Strategy of TB laboratories for TB Control Program in Developing Countries

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TB Control Program
Structure of TB Control

- Establish the TB control program in the country.
- Create the central level
  - National TB program (NTP)
  - TB referral hospital
  - National TB Reference Laboratory (NRL)
- Create the intermediate level
  - Provincial TB supervisors
  - TB operational district, included the OD referral hospital and TB supervision.
- Create the provision level
  - TB Units, public health facility include TB ward and microscopy center.
  - Health Centers where sputum specimens are collected, and some microscopy center situated in some HC.
- When the DOTS expansion program was approved at the lowest level of health care system, health centers must able to provide the DOTS and TB services include the microscopy examination.

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Objectives

• The objectives of a TB control program are to decrease morbidity, mortality and transmission of TB, while avoiding the emergence of drug resistance.

• At the heart of strategy is the identification and cure of infectious TB cases among patients presenting to general health services.

• Strengthening the National TB reference Laboratory (NRL) and all the other TB laboratories in the NTP network.

• Up to now, the efforts to tackle TB among HIV infected people have mainly focused on implementing DOTS strategy for TB control.
Broad Sense in the TB lab network

• National Reference Laboratory,
  – link to the Supra-National TB Laboratory regional.

• TB lab network
  – OD referral hospitals, TB units, Health Centers and TB services, for sputum specimen collection, microscopy centers, and culture in some OD TB lab.

• Quality assurance working between
  – the Supra-national TB laboratory and NRL
    • Semester basis EQA.
  – the NRL and TB Microscopy center
    • Quarterly basis EQA.

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Major Challenges

• Set up the goals
• Identifies:
  – TB is the high prevalence, high incidence.
  – Lack of resources to maintain the functioning to expansion the DOTS service nationwide.
  – TB laboratory strengthening is essential for implementation of expansion of TB control program.
  – Quality assurance issue.
  – Limits the resources to expand other intervention: community DOTS, PPM-DOTS, TB/HIV, MDR-TB.
Major Challenges

• Laboratory strengthening
  – DOTS expansion target.
  – Implementation of expansion-focused interventions to TB/HIV and MDR-TB
  – Improve the diagnosis and management.
  – Support research activities.
  – To measure the impact of the NTP to improve the treatment policy

• Staff capacity and motivation,

• The issue of assuring the free of charge service.
Joint Program Review (JRP)  
National TB Control Program

• Invited: WHO, major partners, include a team of international experts, staff from NTP, and partner agencies.

• JPR report identified a number of lab achievements and gives the series of recommendations.
Main Goals

• Strengthen the capability of TB laboratory network of the National TB Program (NTP) to diagnose new TB cases.

• Optimize the ability of the TB laboratory network to diagnose and manage TB/HIV co-infection and MDR-TB as well as to prevent the emergence and spread of MDR-TB.

• Improve the ability of the NTP to contribute to TB case diagnosis and management by introducing new diagnostic tools recommended by global TB control program and contribute to research activities related to NTP.
Strategic Plan for Strengthen TB Laboratories
Principle of Strategic Plan for TB Laboratories

- Develop in response to a main objective in national health strategic plan,
- Set up the strategy plan in one period, five years example.
- To strengthening the lab capacity, the expansion the DOTS program, the expansion the community DOTS base program, TB/HIV, MDR-TB etc.
Strategic Plan

• Output 1: Policies, plans, guidelines.
• Output 2: Capacity building and human resources development.
• Output 3: Infrastructure, logistics and laboratory supplies.
• Output 4: Service provision.
• Output 5: Monitoring, evaluation and EQA.
• Output 6: Research.
• Output 7: Partnership and advocacy.
• Output 8: Financing
Output 1: Policies, Plans, Guidelines

• Main Strategies:
  – Develop clear practical policies, guidelines and plans for TB laboratories.
  – The implementation of those policies, guidelines and plans activities should be regularly and appropriately monitored and evaluated.
  – The national strategic plans for the TB laboratories need to be developed, disseminated, and reviewed periodically.
Output 1: Policies, Plans, Guidelines

• Main Activities:
  – To formulate strategic plan for TB laboratories in one period in line with national strategic plan for TB control program.
  – To develop an Annual Action Plan for TB laboratories.
  – To develop and/or revise TB laboratory guidelines, Standard Operational Procedures (SOP), training modules including that for EQA, DST, infection control and waste disposal as well as microscope maintenance.
  – To organize the printing of all plans, guidelines, SOPs and modules; and disseminate to all implementers and concerned partners.
  – To conduct an annual TB Lab. workshop at central level to develop work plans and activities include additional workshops for Provincial TB lab supervisors and NRL staff.
Output 2: Capacity building and Human Resources Development

• Main Strategies:
  – Enhance the institutional capacity by strengthening of the management structure at all TB laboratories.
  – Build staff capacity according to identified needs through a continuing education program.
  – Address human resources management and motivation of staff by exploring options of providing incentives through such schemes as performance-based incentive.
Output 2: Capacity building and Human Resources Development

• Main Activities:
  – To access institutional capacity of TB laboratories in all TB units in order to obtain information for formulating actions for capacity building.
  – To develop a database of laboratory technicians in order to assess the number of qualified staff for smear microscopy and culture.
  – To conduct training for new laboratory staff related to the staff turnover.
  – To conduct refreshment training for laboratory staff.
  – To conduct workshop for assessors and cross-checkers.
  – To organize “on-the-job” training (mentorship) to technicians at poor-performing TB laboratories involving NRL and Provincial TB laboratory supervisors.

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Output 2: Capacity building and Human Resources Development

- Main Activities:
  - To strengthen the quality of sputum smears at health center level through additional training on technique of sputum collection and smear-making including transportation of smears.
  - To expand culture capability to at least two additional TB labs through the training of selected TB laboratory staff in culture.
  - To develop a performance evaluation system linked to a performance-based incentive scheme.
  - To seek support for the provision of monetary and non-monetary incentives to lab staff.
  - To organize study tours within the region and encourage participation at international meeting/TB conferences, e.g. IUATLD.
  - To arrange overseas training in TB microscopy, culture and DST, and lab management.
Output 3: Infrastructure, logistic and laboratory supplies

- Main Strategies:
  - Address to overall needs of the TB laboratories as an integral part of general laboratories within the MPA and CPA activity packages of Health Services.
  - Monitor the consumption of TB laboratory materials and consumables, quantify future requirement and provide information about anticipated requirements and estimated budget.
  - Ensure timely and adequate supply of TB laboratory materials and consumables.
  - Enforce quality assurance for laboratory requirement, supplies, and reagents.
  - Invest in physical infrastructure for the delivery of appropriate TB laboratory services, which include the construction or renovation of TB laboratories compassing culture facilities.
  - Improve the communication between the microscopy centers and the health facilities providing DOTS.
Output 3: Infrastructure, logistic and laboratory supplies

• Main Activities:
  – To ensure that activities for strengthening the TB laboratory network will be in line with integrated approach for the development of general laboratories within the MPA and CPA activity packages.
  – To closely monitor the situation of TB laboratory supply consumption at national, operational district and health facility levels.
  – To develop an annual requirement plan and estimated budget for laboratory equipment (microscopes, centrifuges, safety cabinets, etc.), staining reagents, other consumables (slides, sputum cups) and culture media.
  – To coordinate with the Central Department of MoH concerned and the Central Warehouse Service to ensure a timely provision of lab supplies and reagents and sufficient buffer stock, at least 9 month at CWS and 3 months at operational district level; and to closely monitor expiry dates of laboratory reagents.
  – To conduct annual workshop for lab technicians to provide guidance for maintenance of microscopes (based on the SOP for yearly inspection and cleaning of microscopes) and other equipment.
Output 3: Infrastructure, logistic and laboratory supplies

- Main Activities:
  - To coordinate with the Central Department of MoH concerned and procurement agencies to ensure the quality of staining reagents (manufacturers to provide certificate of quality for each batch of reagents).
  - To mobilize financial resources both local and external to ensure availability of laboratory supplies and reagents without interruption for the whole period of the plan and certain years beyond.
  - To carry out an annual inventory of laboratory facilities and equipment.
  - To seek support for strengthening infrastructure for the delivery of appropriate TB laboratory services, which included the construction or renovation of TB laboratories encompassing culture and DST facilities.
  - To expand culture capabilities to some provincial level with financial and technical support from partners.
  - To mobilize resources to provide support for improving communication between health centers and microscopy centers, which include the provision of telephone to microscopy centers to expedite the feedback to health centers particularly for smear results.

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Output 4: Service provision

• Main strategies:
  – Promote “free of charge” laboratory services for the diagnosis and follow of TB at all government health facilities at all levels.
  – Provide resources for the transportation of sputum samples and/or smear slides from health centers to microscopy centers.
  – Maintain the functioning to the existing microscopy centers.
  – Expand the laboratory network with other public and private laboratories in the health sector as part of Private Public Mix DOTS (PPM-DOTS) strategy.
  – Address the priority issues such as the diagnosis and management of MDR-TB, TB/HIV, smear negative and extrapulmonary TB and TB in children.
  – Introduce as appropriate new diagnostic tools for the diagnosis of TB recommended by WHO.
Output 4: Service provision

• Main Activities:
  – To widely disseminate information on “free of charge” lab services for TB diagnosis, especially sputum examination through NTP workshops, community meeting, issue of poster by the MoH and subsidization of services.
  – To provide financial support to ensure a smooth package of services between health centers and microscopy centers related to smear-making, transportation of slides.
  – To ensure that existing microscopic centers receive sufficient resources for their functioning, which include basic logistics supplies, budgetary support and appropriate human resources.
  – To implement the recommendations of the Joint Program Review related to the time taken to deliver specimens from health centers to microscopy center and average time taken to report results.
Output 4: Service provision

• Main Activities:
  – To train staff of TB laboratories at other government institutions such as the military and police hospitals and private health facilities (PPM-DOTS) and monitor the quality of services.
  – To improve methods for diagnosis of smear negative TB and extrapulmonary TB, including those in TB/HIV setting, and TB in children, this includes of tuberculin test and other diagnosis means.
  – To strengthen the referral mechanism to culture/DST centers for diagnosis of MDR-TB and other forms of TB.
  – To seek support to introduce new diagnostic tools for the diagnosis of TB recommended by WHO through collaboration with partners.

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Output 5: Monitoring, Evaluation, and EQA.

• Main Strategies:
  – Review and revise the monitoring and evaluation system of the TB lab network based on the recommendation of the Joint Program Review.
  – Decentralize supervision and mobilize resources to strengthen periodic supervision to TB laboratories from central, provincial and district levels.
  – Decentralize EQA (to provincial levels) and conduct on quarterly basis.
  – Promote partnership with Supra-National Laboratory (in the region) to assist in such areas as EQA and research.
Output 5: Monitoring, Evaluation, and EQA.

• Main Activities:
  – To review and revise the monitoring and evaluation system of the TB lab network based on the recommendations of the Joint Program Review and inline with the revised Monitoring and Evaluation framework of NTP.
  – To revise supervision checklist as necessary.
  – To implement a cost-effective supervision plan that includes feedback to peripheral facilities, monitoring of follow up action and linking of supervisory visits to results of slide rechecking.
  – To decentralize EQA to provincial levels and conduct on quarterly basis.
  – To perform QA on follow up smears separately from initial screening smears.
Output 5: Monitoring, Evaluation, and EQA.

• Main Activities:
  – To provide rapid feedback to sputum collection sites and microscopy units on slide preparation and quality of smears.
  – To work with the supra-national laboratory to get assistance for EQA, DST and research activities etc.
  – To translate, disseminate and implement the use of WHO TB laboratory assessment tool.
  – To review laboratory safety conditions including infection control practices, ventilation, waste disposal, routine disinfection and condition of laboratory equipment.
Output 6: Research

• Main Strategies:
  – To support important NTP surveys and studies such as national TB prevalence and MDR surveys.
  – Initiate, stimulate and participate in operational research related to TB diagnosis and case-management to contribute to the optimization of the NTP policies and guidelines.
  – Study the feasibility of introducing modern technology, including those adapted to resource-constrained setting, to diagnose TB in selected facilities.
  – Study the laboratory practices in the private sector of TB diagnosis and the quality of private practitioners.
Output 6: Research

• Main Activities:
  – To serve as a core TB laboratory for important NTP surveys and studies such as national TB prevalence and MDR surveys.
  – To conduct operational research to determine the reasons for low positive smears at two-month follow-up and to evaluate yield of two vs three sputum specimens in diagnosing TB.
  – To evaluate the use of fluorescence microscopy especially for the diagnosis of TB in high HIV settings.
  – To evaluate the use of molecular diagnostic techniques for the diagnosis of TB and detection of drug sensitivity.
  – To conduct a study on private laboratories and clinics to observe the practices in TB diagnosis and quality of private practitioners.
Output 7: Partnership and Advocacy

• Main Strategies:
  – Establish a TB laboratory technical working group to include national and international partners.
  – Explore possibility of developing Memorandum of Understanding and Terms of Reference with institutions/partners.
  – Collaborate with universities and research institutes (national or international) to share experiences and organize studies relevance to NTP goals.
  – Promote advocacy activities to keep TB laboratories as a high priority for NTP, especially for resource mobilization.
Output 7: Partnership and Advocacy

- Main Activities
  - To conduct monthly meeting of TB laboratory technical working group to review progress and tackle issues.
  - To establish a mechanisms to work with private laboratories involved in the diagnosis of TB to improve capabilities and reliability of those labs.
  - To establish lies with other national institutes to utilize the unique strengths of each institution in supervision, training, QA or molecular diagnosis.
  - To be network with other laboratories performing the culture and DST.
  - To participate in joint research activities with other institutions.
  - Collaborate with universities and research institutes national or international to share experiences and recognize studies relevant to NTP goals.
  - To design and carry out advocacy action plan, which includes campaign and other activities to mobilize resources for TB labs.
Output 8: Financing

• Main Strategies:
  – Develop strategies to mobilize resources for strengthening the TB laboratory network.
  – Develop a detailed annual work plan with estimated budget to secure funding.
Output 8: Financing

• Main Activities:
  – To enlist technical assistance from partners to develop proposals to mobilize resources for the TB laboratories.
  – To promote activities related to resource mobilization for TB lab based on the identified strategies.
  – To organize an annual workshop to develop an annual work plan for the TB laboratory network with clearly defined activities, indicators, budget and responsibilities.
Risk Assessment

• The Strategic Plan to Stop TB has also identified a number of risk factors as the most relevant to the high TB burden countries:
  – Decentralization of TB control activities to lower levels;
  – Loss or decline in commitment to TB control.
  – Social and economic conditions.
  – Shifting TB control responsibilities outside the public sector.
  – Reduced funding level.
TB control Program in Cambodia
Cambodia National Strategic Plan for TB Laboratories

- The National Strategic Plan for TB Lab in Cambodia 2007-2010 has been developed in response to a main objective in the national Health Strategic Plan for TB Control in Kingdom of Cambodia 2006-2010, especially to develop a five years strategic plan for strengthening the National TB Reference Lab (NRL) and the other entire TB lab in NTP network.

- TB Lab strengthening will be on agenda not only for quality enhancement, but also for some new specific activities such as diagnosis and management for MDR-TB and TB-HIV cases, as well as research work.
The recommendations by JPR

• Laboratory achievements observed by the JPR
  – Implementation and decentralization of Lab service.
  – Decentralization of slide preparation to the health center has contributed to increasing access to diagnostic services.
  – Implementation of quality assurance programs.

• Others observations
  – Performance should be improved though strengthened quality assurance implementation.
  – Develop of comprehensive of Standard Operating Procedures (SOP)
  – Regular inventories should be conducted and laboratory procurement and distribution should be strengthened and should include a buffer stock policy.
  – Quality of reading of control slide (month 2, and month 6) should be assessed separately from the standard EQA.
National Strategic Plan (NSP)

• The National Strategic Plan of NTP for the next five years (2006-2010) is focused on the continuing process of decentralization, through the expansion of community DOTS and also through the scaling up TB/HIV collaborative activities and PPM-DOTS, while making efforts to enhance the quality of services, booth clinical and diagnostic.

• The accelerated DOTS expansion program launched during first 5 years plan resulted in a four fold increase in number of TB suspects, from 29 000 in 2001 to 117 000 in 2005 while the number of smear positive TB cases increased from 14 000 to 21 000 an increases of 46%.
TB suspected and smear positive cases

Figure 1: The no. of suspects and the no. and percent of smear positive cases

Source: CENAT, 2007
Strengthen TB Laboratories

• The strengthening the National Reference Laboratory at CENAT and the laboratories network in the country to establish quality diagnosis of extra pulmonary and smear-negative TB, childhood tuberculosis and MDR-TB.

• There has been an increase in the proportions of extra-pulmonary and smear-negative forms, including increased utilization of chest x-ray facilities.

• Training on TB-HIV is expanding and could have a further impact on the capacity to diagnose smear-negative pulmonary TB.
Proportion of extra-pulmonary and smear negative TB cases

Figure 3: Increase in the proportion of extra-pulmonary and smear negative TB cases

Source: CENAT, 2007
Resources Needs

• CENAT would estimate the specific needs of the national TB Reference Laboratory and the TB microscopy network and develop a budget plan for next five years, in line with National Strategic Plan of NTP (2006-2010)

• This would take into consideration the resources required for the implementation of the National Strategic Plan for the strengthening the TB laboratory network and enhancing the TB diagnostic service to improve the diagnosis and management of extra-pulmonary and smear negative TB as well as MDR-TB.
TB Microscopy Network in Cambodia

Source: CENAT, 2007
Achievement of TB Laboratory

Total Number of Examined Slides
Number of TB Suspect
S(+) Rate Among TB Suspect

Source: CENAT, 2007
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Overall trend of EQA from 2002 to 1st Semester 2007

Source: CENAT, 2007

Tuberculosis, Shanghai May, 12-22, 2008
Trend of HIV positive among TB patients

From 2003 - 2007 in CENAT

Tuberculosis, Shanghai May, 12-22, 2008

Source: CENAT, 2007
References

• Strategic Approach for strengthening of laboratory services for tuberculosis control program. Geneva. World Health Organization, 2006
• Strategic plan to stop TB in the Western Pacific 2006-2010. World Health Organization, Western Pacific Region, 2006.
• International Standards for Tuberculosis Care. Tuberculosis Coalition for Technical Assistance, TBCTA 2006
• Strategic Plan for TB Laboratories in Cambodia, MoH/CENAT, 2007.
• National Health Strategic Plan for Tuberculosis Control in The Kingdom of Cambodia, 2006-2010. MoH/CENAT, 2006
• Joint Program Review: National Tuberculosis Program Cambodia, MoH/CENAT 2006
• An Assessment of the Private Sector services for Tuberculosis in Cambodia. CENAT/UCR/USAID, 2004
• Review of law, Policies and clinical Practices of Private Medical and Pharmaceutical Sector for Tuberculosis Control, CENAT/UCR/USAID, 2004
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