Priority Areas for Research & Evaluation under NACP-IV

Epidemiological Studies (1 to 5 years)

Phase-1

- 1. Epidemiological studies to generate Indian data to inform modeling of HIV infections
- a. Survival analysis of PLHA with Adult and paediatric HIV Progression Model (Duration from infection to need for treatment; Duration from need for treatment to death in absence of ART; Survival on ART; Progression between different CD4 brackets with ART and without ART; Annual HIV-related mortality with ART & without ART; etc and Perinatal or postnatal infection; duration of breastfeeding; Effect of child treatment; effect of EID on survival etc.)
- b. Mother to child transmission rates with different feeding and treatment options
- 2. STI: STI Epidemiology (Prevalence/ Incidence of STIs/RTIs in different risk groups as well as in PLHIVs; Emerging viral STIs and their role in HIV Transmission)
- 3. Effect of HIV on age-specific fertility rate/ Fertility patterns among PLHA/ Study of joint effect of duration of HIV infections and age at infection on fertility

Phase-2

- 4. CST: Patterns of HIV transmission among sero-discordant couples (Spousal transmission) testing and treatment related issues
- 5. CST: Burden of Opportunistic Infections (including TB) among PLHIV (pre ART and ART patients enrolled at the ART centre) and their impact on survival; & the cost of OI treatment
- 6. BSD: Epidemiology of Tuberculosis among HIV infected persons (Prevalence, Incidence, drug interactions etc.) ;What are HIV and TB treatment outcomes among HIV infected individuals considered for 2nd line ART or alternate first line at COE?
- 7. TI: Cohort analysis of HRG to assess new infections and progression with HIV
- 8. TI: Modelling of infections averted by varying coverage of NSP and OST in Indian settings
- 9. TI: Impact of seasonal migration and HIV risk in selected corridors

Phase-3

- 10. Tribal Populations: Burden of HIV and STI (integrated Tribal HIV Plan)
- 11. CST: Study on developmental milestones / behavioural patterns of CLHIVs

Socio-Behavioural Studies (1 year)

Phase-1

- 1. TI: Network dynamics among MSM: Research to reach unreached
- 2. TI: Assessment of vulnerabilities and risk among female migrants
- 3. TI: Newer forms of sex work
- 4. CST: Sexual behaviours among PLHA: In context of discordant couples , risk and dynamics of transmission

Phase-2

- 5. TI: Mobility and tracking of HRG & Bridge population
- 6. TI: Barriers of service uptake among TGs and Hijaras
- 7. TI: Analysis of major psycho-social issues identified and addressed through TI project, for MSM and TGs
- 8. TI: Assessment of the burden / risk of HIV infection among drug users vulnerable to injecting; What is a Percentage of shadow users becoming IDUs
- 9. TI: Sexual networks among HRGs in North Eastern India

- 10. Ti: Role of Social Capital/ Networks in mitigating HIV risk among migrants
- 11. <u>Condom: Differential risk among migrants and male clients in terms of risk taking, condom use</u> -(Coordinated and funded by concerned programme division)

Evaluation studies (1 year)

Phase-1

- 1. Impact of following interventions ; especially on behavioural outcomes
 - a. Migrants intervention, including existing interventions in construction, industrial settings
 - b. Trucker interventions
 - c. HIV Counseling & Testing and assessment of competencies of counselor in handling different issues adopting different approaches including mystery clients (onsite performance)
 - d. <u>Link Worker Scheme</u> (Coordinated and funded by concerned programme division)
 - e. <u>IEC Mass Media</u>, Mid-media, IPC, AEP etc. (Coordinated and funded by concerned programme division)
- 2. Evaluation of linkages between HIV/AIDS services and assessment of the synergistic effect on patient retention, behaviours & HIV transmission. What are the barriers of HIV testing under National AIDS Control Programme in different sub-populations (STI clinic attendees, HRGs, TB patients, Pregnant women and general population) and barriers & facilitators to treatment access, discrimination they face & other issues
- 3. TI: Impact of sustaining TI programs or changing implementation approach for creating Sustainable service delivery models for HRGs and their impact on HIV control (Optimal duration for a TI-based approach to create sustainable behavioural change in HRG/bridge population community; etc.)
- 4. TI: Structural, clinical and psycho-social factors associated with long-term outcomes of IDU clients completing treatment with OST and clients dropping out of NACO supported OST programme(including Extent and patterns of treatment non-response) before completing treatment
- 5. Ti: Vulnerability assessment and analysis of service uptake among sex partners of IDUs.
- 6. CST: Are LAC/LAC plus effective strategies for integration including it's Cost effectiveness over the ART centres ; How does presence of LAC affect performance of counselors and response of positive clients in a district and factors responsible for poor linking out of patients on ART to Link ART Centres BSD and
- 7. CST: How effective is our existing LFU prevention & tracking system including efficacy of ORWs?
- 8. STI/CST: Effectiveness, and Impact of STI treatment (package of essential STI services under national programme including efficacy of syndromic management ,enhanced syndromic management and treatment based on laboratory confirmation) on reducing HIV transmission and challenges faced in treatment of various STIs in different sub group populations with high rate of transmission
- 9. EID: Evaluation of EID programme It's impact on clinical outcomes , linkages with care support & treatment , cost-effectiveness and LFU in EID programme
- 10. BSD: Study to understand yield in detection of HIV infected individuals by Provider initiated Counselling & testing (PITC) in general OPD attendees in high HIV settings

Phase-2

- 11. BSD: Assessment of Facility Integrated ICTC model and PPP model ICTC
- 12. BSD: Accreditation / grading of ICTCs based on SOPs
- 13. TI: Effectiveness of outreach in reaching out to difficult and hard-to-reach populations
- 14. Blood Safety: Assessment of quality management in blood banks

Phase-3

15. <u>Condom: Condom Promotion and Impact Survey, Communication (Condom mass media campaign) Impact</u> <u>Evaluation; Condom Access and Coverage Evaluation; Validation of SMO sales and outlet coverage data)-</u> (Coordinated and funded by concerned programme division)

- 16. TI: Effectiveness of early ART on clinical stabilization, QoL, and transmission to sexual and injecting partners of IDUs
- 17. TI: Impact of OST on ART adherence and outcomes in Indian settings
- 18. Programme management: Evaluation of institutional support structures under NACP
- 19. Documentation and review of community mobilisation element under NACP

Operations Research (6 months) (Start Date: 1 Oct, 2013- 1 Mar, 2014)

Phase-1

- 20. Stigma & discrimination at health care settings, education and employment and its impact on access to health care services , educational opportunities and opportunities for accessing descent job by HRGs/PLHAs
- 21. Assessments on Role of Private sector and coverage by them in prevention, care support and treatment including STI treatment : policy issues and recommendations to improve service delivery by Private sector and impact PPP STI scheme in reducing the STI burden in the community
- 22. BSD: What is proportion of general clients in ICTC with symptoms suggestive of TB?
- 23. BSD: Strengthening linkages between HIV (ICTC/ART/PPTCT) & family planning services to reduce the unmet need for contraception among PLHIV (Prong 2 of PPTCT service cascade)
- 24. CST : Factors influencing access of ART services in Children living with HIV
- 25. IEC: Communication Needs Assessment for People Living With HIV/AIDS and High Risk Population
- 26. STI: Development of strategies for convergence of SRH services with STI/RTI services.
- 27. STI: Feasibility and implementation of elimination of congenital syphilis strategies
- 28. Condom: <u>Condom fate study</u> to understand the reason of wastage associated with free condoms and then to take corrective measures to reduce wastage (Coordinated and funded by concerned programme division)
- 29. Condom: <u>Condom Quality audits</u> in the field to understand the quality of condoms available in the field a. (Coordinated and funded by concerned programme division)

Phase-2

- 30. TI: Use of technology or other innovative approaches for outreach among HRGs
- 31. <u>Condom: Female condom as an effective tool to negotiate with regular partners</u> (Coordinated and funded by concerned programme division)
- 32. BSD: Operational study for implementation of sub centre level whole blood screening in high prevalent settings.
- 33. CST: What is proportion of HIV infection and their comorbidities among patients admitted to wards in medical colleges / tertiary care hospitals in high prevalent states?
- 34. CST: Study on factors influencing retention of PLHIV including HRGs in pre ART and pilot intervention for strategies for enhancing ART uptake under National ART Programme
- 35. CST: PPTCT- ART linkages- How far, How much.
- 36. CST: Can we monitor patients on CD4 counts only (does viral load necessary) and see if CD4 is enough : in terms of treatment failure?
- 37. IEC: Content analysis of the IEC material
- 38. IEC: Assessment of barriers to broad-scale implementation of GENDER POLICY
- 39. <u>Condom: Female Condom Acceptability Study (All India General Population</u>)- (Coordinated and funded by concerned programme division)
- 40. Programme Management: Integrated and decentralized supply chain mechanisms for Drugs, Test kits, Consumables, sample transportation a pilot study
- 41. Programme Management: Social equity in the NACP implementation Assessing gaps and barriers including structural barriers
- 42. Blood Safety: Transportation patterns & analysis of an impact of blood transportation across states

Phase-3

- 43. TI: Effectiveness of present IEC materials and Quality of counselling for motivating behaviour change among HRGs
- 44. TI: Cost-effectiveness study on NSP and OST in Indian Settings by goals method
- 45. BSD: What are the counseling needs of HIV positive Adolescents which are not being addressed by existing counseling services
- 46. BSD: Case control study on effect of specialized training on gender and sexuality on client satisfaction at ICTC
- 47. BSD: Supportive supervision through existing model as compared to telephonic / technology based mentoring (ICT) as well as through District ICTC Supervisors / through experienced ICTC counselors (peer model) (Gujarat / Karnataka)
- 48. BSD: Effect / outcome of supportive supervision for Lab technicians through Technical Supervisors of SRLs
- 49. BSD: Feasibility of EID service delivery expansion to all ICTCs in a high prevalent district as compared to existing model
- 50. BSD: Feasibility study of different Outreach delivery model like ILFS model, Health system (Karnataka), ICTC solely
- 51. STI: Introduction of simple STI clinic card and improvement in DSRC data
- 52. CST: Treatment as prevention- knowledge among providers
- 53. CST: Patients and providers perspectives on early ART initiation
- 54. Programme Management: Review of organisational capacity & HR Issues as well as of NACO and SACS and Attrition of health care workers (including Doctors) from HIV field
- 55. Programme Management: Assessment of the gaps in human capacity building & systemic review of capacity building/trainings under NACP
- 56. Blood Safety: Co-relation & assessment of gaps/ seasonal variation emerging in the government & private sector- both health care providers and community perspectives

Bio-medical & Clinical Research (2-3 year) (Start Date: 1 Oct, 2013- 1 Mar, 2015/2016)

Phase-1

- 1. BSD: Assessment of adherence of pregnant women to ARV prophylaxis (triple drug regimen)/ ART during pregnancy & breastfeeding & uptake of HIV testing among exposed infants
- 2. BSD: Bio-availability of Rifabutin 150mg in HIV/TB patients on 2nd line ART or alternate first line at COE?-burden of TB among these cases in India
- 3. STI: Multi Centre Cluster Randomized Trial Comparing Rapid Plasma Reagin and Point of Care Test for Syphilis Case Detection and Treatment among Pregnant Women attending Ante-Natal Clinics
- 4. CST: Pattern of drug resistant mutations in patients on ART and their impact on regimen
- 5. CST: Early warning indicators for patients on ART
- 6. CST: Immunological-virological discordance- its clinical significance?
- 7. CST: Strategies to enhance cervical cancer screening among HIV infected women under national programme

Phase-2/3

- 8. STI: Drug resistance towards common STIs
- 9. CST: Prevalence of HIV- 2 infection- implications on treatment
- 10. CST: Use of low dose of d4T in HAART
- 11. CST: Toxicity profile of first line ART drugs; what is an average time for development of toxicity requiring treatment substitution
- 12. CST: Average time for development of resistance requiring treatment switch to second line ART

- 13. CST: Cardiological manifestations , diabetes mellitus and different cancers among HIV+ve patients on ART and not on ART
- 14. Lab : Comparison of different types of detections (eg. ELISA 3, ELISA 4, NAT) and its advantages
- 15. TI: Effectiveness of Buprenorphine based OST in dependence upon various opioid substances