INDIAN COUNCIL OF MEDICAL RESEARCH

NATIONAL INSTITUTE FOR RESEARCH IN TUBERCULOSIS

ANNUAL REPORT
2024 - 2025

WHO Collaborating Centre for Tuberculosis Research & Training

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PREFACE

It is with great pride and purpose that I present the Annual Report of the Indian Council of Medical Research - National Institute for Research in Tuberculosis (ICMR-NIRT) for the year 2024-2025. This edition encapsulates the collective dedication and scientific excellence of our institute in advancing research across tuberculosis (TB), HIV, COVID-19, and other priority infectious diseases.

With a legacy spanning nearly seven decades, ICMR-NIRT continues to be a cornerstone of India's TB research and elimination efforts. As a WHO Collaborating Centre and a key technical partner to the National Tuberculosis Elimination Programme (NTEP), the Institute remains committed to generating evidence that directly informs policy and public health strategies, both nationally and globally.

This year, our teams made significant strides in diagnostic innovations including validation of non-sputum-based methods such as tongue swab and cell-free DNA, aimed at early detection of both pulmonary and extrapulmonary TB. Artificial intelligence applications have progressed from chest X-ray interpretation to the reading of smear microscopy, underscoring our commitment to digital transformation in TB diagnostics.

Clinical trials, a longstanding mandate of NIRT, continued to yield meaningful insights. Our contribution to the implementation and evaluation of novel regimens such as BPaLM has directly supported national scale-up. Ongoing efforts such as the INSHORT trial for TB meningitis and pharmacokinetic studies in vulnerable populations reinforce our focus on patient-centred care and precision therapeutics.

Recognising TB as a socio-medical disease, we expanded research into social determinants, stigma reduction, and treatment adherence. Our community-focused approach was further strengthened through the Model Rural Health Research Unit (MRHRU) in Madurai, supporting research tailored to local needs. In parallel, the Institute diversified its scientific engagement through work in HIV-TB coinfection, non-tuberculous mycobacteria, post-TB lung disease, pharmacovigilance, and pandemic preparedness. The establishment of the Viral Research and Diagnostic Laboratory (VRDL) at our Thiruvallur campus, and our continued technical support to SEAR member nations, marked key infrastructural and diplomatic milestones.

Departments across ICMR-NIRT demonstrated extraordinary commitment in navigating scientific, administrative, and field challenges. With strong support from ICMR Headquarters, the Ministry of Health and Family Welfare, and our scientific and ethics committees, we have strengthened governance, streamlined processes, and accelerated impactful research.

As we align ourselves with the End TB Strategy and India's mission to eliminate TB by 2025, I extend my deepest gratitude to our scientists, collaborators, frontline workers, and administrative staff. Their resilience, innovation, and teamwork remain the foundation of our progress.

With renewed confidence and a collective spirit, we look ahead to a future free of TB.

- Dr. Manoj Vasant Murhekar
Director (Addl. Charge)
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ABBREVIATIONS

Acronym	Expansion
%EE	Percent Entrapment Efficiency
3HP	3-month weekly regimen of Isoniazid and Rifapentine
6MWT	Six-Minute Walk Test
ABC	Adenosine Triphosphate Binding Cassette
ADME	Absorption, Distribution, Metabolism, and Excretion
ADRs	Adverse Drug Reactions
AHB	Arq-e-Hara Bhara (Unani formulation)
AI	Artificial Intelligence
AIIMS	All India Institute of Medical Sciences
ART	Antiretroviral Therapy
ASHA	Accredited Social Health Activist
ATT	Anti-Tuberculosis Treatment
BACTEC	Bacterial Culture Detection System
BB	Blackbuck
BJGMC	Byramjee Jeejeebhoy Government Medical College
BMHRC	Bhopal Memorial Hospital and Research Centre
bNAbs	Broadly Neutralizing Antibodies
bTB	Bovine Tuberculosis
CAD	Computer Aided Detection
Cas	CRISPR-associated protein (e.g., Cas9, a nuclease)
CBNAAT	Cartridge-Based Nucleic Acid Amplification Test
ccfDNA	Circulating Cell-Free DNA
CCRUM	Central Council for Research in Unani Medicine
CD4	Cluster of Differentiation 4 (T-helper cell marker)
CD8	Cluster of Differentiation 8 (Cytotoxic T-cell marker)
C-DAC	Centre for Development of Advanced Computing
CFP	Culture Filtrate Proteins
CHW	Community Health Worker
CM/AS	Common Mycobacteria / Additional Species
CMC	Christian Medical College
COPD	Chronic Obstructive Pulmonary Disease
COPD-C	COPD due to Smoking

COVID-19	Coronavirus Disease 2019
CRF	Case Report Form
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
CRP	C-Reactive Protein
CTD	Clinical Trial Division
CXCL	Chemokine (C-X-C motif) ligand
CXR	Chest X-ray
Cy-TB	Cytokine release TB test
DBS	Dried Blood Spots
DD	Deputy Director (Health Services)
DHR	Department of Health Research
DICOM	Digital Imaging and Communications in Medicine
DMC	Designated Microscopy Centre
DME	Directorate of Medical Education
DMPK	Drug Metabolism and Pharmacokinetics
DNA	Deoxyribonucleic Acid
DNA	Deoxyribonucleic Acid
DOTS	Directly Observed Treatment, Short-course
DPH	Directorate of Public health
DRS	Drug-Resistant Survey
DRTB	Drug-Resistant Tuberculosis
DSC	Differential Scanning Calorimetry
DSTB	Drug-Sensitive Tuberculosis
DTA	Diagnostic Test Accuracy
DTG	Dolutegravir
DTO	District Tuberculosis Officer
E	Ethambutol
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture
EHR	Electronic Health Record
ELISA	Enzyme-Linked Immunosorbent Assay
EMB	Ethambutol
EPTB	Extra Pulmonary Tuberculosis
EQAPOL	External Quality Assurance Program Oversight Laboratory - Quality

QC	Control
FASTQ	Text-based format for storing biological sequences with quality scores
FDC	Fixed Dose Combination
FGD	Focus Group Discussion
FOT	Forced Oscillation Technique
FTIR	Fourier-Transform Infrared Spectroscopy
GCC	Greater Chennai Corporation
gDSR	Genotypic Drug Susceptibility Report
GFP expression	Green Fluorescent Protein expression
GHTM	Government Hospital of Thoracic Medicine
GRADE	Grading of Recommendations, Assessment, Development, and Evaluation
GTHTM	Government Thiruvatteeswarar Hospital of Thoracic Medicine
GVMC	Government Vellore Medical College
GXU	GeneXpert Ultra
H	Isoniazid
H&E	Hematoxylin and Eosin (staining)
H5N1	Avian Influenza Virus Type H5N1
HAART	Highly Active Antiretroviral Therapy
HbA1c	Glycated Hemoglobin
HDAC	Histone Deacetylase
HHC	Household Contact
HIV	Human Immunodeficiency Virus
HIVDR	HIV Drug Resistance
HPLC	High-Performance Liquid Chromatography
HRQoL	Health-Related Quality of Life.
HRCT	High-Resolution Computed Tomography
HTA	Health Technology Assessment
HTAIn	Health Technology Assessment in India
IAVI	International AIDS Vaccine Initiative
IAVI IIR Call	International AIDS Vaccine Initiative - Investigator-Initiated Research Call
ICER	Incremental Cost-Effectiveness Ratio
ICH	Institute of Child Health

ICMR	Indian Council of Medical Research
ICT	Immunochromatography Test
IEF	Isoelectric Focusing
IFN	Interferon
Ig	Immunoglobulin
IGRA	Interferon Gamma Release Assay
IL	Interleukin
InfA	Influenza A Virus
InfB	Influenza B Virus
INH	Isoniazid
INSHORT	Intensified Short Course Regimen for TB Meningitis Trial
INSTI	Integrase Strand Transfer Inhibitor
IPR	Intellectual Property Rights
IRL	Intermediate Reference Laboratory
IS	Insertion Sequence
ISG	Interferon-Stimulated Genes
ITRC	India Tuberculosis Research Consortium
JALMA	Japanese Leprosy Mission for Asia
JIPMER	Jawaharlal Institute of Postgraduate Medical Education and Research
JJ Hospital	Sir Jamshedjee Jeejeebhoy Hospital
KGMU	King George's Medical University
LJ	Lowenstein-Jensen (medium)
LOD	Limit of Detection
LPA	Line Probe Assay
LRAC	Local Research Advisory Committee
LTBI	Latent Tuberculosis Infection
LZD	Linezolid
MAR	Missing At Random
MBL	Mannose Binding Lectin
MCAR	Missing Completely At Random
MDRTB	Multidrug-Resistant Tuberculosis
MGIT	Mycobacteria Growth Indicator Tube
MI	Multiple Imputation
MIC	Minimum Inhibitory Concentration

miRNA	Micro RNA
MLR	Monocyte-to-Lymphocyte Ratio
MMC	Madras Medical College
MNAR	Missing Not At Random
MO	Medical Officer
MoA	Memorandum of Agreement
MoU	Memorandum of Understanding
MPT64Ag	Mycobacterium tuberculosis Protein 64 Antigen
Mtb	Mycobacterium tuberculosis
MTB	Mycobacterium tuberculosis
MTBC	Mycobacterium tuberculosis Complex
MTBDR	Mycobacterium tuberculosis Drug Resistance
MTC	Metropolitan Transport Corporation
Myc-TB	Mycobacterium tuberculosis
NAAT	Nucleic Acid Amplification Test
NACO	National AIDS Control Organization
NDRS	National Drug-Resistant Survey
NEIGRIHMS	North Eastern Indira Gandhi Regional Institute of Health and Medical Sciences
NET	Neutrophil Extracellular Traps
NICPR	National Institute of Cancer Prevention and Research
NIE	National Institute of Epidemiology
NIH	National Institutes of Health
NIIRNCD	National Institute for Implementation Research on Non-Communicable Diseases
NIN	National Institute of Nutrition
NIOH	National Institute of Occupational Health
NIRBI	National Institute of Research in Biomedical Imaging
NIRT	National Institute for Research in Tuberculosis
NIRTH	National Institute for Research in Tribal Health
NITRD	National Institute of Tuberculosis and Respiratory Diseases
NITVAR	National Institute for Translational Virology and Antiviral Research
NIV	National Institute of Virology
NJILOMD	National JALMA Institute for Leprosy and Other Mycobacterial Diseases

NJILOMD	National JALMA Institute for Leprosy and Other Mycobacterial Diseases
NLR	Neutrophil-to-Lymphocyte Ratio
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitor
NPV	Negative Predictive Value
NRTI	Nucleoside Reverse Transcriptase Inhibitor
NS1	Non-Structural Protein 1
NTEP	National Tuberculosis Elimination Programme
NTI	National Tuberculosis Institute
NTM	Nontuberculous Mycobacteria
NTM-DR	Nontuberculous Mycobacteria – Drug Resistant
ONT	Oxford Nanopore Technology
OOP	Out-of-Pocket
OPD	Outpatient Department
OR	Odds Ratio
PANTA	Polymyxin B, Amphotericin B, Nalidixic Acid, Trimethoprim, and Azlocillin
PBMC	Peripheral Blood Mononuclear Cell
PCR	Polymerase Chain Reaction
PDB	Protein Data Bank
pDST	Phenotypic Drug Susceptibility Testing
PFT	Pulmonary Function Test
PI	Principal Investigator
PI	Protease Inhibitor
PIV3	Parainfluenza Virus Type 3
PK	Pharmacokinetics
PLR	Platelet-to-Lymphocyte Ratio
PM-ABHIM	Pradhan Mantri - Ayushman Bharat Health Infrastructure Mission
PMTS	Post-Mortem Tissue Samples
POC	Point-of-Care
PP	Per Protocol
PPD	Purified Protein Derivative
PPV	Positive Predictive Value
PR	Protease

Pre-XDR	Pre-Extensively Drug-Resistant
PRNT titres	Plaque Reduction Neutralization Test Titres
PRODUCES	Problem, Objective, and Design, (end-) Users, Co-creators, Evaluation, and Scalability
PTB	Pulmonary Tuberculosis
PTEs	Potential Therapeutic Entities
PTLD	Post-Tuberculosis Lung Disease
PTLFU	Pre-treatment loss to follow-up
PZA	Pyrazinamide
QALY	Quality Adjusted Life Years
QFT Plus Test	QuantiFERON-TB Gold Plus Test
QTS	Qurs-e-Tabasheer Sartani (Unani formulation)
R	Rifampicin
RD	Region of Difference
RePORT	Regional Prospective Observational Research for Tuberculosis
RFLP	Restriction Fragment Length Polymorphism
RGGGH	Rajiv Gandhi Government General Hospital
RIF	Rifampicin
RMP	Rifampicin
RMRC	Regional Medical Research Centre
RMRC	Regional Medical Research Centre
RMRC	Regional Medical Research Centre
RMRIMS	Rajendra Memorial Research Institute of Medical Sciences
RNA	Ribonucleic Acid
RRIUM	Regional Research Institute of Unani Medicine
RRTB	Rifampicin-Resistant Tuberculosis
RSV	Respiratory Syncytial Virus
RT-LAMP	Reverse Transcription Loop-mediated Isothermal Amplification
RTPCR	Reverse Transcriptase Polymerase Chain Reaction
SAHA	Suberoylanilide Hydroxamic Acid
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SD	Standard Deviation
SD	Sambar Deer / Standard Deviation (depending on context)

SDS-PAGE	Sodium Dodecyl Sulfate–Polyacrylamide Gel Electrophoresis
SE	Standard Error
SGRQ	St. George's Respiratory Questionnaire
SIST	Sathyabama Institute of Science and Technology
SNP	Single Nucleotide Polymorphism
SPD	Spotted Deer
SR	Sustained Release
SRF	Senior Research Fellow
STO	State Tuberculosis Officer
TAC	Technical Appraisal Committee
TB ACF	Tuberculosis Active Case Finding
TB-IEC	Tuberculosis – Information, Education, and Communication
TBM	Tuberculous Meningitis
TCR	T Cell Receptor
TEM	Transmission Electron Microscopy
Tfh	T Follicular Helper (Cells)
THP-1	Human monocytic cell line derived from an acute monocytic leukemia patient
THSTI	Translational Health Science and Technology Institute
TNA	Total Nucleic Acid
tNGS	Targeted Next-Generation Sequencing
TOPD	TB-Associated COPD
TST	Tuberculin Skin Test
TU	Tuberculosis Unit
UPF	Unani Pharmacopeial Formulation
URL	Uniform Resource Locator
VAS	Veterinary Assistant Surgeons
VRDL	Virus Research and Diagnostic Laboratory
WGS	Whole Genome Sequencing
WHO	World Health Organization
wTB	Wildlife Tuberculosis
XDRTB	Extensively Drug-Resistant Tuberculosis
XRAYCAD	X-Ray Computer Aided Diagnosis
Z	Pyrazinamide

REPORT OF RESEARCH ACTIVITIES

STUDIES IN PROGRESS

1. Role of Artificial Intelligence using XRAY-CAD Software in Detection and Differentiation of TB Using a Phased Approach

Principal Investigator	:	Dr. G. Narendran
Participating Institutes	:	ICMR-NIRT, C-DAC
Source of funding	:	No funding
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Development

Background :

India contributes to nearly 27% of the global TB burden. Despite national efforts, challenges such as limited radiologists and delayed X-ray interpretation hinder early diagnosis and timely sputum collection during surveys. This project aims to develop and validate a web-based, AI-powered chest X-ray CAD system—'XRAYCAD'—to aid early TB detection, with scope for future differentiation of TB from other diseases using radiographic characteristics.

Methods:

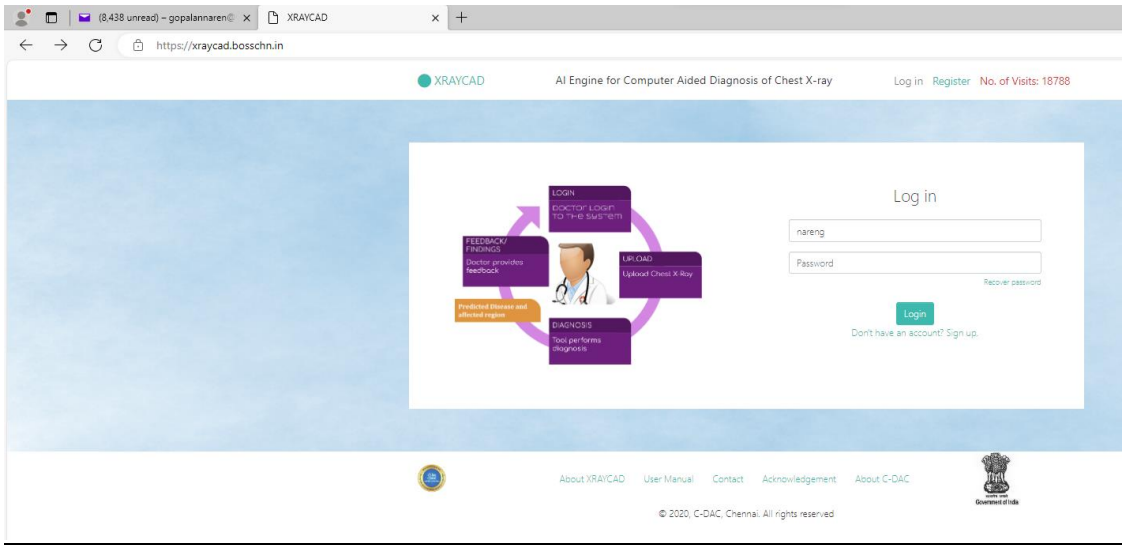
The study will be conducted in three stages using chest X-rays from surveys, clinical trials, and medical colleges. Stage 1 focuses on distinguishing normal and physiologic variants. Stage 2 uses well-characterized, culture-confirmed TB X-rays to build an algorithm for lesion categorization and quantification via heatmaps. Stage 3 will explore the tool's capability to identify TB mimics. All data will be anonymized and uploaded to the secured XRAYCAD web application for AI processing. Feedback from clinicians will refine predictions. Web Application URL: https://xraycad.bosschn.in. The study findings was presented at the India Innovation Summit – pioneering solutions to End TB (March 18-19, 2025)

Study Progress:

Preliminary testing using NIH and CheXpert datasets has shown promising results with high sensitivity and 0.83–0.84 AUROC for multi-disease classification. The system identifies 9 key pulmonary abnormalities and cardiomegaly, and displays disease heatmaps. The tool is under validation using data from ICMR-NIRT's TB prevalence surveys and clinical trials.

Translational Value:

This AI tool will enhance the accuracy and timeliness of TB screening in field surveys and low-resource settings, reduce burden on experts, and improve sputum collection efficiency. It aligns with India's National TB Elimination Programme and contributes towards achieving TB-free India by 2025.



2. Multi-centric prospective cohort study of TB recurrence-free cure among microbiologically confirmed new pulmonary tuberculosis patients treated under NTEP with the 4-month moxifloxacin-containing daily regimen

Principal Investigator	:	Dr. V.V. Banu Rekha, Scientist F
Participating Institutes	:	ICMR, Govt. and Private Institutes across India
Source of funding	:	ICMR-ITRC
Study period	:	2022-2025
Pillar	:	Treat
Category	:	Development

Background:

Earlier randomised clinical trial conducted by ICMR-NIRT showed promising results with a TB recurrence rate of 4.1% using the 4-month moxifloxacin-containing daily regimen (2HRZEM 7 / 2HRM7) in persons with sputum positive pulmonary TB (PTB). To determine the TB recurrence-free cure rate among microbiologically confirmed new drug-sensitive persons with PTB treated under the TB Program with the 4-month moxifloxacin-containing daily regimen (2 HRZEM 7 / 2HREM7).

Methods:

In this multicentric, single-arm study, eligible adult microbiologically confirmed persons with PTB sensitive to isoniazid, rifampicin and quinolone will receive 2 months of HRZEM followed by 2 months of HREM daily (2 HRZEM 7 / 2HREM7). Tab. Moxifloxacin 400mg will be given along with the weight-based Fixed dose Combination (FDC) of HRZE. The enrolled study participants will be followed up every month during treatment and 2 years post-treatment. Sputum examination will be done during follow-up for response to treatment and

for TB recurrence. In addition, drug adverse events will be documented.

Study progress:

The recruitment to the study was completed in April 2023 with 557 patients. All the patients have completed treatment. The follow-up is ongoing.

Translational value:

Effective shorter TB treatment regimens are beneficial to both the patients and health system. The study will provide evidence for shorter 4-month regimen in the treatment of drug sensitive PTB.

3. Effect of Pulmonary rehabilitation on the exercise tolerance in sputum positive pulmonary TB patients

Principal Investigator	:	Dr.P. K. Bhavani
Participating Institutes	:	ICMR-NIRT, NTEP clinics in Chennai and Madurai
Source of funding	:	ICMR Intramural
Study period	:	2022-2027
Pillar	:	Treat
Category	:	Delivery

Background:

Studies with longer follow-up have revealed that a large percentage of patients with treated pulmonary tuberculosis show signs of permanent airflow obstruction or restrictive impairment. Pulmonary Rehabilitation has shown to improve symptoms, exercise tolerance and health-related quality of life in TB patients.

Objectives:

1. To evaluate the effect of a 16-week pulmonary rehabilitation program on the exercise tolerance using 6-minute walk test.

2. To assess the clinical, radiological, functional status and health related quality of life (HRQoL) of these patients one year after ATT completion.

Methods:

Study Design: Controlled clinical trial with cluster design for comparison of the mean difference of two groups with design effect.

Two parallel groups comparing with or without PR during continuation phase of TB treatment for patients with PTB in Madurai and Chennai with a sample size of 240 patients (120 in each arm).

Study population: Drug sensitive adult pulmonary TB patients who were initiated on treatment at selected NTEP centres were enrolled at the end of IP when the sputum smear are negative.

Study Outcomes:

A change in walking distance measured by the 6 MWT pre-intervention to post-intervention.

Measurement of association between lung function impairment and radiological changes

Proportion of participants with optimal respiratory health status.

Study progress:

As on March 2025, screened 117, Enrolled 108

Control group – 53; intervention group: 55; No of patients completed 6 months: 42.

Translational value:

Evidence on Role of Pulmonary Rehabilitation in improving the functional status of persons with Tuberculosis.

4. The Regional Prospective Observational Research For Tuberculosis (RePORT) India Phase II Common Protocol

Principal Investigator	:	Dr. V. Aishwarya
Participating Institutes	:	ICMR-NIRT; ITM, Chennai.
Source of funding	:	DBT
Study period	:	2022-2027
Pillar	:	Detect Treat
Category	:	Delivery

Background:

Evaluate novel diagnostics and biomarkers of diverse states of mycobacterium tuberculosis (Mtb) infection.

Identify markers of treatment response.

Identify markers of lung injury associated with unfavourable TB treatment outcomes.

Methods:

Cohort A – 90 ; Participants screened - Cohort A – 253 participants ; recruited – 90

Treatment response (Aim 2A): 90 - 90

Nutrition and Pharmacokinetic (PK) aim (Aim 2B) : 40 - 40

Lung health assessment (core and advanced, Aim 3): 75 -

Diagnostic Cohort – 150 ; Participants screened – 140; Recruited - 42

Study progress:

Recruitment completed, Follow up ongoing.

Translational value:

The long-term goal of this study is to provide scientific evidence that can be translated into effective TB control. The positive impact of biomarkers on predicting TB outcomes, shortening product development timelines, or yielding effective prevention strategies may benefit future patients with TB.

5. Determination of Pharmacokinetics and Anti-mycobacterial Activity of Bedaqualine, Delamanid, Clofazimine and Linezolid in Children and Adolescents with Drug Resistant Tuberculosis

Principal Investigator	:	Dr. V. Aishwarya
Participating Institutes	:	ICMR-NIRT; JJ Hospital, Mumbai
Source of funding	:	ICMR
Study period	:	2024-2027
Pillar	:	Build
Category	:	Development/Development

Background:

Data on drug-resistant TB (DR-TB) in children are limited. DR-TB is a growing public health concern for children and worldwide, ~25,000–32,000 children develop MDR-TB each year, of whom <5% receive treatment. One of the reasons is the inadequate dosing recommendations for existing therapies in children.

Objectives:

Primary: Evaluate the pharmacokinetic activity of Bedaqualine, Delamanid, Clofazimine, Linezolid in children and adolescents (3 years to 18 years of age) diagnosed with confirmed or probable drug-resistant tuberculosis (DR-TB).

Secondary:

To evaluate the safety and tolerability of Bedaqualine, Delamanid, Clofazimine, and Linezolid in children and adolescents

To describe the clinical outcome of children and adolescents with DR-TB

Methods:

This will be a multi-centre, single-arm study where, 100 children and adolescents aged from 3 to 18 years with confirmed or probable DR-TB, including pre-XDR-TB or XDR-TB, or MDR-TB will be included. These children will receive age/weight appropriate dose of newer drugs (Bedaqualine, Delamanid, Clofazimine, and Linezolid). Venous blood samples will be collected at 0, 1, 2, 3, 4, 6 and 8 hours post dose to quantify drug concentrations in plasma. Drug concentrations will be quantified using high performance liquid chromatography (HPLC) method which has been validated at ICMR-NIRT. Based on the plasma concentration of drugs obtained at different time points, certain pharmacokinetic variables (peak concentration, time to attain peak concentration, exposure, clearance, half-life) will be calculated by non-compartmental analysis.

Study progress:

Recruitment ongoing.

Translational value:

This study will provide novel PK data for appropriate drug dosing recommendations for newer anti-TB drugs to be used for the treatment of DR-TB in children and adolescents.

6. Comparative evaluation of intensified short course regimen and standard regimen for adults TB meningitis: an open-label randomized controlled trial (INSHORT trial)

Principal Investigator	:	Dr. I. Leeberk Raja
Participating Institutes	:	ICMR-NIRT; MMC-Chennai, CMC-Vellore, AIIMS-Jodhpur, JIPMER-Puducherry, NEIGRIHMS- Shillong, KGMU- Lucknow.
Source of funding	:	ICMR- Intramural
Study period	:	2024-2027
Pillar	:	Treat
Category	:	Development

Background:

Despite severe critical, incremental steps achieved in the management of Tuberculous meningitis (TBM), the mortality rates remain high. In spite of national and international guidelines, variation in the choice, dose and duration of drugs exist between countries and clinicians. It is crucial to derive evidence from a robust, multicentric randomized control trial. We aim to compare the intensified short course ATT with standard ATT regimen in reducing composite outcome (mortality and disability) and to compare pharmacokinetic parameters between two groups.

Methods:

An open label randomized controlled trial will be conducted among 372 participants across 6 sites in India. Eligible participants will be randomly allocated in 1:1:1 ratio into either one of the two intervention arms or the control arm. Participants in the intervention arms will receive high dose rifampicin (25mg/kg), moxifloxacin with or without aspirin along with HZ during intensive phase which will be followed by 4HRZ in the continuation phase. Modified intention to treat and a Per Protocol (PP) analysis will be conducted at 12 months and 24 months after the treatment initiation.

Study progress:

The trial began the recruitment on 30th August 2024.

Site	Pre-Screening	Screening	Enrolled
MMC	108	15	13
NEIGRIHMS	103	6	6
CMC	59	11	8
JIPMER	56	6	6
AIIMS	73	7	5
KGMU	Yet to be initiated		
TOTAL	399	45	38

Translational value:

The trial holds immense translational potential as the INSHORT trial is the largest multi-centric clinical trial ever conducted in India for TB meningitis in adults. Given the current TBM regimen's several drawbacks, if the study regimen proves beneficial, it will have policy implications for both national and global TBM treatment in adults

7. Impact of Xpert MTB/XDR in early diagnosis and treatment and 6-month mortality in patients with drug-resistant tuberculosis: a pragmatic quasi-experimental study

Principal Investigator	:	Dr I. Leeberk Raja
Participating Institutes	:	ICMR-NIRT; District TB Office, Chennai
Source of funding	:	ICMR- Ignition grant
Study period	:	2023-2025
Pillar	:	Detect
Category	:	Delivery

Background:

The rapid diagnosis and appropriate treatment of drug-resistant tuberculosis (DR-TB) is essential to prevent severe morbidity, mortality, and further transmission of tuberculosis. The newer Xpert MTB/XDR detects resistance to isoniazid, fluroquinolones and aminoglycosides in a few hours. Though Xpert MTB/XDR has an excellent sensitivity and specificity, it has not been used widely in the TB program and impact of patient outcomes with this test has also not been studied. We aim to determine the reduction in time to diagnosis and time to treatment for drug-resistant tuberculosis with the implementation of Xpert MTB/XDR (intervention) compared to current standard diagnostic algorithm in NTEP (control)

Methods:

We propose a quasi-experimental study among 756 individuals in five NTEP districts of Chennai. Three districts will be offered Xpert MTB/XDR for all the patients with presumptive DRTB and the remaining two districts will follow the routine NTEP diagnostic algorithm. We will record time to diagnosis and treatment in both the arms and evaluate mortality at 3 and 6 months. Independent sample 't' test or Mann-Whitney U test will be used to compare the outcomes such as time to diagnosis and time to treatment between intervention and control districts depending on the distribution of the data. Sensitivity and specificity will be calculated comparing Xpert MTB/XDR results with phenotypic DST.

Study progress:

Study was initiated in March 2025 and enrolled 31 participants.

Translational value :

The study will demonstrate the effectiveness of Xpert MTB/XDR in

reducing the diagnostic delay in patients with resistance to isoniazid and fluoroquinolone, which is currently detected in LPA. If the ethionamide resistance is found based on Xpert MTB/XDR, it will also help to modify the treatment regimen from shorter DRTB regimen to longer regimen. Subsequently, this will enable quick decision and reduce the treatment delay. Overall, reducing the diagnostic delay and treatment initiation will improve patient outcomes and increase the proportion of patients with favourable outcomes and reduce mortality due to DRTB. The study will also indirectly give diagnostic accuracy of Xpert MTB/XDR and strengthen the cause of utilizing this molecular test in the routine diagnostic algorithm in NTEP

8. **Predictors of unfavorable treatment outcomes and emerging drug resistance among patients started on drug regimen for Isoniazid (INH) mono-resistant pulmonary Tuberculosis under NTEP in Tamil Nadu and Kerala: a prospective cohort study**

Principal Investigator	:	Dr I. Leeberk Raja
Participating Institutes	:	ICMR-NIRT; State TB cell and NTEP
Source of funding	:	Intramural
Study period	:	2023-2025
Pillar	:	Treat
Category	:	Description

Background :

Isoniazid mono-resistance is the most common type of drug-resistance in TB. It reduces the treatment success and increases the risk of acquiring additional drug resistance such as rifampicin and fluroquinolones. Studies across the globe have reported unfavourable outcome rates of 7-44% among these patients treated with first line drugs. This study aims to identify predictors for unfavorable treatment outcomes among patients with pulmonary TB patients.

Methods:

All newly diagnosed pulmonary TB patients initiated on treatment regimen for INH mono resistance were recruited. Patients with additional resistance for rifampicin or fluroquinolones were excluded. Demographic details and sputum sample were collected at the baseline. Subsequently, sputum samples were collected during the treatment and post-treatment for smear microscopy, first and second line LPA, culture and DST. During the follow up, details regarding change of regimen, adverse events and TB recurrence were also collected.

Study progress:

We screened 1053 individuals with INH mono-resistant pulmonary

tuberculosis and enrolled 847 participants across 11 districts in Tamil Nadu. The median age was 49 years (IQR- 39 to 58) and majority were men (78.2%). More than of the study participants were malnourished (50.8%) and more than one third were diabetic (39%). Of the participants whose CXR (527/847, 62.2%) was available, 39.3% had cavities. At the baseline, 68.8% samples were culture positive and 1.9% were resistant to fluroquinolone and 10.6% were resistant to pyrazinamide. The follow-up is ongoing.

Translational value :

The factors contributing for the unfavourable treatment outcomes, and drug resistance pattern among these patients will give the researchers, clinicians and program managers good insights on planning newer interventions and strategies in the future. This study will also help us to understand the effectiveness of drug regimen currently used for these patients. Thus, this study also will contribute to the society in achieving the overall goal of TB elimination.

9. Prevalence, pattern and progression of Post TB Lung Disease in India: A prospective single arm study

Principal Investigator	:	Dr. A. Newtonraj
Participating Institutes	:	ICMR NIRT
Source of funding	:	ICMR
Study period	:	2025-2027
Pillar	:	Detect
Category	:	Description

Background:

This study started with the objective to determine the prevalence, pattern and progression of post TB lung disease (PTLD) during and after two years of successful treatment in the newly registered adult PTB, to identify the risk factors of PTLD, to understand the circulating immune markers baseline and longitudinal assessment of PTLD and to understand the psychosocial and economic challenges faced by the PTLD participants at the end of treatment.

Methods:

This is a prospective single arm study design

1. NIRT clinic sites of Chennai and Madurai. With the following outcome measures,
2. Prevalence of patients with PTLD at various time points
3. Pattern of PTLD in each time point (clinical, anatomical and functional)

4. Course of PTLD in two years (clinical, anatomical and functional outcomes)
5. Risk factors of PTLD - Demographic, co-exposure, co-morbidity
6. Host immune responses for PTLD.
7. Treatment and post treatment outcomes (Proportion of successfully treated PTB individuals without TB, died, TB recurrence, lost at 2 years post-treatment) in proportion
8. Qualitative and Thematic representation of psychosocial and economic challenges faced by the PTLD patients in two years.

In this study Eligible participants (PTB patients initiated with 6 months NTEP daily regimen) for the study will be prospectively recruited from the study sites in selected TUs. Consecutive sampling will be done. Data collection for PTLD includes demographic, clinical information, PFT, 6MWT, Xray, HRCT, FOT and SGRQ assessment, which will be collected in a case report forms (CRF). PBMC, Serum and Plasma will be stored at prescribed visits for biochemical and immunological assessments. Follow-up will be done at 0,3,5,12,18,24 and 30th months. The eligibility criteria for the study as follows,

Inclusion/exclusion:

Inclusion:

1. Adult new PTB patients initiated with 6 months daily regimen under NTEP.
2. Age group of ≥ 18 years
3. Willing to participate in the study and follow the trial procedures
4. Willing to give written informed consent
5. Residing within the study area (TUs)

Exclusion:

1. Known patients of COPD, Asthma and autoimmune disorder on treatment
2. Drug resistance TB
3. Pregnant women
4. Severely ill and moribund state

Current status:

At present the study has been started successfully and 40 participants were recruited in the study. The interim analysis would begin in another six months.

10. Accelerating Efforts to END TB in India

Principal Investigator	:	Dr. R.Balaji
Participating Institutes	:	ICMR NIRT (Madurai) and 31 more sites
Source of funding	:	ICMR – NHRP
Study period	:	2023–2025
Pillar	:	All pillars
Category	:	Delivery

Background :

The Indian Council of Medical Research (ICMR) & National Institute for Research in Tuberculosis (NIRT) under the Department of Health Research (DHR), Min. of Health & Family Welfare (MH&FW), Govt. of India is implementing the study in collaboration with the Central TB Division (CTD). ICMR institutes across India is implementing the study in population designated as vulnerable in NTEP guidelines. Sites make detailed micro plans to screen, diagnose and treat the population close to home by active case finding along with contact tracing and treating enhanced by IEC activities, socio-behavioral counselling and nutritional supplementation. The primary outcome of the study is to measure proportional improvement in the yield compared to current indicators such as Tb notification rate, Treatment initiated, Adherence to ATT, TPT initiation among contacts with intensified case-finding activities and follow up.

Objectives

Primary

1. To assess the effectiveness of a comprehensive intervention package in reducing the incidence of TB disease in the selected districts

2. To support NTEP in accelerating TB elimination at district level by promoting early case detection, treatment adherence, contact tracing and preventive therapy through the intervention package

Secondary

1. To screen and initiate ATT for all chest symptomatic / abnormal X ray diagnosed for MTB with molecular test in the community

2. To initiate TPT for all contacts of TB patients and high-risk population

3. To assess the feasibility of providing new shorter all-oral regimens in the selected districts

Methods

The stakeholders involved in the project implement the study in collaboration with the across India among population designated as vulnerable as per NTEP guidelines. NIRT is implementing the study in Madurai district under the following components. The field level activities are to screen, diagnose and treat the population close to home by TB active case finding along with contact tracing

and treating enhanced by IEC activities, socio-behavioral counselling and nutritional supplementation. The primary outcome of the study is to measure proportional improvement in the yield compared to current indicators such as Tb notification rate, Treatment initiated, Adherence to ATT, TPT initiation among contacts with intensified case-finding activities and follow up.

Study progress

The study is active in 32 districts across the country. About 1.5 lakh population was screened at the community level in the mapped areas in Madurai district and diagnosed 58 patients. 104 contacts of TB patients are identified to initiate TPT.

Translational value

This study focuses to build a unique model of state specific implementation. The study uses the amplified implementation approach where all the key stakeholders collaborate to complete the cycle of identification and treatment completion along with follow-up and contact tracing.

Image 1. Community level population screening for Tuberculosis.

11. Scaling up short course TB preventive regimen containing Isoniazid and Rifapentine given once-weekly for three months (3HP) among household contacts of sputum positive pulmonary TB patients in India: A demonstration project

Principal Investigator	:	Dr. S. Ramesh Kumar
Participating Institutes	:	ICMR-NIRT; ICMR-RMRI, Bhubaneswar; NITRD, New Delhi; NTEP of Tamil Nadu, Pondicherry, Karnataka, Gujarat
Source of funding	:	ICMR Extramural
Study period	:	2022-2025
Pillar	:	Prevent
Category	:	Delivery

Study Progress:

Various studies provide evidence that 3HP regimen is non-inferior and perhaps superior to the 6- or 9-month IPT regimen in terms of effectiveness, and is well tolerated with better adherence rates, it is important to demonstrate the targeted scale up however. Primary objective of the study is to determine the feasibility of providing the 3HP preventive therapy to household contacts of bacteriologically positive pulmonary TB patients under program settings. Also aimed to describe the pattern of adverse drug reactions, understand the barriers and facilitators and determine the proportion of household contacts developing TB over a 2 year follow up period. Methods: Multi-centric prospective demonstration study among household contacts of adult Pulmonary TB cases. FGD will be conducted among participants and health Care workers to understand the barriers and facilitators for 3HP implementation. Study progress: Formal meeting, discussion and updating with the State TB Officers of Tamil Nadu, Karnataka and Gujarat followed by study initiation, training, and recruitment of 3HP recipients were done. The 3HP provision for the HHC was based on the concerned State whether they had "Test and treat" or "Treat all" policy. Follow up of HHC participants, the recipients of 3HP have been completed for some and follow up of remaining are being done. FGDs conducted among 3HP recipients and health care workers, few more planned as suggested by ICMR expert committee. Data are collected through Redcap for Tamil Nadu & Pondicherry, New Delhi and Orissa, while data from Karnataka and Gujarat are being extracted from the program data as provided by the concerned STOs.

The site wise numbers of 3HP recipients received and the status of the numbers at 6th, 12th,18th and 24th months of follow up as on 31st March 2025 are presented in the table below.

As on 31-03-2025	Madurai	Thoothukudi	Chennai	Kanchipuram	Puducherry	Odisha	Delhi	Total
No. of HHC Screened for study	645	394	452	431	203	90	251	2466
No. Eligible for 3 HP at enrolment	117	87	180	48	55	86	228	801
No. given 3HP	117	87	152	48	53	80	228	765
No. completed 3HP (at least 11 doses)	113	84	151	43	48	74	196	709
No. completed 12 months follow up	116	84	151	43	48	71	188	701
No. completed 18 months follow up	115	84	150	43	48	54	191	685
No. completed 24 months follow up	107	83	115	33	32	0	193	563
No. discontinued before 12-16 weeks (before 4 months)	4	3	1	5	5	6	32	56
No. with ADRs	19	3	13	5	5	14	25	84
No. discontinued 3HP due to ADRs	4	3	1	5	5	0	6	24
No. of death, with time point (eg No.; Month of event)	2 (6^{th} month and 14^{th} month)	0	2 (8^{th} M % 13^{Th} M)	0	0	0	0	4
No. developed TB during treatments or follow-up	0	1	0	0	0	1	3	5
No unwilling or LFU during treatment	0	0	0	0	0	5	25	30

- Karnataka: 2937 of 3HP recipients, reported that 2310 completed Rx (need to explore the remaining 627), 10 discontinued due to ADRs, 1 death, 6 developed TB

- Gujarat: 2477 of 3HP recipients, reported that 2236 completed Rx (need to explore the remaining 241), 57 discontinued due to ADRs, No death, 5 developed TB
- Focus group discussions (total of 9) were conducted among household contacts of sputum positive pulmonary TB patients who received 3HP and health care providers who delivered 3HP in five districts of Chennai, Pondicherry, Madurai, Tuticorin of Tamil Nadu and Tumkur, Karnataka. FGDs were conducted. The FGDs were able to elicit "barriers in administering 3HP", "reported side effects", and "suggestions from healthcare providers and needs felt by household contacts" to improve implementation.

12. Smoking Cessation among TB patients in Madurai district Corporation centres: aiding TB free Madurai

Principal Investigator	:	Dr. S. Ramesh Kumar
Participating Institutes	:	ICMR-NIRT; DD, (TB), NTEP, Madurai; GRH (Dept of Resp. Med, Dept of Psychiatry), Tobacco Cessation Clinic of Cancer Institute Adyar, Chennai & Madurai branch, DHO, Madurai
Source of funding	:	Partly ICMR intramural and partly office of District Health Officer, Madurai
Study period	:	2023-2026
Pillar	:	Treat
Category	:	Delivery

Background :

Smoking cessation in TB patients improves TB outcome. NIRT Operational study on Smoking cessation strategy study among TB patients established the effectiveness of smoking cessation interventions namely Bupropion SR or Enhanced counselling at field level. We propose to deliver these smoking cessation strategies to TB patients attending NTEP centres and estimate the quit rate and assess the TB outcomes with and without quitting at Madurai district. Methods: To estimate the quit rate when the smoking cessation interventions namely Bupropion SR or Enhanced counselling offered to TB patients who are smokers in Madurai district and assess whether that aids in improving TB free indicators in Madurai. All TB patients attending for TB treatment in NTEP Centres of Madurai district (within Corporation limit, both Public and Private sector) will be screened for history of current smoking. TB patients who are current smokers during the study period are to be offered either drug namely Bupropion SR or Enhanced counselling to enable them in smoking cessation. The intervention will be delivered by the MO/ NTEP Health care worker for Drug and Enhanced counselling respectively. Quitting smoking will be assessed by Self reporting and Carbon monoxide monitoring tests at 2nd month and at end of ATT and follow up at 9th month and year one. Study progress: The study has two phase 1. Training Phase, where in the health care workers will be trained for

delivering Smoking Cessation 2. Study subjects' recruitment phase where in the Subject (TB patients with Smoking) recruitment for the study will take place and the trained Health Care workers will deliver the Smoking Cessation Intervention Strategy. So far recruited about 22 TB patients with current smoking and the enhanced counselling has been delivered by the trained health care workers.

A policy brief mentioning suggesting for implementation of the NIRT Smoking cessation strategy namely Enhanced counselling is in place at the ICMR website. As the Govt of Tamil Nadu was interested in the implementation of the strategy, a cost effectiveness analysis study in collaboration with Tamil Nadu State officials was done and it have shown that proposed strategies are cost effective than those currently implemented in the program, the findings published in January 2025.

13. Stigma and Disclosure Study (TB vaccine trial – Capacity Building Project sub study)

Principal Investigator	:	Dr. P. Murugesan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR- India TB Research Consortium
Study period	:	2024
Pillar	:	Prevent
Category	:	Description

Background:

The study assesses the stigma experience and disclosure among vaccinated TB patients in terms of the type of disclosures they made, disclosure timing, persons with whom the disclosure was made, and the consequences of disclosure.

Objectives:

Qualitative:

1. To qualitatively explore and understand the stigma experiences, and perceptions of Index TB patients and vaccinated household contacts (HHC) who developed TB in the course of the TB vaccine trial.
2. To qualitatively explore and understand the coping strategies and adaptations of Index TB patients and vaccinated household contacts (HHC) in overcoming stigma.

Quantitative:

1. To assess the stigma and disease disclosures made by Index TB patients and vaccinated household contacts (HHC) who developed TB in the course of the TB vaccine trial to their familial and other social relationships and the reasons for discourse.
2. To quantitatively assess the level of stigma and shame experienced by Index TB patients and vaccinated household contacts (HHC).

Methods:

A Cross– sectional study design using mixed methods. The study was conducted at all the ICMR TB-Vaccine trial sites. As there are 18 TB vaccine trial sites, ICMR-NIRT has 4 TB vaccine trial sites – Chennai, Thiruvallur, Vellore, and Madurai.

Status of the study:

Quantitative data were collected from a total of 30 eligible study participants and In-depth interviews were conducted among 24 study participants as part of qualitative data collection. The data was subsequently submitted to ICMR headquarters for analysis and publication.

14. An integrated psycho-social intervention to improve self- efficacy towards treatment uptake and infection prevention among patients and family caregivers – A multi- centric implementation research study

Principal Investigator	:	Dr. N. Karikalan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2024-2025
Pillar	:	Delivery
Category	:	Build

Background:

Psycho-social interventions to improve the treatment self-efficacy and self-management skills to address the multi-dimensional challenges faced by TB patients need to be integrated into the present TB care system.

Methods:

A multi-centric Hybrid I mixed-method implementation design to adapt and evaluate implementation feasibility and efficacy of delivering a self-efficacy-driven intervention using an implementation research approach.

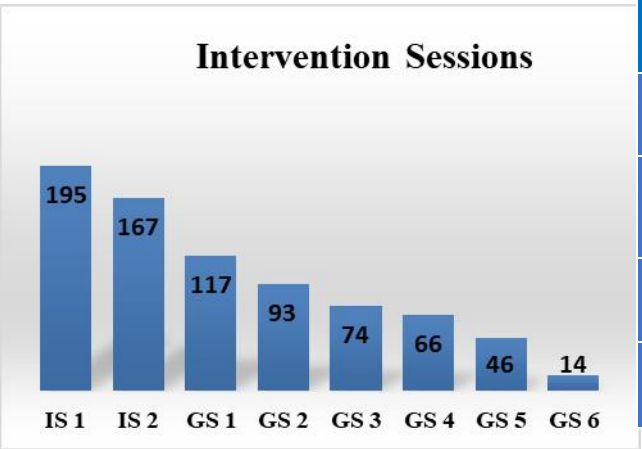
Objectives

To adopt a self-efficacy-driven intervention for improving the treatment self-efficacy of TB patients and family caregivers under the NTEP program and to evaluate its efficacy in comparison to the standard of care on primary outcomes: i) improved TB treatment self-efficacy and secondary outcomes i) improved medication adherence (ii) decreased TB stigma iii) improved infection controls self-management practices.

Study progress

In collaboration with the NTEP staff, the study team obtained the details of the newly diagnosed patients, contacted them, and fixed up appointments based on their convenience and willingness to visit the treatment centre for screening. A total of 649 patients were screened

for the study, of which 390 patients, along with their caregivers, have been enrolled in the study. There are 195 patients in the intervention arm and 195 patients in the control arm across the three districts. 15 Qualitative FGDs have been completed in three sites.



Site	Intervention	Control	Total
Chennai	111	129	**240**
Kancheepuram	31	45	**76**
Tiruvallur	53	21	**74**
Total	**195**	**195**	**390**

15. Reducing pre-treatment loss to follow-up among individuals diagnosed with TB through behavioural nudging intervention - A multi-centric mixed methods implementation study

Principal Investigator	:	Dr. N. Karikalan
Participating Institutes	:	ICMR-NIRT, ICMR-NIOH, ICMR-RMRC, ICMR-NJIL& OMD
Source of funding	:	Intramural
Study period	:	2024-2026
Pillar	:	Delivery
Category	:	Build

Background:

Pre-treatment loss to follow-up (PTLFU) and treatment imitation delays remain major gaps in the TB patient cascade of care in India. PTLFU patients (who are diagnosed but have not initiated TB treatment immediately) remain infectious, experience poor treatment outcomes, and suffer high mortality rates. As of 2020 about 6% of the notified patients have not initiated treatment for TB subsequently in India. There is a need for developing behavior change interventions that could address patient-level barriers and gaps that lead to PTLFU.

Objectives

To assess gaps in the patient referral process and treatment initiation gaps among newly diagnosed DS-TB patients.

To evaluate the incremental effectiveness of a patient behavioural nudging intervention in reducing PTLFU rates as compared to the

standard of care among newly diagnosed DS-TB patients.

Evaluate the implementation process of a behavioral nudging intervention from the perspective of patients, caregivers, and healthcare providers.

Methods

Employing a hybrid two-arm cluster intervention design to evaluate the incremental effectiveness and implementation aspects of delivering a patient behavioral nudging intervention using an implementation research PRODUCES (Problem, Objective, and Design, (end-) Users, Co-creators, Evaluation, and Scalability) framework.

Study Progress

The study investigators discussed the study with local stakeholders and centralized approval was obtained from the DTO, and NTEP of the respective state and received support from them to conduct the study. The study sites were selected based on their caseloads. A total of 480 patients were enrolled in the study across various sites together in the intervention and control arm. A total of 5 in-depth interviews and 2 Focus group discussions were conducted across various sites.

Translational Value

The study will help generate evidence on simple behavioral change nudges for reducing PTLFU rates and reducing early dropouts which further could be scaled up in NTEP program settings where PTLFU rates are high.

16. Transportation workers lead intervention to improve TB literacy among co-workers and demand generation in the community - A quasi-experimental study

Principal Investigator	:	Mrs Chandra Suresh
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2024
Pillar	:	Description
Category	:	Prevent

Background:

Public transportation may serve as a potential pathway for TB transmission due to overcrowding and poor ventilation. Thus, there is an unmet need for transportation workers who are at increased risk of airway transmission of infection to increase awareness and knowledge about TB. On the other hand, public transportation is also used by people from different socioeconomic, demographic, and geographical backgrounds and provides an opportunity for engaging with a large volume of the population. This opportunity for public transportation

workers to engage with lakhs of passengers every day could be utilized for demand generation for TB-related information among the public.

Objectives:

To assess the outcomes of transport ambassador-led lead community engagement strategy in improving TB literacy among co-transportation workers in Chennai.

1. To assess the outcomes of transport ambassador-led community engagement strategy in increasing the demand for TB literacy among passengers in Chennai.

Methods:

Study design: Quasi-experimental design with pre and post-tests to assess the impact of the intervention. (TB-IEC tickets).

Study sites:

Fifteen zones of Greater Chennai Corporation with 31 Metropolitan Transport Corporation [Chennai] Limited bus depots.

Study population:

Conductors and Drivers of MTC workers and public transport passengers of Chennai corporation buses.

Study progress:

Phase 1: Formative phase - data collection completed among Conductors and Drivers of MTC and TB -IEC tickers has been developed. Phase 2: Intervention & Phase 3: Evaluation of Intervention to be started. The study is ongoing.

17. Unmet needs and coping strategies of family caregivers of persons with TB– an exploratory mixed method study – an exploratory mixed method study

Principal Investigator	:	Ms.B. Priscilla Rebecca
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Non-funded
Study period	:	2024
Pillar	:	Description
Category	:	Treat

Background:

Family carers are a part of the healthcare system, therefore the assistance they give improves the quality of life for those receiving care while saving costs for the healthcare system.

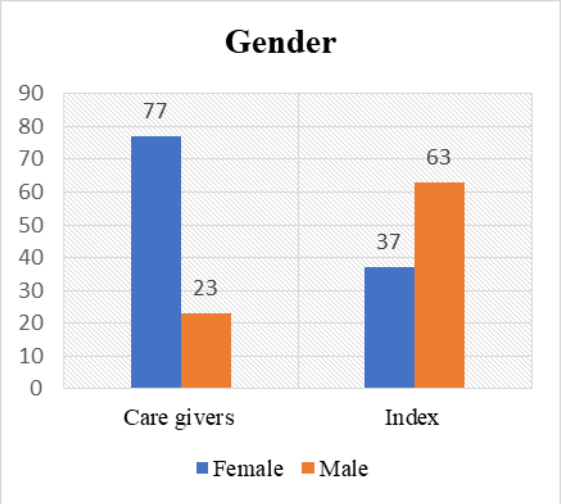
Methods: This study is a mixed methods research design, allowing for an in-depth exploration of the

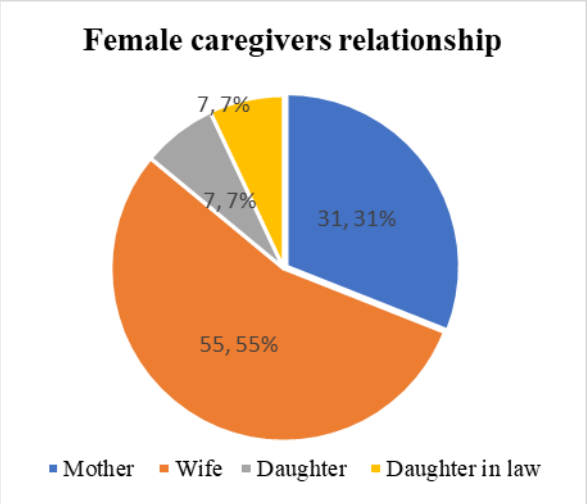
subjective experiences and perspectives of family caregivers and quantitative assessment for measuring, and valuing care.

Objectives:

(1) To understand the experiences, psycho-social challenges, and barriers faced by family caregivers in fulfilling their caregiving responsibilities for persons with TB (DR & DS TB). (2) To identify the coping mechanisms, strategies, and support systems that family caregivers employ to navigate their caregiving roles for persons with TB. (3)To measure and value the level of family care provided by the caregivers on a day-to-day basis.

Study progress: the study was initiated in July 2024, after obtaining permission from the sites selected for conducting the study. Data collection is in progress. Of the required 180 participants for the quantitative measure, 100 participants have been recruited in the study so far. 10 qualitative interviews with the patients and the caregivers have been conducted. This will help assess the workload and time caregivers dedicate to TB patients, guiding the development of a caregiver-centric intervention manual to enhance care and improve patient outcomes in India and other low- and middle-income countries.





18. An innovative approach for engaging student and women organizations to improve Tuberculosis case finding and treatment adherence: A step towards Tuberculosis elimination in Senapati District, Manipur

Principal Investigator	:	Dr. N. Karikalan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intramural
Study period	:	2023-2024
Pillar	:	Detect
Category	:	Description

Background:

TB ACF intervention studies globally, often employing CHWs or ASHA workers, have proven effective. Studies involving students in TB awareness and advocacy have been conducted, with some engaging students in case finding and treatment support.

Methods:

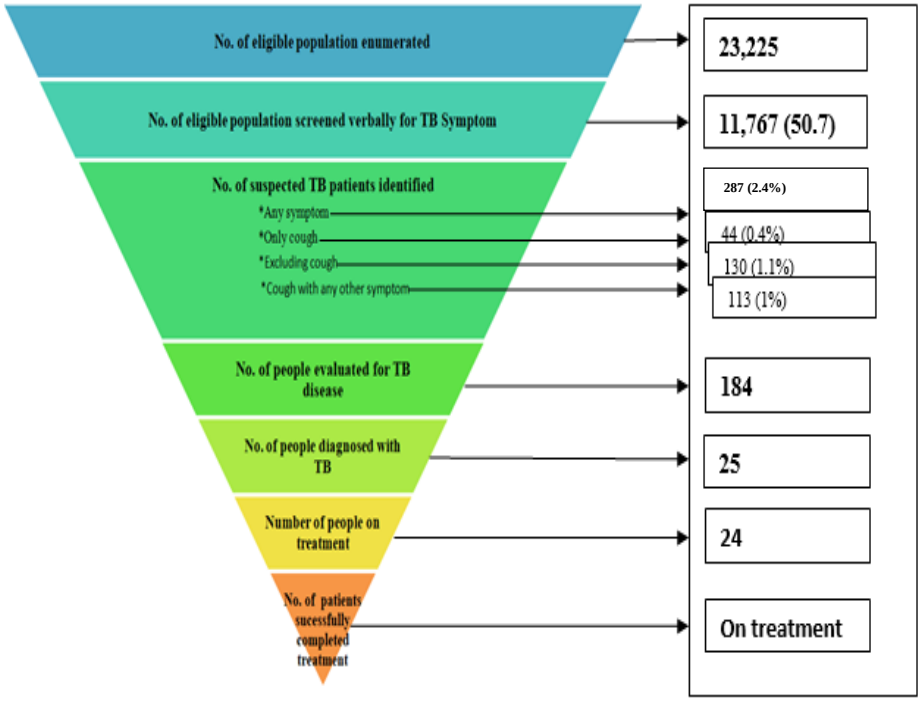
The study is being carried out using a quasi-experimental pre-post design in the whole district of Senapati, Manipur.

Objectives:

To determine the incremental increase in Tuberculosis case-finding rates, treatment adherence, and completion rates by engaging student and women organizations in comparison to routine program strategies.

Study progress:

The household enumeration and the second round of screening have been completed, and cost-effective data collection and preparing final reports, dissemination, and publications will be done.



19. Characterization of M. abscessus, M. kansasii, M. avium-intracellulare Complex - the most common NTM species isolated from presumptive TB patients

Principal Investigator	:	Dr. R. Priya
Participating Institutes	:	ICMR -NIRT
Source of funding	:	Intramural
Study period	:	2024-2027
Pillar	:	Detect
Category	:	Description

Background:

Non-tuberculous mycobacteria (NTM) are increasingly recognized as causative agents of opportunistic infection in humans. In general, Mycobacterium tuberculosis (MTB) and NTM infections have identical clinical symptoms, leading to misdiagnosis of the disease. Patients not responding to treatment, as most of the NTM are resistant to antibiotics and ATT (anti-tuberculosis therapy), instances of them being identified as multidrug-resistant TB are common. Appropriate identification methods for the differential diagnosis of NTM and MTB are needed. In this study, we aim to identify NTM isolated from presumptive TB patients and further characterize them by genotypic and phenotypic methods.

Objectives:

Primary objective:

To identify the pathogenic non-tuberculous mycobacteria causing symptomatic pulmonary disease

Secondary objective

1.To further characterize the most common species, M. abscessus, M.Kansasii, and MAC isolates using different molecular methods

2.To determine the drug resistance pattern of the isolates using different phenotypic and genotypic methods

Methods:

Currently, under the National Tuberculosis Elimination Programme (NTEP) and as part of patient management, sputum samples of the Presumptive TB population from all the NTEP centres of Tamil Nadu and other hospitals are sent to NIRT for culture and identification. Details of the sputum growing AFB but not suggestive of MTB complex in culture will be informed to the concerned treating hospital / medical officer/ laboratory for further treatment, and these isolates will be used for further characterisation at NIRT for this study.

In brief, the positive MGIT/LJ cultures will be tested with ICT (Immunochromatography) test involving MPT64Ag to differentiate MTB and NTM. DNA from NTM cultures will be extracted by Genolyse Extraction kit. Speciation of growth from two positive cultures per patient will be done using Genotype Mycobacterium CM/AS kit. In addition, PCR RFLP will be carried out on the species for further subtyping. Genotypic and phenotypic drug resistance testing will be carried out by the NTM-DR kit and broth microdilution method, respectively.

Study progress

A total of 200 isolates have been subjected to characterisation methods, and 85 have been sent to sequencing so far.

20. Diagnostic evaluation of tongue swab-based tests for detection of M. tuberculosis in presumptive pulmonary TB patients

Principal Investigator	:	Dr. R. Priya
Participating Institutes	:	ICMR -NIRT
Source of funding	:	Intramural
Study period	:	2022-2025
Pillar	:	Detect
Category	:	Description

Background:

Although the World Health Organization (WHO) recommends molecular diagnostics as the preferred frontline testing option, only 38% of all notified cases in 2021 were tested with a WHO-recommended rapid molecular diagnostic at initial diagnosis. Furthermore, only 63% of all notified TB cases were bacteriologically confirmed by any method. Research has shown that people with TB navigate long care-seeking pathways, with multiple visits to health providers before a diagnosis is made. In the absence of simple, point-of-care (POC) testing, primary care providers prefer to empirically manage people with broad-spectrum antibiotics and other non-specific therapies that are more easily available and that help offer immediate relief of symptoms. Decentralized POC tests would enable diagnosis and, therefore, treatment decisions to be made in the first patient consultation. Efforts are underway to evaluate such POC technologies for TB, especially in combination with non-sputum samples that may be more convenient for patients and providers.

Objectives

Primary Objective

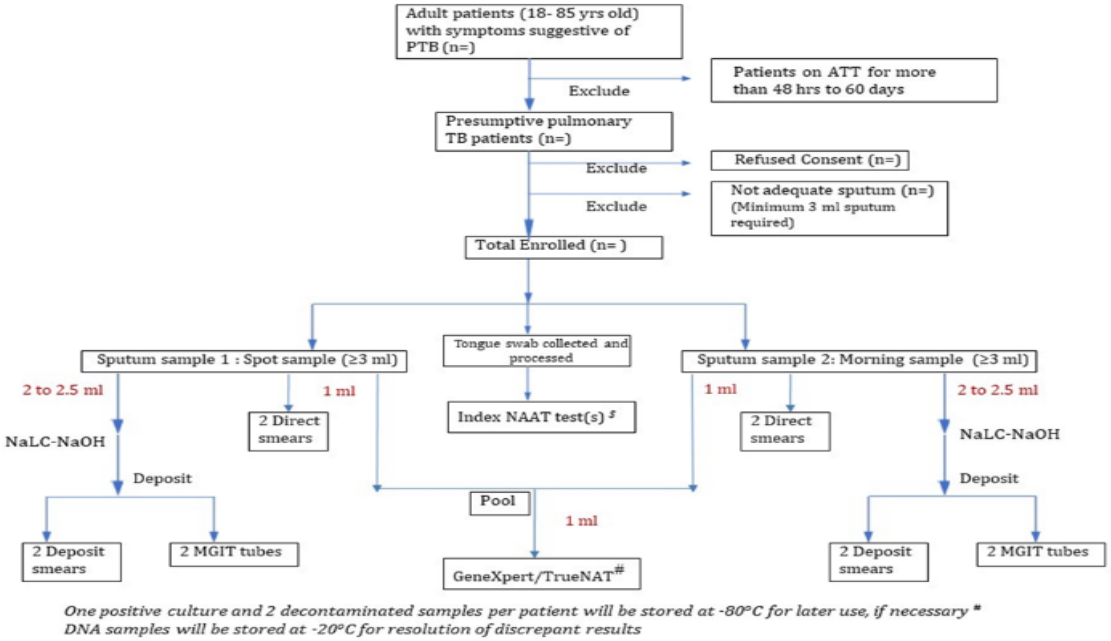
To evaluate the diagnostic characteristics of the tongue swab-based NAAT (index test) using MGIT culture as the microbiological reference standard for detection of M. tuberculosis in presumptive pulmonary TB patients."

Secondary Objective

To compare the diagnostic characteristics of the index NAAT versus those of approved NAAT (GeneXpert/Truenat) using MGIT culture as the reference standard for both the molecular tests

Methodology

The study will include presumptive adult pulmonary TB patients attending hospital OPDs/Chest clinics/district microscopy centers (DMCs), and Directly Observed Therapy Short Course (DOTS) centers. All such consecutive patients willing to provide consent will be enrolled in the study and subjected to procedures depicted in the figure below



Study Progress: Study started in June, and 200 patients have been recruited so far

21. Comparison of molecular methods Xpert® MTB/RIF Ultra and Genotype MTBDRplus assay for detection of rifampicin resistance from sputum samples

Principal Investigator	:	Ms. K. Silambuchelvi
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	ICMR Intramural
Study period	:	2021-2025
Pillar	:	Detect
Category	:	Development

Background:

Drug-resistant TB is a major public health crisis, with 5,58,000 people developing rifampicin-resistant TB (RR-TB) in 2017, 82% of whom had multidrug-resistant TB (MDR-TB). Moreover, globally it was estimated that the MDR/RR-TB as 3.5% of new TB cases and 18% of previously treated cases. The WHO recommends Xpert MTB/RIF Ultra for rapid rifampicin resistance detection, showing increased sensitivity compared to Xpert® MTB/RIF (CBNAAT). The Genotype MTBDRplus (LPA) test also targets the *rpoB* gene for rifampicin resistance. Discrepancies between Xpert MTB/RIF (CBNAAT) and Genotype MTBDRplus (LPA) have been reported, but similar discrepancies between Xpert MTB/RIF Ultra and LPA have not been explored. This study aims to address this gap with the objective to compare the two molecular methods - Xpert MTB/RIF Ultra and Genotype MTBDRplus (LPA) assay for detection of rifampicin

resistance in the discordant samples of presumptive MDR cases.

Method:

In this prospective study, 3-5 ml mucopurulent samples from presumptive and diagnosed TB patients will be tested using Xpert MTB/RIF (CBNAAT)/TrueNat MTB for MDR-TB. Rifampicin-sensitive samples will undergo Genotype MTBDRplus (LPA) for sensitivity to rifampicin and isoniazid. Discordant samples between Xpert MTB/RIF (CBNAAT)/TrueNat MTB and Genotype MTBDRplus (LPA) will be subjected to culture and DST by MGIT960 and also Xpert MTB/RIF Ultra will be performed. MGIT culture and DST will serve as the gold standard. Whole genome sequencing will explore unique mutations in discordant samples to prevent missed rifampicin resistance cases.

Study Progress:

A total of 76 discordant samples received from different NTEP sites were collected so far and the study is still ongoing. Both the Xpert MTB/RIF (CBNAAT)/TrueNat MTB and Genotype MTBDRplus (LPA) are used in the diagnostic algorithm in NTEP. Therefore this study will document discrepancies between the two molecular methods in the said setting with respect to rifampicin resistance. And also likely to provide much needed data required for strengthening or modifying policies on these tests in National TB Elimination Programme.

22. Multicentric validation of phage lysin in comparison with MGIT PANTA to control normal flora in processed sputum specimens for rapid detection of *Mycobacterium tuberculosis* using BACTEC MGIT 960 system

Principal Investigator	:	Dr. S. Balaji
Participating Institutes	:	ICMR-NIRT, Chennai. ICMR-RMRC, Bhubaneshwar. ICMR-BMHRC, Bhopal. New Delhi TB Center, New Delhi.
Source of funding	:	ICMR
Study period	:	2023-2025
Pillar	:	Detect
Category	:	Development

Background:

Bacteriophage lysin was used as an alternative to the traditional use of antibiotics to control the overgrowth of normal flora in sputum specimens. The objectives of the study includes large scale production of phage lysin and the multicentric validation of phage lysin to control normal flora in processed sputum specimens in comparison with antibiotic (MGIT PANTA) for rapid

detection of *Mycobacterium tuberculosis* using BACTEC MGIT 960 system.

Methods:

This is a multi-center, blinded, cross-sectional study to control the rate of contamination in TB patients in comparison to the conventional reference standard. With an assumption of 95% confidence interval, 80% power, design effect of 2 to adjust the site variability and 10% loss of sample or insufficiency; the minimum required sample size will be 528 per site and overall sample size will be 2112 from four sites.

Study progress:

The large-scale production of phage lysin was done with Sathyabama Institute of Science and Technology (SIST), Chennai with an existing MoU between the institutes. The purified phage lysin was showed inhibition on the growth of colonizing flora at 10µg/ml. The purified phage lysin was submitted to all participating institutes to complete the required sample size. The lysin under the project is already patented. Upon successful completion of the project, the lysin will be commercialized to replace the existing use of PANTA in growth based rapid methodologies including MGIT which is being used in the National TB Elimination Program (NTEP).

23. Evaluation of anti-tubercular, safety and immunomodulatory activities of Unani pharmacopeial formulations (UPF) Qurs-e-TabasheerSartani and &Arq-e-Hara Bhara through in-vitro and in-vivo studies

Principal Investigator	:	Dr. V. N. Azger Dusthackeer
Participating Institutes	:	ICMR-NIRT, JALMA, RRIUM
Source of funding	:	CCRUM
Study period	:	2024-2026
Pillar	:	Treat
Category	:	Discovery

Background

1. To determine the invitro efficacy of the two formulations namely Qurs-e-TabasheerSartani (QTS) and Arq-e-Hara Bharaalone (AHB) and in combination with the four first line Anti-TB drugs against *Mycobacterium tuberculosis* (Mtb).
2. To determine the immunoemodulatory role and Ex-vivo efficacy of Qurs-e-TabasheerSartani and Arq-e-Hara Bhara in Mtb infected and uninfected cell lines.
3. To determine the Invivo toxicity of the formulations in infected animal model using guinea pigs alone and in combination with INH and RMP.
4. To determine the immunolmodulatory role played by the formulations Invivo.

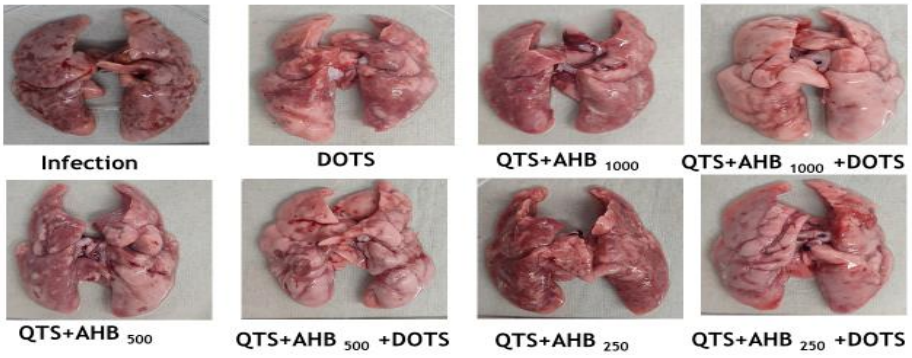
Methods

In vitro Anti mycobacterial activity of Unani pharmcopaeal formulation (UPF) against MTB Mtb-H37RV and 15 MDR-TB isolates were determined by Broth Micro Dilution assay. Drug-Drug interaction of UPF along with Rifampicine and Isoniazid against H37Rv was tested using the checker board method. Invivo toxicity and safety profiling of the formulations in infected animal model using guinea pigs alone and in combination with INH and RMP was carried out at JALMA, Agra.

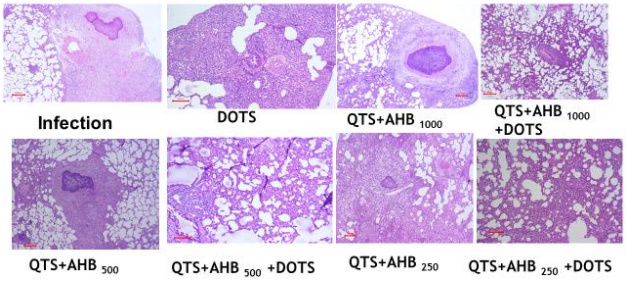
Study progress

Efficacy of Unnani formulations (UPF) was found to be between 5 to 10 mg/ml depending upon the Mtb isolates (was determined against laboratory strains of Mtb which are susceptible to anti-TB drugs and Drug resistant isolates of Mtb). Drug-drug interactions determined and was found to be synergistic and not antagonistic with anti-TB drugs (Isoniazid and Rifampicin). Abrogation of pathological lesions could be visually seen on the organs (liver, spleen and liver) and in histopathological tissues such as liver, spleen and liver with the formulations when administered along with the anti-TB drugs (ATT) when compared to the ATT alone groups. Full lenthgt PK determinations, Immunomodulatory and immune histochemistry are the experiments which will be carriedout in the second year of the study. If the subsequent exeriments align with the results observed till date, the formulations will offer the Tb control programme an effective adjunct therapy to circumvent the important issue of post TB lung sequlae.

Lung morphology of guinea pigs treated with DOTS (INH+RIF+PYZ+ETB), or UPF (QTS and AHB) @ human equivalent doses of 250, 500 or 1000 mg/kg doses respectively at 8th week post treatment

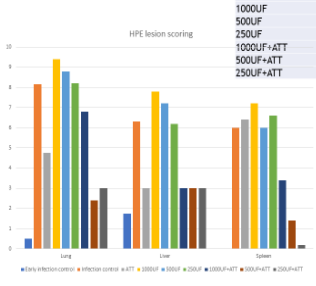


Lung HPE of guinea pigs treated with DOTS (INH+RIF+PYZ+ETB), or UPF (QTS and AHB) @ human equivalent doses of 250, 500 or 1000 mg/kg doses respectively at 8th week post treatment



HPE Lesion scoring

	Lung	Liver	Spleen
Early infection control	0.5	1.75	0
Infection control	8.16	6.3	6
ATT	4.75	3	6.4
1000UF	9.4	7.8	7.2
500UF	8.8	7.2	6
250UF	8.2	6.2	6.6
1000UF+ATT	6.8	3	3.4
500UF+ATT	2.4	3	1.4
250UF+ATT	3	3	0.2



24. In-vitro and In-vivo studies on newly identified MDR-TB efflux pump inhibitors

Principal Investigator	:	Dr. V. N. Azger Dusthackeer
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-Adhoc
Study period	:	2024-2026
Pillar	:	Treat
Category	:	Discovery

Background :

We have been focusing on new efflux pump inhibitors for last few years and in ABC super family in particular in genes namely, Rv1218 and Rv1819c. Few small molecule efflux inhibitors were shortlisted from Dukes database and were tested on MDR and XDR clinical isolated in which Palmitic acid, Rhamnose monohydrate, Methyl stearate and Myo inositol reduced the MIC of rifampicin remarkably in combinational studies with rifampicin. Based on these preliminary data following objectives were built upon further:

- To identify the ADME properties of the selected molecules and to address the results of the DMPK studies (Completed)
- To study the in vitro and in vivo efficacy of the proposed new efflux pump inhibitors in combination with first-line and second-line anti-TB drugs with MDR and XDR clinical isolates (On-going)

Methods

In-silico DMPK analysis of the efflux pump inhibitors methyl stearate, myoinositol, dodecanoic acid and palmitic acid was done and the formulations were prepared by lipid encapsulation and carecterised by FTIR spectroscopy, DSC of pure drug and formulation mixture was performed (DSC, Venchal Scientifics, model 412105), entrapment efficiency and the vesicle size of the formulations were determined. In-vitro and ex-vivo efficacy of new efflux inhibitors, alone and in combination with rifampicin, isoniazid was validated in MDR clinical isolates by broth micro dilution method, checker board techniques and in cell lines respectively.

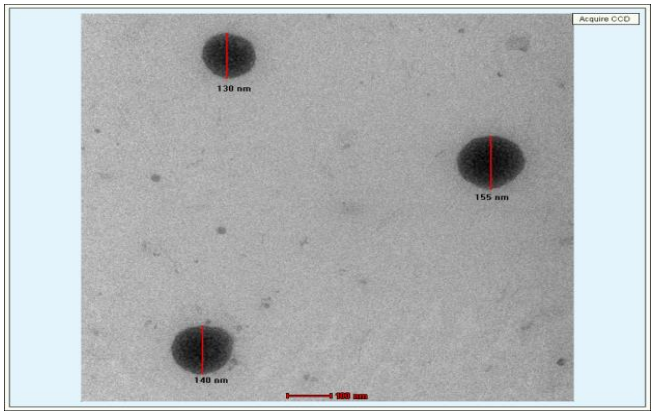
Results:

DMPK indicated the safety profiles of the four targeted molecules; and revealed the incipient nature of the three among them as well.

- Based on the values of parameters such as Log S, Log P, Log D, Plasma protein binding, Adsorption, cyp P450 metabolism, T1/2, Clearance rate etc., we found that apart from myoinositol, the other three efflux pump inhibitors cannot be used as a drug directly and need to be formulated.
- Myoinositol has been directly subjected to determine the efficacy in stored cultures of clinical isolates.

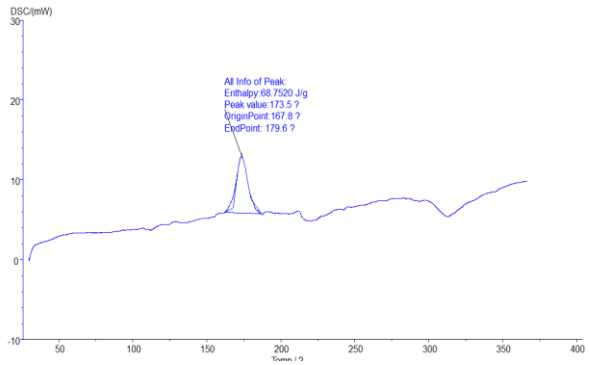
- Myoinositol when tested with Rifampicin in combination using checker board assay, was able to reduce the MIC value of Rifampicin in MDR and XDR.
- The results were confirmed with infection assay in THP-1 cell line.

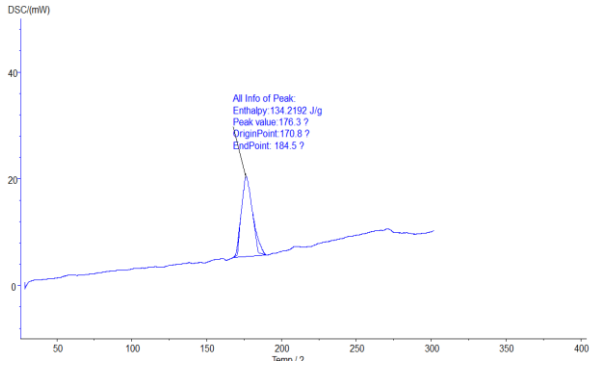
Apart from myoinositol, the other three efflux pump inhibitors cannot be used as a drug directly and need to be formulated. Successful formulations namely– C4, C5, C5R, C6 (**6 fold decrease** in RMP MIC in MDR-TB isolates) were developed, characterized and are about to be given for safety profiling in vivo.



Zeta potential & TEM studies of the encapsulated formulations

DSC of Rifampicin & Formulation mixture





Entrapment efficiency of the developed formulations

Formulation Code	% EE	Formulation Code	% EE
E1	85.6	C3	83.3
SCL	76.3	C31	89.8
IN1	82.1	C4	95.6
IN2	72.9	C5	82.3
C3	83.3	C6	80.4

25. Generic Protocol for Diagnostic evaluation of index molecular test kit(s) compared to the microbiological reference standard for detection of adult pulmonary tuberculosis

Principal Investigator	:	Dr. S. Siva Kumar
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	ICMR Validation Network
Study period	:	2024-2025
Pillar	:	Detect
Category	:	Development

Background:

Tuberculosis (TB) continues to be the second most-leading cause of death due to a single infectious agent as of 2022 after COVID-19. Many affordable new molecular diagnostic tools are being developed for early and more accurate diagnosis, especially for low-resource settings in low- and middle-income countries. In this context, there is a need to develop a standardized protocol for validation of new diagnostic tools. Here, we describe a generic protocol for multi-centric clinical evaluation of molecular diagnostic tests for adult pulmonary TB.

Methods:

This protocol describes a cross-sectional study in TB reference laboratories in India. Adults (>18 yr) visitng the chest clinics or outpatient departments with symptoms of TB need to be enrolled consecutively till the required sample size of 150 culture positives and 470 culture negatives are met. *Mycobacterium tuberculosis* (Mtb) culture (mycobacteria growth indicator tube liquid culture) to be used under this protocol as the gold standard and Xpert MTB/RIF molecular test will be used as the comparator. The sputum samples will be tested by smear microscopy, Mtb culture, Xpert MTB/RIF and index molecular test as per the proposed algorithm. The specificity sensitivity, and positive/ negative predictive values are to be calculated for the index test with reference to the gold standard.

Study progress:

Till date three kits have been validated and one of them have been approve by ICMR and results are presented below: Of the 644 samples analyzed, 37% were culture-positive and 32% were smear-positive. The sensitivity and specificity of Quantiplus® assay with reference to MGIT culture were 86% (95% CI 81–90) and 96% (95% CI 94–98) respectively at Ct ≤ 38. The positive predictive value (PPV) was 93% (95% CI 89–96%) and the negative predictive value (NPV) was 92% (95% CI 89–94).The performance of Quantiplus® assay (v2.0) was comparable to Xpert MTB/RIF ® (κ=0.83,SE=0.02) at Ct ≤ 38. The kit has been presented to NTEP for use in the program.

26. Culture-Free Detection of Drug Resistance in Clinical Samples for MDR-TB Patients Treated Under the National Tuberculosis Elimination Program

Principal Investigator	:	Dr. S. Siva Kumar
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	ICMR Intramural
Study period	:	2024-2026
Pillar	:	Detect
Category	:	Development

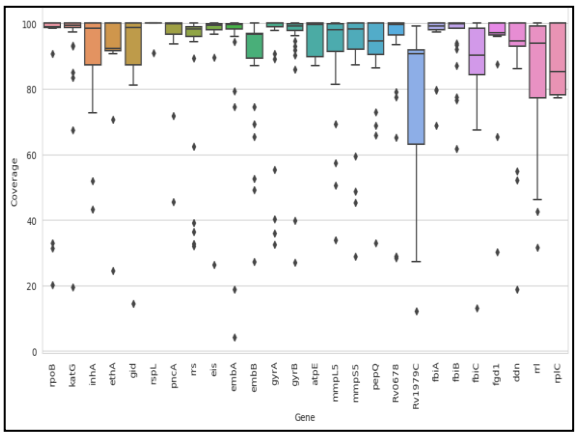
Background:

Timely drug resistance detection is essential to global tuberculosis management. Phenotypic drug susceptibility testing (pDST) takes 6-8 weeks. This limitation can be overcome by whole-genome sequencing. However, the direct sequencing of sputum samples is challenging due to low amounts of M.tb DNA. To overcome this difficulty, an all-in-one targeted deep-sequencing assay has been developed. Nanopore-based DNA sequencing instruments will be used. They are portable, robust, and low-capital-cost sequencers that could conceivably be utilized in near-patient settings to conduct tNGS in a manner that could transform DST for TB and rapid clinical decisions

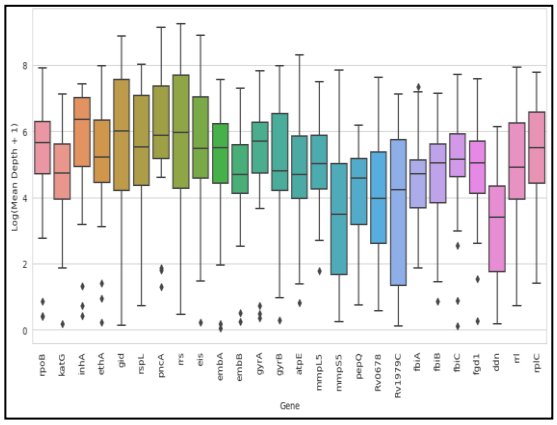
Methods:

Sputum samples/ Mycobacterium tuberculosis (M. tb) isolates from 351 bacteriologically confirmed TB patients between January 2022 and June 2023 were used in the study. A commercial Deeplex Myc-TB primer set was used for species-level identification, genotyping, and antibiotic resistance prediction of M. tb. Library preparation was done using a rapid barcoding kit from Oxford Nanopore Technology (ONT), and the run was done using MiniON Mk1C (ONT). A bioinformatics pipeline was developed in-house for lineage and drug resistance prediction using tNGS data at ICMR-NIRT as part of this study.

Study progress (in brief): The development and validation of primers is completed with 50 sputum samples, further 850 MDR-TB samples will be tested as part of multicentric validation.



Depth of the genes in the sputum sample



Coverage and depth of the genes in the sputum sample

27. Development and validation of a Real-Time PCR (RT-PCR) test for tuberculosis diagnosis and treatment follow-up.

Principal Investigator	:	Dr. S. Siva Kumar
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	ICMR Intramural
Study period	:	2024-2025
Pillar	:	Detect
Category	:	Development

Background

Easy and timely diagnosis of TB is one the priorities in controlling the disease. While the gold standard for TB diagnosis is still mycobacterial culture which is a long process, quick and precise techniques are being developed. With RTPCR machines available in the farthest regions of the country, we have designed this study in order to develop a kit, which can be used with these machines for rapid diagnosis and prognosis of tuberculosis. This study will help us to determine the possibilities of using MTB DNA and RNA to detect the presence of MTB and its drug susceptibility.

Objectives:

1. To develop a Real-Time PCR assay for M.TB and drug-resistant gene detection and validate it compared to an MGIT culture to detect resistance.
2. To develop a Real-Time PCR assay to differentiate nontuberculous mycobacteria and Mtb complex.
3. To develop a Real-Time PCR assay to detect live M.tb using RNA from the stored M.tb isolates

Methods:

Sputum were collected from presumptive TB patients visitng the DMC/NAAT centers consecutively till the required sample size of 150 culture positives and 470 culture negatives are met. *Mycobacterium tuberculosis* (Mtb) culture (MGIT) will be used as the gold standard and Xpert MTB/RIF molecular test will be used as the comparator. The specificity sensitivity, and positive/ negative predictive values are to be calculated for the index test with reference to the gold standard.

Study progress (in brief): Sputum Samples have been collected and stored for the testing. The primers have been standardised and presently validation is being carried out using the stored samples.

28. Sentinel survelliance of drug resistant TB

Principal Investigator	:	Dr. S. Siva Kumar
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	ICMR
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Description

Background:

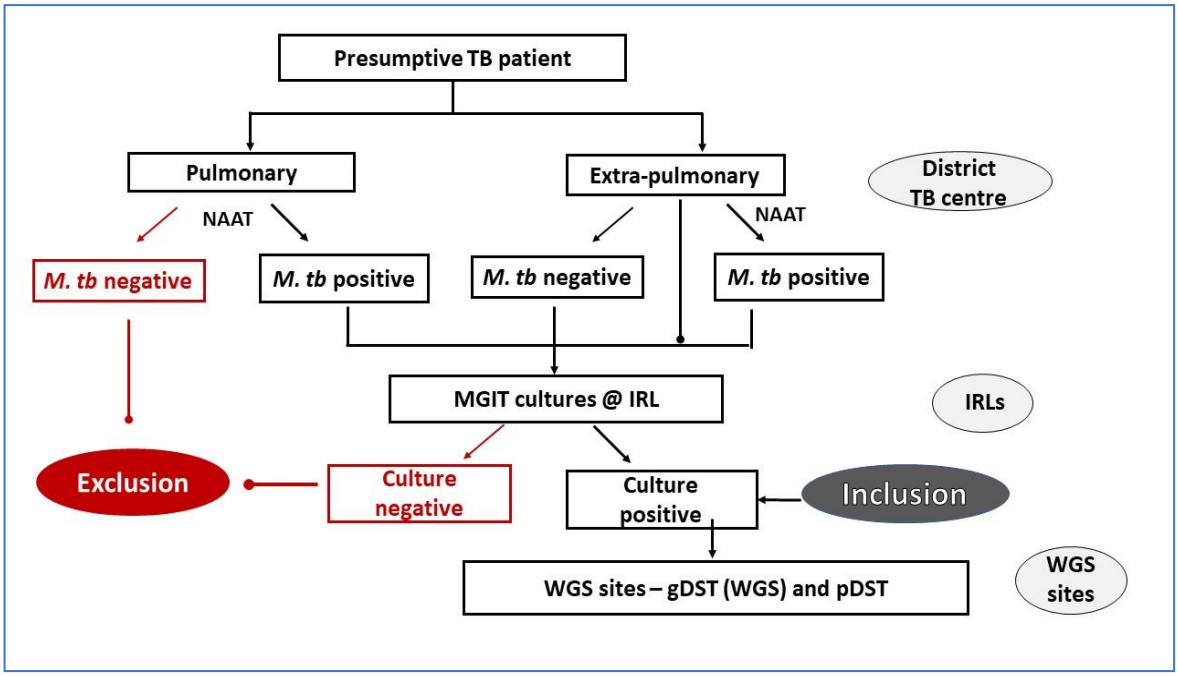
The NDRS was done in 2016 and its more than 5 years since the last survey and also there has been introduction of three new drugs and two repurposed drugs and there is a need for surveillance of drug resistance and the present study was done by both phenotypic and genotypic drug resistance testing. The implementation of a surveillance system for drug-resistant TB leads to improved access to timely and appropriate treatment and care. Additionally, it could provide information of outbreaks, real-time monitoring of the effectiveness of the programmatic interventions. By conducting this surveillance, we can strengthen the overall laboratory capacity, sample transport and referral systems, data management expertise. Although the main aim of this surveillance would be to identify the drug resistance pattern over time, we would also use this study to develop and strengthen a quality-assured whole genome sequencing laboratory network across the country. Inclusion of sequencing technologies in the drug resistance surveillance can provide insights into the phylogenetics of the circulating TB strains. Sequencing overcomes many of the challenges associated with conventional phenotypic tests as well as the limitations of molecular tests. It is currently the only approach with the ability to investigate genome-wide targets for multiple first and second-line anti-TB drugs detecting even the rare mutations that could be missed by rapid molecular assays.

Objective:

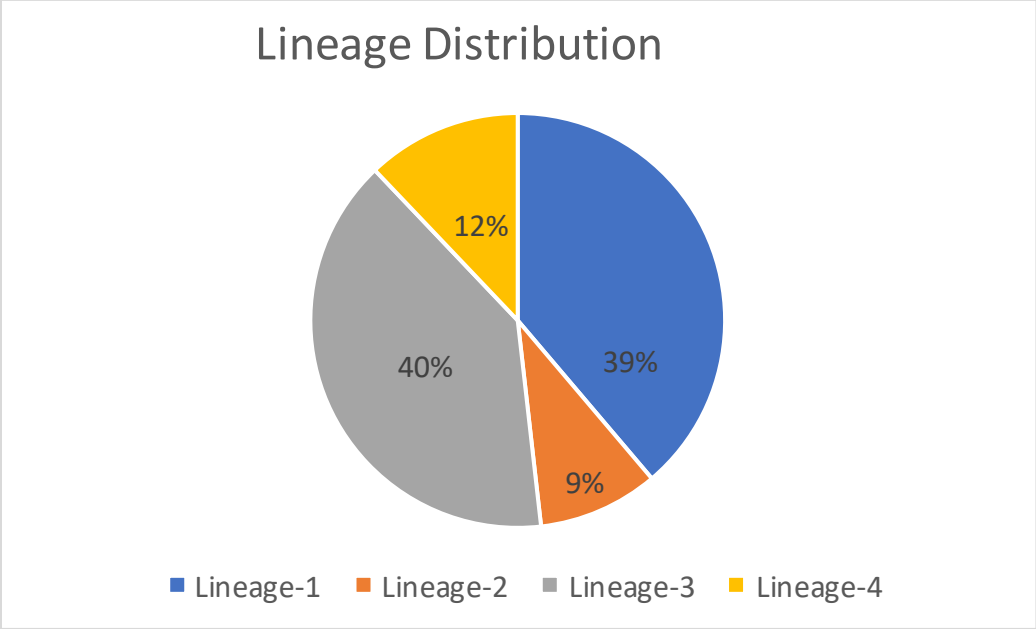
1. To monitor the proportion and pattern of drug resistance among new and previously treated microbiologically confirmed TB patients in selected districts of India
2. To monitor the pattern and emergence of drug resistance mutations and phenotypic resistance of microbiologically confirmed TB patients in India

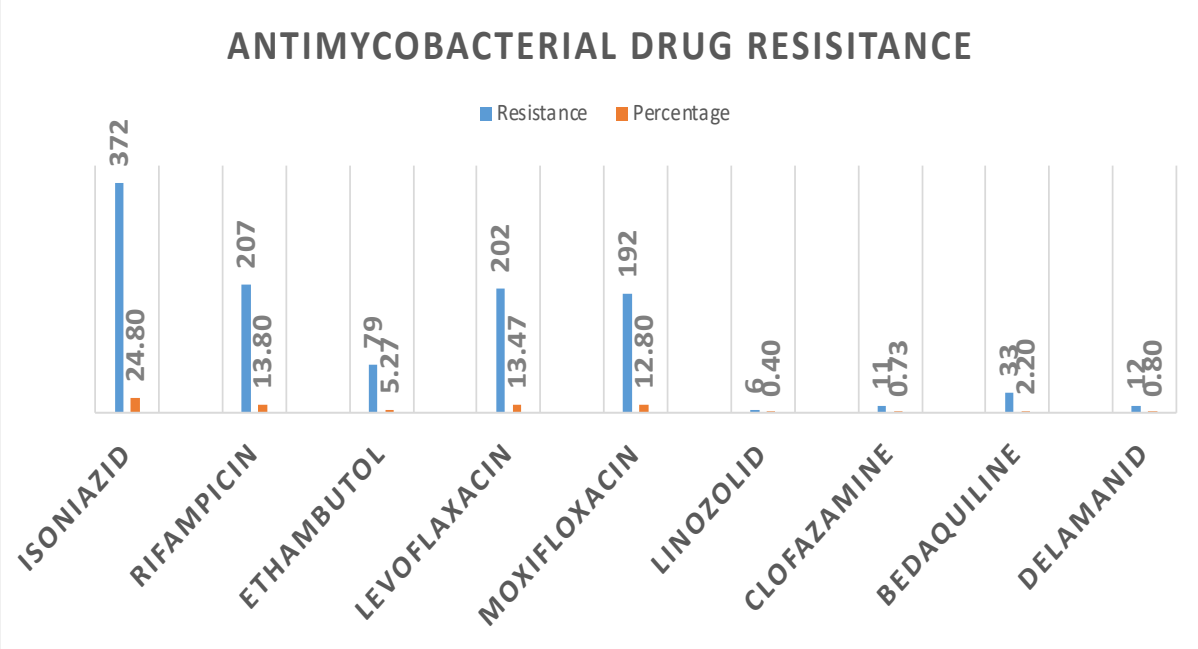
Methods:

Cross-sectional study among all new and previously treated TB patients. Sample
Sampling frame includes 276 Districts of India representing 29 states and 7 union territories in India, and it constitutes two parts: high burden districts and low burden districts with a sample size of 5200 MTB isolates



Study progress: Culture positivity of 92.3% was achieved in the liquid culture system with additional recovery of from Löwenstein-Jensen (LJ) media backup, which further improved the culture recovery rates. DST was performed on culture growth from specimens of 1500 and the DST is ongoing for rest of the samples. DNA extraction has been carried out for 4200 samples and sequencing has been performed for 1500 MTB isolates.





29. Point of care estimation of Vitamin D and C-Reactive Protein for tuberculosis screening in household contacts of active pulmonary tuberculosis patients in Tamil Nadu, India.

Principal Investigator	:	Dr. N. Saravanan
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-EM
Study period	:	2024-2027
Pillar	:	Detect
Category	:	Development

Background :

The missed or delayed diagnosis of active TB led to higher risk of deaths, suffering, longer duration of infectiousness, increased transmission and unexpected economic burdens. To achieve maximum possible elimination of TB, WHO stressed the importance of 'active screening' among high-risk populations such as household contacts (HHCs) of index cases to detect TB early. The primary objective of the study is to compare the diagnostic accuracy (sensitivity and specificity) and the predictive value (negative and positive predictive value) of point-of-care (POC) estimation of C-reactive protein and Vitamin D with WHO symptom-based screening for active TB in household contacts of PTB patients.

Methods:

In this prospective cross-sectional cohort study HHCs of newly diagnosed pulmonary TB (PTB) patients recruited for clinical studies at ICMR-NIRT and any contacts of new PTB patients in Chennai and parts of Tamil Nadu were included (children > 12 years of age and adults, with no IPT and ATT at the

time of enrollment). The sputum samples were examined for the presence of Mtb using smear, culture and molecular assays. The blood samples were assayed for vitamin D and CRP using POC and clinical chemistry analyzer. A 5 mL of blood was collected from the participant and fractions were prepared for further biochemical investigations

Study Progress:

We have recruited 566 HHCs (n = 1600), the bacteriological and biochemical tests have been completed. Presently aggressive participant recruitment is in progress and we will be able to analyze the data only after the completion of the study.

Translational potential:

The study would provide information on the predictive value of CRP and vitamin D for the active TB. As the analysis is simple to perform it can be employed anywhere in the country to other high-risk populations such as tribal populations, people living with HIV etc., as a prerequisite for the costlier confirmatory diagnostic techniques such as Xpert MTB/RIF.

Basic details of study participants*.

Variables	Overall (n=461)	NON-TB (n=455)	TB (n=6)
Age (in years) (Mean ± SD)	38.4 ± 15.0	38.5 ± 15.0	31.5 ± 14.2
Gender: n (%) Male, Female	184(39.9), 77(60.1)	180(39.6),275(60.4)	4(66.7), 2(33.3)
Vitamin D (ng/mL): POC, Median (range)	12.5 (2.4 – 63.3)	12.5 (4.0 – 63.3)	12.3 (2.4 – 30.3)
CRP: POC (mg/L) Median (range)	4.1 (1.0 – 63.6)	4.0(1.0 – 63.6)	4.6 (2.8 – 23.2)
X-Ray, n (%)			
Normal	417(94.1)	415(95.0)	2(33.3)
Abnormal	26(5.9)	22(5.0)	4(66.7)

*As on 28-04-2025, 566 study participants were enrolled. 461 study participants were subjected for basic data analysis

30. Bioavailability of fixed dose combination of first line anti-TB drugs in patients with pulmonary tuberculosis

Principal Investigator	:	Dr. S.M. Jeyakumar
Participating Institutes	:	ICMR-NIRT; GHTM and ICH, Chennai
Source of funding	:	Intramural grant
Study period	:	2021-2024
Pillar	:	Treat
Category	:	Description

Background :

Fixed dose combination (FDC) of drugs is one of the methods to improve compliance and reduce errors. The rationale of FDC is that the presence of all these drugs combined in one tablet can facilitate dosage calculation, prevent prescribing errors, increases patient's acceptance and decreases pill burden. In India, FDC's are recommended for TB patients under the National Tuberculosis Elimination Programme (NTEP) during daily treatment both in intensive and continuation phase. There are four weight bands for adult TB patients receiving INH, RMP, PZA and EMB (75/150/400/275mg) and 6 weight bands for children receiving dispersible FDC's (50/75/150/100) in addition to streptomycin for 2 months in the intensive phase. No study to date has assessed the combined use of the three drugs (FDC's) for TB treatment in different weight bands, both in adults and children, which is of great clinical relevance.

Objectives

To assess the bioavailability of RMP, INH and PZA when administered as FDC in adults and children with pulmonary TB treated in the NTEP in India.

Methods

This study is an observational and bioavailability study, carried out at the Institute for Child Health, Egmore for children and at Government Hospital for Thoracic Medicine, Tambaram for adults. As per the sample size, 12 patients each receiving treatment under 5 different weight bands in adults and while 6 different weight bands in pediatric population, receiving anti-TB treatment will be included according to the inclusion criteria, i) newly diagnosed pulmonary TB patients (both adult and children) as per the NTEP guidelines, ii) willing for blood draws and iii) adult patients or parent/guardian of pediatric patients willing to give written informed consent.

On the day for PK evaluation, eligible patients will be requested to report at the hospital in the morning under fasting condition. A sample of blood (2.5ml) will be collected in a heparinised vacutainer tube, followed by administration of anti-TB medications. The time of drug administration will be noted in the lab reception form. Blood samples (2.5 ml equivalent to half teaspoon) will be collected at 2, 4, 6, 8 and 12 hours in heparinised vacutainer tubes after drug administration. Plasma RMP, INH and PZA levels will be measured by validated HPLC methods.

Study progress:

Recruitment under children category is in progress and HPLC analysis of plasma drug levels for PK from adult weight band category is in progress**.**

31. Pharmacokinetics of linezolid when administered with other second line anti-TB drugs in MDR-TB/Pre-XDR-TB Patients

Principal Investigator	:	Dr. S.M.Jeyakumar
Participating Institutes	:	ICMR-NIRT; GHTM and ICH, Chennai
Source of funding	:	Intramural grant
Study period	:	2021-2024
Pillar	:	Treat
Category	:	Description

Background :

Drug-resistant TB (DR-TB) is more difficult to treat than drug-sensitive TB (DS-TB) and the treatment options are very limited. Addition of linezolid (LZD) in the treatment regimen of DR-TB has been associated with improved treatment outcome with reduction of mortality among MDR-TB and Pre-XDR TB patients. However, limited information is available on the pharmacokinetics of second-line drugs used in the treatment regimen of MDR-TB and Pre-XDR TB, particularly in the Indian context. Therefore, here we plan to undertake a pharmacokinetic study of LZD and other second-line anti-TB drugs used in the treatment of MDR-TB and Pre-XDR TB.

Objectives

1. To develop and validate methods for the estimation of linezolid (LZD) in plasma and saliva by HPLC.
2. To study the pharmacokinetics of LZD and other second-line anti-TB drugs in adult patients with multi-drug resistant (MDR) and pre-extensive drug resistant (pre-XDR) tuberculosis patients.

Methods

It is a prospective study, which will be carried out at the Government Hospital for Thoracic Medicine, Tambaram, Chennai. The study population will be of adult MDR-TB and pre-XDR-TB patients (>18y) being treated in these centres, based on the following inclusion and exclusion criteria. Inclusion criteria: i) Bacteriologically confirmed adult MDR-TB & pre-XDR TB, ii) Treatment regimen containing LZD along with other second line drugs for minimum period of 15 days, iii) Willing for hospitalization for the purpose of the study & willing to give informed written consent. Exclusion criteria: Patients with HIV-seropositive, moribund, pregnant & breastfeeding women, chronic diarrhoea, and liver and renal abnormalities.

On the day for PK evaluation, study participants will be requested to report at the hospital in the morning under fasting condition. A sample of blood (5mL) will be collected in a heparinised vacutainer tube, followed by administration of anti-TB medications. The time of drug administration will be noted in the lab reception form. Blood

samples (5mL) will be collected at 2, 4, 6, 8 and 12 hours in heparinised vacutainer tubes after drug administration. Similarly, saliva (5 ml) will be collected from these patients at each time point of blood collection.

Study progress:

So far 17 patients were recruited for PK study and the recruitment is in progress.

A new HPLC method for plasma LZD along with other second-line drugs (fluoroquinolones and ethionamide) was developed and validated. A research manuscript was submitted a journal, which is under review (DDT-25-01016-OA).

Validation of a new HPLC method for measuring LZD in saliva is in progress.

32. Application of Multiple Imputation approaches to the prevalence estimation in large-scale tuberculosis prevalence surveys

Principal Investigator	:	Ms.Basilea Watson
Participating Institutes	:	ICMR-NIRT
Source of funding	:	NA
Study period	:	2024 - 2025
Pillar	:	Detect
Category	:	Description

Background :

Accurate estimation of TB prevalence is essential for program planning and monitoring in high-burden countries. Population-based TB prevalence surveys often suffer from missing data due to non-participation or unavailable test results. Conventional analyses can underestimate the burden due to these gaps. This study proposes the use of multiple imputation (MI) to handle missing data, along with adjustment for clustering, to derive robust and unbiased TB prevalence estimates.

Aim:

To derive standard and robust TB prevalence estimates using individual-level analysis adjusted for clustering and missing data, as recommended by the WHO's 2011 "Lime Book".

Objectives:

1. Estimate TB prevalence using robust standard error and random effects logistic regression models, with and without MI.
2. Identify the method yielding the least biased estimate.

Methodology:

Design: Secondary analysis of five TB prevalence surveys (1999–2009) conducted by NIRT.

Outcome Definition: Bacteriologically confirmed pulmonary TB.

Models Used:

1. Robust Standard Error (SE) without MI (Model 1)
2. Random-effects logistic regression without MI (Model 2)
3. Robust SE with MI (Model 3)
4. Random-effects logistic regression with MI (Model 4)

Multiple Imputation Process:

Based on WHO guidelines, with sensitivity analyses for MAR, MCAR, and MNAR assumptions.

Study progress:

The preparatory phase of the study has been completed, including identification of data sources and finalization of the analytical framework in line with WHO guidelines. Preliminary steps for data cleaning and multiple imputation modelling are in progress, paving the way for detailed statistical analysis in the upcoming months.

Expected Outcome:

The study will guide selection of optimal analysis methods for TB surveys and inform future prevalence estimations, ensuring minimal data loss and bias.

33. DLSS: Sentinel Surveillance for Tuberculosis burden in India 2023-2024" under the project strengthening and monitoring of Tuberculosis Elimination in India.

Principal Investigator	:	Dr. Mukesh Kumar.S, Dr. Sriram Selvaraju
Participating Institutes	:	ICMR-NIRT, NIRT, NIN, NIOH, NITVAR, NIRTH, NIIRNCD, NICPR, NJILOMD, RMRC Gorakhpur, RMRC, Dibrugarh, NIRBI, RMRIMS, RMRC, Bhubaneshwar, NTI.
Source of funding	:	Global Funds
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Description

Background :

The changing trend of the TB prevalence should be monitored to provide insights into impact of NTEP interventions and to inform public health action. The primary Objective is to develop national TB curve fitting mathematical model for incidence estimation on annual basis using community-based sentinel survey in India. The secondary objectives are to monitor national trends of TB prevalence, TB infection, health seeking behavior, Prevalence to

Notification ratio and tuberculosis mortality rate at national level.

Methods:

This is a population-based cross-sectional survey with cluster sampling design and cluster selection using PPS sampling method. The survey is conducted across 50 districts in India, with six clusters per district and a cluster size of 500, to achieve a national sample size of 150,000 individuals. In 50 clusters Cy-TB skin test is done to estimate TB infection rates among the surveyed population. Demographic details, anthropometric measurement, comorbidities, risk behaviours, chest symptoms and health-seeking behaviour will be collected. Chest X-rays will be performed for all participants, except pregnant women. Among the sputum eligible participants 2 sputum samples will be collected. The first sputum sample will undergo CBNAAT testing on-site, with a second sample sent to the National Reference Laboratories for smear microscopy and liquid culture. If CBNAAT results are positive in the first sample, a third sputum sample will be collected for further CBNAAT, smear, and liquid culture testing at the reference laboratory. Participants diagnosed with TB will be referred for TB treatment under NTEP.

Study Progress:

The survey has been initiated in Tamil Nadu, Uttar Pradesh, Uttarakhand, Rajasthan, Haryana, Bihar, West Bengal, Assam, Odisha, Chhattisgarh, Madhya Pradesh, Maharashtra, Gujarat, Telangana, Andhra Pradesh, and Karnataka. Till April 2025, 122 out of the planned 300 clusters have been covered across various states.

Translational Value:

The survey provides real-world national level TB estimates to guide TB control strategies and refine national TB burden estimates through incidence modelling. TB infection assessment will inform preventive treatment policies. The health-seeking behaviour enhances patient-centered care. The population attributable fraction of the risk factors will help to identify high risk groups for targeted interventions.

34. Health Technology Assessment in India Project, Department of Health Research

Principal Investigator	:	Dr. M Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	HTA, Department Health Research
Study period	:	2018-2026
Pillar	:	Prevent, Detect, Treat & Build
Category	:	Description and Delivery

Background:

The Department of Health Research (DHR) under the Ministry of Health and Family Welfare established the Health Technology Assessment in India (HTAIn) to promote evidence-based, equitable, and cost-effective healthcare decision-making. HTAIn plays a pivotal role in optimizing national health spending by evaluating the clinical and economic value of technologies such as drugs, devices, vaccines, and procedures. The objectives of the project include maximizing population health, reducing out-of-pocket expenditure (OOP), and minimizing inequities in healthcare access. It also aims to support health policy formulation at national and state levels by generating and disseminating reliable, scientific evidence through a transparent and inclusive assessment process.

Methods:

The project employs established methodologies including systematic reviews, meta-analyses, and decision-analytic models like Decision Trees and Markov models. Economic evaluations such as cost-effectiveness, cost-utility, and cost-benefit analyses are used to estimate outcomes in terms of cost, clinical effectiveness, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs). Sensitivity analyses, including one-way and probabilistic approaches, are conducted to assess the robustness of findings and inform policy decisions.

Study Progress:

The project has made significant progress in collaboration with the Government of Tamil Nadu and the Government of India. A total of 15 proposals have been developed, and seven Health Technology Assessment studies have been completed and approved by the Technical Appraisal Committee (TAC), Department of Health Research. Policy briefs based on these studies have been approved for implementation. Additionally, a capacity-building workshop on economic evaluation modelling was conducted with ICMR-NIV, Pune, enhancing technical skills for future HTA work.

35. Cost Analysis of RT-PCR Kits for Tuberculosis Detection in India

Principal Investigator	:	Dr. M Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	HTA, Department Health Research
Study period	:	2024
Pillar	:	Detect
Category	:	Description and Delivery

Background:

Tuberculosis (TB) remains a significant public health challenge in India, with increasing drug resistance and diagnostic delays. This study evaluates the cost-effectiveness of Reverse Transcription Polymerase Chain Reaction (RT-PCR) as an alternative diagnostic tool to GeneXpert MTB/RIF, currently the standard under India's National TB Elimination Programme (NTEP). Objectives included evaluating the cost-effectiveness of RT-PCR, estimating incremental costs, determining additional true cases detected, and analyzing the financial implications of nationwide implementation.

Methods:

A decision tree model was developed from a health system perspective to compare RT-PCR with GeneXpert for diagnosing TB and multidrug-resistant TB (MDR-TB) in adults (>15 years) presenting to public health facilities. Cost analysis included human resources, equipment, and consumables. Diagnostic sensitivity and specificity data were sourced from literature and field reports. Incremental cost-effectiveness ratios (ICERs) were calculated to estimate cost per additional true positive or true negative detected. One-way and probabilistic sensitivity analyses, along with a budget impact assessment, were conducted to assess robustness and feasibility.

Study Progress:

The study has completed model development, data collection, and initial analysis. RT-PCR demonstrated higher sensitivity (99%) and specificity (99%) compared to GeneXpert (92.3% and 60.8%). These findings highlight the potential of RT-PCR to enhance TB detection accuracy and accessibility by leveraging existing molecular infrastructure from the COVID-19 response.

Translational value:

This analysis supports evidence-based policymaking and may contribute to the integration of RT-PCR in TB diagnostics under NTEP. The study holds translational value for improving national TB control efforts through cost-effective and accurate diagnostics.

36. Costing analysis of RT-LAMP for tuberculosis detection in India

Principal Investigator	:	Dr. M Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	HTA, Department Health Research
Study period	:	2024
Pillar	:	Detect
Category	:	Description and Delivery

Background:

Tuberculosis continues to pose a major public health burden in India. This study evaluates the cost-effectiveness of Reverse Transcription Loop-Mediated Isothermal Amplification (RT-LAMP), a rapid and affordable molecular diagnostic tool, compared to Truenat, currently endorsed under NTEP. Objectives included estimating the cost of RT-LAMP versus Truenat, determining the incremental cost, calculating the cost per additional true positive or true negative detected, and estimating the budget impact of scaling RT-LAMP nationwide.

Methods:

A cost-effectiveness analysis was conducted from a health system perspective using a deterministic decision tree model developed in Microsoft Excel. Costs were estimated through a resource-based approach using market rates and laboratory data. Diagnostic accuracy parameters were derived from published and unpublished studies. Sensitivity analysis assessed the robustness of findings. Additionally, a qualitative assessment compared RT-LAMP and Truenat based on operational factors such as ease of use, infrastructure requirements, turnaround time, and feasibility in resource-limited settings.

Study Progress:

The study was reviewed by the TAC, following which the cost and cost-effectiveness analyses were completed. Data collection and analysis are complete, and the final report is being prepared for submission to the DHR. RT-LAMP demonstrated higher sensitivity (89.36%) and specificity (94.06%) than Truenat.

Translational value:

This study provides critical evidence to support policy decisions on adopting cost-effective TB diagnostic technologies. Findings are expected to inform national TB diagnostic strategies, with potential translational value for inclusion under NTEP to improve TB detection and reduce diagnostic delays.

37. Cost-Effectiveness of Upfront CB-NAAT Using Different Algorithms for Diagnosing DS/DR-TB Among Presumptive Pulmonary TB Patients in India

Principal Investigator	:	Dr. M Muniyandi
Participating Institutes	:	ICMR-NIRT
Source of funding	:	No funding
Study period	:	2024
Pillar	:	Detect
Category	:	Development and Delivery

Background:

Timely and accurate diagnosis of drug-sensitive (DS) and drug-resistant (DR) tuberculosis (TB) remains a challenge in India. This study evaluates the cost-effectiveness of various diagnostic algorithms incorporating upfront Cartridge-Based Nucleic Acid Amplification Test (CB-NAAT), compared to the current algorithm recommended by the National TB Elimination Programme (NTEP), to identify optimal diagnostic strategies for DS/DR-TB. Key objectives included comparing QALYs gained across diagnostic strategies, evaluating the ICERs of CB-NAAT-based algorithms, and identifying the most cost-effective approach relative to current practice.

Methods:

A decision-tree model was developed from a health system perspective using Microsoft Excel and TreeAge Pro. Diagnostic strategies included smear microscopy, NAAT-based testing, and combinations of smear, chest X-ray, and CB-NAAT. Cost and effectiveness data were drawn from secondary sources, including published literature. The analysis estimated incremental costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratios (ICERs). Strategies were compared based on diagnostic accuracy, cost per QALY gained, and potential to minimize false positives and negatives.

Study Progress:

Data collection and analysis are complete. Preliminary results show that three strategies—smear-only, NAAT-only, and smear followed by NAAT—are cost-effective with favorable ICERs. In contrast, strategies involving chest X-ray showed limited cost-effectiveness. These findings support the integration of CB-NAAT into diagnostic pathways to improve accuracy, reduce diagnostic delays, and enhance resource utilization.

Translational value:

This study provides evidence to inform national policy for optimizing TB diagnostic algorithms. The results have strong translational value for strengthening NTEP through the adoption of cost-effective and scalable diagnostic approaches.

38. CRISPR mediated platform for diagnosis and rapid detection of drug-resistant pattern in Mycobacterium Tuberculosis

Principal Investigator	:	Dr. K. R. Uma Devi
Participating Institutes	:	ICMR-NIRT, GHTM.
Source of funding	:	ICMR Intramural
Study period	:	2018-2026
Pillar	:	Detect
Category	:	Development

Background:

A rapid, simple, and highly sensitive diagnostic method is essential for the detection of tuberculosis (TB). Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) and associated Cas proteins have emerged as powerful tools for clinical diagnostics due to their high flexibility, sensitivity, and specificity.

Objectives:

This study aimed to develop a CRISPR-Cas13a-based assay for the detection of *Mycobacterium tuberculosis* (MTB) and the determination of its drug resistance pattern. We further sought to evaluate its diagnostic performance using clinical isolates and biological specimens.

Methods:

We optimized the CRISPR-Cas13a assay by determining its limit of detection (LOD), specificity, and optimal trans-cleavage time. The assay's diagnostic performance was subsequently evaluated using MTB-clinical isolates, sputum, and urine samples.

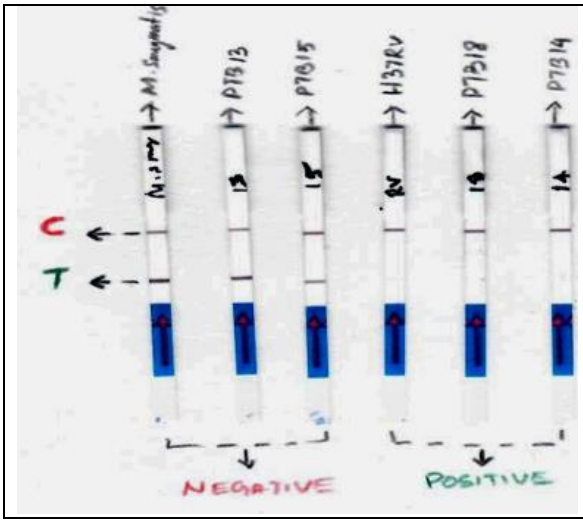
StudyProgress:

The CRISPR-Cas13a assay demonstrated excellent sensitivity without compromising specificity for detecting MTB DNA in cultured isolates, sputum, and urine samples. Currently, we are advancing this work by developing a CRISPR-Cas13a-based multiplex assay and detecting drug resistance patterns.

Translational Value: The CRISPR-Cas13a-based assay offers a rapid, sensitive, and non-invasive diagnostic approach for TB detection. Its robust performance supports potential clinical application and future commercialization.

Patent:

Based on the assay's performance and findings, a complete patent application was filed on October 20, 2024. The assigned application number is 202311071943.

	**CRISPR-Cas13a MTB detection assay in lateral flow assay format:** In Lateral Flow readout format, Positive sample will have band at the T line while negative sample will have band at the T and C lines.

39. Molecular Profiling of Inflammatory Markers among individuals with Latent TB infection

Principal Investigator	:	Dr. B. Ramalingam
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR- Intramural
Study period	:	2024-2027
Pillar	:	Detect
Category	:	Discovery

Background :

The key inflammatory drivers and their dual roles in either promoting disease progression or maintaining protection in latently infected individuals remain poorly understood. As a result, identifying robust and reliable biomarkers that can distinguish between these divergent outcomes is a critical research priority. The primary objective of this research work is to explore and profile the proteomic, nutritional and transcriptomic markers associated with inflammation in LTBI to establish a peripheral blood-based biomarker profile for latent infection.

Methods:

The minimum required sample size is 40 per group and the total sample size is 80. Classical biochemical and hematological parameters will be measured for each participant. In addition to these, trace element analysis and cytokine and chemokine profiling were also carried out in serum and plasma samples. From the plasma samples, miRNA is isolated and used for transcriptomic profiling.

Study Progress:

Sample recruitment has been initiated, and 65 baseline samples were collected and categorized. From the 63 baseline samples tested, 27 samples were found to be LTBI+ and 36 samples were

found to be LTBI–. Serum, plasma and PBMCs were stored for all the samples for future analyses. Demographic data has been collected for all the participants. Hematological ratios (NLR, PLR, MLR) and Vit D levels were analysed for all the samples and compared between the groups. Initial hematological parameters did not show much significant differences between the LTBI+ and LTBI- groups. In addition to baseline data collection, participant follow-up has also been initiated as part of the longitudinal design of the study. Longitudinal data will further strengthen the study's ability to identify dynamic inflammatory signatures associated with LTBI status. Proteomic and transcriptomic analyses will be carried out in the subsequent phases of the study to further explore inflammation-related markers. The study is ongoing, with further analysis of more complex markers expected to reveal deeper insights into LTBI.

Translational Value:

This study will help in identifying the biosignature of LTBI. Inflammatory, nutritional and transcriptomic marker profiling will help us in deciphering the pathophysiology of LTBI and can be helpful in predicting the risk of LTBI progression.

40. Assessment of monocyte miRNA signatures as a biomarker in TB infected and diseased individuals

Principal Investigator	:	Dr. B. Ramalingam
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR-Intramural
Study period	:	2023-2026
Pillar	:	Detect
Category	:	Discovery

Background:

We proposed to identify monocyte-specific miRNAs that may serve as potential diagnostic biomarkers for tuberculosis (TB). Our hypothesis is that different clinical outcomes following TB exposure will be uniquely reflected in host's monocyte miRNA profiles, which can help us to reveal the essential pathways involved in the progression of the disease and to establish stage specific molecular signatures associated with different states of the disease.

Objectives:

1. To study the miRNA profiles obtained from the sorted monocytes from latent infection, drug sensitive and resistant pulmonary TB and extra pulmonary TB and compared to healthy controls by comprehensive transcriptomic profiling.

2. To explore the gene targets for the identified miRNAs towards disease protection and pathological responses through network and pathway analysis.
3. To validate the identified miRNA targets and their interacting gene network by quantitative real time PCR for its biomarker utility.

Methods:

We plan to use two technologies: flow cytometry for monocyte sorting and NanoString for miRNA profiling from sorted monocytes. The study is designed as a cross-sectional investigation, with sample collection at a single time point across RNTCP centres located in Chennai.

Study progress:

Ethical approval for the recruitment of both pulmonary and extrapulmonary TB cases has been recently obtained from Chennai Corporation and Tambaram Ethics Committee. Meanwhile, we have optimized antibody volumes based on PBMC concentrations and standardized the monocyte sorting protocol using flow cytometry. Thus far, monocytes have been successfully sorted and stored from 10 healthy individuals. Further recruitment and sample processing will resume once the required reagents are procured.

41. Screening for the presence of *Mycobacterium tuberculosis* complex (MTBC) organisms in wild ungulates (spotted deer and blackbuck) and their environment in Chennai-an explorative study

Principal Investigator	:	Dr. P. Kannan
Participating Institutes	:	ICMR-NIRT, Madras Veterinary College
Source of funding	:	ICMR (under SRF Scheme)
Study period	:	2023-2026
Pillar	:	Prevent
Category	:	Description

Background :

Wildlife tuberculosis (wTB) is an understudied area in India, a country with a high TB burden and significant zoonotic risk. To achieve the End TB goal with a One Health approach, it's crucial to investigate wTB incidence and the *Mycobacterium tuberculosis* complex (MTBC) in wildlife. Guindy National Park in Chennai, India, home to spotted deer (SPD), sambar deer (SD), and endangered blackbuck (BB), provides a unique setting. We plan to collect and test fecal pellets and post-mortem tissue samples (PMTS) from these animals, along with soil and water samples from their environment, to detect MTBC presence, shedding light on wTB dynamics.

Methods:

PMTS showing pale-yellow granulomatous lesions in lungs and lymph nodes were collected from four BBs, six SPDs, one SD, and one barking deer. Culture, PCR, spoligotyping, and Illumina-based whole genome sequencing (WGS) were performed. SNP-based phylogenies were constructed using Galaxy/vSNP and RAxML. RDAnalyser and RDScan identified regions of difference (RD). Insertion sequence (IS) analysis was performed using ISMapper for IS6110 and IS1081 detection. Histopathology (H&E staining) was done on formalin-fixed tissue sections. Observation of calcified mesenteric lymph nodes prompted fecal sampling from six SDs, four BBs, and four SPDs, followed by screening with GeneXpert Ultra (GXU), line probe assay (LPA), and PCR.

Study Progress:

Seven PMTS isolates were confirmed as drug-sensitive *M. orygis* (ST587). RD analysis revealed deletions in RD7–10, RDOryx_1/4, RD12Oryx, RD301, and RD315. Phylogenetic analysis placed them within global *M. orygis* clades. Among 31 *M. orygis* genomes from Chennai, eight transmission clusters were identified across isolates from both cattle and wild ungulates recovered at different labs. Unique SNPs were observed in *embR*, *mmpL5*, *cfp21*, *clpC1*, *pepD*, *recC*, *dinG*, and *ligC*. IS6110 copies ranged from 0–54, with two insertions unique to Chennai. Five IS1081 insertions were detected, including one novel site. MTBC was detected in 7/14 fecal samples; two from BBs showed drug resistance (one INH-resistant, one MDR).

Translational Value:

Detection of *M. orygis* and MDR MTBC in wild ungulates highlights potential for cross-species transmission. Findings underscore the need for One Health-integrated surveillance in endemic settings

42. Identification of Bovine tuberculosis specific proteins by the Immunoproteomic approach

Principal Investigator	:	Dr. P. Kannan
Participating Institutes	:	ICMR-NIRT, Madras Veterinary College
Source of funding	:	ICMR Extramural Funding
Study period	:	2021-2025
Pillar	:	Prevent
Category	:	Development

Background :

Bovine tuberculosis (bTB) is a major health and economic issue. The major diagnostic test for bovine tuberculosis is the tuberculin skin test (TST). In this test, animals receive intradermal *M. bovis* purified protein derivative (PPD). Bovine PPD is a poorly characterised protein, lipid, and carbohydrate combination. Environmental

Mycobacterial species share certain Bovine PPD components. It sometimes causes false positives. In order to uncover bovine tuberculosis-specific antigens, we propose to analyse the immune response of the culture filtrate proteome of *Mycobacterium tuberculosis* of bovine origin isolated from prior NIRT studies. These methods will detect new bovine TB antigens. This helps produce a more sensitive bovine TB blood test.

Methods:

Culture filtrate proteins were initially separated based on their isoelectric points using the Rotofor apparatus, resulting in 20 distinct isoelectric focusing (IEF) fractions. Each of these IEF fractions was then subjected to preparative SDS-PAGE to separate the proteins further by molecular weight. Proteins from the gels were subsequently eluted using a whole gel eluter apparatus, yielding 30 molecular weight–based sub-fractions from each IEF fraction.

Study Progress:

A total of 13 preparative SDS-PAGE runs were performed to separate the culture filtrate proteins. Following electrophoresis, proteins were eluted from the gels using the whole gel elution method, resulting in 390 distinct fractions. The protein concentration in these fractions ranged from 25 µg to 650 µg. Selected whole gel-eluted fractions were further analyzed by analytical SDS-PAGE to assess the quality and distribution of the separated proteins.

Translational Value:

Novel proteins specific to bovine TB identified from culture filtrate proteins (CFP), they could serve as highly specific antigens for diagnosing bovine tuberculosis. This discovery would pave the way for the development of more sensitive blood-based diagnostic tests, allowing for earlier and more accurate detection of the disease in cattle populations.

43. Characterisation of Immune Responses in Tuberculosis Associated Chronic Obstructive Pulmonary Disease

Principal Investigator	:	Dr. N. Pavan Kumar
Participating Institutes	:	ICMR-NIRT, ITM, RGGGH, GCC, GVMC
Source of funding	:	ICMR Ignition Grant
Study period	:	2025-2027
Pillar	:	Prevent
Category	:	Description

Background :

Post-TB airflow obstruction shares similar pathways with COPD, marked by persistent airflow limitation and severe lung impairment. This study aims to identify and compare circulating immune biomarkers in TB-associated COPD (TOPD) and smoking-related COPD (COPD-C) relative to healthy controls, and to delineate TB antigen-specific innate and adaptive immune responses distinguishing TOPD from COPD-C.

Methods :

Study team will enrol from respiratory clinics consecutive patients who fulfil the definition of TOPD, COPD-C and controls [i] TOPD are patients with past history of pulmonary TB and subsequently developed symptoms, and were diagnosed as COPD (TOPD) [ii] COPD-C are patients diagnosed with COPD, with history of tobacco smoking. We will be use multiplexing ELISA and Flow cytometry to measure the inflammatory and activation immune markers in blood samples of study participants.

Study Progress:

The study commenced in mid-February, and to date, pre-screening has been conducted for 316 participants, with 67 undergoing full screening. From these, 19 participants have been enrolled. Peripheral blood mononuclear cells (PBMCs) were isolated from all enrolled individuals and cryopreserved in liquid nitrogen for the analysis of TB antigen-specific host immune responses in TB-associated COPD. Additionally, plasma samples were collected and stored to investigate inflammatory cytokine profiles across the study populations.

Translational Value:

This study holds public health significance due to the potential impact of post-TB sequelae. Gaining insights into the underlying immunological mechanisms and the interplay between TB and COPD could help guide targeted therapies, ultimately reducing the burden of post-TB complications and improving quality of life.

44. Immune response to precautionary third dose of COVISHIELD/COVAXIN among healthy adult population: an ICMR Cohort study, India

Principal Investigator	:	Dr. N. Pavan Kumar
Participating Institutes	:	ICMR-NIRT All ICMR Institutes
Source of funding	:	ICMR Extramural Funding
Study period	:	2022-2025
Pillar	:	Prevent
Category	:	Description

Background / Objectives:

With the rapid rise in COVID-19 cases driven by the Omicron variant, India has initiated a third vaccine dose for healthcare/frontline workers and individuals over 60 with comorbidities. Limited data exists on immune responses to this additional COVISHIELD/COVAXIN dose using a homologous regimen. This study aims to establish a cohort at ICMR institutes to assess humoral and cellular immune responses following the third dose.

Methods:

This cohort study targets fully vaccinated staff (two doses of Covishield or Covaxin, at least nine months prior) across ICMR institutes in India. Eligible participants include permanent or project staff willing to be followed for one year. Those vaccinated with other vaccines or only partially vaccinated will be excluded.

Study Progress:

To date, 44 participants have been enrolled and blood samples collected from COVID-19 vaccinated individuals, with an additional 32 samples from ICMR-NIE for cell-mediated immune response analysis. PBMCs, serum, and plasma have been cryopreserved. SARS-CoV-2-specific IgG (S) and neutralizing antibodies against the wild-type virus were measured at pre- and post-vaccination time points. In vitro cell culture experiments are ongoing, using peptide pools from SARS-CoV-2 (Prot_S1, Prot_M), including Omicron and Delta variants. Multifunctional T cells, memory T cells, and immune activation markers are being assessed at multiple time points: M0, M1, M6, M12, M15, M18, and M24.

Translational Value:

It will provide valuable data on the real-world effectiveness of the precautionary booster in preventing symptomatic infections, which could inform booster dose policies, optimize resource allocation, and support long-term COVID-19 management strategies in India and comparable regions.

45. Development and validation of artificial intelligence tool for screening/ Detection of pulmonary TB and other lung diseases using chest X-RAY

Principal Investigator	:	Dr. C. Ponnuraja
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR
Study period	:	2022-2025
Pillar	:	Build
Category	:	Development

Background :

India is the leading contributor to the global tuberculosis burden as per the WHO report 2019. Effective and timely tuberculosis screening at the peripheral health sector level and in remote India remains a constant issue for the health sector. AI tools that can mimic human-like thought processing, reasoning, and self-correction abilities. Artificial intelligence technologies include training of tools and deep learning. Deep learning is a particular kind of machine learning that achieves great power and flexibility by learning to represent the world as a nested hierarchy of concepts, with each concept defined as simpler concepts, and more abstract representations computed in terms of less abstract ones. Hence, the development of an AI Tool is needed to bridge this diagnostic gap and facilitate affected individuals to reach the management centers at earnest therefore contributing to the national interest of combating tuberculosis by 2025. It aims to develop a computer-aided detection (CAD) system for using chest X-rays for peripheral settings and under a national Program for screening and diagnosing TB and other lung diseases.

- To develop a computer-assisted screening system to differentiate clinically normal chest x-ray from clinically abnormal types.
- To develop a computer-aided detection system that enables auto differentiation of TB from other chest diseases/ other lung diseases using X-rays
- To further develop the computer-aided detection system for auto identification of various presentations of pulmonary tuberculosis.

Methods:

Phase 1: Development of tool: (learning and training)

Milestone 1: The initial proposal would consist of the use of retrospective validated data by IPR, provided by participating Institutes for the development of the tool to differentiate between normal from abnormal chest x-ray and then segregate the X-rays with suspected TB lesions. The data would consist of X-ray images: The participating Institutes would collect the images along with the clinical diagnosis and results of diagnostic tests (gold standard). The images would be annotated by the experts for the demarcation of the lesion clearly indicating the diseased area(s) on the X-ray image. The data would be uploaded to the ICMR portal IPR would access the data through the ICMR Portal and use the images for training of AI tool. There would be a central annotation team that would reconfirm the annotation done by the site before the images are shared with IPR.

Milestone 2 (Objectives 2 and 3): This milestone would be undertaken wherein an algorithm would be built that would detect tuberculosis and differentiate it

from other non-tuberculous diseases and other lung diseases.

The AI tool would also detect TB with great accuracy including differentiation of all possible presentations of tuberculosis. The annotated images would be obtained, along with clinical information and diagnosis confirmed via the gold standard method, and uploaded on the ICMR portal via software. The assessment of the performance would be done on a test data set in terms of the sensitivity and specificity of the artificial intelligence tool. Impact Assessment Progress: Evaluation of the progress (technical progress) for the use of AI Tools for automated detection of TB in India. The feasibility study would be conducted in peripheral areas for Implementation, accuracy, and use of AI tools in peripheral settings. The AI Tool for the automated detection of TB projects will be provided to the collaborating partners in the future.

Study progress:

This AI tool with high sensitivity and specificity for the detection/screening of TB using chest X-rays and other lung diseases. The final version of the tool will greatly facilitate bridging the gap between diagnosis and treatment more so in economically or geographically difficult populations and hence significantly cater to the National Goal of Eliminating Tuberculosis By 2025 as well as the END TB Strategy of the Sustainable Development Goals

46. Gold Standard Datasets on Tuberculosis with Radiological Images

Principal Investigator	:	Dr. C. Ponnuraja
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR
Study period	:	2024-2025
Pillar	:	Build
Category	:	Delivery

Background :

Every day, healthcare professionals generate tremendous amounts of clinical data. Electronic Health Records, which are created clinical data maintained digitally as a central repository of information for hospitals (EHR). EHR data is also used for a range of secondary uses, such as clinical research, disease surveillance, and clinical audits for quality improvement. This can be accessed using wired or wireless networks. Recent research indicates that reviewing electronic health records (EHRs) takes more time per patient for the clinician. The ICMR-NIRT has produced a vast amount of data, clinical and sociodemographic profiles, laboratory results, and information on treatments and diagnoses with digital images of X-rays. This aggregated data source could be used effectively and even though we have a wealth of information, very little of it is

extracted. To create a clinical and radiological data repository that combines data such as demographics, lab results, radiology images, referrals, diagnoses, and treatment regimens from several clinical trials and studies.

- To electronically capture clinical, laboratory, and other relevant data of patients being enrolled at NIRT – both at the base institute and at the other satellite and collaborative sites;
- To digitize all readily available X-rays into DICOM image and DICOM viewer embedded in EHR
- To enable a ready analysis of digitized data for day-to-day patient care, follow-up, and treatment compliance and undertake clinical research;

Methods:

Electronic Data Capture (EDC) system is software that stores patient data collected in clinical trials. Data is usually recorded on paper and is then transcribed into the system and saved in various types of electronic case report forms (eCRF). System integration that is seamless hospital information systems, document management systems, Integration with diagnostic labs, pharmacies, and other facilities of a similar nature, administration of electronic documents

Study progress:

Procurement of equipment and recruitment of staff is in progress.

47. TB Vaccine India study for accelerating development and introduction of tuberculosis vaccine: A mathematical modelling approach

Principal Investigator	:	Dr Adhin Bhaskar
Participating Institutes	:	ICMR-NIRT, IAVI, CTD, THST and WHO
Source of funding	:	IAVI
Study period	:	2024-2025
Pillar	:	Prevent
Category	:	Description

Background :

As India prepares for a large-scale push to end TB, it is important to anticipate the impact that effective TB vaccination may have on the TB epidemic in India in alignment with other preventive strategies. the current study proposes to assess potential vaccine roll-out strategies in alignment with other TB preventive interventions for maximal impact in TB burden reduction in India and assess its cost-effectiveness

Methods:

Using a “live” compartmental mathematical model of TB transmission dynamics, calibrated to the TB epidemic in India, the study would assess TB disease burden by age-group and risk groups, potential health impact of new TB vaccine

introduction on TB burden, potential programmatic cost and cost-effectiveness of new vaccine introduction, and potential impact of new TB vaccine introduction on equity

Study progress:

The model has been calibrated for the Indian settings and interventions. The input parameters from secondary date with respect to risk group are obtained. The cost data towards the vaccine implementation is being collected.

Translational value:

This study findings will help to strategies the TB vaccination in most effective way in the country. By identifying the population to be prioritized and most effective vaccination strategies, this study can help to achieve maximum benefit of TB vaccination in short time in a cost-effective manner.

48. Identification of biomarkers for predicting progression from Latent Tuberculosis Infection to Active Tuberculosis disease

Principal Investigator	:	Dr Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT, BJGMC
Source of funding	:	ICMR Intramural
Study period	:	2022-24
Pillar	:	Detect
Category	:	TB

Background :

Among one-fourths of the global population infected with *Mtb*, only 5-10% develop active TB disease, the reasons for which are still unclear. There is significant amount of literature to suggest that TB is genetically primed and therefore in this study we explored the role of ten commonly reported gene polymorphisms known to be associated with increased susceptibility to TB in a cohort of healthy household contacts (HHCs) of TB patients who developed TB during follow-up (Progressors) versus those who did not (non-Progressors).

Methods

The study included 43 Progressors and 49 Non-Progressors. SNP genotyping was performed using TaqMan assays and disease associations were calculated using $\chi 2$ and Fishers exact test. The levels of corresponding cytokines and chemokines were measured using multiplex luminex assay.

Results

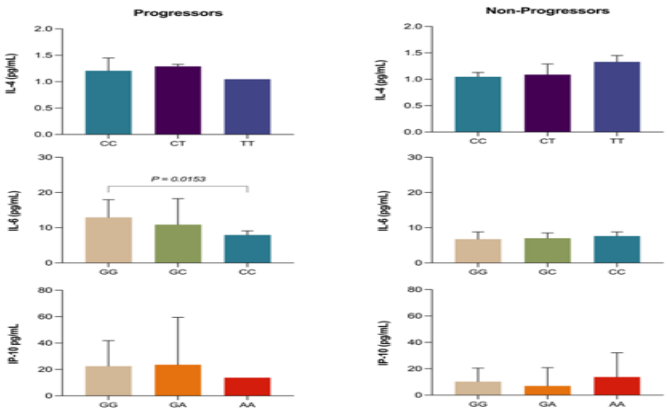
The −135G>A polymorphism in the CXCL10 gene was found to be associated with protection against TB [OR: 0.47(0.23-0.97), P=0.0413]. Similarly, the -572G>C polymorphism in the IL-6 gene was found to be

associated with a lower risk of progression [OR: 0.36(0.13, 0.97), P=0.0436]. In contrast, the -33C>T polymorphism in the IL-4 gene was found to be associated with a 2.78-fold increased risk for progression to TB disease (p=0.0286). We observed that the genotypes corroborated well with the expressed levels of the corresponding cytokines (IP-10, IL-6 and IL-4) as measured in the plasma of Progressors and Non-progressors (Figure 1).

Conclusion

The findings reveal crucial associations between rs1800796 in the IL-4 gene, rs2070874 in the IL-6 gene, and rs5606198 in the CXCL-10 gene, and increased susceptibility to TB, paving the way for early detection and diagnosis in high-risk populations.

Figure 1: Cytokine levels measured in plasma of Progressors and Non-progressors with different cytokine genotypes



49. Pan-India antigenic characterization of dengue viruses: early warning signal for a potential pandemic

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT, Multi centric
Source of funding	:	ICMR under PM-ABHIM Scheme
Study period	:	2023-2026
Pillar	:	Discovery
Category	:	Viruses

Background

Rapid response and early detection of an outbreak is the key to combating an emerging viral disease before it turns into an epidemic. Vector-borne flavivirus infections like dengue have an epidemic potential given the endemicity of flaviviruses in India. Like all RNA viruses, the dengue virus undergoes frequent genetic changes resulting in multiple circulating genotypes/quasispecies within a serotype. These genetic changes may or may not translate into antigenic

differences. However, if the former happens it could result in significant differences in their neutralization profile and influence the clinical manifestation and disease outcome. Substantial antigenic variation is therefore a key early warning signal for an impending epidemic. There is currently insufficient data on the antigenic characteristics of the circulating dengue virus strains in India and their correlation with severity and outcome of disease, as well as their response to treatment or vaccines that may become available in due course.

The following are the specific objectives of the study:

Primary objectives:

To study the antigenic characteristics of dengue viruses circulating across India

(i) To develop spatio-temporal antigenic maps on real-time basis to indicate the antigenic evolution of dengue viruses across India.

Secondary objectives:

(i) To study the genomic variation of dengue viruses through routine pan-India surveillance and understand factors associated with the cause of variation such as vector, environment and host.
(ii) To study the effect of genomic diversity on antigenic variation of dengue viruses by *in silico* analysis and its correlation with wet lab validation.

Exploratory objective:

(i) To determine the impact of antigenic variation on the efficacy of potential vaccines and specific therapeutic interventions that may become available during the course of the study.

Methods

Surveillance for dengue virus will be undertaken using commercially available serological and RT-PCR tests. All positive samples will be subjected to whole genome sequencing to determine the genetic variation and clustering of circulating strains with known genotypes. Standard bioinformatics tools will be applied for analysing viral evolution and antigenic clades will be defined based on envelope and pre-membrane protein sequences. From each distinct antigenic clade, representative samples will be selected and characterized by plaque reduction neutralization test using rabbit serum raised against reference strains of each serotype. Based on the PRNT titres, real-time antigenic maps will be prepared to depict antigenic relatedness.

Study progress

A total of 429 presumptive dengue cases including 268 adults and 161 paediatric cases were recruited at ICMR-NIRT. All samples were tested for dengue IgM and NS1 positivity. We identified 135 NS1 positive cases which were subjected to serotyping. We identified 17 isolates belonging to serotype 1, 28 belonging to serotype 2, 24 belonging to serotype 3 and 1

belonging to serotype 4. Whole genome sequencing was performed for 26 isolates and PRNT was performed on 20 isolates. The study is ongoing.

Expected outcome

The study will result in the establishment of a network of laboratories that will undertake year-on-year antigenic monitoring of dengue viruses circulating in the country to enable early identification of significant antigenic variants that could signal a potential pandemic.

50. Role of Persistent Immune Activation and Systemic Inflammation on accelerated Immune Senescence and Increased Mortality in Successfully Treated and Cured TB patients

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR Adhoc Scheme
Study period	:	2022–2025
Pillar	:	Build
Category	:	TB

Background:

Although tuberculosis is a treatable and curable disease, several studies have shown significantly higher rates of mortality in successfully treated and cured TB patients than in the general population. It has been reported that ~20% of post-treatment deaths occurring in TB patients are attributable to co-morbid conditions such as cardiovascular disease and cancer. We hypothesize here that accelerated immunosenescence due to persistent immune activation and systemic inflammation despite cure, contributes to early onset of age-associated metabolic abnormalities which in turn lead to enhanced risk of mortality in cured TB patients.

The study has the following specific objectives:

i. To assess the levels of systemic inflammation and immune activation by measuring soluble markers of inflammation and immune activation in the plasma.
ii. To assess the level of immunological senescence by measuring the expression of senescence markers on immune cells.
iii. To analyse changes in the frequency of CD4 and CD8 memory cell subsets.
iv. To analyse alterations in the cytotoxic potential of terminally differentiated immune cells.
v. To assess the extent of mitochondrial dysfunction, telomere length and telomerase activity in immune cells.

Methods

This is a case-control laboratory study comprising of equal numbers of previously treated and successfully cured TB cases (Group 1) and healthy controls (Group 2) with no prior or present history of TB, matched for age, sex and life style (smoking, alcohol use, etc.). Socio-demographic data regarding the life style and habits of participants, past history of TB, history of other medical conditions, medications taken, etc. were collected from consenting participants using a structured questionnaire. A thorough clinical exam was performed to rule out TB and 15ml of venous blood was obtained for routine hematology, biochemistry as well as immunological and molecular studies.

Biochemical investigations included random blood sugar, HbA1C levels, lipid profile, LFT and RFT. All samples were screened for HIV, Hepatitis B and Hepatitis C. Group 2 participants were tested for their IGRA status using the 4th generation QFT Plus test. PBMCs were obtained by density gradient centrifugation and used for immunological assays including multiparametric flow cytometric analysis and multiplex immunoassays, biochemical assays including measurement of beta galactosidase and telomerase activity, and molecular assays including telomere length analysis and sequencing for detection of mitochondrial mutations.

Study progress

Participant recruitment and data collection have been completed. Sample collection and processing for routine investigations including hematology, biochemistry and IGRA status have been completed for all participants. Downstream analysis for various immunological, biochemical and molecular parameters are currently ongoing.

Expected outcome

Data generated from this study would help clarify the role of inflammation and immunosenescence in contributing to the excess mortality seen in cured TB patients. Such information could form the basis for development of recommendations for long-term treatment and care of TB patients beyond the period of disease, so as to promote healthy longevity.

51. Role of interferon stimulated genes (ISGs) in the establishment/maintenance of latency in HIV and HIV-TB infections

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR
Study period	:	2022-2025
Pillar	:	Prevent
Category	:	Discovery

Background:

The focus of this study is to understand the role played by type I/type II interferons in the establishment/reversal of HIV-1 latency using J-Lat cells (6.3), a Jurkat T cell line containing a fully integrated transcriptionally silent HIV-1 genome that produces GFP upon activation. Previously we showed that J-Lat cells treated with type I IFN alone did not increase GFP expression, but when J-Lat cells were treated with type I IFN in combination with SAHA (Vorinostat), an HDAC inhibitor, GFP expression was significantly increased. This observation made us hypothesize that interferons might play a role in reversing HIV latency, through some unidentified mechanism, which we aimed to prove through this study.

Objectives

i. To identify critical ISGs involved in mediating HIV-1 latency.
ii. To establish the role of the identified ISGs in HIV-1 latency by demonstrating latency reversal through knock down of the ISGs.
iii. To investigate the epigenetic mechanisms involved in the establishment/maintenance of viral latency.
iv. To correlate the level of epigenetic modifications in target gene expression with the size of the viral reservoir in HIV and HIV-*M. tuberculosis* co-infected persons.

Methods

Identification of critical ISGs regulated by IFN will be evaluated through analysis of transcriptomics data of latently infected and productively infected cells using total RNAseq analysis. The role of the key genes identified through this analysis in latency reversal or maintenance will be analysed using gene known out studies with specific siRNAs. Western blot analysis will be performed to confirm the results of the gene editing studies. Latency reversal will be analysed using flow cytometry and qRT PCR analysis.

Study progress

Transcriptomics analysis has been completed and differentially expressed genes were identified in latently versus productively infected cells. Gene known out studies and epigenetic profiling are currently underway.

Expected outcome

The findings of the study will throw light on some of the molecular mechanisms that contribute to maintenance and reverse of latency in HIV-infected cells. This information can lead to the design of strategies that can be effectively employed to cure HIV infection.

52. Design and characterization of of peptido-mimetics of broadly neutralizing antibodies targeting vulnerable sites on the HIV-1 envelope

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Intra-mural
Study period	:	2024-2026
Pillar	:	Treat
Category	:	Discovery

Backgrounds:

HIV-1 broadly Neutralizing Antibodies (bNAbs) target five key vulnerable sites on the HIV-1 envelope. Previous studies have shown that ultra-short peptides of size, up to seven amino acids have several potential features including biocompatibility, tunability, non-immunogenicity, biodegradability and most importantly, efficient survival against proteolytic degradation in the gastrointestinal tract, as compared to longer peptides. Therefore, the present study focussed on the design of effective biomimetics, based on the hypothesis that short peptides derived from the paratope of broadly neutralizing antibodies might function as potent peptido-mimetics of these antibodies.

Objectives:

1. To identify short peptide-mimetics of HIV-1 broadly neutralizing antibodies (bNAbs) from the paratope of well characterized bNAbs using *in silico* methods
2. To characterize the physico-chemical properties of the identified peptido-mimetics using cell-based assays
3. To characterize the function of the identified peptido-mimetics in blocking HIV infection

Methods

Briefly, the co-crystal structures of broadly neutralizing antibodies targeting five conserved sites on the HIV-1 envelope were retrieved from Protein Data Bank (PDB). Empirical characterization of the co-crystal structures was done by using the PDBsum webserver. Peptides of size 6 or 10 amino acids long were derived from the paratope of bNAbs using Rosetta peptiderive protocol. MD simulation of 200ns were carried out to check the stability of the peptide-antigen complexes.

Results

A total of eleven peptides were identified from the co-crystal structures of well characterized bNAbs (Table 1). These peptides are currently being characterized for their physicochemical properties, biological activity and cytotoxicity using *in vitro* laboratory studies.

Table 1. Potential peptide mimetics targeting five major epitopes on the HIV-1 envelope

Target on the HIV-1 envelope	Size of the peptide	Peptide sequence
CD4-BS	6	RDRSTG
		VNYARP
V1/V2 glycan	10	RNGYNsYsYDFY
		LYNEYGPNYE
V3 glycan	10	RIYGVVALGE
		EVLRYTDPWK
MPER	6	KYYDFW
		SFSYWY
		AHSTPW
Gp120-gp41 interface	6	LTGSSP
		WSGRNY

53. Study of Virologic response and HIV Drug resistance (pre-treatment and acquired) in adults newly initiated on an INSTI-based first line ART regimen in a representative population from Chennai, Tamil Nadu

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT,GHTM-Tambaram
Source of funding	:	ICMR intramural
Study period	:	2022-2025
Pillar	:	Detect (HIV)
Category	:	Description

Background :

As per recent WHO recommendations, a dolutegravir (DTG)-based ART regimen comprising of tenofovir disoproxil, lamivudine and dolutegravir, was introduced in the National ART program as the first line regimen in 2020. As the use of DTG-based first-line ART is being scaled up in the country, it becomes important to conduct periodic surveys to document the emergence of drug resistance mutations to this new class of drugs (integrase strand transfer inhibitor/ INSTI) drugs that may affect population level treatment outcome.

The specific objectives of the study are as follows:

1) To determine the prevalence of baseline HIV drug resistance (HIVDR) in treatment-naive individuals newly initiated on first line ART.
2) To document viral suppression and emergence of HIVDR at one year post-treatment initiation (Acquired Drug Resistance).
3) To investigate the association between viral failure and drug resistance with specific ART regimen, adherence patterns, and

other demographic and clinical factors.

Methods

Study Design: Prospective observational study

Study Group: Newly diagnosed HIV positive adults naïve to ART (n=200)

Laboratory tests:
1**)** CD4/CD8 testing by flow cytometry at baseline (prior to start of ART) and at 12 months post treatment initiation.

2) HIV Viral load testing using the Abbott m2000RT system at baseline and 12th month.
3) HIV drug resistance testing by sequencing at baseline and 12th month (if VL>1000 Copies/ml).

Study Progress

Two hundred HIV-1 infected ART naïve participants have been screened and enrolled into the study. CD4 test and HIV-1 viral load assay were performed for all the participants. Viral RNA extraction and HIV DR genotyping by sequencing of integrase, reverse transcriptase and integrase gene have been completed for all the 200 participants' baseline samples. The follow-up of participants, clinical data retrieval at GHTM and data analysis are ongoing.

54. Biomarker Discovery-Dual Rnaseq study

Principal Investigator	:	Dr. V. Umashankar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR intramural-Part of Biomarker Multi-PI study
Study period	:	2024-2026
Pillar	:	Detect
Category	:	Discovery

Background :

Tuberculosis (TB) remains a major global health challenge, driven in part by the intricate biological interactions between the human host and *Mycobacterium tuberculosis* (M.tb). Gaining deeper insight into this host-pathogen relationship at the transcriptomic level could pave the way for the discovery of novel biomarkers and therapeutic targets. This study is designed to harness the power of Dual RNA-Seq technology to simultaneously capture and analyze gene expression profiles from both the host and pathogen during in vitro infection, with the goal of identifying key molecular signatures as biomarkers.

Methods

Two human cell lines namely, HEK-293 (embryonic kidney) and A549 (lung epithelial) were successfully

revived and cultured under sterile conditions. Alongside this, a modular and scalable Dual RNA-Seq computational pipeline has been developed and is undergoing stepwise refinement. The pipeline supports both host-first and pathogen-first read mapping approaches and is capable of processing mRNA, miRNA, and lncRNA data. Key features include differential gene expression analysis, fusion gene detection, functional annotation, and pathway enrichment. Raw FASTQ reads from mRNA and small RNA libraries are being analyzed to support biomarker discovery.

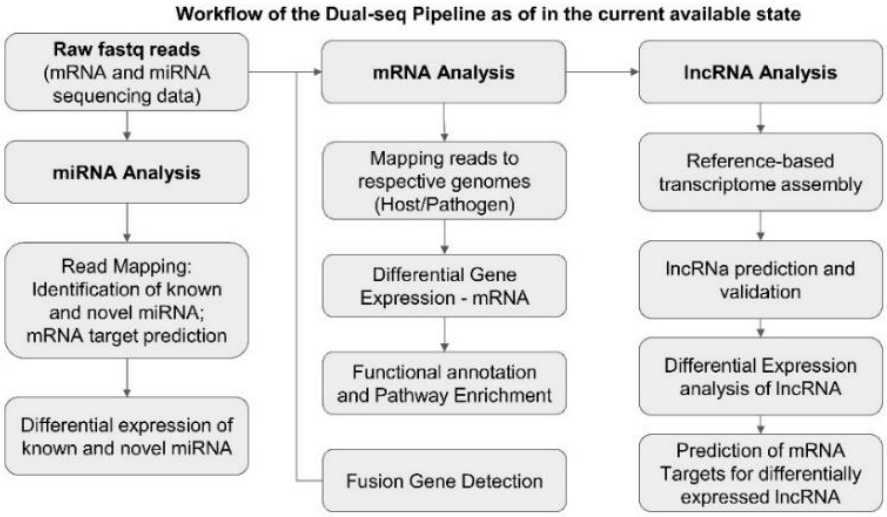
Results

As of March 2025, the development of the computational pipeline is 70% complete, with initial components validated using publicly available datasets (Figure 2). A major milestone achieved so far is the publication of the optimized dual mapping strategy in *Bio-Protocol*. Standardized protocols for culturing HEK-293 and A549 cell lines have been successfully established. Infection experiments with Mtb H37Rv are currently in progress to generate time-series samples for downstream transcriptomic analysis. The pipeline is also being adapted for cross-system comparisons across various host-pathogen datasets.

Translational Value

This study's Dual RNA-Seq strategy provides a comprehensive and real-time snapshot of host-pathogen interactions, offering unique insights into the molecular underpinnings of TB. With its flexible architecture and intuitive commandline interface, the pipeline is well-positioned to serve as a powerful tool for biomarker discovery. Once validated, this approach has the potential to support early diagnosis, disease staging, and treatment monitoring for TB, ultimately reinforcing both national and global efforts toward TB control and elimination.

Figure 1: In-house pipeline for dual RNAseq data analysis



55. Neutrophil extracellular trap (NET) formation in patients with pulmonary tuberculosis and diabetes mellitus

Principal Investigator	:	Dr. Nancy Hilda J
Participating Institutes	:	ICMR- NIRT, RGGGH, GTHTM
Source of funding	:	Intramural
Study period	:	2024-2026
Pillar	:	Discovery
Category	:	Laboratory

Backgrounds:

Neutrophil Extracellular Traps are well established components of the immunological responses, yet there are very few studies on the role of NETs in tuberculosis and no studies to our knowledge pulmonary tuberculosis (PTB)-diabetes comorbidity. Conversely, in diabetes, several studies are available to support the role of NETs as major contributors to disease pathology. Hence, understanding the role and features of NETs in PTB-diabetes co-morbidity will aid in better understanding of the role of these structures in the immunological response to disease. Hence this study was designed to assess NET formation in four groups of individuals, those with either PTB or diabetes as well as those with both diseases and those without both diseases. As there is no literature available on changes in NET formation during the course of anti-TB treatment, a longitudinal analysis of NET markers during treatment is being undertaken. Various immune parameters and their correlation with NETs will also be studied to understand the effect of NETs during tuberculosis treatment.

Methods

Study population:

1. Healthy Volunteers (n=45)
2. Pulmonary Tuberculosis patients (n=45)
3. Those with both Pulmonary Tuberculosis and diabetes mellitus (n=70)
4. Known diabetics (n=45)

Twelve millilitres of whole blood will be collected from the TB patients at four time points (baseline, 2nd month, 4th month and end of treatment), and at one time point for healthy volunteers and those with diabetes but no tuberculosis. Plasma will be separated and neutrophils will be isolated. Part of neutrophils will be subjected to culture, and analyzed for oxidative burst. Cultured cells will be used to measure degranulation markers, culture supernatants will be used to measure NET markers and cytokines. RNA will be extracted from the cells and used to measure expression of genes related to NET formation.

Study Progress

Procurement of reagents and standardization of experiments are

complete. Ethical clearance from participating Institutions has been obtained and participant recruitment will begin by May 2025.

Expected Outcome

The results of the study will help in understanding the dynamics and role of neutrophil extracellular traps in tuberculosis and TB-diabetes comorbidity, before, during and after anti- tuberculosis therapy.

56. Complement proteins as prognostic biomarkers in paediatric tuberculosis

Principal Investigator	:	Dr. Nancy Hilda J
Participating Institutes	:	ICMR-NIRT,
Source of funding	:	Intramural
Study period	:	2024-2025
Pillar	:	Discovery
Category	:	Laboratory

Background :

Pediatric TB has always been an area of diagnostic and/or prognostic challenge, largely due to the non-availability of a point-of-care (POC) test that can use non-sputum specimens. Thus, a minimally-invasive, non-sputum-based, highly sensitive and specific diagnostic test that uses easily accessible biological specimens such as blood and urine is an urgent need of the hour. There is also a need for a good, blood-based prognostic biomarker test that can be used to monitor response to treatment and detect unfavourable outcomes quite early. While various components of the immune system have been highly explored in tuberculosis research pertaining to diagnosis/prognosis, the complement system is comparatively less explored. The complement is a complex innate immune surveillance system and a predominant player in host homeostasis, inflammation and defense against pathogens. Our proposed project has two components.

(a) A retrospective component (Phase I) - where we will investigate the potential of complement proteins (identified in our pilot study in adults) as prognostic markers in paediatric tuberculosis. The possibility of using them as surrogate diagnostic tools also will be studied.
(b) A prospective component (Phase II) - where we will conduct functional assays to determine the effect of promising complement proteins identified in phase I on their respective receptors.

Methods

Sample selection (Phase I): Plasma samples stored from other TB studies

of ICMR-NIRT will be used for the pilot phase with appropriate ethical approval. Multiplex ELISA will be used to quantify complement proteins (C1q, C3b, C3b/iC3b, C4, C4b, C5a, complement factor B, complement C3a, complement factor H and MBL).

Sample Collection (Phase II): 6ml of blood will be collected from 20 consenting participants. Monocytes and neutrophils will be isolated from whole blood and cultured with plasma from different study groups. Flow cytometry will be performed to analyse the expression of complement receptors CR1, CR3, CR4 and CR5 on cultured monocytes and neutrophils.

Results

Procurement of reagents and standardization of experiments are complete. Multiplex ELISA to quantify complement proteins is currently being done.

Expected Outcome

The results of the study will help in understanding the scope of complement proteins as prognostic biomarkers for TB.

57. Harnessing T Cell Repertoires (TCR) and metrics of diversity and clonality for HIV vaccine development

Principal Investigator	:	Dr. Nancy Hilda J
Participating Institutes	:	ICMR- NIRT, GHTM
Source of funding	:	ICMR IAVI IIR call 2023
Study period	:	2024-2027
Pillar	:	Discovery
Category	:	Laboratory

Backgrounds:

In CD8 T cell-based vaccine research, the increased use of computational optimization methods has made it conveniently feasible for mosaic and multivalent immunogen design approaches that can mitigate the challenges caused by HIV diversity and optimize the coverage of T cell epitopes. Furthermore, it has been shown that the ability of an epitope to induce clonally diverse T cell responses is dictated by the epitope sequence. As such, clonal level characterization of TCR utilization can facilitate optimal peptide/epitope selection and augment altered peptide design approaches for enhanced T-cell immunogenicity in immunogen design. We propose to use next generation sequencing (NGS) to assess T Cell Repertoire (TCR) sequences qualitatively and quantitatively before and after antigen challenge to sensitively delineate and characterize immunogenic conserved epitope variants within the HIV-1 gag and pol antigen. This approach will provide clonal level CD8+ T-cell characterization that is crucial for the determination of key immune responses

and their immunogenic efficacy for vaccine development. Although CD8 T cells differentially express TCR in predominantly genetically determined repertoires, inter-individual sharing of TCR sequences has been observed within the memory T cell compartment specific for an epitope within the context of a given MHC-I molecule. Such shared or "public" TCRs in specific memory T cell populations are the result of convergent recombination of V(D)J TCR genes resulting in multiple individuals sharing TCRs in an immune response. As a major component of the naïve T cell population, public TCRs are biologically relevant in defining the initial T cell response to vaccine and acute infection within a given population. In HIV infection, public TCRs appear to confer better protective T cell responses. We hypothesize that, an ideal conserved immunogen for inclusion in vaccine design should also trigger clonally diverse TCRs within an individual for a durable response. In addition, the epitopes identified should ideally induce convergent TCR clonotypes that are globally relevant.

Methods

1. Identification of potential T cell epitopes from circulating transmitter founder viruses in the south Indian population.
2. Measuring the immunogenicity of the selected and conserved PTEs.
3. Measuring heterogeneity in T cell responses by assessing the clonal variations in the TCRs to the chosen PTEs as a measure of immunogenicity.

Results

Procurement of reagents is complete. Standardization of experiments is ongoing.

Expected Outcome:

The study will pave way for the design of a universally protective T cell-based vaccine against HIV infection.

58. Evaluation of Immunogenicity of ChAdOx1 nCoV-19 (Covishield) Vaccine in Adults with Diabetes mellitus

Principal Investigator	:	Dr. P. L. Natarajan
Participating Institutes	:	ICMR-NIRT and RGGGH, Chennai
Source of funding	:	Intramural
Study period	:	2021-2024
Pillar	:	Build (Covid-19)
Category	:	Description

Background:

Diabetic individuals infected with SARS-CoV-2 are known to be at a significantly higher risk of hospitalization, intensive care unit admission, intubation, or death - a trend that has been observed globally as well as in India. Neutralizing antibodies (NAbs) play a crucial role in protecting against acute viral infection. A preliminary study by Pal et al. (2021) demonstrated impaired anti-SARS-CoV-2 antibody responses in non-severe COVID-19 patients with diabetes mellitus, with neutralizing activity serving as a predictor of survival. Older diabetics are known to mount reduced responses to Hepatitis B and CoronoVac vaccines. Despite WHO's recommendation for a three-dose regimen of Covishield for adults, there is limited data on the immunogenicity of booster doses in diabetic patients, and reinfection among diabetics. The present study is an investigation into the immunogenicity and durability of the vaccine-induced immune response in individuals with diabetes mellitus.

Objectives

Primary: To compare the kinetics of anti-spike IgG antibody and neutralizing antibody responses to three doses of Covishield SARS-CoV-2 vaccine in diabetic patients and healthy controls.

Secondary:

1. To analyse T follicular helper (Tfh) and B cell responses to Covishield vaccine.

2. To determine the level of anti-spike IgG antibody induced by the vaccine and to correlate it with frequencies of Tfh cells and B cells.

Methods

Study Design and Population: Prospective observational cohort study including 3 study groups:

- Cohort I: Healthy controls receiving three doses of the Covishield vaccine.
- Cohort II: Individuals with diabetes receiving three doses of the vaccine.
- Cohort III: Individuals with breakthrough COVID-19 infections.

Participants in Cohorts I and II were recruited through random sampling from the COVID Vaccination Center at the Rajiv Gandhi Government General Hospital (RGGGH), Chennai, and those in Cohort III were recruited from the COVID-19 ward with the written informed consent of the participants.

Vaccination Schedule, Blood Sampling, and Follow-up

After collecting demographic data, vital signs, and information on diabetic status, medication and clinical history, participants received the Covishield vaccine in a three-dose regimen at 0, 3 and 9 months. Blood samples were collected at baseline, 14 and 28 days post-prime dose, as well as at months 3, 4, 6, 9, 10, 12 and 15, and at the time of COVID-19 infection, if relevant. Participants were followed up bi-weekly via telephone call throughout

the study period to gather information on COVID-19 infection. The collected blood samples were used for analysis of antibody levels and immune cell frequencies and function.

Results

Follow-up is completed. Analysis of T and B cell activation markers at different time points post-covishield vaccination booster doses are being performed. Estimation of cytokines and anti-spike IgG antibody levels in serial serum/plasma samples are also being planned.

Translational Value

The combined analysis of T / B cell activation markers, cytokines and serial anti-spike IgG levels will reflect the true extent of booster-induced immune activation and this inturn will throw light on the vaccine effectiveness between diabetic and healthy controls.

59. Molecular detection of Mycobacterium tuberculosis (Mtb) derived circulating cell-free DNA and validation of host transcriptomics signatures and circulating microRNAs in diagnosis of pulmonary and extrapulmonary tuberculosis (PTB & EPTB): An exploratory study.

Principal Investigator	:	Dr. N. Sudhakar
Participating Institutes	:	ICMR / NIRT
Source of funding	:	ICMR - Intramural funding
Study period	:	2024-2026
Pillar	:	Detect
Category	:	TB

Background :

Primary objectives:

1. Detection of *M.tb* derived cell-free DNA in stored plasma samples from pulmonary (PTB) and extrapulmonary tuberculosis (EPTB) patients.
2. To compare the sensitivity and specificity of *M.tb* derived cell-free DNA to the standard culture and NAAT (GeneXpert).

Secondary objectives:

3. Validation of mRNA-based host transcriptomic signatures in blood at diagnosis and during treatment of PTB and EPTB patients.
4. Studying circulating micro RNAs (miRNAs) in plasma of PTB and EPTB patients.

Methods

Study Design : An exploratory study
Study Setting : NIRT, Chennai
Study population : Smear positive or negative, microbiologically confirmed pulmonary TB, EPTB and non-TB controls from healthy house-hold contacts of C-TRIUMPH study samples stored in NIRT biorepository.

Study groups:

Group A : Pulmonary tuberculosis [PTB] [n=150]
Group B : Extra pulmonary tuberculosis [EPTB] [n=150]
Group C : Non-TB controls from healthy house-hold contacts [n=150]

Study progress

A total number of 46 plasma samples from Cohort A (PTB/EPTB) were retrieved from biorepository, which included PTB (Adults) = 12, EPTB (Adults) = 13, and EPTB (Pediatric) = 21. Circulating cell-free DNA (ccf DNA) was isolated from 1 ml plasma sample of PTB/EPTB (n=46) using QIAmp minelute ccf DNA kit (Qiagen). The detection of M.tb specific cf DNA was conducted using droplet digital PCR (DD-PCR) using IS6110 and MPT64 gene as dual targets.

We are currently in the process of designing and synthesis of customized primers and probes for the 7 gene expression signature comprising of FCGR1B, ANKRD22, CARD17, IFITM3, TNFAIP6, FCGBP and KLF12 that was identified by us earlier using bioinformatics analysis as biomarkers for distinguishing between active and latent TB.

Results:

Out of 46 PTB/EPTB samples, at least one target for M.tb specific cf DNA was detected in 21/46 samples, which is giving a sensitivity of 45.6%. The work is in progress.

The preliminary findings from the study indicates that the M.tb specific cf DNA can be used as a non-sputum based method for diagnosis of TB with emphasis on EPTB.

60. Surveillance of Zoonotic Respiratory Viral Infections in animal farms from Thiruvallur District, Tamil Nadu: A model project with a focus on One Health approach

Principal Investigator	:	Dr. N. Sudhakar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR under PM-ABHIM Scheme
Study period	:	**2023-2026**
Pillar	:	Description
Category	:	Viruses

Background :
Objectives:

1. To establish a surveillance system for zoonotic respiratory viral infections among farm animals, animal handlers, and farm environment for early detection of emerging and re-emerging respiratory viral infections.
2. To identify the zoonotic respiratory viruses circulating among farm animals, animal handlers and environment in the given area and to study the effect on climate on the emergence, transmission and outcome of viral infections.

Methods

Study design : Surveillance and Experimental Study
Study sites : Representative Taluks of Thiruvallur, Poonamallee, Madhavaram, and Ponneri in Thiruvallur District of Tamil Nadu
Study duration : 3 years

Study groups on Animals, animal handlers, and environmental samples from animal farms
Group A : Animals (n=920)
Group B : Animal handlers (n=120)
Group C : Environmental samples (n=120)

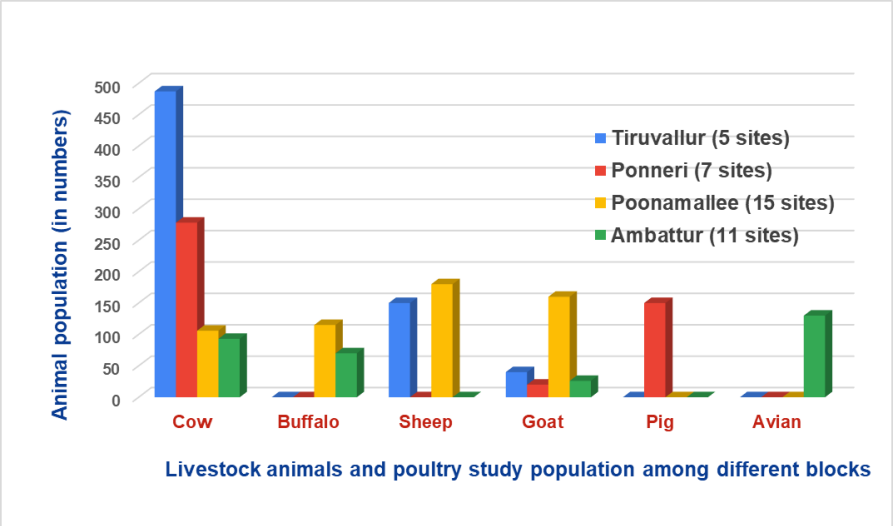
Study progress

As part of the preparatory phase, we conducted field visits to veterinary dispensaries located in representative blocks within the study area and held detailed discussions with the respective Veterinary Assistant Surgeons (VAS). Accompanied by the VAS or following initial telephonic contact, we visited individual animal farm units to assess eligibility and engage with farm owners.

For the purpose of this study, any household maintaining a minimum of 15 animals was classified as a farm unit. Based on this criterion, 38 animal farm units were identified for inclusion in the study.

During our visits, farm owners were sensitized to the importance of screening for zoonotic respiratory viral infections among livestock, animal handlers, and the surrounding farm environment. A strong positive response was observed, with over 90% of owners of cattle, buffalo, sheep, and goat farms providing informed consent to participate in the study. In contrast, poultry farm owners exhibited a high degree of hesitancy, with significantly lower participation and consent rates, highlighting the need for targeted engagement strategies in this subgroup.

Figure 1: Graphical representation of livestock animals in the study sites



Lab work plan and progress

Viral RNA was extracted from swab samples collected from livestock animals using manual method or automated method. The optimization for the extraction of viral RNA from environment (waste water) samples and surveillance is ongoing. Screening of Inf A, Inf B, and SARS CoV-2 was performed by setting up of one step RT-PCR reaction using Real-time PCR with optimized primers and probes, and thermal conditions.

Pooled testing of samples

Screening of avian influenza virus (H5N1) infection using one-step qRT-PCR was optimized. Screening of species-specific viruses such as bovine coronavirus, bovine RSV, and bovine parainfluenzavirus 3 (PIV3) was conducted by pooled testing using one-step qRT-PCR with specific primers and probes in swab samples collected from cattle, buffalo, sheep, and goat. Pooled testing was performed by pooling of 4 viral RNA samples in a sample pool. A negative control was included in every assay. Animal specific GAPDH gene was used as an internal control. A trial run has been conducted from 15th February 2025 to 15th April and a total of 256 samples (Cattle – 132; buffalo – 115; Sheep – 31, and goat 8) were so far collected and tested from animal swab samples for Inf A, Inf B, SARS CoV-2, avian influenza H5N1, bovine coronavirus, bovine RSV, and bovine PIV3 (Figure 3). The study is ongoing.

Surveillance for zoonotic respiratory viral infections in animal farms, animal handlers, and environment through One Health approach will provide useful leads for understanding the importance of zoonotic infections, and help us to devise strategies to prevent disease transmission between animals and humans in a timely manner.

Translational value

This model project with a focus on One Health approach has translational value in monitoring the viral disease outbreaks and development of molecular diagnostics.

61. Characterizing the molecular mechanisms of Protease Inhibitor resistance in HIV-1 infected individuals

Principal Investigator	:	Ms. Lucia Precilla K
Participating Institutes	:	ICMR-NIRT, GHTM
Source of funding	:	ICMR intramural
Study period	:	2023-2026
Pillar	:	Prevent
Category	:	Discovery

Background:

HIV drug resistance is becoming increasingly prevalent across the world, rendering a huge challenge to effective treatment and control of the disease. The Protease Inhibitor (PI) class of drugs play a crucial role in the success of Highly Active Antiretroviral Treatment (HAART), by serving as key components of salvage therapy for patients who fail on the initial regimen. Some studies have demonstrated that the protease genotype does not always correlate with clinical and virological outcomes. Hence, the main goal of this project is to delineate the underlying mechanisms of PI resistance so as to understand the optimal strategies that may be employed to combat resistance to this class of drugs.

Methods

RNA was extracted from plasma of PI-exposed and PI-unexposed HIV-1 infected individuals. The HIV-1 protease (PR) and gag genes were amplified separately by reverse transcription, followed by nested PCR using validated primers. The PCR amplicons were sequenced bi-directionally using the Applied Biosystems 3500 genetic analyzer. The sequences were submitted to HIV Standford drug resistance database for mutational analysis.

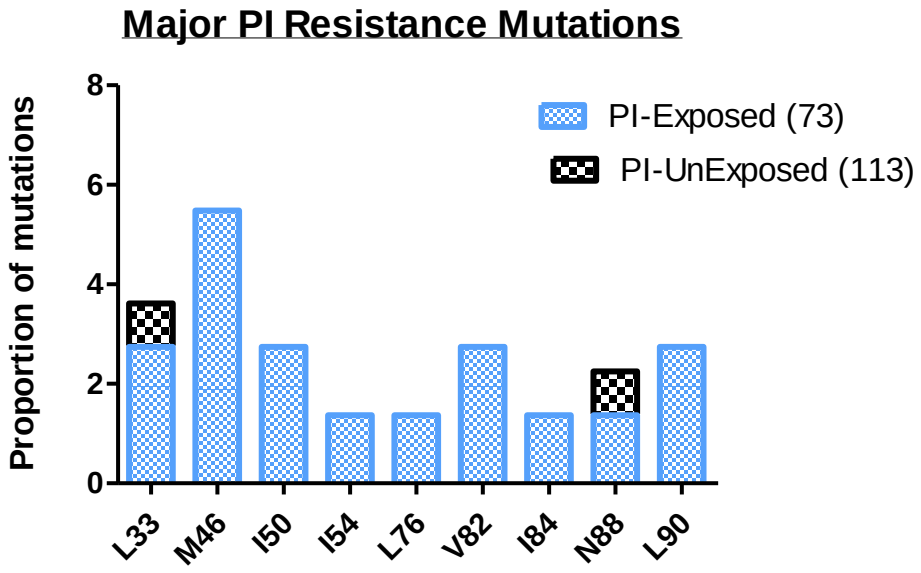
Results

The study included 73 HIV-infected individuals on a PI-based ART regimen (PI-exposed) and 113 HIV-positive individuals on a non-PI-based regimen (PI-unexposed). PI mutations were detected in 9.6% of PI-exposed and 1.8% of PI-unexposed individuals respectively. The frequency distribution of major PI resistance mutations as per HIV Standford database is shown in Figure 4.

Translational Value:

This work will uncover the extent of correlation between HIV drug resistance genotype, *in vitro* phenotype of the virus (i.e. drug susceptibility), and virologic outcome (i.e. virologic success or failure), and throw light on the mechanism of PI resistance in the absence of PI mutations.

Figure 1: Major PI mutations identified in the study population



62. Development of a simple and affordable assay for screening of Dolutegravir (DTG) resistance in HIV-1 infected persons

Principal Investigator	:	Mr. S. Manohar Nesakumar
Participating Institutes	:	ICMR-NIRT
Source of funding	:	ICMR intramural
Study period	:	2022-2025
Pillar	:	Detect/HIV
Category	:	Development

Background :

Drug resistance mutations (DRMs) are linked to reduced efficacy of antiretroviral drugs. Currently, HIV drug resistance genotyping is not routinely available in the national ART program due to limitations such as the absence of Sanger/NGS sequencing infrastructure and high costs. To address this, a “targeted genotyping” method using modified real-time PCR has been developed to detect drug-specific mutations, particularly for (N)NRTI-based regimens. However, no method other than sequencing exists for detecting DRMs to the integrase inhibitor dolutegravir (DTG), which has recently been added to the National ART program as a first-line drug. In India, where subtype-C HIV prevalence is high and data on integrase inhibitor resistance is lacking, it is crucial to screen for DTG resistance mutations before initiating them on a DTG-based regimen. The objectives of the study are:

1) To develop a real time PCR-based assay for detection and identification of HIV-1 drug resistance mutations at four

important drug resistance associated codons that are markers of various HIV-1 integrase class of inhibitors including Dolutegravir.

2) To design various sets of primers and probes and carry out standardization experiments.
3) To evaluate the performance of the qualified primers and probes set in the initial standardization further using synthetic templates and NGS characterized drug resistant EQAPOL QC panel samples.

Methods

Study Design: Laboratory assay development and validation

Assays:1**)** Bioinformatics analysis for primer and probe design 2) Real time PCR 3) Sanger sequencing

Study Progress

Synthetic double-stranded DNA spanning codons 103–192 and 215–288 of the HIV-1 integrase gene was designed to evaluate the sensitivity and specificity of primers and probes for the HIV DR Assay. Drug-resistant and wild-type codons corresponding to DRP-118, DRP-148, DRP-155, and DRP-263 were incorporated into the gBlocks® Gene Fragments (Integrated DNA Technologies, IA, USA), both with and without polymorphic mutations surrounding the probe-binding regions. Various combinations of these mutations were included across 22 different GBlocks, representing both wild-type and mutant genotypes at the four drug-resistance-associated codon positions 118,148,155 and 263 of the HIV-1 Integrase gene. The specialized LNA primers and TaqMan probes designed for DRP-118 were initially evaluated using the HIV-1 Subtype C reference laboratory strain, pIndie. Different concentrations of primers and probes were tested using gradient PCR. The optimal conditions for the DRP-118 assay, based on Cq values, were found to be: 41 °C annealing/extension temperature, DRP-118 LNA main primer at 400 nM, adaptation primers at 200 nM, and DRP-118 probe at 400 nM.

The assay was performed using a Bio-Rad CFX96 Real-Time PCR system. Each 20-µL reaction included 10 µL of reaction buffer (KAPA Probe Fast, Kapa Biosystems), optimized concentrations of forward and reverse LNA main and adaptation primers, FAM-labeled wild-type probe, and DRM-specific HEX-labeled probe. The thermal cycling protocol consisted of an initial denaturation at 95 °C for 3 minutes, followed by 10 adaptation cycles of 95 °C for 5 seconds, 50 °C for 60 seconds, and 60 °C for 30 seconds. This was followed by 35 amplification cycles of 95 °C for 5 seconds and 41 °C for 90 seconds, during which fluorescence data were captured. The study is ongoing.

Translational Value

The project aims to deliver a rapid, cost-effective, and field-adaptable tool for HIV drug resistance surveillance and clinical decision-making within routine care settings.

63. Central Biorepository for TB Specimens - Phase II

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Department of Biotechnology
Study period	:	2023-2026
Pillar	:	Build
Category	:	Tuberculosis (TB)

The RePORT India Central Biorepository was established in 2016 at ICMR-NIRT with support from the DBT and became fully operational in April 2017. The Central Biorepository (CBR) receives, stores and disseminates high quality biospecimens with well characterized data to support future research in TB. Yet another major activity of the CBR is to provide proficiency testing for cryopreservation of peripheral blood mononuclear cells (PBMCs) to the RePORT India sites as part of the ICMR-NIRT PBMC EQA Program which is the only such program available in the country for labs preparing PBMC for future immunological studies to participate. Through this program the participating labs are scored for the quality of PBMCs prepared and stored based on PBMC viability and recovery on a quarterly basis.

The CBR receives clinical samples from nine participating sites located in various parts of the country. The samples are collected from 3 major cohorts, namely, a Diagnostic Cohort of presumptive TB cases (DX), a TB Cohort of newly diagnosed TB patients (Cohort A) and a Healthy Household Contact Cohort of the index TB patients (Cohort B). The types of specimens received and stored at the CBR include Mtb isolates, whole blood in Pax gene tubes for RNA analysis, whole blood for DNA extraction, plasma, sputum/nasopharyngeal aspirate/gastric lavage, saliva, oral swabs, extra pulmonary specimens, urine and stool, Peripheral Blood Mononuclear Cells (PBMCs), serum and QFT Plus supernatants collected from the participants. All samples other than PBMCs are stored in Ultra-low deep freezers at -80°C, and PBMCs are stored in the vapour phase in Liquid Nitrogen. Figures 5 and 6 are snap shots of the storage equipment in the CBR.

Figure 1: Ultralow deep freezers in the CBR

Figure 2: Liquid nitrogen storage systems in the CBR

64. Setting up of Nation-wide Network of Laboratories for managing Epidemics and National calamities – Medical College level VRDL

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	Department of Health Research (GoI)
Study period	:	2021-2026
Pillar	:	Build (Emerging and re-emerging viruses)
Category	:	Development (Emerging and re-emerging viruses)

A medical college level VRDL was established at the ICMR-NIRT Thiruvallur campus and became operational in 2024.

The scope of the VRDL is to:

i) Provide infrastructure for timely identification of viruses and other agents causing epidemics or morbidity significant at the public health level and specifically agents causing epidemics.
ii) Develop capacity for identification of novel and unknown viruses and other organisms, and develop diagnostic kits.
iii) Provide training to health professionals.
iv) Undertake research for identification of emerging and newer genetically active/ modified agents.

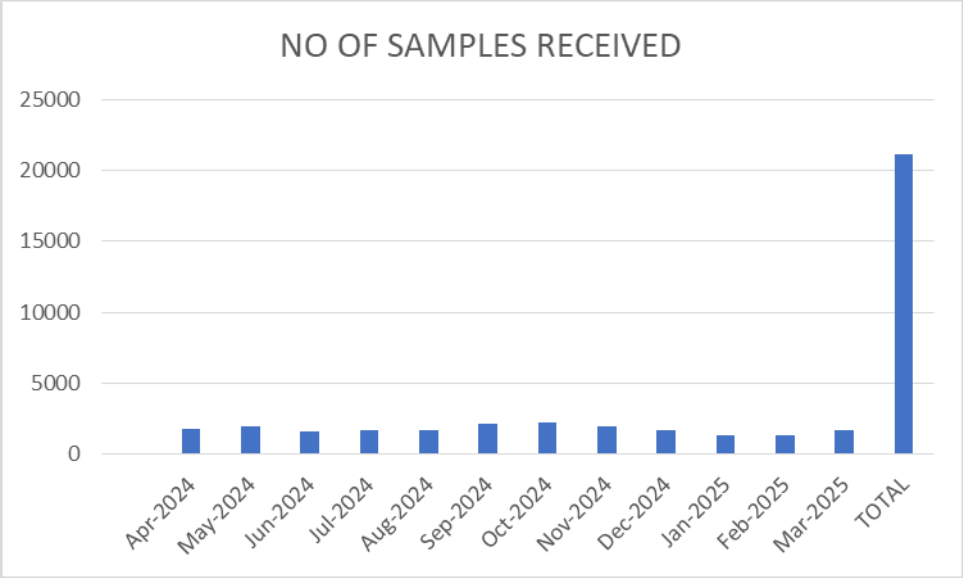
The VRDL has been participating in PT panel testing for a number of viruses including Influenza A, Influenza B, SARS-CoV-2, Dengue, Japanese Encephalitis Virus, Scrub typhus, Hepatitis A and Hepatitis E virus.

65. Universal Viral Load Testing of all PLHIVs across the country under NACP Phase IV extension

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	National AIDS Control Organisation (NACO)
Study period	:	2010- ongoing
Pillar	:	Treat & Prevent (HIV/AIDS)
Category	:	Delivery HIV/AIDS

The Department of Virology & Biotechnology has been functioning as a Regional Reference Laboratory for NACO for the National ART Program since 2009, providing HIV-1 viral load testing services to linked ART Centres. The assay is performed on the fully automated Abbott *m2000* system and results are dispatched through an online portal. Figure 7 shows the number of samples tested during the period of the report.

Figure 1: Number of HIV-1 viral load tests performed for the National AIDS Control Program at ICMR-NIRT



66. HIV-1 Early Infant Diagnosis Program

Principal Investigator	:	Dr. Luke Elizabeth Hanna
Participating Institutes	:	ICMR-NIRT
Source of funding	:	National AIDS Control Organisation (NACO)
Study period	:	2010-Ongoing
Pillar	:	Detect (HIV/AIDS)
Category	:	Delivery (HIV/AIDS)

The Department of Virology & Biotechnology of ICMR-NIRT has been functioning as a Regional Reference Laboratory for NACO's Early Infant Diagnosis Program since 2010, providing molecular testing for detection of HIV infection in infants born to HIV positive mothers. The laboratory receives blood samples in the form of dried blood spots from ICTCs located in the states of Tamil Nadu, Kerala, Puducherry and Odisha. Samples are tested using the Abbott m2000 platform and results are submitted in an online portal. Table 1 provides the details of the number of samples received and tested during the period of report at ICMR-NIRT.

Table 1: Details of HIV-1 TNA PCR done during 2024-25

HIV-1 TNA PCR testing details			
HIV-1 Screening test		**HIV-1 Confirmatory test**	
Total DBS received	1481	**Total DBS received**	60
No. of DBS tested (including previous March 2024 samples)	1607	**No. of DBS tested (including previous March 2024 samples)**	58
HIV-1 Detected	53	**HIV-1 Detected**	33
Not Detected	1554	**Not Detected**	25

67. Model Rural Health Research Unit (MRHRU) at Thoppur, Madurai

Nodal Officer	:	Dr. S. Ramesh Kumar
Participating Institutes	:	ICMR-NIRT; DHR, Government of India; Government of Tamil Nadu.
Source of funding	:	Department of Health Research (GoI)
Study period	:	2024-Ongoing
Pillar	:	Build
Category	:	Development

Establishment of a Model Rural Health Research Unit (MRHRU) at Thoppur, Madurai

The establishment of a Model Rural Health Research Unit (MRHRU) at Thoppur, Madurai, was sanctioned by the Department of Health Research (DHR), Government of India, in March 2024, along with the release of ₹1.5 crore (₹1 crore for civil works and ₹50 lakhs for equipment) as the initial instalment. ICMR-NIRT has been designated as the mentoring institute, with Dr. S. Ramesh Kumar, Scientist-F, serving as the Nodal Officer. Madurai Medical College is the affiliating government medical college. A Memorandum of Agreement (MoA) has been signed between the Government of Tamil Nadu, the Director of ICMR-NIRT, and DHR, Government of India. A proposed land parcel of 22,500 square feet has been identified in Thoppur, Madurai, for the construction of the MRHRU building. The administrative process for land transfer is currently underway at the office of the Health Secretary, Government of Tamil Nadu.

Procurement of computers, furniture, and other items has been completed. The procurement of additional equipment, including biochemistry and haematology testing machines, is in progress. A Local Research Advisory Committee (LRAC) has been constituted as per DHR guidelines, with representatives from ICMR-NIRT, DHR, the Directorate of Public Health (DPH), Tamil Nadu, the Directorate of Medical Education (DME), Tamil Nadu, and other subject experts. The first LRAC meeting was conducted on 25th October 2024, during which five collaborative study proposals were presented, including those by investigators from DPH and DME. A population-based health survey, which serves as a common protocol for MRHRUs, was also presented and approved. A second instalment of ₹92 lakhs (₹50 lakhs for CCT and ₹42 lakhs for staff salaries) was received from DHR in November 2024. Two out of the ten project staff members have been recruited, and the recruitment process for the remaining positions is underway. Temporary space for MRHRU Madurai has been provided by the State Government and is currently being utilized for research activities. This includes one office room at Madurai Medical College and three rooms in Thoppur near the proposed site.

A Research Methodology Workshop was conducted from 20th to 21st February 2025 to train faculty members from Madurai Medical College and other potential investigators. The objective was to help them develop research proposals for implementation at MRHRU. Ten concept proposals were developed during the workshop.

68. Establishment of Technical Resource Centre under Centre for Evidence-based guidelines, Department of Health Research

Principal Investigator	:	Dr Leeberk Raja I
Participating Institutes	:	Centre for Evidence-based guidelines
Source of funding	:	DHR
Study period	:	2024-2027
Pillar	:	Build
Category	:	Development

Background:

The Technical Resource Centre at ICMR-NIRT has been established by the DHR to systematically synthesize and evaluate evidence, develop and promote evidence-based guidelines, and enhance the adoption of evidence-based practices in healthcare. This is a novel process that has been instituted within the Ministry of Health & Family Welfare to collaboratively formulate a comprehensive set of evidence-based guidelines for the country.

Objectives

1. Conduct systematic reviews and meta-analyses to generate high-quality evidence for the development of clinical guidelines, utilizing the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach.
2. Organize training programs and workshops to disseminate best practices in evidence synthesis and the application of the GRADE methodology, supporting effective and rigorous guideline development

Specific activities:

- TRC at ICMR- NIRT is currently leading two systematic reviews on Community-acquired pneumonia that will inform the country-specific antibiotic guidelines
- TRC has also been conducting hands-on workshops on systematic reviews of diagnostic test accuracy (DTA) and GRADE methodology.
- Capacity building in systematic reviews and meta-analysis for the researchers and faculty of medical colleges
- SARANSH (Systematic Reviews and Networking Support in Health), a week-long workshop is scheduled to be held in October 2025. This program is aimed at strengthening evidence-based healthcare research by providing training and support in systematic reviews and meta-analysis across the country.
- Supporting the activities of Centre for evidence-based guidelines, Department of Health Research.

COMPLETED STUDIES

SNo.	Title of project	Name of PI with designation	Source of funding And Duration of project	Category	Pillar	Outcome: Benefits/ policy changes/ implications
1	Prevalence of cardiopulmonary perfusion defects and vascular damage among post-COVID-19 patients using Q-SPECT/CT hybrid imaging and correlation with biomarkers for prognostication – a longitudinal study (POCOS)	Dr. G. Narendran, Scientist 'F' (Medical)	ICMR call for COVID-19 proposals 2021-2035; 2022-2025	Description	Detect	The findings will provide a clarity on the sudden cardiac deaths occurring in the post-COVID era and suggests who need to have a further evaluation done. Manuscript submitted for publication
2	A Phase III, Randomized, Double-blind, three arm Placebo controlled study to Evaluate the Efficacy and Safety of two vaccines VPM1002 and Immuvac (M*w*) in Preventing TB in Healthy Household Contacts of Newly Diagnosed Sputum Positive P TB patients	Dr. V.V. Banu Rekha, Scientist 'F' (Medical)	ICMR-ITRC 2019-2024	Development	Prevent	Study generated evidence on the efficacy of VPM1002 and Immuvac (M*w*) vaccines in the prevention of TB disease
3	Evaluate the effectiveness, safety and tolerability of various doses of Linezolid in combination with Bedaquiline and Pretomanid in Adults with Pre-Extensively Drug-Resistant (Pre-XDR), Or Treatment Intolerant/Non-responsive Multidrug-Resistant (MDRTI/NR) Pulmonary Tuberculosis in India	Dr. C. Padmapriyadarsini, Former Director, ICMR-NIRT Dr. D. Bella Devaleenal, Scientist 'E' (Medical)	UNION (iDefeat project) 2021-2024	Development	Treat	1. This multicentric clinical trial showed that structured dose reduction of Linezolid when given along with Bedaquiline and Pretomanid (BPaL), maintained efficacy with reduced toxicity. National TB Elimination Programme (NTEP) implemented BPaLM/BPaL regimen in the Programme in November 2024. 2. The end of treatment results was published in Clinical infectious Diseases Journal. Manuscript with the final results is submitted for publication

SNo.	Title of project	Name of PI with designation	Source of funding And Duration of project	Category	Pillar	Outcome: Benefits/ policy changes/ implications
4	Role of Vitamin C supplement as an adjunct to tuberculosis treatment in new smear sputum positive pulmonary tuberculosis – An exploratory trial	Dr. D. Bella Devaleenal, Scientist 'E' (Medical)	ICMR-NIRT Intramural 2022-2024	Development	Treat	This pilot study with a sample size of 45 persons with newly diagnosed TB showed that addition of vitamin C 500mg OD/BD to HREZ/HRE did not offer any added benefits in sputum smear or culture conversion. However, the sample size is too small to conclude and manuscript preparation is currently in progress.
5	Assessing the utility of different biological samples (Urine, stool, and respiratory specimens) for pediatric pulmonary TB detection – a cross-sectional study	Dr. R. Priya, Scientist 'D'	NIRT intramural	Description	Detect	The MTB detected from the stool was higher compared to the respiratory sample. Analysis is ongoing to determine the sensitivity and specificity of the Stool MTB test.
6	Assessing the cost-effectiveness of the new treatment BPaLM/BPaL for multi-drug resistant, rifampicin resistant (MDR/RR) TB as compared to the shorter oral Bedaquiline containing regimen	Dr. M Muniyandi, Scientist 'E'	DHR	Delivery	Treat	1. Study findings indicate BPaL based regimens are likely to be cost-saving and more effective than the current mixed SoC in a range of settings. Countries should consider Programmatic uptake of BPaL based regimens. 2. Based on our study finding government of India has incorporated BPaLM treatment regimen into the NTEP.
7	Comparing Cost-effectiveness of Shorter Course Regimens for MDR-TB Treatment	Dr. M Muniyandi, Scientist 'E'	The Union, New Delhi	Delivery	Treat	This study shows that all short course Bedaquiline based regimens are more cost-effective than current SoC regimen. The implementation of Bedaquiline based

SNo.	Title of project	Name of PI with designation	Source of funding And Duration of project	Category	Pillar	Outcome: Benefits/ policy changes/ implications
						regimen to treat DR-TB in India has become more effective, shorter, less burden to health system. The manuscript submitted for publication.
8	Cyp27b1 promoter -1918 (C/T) polymorphism in pulmonary tuberculosis	Dr. B.RAMALINGAM, Scientist-'F', Dr. M.Harishankar, Technical Officer-'C'	NIRT-Intramural 2024-25	Description	Build	1. In co-dominant model, a substantial linkage was detected in heterozygous -1918 "CT" genotype with TB risk. Moreover, men were associated with more risk than females. 2. A protective linkage was detected in less recurrent -1918 "TT" genotype with TB. 3. Vitamin D deficiency (<20ng/ml) was detected higher frequency in PTB patients than healthy controls in -1918 "CT" genotype. 4. Those risky individuals may be recommended for vitamin D supplementation to overcome the disease.
9	Molecular Analysis of Monocyte Subsets from Humans Infected with *Mycobacterium tuberculosis*	Dr. B. Ramalingam, Scientist 'F'.	DBT Ramalingaswami Fellowship 2016-2024	Description	Detect	1. Monocyte abundance (particularly intermediate monocyte subsets) in the periphery correlates with inflammation, and disease severity 2. Hypercytokinemia in active disease 3. IL-17 and CXCL9 emerged as potent stage specific biomarker targets 4. Differential expression of 7749

SNo.	Title of project	Name of PI with designation	Source of funding And Duration of project	Category	Pillar	Outcome: Benefits/ policy changes/ implications
						mRNAs and 107 miRNAs suggest loss of protection in DS-TB and Hyper immune reaction in DR-TB Identified Bio signatures, upon validation, can serve as high-priority target product profiles (TPPs) for tuberculosis diagnostics and Therapeutics.
10	Immunomodulation of serum vitamin D levels combined with circulatory proteins	Dr. Ramalingam B, Scientist E. Dr Subash Babu, Scientific Director ICER.	DBT and ICER	Description	Prevent	1. Found Vitamin D metabolism has a significant role in PTB, by showing the plasma Vitamin D levels significantly decreased than LTB and non-LTB individuals. 2. After ATT in PTB patients, the plasma Vitamin D levels have increased significantly than before ATT. 3. BMI has an positive correlation in the Plasma Vitamin D levels in PTB. 4. Vitamin D is associated with all other immunological parameters that distinguishes inflammation in the host. 4. IFNγ, TNFα, IL17A, IL-4, Resistin and G-CSF has an impact in Vitamin D metabolism.
11	Study on Mutations Associated with Pyrazinamide Resistance in *Mycobacterium tuberculosis*	Dr. P. Kannan	ICMR (Under SRF scheme)	Description	Prevent	The study found a 7.7% PZA resistance among clinical isolates, emphasizing the need for vigilant drug resistance monitoring in tuberculosis. The study

SNo.	Title of project	Name of PI with designation	Source of funding And Duration of project	Category	Pillar	Outcome: Benefits/ policy changes/ implications
						underscores the importance of minimizing false-resistant results in the MGIT PZA DST by diluting bacterial load and employing minimal inoculum. Successful changes to the MGIT PZA DST could enhance tuberculosis diagnosis and treatment, positively impacting public health.
12	Characterization of immune responses against SARS-CoV-2 and variants of concern in SARS-CoV-2 naturally infected and COVID-19 vaccinated individuals	Dr. N. Pavan Kumar	ICMR Extramural funds; 2022-2024	Description	Prevent	1. Our findings reveals that both the vaccines (Covishield and Covaxin), are more effective toward the wild-type virus and variants of concern 2. Findings imply that immunisation may protect against inflammation even in the presence of breakthrough symptoms of infection
13	Cost-effectiveness analysis for implementation of smoking cessation strategies at primary health care settings in Tamil Nadu	Dr. S. Ramesh Kumar, Scientist 'F' (Medical) Dr. Vasantha M, Technical Officer-C.	DHR	Delivery	Prevent	Our study findings indicate that Enhanced counselling with the combination of Nicotine Replacement Therapy and Bupropion Sustained Release is the most cost saving strategy Compared to current practices.

PUBLICATIONS

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
1	Gopalan N, Viswanathan VK, Srinivasalu VA, Arumugam S, Bhaskar A, Manoharan T, et al. Prediction of mortality and prioritisation to tertiary care using the “OUR-ARCad” risk score gleaned from the second wave of COVID-19 pandemic—A retrospective cohort study from South India. PLoS ONE. 2025 Jan 24;20(1):e0312993–3.	G. Narendran, S. Vignes Anand, Adhin Bhaskar, M Tamizhselvan, C. ponnuraja, Manoj Vasant Murhekar	PLoS ONE, 2025, IF: 2.9
2	Gurumurthy M, Gopalan N, Patel L, Davis A, Srinivasalu VA, Rajaram S, et al. Treatment outcomes in people with diabetes and multidrug-resistant tuberculosis (MDR TB) enrolled in the STREAM clinical trial. Francis JM, editor. PLOS Global Public Health. 2025 Apr 1;5(4):e0004259.	G. Narendran, S. Vignes Anand	PLOS global Health, 2025, IF: NA
3	Goodall RL, Nunn AJ, Meredith SK, Bayissa A, Bhatnagar AK, Chiang CY, et al. Long-term efficacy and safety of two short standardised regimens for the treatment of rifampicin-resistant tuberculosis (STREAM stage 2): extended follow-up of an open-label, multicentre, randomised, non-inferiority trial. The Lancet Respiratory Medicine. 2024 Oct 1;	G. Narendran, S. Vignes Anand	The Lancet Respiratory Medicine, 2025, IF: 38.7
4	Daniel BD, Venkatesan M, Padmapriyadarsini C, Thakor M, Pereira P, Srinivasan R, Ketharam A, Sabde Y, Kumar NP, Gowda V, Hadaye R. Safety	Daniel BD, Venkatesan M, Padmapriyadarsini C, Srinivasan R	Indian Journal of Tuberculosis, 2024, IF: NA

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
	profile of BCG revaccination for COVID prevention among elderly individuals in India. Indian Journal of Tuberculosis. 2024 Oct 1;71(4):380-2.		
5	Kumaravadivelu S, Daniel BD, Rathinam P, Kumar R. Hypercalcemia in pulmonary drug resistant tuberculosis patient on modified BPaL regimen. Indian Journal of Tuberculosis. 2024 Jul 14	Kumaravadivelu S, Daniel BD, Kumar R	Indian Journal of Tuberculosis, 2024, IF: NA
6	Daniel BD, Selladurai E, Balaji S, Venkatesan A, Venkatesan M, Giridharan P, Shanmugam S, Natrajan S, Karunaianantham R, Kandasamy D, Subramani R. Clinical and diagnostic features of central nervous system tuberculosis in Indian children–a descriptive study. Therapeutic Advances in Infectious Disease. 2024 Sep;11:20499361241274251.	Daniel BD, Venkatesan M, Giridharan P, Shanmugam S, Natrajan S, Karunaianantham R, Kandasamy D, Subramani R.	Therapeutic Advances in Infectious Disease, 2024, IF :3.6
7	Jain SS, Harahsheh AS, Lee S, Raghuveer G, Dahdah N, Khoury M, Portman MA, Wehrmann M, Sabati AA, ……Venkataraman A,…..Fabi M, Thacker D. Factors Associated With Shock at Presentation in Kawasaki Disease Versus Multisystem Inflammatory Syndrome in Children Associated With Covid-19. Canadian Journal of Cardiology. 2024 Nov 30	Aishwarya Venkataraman	Canadian Journal of Cardiology, 2024, IF: 5.8
8	Venkataraman A, Thiruvengadam K, et al.	Nancy, Aishwarya Venkataraman	ERJ Open Research, 2024, IF: 5

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
	Evaluation of platelet indices as markers of tuberculosis among children in India. ERJ Open Res. 2024;10(1):00734-2023		
9	Rajamanickam, A., Kumar, N.P., Venkataraman, A. et al. Sex-specific differences in systemic immune responses in MIS-C children. Sci Rep 14, 1720 (2024).	Pavan Kumar, Aishwarya Venkataraman	Scientific Reports, 2024, IF: 3.8
10	Gopalan N, Newtonraj A, Elizabeth LK, Shanmugam SK, Ranganathan UD, Muniyandi M, Ramraj B, Devaleenal B, Venkataraman A, Nagarajan K, Bethunaickan R, Sathya Narayanan MK, Deka M, Selvaraju S, Santhanakrishnan R, Krishnan R, Chinnaiyan P, Palaniyandi K, Vetrivel U, Jeyakumar SM, Natarajan S, Mathur A. Current challenges and future development of India's healthcare system' towards tuberculosis free India – research evidence and programmatic initiatives. The BRICS Health Journal. 2024;1(1):35–58.	Gopalan N, Newtonraj A, Elizabeth LK, Shanmugam SK, Ranganathan UD, Muniyandi M, Ramraj B, Devaleenal B, Venkataraman A, Nagarajan K, Bethunaickan R, Sathya Narayanan MK, Deka M, Selvaraju S, Santhanakrishnan R, Krishnan R, Chinnaiyan P, Palaniyandi K, Vetrivel U, Jeyakumar SM, Natarajan S	The BRICS Health Journal, 2024, IF: 1
11	Prathiksha G, Newtonraj A, Thiruvengadam K, Frederick A, Selvaraju S. TB prevalence is higher among smokers. Int J Tuberc Lung Dis. 2025 Jan 1;29(1):29-34. doi: 10.5588/ijtld.24.0359. PMID: 39754282.	Prathiksha G, Newtonraj A, Kannan, Sriram Selvaraju	International Journal of Tuberculosis and Lung Disease, 2025, IF: 4

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12	Ramraj B, Nagarajan K, Purakayastha DR, Madhukar M, Kumar M, Raj N, Kumar S, Unger BS, Rajamani N, Bangar SD, Selvamuthu P, Singh AR, Das A, Chinnakali P, Wilson N, Kalaiselvi S, Swaminathan S. A qualitative study of nutritional support-related perceptions and preferences among persons affected by TB, family caregivers, and healthcare providers in India. *Trop Med Infect Dis.* 2025;10(4):114. doi:10.3390/tropicalmed10040114.	Balaji Ramraj, Karikalan Nagarajan, Makesh Kumar, Sarath Kumar, Murugesan Periyasamy, Yasaswany Santhoshkumar, Ramesh Kumar, Chandrasekaran Padmapriyadarsini	Tropical Medicine and Infectious Disease, 2025, IF: 2.8
13	Prathiksha Giridharan, Leeberk Raja Inbaraj, Frederick A, Sriram Selvaraju, Balaji Ramraj, Kannan Thiruvengadam, et al. Diagnostic accuracy of screening and diagnostic tests used in a state-wide tuberculosis prevalence survey in India. Scientific Reports [Internet]. 2025 Mar 18 [cited 2025 Apr 22];15(1)	Leeberk Raja Inbaraj, Sriram Selvaraju, Balaji Ramraj, Bella Devaleenal, Chandrasekaran Padmapriyadarsini	Scientific Reports, 2025, IF: 3.8
14	Daniel BD, Inbaraj LR, Kumaravadivelu S, Subramanian K, Ramraj B, Manesh A. Optimizing Pyrazinamide Use: A Low-Hanging Fruit in Improving Outcomes with Tuberculous Meningitis? Narrative Review. Infectious diseases and therapy. 2025 Feb;14(2):317–25.	Bella Devaleenal Daniel, Leeberk Raja Inbaraj, Kumaravaidvelu Shanmugapriya, Kadhirvel Subramanian, Balaji Ramraj	Infectious Diseases and Therapy, 2025, IF: 4.7
15	Inbaraj LR, Manesh A, Ponnuraja C, Bhaskar A,	Leeberk Raja Inbaraj, Ponnuraja	BMC trials, 2024, IF: 2.0

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	Srinivasalu VA, Daniel BD. Comparative evaluation of intensified short course regimen and standard regimen for adults TB meningitis: a protocol for an open label, multi-center, parallel arms, randomized controlled superiority trial (INSHORT trial). Trials. 2024 May 2;25(1).	Chinnayan, Adhin Bhaskar, Vignes Anand Srinivasalu, Bella Devaleenal Daniel	
16	Jose RA, Inbaraj LR, Catherine Vincent R, Baskar A, Mathew R. Diagnostic accuracy of truenat MTB plus for the detection of pulmonary and extrapulmonary tuberculosis. Indian Journal of Medical Microbiology. 2024 Sep;51:100709	Leeberk Raja Inbaraj, Adhin Bhaskar	Indian Journal of Medical Microbiology, 2024, IF: 1.4
17	Brauer M, Roth GA, Aravkin AY, Zheng P, Kalkidan Hassen Abate, Yohannes Habtegiorgis Abate, et al. Global burden and strength of evidence for 88 risk factors in 204 countries and 811 subnational locations, 1990–2021: a systematic analysis for the Global Burden of Disease Study 2021. Lancet. 2024 May 1;403(10440):2162–203	Leeberk Raja Inbaraj	Lancet, 2024, IF: 98.4
18	Bryazka D, Reitsma MB, Abate YH, Abd Al Magied AHA, Abdelkader A, Abdollahi A, et al. Forecasting the effects of smoking prevalence scenarios on years of life lost and life expectancy from 2022 to 2050: a systematic analysis for the Global Burden of Disease Study 2021. The Lancet Public Health. 2024 Oct;9(10):e729–44	Leeberk Raja Inbaraj	Lancet Public Health, 2024, IF: 25.4

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
19	Malekpour MR, Rezaei N, Azadnajafabad S, Khanali J, Azangou-Khyavy M, Moghaddam SS, et al. Global, regional, and national burden of injuries, and burden attributable to injuries risk factors, 1990 to 2019: results from the Global Burden of Disease study 2019. Public Health. 2024 Dec;237:212–31.	Leeberk Raja Inbaraj	Public Health, 2024, IF: 3.9
20	Arndt MB, Abate YH, Mohsen Abbasi-Kangevari, Samar Abd ElHafeez, Abdelmasseh M, Sherief Abd-Elsalam, et al. Global, regional, and national progress towards the 2030 global nutrition targets and forecasts to 2050: a systematic analysis for the Global Burden of Disease Study 2021. The Lancet [Internet]. 2024 Dec 1	Leeberk Raja Inbaraj	Lancet, 2024, IF: 98.4
21	Kerr JA, Patton GC, Cini KI, Abate YH, Abbas N, Abd Al Magied AHA, et al. Global, regional, and national prevalence of child and adolescent overweight and obesity, 1990–2021, with forecasts to 2050: a forecasting study for the Global Burden of Disease Study 2021. The Lancet [Internet]. 2025 Mar;405(10481)	Leeberk Raja Inbaraj	Lancet, 2024, IF: 98.4
22	Ng M, Gakidou E, Lo J, Abate YH, Abbafati C, Abbas N, et al. Global, regional, and national prevalence of adult overweight and obesity, 1990–2021, with forecasts to 2050: a forecasting	Leeberk Raja Inbaraj	Lancet, 2024, IF: 98.4

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
	study for the Global Burden of Disease Study 2021. The Lancet [Internet]. 2025 Mar;405(10481).		
23	Muniyandi M, Nagarajan K. Economic aspects of shortening the duration of tuberculosis treatment. *Lancet Glob Health.* 2024 Jun;12(6):e901–2. doi:10.1016/S2214-109X(24)00126-8. PMID: 38762291.	Muniyandi M, Nagarajan K	The Lancet Global Health, 2024, IF: 38.9
24	Muniyandi M, Mathiyazhagan K, Karikalan N. Self-reported prevalence of tuberculosis: unveiling spatial representation in the districts of Tamil Nadu. *Int Health.* 2024 Oct 18; ihae072. doi:10.1093/inthealth/ihae072.	Muniyandi M, Nagarajan K	*International Health,* 2024, IF: 2.4
25	Kuppusamy C, Rebecca P, Leslie J, Mariappan L, Ravi P, Jeevnathi, Nagarajan K, Bhaskar A, Angamuthu D. Imparting tuberculosis (TB) literacy using a youth-friendly puzzle game: a pilot quasi-experimental study, Tamil Nadu, 2022–2023. *Tamil Nadu J Public Health Med Res.* 2024;4(4)	Priscilla Rebecca, Karikalan Nagarajan, Adhin Bhaskar, Dhanalakshmi Angamuthu	*Tamil Nadu Journal of Public Health and Medical Research, 2025, IF: NA*
26	Karikalan N, Ramesh PM, Viswanathan VK, Kaleshwari M, Suresh C, Murugesan P, Sellappan S, Dhanalakshmi A, Rani S, Stephen A, Priscilla B, Karthikeyan K, Padmapriyadarsini C, Federick A. Wings of Support (Udhavum Siragugal): a holistic psycho-	Karikalan N, Chandra Suresh , Murugesan P, Sellappan S, Dhanalakshmi A, Rani S , Stephen A , Priscilla B, K Karthikeyan, Chandrasekaran	*Tamil Nadu Journal of Public Health and Medical Research, 2024, IF: NA*

SN.	Title (Vancouver reference style)	Authors from ICMR-NIRT	Journal name Year of publishing Impact factor
	social intervention for TB persons and caregivers in a tertiary care facility in Tamil Nadu, an implementation research approach. *Tamil Nadu J Public Health Med Res.* 2024;4(Special Edition)	Padmapriyadarsini	
27	Muniyandi M, Nagarajan K, Mathiyazhagan K, Tyagi K, Rajsekar K, Padmapriyadarsini C. Evaluating the cost-effectiveness of Cy-Tb for LTBI in India: a comprehensive economic modeling analysis. *Int Health.* 2024; ihae048. doi:10.1093/inthealth/ihae048.	Malaisamy Muniyandi, Karikalan Nagarajan, Kavi Mathiyazhagana Chandrasekaran Padmapriyadarsini	*International Health, 2024*, IF: *2.4*
28	Dasan B, Munisankar S, Pavan Kumar N, Moideen K, Pandiarajan AN, Nott S, Viswanathan V, Shanmugam S, Hissar S, Thiruvengadam K, Kornfeld H. Coexistent anemia modulates systemic inflammation and exacerbates disease severity and adverse treatment outcomes in tuberculosis. Frontiers in Tuberculosis. 2025 Jan 14;2:1462654.	Nathella Pavan, Sivakumar Shanmuga, Syed Hissar	Frontiers in Tuberculosis, 2025, IF: NA
29	Kumar NP, Munisankar S, Dasan B, Nancy A, Thiruvengadam K, Moideen K, Nott S, Viswanathan V, Sivakumar S, Hissar S, Kornfeld H. Impact of Strongyloides stercoralis Coinfection on Disease Severity and Treatment Outcomes in Pulmonary Tuberculosis. InOpen Forum	Pavan Kumar N Sivakumar S Hissar S	InOpen Forum Infectious Diseases, 2025, IF: 3.8

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No.1, Mayor Sathiyamoorthy Road, Chetpet, Chennai - 600 031. Tamil Nadu, India.
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