The World Bank Regional Health Systems
Strengthening TB and Laboratory Support Project

Report of Assessment Mission to Kenya
April 13-17, 2009
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A mission composed of Devery Howerton (Lab specialist, CDC), Mark Rayfield, (Lab specialist, CDC), and François Boillot (Health System specialist, Alter) visited Kenya from 13 to 17 April 2009. Meetings were conducted with key informants in the tuberculosis program, the national public health laboratory, CDC and the private sector. Due to the coincidence of the mission with the Easter vacation season several key informants on leave could not be met.

Travel constraints have significantly impacted on the mission calendar and at times put significant constrains on national counterparts. The consultants would like to express their gratitude to them for the warm welcome and support they have provided the mission with, hence allowing to collect and discuss a significant set of information in a limited time.

**Introduction**

The Kenya health service delivers medical laboratory tests through a network of 958 laboratories, of which 70% belong to government, 20% to the voluntary sector, and 10% to the private sector. 81% of these laboratories participate in the national tuberculosis program. Clinical laboratories are embedded in hospitals, health centers and a good part of dispensaries. They are involved in the provision of laboratory tests provided under national public health programs (e.g. tuberculosis, HIV-AIDS, etc.) and for those, they receive support from central reference laboratories (CRL), whose function is to support quality and provide specialist services. CRLs are grouped under the umbrella of the National Public Health Laboratory (NPHL), which has similar responsibility across the system. Under NPHL, CRLs maintain close links with their counterpart national programs, to which they are today, at least implicitly, accountable. The contribution of laboratories to research is assured by the Kenya Medical Research Institute, which also maintains a solid network of laboratories and benefits from substantial international support.

**The Network of laboratories in the Kenyan medical services**

<table>
<thead>
<tr>
<th></th>
<th>GOK</th>
<th>NGO</th>
<th>PR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>149</td>
<td>75</td>
<td>61</td>
<td>285</td>
</tr>
<tr>
<td>Health Centers</td>
<td>504</td>
<td>87</td>
<td>21</td>
<td>612</td>
</tr>
<tr>
<td>Dispensaries</td>
<td>693</td>
<td>128</td>
<td>27</td>
<td>848</td>
</tr>
<tr>
<td>Other</td>
<td>3</td>
<td>10</td>
<td>38</td>
<td>51</td>
</tr>
<tr>
<td>Total</td>
<td>1349</td>
<td>300</td>
<td>147</td>
<td>1796</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Laboratories</th>
<th>GOK</th>
<th>NGO</th>
<th>PR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFB diagnostics</td>
<td>505</td>
<td>171</td>
<td>100</td>
<td>776</td>
</tr>
</tbody>
</table>

Source: National TB laboratory strategic plan
The recent creation of two ministries of health poses a substantial constraint to the laboratory system as hospital laboratories (at zonal, provincial and district level) largely contribute to public health programs, while falling under the umbrella of Ministry of Medical Services. In addition, the NPHL falls under Ministry of Public Health, and so does the Tuberculosis CRL, but there are ongoing discussions on whether the AIDS CRL should be attached to Ministry of Medical Services or remain under public health. The former option would create significant institutional problems to the NPHL. Beyond the present constraint, this situation offers a significant opportunity in terms of system development, as the Ministry of Medical Services appears in a situation of service provider to the Ministry of Public Health, for the provision of public health programs. Provided that adequate mechanisms are put in place, such model would support the shift of the State from a position of provider to a position of regulator. Such regulation would merely involve the development of contractual relationships between ministries, supported on the one hand by financing mechanisms allowing a purchase of services from medical services by public health programs, and on the other hand by quality support systems ensuring the objectives of quality and equity. In case found useful by parties involved in sector development, laboratories offer a sufficiently well framed scope of services to pilot such a contracting intervention, provided adequate provision is made to ensure quality.

**Tuberculosis situation**

Kenya is one of the countries in the world with the highest burden of tuberculosis. Sustained efforts by the Ministry of Health (MoH) have permitted to go beyond the targets set by the WHO. In 2007\(^1\), the National Leprosy and Tuberculosis Program (NLTP) was able to detect 80% of incident cases, while the treatment of 85% of new cases was successful. This impressive achievement, assuming WHO estimates are accurate\(^2\), would imply that reaching the remaining cases would possibly require tailored strategies to be developed. The burden of TB cases is unequally distributed in the country, though coinciding with population densities and/or concentration areas (e.g. refugee camps). No in depth analysis of case finding in relation with population density is available. Although non-Kenyan patients may represent a fair proportion of the annual cohorts of tuberculosis patients, the exact number is not known.

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\(^1\) WHO, Global tuberculosis report, 2009

\(^2\) This will be verified by the prevalence survey to be undertaken with support from Global fund
CDC is about to complete a prevalence survey in Nyanza province (sample 20,000 pop.), one of the highest burdened provinces in the country, with a TB epidemic largely fueled by HIV (15% prevalence in general population, 75% co-infection). Nyanza also enjoys good physical access to TB diagnosis services. Preliminary results indicate that only ¾ of TB patients are actually known to the NTP, and actual co-infection is around 50%. This deficit of demand is not likely to be due to an insufficient supply of diagnosis services. Further analyses will have to confirm whether the current strategy (which reposes on direct smear microscopy – DSM) will remain adequate to confirm cases. The consequence of this uncertainty for programming the World Bank intervention is that sufficient flexibility should be provided for case finding strategy adjustments, and equal provision should be made for the development of policy driven by empirical evidence. Despite achievements in tuberculosis control, the development of such strategic planning is still at its early stages in Kenya.

**Direct smear microscopy**

Direct smear microscopy (DSM) for acid-fast bacilli (AFB) is implemented on routine with light microscopy from the level of selected health centers (diagnosis centers). At the moment, the AFB DSM network covers around 1,000 laboratories in the country, from health center to zonal hospital, and the availability of DSM is 1/37,000 pop.

Fluorescence microscopy was available until now only at CRL level given the cost of the method and relative complexity to operate. The Light Emitting Diode (LED) technology has permitted to simplify fluorescence microscopy, and an initial pool of LED microscopes purchased with Global Fund support will be made available in the coming months to centers with higher turnover. The value of LED fluorescence microscopy will remain to be evaluated under field conditions, and such evaluation could be supported by the World Bank intervention.

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3 Acid-fast bacilli are bacteria belonging to the same family as *M. tuberculosis*
Availability of, and coverage by TB smear microscopy services

**DSM quality assessment**

Kenya implements external quality assessment by batch sampling and external reading is done at the CRL. The analysis of DSM results in all provinces shows that a large part of the smears done in the laboratories are negative. This situation may be explained by TB-HIV co-infection. While external quality assurance remains necessary, it is essential that microscopist proficiency remains ensured, particularly for paucibacillary cases[^4], this configuration calls for establishing parallel proficiency testing. Such a development could be supported by the World Bank intervention.

The table below presents EQA coverage progress as per the end of 2008. As can be seen from the targets, not all labs will have available two technicians trained in EQA. The need for further support should be explored.

[^4]: Excreting few AFBs, as may be the case with TB-HIV coinfected patients.
Progress in EQA coverage resulting from Global fund Round 5 support

<table>
<thead>
<tr>
<th>Number of laboratory staff trained in EQA</th>
<th>Baseline 2004</th>
<th>Target 2011</th>
<th>End 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>600</td>
<td>1 500</td>
<td>838</td>
</tr>
</tbody>
</table>

Number and percentage of TB microscopy units for which slide rechecking results are available for a specified time period among all TB microscopy units

<table>
<thead>
<tr>
<th></th>
<th>NA</th>
<th>420 (40%)</th>
<th>314(74.8%)</th>
</tr>
</thead>
</table>

Source: NLTPLD

Regional coverage of TB EQA Services, end 2008

<table>
<thead>
<tr>
<th>Region</th>
<th>District covered</th>
<th>H/centers</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rift valley South</td>
<td>9</td>
<td>87</td>
<td>96</td>
</tr>
<tr>
<td>Eastern North</td>
<td>4</td>
<td>22</td>
<td>26</td>
</tr>
<tr>
<td>Eastern South</td>
<td>9</td>
<td>75</td>
<td>84</td>
</tr>
<tr>
<td>Nyanza</td>
<td>12</td>
<td>140</td>
<td>152</td>
</tr>
<tr>
<td>North Eastern</td>
<td>4</td>
<td>21</td>
<td>25</td>
</tr>
<tr>
<td>Central</td>
<td>7</td>
<td>75</td>
<td>82</td>
</tr>
<tr>
<td>Coast</td>
<td>7</td>
<td>66</td>
<td>73</td>
</tr>
<tr>
<td>Rift Valley north</td>
<td>9</td>
<td>75</td>
<td>84</td>
</tr>
<tr>
<td>Western</td>
<td>8</td>
<td>77</td>
<td>85</td>
</tr>
<tr>
<td>Nairobi North</td>
<td>4</td>
<td>39</td>
<td>43</td>
</tr>
<tr>
<td>Nairobi north</td>
<td>4</td>
<td>53</td>
<td>57</td>
</tr>
<tr>
<td></td>
<td>77</td>
<td>730</td>
<td>807</td>
</tr>
<tr>
<td>Crl</td>
<td>12</td>
<td></td>
<td>819/910 x100=90%</td>
</tr>
</tbody>
</table>

Source: NLTPLD

CRL services for quality assurance are currently limited to the public sector. No provision currently exists at national level for quality for large private sector hospitals. The reasons that explain this situation include a difficult institutional communication between public and private sectors, and the fact that private hospitals in the last phase of achieving ISO accreditation hardly recognize CRL as a provider of quality assurance services.

The mission was also informed that AMREF implements quality assurance by constituting proficiency panels and sending them to labs, but direct confirmation could not be obtained, and this intervention was unknown to TB CRL. Clarifications have to be obtained in next steps of the World Bank intervention identification. If necessary, coordination mechanisms for quality assurance will have to be put in place.

CRL receives support from the Supranational reference laboratory (SRL), Brisbane, Australia. This support at the moment is limited to EQA reports on culture batch sent. Some direct technical support has been provided by the SRL Antwerp, Belgium. Improvement of supervision by CRL will require the strengthening of provision of technical support by SRL
to CRL. As reference laboratories operate on a supplier-client basis, adequate financing mechanisms have to be put in place to allow sourcing these services from outside.

**Regional coverage of TB EQA Services, end 2008**

<table>
<thead>
<tr>
<th>Region</th>
<th>Slides read</th>
<th>HFP</th>
<th>LFP</th>
<th>HFN</th>
<th>LFN</th>
<th>QE</th>
<th>No. of errors</th>
<th>% Concordance</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nairobi N</td>
<td>477</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>30</td>
<td>37</td>
<td>92</td>
<td></td>
</tr>
<tr>
<td>Nairobi S</td>
<td>757</td>
<td>3</td>
<td>12</td>
<td>17</td>
<td>12</td>
<td>0</td>
<td>44</td>
<td>94</td>
<td></td>
</tr>
<tr>
<td>N. Eastern</td>
<td>36</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>97</td>
<td></td>
</tr>
<tr>
<td>E. North</td>
<td>31</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td>E. South</td>
<td>107</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>83</td>
<td></td>
</tr>
<tr>
<td>Coast</td>
<td>60</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>6</td>
<td>90</td>
<td></td>
</tr>
<tr>
<td>RVS</td>
<td>108</td>
<td>2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>RVN</td>
<td>118</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>4</td>
<td>5</td>
<td>97</td>
<td></td>
</tr>
<tr>
<td>Nyanza</td>
<td>60</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>7</td>
<td>88</td>
<td></td>
</tr>
<tr>
<td>Western</td>
<td>96</td>
<td>1</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>96</td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>108</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>100</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Culture and sensitivity testing**

NTP policy is to offer diagnostic services for multiple drug resistant tuberculosis (MDR-TB) to all patients. At the moment (4th quarter 2008) around 50% of all Retreatment cases in the country have access to culture and drug sensitivity testing (DST), a service provided so far at the TB CRL. An effective courier service has been contracted out after pooling from remote places was put in place.
Culture is currently available at the CRL and in 7 non-government sites. The CRL strategic plan provides for an increase in coverage by decentralizing culture to zonal level. The current technologies involved in culture and DST are Lowenstein Jensen (LJ) solid media culture, then subculture is done with semi-automated Bactec MGIT®, and sensitivity of isolated strains is carried out for suspected MDR cases using genotyping by a molecular line probe assay (GeoType® MTBDRplus, Hain Lifescience). The line probe assay detects mutations in the target genes of M. Tuberculosis that confer resistance to rifampicin and/or isoniazid (high level rifampicin / rpoB; high level isoniazid KatG; low level isoniazid / inhG) – sensitivity testing is not done for other drugs. At the time of the visit, no testing was going on for lack of power supply. First line drugs other than rifamicin and isoniazid, and second line drugs are not yet tested for sensitivity, and this could be developed with World Bank support.

**Culture quality assessment**

The CRL’s culture quality assessment is rudimentary. Culture contamination rates, no growth rates, and turn around times are not routinely tracked. Informal external quality assessment is obtained from the Mycobacterial Reference Laboratory in Brisbane, Australia. The American Society for Microbiology (ASM) through PEPFAR funded grants has made multiple technical assistance visits to the CRL in the past four months to identify areas that need to be strengthened, including quality assessment.

**Histopathology**

Histopathology services are available.

**TB lab services development**

The following priorities are identified for the development of TB laboratory services in the 2006-10 strategic plan. All are sound and do not call from specific comment from the consultants

**Equipment**

- Microscopes-LED/Light microscopes
- Maintenance
- BSC

**HRM**

- Quantity and quality
- Refresher causes

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5 Aga Khan Foundation Hospital Nairobi and Mombasa, Nairobi Hospital - Nairobi, Acacia Hospital – Nairobi, Pathcare Hospital, Nairobi, Nyanza – CDC, and a hospital in North-West Kenya supported by MSF
- Training
- Mentorship at supranational labs.

Quality assurance
- Supervision
- EQA/proficiency testing
- SOPs/guidelines
- Lab. Networks-PPM

Culture services
- Decentralization to regional hospitals and high volume DH

Infrastructure
- Assessments
- Renovation
- New facilities

Laboratory consumables
- Culture/DST
- AFB microscopy
- Rapid assays

Laboratories policy
Kenya has been a pioneer country in issuing as early as 2006 a comprehensive medical laboratory services policy to improve the quality of equitable and sustainable laboratory services. This policy document clarifies the roles and functions of the different institutions involved in the provision of laboratory services, and coordination mechanisms. It also describes the organization and management of the laboratory services, the provision of quality and safety procedures, the production and management of laboratory information, research, monitoring and evaluation of laboratory procedures, and the financing mechanisms operating for laboratory services.

The Kenya laboratory policy is obviously in development, and its current status reflects this. It still includes minor inconsistencies, possibly resulting from the limited dialogue between programs and lab services. For instance, the policy recognizes to level II dispensaries and clinics the capacity to operate Direct smear microscopy with the Gram stain (e.g. for the diagnosis of STIs) but allows use of the Ziehl Nielsen (ZN) stain for TB only at level III,
Despite both tests involve similar skills. If functional, the practice of ZN at level II would, at least in some circumstances, improve the equitable availability of TB diagnosis. At least, such a development deserves to be explored.

There are no comprehensive national guidelines for standardizing laboratory tests, techniques and equipment at each level of health facility. Microscopes supplied by the TB program are used principally for tuberculosis smear. Gram stain is done only in hospitals. Despite a recommendation in that sense, utilization of microscopes for malaria smears remains irregular. However, at the time of the mission, and while Global Fund round 9 country application is being prepared, provision is made that future microscope procurement be common between TB and malaria programs, as part of a health system strengthening component. The availability of microscopy platforms at all levels of the health services offer the opportunity to expand the use of smears to other diseases, including sexually transmitted infections (Gram stain) or AIDS opportunistic infections (India ink). Such an expansion in scope would require the development of appropriate quality assurance mechanisms. These could be piloted as part of the World Bank intervention.

Policy development is constrained by the current aid mechanisms in support to lab services. The challenge is not so much that major financing flows follow program channels than the fact that programs are confused with departments having responsibility for their implementation. For instance, Global fund grants for TB are the responsibility of the NLTLDp, including CRL services, while no support flows through NPHL. This results into TB-CRL becoming implicitly integrated into its client program, rather than both NLTLDp and NPHL coordinating efforts in implementing the activities of the national TB program. The mission has not had time to assess whether this assessment is equally valid for other programs, but given the limited support so far received by NPHL as an integrated entity, this may be the case. A possible area for World Bank support would be to identify the most suitable funding and financing mechanisms to develop and operate a national laboratory system in support to national programs.

Although a NPHL strategic plan and budget have been developed, no provision was made for their update. Among the reasons explaining this situation, it is possible that the limited availability of funding has constituted a negative incentive. The subsequent development of specific CRL strategic plans may also have contributed to the process. The development of a strong capacity to plan for and advocate laboratory strategic developments constitutes an area where support from the regional intervention may create substantial added value. This would also support other GoK and World Bank efforts to develop mid-term expenditure frameworks (MTEF) by clearly providing principals with the size of costs to be financed.

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6 In such a system, NPHL could for instance become sub-recipient of Global Fund grants, in common for the 3 diseases and possibly other mechanisms supporting equitable access to lab tests likely to contribute to Global Fund specific outcomes (e.g. diagnosis of STIs)
Quality and accreditation

A Medical Laboratory Quality Assurance Advisory Body (MLQAAB) has been established but is still not fully functioning. A number of programs have developed targeted laboratory quality assurance systems to monitor and improve specific laboratory services, e.g. NLTP, NBTS, CT and KEPI.

In the public sector, TB CRL has initiated an upgrading process to work toward ISO certification. Several consultants funded through the American Society for Microbiology (ASM) grants have visited the laboratory during the past few months to provide assessments, technical assistance, strategic planning and recommendations to the laboratory staff regarding changes and improvements necessary for implementing a quality system that would meet ISO 15189 standards. A few of these recommendations have been implemented, but substantial work is still necessary.

In the private sector, large hospitals are at an advanced stage in the process. The Aga Khan Foundation teaching hospital, Nairobi, has for instance programmed ISO 15189 certification in early 2010. It is stuck in the process for lack of capacity to access TB EQA services, as attempts to develop this with CRL have remained unsuccessful. It is today in the paradoxical situation to have to procure TB EQA from outside Kenya. An obvious set back in the development of a functional NPHL capacity, this situation requires urgent solutions. Although this may fall in the scope of possible World Bank support, it is desirable earlier solutions be found.

Security

The laboratory policy does not yet mention any comprehensive national laboratory safety program. Biosafety is a primary concern in the TB CRL as the facility is inadequate and unsafe for handling TB cultures and staff lack the needed training and personal protective equipment to prevent infections. This concern was strongly expressed by the ASM consultants. At the very least, the laboratory needs a reliable power supply (generator), biosafety cabinets, gowns, room air flow control, and staff need safety training. This is an area in which World Bank funding could provide an immediate impact.

Information

Laboratory information systems consisted so far mainly of bench registers used to record tests, with activity reports stacking at central level. A laboratory working group receiving PEPFAR support has designed a new paper based system that would allow simultaneous activity reporting and laboratory-based epidemiological surveillance. In parallel, implementation of lab computerized information systems is starting with a top-down approach, key central laboratories serving as pilots. The TB CRL is one of those pilots.

An automated HIV lab information system is offered by PEPFAR implementer Columbia University. No further information could be obtained.

The NLTLDP information system based upon WHO/IUATLD recommendations still does not use laboratories as a source of information. The need for change may be considered if alternative lab reporting systems demonstrate effectiveness.
**Infrastructure**

Although the policy recognizes that "there is poor laboratory infrastructure at every level", no actual assessment supported the statement at the time it was expressed. An assessment of laboratories currently implemented with support from the PEPFAR component implemented by CDC. Results are expected by the end of April 2009.

The laboratory working group has finalized standardized plans for laboratories at all levels. This process has been based on plans previously developed in Zambia and Zimbabwe, and has received technical input from the Association of Public Health Laboratories (APHL). These plans will serve the purpose of either direct use for lab erection, or providing standards for lab rehabilitation. Support to laboratory renovations is provided under Global Fund Round 6 (GF-R6), but this is limited in size (250 labs) and scope (only the TB part). The mission has not been able to document similar support from other GF grants.

**Technologies and maintenance**

A medical engineering division is established under the Ministry of Medical Services, with a medical engineering workshops throughout the health care facility system, including the NPHLS. These departments are supposed to organize training of equipment users in all health facilities on safe handling and preventive maintenance of equipment. Medical engineering workshops have the direct authority to examine and remove obsolete or unserviceable equipment, and to dispose of these items as necessary, but the procedures are cumbersome and difficult to implement. They have direct authority to examine and remove obsolete or unserviceable equipment, and to dispose of these items as necessary.

The maintenance system is however not functional, and early findings of the laboratory assessment mentioned earlier suggest that laboratories have to outsource maintenance; however, above 2/3 of labs may not be able to access outsourced lab maintenance. An attempt to outsource microscope maintenance was made by NLTLDP under GF-R6. The limited volume of such a contract did not raise concern of grant planners with limited experience with lab issues, and no tenders have been received after the call was issued.

*Progress in outsourcing microscope maintenance under GF-R6*

<table>
<thead>
<tr>
<th>Proportion of microscopes serviced</th>
<th>Baseline 2006</th>
<th>Target 2011</th>
<th>End 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>10 (20%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

**Human resources**

**Pre-service training**

While Kenya has a surplus of trained laboratory technicians and technologists, pre-service training, in general, needs strengthening. New graduates often have knowledge and skill
gaps that require intensive in-service or on-the-job training, and this training is spotty and inconsistent, depending on where individuals are employed.

**Mobilization and motivation**

Difficulties in recruiting additional lab personnel is one constraint expressed by most interlocutors of the mission, due to ceilings set by Establishment. Although these may remain true, such statements not pay tribute to the efforts to find solutions developed by the Human Resources Department, Ministry of Public Health. To date, difficulties have been overcome and the 88 new staff planned under GF-R6 are being recruited on a contract basis.

*Progress in contracting laboratory staff for TB under GF-R6*

<table>
<thead>
<tr>
<th>Number of staffs recruited and retained at the primary health care facilities</th>
<th>Baseline 2006</th>
<th>Target 2011</th>
<th>End 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>88</td>
<td>88</td>
</tr>
</tbody>
</table>

Between ministries, Division of Medical Laboratory Services (DMLS) has also seconded staff to the following programs: DOMC, NASCOP, NLTLD, DOMU, KEPI and Nairobi City Council.

Preliminary results of the laboratory survey mentioned above (conducted on a 12% sample of laboratories), reveals that current level of lab staffing is around 10 staff per lab, a number in principle sufficient for smooth absorption of the workload. Lab technologists may represent the largest proportion of them (around 2/3) and technicians ¼. The study also revealed an acute shortage of cadres, as pathologists represent less than 1% of the lab workforce. These preliminary results are yet pending confirmation.

Information obtained from the Registrar office indicates that around 8,000 lab staff may be available on the Kenya labor market. If this is confirmed, these may not only represent a solution to fill a large part of the Kenya lab workforce gap, but also represent a solution for temporarily addressing HR gaps in neighboring countries. Both solutions could be developed under the Regional World Bank Intervention.

**Continuing education**

Training and mentoring is needed in technical, laboratory quality and safety management systems, strategic planning and other management issues.

**Financing**

The NPHL Policy makes provision for funding laboratory services through several mechanisms including:

- Support to supply (“push” mechanisms):
  - Government budgetary provision
  - Donations and grants from development partners. All donations will be channeled through the Ministry of Health headquarters
• Demand financing ("pull" mechanisms):
  o User fees, including patients out of pocket funds (under a cost sharing principle) and institutional trade of lab services.
  o Insurance claims

The national TB policy requests that TB services – including laboratory services – be provided free of charge to suspects and patients. Weak PPP mechanisms that do not provide for laboratory service costs to be financed in the private sector to secure free access to all result in suspects and patients being charged in private facilities not benefitting from subsidies (which is about all of them since the rise of the Global Fund has cut most public private direct transfers), with significant inequity being generated in the provision of a public good. This situation calls for urgent measures, possibly before, certainly during and with support from the regional World Bank Intervention.

The policy remains silent on ensuring how services may benefit from adequate financing levels, and on the mix of mechanisms and sources that would be optimal to that effect. Developing these mixes would be an area where support from a World Bank project would have particular added value.

Current budgeting of laboratory services is also constrained by the level of development of budgeting instruments. Global Fund grants allow better visibility on laboratory budgets, but there is currently no provision for consolidation between the three diseases grants. The table below provides an example of TB budgets, consolidated by the consultants between round 5 and 6 grants. The mission did not have sufficient time to do the same with, and between, other diseases grants.

Discussions with members of the TB round 9 proposal working group indicate that sustaining Round 5 activities with the current application has not been considered. This appears to the consultants a significant threat to sustainability, resulting from the use of a development mechanism – projects – to sustain recurrent activities (though their scale may be increasing). The consultants were informed that the Kenya CCM has applied to the new Global Fund mechanism called National Strategy Applications (NSA) whereby countries apply for the funding of a national plan. This mechanism has been applied only for malaria, and the content of the application is still to be developed. Identification of the content of this support and of Global Fund support to come remains to be carried out in the next steps of the Intervention development.

*Current financing budgeted for laboratory activities under Global Fund R5 and R6 TB grants. Amounts in US$*

<table>
<thead>
<tr>
<th></th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ROUND 5: START DATE-2006-END DATE-2011</strong></td>
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<tr>
<td>Refresher Training in AFB microscopy of laboratory staff in 74 districts</td>
<td>148 000</td>
<td>155 400</td>
<td>163 170</td>
<td>171 329</td>
<td>179 895</td>
<td></td>
<td></td>
<td>817 793</td>
</tr>
<tr>
<td>Quarterly supervision of Laboratory diagnostic facilities for EQA</td>
<td>56 000</td>
<td>58 800</td>
<td>61 740</td>
<td>64 827</td>
<td>68 068</td>
<td></td>
<td></td>
<td>309 435</td>
</tr>
<tr>
<td>Description</td>
<td>Budget 1 (US$)</td>
<td>Budget 2 (US$)</td>
<td>Budget 3 (US$)</td>
<td>Budget 4 (US$)</td>
<td>Budget 5 (US$)</td>
<td>Budget 6 (US$)</td>
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<td>------------------------------------------------------------------------------</td>
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<tr>
<td>Freighting of culture samples to the supranational national laboratory in Australia</td>
<td>4 000</td>
<td>4 200</td>
<td>4 410</td>
<td>4 631</td>
<td>4 862</td>
<td>22 103</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement of slide boxes for EQA</td>
<td>5 400</td>
<td>1 280</td>
<td>1 493</td>
<td>1 750</td>
<td>2 020</td>
<td>11 943</td>
<td></td>
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<tr>
<td>Procure laboratory reagents</td>
<td>60 000</td>
<td>63 000</td>
<td>66 150</td>
<td>69 458</td>
<td>72 930</td>
<td>331 538</td>
<td></td>
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<tr>
<td>Procure Microscopes dedicated EQA</td>
<td>148 000</td>
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<td></td>
<td></td>
<td>148 000</td>
<td></td>
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<tr>
<td><strong>ROUND 6: START DATE-2008-END DATE-2012</strong></td>
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<tr>
<td>Heath facility physical infrastructure improvement by additional 250 new DSM labs to existing 700</td>
<td>104 150</td>
<td>104 150</td>
<td>104 150</td>
<td>104 150</td>
<td>104 150</td>
<td>520 750</td>
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<tr>
<td>Procurement and distribution of 250 electric scopes and other lab equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>868 055</td>
<td></td>
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<tr>
<td>Procurement of laboratory consumables</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>125 000</td>
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<tr>
<td>Procurement of other health facility physical items e.g. furniture for 250 labs</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>173 610</td>
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<tr>
<td>Procurement of power supply equipment, one solar panel and battery for each of 250 labs</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>173 610</td>
<td></td>
<td></td>
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<tr>
<td>Maintenance of equipment and physical infrastructure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>86 805</td>
<td></td>
<td></td>
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<tr>
<td>Recruitment and deployment of 88 Lab techs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 583 330</td>
<td></td>
<td></td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>421 400</td>
<td>282 680</td>
<td>1 203 195</td>
<td>1 218 227</td>
<td>1 234 007</td>
<td>6 171 972</td>
<td></td>
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</tr>
</tbody>
</table>

Source NLTLDP

No similar budgets could be found for other agencies, either because of flexible mechanisms (PEPFAR), budgets not yet defined (JICA), or just not available. Consolidation of lab aid financing would clearly constitute a significant improvement as this would improve aid predictability (Paris declaration), and allow better matching between the MTEF and funding sources. This could be the first stage of a process leading to common financing mechanisms as part of the SWAp in development. These could be another area where World Bank support could not only have added value for laboratories, but also generate externalities as laboratories are a well circumscribed field that may serve as a pilot in the sector.

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7 Shipping one batch of samples (cir. 3Kg) in accordance with IATA regulations costs 5-600 US$
Partnerships

Public-public
Ministries of public health
Ministry of Public Health and Ministry responsible for veterinary medicine

Public-private
Current plan makes provision for partnership between public and private organizations; this may happen only if private organizations – be they not for profit / faith based, or for profit – are capable of mobilizing financing of their own. No provision exists to allow MoPH to contract out services, a situation that may prevent smooth development of the regulatory role of the ministry of health.

Discussions with private providers (Aga Khan foundation) suggest that the private sector is open for discussion on contract based services; such contract may be supported either by fee-for-service, or by tax-exemption mechanisms. The development of such mechanisms is a field where World Bank support may be of particular added value.

Aid
The ‘plural governance’ model is particularly vibrant in USG support. It has clear flexibility advantages, but it deprives the Kenyan counterparts from a clear assessment of partners’ intentions by not plainly differentiating principals from their agents and their contractors. It also prevents smooth development of aid predictability. This model also does not necessarily permit peer level coordination, in particular at principal level.

Laboratory systems development and operation currently benefits from support from the US Government. Bilateral support is provided by the USA, through PEPFAR (1 and 2), the USAID country program, along with CDC research programs. Both funding sources operate through an array of contractors. While PEPFAR 1 (worth $15 billion over five years) has provided largely vertical HIV-AIDS support, PEPFAR 2 (worth $48 billion through 2013) operates a paradigm shift and contributes to HIV-AIDS outcomes from a broader cross-cutting perspective. PEPFAR grants are implemented under CDC leadership by a set of different contractors whose mission is to work side by side with the national systems they are providing support to. These contractors are, however, held responsible for the final outcome of the intervention. This approach may at times create confusion on the sustainability of the outcomes, as no provision is made to capture the actual capacity of the national systems to deliver by themselves at similar levels. CDC is also a direct PEPFAR implementer and provides through PEPFAR a large amount of technical assistance and support to infrastructure and operation of laboratory services.

Tuberculosis is addressed by PEPFAR as part of the AIDS opportunistic infections. Although from a technical point of view TB presents more as a co-infection than as an opportunistic infection, this situation allows tuberculosis programs to benefit from substantial PEPFAR funding. In coherence with the ‘TB as an opportunistic infection’ approach, CDC supports the building of a new central TB reference laboratory within the premises of the central microbiology reference laboratory of the National Public Health Laboratory. CDC is in the
final process to support construction of a BSL2+3 facility for the microbiology (TB + other microbiological activities) dept of the National public health laboratory. We have been able to see the plans of this 3 floor building to be erected / rehabilitated on the premises of the ancient hospital lab, close to present NLTP HQ (see attachment with BSL 3 floor plan). A discussion with contractor architect indicates that at this stage, should CDC non object to the continuation of the process, tender is about to be launched, and works contract awarded this July. Delivery is expected during 3rd quarter 2010. Project is to be financed from the initial $700K plus a complement from PEPFAR funds (complete costing was not available).

Kenya so far benefits from rounds 5 and 6 grants for tuberculosis, while a round 8 application has not been recommended for funding. An application to Round 9 is at its early development stages; from discussions held with members of the Round 9 working group, it appears that support to laboratories interventions (still to be fully identified) will be presented as part of a specific HSS cross-cutting component (section 4.B of GF applications), to be hosted by the Malaria proposal. The mission has not has the opportunity to discuss the rationale behind this choice, as far as laboratories are concerned. Given its potential strategic implications, this should be clarified in the next steps.

The only mechanism mentioned by our interlocutors with respect to laboratory system development is a so-called Interagency Coordination Committee (ICC) that gathers around MoH stakeholders represented by NPHL and the three poverty diseases programs the following organizations: CDC, APHL, MSH, Clinton Foundation, AMREF, JICA, major hospitals, and the dept. of microbiology of the University of Nairobi. As mentioned earlier with partnerships, this coordination mechanism makes no provision to distinguish between principals and agents, which may explain so far its limited effectiveness. As mentioned, the development of effective mechanisms is urgently needed.

**APHL support**

The Association of Public Health Laboratories (APHL), funded through PEPFAR, has a number of initiatives in Kenya. Recent and current initiatives are listed below. APHL anticipates continuing work in Kenya, however this is contingent upon continued PEPFAR funding which is currently being competed for the next funding cycle. APHL activities include:

- **Laboratory Information System:** assistance is being provided to the CRL (HIV, TB and Micro) for LIS implementation using Labware and CBS.
- **Laboratory Quality Management System training:** A Laboratory Management Workshop was provided in November 2008 resulting in a follow up workshop on strengthening schemes for QA and EQA in March 2009 for laboratorians from the National (Central), Provincial and District labs.
- **MOM lab building specifications:** The architectural firm, CUH2A, provided initial advisement to develop plans for a new three story laboratory adjacent to the current existing National Public Health Laboratories.
Site visits to US state public health laboratories: Top Managers will be visiting the Maryland and Delaware state public health laboratories in July 2009. On this visit they will:

- Describe the Laboratory Organizational Structures and Systems in operation both at the Clinical and Public Health areas.
- Specifically observe LABWARE LIMS in full operation in Delaware labs and learn the challenges and functionalities to expect in Kenyan lab operations. The Labware LIMS is currently being installed in Kenyan Labs. Compare the LabWare LIMS with the Maryland Lab.
- Specifically observe organization of Quality systems in operation in these Labs.

Non government support

ODA programs implemented by NGOs are excluded from this framework. The time available to the mission has not been sufficient to map this support with precision, and this may be usefully carried out in the next steps.

Recommendations for next steps

At the end of this country scoping visit the team wishes to formulate the following recommendations to the World Bank, to guide implementation of the next steps of the feasibility assessment of the Regional Intervention:

1. Do not break momentum

The significant progress Kenya has achieved in developing its laboratory system is the fruit of the commitment and tenacity of a group of individuals sharing a clear and sound vision of the role of laboratories in a modern health system. This group has also been successful in constituting a network of technical support, which should be protected as it reposes on ‘weak ties’\(^8\). Although this group is small and for the moment has limited visibility, the mission believes it may have a significant catalyst role in the following steps. We recommend that this group be clearly identified and given an open position and agenda.

2. Preserve TB functions

Bringing TB control to the HSS faith has been in the past traumatic\(^9\), especially when the HSS dynamics has failed to adequately address its specificity and needs. Future systemic


\(^9\) This particularly refers to the Zambian experience, where insufficiently prepared ‘integration’ resulted in an almost collapse of the TB program.
developments should be undertaken with permanent concern about not putting TB program achievements and outcomes in danger.

3. **Strengthen partnership**

The scoping mission has found that the World Bank will intervene in the field of laboratory strengthening together with strong partners, the US Government and The Global Fund. Both have so far provided support apart from the dynamics of sector coordination initiated around the MTEF and may not be familiar with this process. Both have also provided so far support through flexible funding approaches, which may prove of added value. Efforts in coordination of strategies and work programs can be paralleled by efforts in streamlining resources only if adequate attention is also paid to the internal constraints met by the US Government to coordinate and develop substantial aid mechanisms.

As coordination appears critical, it is of particular importance for improved coordination but also for the success of future requests to The Global Fund, that a clear mapping of each partner’s support to the plan be developed. This requires that principals all come around the same table to reconcile way forward and the present moment offers a window of opportunity for that to occur. A well functioning partnership would clearly constitute an asset to leveraging resources from this important instrument to achieving the sustainability of investments. The creation of such a discussion forum would also create a significant opportunity to put strong laboratory plan development mechanisms in place. This includes the process of regularly matching plan and achievements, and reassessing gaps and constraints. This should also permit to make decisions on support mechanism based on mechanism added value and opportunity.

A particular achievement in strengthening the partnership may take place right in the following steps, and as soon as the Government of Kenya has demonstrated its interest in the Intervention. This would consist of achieving consensus on the roles of the different partners in the construction of the NPHL infrastructure. As the situation remains fairly open as long as CDC has not given a non-objection to the process, we propose in the table below an analysis of three scenarios to assist the choice.

<table>
<thead>
<tr>
<th>Scenario</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>USG proceeds as planned and WB pulls out of central level development as TB need is covered. WB will join USG for peripheral level strengthening</td>
<td>USG pulls out and WB takes lead over full NPHL building project, while USG takes lead over development of peripheral level</td>
<td>USG does microbiology +TB and WB complements to reach fully integrated NPHL. WB further contributes to peripheral level</td>
<td></td>
</tr>
<tr>
<td>Sooner availability of microbiology and TB</td>
<td>Easiest and most efficient way to fully integrated</td>
<td>Sooner availability for TB CRL.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>2</td>
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<tr>
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<tr>
<td></td>
<td>CRLs</td>
<td>infrastructure</td>
<td>Frustration of national counterparty controlled</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Allows earlier decentralization of TB culture through shift of US support to provincial level and below</td>
<td></td>
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<tr>
<td>Cons</td>
<td>Missed opportunity to achieve full NPHL integration, and in particular to get TB and HIV CRLs closer</td>
<td>Availability delayed by 18-24 months, possibly resulting into frustration of national counterparty</td>
<td>Possibly less efficient as current TB space may not reflect need once decentralization will be completed</td>
</tr>
<tr>
<td></td>
<td>Possible efficiency loss as TB CRL design may not have fully considered impact of decentralization</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Comments | Comparative advantages of USG and WB to develop specialized health infrastructure are to be reviewed.  
An earlier implementation of the provincial level of lab strengthening may allow a better definition of TB CRL needs at central level | Need to reassess current project to accommodate more space (elevation / area) |