**NTEP Operation Research Priorities 2020**

Listed below are some of the suggested operation 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 be aligned to NTEP programme with clear objectives, detailed literature review,rationale for the study, appropriate methodology, study design, style of writing, representative and adequate sample size, sampling technique, sources of study subjects/samples, statistical analysis and defined independent and dependent (outcome)variables(as far as possible). Avoid grammatical mistakes and printers’ devils (generally).

Latest references should be included especially in Indian context. If there has been any pilot study carried out before, study report/publication should be attached with the proposal. If there is any questionnaire, the same should also be attached.

Proposals with a budget above Rs 5 Lakhs should be sent to CTD. Proposals with budget below Rs 5 Lakhs are to be sent to the respective Zonal OR/State OR Committee as per their norms and timelines. Detailed head-wise and line item-wise budget with justification (in terms of unit cost, no. of units, and frequency) should be attached. We do not normally fund for purchase of equipments (as a capital cost). We support salary of technical staff as per the ICMR norms. We do not support salary of PI. Travel grants are to be restricted as per the requirement of field work. No travel grant for attending meetings shall be allowed as most of the meetings are held online during COVID times. All proposals for clinical trials are to be submitted to ICMR. All foreign funded proposals are to be submitted to HMSC (ICMR). Research proposals which require Nikshay data should be of collaborative nature (with DTO/STO) and all such studies should obtain permission from CTD (through the local collaborators – DTO/STO) as per the defined procedure. Permission from CTD may be granted on case-to-case basis.

1. **Studies on strengthening surveillance and tuberculosis notifications**

* Studies (IT solutions) to improve quality of data that is collected through the Nikshay notification system
* Studies regarding quality and completeness of reporting of medical certification of the cause of death related to TB and its improvement.

1. **Studies for improvement of TB disease burden estimation; improved TB diagnostics including childhood TB and extrapulmonaryTB (EPTB)**

* TB prevalence survey in special groups, tribal, 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.
* Non tubercular mycobacterium (NTM) diagnosis. Proportion of NTM disease among treatment non-responders. Studies that assess the diagnostic algorithms and treatment regimens forNTM.
* 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.
* Evaluation studies of different AI software on reading chest radiographs in diagnosis of pulmonaryTB.
* Modelling studies on impact of COVID on TB burden and its trends.

1. **Studies on TB transmission and its interruption**

* Identify hot spots for TB transmission– Using molecular epidemiological methods.
* Cost effective technologies to disinfect Hospital/OPD ambient airborne TB infection and its monitoring and control.
* Assess the compliance to airborne infection control guidelines (TB and COVID-19) at health facilities and interventions aimed at improving the compliance.

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

* Implementation studies of innovative approaches for reduction of TB burden in tribal communities and other high-risk groups such as miners, silica workers, night shelters, etc.

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

* Studies to address discordant results (CBNAAT – LPA- Liquid culture – Solid culture-Others).
* Drug resistance (Hospital or community) surveillance and monitoring. Conventional drug resistance (INH; Rifampicin) as well as newer (Bedaquiline, Delamanid etc.).
* Studies on baseline INH resistance in community and its relevance in relation to INH prophylaxis.
* Prevalence of drug resistant 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 sequencing methods.
* Study of adverse drug event reporting: first line/second line/individual drugs. How to develop a nation-wide recording system?
* DRTB prevalence among privately-treated patients

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

* Intervention studies to prevent post -TB treatment loss to follow-up.
* Demonstration studies using new tools to improve adherence (e.g. medication monitors).
* Studies assessing compliance/feasibility of monthly clinical monitoring of patients (including children) on TB treatment.

1. **Studies on Preventive therapy**

* Studies on LTBI prophylaxis and issues in Indian context.

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

* Evaluation of the access of TB patients to government welfare schemes and other entitlements.
* Demonstration of models to link TB patients to various (national or state) welfare schemes (health or others) and its impact on treatment outcomes.
* Role of counseling along with TB treatment in clinical outcome of TB/DRTB patients: How strong is the evidence?
* Difficulties faced by TB survivors (and their families) and their coping mechanisms? What were the side effects of anti TB treatment? Behavioral issues, family relationships and acceptance, psychosocial and nutritional aspects and post-treatment prospects. Recurrence of TB in survivors, new infections among family members. Non-TB morbidity and mortality among TB survivors and affected families.
* Role of balanced nutrition including trace elements; in overall outcome of TB patients on anti TB treatment.

1. **Strengthening NTEP management**

* Studies addressing managerial issues (infrastructure, administration, human resource, finance, procurement, logistics etc.).
* Studies pertaining to NTEP liaison/collaboration/integration with other vertical health programs: issues and challenges.
* Studies on patient satisfaction.
* Studies to improve data quality and data accuracy.
* Management issues in relation to effective infection control measures in institutions/clinics.
* Innovative strategies to strengthen health system towards TB notification (private and public).
* Management studies to improve TB services among migrantpopulations
* 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 or other interventions on psycho-social condition of TB patients.
* To find the optimum combination of interventions for early case detection and improved 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.
* Program implementation challenges during COVID era and effective mitigation strategies.

1. **Integration with state insurance and universal health coverage initiatives**

* 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.

1. **TB therapeutics including that for 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 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 drug naive, Drug Experienced, drug resistant and MDR TB patients; for first line and second line anti TB drugs -especially newer drugs like Bedaquiline and Delamanid and repurposed drugs.
* Long term follow-up of treated patients for guiding Program policy.

1. **Co-morbidity studies**

* TB-Diabetes co-morbidity and prevalencestudies.
* TB-smoking co-morbidity and prevalencestudies.
* TB-drug addiction studies
* TB-undernutrition studies

1. **Laboratory, supply chain, sample transportation**

* Use of Information Communication Technology (ICT) 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.

1. **Advocacy, Communication, Social Mobilization(ACSM)**

* Studies to identify context-specific communication strategies for early and complete detection of TB cases.
* Research on community engagement/community ownership activities as a 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.

1. **Collaborative studies with other ministries**

* Yoga- Ayurveda intervention studies to identify the beneficial effects along with the conventional drug treatment (better/earlier treatment outcomes, amelioration of drug induced side-effects, etc.)
* Linkages with veterinary public health: studies on bovine TB.