NTEP RESEARCH Priorities

Listed below are some of the suggested research areas/priorities. These thematic areas may overlap (at times). Though the list is exhaustive it does not mean that there could not be other important areas of operation research. Project proposal should be written with care. Proposal should have proper methodology, design, and style of writing with statistical analysis and outcome parameters (as far as possible). Avoid grammatical mistakes and printers' devils (generally). Newer areas (subjects) of research have been underlined. Latest references should be included especially in Indian context.

1. Studies on Strengthening surveillance and tuberculosis notifications

- To test newer interventions to strengthen the case based electronic TB notification system (Nikshay) enumerating user related implementation challenges for both public and private sectors across India.
- Identification of sources and reasons for under-notification of TB cases through inventory studies (capture/ recapture).
- Studies to determine challenges / solutions in Integration of routine laboratory screening for TB & DR-TB from public and private sector laboratories into a unified TB and DR-TB reporting and surveillance systems.
- Studies (IT solutions) to improve quality of data that's collected through Nikshay notification system
- Studies regarding quality and completeness of reporting of medical certification of the cause of death related to TB and its improvement.

2. Studies for Improvement of TB disease burden estimation; improved TB diagnostics including Childhood TB and Extrapulmonary TB

- TB prevalence survey in special groups , tribal's , migrants , slums , pediatric population etc and study of its unique dynamics (epidemiological factors).
- Computer model of developing vulnerability mapping (ALGORITHM) and its applicability in different states.
- Point of care diagnostic tests to confirm extra pulmonary TB (EPTB).

- Non tubercular Mycobacterium (NTM) diagnosis. Proportion of NTM disease among treatment non-responders. Studies that assess the diagnostic algorithms and treatment regimens for NTM.
- Role of LAMP as a molecular tool and development of a diagnostic algorithm for EPTB.
- Diagnostic algorithm for latent TB (Incipient TB) diagnosis. How effective is the available C-tb and or IGRA for the diagnosis of latent TB or subclinical TB?
- Molecular detection of AFB from stool by CBNAAT/TruNAAT; its efficacy and diagnostic algorithm.
- Studies on biomarkers of TB for diagnosis; prognosis and cure or its attribution to cell mediated immune status.
- Studies to access the accuracy of Clinical diagnosis (smear negative) at various levels of health system.
- Studies that assess the effect of capacity building (for MO-PHIs) on reading chest radiographs in diagnosis of pulmonary TB.

3. Studies on TB transmission and its interruption

- Identify hot spots for TB transmission– Using molecular epidemiological methods.
- Assess the compliance to airborne infection control guidelines at health facilities and interventions aimed at improving compliance.
- Cost effective technologies to disinfect Hospital /OPD ambient airborne TB infection and its monitoring and control.
- Assess the compliance to airborne infection control guidelines at health facilities and interventions aimed at improving the compliance.

4. Studies related to systematic screening of high-risk groups and intensified case findings

- Studies to assess the feasibility, acceptability, operational challenges, predictability, effectiveness in reducing diagnostic delays etc., of the various diagnostic algorithms.

- Evaluate the accuracy, treatment outcome and cost-effectiveness of currently implemented active case finding approaches in high risk populations.
- Implementation studies of innovative approaches for reduction of TB burden in tribal communities.
- **Computer model of developing vulnerability mapping (algorithm) and its applicability in different States.**
- Prevalence of TB in slums (e.g. Mumbai).

5. **Drug resistant TB management (Drug resistance surveillance and ADR monitoring)**

- Studies to address discordant (CBNAAT – LPA- Liquid culture – Solid culture).
- In- vitro drug susceptibility test results and to provide solutions for the same.
- Studies on changed schedule of follow up sputum smear examination post TB treatment) for early diagnosis of MDR TB.
- Evaluate interventions to reduce transmission in urban slums and congregate settings. (E.g., Effectiveness of various interventions to promote cough hygiene at the community level).
- Studies to explore vulnerable groups for TB to facilitate targeted interventions (Drivers, migrants, miners etc).
- Evaluation of various methods of treatment support.
- Studies for streamlining the management of Mono-Poly drug resistant TB/MDR-TB with mixed patterns of resistance.
- **Drug resistance (Hospital or community) surveillance and monitoring. Conventional (Inh; Rifampicin) as well as Newer (Bedaquiline; Delamanid etc)**. Multicentric study to be preferred.
- **Studies on baseline INH resistance in community and its relevance in relation to INH prophylaxis.**
- Prevalence of drug resistance tuberculosis (In high burden or low burden settings) and its monitoring-management and prevention.
- Prevalence and clinico-epidemiological significance and treatment outcome of drug resistant mutants in first line / second line anti TB

drugs (novel mutations) by segueing methods.

- Study of adverse drug event reporting: First line /second line /individual drugs. How to develop a nationwide recording system.

6. Studies related to the cascade of care in public and private sector

- Intervention studies to prevent pre-TB treatment loss to follow-up.
- Demonstration studies using new tools to improve adherence (e.g., medication monitors).
- Demonstration of models to link patients to various welfare schemes and its effect on patient welfare and TB treatment outcomes.
- Studies evaluating the effect of providing financial incentives to patients and providers of treatment support in promoting adherence to treatment and treatment outcomes (e.g., cash transfer, microfinance interventions).
- Studies assessing compliance/feasibility of monthly clinical monitoring of patients (including children) on TB treatment.
- Identify barriers to culture based declaration of treatment outcomes and how to address them?
- Death Audit. Development of tools and demonstrating its feasibility under various programmatic conditions.
- Use/efficiency of ICT (e.g., NIKSHAY) in tracking patients who migrate during TB treatment.
- Studies on Post treatment follow-up.
- Assessing feasibility and addressing barriers for implementing the current NTEP guideline of 2 years post treatment follow-up of TB patients and to identify early relapse.

7. **Studies on Preventive therapy**

- Effectiveness and feasibility of shorter preventive treatment regiments.
- Studies on LTBI prophylaxis and issues in Indian context.

8. Socio-economic impact and poverty alleviation (Social determinants of TB)

- Evaluation of the access of TB patients to government welfare schemes.
- Demonstration of models to link T.B patients to various welfare schemes and its effect on treatment outcomes.
- Role of counseling along with TB treatment in clinical outcome of TB/DR

TB patients: How strong is the evidence?

- Interview of the difficulties faced by TB Survivors and their coping mechanisms? What were the side effects of anti TB treatment? (Behavioral mechanisms - family relationships and acceptance).
- Role of balanced nutrition including trace elements; in overall outcome of TB patients on anti TB treatment.

9. Strengthening NTEP management

- Studies addressing managerial issues (Infrastructure, Administration, HR, Finance, Procurement, Logistics etc).
- Studies pertaining to NTEP integration with other vertical health programmes: issues and challenges.
- Barriers to utilization of NTEP services in high risk populations - urban slums, tribal areas, migrants, prisoners, elderly, diabetics, PLHIVs and other high risk occupational groups.
- Studies on patient satisfaction surveys.
- Studies to improve data quality and data accuracy.
- Improving routine data usage at district and state levels to improve programme performance (MIFA).
- Locating correlates of health system resilience at district level in dealing with challenging situations (such as high TB-HIV burden, high MDR-TB burden etc.,) and developing interventions to cope with these challenging situations.
- Management Issues in relation to effective Institutional / Clinics infection control measures.
- Innovative strategies to strengthen health system towards TB notification (private and public).
- Management studies to improve TB services among migrant populations
- Determining the direct and indirect costs (out of pocket expenditure) incurred by TB patients during diagnosis and treatment in various contexts and identifying interventions to reduce them.
- Studies on Impact of social interventions on psycho-social condition of drug susceptible and drug resistance TB patients.
- To find the optimum combination of interventions for early case detection and improving treatment outcomes both in public and private sectors.

- Assessing the cost effectiveness of various models to engage private sector health care providers in India for diagnosis and treatment of TB patients.

10. Integration with State Insurance and UHC initiatives Research Priorities

- Evaluation of the access of TB services under various public and private health insurance scheme.
- Demonstration of models to link patients to various insurance schemes and its effect on treatment outcomes.

11. TB therapeutics in including recurrent- reinfection TB

- These studies should attempt to provide information on the distribution of various genotypes/ strains in India, strains/mutations associated with drug resistance etc., and also the prevalence of mixed infections with various strains.
- Studies on TB treatment outcomes e.g. PROSPECTIVE COHORT study for TB patients treated with daily FDCs – especially among subgroups (e.g. non-RIF DR-TB, HIV, diabetics), including genotyping.
- Pharmacokinetic and pharmacodynamics studies in the light of issues of daily FDC introduction (under dosing of INH in 25-39 weight band, overdoing of Rifampicin in >70kg and overall HIV and pediatric group for Indian population).
- Multi centre RCT studies of counseling interventions to address alcohol use disorder, smoking, and malnutrition, to promote better TB medication adherence and treatment outcomes.

12. Co morbidity studies

- TB – Diabetes co morbidity and prevalence studies.
- TB- smoking co morbidity and prevalence studies.
- TB- drug addiction studies (e.g.in Sikkim).
- TB- Under nutrition studies (e.g.in Chhattisgarh).

13. Laboratory (supply chain; sample transportation)

- Use of Information Communication Technology for lab information

systems and its effect on patient tracking and preventing pre-treatment loss to follow-up.

- Studies to evaluate / modify lab quality assurance protocols.
- Cost effective solutions for supply chain management and or sample transportation (especially in remote areas with no Laboratory facility) with special reference to Hub and Spoke model.

14. Advocacy Communication Social Mobilization (ACSM)

- Studies to identify context specific communication strategies for early and complete detection of TB cases.
- Innovative strategies using CBOs and NGOs to spread TB awareness in the community and its effect on controlling TB in the communities.
- Research on community engagement/community ownership activities as part of ACSM.
- Community driven models to evaluate the quality of NTEP services using grass root level workers and community representatives for timely intervention.
- Studies on care seeking behavior among migrants and hard to reach groups in NTEP.

15. Collaborative studies (Ministry of Ayush – Ministry of Health)

- Yoga- Ayurveda intervention studies to see if there is any beneficial effects of Yoga / Ayurvedic regime along with conventional drug treatment for better –earlier treatment outcomes and amelioration of drug induced effects.