Accelerating Universal Access to Early and Effective Tuberculosis Care

Joint Review Mission: October 14-20, 2014

AIDE-MEMOIRE

A. INTRODUCTION

1. An International Development Association (IDA) credit of US$ 100 million was approved by the World Bank Board of Executive Directors and became effective on June 26, 2014 (P148604). The Project Development Objective (PDO) is *to support the aims of India's National Strategic Plan for Tuberculosis (TB) Control to expand the provision and utilization of quality diagnosis and treatment services for people suffering from TB*. The credit contributes to financing of implementation of the National Strategic Plan along with domestic funding and support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Its results framework thus encompasses indicators and targets for the program as a whole regardless of the source of funding for particular activities.[1]

2. A Joint Review Mission (JRM) to provide implementation support to the Revised National TB Control Program (RNTCP) was undertaken between October 14 and 20, 2014. The mission was coordinated by the Central TB Division (CTD) of the Ministry of Health and Family Welfare (MoHFW) and included representatives of the World Bank, the World Health Organization (WHO), GFATM, the India Country Coordinating Mechanism (CCM), the United States Agency for International Development (USAID) and the International Union Against Tuberculosis and Lung Disease. The objective of the mission was to review implementation of the National Strategic Plan and provide recommendations on several focus areas, specifically, drug-resistant TB (DR-TB) control, urban TB control, public-private engagement, information and communications technology (ICT), TB-HIV services and drug procurement and supply. The mission included field visits to several districts in the states of Gujarat, Maharashtra, Rajasthan and Telangana.[2]

3. The mission teams debriefed with the Secretaries, Health & Family Welfare, of the respective states and participated in wrap up meetings chaired by the Principal Secretary, and Director General, Health Services, MoHFW, on October 20, 2014. The mission would like to thank Dr. Jagdish Prasad, Director General, Health Services, MoHFW; Mr. Anshu Prakash, Joint Secretary, MoHFW; Mr. J.P. Gupta, Secretary & Commissioner, Health & Family Welfare, Government of Gujarat; Ms. Sujata Sounik, Principal Secretary, Public Health & Family Welfare, Government of Maharashtra; Mr. Deepak Upreti, Principal Secretary, Health & Family Welfare, Government of Rajasthan; Mr. Suresh Chanda, Principal Secretary, Health & Family Welfare, Government of Telangana; Dr. R.S. Gupta, Deputy Director General, Central TB Division, MoHFW; and state and district health department officials in each state. This Aide Memoire summarizes the main findings and recommendations of the mission.

[1] The Project Appraisal Document (PAD) and other information are available at: http://www.worldbank.org/projects/P148604?lang=en

[2] Ahmedabad, Mehsana and Surat in Gujarat; Mumbai and Thane in Maharashtra; Ajmer and Jaipur in Rajasthan; and Hyderabad and Medak in Telangana.

B. IDA CREDIT

		Ratings		
Board approval	April 8, 2014		Last	Now
Effectiveness date	June 26, 2014	Project Development Objective	S	MS
Closing date of IDA credit	March 31, 2017	Implementation Progress	S	MS
Mid-term review date	December 31, 2015	Procurement	S	MS
IDA credit amount	US$ 100 million	Financial Management	S	MS
Total amount disbursed	US$ 0			

U = Unsatisfactory, MU = Moderately unsatisfactory, MS = Moderately satisfactory, S = Satisfactory

C. RESULTS INDICATORS

	Baseline (2012)	Year 1 target (2014)	End-project target	Current (January-June 2014)
Outcome indicators				
Direct project beneficiaries (cumulative)[3]	0	1.5 million	3.1 million	0.74 million
Of which female	33%	35%	37%	NA
1. People receiving TB treatment in accordance with the WHO recommended DOTS (cumulative)[4]	0	1.5 million	3.1 million	0.74 million
- of which female	33%	35%	37%	NA
2. TB patients receiving care in the private sector notified to the government (annual)	40,000	60,000	100,000	103,095
- of which female	13,200	21,000	37,000	NA
3. Drug resistant TB patients who have initiated treatment (annual)	25,000	32,000	40,000	11,433
- of which female	6,000	8,000	11,000	NA
4. TB suspects and patients who have received drug-sensitivity testing (DST) (annual)	130,244	150,000	175,000	119,040
Intermediate outcome indicators				
1. Public private interface agencies contracted (cumulative)	0	2	4	0
2. Intensified case finding programs implemented among high risk populations in urban areas (cumulative)	0	2	14	2
3. TB units using information system for case notification and patient monitoring (cumulative)	0	4,000	5,900	3,015
4. TB service providers receiving payments through electronic transfer (cumulative)	0	2%	5%	0
5. Districts with drug susceptibility testing capacity located in the district (cumulative)	70	170	370	374
6. Analysis of socio-economic profile of drug-sensitive and drug-resistant TB patients	No	No	Yes	No

[3] This is the cumulative number of TB cases notified to the government from the public and private sectors.
[4] This formulation is used for IDA reporting purposes. In the India case, it is equivalent to the cumulative number of TB cases notified to the government from the public and private sectors.

completed				
7. Drug-resistant TB patients who have completed treatment (annual)	48%	52%	56%	48%
8. Block level health administrations with TB units integrated (cumulative)	2,700	4,000	5,900	3,015
9. Months between start of financial year and release to the states of funds for TB program implementation (annual)	5	4	3	4
10. Pediatric TB cases initiated on treatment in the public sector (annual)	81,000	85,000	90,000	39,185

NA = not available

4. Overall, results indicators for the IDA credit show some progress towards targets, reflecting implementation of the various parts of the Revised National TB Program (RNTCP), including continued delivery of first-line services for drug-sensitive TB patients, as well as pediatric and TB-HIV services, and expanded services for DR-TB. A case-based online ICT system (*Nikshay*) has been put in place, while existing public-private mix (PPM) schemes continue and some new strategies to engage the private sector have been initiated to a limited extent. Project ratings are Moderately Satisfactory (MS) due to only partial implementation of some of the new strategies under the National Strategic Plan to be supported by the credit (notably in the areas of public-private engagement and ICT) and to the fact that there has been no disbursement to date from the IDA credit.

5. Overall, performance of the program remains stable, as it provided treatment to approximately 1.4 million new TB patients in 2013, similar to annual numbers since 2006. Although gender is specified in patient records, the program needs to modify data entry and reporting in order to compile aggregate figures on the gender breakdown of TB patients (first-line and DR-TB, public and private sectors). The number of suspects examined in order to identify a smear-positive case of TB has steadily risen, from 7.5 in 2008 to 8.7 in 2013, indicating that greater effort is required to identify TB cases. Program data have also shown that significant numbers of smear-positive cases who are diagnosed are not notified as they are not registered for treatment by the program (about 130,000 in 2013, or 14% of diagnosed cases). Notification of each TB case at diagnosis would be a first step to encouraging accountability for tracking and ensuring treatment of all diagnosed patients.

6. WHO (2012) estimates that there are 2.2 million new TB cases in India (with the estimate range being 2.0 to 2.4 million). As RNTCP notifies about 1.4 million new cases annually, there are some hundreds of thousands of TB patients who are not known to the program and seek care in the private sector. At the same time, data limitations mean that there are uncertainties about the epidemiology of TB in India, while some recent prevalence and household surveys (the latter measuring self-reported TB treatment) provide indications that the TB burden may be decreasing at a slower rate than estimated. The National Strategic Plan is designed to address these challenges, including expansion of program capacity, increase in DR-TB services and scaled-up notification and support to TB patients in the private sector.

7. In order to achieve its objectives, The National Strategic Plan envisioned total central-level funding for the TB program of US$ 833 million during the five year period 2012-17, of which a total of US$ 285 million were programmed in the first two years (2012-13 and 2013-14). Actual

expenditures were around INR 500 crores in each of those years, for a total of about INR 1,000 crores (US$ 167 million).

D. DRUG-RESISTANT TB

8. RNTCP has had good performance for the effective treatment of drug-susceptible TB. There is a 42% reduction in TB mortality and 51% reduction in TB prevalence rate by 2012 as compared to 1990 level (based on WHO estimates). The treatment success of pulmonary sputum positive cases notified under RNTCP is 88%. The treatment success among notified smear-positive re-treatment TB cases needs to be improved among the sub-group of failures and treatment after default. Outcome for Category II in Rajasthan state is slightly higher (79%) compared with the national average (70%).

9. Since 2007, the implementation of Programmatic Management of Drug Resistant TB (PMDT) successfully established quality-assured Culture-DST laboratories (40 labs for solid culture-DST; 49 for Line Probe Assay (LPA) and 17 for liquid culture- DST, and 89 sites with Cartridge Based Nucleic Acid Amplification Test (CB-NAAT)). Second-line DST is available in 10 laboratories.

10. The improved diagnosis for drug-resistant tuberculosis tested 450,000 presumptive DR-TB cases and enabled the treatment of 54,000 confirmed DR-TB cases and 1,000 confirmed XDR-TB.

11. Treatment success for DR-TB is 49%, with approximately 20% death rate, 20% default rate and 7% treatment failures. Outcomes for XDR-TB cohorts are not yet available and the management of mono and poly-resistant cases is made with first line drug regimens. The cohort evaluation of the latter group has poor outcomes and developing resistance to Rifampicin during the course of the treatment. As an attempt to improve the current outcomes, a National Consultative Workshop was organized in late August to discuss and draft the guidelines for drug-sensitivity test (DST) guided treatment regimen for DR-TB. The proposed protocols are in line with the updated WHO guidelines for the Programmatic Management of DR-TB.

12. The success of the proposed strategy will require the scale-up of DST capability in the country for first and second line drugs as well as the procurement of second line drugs (Group V: Clofazimine, Clarithromycin, Linezolid, Amox/Ac. Clavulanate, INH).

13. In order to decrease the default and death rates, several strategies need to be implemented and evaluated under program conditions in selected states. The need for improvement of the nutritional status of the patients has been identified as one key issue to be addressed. Linkage of DR-TB patients with other social protection programs is highly recommended.

14. The health facilities visited have partially implemented administrative infection-control measures. N-95 respirators are not available for the use of health staff except in the laboratory area. However, surgical masks are used by some of the patients and health care providers. An assured provision of N-95 respirators is encouraged to allow use by health staff even outside the laboratory areas, should they choose to do so.

15. Recommendations

(i) Additional technical and financial support may be provided to states which have achieved good outcomes from DOTS in order to improve cure rates for DR-TB. Some sites in Rajasthan with good DOTS outcomes may be considered for inclusion in the pilot for DST-guided treatment for DR-TB patients.

(ii) CTD may require technical support for developing and establishing a more conducive procurement and logistics system for DR and XDR-TB drugs in support of improved outcomes amongst DR-TB patients.

(iii) The program should aim for universal DST-guided treatment of DR-TB.

(iv) The program should develop a concrete action plan to improve provision of psycho-social and nutritional assessment and management in order to improve treatment adherence amongst DR-TB patients.

(v) Implementation of Airborne Infection Control (AIC) guidelines must be emphasized and facilitated in both the public and private sectors, including finalization and adoption of the draft guidelines.

(vi) Health care worker surveillance must be undertaken to inform policy decisions on safeguarding their health. Extending coverage to health workers of relevant government insurance schemes should be considered.

E. PUBLIC-PRIVATE ENGAGEMENT

16. The results framework for the IDA credit includes targets of 100,000 annual notifications of TB patients receiving care in the private sector and of 4 Public-Private Interface Agencies (PPIAs) contracted. In 2013, 38,596 private sector TB patients were notified, while till June 2014, this figure is 34,908. PPIA's are in place as part of pilot programs in Mumbai and Patna, but the government has not yet directly contracted a PPIA.

17. The team focusing on public-private engagement visited Gujarat (population 63.4 million), including Ahmedabad, Surat and Mehsana. Overall, RNTCP is clearly being implemented well in Gujarat, with over 74,000 new TB patients registered in 2013, consistent with previous years. Consistent with the national pattern, the number of suspects examined has been increasing (over 450,000 in 2013), indicating the need for increased effort to identify each case. Program capacity has been increased through alignment of Tuberculosis Units with the block-level administrative structure of the National Health Mission, as 59 additional Tuberculosis Units were created in 2013-14 and 104 more are planned for 2014-15. (There are currently 203 Tuberculosis Units in the state). Overall, state government health spending has been increasing substantially in recent years, budgeted this year at INR 7,216 crores (US$ 1.2 billion, or about US$ 20 per capita). Expenditures for RNTCP in the state totaled 22 crores in 2013-14, compared to 19 crores in the previous year.

18. In Surat Municipal Corporation (population 4.7 million), the mission observed well-functioning government urban health services, including 41 Urban Health Centers, with evident demand from the population. The mission visited several private institutions engaging with

RNTCP, including a Designated Microscopy Center (DMC) located in a private laboratory, a DOTS center run by a faith-based organization, a laboratory contracted to provide culture Drug Sensitivity Tests (DST), a TB/HIV clinic and a TB hospital that is notifies to the program the largest number of patients in the private sector (2,273 last year).

19. Gujarat is thus an example of a well-functioning program that is implementing the range of existing RNTCP services and schemes that involve the private sector. Nonetheless, state officials recognize that significantly more needs to be done in order to reach greater numbers of patients in the private sector. Although medical colleges contribute a significant proportion of cases to the program (22,731 in 2013), only 7.5% of cases (5,534 in 2013) are treated by private practitioners under RNTCP's public-private mix (PPM) schemes. According to state officials, a recent prevalence survey indicates that this proportion should be at least 30%.

20. It is thus evident that the existing strategies, however well-implemented, are not enough to reach and improve the care of TB patients in the private sector. New strategies, leadership and direction from the center, as well as greater resources, are needed to push the national program beyond the plateau where it has been situated since 2006 of 1.4-1.5 million cases notified annually.

21. The mission visited a pilot program in Mehsana district that provides vouchers for free-of-charge provision of anti-TB medicines to patients receiving care from private providers. In five weeks of implementation, this extended support to about 400 patients (which can be compared to the total of 2,075 cases notified in the district in 2013). A private doctor and pharmacist involved in the pilot indicated that the reduced out-of-pocket spending on medicines for TB patients will have major benefits in terms of maintain adherence to the full course of treatment. This pilot is being implemented by RNTCP staff. The mission also took note of pilot programs in Mumbai and Patna, designed and implemented with technical support and oversight of the CTD, where Public-Private Interface Agencies (PPIA) have also recently started implementation of strategies to extend support to private sector TB patients, including free-of-charge diagnosis and medicines. (The mission noted the potential for evaluations of these pilots – particularly Mehsana – to provide lessons for the planned free essential drugs scheme).

22. These pilots are providing initial experience with on-the-ground implementation of new strategies outlined in the National Strategic Plan. At the same time, other elements necessary to meaningful scale-up of support to TB patients in the private sector have been initiated, notably:

(i) adoption of the Standards for TB Care in India (STCI);

(ii) mandatory notification of all TB cases;

(iii) implementation of the case-based *Nikshay* online information system, including private sector cases;

(iv) initiation of the procurement process for the planned Technical Support Group (TSG), which will provide support to CTD and the states on public-private engagement strategies, including contracting and management of PPIAs; and

(v) development of terms of reference for the planned PPIAs.

23. The mission also noted that alignment of Tuberculosis Units with Block administrations (and consequent increase in program capacity and human resources) will be required for successful leveraging of the enormous capacity of the private sector to reach and support TB patients. (The Mehsana pilot has demonstrated the increased workload involved).

24. Recommendations

(i) Revised PPM schemes, which have been under discussion and review for some time, should be adopted and start implementation (by December 31, 2014).

(ii) The TSG should be contracted and functioning (by June 30, 2015).

(iii) The planned PPIAS in four metros should be contracted and functioning (during the course of the next fiscal year).

(iv) CTD should conduct a detailed assessment of progress in implementation of the revised PPM schemes and the pilots in Mehsana, Mumbai and Patna (by March 31, 2014).

(v) Economic and programmatic evaluation of the Mehsana pilot should be initiated (by June 30, 2015).

(vi) CTD should examine possibilities for extension of outpatient and inpatient TB services for coverage under RSBY in states where outpatient services are covered by the scheme (by April 30, 2015).

F. INFORMATION AND COMMUNICATIONS TECHNOLOGY (ICT)

25. The results framework of the IDA credit includes targets of 5,900 Tuberculosis Units using the information system for case notification and patient monitoring and of 5% of TB service providers receiving payments through electronic transfer. To date, 3,015 Tuberculosis Units are entering patient data in the *Nikshay* online case-based information system. As yet, no electronic payment transfers have been made by the program. Electronic payments are planned to be implemented this fiscal year in one district in Chhattisgarh.

26. The *Nikshay* system was initiated in 2012 and includes TB patient registration and details (i.e. diagnosis, DOT provider, HIV status, follow-up, contract tracing, outcomes), as well as provision (including a recently-developed mobile application) for registration of private providers and notification of patients in the private sector. To date, the records of 3.2 million TB patients have been entered in the system. A total of 44,000 government and RNTCP-affiliated health facilities are registered in the system, as well as 79,000 private (non-RNTCP) health services. A total of 131,199 private sector patients are registered in the system (including 38,596 in 2013).

27. At the same time, objectives for leveraging ICT to improve TB care, including for patients in the private sector, are considerably more ambitious, requiring the system to move well beyond the current focus on record-keeping and reporting. Further development of the system would encompass real-time patient monitoring and follow-up, improved monitoring and follow-up of diagnostic samples and results, enhanced communication with patients and providers, payment management, drug supply management, GIS-based hotspot identification and epidemic

prediction, etc. Pilot programs in Mehsana, Mumbai and Patna will include ICT strategies that should provide examples and lessons for the national system. A Detailed Project Report (DPR) totaling INR 67.25 crores (US$ 11 million) was recently submitted for funding by the national e-governance program (*e-Bharat*) of the Ministry of Communications and Information Technology.

28. Recommendations

(i) The DPR for further development of *Nikshay* (e-TB) should be approved and funded by the Ministry of Communications and Information Technology.

(ii) If funding is not forthcoming from the Ministry of Communications and Information Technology, CTD will propose financing of the DPR from Bank Credit for approval.

(iii) The existing *Nikshay* database should be exploited through (a) development of automated reports for epidemiological analysis and (b) assignment of responsibility and development of capacity (possibly in NTI) for routine use of *Nikshay* data for this analysis.

(iv) Program management applications should be developed on priority including supply chain management, laboratory management, financial management, etc.

G. URBAN TB CONTROL

29. More than 30% of India's population lives in urban areas, of which (in most big cities) about half live in unplanned slums. Due to overcrowding and poor living conditions, slum dwellers and migrant populations are exposed to increased risk of TB infection. In the meantime there are limited public health services networks (administratively each city is considered one district) under the auspices of the Municipal Corporation, which is not under MoHFW. Therefore most health services are being provided by private sector health care providers and NGOs. Hence an important challenge in the urban areas for the TB program is to coordinate different stakeholders both within the government and also in the private and NGO sectors.

30. Considering the issues in the cities, they present an exaggerated form of the TB control challenges in the country. Thus addressing urban TB issues constitutes one of the key areas for achieving the Universal Access spelled out in the National Strategic Plan for TB control 2012-2017. This necessitates the successful implementation of the new schemes under the National Strategic Plan including; i) effective PPM; ii) expanding PMDT; ii) expanding HIV-TB; iii) leveraging ICT; and iv) effective ACSM.

31. The IDA project document envisages development of city specific strategies, plans and budgets to strengthen TB control in urban areas. This includes increasing the number of TB units and human resources on par with the population size of each city as well as implementation of active case finding especially in urban slums along with robust evaluation.

32. Given the importance of the private sector in the urban areas, the effective engagement of the RNTCP with the private sector through PPM schemes is of paramount significance. The engagement of the private sector is important for: awareness raising, case finding, specimen

transport, diagnosis, treatment, patient support and counselling. Currently two pilots are going on through deployment of PPIAs: one in Mumbai and one in Patna.

33. The mission visited Mumbai and Thane cities in the state of Maharashtra. Overall the following issues were noted: i) delays in the transfer of funds from state Treasury to the state TB Society for the last three months; ii) lack of a full time city TB officer; the current city TB officer is also in charge of other disease control such as malaria, dengue fever, ebola, etc. iii) insufficient human resources as each TBHV caters for 1 lakh population; iv) lack of TB awareness especially among the poor, etc.

34. The PPIA in Mumbai city has targeted eight high TB burden wards (covering more than 85% of the slum population) in the city, providing diagnostic, treatment and treatment adherence support for TB patients in the private sector. The PPIA has conducted house to house active case finding in these wards. The PPIA has engaged General Practitioners, MDs, MBBS, chest physicians, laboratories and pharmacies. All of the providers have been trained on the standards of TB Care in India. Each of the private providers have been linked to a "hub center" which has a Chest/MD physician for consultation, a digital chest X-ray facility and a pharmacy with first line anti-TB drugs. Through a voucher system the PPIA is providing free first line anti-TB drugs via engaging private pharmacies, free chest X-rays for symptomatic TB suspects and subsidized CB-NAAT (INR 500) via IPAQT laboratories for MDR suspects. The program has been under implementation for about a month. To date a total of 283 TB positive cases have been diagnosed of which 23 are DR-TB cases.

35. Recommendations

(i) CTD will provide guidance to municipal governments for establishment of program management and monitoring structures and placement of human resources in City TB Units for TB prevention and control.

(ii) In view of the unique socio-economic-cultural characteristics of urban areas, CTD will develop and deploy an urban-specific Advocacy, Communication and Social Mobilization (ACSM) strategy within the National Strategic Plan period.

(iii) CTD will update the database of existing social welfare schemes which could be accessed by TB patients at the district, state and central levels, and organize for its geo-coded disclosure through the National Informatics Center.

(iv) CTD will identify those areas or populations suffer from exceptionally high TB burden, and prioritize those groups for systematic screening and targeted ACSM and service delivery, either in health care facilities (for clinical high risk groups) or in the community (for areas with dense populations of persons from social risk groups).

(v) CTD will develop a template of city-specific plans for TB control and ensure its inclusion in the Project Implementation Plan (PIP) template of the National Health Mission (NHM) for deployment to states.

H. TB-HIV INTERVENTIONS

36. One of the key objectives of the National Strategic Plan (2012-17) is to achieve decreased morbidity and mortality of HIV associated TB. RNTCP aims to target with expanded and intensified support people living with HIV/AIDS (PLHIV), who are more susceptible to TB disease, with increased access to testing and complete treatment. This it intends to do by enhancing collaboration with the National AIDS Control Program (NACP) to ensure that PLHIV identified as TB suspects are referred for TB testing. Additionally, PLHIVs who are TB patients will be tested for drug susceptibility to identify DR-TB. Conversely, identified TB patients will be referred for screening for HIV. The National Framework for TB-HIV, revised in 2009 and again 2013, provides evidence-based guidance for establishment of coordination mechanisms between the NACP and RNTCP through: defining joint objectives; outlining monitoring and evaluation mechanisms; specifying roles and responsibilities of staff, drugs and logistics management; and financial management. This framework has been gradually scaled up for implementation across the country since July 2012. All TB-HIV joint interventions recommended by WHO find place in the revised National Framework for TB-HIV.

37. The essential package of services to be implemented under the joint framework include (i) establishment of coordination mechanisms and technical working groups at the national, state (sub-national) and district levels; (ii) joint training of NACP and RNTCP programme staff on TB/HIV; (iii) intensified TB case finding at all the HIV testing and anti-retroviral therapy (ART) facilities; (iv) risk-based offer of HIV testing to TB patients (i.e. only those having high risk to be referred for voluntary counselling and testing); and (v) referral of HIV-positive TB patients to the NACP for care and support, including antiretroviral treatment. The intensified TB/HIV package for high HIV burden settings includes (i) routine offer of HIV counselling and testing to all TB patients (PITC); (ii) decentralized provision of Cotrimoxazole Prophylaxis Therapy (CPT) to HIV-positive TB patients; (iii) referral of HIV-positive TB patients to ART centres and provision of ART based on eligibility; and (iv) expanded recording and reporting system including documentation of HIV status on TB treatment cards and registers. The formerly-named ‘intensified package’ of HIV/TB services is now the national TB/HIV policy standard for all states.

38. The mission observed in the state of Telangana that the revised framework for TB-HIV is jointly owned by the State TB and AIDS control programs. Despite recent gaps in leadership in the State AIDS Control Society (SACS) of Telangana, on account of the bifurcation of the state of Andhra Pradesh, the framework has percolated to the district levels with visibly strong coordination and collaboration to record, counsel, screen, treat, follow-up and monitor TB-HIV patients. Though the Coordination Committee for TB-HIV at the state level has not convened in the past 18 months, coordination and collaboration at the district level between the District TB Center (DTC) and the District AIDS Control and Prevention Unit (DAPCU), under the chairmanship of the District Collector, is not affected.

39. Early detection of HIV: 95% of the designated microscopy centers in the state are co-located with ICTCs or Facility Integrated ICTCs (FI-ICTCs) to ensure easy access for TB or HIV patients to screening and treatment of the other condition. In the last two quarters ending June 2014, the percentage of registered TB cases tested for HIV has plateaued at 98%, yielding

7% positivity. The positivity is identified to be higher in urban districts. Improvements in consistency and quality of referrals and screening need emphasis in low yield districts. The state is also implementing Provider Initiated Testing and Counseling (PITC) among presumptive TB cases since quarter 1 of 2013. As of quarter 2 of 2014, 89% of TB suspects were counseled and tested for HIV at health facilities. The yield of 8% HIV positive patients is significant enough to emphasize PITC among presumptive TB cases in all high HIV prevalence areas (i.e. areas with antenatal care prevalence >1% and or areas with high-risk group (HRG) prevalence >5%).

40. Early diagnosis of TB in HIV care settings: It was observed that 11.1% of persons visiting ICTC centers and suspected to have TB were referred to DMCs in quarter 1 of 2014. 6.2% of the TB suspects referred were diagnosed with TB. The positivity ranges from 1% in certain districts like Nizamabad to 10% in Warangal and Mehboobnagar districts. It is important to review quality of screening at DMCs in districts yielding low positivity rates and address issues that may be affecting it. While ICTC centers were yielding appreciable number of TB patients, ART centers have in the past 18 months plateaued referrals to DMC at 2% of cases. The TB positivity amongst patients referred from ART centers is a high 17.5%. Given that 10% of HIV patients would suffer from TB in a year, the yield from ART centers is grossly inadequate. The use of an expanded clinical algorithm for TB screening that relies on presence of four clinical symptoms (current cough, weight loss, fever or night sweats) instead of only cough, to identify patients with presumptive TB was found to be limited.

41. Quality treatment: It is encouraging to note that CPT is initiated for 98% of the co-infected patients by the TB program, while ART follows closely behind for 94% of the co-infected patients for the quarter ending March 2014. States which have consistently demonstrated >90% rates for CPT and ART provision in the public health system must now focus on improvement in quality of access to CPT and ART by minimizing delays in start of either therapy. Similarly, in contrast to the WHO-recommended daily anti-TB regimen among TB patients infected with HIV, the program is currently using a thrice weekly regimen. However, it is encouraging to know that the program is moving forward with daily regimen for these sub-groups of patients.

42. TB prevention: The inability of Telangana (as has been the case across the country) to procure isoniazid has adversely affected the strategy for initiating Isoniazid Preventive Therapy (IPT) for TB prevention amongst PLHIV. The knowledge and implementation practices for air born infection control measures were found limited. Comprehensive implementation of Air Borne Infection Control guidelines in HIV care settings will require systemic sensitization and training of concerned administrators and staff.

43. Capacities need to be built and systems strengthened to ensure every eligible PLHIV is referred to a DMC center, and where rapid diagnostic CB-NAAT machines are available, for early and specific diagnosis of TB. The time lag between TB diagnosis and initiation of CPT/ART must be minimized. Treatment outcomes in TB-HIV co-infected cases for all registered cases in quarter 2 of 2013, indicate 42% patients completed treatment, 36% were cured and 14% of patients died during treatment. The proportion of deaths amongst TB-HIV co-infected is proposed to be brought down to 7% by 2016, with intensive case finding amongst high risk groups, early referral, screening, early treatment (linking TB-HIV patients to ART within 15 days of initiation of TB treatment) and consistent follow-up to ensure better treatment

outcomes. The inability of both RNTCP and thereafter individual states, including Telangana, to procure isoniazid, has adversely impacted the ability to roll out of decentralized Isonazid Prevention Therapy (IPT) to minimize occurrence of TB amongst HIV positive patients, accessing care at ART or Link ART centers.

44. Observations and data collated from the field visit to Telangana demonstrated leadership in implementation of National Framework for TB-HIV in the state that is well placed initiate qualitative improvements to TB-HIV program management. While Telangana may not be representative of performance of all states on the revised national framework, it provides assurance that gains accrued by the state could well be replicated in other states. It is essential, therefore, for states at par with Telangana to concentrate on improvements in quality, and the lagging states to learn from the operational experience of Telangana to fast-track quantitative achievements of goals set for treatment outcomes for TB-HIV patients.

45. Recommendations

(i) CTD will pursue joint sensitization and training of NACP and RNTCP staff through e-learning modules for intensified case finding, cross referral, early initiation of the proposed daily regimen treatment, and IPT.

(ii) Joint regional review meetings will be institutionalized at the central level on a bi-annual basis and at the state levels on a quarterly basis, with the latter reviews incorporating sessions for continued medical education (CMEs) for staff prior to the review.

(iii) CTD in collaboration with the National AIDS Control Organization (NACO) will emphasize that joint monitoring reports be reviewed for performance by the district nodal officers of the respective programs.

(iv) CTD in collaboration with NACO will intensify efforts to co-locate ICTC/FI-ICTC with DMC in states yielding a poor throughput for TB-HIV co-infected.

(v) CTD will fast-track procurement and deployment of isoniazid for IPT to all states.

(vi) CTD will issue guidance to all states for prioritized DST-guided treatment for HIV-TB patients.

(vii) CTD will coordinate with NACO for re-emphasis of AIC under joint TB-HIV activities.

(viii) CTD will ensure active engagement with NACP by ensuring participation in joint review and monitoring missions of either program.

(ix) NACO will develop and align case-based recording and reporting systems with *Nikshay*.

I. PROCUREMENT AND SUPPLY MANAGEMENT

46. *Advance contracting/retroactive financing.* MoHFW has decided not to seek IDA reimbursement of expenditures on anti-TB drugs for which procurement processes were completed before credit effectiveness (totaling approximately INR 100 crores or US$ 17

million). In consultation with the World Bank team, the procurement plan for the IDA credit will need to be revised in order to reallocate these resources.

47. *Goods procurement for 2014-15:* Bids for first line anti-TB drugs of estimated value INR 100 crores (US$ 17 million) were opened on September 2, 2014 and the bids for second line anti-TB drugs of estimated value INR 60.4 crores (US$ 10 million) were opened on August 6, 2014. The bid evaluation reports (BERs) for both procurements are under preparation with RITES and should be shared with MoHFW shortly.

48. For procurement of microscopes (estimated to cost INR 11.8 crores (US$ 2 million), the MoHFW's IPC meeting of September 16, 2014 has signed off on the recommendation of contract award. The contract for this package is likely to be signed soon.

49. The Bank team expressed concerns about the time taken in the bid evaluation and decision-making process and requested MoHFW to expedite contract award in the above cases. The Bank team clarified that the management fee payable to RITES is eligible to be funded from the IDA credit.

50. MoHFW also confirmed that there is no stockout of essential drugs.

51. *Service procurement for 2014-15:* The ToR for national media agency (estimated value INR 16 crores or US$ 2.7 million) is finalized and the request for expressions of interest (REOI) is being prepared, which will be published by November 15, 2014. Simultaneously, the RFP for the consultancy is being prepared by CTD and will be shared with the Bank after short-listing is completed. Five private agencies have been shortlisted for lab testing of drugs post-dispatch (estimated value INR 0.5 crores or US$ 83,000). The request for proposals (RFP) document for the assignment has been prepared and is pending internal MoHFW clearance, after which it will be issued to shortlisted agencies. It is expected that the contract will be awarded by end-January 2015 (this will be post-review package). MoHFW will also initiate fresh selection for hiring of logistics management agency.

52. The ToR for a human resource (HR) agency for provision of technical support to CTD at central level has been prepared. However, in view of space constraints at CTD, MoHFW has decided that a domestically-financed contract for office space (approximately 10,000 sq. ft.) will be awarded first. The DG, MoHFW, has approved this contract and procurement process is ongoing. A detailed project report for ICT intervention (*Nikshay*) has been shared with e-Governance program and is pending approval. The use of the National TB Institute (NTI) for supporting operational research requires decisions on how to proceed with the procurement/MOU arrangement.

53. *Shifting of responsibility for goods procurement to the Central Medical Services Society (CMSS):* MoHFW indicated that the contract for RITES will not be extended post March 31, 2014. However, RITES is mandated to complete all ongoing drug procurement by February 2015. It was also noted that contract for the testing agencies (working with RITES) is valid only till March 31, 2015 and requires further extension so as to retain the existing panel till supply under the contracts handled by RITES is completed. All rebidding cases will be handed over to

CMSS. The Bank will separately conduct a capacity assessment of CMSS and agree on an action plan for areas identified during the assessment. The contract of RITES is currently valid up to March 2015 and requires a no-cost extension till supply under contracts to be awarded by it is completed. It was clarified by the Bank that as CMSS is a dependent agency of MoHFW, the Bank will not be able to reimburse the management fee payable to CMSS. However, actual expenses incurred by CMSS (for example on hiring of testing and inspection agencies) will be eligible for IDA financing.

54. The indents for procurement of first line anti-TB drugs for 2015-16 are planned to be shared with CMSS by end-December 2014 as MoHFW is considering changes in treatment regimen. For second line anti-TB drugs, the indents for 2015-16 will be shared with CMSS by end-October 2014. CMSS has already acquired 21 warehouses in the states and is in the process of refurbishing these with works, air conditioning, and equipment such that each state capital will have at least one drug warehouse. Staff are being contracted for each warehouse. It is proposed that first line anti-TB drugs will be stored in Government Medical Store Depots and second line anti-TB drugs in the State Drug Stores. However, this needs to be agreed between CTD and CMSS. The mechanism of transfer of drugs from the CMSS warehouses to the state warehouses is yet to be finalized. CMSS is also likely to assign the task of preparing patient-wise treatment boxes for second line drugs.

55. *Procurement post-review:* MoHFW clarified that there has been no post review contract issued during the period July 2013 to June 2014 and accordingly there is no need to conduct post review by the Bank.

56. Recommendations

(i) Share the BERs for first and second line drugs with the Bank.

(ii) Share with Bank proposal for IDA support to procurement of e-aushadhi software and its downstream deployment to states for drug logistics management.

(iii) Award contract for media agency to develop and roll out the Advocacy, Communication and Social Mobilization Strategy for the program.

(iv) Publish the expression of interest for procurement of the HR agency.

(v) Initiate recruitment of a procurement consultant for CTD.

(vi) Update and share with the Bank the revised procurement plan for the IDA credit.

(vii) To support timely and cost effective procurement of drugs for the program at the state level, going forward, CTD will provide at least a three month lead notice to states.

(viii) Consider using the IDA credit to support capacity development of the CMSS.

J. FINANCIAL MANAGEMENT AND DISBURSEMENT

57. As of date, the allocation of SDR 65 million (equivalent to US$ 100 million) under IDA 5376-IN remains undisbursed. The first set of Interim Financial Reports (IFRs) for the period ended September 30, 2014 are due for submission by November 15, 2014. CTD agreed to review operational expenditures and determine those that may be eligible for financing under the

project. The requirement for submission of the audit report for FY13-14 will therefore be subject to eligibility of expenditures during the retroactive period – in the event that no expenditures are to financed, a waiver for the submission of the audit report for FY13-14 will be processed.

58. All teams visiting the states were informed of delays in funds release this fiscal year.

59. Recommendation

(i) To facilitate early access to program funds through the State Treasury-Health Society route, CTD will provide guidance to all states on processes to be adopted for streamlining funds flow.

K. ENVIRONMENTAL AND SOCIAL SAFEGUARDS

60. *Environmental safeguards*: The mission undertook a visit to Jaipur, Rajasthan, and visited the SMS Medical College, Institute of Respiratory Diseases and Kawatia Hospital. The field visits and the discussions indicated that there is a well-functioning system of infection control and waste management, which includes training and reporting in an integrated manner. The mission was heartened to see that staff trained earlier under the Rajasthan Health System Development Project continue to provide training to RNTCP staff. The labs and TB wards visited were up to standard, well-ventilated and clean. Labs are also systematically modulated, run by knowledgeable and well-trained technicians. While the sites visited were well-performing, they may not be representative of all TB centers and hospitals across the state and country. The Environment Management Plan prepared by CTD in 2013 includes a number of actions which need to be taken between Sept 2014 and May 2015, which will be reviewed during the next mission in the first half of 2015. During the review, there may be need to assess the policy and guidelines for administrative and environmental controls and PPE provision in health-care facilities and their revision, if needed.

61. The mission noted that there is adequate provision for procurement of goods (i.e. needle cutters) and consumables (i.e. masks, gloves, bins, bags, phenol) at the health facility level for implementation of the Infection Management and Environment Plan (IMEP) adopted by the MoHFW. Field observations in the state of Telangana indicated that Infection Control and Waste Management (ICWM) in DMCs, Treatment Units (TUs), DTC and IRL were in line with the IMEP with regard to disinfection, segregation, storage and disposal. This fiscal year, delayed release of funds to the program in many states has affected procurement of consumables for ICWM, except in those health facilities where the Medical Officer in charge has prioritized it. While higher centers were linked to Common Treatment Facilities run by private providers for transfer and disposal of bio-medical waste, lower facilities made use of deep burial pits for the same.

62. Airborne infection control (AIC) for TB and its drug resistant variants is a serious concern for RNTCP. Draft guidelines for AIC with technical support of WHO have been published and disseminated by CTD. State AIC committees have been constituted and sensitized on the guidelines. AIC assessment kits have been procured and are used in a pilot being implemented in 35 health facilities comprising medical colleges, district hospitals, community health centers, primary health centers, private hospitals, IRLs, PMDT sites and ART centers in three states, to

showcase effective AIC interventions as defined by the national guidelines and approved by the National AIC Committee. RNTCP is implementing the AIC guidelines in all public health facilities, especially in high risk settings—DR-TB centers, C&DST labs and ART centers.

63. *Social safeguards*: The program has identified women, children, HIV/AIDS patients, and tribal people as groups vulnerable to TB, and based on findings of a social assessment undertaken in 2011, developed a Social Action Plan and Tribal Action Plan to bridge gaps in access and utilization of TB prevention, screening and treatment facilities in the public health care settings. The National Strategic Plan has enumerated several enhanced incentives to be rolled out to improve information and uptake of services amongst the vulnerable and marginalized groups. While guidance on the enhanced incentives has been transmitted to all states, it was observed during field visits that the knowledge is not adequate in either the community or with the front line staff.

64. A study of socio-economic characteristics of TB patients (including DR-TB patients) is planned and is an indicator in the results framework of the IDA credit. ToR for the study need to be developed.

65. Recommendation

(i) ToR and budget for a study of socio-economic characteristics of TB patients should be developed (by December 31, 2014).

L. NEXT MISSION

66. As part of its technical and fiduciary obligations, the Bank undertakes implementation support missions every six months. The next mission will be encompassed in a planned Joint Monitoring Mission to be coordinated by CTD with the support of WHO in March-April 2015.

ANNEX 1. MISSION PARTICIPANTS

Name	Designation
Ministry of Health & Family Welfare (MoHFW), Government of India	
Dr. Jagdish Prasad	Director General Health Services, MoHFW, Government of India
Mr. Anshu Prakash	Joint Secretary, MoHFW, Government of India
Central TB Division, MoHFW, Government of India	
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Dr. K.S. Sachdeva	Additional Deputy Director General
Dr. Neeraj Kulshrestha	Additional Deputy Director General
Dr. V.S. Salhotra	Additional Deputy Director General
Dr. Smrity Kumar	National Consultant, Planning and Donor Coordination
Mr. Arindam Moitra	National Consultant, Partnership
Dr. Kiran Kumar Rade	National Consultant, TB Epidemiologist
Dr. Amar Shah	National Consultant, TB/HIV
Dr. Anand	Consultant Lab
Dr. Imran	National Consultant, MDR-TB
Dr. Mayank Ghedia	National Consultant
Mr. Ashish Choudhary	Consultant, Drugs & Logistics
Ms. Sheffali Sharma	Consultant, Drugs & Logistics
Dr. Mohan P S Kohli	Consultant, PPM
Dr. Bharti Kalottee	Grant Manager, GFATM
Dr. S.N. Rai	Consultant
Rina Sinha	Consultant, ACSM
Anukampa Sangwan	Consultant, ACSM
Mr. Rajan Chauhan	Consultant, Financial Management
Mr. R.K. Sachdev	Consultant, Financial Management
Central Medical Services Society, Government of India	
Mr. S. M. Khan	General Manager
RITES	
Mr. V. Sudhakara Rao	General Manager
Mr. Nitin Jain	Engineer

World Bank Group

Mr. Patrick M. Mullen	Senior Health Specialist & Task Team Leader
Dr. Ghulam Dastagir Sayed	Senior Health Specialist
Dr. Jaime Bayona	Senior Public Health Consultant
Mr. Shanker Lal	Senior Procurement Specialist
Ms. Manvinder Mamak	Senior Financial Management Specialist
Ms. Ruma Tavorath	Senior Environment Specialist
Ms. Sangeeta C. Pinto	Operations Officer
Mr. Satya Mishra	Social Development Specialist
Mr. Ajay Ramdass	Program Assistant

World Health Organization (WHO) India

Dr. A. Srinivas	National Professional Officer – TB
Dr. Malik Parmar	National Professional Officer - PMDT
Dr. Ranjini Ramachandran	National Professional Officer - Lab
Mr. E. Thanaraj	Focal Point (GDF & Drugs)

Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)

Mr. Andreas Tamberg	Fund Portfolio Manager, India
Ms. Rozina Merali	Specialist, Health Products Management
Ms. Lalla Haidara	Program Officer India
Mr. John Machro	Program Officer India
Ms. Inna Ivanova	Finance Officer
Mr. Wilson Lo	M&E Officer

India Country Coordinating Mechanism (CCM)

Dr. Jagdish Kaur	India CCM Coordinator

United States Agency for International Development (USAID)

Dr. Hari Singh	Global Fund Liaison
Dr. Reuben Swamicken	Project Management Specialist, TB

International Union Against Tuberculosis and Lung Disease

Mr. Subrat Mohanty	Project Coordinator