World Health Organization

REPORT

Meeting on Procurement of Laboratory Items

WHO/HQ, Geneva

27 - 28 October 2008

Jointly organized by

AIDS Medicines and Diagnostics Service
HIV Department

Diagnostics and Laboratory Technology
Essential Health Technologies

Table of Contents

Acronyms

AFB	Acid-fast bacilli (TB)
AFRO	WHO Region Office for Africa
AMDS	AIDS Medicines and Diagnostic Service
ART	Antiretroviral Therapy
APHL	Association of Public Health Laboratories
ASCP	American Society for Clinical Pathology
CDC	Centers for Disease Control and Prevention
CHAI	Clinton HIV/AIDS Initiative
CPS	Contracting and Procurement Service
DLT	Diagnostics and Laboratory Technology
DST	Drug Sensitivity Testing
EHT	Essential Health Technologies
EQAS	External Quality Assurance Scheme
FIND	Foundation for Innovative New Diagnostics
GDF	Global Drug Facility
GMP	Global Malaria Programme
GPRM	Global Price Reporting Mechanism
HBAg	Hepatitis B surface antigen
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HSS	Health Systems Strengthening
IDA	International Dispensary Association
IT	Information Technology
LMIS	Logistic Management Information System
M&E	Monitoring and Evaluation
MDRTB	Multi drug resistant TB
MoH	Ministry of Health
PEPFAR	Presidents Emergency Plan for AIDS Relief
MSH	Management Sciences for Health
PHC	Primary Health Care
PMS	Post Market Surveillance
PMTCT	Prevention of Mother to Child Transmission
PQDx	Prequalification of Diagnostics
PSM	Procurement and Supply Management
QMS	Quality Management System
SCMS	Partnerships for Supply Chain Management System
SOP	Standard Operating Procedure
SSH	Systems Strengthening and HIV
STB	Stop TB
STD	Sexually transmitted disease
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNICEF	United Nations Children Fund
USAID	United States Agency for International Development
XDR-TB	Extensively drug-resistant TB
WHO	World Health Organization

Executive Summary

Issues and Objectives

The procurement of laboratory items is an important issue which was discussed during the Annual AMDS Partners and Stakeholders Meeting held in Geneva, 12-13 December 2007. The Annual AMDS Partners Meeting noted that laboratory items are numerous and create serious challenges to procurement agencies. The Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization, held in Maputo, 22-24 January 2008, has provided more information on this issue. Furthermore, significant progress has been made by WHO in the area of laboratory items (evaluation, prequalification, technical guidance and generic technical specifications) which could be of great assistance for procurement agencies and other partners involved in strengthening laboratory services.

It is in this context that the AIDS Medicines and Diagnostics Service (AMDS) and the Essential Health Technologies (EHT) jointly organized the present consultative meeting on procurement of laboratory items with the following objectives:

(1) To share information about the conclusions, practical implications and next steps of the Consultation Meeting on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization held in Mozambique, Maputo, 22-24 January 2008;
(2) To exchange on (a) current generic technical specifications, norms and guidance and (b) current progress on prequalification of lab items
(3) To take stock of field experiences and country examples on practical issues related to technical specifications and actual procurement process of laboratory items
(4) To take stock of case studies carried out on standardization & harmonization of procurement of laboratory items in selected Sub-Saharan African countries
(5) To make an overview of mostly procured laboratory commodities and laboratory items.

Methodology

There were short presentations followed by interactive discussions. Several topics were presented and discussed in line with the above mentioned methodology. All the topics listed in the agenda found in Annex 1 were covered.

Recommendations and next steps

Before concluding the meeting, Dr Jos Perriens, Coordinator of HIV/SSH, invited participants to propose and agree on areas on which partners could collaborate to contribute to the improvement of procurement of harmonized and standardized laboratory items. The following suggestions of next steps were agreed:

1. WHO recommendations for donated equipment should be disseminated for their use to guide donors and recipients of laboratory equipment.
2. It was recommended to establish a working group on generic specification and definitions of laboratory items to harmonize the work being undertaken by various partners. It was felt that various institutions should collaborate to maximize their effect through synergic efforts.
3. It was also recommended to establish a working group on national laboratory strategic planning of harmonized and standardized laboratory tests. All PEPFAR-supported countries and five countries within the African region have planned to make progress on this endeavor. There was agreement that harmonization/standardization needs to be a country-driven process.
4. Significant progress on harmonization/standardization of laboratory tests has already been made in some countries e.g. Zambia, Kenya, Ethiopia, Rwanda, Mozambique and Cote

d'Ivoire. It was recommended that country case studies on the above successes be developed and disseminated to other countries to raise awareness on the importance of harmonized/standardized laboratory tests. The case study will cover the following sections:

- Background: rationale and reasons behind this endeavour, partners involved, supporting environment such as policy documents, national strategic planning, donor requirements, problems identified during situation analysis, etc.
- Standardization process: steps, challenges, solutions implemented to overcome the challenges, enabling factors, involved partners, number of health facilities and districts covered, time-frame/duration of the process, human and financial resources invested, etc.
- Outcomes: coverage of patients in need (scale-up), financial and programme efficiencies, reduction of the number of required lab items, performance of the supply chain for laboratory supplies, flexibility/exchange of products between services and other opportunities/flexibilities the system offers which would have been impossible without harmonization/standardization.
- Spin-off for the strengthening the health system: e.g.. improved service delivery not only for HIV but also for other diseases, improved management information system for laboratory services and other related health services, human resources performance, improved governance and coordination, etc.
- Conclusion: lessons learned, conditions for success, challenges, how where they overcome, sustainability of the system and next steps.

Successful country experiences can then be used as models for other countries with adaptation to local context.

Dr Jos Perriens concluded the meeting by thanking all partners and indicated that AMDS will follow up with each partner for the establishment of the two working groups. A teleconference with each working group will be convened by AMDS to define the structure of the working group, activities to be carried out, timeline and expected results and the regularity of teleconferences.

For the working group on harmonization and standardization, the focal points from interested institutions who are going to work on this subject need to be identified. Among other activities to be defined, the focal person would provide the list of countries in which the institution is implementing or will implement harmonization and standardization of laboratory tests and timeline. There was some agreement that standardization and harmonization needs to be a country-driven process.

For the working group on generic specification, a first teleconference at a time which is convenient to every member of the group will be convened. The structure of the working group, activities to carry out, timeline and expected results and the regularity of a teleconference to share information will be decided.

1. Introduction

The efficient and effective procurement of laboratory items critically impacts the quality of all laboratory services. This was discussed during the Annual Meeting of AMDS partners and stakeholders organized in Geneva, 12-13 December 2007. Laboratory items are numerous and create serious challenges to procurement agencies. The Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization (Maputo, 22-24 January 2008) has reviewed and provided updated guidance on which tests should be made available at each level of the health system.

Furthermore, significant progress has been made by WHO in the area of laboratory items (evaluation, prequalification, technical guidance manuals and generic technical specifications) which could be of great help for procurement agencies and other partners involved in strengthening laboratory services.

It is in this context and in line with the recommendation of the Annual AMDS Partners meeting that the AIDS Medicines and Diagnostic Services (AMDS) and Essential Health Technologies (EHT) are jointly organizing this consultative meeting on procurement of laboratory items.

The overall objective of the meeting is to find ways for partners to work together in order to improve current process for the procurement of laboratory items.

The specific objectives of the meeting were:

(1) To share information about the conclusions, practical implications and next steps of the Consensus Meeting on Clinical Laboratory Testing Harmonization and Standardization held in Mozambique, Maputo, 22-24 January 2008;
(2) To exchange on (a) current generic technical specifications, norms and guidance and (b) current progress on prequalification of laboratory items
(3) To take stock of field experiences and country examples on practical issues related to technical specifications and actual procurement process of laboratory items
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Dr Steffen Groth, Director, Essential Health Technologies (EHT), noted in his opening remarks that EHT has been asked for an action plan for laboratory assessment and acquisition including guidelines on procurement. and that this meeting is in line with this action plan. Lack of leadership (including laboratory human resource management), advocacy and infrastructure highlight the need to develop national plans and strategies. Dr Groth noted that 'limited capacity limits treatment' and that this meeting is timely in that it coincides with release of the WHO World Health Report 2008 that addresses primary health care and ensuring universal access to services for health. The chairperson, Dr Vincent Habiyambere (AMDS) asked the participants to make a self presentation before the presentations started. The meeting rapporteur was Jeanette Twell (EHT).

2. Presentations and discussions

2.1 Technical and operational recommendations for clinical laboratory testing harmonization and standardization

Dr Guy-Michel Gershy-Damet (AFRO), presented a summary of the Recommendation on Clinical Laboratory Testing Harmonization and Standardization Meeting January 22-24 2008, Maputo, Mozambique. The main points from the Maputo meeting were discussed and the final comprehensive report from this meeting was distributed to participants. Dr Gershy-Damet presented laboratory tests to be performed at each level of the health system and a suggested national laboratory network as agreed upon at the Maputo meeting. This process took into account minimum requirements, current practices and human resource capacity at each level of the health system. It also incorporated the concept that each laboratory performs tests for multiple disease rather than focused on diagnosis of HIV and monitoring of infection only.

Emphasis was made on the importance of laboratory accuracy and having a quality management system (QMS) and laboratory equipment standardization. The problems arising if the laboratory equipment is not standardized (e.g. training, procurement of lab items and maintenance of equipment) were highlighted. Equipment maintenance and service contracts, especially after-sale service contracts were discussed. It was suggested that they should be incorporated in the laboratory QMS. Problems caused by donated laboratory equipment were also discussed. It was suggested that WHO recommendations for donated equipment should be adopted. The importance of quality of diagnostics and laboratory commodities to drive procurement rather than cost was emphasized.

Attention was drawn to the Maputo Declaration. The participants were briefed on the Maputo Declaration on Strengthening Laboratory Systems and a copy of this declaration was distributed. Some of the major points of this Maputo Declaration include: the need to expand and further develop quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings; the need for a national strategic laboratory plan in order to improve and sustain access to laboratory systems; the call on national governments to support laboratory systems and develop national strategic laboratory plans; the call to address the laboratory human resource agenda and the commitment to work collaboratively and accelerate efforts to develop new diagnostic tools. Some countries have already positive outcomes from that Maputo Declaration which gives a clear direction for political commitment and an advocacy tool to add authority to their laboratory strengthening initiatives. The topic below will cover some of these country experiences.

2.2 Standardization/harmonization of laboratory tests & equipment: country experiences

Sherry Orloff (CDC) presented the country experience of standardization and harmonization of laboratory tests and equipment in Tanzania, Cote d'Ivoire, Ethiopia and Botswana. These four countries are supported by Presidents Emergency Plan for AIDS Relief (PEPFAR). Since the Maputo meeting, they have made much progress in standardization of lab equipment and processes. Other countries are active in this area too and there is a need for a mechanism to share information between countries and learn from each other. As a result, it is expected that more countries will adopt harmonization and standardization of lab items.

The participants asked a few questions for clarification. It was confirmed that the PEPFAR programme does not favor US equipment (i.e. US owned or US manufactured) and CDC does not make any specific recommendations in this direction. For procurement of medicines, the PEPFAR programme does favor ARVs which are FDA approved but there currently exists no such restrictions on procurement of laboratory equipment.

The progress depends on the national infrastructure and context. Botswana has made great progress, Tanzania and Ethiopia are well on track and Cote d'Ivoire is moving forward in February 2009.

2. 3. Identification and specifications of laboratory items

This topic was presented by Ludo Scheerlinck (of UNICEF). Twenty UNICEF programmes have a laboratory component and a list of 300 basic and essential laboratory items has been developed with generic specifications developed for many items. UNICEF relies on suppliers to be certified and holding ISO 9001:2000 or ISO 13485:2003 certification.

2. 4. Specifications for WHO procurement of tests for HIV, hepatitis B and C.

This topic was presented by Anita Sands (EHT). An assessment is made of the operational characteristics of commercially available assays including: performance characteristics (sensitivity, specificity, inter-reader variability, predictive values) shelf life, storage temperature, kit size, environmental aspects, package insert clarity (safety instructions and language). The WHO Specimen Reference Panel is used to determine the performance characteristics through a laboratory evaluation conducted at a WHO Collaborating Centre using a geographical diverse specimens and commercially acquired seroconversion and performance panels. A similar exercise is also completed for assays to detection hepatitis C and hepatitis B infection.

When evaluating the diagnostics accuracy of molecular technologies that measure HIV viral load the following considerations should be made: subtype sensitivity, linearity and dynamic range plus ability to utilize dried blood spot (DBS) specimens. Thus far, three companies have developed a protocol for DBS on viral load technologies but these would require further extensive validation including investigation of the effects of specimen transportation. Other considerations are closed versus open systems, the additional equipment required, and level of automation e.g. for nucleic acid extraction.

There are a number of generic commercial aspects that should be considered when undertaking procurement of laboratory items include re-branding, commercial viability of the manufacturer, production capacity, effects of embargos and intellectual property issues such as patents.

Extensive discussions were held on the nature of transportation conditions. Transportation specifications need to be precise e.g. not 'room temperature' but state an exact range e.g. 25°C - 30°C specifically. To transport at 2-30°C degrees would probably mean 'cold chain' but this would depend upon the destination and the mode of transport such as an ocean shipping containers. The manufacturer is obliged to transport products correctly to the end-user. Disposal of hazardous materials must be taken into account e.g. sulphuric acid (H_2SO_4) used as the stop solution necessary for some test procedures.

The language used for the package insert accompanying any diagnostic (particularly rapid tests) is an important element and a process is used by WHO to assess the suitability of the insert. Some products have a simple pictorial depiction. Manufacturers are required to quality assure any software that is mandatory for the performance of an assay but laboratory information technology (including computer security) is out of the scope of this meeting.

2. 5. Technical specifications for TB laboratories

Véronique Vincent (Stop TB) presented this subject. Expectations made of the laboratory are quite high for the safe diagnosis of tuberculosis (TB). Acid-fast bacilli (AFB) smear microscopy for detection of TB bacilli can provide confirmation of diagnosis within a few hours. However, the technique suffers from lack of sensitivity. In 2006, WHO recommended that the presence of at least one AFB in at least one sputum specimen in countries with a well functioning external quality assurance system is now sufficient for confirmation of TB. Culture greatly improves the sensitivity of diagnosis but requires 3-4 weeks on solid media and is particularly useful for AFB smear negative individuals such as those with HIV co-infection. There is an increasing use of liquid media procedures to hasten diagnosis by shortening the time of culture incubation and possibility for increased automation of the technique. In 2008, with the increased recognition of the problem of drug resistance including multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) (>5% of cases who never been on TB treatment on average at the global level have drug resistant TB), WHO is now able to recommend the use of molecular line probe assays . The significant association between TB and HIV has promoted closer collaboration between laboratory services responsible for detection of HIV and detection of TB including joint training for technicians etc. An effective response to the diagnostic challenges of TB-HIV and MDR-TB requires urgent and massive scale-up of laboratory services.

TB is an airborne disease and may be acquired in laboratory by technicians. Staff are entitled to work in safe conditions and bio-safety cabinets are critical for protection. The risk of TB is the same as for the general population when performing microscopy but when performing drug resistance testing, the risk has been found to be 20 times higher if adequate protection is not provided. In a laboratory in Russia, it was found to be 100 times higher for technicians, this risk was reduced to zero staff cases after the laboratory was renovated to improve biosafety capabilities. This is the reason why staff are entitled to work in safe conditions. As the first step of biosafety and security, WHO recommends no access to TB laboratory to individual unless they work in that laboratory.
Lessons learned include ensuring staff and procurement officers are aware of the difference between Laminar Flow Cabinets and Biological Safety Cabinets (protects the worker). Installation and maintenance of bio-safety cabinets (BSCs) are problematic due to lack of qualified installers and bio-engineers.

Generic detailed specifications are needed for procuring all laboratory equipment related to detection of TB. To avoid duplicative efforts, the WHO Global Laboratory Initiative (an interagency working group comprised of UNICEF, UNDP, WHO and other partners) is developing guidelines for the purchase of high quality laboratory products with the description of detailed technical specifications for equipment, consumables and reagents needed in TB laboratories for quality-assured services. The document provides guidance for proper management of equipment and supplies, with specific focus on biosafety. It would be useful to have specifications universally agreed and available. Such specifications could be placed on the PSM Toolbox website which is also available on CD ROM for wide dissemination and easy access.

2. 6. Prequalification of diagnostics and post market surveillance

This topic was presented by Gaby Vercauteren (EHT). She brought to the attention of the meeting participants that in the global market there is confusion regarding re-branding, licensing and manufacture e.g. if a diagnostic is produced in the USA for export, it may not be produced under the same QMS as that produced for the local market.

The main aims of the WHO Prequalification of Diagnostics programme (PQDx) are to promote quality of diagnostics and to build the capacity in the areas of regulation, manufacture and post market surveillance (PMS) of diagnostics. There are 4 parts of WHO PQDx process: (1) review of product dossier, (2) inspection of site of manufacture of the QMS (based on internationally recognized standards), (3) laboratory evaluation (including operational characteristics) and (4) to build the capacity of national regulatory authorities and national laboratory reference laboratories for PMS. The current focus of the programme is on priority diagnostics for resource-limited settings. With regard to already regulated products being fast tracked through the PQ process, an assessment regarding the suitability of necessary equipment to the environment for which it is intended will be made. As part of the PQDx programme, it is a requirement that the manufacturer report to WHO any changes made to the product.

With regards to extending the programme to other laboratory equipment, it was noted that many national blood transfusion services and the WHO EQAS programme for hematology and clinical chemistry have information on the performance, maintenance and training for such equipment as centrifuges, refrigerators, etc.

2. 7. Technical specifications and laboratory procurement: Practical issues

Catherine Mundy (MSH) made a presentation on practical issues related to technical specifications and laboratory procurement. Important issues were noted on the need for adaptation of international guidelines, standard operating procedures (SOPs) which suit the national environment, training of human resources, quality assurance and advocacy for strengthened laboratory services. Different funding is often provided for different disease programmes in a vertical manner e.g. Global Fund, UNITAID, PEPFAR, etc and hence the same items may be purchased by several partners at country level. Quantifying needs is difficult to perform and especially if there are multiple procurement systems and vertical programmes in the country. A nationally-agreed list of laboratory items to be used and purchased, coordinated procurement planning among partners at country level and improving stock management of laboratory items could be the way forward to overcome such difficulties.

A project aimed at strengthening the laboratory services in Kenya was presented. The objective of this project is to improve the knowledge, skills and practices of facility-based staff in laboratory equipment and supply chain management. The expected outcome is a continuous supply of all laboratory commodities required to provide HIV diagnosis and monitoring of infection to ascertain eligibility and effectiveness of ART.

2. 8. Standardization: Prerequisite for optimizing laboratory supply chains

Patrick Msipa (USAID/DELIVER) presented the Kenya case study on standardization and harmonization of laboratory items. The required steps in standardization and the challenges were highlighted. The Kenya case study where steps in standardization involving 16 facilities were undertaken in 2005 resulted in 88% reduction of the number of laboratory items procured (2500

reduced to 300 items). This was the result of a consensus on test menus, techniques, equipment for district and provincial levels and an agreed list of selected reagents and consumables for each assay.

Wendy Nicodemus (SCMS) presented the Zambia country case study where the standardization process commenced in 2006. As for Kenya, there was agreement on laboratory tests by level; identification on techniques for each test and agreement on required laboratory equipment by level of health system.

The importance of building a collaborative effort among partners under the government leadership was highlighted. The following achievements were noted as a result of the standardization process: (1) Agreement on 185 priority laboratory commodities; (2) negotiated maintenance contracts together with purchase of reagents; (3) Stock transfer from one facility to another with savings estimated at USD 30'000 in potential losses from expiry; (4) Avoided stock outs by transferring excess stock from facility to central warehouse or to another facility; (5) Roll out of national laboratory commodity logistics system for 185 priority lab items; (6) Economies of scale with better prices and decreased procurement costs.
The time and resources contributed by multiple stakeholders towards the above achievements in Zambia included: one and a half days of workshop, many technical working groups meetings, validation meetings with MOH, two full-time equivalents (FTEs) at SCMS, and 1-2 FTEs at MOH. There are now four FTEs to support the MOH for the sustainment and the coordination of this programme (currently in the pilot stage) which will be fully implemented in most laboratories by late 2009.

There were no national procurement regulatory acts that would present any particular challenges. Monopolies resulting from standardization can be a threat as competition and innovation is deterred. With regard to regulatory issues in Zambia, pharmaceuticals are regulated but laboratory supplies are not. New equipment does require validation and there is a list of laboratory items that have been validated by the University Teaching Hospital. The logistics system is partially linked to the laboratory information system with logistics data points used to decide re-supply quantity. This decision is made by counting items used, noting quantity of the product on hand, and noting the number of tests performed and equipment functionality. Another supply chain metrics is the monitoring of stock levels on 200 items with other metrics yet to be established.

Key lessons learned from the above country experiences include: (1) standardization is a process which requires time and resources (the standardization process took two years in Zambia); (2) standardization should be a collaborative effort among partners and the MOH; and (3) standardization is a key first step in optimizing and strengthening the laboratory supply chain management system.

2. 9. Harmonization and standardization of laboratory equipment and supplies

Paula Fernandes (APHL Consultant) provided an overview of challenges encountered from four perspectives: the laboratory worker, the central level (ministry), the foreign implementing partner and the vendor / distributor of laboratory supplies.

The laboratory worker’s perspective often reflects limited control. The flow of information within the supply chain is mostly unidirectional and the process of procurement far more push (from the central level) than pull (by the end user). Laboratory staff may source supplies from the open market creating concerns over quality. There are major issues with reagent shelf life and 'vendor dumping' of near expired reagents. There is a lack of adequate training by vendors combined with

high staff turnover. Laboratory workers are not empowered to forecast and order reagents based on demand.

The central level perspective is often dominated by limited resources. Countries may lack laboratory representation at the central level, particularly in procurement. Buyer time for procuring supplies can be long and forecasting is a challenge. There may be difficulties using local vendors and there is often limited recourse when contract terms are violated. In addition to the difficulties choosing appropriate equipment for the setting, there is limited control over donations.

The foreign implementing partner's perspective is often influenced by limited choice. Foreign partners may be under pressure to rapidly implement or scale up operations. This leads to the development of parallel procurement systems in order to fast track equipment and supplies rather than strengthening supply chains at the country level.

The vendor perspective is often impacted by variable demand. Buyer time and payment processing may be long and bulk orders may not reflect true need. Inadequate training, high staff turnover and lack of maintenance leads to frequent equipment breakdown. The cost of doing business is sometimes high.

During the discussion, concern was expressed over the lack of coordination of donated equipment. It was suggested that WHO and other organizations help coordinate donations to fit within existing nationally validated testing algorithms and standardization requirements. In addition, there are some guidelines for donations of medical devices and equipment produced by WHO/EHT and countries should set their standards and only accept suitable equipment that include reagent support, spare parts etc. Co-ordination at country level is often difficult as Ministries outside of the MOH may have influence over donated equipment. Broken down equipment from both health and research programs presents laboratories with space and safety issues. The need for policies on the safe disposal of unwanted and unused equipment were discussed at length at the Maputo meeting.

The laboratory supply chain is a complex part of the health system and should form an integral part of a country's national strategic plan for laboratory services. The plan should emphasize the need for clear lines of communication on supplies from the central to regional / district levels. There is a need to strengthen stock management at the local (laboratory) level to enable more accurate forecasting by encouraging more pull than push processes. Local vendors can play an important role in the laboratory supply chain. However, responsibilities concerning installation, training, servicing and maintenance must be clearly defined in contractual terms. There is a need for strong legal representation on laboratory supply issues from the central level. Standardization of equipment and supplies should improve training and maintenance and help control external donations. However, caution is required to prevent creation of monopolies and weakening of local suppliers that provide good service.

2. 10. Standardization of diagnostics with regard to innovative diagnostics

Evan Lee (FIND) presented the contribution of the Foundation for Innovative New Diagnostics (FIND) in assisting the development of innovative laboratory technologies for resource-limited settings. FIND provides funding and technical assistance in development of diagnostic tools. The process is ISO 13485:2003 and ISO 9001:2000 certified and FIND is considered a non-profit organization under Swiss law. WHO prequalification would be a pre-requisite for uptake by countries of these tools. Products of interest include the following:

Molecular line probe assays (as already presented by Dr Vincent) were endorsed by the WHO Strategic and Technical Advisory Group for TB (STAG) in 2008. This technique reduces the time to diagnosis from six weeks to two days through a process of PCR amplification and hybridization of product by line assay. It may be performed on cultured isolates. The FIND validation process involved a large field trial with some 20,000 specimens tested from a population in South Africa. FIND provided funding and technical assistance in development of this technique and its resultant validation.

The TB loop-mediated isothermal amplification (TB-LAMP) is a novel nucleic acid amplification method for diagnosis of malaria, TB and HAT (human African trypanosomiasis known as sleeping sickness). FIND supports the development of a LED platform with the company Zeiss that provides conventional microscopy combined with fluorescence for TB. The GeneXpert® system is a PCR extraction, amplification and detection 'all in one' platform in a closed system, that is still in the developmental stage.

Quality assurance for malaria diagnostics is seen to be important to ensure health care workers value the result of a diagnostic test and use it accordingly to ensure anti-malarial drugs are administered appropriately. FIND has assisted with manuals for storage and transport of rapid diagnostic tests aimed at two audiences: central medical store facilities and peripheral site facilities.

2. 11. SCMS Procurement of laboratory products in Sub-Saharan Africa

Rochika Chaudhry (SCMS) gave an overview of Supply Chain Management Systems (SCMS), which was established in 2005, to provide a sustainable solution to supply chain challenges, particularly to support the effective implementation of PEPFAR-related medical and laboratory projects. SCMS provides procurement and delivery of HIV medicines and other medical/laboratory supplies; it provides technical assistance and global collaboration for long-term local solutions. It covers the following 16 developing countries: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, Zambia and Zimbabwe. In all these countries, the supply chain has improved and more PLWHIV have regular access to ARV treatment and care.

Sameer Sakallah (SCMS) made a presentation on SCMS experience with procurement of laboratory products in Rwanda, Ethiopia and Zambia. The volume and the values of laboratory supplies have increased over time as the PEPFAR programmes scale up. Some of the issues encountered include problems in obtaining exact specifications and respective shelf life. SCMS used a questionnaire regarding storage conditions, transport and shelf life which was helpful. Reported shelf life changes frequently indicating that such values are either 'invented' or that the product is unstable. Products are best manufactured to order with allowances for transportation time. Especially problematic are assay controls that may have shelf life of one month. Other advice includes the use of start-up kits: there are a finite number of platforms but they often require 50 or more articles to make them viable. There are shopping lists on the SCMS web site for multiple start-up projects kits and in-country procurement is encouraged by SCMS.

Following the presentation, meeting participants had very active interactive discussion on this topic: Mozambique has reagent rental arrangement for CD4 instrumentation from an in-country vendor and this provides a strong incentive for the vendor to keep the instrument running. The importance of a proper contract, perhaps drawn up by a contract lawyer, that allows come-back if the equipment fails, was emphasized. Reagent rental may need to be presented as an option to donors who may prefer to pay for a capital purchase.

Funding is seldom allocated for servicing of equipment including installation, maintenance and training. General discussion followed regarding the issues of servicing, availability of trained engineers, rationality of decision-making in MOH, and the need to allow for upgrades and integration of chemistry and hematology testing. In-country distributors (as the official agents) are usually preferred as this allows justification of discounted pricing of equipment.

The advantage of buying through an organization such as SCMS is that all purchases are put out to tender and are therefore, in theory, most economical and SCMS can give technical advice. However, the tender process can often lead to too many item choices and therefore be counterproductive to the standardization process. The importance of robust specifications was emphasized

In many countries, it is a regulatory requirement that expired products cannot be used and justifiably so. However, the difficulty arises when a product is stored out of its prescribed environment as defined in the package insert (e.g. >4°C) for even as short a time as 30 minutes. An example was given where a MOH representative signed off on the receipt of a product but the cold chain had not been maintained (the vendor checked this) and the question of who was responsible for the unusable product. The cold chain conditions should be maintained until the product is used.

2. 12. Procurement of laboratory items by UNDP

Ann Janssens (UNDP) made a summary of UNDP laboratory procurement given their scope as the manager of certain Global Fund programmes through 60 active grants worth about US$800 million. Microscopes were the most commonly procured item in 2006, 2007 and 2008 with a large volume of refrigerators anticipated for 2009. The forecast is that diagnostic test kits, mostly HIV test kits, will be in demand. In order of volume, biochemistry reagents and then malaria tests will also be in demand.

During the discussion, it was noted that in the field most CD4 T+ cell enumeration equipment is not operational. There is a need to interest companies/suppliers/vendors, procurers and end-users to engage in reliable maintenance contracts and to include equipment maintenance as part of the initial purchasing contract. Maintenance is often not commercially viable for a supplier as there are too many machines. Biosafety cabinets (BSCs) procured by UNDP also require maintenance in order to continue to protect the health worker. Therefore, the need for a service contract linked to purchase would be suggested with possibly adding '15%' to the purchase cost to cover this. Another alternative is to train local staff members to perform the maintenance processes if there are a small number of instruments in the field.

2. 13. Procurement of laboratory items by UNICEF

Ludo Scheerlinck (UNICEF) made a summary of UNICEF laboratory procurement. He noted that there is a decrease in requests for microscopes possibly due to the increased use of malaria RDTs. CD4 T+ cell enumeration equipment and reagents are increasingly requested while there are few requests for nucleic acid testing (NAT) equipment made. Local or in-country procurement that is technically supported is recommended for NAT equipment and reagents. There is very little procurement of BSCs or TB culture systems.

Challenges and opportunities include that high end devices are requested when basic needs still go unmet, non-clinical laboratory items are requested, and needs versus wants are not always clearly defined. There is a wish to work with private sector and this has not been addressed in this current meeting.

2. 14. Overview of the WHO procurement of diagnostics

Anita Sands (EHT) gave a summary of WHO laboratory procurement. It was noted that WHO has not recently been a large player in terms of dollar value for procurement of diagnostics and laboratory supplies. There has been a drop in procurement to the Eastern Mediterranean region and increase in procurement destined for the African region. WHO has evaluated many rapid tests and other serological assays. However, some companies with ill performing products are known to not submit for the yearly tender process. Commercial reasons may be an important factor and especially in an era of many re-branding arrangements. Uganda procured extremely large volumes of HIV rapid assays through WHO in 2007 but it is unknown if this will be repeated in the future.

Malaria tests are sold mainly to the African and Western Pacific regions. While HCV tests are procured for the South-East Asian region (Bangladesh in particular). The Eastern Mediterranean region is the most common destination for HBsAg tests but too few countries order the neutralization reagents that are necessary for confirmation of a reactive test result.
One of the major issues encountered is that recommended nationally validated testing algorithms are not often not utilized when cheaper products enter the market under open competitive bidding processes..

2. 15. Diagnostic Procurement - The Clinton Foundation HIV/AIDS Initiative

This topic was presented by Maurine Murtagh (CHAI) . CHAI has offices in 22 countries but does not provide direct funding, working only in public sector with provision of HIV/AIDS care and treatment. Moderate reduction of prices of ARVs and diagnostics including rapid tests, CD4 and NAT tests for viral load has been achieved and CHAI is working on the cost reduction of biochemistry and hematology analyzers. In late in 2006, CHAI was chosen by UNITAID to act as a partner for their pediatric programme. CHAI formed a procurement office for this purpose and now directly procures HIV rapid assays, CD4, DNA PCR and RNA PCR for the purposes of early infant diagnosis. UNITAID pre-approves these products before purchase.
Procurement challenges include standardization of test menus, shelf life, cold chain maintenance (be sure to ship early in week so reagents do not arrive over the weekend) and laboratory instrumentation. For example, DNA PCR tests use mostly Roche reagents but not a Roche instrument and Roche provides training. This requires significant co-ordination. Countries often prefer to own the instrument or have it already and do not want to lease or reagent rental.

UNITAID donations focus on pediatrics and so CHAI created a functional kit i.e. all items that are needed to do the DNA PCR test. This was standardized so that no replacement items were authorized. This was generally accepted and resulted in an increased rate of procurement of DNA PCR. This may be done for NAT testing later. These functional kits are put together by private company at a small cost. UNITAID now funds testing for parents as well as testing for the infants as part of their pediatric programme.

2. 16. Procurement of laboratory items by Crown Agents

David Whybrew (Crown Agents) presented Crown Agents' experience in the procurement of laboratory items. He stressed the importance of communication throughout the procurement cycle. Contact with the end-user was also essential to clarify and expand the requirement in order to eradicate the potential purchase of incorrect/unnecessary goods. For example, the number of diagnostic tests required (as kit sizes are variable), the accessories required for a centrifuge in order

for it to operate, and the type of safety cabinet required (bio-safety versus storage cabinet). Blood collection tubes also have multiple uses and pack sizes. Management of the procurement cycle to achieve successful door to door delivery (including installation/commissioning) is crucial. It incorporates the correct Incoterms, scheduled deliveries, cold chain, appropriate freight method, individual country conditions, QA of the product prior to distribution and local representation to maintain the products beyond the standard warranty period. The warranty should only commence at the point of handover i.e. following commissioning and training of the end-user.

2. 17. Procurement of laboratory items by Missionpharma

Bo Birk (Missionpharma) presented the experience of Missionpharma with procurement of laboratory items. Based in Denmark, Missionpharma was formed in 1975 to provide pharmaceuticals for primarily Danish missions. With measures of QA and QC introduced into the procurement process and a good IT system for data extraction, Missionpharma believes itself to have a competitive advantage. Some 50% of staff are dedicated to quality and QC with prequalification of pharmaceuticals performed by WHO and not duplicated on the same sites of manufacture. Procurement relies on communication from end-user back to specifier for product specification, MOH & central medical stores for product compatibility with local context. Defective products (equipment) are returned to the manufacturer for repair then transported back to the user. Missionpharma handles this process. The long term strategy is to consider manufacturers as partners.

2. 18. Procurement of laboratory items by Action Medeor

Dick Angemeer (Action Medeor) presented this topic. Action Medeor is a small German non-governmental organization founded in 1964 to serve primarily rural areas and improve access to medical care in remote health centres. Action Medeor is certified Humanitarian Procurement Center. It performs non-profit wholesaling activities especially for pharmaceuticals with just 10% of procurement for laboratory items.
There is a major supplier to Action Medeor with 40 sites with flow cytometers. These sites send a monthly user report and Action Medeor uses these reports to follow up on repairs with the manufacturer. This ensures that machines stay running. These instruments come with starter kit i.e. everything to run the machine, and the cost is included in purchase price. Average cost per HIV test is $1. These machines are being used less in countries where they are no longer allowed by new laboratory equipment standardization policies.

2. 19. Procurement of laboratory items by IDA Foundation

Wendy Eggen (IDA) presented the experience of IDA with procurement of laboratory items. IDA was founded in 1972 in Amsterdam and provides essential medicines and medical supplies. It has a 3000 product range and is quality certified. Partners include UN and local NGOs. A share of 5-6% of their total procurement representing €10million is for laboratory items and thus it does not represent their core business. Of this total, 38% is for diagnostics. Other laboratory-related procurement includes microscopes, autoclaves, diagnostic tests, laboratory equipment, laboratory supplies and other laboratory category items. Challenges include shelf life being shorter than expected or guaranteed. Staggered shipments may help this but would increase costs. At least 80% of expected shelf life must be remaining at time of delivery. Also, instruments that have reagents with short shelf life (plus servicing problems, etc.) are avoided. Quantification data is balanced with the schedule of manufacture to reduce these issues.

3. Group work

Group 1: the development of a roadmap for harmonization and standardization of laboratory equipment at country level.
The following roadmap was suggested after much discussion.

- Establish laboratory leadership at MOH level for advocacy to drive process
- Develop national laboratory strategic plan
- Key component - standardization initiative
- Pull all together and gain partner agreement
- Do situational analysis (all laboratories, test menus, equipment, facilities, personnel)
- Set goals for testing at each level of system based on defined health package, country policy
- Create together implementation team with key partners
- Partners provide active support with case studies, tools, to gain commitment
- Evaluate outcomes and timeframes
- Focus on primary platforms with numerous consumables

Discussion and comments:
Harmonized descriptions of products by procurement agencies e.g. centrifuges specifications, definition of a test kit, would make it easier to compare procurement data.

Group 2: Group 2 worked on the identification of major problems encountered and suggestions for solutions from a procurement perspective.
The following major problems were identified after much discussion.
In-country issues

- Lack of standardization of laboratory items
- What happens to equipment that is already in country that is not on the standardized list
- What to do with donated equipment that is not on the standardized list
- Need for product specifications (generic)
- Clarify needs of customers
- Lack of forecasting & quantification
- Volume required
- Firm ordering & ongoing confirmation of deliveries
- Delivery Plan
- Donor harmonization
- Lack of inventory management
- Technical Support
- Maintenance
- Regent rental vs. capital purchase
- Training - initial & ongoing
- Technical hotline for end-users to call
- Language of manual/package insert
- Operational requirements
- Shelf life
- Guaranteed shelf life upon delivery - is 80% realistic for all laboratory items/products?
- Specimen through-put
- Definition of test kits
- What is needed to perform the assay that is not included in the test kits?
- Procurement lots
- Commercial aspects
- Regulatory issues respecting national requirements (NRAs)

- Embargos
- Cessation of production & guarantee that support will continue
- Will reagents continue to be produced?
- Will spare parts continue to be produced?
- Will service continue as there may be a higher likelihood that equipment will break down the closer it comes to the end of its life
- Delivery times
- Lack of INCO terms

Solutions:

- Standardized checklist to be used upon request for procurement
- Support of UN agency document on specifications for procurement
- Specify items required to perform the assay but not provided within the test kit
- Specify items required to use certain equipment e.g. computer, vortex mixer, centrifuge, pipettes, centrifuge buckets

4. Recommendations and conclusion

Before concluding the meeting, Dr Jos Perriens, Coordinator of HIV/SSH, invited participants to propose and agree on areas on which partners could collaborate to contribute to the improvement of procurement of harmonized and standardized laboratory items. The following suggestions of next steps were agreed:

(1) WHO recommendations for donated equipment should be disseminated for their use to guide donors and recipients of laboratory equipment.

(2) It was recommended to establish a working group on generic specification and definitions of laboratory items to harmonize the work being undertaken by various partners. It was felt that various institutions should collaborate to maximize their effect through synergic efforts.

(3) It was also recommended to establish a working group on national laboratory strategic planning of harmonized and standardized laboratory tests. All PEPFAR-supported countries and five countries within the African region have planned to make progress on this endeavor. There was agreement that harmonization/standardization needs to be a country-driven process.

(4) Significant progress on harmonization/standardization of laboratory tests has already been made in some countries e.g. Zambia, Kenya, Ethiopia, Rwanda, Mozambique and Cote d'Ivoire. It was recommended that country case studies on the above successes be developed and disseminated to other countries to raise awareness on the importance of harmonized/standardized laboratory tests. The case study will cover the following sections:

- Background: rationale and reasons behind this endeavor, partners involved, supporting environment such as policy documents, national strategic planning, donor requirements, problems identified during situation analysis, etc.
- Standardization process: steps, challenges, solutions implemented to overcome the challenges, enabling factors, involved partners, number of health facilities and districts covered, time-frame/duration of the process, human and financial resources invested, etc.
- Outcomes: coverage of patients in need (scale-up), financial and programme efficiencies, performance of the supply chain for laboratory supplies, etc.
- Spin-off for the strengthening the health system: e.g.. improved service delivery not only for HIV but also for other diseases, improved management information system for laboratory services and other related health services, human resources performance, improved governance and coordination, etc.

Successful country experiences can then be used as models for other countries with adaptation to local context.

Dr Jos Perriens concluded the meeting by thanking all partners and indicated that AMDS will follow up with each partner for the establishment of the two working groups. A teleconference with each working group will be convened by AMDS to define the structure of the working group, activities to be carried out, timeline and expected results and the regularity of teleconferences.

For the working group on harmonization and standardization, the focal points from interested institutions who are going to work on this subject need to be identified. Among other activities to be defined, the focal person would provide the list of countries in which the institution is implementing or will implement harmonization and standardization of laboratory tests and timeline. There was some agreement that standardization and harmonization needs to be a country-driven process.

For the working group on generic specification, a first teleconference at a time which is convenient to every member of the group will be convened. The structure of the working group, activities to carry out, timeline and expected results and the regularity of a teleconference to share information will be decided.

Annex 1 - Agenda

Chair: Vincent Habiyambere, WHO **Rapporteur: Jeanette Twell, WHO**

Monday 27 October 2008

Time	**Topics**	**Presenter**
9.00 – 9.30	Opening remarks Tour de table Context, objectives & expected outcome of the meeting	S Groth, Director, EHT V Habiyambere, Chair
9.30 – 10.30	Joint CDC/AFRO presentation: Recommendations, practical implications and next steps of the Consultation on Technical and Operational Recommendations for Clinical Laboratory Testing Harmonization and Standardization in Maputo Country experiences on harmonization/standardization	G-M Gershy-Damet, Regional HIV Laboratory Advisor, AFRO S Orloff, Deputy Chief, International Laboratory Branch, CDC
10.15 – 10.30	**Coffee Break**	
11.00 – 11.45 11.45 – 12.30	Current generic technical specifications, norms and guidance (UNICEF & WHO/EHT) Specification for WHO procurement of laboratory tests Current generic technical specifications, norms and guidance (Guidelines for TB Laboratories)	L Scheerlinck, UNICEF A Sands, WHO/EHT V Vincent, WHO/STB
12.30 – 14.00	**Lunch**	
14.00 – 14.30 14.30 – 15.00	Prequalification of laboratory items (diagnostics, equipment) for high burden diseases Practical issues linked to technical specifications and actual procurement process : based on field experiences both in commodity management and in laboratory systems strengthening.	G Vercauteren, WHO/EHT C Mundy, MSH
15.00 – 15.15	**Coffee Break**	
15.15 – 17.00	Harmonization and standardization of laboratory items (ex. diagnostics, equipment): current experiences, opportunities and challenges	- P Msipa, USAID | DELIVER - W Nicodemus, SCMS - P Fernandes, APHL - E Lee, FIND
17.00 – 17.15	Wrap up of the day	V Habiyambere, Chair

Tuesday 28 October 2008

Time	Topics	Presenter
9.00 – 10.30	SCMS: Saving lives through stronger supply chains Case studies carried out on procurement of laboratory items in 3 Sub-Saharan African countries: Rwanda, Ethiopia and Zambia	R Chaudhry, SCMS S Sakallah, SCMS
10.30 – 11.00	**Coffee Break**	
11.00 – 12.30	Overview of (a) procured laboratory commodities and (b) other laboratory items (by quantities and other relevant information)	A Janssens, UNDP L Scheerlinck, UNICEF A Sands, WHO/EHT M Murtagh, CHAI
12.30 – 14.00	**Lunch**	
14.00 – 15.00	Overview of (a) procured laboratory commodities and (b) other laboratory items (by quantities and other relevant information) **Cont'd**	D Whybrew, Crown Agents B Birk, MissionPharma D Angemeer, MEDEOR W Eggen, IDA Foundation
15.00 – 15.30	**Coffee Break**	
15.30 – 16.30	**2 Group work**: Discussion of next steps on the above interactions	Group work
16.30 – 18.00	**Group reports and plenary session:** Discussion of conclusions and next steps	All
18.00 – 18.15	Closing remarks	J Perriëns, Coordinator, HIV/SSH

Annex 2 - List of Participants

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