Conceptual Framework for Technical Assistance on Strengthening Laboratory Services

Project for Accelerated Technical Assistance and Integrated Capacity Building for HIV/AIDS (PRATIBHA)

2009 - 2014
Clients benefit from improved quality of HIV testing services due to:

- **Accuracy in testing**
  - reduction in false positives and false negatives
- **Efficiency in testing**
  - reduced Turn Around Time (TAT) in reporting test results
- **Effectiveness in reporting and response**
  - appropriate counseling, care and treatment by health care services providers

### Origin

The Department of AIDS Control (DAC), formerly The National AIDS Control Organization, in the third phase of the National AIDS Control Program (NACP III 2007 to 2012), focused on 1) prevention of new Human Immunodeficiency Virus (HIV) infections, 2) providing greater care, support and treatment to a larger number of people living with HIV/AIDS, 3) strengthening the infrastructure, systems and human resources in prevention, care, support and treatment programs at the district, state and national levels and 4) strengthening nationwide monitoring system. Improving reach and quality of HIV testing services, a critical activity for public health surveillance, preventing new infections and effective response for counseling, care and treatment for HIV was prioritized. A laboratory services division was established under DAC in 2008.

NACP III envisioned decentralization of the Integrated Counseling and Testing Centers (ICTCs) such that testing services became more accessible to the populace. The government anticipated a fourfold increase in the volume of HIV testing at ICTCs, implying about 20 million clients or 15 tests per day per ICTC by end of the third phase of the NACP\(^1\). Thus, the program had to achieve and maintain high-quality laboratory services along with reaching out to more clients. Voluntary accreditation for HIV testing reference laboratories was introduced in this phase of the national program. Achieving accreditation requires sustained efforts leading to a functional Quality Management System (QMS) for continual quality improvement as per specifications of the assessing agency. The National Accreditation Board of Testing and Calibration Laboratories (NABL), an autonomous body of the Government of India provides accreditation services for testing, calibration and medical laboratories in accordance with International Organization for Standardization (ISO).

Some laboratory services strengthening initiatives were in place such as the National External Quality Assurance Scheme operational since 2001. The scheme covers 13 National Reference Laboratories (NRLs, including an Apex lab), 117 State Reference Laboratories (SRLs) and over 12,000 ICTCs linked to the SRLs. Together they form a tiered structure for quality assurance, mentorship and administrative support.

A nation-wide NRL and SRL assessment was conducted in 2008 and 2009 respectively, using the WHO laboratory level II checklist based on Quality System Essentials (QSE). QSEs are globally endorsed building blocks for a QMS and assessing lab’s preparedness for a more rigorous assessment for accreditation. This assessment indicated gaps in compliance with Good Clinical Laboratory Practices (GCLP) for most laboratories. None of the labs were accredited at this point in time\(^1\). U.S. Centers for Disease Control and Prevention (CDC) along with Project Concern International (PCI) collaborated with DAC to provide technical assistance on developing and implementing a QMS for the NRLs and SRLs through the Project for Accelerated Technical Assistance and Integrated Capacity Building for HIV/AIDS (PRATIBHA). PRATIBHA, is a five year initiative (2009-2014) with the goal of enabling HIV testing reference laboratories across the country to achieve accreditation as per ISO 15189: 2007 standard and the NABL specifications. As accreditation is a

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voluntary process, PRATIBHA has aligned it’s interventions to the national program. PRATIBHA intervenes on continual quality improvement of HIV testing reference laboratories at the policy, laboratory network and laboratory staff levels.

Principles and prerequisites
As the second phase of the President’s Emergency Plan for AIDS Relief, 2009-2013, emphasizes country ownership and sustainability, PRATIBHA is designed as a technical assistance project with an integrated capacity building and sustainability approach.

1. Effective partnerships
PRATIBHA is a partnership of DAC, State AIDS Control Society (SACS), the HIV testing laboratory network, CDC and PCI, with CDC and PCI as the providers of need based technical assistance and capacity building inputs to DAC’s country wide HIV testing reference laboratory network.

- Need based support - This partnership is based on common understanding and agreement on needs for a functional QMS for HIV testing reference laboratories identified through lab assessments, onsite visits, and pre- and post- training tests.
- Clarity of goals, expectations, and roles among partners - Roles and responsibilities are mutually agreed among partners. A skilled team of laboratorians with in-depth understanding of government schemes and HIV reference laboratory network is critical to leading this process.
- Sustainability - Interventions have been designed and implemented such that external interventions (that is CDC-PCI supported) can be sustained through existing systems, beyond life of project.
- Trust, confidentiality and strong collaboration - Partnership is based on responsiveness, mutual trust and maintaining confidentiality in sharing information (e.g. Laboratory assessment information collected through PRATIBHA is used to mentor and support each lab; this information is not shared outside the laboratory network).

2. Evidence based and resource efficient interventions
PRATIBHA implements evidence-based interventions. Through assessments and on-site visits, the project gathers information on the performance of laboratories on implementation of the 12 QSE. The labs and themes for providing technical assistance are prioritized based on this evidence, in consultation with all partners. The pre-requisites for receiving technical assistance such as willingness to develop and implement QMS, competence and availability of key lab staff are considered during a prioritization exercise. In order to maximize return on investment, PRATIBHA uses a phased approach in prioritization. Labs scoring 80% or above, that is, ready to apply for accreditation receive inputs on preparation for NABL assessment, while labs scoring below 60% undergo review of all operations and are motivated for developing and implementing QMS. The project has undertaken geographic clustering in order to make technical assistance more accessible and resource efficient (with decentralized locations in the north, south, east-northeast and west regions). Resource efficiency is also aimed through ripple effect of interventions such as increasing scope of accreditation to tests beyond HIV through ongoing efforts.

3. Technical leadership and capacity building
PRATIBHA has promoted a culture of quality through the use of a four-pronged strategy comprised of:
1. Securing leadership commitment for QMS through evidence-based dialogue,
2. Capacity building through technical updates, regional workshops and mentoring for applying state-of-the-art techniques
3. Motivating individuals to strive for excellence, through incentives and recognition
4. Promoting a positive deviance approach, encouraging exchanges across accredited labs, labs complying with GCLP and other labs.

Interventions target the entire spectrum of stakeholders that includes policy makers, the laboratory network, individual laboratories and laboratory staff. Inputs are defined at laboratory staff level by required competencies; at the laboratory level by needs emerging from performance on QSE; at the laboratory network level by coordination between DAC/SACS and labs; and at the policy maker’s level by commitment for high-quality lab services in the country. Capacity building interventions at the laboratory staff and network levels include 1) promoting accreditation, 2) regional workshops on QMS themes, 3) on-site mentoring, monitoring and supervision by experts and 4) facilitating training and on-site support for SRLs through NRLs. At the policy makers level, PRATIBHA promotes evidence-based policy dialogue, collaborates on the preparation of laboratory strengthening plans, and provides expertise for revisions of HIV testing and laboratory guidelines.

Accreditation is not a one-time activity. Once achieved quality standards have to be maintained through continual quality improvement. PRATIBHA continues to provide technical assistance to accredited labs for maintaining accreditation status.

4. Outcome oriented and measurable
PRATIBHA captures and measures change through its rigorous monitoring and evaluation systems coupled with laboratory assessments.
- At the policy makers level the project measures development and dissemination of state-of-the-art testing and laboratory guidelines, leveraging of funds and human resources for capacity building activities and increased commitment for laboratory services strengthening all leading to a more favorable environment for a functional QMS.
- At the laboratory network level, the project measures improvement in networking and enhanced mentoring of SRLs by NRLs.
- At the laboratory level, the project monitors changes in performance on QSEs and how gaps in performance are bridged.
- At the laboratory staff level, the project captures its reach on training and skill building and actual work-site performance, through on-site visits and assessments.

DAC monitors all technical, operational, and financial issues of the laboratories and their network.

...during the nationwide SRL assessments in 2009, I was exposed to the realities of quality standards across SRLs in the country. Going through the QSE checklist with staff in these laboratories, raised questions like “What am I doing about my lab?”, “How can I assess and question other labs when we ourselves have not striving for accreditation?”. I was 100% sure about the accuracy of our laboratory tests and reporting but we did not have the stamp of global standards in HIV testing.

(NRL in-charge)
### Components of PRATIBHA’s technical assistance framework

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<td>Regional workshops</td>
<td>Evidence on lab quality available for decision making</td>
<td>Accreditation of HIV testing reference laboratories</td>
<td>Clients receiving HIV testing services as per highest quality standards</td>
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<td>Induction training*</td>
<td>Improved adherence to QMS</td>
<td>Monitoring accreditation status</td>
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<td>Onsite mentoring, monitoring and supervision</td>
<td>Increased pool of assessors and auditors</td>
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<td>Virtual technical support</td>
<td>Strengthened NRL mentorship</td>
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<td>Job-aids</td>
<td>Leadership committed for improving laboratory services</td>
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<td>Motivational activities</td>
<td>State-of-the-art technical guidelines</td>
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<td>Promote relevance of accreditation</td>
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<td>Improve SACS-NRL-SRL networking</td>
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<td>Leadership, assessor and auditor trainings</td>
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<td>Advocate for quality improvement of lab services in policies and plan</td>
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<td>Advise on revision of guidelines</td>
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* PRATIBHA experts as faculty

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**Evidence from laboratory assessments and re-assessments**

**Policy makers**

**Laboratory networks and SACS**

**Referral laboratory staff**

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