

## **Report of the laboratory services working group for NACP IV;**

**19<sup>th</sup> July 2011**

### Introduction

Laboratory services are a critical and core component of the NACP. Increasingly, it is being recognised that work related to laboratory services is not confined to HIV testing alone, but is overarching and impacts on other NACP interventions such as prevention, care, support and treatment, STI management, safety of blood and blood products, procurement and supply chain management. Emphasis on quality assured laboratory service delivery is paramount to the success of NACP IV.

### **Status of laboratory services in NACP III**

NACP III PIP had no defined focus on laboratory services as a distinct area in the program. In order to address critical issues, a separate laboratory services division was created in 2008. The division started by addressing concerns on technical and procurement issues related to HIV testing. As the importance of quality started to be recognised, steps were initiated to strengthen capacity of HIV testing through a unique structured and standardised training initiative. Technical support was provided to testing laboratories through the existing tier based network of referral laboratories at the apex (1), national (12) and state level (118).

During the first four years of NACP III, there was nearly a two-fold increase in HIV testing centres (from 2815 to 5246) and a ten-fold increase in CD4 testing laboratories (from 23 to 211). The External Quality Assurance system was galvanized into action. This included proficiency panel testing and/or rechecking of a representative sample of the specimen load with the higher tier laboratory. This resulted in increased participation and higher levels of proficiency.

Despite lack of separate allocation of resources for laboratory services, several quality assured novel initiatives were taken during this phase:

- HIV viral load testing for those failing first line ART
- DNA PCR for infant and child diagnosis of HIV
- Formation of a consortium of select laboratories for evaluation of HIV, HCV and HBV test kits.
- Capacity building and setting up testing facilities for HIV drug resistance testing was also carried out.

All these initiatives were only possible because of availability of additional donor funding and harnessing existing technical resources within established institutions. In order to sustain these activities the key challenge is to ensure their integration into the next phase of the program. Another challenge is to ensure the quality of testing services which, though initiated through gap analysis and capacity building for accreditation of referral laboratories, needs to percolate down to all the testing facilities.

## **Ideas emanated regarding next phase (NACP IV)**

### **Vision:**

Universal availability and routine access to quality assured HIV related laboratory services

The **priorities** for NACP IV include the following:

- Positioning laboratory services as a distinct component of the program at the national level
- Focus on quality in laboratories at all levels
- Integrating HIV testing into all existing healthcare delivery systems (such as NRHM, IDSP, RNTCP and other public and private sector establishments) in a phased manner

### **Emerging challenges to be addressed:**

- Structured approach for enhanced capacity building and continuous supervision, monitoring and evaluation
- Assured availability of financial resources
- Fostering partnerships and building ownership of the ongoing initiatives across programs and institutions
- Enhanced awareness of development and maintenance of quality management systems

### **NACP IV Focal Areas:**

1. Laboratory services to be an integral component of the program – The strategy to achieve this objective would involve development of teams of technical experts (technical resource groups) at central and state levels guided by the Laboratory Services Division of NACO.
2. Ensuring continuation and sustainability of existing structure and activities of the laboratory services division
3. Mentoring of the laboratory staff through the laboratory network - The strategy to achieve this objective would involve ensuring mentoring and monitoring through a three tiered pyramidal system focused on bringing about total quality management. The laboratory personnel would be supervised by qualified laboratory experts for improvement of their capacity.
4. Review of HIV testing policy – In keeping with the newer developments in the field of HIV diagnosis, the HIV testing strategies should be delinked from the existing policy document in order to permit their regular review and revision.
5. Improving and sustaining quality standards in laboratory services - The strategy to achieve this objective would involve investment of financial and human resources into encouraging alignment with international and national quality standards. Additionally continuing education of laboratory staff would be carried out.

6. Improvement in laboratory safety - The strategy to achieve this objective would involve ensuring safety of laboratory personnel, service users, community and the environment as per national/state norms.
7. Optimal human resource management - The strategy to achieve this objective would involve capacity building, multitasking (laboratory testing), adequate remuneration and decreased attrition of the laboratory workforce. The range and quality of laboratory services will be increased in collaboration with other national health programs.
8. Innovative strategies for enhancing implementation of laboratory services – The strategies to achieve this objective would be to:
  - a. Create e-resource for addressing needs of laboratories
  - b. Evaluate appropriate newer technologies including point of care diagnostics
  - c. Explore incidence testing for augmenting HIV sentinel surveillance
  - d. Evolve operational research strategies for optimal service delivery
  - e. Sustain and expand the scope of NRL Consortium on Quality
  - f. Explore partnerships in public and private sector
9. Integration with existing healthcare delivery systems (such as NRHM, IDSP, RNTCP, other public and private sector establishments) - The integration with NRHM would be carried out in a phased manner starting with pilot projects in a few states in the field of MCH/RCH including selected STI serosurveillance in medical colleges with SRLs.
10. Advocate with MCI, DHR, DCG(I), state counterparts and other national programs on impact of adherence to quality standards.

### **Important program targets and indicators**

- Constitution of central and state level Technical Resource Groups (TRG) – NACO/SACS shall set up 15 state level technical resource groups with representation from NRLs and SRLs, as per program priority and availability of regional resources.
- All SACS shall designate a regular employee as Nodal Officer and appoint Quality Manager (contractual if not available from regular service) for implementation of laboratory services component.
- Targets for
  - a. HIV testing - .....
  - b. CD4 testing - .....
  - c. Viral load - .....
  - d. DNA PCR for HIV diagnosis in children below 18 months - .....
- Number of Medical Colleges with SRLs in which STI laboratories to be supported for serosurveillance of syphilis - 40
- Mentoring of the laboratory staff through the laboratory network – At least 75% of testing facilities to be linked to a technically trained person and supervised annually by onsite visits.

- Review of HIV testing strategy – In keeping with the newer developments in the field of HIV diagnosis, the HIV-1 and HIV-2 testing strategies should be reviewed annually.
- Improving quality standards in laboratory services - 90% NRLs should attain and retain accreditation and 60% SRLs should enter accreditation cycle. The remaining 40% should score at least 60% in internal audits conducted by NACO based on assessment checklist.
- Optimal human resource management – 3000 laboratory personnel in the country, in the existing health systems outside of NACO staff, would be trained for HIV testing.
- Integration with existing healthcare delivery systems – 14 million ANC attendees would be tested for HIV annually by end of NACP IV.

### **Activities that can be integrated with NRHM**

The integration with NRHM would be achieved in a phased manner starting with the field of MCH/RCH and extending partnerships to other components of the state health systems.

- Initiation of pilot projects in some states in consultation with NRHM e.g. HIV and STI testing of ANC attendees – 1 state per year for three years
- Widen sphere of activity to encompass diagnosis and laboratory based surveillance for other communicable diseases through partnerships with IDSP and RNTCP.
- Provide technical resources to enable combined training programs

### **Crosscutting issues:**

The implementation of NACP IV by other NACO divisions would necessarily crosscut with the laboratory division, which is integral to all activities. This is especially true of areas like capacity building and training, procurement and supply chain management and information management systems.

Another critical issue is the harmonization of remuneration, which needs to be addressed with other departments and programs under the Ministry of Health and Family Welfare.

### **Implementation structure:**

- Central level: Laboratory services division headed by at least an ADG level officer who shall be a medical microbiologist, supported by three appropriately qualified program officers, as well as three technical officers and other support staff.
- State level: Designate nodal officer and appoint quality manager for laboratory services in all SACS
- Facility level: Appoint Technical Officers at NRLs, SRLs and molecular testing facilities.

- Establish a structure for technical supervision at every level located at the NRLs, SRLs, CD4 and molecular testing laboratories and catering to all HIV testing facilities.

## **Annexures**

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