Conceptual Framework: Integrated laboratory strengthening for high burden diseases (tuberculosis, HIV, malaria, and neglected tropical diseases)

Background

Laboratory services in resource-poor countries are essential to meet the Millennium Development Goals for Health and those of major global health initiatives and financial mechanisms such as The Global Fund and PEPFAR. Member states are also now required to report to WHO any potential public health risk under the International Health Regulations, which necessitate the availability of accurate, reliable, and rapid laboratory results. Arguably the weakest component of health systems, laboratory services in developing countries have historically been grossly neglected and underfunded. Diagnostic capacity is therefore a major bottleneck for scaling up management and control of the highest-burden infectious diseases, largely as a result of one or more of the following factors:

- Lack of recognition of laboratory services as an integral component of disease control;
- Inadequate and unsafe laboratory infrastructure;
- Insufficient and underfunded country-level strategic plans for laboratory strengthening;
- Vastly inadequate numbers of skilled technical staff;
- Slow diagnostic tool development and delayed, extremely slow, technology transfer;
- Insufficient and uncoordinated technical assistance at country level to strengthen laboratories.

Rationale

Increased funding for global health initiatives, and in particular for health systems components, require a focused approach to strengthening of key elements that cut across diseases. At the same time, increasing investment in research on and development of new diagnostic tools has resulted in the largest pipeline of new products ever. Shared technological platforms (e.g., for molecular assays and advanced/modern microscopy) and increasing convergence in test platforms (e.g., rapid tests for HIV, TB, malaria) present a unique and exciting opportunity for combined use of diagnostic equipment and laboratory space, and for expanding diagnostic capacity to remote health facilities. New tools will, however, be impossible to implement if the required laboratory network, infrastructure, training and deployment of laboratory workers, quality assurance and information systems are not developed and maintained in tandem. Key sustainability factors include:

- Adequate funding for laboratory infrastructure and equipment, maintenance, commodities and supplies;
- Strengthened regulatory frameworks to safeguard quality, safety, performance, accuracy and cost-effectiveness of diagnostic tests;
- Comprehensive, targeted strategies and adequate funding for human resource development;
- Appropriate systems for specimen referral, supply chain management and logistics;
- Appropriate systems for information management and rapid and effective information sharing;
- Quality assurance and documented evidence of continuous laboratory quality improvement.

Shared technological platforms for diagnostics, common health system barriers to implementing laboratory services and the shared disease burden of especially TB, HIV and malaria in many developing countries point to the need - and opportunity - to establish tiered yet integrated laboratory systems at appropriate levels of the health care service to ensure universal access to diagnosis and patient care. TB, HIV and malaria have attracted significant donor funding, albeit through different funding streams. Synergy of these different funding sources to effect much needed strengthening laboratory strengthening will be one of the most cost-effective interventions to improve diagnosis and care of patients, while providing a concrete model for health system strengthening through the full development of one of its crucial components.
Cross-cutting health system components of laboratory services amenable to integration, areas for close collaboration between disease-specific programmes, and areas requiring a disease-specific focus are summarized in the proposed Conceptual Framework below.

**Aims**

The overall aim of the cluster-wide initiative is to create a global platform for cross-cutting and integrated laboratory services as one of the pillars of health systems strengthening, with the following objectives:

- To identify and prioritise areas in which increased internal investment and synergy could have the greatest impact on cluster-wide laboratory strengthening, based on different strengths in the different departments and partnerships;
- To engage and mobilise key external stakeholders essential to accelerating technology transfer and expanding diagnostic capacity in a concerted effort in high-burden countries;
- To facilitate and coordinate technical assistance in order to significantly and rapidly strengthen laboratory capacity at regional and country levels;
- To increase and accelerate resource mobilization for laboratory strengthening as an integral component of health systems strengthening.

Key stakeholders to enable this initiative to work include WHO regional and country offices, member countries, and external stakeholders such as the Foundation for Innovative New Diagnostics (FIND), the diagnostics industry, and technical and funding agencies able to accelerate support and technical assistance at country level.

**Expected outcomes**

- Agreed plan and deliverables for cluster-wide integrated laboratory strengthening;
- Rapid expansion of quality new technologies within adequate regulatory frameworks and integrated laboratory services in high disease-burden countries;
- Increased, coordinated and sustainable technical assistance efforts at regional and country level ensuring maximum resource efficiency, country absorptive capacity and sustainability;
- Accelerated and expanded access to diagnosis and care for affected patients.
Conceptual framework for cluster-wide laboratory activities

| Departmental (Technical, disease and/or technique-specific) | • Evidence-based policy development  
• Norms and standards  
• Standard operating procedures  
• Training manuals and tools  
• Quality assurance and proficiency testing |
| Collaborative | • Country support and technical assistance through regional and country offices, and external partners  
• Stakeholder liaison  
• Donor coordination at global, regional and country level  
• Operational research  
• Advocacy and resource mobilization |
| Integrated (Health systems components) | • Regulatory framework to safeguard quality, safety, performance, accuracy and cost-effectiveness of diagnostic tests  
• Infrastructure development, upgrade and maintenance of laboratory networks at country level  
• National laboratory strategy development, country national laboratory plans, operational manuals (with adequate specificity for disease-specific needs)  
• Human resource development, including skills mapping, competency analyses, curriculum development, training and retention strategies, task-sharing and task-shifting  
• Training, eg. Good Laboratory Practice (GLP)  
• Logistics and supply chain management, including specimen referral systems, procurement strategies, equipment specifications and maintenance;  
• Laboratory administration and management systems, quality management and supervision, laboratory information systems;  
• Laboratory accreditation and certification; |