World Health Organization
REGIONAL OFFICE FOR Africa

6th meeting of the regional HIV/AIDS public health laboratories network

ABIDJAN, COTE D'IVOIRE

11-13 September, 2012

INTRODUCTION

Diagnostics and laboratory technologies are essential tools in the prevention and surveillance of diseases and for patient monitoring. The role of diagnostics and laboratory monitoring is critical in the scaling up of treatment for major diseases, such as HIV/AIDS.

The early and accurate diagnosis of HIV is important for both prevention and care. Diagnostics are used to screen donated blood to prevent the transmission of bloodborne infections via transfusion and to diagnosis individuals' HIV status. Reliable HIV tests and appropriate testing strategies are therefore important in the prevention of mother to child transmission and for testing and counseling services. Diagnostic tests and functioning laboratory services are also essential for surveillance, which provides epidemiological data to monitor the spread of the disease, including drug resistance.

Today, approximately four million people have access to HIV antiretroviral therapy (ART). However, the real need is at least six times higher and efforts are being scaled up accordingly. Parallel to the need for increased access to ART is a similar need for appropriate diagnostics and laboratory support for clinical decision-making (4Ss: when to Start, Substitute, Switch of Stop ART) and monitoring the effectiveness and safety of the treatment regimens. In addition to CD4 counts and virological tests such as viral load determination, basic laboratory tests are required to ensure the safety and efficacy of the therapy.

Many national programmes in the African region face a range of challenges, including sub-optimal national laboratory networks and regulatory authorities, weak procurement and supply systems, lack of suitable infrastructure or human resources and inequities between urban and rural settings. As a result, the quality of laboratory performance is variable and available equipment is often either inappropriate or not maintained.

In order to strengthen laboratory capacity in response to the HIV/AIDS epidemic, WHO Regional Office for Africa (WHO/AFRO= established in February 2001, in collaboration with the Global AIDS Program of the Centers for Disease Control and Prevention (CDC-GAP), a regional HIV/AIDS Public Health Laboratories Network. The role of this network is to improve laboratory services for prevention, diagnosis and monitoring HIV/AIDS in the African region. Significant progress has been made in implementing the network's terms of reference, including developing plans of action for HIV laboratory services in countries, provision of external quality assurance programmes and training.

The fifth meeting of the regional HIV/AIDS Public Health Laboratories Network was held in Dakar, Senegal, in September 2008. The meeting made recommendations for improving laboratory performance and support for HIV prevention and care programmes.

The sixth meeting of the Network was convened in Abidjan, Côte d'Ivoire, on 11-13 September 2012 in order to assess progress made, familiarizing key partners and potential donors on HIV laboratory issues and constraints. The meeting was attended by participants from 36 countries from the African region as well as by partners such as CDC/ILB (International Laboratory Branch), ASLM (African Society for Laboratory Medicine), and APHL (American Public Health Laboratories).

OBJECTIVES OF THE MEETING

The overall objective of the meeting was strengthen the contribution of HIV laboratories scaling up towards Treatment 2.0.

The specific objectives were the following:

- To review the status of implementation of the 2008 recommendations of the HIV Public Health Laboratories Network
- To review the current status and management of HIV laboratory services
- To advance solutions for maintaining a quality and reliable diagnostic support for HIV programmes
- To finalize a plan of action for the Laboratory Network for 2012-2014.

Opening remarks were given by Prof Amonkou Antoine, representing the Ministry of Health and fight against HIV/AIDS, Côte d'Ivoire. Prof Amonkou noted the importance of the role of laboratories in the chain for the struggle against the HIV/AIDS pandemic and the process to achieve the Millennium Development Goals and the elimination of mother-to-child transmission of HIV.

Dr Allangar Youkouidé, WHO Representative, Côte d'Ivoire commented on the necessity of a well performing laboratory network given its importance in the effort to scale up prevention, treatment and surveillance activities.

Dr David Cross, CDC representative recalled the excellent working relationship between his organization and WHO since the establishment of the network in Harare. He noted that given the increase in availability of HIV assays, laboratory services have become a major challenge and called on partners to work with Ministries of Health to improve the quality and coverage of national laboratory services.

OBJECTIVE 1: TO REVIEW THE STATUS OF THE IMPLEMENTATION OF 2008 RECOMMENDATIONS OF THE HIV LABORATORY NETWORK

OVERVIEW OF HIV LABORATORY SERVICES IN THE REGION

Dr Guy-Michel Gershy-Damet presented key findings of the WHO/AFRO study of HIV laboratory capacity in the Africa region completed in 2011, sharing trend data from 2003, 2007 and 2011. A final report containing the 2011 conclusions is expected to be issued in later in 2012.

The report will cover the following areas:

- Policy and planning, measured by the presence of action plans for laboratories at a national level allowing the coordination and thus the strengthening of laboratory services. An increase from 69% of countries in 2003 to 78% in 2011 was observed.

- Financing was measured by the proportion of funding provided by national governments and partners. Results from the survey showed that most countries solidly depend on partners for implementation of

activities, especially in terms of provision of equipment and reagents, yielding a 57% of the total budget. Governments mainly support through provision of infrastructure and personnel.

- HIV serology, measured through capacity to perform HIV screening at each level of the healthcare system showed an increase in testing performed at all levels (central, regional and district). As a general rule, EIAs are exclusively performed at central and regional levels given the lack of electricity and running water at sites at lower levels. HIV rapid testing is performed at a high proportion at all levels. The proportion of laboratories following appropriate WHO testing strategies for HIV diagnosis, surveillance and blood safety increased.

- Data showed that although some private facilities perform molecular techniques, most of the molecular testing capacity resided in the public sector. Immunological testing is increasingly decentralized.

- In terms of laboratory supplies and logistics, 51% of countries reported no reagent stock outs in 2011 decreasing from 66% in 2007. 65% of countries have a Laboratory Information System in place and 78% have access to the internet at the national reference laboratory level which shows a slight decline from 2007.

- On the subject of Quality Assurance, 92% of countries reported participation to an External Quality Assessment scheme (EQA) for serology. EQA participation for CD4 subset enumeration testing and drug resistance testing, coverage remains lower at around 19 and 46% respectively. WHO and CDC remain major EQA providers in the region.

Participants expressed interest in obtaining the data from the upcoming report per country breakdown in order to use is it as an advocacy tool.

STANDARDIZATION AND HARMONIZATION OF HIV EQUIPMENT AT ALL LEVELS (TANZANIA)

Tanzania presented on the country's experience with the integration and standardization of HIV laboratory services at different levels of the national health system both in terms of equipment and health personnel, in an attempt to simplify procurement, training and maintenance activities. An overview of the levels of health laboratory services was presented. Currently, there is existing capacity for HIV serology, CD4 subset enumeration, clinical chemistry, haematology and viral detection, the latter only being available at the national level.

On the subject of quality assurance (QA), Tanzania reported an increase in the implementation of HIV rapid testing using dried tube specimen (DTS) as a tool for EQA, to 937 sites from 364 sites in 2007. HIV DNA PCR for Early Infant diagnosis (EID) is performed in five testing sites (all regions in collect DBS and transport to respective zonal laboratory). 154 (35 in 2005) sites participate in Health Canada Quality Assessment Program for Measures Relevant to HIV/AIDS (QASI) EQA programme for CD4 technologies.

Challenges remain around service contracts for equipment mainly due to shortage of local biomedical engineers and availability of engineers from local vendors. Other challenges include the shortage of human resources and unreliable procurement practices.

In order to tackle these challenges, an increase of laboratory training institutions have been registered to train more qualified laboratory staff. The Ministry of Health and Social Welfare (MOHSW), Tanzania has established a biomedical engineering training program through DIT. MOHSW, through TACAIDS, will establish HIV/AIDS Trust Fund to support this area

Future plans include the accreditation of laboratories through the Southern African Development Community Accreditation Service (SADCAS). Post-Market Surveillance activities for HIV test kits will be carried out in Medical Store warehouses. New HIV rapid assay evaluations will be conducted in order to establish new HIV testing algorithms.

QUALITY OF RAPID TESTING: STANDARDIZED LOG BOOK AND DBS EQA (ZIMBABWE)

The Zimbabwe National Quality Assurance Programme (ZINQAP) manages the national External Quality Assessment scheme for HIV rapid testing. Currently there more than 1000 testing sites in Zimbabwe. However, only 174 sites participate in the scheme due to the required fee as ZINQAP is a private organization.

New test kit and technology evaluations for pre-market approval are carried out by National Microbiology Reference Laboratory (NMRL) prior to their introduction in the country. The NMRL will also be responsible for lot testing of consignments of test kits entering the country.

Other existing QA programmes in Zimbabwe include a dried blood spot (DBS) Proficiency Testing programme launched in 2011 by CDC's International Laboratory Branch (CDC/ILB) and the use of standardized log books collected to monitor the quality of HIV rapid tests, ART registers and PMTCT registers. Furthermore, the QASI and CHAI are currently assisting Zimbabwe in developing an EQA programme aimed at POC CD4 technologies.

EXPANSION OF QUALITY HIV LABORATORY SERVICES FOR TESTING AND CARE OF PATIENTS IN GHANA

The Ghana Health Service has been very active in its efforts to improve the quality of health care. Several activities have been carried out in collaboration with partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), CDC, WHO and Global Health Systems Solutions (GHSS). These efforts have led to the enrolment of selected regional hospitals in the Strengthening Laboratory Management Toward Accreditation (SLMTA) programme, the implementation of a DTS EQA scheme to monitor HIV testing, enrolment in DigitalPT for Chemistry and Hematology testing, CD4 PT for some district and regional laboratories and the HIV Sentinel Survey carried out by the National AIDS Coordination Programme (NACP).

Ghana has started implementing the DTS proficiency testing programme administered by NPHRL which was piloted in 37 sites. It is currently being rolled-out to 250 sites across the whole country. Regional teams have been formed to assist with administration of programme. The surveys consist of panels prepared by NPHRL and sent to the regional teams for distribution to testing sites. In 2012, panels were distributed to 250 sites with a target of 450 sites set for 2013.

Challenges remain and are mainly related to stockouts and shelf-life of reagents, failure in submitting results in a timely fashion and lack of funding required to support the regional teams.

COUNTRY EXPERIENCE IN REGIONAL EQA SCHEME FOR HIV SEROLOGY (SENEGAL)

The Système Régional d'Evaluation Externe de la Qualité (SREEQ) is an EQA scheme for HIV and HBV serology whose objective is to monitor the performance of reference laboratories in 18 different Francophone countries in the region. From 2001-2009 within the WHO EQA framework, ten plasma specimens were prepared, characterised and distributed by the bacteriology and virology laboratory at Le Dantec University Hospital in Dakar. The laboratory has, since 2010, established DTS as a good alternative specimen for the purpose of EQA given that no cold chain is required.

The AfriQualab Proficiency Testing Program is a structure created within the LBV/CAD University Hospital of Le Dantec, Dakar in Senegal. The program deals exclusively with the organization of external quality assessment (EQA) in all the fields of medical biology to African laboratories. Materials will be purchased in bulk from HealthMetrix (DigitalPT) and repackaged and distributed from LBV.

The results of the EQA programme show that there has been consistent improvement in performance of laboratories and those that have reached 100% concordance have maintained the quality of testing. Furthermore, it has allowed the following observations: testing algorithms and test kits used are varied but WHO testing strategies seemed to be preferred as well as WHO prequalified test kits.

LABORATORY MAINTENANCE: CONSTRAINS AND CHALLENGES (CÔTE D'IVOIRE)

In Cote d'Ivoire, a central agency coordinates maintenance of all hospital equipment and infrastructure (Direction des Infrastructures de l'Equipement et de la Maintenance [DIEM]) following a national maintenance plan and a maintenance policy and in collaboration with partners. Six regional agencies (Centre Régional des Infrastructures de l'Equipement et de la Maintenance [CRIEM]), all coordinated by the DIEM, with biomedical engineers (trained by suppliers) provide service to the region, including to the peripheral laboratories. Maintenance workshops are carried out by level of health facilities: general hospitals, regional level and university hospitals and specialized institutions.

The Ministry of Health has set up a technical working group of key stakeholders including ministry, partners and national institutions and charged them with a standardization exercise for equipment at all levels of the health system. However, procurement of equipment is currently very decentralized with some DIEM not always made fully aware. Not all equipment is covered by preventative/corrective maintenance contracts, with insufficient human resources and trained maintenance experts. Equipment is prone to breakdown due to electricity fluctuations.

ACCREDITATION OF HIV LABORATORY SERVICES (CAMEROON)

In collaboration with CDC, a national policy has been implemented in which the country has been divided in ten different regions and each region has been assigned a reference laboratory, in charge of mentoring other laboratories. All regional laboratories are mentored by the national public health laboratory. In 2010, five of these laboratories have been selected for the Strengthening Laboratory Management Towards Accreditation (SLMTA), a training approach in laboratory management and quality management systems with the goal to prepare laboratories for accreditation based on international clinical laboratory standards. The process will be extended to an additional seven laboratories. However, maintenance of equipment, procurement of reagents and equipment, funding and training remain major issues.

In order to tackle some of these challenges, CDC will be conducting staff training in equipment maintenance and will set up a quality assurance center. Quantification of HIV commodities has been done for one year and orders will only be placed for reagents with a shelf-life of at least two years.

RECOMMENDATIONS

Given the current trend to increase equipment automation, problems related to maintenance and servicing of equipment will grow. There was a strong recommendation to educate individuals at a higher level so that contracts specify lead times allowed between equipment breakdowns and prices include the cost of preventive and curative maintenance. However, this may prove difficult in countries were procurement is coordinated by central medical stores and in cases where funding depends solely on partners. Advocacy is still required in order to obtain specific budget lines for equipment maintenance and improvement of procurement practices.

There was general agreement that the use of DTS is cost-effective alternative as it reduces cost and the need for cold chain.

UPDATE FROM THE AFRICAN SOCIETY FOR LABORATORY MEDICINE (ASLM)

The mission of ASLM is to advance professional laboratory medicine practice, science, systems and networks in Africa needed to support preventive medicine, quality care of patients and disease control through partnership with governments and relevant organizations. ASLM was inaugurated in 2011; headquarters are located in Addis Ababa.

ASLM has eight strategic objectives which are:

- Policy
- Advocacy, Communication and Resource Mobilization
- Laboratory accreditation and Quality management systems
- Laboratory Workforce Development
- Laboratory Clinical Interface
- Research Capacity and Publication
- Technical Assistance
- Laboratory strategy and networks

ASLM has partnered with WHO/AFRO to set standards for laboratory quality and contributed to the development of WHO/AFRO SLIPTA Guidance Document and Checklist to be used as a framework for countries to improve national laboratory services towards ISO 15189 accreditation and established ASLM as a SLIPTA implementing partner. ASLM has also established an independent accreditation advisory committee (IAC).

ASLM has established 6 Collaborating Centers including: Nigeria, Senegal, S. Africa, Tanzania, Kenya and Ethiopia. The first ASLM ambassador has been appointed, with more ambassadors to come. A total of 20 (4 part-time) mentors have participated in three workshops and trainings.

UPDATE ON THE IMPLEMENTATION OF THE WHO/AFRO STEPWISE LABORATORY QUALITY IMPROVEMENT PROCESS TOWARDS ACCREDITATION (SLIPTA)

The SLIPTA guidelines and checklist were finalized and approved at a meeting held in July 2011 in Nairobi. The guidance document serves as a framework for countries to improve national laboratory services towards ISO 15189 standard in a stepwise manner. The accompanying SLIPTA checklist is aligned with ISO 15189 standard and the Quality Systems Essentials (QSE) from the Clinical and Laboratory Standards Institute (CLSI).

The stepwise process is based on star ranking system (Figure 1) and is initiated by an audit. Laboratories that fail to achieve at least 55% compliance are not awarded any star ranking. Laboratories that achieve > 95% upon audit will receive a five star rating. Following the initial audit, laboratories are expected to maintain their star status and work towards achieving the next star, which would be evaluated during an additional audit. Laboratories that achieve five stars are strongly encouraged to apply for accreditation against ISO 15189.

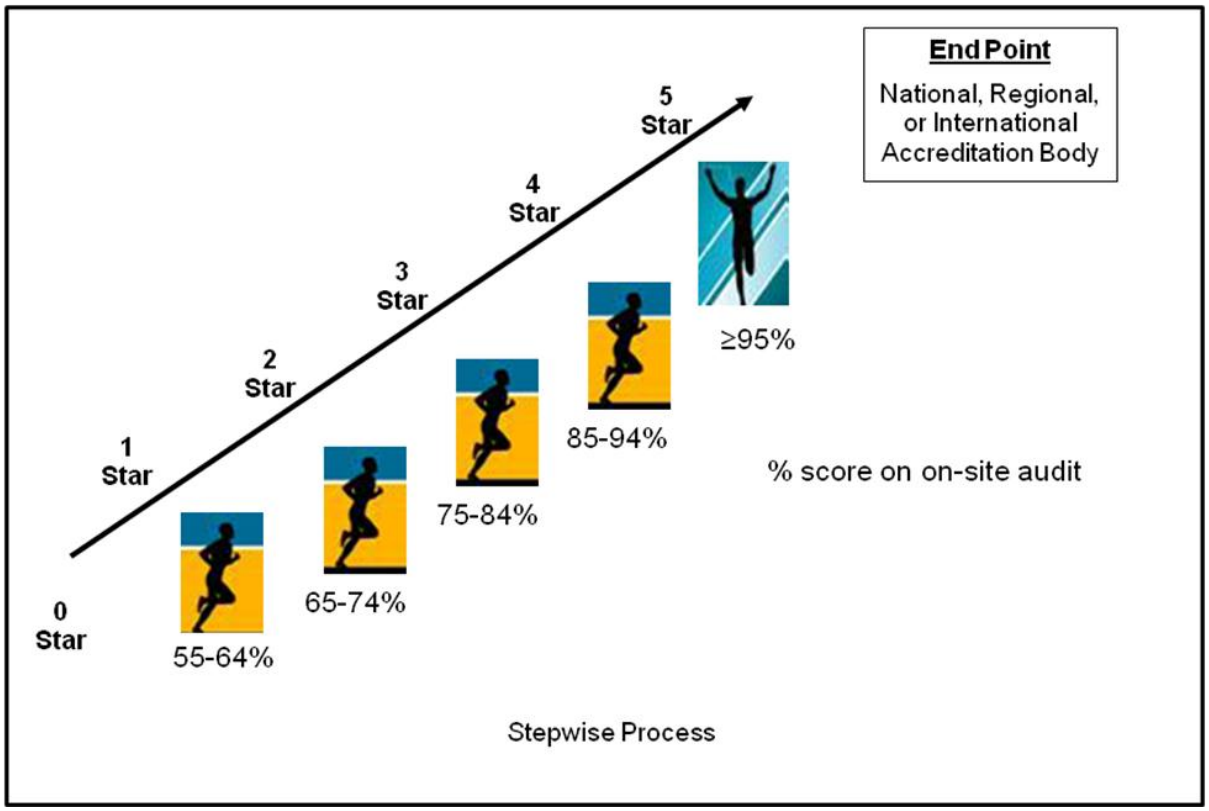

FIGURE 1 SLIPTA STAR RANKING SYSTEM

ASLM has signed an agreement with the Southern African Development Community Accreditation Service (SADCAS) to train laboratory auditors. Additionally, ASLM identifies and collaborates with locally available organizations such as the Centre Régional d'Evaluation en Santé et d'Accréditation des Etablissements Sanitaire en Afrique (CRESAC), the Global Health Systems Solutions (GHSS) and the Federation of African Associations of Medical Laboratory Scientists (FAAMLS). Auditors are trained using a standardized curriculum over five day programmes in collaboration with CDC, CLSI and Vijay Consulting.

The minimum requirements to participate in the SLPITA scheme are the laboratory must have conducted a self-evaluation using the SLIPTA checklist and score a minim of 143 points (55%). Furthermore, laboratories should be enrolled in a EQA scheme, routinely run Internal Quality Control (IQC) for all test methods, have evidence of having conducted internal audits and have laboratory quality management system documents.

The SLIPTA implementation structure is governed by the ASLM SLIPTA Secretariat which involves the following stakeholders:

- MoH SLIPTA Focal Point
- WHO/AFRO SLIPTA Focal Point
- Ministries of Health and Applicant Laboratories
- ASLM SLIPTA-Certified Auditors
- ASLM SLIPTA Independent Advisory Committee (IAC)

UPDATE FROM US CDC ON COMPREHENSIVE APPROACH TO IMPROVE THE QUALITY OF HIV TESTING

Current targets aiming at increasing considerably the number of individuals tested for HIV have so far neglected to include a substantial effort to ensure and improve the quality of HIV testing. Additionally, the increase in procurement of HIV RDTs has created a major strain on manufacturers which could potentially lead

to an impact on the quality of the test kits. Quality of HIV tests and HIV testing remains a major concern. Simple and practical tools are available to ensure the quality of testing and should be implemented: DTS for PT, validated test kits and standardized log books.

DTS-PT Programme Roll Out

DTS technology has been transferred to participating countries through regional workshops for staff in national reference laboratories and in-country training. CDC has assisted in the development of a country implementation plan, provision of training materials and DTS supplies, SOPs and forms and data analysis. Sites have been selected by MoH and trained for preparation of the PT panels.

Results have shown a participation rate ranging from 53% to 100% and performance rates ranging from 45% to 100%. The main reasons for low participation rate and high failure rates can be explained by deviations from the country's testing algorithm, incorrect interpretation of test results, transcription errors, use of expired test kits, test kit stock outs, high staff turnover, lack of training and by errors in the panel preparation by NRLs.

Standardized HIV Logbook

CDC has developed a standardized logbook to facilitate the reporting of data. The logbook has been translated in multiple languages (French, Portuguese, Dari, Chinese, Swahili). It is currently being implemented at various stages in more than ten countries. The use of the logbook has been included in national HIV rapid testing guidelines in China, Namibia, Côte d'Ivoire and Tanzania.

The widespread use of the logbook remains challenging given the lack of buy-in at various levels. Moreover, the use of multiple logbooks in some testing sites increases the workload, clerical errors, printing costs and training of end-users remain a barrier to the successful roll out of the logbook.

Update from WHO on the WHO Prequalification of Diagnostics programme

Most WHO Member States lack specific regulation for in vitro diagnostics and wherever it does exist, it is often poorly understood or enforced. WHO does not develop standards for Quality Management Systems for diagnostics, however, it relies and collaborates closely on institutions and standards such as the International Organization for Standardization (ISO), the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The former produces relevant standards such as ISO 13485 and 15189, the latter are organizations which include manufacturers and regulators and strive to harmonize regulatory approaches globally.

The WHO Prequalification of Diagnostics programme aims to increase access to affordable diagnostic technologies of assured quality that are appropriate for use in resource limited settings. The programme provides Member States, UN agencies and other partners with technical information and advice on the quality and performance of currently available HIV/AIDS, malaria and hepatitis B and C test kits and technologies.

The WHO Prequalification process comprises four stages. The first stage includes a formal application to the programme and a dossier review. Applications from manufacturers with priority diagnostics, which serve the immediate needs of WHO Member States, take precedence. Once an application is accepted, the manufacturer is invited to submit a dossier, sign an agreement and pay a prequalification assessment fee. The dossier is reviewed with the purpose of gaining an understanding of the product and how it performs; gaining an understanding of the manufacturing process; determining if the product is suitable for WHO Member States; and if it is ready for a laboratory evaluation and site inspection. Once a dossier is accepted, the prequalification proceeds to the laboratory evaluation and the manufacturing site inspection. The laboratory evaluation is carried out by a WHO Collaborating Centre and assesses the technical performance and operational characteristics of a product. The manufacturing site inspection is carried out to assess the adequacy and effectiveness of the manufacturer's quality management system and the correct implementation of

documented procedures. The inspection is based on internationally recognized standards and is carried out by a WHO inspector, an external inspector and observers from National Regulatory Authorities. If a product is found to have met the prequalification requirements, it can then become eligible for inclusion in UN procurement tenders.

The fourth component of prequalification is post-market surveillance (PMS). As prequalified products are placed on the market, it is necessary to make sure that they continue to meet all safety and performance requirements and standards that were required for prequalification and that problems with the product are dealt with and reported through appropriate channels. The PMS pilot project initiated by WHO will ensure compliance of the products and strengthens National Regulatory Authorities (NRAs) by providing operational guidance documents and training programmes on PMS.

More information is available on the Diagnostics and Laboratory Technology team's website: http://www.who.int/diagnostics_laboratory/evaluations/en

UPDATE FROM WHO ON QUALITY OF HIV RDTS

The quality of HIV RDTs is affected by a variety of factors, through the WHO Prequalification of Diagnostics programme, these determinants of performance are reviewed and then verified through a laboratory evaluation and site inspection. The sensitivity and specificity of HIV RDTs is generally good, however, some products perform poorly during seroconversion (early in infection). HIV RDTs that discriminate between HIV-1 and HIV-2 can exhibit poor HIV-2 specificity due to high cross-reactivity between HIV-1 and HIV-2 antibodies, the manufacturers validation claims related to HIV-2 detection are often poor. Products should meet a minimum performance of ≥99% for sensitivity and ≥98% for specificity with a minimum inter-reader variability of 5%.

The instructions for use must be clear and unambiguous so that all health workers can perform testing. If the test procedure is not followed exactly, quality issues may occur. The following aspects are critical: fingerpick specimen must be taken correctly, correct buffer volumes must be added, in the correct specimen transfer pipette, and precision pipettes must be used, when required, recommended reading times and the recommended end point stability must be not observed. For many HIV RDTs, the in-built control line is a reagent addition control rather than specimen addition control, although the latter is preferred.

Stability of RDTs is affected by time and temperature, manufacturers must use appropriate study protocols to validate the stability claims. Similarly, an appropriate procedure for quality control of lots released from the manufacturing site must be in place. This will ensure that the product continues to meet the expected performance requirements. Manufacturers must quality control their key suppliers and all incoming components used to manufacture tests. These elements are integral to the quality management system at the site of manufacture, WHO inspections still observe poor quality practices.

National programmes for QC specimens to fill these gaps should exist to fill these gaps. QC specimens could be used weekly, and for each new lot, and new operator. Similarly, national EQA programmes using the DTS approach should be rolled out to all levels of the health system.Post-market surveillance is critical to monitor quality and to report complaints, WHO has a complaint form[1] that can be filled and submitted to the WHO Prequalification of Diagnostics programme for further investigation.

[1] WHO PQDx complaint form
http://www.who.int/diagnostics_laboratory/procurement/complaints/en/index.html

RECOMMENDATIONS

Participants expressed concerns related the lack of country buy-in in order to implement quality assurance measures and post-market surveillance systems including strengthening of national reference laboratories. High level advocacy is essential to garner support. Challenges remain around QA for HIV rapid testing sites. The DTs approach has been successfully rolled out in a number of countries but is very resource intensive While certain QA measures may prove easier to implement for CD4 testing and viral load testing given the lower number of sites providing this service, how can quality be monitored in over 7000 HIV rapid testing sites countrywide?

OBJECTIVE 2: TO REVIEW THE CURRENT STATUS AND MANAGEMENT OF HIV LABORATORY SERVICES AND OTHER PUBLIC HEALTH LABORATORY SERVICES AND ADVANCE SOLUTIONS FOR MAINTAINING A QUALITY AND RELIABLE DIAGNOSTIC SUPPORT FOR HIV PROGRAMME AND UPDATE ON NEW DEVELOPMENTS IN THE FIELD

WORKING GROUPS

Participants were separated into four different working groups, two Anglophone and two Francophone groups and asked to discuss the two subjects below:

Subject A: Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) across diseases of public health laboratories in Africa.

Subject B: Strategies to improve quality of testing as programs are scaled-up and ways to implement Strengthening Laboratory Management Toward Accreditation (SLMTA) in Africa.

The following questions were provided in order to guide the discussion and rapporteurs from each group were charged with presenting the recommendations at the plenary session.

A/ STEPWISE LABORATORY IMPROVEMENT PROCESS TOWARDS ACCREDITATION (SLIPTA) ACROSS DISEASES OF PUBLIC HEALTH LABORATORIES IN AFRICA:

1. Is there a certification and accreditation system(s) for laboratories in your countries?
2. If yes, what is the contribution of your reference laboratory into the system?
3. If no, what are the reasons for the absence of such a system?
4. How do you intend to establish it (if it does not exist) or improve it (if it exists already) in your respective countries?
5. What are your comments on the proposed WHO Accreditation Scheme?
6. Make 3 recommendations which you consider important. Working group discussion

As a general rule, Anglophone countries acknowledge the existence of a certain forms of national accreditation and certification mechanisms in place in their country. Francophone countries rely mostly on regional or international bodies such as CRESAC through its evaluation unit (Unité d'Evaluation en Santé et d' Assurance Qualité [UESAQ]). Other alternatives include the UEMOA initiative, RESAOLAB supported by the Fondation Mérieux and the European Union in some west African countries. It was recognised by all of the participants that the NRL plays a very important role in certification and accreditation mechanisms, by ensuring the development of SOPs, preparation and management of EQA specimens and surveys and conducting training. Wherever systems are not in place, the main reasons given were a lack of a legal framework, and lack of

implementation of the laboratory strategic plan as part of a wider health strategic plan. Shortage of financial resources and trained staff was also mentioned as a major obstacle. Lack of government commitment to the accreditation process was widely considered to hamper efforts for improving the quality of laboratory services.

In order to establish and/or implement national systems of accreditation and certification, decision-makers should be educated in the added value of quality in the health system and laboratory, through intense advocacy efforts. It is of paramount importance that heads of laboratory be involved in this decision-making process at the MoH level, preferably through the establishment of a laboratory commission or national body in charge of public health laboratories. Additionally, countries and accrediting bodies in the region should create closer links and collaborate wherever possible working towards a harmonized approach. Monitoring and evaluation of existing systems should be promoted and strengthened. Furthermore, in order to tackle the issues around human resources and lack of commitment to quality systems, there is a need to include quality management systems training within existing training curricula.

WHO and implementing partners are expected to provide a certain level of assistance, namely, advocacy in order to create awareness at the decision-making level on the need for quality systems in laboratories and accreditation. WHO and implementing partners should also continue to provide technical assistance and training. However, participants felt that synergies should be created between partners, in order to avoid duplication of work or confusion. The establishment of a national laboratory accreditation plan (adjunct to the national strategic laboratory plan) would also facilitate implementation of the SLIPTA scheme.

The recommendations reiterate the need for assistance from partners in advocacy efforts supporting laboratory accreditation schemes and creating awareness to its added value.

B/Strategies to improve quality of testing as programs are scaled-up and ways to implement Strengthening Laboratory Management Toward Accreditation (SLMTA) in Africa:

1. Make a brief description of quality assurance activities in the countries represented in your group.
2. Identify strengths and weaknesses
3. What constraints are limiting further implementation?
4. Are tests on the market subjected to post marketing surveillance?
    a. If yes, how does this help you to maintain the quality of the test?
    b. If no, what plans are there for post marketing surveillance?
5. Propose possible measures to enable further implementation with due respect to quality standards.
6. What support do you expect from WHO and its partners to help you improve implementation with respect to quality standards?
7. Make 3 recommendations which you consider important

Strengthening Laboratory Management Toward Accreditation (SLMTA) is a training approach developed by US/CDC and WHO/AFRO that promotes improvement in laboratories in resource-limited settings. The SLMTA programme consists of hands-on activity-based curriculum in the format of a laboratory management framework. Many of the participants have already undertaken some form of SLMTA training and found it to be beneficial. SLMTA is different to other types of laboratory training, as it focusses specifically on improving the laboratory management skills rather than on training on testing procedures.

Participants called on their governments and implementing partners to remember commitments made in Yaounde upon adopting the WHO/AFRO Resolution AFR/RC58/R2 on Public Health Laboratory Strengthening.

OVERALL MEETING RECOMMENDATIONS

1. Countries and governments to be sensitized on the need for laboratory accreditation and commit to its sustainability by developing national laboratory accreditation plans which would be incorporated into the national strategic laboratory plan.
2. Accreditation tools and checklists should be harmonized, ASLM-trained auditors to be mentored in order to have hands-on experience with the actual auditing process.
3. Quality management systems need to be strengthened, (document control [SOPs], record keeping, internal audit, etc.), through inclusion of quality management systems elements in laboratory training curricula i.e. through wider roll-out of Strengthening Laboratory Management Toward Accreditation (SLMTA) .
4. A comprehensive quality assurance initiative for HIV rapid diagnostic tests to be initiated.
5. WHO to provide normative guidance on systems for post-market surveillance (PMS).
6. Resource mobilization efforts should focus on sustainable scale-up of external quality assessment (EQA) schemes using the dried tube specimen (DTS) approach.

OBJECTIVE 3 : TO FINALIZE A PLAN OF ACTION FOR THE LABORATORY NETWORK FOR 2012-2014

PLAN OF ACTION

- Support the development of a strategy and process for implementing Quality Management Systems in countries of Africa leading using formal laboratory accreditation using the Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) approach
- Launch a comprehensive Quality Assurance Program including post market surveillance, proficiency testing, and logbook, and initiative for quality assurance for RDT
- Support the development of human resources for laboratory including certification of operators
- Support for development of integration of laboratory activities across major diseases of public health importance
- Support for the further development of supply chain management systems
- Support resource mobilization to implement laboratory network activities

ANNEXES

A. Programme of work

6th MEETING OF THE REGIONAL HIV/AIDS PUBLIC HEALTH LABORATORIES NETWORK

Abidjan, Cote d'Ivoire, 11 to 13 September 2012

Improving Quality and Access of Laboratory Services

PROGRAMME OF WORK

Tuesday 11 September 2012		
8:00 - 9:00	**Registration**	
9:00 - 10:00	▪ Statement by CDC ▪ Opening remarks ▪ Opening of the meeting	⇒ **CDC** ⇒ **WR/Cote d'Ivoire** ⇒ **Official authorities**
10:00 - 10:30	**Coffee break**	
10:30 - 10:45	• Objectives and expected outcomes • Overview of HIV laboratories services in the Region	**Dr Gershy-Damet, LAB/RPA**
Objective 1: To review the status of the implementation of 2008 recommendations of the HIV laboratory network		
10:45 - 11:45	Country presentations: 1. Country Experience on Expansion of quality HIV Laboratory Services for Testing and Care of Patients at national, regional and provincial level 2. Country Experience on Standardization and harmonization of HIV Laboratory Services equipment at Different Levels of the National Health System. 3. Country Experience on quality of rapid testing: standardized logbook and dried tube specimens for proficiency testing	⇒ **Ghana** ⇒ **Tanzania** ⇒ **Zimbabwe**
11:45 - 12:30	Discussion	
12:30 - 14:00	**Lunch**	
14:00 - 15:00	Country presentations (continued) 4. Country Experience on Accreditation of HIV Laboratory Services 5. Country Experience on Regional External Quality Assurance Scheme For HIV serology 6.Country Experience on Laboratory Maintenance: Constraints and Challenges	⇒ **Cameroun** ⇒ **Senegal** ⇒ **Côte d'Ivoire**
15:00 - 15:30	Discussion	
15:30 - 15:45	Establishment of EQA schemes in the African region: a key factor in supporting countries to implement SLIPTA Process.	**Dr Jean Bosco Ndihokubwayo, LAB/DSD/AFRO**

15:45 - 16:00	Update on the implementation of the WHO-AFRO SLIPTA process	**Dr Jean Bosco Ndihokubwayo, AFRO and Teferi Mekonen ASLM**
16:00 - 16:15	Update on the African Society for Laboratory Medicine	**Dr Celestin Hakiruwizera, ASLM**
16:15 - 16:30	A comprehensive approach to improve the quality of HIV rapid testing	**Dr Mireille Kalou CDC/CGH/DGHA**
16:30 - 16:45	**Coffee break**	
16:45 - 17:00	Prequalification of diagnostics and post market surveillance	**Ms Mercedes Perez Gonzalez, WHO/HQ**
17:00 - 17:15	Quality of current HIV tests	**Ms Anita Sands, WHO/HQ**
17:15 - 17:30	Discussion	
Wednesday 12 September 2012		
Objective 2: To review the current status and management of HIV laboratory services and other public health laboratory services and advance solutions for maintaining a quality and reliable diagnostic support for HIV programme and update on new developments in the field		
9:00 - 10:00	**Group work (Parallel session for different group)** 1. Step-Wise Approach to Implement Laboratory Accreditation across Diseases of Public Health Laboratories in Africa 2. Strategies to improve quality of testing as programs are scaled-up and ways to implement SLMTA in the Region	
10:00 - 10:30	**Coffee break**	
10:30 - 13:00	**Group work** 1. Step-Wise Approach to Implement Laboratory Accreditation of Public Health Laboratories in Africa (Continued) 2. Strategies to improve quality of testing as programs are scaled-up and ways to implement SLMTA in the Region (Continued)	
13:00 - 14:30	**Lunch**	
14:30 - 16:00	Plenary presentation of Group work	
16:00 - 16:30	**Coffee break**	
16:30 - 17:00	Discussion	
Thursday 13 September 2012		
Objective 3:	To finalize a plan of action for the laboratory Network for 2012-2014	
8:15 - 8:30	Introduction to Group work	**Dr Gershy-Damet, LAB/RPA**
8:30 - 10:00	Group work	
10:00 - 10:30	**Coffee break**	
10:30 - 11:30	Plenary presentation of Group Work	

11:30 - 12:30	Discussion
12:30-13:00	Recommendations and next steps
13:00 - 14:00	Closing ceremony

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