PROPOSAL SUBMITTED TO

BBMP

TB BOND

TB Impact Investment

Indian Centre for Social Transformation
(Indian CST)

National TB Elimination Programme (NTEP)

Bruhat Bengaluru Mahanagara Palike
(BBMP)

Indian CST Consortium
Contact: Sri Raja Seevan
Dr Prasad BM

Demonstrating the TB Impact Investment – TB Bond

Proposal Submitted to Bruhat Bengaluru Mahanagara Palike (BBMP) by the following consortium partners lead by Indian CST.

Lead Partner	Indian Center for Social Transformation (Indian CST)	Sri Raja Seevan Chairman and Founder **Indian Centre for Social Transformation (Indian CST**), Research & Development Centre, Grace Mansion #25, 1st Floor, Infantry Road, Bengaluru-560001, Karnataka, India
Laboratory Partner	Precise medical diagnostics	Dr. Ranganatha R Managing Director **Precise medical diagnostics** #10, Janitva, new Thippsandra main road, opp to Thippsandra post office, near BEML circle, Bengaluru, Karnataka-560075.
Diagnostic Partner	Thryrocare Technologies Limited	Dr Chaitali Nikam Head - Infectious Diseases **Thyrocare Technologies Limited**, D-37/1, opp. Sandoz, TTC Industrial Area, MIDC Industrial Area, Turbhe, Navi Mumbai, Maharashtra 400703, India

Background:

Globally, Tuberculosis (TB) programs have prioritized early diagnosis, initiation of treatment, and ensure treatment completion. The basic assumption to early diagnosis is that all presumptive TB patients (PTBPs) will access healthcare facilities for consultation and eventually be diagnosed with TB. However, in high TB burden countries, lack of awareness about TB in communities, availability of services at health facilities, and socioeconomic and cultural-environment conditions are key factors. These factors may contribute to delay in the diagnosis of TB and among them – "systems delay" which is critical and may be easily addressed. Health systems delay occurs when presumptive TB patients (PTBPs) have to make repeated visits to the same health facility/center for diagnosis. In a given setting, a PTBP may have to visit 2 to 4 times to facility/facilities prior to being diagnosed with TB and initiation of treatment. During this process may transmit infection and might infect up to 10-15 people annually as a result of delayed diagnosis. Multiple visits may also lead to an incomplete diagnostic assessment, and inappropriate treatment resulting in the amplification of drug resistance.

The National Strategic Plan to End TB 2020 -2025 with a focus on building and strengthening the health system for early detection, and appropriate treatment to end TB by 2025. NSP for early detection through high-sensitivity diagnostics and universal access to quality TB diagnosis is one of the key emphasis areas. The diagnostic network under the National TB Elimination Programme (NTEP) has expanded with molecular diagnostics at districts and sub-district level (5090 sites with Xpert/Truenat) and TB culture and drug-susceptibility testing facilities (83 Culture and Drug Susceptibility Testing (DST), 34 Intermediate Reference Laboratories) with cutting-edge technologies at State and National level (six National Reference Laboratories).[i] The diagnosis of Drug– Susceptible TB (DS-TB) and Drug Resistant TB (DR-TB) require sequential testing and these tests are available at different levels of the health system. At times completing the diagnostic assessment of identified presumptive TB patients could be a challenge and may result in the loss of patients along the care cascade.[ii] Tracking PTBPs has been a challenge for the reasons listed may not be limited to, (a) where a physician may refer PTBP to microscopy, (b) where a physician may refer PTBP Chest X-ray (CXR), and (c) where a physician may ask for a follow-up after two weeks. Given these, there is a missed opportunity for the diagnosis of TB among identified PTBPs which is the key to ensuring NTEP achieves END-TB goals.

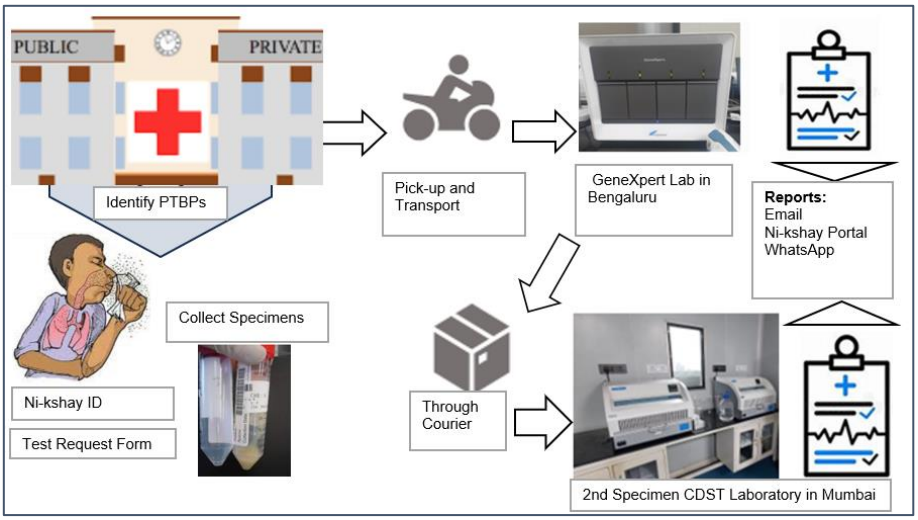
The Proposed Intervention:

The NTEP has recently endorsed "One-stop TB/DR-TB diagnostic solution" model which was implemented with the objective to engage private-sector laboratory for end-to-end diagnostic assessment for TB and Drug-Resistant TB patients as per NTEP's diagnostic algorithm in selected geography.[iii] In the model public/private providers identify and refer the PTBPs/TB patients for specimen collection. The collected specimens are transported from point of collection to a centralized NTEP certified private laboratory where requisite tests

are performed as per the NTEP diagnostic and treatment algorithm (Appendix 1). The test reports are updated in Ni-kshay web-portal as and when available. The results are also communicated to program staff via email, and the referring physician for initiation of treatment.

The **"One-Stop TB/DR-TB Diagnostic solution"** model is proposed to be implemented in districts of Bruhat Bengaluru Mahanagara Palike (BBMP). The Central TB Division, Ministry of Health and Family Welfare has communicated to states NTEP programme officers to explore the possibilities of having such a model in the state (Appendix 2, letter to state from CTD along with Brief Report).

Figure 1 Schematic outline of One-Stop TB Diagnostic Solution Model



The Model Implementation:

The NTEP staff at District and other stakeholders from BBMP will be briefed about the implementation process of the model (Figure above). The Indian CST team will have a series of meetings with BBMP doctors, private doctors, NTEP staff and conducted brainstorming exercises to sensitize about the model. During these meetings, the role of stakeholder will be emphasized. Through these meetings official letters is to be issued to all concerned officers of respective health facilities through proper channel. The site coordinators employed by Indian CST will make regular visits to all the TUs and DMCs (with OPDs) and key private doctors to sensitize them about the model.

Orientation of NTEP Staff will be conducted by Indian CST Team where it will be emphasised on (a) identification of PTBPs at respective facilities (b) collect specimens from identified PTBPs and complete the Test-Request-Form (TRF), and (c) generate Ni-kshay IDs for identified PTBPs. The representatives from Precise diagnostics will collect the specimens along with duly filled TRF. All reports from will be updated in Ni-kshay and shared to DTO via email. The signed copies of results will be shared from DTC to respective centers through STS.

The Laboratory Consumables for specimen collection and transportation – falcon tubes, tapes, etc were provided through Precise diagnostics. The consumables were also supplied to private healthcare facilities requesting for tests.

The NTEP staff to ensure that the quality of specimens and examine if there are leakages, missing Nikshay IDs, and insufficient specimen quantity. The quality issues to be addressed through continued monitoring and through support of DTC staff.

The specimen collection, transportation, and testing will be conducted by Precise for Xpert, and Thyrocare a NTEP-certified private laboratory to conduct First Line, Second Line LPA and Second Line Drug Sensitivity test (DST). The results will be updated in the Ni-kshay portal against the IDs, as and when available. The coordinator will facilitate the communication of results via email to referring doctors.

Expected Output:

1 Tuberculosis Case Detection

- Two fold increase in TB Case Detection
- Two fold increase in DR-TB Case Detection

2 Complete Diagnostic Care Cascade

- 100% of identified PTBP complete Diagnostic Care Cascade
- All Xpert Positive to have DST Results avalaible within stipulated turn-around-time

Expected Outcome:

1 TB Impact Investment Model

- Demonstrated the TB Impact Investment Model
- Raise TB Investment Bonds

2 DST Guided Treatment

- Diagnosed TB patient to have DST results avalible to initiaiton of Treatment

Estimated Budget:

The intervention is focused on increasing case detection in the said geography along with completing the diagnostic care cascade of diagnosed TB patients as per NTEP guidance. Therefore, a major proportion of budget is allocated to diagnostic services which includes, specimen collection and transportation, Xpert tests and sequential TB tests and site coordinators. Secondly, a project implementation budget is arrived that includes the travel of senior staff, part salaries, and sensitization workshops at the identified sites. All other shared cost, administration related, GST cost and finance related costs are budged in overall project implementation budget.

Given the model is to demonstrate TB investment bond and therefore the volume of tests and resources required are directly proportion to total case detected. The model proposes to detect a minimum of 180 TB patients per month to meet the operational costs. For detecting one bacteriologically positive patient it is estimated to cost Rs 25,000 – Rs 30,000 which is the same cost of detected TB patient in public sector. The policy brief document shared by CTD, suggests to explore the possibility of **strategic purchase of services** (See Appendix 2). Along with detecting the TB patient, the model offers complete sequential testing of diagnosed TB patients. Over 85% of the amount is allocated for diagnostics and about 15% is allocated for project implementation.

The proposed model will be implemented by the consortium partners led by Indian CST partnering with Precise Medical Diagnostics and Thyrocare Technologies Limited (see Appendix 3 for profile of organization).

Services Offered in the Model:

1. Specimen Collection and Transportation from identified facilities (Pulmonary and Extra Pulmonary specimens)
2. GeneXpert Test is conducted for Specimens collected and reported through Ni-kshay platform
3. Specimens with MTB detected is subjected to Line Probe Assay (First Line and Second Line)
4. 100% Specimens eligible for Liquid Culture is performed.
5. 100% Specimens eligible for Liquid Culture DST is performed as per NTEP algorithm.
6. All reports are updated in Portal and shared via email to respective NTEP official or doctor.

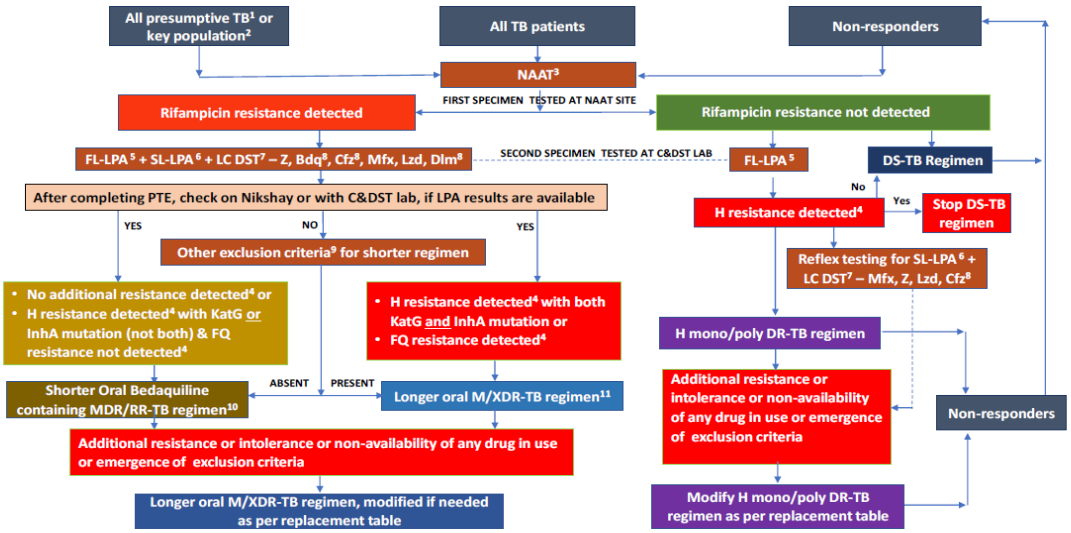
[i] GOI, "India TB Report 2023 Leading the way," Central TB Division, Ministry of Health and Family Welfare, New Delhi, 2023.

[ii] R. Subbaraman, T. Jhaveri and R. R. Nathavitharana, "Closing gaps in the tuberculosis care cascade: an action-oriented research agenda," Journal of Clinical Tuberculosis and Other Mycobacterial Diseases, vol. 19, no. 100144, 2020.

[iii] Raju R, Prasad BM et.al Experience of "One Stop TB Diagnostic Solution" Model in Engaging a Private Laboratory for End-to-End diagnostic services in National TB Elimination Programme in Hisar, India. https://pubmed.ncbi.nlm.nih.gov/37685361/

For more details please contact:
Dr Prasad BM
Ph 9999296958

Appendix 1: Program Management of Drug-resistant Tuberculosis: National Tuberculosis Elimination Program Diagnostic and Treatment Algorithm



CBNAAT=cartridge- or chip-based nucleic acid amplification test, DR-TB=drug-resistant tuberculosis, DS-TB=drug-sensitive tuberculosis, DST=drug susceptibility testing, EPTB=extrapulmonary tuberculosis, FL -LPA=first-line line probe assay, LPA=line probe assay, NAAT=nucleic acid amplification test, PLHIV=people living with HIV, SL-LPA=second-line line probe assay, TB=tuberculosis

Appendix 2:

From: Nishant Kumar <kumarn@rntcp.org>
Sent: Thursday, April 6, 2023 6:01:32 PM
To: STO <sto@rntcp.org>
Cc: Consultants <Consultants@rntcp.org>; CTD Lab <ctdlab@rntcp.org>; STDC <stdc@rntcp.org>; Saini, Sanjeev <Sanjeev.Saini@icf.com>; Umesh Alavadi <ualavadi@usaid.gov>; STO Haryana <stohr@rntcp.org>; Ranjani Ramachandran <ramachandranr@who.int>; Kirankumar Rade <radek@who.int>; PARMAR, Malik <parmarm@who.int>; KANDARATH BALAKRISHNAN, Shibu <balakrishnansh@who.int>; Regional Team Leads <rtl@rntcp.org>; CMO <cmo@rntcp.org>; DDG TB <ddgtb@rntcp.org>
Subject: Cross learning amongst the States/UTs-Reg

Dear All,

Greetings from Central TB Division (CTD).

This is with reference to the communication from STO Haryana in a trailing email, sharing a brief report (attached) about initial learnings of "One-Stop TB/DR-TB Diagnostic Solution" Model, being implemented in the Hisar District of Haryana for your information and to promote cross learning amongst the States/UTs.

For more information in this regard, you may please connect with STO Haryana.

Thanks and Best Regards,

Dr Nishant Kumar
Joint Director (Public Health)
Ministry of Health & Family Welfare
205, 2nd Floor,Jeevan Vihar Building,
#3 Sansad Marg, New Delhi 110001

Brief Report

March 2023

Key messages

- Build awareness and understanding of strategic purchase of TB lab services in India for provision of One-stop TB/DR-TB diagnostic solutions under the National TB Elimination Programme (NTEP).
- Rationalize and target available options for TB lab services at different levels of NTEP implementation to respond to evolving and emergent needs of the capacity and complexity for complete diagnostic evaluation of TB and DR-TB.
- Enable NTEP managers at national, state, and district level to design, deploy and manage efficient TB diagnostic services by maximizing complementarities and layering of available public and private sector TB diagnostic networks.
- Integrate diagnostic priorities and possible options to meet the demands, in annual work plans and budgets at all levels of NTEP implementation.

Strategic Purchasing of TB Lab Services in India-

Learnings from 'One-Stop TB/DR-TB Diagnostic Solution' model in Hisar, Haryana

1. Background

In recent years, the National Tuberculosis Elimination Program (NTEP) has focused on strengthening public sector institutions and strategically engaging the private sector to address the gap in tuberculosis (TB) case detection. Despite the untiring efforts to expand the TB lab and diagnostic services with latest diagnostic platforms and ensure the sustainability of laboratory operations to meet the increasing demand, challenges remain and require the program to test and adopt newer transformative ways to facilitate diagnosis of Drug Susceptible TB (DS-TB) and Drug Resistant TB (DR-TB) in a desired turnaround time (TAT) and minimize patient discomfort by bringing the services closer to the community. NTEP supports the diagnostic assessment of presumptive TB patients (PTBPs) through the network of TB laboratories established at different levels of the health system (Smear Microscopy and Nucleic Acid Amplification Tests at sub-district and district level; Line Probe Assays and Cultures and drug susceptibility testing at the state and regional level) in the public sector for the detection of DS-TB or DR-TB. Building new laboratories and maintaining their functionality has multiple challenges and is resource intensive. The NTEP proposes to explore partnership options with private laboratories to expand the reach of diagnostic services by adopting newer engagement strategies outlined in the National Strategic Plan and the guidance document on partnership engagement.

Private sector lab engagement model i.e. "One-stop TB/DR-TB diagnostic solution"

The Infectious Disease Detection and Surveillance (IDDS), a United States Agency for International Development (USAID) - supported global project, has conceptualized and implemented "One-stop TB/DR-TB diagnostic solution" model in consultation with the Central TB Division (CTD),

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key stakeholders and private laboratories by engaging an NTEP-certified private sector laboratory for quality-assured diagnosis along the TB diagnostic care cascade in NTEP. IQVIA through the iDEFEAT -TB project (USAID/India's flagship TB project) is evaluating this intervention for feasibility, impact, and cost implications. The model is implemented in Hisar district (population of about 20 lakhs and mix of urban, semi-urban and rural geography) under the leadership of CTD, and State TB Cell of Haryana, and in collaboration with Hisar District TB Cell and NTEP staff.

. Key features of the model design

2.1 Onboarding laboratory and field staff

For the implementation of the project, private laboratory Thyrocare Technologies Limited (TTL) was engaged through a competitive bidding process. A district and five (5) block site coordinators have been placed by IDDS project to coordinate and monitor the implementation in coordination with District TB Officer (DTO) and staff.

2.2 Provision of additional support to the existing TB diagnostic network in Hisar

Prior to the implementation of the model, 13 of the 20 Designated Microscopy Centers (DMCs) in district Hisar were also designated as specimen collection centers and specimen transportation was facilitated by couriers – The India Post in rural areas and by Rotary club in urban areas. There were two GeneXpert (Gx) and two Truenat machines, the functionality of which was dependent upon the availability of the cartridges and equipment maintenance and repair. District Hisar is linked with Intermediate Reference Laboratory (IRL) at Karnal for C-DST services, including liquid culture (LC), First-line (FL) and Second-line (SL) Line Probe Assays (LPA), the services of which were suboptimal due to ongoing upgradation of the IRL. Pre-treatment evaluation (PTE) tests were being conducted at district hospital for patients with DR-TB. Under the model the overlay of services included sample collection and transportation from over 44 centers at public and private facilities through runners engaged by the contracted lab, additional Gx, C-DST capacity at private sector central lab facilities and X-Rays at sub-contracted centres at district and sub-district were made available for PTBP and diagnosed TB patients.

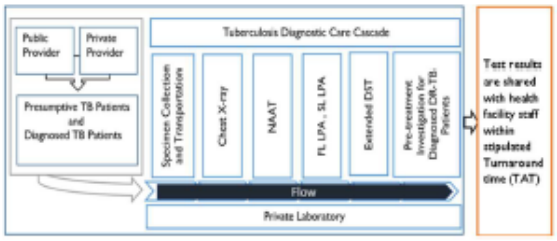

Figure 1: End to End "One Stop TB/DR-TB Diagnostic Solution" Model

2.3 Streamlining mechanism for specimen flow and communication of results

The route plans were prepared for Thyrocare runners to strategically cover all mapped health facilities to ensure same-day specimen collection and transportation to the testing facility, in consultation with staff from the district TB cell, mapped the flow of TB patients, and understanding shortest routes using GIS mapping. Currently, runners are collecting samples on five (5) routes, including public and private sector. At collection center, laboratory technician or the designated person were sensitized to collect two sputum specimens in 50 ml conical tubes, update Ni-kshay details or generate Ni-kshay ID and fill the NTEP Test Request Form (TRF). Specimens are packed as per the NTEP guidance and the Thyrocare runner on the designated route are informed over call or WhatsApp for collection from the facility.

Healthcare providers from public and private sector identify PTBPs and diagnosed TB patients for further diagnostic evaluation and refer them for providing specimens to the nearest collection point along with duly filled-in NTEP TRF.

Capacity building of the District NTEP staff and private providers was done through continued workshops and refresher trainings to ensure

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effective implementation of the model.

While the existing system continues to operate, the specimens directed to model are collected by runners on bikes and transported to the repository at Hisar district headquarter (HQ) by 4.00PM daily for public sector and by 6:00 PM daily for private sector, and then further transported to the Thyrocare laboratory in Gurgaon, where GeneXpert tests are done overnight. The results are communicated back to the concerned Medical Officers within 24 hours of specimen collection through email to the concerned health facility, and simultaneously entered on Ni-kshay portal. The lab technicians (LTs) coordinate to communicate results to the patients and to facilitate initiation of treatment. Some LTs are also trained to perform phlebotomy and collect blood specimens for PTE of DR-TB patients, which are also transported to district HQ through runners and further to the Thyrocare lab at Gurugram. The model aims to complete the sequential diagnostic tests of TB patients as per NTEP's diagnostic algorithm within the stipulated Turn Around Time, while reducing the number of patient visits to health facilities and frequency of specimen collection. The model is complementing district NTEP efforts in completing the diagnostic work-up of TB patients.

Figure 2: Flow of specimens from identified collection centers to Thyrocare Lab for TB diagnosis

3. Assessment Methodology

The assessment of "One-stop TB/DR-TB diagnostic solution" model has been done through an evaluation framework based on the pillars of Relevance, Efficiency, Effectiveness, and Feasibility (REEF). The Relevance criteria in REEF framework relates with the situational analysis to fulfill the gap and the strategic choices made through One-stop TB/DR-TB diagnostic solution model to provide end-to-end quality assured TB diagnostic solutions. Similarly, effectiveness relates to whether the model was able to achieve the pre-stated objectives and whether there was an incremental yield in the number of patients completing the diagnostic cascade as NTEP policy. Efficiency talks about whether the model can address the challenges of diagnostic cascade in terms of improving turn-around-time of the diagnostic tests and efficiently providing quality-assured tests in a timely manner. Lastly, the feasibility factor focuses on capturing the perception of the program stakeholders on the key elements that facilitated and/or hampered the model implementation as well as the patient perspective through a means of quantitative and qualitative research techniques.

The assessment studies are divided in three phases to include baseline, midcourse and end-line assessments. Baseline was conducted for Year 2021 (Jan-Dec) and Q1 2022 (Jan-Mar). A mid-course assessment has been done for initial 3.5-month implementation period i.e., 14th May-31st Aug 2022 to study the effect of initial implementation of the model on the diagnostic care cascade services in Hisar to identify and highlight implementation areas, where any mid-course correction is required.

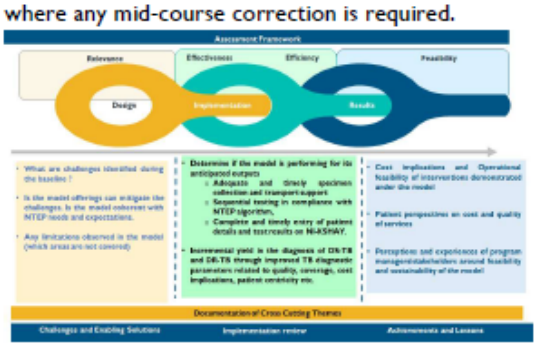


Figure 3: Assessment framework

4. Findings

This section compares the 'district performance' during model implementation corresponding to the duration (May 14 – August 31) of Mid-course assessment as compared with two-time intervals of Baseline i.e., Year 2021 and Q1 2022 vis' a vis' following key result areas:

4.1. Upfront molecular test coverage

An increase in the number of total TB diagnostic tests conducted in the district is observed with 22,583 (annualized) tests during mid-course evaluation period, compared with 6,684 (annualized) tests in Q1 of 2022 and 13,000 tests in year 2021.

During midcourse evaluation period 6,584 NAAT test were done for diagnosis of TB in Hisar of which 40% tests were done through the model without destabilizing the existing system in the district. The Testing of PTBPs with upfront NAAT for increased to 63% during midcourse as compared to 26% during year 2021 and 31% in first quarter in year 2022.

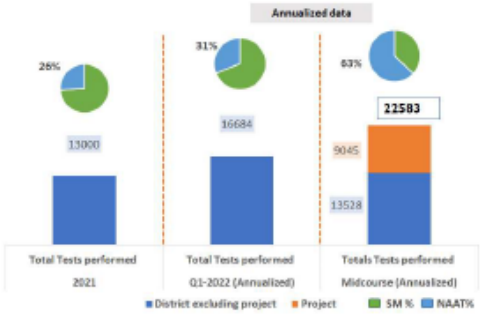


Figure 4: District achievements – Total diagnostic tests and Upfront NAAT in Hisar

4.2. Universal Drug Susceptibility Testing (UDST) coverage

There has been an improvement in the proportion of notified TB patients tested for Rifampicin resistance (RR) during midcourse compared with the baseline.

Sixty-six percent (66%) of all notified patients were subjected to UDST during midcourse which was 44% and 31% during year 2021 and Q1 2022 respectively. Proportion of patients offered UDST within 15 days was 64% during mid-course, higher than 39% during the year 2021 and 24% in Q1 of 2022.

Figure 5: District Trends in time taken for UDST of all notified TB patients in Hisar

4.3. Completion of sequential testing for TB diagnosis

An analysis of notified TB patients was conducted to review compliance with TB diagnostic algorithm, based on seven key diagnostic indicators listed in NTEP's PMDT guidelines (Yr. 2019). Gains were observed for all indicators, 41% vs 22% of notified TB patients had upfront NAAT for diagnosis of TB, 94% vs 79% of bacteriologically confirmed TB patients were tested for RR 81% vs 22% of RR TB patients and 85% vs 34% of Rifampicin Sensitive (RS) TB patients received FL-LPA results, 53% vs 6% of RR and 80% vs 62% of INH Resistant (Hr) TB patients received SL-LPA results, and 16% vs 1% had extended DST done in midcourse compared with Year 2021, respectively.

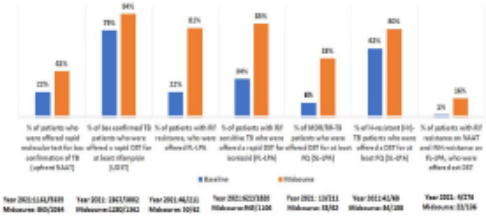


Figure 6: Notified TB patients tested in compliance with TB diagnostic algorithm in Hisar- Baseline vs Mid-course

4.4. Turnaround Times (TAT) for completion of diagnostic cascade

Turnaround Time was estimated for each TB

patient from the time of specimen collection to the generation of the last result needed for completing diagnostic evaluation of DS-TB or DR-TB and averages calculated.

It is evident that TAT has reduced significantly during the mid-course interval compared to baseline year 2021. This may be attributed to timely specimen collection and transportation from periphery to NAAT labs and subsequent fast tracking to C&DST lab for sequential testing through the model as well as close monitoring of lab level TATs for various tests being conducted through the model. Although this applied to the specimens flowing through the model, the result has been an overall reduction of TATs in the district.

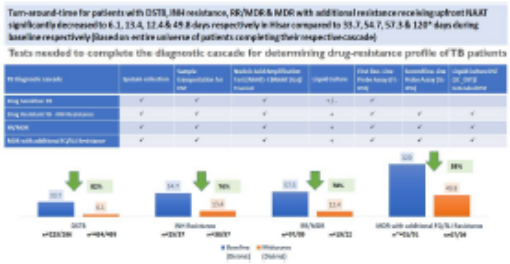


Figure 7: Turn-Around-Time for completion of diagnostic cascade in Hisar (Baseline vs Mid-course)

4.5. Cost implications

As an adjunct to the on-going assessment of the Hisar model, the IQVIA team is studying the cost implications for implementation of part or entire set of interventions introduced through the model. An overview of the cost of various diagnostic tests for diagnosis of TB has been attempted through a combination of approaches, including - Literature review and estimation of current Unit Cost of TB test services in public sector in India in INR; Market scanning through volume based rates of TB tests quoted by private labs and lab networks; Estimating cost of missing elements such as cost of packaging and transportation of samples as well as cost of LC-DST and Extended DST as envisaged in NTEP diagnostic algorithm, through deliberations with NTEP personnel and lab experts.; and also by understanding patient perspectives in terms of number of visits done and associated out of pocket expenses incurred by the patient while completing the TB diagnostic cascade.

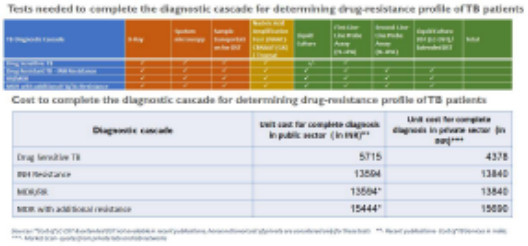
Estimated Unit Cost of TB Diagnostic tests

Name of Test	Public sector cost based on recent publications#	Market Rate and Volume based price##
	Cost for each test (INR)$	Volume based price (INR)
Sputum microscopy ZN	218-363	-
CXR Digital	252-457	230-500
CXR Film	173-292	-
CBNAAT	1543-2650	1600-2200
Truenat	-	-
Liquid culture	774-1221	600-1250
FL-LPA	1763-3458	1500-1800
SL-LPA	1650-3307	1550-6500
DST_FL_liquid	2007-2545	
DST_SL (FQ/SLI)		
LCDST (Mfx, Z, Lzd, Cfz*)	-	4000-7800
Extended DST (Z, Bdq*, Cfz*, Mfx, Lzd, Dlm*)	-	5000-10500
Public sector cost based on inputs from NTEP$$$		
Cost of packaging and transportation	*214-197*	-

Figure 8: Estimated Unit Cost of TB Diagnostic tests

A comparison of cost estimates for diagnosis of single patient with either drug sensitive or any drug resistant TB undergoing sequential testing in public vs. that in private sector was done by grouping the cost of all sequential tests needed to complete the relevant diagnostic cascade.

Estimated Cost of TB Diagnosis



Cost to complete the diagnostic cascade for determining drug-resistance profile of TB patients

Diagnostic cascade	Unit cost for complete diagnosis in public sector (in INR)**	Unit cost for complete diagnosis in private sector (in INR)***
Drug Sensitive TB	5715	4378
INH Resistance	13594	13840
MDR/RR	13594*	13840
MDR with additional resistance	15444*	15690

Figure 9: Estimated cost of TB diagnosis

It is concluded that the cost of performing individual tests, as well as the cost of completing the diagnostic cascade for a single patient having either drug sensitive or any drug resistant TB, in public sector laboratories, are generally comparable with the price of tests and cost incurred when the diagnostic services are purchased from the private sector.

5. Guidance on strategic purchasing of TB lab services

- Given the complexity of the TB diagnostic cascade, the availability of different diagnostic services in different settings of the health system as well as variability in demand and corresponding diagnostic capacities within the public TB diagnostic network, in most circumstances it makes sense to "buy" additional capacity to meet the existing and emergent gaps compared with the option to "maintain and run" or "build" so that high quality TB diagnostic services are available in expected turnaround times, an uninterrupted manner.
- The One stop TB/DR-TB diagnostic solution model/ Hisar model has demonstrated that the additional TB diagnostic services purchased from the private sector can seamlessly fill the capacity gap without destabilizing the existing public sector services, effectively adding to the number of diagnosed TB patients who complete the entire test cascade, prior to getting the most appropriate treatment.
- A parallel study capturing the patients' perspectives on number of visits and out of pocket expenses reiterates the gains and emphasizes the value of having an efficient TB diagnostic network through a judicious mix of public as well as outsourced private services in providing good programmatic outcomes as well as beneficiary experience.
- It is expected that the notional costs of TB tests will help the TB program managers in taking informed decision during planning and budgeting of TB diagnostic services, while incorporating partnership options. The estimated costs are notional and vary from the actual costs, basis variations in difficulty of terrains as well as possible negotiations for higher volume of tests.
- It is recommended that the program managers may also consider adding program management services with corresponding clauses in the contracts with contracted labs to ensure quality of services, including recommended turn-around times, monitoring of flow of samples for sequential testing, and prompt communication of results, as was done by the site coordinators deployed in the Hisar model.

Appendix 3

Associate 2 Transform & Excel

Indian Centre for Social Transformation

GPMS Transportal

Universal Healthcare

About the Organization

Joining with **TB Free India** Mission, under ICMR Project,

Screened **60,000** households for TB in Karnataka

Identified and traced >5000 TB patients to ensure Treatment completion

Indian Centre for Social Transformation (Indian CST) is a registered Public Charitable Trust (Registration No. HLS-4-00228-2009-10 dated 26/12/2009) with the mission to work towards realization of the national vision set out in Article 51A (j) of the Indian Constitution.

The vision is to "Enable Social Transformation by Digitally Empowering the Citizens" with the mission to "Make Healthcare Affordable and Agriculture Profitable by bridging the Digital Divide."

The GPMS-TB Transportal developed by Indian CST provides integrated system level platform connecting TB patients with healthcare service providers in the State of Karnataka for identifying high density areas, individual case data (linking to Nikshay or other relevant government portals). The bilingual APP is compatible on android tablets and smart phones which can utilised by ASHA workers at the grassroots.

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Associate 2 Transform & Excel

Indian Centre for Social Transformation

The GPMS-TB In the ICMR Project on Active case finding (ACF) in TB; Indian CST signed an MoU with Share India (Delhi) to take up the daunting task of helping find the missing millions. Indian CST with an expertise in digital technologies partnered with Ramaiah hospital and Karnataka State Health TB officer-Bengaluru; initiated the TB survey and TST administration at various construction sites, organising training programs and workshops for capacity building, etc.

Universal Health Care Services

Geno Cluster	• Resulted in the identification of 4 new SARS virus, which led to the invention of CoVaxin
Newer Drugs	• Identification of 20 novel lead molecules in MTB including 4 FDA approved drugs
SGD 3.0	• Real time monitoring system for policy decisionsfor SDG 3 0
ICT Integration	• End to end ICT integration, GPMS Transportal integrated with IoT

Empowering **CITIZENS**.... Empowering the **NATION**....

Grace Mansion, #25, 1st Floor, Infantry Road, Bengaluru - 560 001, Karnataka, India, Tel : 80 22868185, Email: rajaseevan@indiancst.in

PRECISE MEDICAL DIAGNOSTICS
Precision is in our DNA

Precise Medical Diagnostics
(A unit of V CARDS Health Care Pvt Ltd)
080-25262633
info@precisehealth.in
www.precisehealth.in

Company Profile

Precise Medical Diagnostics is a unit of V CARDS HEALTH CARE Pvt. Ltd. Promoted by a team of distinguished medical specialists who have excelled in clinical expertise and possess an intense interest in shouldering the social responsibility over the last one decade, they are focused to serve the ailing mass in particular and the population at large.

Our Vision
To provide an Ethical and Affordable Medical Diagnostic Solutions with Reliable/Clinical Precision.

- To establish an accuracy driven Diagnostics Company that will set a benchmark in Medical Diagnostic Solutions in the Country on par with any other international Medical Diagnostic Solutions.
- To serve the country by empathetically detecting the pulse of medical conditions of the society that will result in healthy working population.
- To reduce the long-term health expenditures of both the community and Country by timely intervention through precise diagnostics.

Our Mission
"Declare the past, diagnose the present, and foretell the future"

Objectives of the work and methodology

The objectives of the proposed work are

- To collect the specimen (Pulmonary & Extra Pulmonary from designated point or designated hospital/laboratory)
- To transport the sample to Gene Xpert processing laboratory in an appropriate container
- To process the sample in Gene Xpert laboratory
- To share the softcopy and hard copy of the results with BBMP staff within 48 hours of receipt of samples (Using SMS Alert/mobile application/Laboratory Information Management System)
- To coordinate with BBMP staff for smooth logistic run and tracking status of the specimen
- To ensure laboratory quality standards all the time.
- To generate monthly status report on a monthly basis and report to concerned authorities

Laboratory has dedicated staff to carry out entire task to collect the specimen from designated collection points. The specimen collected is registered in our dedicated Laboratory Information and Management System and assigned a bar code on spot. The

specimen are packed in an appropriate leak-proof container with biohazard symbols to central processing laboratory by fastest transport mechanism. The sample are processed in the central laboratory as per Gene Xpert protocol (Precise Medical Diagnostics is having 2 four module Gene Xpert Equipment's in the central laboratories in Bangalore & Hyderabad - Can handle approximately 80 tests/day) and share the soft copy to provider's staff. The hard copy of the reports are delivered to concerned designated sites within 48 hours of the receipt of the sample

As on November 2023, we are having 2 central laboratories in Bengaluru and Hyderabad. We also have 5 satellite laboratories inside 5 multispecialty hospitals/clinics in Bangalore and more than 42 collection centers across India.

1. Name of the Agency: Precise Medical Diagnostice (A Unit of V Cards Health Care Pvt. Ltd)
2. Address of the Agency: #10,Janitva, New thippasandra Main road, opposite Post Office, New thippasandra District Bangalore PIN 560075
3. Email Address: precisemedicaldiagnostics@gmail.com
4. Agency profile (*)

- Name of the top executive: Dr. Ranganatha R
- Designation: Managing Director
- Email Address: rrpulmo@gmail.com
- Mobile Number: 9740200774
- Service Tax Number: Not Applicable
- PAN: AAFCV3448P
- Office Strength Technical: 37 Nos.
- Administrative: 5 Nos

PRECISE MEDICAL DIAGNOSTICS BANGALORE-75

Date: 29-11-2023
Place: Bangalore

PRECISE MEDICAL DIAGNOSTICS
(A Unit of V CARDS Healthcare Pvt Ltd)
Bangalore - 560 075

Thyrocare

Tests you can trust

TB - Public Private Partnerships

National Burden of Tuberculosis

India has the highest burden of tuberculosis (TB), accounting for nearly 24% of the global TB incidence. In India, two deaths occur every 3 minutes from TB. Nearly 350 million Indians are latently infected with TB, and 4 million new TB infections occur annually. Extensively drug-resistant (XDR) TB - a rare type of multidrug-resistant (MDR) TB - has become a new threat to TB control in India. Hon'ble Prime Minister Shri Narendra Modi ji gave the clarion call to end TB in the country by 2025, 5 years ahead of the SDG target of 2030. The Government of India and National TB Elimination Project (NTEP) have done commendable work in order to push for TB elimination by 2025 in spite of the setbacks due to COVID pandemic. As a nation we have a herculean but achievable task in front of us to end TB by 2025, and quality assured TB diagnostic services are essential to reach this goal.

About Thyrocare

Thyrocare, India's leading clinical diagnostic laboratory, is a pioneer in providing high-quality and affordable diagnostics services. At Thyrocare, we envision serving India and making a difference to the lives of every Indian. Our mission is to provide high-quality and affordable diagnostics services to everyone.

With a legacy of 26+ years, Thyrocare is the only player with a true PAN-India presence serving 500+ districts. Thyrocare is one of the first Indian diagnostic laboratories to obtain internationally renowned quality accreditations, like NABL, ISO 9001-2000 in 2001 (now ISO 9001:2015) and CAP certification in 2007 by following strict Good Laboratory Practices (GLP).Our tagline "Tests You Can Trust" underlines our promise of uncompromised quality.

Thyrocare's TB Diagnostic Capabilities

We conduct all the tests defined by the NTEP mandates in the algorithm of TB diagnostics. These include screening, confirmatory and drug susceptibility TB tests such as:

- **NAAT**
- **Smear Microscopy**
- **MDR/XDR LPA**
- **TB Culture and Drug Susceptibility Testing**

Along with above tests we also perform **TB IGRA, TB-PCR**, and **Whole Genome Sequencing.**

Thyrocare

Tests you can trust

Established in 2017, our TB lab has been certified by NTEP, NABL and CAP since 2018. Today, we have the capacity to process 100+ samples per day. We have the capability to collect samples from all across India through a fleet of 900 company phlebotomists and 800 franchise partners. Additionally, we have a robust logistics network for sample transportation.

We have conducted over 4.5 Lacs tests in both public and private domains in the past 5 years.

Thyrocare's Existing Work in TB

Our most notable project in the public domain has been at Hisar Haryana, in association with USAID and IDDS (Infection Diseases Detection and Surveillance) where we have successfully demonstrated public-private partnership (PPP) model for the completion of diagnostic algorithm from NAAT to culture DST (Drug Susceptibility Test). In terms of TB notifications in Haryana, Hisar has moved upwards from the last to first position through joint efforts of the Haryana government, USAID, IDDS and Thyrocare by implementation of **One Stop TB/DR-TB Diagnostic Solution model (Hisar model).** The patient test rate in Hisar increased by **74%**, whereas the Patient Notification rate improved by **43%** during the course of the project.

Hisar Model is now considered an ideal PPP model for the implementation, monitoring and detection of TB by state governments and agencies across the country and globally.

Our other key projects with funding agencies and government organizations are:

- National Tuberculosis Elimination Programme (Served 21 Districts)
- William J Clinton Health Foundation (Jaipur, Udaipur, Bikaner, Jodhpur, Kota, Surat, Ahmedabad, Bhopal, Indore)
- J&J Project (Mumbai Suburbs)
- Doctors for you - Pre test evaluation (Uttar Pradesh)
- MCGM & Alert India - CBNAAT Testing

We are keen to leverage our experience and expertise gained while working with the Government of Haryana at Hisar and other organizations in order to partner with the Government of India and work towards a goal of TB-free India. Yes, together we can ENDTB2025.

TB Harega. Desh Jeetega !

Thyrocare Technologies Limited

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