only 91 are registered for treatment.
- Smear-negative cases form only 25% of the notified new PTB cases.
- Contribution of the Axshya project is small (>1%), but increasing.

Recommendations

- Case-finding activities must be intensified through (i) strict screening of contacts; (ii) the enforcement of referral from the rural health department; (iii) the promotion of referral from private facilities; and (iv) improvements in the infrastructure and providers' awareness of the need for chest radiography.
- There is a need for strategic implementation of the Axshya project to improve case-finding in underserved areas.
- Minimize the possibility of missing cases that need to be put on treatment by (i) tracing those who default initially; and (ii) implementing private notification.

Diagnostics and laboratories

Observations

- There are 270 DMCs. EQA is being conducted satisfactorily at the STDC level.
- The IRL started LJ work in February 2012, but accreditation is being pursued at a slow pace.
- A CBNAAT laboratory was established at the IRL in mid-August 2012. Samples from nine districts have been covered under criteria B.
- With the support of FIND, the state has already identified rooms, which will have a clean room finish, for the introduction of an LPA laboratory at the IRL.
- TB laboratories have done a good job of documenting facility-wise (including PP) referrals of TB suspects.
- Private laboratories are hardly engaged in RNTCP activities.
- There is some evidence (from one private laboratory in Gurdaspur) that the ban on serology is being adhered to.

Recommendations

- It is necessary to expedite the accreditation of the Patiala IRL for LJ.
- The IRL must be upgraded so that work may be done under BSL-3 conditions and liquid culture may be introduced. Perhaps the general laboratory could be moved to create space for this.
- More private laboratories need to be engaged.

Treatment and treatment support

Observations

- Initiation of treatment for the diagnosed cases is timely.
- Level of involvement of trained ASHA volunteers in providing supervised treatment is good.
- Patients accept and adhere to supervised treatment. The treatment success rate is good and the attrition rate is relatively low.
- There has been a complete failure to influence the treatment choices of large numbers of patients, who are managed by Pps.

Recommendations

- It is essential to ensure timely payment of honoraria to all community DOT providers.

Patiala Medical College

Observations

- The faculty expressed keen interest in the RNTCP and its provisions, and was committed to the implementation of the programme in the medical college.
- Two faculty members pursuing their MD (Respiratory Medicine) have priority areas of RNTCP as their thesis topic.
- There is a lack of awareness among the college faculty members of several clinical departments regarding:
 - Availability of “prolongation pouches” for the initiation of DOTS among in-patients admitted, and
 - Provision in the RNTCP for extending the continuation phase on the basis of individual cases, where appropriate.

Recommendation

- More intense sensitization is required on these provisions during the meetings of the core committee.

Programmatic management of DR-TB

Observations

- PMDT services were initiated on January 2012. At present, eight of the 20 districts are covered and there are plans to cover the entire state by September 2012.
- The IRL is yet to be accredited. Samples are being sent to the LRS and AIIMS (Delhi) for LPA.
- Three DOTS sites have been identified (Patiala, Amritsar, Faridkot). These may be insufficient.
- MDR-TB services are available at Patiala and Gurdaspur, where 14 and four patients, respectively, are on treatment.
- Training of MOs and laboratory technicians on PMDT is yet to be completed.
- There are delays in the identification of those suspected to have MDR-TB.
- DOT is provided only at health facilities.
- MDR-TB patients from Gurdaspur are referred to Amritsar (around 90 km away) even for minor adverse reactions.
- These plans do not make provision to cater to the increasing number of MDR patients. If this reality is not planned for, there is a risk that the regular DOT services may be compromised.

Recommendations

- Develop a comprehensive plan for the operationalization of PMDT services at the district level.
- Community DOT providers must be identified for MDR-TB patients.
- There is a need to undertake line-listing of MDR-TB suspects to facilitate early identification.
- Capacity of specialists at the district level should be strengthened so that less serious complications can be managed locally.

TB care in private sector, PPM

Observations

- RNTCP staff has only a vague knowledge of the number and distribution of qualified and unqualified private providers, chemists and laboratories.
- Several types of anti-TB drugs are sold by most chemists.
- IMA has sensitized 7000 doctors and trained 800–1200, but there have been few referrals and less than 100 cases have been managed under DOT.
- The engagement of PPs in the RNTCP's schemes is negligible. The programme has failed to honour the terms of a few MOUs. At the moment, there are no MOUs.

Recommendations

- There is a need to honour MOUs and pay honoraria to all DOT providers.
- The District Commissioner and CS should convene a meeting of associations of PPs to discuss the issue of notification.
- New ways need to be developed, at all levels, to strategically engage large number of PPs (informal and formal, including shops and laboratories). One of the means is professional contracting of intermediary agencies (as per the NSP).
- RNTCP should improve the training of its staff on issues such as the need for PPM and its potential.

TB-HIV

Observations

- There is good coordination between the TB and HIV programmes.
- Steps have been taken to co-locate ICTCs and DMCs at most health facilities.
 - Meetings are held to ensure regular coordination between TB and HIV programmes.
 - Field staff is aware of issues related to HIV and the need for cross-referrals between the two programmes.
 - Records and registers are maintained well.
- Good coordination has resulted in:
 - Gradual increase in the coverage of HIV testing for TB patients.
 - Provision of CPT to most patients identified to have HIV-TB.
 - Linkage with ART and the initiation of ART.

Recommendations

- The need for prompt initiation of ART in all TB-HIV cases should be emphasized.
 - The staff concerned with ART needs to be sensitized on the issue of cough hygiene.

Human resource development

Observations

- Most of the HR staff is in place and trained.
- Of the 429 contractual posts, 25 (around 5%) are vacant. These include the post of MO at the STC, and those of DOTS Plus MOs, STS and STLS.
- The STO has the additional responsibility of implementing leprosy control and Right to Information (RTI).

- There is no DTO in at least one district, while there are part-time DTOs in another three.
- Two state-level contractual posts have been lying vacant for over a year. The recruitment process is in progress.

Recommendations

- There is a need to train and involve rural medical officers on a large scale.
- Additional responsibilities must not be given to the STO and DTOs, as far as possible.
- There should be no delays in recruitments to key posts.
- Commitment of the staff should be sustained through measures such as:
 - Timely disbursement of salaries;
 - Pay parity with the contractual staff of other programmes under the NRHM;
 - Considering the provision of incentives/recognition for exceptional work; and
 - Provision of training opportunities.
- There should be regular assessment of the knowledge and level of skill of the staff. Need-based capacity-building should be undertaken through:
 - Refresher training/retraining; and
 - On-site training during supervisory visits.

Epidemiology, M&E, notification

Observations

- Half of the notified cases are of people below 35 years of age.
- There is a possibility of missing out on older patients.
- A total of the 60% of the registered, previously treated cases are cases of relapse. The time for the development of relapse is short indicating the possibility of masked failure. There is a need to look into the quality of follow-up microscopy.
- The high density of persons per room, indoor air pollution and multiple relapses indicate contact infection and re-infection.

Recommendations

- A state epidemiologist should be recruited, epidemiological analysis carried out and cases mapped.
- There is a need for stringent screening of contacts, and the families of patients must be educated on residential AIC.
- The quality of follow-up microscopy needs to be monitored.

Drugs and supplies

Observations

- The management of the supply chain is excellent. This includes stocking, monitoring, priority consumption and reconstitution.
- There are limited storage facilities at the district and TU levels.
- Currently, there is a stock-out, originating at the national level, of rifampicin (150 mg) and streptomycin injection.
- There are repeated undue delays in supply from the GMSD, Karnal.

Recommendations

- Drug stores that supply SLDs should be provided dual air conditioners with a switch-over timer.
- Need for temperature regulation in state and district stores that supply FLDs.
- Action is required at the national level to prevent/compensate for stock-outs.

Programme financing and strengthening of health system

Observations

- Late receipt of funds, at the state and district levels, is a major constraint in making the programme effective.
 - The staff is sometimes paid late
 - Pending payment for honoraria and schemes

Recommendations

- The state should use the funds available for TB under the NRHM to pay the honoraria of community DOT providers.
- The state and districts should systematically monitor delays in making these payments.

Advocacy and communication

Observations

- Good rapport has been established with the patients and community.
- There is an annual ACSM plan at the state level, not at the district level.
- The Axshya project, which has been under implementation since a year, is focusing on vulnerable populations, increasing sensitization, health talks, etc.
- ACSM activities are limited mostly to the printing of handbills and posters.
- Collaboration and involvement of other stakeholders, such as ASHA, Anganwadi workers, and IEC personnel of the NRHM, is limited.

Recommendations

- There is a need to build the capacity of DTOs and other staff at the district level in ACSM.
- There should be better coordination with the Axshaya project. This should be strategically utilized to improve the coverage and implementation of the RNTCP.
- A clear plan for ACSM must be chalked out at the district level. This should include measures for the scale-up of prevention and health promotion activities.
- While preparing IEC material, more thought should be given to the type of material required. The design and layout of the content need to be more creative and innovative.
- The programme should address the stigma and discrimination faced by patients.

Engagement of the community

Observations

- Level of motivation among the community workers, such as DOTS providers, STS and TBHVs, is high.
- Efforts have been made to engage the larger community, but they are limited to the Rotary Club, Lions Club and District TB Association.

Recommendations

- Focused efforts must be made to enlist the participation of the larger community.
- District teams should be trained in soft skills and “patient-centred approach”.
- Cured TB patients should be identified with the purpose of building their capacity to act as advocates in the community.

Technical assistance

Observations

- The present level of technical support is inadequate: there is one technical consultant (WHO) and one ACSM consultant (the Union).
- Additional technical support is required for:
 - Rollout of PMDT;
 - Analysis, interpretation and use of data to improve the programme's performance;
 - Effective supervision and monitoring;
 - Operational research; and
 - Designing, piloting and implementing innovative approaches.

Recommendations

- WHO could consider providing an additional technical consultant.
- It would be useful to create a state-level pool of technical experts, drawn from medical colleges, DTOs/MO-TCs that are performing well, the NRHM and technical agencies, to provide need-based and demand-based support.

Other issues

- **Infection control measures**

Observations

- The measures for infection control at the health facilities visited, including DMCs, OPD rooms, the ICTC and ART centres, were inadequate.
- Patients and their families were not made aware of cough hygiene and how to dispose the sputum.

Recommendations

- Simple measures, such as ensuring adequate ventilation, can be taken. This can be done by:
 - Keeping the windows open; and
 - Provide windows, and if this is not possible, provide mechanical ventilation (exhaust fans).
- Emphasis should be laid on the education of patients through counselling and IEC material.

Uttar Pradesh

The team visited the districts of Lucknow and Varanasi.

Facilities visited:

Lucknow

- DTC, Rajendra Nagar
- CSM Medical University (erstwhile King George Medical College)
- Community Hospital 1
- Community Hospital 2
- Dr CP Singh Permar clinic
- Private pharmacy
- SDS

Varanasi

- DTC
- DMCs – PHC
- Medical college
- DR-TB treatment centre
- ICTC
- Private laboratory and hospital
- SDS
- CMO's office
- District magistrate's office

Political and administrative commitment to universal access to TB care

Achievements

- Administrative leaders have identified TB as a major public health problem related to poverty.
- A TB control programme is in place in all districts of the state. The programme is functional despite funding issues within the NRHM.

Constraints and gaps

- There is no additional support under the state budget for activities related to TB. Initiatives such as the setting up of DR-TB centres, C/DST laboratories and drug stores are not succeeding due to the shortage of funds.

- STOs and DTOs are transferred frequently.
- There is a shortage of manpower at the state TB cell.
- The STO has no control over TB funds.

Recommendations

- Additional funds should be provided to support TB activities on the basis of the needs of the state TB cell.
- Plans must be developed for the retention of staff. The aim should be to ensure that skilled staff remains in place for at least three years, as this would contribute to continuity of the programme and optimize its functioning.
- The state should be divided into 4–6 regions and additional staff deployed under the STO to coordinate TB activities in these regions.
- The STO should be empowered to manage and control TB funds.

Programme financing

- There is a major problem with respect to the downward flow of finances from the NRHM.
- Salaries and honoraria of all contractual staff have not been paid for the past few months.
- Supervision has been affected due to limited funding for travel.
- Morale of the staff is low and this is hampering the achievement of the programme's objectives.
- Failure to make timely payments is affecting PPM projects, especially the involvement of NGOs in DMCs.

Case-finding activities

Achievements

- With its stepped up efforts, the state has achieved the targets for the detection of new smear-positive cases and treatment success. These achievements have been sustained.

Constraints and gaps

- Not very active efforts have been made towards case-finding. The rate of examination of those suspected of TB is low and stationary.
- Number of private sector referrals to the DMC is negligible.
- Contact tracing investigation is not conducted rigorously.
- No evidence of high-risk groups, such as slum-dwellers, diabetics and smokers, being targeted.
- Access to X-ray facilities for the diagnosis of smear-negative PTB is limited.

Recommendations

- Feasible strategies must be planned for active community screening for symptoms of TB and for the investigation of cases.
- There is a need to ensure that the contacts of smear-positive TB cases are screened and investigated.
- Strategies targeting high-risk groups (slum-dwellers, diabetics, the malnourished, etc.) should be developed and implemented.
- A plan should be drawn up to improve access to chest radiography services to facilitate the diagnosis of smear-negative PTB.

Diagnostics and laboratories

Achievements

- DMCs are covered under the network of a functioning EQA system.
- NGOs have been involved in the programme and are running DMCs.

Constraints and gaps

- The number of C/DST laboratories planned is much less than what is required. Private laboratories with the capacity to perform C/DST are not involved in RNTCP activities.
- The functioning of the system for the collection and transportation of sputum under cold chain is not up to the mark. Many samples were found to be leaking or contaminated.
- The measures for infection control are inadequate and the practices followed for biomedical waste management are poor.

Recommendations

- A more ambitious and realistic plan should be developed with respect to C/DST laboratories to increase the capacity to diagnose DR-TB.
- There is a need to strengthen coordination between sputum collection and the transportation mechanism under cold chain.
- The staff concerned and laboratory technicians should be sensitized on the disinfection of infected materials produced especially at DMCs, on proper disposal (as per the guidelines), and on the monitoring of implementation.

Treatment and treatment support

Achievements

- The state has achieved and sustained a treatment success rate of >85%.

Constraints and gaps

- There is rampant use of fluoroquinolones even in public sector health facilities, including DTCs.

- Diagnostic delays are inevitable due to the present diagnostic algorithm, which requires the administration of antibiotics for two weeks.
- There is an average delay of a week in the initiation of treatment due to the requirement of a mandatory initial home visit. (This results in an initial loss to follow-up.)
- DOT is not always practised.

Recommendations

- Judicious use of fluoroquinolones must be ensured in all public sector health facilities, with stricter monitoring by the CMOs.
- There is a need to consider making changes in the diagnostic algorithms at the national level to prevent delays in diagnosis.
- Anti-TB treatment should be initiated immediately after diagnosis.
- There is a need to initiate state and national dialogue on the successful implementation of DOT.

Programmatic management of DR-TB

Achievements

- A plan has been drawn up for the scale-up of PMDT services across the state.
- A system for communication through e-mail is in place for the purpose of sharing the results of C/DST.
- PMDT services are available in eight districts.
- Medical colleges offer DR-TB services.

Constraints and gaps

- The planned capacity of the C/DST laboratory is short of requirement, as the population that needs to be covered is large.
- The progress in the expansion of PMDT services is slow.
- There are gaps in the case-finding activities for those suspected to have MDR-TB, e.g. in sample collection for C/DST.
- The patient support system is inadequate.

Recommendations

- Regular reviews of the progress in the implementation of PMDT services must be undertaken.
- There is a need for regular reviews of case-finding activities for MDR-TB.
- The uptake of new tools for the rapid detection of DR-TB (Gene Xpert/LPA) should be encouraged.

TB-HIV

Achievements

- TB-HIV coordination committees have been formed in most of the districts and collaborative activities are being undertaken.

Constraints and gaps

- Only 27% of the TB patients know their HIV status.
- The state TB cell and SACS have not made any joint field visits.
- The number of ICTCs in the state is insufficient to ensure that testing for HIV is conducted.

Recommendations

- The state TB cell and SACS should make joint visits at least on a quarterly basis.
- A concrete plan should be drawn up, in consultation with NACO/CTD and the UPSACS, for facility integrated ICTCs in the whole state.

Human resource development

Achievements

- Most of the contractual staff has been engaged, but their salaries are delayed, and related issues are a matter of concern.
- The state has developed an HRD plan including the training calendar by the STDC.

Constraints and gaps

- There are several vacancies at the state/district level, C/DST laboratories, drug stores and DR-TB centres.
- There are delays in the payment of salaries and POL.
- Training is not being conducted on a regular basis.

Recommendations

- There is a need for a national decision to be taken on whether the contractual staff should be made regular for the sustainability of activities.
- The contractual staff must be paid in a timely manner.
- A priority-based, feasible training plan needs to be developed and implemented.

Epidemiology, M&E, notification

Achievement

- The state plans to depute six public health officers to liaise with the districts to improve supervision and monitoring.

Constraints and gaps

- The DTOs have been unable to carry out their supervisory duties regularly due to the lack of transportation facilities.
- Nikshay is yet to become operational because of gaps in funding. Start-up training for Nikshay has not taken place.

Recommendations

- The DTOs should be provided with the necessary means of transportation to help them with their supervisory duties.
- It must be ensured that the block-level DEOs start using Nikshay.

Drugs and supplies

Achievements

- Drug stocks are being maintained at all levels and stock registers are being used.
- There have been no major stock-outs.

Constraints and gaps

- The building of the SDS in Lucknow is old and in bad repair.
- There is no computer available at the SDS.
- There is not enough space for a store with SLDs at SDS.
- Streptomycin injections and rifampicin capsules (150 mg) are in short supply.
- Expired drugs are still in circulation.
- Absence of a security guard or sweeper/attendant.
- Absence of a fire extinguisher.

Recommendations

- Adequate support must be ensured for the SDSs, in terms of manpower, security and infrastructure.
- Efforts must be made to coordinate with the CTD to prevent shortages of rifampicin capsules (150 mg) and streptomycin injections.
- Expired drugs should be separated out from the main stock.

Advocacy and communication

Constraints and gaps

- There is no evidence of activities for advocacy at any level.
- All communication activities aimed at the general public have failed.
- There is no evidence of community involvement through social mechanisms such as SHGs and mahila mandals.

Recommendations

- The programme needs to create advocacy panels/agencies to raise critical issues.
- Focused strategies need to be developed for communication with the masses.

TB care in private sector, PPM

Achievements

- The IMA project is running and continuing medical education (CME) is being provided regularly.
- The DMC of the IMA has just started operating.

Constraints and gaps

- Very few PPs are making referrals and no private laboratories are engaged in the existing schemes.
- Diagnostic practices continue to be suboptimal in the private sector, which relies excessively on serology, despite the ban. Sputum smears are not the preferred option.
- No demonstrated experience of formal engagement of the private sector.
- Informal providers and chemists/druggists are a major source of first-contact care for patients with chronic cough, but the programme has not engaged them yet.

Recommendations

- The IMA model for DMCs should be evaluated and such linkages should be promoted.
- Interface agencies should be used to facilitate more proactive engagement with the private sector.

West Bengal

Political and administrative commitment

Achievement

- There is a high level of commitment to the programme, both at the district and state levels.

Constraints and gaps

- The involvement of the general health system in the TB programme is inadequate.
- The programme is coordinating with the municipal authorities in North 24 Parganas.
- The STO is overburdened with duties related to other programmes.

Recommendations

- The general health system should be involved in the monitoring of the RNTCP.

Case-finding activities

Achievement

- A good system has been put in place for the diagnosis of TB.

Constraints and gaps

- The referrals made to laboratories by public sector facilities and the medical colleges are incomplete, and the attitude with respect to referrals is a passive one.
- The involvement of PPs (trained, untrained) is limited, and the corporate sector is not involved at all.
- Most paediatricians are not involved.
- The number of smear-negative cases detected is low and there is a declining trend.
- Contact Investigation is not being carried out systematically. In addition, the findings are neither recorded, nor reported.
- Medical colleges are making very few referrals for treatment.

Recommendations

- The order requiring mandatory notification should be communicated and implemented.

- A TB helpline and notification line (Mile or SMS) should be started.
- Better use should be made of chest X-rays and new technology (Gene Xpert).
- There is a need for active screening among groups at risk and during outreach events, e.g. polio immunization.
- Revision of the diagnostic algorithm could be considered (an issue that concerns the CTD).
- There is a need to ensure the notification of diagnosed cases, and not merely that of treated cases ([an issue that concerns the CTD).

Diagnostics and laboratories

Achievements

- EQA of microscopy is satisfactory and records are maintained well.
- Efforts with respect to sputum collection have been satisfactory and NGOs are involved in the activities in North 24 Parganas.
- Gene Xpert pilot shows good results (741 suspects; 141 TB, including 37 smear-negative and 19 R resistant).
- LED-FM has increased positivity (e.g. from 15%- 20% in one medical college).

Constraints and gaps

- The laboratory capacity is not sufficient for the requirements of PMDT.
 - The establishment of the IRL, North Bengal, has been delayed.
 - Only one private laboratory has been involved. The others have not responded.
- Standard sputum transport containers are not available.
- Microscopy in the absence of electricity continues to pose a challenge.

Recommendations

- A plan should be drawn up to provide technical assistance to laboratories for the scale-up of the drive against MDR-TB.
- There is a need to phase in LED FM.
- Attempts should be made to scale up Gene Xpert.
- Some thought should be given to whether the number of cultures for MDR-TB FU should be reduced (an issue that concerns the CTD).

Treatment and treatment support

Achievements

- The implementation of DOT is satisfactory.
- PMDT ambulatory DOT by RMP PP has been successfully done.
- Patients are being provided with food support, e.g. the "12 kg Rice Programme" in North 24 Parganas.

Constraints and gaps

- The PPs favour a daily regimen.
- Streptomycin and rifampicin (150 mg) are not available.
- The treatment default rate is high and increasing, due to various reasons (migration, alcohol, etc.).

Recommendations

- There is a need to reconsider the RNTCP regimen.
- There is a need for operational research to be conducted to reduce the treatment default rate.

Programmatic management of DR-TB

Achievement

- Efforts to make ambulatory treatment available for MDR-TB have been successful.

Constraints and gaps

- Progress has been limited to the implementation of criteria A (only failures).
- Paediatric MDR-TB poses a challenge in both diagnosis and treatment.

Recommendations

- There is a need to focus on quality while expanding DOTS Plus sites.
- The state must scale up PMDT to criteria C.

TB care in private sector, PPM

Achievement

- The state can boast of some good examples of the involvement of NGOs.

Constraints and gaps

- The involvement of private practitioners is limited.
- Interest has not translated into partnership due to the inflexibility of the RNTCP.

Recommendations

- There is a need to engage interface agencies.
- Attempts should be made to encourage notification (by SMS) from the private sector or patients.
- There is a need for greater flexibility.

TB-HIV activities

Achievements

- Meetings for coordination have been taking place.
- The percentage of TB patients tested for HIV rose from 30 in 2010 to 54 in the first quarter of 2012.
- Eighty per cent of TB-HIV cases are on CPT.

Constraints and gaps

- There are few HIV testing facilities (only 20% of DMCs have a co-located facility).
- North 24 Parganas does not have an ART centre.
- Less than 70% of patients have been started on ART.
- Intensified case-finding (ICF)
 - The number of referrals from the ICTC to the RNTCP is low (less than 2% of the ICTC clientele).
 - Less than 2% of those attending ART centres have been identified as TB suspects.
- Reporting on TB-HIV is delayed and incomplete, e.g. only 5 of the 9 ART centres are reporting on TB-HIV.

Recommendations

- Implementation of ICF needs to be improved in voluntary counselling and testing (VCT) and ART centres.
- The use of Gene Xpert should be considered at ART centres.
- TB patients should be given better access to ART.
- IPT among PLHIV without TB (CTD issue).

Paediatric TB

Achievement

- The staff has a good knowledge of the signs and symptoms of paediatric TB, IPT, etc.

Constraints and gaps

- Extremely low proportion of childhood TB notified to programme.
- Paediatricians in the private sector are not involved in the RNTCP's activities.
- No disaggregation on the basis of age and type of TB in quarterly reporting (CTD issue).

Recommendations

- The new guidelines must be implemented.

- Paediatricians should be involved in the programme via the Indian Academy of Paediatrics (IAP).
- Efforts should be made to promote disaggregated reporting (0-5 years CTD issue).

M&E, notification

Achievements

- NIC system is operational and appears to have good potential for notification.
- Internal evaluations are being conducted.

Recommendations

- Implement Mile/SMS data input into the NIC system of notification.
- Notification of cases outside the RNTCP should be encouraged
- Notification should be based on diagnosis, as opposed to treatment (an issue that concerns the CTD).

Drugs and supplies

Achievements

- Good practices are being employed in the management of drug stocks at the district level.
- There have been no stock-outs in the past.

Constraints and gaps

- Currently, streptomycin and rifampicin (150 mg) are stocked out.

Advocacy and communication

Achievements

- A state IEC officer has been appointed.
- There are no problems with funding.
- The community is generally aware of TB.
- Attempts are being made to implement the patients' charter.

Constraints and gaps

- The IEC plan is not innovative.
- The timing of funding is not predictable.
- The Bulgam Bhai campaign has not been launched. Before it can be launched, it must be adapted to the local context.
- There is no proper system of coordination, e.g. between the IEC officer and the NGOs of the Akshaya project.

- The Akshaya project has become non-functional since April due to lack of funds.
- The tendency to receive credit for the detection of cases has given rise to negative competition.

Recommendations

- Bottom-up planning would help rectify the situation.
- Attempts should be made to improve coordination.

Community engagement

Achievement

- Community volunteers have been involved in the programme's activities.

Constraints and gaps

- Though SHGs exist, they are not involved in the RNTCP's activities.

Recommendations

- SHGs need to be involved.
- An NGO coordination committee should be established at the state level.
- The participation of religious leaders and faith-based organizations must be enlisted.

Finance

Achievement

- Funding was not cited as a problem.

Constraints and gaps

- The funds released for laboratory consumables amounted to only 10% of the approved amount (by June 2012) in the case of both districts.
- The expenditure on honoraria was very low in North 24 Parganas, as was that on the maintenance of vehicles in Kolkata.
- No funds were released in either district under the head of NGO/PP (North 24 Parganas received funds in July, but there were delays in payments to NGOs, which were paid only once a year).
- The funds allocated for operational research had not been spent.

Recommendation

- Better financial management needs to be established at the state and districts level with quarterly review of their performance.

Additional recommendations based on requests made by the state during debriefing

- RNTCP staff and support for the programme should be provided in 8 new districts.
- Plans should be developed to scale-up Gene Xpert and LED-FM.
- The norms governing the salaries of contractual staff across all programmes should be uniform (this is an issue concerning the CTD).

Conclusion

- Good systems are in place to manage current levels of TB care and control.
- Current efforts are clearly insufficient to achieve universal access to care and the targets set out in the NSP.
- There is a need for:
 - Greater ambition (consistent with the NSP).
 - New technology and innovative approaches.
 - Flexibility in approach.



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