Optimizing Diagnostic Networks in Uttar Pradesh

Enhance Coverage and Reduce Inequity in Access to Tuberculosis Diagnostic Services

List of Abbreviations

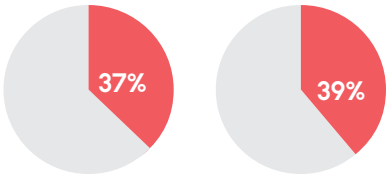
AAM	Ayushman Arogya Mandir
AI	Artificial Intelligence
ASHA	Accredited Social Health Activist
CNR	Case Notification Rate
C&DST	Culture and Drug Susceptibility Testing
CXR	Chest X-Ray
DMC	Designated Microscopy Centre
DNO	Diagnostic Network Optimization
DRTB	Drug-Resistant Tuberculosis
DSTB	Drug-Sensitive Tuberculosis
FL-LPA	First Line-Line Probe Assay
IRL	Intermediate Reference Laboratory
L	Lakh (100000)
LPA	Line Probe Assay
MTB	Mycobacterium Tuberculosis
mWRD	Molecular WHO-Recommended Rapid Diagnostic Test
NAAT	Nucleic Acid Amplification Test
OPD	Outpatient Department
PHC	Primary Health Centre
PPM	Public-Private Mix
PM-ABHI	Prime Minister Ayushman Bharat Health Infrastructure Mission
PPSA	Patient Provider Support Agency
PTB	Pulmonary Tuberculosis
PTER	Presumptive TB Examination Rate
QA	Quality Assurance
QR Code	Quick Response Code
RIF	Rifampicin
RR	Rifampicin Resistance
SCT	Specimen Collection and Transportation
SOPs	Standard Operating Procedures
SL-LPA	Second Line-Line Probe Assay
SSM	Sputum Smear Microscopy
STDC	State TB Training And Demonstration Centre
STF	State Task Force
STSU	State Technical Support Unit
TB	Tuberculosis
TU	Tuberculosis Unit
UDST	Universal Drug Susceptibility Testing
XDR-TB	Extensively Drug Resistant Tuberculosis

Introduction

Uttar Pradesh with 16% of India's population accounts for more than one-fifth of TB notified in India.

India bears 27% of the global Tuberculosis (TB) burden[1,2]. With the exception of a couple of years during the Covid-19 pandemic, TB ranks first among the infectious diseases cause of death despite being preventable and treatable. India's National Strategic Plan (2017-2025) aims to end TB five years ahead of the Sustainable Development Goal by 2030[3].

Uttar Pradesh (UP) with 16% of India's population accounts for more than one-fifth of the TB cases notified in India. In 2022, the number of individuals notified with TB in UP surpassed the 2019 pre-pandemic peak. About two-thirds of individuals with TB symptoms who seek care from a qualified provider, first seek care in the private sector[4]. Yet in 2022, about 70% of 0.52 million individuals notified with TB in UP, were diagnosed and treated in the public sector. Microbiological confirmation among all TB diagnosed remained sub-optimal in the previous two years, at 37% and 39%, more than half of which was contributed by sputum smear microscopy (SSM) in 2020 and 2021 (Table 1a).



Moreover, there was a high level of inequity in the coverage of microbiological confirmation among individuals who accessed care in the public compared with the private sector.

Table 1a Patterns of Basis of Diagnosis in Uttar Pradesh prior to 2023

Year	Notification	Microbiological confirmation	Microscopy	Molecular Diagnosis	Chest Xray	Other
2020	366641	137306 (37%)	89088 (24%)	47896 (13%)	172217 (47%)	57440 (16%)
2021	453712	175391 (39%)	90138 (20%)	84916 (19%)	203981 (45%)	74677 (16%)
2022	522850	201888 (39%)	91672 (18%)	110216 (21%)	229428 (44%)	91534 (17%)

Source: India TB report 2021, 2022, 2023

Table 1b Basis of Diagnosis in Public and Private Sector (2022)

Health Facility Type	Notification	Microbiological confirmation
Public	375581	218474 (58%)
Private	147269	24731 (17%)
Grand Total	522850	243205 (47%)

Source: Nikshay (notification register), date of data download - 15 September 2023

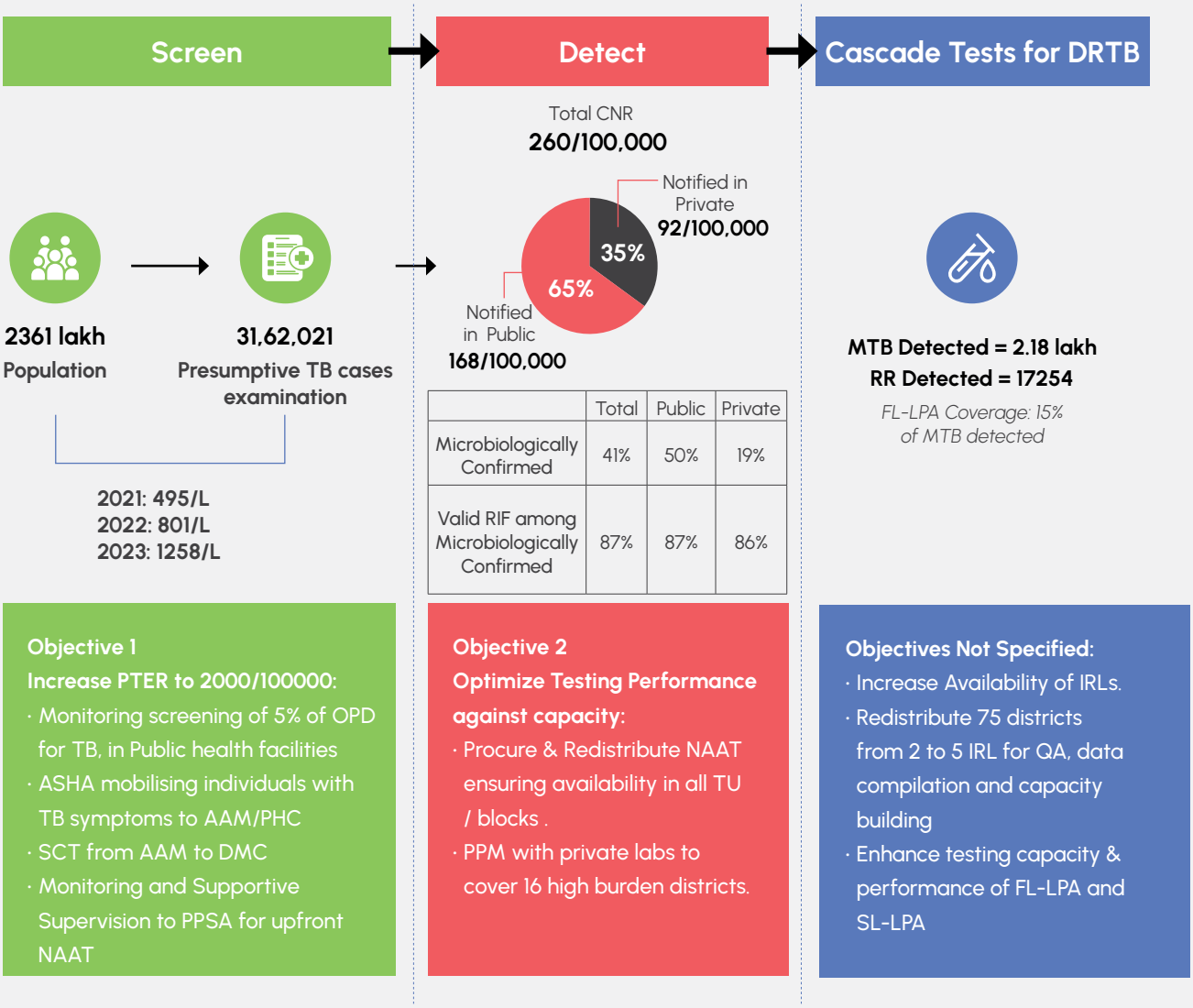
1. Central TB Division, India TB Report 2023, National TB Elimination Program Annual Report
2. Global tuberculosis report 2022. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO
3. MOHFW, CTD, National Strategic Plan to End TB in India (2017-25), https://tbcindia.gov.in/WriteReadData/NSP%20Draft%2020.02.2017%201.pdf
4. ICMR, CTD, WHO, National TB Prevalence Survey in India 2019 – 2021 https://tbcindia.gov.in/showfile.php?lid=3659

The National TB Prevalence survey estimated that 6% of adults had symptoms of TB[3]. While this may be an over-estimate considering that the survey was conducted during the Covid-19 pandemic, an assumption of half that rate, will require UP to increase its Presumptive TB Examination Rate (PTER) to at least 3000/100000 (3% of population). Timely and accurate testing is essential for diagnosing TB, and early diagnosis and treatment should theoretically improve treatment outcomes, even though evidence for this is not consistent across studies[5]. The proportion among those diagnosed with TB by molecular WHO-recommended rapid diagnostic tests (mWRD) is increasing in UP (Table 1a), and can be further optimised for better coverage, access and efficiency. Utilisation of mWRD is largely dependent on the public sector's availability of equipment and infrastructure, trained and competent human resources and supplies of test kits and consumables. Vulnerable population sub-groups and remote geographies have less access to TB diagnostics because of social and structural factors[6]. There is a wide disparity in coverage and utilisation of NAAT testing between individuals diagnosed with TB in the public and private sector (Table 1b) and a high variability in access by geography, both at district and TB Unit (TU) level[7].

In December 2021, the Central TB Division, Ministry of Health and Family Welfare, Government of India awarded the TB State Technical Support Unit (TB-STSU) to India Health Action Trust[8]. This is a World Bank-funded initiative that works closely with the State TB Cell and State Health Mission to enhance the state's capacity to engage with the private sector, strengthen health systems and expand multi-sectoral engagement for an enhanced TB response. In December 2023, IHAT initiated the Diagnostic Network Optimization (DNO) project with support from the Gates Foundation. The DNO project aims to provide technical support to the state to 'Optimize the TB Diagnostic network', thus improving access, performance and utilisation of mWRD both for microbiological confirmation and Universal Drug Susceptibility Testing (UDST) for TB, and reducing inequity in access to TB testing between the public and private sector.

5. L Telisinghe, M Ruperez, M Amofa-Sekyi, L Mwenge, T Mainga, R Kumar, M Hassan, L.H Chaisson, F Naufal,A.E Shapiro, J.E Golub, C Miller, E.L Corbett, R.M Burke, P MacPherson, R.J Hayes, V Bond, C Daneshvar, E Klinkenberg, H.M Ayles, Does tuberculosis screening improve individual outcomes? A systematic review,
   EClinicalMedicine, Volume 40, 2021, 101127, ISSN 2589-5370, https://doi.org/10.1016/j.eclinm.2021.101127.
   (https://www.sciencedirect.com/science/article/pii/S2589537021004077)
6. Litvinjenko S, Magwood O, Wu S, Wei X. Burden of tuberculosis among vulnerable populations worldwide: an overview of systematic reviews. Lancet Infect Dis. 2023 Dec;23(12):1395-1407. doi: 10.1016/S1473-3099(23)00372-9. Epub 2023 Sep 8. Erratum in: Lancet Infect Dis. 2023 Nov;23(11): e467. doi: 10.1016/S1473-3099(23)00625-4. PMID: 37696278; PMCID: PMC10665202.
7. Unpublished reports 2024, on Population Accessibility to TB Diagnostic sites in Uttar Pradesh
8. https://www.ihat.in/state-technical-support-unit-tb-uttar-pradesh/

Figure 1 Summary of TB Diagnostic Network in Uttar Pradesh (2023)



	Total	Public	Private
Microbiologically Confirmed	41%	50%	19%
Valid RIF among Microbiologically Confirmed	87%	87%	86%

Diagnostic Network Optimization

Diagnostic network optimization (DNO)[9] is a geospatial analytics approach to

Analyse the current diagnostic network

Determine and support actions to enhance the performance of the existing diagnostic network and suggest the optimal type, number and location of diagnostics and an associated sample referral network to improve coverage and reduce inequity in access to TB diagnostics

9. Chênes C, Albert H, Kao K, Ray N. Use of Physical Accessibility Modelling in Diagnostic Network Optimization: A Review. Diagnostics. 2022; 12(1):103. https://doi.org/10.3390/diagnostics12010103

Objectives

The DNO project aims to:

Increase identification and testing of presumptive TB patients in UP to achieve a PTER of 2000/100000 by 2026.

Increase the use of molecular diagnostics to 70% as the initial test and 85% among diagnosed individuals with TB by 2026.

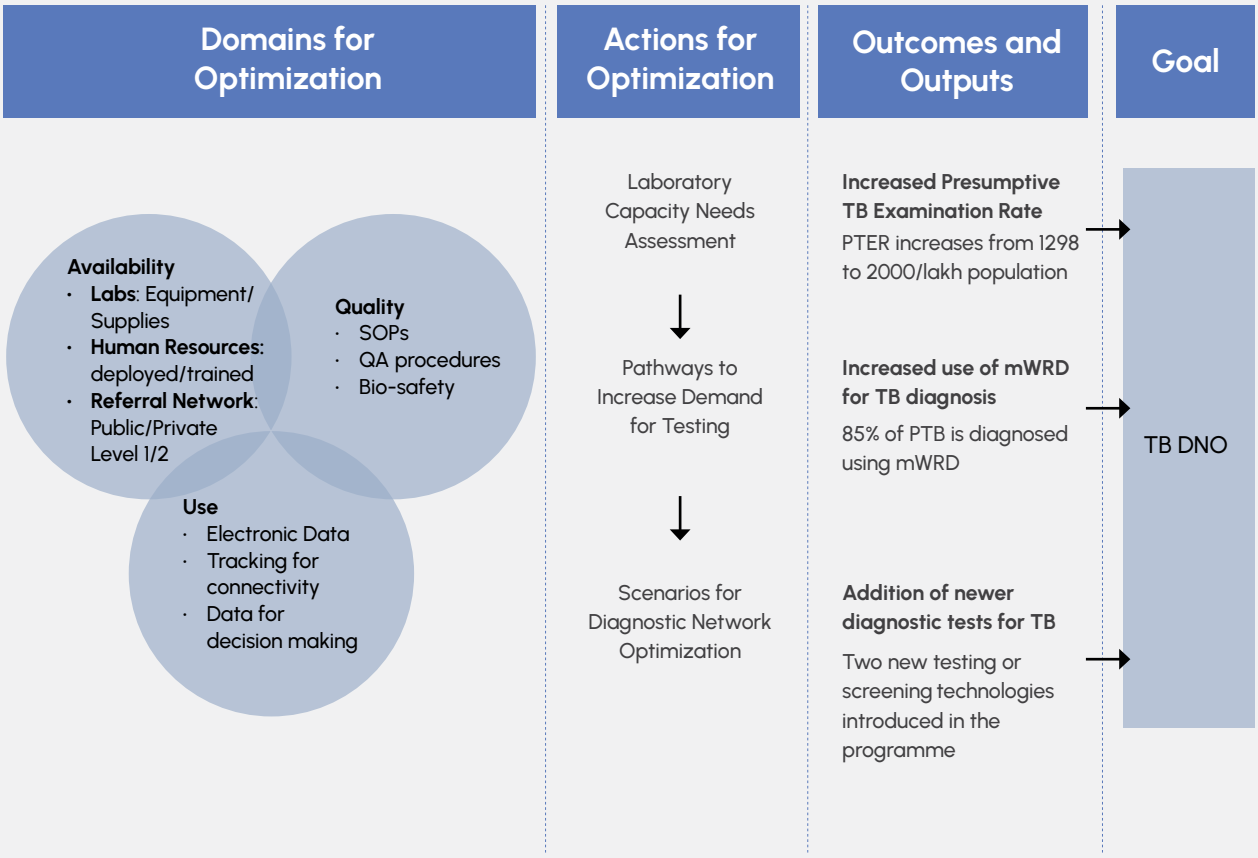
Support decentralisation and increased access to molecular diagnostics at the primary care level through a network of specimen collection and transportation mechanisms.

Enhance equity of diagnostic access to patients seeking care in public and private health services.

Facilitate uptake of newer indigenous low-cost molecular tests emerging from validation.

Design for Optimizing the TB Diagnostic Network

Figure 2 Design for Optimizing TB Diagnostic Network



Monitoring, Research and Evaluation:

- Improved Coverage and Quality of Laboratory Data entry and analyses from Nikshay
- Integration of Nikshay with other digital platforms (e-kavach & Unified Disease Surveillance Platform).
- Enhanced Operations and Implementation Research pertaining to current and emerging TB diagnostics.

Training and Sustenance:

- Improved State Capacity for Private Sector Engagement.
- Improved skills at STDC to roll out trainings of laboratory staff to use high through-put and newer emerging technologies for TB diagnosis.
- A network of institutions created for Operations and Implementation Research.

The DNO project strives to strengthen the 'Detect' pillar with a focus on detection of active TB.

Approach

A systematic 'health systems' approach is being implemented to continuously improve and optimize the TB diagnostic network capacity based on local (state and district) epidemiology, National TB Elimination Program (NTEP) policies and guidelines, needs assessment and network analyses, demonstration of proof of concept for innovations and technical assistance to scale up TB diagnostic interventions for population-level impact. This aligns with the effective coverage cascade[10] for the identification of presumptive TB and the offer and access to the appropriate diagnostic test among those diagnosed with TB.

The National Strategic Plan (2017-25) to End TB in India is constituted on the four pillars of detect, treat, prevent and build. The DNO project strives to strengthen the 'Detect' pillar with a focus on detection of active TB. The project leverages diagnostic resources from the XV Finance Commission Prime Minister Ayushman Bharat Health Infrastructure Mission (PM-ABHIM) and the opportunities that arise within the National Health Mission's Project Implementation Plans (2024-26) to accelerate and optimize the molecular diagnostic network for TB in Uttar Pradesh.

Intervention Areas

01 Conduct comprehensive mapping and situational needs assessment of the TB diagnostic facilities in the public and private sector

Mapping existing human resources, laboratories, equipment and performance of stand-alone and general health system integrated laboratories performing TB tests. Map both public and private sector for mWRD and digital X-ray.

Exploration of sample collection, transportation and testing mechanisms in the public and private sector for:

1. Reducing turn-around-time between sample collection and test reporting,
2. Ensuring quality of samples received before testing.

Estimate and evaluate the potential capacity and actual performance of mWRD labs to identify gaps and enablers for performance, standard testing capacity per month, HR availability & training status, supplies, SCT sites linked/samples received vs tested.

Conduct geospatial analyses of the distribution of labs and their capacity and compare this with population size and characteristics and TB case notification rates.

10. Ng M, Fullman N, Dieleman JL, Flaxman AD, Murray CJL, Lim SS (2014) Effective Coverage: A Metric for Monitoring Universal Health Coverage. PLoS Med 11(9): e1001730. https://doi.org/10.1371/journal.pmed.1001730

02 Design pathways to increase demand and uptake of services:

Targeted approach to improve coverage and access to TB diagnostic services within the private sector

Enhancing integration to cover the range of TB diagnostic, treatment, prevention and support activities into Ayushman Arogya Mandir - Specimen Collection and Transportation system, QR code for tracking, etc.,

Enhance the involvement of private labs and pharmacies. Example: Pharmacy Application, Public Private Mix between government and private labs.

Micro-planning for Active Case Finding campaigns among vulnerable population groups. Example: urban slums, rural hot-spots, elderly, undernourished, people with HIV.

Setting and monitoring targets for provider-initiated TB screening and testing within out-patient public health facilities.

Focused effort to enhance the role of medical colleges for TB control within the state.

The project will focus on the different pathways in a phased manner.

03 Create Optimised Scenarios for TB Diagnostic network

In order to create optimised scenarios for the required TB diagnostic network, IHAT supports the state in planning and implementing a TB diagnostic network to meet identified goals.

Digitise sample collection and transportation systems to enhance access to testing and reduce inequity to mWRD for both drug-sensitive and resistant TB (Truenat, CBNAAT-RIF, CBNAAT-XDR, Culture & Susceptibility testing and Line Probe Assay) – data capture in real time, visualisation of collection, testing and reporting, response to low performing sites.

Optimize placement and deployment of newer emerging technologies at various levels in the health care system. Demonstrate newer

technologies a) use of chest X-rays (CXR) with Artificial Intelligence (AI) to screen and thus optimize the use of molecular diagnostics (only 10-12% of CXR among those with symptoms of TB and vulnerable contacts or population groups have an abnormal radiograph), b) cough as a screening tool, Tongue swab for TB screening .

Capacity building of public and private healthcare providers to increase microbiological confirmation for Extra-Pulmonary TB (pleural tap, lymph node aspirate, synovial fluid, etc.,).

Implementation Research: QR code to track and reduce sample testing turn-around-time, knowledge synthesis of emerging evidence on newer diagnostic technologies.

04 Expanded Technical support to the state

In order to create optimized scenarios for the required TB diagnostic network, IHAT supports the state in planning and implementing a TB diagnostic network to meet identified goals by 2025.

Establish, scale, monitor and evaluate sample collection and transportation systems, (e.g., from HWC to NAAT sites; NAAT sites to TB C&DST laboratories).

Contracting private sector agencies for sample collection, transportation and providing diagnostic services using existing and newer technologies.

Identify, evaluate, and implement innovations that expedite the achievement of the project goals. Example: PM ABHIM to procure devices and reagents; sample collection and transportation innovations; CXR screening and AI; use of multi-diagnostic platforms for TB and other diseases; use of QR code to track transportation which is already built into Nikshay; and other innovations).

05 Monitoring, Research and Evaluation

Nikshay as the single source of truth: Improved completeness and accuracy of laboratory data entry to enable direct analyses from Nikshay.

Explore and work towards integration of Nikshay with other digital platforms: e-kavach, Unified Disease Surveillance Platform.

Enhanced Operations and Implementation Research pertaining to current and emerging TB diagnostics.

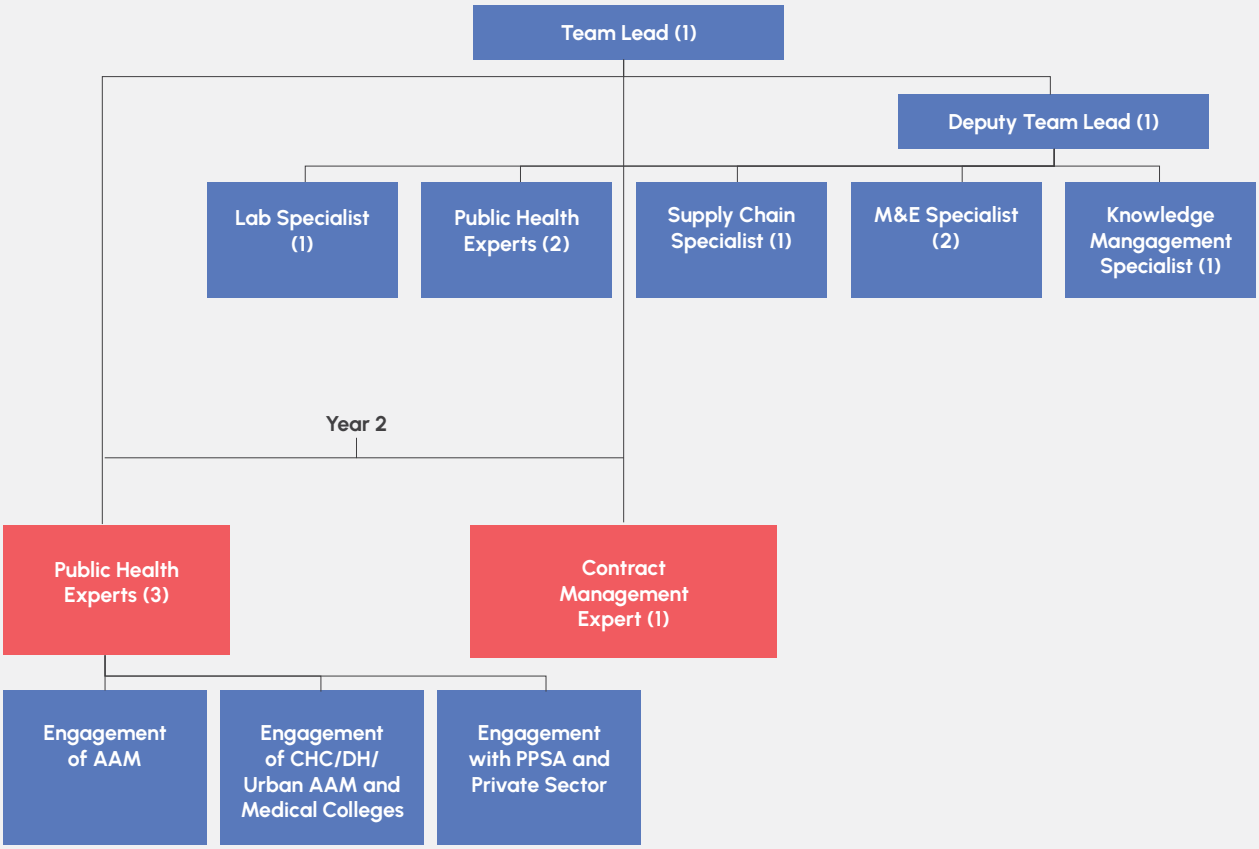
06 Expand and build partnerships for long-term sustenance

The project works in close collaboration with the State TB Training and Demonstration Centres (STDC) and the State Task Force (STF) of medical colleges from its inception, thus ensuring that capacity of local institutions is enhanced significantly to sustain the gains made.

Core Project Team

The DNO multidisciplinary project team is streamlined with the State TB Technical Support Unit and consists of individuals with expertise in Public Health, Microbiology, Laboratory techniques, data analysis, monitoring and evaluation and supply chain management. A knowledge management specialist captures best practices and ensures documentation of critical processes, testing of tools and state level achievements.

Figure 3 Core Project Team, DNO



Acknowledgement: State TB Cell, Lucknow (Uttar Pradesh)

India Health Action Trust
Bharathi Enclave,
2nd Floor, No. 197, 10th Cross,
CBI Road, Ganganagar,
Bengaluru – 560032
Karnataka, India

State Technical Support Unit TB - Uttar Pradesh
India Health Action Trust 105 & 105A,
1st Floor Ratan Square No. 20-A,
Vidhan Sabha Marg
Lucknow - 226001
Uttar Pradesh, India
Phone: +91-522-4057072