

EAST AFRICAN INTERCOUNTRY MEETING  
ON STRENGTHENING CAPACITY FOR  
POST-MARKET SURVEILLANCE OF DIAGNOSTICS

AND

THIRD REGIONAL MEETING OF THE  
EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT  
SCHEME - EA-REQAS

MEETING REPORT

March 15-17, 2010



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## Abbreviations

AMREF	African Medical and Research Foundation
ATM	AIDS, Tuberculosis and Malaria
CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CPHL	Central Public Health Laboratory
EC	European Conformity
CoE	Centre of Excellence
EAC	East African Community
EA-REQAC	East African Regional External Quality Assurance Committee
GOK	Government of Kenya
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IDSR	Integrated Disease Surveillance and Response
ILAC	International Laboratory Accreditation Cooperation
KEMRI	Kenya Medical Research Institute
MOH	Ministry of Health
MOH&SW	Ministry of Health and Social Welfare
MOMS	Ministry of Medical Services
MOPHS	Ministry of Public Health and Sanitation
MOU	Memorandum of Understanding
MSH	Management Sciences for Health
NACDS	National Association of Chain Drug Stores
NHLQTC	National Health Laboratory Quality and Training Centre
NIC	National Influenza Centre
NICD	National Institute of Communicable Disease
NPHLS	National Public Health Laboratory Services
NTRL	National Tuberculosis Reference Laboratory
PHL	Public Health Laboratory
PHLB	Private Health Laboratory Board
PMS	Post Market Surveillance
RCC	Regional Coordinating Centre
SANAS	South African National Accreditation System
SOP	Standard Operating Procedure
TAT	Turn Around Time
TB	Tuberculosis
TFDA	Tanzania Food and Drug Authority
TTI	Transfusion Transmitted Infection
WHO	World Health Organization
WHO-AFRO	World Health Organization – Regional Office for Africa
WHO/IST/ESA	WHO Inter-country Support Team East and Southern Africa
YF	Yellow Fever

# Introduction

## Post Market Surveillance of Diagnostics

Communicable diseases are prevalent in developing countries and emerging and re-emerging infections have assumed great public health importance. The use of quality reagents and test kits can ensure accurate diagnosis for the management of these diseases. Recent advances in modern technology have facilitated production of numerous diagnostic kits and reagents for infectious disease diagnosis; however, in the absence of policy guidelines and adequate regulation, health laboratories may be offered sub-standard diagnostic kits that may adversely affect the quality and reliability of laboratory investigations.

Many developing countries lack technical capacity or sufficient resources to develop mechanisms to assure the quality of both imported and indigenously produced diagnostic reagents and kits. The World Health Organization (WHO) has therefore considered the need to develop generic guidelines on quality testing, regulation and procurement of diagnostic kits and reagents that can be adapted by member countries to enhance the proper selection and use of quality diagnostic kits, leading to more accurate diagnosis and better quality of care.

An intercountry workshop was organised in Jakarta, Indonesia in May 2001 to review the situation, identify constraints and develop standard policy guidelines for the procurement and use of diagnostic reagents and kits. These guidelines are intended to be used by national policy makers as well as technical personnel to initiate measures to assure the quality of diagnostic kits and *in vitro* diagnostic devices. The delegates discussed the current challenges involved in the procurement and use of various diagnostic kits, reagents and equipment within the East African region and charted the way forward to achieve the desired improvements.

### *Importance and constraints of laboratory services*

Effective laboratory services are an essential component of a functional health care system. Laboratories provide confirmatory diagnosis, contribute to improved management of disease, and provide essential public health information for disease surveillance. However, laboratory services in many resource limited settings are not effectively managed rendering them less effective; in addition, laboratory services are often ignored by clinicians resulting in under-utilisation of diagnostic testing for disease management and reduced quality of patient care.

Laboratories in developing countries face numerous challenges to providing quality services, including poor selection of techniques, unavailability of essential equipment, lack of quality control materials and quality assurance systems, personnel issues and shortages of supplies (Carter *et al.*, 2002). In addition, quality assurance in clinical laboratories is highly dependent on the competence of laboratory staff. An important component of ensuring quality is participation in an external quality assessment (EQA) scheme also known as a Proficiency Testing (PT) programme. EQA plays a fundamental role in improving the quality of health care by demonstrating that laboratory methods in use including specimen processing and reporting of laboratory results will give the correct result with an unknown random specimen.

EQA is also important for the continuing professional development of health care workers. Programmes for accreditation of health laboratories consider participation in EQA schemes as a key element for maintaining quality services. It is therefore of utmost importance for laboratories to participate in EQA schemes that are relevant to the tests being conducted.

## ***EA-REQAS in brief***

In 2000, the Ministries of Health of Kenya, Tanzania Mainland, Zanzibar and Uganda, in collaboration with the African Medical & Research Foundation (AMREF) and World Health Organization (WHO) headquarters, established a pilot project to develop and implement an East African Regional External Quality Assessment Scheme (EA-REQAS) with the overall goal of improving the quality of essential diagnostic services in peripheral health facilities. The main focus of EA-REQAS is to involve national and local administrations in the coordination and implementation of the scheme, and to share resources and experiences across the three countries.

Following preliminary discussions, a major regional meeting was held in Arusha, Tanzania, in 2003 with representatives from the medical laboratory authorities, professional clinical and laboratory bodies, health laboratory boards and councils, research institutes and private institutions. Resolutions and recommendations were drawn up addressing sharing of laboratory standards and materials, developing standard documents for both clinicians and laboratory staff, establishing or strengthening National Quality Assurance bodies, and forming an East African Regional Quality Assurance Committee (EA-RQAC). AMREF was appointed the interim Regional Co-ordinating Centre (RCC) for the project.

At the first regional committee (EA-REQAC) meeting held in Zanzibar in 2006, the frequency of scheme surveys, critical tests to be assessed, selection of reference laboratories from each participating Ministry to supply proficiency testing materials, and development of Standard Operating Procedures (SOPs) for material preparation were agreed. Selected tests included thick blood films for parasites, thin blood films for blood cell morphology, stool and urine examination for parasites, Gram staining, Ziehl Neelsen staining, serology and haemoglobin estimation. The RCC was assigned to prepare questionnaires, package materials for the participating laboratories, mark the responses and prepare reports. Questions are designed to assess laboratory technical expertise, and measure the level of cooperation and interaction between clinical, laboratory and public health staff. The pilot scheme targeted a total of 200 facilities within selected districts in each country. Sensitisation workshops were held with district clinical and laboratory supervisors to aid the successful implementation of pilot project activities by emphasising their vital role in carrying out remedial activities as needed.

A second EA-REQAC meeting was held in Kampala, Uganda, in February 2009, to review scheme activities and participating laboratory performance, and chart the way forward including modalities for expansion of the scheme within existing countries and to other member states of the East African Community (Rwanda and Burundi).

This third meeting marked the end of the pilot phase of the scheme. The meeting aimed to discuss the progress of the scheme, review challenges, and set up plans for scaling up the scheme in existing countries, and expansion to the other countries in the region. The pilot phase of the scheme has been supported by the World Health Organization Headquarters and the Izumi Foundation, USA.

## **Mission and Purpose of the EA-REQAS**

### **Mission**

To establish and operate a well coordinated regional laboratory quality assessment scheme (EA-REQAS) through participation of country health care providers and development partners, aimed at improving diagnostic services to enhance quality health care delivery.

## Purpose

A scheme for establishing standards of laboratory operation and sharing resources and experiences across the three East African countries (Tanzania, Kenya and Uganda) with the aim of improving the quality of health laboratory services.

## Day 1: Opening ceremony and WHO Post Market Surveillance of Diagnostics

### Session 1: Introduction, Meeting Objectives and Opening remarks

***Ms Jeanette Twell*** – Technical Officer, Department of Essential Health Technologies, Diagnostics and Laboratory Technology, WHO Geneva



The Chairperson for Day One, Ms Twell, welcomed the delegates to the meeting and outlined the purpose of the meeting which was to discuss ways to strengthen capacity for post-market surveillance of diagnostics; to review the progress of the pilot phase of the East African - Regional External Quality Assessment Scheme (EA-REQAS); and to chart the way forward. She invited all the delegates to make self introductions (see Appendix 1 for list of delegates).



Following introductions, Ms Twell proceeded to highlight the objectives of the first day of the meeting as follows:

1. To discuss WHO support to EA-REQAS and the Regional Coordinating Centre (RCC), AMREF
2. To review the activities of the WHO Diagnostics and Laboratory Technology Team
3. To review the activities and accomplishments of the laboratory activities of the WHO Regional Office for Africa (WHO AFRO)
4. To provide an overview of the WHO AFRO Laboratory Accreditation Scheme
5. To provide information about the WHO post market surveillance project for priority diagnostics
6. To identify the key challenges related to quality of diagnostics and suggested solutions



***Ms Jeanette Twell*** (top) and other members introducing themselves

## Opening Remarks

The Master of Ceremonies, Mr Sam Ongayo, Clinical Programme Manager, AMREF in Kenya, welcomed all guests and invited the first speaker, Dr Jane Carter, to give her remarks and invite other guests.

### ***Dr. Jane Carter, Director of Clinical and Diagnostic Programme, AMREF***

Dr Jane Carter welcomed the Guest of Honour, the Permanent Secretary, Ministry of East African Community, Kenya; representatives from the Ministries of Health (MoH), Kenya, Uganda, Tanzania and Zanzibar; WHO representatives and partners from different organisations.

#### ***Dr Carter giving her opening remarks***

*"It is timely that action is being taken towards strengthening laboratory services by establishing relevant policies; and that attention is being given to improve the quality of results produced by laboratories" Dr Carter*



She stated that this important meeting brought together regional representatives from the Eastern and Southern African regions, as well as representatives from the World Health Organization (WHO), to review the post market surveillance of diagnostics and also noted that it was the third time the Regional External Quality Assurance Committee (REQAC) of the East African Regional Quality Assessment Scheme (EA-REQAS) had met to discuss the performance of the Scheme.

She indicated that for many years, the syndromic approach to disease management and symptomatic treatment was the default response of health services systems and therefore there was need to build the confidence of clinicians in laboratory testing.

She continued to say that the emergence of drug resistant forms of Tuberculosis (TB), and the rising costs of medicines has prompted the world to realise the importance of accurate diagnosis for both patient care and public health.

### ***Dr Denis Lwamafa, Commissioner of Health Services, Department of National Disease Control, Ministry of Health, Uganda***

*"The measures taken so far have been helpful in removing the doubts of laboratory users, including clinicians, concerning the quality of laboratory services" Dr Lwamafa*



Dr Lwamafa, the head of the Uganda delegation, reiterated that the Government of Uganda strongly supports the initiative of boosting laboratory services as a measure to improve the overall quality of health services. He said that the MoH of Uganda has sought to consolidate and enhance the national quality assurance programme, a commitment that has seen it revise the National Health Sector Strategic Plan (HSSP). He also noted that Uganda has made great progress in improving the quality of laboratory services since the Arusha meeting in 2003. Dr Lwamafa highlighted the following measures that have been undertaken to improve the laboratory services in Uganda through support from donors and partners including WHO, CDC, AMREF and USAID, to mention but a few.

- Formulation and implementation of a National Health Laboratory Policy throughout Uganda
- Development of a five year Laboratory Services Strategic Plan

- Development of a National Laboratory Quality Assurance Master Plan
- Setting up a National Health Laboratory Technical Advisory Committee, which has a subcommittee charged with monitoring quality assurance
- Setting up a credit line in which public, private, and not-for-profit health providers can obtain quality reagents and supplies
- Establishing a full time national Laboratory Quality Officer, tasked with coordinating quality control measures countrywide
- Establishing a quality assurance unit at the Central Public Health Laboratory
- Setting up an in-service training programme for various cadres of health laboratory workers, an initiative that includes a mentoring and supervision programmes conducted at sub-national, district, and sub-district levels
- Remodeling of the laboratory infrastructure to conform to national standards, at the rate of 36 facilities per year
- Consolidating and integrating various External Quality Assessment (EQA) schemes countrywide
- Initiating plans to set up a national accreditation and certification programme based on the step-wise WHO model.

***Mr. Vincent Mgaya, Principal Laboratory Technologist, Ministry of Health and Social Welfare, Tanzania***

Mr Mgaya, the head of the delegation from Tanzania began by recognising the long history of collaboration of the health authorities of Tanzania with AMREF in initiating a comprehensive programme of assessing laboratory services. He reported that the Ministry of Health and Social Welfare established a laboratory policy in 1991, complete with operational guidelines; this policy has been reviewed several times. He also indicated that a national health policy has been put in place which contains guidelines targeting laboratory services. He noted progress in the following areas:

***Mr Mgaya giving his remarks***



*"There is need to share experiences and learn from each other on ways to improve laboratory services" Mr Mgaya*

- Formulating a National Quality Assurance document
- Setting up a mechanism to monitor laboratory services with support from CDC
- Setting up a programme for international accreditation of laboratories in Tanzania
- Through the help of the American Health Alliance, some regional laboratories will soon be taken through the process of accreditation
- Setting up a modernisation programme to improve laboratories
- Appointing a national coordinator to oversee laboratory quality systems
- Setting up a national quality assurance training centre



***Dr Jamala Taib, Director, Mnazi Mmoja National Reference Hospital, Ministry of Health and Social Welfare, Zanzibar***

Dr Taib reported that Zanzibar has been participating in the EA-REQAS programme since its inception. He informed the delegates that Zanzibar has two reference laboratories. He also said that the Ministry of Health and Social Welfare is currently in the process of reviewing its health policies and this is the right time to lobby for the inclusion of a policy towards strengthening laboratory services in Zanzibar.

*"This is the right time to lobby for the inclusion of a policy towards strengthening laboratory services in the Ministries of Health" Dr Taib*



***Dr Taib giving his remarks***

He went further to say that although Zanzibar is still in the initial stages of setting up the infrastructure for improving quality of laboratory services, the country has made some worthwhile breakthroughs, namely:

- Reducing malaria infection, a situation that makes a strong case for quality laboratory services that has assisted a great deal in this reduction
- Five laboratories in Zanzibar are in the process of attaining accreditation

***Dr Michael Smalley, Director General, AMREF***

Dr Smalley welcomed the Guest of Honour and delegates on behalf of AMREF and indicated that AMREF as an organisation was pleased to be part of this important meeting.

***Dr Smalley addressing delegates***



*"AMREF as an organization remains committed towards ensuring access to quality health care of which laboratories play a critical part" Dr Smalley*

He indicated that his personal experiences at an early age in his career as a health worker in Africa, and as a patient thereafter in England, had taught him the importance of quality laboratory services and testing in the care and management of patients.

He indicated that AMREF has always supported quality laboratory work, which is part of the current strategy to bring communities into the health system as part of a strategy to deliver quality care to communities who so often fall outside the health system.

He noted how important quality laboratory services are for the delivery of health care and indicated that the aim of the laboratory diagnostics programme within AMREF is to work towards strengthening laboratory services and health systems as a whole.

**Dr David Okello, WHO Representative, Kenya**

Dr Okello stated that he recognised the importance of accurate and reliable diagnosis in clinical medicine and general public health practice. He indicated that the costs of inaccurate diagnosis can be overwhelming for patients including the social and psychological impacts of a false positive or negative test such as an HIV test. He indicated that there is an overwhelming need to address the following issues:

**Dr Okello addressing delegates**



*"We cannot and we must not lose faith in the laboratory. If there is a problem in the laboratory let us fix it; we cannot afford to lose faith else it would be very, very, dangerous to public health". Dr Okello*

- The serious problem of quality control in laboratories, to avoid conflicting test results between laboratories
- Standardisation and availability of equipment and training to carry out common diagnostic procedures
- The critical need for greater collaboration in the East African region. There is need to move towards having common standards, harmonise laboratory services and if possible develop a legislative framework towards this end
- The need to celebrate, document and share the success stories of this programme. The progress this programme has made thus far should be properly documented and tabled to the East African Community.

He stated that the role of WHO is to provide technical guidance as it cannot impose any legislative framework on the East African member states; and that it is the responsibility of the Ministries of Health to push for harmonisation, standardisation, and common training arrangements. He thanked AMREF on behalf of WHO for acting as coordinator for the EA-REQAS and for guiding the process.

**Mr David Nalo, Permanent Secretary, Ministry of East African Community, Kenya, & Guest of Honour**

**Mr Nalo giving the opening speech**



*"With new emerging programmes that require laboratory support such as Antiretroviral Therapy (ART), Management of Opportunistic Infections, Management of Non-Communicable Diseases (NCDs) and Management of Neglected Diseases, I would urge the EA-REQAS Committee to consider fast tracking the scale-up of the scheme to all districts and widening the range of tests for assessment". Mr Nalo*

Mr Nalo reiterated the importance of quality assurance in the delivery of health services, emphasising the role of laboratory services in guiding decisions on clinical management of patients and public health interventions, as well as in research activities. He also indicated that the Ministries of Health across East Africa recognise the important role that laboratory services play in health service delivery, and have placed laboratory services among the high priority areas that need strengthening.

Mr Nalo reported that in the last three years, deliberate steps have been taken to implement a policy of affirmative action for quality laboratory services in line with the Maputo Declaration and the Lyon Resolutions. He noted that considerable progress has been registered in the following areas:

1. **Human resource capacity building:** Continuing Medical Professional Training has been intensified in the countries within East Africa. The MoEAC appreciates the contributions of AMREF, CDC, MSH and other partners in this area.
2. **Provision of Guidelines, Standard Operating Procedures and Reference Materials:** Various guidelines, SOPs and text books have been distributed to all laboratory units to supplement Continuing Professional Development (CPD) programmes.
3. **Infrastructure improvement:** In collaboration with partners including AMREF and CDC, infrastructure in terms of laboratory space, running water, power and equipment is being improved in a phased manner.
4. **Policy Development:** Comprehensive National Laboratory Services Policies and Strategic Plans have been developed and are being implemented. These policies will enhance the quality of laboratory systems that will ultimately support quality health care service delivery.

Mr Nalo also acknowledged the role EA-REQAS is playing to assess the proficiency of laboratory networks, identifying factors affecting performance, and instituting remedial action with the aim of improving the quality of health care.

He noted that the results of the successfully completed pilot phase of the EA-REQAS have been useful in identifying facilities that need further support from the Ministries of Health. He also recognised and commended the approach of EA-REQAS concerning the selection of the range of tests performed at peripheral level which he noted was cost effective, sustainable and aimed to support facilities that serve the majority of patients in the different countries.

## Session 2: Overview of the World Health Organization Diagnostics and Laboratory Technology Activities

### *Overview of the World Health Organization Diagnostic and Laboratory Technology Team*

*Ms Anita Sands, Technical Officer, Department of Essential Health Technologies, WHO Geneva*

The role of laboratory services in any health facility is underscored by the need to ensure blood safety, for surveillance and monitoring of diseases, and for patient care and facilitating effective treatment. All categories of laboratories, from sub-national and district to national referral laboratories, need competent staff, up-to date equipment and should be able to perform the required tests and give reliable results.

The Maputo Declaration of January 2008 on Strengthening Laboratory Systems was identified as an important document that guides the activities of the WHO teams. This declaration calls for stakeholders to integrate quality diagnostic services into the core of its health system functioning.

WHO considers prequalification of *in vitro* diagnostic medical devices as vital to ensuring that users procure diagnostics of the highest quality. This screening function also facilitates subsequent mechanisms for ensuring quality such as field-testing and promoting harmonisation and standardisation of equipment. Prequalification is important because it allows for evidence based selection of assays from the performance data that is generated; it also facilitates harmonisation and standardisation of laboratory commodities. A list of prequalified products allows for easier and streamlined procurement and in turn allows for better forecasting and quantification of resources.

The importance of improving Laboratory Quality Systems was emphasised. This comprises the following:

1. Quality Management (integrated organisational approach to achieve quality)
2. Quality Control (verifies the test is working correctly)
3. External Quality Assessment (verifies the proficiency of the testing process)
4. Quality Improvement (a continuous cycle of identifying opportunities for improvement)

WHO provides funding for a number of international EQAS through professional EQA providers addressing Haematology, Clinical Chemistry, Coagulation and HIV CD4 enumeration among other areas. Internal and External QC is often found to be problematic especially in primary facilities where non-laboratory technicians who have been trained to perform rapid testing, are not able to accurately read and report results. Issues of compromised quality can also be attributed to poor record keeping and poor stock management.

WHO maintains useful online manuals for maintenance of laboratory equipment, basic laboratory techniques for HIV testing, and evaluation of technologies that aim to ensure reliable and accurate testing.

## **Laboratory Capacity Building in the African Region**

*Dr Jean Bosco Ndiokubwayo, Programme Manager, Blood Safety, Laboratories and Health Technologies within the Cluster of Health Systems and Services, WHO Regional Office for Africa, AFRO Brazzaville, Congo*

### ***Laboratory policy***

Technical Guidelines for Integrated Disease Surveillance and Response in the African Region were developed by WHO/AFRO in close collaboration with CDC Atlanta. This document is intended to support policy makers and national public health authorities to carry out activities for improving laboratory support to the Integrated Disease Surveillance strategy.

WHO/AFRO in close collaboration with WHO/HQ in Geneva and other partners including CDC is developing guidelines to orient countries on the development and implementation of comprehensive national laboratory policies and plans to establish functioning national health laboratory services.

### ***Laboratory based surveillance***

Concrete examples on how laboratories in countries contribute to the surveillance of priority diseases were given. Laboratory-based surveillance of meningitis epidemics has played a significant role in timely outbreak response. Countries in the meningitis belt provide laboratory data on a weekly basis and feedback on this data is given to all contributing laboratories. A monthly bulletin on epidemiological and laboratory data is also issued and shared with countries and partners. The regular analysis of laboratory data allows countries to predict the circulating meningitis serotype and thus select the appropriate vaccine. The polio laboratory network is linked to an active community-based surveillance system that collects specimens from suspected cases and forwards them to laboratories for processing. Laboratories have developed capacity to provide genetic information that is necessary for tracking the spread of viruses. The lessons learnt from this work on polio have been useful in establishing measles surveillance systems that are integrated with acute flaccid paralysis surveillance in a number of countries.

### ***External Quality Assessment Schemes***

External quality assessment schemes have been implemented for enteric diseases, meningitis, plague, tuberculosis, malaria, polio, measles, yellow fever, highly pathogenic avian influenza and HIV/AIDS. For clinical laboratories, a scheme has been introduced for hematology and clinical chemistry. Some challenges have been encountered, for example, some laboratories do not follow the established guidelines for antimicrobial resistance testing, and some laboratories lack essential equipment and supplies.

### ***Progress and challenges***

Despite the progress and efforts being made to strengthen laboratory capacities in the region, challenges remain. These include the lack of national policy and strategy for laboratory services, insufficient funding, inadequately trained laboratory staff, weak laboratory infrastructure, old or inadequately serviced equipment, lack of essential reagents and consumables, and limited quality assurance and control protocols including lack of national EQAS. Laboratories are usually given low priority and recognition in most national health delivery systems. The challenge is developing a comprehensive national laboratory policy which addresses the above issues. Availability and access to quality laboratory services are among the major challenges contributing to delayed or inappropriate responses to epidemics, disease control and patient management.

### **Way forward**

Resolution AFR/RC58/R2 adopted by Member States during the 58<sup>th</sup> session of the Regional Committee held in Yaounde, Cameroun, in September 2008, summarises actions that need to be taken to build laboratory capacity in the African region. These actions include:

- Development of comprehensive national laboratory policies and formulations of national strategic plans
- Reinforcement of national capacity in laboratory management and leadership
- Establishment of National EQA schemes, ensuring laboratory equipment maintenance and funding for public health laboratory services
- Setting up Proficiency Testing schemes for Transfusion Transmitted Infections (TTIs) including Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV) and Syphilis in blood banks
- Countries to increase investments (both financial and human resource) in their national health laboratory services to ensure laboratory quality and safety, and strengthened laboratory-based surveillance for improved disease prevention and control in the African region.

Since laboratories are instrumental in disease prevention and control, there is need for sound laboratory infrastructures to be set up in countries. Adoption by countries of policy orientation documents such as **AFR/RC58/6** on public health laboratory strengthening, and **AFR/RC59/11** on establishment of Centres of Excellence for disease surveillance, public health laboratories, food and medicines regulation, are important indications of political commitment by member states to address laboratory issues in the Region.

### **Discussion**

- There is need for a coordinating mechanism or institution to assess laboratory capacity to ensure facilities perform the tests assessed in EQA. For example, in Tanzania, some laboratories do not routinely test samples for Rotavirus, yet they are involved in this EQA programme. The Ministries of Health should identify laboratories that participate in each EQA challenge, and there is need to integrate all EQA activities.
- To be eligible for or keep their accreditation status, laboratories need to perform a minimum number of specified tests.
- The need for governments to develop human resources to fulfill technical roles in the laboratories. This will address the issues of understaffing that is currently a problem in most countries.
- The role of the WHO is mainly advisory and also lobbies governments to keep their commitments. There will soon be a report on how far these countries have gone in keeping their pledges.

### **WHO/AFRO Laboratory Accreditation Scheme**

***Dr Fatim Cham, HIV Laboratory Technical Officer, WHO/ IST/ESA, Harare, Zimbabwe***

### **Strengthening Laboratory Capacity**

WHO's primary concern is to strengthen and support health systems in countries with limited resources through:

- Supporting collaboration between all donors and partners with coordination from government ministries
- Supporting the development of national laboratory policies within the national health development plan that will guide the implementation of a national integrated laboratory strategic plan

- Assisting in development of a five year national laboratory strategic plan that address quality diagnosis, and monitoring and surveillance of diseases of public health importance
- Strengthening political commitment and ensuring adequate and sustained funding
- Establishing an accreditation scheme for all levels of laboratory services

### ***WHO AFRO Stepwise Accreditation***

The WHO Laboratory Accreditation Scheme was set up in 2009 with key functions including:

- Strengthening laboratory management for immediate and measurable laboratory improvement
- Training of assessors to assess laboratories and accredit them to five star status
- Serving as a stepping stone towards achieving international/regional accreditation, ISO15189/SANAS, CAP

### ***Benefits of Accreditation***

- Accreditation is a warranty of quality services. It has enormous spillover effects, ensuring the credibility of laboratory services, boosting operational efficiency and productivity, and reducing patient care costs. Accreditation ensures that overall operating standards are improved to acceptable levels. However, accreditation has an immediate impact on the need for increased management of laboratory services. Enhanced quality of testing means that more resources and training are needed. More than one hundred laboratories in several African countries, including Côte d'Ivoire, Kenya, Ethiopia, Cameroon, Nigeria, Tanzania, Zambia, Zimbabwe, Uganda, Lesotho, Botswana, Rwanda and Senegal are already moving forward with WHO/AFRO accreditation activities.

### ***Challenges of attaining international accreditation***

Gaining international accreditation is involving and demanding and is faced by many challenges, including:

- Laboratory managers have not been trained in quality management systems
- Few national laboratories have achieved accreditation to serve as a role model. There are only 28 laboratories in sub-Saharan Africa (excluding South Africa) that have attained international accreditation.
- Most laboratories operate with limited funding and technical deficiencies
- The cost of gaining international accreditation is high, with US\$ 235,150 needed to undertake the interventions to qualify for accreditation and another US\$ 92,200 needed to maintain the status of accreditation.

WHO AFRO accreditation provides a less expensive stepwise scheme to encourage participation of many laboratories, and to ensure that results from these laboratories are comparable across the region

### ***Process of attaining accreditation***

In 2008, WHO and CDC held a meeting in Lyon, France, focused on strengthening laboratory systems. The international organisations represented resolved to encourage nations to take a phased approach to gaining accreditation through seeking regional or international accreditation. In this regard, the WHO checklist can be a useful assessment of the status of a laboratory. This checklist is based on 12 quality system essentials (QSE) derived from ISO 15189. The checklist is thorough and comprehensive and deals with an array of issues, including organisation and personnel, stock and data management, purchase inventories, internal audits, information management, corrective and preventive measures, storage and safety, assessment of tests, waste management, and customer service.

Accreditation teams review annually the records of laboratory performance including laboratory procedures and safety issues. If laboratories do not conform to the requirements outlined in the checklist, a WHO coordinator will work with the laboratory to address areas of weakness.

### ***Criteria for gaining accreditation***

- At least 80% of the specimens must be reported within the specified turnaround time.
- A sufficient number of tests are performed on a quarterly basis to maintain laboratory competency
- Internal quality control procedures are practised for all test methods used by the laboratory
- The score on the most recent WHO approved proficiency test is over 90%
- The score from the annual on-site review of laboratory operating procedures and practices is at least 95% (5 star rating)

Laboratories who achieve less than the passing score for the above criteria, work with the WHO Regional Laboratory Coordinator to:

- Identify areas where improvement is needed
- Develop and implement a work-plan
- Monitor laboratory progress
- Provide for pre-assessment specimen for proficiency testing (PT) panels where required
- Continue with steps towards achieving full accreditation

### ***Way forward***

- There is need to develop country specific plans to improve quality in all tiers of the laboratory hierarchy
- There is need to commit to training a quality manager, who should preferably be a senior member of staff
- There is need to develop internal laboratory standards, and monitoring and evaluation tools to facilitate preparedness for accreditation
- There is need to establish mechanisms and systems that enable continuous quality improvement
- There is need to work with partners to develop resources for quality management in the context of an accreditation application
- There are several normative tools that countries can use; they include a range of guidelines and manuals from WHO, including post-market surveillance guidelines and protocols, quality management training guidelines, laboratory bio-safety manual, equipment maintenance guidelines, and laboratory safety plans.

### ***Discussion and comments***

- **Accreditation of lower level laboratories:** WHO would consider assessing any laboratory for accreditation. There is no need to wait for accreditation of reference or national laboratories to accredit subordinate laboratories.
- **Training programme for laboratory managers:** A training schedule or program exists that covers a range of topical issues. WHO however, encourages partners to self-assess their needs as a preliminary step towards accreditation; it infers training needs through such evaluation reports.
- **Relationship between WHO AFRO and the International Laboratory Accreditation Cooperation (ILAC):** the ILAC accredits accrediting institutions, and WHO helps them to develop standards. WHO is lobbying for accrediting organisations to join ILAC and for laboratories to seek accreditation from agencies that are affiliated with ILAC.



- **Relationship between WHO assessors and East African trained assessors:** the WHO effort is not to duplicate efforts of these assessors but to complement their work.
- **Hiring independent assessors for accreditation:** The WHO/AFRO accreditation scheme was launched in 2009 in Kigali and 30 assessors from different countries have been trained so far. There are plans to train additional assessors. The WHO Advisory Board has, likewise, been constituted and is waiting for the approval of the Regional Director to begin its work.
- **Role of WHO in accreditation:** WHO is not an accrediting body, it simply creates a mechanism or procedure that allows laboratories to follow through on their application for accreditation. This reality needs to be clarified.

### **WHO Regulation and Post Market Surveillance of Diagnostics Project** ***Ms Jeanette Twell, WHO Geneva***

WHO has a keen interest in the quality of rapid tests for HIV, malaria, and TB and is interested in seeing regulatory authorities grow and develop capacity to screen diagnostic kits to meet optimal demands for safety, performance, and quality. The Prequalification of Diagnostics Programme has the following major components:

- Application and product dossier for review
- Site inspection of manufacturers (compliance with ISO 13485 and WHO requirements)
- Laboratory testing at WHO collaborating centres
- Post market surveillance (deemed as the “cornerstone” of the process)

There is need for the following:

- Partners to report any problems with use of testing equipment or *in vitro* medical devices within and outside their countries
- Regulatory authorities to require and ensure the provision of technical means to assess the quality of *in vitro* medical devices.

WHO supports the development of country specific strategies and legal frameworks regarding diagnostics and is ready to assist in advising about the evaluation of test kits.

### **Presentation on Tanzania experience of post-market surveillance of diagnostics** ***Dr Judica Mbwana, Programme Manager, WHO, Tanzania***

Although it has drawn up the requisite strategy plan, Tanzania is yet to formally implement Post Market Surveillance (PMS) for *in vitro* diagnostics. However the following progress has been made so far:

- The Medical Devices Assessment and Enforcement Committee is set to begin implementing guidelines for the registration of medical devices and screening in 2010.
- A sound Medical Devices Testing Laboratory has already been established and plans are also underway to train staff to do *in vitro* diagnostics post market surveillance.
- The Private Health Laboratory Regulations Act of 1997 was established to ensure screening of medical devices and techniques. This law is elaborate on the process and standards that must be complied with before any laboratory supplies or equipment are permitted into Tanzania. Beyond this, equipment must be evaluated before use in laboratories. However, not enough is being done to ensure that the authorities do vigorous PMS of diagnostics as stipulated in existing guidelines. In 2009, a

WHO mission assessed the capacity of several regulatory authorities including the Tanzania Food and Drug Authority (TFDA), Public Health Laboratory (PHLB) and National Health Laboratory Quality Assurance Training Centre (NHLQTC) regarding their participation in the PMS pilot project. The mission found that Tanzania has the capacity to undertake the activity through TFDA but TFDA needs to work more closely with other partners.

#### ***Way forward and next steps***

- The need to strengthen country capacity substantially to implement the regulations and PMS
- The need to build capacity for PHLB and the NHLQTC to undertake PMS in collaboration with TFDA (TFDA will not be responsible for the actual testing aspect of PMS; laboratory technologists are better placed to do so).
- The need to identify a core set of staff and partners with the right expertise to lead the project
- Develop a proposal and plan of action that will include strengthening the regulatory capacity for diagnostics and PMS in Tanzania
- Establish linkages with partners who have the necessary expertise to perform the pilot study
- Identify a project implementation team with WHO as the Secretariat

#### ***Discussion***

- Information on the performance of any equipment should be shared with other facilities using the same equipment within the country and the region.
- Where PMS begins: Surveillance should start at the manufacturing stage; WHO believes in pre-qualifying diagnostics by doing site inspections, reviewing dossiers of product information and conducting laboratory evaluations to ensure quality of diagnostics. Post-manufacture surveillance is of equal importance but rather more difficult to implement.
- In Tanzania, the authorities sample all medical equipment at the point of entry.
- The Private Health Laboratory Board (PHLB) registers medical equipment, inspects all items, issues certificates, and conducts evaluation of new products/technologies in Tanzania. A regulatory body facilitates PMS.
- There should be a clear demarcation of responsibility between the TFDA and PHLB to avoid conflict of responsibilities.

## Session 3: Group Work – Key challenges and issues related to quality of diagnostics and suggested solutions

### Group Questions

Participants broke into 4 groups to discuss the following questions:

1. What are the problems with quality of test kits in your country?
2. What are the problems with procurement of test kits, equipment and laboratory items?
3. What can be done:
  - At country level
  - By Ministries of Health
  - By international partners
  - By WHO
4. List 5 desired improvements that you would like for your laboratory that can easily be implemented in the short term

### Group Discussions and Feedback

The participants provided the following responses:

#### 1. Problems with quality of test kits in countries

- Inadequate in-country evaluation systems and poor links between procurement and inventory management (packaging, expiry, damage) because many countries lack a Post Market Surveillance system.
  - There is no clear policy for evaluating kits to select superior products
  - There is political influence in selection of suppliers resulting in inferior products being supplied.
- Poor supply chain management: there is sometimes delay in delivery of kits and other supplies; as a result required storage temperatures are not maintained, especially for items that require cool chain:
  - Storage of test kits that need the cool chain are a problem in facilities that lack refrigerators and/or electricity.
  - Temperature stability (transport, storage and use) is a key concern, particularly in areas where temperatures routinely exceed manufacturers' recommendations. Cool boxes may be used for transportation and storage; however, availability and practicality of use is limited.
  - There is a short shelf-life of some testing kits
- There is generally failure to validate donated test kits
- There is low EQA coverage and limited use of internal quality controls to assess kit performance
- Problems related to use of Rapid Diagnostic Tests (RDTs) were cited as follows:
  - SOPs for RDT use may not be available in the ward/peripheral facilities
  - Personnel who commonly use malaria RDTs have low levels of training and experience. Interpretation of RDTs in peripheral health facilities is done by health workers without the most basic training.
  - Great variation of RDTs from different manufacturers makes it difficult to standardise training for peripheral health workers
  - Many manufacturers produce large volumes of diagnostic kits, resulting in compromised quality.

## 2. *Problems with procurement of test kits, equipment and laboratory items*

- Inadequate procurement plans for laboratories in all countries lead to poor stock and inventory data management. Most laboratory personnel lack of training in supplies quantification, forecasting and inventory management.
- Long procurement processes causing delays in acquisition of equipment and supplies and failure to involve end-users in the procurement process
- Vendors within countries who are not sole agents for particular equipment and do not directly represent manufacturers often fail to provide proper service contracts and provide poor follow up services.
- Poor relationships between vendors and end-users of equipment and supplies
- Lack of standardised systems for equipment procurement and validation/calibration before placing the equipment in use
- Lack of guidelines and adherence to disposal of medical waste/equipment.
- Lack of guidelines on donation of equipment resulting in dumping of equipment that is not suitable, difficult to maintain, nearing obsolescence, for which supplies are hard to obtain
- Lack of systems to ensure that all products in the market have been officially verified as meeting their expected performance before entering the market
- Limited funding for procurement of equipment and supplies

## 3. *Recommended actions*

- **At country level and MoH**
  - MOH in collaboration with development partners conduct sensitisation to increase awareness of PMS
  - Advocacy to enact laws on regulation of laboratory supplies and equipment including policies on procurement, maintenance, service contracts and disposal of obsolete medical equipment and supplies
  - Involve laboratory technical persons in the procurement process, particularly in selection of items
  - Establish quality systems for supplies transportation and storage conditions
  - Provide support supervision and guidelines for commercial kit evaluation prior to use
  - Institute routine quality assurance measures including quality control
  - Provide adequate allocation of resources for laboratory services at the ministry level
  - Ensure coordination and supervision of partners within each country to ensure that all activities are in line with MOHs goals
  - Ensure comprehensive equipment management programmes
  - Ensure that the pre-service training curricula for medical laboratory technicians, technologists and scientists addresses logistics management
  - Provide in-service training of laboratory personnel in procurement and inventory management
- **By WHO and other Partners**
  - Provide technical assistance and capacity building in PMS implementation and provide training and mentorship in commodity management
  - Adhere to national policies and guidelines of each country, rather than pursuing individualised activities
  - Align to the goals of the country
  - Equipment in MOH facilities must be the property of MOH and must be put in place in accordance with national standards

#### **4. Desired improvements that can be implemented in the short term**

- Countries should establish Continuous Professional Development (CPDs) programmes to train laboratory personnel in commodity logistics management, record keeping and QA
- Countries should develop and improve usage of SOPs and job aids in laboratories
- Internal quality control programmes should be strengthened within laboratories
- Partners should provide supportive supervision with on-site training and mentorship
- Training, SOPs, supervision and ongoing monitoring of test quality are required
- Laboratory Information Management System (LIMS) should be established or strengthened in laboratories
- MoH should provide a road map for standardising national equipment lists
- Each country should strengthen national supply chain management to ensure that procurement and delivery systems guarantee the quality of test kits
- PMS systems should be set up in each country to evaluate and approve kits for use. PMS needs to be implemented and strengthened to ensure that kits or instruments perform as expected

## **Day 2: EA-REQAS Proceedings**

### **Session 4: Performance Report – Regional Coordinating Centre**

#### ***RCC Presentation 1: Review of Activities of the EA-REQAS Scheme***

***Dr Jane Carter, Regional Coordinating Centre, AMREF Headquarters***

#### **Background of EA-REQAS**

The history of EA-REQAS and the role of WHO in its formation was highlighted. Consensus and agreement were sought at a Regional Technical Meeting of EA-REQAS held in Arusha, Tanzania, in 2003 to roll out the scheme.

#### **Advantages of a Regional EQA Scheme**

- Standard laboratory procedures regionally
- Standard quality of scheme materials with comparison of performance across the region
- Wider range of specimens
- An opportunity to share resources for material preparation – economies of scale
- Availability of more national resources available for much needed remedial action
- Lessons learned from regional experience
- Increased regional co-operation

#### **REQAC Activities**

Following establishment of the Scheme, the regional and national components of the scheme were identified, a technical working group, the Regional External Quality Assurance Committee (REQAC), was established, two representatives from each Ministry were nominated, and a Regional Coordinating Centre was established to coordinate the scheme. EA-REQAC held its first meeting in Zanzibar in 2006 and determined the criteria for selection of tests and techniques as well as identifying reference laboratories to produce standard materials for EA-REQAS.

The criteria for selection of tests and techniques were as follows:

- Tests of clinical importance
- Test of public health importance
- Tests and techniques performed at primary health care level
- Techniques of accepted accuracy
- Tests for which methods of material preparation/preservation are available
- Tests for which standards of measure/recognition are available

At the same meeting, districts in each country were selected to participate in the EA-REQAS. A total of 193 facilities were selected with each district having five to eight facilities representing public, faith-based and private facilities. Ministries of Health in each country were requested to carry out sensitisation workshops for the district clinical and laboratory supervisors to inform them about the scheme and their very vital role in conducting remedial action.

### *Discussion*

- **Awards for participation and good performance:** no certificates for regular participation or good performance have been awarded thus far. However there are plans to issue certificates of participation and good performance in future.
- **Feedback to the participating laboratories and corrective action:** There is immediate feedback to the participating laboratories and their district headquarters; in addition, a composite report is prepared and sent out to the respective Ministries of Health for action at the end of each survey. The major constraint with this is the long turn-around-time.
- **Reference Laboratories and Coordinating Centres relationship:** The reference laboratories to produce materials for EA-REQAS were selected by the regional committee members. Some reference laboratories are now producing the required materials; there however is need for discussions to be held with the respective Country QA Committees to better coordinate and harmonise this process. Challenges include getting laboratories to produce adequate materials of high quality.
- **Integrating the regional scheme with national QA bodies:** The purpose of this scheme is not to duplicate already existing EQA schemes, but to support them. One of the key aims of REQAS is to relieve the Ministry of Health from the complexities and efforts involved in running schemes and allow countries to focus on taking remedial action and addressing policy issues.
- **Accreditation of Reference Laboratories:** One of the key outcomes of the last regional meeting in Uganda was the need to accredit all laboratories that produce reference materials.
- **Mandatory/voluntary participation in EQA:** The scheme is supposed to be mandatory as it is a Ministry of Health scheme. Ministries need to strengthen participation by instituting legislation for mandatory participation in EQA. Some countries are considering linking participation in EQA with annual registration.
- **EA-REQAS Terms of Reference:** These need to be reviewed and revised as some of them are excessive.

## ***RCC Presentation 2: Materials Production, Distribution and Feedback***

***Rodgers Dena, Regional Coordinating Centre, AMREF Kenya***

The materials sent to participating laboratories in different surveys were reviewed. Each EQA challenge contains clinical and public health questions in addition to laboratory questions.

### **Quality of prepared materials**

Materials are prepared by the reference laboratories using the SOPs provided; these SOPs were developed by the EA-REQAC technical working group. After preparation, the laboratories are required to perform quality control on 10% of the materials and give a feedback report to the RCC. Upon receipt of the materials from the laboratories, the RCC is also required to perform a 10% QC check and make a report. When all the materials have been received, samples of the material are sent to validating laboratories for examination. The results of the validating laboratories are used to generate consensus results against which participants are graded.

### **Challenges in material production**

In some cases, materials are poorly prepared, or some reference laboratories fail to prepare the materials at all. This results in delays as the RCC is forced to prepare the materials themselves. The reference laboratories need to play their part to ensure timely production of quality materials and maintain the participatory spirit of the scheme.

### **Turn-around-time**

Turn-around-time has proven to be a major challenge to the RCC. Materials sent to participating laboratories for analysis are usually not received back within the stated time frame. The turn around time has been as long as 110 days; part of this is attributed to lack of funds to send the results back after analysis. RCC conducted a telephone survey in Kenya to establish the causes of delays in response; the following reasons were given:

- No hand over when a staff member is transferred, so the replacement person usually has no idea about the scheme and what should be done
- Results that are sent out get lost along the way or within the laboratory
- Heavy workload of the staff members prevents them from analysing the EQA samples in a timely manner
- Lack of funds to send back the results
- No electricity to carry out the analysis; despite this laboratory services were being conducted as usual
- Because of the sub-division of districts, the District Medical Laboratory Technologist (DMLT) cannot supervise activities in another district
- Clinicians take too long to respond to their sections due to their heavy workload

## ***RCC Presentation 3: Results of countries performance in EQA***

***Martin Matu, Regional Coordinating Centre, AMREF Kenya***

### **Level of participation**

This presentation gave results of the three surveys conducted in Zanzibar, Tanzania, Uganda and Kenya during the pilot phase; the fourth survey was sent out in February 2010 and results are not yet analysed. The overall response of the first survey was 80% but the number of responses declined in Surveys Two and Three. The governments need to execute a policy that would make it mandatory for laboratories to participate as one of the major challenges is poor or low response from facilities.

The government facilities' response in Surveys One and Two was better than the faith-based and private facilities. The overall participation in Survey Three dropped to 54% with Tanzania having the lowest participation at 35% while response by laboratories in Kenya was 70%.

### ***The Marking Process***

For the qualitative responses, in Surveys 1 and 2 manual marking was carried out by three RCC staff members individually evaluating and marking every response. In Survey 3, coded answers were introduced to limit the number of responses and to ease the marking process and awarding of marks.

### **Country performance**

The mean performance of all countries based on questions set in Surveys 1, 2 and 3 ranged between 41% – 58% for hospitals and 34% – 55% for health centres. The mean performance of hospitals was better than health centres in all countries.

The results showed that in Survey 3, in Kenya faith-based facilities performed better in public health questions while government facilities in Tanzania performed better in both laboratory and public health questions. Health centres in Kenya and Uganda did better than hospitals in public health and clinical questions.

Poor performance was identified in the following areas in all three surveys:

- Haemoglobin (Hb) estimation
- Filariasis diagnosis
- Peripheral blood film (PBF) examination
- Gram staining

It was established that poor performance from laboratories could be attributed to the following:

- Level of staffing
- Source of power for microscopes
- Method of Hb estimation - laboratories using Sahli or Lovibond comparator for Hb estimation performed poorly.

### **Summary of results**

- Participation declining:
  - 80% (Survey 1) to 54% (Survey 3)
  - Government facility participation was better than private and faith-based facilities
- Qualitative questions marked manually:
  - Introduction of coded answers
  - Grading scale of 3 (best answer) to – 1 ( clinically dangerous response)
- Overall performance improved in Survey 2 but declined in Survey 3 in all countries
- Generally hospitals performed better than health centres in all surveys
- Health centres in Kenya and Uganda did better than hospitals in public health and clinical questions



***RCC Presentation 4: Feedback, challenges and suggested way forward***  
***Enock Marita, Regional Coordinating Centre, AMREF Kenya***

**Reporting and Feedback**

There are two forms of reports prepared and sent out:

- a. **Immediate feedback report:** This is sent to each participating laboratory and includes details of performance, how performance can be improved and also proposes remedial actions. Copies of this report are also given to the district or regional supervisors.
- b. **Composite report:** This report is sent to the respective Ministries of Health and contains results of each participating laboratory, coded results of all participating laboratories in the other countries and an analysis showing potential sources of errors.

**Overall achievement of the pilot phase**

- A total of 95 laboratories (49%) participated in all the three surveys
- A total of 24 laboratories (12.4%) showed overall improvement in performance
- There has been full support and collaboration from the four Ministries of Health
- There has been interest from other countries (Rwanda and Burundi) to join the scheme
- There has been support from governments, donors and WHO for scheme activities

**Key challenges faced in the pilot phase**

- Failure by reference laboratories to produce materials or production of substandard materials
- Difficulty in sourcing some of the supplies locally, e.g., carbon tetrachloride, which has strict regulations for importation.
- Long turn-around-times and poor levels of participation
- Incomplete responses by participating facilities
- Slow database development
- Laxity in following scheme instructions by the health facilities

**Lessons learned during the pilot phase**

- EQAS is an assessment tool for diagnostic services; analysis is done for staffing, equipment, test kits and methods used throughout all health facilities
- EQAS identifies major problems in laboratory performance at peripheral level that need urgent action
- EA-REQAS provides distance learning
- EA-REQAS provides staff motivation
- EA-REQAS influences policy change
- EQAS identifies areas that require long-term investment in laboratory service strengthening
- EQAS can be effectively operated through regional cooperation

**Suggested Way Forward**

- National QA bodies to ensure validation of QA materials before submission to RCC
- Replace non-performing reference laboratories and identify more reference laboratories to produce materials
- Facilitate accreditation of the RCC and all reference laboratories as well as the EA-REQAS scheme
- Scale-up: Increase the number of laboratories and expand to other countries (Rwanda and Burundi)
- Increase the range of materials in panels and increase the frequency of surveys
- Have in place regular supervision of participating laboratories for remedial action by governments

- Use Posta EMS services to transport materials and e-mail/mobile phones to send back results
- Ministries of Health to enforce mandatory participation of health facilities
- Governments should provide budgetary allocations for local country costs

## Discussion

- **Results included in analysis:** The results shown in the presentation are the results obtained from all reports of the surveys that have been received back.
- **Training for staff in participating facilities and awareness-raising of EQA:** When enrolling facilities in the scheme, sensitisation workshops are conducted for clinical and laboratory district supervisors and publications (SOPs and manuals) are distributed during these meetings for all facilities represented.
  - There is need for wider sensitisation so that the activity is taken up by departments rather than individual district supervisors
  - There should be training of staff in the participating laboratories to learn how to manage the received EQA panels.
- **Feedback reports:**
  - This scheme has been in place for the last two years and therefore the lessons learned should act as a basis to move forward. This pilot scheme should inform national policies, programming, planning and decision-making at country level.
  - As well as giving feedback to the MOH, there is also need for the same feedback to be given to the regulatory body (Board or Council) so that follow-up can be made with the non-participating facilities. Proceedings from meetings such as this should be submitted to regulatory bodies for their action and follow-up.
  - Information on the performance of different equipment should be published to act as an advocacy tool for lobbying purposes to ensure to better standards of equipment are provided to health facilities.
- **Improvement of malaria diagnosis:** There is need for training of laboratory technologists in malaria diagnosis and microscopy. There is a programme that focuses on training in malaria microscopy that can support the improvement of malaria diagnosis.
- **Capacity of RCC to prepare all the materials required:** The scheme is not AMREF owned but is owned by MOHs within East Africa. However, the RCC would be able to carry out these tasks if properly supported and capacitated.
- **Turn-around-time:** CDC has faced the same challenge of long TAT and introduced a submission date of 18 days for the institution to submit the results after which the results will not be evaluated.
  - A calendar of events can also be drawn-up so that all laboratories are made aware of when the samples will be received and submitted.
  - The use of e-mail to send alerts has proved to be very useful and should be used more. For the district hospitals, a coordinator has been identified to monitor all districts hospitals to ensure they forward their results.
  - Staff transfers/not handing over and delays in transportation of samples are issues that need to be urgently addressed.
- **Internal quality control (IQC):** There is need to strengthen IQC in laboratories and ensure full participation and commitment from all staff.
- **Mandatory participation:** The MOH needs to institute a clear policy for mandatory participation in EQA. Some facilities communicated their disinterest in participating.

- **Scheme players:** There is need to fully define the roles of the different players in the scheme: the government, both at district and facility level, and the regulatory bodies.
- **Integration of Regional and National EQA schemes:** The coordinating team needs to discuss with scheme organisers on how to integrate the regional scheme into national schemes:
  - In Kenya, the HIV reference laboratory is mandated to coordinate all HIV testing activities in the country. The RCC needs to partner with the HIV reference laboratories to share experiences on panel preparation and harmonise distribution.
- **Support supervision:** Support supervision of laboratory facilities needs to be strengthened to provide on-site training and staff support.
- **Scheme Ownership:** There is need for regular updates for the Ministries by the RCC:
  - RCC to give updates and recommendations to governments who have the responsibility for follow-up of facilities.
  - There is need to review the membership in the different EQA advisory committees.

### **Key Points for Follow-up**

1. Award participating facilities with certificates for good performance and regular participation
2. Establish return submission dates to improve long turn-around-times
3. Identify ways to improve logistical difficulties in transporting materials
4. Establish a strong coordinating body in each country to ensure quality of materials produced by reference laboratories before submission to the RCC
5. Support the accreditation of laboratories that produce materials
6. Review the Terms of Reference of the Regional Quality Assurance Committee (REQAC)
7. Lobby governments to institute a policy to make it mandatory for laboratories to participate in the scheme
8. Integrate the regional scheme into national schemes and ensure the regional programme is owned by the regional governments.

## **Session 5: Country Presentations**

Representatives from each Ministry of Health participating in EA-REQAS presented the activities of their QA Committees and National Reference Laboratories.

### **Zanzibar**

**Dr. Salum Seif Salum, Laboratory Scientific Officer, Ministry of Health & Social Welfare**

**Role of National QA committee and National Reference Laboratory (NRL):** The National QA Committee of Zanzibar comprises of 12 members, with the role of providing oversight, advice and guidance to implementation of the QA programme, internal QC and EQA performance, following up the recommended corrective action, providing support supervision and carrying out monitoring and evaluation of QA in the country. The NRL of Zanzibar is responsible for supervisory visits and sensitisation of district laboratories; and in addition the NRL prepares standard EQA materials for various parasitic infections, distributes EQA materials to the participating facilities and develops SOPs for sample collection and material production.

**Achievements:** Some of the key achievements include: preparation of blood slides for microfilariae, stool specimens for intestinal parasites, and urine samples for *Schistosoma haematobium*. Additionally, all participating laboratories in pilot districts have been visited.

**Challenges:** Key challenges encountered during the pilot phase includes; lack of a budget line within the Ministry to support transportation of EQA material; inconsistent education on EQA for laboratory staff; weak monitoring of REQAS activities including failure to carry out follow up after recommendations for remedial action; and high staff turnover in many private facilities.

**Way Forward:** To improve the performance of the scheme and the role of Zanzibar, there is need for provision of a budget line to support transportation of EQA material and communication; to conduct regular sensitisation and educational meetings to participating laboratories to increase awareness; to prepare a plan for support supervision; to evaluate appropriate means for distributing EQA materials; and to review the policy for strengthening laboratory services in the country.

## **Tanzania**

**Mr. Gamaliel Kisyombe, Secretary of the National QA Committee, Ministry of Health & Social Welfare**

**Activities of the National QA Committee and NRL:** the National QA committee in Tanzania is responsible for the development and review of policy guidelines on laboratory QA including operational plans for approval by the National Association of Chain Drug Stores (NACDS); advising the NACDS on implementation of the national Laboratory Quality Assurance (LQA) programme; reviewing internal QC and EQA performance data; and recommending corrective action and reviewing the implementation of the action plan on a half yearly basis. NRL identifies and visits reference laboratories responsible for preparing standard materials, prepares SOPs for material preparation and is responsible for preparation of standard specimens for HIV and syphilis tests and blood slides for malaria.

**Challenges:** These include: preparation of specimens that do not meet quality standards; and late submission of materials to the RCC.

**Way forward:** These include; revisiting reference laboratories to identify constraints and institute corrective measures; identifying other reference laboratories for material production; using participation in EQA as one criterion for laboratory registration; follow up of all poorly performing laboratories and non-responders; and providing incentives such as training and conference attendance to well-performing laboratories.

## **Uganda**

**Mr Peter Awongo, Member of the National Quality Assurance Sub-committee, Ministry of Health**

**Activities of the National QA Committee and NRL:** The national QA body is responsible for developing a national QA plan, planning for national laboratory accreditation and developing a laboratory management training curriculum. NRL is involved in making arrangements for preparation of standard materials such as blood slides for trypanosomes by NALiRi and TB smears by the National TB Reference Laboratory (NTRL).

**Challenges:** Poor coordination between the AMREF Country Office, the Central Public Health Laboratories (CPHL) and the districts; poor linkages between districts and participating laboratories; and limited ownership by some reference laboratories

**Way forward:** There is need for discussions to harmonise EA-REQAS with other national schemes. A comprehensive laboratory QA Master Plan is being developed and harmonisation of different schemes is being addressed in the plan. Linking participation in EQA with certification/accreditation and improving coordination of national stakeholders are being considered for implementation. Roll out of this scheme in Uganda is recommended.

## **Kenya**

**John Matoke, National QA Officer, Ministry of Public Health and Sanitation**

**Activities of the National QA Committee:** The National QA Committee of Kenya is required to receive materials from the country coordinating centre and distribute them to participating facilities, receive results from the RCC, distribute educational materials to participating laboratories and provide support to provincial and district supervisors.

**Achievements:** During the pilot phase of the scheme, sensitisation workshops were conducted for district supervisors (district clinical officers and medical laboratory technologists) in seven participating provinces.

**Challenges:** Lack of production of materials by some reference laboratories; preparation of specimens that did not meet the standard; and slow return of results by participating laboratories.

**Way forward:** There is need for more involvement of the National QA committee in providing support supervision; evaluation of different ways of effective distribution of EQA materials; and provision of a budget line for EQA participation within the Ministries of Health.

### **Summary of Recommendations**

- **Coordination of REQAS activities by National QA committees:** There is need to have a mechanism in place to strengthen national QA committees to share reports from the RCC with the respective Heads of Departments within the MOH.
- **Budgetary allocation for EQA:** There is need to lobby for funds from the government for EQA activities to ensure the scheme is sustainable.
- **Addressing challenges:** There is need to resolve problems experienced in the pilot phase as a matter of priority
- **Material distribution:**
  - Changing from serum to dry tube specimens is an option that may be considered
  - Explore options for transportation of EQA materials
  - Communication – use of SMS for communication can be explored
- **Ownership:** EA-REQAS is not seen as an MOH initiative because there is inadequate communication between the coordinating committee and the MOH. There is need for a focal person within the MOH to help coordinate and implement the various scheme activities.

## Day 3: EA-REQAS Group Discussions

### Session 6: Group Discussions on EA-REQAS

Group discussions were carried out to address selected issues, review challenges and chart the way forward for improving the implementation of EA-REQAS activities. The participants were divided into four groups to discuss the following:

- Policies and Guidelines
- Material production, transportation, distribution and feedback
- Scale up plan for survey materials and participating health facilities
- Review of Terms of Reference of EA-REQAS Bodies/Committees

**Table 1: Issues for Group Discussion**

Group 1 – Policies and Guidelines	Group 2 – Material production, transport, distribution and feedback	Group 3 – Scale up plan	Group 4: Review of Terms of References (TORs)
<ul style="list-style-type: none"> <li>• Integration of REQAS with National QA bodies</li> <li>• Mandatory participation</li> <li>• Addressing poor performance</li> <li>• Internal quality control</li> <li>• Training</li> <li>• Budgetary allocations for EQA</li> <li>• Regular support supervision of participating laboratories</li> <li>• Accreditation of the Regional Coordinating Centre laboratories, the EA-REQAS scheme, and reference laboratories</li> </ul>	<ul style="list-style-type: none"> <li>• Material production</li> <li>• Transportation</li> <li>• Communication of results</li> <li>• Turn-around time</li> </ul>	<ul style="list-style-type: none"> <li>• Scale up plan</li> <li>• Increase number of tests in the panels</li> <li>• Increase frequency of surveys</li> <li>• Role of Ministries of Health in scale-up</li> <li>• Technical Support from WHO and other partners</li> </ul>	<ul style="list-style-type: none"> <li>• The role of different bodies               <ul style="list-style-type: none"> <li>○ Reference laboratories</li> <li>○ National QA bodies</li> <li>○ Regulatory Bodies</li> <li>○ REQAC</li> </ul> </li> <li>• Government participation               <ul style="list-style-type: none"> <li>○ Standards/QA departments</li> <li>○ Other key government departments e.g. biomedical engineering</li> </ul> </li> </ul>

#### Summary of Discussion

##### *Group 1 - Policies and Guidelines*

- **Integration of REQAS with National QA bodies:** the MOH should own the programme and should include QA issues in national policies and strategic plans. Each country should strengthen the national QA body to coordinate QA activities in the country; and appoint a national focal person to chair the national QA body and oversee QA activities, and act as the link person with the RCC. There should be a link between the national QA advisory bodies, partners and national laboratory administrations within each MoH to improve communications between different partners.

- **Mandatory Participation in EQA:** The national QA body should oversee participation and follow up facilities that fail to participate. Countries should launch aggressive awareness campaigns to advocate for participation in EQA.
- **Poor performance:** To address issues of poor performance especially in Hb estimation, Malaria, TB and HIV diagnosis:
  - MOHs in each country must discontinue the use of visual techniques for Hb estimation
  - Ensure that participating laboratories have the necessary equipment and materials
  - Ensure staff are trained to perform the tests as required
  - National bodies should ensure follow up to address the suggested corrective actions, through:
    - Staff training
    - Equipment maintenance
    - Enhance linkages and communication between laboratories and clinics
- **Internal Quality Control:** All laboratory testing should include internal quality control and QA officers need to be appointed in facilities down to district level to ensure quality activities are carried out.
- **Training and support supervision:** Training and supervision were noted as very important issues that need to be addressed:
  - National QA bodies should assess and address specific training needs in laboratories through various means, including regular refresher training courses.
  - National QA bodies should oversee on-site supervisory visits and mentoring, and assist laboratories to develop and use SOPs
  - Governments should work towards ensuring retention of trained staff
  - Pre- and in-service training curricula need to be reviewed to include elements of new technology and laboratory QMS
- **Budgetary allocations for local costs by governments:** To address the limited budgetary allocation for EQA activities including costs of transportation and communication:
  - Laboratory strategic and operational plans need to be developed, with costs to justify budget allocations for EQA activities
  - Stakeholders and development partners should be involved in implementing the developed plans and provide additional support
- **Accreditation of laboratories:** It is important to prepare the RCC laboratory and reference laboratories for accreditation to ensure quality of the standard materials produced. Different approaches may be explored such as the WHO/AFRO step wise approach or accreditation based on ISO 15189.

## **Group 2 – Material production, transport, distribution and feedback**

- **Material Production:**
  - Each ministry should establish a National QA Coordinating Centre (NQACC) responsible for quality control checking of materials produced by the reference laboratories in the country before submission to the RCC.
  - The national QA body in each MoH should oversee the production of standard materials by the reference laboratories within their respective countries and coordinate the quality control by NQACC.

- Each country should identify additional reference laboratories to ensure adequate production of quality EQA materials (by end of April 2010).
- **Specimen distribution:**
  - The RCC will re-examine all materials and send samples of all materials to the selected validating laboratories.
  - The RCC should send survey packages to participating laboratories through the National QA body. Opening and closing dates for each survey should be established and communicated to the participating laboratories.
  - The governments need to provide a budget line at national level for:
    - Specimen collection and material preparation
    - Transport of materials to RCC
    - Transport of survey packages to participating laboratories
    - Return of results from participating laboratories to RCC
    - A system for QA data recording and analysis to facilitate evaluation of health facility performance over time.
- **Results and reports communication:**
  - The RCC should give acknowledgement of receipt within 5 working days and provide immediate feedback within 21 working days. The immediate feedback should be sent directly to the participating laboratories with copies to districts and national QA committees
  - Composite reports should be sent to national QA committee for sharing with the MoH and national regulatory authority (Board or Council).
  - The National QA focal person should follow up on each stage of the scheme process.
  - Due dates for corrective action should be established and copied to the national QA committees.
  - The National QA focal person should follow up to ensure that recommended corrective actions have been addressed.
- **Turn around time:** To monitor the turnaround time and improve on planning of the surveys, a calendar of events should be drawn up as shown in the following table 2:

**Table 2: Calendar of distribution for EA-REQAS**

Specimen collection & material preparation	Validation	Distribution	Acknowledgement of receipt by RCC	Immediate Feedback Report by RCC	Corrective action by health facilities	Composite report by RCC
January/ February	March	April/May Participating laboratories analyse and return results in 30 days	Within 7 days from receipt at RCC	Within 30 days from receipt at RCC	30 - 60 days from receipt of Immediate Feedback report	August/ September
June/July	August	September/ October Participating laboratories analyse and return results in 30 days	Within 7 days from receipt at RCC	Within 30 days from receipt at RCC	30 - 60 days from when the survey report is received	January/ February



### ***Group 3 – Scale-up plan for survey materials and participating health facilities***

- AMREF should prepare a scale-up plan for REQAS and share with respective MOHs. Each MOH should provide a list of additional facilities to be included in the scale-up. A phased approach should be used. There are currently 213 participating laboratories.
- The MoH of Rwanda and Burundi need to be visited to initiate them into the scheme.
- The range of materials in the panels needs to be increased to include other tests such as chemistry and blood grouping.
- Consideration should be given to increasing the survey frequency to 3-4 times a year while enforcing the turn-around-time of less than 30 days by setting closing dates for each survey.
- There should be clear ownership of the scheme by the MOH within each country, who should commit resources and support by:
  - Working towards standardisation of test systems and kits to ensure results are comparable
  - Establishing a monitoring and evaluation programme for the scheme and prioritising remedial action and follow-up
  - Dedicating funding for operation and scale-up of the scheme and investing in remedial action
- Including QA activities in national laboratory strategic plans.
- Consider including research institutions and laboratory training institutions in the scale-up plan for EA-REQAS.

### ***Group 4 – Review of Terms of References***

#### **Reference Laboratories**

- Produce EQA materials for REQAS in a timely manner using the stipulated standard SOPs,
- Examine 10% of the samples produced and prepare a QC report to be sent with the materials
- Package EQA materials and send to the NQACC for examination and forwarding to the RCC

#### **National QA Bodies**

- Develop and review policy guidelines on laboratory QA including operational plans for approval by the relevant ministries
- Advise on issues relating to implementation of a national laboratory QA programmes
- Provide oversight and guidance on implementation of national laboratory QA programmes
- Review QA performance data and coordinate implementation of corrective actions
- Provide a national framework for integration of EA-REQAS with national QA programme (s)
- Ethical approval issues:
  - Liaise with Ethical Review Boards and Committees (ERC) where approval for handling specimens is required
  - Ensure specimen transport regulations are in place and applied

#### **Regulatory Bodies role in EQA**

- Regulate laboratory practice and in particular participation in EQA
  - Ensure laboratories participate in REQAS and other national EQA programmes as a condition of renewal of practice licences
- Carry out advocacy for REQAS
- Establish and promote CPDs addressing QA issues

## **Regional External Quality Advisory Committee (REQAC)**

Support the development and operation of the EA-REQAS including:

- Selection of tests and techniques
- Selection and monitoring of reference laboratories for quality material production
- Selection and monitoring of the performance of the RCC
- Monitor scheme activities including donor reports and composite reports (number of facilities reached, questions prepared and laboratory performance)
- Review of impact of scheme activities through review of reports from national administrations/regions/districts
- Create ideas for innovative methodologies and approaches to establish best practices for the operation of the EA-REQAS
- Promote operational and scientific research on activities of the EA-REQAS
- Ensure documentation and dissemination of experiences and best practices, including preparation of technical papers and presentations
- Ensure regular communication between regional committee members in partner countries
- Enhance relationships with the MOH, WHO, EAC, other international and regional organisations, and development and technical partners to promote awareness and ensure sustainability of EA-REQAS
- Establish linkages with international EQAS
- Participate in plans for expansion of EA-REQAS within the three EA countries and other countries, as appropriate
- Hold meetings at least once a year to review progress and future plans

### **WHO and other partners**

- Harmonise WHO schemes with EA-REQAS and national and international schemes
- Support strengthening of national reference laboratories:
  - WHO and partners to support capacity-building and infrastructure improvement
- Assist the MoH to monitor health facility participation in the scheme

### ***Meeting Resolutions and Way Forward***

- Evaluating the performance and quality of test kits pre-entry and post-market is critical. Test kit evaluation should be carried out at nationally-appointed centres, and a system for post-market surveillance introduced.
- Laboratory end-users need to be included as part of procurement decisions and planning processes.
- Internal quality control procedures must be established in laboratories at all levels.
- There is need to strengthen national EQA programmes to develop capacity and knowledge to ensure full coverage of peripheral laboratory facilities.
- Participating countries need to review their respective policies and guidelines to establish appropriate organisational and operational structures to support EQA.
- Ministries of Health in participating countries need to take full ownership of the national components of the EA-REQAS scheme.
- Representatives from the Ministries of Health from the participating countries should accompany AMREF to the meeting with the Head of the Health Desk of the East African Community in Arusha, Tanzania, where the data of the scheme activities and outcomes of this meeting will be presented.
- Participating countries need to explore ways of harmonising national QA schemes with EA-REQAS activities.

- Each country should establish a National QA Coordinating Centre and a focal person to oversee EQAS activities in each country, including EA-REQAS.
- The Ministries of Health should establish a policy to ensure mandatory participation in EQA.
- AMREF should coordinate all regional activities related to EA-REQAS in each country.
- Burundi will be invited to host the 2011 REQAS Meeting; Tanzania to act as an alternative host.
- EA-REQAS will use the new logo that has been adopted during this meeting (See Appendix 2 for the Logo).

### *Summary of Action Points*

	<b>Regional Coordinating Centre</b>
1.	Award participating facilities with Certificates of Good Performance
2.	Put in place plans for accreditation of EA-REQAS
3.	Put in place plans for accreditation of the RCC
4.	Scale-up: Increase the number of participating laboratories and expand to other countries (Rwanda and Burundi)
5.	Explore use of dried tube samples for serology
6.	Increase the range of tests in the EQA panels
7.	Explore the use of more efficient and economical methods of distribution of materials and return of results, for example Posta EMS services to transport the materials; e-mail/mobile phones to send back results
8.	Establish submission and closing dates for each survey and provide a calendar of EA-REQAS survey distribution. Employ use of reminders to participants for reporting deadlines
9.	Provide training to educate staff in health facilities on processes for receiving EQA panels and interpretation of the feedback reports
10.	Share Composite Survey Reports with regulatory bodies (Boards) to assist in monitoring performance and corrective action
11.	Update the new MOH departments such as Department of Standards on the activities of EA-REQAS
12.	Discuss with National QA Committees to chart the way forward on how to integrate EA-REQAS with national EQA schemes
13.	RCC team to visit EAC and all NQA committees. Have a meeting with National Quality Assurance to chart way forward on how to integrate the EA - REQAS with the other national schemes
14.	Acknowledge receipt of results and respond within 31 days
15.	A calendar of events to be drawn-up so that all laboratories are aware of when the samples are to be received and submitted.

<b>Ministries of Health / National QA Centres (bodies)</b>	
1.	Establish a strong National QA Coordinating Centre and a focal person to coordinate all national EQA schemes, including EA-REQAS, and communicate regularly with the RCC
2.	Identify additional reference laboratories and replace non-performing reference laboratories in each country
3.	Support training, recruitment, retention and appropriate deployment of all required cadres in the laboratory services
4.	Regularly review laboratory policies in each country to promote strengthening of laboratory services
5.	Strengthen links between National QA advisory bodies, the RCC and the Ministries in each country
6.	Enforce mandatory participation of health facilities in EQAS
7.	Strengthen internal quality control in laboratories and awareness of the importance of participation in EQAS to gain commitment from all staff in the participating facilities
8.	Explore efficient and economical means for distributing EQA materials within the country
9.	Strengthen monitoring of EA-REQAS activities including material preparation, distribution of surveys, return of results and follow up of corrective action
10.	Allocate funds for local costs such as material preparation, distribution of surveys, communication of results and support supervision and follow up
11.	Support regular support supervision of participating laboratories and undertake remedial action
12.	Establish plans for accreditation of reference laboratories in each country
13.	Each country must provide a 2-3 year scale up plan with names of health facilities/ Districts

## Session 7: Closing Remarks

### Ms Jeanette Twell, WHO Geneva

This meeting has been extremely fruitful; key outcomes of the discussions include the following:

1. Quality of the testing: This is with regard to pre-market issues, specifically regulation and registration of diagnostics, the WHO prequalification programme, the European Conformity (CE) mark and batch testing. Post-market issues were also addressed with reference to post-market surveillance, vigilance and field testing.
2. EQA participation: With little if any regulation of diagnostic tests entering the countries, the EA-REQAS programme currently fulfils a significant role of evaluating the quality of laboratory testing.
3. The need for laboratory accreditation came out clearly in the meeting.
4. There is need for increased political will and for the Ministries of Health to take on board the issues that have come out of this meeting.
5. The REQAS programme is a well structured programme that provides an excellent baseline on which to measure improvement in laboratory performance. It also provides strong numerical evidence on the difficulties being faced by laboratories and their need for assistance. The REQAS programme is a clear road to quality and progress.

### Dr Jean Bosco Ndiokubwayo, WHO AFRO

Emphasis needs to be placed on the following issues:

1. The EA-REQAS programme is a very good initiative that needs major support from WHO, the East African Community and participating countries.
2. There is need to ensure collaboration and harmonisation of in-country EQA schemes.
3. There is need for ownership to be taken by the Ministries of Health of the respective countries.
4. Ministries of Health in the respective countries need to make participation in EQAS schemes mandatory for all laboratories.
5. The outcomes and progress of the REQAS scheme needs to be monitored and evaluated.
6. Immediate and corrective action needs to be taken to address poor performance by laboratories.
7. Quality Assurance and Accreditation should be made part of national policies and plans in participating countries.

### Mr Gamaliel Kisiyombe, Secretary of the National QA Committee in Tanzania

Tanzania values the efforts of AMREF and WHO in spearheading this scheme; these two organisations also participated in developing the countries' strategic plans and Quality Assurance framework. Tanzania currently has five laboratories awaiting accreditation so the convening of this meeting has been timely as it has addressed EQA which is a requirement of ISO 15189 accreditation. The Ministry of Health and Social Welfare (MOH&SW) – Mainland Tanzania will take up the resolutions of this meeting and ensure the success of this programme as all health facilities in the country should provide quality laboratory services by 2015.

**Dr Jamala Taib, Director of Mnazi Mmoja Hospital**

This meeting has brought out the fact that the challenges facing Zanzibar are similar across the countries and thus there is need to have a common strategy to address them. The issue of ownership has come out strongly in this meeting and our respective Ministries need to take the lead and with development partners align themselves with the countries' priorities and participate fully in the EQA scheme. The Ministry of Health and Social Welfare, Zanzibar, looks forward to the implementation of the recommendations of this meeting.

**Mr Gaspard Guma, Ministry of Health, Uganda**

Uganda is satisfied with the outcome of this meeting and looks forward to immediate actions on the resolutions. At the national level, the Uganda delegation commits to ensuring that the recommendations from this meeting will be communicated to the Government of Uganda and necessary follow-up made. At the regional level, we urge the RCC to table the outcomes of this meeting to the East African Council of Ministers so that the laboratory agenda is appropriately included among the activities of the EAC Health Desk.

**Dr Jane Wasike, Head, National Public Health Laboratories, Ministry of Public Health and Sanitation, Kenya**

I am honoured to be associated with this very important meeting that has discussed the Regulation and Post-Market Surveillance of Rapid Diagnostic Tests and the East African Regional External Quality Assessment Scheme (EA-REQAS). It has been essential for the Ministry of Public Health and Sanitation and Medical Services in Kenya to have participated in this event.

An important component in the control of any laboratory procedure is post-market surveillance of medical devices and participation in an External Quality Assessment (EQA) or Proficiency Testing programme. WHO member countries are moving towards accreditation of medical laboratories and EQA is an essential component of this process. The mission of the East African Regional External Quality Assessment Scheme has been to establish and operate a well coordinated regional laboratory quality assessment scheme through participation of country health care providers and development partners, aimed at improving medical diagnostic services to enhance quality health care delivery, which is in line with the Millennium Development Goals; this should be endorsed by all Ministries of Health.

From the deliberations of this meeting we hope that the Governments of the East African countries will take ownership of this scheme and give it full support by establishing national mechanisms for coordinating national Quality Assurance programmes. We have heard that the East African communities have agreed to allow free movement of health workers across East African borders so it is even more vital that the East African countries embrace regional standards of laboratory practice. The Ministries of Public Health and Sanitation and Medical Services of Kenya have every intention of providing full support to these noble endeavours.

## Appendix 1: List of conference delegates

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## Appendix 2: EA-REQAS Logos presented

