

Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization

*22-24 January 2008
Maputo, Mozambique*

Helping to Expand Sustainable Quality Testing to Improve the Care and Treatment of People Infected with and Affected by HIV/AIDS, TB and Malaria



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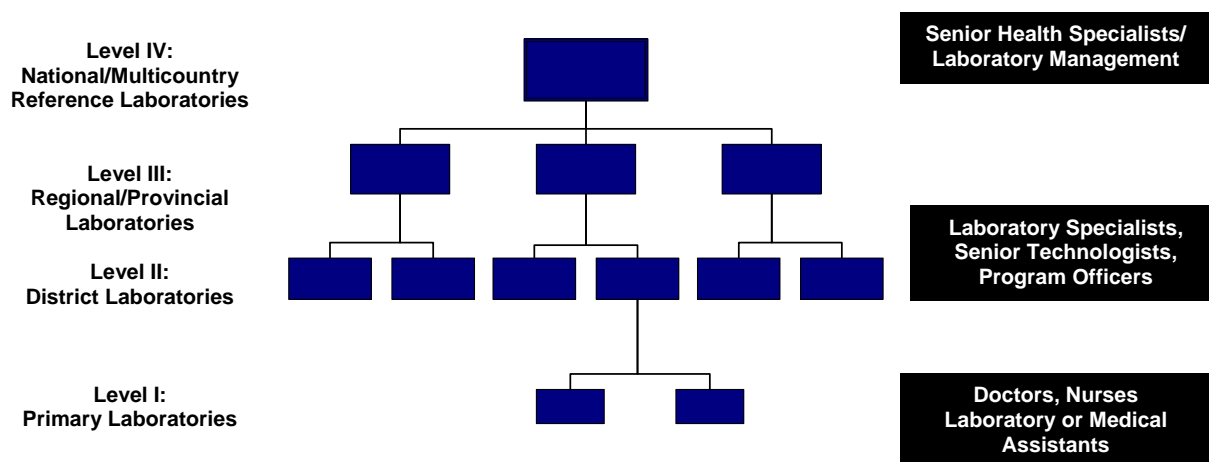
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I. Introduction

A consensus meeting of major stakeholders who were charged with making recommendations on laboratory testing standardization and harmonization in three major areas was held on 22-24 January 2008 in Maputo, Mozambique. The three areas discussed were: 1) testing needed at each level of a tiered, integrated laboratory network; 2) standardization of laboratory equipment and supplies at each level of a tiered laboratory network; and 3) key considerations to guide maintenance and service contracts for equipment at each level of a tiered laboratory network.

This effort seeks to strengthen laboratory capacity in resource-limited settings. It is believed that the best way to do this is by building sustainable laboratory capabilities that will provide access to high quality, rapid, and affordable diagnostic tests for the care, treatment, prevention and surveillance of HIV/AIDS, tuberculosis (TB) and malaria. A tiered, integrated laboratory network (see **Figure 1**) may provide the best model for service delivery across various levels of the public health system in resource-limited settings.

Figure 1: The Tiered, Integrated Laboratory Network



Accurate and reliable clinical laboratory testing is an important component of a public health approach to disease management in resource-limited settings. Laboratory data are essential for clinicians to accurately assess the status of patients' health, make accurate diagnoses, formulate treatment plans, and subsequently monitor the effects of treatment. The clinician must be able to trust the test results from the laboratory in order to use them for clinical diagnosis and treatment. As a result, the results must be accurate, reliable and timely.

In order for laboratories to provide high quality test results, the following systems must be available:

1. **Human capacity** - Competent staff who are adequately trained; effective supervision by managerial staff. Recruitment and retention programs are required to maintain trained personnel. Formal, pre-service training programs as well as orientation, performance appraisals, and in-service training systems must also be available.

2. **Infrastructure** - A safe and suitable physical environment with ample space, power, climate control, water and transport access. There should be an uninterruptible power supply (UPS) supporting laboratory equipment in case of power surges. Sufficient light, bench space, mains or bore hole water, and distilled water are also required. In place must be high quality, functioning laboratory equipment and a supply chain management system to provide adequate supplies of reagents, consumables and quality control (QC) materials. The laboratory environment should have enough space to perform day-to-day operations safely and efficiently and to store cold chain and non-cold chain supplies.

3. **Management of Quality Systems** - Effective laboratory quality systems, including well-written policies and procedures, a QC system, quality improvement (QI), external quality assessments (EQA), and accreditation standards should exist. Standard operating procedures (SOPs) must be understood and implemented to ensure overall test reliability, which includes test accuracy and precision. Laboratory professionals should routinely perform QC testing to guarantee that the test methods and equipment perform according to the established standards. Laboratory professionals must participate in EQA/proficiency testing (PT) programs in order to demonstrate that they have acceptable systems and that specimens are collected and processed appropriately.

II. Introduction to the Tiered Laboratory Network

The Laboratory Network in Resource-Limited Settings

A tiered laboratory network is an integrated system of laboratories organized in alignment with the public health delivery network in a country. In resource-limited settings, the following four levels of laboratories are desirable to best deliver services in a national laboratory network:

1. **Level I-Primary:** Health post and health center laboratories that primarily serve outpatients.
2. **Level II- District:** Laboratories in intermediate referral facilities (e.g., district hospitals).
3. **Level III-Regional/Provincial:** Laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health bureau.
4. **Level IV-National/Multicountry Reference Laboratory:** The national/multicountry public health reference laboratory for one or more countries.

The tiered levels of a laboratory system and the testing performed at each level may vary depending on the population served (e.g., infants, adults), level of service available, physical infrastructure, electricity, water, road conditions, and the availability of trained technical personnel in-country.

Level I Laboratories

Level I laboratories would consist of health post or health center laboratories that would primarily serve outpatients. Essential infrastructure, such as clean water, refrigeration and electricity, may or may not be available. These laboratories would serve as peripheral branches of Level II laboratories, which would be the center or hub. Health posts may collect and/or refer specimens to health center laboratories. Diploma level staff at Level I laboratories would be very limited, with usually no more than one trained laboratory assistant or nurse providing services. Basic quality assurance (QA), QC and record keeping functions must be performed at this level. QA activities would focus on adequate specimen collection and basic reagent use. The laboratory would offer diagnostic and monitoring services for HIV/AIDS, TB and malaria. If essential infrastructure were lacking, then the on-site test menu would be restricted to manual tests. In many instances, Level I laboratories would perform specimen collections and simplified techniques such as the collection of dried blood spot (DBS) and rapid/dipstick tests. Sites with reliable power and water would perform certain automated chemistry tests required for antiretroviral therapy (ART) monitoring. Same day performance and delivery of results must be available while the patient is present in order to provide immediate counseling, treatment and regimen modification.

When required testing exceeds the scope of services available from Level I facilities, the “parent” Level II laboratories would provide a range of consultant services, including the receipt of referral specimens and patients. In many cases, such as with DBS or a TB culture, the specimen may bypass a Level II laboratory and go directly to the nearest performing laboratory.

Level II Laboratories

Level II laboratories would consist of district hospitals or primary hospital laboratories that perform tests beyond the capabilities of Level I facilities. Health posts may refer specimens to Health Center Laboratories under Level I. Serving inpatients, these laboratories would have dedicated laboratory space, formally trained personnel, UPS systems and a consistent source of reagent grade water. The laboratory would be staffed by a minimum of three formally trained technologists or technicians. One staff member who has managerial skills would serve as the senior or supervisory technologist.

The Level II laboratories would have more extensive test menus for diagnoses and treatment. Consolidating testing at the district level for certain tests provides necessary volumes for automated equipment platforms. The Level II laboratories would coordinate the services of Level I laboratories in the district as well as serve as reagent and supply reservoir/back-up repositories for these laboratories. In addition, Level II laboratories would provide the following consultant services and support for Level I laboratories:

- Managerial oversight of an outreach program of peripheral primary laboratories (Refer to Annex J, Reference No. 1)
- Referral laboratory services with a more extensive test menu
- On-site quality assessment visits
- Assistance with resolving technical problems
- Data management support with a strong paper-based laboratory information system (should be part of a national system of data collection by the Ministry of Health [MOH])
- Development and implementation of QA activities (including, but not limited to QC, QI and EQA/PT)
- Periodic review of QC
- Information and training for adequate specimen collection
- Collection of data for assessment of quality indicators
- Approval and annual review of SOPs and policies to ensure alignment with current practices
- Assistance with development of SOPs and safety procedures
- Staff development/training, performance management, competency assessment, and retraining
- Coordination of courier/transport services
- Assistance with results reporting and record retention
- Equipment maintenance and service support including review of maintenance logs
- Follow-up on laboratory incident and accident reports
- Assessment of safety management practices

Level III Laboratories

Level III laboratories would consist of laboratories in tertiary referral facilities such as regional or provincial hospitals. These laboratories would perform a complete menu of testing for HIV/AIDS, TB and malaria as well as testing for many other diseases. Level III laboratories would complete the more sophisticated tests at a higher throughput level that Level II laboratories were not able to perform. These facilities must have dedicated laboratory space that would include a separate microbiology space and UPS systems. While a Biosafety Level III designated area would be desirable, the minimum requirement in areas where specimens are handled would be Biosafety Level II. Reagent grade water would also be required. Formally trained, diploma level technologists who are able to meet workload demands would staff Level III laboratories. One technologist who has managerial skills would serve as the laboratory supervisor. Level III laboratories would act as laboratory resource groups for the facilities in their regions.

In addition, Level III laboratories would provide the following services:

- A more comprehensive test menu than that provided at Level II laboratories

- Coordinate laboratory services and information management with other Level III laboratories
- Perform assessments of laboratories in the region; evaluate the QA data from laboratories in the region
- Coordinate surveillance data collection from lower levels in an effort to obtain country-wide statistics
- May collect and submit inter-laboratory comparisons and EQA data for the region to the national reference laboratory
- Develop training programs and coordination of continuing education
- Assure adequate requisition and reporting mechanisms as well as record retention procedures
- Standardize units, methodologies and reference ranges based on national reference laboratory recommendations
- Determine the amount of patient history/clinical presentation required for tests referred to other levels
- Provide logistical and management support to their service areas

Level IV Laboratories (National/Multicountry Reference Laboratories)

Level IV national/multicountry reference laboratories are recommended to strengthen laboratory capacity for diseases of public health concern. Ideally, they would provide linkages with research laboratories, academic institutions and other public health laboratories, forming integrated laboratory networks that can provide assistance in clinical trials, evaluation of new technologies and surveillance. Senior program employees, laboratory management and senior laboratory technologists/scientists would staff these laboratories. Level IV laboratories would possess the infrastructure, equipment, information systems, and logistical capabilities of sophisticated reference laboratories (i.e., Biosafety Level III specifications). In some countries lacking a unique national/multicountry reference laboratory, Level III laboratories may serve as national reference laboratories.

Level IV National/Multicountry Reference Laboratories would:

- Perform molecular and esoteric testing beyond the technical capabilities of Level III laboratories (e.g., nucleic acid assays, HIV drug resistance studies, TB drug susceptibility studies)
- Develop and/or adopt laboratory standards (i.e., ISO 15189) and processes for laboratory accreditation
- Develop monitoring and evaluation activities for laboratories
- Serve as the national coordinator for HIV, TB and malaria laboratory programs
- Maintain national database of equipment and maintenance in country(s)
- Participate in international EQA programs and develop/oversee national EQA programs
- Provide input on national laboratory policy development
- Determine what information needs to be supplied with the test result to better interpret the results
- Provide courier and logistics management support for the regions

- Develop and implement testing algorithms and automatic performance of additional tests (reflex) for laboratory utilization
- Establish standards for quality management and assist with policy and procedure development
- Provide assistance with reference range validations and development of national reference ranges specific to equipment/methods used
- Coordinate the collection of surveillance data to obtain and monitor country-wide statistics
- Introduce and implement new technologies, appropriate for each level, to reflect current best practices
- Select and evaluate diagnostic tests
- Define sensitivity and specificity requirements in order to select methods that would be evaluated with a method validation plan

Group Work and Recommendations

Breakout Session 1: Review and agree on the laboratory tests and services needed at each level of a tiered, integrated laboratory network.

The participants were divided into five breakout groups. The major task was to review the *Draft Working Resource Document and WHO Technical Consultation Report* to agree on the different levels of laboratories and to establish the tests required at each level of the laboratory network. The basic questions for consensus discussion included:

- 1) What are the definitions of each level of a tiered laboratory network?
- 2) What tests are required at each level?
- 3) What are the infrastructure requirements for testing at each level?

Question 1: The groups agreed that four levels are recommended for laboratory networks in resource-limited countries: Level I (Primary), Level II (District), Level III (Regional/Provincial) and Level IV (National/Multicountry Reference Laboratory). The groups added Level IV, recognizing the need for national coordination of laboratory services, administrative policy support, QA, test development, EQA and surveillance support. The descriptions of each level in a tiered laboratory network are included earlier in this section.

Question 2:

Level I laboratory tests and services

- HIV rapid tests
- Hemoglobin
- Whole blood glucose by glucometer
- Rapid syphilis test
- AFB smear by light microscopy
- Wet mounts
- Urine pregnancy rapid test

- Malaria rapid test
- Malaria smear
- Urine dipstick
- DBS collection
- ALT and creatinine (could be considered at sites with adequate infrastructure)

Level II laboratory tests and services

- All tests and services performed at Level I
- CD4 counts (absolute required; % is preferable)
- HIV serology by EIA (could be considered at Level II if volume and technical capabilities support it)
- Complete blood count (CBC) with differential
- Chemistries
 - Liver function tests (ALT, bilirubin)
 - Serum electrolytes
 - Renal function tests (creatinine, urea nitrogen)
 - Lipid profile
 - Serum amylase
 - Glucose
- Whole blood lactate
- Syphilis serology test
- Cryptococcal antigen
- India ink
- Gram's stain
- Urine dipstick with microscopy
- Type and crossmatch
- CSF/body fluid cell counts
- Hepatitis B
- Hepatitis C (guided by local prevalence)

Note: Microbiology culture and susceptibilities may be offered at higher volume sites.

Level III laboratory tests and services

- All tests and services performed at Levels I and II
- Microbiology culture, identification and susceptibilities
- Blood cultures
- Complete chemistry panel
- AFB smear (by fluorescent technique)
- AFB culture, identification and susceptibility (first-line drugs)*
- Quantitative nucleic acid test for ARV monitoring (PCR, bDNA)
- Qualitative nucleic acid testing for diagnosis of infants (DNA PCR)

*TB susceptibility based on burden and reference laboratory capacity

Level IV laboratory tests and services

- All tests and services performed at Levels I, II and III
- HIV resistance testing
- AFB susceptibility (for first- and second-line drugs)
- Ultrasensitive p24 antigen
- Quantitative nucleic acid testing for ARV monitoring (HIV RNA)
- Qualitative nucleic acid testing (HIV RNA)
- Variety of diagnostic testing
- Other esoteric reference lab testing as needed

See **Annex C** for the summary of workgroup recommendations for laboratory tests performed at each level of a laboratory network.

Question 3: The workgroups agreed with the infrastructure requirements for each level as described earlier in this section.

III. Acquisition and Standardization of Laboratory Equipment

Laboratory test quality relies on the availability of laboratory equipment, reagents and consumables that meet minimum quality standards. In an effort to enhance quality and promise efficient resource use, equipment should be standardized wherever possible in a tiered laboratory network.

Standardization and procurement policies should be defined by MOH in collaboration with physicians, laboratory staff and policy makers. Standardizing the type of platform for laboratory equipment in chemistry, hematology and CD4 across different laboratory levels offers many benefits, including:

- Cost reduction due to bulk procurement
- Ease of service due to a limited variety of platforms
- Higher manufacturer investment in service and distribution capability in-country
- Ease of staff training due to common user interface on the systems
- Minimal additional training needed when staff members move from laboratory to laboratory
- Better standardization of reference ranges and test results, thus better continuity of care for patients who transfer from health centers to district facilities

Standardization of equipment requires that manufacturers provide truly scalable equipment options that meet the low, medium and high volume testing needs of Level I, II, III and IV laboratories. If this is not possible, standardization of no more than two equipment platforms should be considered. While standardization provides many benefits, each country must make sure, through good contract language (see **Section V**), that it receives the financial and maintenance benefits associated with sole sourcing. In many resource-limited countries, there is currently a diversity of equipment platforms as a result of the lack of standardization, regulations that promote competition, donated equipment, and decentralized procurement systems.

To provide guidance on vendor selection, pre-qualification conditions can be set for major laboratory equipment and commodities. Presently, there is limited guidance on the quality of reagents and equipment, especially for hematology and chemistry machines. Purchasers may need to obtain independent evaluation information on the quality of equipment from a variety of sources (particularly other users). The WHO guidelines on diagnostics are expanding and now exist for certain test domains, including CD4, HIV (rapid and ELISA) and rapid syphilis testing. Geneva's Stop TB Department is currently preparing technical specifications for TB lab equipment and supplies plus guidelines for management. The finalized specifications, which are complimentary to this report, will be available in September 2008 and will be posted on WHO's website. Refer to **Annex J** for a complete list of available reference documents.

The first step in standardization of equipment in a laboratory system is to define the tests performed at each level in order to match test system capacity with expected volumes for each test. A list of potential manufacturers who meet basic requirements must be developed and assessed for domestic or international historical performance. Ideally, a list of pre-qualified vendors would be established based on WHO guidelines. A team of laboratory technicians should provide input, and along with procurement specialists, should develop technical specifications for equipment acquisitions. **Table 1** lists important aspects to consider when selecting laboratory equipment.

Table 1: Key Criteria for Selection of Laboratory Equipment

❖ Infrastructure (power, generator, water, temperature, space)
❖ Environmental conditions
❖ Laboratory workload; staff skills and training
❖ Vendor support, reliability and availability (in-country or region)
❖ Availability, stability and temperature sensitivity of reagents, controls and calibrators
❖ Availability of local service, technical and training support
❖ Simplicity of operation; ease of maintenance and calibration
❖ Track record of performance (domestic and/or international)
❖ Analytical performance/technical quality (sensitivity, specificity, reliability, level of detection)
❖ Test menu (consider scalability for various volumes)
❖ Open or closed test/reagent system
❖ System costs (includes equipment, service, reagents, and supplies); cost per reported test
❖ Specimen types
❖ Throughput
❖ Turnaround time
❖ QC and QA required
❖ Availability of EQA and inter-laboratory comparisons
❖ Data management capability; interface capability
❖ Safety
❖ Availability of back-up methods
❖ Supply chain management capability

A variety of acquisition methods exist for laboratory equipment. The three most common are:

1. Purchase
2. Lease
3. Reagent rental

All three methods entail expenses for equipment, service and reagents/consumables, with invoices and payments being handled in different ways. Purchasers should carefully evaluate the equipment acquisition contracts to identify minimum volume commitments, service requirements, training that is included, user support, warranty provisions and reagent pricing discounts. Negotiation of these elements in the contract is required to guarantee that the best value and the lowest costs are obtained from the vendor. Refer to **Annexes H and I**, which include important considerations when procuring laboratory equipment and negotiating contracts. It's important to note that everything in the contract is negotiable (see **Section V**). The input of the MOH officials would be desirable in the procurement and negotiation for laboratory equipment, service, reagents and supplies.

Key considerations for the most common acquisition methods for laboratory equipment are displayed in **Table 2**.

Table 2: Considerations for Laboratory Equipment Acquisition

PURCHASE	LEASE	REAGENT RENTAL
Can result in discounted price	Requires minimum initial cash outlay	Requires minimum cash outlay
Reagent cost may be less	Risk of obsolescence is less as lease term is usually no more than 5 years	Agreements are easy to set up with the vendor
Equipment expense can be depreciated	Equipment can be upgraded for a new model and can be returned after the lease period	Cost of equipment, reagents and service is spread across each test as you are paying a fixed amount on a per-test basis
Can be used as a trade-in for upgraded models	Difficulties returning equipment may exist in certain countries	Reagent costs are higher as cost of equipment and service is bundled in reagent cost
Requires a significant initial cash outlay	Vendors may be hesitant to lease equipment unless risks are minimized (assured return)	Volume commitments must be accurate as these are the basis for pricing
Risk of obsolescence in 5-7 years	Allows options for buying equipment at the end of the lease such as 1 USD or fair market buy-out	Flexible option with predictable fixed costs per month
Equipment must be disposed of at some point	Allows for trying out the equipment before buying it	Equipment issues regarding import and return are similar as for leasing
	Total cost is higher than purchase due to financing	A buy-out option does not exist
	Reagent pricing must be negotiated separately from the lease based on volumes	Most desirable for changing technologies and high-cost systems due to risk of obsolescence in 5 years

Group Work and Recommendations

Breakout Session 2: To develop a consensus to guide standardization of laboratory equipment at each level of an integrated, tiered laboratory network.

The participants were divided into five breakout groups. The major task was to review the *Draft Working Resource Document* tables and equipment considerations in order to make recommendations on laboratory equipment for each level of the laboratory network. The basic questions for consensus discussion included:

- 1) What are the criteria for the selection of laboratory equipment?
- 2) What laboratory equipment is appropriate for the different tests performed at the different levels of an integrated laboratory network?
- 3) What are the recommendations regarding donated equipment?

Question 1: The groups concurred with the criteria for equipment selection listed in **Table 1**.

Question 2: There was agreement that specifications should be defined for each type of equipment. In addition, examples of equipment that meet those specifications should be listed. The WHO guidelines for equipment/methods should be used where available. The workgroups' suggestions regarding tests and equipment for each level of testing as well as manufacturer options are listed in **Annex E**. This list is not meant to be inclusive of all available equipment or vendor choices, but rather to provide options that meet the specifications listed.

Question 3: The workgroups agreed to use the *WHO Guidelines on the Donation of Medical Equipment*. (Refer to Annex J, Reference No. 2). In addition to the WHO guidelines, the following recommendations were made for donated laboratory equipment:

- Donated equipment should be accepted only if part of the laboratory strategic plan.
- Donors should be involved in national laboratory planning.
- Countries should have clear policies at the central level with a list of acceptable reagents and equipment.
- Donors should send equipment specifications prior to delivery.
- Donated laboratory equipment should have at least 80% useful life remaining at time of donation.
- Donated equipment should follow normal supply management processes to assure adequate reagents and supplies; service, maintenance and training systems must be available.
- Vendors should be pre-qualified where possible within the country by the national laboratory system.
- Equipment retirement procedures need to be developed and followed for donated and other equipment.

IV. Equipment Maintenance and Service Contracts

The purchase and maintenance of laboratory equipment are critical to ensuring quality laboratory testing. With quality testing, analyses will be accessible and timely; the requirements for specimen transport will be minimized; and, ultimately, the needs of the patients and communities will be better served. Laboratory equipment maintenance begins with equipment selection and purchase, and is later influenced by infrastructure, training, preventative maintenance and servicing. Therefore, these are all important considerations.

Selection criteria for equipment were previously listed (**Section IV, Table 1**). An important consideration for laboratory maintenance is selecting platforms that are multipurpose (e.g., ELISA platform that provides multiple assays). Having to maintain a single piece of equipment that performs multiple tests will allow for higher quality laboratory testing than having several pieces of equipment with each performing one test or analysis.

Proper infrastructure is also essential for good laboratory maintenance. Equipment must be housed in a proper environment, with consideration of power sources, water quality, dust, climate and appropriate space.

Various purchase methods were previously discussed (**Section IV, Table 2**). The method of equipment acquisition—purchase, lease or reagent rental—is important since it is associated with varying degrees of maintenance support. Proper staff training (initial and follow-up) should be negotiated as part of the equipment purchase. Training is required, not only for the proper operation of laboratory equipment, but also for good laboratory practices, quality testing, proper specimen collection, reagent forecasting and SOP development.

Two types of preventative maintenance are required: laboratory-initiated and manufacturer/service provider-initiated. As part of the initial training, laboratory personnel should learn to provide daily, weekly, monthly and semi-annual preventative maintenance. The timing of the preventative maintenance varies by equipment so a maintenance schedule should be provided for each piece of equipment. Although many maintenance requirements will also be specific to each piece of equipment, there are some general guidelines:

- Internal controls must be run to ensure proper function of the equipment and reagents.
- Proper specimen collection techniques must be practiced and proper reagents must be used.
- Equipment should be covered when not in use and dust should be wiped off at least once a week.
- Maintenance procedures, maintenance logs for documentation, and supervisory reviews of maintenance performed should be developed and shared by laboratories.

The manufacturers' responsibilities for providing preventative maintenance checks on equipment are included in the warranties or service contracts. Quarterly or bi-annual preventative maintenance visits should generally be expected and negotiated. In addition to preventative maintenance details, service contracts and warranties will describe how manufacturers should respond to service needs. Services provided (e.g., troubleshooting, loaners, upgrades, spare parts, scheduling of maintenance visits, training) and costs incurred (e.g., parts, labor, travel, shipping) need to be negotiated and

defined in the service contracts. **Annexes H and I** include important considerations when procuring laboratory equipment and negotiating contracts.

There are significant maintenance challenges in resource-limited countries, including poor infrastructure, equipment placed in remote locations, perceived inability to negotiate with vendors, inadequate procurement and distribution systems, as well as the lack of trained staff, manufacturer presence, communication, information and integration.

These challenges may be addressed by:

- Addressing infrastructure needs
- Developing partnerships between laboratories and manufacturers
- Cross-training personnel on equipment service
- Encouraging manufacturers to establish local representation
- Insisting that manufacturers have available loaners
- Ensuring that laboratories have back up equipment or techniques
- Providing continuing education for laboratory staff
- Developing an integrated laboratory network

In addition, accountability for laboratory performance is critical. Supervision by management staff is integral to maintaining a quality system of equipment and supplies. Also essential to developing proper maintenance practices within a laboratory is involving all staff members in the process. This entails utilizing the individual or collective power of countries/regions with manufacturers and vendors, setting high goals (but reasonable within the laboratory capacity), and helping to redefine existing norms that will make certain that quality laboratory testing is accessible to patients in their communities.

Group Work and Recommendations

Breakout Session 3: To develop a consensus on the key considerations to guide maintenance and service contracts for equipment at the various levels of an integrated, tiered laboratory network.

The participants were divided into five breakout groups. The major task was to review the questions for consensus and to identify maintenance and service issues. In addition, to help guide decision-making, the groups were to make recommendations on equipment service, maintenance and supply delivery. The following questions were discussed:

- 1) What are the issues that exist in the areas of service contracts, service delivery and reagent/supply delivery?
- 2) What maintenance, processes, and service and supply chain management infrastructure must exist to assure continuous testing for patient care at each level of the laboratory network?

Question 1: The major issues identified in each area by the workgroups were:

Service Contracts

- Inadequate service contracts
- High cost of service contracts
- Insufficient laboratory contracting knowledge/expertise
- No service contract in place after equipment warranty expires
- No penalties in contract for failure to deliver service

Service Delivery

- Lack of well-trained local service representatives (vendors or local engineers)
- Difficulties in obtaining service and spare parts for equipment in a timely manner
- Limited presence of suppliers and service providers in-country
- Insufficient preventative maintenance
- Inadequate number of service engineers to cover entire country
- High turnover of in-country trained engineers

Reagent/Supply Delivery

- Problems with accurate inventory and supply chain management especially for cold chain items
- Lack of standardized forecasting models in use
- Cumbersome purchasing processes
- Lack of central purchasing system in certain countries
- Weak delivery system by suppliers

Question #2: Considerations for maintenance and service infrastructure included:

Service Contracts (after-sale maintenance contracts)

- Service contracts should be negotiated at time of equipment procurement.
- Reagent rental agreements with bundled service and reagents should be considered.
- Contracts could be for a minimum of 3 years, renewable with no cost increase annually.
- Service contracts should include at a minimum:
 - Response time (ideally within 48 hours).
 - Number of preventative maintenance visits (as required by the manufacturer).
 - Training of local service engineers and users.
 - Availability of routine/emergency service.
 - Costs incurred outside of the contract.
- Penalties should exist in the contracts for failure to meet the conditions of the agreements.
- A periodic contract review process to determine compliance should be in place.
- Local service providers should be certified by the manufacturer.
- Contracts should provide for backup support (loaners) within 72 hours and access to spare parts.
- Contracts should include a contingency plan for returning equipment for service if repairs cannot be done in-country.

- In-country support should be guaranteed in the contracts.

Service Delivery

- Qualified service technicians should exist locally for the number of equipment.
- Structured formal training programs should exist to train and qualify local engineers.
- Engineers should install, train, service and help users with problem solving (in order to accomplish this, they should speak local language).
- Regular schedules of preventative maintenance should be established and followed by laboratory users and service providers.
- Laboratory sites should obtain and retain documentation of services performed by service providers.
- Hotlines for real time support should be available.
- Engineers should arrive with proper equipment and spare parts.
- Engineers should have access to loaner equipment to swap out if on-site repairs are not possible.
- Troubleshooting and service tips should be shared with users.
- Local service providers should have good relationships with manufacturers.
- Vendors should provide periodic information on recalls and updates.
- Laboratories should actively monitor equipment including service and maintenance as part of the QA program.
- Laboratories should report any adverse events to the manufacturers, documenting downtime and service problems.

Reagent/Supply Delivery

- Defined forecasting and inventory management systems should be operational in each laboratory.
- Reagent rental and standing orders for reagent delivery should be options.
- Central coordinating bodies should perform regular reviews and verify sustainable supply chain management systems.
- Lot assurance should be provided by suppliers.
- Pack size should meet facility and transportation requirements.
- Cold chain requirements should be met in transport and storage at each site.
- Effective clearance procedures and duty waivers should be available.
- National policy should exist for minimum expiry dates on reagents.
- Feedback from users on reagent/supply delivery systems should be obtained.
- Reliable distributors/agents should exist in-country.
- Replacement policy for unusable or expired products should be defined in contracts.
- Quality assessment of products to be used in-country must be performed.
- Quality should drive procurement more than cost.
- Sole sourcing should occur only if unavoidable.
- Global pricing may be useful to reduce high local costs.
- A centralized, transparent procurement system is desirable.
- Streamlined purchasing and payment processes should be in place to avoid stock-outs.

- Competition among quality suppliers should be encouraged.

ANNEXES

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