FIRST REGIONAL TECHNICAL MEETING

OF

THE EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (EA-REQAS)

ARUSHA TANZANIA
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AMREF Laboratory Programme

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ACRONYMS

AIDS	Acquired Immune Deficiency Syndrome
AKMLSO	Association of Kenya Medical Laboratory Scientific Officers
AMREF	African Medical and Research Foundation
APECSA	Association of Pathologists of Eastern, Central and Southern Africa
CRHCS-ECSA	Commonwealth Regional Health Community Secretariat for Central and Southern Africa
EAC	East African Community
EANMAT	East African Network for Monitoring Antimalarial Therapy
EA-REQAS	East African Regional External Quality Assessment Scheme
EA-RQAC	East African Regional Quality Assurance Committee (for Health Laboratories)
EA-RQACC	East African Regional Quality Assurance Coordinating Centre (for Health Laboratories)
EQA	External Quality Assessment
EQAS	External Quality Assessment Scheme
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodefficiency Virus
IDSR	Integrated Disease Surveillance and Response
IT	Information Technology
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
MeLSAT	Medical Laboratory Scientists Association of Tanzania
MOH	Ministry of Health
NACP	National AIDS Control Programme
NBS	National Bureau of Standards (Uganda)
NELQAS	National External Laboratory Quality Assessment Scheme (Uganda)
NEQAS	National External Quality Assessment Scheme
NGO	Non Governmental Organisation
NHLACC	National Health Laboratory Advisory and Coordination Committee (Uganda)
NMLQAAB	National Medical Laboratory Quality Assurance Advisory Body (Kenya)
NPHLS	National Public Health Laboratory Services (Kenya)
NTLP	National Tuberculosis and Leprosy control Programme
PHC	Primary Health Care
PMCT	Prevention of Mother to Child Transmission (of HIV)
QA	Quality Assurance
SMS	Short Message Services
SOP/SOPs	Standard Operating Procedure(s)
STI	Sexually Transmitted Infection
TB	Tuberculosis
UK	United Kingdom
UVRI	Uganda Virus Research Institute
VCT	Voluntary Counselling and Testing
WHO	World Health Organisation
WR	WHO Country Representative
ZEQAS	Zonal External Quality Assessment Scheme (Tanzania)

BACKGROUND

Laboratory services are an integral part of health care delivery, especially in tropical countries where many of the commonly presenting conditions, and diseases which are responsible for outbreaks, may be diagnosed using simple laboratory tests. Currently in eastern Africa, the Ministries of Health are standardising services provided by laboratories at each level of health facility and establishing Health Laboratory Quality Assurance Programmes.

The African Medical and Research Foundation (AMREF) has been operating an External Quality Assessment Scheme (EQAS) for primary health care laboratories since 1993, which has shown that laboratories that participate regularly improve in service quality. AMREF, in collaboration with the World Health Organization (WHO), has established a 3-year pilot project to develop and implement a Laboratory Quality Assurance Programme in Kenya, Tanzania and Uganda. The project will involve the National and Local Administrations of selected Districts in each country in the coordination and implementation of an External Quality Assessment Scheme as a Regional initiative, in order to share resources and experiences across the three countries.

Since 2001, the Project and the concept of the Regional Scheme has been introduced to the Ministries of Health in Kenya, Tanzania mainland and Uganda and Zanzibar. In each of the countries, meetings have been held with the Head of Diagnostic Services and other Senior Ministry of Health Officials, Professional bodies, Health Laboratory Boards and Councils, and the project has been accepted. Where National EQA Schemes exist, the countries have indicated their willingness to integrate the Regional Scheme into their National Schemes. In order to harmonise the process of integration and to confirm the model of operation of the Regional Scheme, a two day regional meeting was held in Arusha, Tanzania on 3rd and 4th April 2003 (see Time Table, Appendix 1). In attendance were Heads of Laboratory Services, Chief/Principal Laboratory Technologists, Officers i/c of Laboratory Quality Control, Heads of Laboratory Registration and Licensing Boards / Councils, Chairpersons of Laboratory Professional Associations, Chairpersons of Associations of Clinical Pathologists, and Representatives from Research and Public Health Institutes, Disease Surveillance Units of the Ministries of Health and Private Health Institutions. Other participants were representatives from WHO Country Offices, the East African Community (EAC), the Commonwealth Regional Health Community Secretariat for Eastern, Central and Southern Africa (CRHCS-ECSA) region and AMREF (see List of Participants, Appendix 2).

PROCEEDINGS

INTRODUCTORY REMARKS

By Dr Mores Loolpapit, Directorate of Programmes, AMREF Headquarters, Nairobi

The representative of the Directorate of Programmes introduced AMREF, and outlined the purpose and objectives as well as the expected outcomes of the meeting. It was noted that AMREF is a Non-Governmental health development organisation whose mission is to improve the health of the poor and disadvantaged people of Africa as a means for them to escape poverty and improve the quality of their life. AMREF has offices in 12 countries in Europe and North America dedicated to raising resources to support Africa-based activities. AMREF develops and implements projects emphasizing a *community based approach* and *capacity building*; learns lessons from these projects and derives best practices (*operations research*) and seeks out opportunities to use the information and knowledge to influence others (*advocacy*).

The purpose and objectives of the meeting were outlined as:

- To harmonise technical issues and further develop modalities for regional cooperation on laboratory quality assurance in the East African region.
- To develop modalities for sharing of resources and experiences on laboratory quality assurance with the ultimate aim of improving quality of diagnostic services in the region.

It was pointed out that at the end of the meeting, the following outcomes were expected:

- Consensus and harmonisation of the technical activities within the three countries including modalities for development of written materials to be used in the three East African countries, methodologies for material production and distribution, and identification and definition of roles of the co-ordinating centre;
- An environment allowing increased cross-border sharing of experiences on Laboratory Quality Assurance;

- A better understanding of the challenges and opportunities of the EA-REQAS;
- Drawing up a regional action plan for the implementation of the EA-REQAS.

The handout of the presentation by the representative of the Directorate of Programmes of AMREF is shown in Appendix 3.

WELCOME AND OPENING SPEECH
By Hon. Nuwe A. Mushega, Secretary General, East African Community, Arusha

The Secretary General emphasised that the role of the EAC is to reduce poverty amongst the people of the member states. Provision of quality health care services is one of the strategies adopted by the EAC. The Secretary General welcomed the idea of developing a Regional Quality Assurance Scheme as this will harmonise the quality of laboratory services across the three countries. The Secretary General also underscored the need to develop Technical Guidance and Manuals to be used across the three East African countries.

The Secretary General pointed out that the EAC has established a Sectoral Committee on Health which facilitates implementation of the activities identified by the three countries under the Regional Health Cooperation. The Committee on Health has three Working Groups to facilitate implementation of the different programmes and activities:
- Working Group on Control and Prevention of Sexually Transmitted Infections (STI's) and HIV/AIDS;
- Working Group on Control of Communicable Diseases;
- Working Group on Health Research, Policy and Health Systems Development.

The Secretary General pointed out that AMREF has a lot to share and gain by working closely with the EAC through the Sectoral Committee on Health and its specialised Working Groups. The Secretary General welcomed AMREF in the future meetings of the Health Committee in order to participate and contribute to the process of defining a proactive Regional Agenda on Health.

The full opening speech of the Secretary General is attached in Appendix 4.

SESSION 1: COUNTRY EXPERIENCES OF NATIONAL QUALITY ASSURANCE SCHEMES

1. 1 Uganda Experiences
By Dr D.K.W. Lwamafa

Uganda has established a National Minimum Health Care Package. To implement the components of the Package, an efficient Laboratory Service is required. Different Levels of Health Laboratory Services have been defined:
- Central Public Health Laboratories;
- Specialised Research and Reference Laboratories e.g. UVRI;
- University Teaching Laboratories;
- National Tertiary Hospital Laboratories;
- Regional Referral Hospital Laboratories;
- District Laboratories;
- Sub-District Hospital Laboratories; and
- Health Centre Laboratories.

Quality Assurance activities undertaken:
- Refresher Training for Laboratory staff in 3 Regional Hospital laboratories;
- Development of Laboratory Guidelines for Specimen Collection, Preservation, Transportation and Storage Procedures.
- Checklists for Support Supervision developed;
- Laboratories involved in both Internal and External Quality Control methods;
- SOPs developed for essential equipment, preparation and storage of culture media, isolates and reagent for culture and sensitivity.
- Use of Control Organisms and Reference reagents is being done;
- Laboratory Data management system at all levels has been established;
- Recruitment and re-orientation of qualified personnel; and

- SOPs for all basic tests for use in the National External Quality Assessment Scheme are being developed.

In Uganda, the Laboratory Services are an integral part of various Disease Surveillance programmes of the MOH. These are:
- Epidemiological Surveillance Division;
- Malaria;
- HIV/ AIDS/ STIs;
- TB/Leprosy;

The Central Public Health Laboratories participate in:
- Research Programmes on malaria including monitoring of sensitivity of anti-malarial drugs, sleeping sickness, cholera, meningitis, dysentery and typhoid fever;
- Epidemic investigation, preparedness and response;
- Surveillance and monitoring of diseases of epidemic potential;
- Screening food handlers;
- Monitoring of safe water supplies;
- Surveillance of antibiotic sensitivity of bacteria commonly causing infections;
- Coordination of laboratory activities; and
- Provision of Laboratory Technical Support country wide

Quality Assurance activities in Uganda are faced with the following constraints and challenges:
- Inadequate resources (human, material, financial);
- Poor communication (IT, vehicles);
- Poor laboratory infrastructure;
- Absence of Laboratory Focal Persons in some Districts;
- Rapidly growing number of substandard Private laboratories;
- Staff require orientation in order to appreciate the importance of Quality Assurance Schemes;
- Integration of Quality Assurance Schemes in basic training curricula;
- Integration of Quality Assurance in the existing health programmes.

The handout of the presentation on Uganda Experiences on the National Quality Assurance Scheme is attached in Appendix 5.

1. 2 Kenya Experiences
By Dr J.A. Nyamongo

The relevant statistics showing population and administrative structure of the health facilities in Kenya were presented. The disease surveillance activities were also presented and include Integrated Disease Surveillance and Response (covering 22 Districts), tuberculosis control (nationwide), malaria surveillance (8 sites) and HIV surveillance (36 sites).

Disease surveillance requires good quality laboratory services. The following activities related to Quality Assurance of Laboratory Services are carried out:
- Procurement of appropriate laboratory equipment;
- Development of appropriate laboratory training modules;
- Training of Laboratory personnel;
- Validation of laboratory test systems and techniques at Central level;
- Proficiency testing for tuberculosis and malaria.

It was noted that there is no National Quality Assurance Scheme for the Laboratories. However, laboratories carry out a number of Internal Quality Control activities including the use of controls and standards provided in the kits by the manufacturers or in-house control, inter-observer checks, and reagent and test validation exercises.

Also it was noted there are a number of External Quality Assessment Schemes covering a small number of laboratories. These Schemes include EQAS on culture and sensitivity of enteric organisms covering 8 Provincial hospitals, clinical chemistry (Chemlabs^{R}) covering 34 private laboratories, AMREF EQAS for Primary Health Care Laboratories covering 34 rural facilities. There are a few laboratories in Kenya that participates in the Randox^{R} EQAS in Clinical Chemistry and Bacteriology EQAS from Colindale, UK. The National Public Health Laboratory Services also participate in the

WHO sponsored Schemes on HIV, HBV & HCV (from Vienna); Bacterial culture, identification and drug susceptibility testing (from South Africa) and on Blood Transfusion (from Harare).

The handout of the presentation on Kenya Experiences on the National Quality Assurance Scheme is attached in Appendix 6.

1. 3 Zanzibar Experiences
By Dr T.F. Thani

Curative services in Zanzibar is provided through Mnazi Mmoja hospital (referral centre for Zanzibar), 3 District Hospitals (in Pemba), 4 Cottage hospitals (2 in Pemba and 2 in Unguja), and the Primary Health Care Units. All hospitals have laboratory services while only a few PHCU have some laboratory services.

The Public Health Laboratory in Pemba is responsible for disease surveillance. Various disease control programmes are currently being implemented including the control of filariasis, malaria and schistosomiasis. Voluntary counselling and testing for HIV is also being implemented as one of the key strategies for control of HIV in Zanzibar.

There is a Central Laboratory and a Government chemist laboratory in Unguja. The physical facilities of these laboratories have been recently improved. DANIDA has shown an interest to support provision of equipment. The Central Laboratory supervises cottage hospital laboratory once every three months. The laboratory services in the Public sector are free. There is no cost sharing for the laboratory services.

In Zanzibar, the private sector is being encouraged. Currently, the Private hospital laboratories run a few essential tests including stool and urine examination, blood slides for blood parasites, haemoglobin estimation, AFB microscopy and HIV and Syphilis screening in some facilities. There is an Advisory and Registration Board for Private Hospitals. The Board also conducts inspection and supervision of Private Hospitals. It has been suggested to extend the Board's mandate to include Private laboratories. There is no a comprehensive quality assurance programme for laboratories in Zanzibar.

1. 4 Tanzania Mainland Experiences
By Dr Y.A. Ipuge

In Tanzania Mainlan, the Health Laboratory Services are under the Diagnostic Services Section of the Ministry of Health. Other units under the Diagnostic Services are Diagnostic Radiology and Imaging Services, Health Care Equipment Technical Services and the Private Health Laboratory Board.

Health laboratories are categorised into:
- National Reference Laboratory (Central Pathology) at the Muhimbili National Hospital;
- Zonal Reference Laboratories at Kilimanjaro Christian Medical Centre, Bugando Medical Centre and Mbeya Referral Hospital;
- Regional Laboratories;
- District Laboratories; and
- Health Centre and Dispensary Laboratories.

Although there are autonomous health laboratories in the Private Sector, the public health laboratories are hospital-based. The public health laboratories are decentralised and different levels of the government are accountable for provision of services. The public health laboratories are integrated within the management of individual hospitals and there are inadequate linkages and coordination amongst the laboratories. The quality and efficiency of the Health Laboratory Services have declined dramatically in the past two decades due to inadequate qualified laboratory staff, equipment, reagents and supplies, monitoring and supervision, and due to lack of a comprehensive quality assurance programme.

The Government has initiated Health Sector Reforms, which include Health Laboratory Reforms to address the identified constraints in the provision of quality Health Laboratory Services. The following has been achieved:
- Establishment of a legal framework for Health Laboratory Services: Private Health Laboratory Act (No 10 of 1997) and Health Laboratory Technologists Registration Act (No 11 of 1997) are in place;

- Standard Guidelines for Health Laboratory Services are in place;
- A District Health Laboratory Strategy has been developed;
- A situation analysis has been carried out by Ministerial Technical Task Force which recommended establishment of a centralised model for laboratory services delivery by creating an autonomous National Health Laboratory Service whereby the National, Zonal and Regional laboratories are under one management, and investment in Laboratory Quality Assurance will be a priority.

Quality Assurance programmes currently available in Tanzania include:
- National External Quality Assessment Scheme (NEQAS) operating from the Central Pathology Laboratory for Zonal Referral and Regional laboratories;
- Zonal External Quality Assessment Scheme (ZEQAS) operating from the Zonal referral centres for lower level health facilities (formerly REQAS operating from the Regional laboratories). The Regional laboratories act as supervising and distributing arms of the Scheme. NEQAS and ZEQAS mainly cover the Government owned laboratories;
- National Tuberculosis and Leprosy Control Programme (NTLP) Quality Assurance programme on AFB microscopy;
- National AIDS Control Programme on HIV testing;
- AMREF Quality Assurance Programme involving EQAS for Primary Health Care Level, on site training and supervision, and Refresher Courses; and
- Some Referral laboratories participate in various International EQA Schemes.

Lessons learnt from the QA Schemes in Tanzania:
- Health laboratories participating in the NEQAS have improved their performance;
- Response from the laboratories participating in the NEQAS has increased from 64% to 90%;
- NEQAS started with 20 centres and has now expanded to 56 centres;
- ZEQAS has shown improvement over the REQAS. In the Eastern Zone the scheme has reached 99 laboratories. (Proposals have been developed seeking support to establish ZEQAS in the three remaining Zones).
- NTLP QA scheme has identified Regions that are weak in AFB microscopy. Refresher training has been carried out in 5 Regions where 84 (about 50%) of identified staff have been trained;
- Supervisory Guidelines for NTLP have been developed and used and are very useful;
- EQAS is a useful tool for early warning of poorly performing laboratories;
- Laboratories may use EQAS feedback to directly pinpoint areas of weakness and institute appropriate remedies;
- EQAS encourages the use of Internal Quality Control;
- Meetings involving all participating laboratories and the organizing centre provide opportunities for better communication;
- Disease Control Programmes may use EQAS to verify function and quality of equipment and techniques.

Challenges and constraints of QA programmes in the health laboratory services in Tanzania:
- Shortage of qualified staff;
- Inadequate laboratory physical infrastructure and equipment, poor equipment maintenance;
- Poor transport and communication facilities;
- Inadequate funds to run the scheme and for follow up of laboratories with poor performance;
- Poor coordination/linkages of the existing QA schemes (NLTP, NACP, AMREF, International Schemes).

Existing opportunities to Strengthen QA Programmes in Tanzania:
- Zonal Laboratories have been mandated to initiate ZEQAS in collaboration with Partners;
- Vertical Disease Control Programmes have Laboratory QA components;
- WHO supports training in integrated disease surveillance;
- AMREF is spearheading the EA-REQAS;
- The two Laboratory Acts (No 10 & 11 of 1997) provide the legal mandate for implementation of the National Standard Guidelines for Health Laboratories, licensing and registration of laboratory staff, and for regulation of private health laboratories.
- It is a legal requirement for all private laboratories to participate in Quality Assurance programmes; and
- The ongoing Health Sector Reforms leading to restructuring of National Health Laboratory Services.

The handout of the presentation on Tanzania Experiences on the National Quality Assurance Scheme is attached in Appendix 7.

1. 5 Discussion

Several issues were raised for discussion after presentations of the country experiences.

1. Participants wanted to know how the Ministry of Health in Tanzania is planning to include all roles of the Health Laboratory Services under one management structure. It was clarified that only Public Health functions, Diagnostic functions, Equipment (and repair) and Training functions are being considered during the reforms. The Research and the Chief Government Chemist laboratories are not included.

2. Participants wanted to know of existence of any Quality Assurance programmes on food, water and milk testing in the region. It was noted that in Uganda the quality testing is carried out by the National Bureau of Standards (NBS) and the Bureau is well equipped. It was noted that there are several fora where the staff of the Ministry of Health charged with the responsibility of Quality Assurance meet their counterparts in the NBS.

3. Participants observed that all of the existing QA Programmes were on Clinical Chemistry, Microbiology and Haematology. It was noted that there are no QA Programmes on Histopathology. It was noted that the major limitation was availability of human resources. For example, there is no pathologist in the whole of Zanzibar.

4. Some participants questioned the level of application of Quality Assurance given the existing problems of lack of basic equipment, reagents and skilled manpower in the National Laboratory Services in the region. It was noted that Quality Assurance is vital at all levels of the Health Laboratory Services. The regional EA-REQAS recognises the existing problems hence the involvement of various players especially at the stage of taking remedial action.

5. Participants wanted to know how the EQAS programmes are linked to other QA Programmes of the Ministries of Health e.g. the link between NELQAS and the "Yellow Star" programme in Uganda. It was noted that Laboratory QA Programmes are part and parcel of the overall Quality Improvement Programmes of the Health Care Systems. In Uganda, the Laboratory is represented in the National Quality Assurance Advisory Committee and health laboratories are one of the components that are assessed prior to awarding a "Yellow Star" to a health facility.

6. Participants observed that the Eastern African region is in desperate need of a comprehensive Quality Assurance Programme for health laboratory services. Participants wanted to know of the linkages between the Quality Assurance programmes and the law. It was observed that there has been an attempt to use the judiciary to deal with violators of quality standards e.g. non-registration of private laboratories. The experience shows that there is need to strengthen the legal support of the Health Laboratory Councils. However, it was noted that currently the intention is not to make the Quality Assurance programmes punitive, but rather educational and supportive so as to change the attitudes of the health staff towards the programmes. The need to institutionalise Quality Assurance Programmes into the Health Care system was noted.

7. It was observed that there are costs involved in implementing QA programmes. Currently, in Tanzania the National Schemes obtain funds from the Government, Partners and from the Basket Fund of bilateral donors. It was noted that implementing EA-REQAS is quite a challenge especially considering the existing financial constraints of providing basic health services by the Ministries of Health. A suggestion was made to approach regional bodies for financial support for the EA-REQAS.

8. It was noted that the existing EQAS schemes lack comprehensive data management. This was attributed to lack of coordination of all EQAS schemes at National level, e.g. in Kenya it was noted that although WHO and AMREF supported EQAS programmes are coordinated by the National Public Health Laboratory services, the other EQAS programmes targeting Private labs such as the Randox^{R} & Chemlabs^{R} are not centrally coordinated. Poor IT and communication equipment were also cited as contributory factors. A suggestion was made to establish a regional EA-REQAS coordination team.

9. A suggestion was also made that the EA-REQAS Regional Technical meeting becomes a permanent forum. A suggestion to include other countries in Central and Southern Africa e.g. Malawi and Zimbabwe was made.

SESSION 2: UPDATE ON THE REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME

2. 1 Outline of the EA – REQAS
By Dr J. Carter

The purpose of an External Quality Assessment Scheme is:
- To measure laboratory performance;
- To identify and rectify problem areas;
- To standardise techniques;
- To provide continuing education;
- To evaluate training activities; and
- To improve communication between clinical , laboratory and public health staff.

It was noted that, although each country has established some activities to ensure quality of laboratory services including National External Quality Assessment Schemes, there are several advantages of a regional EQAS. The advantages include:
- Standardisation of laboratory procedures across the region;
- Standardisation of quality scheme materials;
- The regional scheme will cover a wider range of specimens;
- There is a potential for sharing resources for material preparation;
- An independent laboratory coordinating the regional scheme will provide a more objective assessment of laboratory performances;
- The regional scheme will relieve the burden of preparing different types of materials for EQAS from the countries. More National resources will be spent on remedial action;
- Lessons will be learnt from the regional scheme; and
- The scheme will result into an increased regional cooperation.

It was noted that the regional EQAS will not replace, but rather strengthen, the National schemes. There are activities of the regional scheme that will be carried out regionally, while there will be activities to be carried out at country level.

The Regional components of the EA-REQAS were presented as:
- Selection of tests to be included in the regional scheme;
- Standardisation of test techniques;
- Selection of laboratories for material preparation;
- Standardisation of techniques for material preparation;
- Selection of a Coordinating Centre; and
- Deciding frequency and mode of submission of EA-REQAS materials and reports.

The National components of the EA-REQAS were presented as:
- Selection of sites and distribution of materials;
- Sensitisation of scheme participants and supervisors;
- Review of questionnaires accompanying EA-REQAS materials;
- Review of reports and educational materials provided through the EA-REQAS; and
- Taking remedial action which will include support supervision, provision of supplies, equipment and repair, and, organising training workshops.

The handout of the presentation on the outline of the EA-REQAS is attached in Appendix 8.

2. 2 EA-REQAS activities in Kenya
By Mr O. Lema

AMREF's EQAS for PHC laboratories started in 1993, initially covering a few Health Centre laboratories in Kenya. This was soon expanded to include Primary Level Hospital Laboratories in Tanzania. The need to involve the Central Laboratory Administration and all organs charged with the responsibility of ensuring Quality Assurance of laboratories was learnt. Also it was established that the

techniques used in the laboratories at PHC level and the problems affecting quality of the services in different countries were very similar. The EA-REQAS idea was conceived following these experiences and a proposal to develop the regional scheme was drawn up.

Following financial support to develop the regional EA-REQAS from WHO-Geneva received in the year 2000, a meeting was held to introduce the regional scheme to the staff of the National Public Health Laboratory Services (NPHLS), Kenya, in April 2001. The idea of the regional scheme was accepted and the staff of the AMREF Laboratory Programme in conjunction with the NPHLS also introduced the concept to the WHO Country Office. The WHO Country Representative (WR), Kenya pledged to support the National component of the Scheme.

The Kenya Medical Laboratory Technicians and Technologists Board also endorsed the EA-REQAS and a structure to implement the regional scheme was put in place: A National Medical Laboratory Quality Assurance Advisory Body (NMLQAAB) to oversee all activities related to Quality Assurance and a Technical Arm of the NMLQAAB consisting of AMREF and NPHLS were established. The Terms of Reference for both the Technical Arm and NMLQAAB were drawn up (May – June 2001).

Several planning meetings were held after June 2001 to discuss the EA-REQAS. In December 2001 a major two day meeting was held in Nairobi with all relevant bodies charged with the responsibility of laboratory Quality Assurance including members of the Kenya Medical Laboratory Technicians and Technologists (KMLTTB), senior representatives from NPHLS, senior members of the Association of Kenya Medical Laboratory Scientific Officers (AKMLSO) and members of staff of the AMREF Laboratory Programme from Kenya, Tanzania and Uganda. The meeting specifically discussed the establishment of a National External Quality Assessment Scheme in Kenya and integration with the EA-REQAS. The main outcomes of the meeting were:

- Strengthening of the EQAS for PHC laboratories in Kenya was endorsed. Tests, techniques, preserved materials and essential documents required for the EQAS for PHC laboratories were identified. Individuals to participate in the development of the required documents were identified.
- Strategies for implementation of the EQAS for PHC laboratories were identified i.e. The EQAS for PHC laboratories will have a District focus (all laboratories in the District whether public or private will be included in the scheme), integration of QA activities of vertical disease control programmes, involvement of Clinicians, and collaboration with National organs and Legal entities charged with Laboratory QA activities.

Progress made in Kenya:

- The proposal to strengthen the NEQAS (based on the above principles) has been developed and endorsed by the Ministry of Health and submitted to the WHO Country Office.
- Draft documents have been developed by the staff of the AMREF Laboratory Programme in conjunction with the selected individuals. The draft documents include: Standard Operating Procedures (SOP's) for all basic tests, Quality Manual, Clinical Quality of Care Manual and Clinical SOP's on the use of basic laboratory tests.

The handout of the presentation on the update of EA-REQAS activities in Kenya is attached in Appendix 9.

2. 3 EA-REQAS activities in Tanzania Mainland and Zanzibar
By Mr D. Ocheng

The EA-REQAS was introduced to the Ministries of Health in Tanzania Mainland and Zanzibar and the WHO Country Office in May 2001. The regional scheme was welcomed both by the Ministries of Health and the WHO Country Representative.

In Tanzania Mainland, several activities were undertaken to strengthen the National External Quality Assessment Scheme including:

- Review of policy papers for NEQAS;
- Review of existing MOH policy documents related to laboratory quality assurance such as Guidelines for a National Quality Assurance Programme for testing of antibodies to HIV (1991), Health Laboratory Technologists Registration Act (1997), Standard Guidelines for Health Laboratory Facilities (1998) and Draft National Health Laboratory Services Quality Assurance Scheme (2001);

- Plans are underway to establish National and Zonal Quality Assurance Advisory Committees to oversee the development of both the National and EA-REQAS Schemes;
- Draft proposal for the development of a National EQAS was drawn up;

In May 2002, a two-day workshop to discuss the EA-REQAS was held with senior MOH officials, Zonal Representatives and staff of the AMREF Laboratory Programme from Tanzania, Kenya and Uganda. The workshop reviewed and discussed strengthening of the NEQAS in Tanzania Mainland, strategies for integration of EA-REQAS into the NEQAS and formulation of a way forward for implementation of both NEQAS and EA-REQAS. The main outcomes / agreements of the workshop included:

- Include representatives of the Medical Laboratory Technologists Council, the Medical Laboratory Scientists Association of Tanzania (MeLSAT) and from Private Laboratories into the Quality Assurance Advisory Committee; and
- Zonal Referral Hospital Laboratories were given the mandate to coordinate the EA-REQAS activities.

The handout of the presentation on the update of EA-REQAS activities in Tanzania is attached in Appendix 10.

2. 4 EA-REQAS activities in Uganda
By Mr C. Munafu

The EA-REQAS was introduced to the Ministry of Health and WHO Country Office in April 2001. The WHO Country Representative agreed to support the National component of the Project.

The Ministry of Health in Uganda recommended the (existing) National Health Laboratory Advisory and Coordination Committee (NHLACC) to oversee the development of the EA-REQAS in Uganda. In May 2002, a country specific proposal to strengthen the National External Laboratory Quality Assessment Scheme (NELQAS) was presented and accepted by the NHLACC. The proposal was submitted to the WHO Country Office.

In October 2002, a two-day workshop was held in Kampala to discuss the EA-REQAS. The workshop also reviewed and discussed strengthening of NELQAS, strategies for integration of EA-REQAS into the NELQAS and formulated a way forward for implementation of both NELQAS and EA-REQAS. Major outcomes of the workshop:

- Tests to be covered by the EA-REQAS were endorsed;
- Format of SOPs for the laboratory tests was developed;
- Three Districts to participate in the EA-REQAS were selected (Ntungamo, Kumi and Nebbi); and
- Model for implementation of the EA-REQAS was suggested (see presentation of regional issues below).

In November 2002, initial funding to strengthen NELQAS was provided by WHO Country Office in Uganda. Several activities have been implemented:

- SOP's for use in all laboratories participating in the NELQAS and EA-REQAS have been developed. (The process of SOPs development is discussed further in the presentation by Dr G. Bimenya below). The SOPs will be presented to the NHLACC for approval prior to printing and distribution.
- The selected Districts have been visited for initial discussions on the EA-REQAS and inventory of all laboratory facilities in these Districts have been established.

The handout of the presentation on the update of EA-REQAS activities in Uganda is attached in Appendix 11.

2. 5 Preparation of Standard Operating Procedures of Basic Laboratory Tests: Case study from Uganda – *By Dr G. Bimenya*

Testss selection was based on a variety of considerations including tests which:

- Provide useful Clinical and Public Health information;
- Contribute maximally to patient management;
- Are sufficiently rapid, sensitive and specific;
- Are useful for diseases that are difficult to diagnose clinically;

- Diagnose diseases that require long, high risk and expensive treatment;
- Diagnose diseases that are epidemic prone with high mortality and morbidity and may lead to disability;
- Establish base line value for follow up and help to assess efficacy of treatment;
- Help in the rational use of drugs;
- Assess severity of illness and likely disease outcome;
- Identify disease carriers and promote community health.

Selection of test techniques was based on several considerations including:
- Patient considerations;
- Levels of laboratory staffing, equipment available, power supply and safety issues; and
- Cost.

The test and techniques selection was done collectively by a group of Clinical and Laboratory experts from the Ministry of Health, Medical Laboratory Training Institutions, Makerere University and from Private Laboratories in Uganda as well as the staff of the AMREF Laboratory Programme from Uganda, Tanzania and Kenya. A Standard Operating Procedure for each test was developed following a standard format showing:
- Title;
- Staff authorised to carry out the test;
- Principle and purpose of the test;
- Reagents required and preparation including quality verification;
- Sample required;
- Method of carrying out the test including internal quality control;
- Reporting results;
- Reference range; and
- References.

The SOPs are all contained in a Manual entitled "Standard Operating Procedures for the National External Laboratory Quality Assurance Scheme in Uganda". The SOPs will enable the laboratory staff to:
- Understand Clinical and Public Health indications of each test;
- Perform the tests under controlled conditions and give most accurate and timely results;
- Perform the tests safely and effectively without waste;
- Calculate, report and record test results correctly; and
- Avoid shortcuts.

The SOPs were written in a manner that is user friendly, are applicable in the laboratories where they will be used and may be updated.

The handout of the presentation on the update of EA-REQAS activities in Uganda is attached in Appendix 12.

2. 6 Discussion

A number of issues raised by the participants were clarified.

1. The SOP is not limited to a particular disease. For example the SOP for examination of stained thick blood films covers many blood parasites. Likewise, a test such as chemical testing of urine may be performed for the investigation of a wide range of diseases such as diabetes, kidney diseases, liver diseases, etc.

2. AMREF's agenda in advocating for the EA-REQAS is purely to promote Quality of Laboratory Services in the region.

3. It was clarified that, currently all the support for the EA-REQAS has been obtained from WHO. However, AMREF is willing to work with other donors that will be identified by the member countries who may be interested in supporting the Regional Scheme.

4. The EA-REQAS meeting was applauded by the participants for creating a forum for discussion that includes both Technologists and Pathologists. It was also learnt that the constitution of the Association of Pathologists of Eastern, Central and Southern Africa (APECSA) established in 1992

does allow any pathology staff (whether Technologists or Pathologists) to become a member (**Dr Bimenya to re-confirm this**).

5. Also, it was noted that the EA-REQAS initiative is of interest to regional bodies such as the Commonwealth Health Regional Community Secretariat for Eastern, Central and Southern Africa (CHRCS-ECSA). The CHRCS-ECSA would like to see the initiative expanded into "ECSA-REQAS".

SESSION 3: EA-REQAS, REGIONAL ISSUES

3. 1 Introduction of Regional Issues
By Mr O. Lema

The issues to be discussed at Regional level i.e. the regional component of the EA-REQAS, were introduced for Inter-country group discussion. Criteria for the selection of tests and techniques for the EA-REQAS were presented. Criteria for selection of pathology/specimens for inclusion in the regional scheme were suggested. Based on the criteria a set of basic tests for laboratories at Primary Health Care level were suggested for inclusion in the EA-REQAS. These are:

- Haemoglobin estimation;
- Thick blood films;
- Peripheral blood film;
- Stool examination;
- Urine chemical testing;
- Urine microscopy;
- AFB microscopy (on sputum and skin smears);
- Gram stain (on pus smears and CSF deposits);
- Syphilis screening;
- HIV screening; and
- Blood glucose.

To harmonise technical issues, the need to adopt similar documents for the EA-REQAS was suggested. The essential documents required for EA-REQAS for use across the countries in the region were presented. The following documents were suggested:

- SOPs for test procedures (to be used by all participating laboratories in the region);
- SOPs for use of basic equipment (without referral to a particular model);
- SOPs for EQAS material preparation;
- SOPs for clinical utilisation of laboratory tests;
- Quality Manual for clinical, laboratory and administrative staff (specifying clinical and laboratory standards and check lists, and administrative issues including patients rights and systems of dealing with complaints);
- Clinical Quality of Care Manual (a basic reference of quality clinical procedures, ordering laboratory tests and interpreting results); and
- Educational posters for both clinical and laboratory staff.

It was noted that the staff of the AMREF Laboratory Programme have already produced most of the draft documents which may be adopted for use in the region.

Criteria for selection of laboratories for preparation of EQAS materials and roles and responsibilities of the Scheme Coordinating Centre were suggested. Also issues relating to materials and reports submission to and from the participating laboratories were discussed. A model for operating the EA-REQAS incorporating a regional Coordinating Centre, National or Zonal Coordinating Centres, Material producing and participating laboratories was suggested.

The handout of the presentation on the introduction of the Regional issues of EA-REQAS is attached in Appendix 13.

3. 2 Group work

The participants were divided into groups comprising members from different countries. The following assignments were given:

1. Review selection of tests and techniques to be included in the scheme:
   - criteria for selection of tests & techniques
   - criteria for selection of pathology
2. Selection of laboratories for material preparation:
   - review criteria for laboratories to produce materials
   - identify and name laboratories for material preparation in Kenya, Tanzania & Uganda

3. Preparation of documents:
   - review documents that are required
   - review the current status of document preparation
   - identify the work that remains to be done
   - suggest ways in which this could be completed
4. Co-ordinating Centre:
   - review roles & responsibilities
   - identify and name an appropriate Co-ordinating Centre
5. Submission of materials & reports:
   - how should materials be submitted to the Co-ordinating Centre from the laboratories producing them?
   - how should the Co-ordinating Centre submit packages to peripheral laboratories?
   - how should the results be returned from peripheral laboratories to the Co-ordinating Centre?
   - how should the reports be returned to the participating laboratories & central laboratory administrations?

3. 3 Group work Presentation & Discussion

1. Participants endorsed the criteria for the selection of tests and techniques to be included in the EA-REQAS. The suggested list of tests and techniques was also endorsed. Participants endorsed the criteria for selection of pathology. The list of pathologies to be included in the EA-REQAS was also endorsed (see Appendix i).

2. Participants endorsed the criteria suggested for selection of laboratories for preparation of materials for EA-REQAS. In addition, participants suggested that the laboratories should be run by a University, a recognised Health NGO or Research Institution, or a National Reference Laboratory. A suggested list of Institutions/laboratories for material preparation includes:
   a. Kenya: Kenya Medical Research Institute, University of Nairobi, Moi University, National Public Health Laboratory Services, Coast Provincial Hospital Laboratory and Aga Khan Hospital Laboratory (Nairobi).
   b. Tanzania: National Institute of Medical Research, Muhimbili University College of Health Sciences, Central Pathology Laboratory, Kilimanjaro Christian Medical Centre, Bugando Medical Centre, Public Health Laboratory (Pemba) and National Pathology Laboratory (Zanzibar).
   c. Uganda: Uganda Viral Reseach Institute, Joint Clinical Research Centre, Central Public Health Laboratory, Livestock Investigation Research Institute, Makerere University College, Mbarara University, Central Tuberculosis Laboratory, Nagulu Medical Laboratory Services, Kampala Biotechnology Laboratory, National Blood Bank Nakasero.

   The participants indicated the need to establish a mechanism for monitoring the quality of the laboratories assigned to prepare EQAS materials for the Regional Scheme.

   (Comment: Time was insufficient for listing all types of materials required for EA-REQAS)

3. Participants agreed with the suggested list of documents required for implementing EA-REQAS. In addition the following documents were suggested as essential:
   a. A summary of laboratory findings in common pathological conditions;
   b. Bio-safety manual;
   c. Manual for Quality Laboratory Management including planning, budgeting, etc;

d. Guidelines for Continuing Education;
e. Bench Aids showing photographs of common pathologies; and
f. A website for the EA-REQAS was also suggested (www.ea-reqas.com)

It was suggested that for those documents that are already available in draft, National workshops may be conducted to review, adopt and finalise the documents.

4. Participants agreed with the suggested roles and responsibilities of the Coordinating Centre (see Appendix ii). In addition participants suggested that the Coordinating Centre should:
    a. Be accredited by other recognised National and International organisations;
    b. Advise the National QA Advisory body of necessary remedial/corrective action;
    c. Solicit funds from donors and Governments for its administrative functions and activities like continuing medical education and facilitating exchange of expertise in various disciplines.
    d. Be responsible for monitoring and evaluation of the EA-REQAS; and
    e. Spearhead development of regional standards of health laboratory services.

Participants felt that it is unrealistic for a Coordinating Centre to validate all types of EQAS materials. The Coordinating Centre may not have expertise and capacity in all fields. However, it was noted that the Coordinating Centre will set up a system of verification of all specimens prior to sending to the participating laboratories. This may be achieved by sending the materials to other competent laboratories for testing.

Participants suggested AMREF to act as the Coordinating Centre in the short term. In the long term, the National laboratories of the three countries may become the Coordinating Centre on rotational basis. Alternative views were also expressed that the Coordinating Centre activities may be carried out by a Secretariat and not necessarily by an organisation or institution.

5. Participants made the following suggestions related to submission of materials and reports (see Appendix iii):
    a. Consider cost effectiveness when selecting a method for delivery of materials from the production centres to the Coordinating Centre.
    b. Use a courier system that is regional for delivery of materials from the production centres to the Coordinating Centre.
    c. Use courier services for delivery of materials from the Coordinating Centre to peripheral laboratories.
    d. Use e-mail, Telephone (SMS), Fax, Postage for sending results from participating laboratories to the Coordinating Centre. Copies of the results to be sent to the National Centre via the Regional/Zonal (supervising) laboratory.
    e. Use e-mail or courier services for sending reports/feedback from the Coordinating Centre to the participating laboratory. Copies of the feedback reports to be sent to the National Centre.
    f. The Coordinating Centre and National Centres to store and maintain a retrieval data bank.

SESSION 4: EA-REQAS, NATIONAL ISSUES

4. 1 Introduction of National Issues
By Mr D. Ocheng

The National component of the EA-REQAS were introduced for Country group discussion. The National issues noted include:

- Criteria for selection of sites for initial implementation of the EA-REQAS. It was suggested that the sites should be reasonably accessible, be involved in a disease control programme with a Laboratory Quality Assurance component e.g. Integrated Disease Surveillance and Response (IDSR), Tuberculosis and Leprosy Control, Sexually Transmitted Infection control, HIV initiatives for Voluntary Counselling and Testing (VCT), Prevention of Mother to Child Transmission (PMCT), or Malaria control or a Blood Bank. It was also suggested that the sites should have an adequate supervisory structure in place and a quality assurance commitment from the District Authorities.

- Sensitisation process for EA-REQAS participants and supervisors: It was suggested to organise workshops at various levels for both supervisors and participants.
- Setting up a system for reviewing reports of laboratory performance e.g. by the National Advisory bodies, and establishing links of the Regional Scheme to the National Legal framework e.g. Registration and Licensing of laboratories and personnel.
- A system of presentation of certificates to the laboratories with consistently good performance was suggested.
- Commitment to remedial action by the National authorities e.g. supply and repair of equipment, provision of supplies, training workshops and support supervision.

The handout of the presentation on the introduction of the Regional issues of EA-REQAS is attached in Appendix 14.

4. 2 Selection of sites for implementation of EA-REQAS: Case study from Uganda
By Mr G. Guma

Uganda has already selected Districts that will participate in the initial phase of implementation of EA-REQAS. Criteria for selection of the Districts for the initial phase were given. The following considerations were made:
- Districts that are located within the catchment of Regional Health Laboratories that have been strengthened by MOH/WHO programme;
- Prevalence of priority diseases identified for IDSR;
- Availability of functional laboratories and personnel;
- To ensure Regional balance across the country;
- Accessibility (no insecurity due to insurgency or cattle rustling);
- Population served;
- Districts that represent well performing, moderately performing and poorly performing laboratories.
- Districts selected are Kumi, Ntungamo and Nebbi.

These Districts have been visited for a baseline survey and taking an inventory of the laboratory services (both public and private). Kumi has 8, Ntugamo has 6 and Nebbi has 10 health facilities with laboratory that will be enrolled in the initial phase of the programme.

The handout of the presentation on Selection of Districts to Participate in the NELQAS (and EA-REQAS) is attached in Appendix 15.

4. 3 Group Work

The participants were divided into country groups. The following assignments were given:

1. Sites for Phase One implementation (Uganda delegates were exempted):
   - review the criteria for selection of sites
   - discuss the levels of laboratories that should be included
   - discuss whether private laboratories should be included
2. Sensitisation process for participants & supervisors:
   - who should be included in the sensitisation process (levels of laboratories, supervisors, clinicians/laboratory workers/Medical Officers in charge)
   - what should be the format for the sensitisation process
   - how should the sensitisation process be conducted, and by whom
3. Roles and activities of National Advisory bodies:
   - Membership & structure
   - Process for review of tests/questions/educational materials/reports from the Co-ordinating Centre
   - frequency of review meetings
   - links to bodies that conduct remedial action
   - links to registration/licensing bodies
4. Remedial action:
   - types of remedial action
   - bodies responsible for remedial action
   - means for procuring equipment/supplies/equipment repair
   - identification of other requirements, e.g. supervisory tools

4. 4 Group work Presentation & Discussion
(also see appendixes iv, v & vi)

1. **Sites selection**
   Participants endorsed the criteria for selection of sites for phase one implementation. Additional criteria were suggested:
   a. Presence of a Pathologist in a Zonal/supervising laboratory;
   b. Framework for supervision and management in place;
   c. Adequate capacity at the Zonal/supervising laboratories;
   d. Laboratories meet minimum requirements according to the National guidelines; and
   e. Private laboratories are registered.

   A suggestion was made to develop an objective scoring system to be employed when selecting Districts for participation in EA-REQAS. Also, it was noted that although the issue of regional balance is political, it may be essential in some circumstances.

   Primary Hospital and Health Centre level laboratories were confirmed to be appropriate levels for enrollment in the EA-REQAS, including Public, Mission and Private Laboratories. In Tanzania, the suggestion to include Regional laboratories was also made.

2. **Sensitisation process**
   Participants suggested:
   a. National leaders, Regional/Provincial and District/Local Government leaders; Laboratory Managers at all levels, Hospital Management teams and Clinicians (from participating areas) to be involved.
   b. AMREF, WHO & other partners to be involved in advocacy meetings with National and Regional / Provincial leaders
   c. The staff of the National Advisory Committee to be involved in the sensitisation workshops for supervisors and participating laboratories. The sensitisation workshops for supervisors to be conducted separately from those of the participating laboratories.

3. **National Advisory Bodies**
   a. Membership to include Heads of Diagnostic Services, representatives from health laboratory regulatory bodies, professional associations, reference laboratories, private laboratories & Quality Assurance/Standards Divisions of the Ministries of Health.
   b. The roles of the National Advisory Bodies were suggested as follows:
      i. To identify sites, experts, materials, etc for QA Programmes implementation;
      ii. To approve SOPs;
      iii. Monitor and evaluate QA programmes e.g. by reviewing tests, questionnaires and educational materials sent to participating laboratories;
      iv. To liaise with the Laboratory Councils/Boards and Professional Associations on Laboratory QA matters;
4. **Remedial action**
   a. Types of remedial action suggested:
      i. Training;
      ii. Provision of equipment and supplies;
      iii. Selection and standardizing of equipment and supplies;
      iv. Equipment maintenance and repair.
   b. Suggested bodies responsible for remedial action:
      i. Professional associations and Laboratory Boards and Councils;
      ii. The Ministries of Health / Diagnostic Sections;
      iii. District Health Services / Local Government Authorities/Hospital Management Teams.
   c. Means for procuring equipment/supplies/equipment repair:
      i. Government procurement systems;
      ii. Guidelines for importation of products and supplies - for Private Laboratories;
      iii. Development partners.
   d. Supervisory tools:
      i. Supervisory checklists;
      ii. Mobile laboratories;

iii. Photomicrographic slides of common pathological conditions;
iv. Standards and controls.

SESSION 5: EA-REQAS, ORGANISATIONAL ISSUES

5. 1 Introduction of Organisational Issues
By Mr C. Munafu

Issues related to organisation of EA-REQAS were introduced for discussion. The following issues were covered:

- The need to follow National and International regulations when transporting materials for EA-REQAS.
- Identification of regional fora that may be used for advocating for the EA-REQAS. Examples were given as IDSR, EANMAT, HIV/AIDS/ STI, Commonwealth Secretariat, APECSA.
- The need to establish regular EA-REQAS regional meetings. Participants were requested to consider the purpose of such meetings, frequency, sites for the meetings, coordination of such meetings and the range of participants.
- Financial issues were also introduced for consideration:
    - How to meet operational costs of the Coordinating Centre and support to laboratories preparing materials for EA-REQAS?
    - How to fund the National components of the scheme i.e. carrying out sensitisation meetings and workshops, reviewing documents required for EA-REQAS, distribution of EQAS materials and reports & taking remedial action.
    - How to fund / support the regional EA-REQAS meetings?

The handout of the presentation on Organisational issues of the EA-REQAS is attached in Appendix 16.

5. 2 Discussion

1. Participants suggested AMREF to take a lead in advocating for the EA-REQAS in various regional fora.
2. Participants confirmed the need to establish regular regional EA-REQAS meetings. Suggestions were made that the regional meetings should be held once a year on a rotational basis amongst the member countries. National Quality Assurance Advisory bodies should coordinate the regional meetings.
3. Participation in the regional EA-REQAS meetings to include:
    a. Policy makers;
    b. Members of National QA Advisory bodies;
    c. Pathologists, Technologists, other Laboratory professionals and Clinicians.
    d. The suggestion was made for AMREF to liaise with the Heads of Laboratory Services in organising the next EA-REQAS meeting.
4. Suggested sources of funding for the EA-REQAS activities include:
    a. Existing disease control programmes with a Laboratory QA budget e.g. HIV, Tuberculosis control, IDSR;
    b. Professional bodies;
    c. MOH to budget for QA activities;
    d. International Non Governmental Organisations;
    e. Regional and International bodies;
    f. Bodies responsible for administration of laboratory QA e.g. Laboratory Registration /Licensing Boards and/or Councils.

SESSION 6: WAY FORWARD, ACTION PLAN FOR THE EA-REQAS also see Appendix 17).

Action Plan

Participants suggested / recommended the following:

1. **Regional level**
    a. AMREF to present the status of EQAS in East Africa at the next CRHCS-ECSA Ministers' meeting.

b. AMREF to report the outcomes of the first regional EA-REQAS meeting to the Secretary General of the EAC and request for inclusion of the EA-REQAS in the agenda of the forthcoming Health Committee Meeting with a view to establishing a Technical Working Group on Laboratory Quality Assurance in the region.
c. Finalising the essential documents for the EA-REQAS:
    i. The SOPs developed by the Ministry of Health, Uganda to be adopted for use in the East African region.
    ii. Clinical SOPs to be finalised by the Ministry of Health, Tanzania. Suggested timeline – 3 months.
    iii. Quality Manual to be finalised by the Ministry of Health, Kenya. The suggestion was made to include aspects of Training on QA in the manual. Suggested timeline – 3 months.
d. A website for Laboratory networking be developed.
e. An Interim Committee for the EA-REQAS be formed consisting of two members from each country from the National Quality Assurance Advisory Bodies and AMREF. The suggestion was made for the first Interim Committee meeting to be held by July 2003.
f. The Secretariat for the Interim Committee was formed. Suggested members are AMREF and a representative from the Ministry of Health, Kenya.
g. The suggested model for operating the EA-REQAS was endorsed and adopted.

2. **National Level**
    a. Each country to strive to set up a National External Quality Assessment Scheme.
    b. The Heads of Laboratory Services to start the sensitisation process by debriefing the Senior MOH Officers and Policy makers on the EA-REQAS upon returning to their offices.
    c. Each country to set up a National Advisory Quality Assurance Committee. The Committee to formulate strategies for soliciting funds for Laboratory QA activities from the Government including establishing a budget line for Laboratory QA programmes.
    d. Each country to identify sites (Districts and participating laboratories), confirm laboratories for material preparation, and establish the National organising centre for the EA-REQAS. Suggested timeline – September 2003.

SUMMARY OF MAJOR RESOLUTIONS & RECOMMENDATIONS

1. Resolutions
a. In order to realise the EA-REQAS for Health Laboratories, each country will strive to set up a National External Quality Assessment Scheme (NEQAS).
b. In each country, there is an urgent need to formulate a National Quality Assurance Advisory Body, which will coordinate all Quality Assurance activities including sensitisation of the Ministry of Health and other stakeholders of the need to initiate NEQAS and to provide a budget line for Government provision of funds for Quality Assurance programmes for health laboratories.
c. The East African Regional Quality Assurance Committee (EA-RQAC) for Health Laboratories will be formed comprising two members from each of the National Quality Assurance Advisory Bodies, and AMREF.
d. AMREF together with one member representing the Ministries of Health of the Region will act as the Interim Secretariat of the EA-RQAC.
e. An East African Regional Quality Assurance Coordinating Centre (EA-RQACC) for Health Laboratories will be established. AMREF was appointed to act as the EA-RQACC in the short term.

2. **Recommendations**
a. To enhance further the realisation of the EA-REQAS, the development of quality assurance materials, tools and standards for health laboratories should be shared amongst the member countries and a website for networking should be established.
b. The Interim Secretariat should report the outcomes of the First Meeting of the EA-REQAS to the Secretary General of the East African Community (EAC). The Interim Secretariat should request for an opportunity to discuss the implementation of the EA-REQAS at the next EAC Health Committee meeting and explore the possibility of forming a Working Group on Quality Assurance for Health Laboratory Services in the region.

c. The Secretariat should request for an opportunity to present the status of the Quality Assurance of Health Laboratories in the East African Region at the next Commonwealth Regional Health Community Secretariat for Eastern, Central and Southern Africa (CRHCS-ECSA) Ministers meeting.

CLOSING REMARKS

The Heads of Laboratory Services from the member countries and the representative from the Commonwealth Secretariat closed the meeting with the following remarks:

- The ground work done by the staff of AMREF was appreciated;
- The meeting was a historical landmark, bringing together laboratory professionals in the region for the first time to discuss issues of laboratory quality;
- The Scheme was a 'home grown' solution to the common problems of quality of laboratory services in the region;
- Participants were urged to establish and maintain links, collaboration and networking to ensure the resolutions made are carried forward in order to improve the status of health laboratory services in the region. Assurance was given that the strength of the EA-REQAS lies in the collectivity of the participants.

Orgenes Lema
Interim Secretariat, EA-REQAC

2nd May 2003.

APPENDICES

APPENDIX - 1

FIRST REGIONAL TECHNICAL MEETING OF THE EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (EAREQAS)

ARUSHA, TANZANIA
3 – 4 April, 2003

PRELIMINARY MEETING AGENDA

Thursday 3rd April

08.00 – 08.30 Registration, Coffee

08.30 – 08.45 Introductory Remarks : Dr Mores Loolpapit, Directorate of Programmes, AMREF Headquarters

08.45 – 09.00 Welcome and Meeting Objectives: Secretary General, East African Community

Session One: Country Experiences of National Quality Assurance Schemes & Links to Other Programmes: Activities, Benefits & Constraints

Chair: Tanzania - Mainland

09.00 – 09.20 Uganda: Dr DKW Lwamafa
09.20 – 09.40 Kenya: Dr JA Nyamongo
09.40 – 10.00 Zanzibar: Dr TF Thani
10.00 – 10.20 Tanzania: Dr YA Ipuge

10.20 – 11.00 Discussion

11.00 – 11.30 TEA

Session Two: Update of project activities so far

11.30 – 11.45 Outline of the Regional External Quality Assessment Scheme: Dr J Carter
11.45 – 12.00 Kenya: Mr O Lema
12.00 – 12.15 Tanzania - Mainland & Zanzibar: Mr D Ocheng
12.15 – 12.30 Uganda: Mr C Munafu

12.30 – 12.45 Case Study from Uganda: Preparation of Written Materials: Dr G Bimenya

12.45 – 13.00 Discussion

13.00 – 14.00 LUNCH

Session Three: Discussion of Regional Issues
Chair: Kenya
14.00 – 14.30 Presentation of Regional Issues: Mr O Lema

- Selection of Laboratories for Material Preparation
- Roles & Responsibilities of Coordinating Centre
- Identification of Coordinating Centre

14.30 – 16.00 Group Work Discussion (mixed country groups)

16.00 – 16.30 TEA

16.30 – 18.00 Presentation of reports from each Group and Discussion

Friday 4th April

Session Four: Discussion of National Issues

Chair: Tanzania - Zanzibar

08.30 – 08.45 Summary of previous day's activities and conclusions: AMREF

08.45 – 09.00 Presentation of National Issues: Mr D Ocheng
- Sites for phase one implementation
- Sensitisation process for participants & laboratories
- Commitment to remedial action
- Frequency of national meetings

09.00 – 09.15 Case Study from Uganda: Selection of Phase One Sites: Dr DKW Lwamafa

09.15 – 11.00 Group Work Discussion (country groups):

11.00 – 11.30 TEA

11.30 – 13.00 Presentation of Reports from each Group and Discussion

13.00 – 14.00 LUNCH

Session Five: Discussion of Organisational Issues

Chair: Uganda

14.00 – 14.15 Presentation of Organisational Issues: Mr C Munafu/Dr J Carter
- Frequency of Regional meetings
- Regional Laboratory Networking
- Funding/sustainability

14.15 – 15.15 Plenary Discussion

15.15 – 16.00 Way Forward and Action Plan for the Regional Scheme

Plenary Discussion

16.00 – 16.30 TEA

APPENDIX II

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APPENDIX - 3

1st TECHNICAL MEETING OF THE EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME (EAREQAS)

Harnessing Regional Synergies

by
Dr Mores Loolpapit Bsc, MB ChB, MPH
AMREF HQ
Arusha, Tanzania
April 3rd 2003

How do we work?

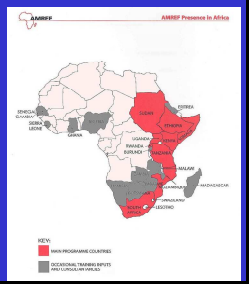
- AMREF develops & implements projects (emphasizing *capacity building & community-based approach*) at 1° health care level;
- ⇒ Learns the lessons from these projects and derives best practices (*operations research*);
- ⇒ seeks out opportunities to use information and knowledge to influence others (*advocacy*);
- Example: Pilot EQAS for 1° health care laboratories started in Kenya 1993 ⇒ EAREQAS with support from WHO Geneva).

What is AMREF?

- African Medical and Research Foundation;
- Founded in 1957 by three surgeons from the UK, USA and New Zealand;
- Non-governmental health development organization based in Africa and dedicated to improving the health of the people of Africa with a focus on the poor and the disadvantaged;
- Offices in 12 countries in Europe and North America dedicated to raising resources to support Africa-based activities, annual budget ≈ US$ 20m, 100 projects;
- Mission: To improve the health of disadvantaged people in Africa as a means for them to escape poverty and improve the quality of their life.

AMREF Presence in Africa

- Kenya
- Uganda
- Tanzania
- South Africa
- Ethiopia
- Mozambique
- Somalia
- Rwanda
- Southern Sudan



Why Regional Projects/ Programmes?

- Clear recognition that health problems traverse borders ⇒ may benefit from more concerted regional efforts e.g. HIV/Aids, Malaria, TB but also Leishmaniasis, trachoma;
- Supportive political environment offered by the EAC – allow us to harness regional technical competencies;
- Offer opportunities & challenges for national programmes to share experiences & learn from one another in a more structured way;

Do Regional Projects work?

- EANMAT: started in 1997 by KU&T, focus initially regional information base for parasite chemo sensitivity ⇒ rational treatment policy;
- Yes (but… working albeit at different rates) e.g. sharing standardized protocol, harmonising research projects across countries & building capacity for research in the south through collaborations with northern universities Liverpool & Belgium: starting in Uganda & now also Rwanda;
- Model recognised by the RBM partnership and has stimulated creation of similar networks in southern Africa (SANMAT), central Africa (RACTAP) & southern America (RAVREDA).

Other Regional Projects

- LSDI malaria control programme: Mozambique, Swaziland & South Africa which aims to protect communities, enhance development & protect economic investments in area with great potential for agriculture & tourism. Started in 1999 through PPP, today GFATM supported for next ;
- ? Lessons for East Africa to learn e.g. the Lake Victoria Initiative supported by the EAC with long-term commitment from SIDA. Objective: equitable & sustainable development in LVR;
- Lessons on the process of developing EAREQAS will be useful in enriching our understanding on challenges & opportunities of regional projects.

Appendix IV

WHO Medical Representatives,
Executive Secretary, Commonwealth Health,
Director of AMREF,
Heads of Laboratory Services
AMREF staff Members,
Distinguished Delegates
Invited Guests
Ladies and Gentlemen

It is a great pleasure for me to address this first Regional Technical Meeting of the East African Regional External Quality Assessment Scheme (EAREQAS) which has been organized by AMREF.

On behalf of the East African Community and on my behalf, I take this opportunity to welcome you to Arusha, the Headquarters of the EAC. Permit me also to briefly introduce to you distinguished delegates, the East African Community.

The East African Community is the Regional Intergovernmental Organisation of the Republic of Kenya, Republic of Uganda and the United Republic of Tanzania.

As you may be aware the current Community is not the first effort in regard to cooperation by the three countries, there has been past regional ingeneration arrangements which have brought the people of East Africa together. This includes the Customs Union between Kenya and Uganda in 1917, which the then Tanganyika later joined in 1927; the East African High Commission (1948-1961); the East African Community (1967-1977) and the East African Co-operation (1993-2000).

Following the collapse of the former East African Community in 1977, the Mediation Agreement for the Division of Assests and Liabilities of the East African Community was signed in 19984. In the Mediation Agreement, Kenya, Uganda and Tanzania agreed to explore ways to resume regional co-operation. This led to the 1993 Agreement for the Establishment of the Permanent Tripartite Commission for the East African Co-operation.

On 14 March 1996, the EAC Secretariat was launched at the Headquarters in Arusha, Tanzania and full operation of the East African Co-operation commenced.

On 29 April 1997, the East African Head of State directed the Permanent Tripartite Commission to start the process of upgrading the Agreement establishing the Permanent Tripartite Commission for East African Co-operation into a Treaty. The Treaty-making process, which involved negotiations among the Members States as well as wide participation of the public, was successfully concluded within three years.

The Treaty for the Establishment of East African Community was signed on 30 November 1999. It entered into force on 7 July 2000; and the East African Community was officially launched on 15 January 2001.

CHAIRPERSON,
Distinguished delegates,

I have gone through the two days programmers of this meeting and have taken note of the fact that the purpose of this meeting is to harmonise Regional and National Technical issues with respect to laboratory quality assurance across the three countries. It will also focus on the preparation of the Technical guidance and manuals as well as the roles and responsibilities of a coordinating Centre for the East African External Quality Assessment Scheme.

I am made to understand that quality assurance refers to all the measures that are undertaken by a laboratory to ensure the accuracy and quality of the final product. It also has two separate aspects – i.e. Internal Quality control and External Quality Control.
I am sure that all delegates assembled here today, are aware of the importance of these two processes and their contribution to the overall improvement of health of the people. I need to emphasize here that a good number of the people who attend hospitals and clinics do not really understand the work Clinical Pathologists, laboratory technologists, and clinicians. You therefore have a tall agenda to created

awareness of the work you do and its overall contribution as an integral part of the diagnostics and preventive activities of a health unit.

Allow me at this juncture, to take this opportunity to pay tribute to the African Medical and Research Foundation (AMREF), the organisers of this workshop for their outstanding role and contribution in the improvement of Health and the well being of the most disadvantaged populations in East Africa and in most parts of Africa. I am aware that clinics/laboratory services are one of the five programme areas of AMREF which also includes Sexual and Reproductive Health, Child and Adolescent Health and Development; Environmental health, Health Policy and Systems Reform.

Today, almost forty six years after the founding of AMREF in East Africa, its greatest strength still lies in its ability to help the poorest people and marginalized communities in Africa through the delivery of quality services; its ability to learn from its own experience and to document and use its learning to collaborate and network with others with the overall objective of improving and delivering quality health services.

Chairperson,
Distinguished delegates,

The East African Community has established a Sectoral Committee on health in order to facilitate action and implementation on the areas identified under Regional Health Cooperation by the three countries as outlined in Article 118 of the Treaty for the establishment of the East African Community.

The Committee on Health has further established three Working Groups to facilitate implementation of different programmes and activities.

These are-

- Working Group on the control and prevention of Sexually Transmitted Infections (STI's) and HIV/AIDS;
- Working Group on the Control of Communicable Diseases;
- Working Group on Health Research, Policy and Health Systems Development.

Within the mandate of the five programmatic areas of AMREF it is quite clear to me that AMREF has a lot to share and gain by working closely with the EAC through the sectoral committee on Health and its specialized working groups.

It is my sincere conviction that this unique workshop will contribute to the Harmonisation of regional and national technical issues with respect to laboratory quality assurance in the region and it will also lead to greater improvement of clinical and laboratory diagnostic services in order to develop effective and sustainable strategies to improve the quality of patient care and public health approaches.

In concluding my remarks, I want to emphasize that EAC welcomes AMREF's participation in the future meetings of the Health Committee, in order to participate and contribute to the process of defining a proactive Regional Agenda on Health.

We look forward to a continued fruitful and beneficial working relationship with AMREF.

Once again, welcome to Arusha and I wish you successful deliberations.

Thank you!

APPENDIX - 5

Uganda Experiences of Quality Assurances Schemes and Links to Other Programs

By Dr. D.K.W. Lwamafa,
Commissioner Health Services,
Department of National Disease Control,
Ministry of Health, Uganda.

Background 1

- Laboratory Quality Assurance is a System for ensuring continuous reliability, efficiency and proper utilisation of Laboratory Test Results and Services.
- It has 2 key Components namely:

  Quality Control and Quality Improvement.
- It is achieved by monitoring & measurement of the performance of the participating Labs.
- Results of the assessment are used to plan for corrective interventions.

Background 2

- In Uganda Health Service Delivery is undertaken through a Decentralized System.
- The Country is divided into 56 districts which are subdivided into 214 health Sub-Districts.
- There are 58 Government, 33 Mission, 12 Private for Profit and 5 Parastatal Hospitals.
- There are 931 Health Centers with functional Laboratories.

Country Experience 1

- Effective implementation of the components of the Ugand National Minimum Health Care Package require the contribution of efficient Laboratory Services.
- This is done through the establishment of different levels c Laboratory Services i.e:
  - ✓ Central Public Health Laboratories,
  - ✓ Specialized Research and Reference labs e.g UVRI
  - ✓ University teaching
  - ✓ National tertiary and Regional Referral Hospital Laboratories,
  - ✓ District and Health Sub-District Laboratories.

Country Experience 2

- Refresher Training for Lab. Staff in the 3 Regional Hospital Labs has been done.
- Laboratory Guidelines for Specimen Collection, Preservation, Transportation and Storage Procedures have been developed.
- Checklists for Support Supervision have been developed.
- Laboratories are involved in both Internal and External Quality Control Methods.

Country Experience 3

- Use of Standard Operating Procedures (SOP's) for Essential Equipment, Preparation and Storage of Media, Isolates, Chemicals and Reagents for Culture and Sensitivity.
- Use of Control Organisms and Reference Reagents is being done.
- Laboratory Data Management is done at all levels.

Country Experience 4

- The process of Recruitment and Re-orientation of qualified personnel is taking place for various laboratory levels.
- The development of SOP's is a pillar in the establishment of our NELQAS.
- This is an essential step in the fulfillment of the objective of the National Health Policy and Health Sector Strategic Plan.

Links to other Programs

- Laboratory support is an integral part in various Surveillance activities of the Ministry of Health Programs i.e:
  - ✓ Epidemiological Surveillance Division
  - ✓ Malaria
  - ✓ HIV/AIDS/STIs
  - ✓ TB/Leprosy
  - ✓ Others.
- The key role of the PH lab in this linkage is the confirmation of diseases of epidemic potential and monitoring of priority diseases as well as drug resistance.

Major Activities 1

- Central Labs participate in Research Agenda (OR), Disease Surveillance, Quality Assurance and production of Biological Materials.
- CPHL supports MOH Research Programs in Malaria (EANMAT), Sleeping Sickness, Cholera, Meningitis, Dysentery and Typhoid Fever.

Major Activities 2

- Participation in Epidemic Investigation,Preparedness and Response
- Surveillance and Monitoring of diseases of epidemic potential.
- Screening of Food Handlers.
- Monitoring of Safe Water Supplies.
- Regular Surveillance of antibiotic sensitivity of bacteria commonly causing infections.
- Monitoring of sensitivity of anti-malarial drugs.

Major Activities 3

- Coordinating Lab. activities at Health Sub-District Health Facilities, District and Regional Hospitals on Lab. investigation, diagnosis and reporting of results to the centeral and lower levels.
- Coordination of activities closely with those of all laboratory based vertical programs in Uganda.
- Provision of Laboratory Technical Support Supervision countrywide.

Benefits

- Confidence building among users of Laboratory Services – i.e. provision of reliable laboratory results.
- Laboratory staff motivation – from satisfied end-users.
- Continuous improvement in Laboratory Service provision.
- Strengthening of implementation of Disease Control Programs.
- Contribute to overall reduction in mortality objectives.

Constraints

- Inadequate Resources (human, material and financial).
- Poor communication (lack of IT, vehicles).
- Poor Laboratory Infrastructure (lack of lab space and utilities).
- Absence of Laboratory Focal Persons on DHTs in many Districts.

Challenges

- Growing number of Private Laboratories need to be monitored.
- Orienting current Staff to appreciate Quality Assurance Scheme (QAS) concept.
- Integration of QAS into basic training curricula.
- Integration of QAS in the existing health programs.

APPENDIX - 6

EAST AFRICAN REGIONAL QUALITY ASSESSMENT SCHEME

KENYAN SITUATION

DR. JACK NYAMONGO

STATISTICS - KENYA

- Population - 30 million
- 8 provinces, 76 districts
- 2 National Referral and Teaching Hospitals
- 7 Provincial General Hospitals
- 5000 doctors (588 in public sector)
- 38000 nurses
- >3000 technologists - 1700 in Public Sector

Statistics Contd.

- No. of Facilities

Facility	**GOK**	**NGO**	**PRIVATE**
Hosp	109	67	42
H/C	460	100	15
Disp	1537	595	391
Mat	0	11	180
Clinic	43	72	592

Surveillance

IDSR	22 DISTRICTS
TB CONTROL	NATIONWIDE
MALARIA	8 SITES
HIV	36 SITES

- Activities
  - Equipping laboratories
  - Development of laboratory modules
  - Training personnel
  - Validation of tests at Central level
  - Proficiency testing for TB and Malaria

Internal Quality Control

- No national QC Guidelines
- Internal QC Consists of
  - Use of manufacturers controls/standards
  - In-house controls
  - Inter-observer checks
  - Reagent and Test Validation

Current EQAS Activities

- NATIONAL
  - Bacteriology (diarrhoeal diseases)
    - Mombasa
    - Nyeri
    - Kisumu
    - Nakuru
    - Kakamega
    - Garissa
    - Embu
    - Mbagathi

Contd.

- AMREF NEQAS
  - 34 Rural facilities
    - Routine laboratory tests for this level
    - Feedback to facility and to NPHLS

CHEMLABS EQAS

- In 2nd year of operation
- Clinical chemistry
- 34 laboratories enrolled, mainly private hospital and clinics
- 2 cycles/year (8 samples each)
- 3 modules
  - 6 parameters (9300/=)
  - 9 parameters (12300/=)
  - 12 parameters (15300/=)

WHO EQAS

- HIV, HBV, HCV (Vienna)
- BACTERIOLOGY (South Africa)
- BLOOD TRANSFUSION (Harare)
  - Only NPHLS participating

OTHER EQAS

- CLINICAL CHEMISTRY (RANDOX)
- BACTERIOLOGY (COLINDALE)

APPENDIX - 7

December 2002

EXPERIENCES OF THE NATIONAL QUALITY ASSURANCE SCHEME IN TANZANIA: 1986-2003

Presented at the first regional Technical meeting of the East African Regional External Quality Assessment Scheme (EAREQAS) 3-4 April 2003, New Arusha Hotel

DR Y. A. IPUGE
HEAD, DIAGNOSTIC SERVICES

Functions of Health Laboratory Services

- To assist clinicians in diagnosis of disease conditions and monitoring treatment of patients.
- Epidemiological surveillance of diseases and health conditions
- Surveillance of potentially epidemic diseases and response to epidemics.
- Analysis of environmental samples (water, food)
- Training of health personnel.
- Supporting research and clinical trials.

December 2002

Organisation and Management of Diagnostic Services in Tanzania

- Diagnostic Services Section established 1998 comprises of:
  - Health Laboratory Services
  - Diagnostic Radiology and Imaging Services
  - Health Care Equipment Technical Services
  - Private Health Laboratory Board
- The National TB/Leprosy Programme and National AIDS Control programme have own laboratory service units

December 2002

Functions of Diagnostic Services Section-1

- To formulate policy guidelines and manuals on medical radiology, medical laboratory and health care equipment services
- To formulate standard operating procedures for medical radiology and laboratory investigations
- To co-ordinate, monitor, and evaluate implementation of medical diagnostic services policy guidelines.

December 2002

Functions of Diagnostic Services Section-2

- To recommend and advise on issues pertaining to the management of diagnostic services
- To monitor the quality of reagents, chemicals and apparatus including instruments for diagnostic services.
- To liaise with the Human Resources Development Division in training health laboratory and medical radiography personnel.

December 2002

Organisation and Management of Health Laboratory Services in Tanzania

- Health Laboratories are categorized into:
  - National Reference Laboratory – Central Pathology Laboratory at the Muhimbili National Hospital
  - Zonal Reference Laboratories at Kilimanjaro Christian Medical Centre, Bugando Medical Centre and Mbeya Referral Hospital
  - Regional Laboratories
  - District Laboratories
  - Health Centre and Dispensary laboratories

December 2002

Organisation and Management of Central Pathology Laboratory, Muhimbili

- Prior to 1976, three institutions existed at the Muhimbili Complex
  - Muhimbili Hospital under Medical Superintendent
  - Faculty of Medicine of UDSM under Dean
  - Central Pathology Laboratory under Chief Pathologist
- Muhimbili Medical Centre Act of 1976 merged the Hospital and Faculty of Medicine to form Muhimbili Medical Centre
- CPL was not dissolved but departments operated as part of MMC, Chief Pathologist moved to MOH. Post remained vacant from 1982.

December 2002

Organisation and Management of Laboratory Services in Tanzania

- Draft National Policy Guidelines for Health Laboratory Services (1996) have not been fully implemented
- Public-owned Health laboratories are Hospital based.
- Autonomous Health Laboratories exist in the Private Sector
- Existing Legislation (Act No 9 and Act No. 10) passed in 1997 covers some aspects of the draft policy guidelines.

December 2002

Current Situation of Health Laboratory Services

- Laboratory services are decentralised and different levels of government are accountable for provision of services.
- Health Laboratories are integrated within the management of individual hospitals with inadequate linkages and coordination
- Quality and efficiency of Health Laboratory Services has declined dramatically in the past two decades.

December 2002

Current Situation of Health Laboratory Services

- deficiency of qualified laboratory staff in health laboratories at all levels
- Availability and quality of equipment, reagents and supplies, in most cases, is inadequate.
- limited services are offered with inadequate monitoring and supervision
- poor quality assurance of testing processes

December 2002

Current Situation of Health Laboratory Services

- Although laboratories are understaffed, some laboratory personnel are doing very little due to inadequate facilities and lack of reagents
- Lack of a comprehensive quality assurance programme.
- Due to poor performance, clinicians have limited confidence in the capacity of Laboratory services to assist in the patient management

December 2002

Health Sector Reforms and Reform of Laboratory Services

- Government has initiated wide ranging reforms in the health sector in order to improve the quality, efficiency, equity and financial viability of health services.
- Reform of Laboratory services is part and parcel of overall health sector reforms, and in particular, the Hospital reform Strategy
- Some laboratory experts have urged MOH to have have a separate Health Laboratory reform strategy!

PRIORITIES OF THE LABORATORY STRENGTHENING PROGRAM

- Reforming the Tanzania Laboratory System
- Investment in Laboratory Quality Assurance
- Introducing simple technology and protocols
- Evaluations Test kits and new techniques
- Technical expertise
- Collaborations and linkages

Objectives of the Reformed National Health Laboratory Service

- Provide essential public health laboratory functions
- Improve reference laboratory services
- Ensure quality assurance and oversight of diagnostic laboratory testing
- Standardize use and maintenance of equipment, supplies and reagents
- Improve and increase human resources and ongoing training and research

Health Sector Reforms and Reform of Laboratory Services

- In respect to strengthening laboratory services, the following have been undertaken:
  - Enactment of the Private Health Laborory Regulation Act (No. 10 of 1997) and the Health laboratory Technologists Registration Act (No 11 of 1997)
  - Standard guidelines for Health Laboratory Services
  - District Health Laboratory strategy developed with support from Ireland AID
  - A ministerial technical task force conducted a situational analysis and submitted recommendations on reform of laboratory services.
  - Partnership with CDC-Tanzania in strengthening Health Laboratory Services.

Recommendations of Task Force

- Centralized model for the laboratory services delivery by creating an autonomous National Health Laboratory Service with national, zonal and regional laboratories under one management
- Economic analysis of the recommended option needed
- A stakeholders' meeting needed to assure support and funding of the selected option

INVESTMENT IN LABORATORY QUALITY ASSURANCE

Why Invest in Quality Assurance?

- Even the simplest of testing is not fool proof
- Quality assurance is the framework for guaranteeing reliable and accurate test results
- Doctors and users of test results expect quality results and nothing less is acceptable
- Quality assurance is cost effective

Quality Assurance in Tanzania Laboratory Services

Challenges

- Poor quality services may undermine:
  - surveillance, prevention, and blood safety;
  - Credibility of health system

Quality Assurance in Tanzania Laboratory Services

- National workshop convened in 1986 to plan and operate national external quality assurance scheme (EQAS)
- Started operating with Central Pathology Laboratory as the organising Centre
- In 1994 first guidelines for EQAS protocol were developed establishing:
  - National External Quality Asessment Scheme (NEQAS);
  - Regional External Quality Asessment Scheme (REQAS);

Quality Assurance in Tanzania Laboratory Services

- National External Quality Asessment Scheme (NEQAS) assesses referral laboratories and Regional Laboratories
- Regional External Quality Asessment Scheme (REQAS) assessed lower levels
- QA was mainly conducted in government owned laboratories

Quality Assurance in Tanzania Laboratory Services

- 1998 and 2002 review and planning workshops proposed establishment of Zonal External Quality Assessment Scheme (ZEQAS)
- Regions to act as
  - supervising and distributing arms for ZEQAS
  - Strengthening internal Quality control arm of the quality assurance shceme

Quality Assurance in Tanzania Laboratory Services

- There are special programmes for Quality Assurance that complement NEQAS organised by
  - the National Tuberculosis Programme,
  - AMREF-Tanzania
  - and National AIDS control Programme
  - Collaboration between specific laboratories with international quality assurance schemes

National TB/Leprosy Programme

- NTLP conducted an inventory of laboratories conducting AFB microscopy and piloted a blinded centre to periphery proficiency testing
- Also introduced rechecking of samples perfomed at the periphery by regional and National levels, also blinded.
- At present 455 centres are participating, expansion to 600 centres is planned
- NTLP provides financial support to regions for supervision, check lists and equipment

AMREF-Tanzania

- Sends QA exercises to various laboratories
- Conducts supervision to participating centres
- Conducts refresher courses

Experiences in NEQAS

- Health laboratories participating in the scheme have improved their performance standards as well as the attitudes, skills and knowledge
- Responses from laboratories participating in NEQAS increased from 64% to about 90%.
- This allowed the scheme to expand and reorganize itself and increase frequency

Experiences in NEQAS

- The National level started with only 20 centres but now expanded to 56 centres.
- The regional level has several participating health laboratories depending on the number of health laboratories in each region

Experiences in NEQAS

- Since introduction of the Zonal External Quality Assurance Scheme to take over the Regional level, some zones have already started to implement
  - the Eastern Zone has already prepared two batches of samples and distributed to 99 small laboratories in the Eastern Zone.
  - A proposal has been submitted for support and when accepted, the other zones will start.

Benefits of NEQAS/REQAS

- The performance of the scheme has encouraged use of internal quality controls.
- The taskforces had chances to monitor changes in technology and test procedures.
- meetings involving all participating centres and organizing centres provide opportunities for better communication.
- NTLP was able to verify the quality of equipment and function in the country

Quality Assurance in Tanzania Laboratory Services

Challenges/Constraints

- Shortage of Qualified staff
- Laboratory physical infrastructure, equipment ad supplies
- Transport to facilitate communication and follow up of poor performing laboratories
- reference & training materials,
- Inadequate funds to run the scheme, refresher training and supervision
- National Committee has not yet been formed

Quality Assurance in Tanzania Laboratory Services

Challenges/Constraints

- Motivation of laboratory staff
- QA reports from NTLP, NACP, AMREF not linked with National Scheme
- Participation in international QA scheme not nationally coordinated
- Equipment maintenance and repair needs to be strengthened

Quality Assurance in Tanzania Laboratory Services

Links and collaboration

- K.C.M.C with initial support from Cord Aid and collaboration with AMREF provides support to Regions within the Northern Zone to conduct REQAS activities
- Collaboration with CDC for Strengthening of Laboratory Services aims to
  - invest in laboratory quality assurance
  - Strengthening QA of HIV testing for NACP surveillance

Quality Assurance in Tanzania Laboratory Services

Links and collaboration

- WHO supports training, integrated disease surveillance
- AMREF spearheading EA collaboration in Quality Assurance
- Participation in international external quality assessment schemes
  - individual departments and laboratories participate
  - Not nationally coordinated

Quality Assurance in Tanzania Laboratory Services

Opportunities

- The enactment of the two Acts provided the legal mandate for
  - the licensing and full registration of all health laboratory staff
  - regulation of private health laboratories in Tanzania respectively.
  - Legal requirement for all private laboratories to participate in Quality assurance
  - implementation of standard guidelines for health laboratory facility

Quality Assurance in Tanzania Laboratory Services

Opportunities

- The on going health sector reforms leading to establishment of National Laboratory services.
- The efforts to establish eastern Africa external Quality Assurance Scheme.

In Closing

- A wide range of activities are being undertaken to strengthen laboratory services which are critical to disease prevention and clinical care
- Support for renovation and equipping of laboratory infrastructure to some extent has been secured, negotiations on going.
- As a result of these accomplishments, the goal of reliable and accurate testing is achievable

APPENDIX - 8

Outline of the East African Regional External Quality Assessment Scheme: EA-REQAS

Jane Carter, MBBS, FRCP(C)
Head, Clinical Services
African Medical & Research Foundation

First Regional Technical Meeting of EA-REQAS
Arusha, Tanzania
April 3-4, 2003

Review of Meeting Objectives

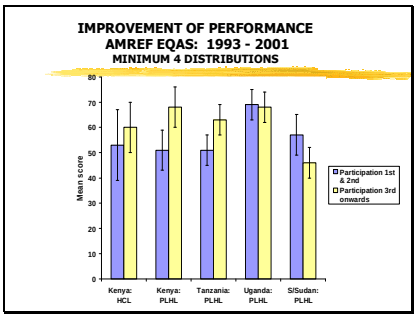
- Review current EQAS activities and linkages to other health programmes in each country.
- Outline the concepts of the EA-REQAS.
- Determine issues & define operations for the Regional activities of EA-REQAS
- Determine & review the National components of EA-REQAS
- Identify constraints to the operations of EA-REQAS
- Develop an Action Plan for the Regional & National activities of EA-REQAS

Expected Outcomes

- Harmonise technical issues and develop modalities for Regional co-operation for laboratory quality assurance in the East African region, through a consultative process.
- Establish means of sharing experiences between the three countries, through Regional networking.

Purpose of an External Quality Assessment Scheme

- Measure laboratory performance
- Identify and rectify problem areas
- Standardise techniques
- Provide continuing education
- Evaluate training activities
- Improve communication between clinical, laboratory & public health staff



Advantages of a Regional External Quality Assessment Scheme

- Standardisation of laboratory procedures
- Standardisation of quality of scheme materials
- Wider range of specimens
- Sharing resources for material preparation
- Objective assessment by an independent laboratory
- More national resources spent on remedial action
- Lessons learnt from regional experience
- Increased Regional co-operation

Regional Components of the Scheme

- Selection of tests
- Standardisation of test techniques
- Selection of laboratories for material preparation
- Standardisation of material preparation
- Preparation of documents: SOPs, Quality Manual, etc
- Selection of a Coordinating Centre
- Submission of materials & reports

National Components of the Scheme

- Selection of sites & distribution of materials
- Sensitisation of participants & supervisors
- Review of tests/questions/educational materials for each distribution
- Review of summary reports
- Taking remedial action:
  - support supervision
  - provision of supplies/reagents
  - equipment and equipment repair
  - training/workshops

Organisational & Funding Considerations

- Packing & transportation of materials
- Regional review meetings & networking
- National review meetings
- Financial operations & sustainability:
  - Regional activities:
    - Coordinating Centre
    - Laboratories for material preparation
    - Documents
  - National activities:
    - Remedial action

APPENDIX 9

EA – REQAS: ACTIVITIES UPDATE, KENYA

Orgenes Lema
Chief Laboratory Technologist
AMREF Laboratory Programme

Arusha, 3rd April 2003

Activities update, Kenya - 3

- EQAS for PHC laboratories, 1993, AMREF & NPHLS.
- EQAS for PHC laboratories expanded to include laboratories outside Kenya (1993).
- EA-REQAS idea→concept→proposal (1996-98).
- Initial funding from WHO-Geneva (2000).
- Meeting to introduce the EA-REQAS to NPHLS (April 2001)
  - Idea accepted; sharing of resources fore seen

Activities update, Kenya - 4

- Meeting to introduce EA-REQAS to WR-Kenya (April 2001)
  - Pledge to support National component of the scheme
- AMREF staff – members of the Standards, Training Committee of KMLTTB (June 2001).
  - Approval by the KMLTTB
- Structure to implement the EA-REQAS (& NEQAS) established (June 2001)
  - NMLQAA Body
  - Technical arm (AMREF, NPHLS)
    - TOR drawn

Activities update, Kenya - 5

- Meeting to discuss the NEQAS: KMLTTB, NPHLS, AKMLSO, AMREF (K,T, U) - December 2001.
  - Outcome:
    - Strengthening EQAS for PHC labs endorsed. (tests, techniques, materials for EQAS, documents required identified).
    - Strategies identified: District focus; Integration of QA activities; Involvement of Clinicians; Collaboration with National organs / Legal entities charged with QA responsibilities.

Activities update, Kenya - 6

- Progress:
  - Proposal to strengthen NEQAS in Kenya (based on the above principles) developed and submitted to WHO
    - Endorsement from the MOH obtained
  - Draft documents developed:
    - SOP's (for all basic tests); Quality Manual; Clinical Quality of Care Manual; Clinical SOP's (on the use of basic tests).

Activities update, Kenya - 7

- Plans: (subject to the outcome of discussion of National issues)
  - Confirmation of funds (re: WHO proposal)
  - Confirmation of written documents
  - Confirmation of participating Districts
  - Sensitisation workshop for participating Districts
  - Establish mechanisms for remedial action
  - Launch the programme (Before end of 2003).

APPENDIX 10

EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME MEETING, ARUSHA, APRIL 3RD - 4TH 2003

Tanzania Update

David MA Ocheng
Project Manager, AMREF Laboratory Programme

Background information - 1

1

- Introduction of the project to Head of Diagnostic Services, MOH:
  - ✓ Tanzania Mainland in May 2001
- Introduction of the project to WHO Country Office:
  - ✓ May 2001
- Introduction of the project to MOH Zanzibar:
  - ✓ Dialogue and recent opening of Public Health Laboratories in Pemba 2001
  - ✓ December 2002

Background information - 2

- Review of policy papers for NEQAS:
  - ✓ Main points
    - Tests at each level must be relevant, reliable, reproducible and accurate
    - Samples analyzed as soon as possible upon receipt in laboratory
    - Clinicians get results without delay, legible and understood
  - ✓ Participants
    - MOH officials, RLT, SMLT
    - Zonal Laboratory Technologists
    - Heads Pathology, C/Chemistry, Micro/Immunology, Histopathology
    - MUCHS
    - Equipment Technicians
    - Laboratory scientists

Background information - 3

- Existing MOH documents reviewed:
  - ✓ Health Laboratory Technologists Registration Act, 1997
  - ✓ Standard Guidelines for Health Laboratories Facilities 1998
  - ✓ Draft National Health Laboratory Services Quality Assurance Scheme (NHLSQAS) 2001
  - ✓ Guidelines for a National Quality Assurance Programme for the testing of antibodies to HIV 1991

Background information - 4

- Establishment of body to oversee the Scheme (committee & subcommittee)
  - ✓ The National Diagnostic Services Advisory Committee
  - ✓ The Zonal Diagnostic Services Advisory Committee
    - Sub-committee for Quality Assurance/Assessment Scheme
    - Other Sub-committees are: Laboratory Services, Blood safety, Medical Equipment and Radiology/Imaging Services
  - ✓ Function of NDSAC to advice CMO on the Diagnostic Services policy guidelines for efficient operation at all levels
- Role of NDSAC sub-committee
  - ✓ Oversee and coordinate quality assurance activities
  - ✓ Preparation of policy guidelines, monitoring and evaluation activities
  - ✓ Promote research and information dissemination on new diagnostic equipment, reagents and techniques

- **Outcomes**
  - ✓ **Agreements:**
    - **The committee to include representative from The Council, MeLSAT**
    - **Private Laboratories represented in the Advisory Committee**
    - **Zonal Referral Hospital Laboratories given mandate to coordinate EA-REQAS schemes activities – entry point for EA-REQAS**

Background information - 5

- **Role of NDSAC sub-committee QAS**
  - ✓ **Establish effective mechanisms for distribution of samples, analysis and feedback of results**
  - ✓ **Take appropriate remedial actions including supportive supervision, training and other corrective measures to improve quality**
- **Draft proposal for the development of national EQAS drawn up and ready for submission**

2.

- **Two-day workshop to introduce and discuss the regional Scheme in May 2002**
  - ✓ **Attendance**
    - **16 participants attended from MOH, KCMC, Mbeya Zonal Referral Hospital, Bugando Medical Centre, NACP, Muhimbili National Hospital and AMREF**
    - **50% Laboratory scientists, 6% Pathologists**
    - **31% Clinicians, 13% MOH**
- **Objective of the workshop**
  - ✓ **To review and discuss strengthening of NEQAS in Tanzania**
  - ✓ **To introduce the regional EA-EQAS concept**
  - ✓ **To discuss and identify key strategies for integration of EA-EQAS into the NEQAS**
  - ✓ **To formulate the way forward for the implementation of both NEQAS and EA-EQAS**

- **Outcomes**
  - ✓ **Recommendations:**
    - **MOH promotes appropriate use laboratory services**
    - **QAS scheme should accredit laboratories**
    - **Strengthened NEQAS to distribute materials x3 per year**
    - **AMREF to implement EA-EQAS programme starting with few laboratories under direction of Diagnostic Services, MOH**
    - **Materials distributed should observe International Postage Regulations**
  - ✓ **Specific tasks assigned:**
    - **Diagnostic Unit responsible for strengthening NEQAS and making it operational**
    - **Zonal NEQAS centres established at Zonal Referral Hospitals**
    - **AMREF coordinate and organize meeting**
- **Progress of tasks**
  - ✓ **Draft proposal ready for submission**
  - ✓ **Plan to review draft SOPs for preparation of materials, tests, clinical**

APPENDIX - 11

Regional External Quality Assessment Scheme Activities in Uganda

By

MUNAFU Charles
Training Officer

3RD April, 2003

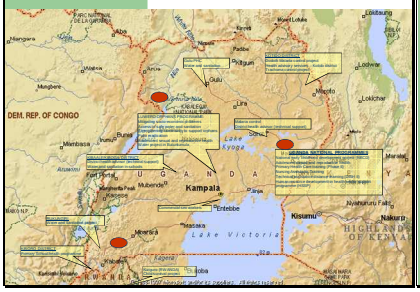
Activities 1

- Project was introduced to the MoH. The MoH team was headed by the Commisioner of health, National Disease Control (April 01)
  -Project was to strengthen existing MoH quality assurance programme.
  -The National Health Laboratory Advisory and Coordination Committee (NHLACC) to oversee the project

Activities 2

- Project introduced to WHO Uganda Representative in presence of MoH (April 01)
- WHO suggested development of country specific proposal
- Proposal presented to and accepted by first NHLACC (May, 02) and then WHO (Nov.'02).
- Initial funding were provided by WHO

UGANDA



Activities 3

- EA-REQAS -start up meeting.
- Meeting opened by Ag. Director General of Health (October '02)
  -Tests selected
  -Format of SOPs developed
  -Districts to participate in EA-REQAS selected
  -Implementation strategies suggested.

Activities 4

- SOPs prepared for Service labs and preparation of materials.
  -To be presented to NHLACC for approval

- Selected districts visited
  -Co-ownership established
  -Laboratory inventory established

APPENDIX 12

Preparation of National Quality Assurance Schemes written material: A Case study from Uganda

By
Dr G. S Bimenya
Head of Pathology department
Makerere University

Introduction1

- We are here to prepare for a Regional External Quality Assurance Scheme (EQAS)for East Africa.
- EQAS is an external agency which retrospectively compares performance of laboratories to establish between lab comparability of test results.
- Inter lab comparability demands for uniformity in performance.

Introduction 2

- Standard Operating Procedures (SOPs) for peripheral lab tests in Uganda for its conditions.
- Objective is to to convince you after reflection that what is good for the goose is also good for the gander.
- If we adopt this principle we shall be a long way to achieving uniformity.

Introduction 3

- Clinical Audit was used as modulus operandi for the SOPs.
- Colleagues of talent mix came together and reflected on their work systematically, critically and objectively to enable them agree how to do it and check improvements to achieve laboratory comparability.

Laboratory tests1

Selection of Essential peripheral laboratory tests:

1. Core Laboratory diagnostic tests

- Provide useful clinical or Public Health Information.
- Contribute maximally to patient management and quality of care.
- Sufficiently rapid, reliable, sensitive, or specific for the purpose of clinical and Public Health consideration.

Laboratory tests2

2. Priority diagnostic tests

- Diseases difficult to diagnose clinically alone.
- Diseases of lengthy, high risk, expensive treatment.
- Epidemic prone with high mortality, very ill health or disability.

Laboratory tests3

3. **Preventive and Management tests**

- Establish base line value for follow up
- Help achieve rational and selective use of drugs.
- Assess severity of illness and likely disease outcome.
- Make treatment and care safer and help assess efficacy.
- Identify disease carriers and improve case finding.
- Promote community health.

Broad considerations in test selection1

Patient Consideration:

- Most of our patients are young children requiring appropriate specimen collection.
- All techniques should be humane, safe, respectful, culturally acceptable and stress free.
- Rapid technique i.e most patients are out patients requiring results prior to treatment.

Broad considerations in test selection2

Laboratory Consideration:

- Competence and experience of local staff.
- Standardization and control of test.
- Reagents, standards, controls and consumable availability.
- Equipment, cost, power, complexity, safety and robustness.
- Type of specimen required i.e collection, stability, transport, storage and disposal.
- Communication and transport links.

Broad considerations in test selection 3

Cost Consideration:

- How expensive alternative tests are.
- What the cost of different technologies are.
- How cost effective the test is to the district.
- How the cost of the test will met in the district.

Choice of tests

Two needs guided the choice of tests for the districts

- The commonest and most threatening conditions in the districts.
- The most difficult conditions to diagnose clinically.

Standard Operating Procedure standardization

- Title, Staff required, principle and purpose, reagents , sample, method, reference range and references.
- These are all contained in the
- "***National Operating procedures for the External Laboratory Quality Assurance Scheme in Uganda***"

The essential facts Standard Operating Procedures provide

- Understand why a test is required i.e clinical and Public Health indications for test request.
- Perform and control a test in the most accurate and timely result.
- Perform the test safely.
- Perform the test effectively without waste.
- Calculate, report and record a test result correctly.
- Avoid shortcuts.

Primary purpose of each SOP

- Improve and maintain the Quality of laboratory service.
- Provide consistency and performance to the acceptable standard.
- Avoid short cuts.

Attributes of SOPs inUganda

- Achievable and applicable in laboratories where they will be used.
- Clearly written easy to understand and follow.
- Updated to appropriate technology.

Salient features for the east African Region

- The salient features of SOPs are applicable to the whole East African Region.
- SOPs will improve the quality of diagnostic services within each Country.
- SOPs will help us as East Africans share resources and experience in the spirit of East African Community.

Thank You!

APPENDIX 13

EA – REQAS: REGIONAL ISSUES

Orgenes Lema
Chief Laboratory Technologist
AMREF Laboratory Programme

Arusha, 3rd April 2003

Criteria for Selection of Tests and Techniques

- Tests of clinical importance
- Tests of public health importance
- Tests & techniques performed at primary health care level
- Techniques of accepted accuracy
- Tests for which material can be preserved

Criteria for Selection of Pathology

- Common/important pathology/conditions
- Methods of sample preparation & preservation are available
- Pathology for which international standards of measurement/recognition are available

Tests, Techniques, Pathology

Haemoglobin	Haemiglobincyanide ? Alkaline haematin D	Anaemia: mild, moderate, severe
Thick blood film	Field stain Giemsa stain	*Plasmodium falciparum, P malariae, Borrelia* Trypanosomes Microfilariae
Peripheral blood film	Field stain Leishman stain	Hypochromia/microcytosis Megaloblastosis Neutrophilia Leucopaenia Parasites
Stool examination	Direct microscopy	Cysts of protozoa Helminth ova

Tests, Techniques, Pathology

Urine examination	Chemical testing ? Direct microscopy	Protein, haemoglobin, glucose, helminth ova
Sputum examination Skin examination	Ziehl Neelsen stain	AFB
Pus examination CSF examination	Gram stain	GNID Gram positive cocci
Syphilis screening	VDRL/RPR	Positive, weak positive
HIV screening	ELISA, Rapid tests	Positive, weak positive
Blood glucose	Colorimetric	High, low

Include normal/negative samples

Documents

- SOPs for test procedures
- SOPs for use of basic equipment
- SOPs for material production
- SOPs for clinical utilisation of laboratory tests
- Quality Manual for clinical, laboratory and administrative staff
- Clinical Quality of Care Manual
- Educational posters

Laboratories for material preparation

- **Selection criteria:**
  - Professional staff
  - Location, accessible
  - Equipment
  - Facilities: IT, communication
  - Participating in relevant EQAS
  - Commitment to NEQAS
- **Identification**: Which labs for which materials?

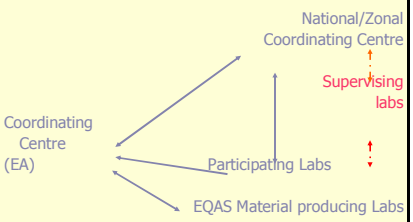
EA-REQAS Coordinating Centre

- **Roles / Responsibilities:**
  - Preparation of some materials
  - Validation of quality of materials prepared from all centres
  - Preparation of questionnaires, answer sheets & marking key
  - Receiving materials, packing and distribution
  - Receiving, marking and analysing results
  - Reports submission: to participating labs, central lab administration
  - Preparation and submission of educational materials
- Identification of Coordinating Centre??

Materials & Reports submission

- Materials:
  - Direct to participating labs
  - Through national/zonal distribution centres
  - To supervising Labs ?
  - A Specialised scheme for supervising labs??
- Reports:
  - To both participating labs & central lab administration

Suggested Model



Thank you

APPENDIX 14

EAST AFRICAN REGIONAL EXTERNAL QUALITY ASSESSMENT SCHEME MEETING, ARUSHA, APRIL 3RD - 4TH 2003

Discussion of National Issues

David MA Ocheng
Project Manager, AMREF Laboratory Programme

Site for Phase One Implementation

- Sites reasonably accessible
- Involved in national programme with laboratory QAS component e.g. IDSR; TB & Leprosy control, STI control, HIV initiatives for VCT, PMTCT, Blood Bank, malarial control
- Adequate supervisory structure in place
- Commitment from District/Regional authorities
- Private sector? What is their role?

Sensitization process for participants and supervisors

- Workshops to introduce the scheme , outline purpose, procedures for processing of materials
  - Target groups
  - Participants
- Purpose and procedures for support supervision
  - Roles and responsibilities
  - Supervisory tools
  - Logistics/supplies
- Involvement of clinicians
  - Why?
  - When?

Review of tests/questions/educational materials by each National Advisory Body

- Review of reports by each national advisory body
- Links to national legal framework:
  - The Boards/Councils
  - Registration and licensing
  - Importation of products/supplies
- Presentation of certificates?
  - MOH Yellow star project (Uganda)
  - Green Star (Family planning in Tanzania)
  - ANGAZA

National Advisory Bodies

- Membership
  - Composition
  - Number
- Technical subcommittees
- Terms of Reference
- Frequency of meetings
- Responsibility for action

Commitment to remedial action: national and local activities

- SOPs for test procedures
- Selection and supply of standardized equipment
- Equipment repair
- Provision of supplies and reagents
- Training workshops specific problems identified (if appropriate)
- Regular support supervision – acceptable supervisory tools - **'SMART'**
  - **Feedback**
  - **Documentation**

- **Long live Quality Laboratory Services**
- **Long Live the East African Community**
- **Proudly East African**

APPENDIX - 15

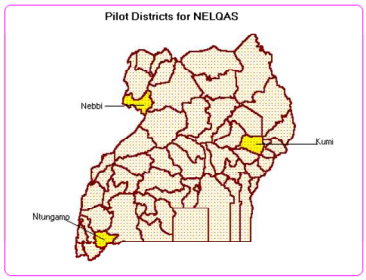
Selection of Districts to Participate in the National External Laboratory Quality Assessment Scheme

By: Mr. G.B.Guma
CPHL
Ministry of Health.
UGANDA

GENERAL CONSIDERATIONS FOR THE INITIAL PHASE OF IMPLEMENTATION.

- Located within catchments area of the Regional Reference Laboratories already being strengthened by MOH/WHO (Mbarara, Mbale, Arua, Gulu, Fort portal and Hoima)
- Prevalence of country priority diseases identified for IDSR.
- Availability of functional laboratories.

- Availability of laboratory personnel in the health units
- Regional balance
- Accessibility – the project cannot be well supervised in districts where there is insecurity due to insurgency or cattle rustling.
- Population
- Representation of well performing; moderate performing and poorly performing districts.



2. SUGGESTED DISTRICTS

Based on the above criteria, the following three districts have been suggested

DISTRICT	STRENGTHS	WEAKNESSES
NEBBI	• Frequently experiences epidemics (cholera, plague, dysentery) • No insecurity • All 3 HSD and number of HC III have functional labs • Has been referring specimens to CPHL	• Air traveling will be required

DISTRICT	STRENGTHS	WEAKNESSES
NEBBI	● A district lab focal person available ●Political and civic support ●Representing Northern Region ●NGO/Private units supported by districts	•Representing poorly performing district •Lab do not apply QC methods

DISTRICT	STRENGTHS	WEAKNESSES
KUMI	• Frequently reports high cases of epidemic potential diseases •No insecurity •All four HSD labs and a few HC III lab units are functional. ▪ Has an active district lab focal person ▪Population 388015	•Has no lab worker higher than a technician in the whole district. •No bacterial culture procedures performed in the whole district.

DISTRICT	STRENGTHS	WEAKNESSES
KUMI	• Easily accessible to Mbale Regional lab and Centre. •Has been preparing and sending regular lab reports •Representing well performing districts. •Representing Eastern Region.	

DISTRICT	STRENGTHS	WEAKNESSES
NTUNGAMO	• Frequently reports cases of epidemic potential diseases • All five HSD laboratories are functional • Has already appointed a district laboratory focal person • Easily accessible to regional lab in Mbarara and the centre	• Has not been referring specimens to Centre or Regional lab in spite of provision of supplies under IDSlite. • Has not been giving regular reports to regional lab or centre

DISTRICT	STRENGTHS	WEAKNESSES
NTUNGAMO	• No insecurity • It is one of the IDSlite districts •Representing medium performing districts. •Representing Western Region •Population 386816	•No bacterial culture facilities in the whole district

SELECTION OF H.U.

- Functional lab
- Easy accessibility
- Range of lab tests offered
- Willingness of staff to participate

TOTAL NUMBER SELECTED AND LEVELS

		Nebbi-	Kumi	Ntungamo
District Hospital	3	3	1	
Health Centre	IV	1	1	3
Health Centre	III-	5	2	1
Private Clinic		1	2	1
Total		10	8	6

MAJOR CONCERNS TO ADRESS

- Stool microscopy results show high prevalence of flagellates
- Serology gives high prevalence of typhoid and syphilis
- Malaria results tend to mismatch clinical picture
- Ltd support of the labs at HCIII by HC1V
- 1nadequate CPD
- Erratic provision of supplies
- No coherent system for maintenance and repair of lab equipment

SUSTAINABILITY

- Integrate lab QC scheme activities into over all district health activities
- Improve and continue to upgrade std of lab workers at all levels

APPENDIX - 16

ORGANISATIONAL & FINANCIAL ISSUES

EA-REQAS

CHARLES MUNAFU
Training Officer
AMREF Laboratory Programme

PACKING & TRANSPORTATION OF MATERIALS

- National regulations
- International regulations
- Facilitation of material transport

REGIONAL FORA

- EA-REQAS Meetings
- Other Regional Programmes:
  - IDSR
  - EANMAT
  - HIV/AIDS, STI
- Commonwealth Secretariat
- East African Community
- APECSA

EA-REQAS MEETINGS

- Are they needed?
- Purpose
- Frequency
- Site
- Coordination
- Participation

FINANCIAL

- Coordinating Centre Operations
- Support to laboratories preparing materials
- National activities:
  - sensitisation
  - reviewing written materials
  - distribution
  - remedial action
- Regional meetings

APPENDIX - 17

Way Forward - Discussion Points - Regional Issues

- **Advocacy at Regional Level**
  - Involve policy makers at higher levels
  - WHO, CRHCS-ECSA, EAC
- **Meetings**
  - National focal points
  - Organising laboratories
- **Finalisation of Documents**
  - SOPs - Uganda (Done & presented)
  - Clinical SOPs – Tanzania (Dr. Sam & Prof. Kaaya) – 3 months
  - Quality manual SOPs – Kenya (zero draft available)
  - Equipment specifications - AMREF
- **Networking of laboratories**
  - Create a website
- **Interim EA-REQAS committee**
  - Meet quarterly
  - In July 2003 – AMREF secure funds committee

Way Forward - Discussion Points (National Issues)

- **Set up of NEQAS**
  - Organisational & management infrastructure
  - Implementing mechanisms
  - Reporting & remedial mechanisms
    - By June 2003
- **Sensitisation**
  - Report to MOH
  - Workshops & meetings
    - By June 2003
- **Seek government commitment for:**
  - Funding
  - Support
  - Resource mobilisation
    - NAC to advocate to govt. for funds
- **Identify:**
  - Districts – by September 2003
  - Organising labs - before June 2003
  - Participating labs – b

GROUP DISCUSSIONS

GROUP DISCUSSION

APPENDIX - i

Review of tests and Techniques to be included in the scheme

By
Group 3 Members:
Jane, Moses, Silvano, Benjamin, James, Ali,
Gamalieli, Leonard, Gabriel, Mohammed, Sabas

Criteria for selection of Tests and Techniques

- Tests of clinical importance e.g B/slides for malaria and glucose for diabetes.
- Tests of Public Health importance e.g cholera.
- Tests and techniques performed at all health care facilities.
- Techniques of accepted accuracy.
- Tests for which materials can be preserved for transportation.

Criteria for selection of Pathology

- Common/important pathology or conditions.
- Methods of sample preparation and preservation available.
- Pathology for which international standards of measurement/recognition are available.

Criteria for selection of tests/techniques 1

- Haemoglobin: Haemoglobincyanide technique or conditions.
- Thick blood film: Both Field and Giemsa stains
- Peripheral blood film: Field and Leishman stains
- Stool Exam: Direct microscopy.
- Urine: Direct microscopy and dry chemistry for protein and glucose.
- Sputum Exam: ZN stain
- Pus exam: Gram stain
- CSF: Gram stain

Criteria for selection of tests/techniques 2

- Syphillis screening: VDRL/ RPR
- HIV Screening: ELISA, Rapid tests
- Blood glucose: Colorimetric technique

GROUP DISCUSSION

APPENDIX - ii

Roles and Responsibilities of a Coordinating Centre

By
Group 3 Members:
Jane, Moses, Silvano, Benjamin, James, Ali,
Gamalieli, Leonard, Gabriel, Mohammed, Sabas

Roles and Responsibilities - 3

- It should advise the National Central Lab on remedial/correct action.
- It should solicit for funds from various donors including governments for its activities like CME sessions, purchases and administrative functions, facilitate in exchange of expertise in various disciplines.
- Responsible for Monitoring and Evaluation of the program.

Roles and Responsibilities - 1

- Preparation of materials i.e preparation of some Quality controls materials.
- Validation of quality of materials prepared from all centers.
- Validation of the questionnaires, answer sheets and marking key.
- Receiving materials, packing and distribution

Roles and Responsibilities - 2

- Receiving, marking and analysis of results and compile these results to be disseminated to various levels e.g participating laboratories, Central laboratories MOH.
- Receiving, Preparation and submission of various educational materials with adaptation to local circumstances .
- The co-ordinating center should be accredited to other recognized National and International organizations

Roles and Responsibilities - 4

- To develop Regional standards of measurement.

Identification, naming of an appropriate Coordinating Centre

- Short term: AMREF
- Long term: National laboratories of the 3 countries on rotational basis.

Challenges

- Sustainability.
- Capacity in terms of human resource, finances, infrastructure.

GROUP DISCUSSION

APPENDIX - iii

SUBMISSION OF MATERIALS & REPORTS

By

Mr. Mugisha W, Mr. Mbeya, Dr. Sam E, Dr. Rajab J, Dr. Mandalya K, Mr. Mzee, Dr. Kigonya, Mr. Gachare J, Dr. Thani T, Mr. Koskey J.

- METHOD OF DELIVERY OF MATERIALS FROM PRODUCTION CENTRE TO COORDINATING CENTRE
  - CONSIDER COST EFFECTIVENESS
  - USE COURIER SYSTEM THAT IS REGIONAL
- COORDINATION CENTRE TO PERIPHERAL LABS
  - USE REGIONAL COURIER SERVICE
- RESULTS OF TESTS TO COORDINATING CENTRE
  - Use E-mail, Telephone (SMS), Fax, Postage
  - Copies to National Reference Centres or nearest Zonal (supervisory) Centre

- REPORTS FROM COORDINATING CENTRE (DETAILED REPORT)
  - Use : E-mail, Courier;
  - Copies to be sent to National Reference Centre and other relevant administrative bodies (for monitoring)
- ESTABLISH A CENTRAL STORAGE AND RETRIEVAL DATA BANK.

APPENDIX - iv

NATIONAL ISSUES - KENYA

SITES FOR PHASE ONE IMPLEMENTATION

1. CRITERIA FOR SELECTION OF SITES
- reasonably accessible
- Adequate superstructure in place
- Commitment of the authorities
- Involvement in other programmes will be an added advantage
- High burden of specific diseases
- Balanced regional representation

SITES FOR PHASE ONE IMPLEMENTATION

- LEVELS OF LABS TO BE INCLUDED
  - District, Sub-District & Health Centre level labs
  - These would include Public, Mission and Private labs.
- NO. OF FACILITIES
  - All labs in the selected Districts, about 20 per District.

SENSITIZATION

For who?
- 2 levels.
- Level 1: Central for Administrators, Programme Managers, Supervisors;
- Level 2: Participating facilities/Clinics as per guidelines

How?
- Workshops, meetings, seminars; and/or
- Relevant print materials

SENSITIZATION

By who?
- National Advisory Committee;
- The above committee to decide on how each group will be approached.

Roles and Activities of National QA Advisory Committee

- Membership/structure
  - Regulatory bodies, NPHLS, Professional associations, NGO/Private/Mission representatives
  - Research institutions/Universities
  - Standards Division of the MOH
- Structure
  - NPHLS: To chair the National QA Advisory Committee;
  - TECHNICAL ARM – already established
  - SUB COMMITTEES, REGULATORY ARM - to be formed.

APPENDIX - v

NATIONAL ISSUES: TANZANIA MAINLAND

By
E. Kaaya, Y. Ipuge, V.Y. Mgaya, G. Kisyombe, J. Mapalala, M. Kubali, A. Honest, S. Mrina, E. Anga & L. Mboera

1. Sites for Phase I implementation

Criteria for selection of sites

Region – to be selected as sites

- Presence of Coordinator Pathologist
- Framework for supervision and management
- Existing initiatives and linkages
- Capacity of the Zonal Centre
- Meets minimum requirements, according National Guidelines
- Registered private health labs
- Commitment of regional and/or local government authority
- IDSR*lite* districts, NTLP, HIV/STI

Levels of laboratories to be included

- B1 - Regional
- B2 - District
- C – Dispensary & Health Centre (Depending on proved performance)

Inclusion of Private Laboratories

- Registered private laboratories
- Those participating in NEQAS

Number of Laboratories

- Level B1- (Regional Laboratories in the Zone = 9)
  - Northern Zone: Tanga, Kilimanjaro, Arusha, Singida and Dodoma
  - Southern Zone: Mbeya, Iringa, Rukwa and Ruvuma
  - No private lab under B1category
- Level B2 = 15 laboratories
  - Public labs =10 labs (5 per zone)
  - Private labs = 5 labs
- Level C = 10 (5 from each zone)
  - Public - 6
  - Private 4
- Total 34 facilities to participate

2. SENSITISATION PROCESS

Who to be included in the sensitization process

- National leaders
- Regional and local government leaders (RHMT/CHMT)
- Laboratory managers at all level (in participating sites)
- Hospital Management Team (MO i/c, NO i/c)
- Clinicians

Format for the sensitization process

- One day advocacy meeting for National and Regional Leaders (AMREF, WHO, OTHER PARTNERS)
- Planning and Training workshop for the rest (National, Zonal & AMREF

3. ROLES AND ACTIVITIES OF THE NATIONAL ADVISORY BOARD

(With Sub-committee of Quality Assurance)

Members and structure (12)

- Head of diagnostic service, Ministry of Health
- Principal Health Laboratory Technologist (MoH)
- Quality assurance coordinator (MoH)
- Pathologists (2)
- Lab technologists (2)
- Clinicians (2)
- Hospital management team (MO i/c, NO)
- Registrar of Private Hospitals

Roles, cont…

- Coordination Centre – East Africa- REQAS
- Review of Tests/Questions/Education Material – by the National Sub-committee of Quality Assurance
- Frequency of review meetings – The Sub-committee will meet quarterly
- Links to bodies that conducts remedial actions - Through Council, Boards (Private Health Lab/ Health Facilities), and Professional Associations (MeLSAT & Association of Pathologists Tanzania)

Roles, cont…

- Remedial action
- Capacity building
- Accreditation of members
- Information dissemination

4. REMEDIAL ACTION

Types – Training (including on-job training, supervision)

- Legal actions –
- Provision of equipment and supplies and maintenance
- Validation of laboratory products and supplies

Bodies responsible for remedial action

- Diagnostic Section of the MoH
- Boards and Councils
- Professional Association and Health Programmes
- RHMT, CHMT and Hospital Management Team

Means of procuring equipment/supplies/equipment repair

- Follow government procurement systems (MSD etc)
- Guidelines for importation of products and supplies (Private Labs)

Supervisory tools

- -SOPs & Operational guidelines

APPENDIX - vi

National Issues: Uganda

By: S.A. Anguma
Uganda Group (12 members)

Sites for Phase one Implementation

- Selection adapted as was presented by Mr. G. Guma.
- In addition, objective scoring system of the selection criteria items has been added.

Sensitization process for participants and supervisors 1

- We have already started this process: Visitation to districts has already been done : A pre-visit to DDHS and later DHT, Health unit in-charges, laboratory staff, clinicians, political, administrative and civic leaders.

How the sensitization was done

- Meetings
- Workshops/seminars
- Circulation of manuals

Sensitization process for participants and supervisors 2

What the format should be:

- Definition
- Purpose
- Procedure
- Expected outcome

By Whom

- MoH, CPHL, Regional labs, National Coordinating Committee, Reference labs, AMREF.

Roles and activities of the National Advisory body: NHLACC 1

Membership and structure:

- National Health Laboratory Advisory and Coordinating Committee (NHLACC).

Membership of the NHLACC

- DG
- DHS in charge of community health and clinical services
- Representation from National Disease Control, Clinical services, Epidemiological Surveillance Division, CPHL, National reference hospital, Regional labs, District labs, University medical schools, Private sector, Development partners, Religious medical bureaux

Roles and activities of the National Advisory body: NHLACC 2

Process for formulation and review of tests/Questions/materials, reports from coordinating centre

- Identify experts, sites, materials, pathology disciplines and tests.
- Design procedures (SOPs)
- Pilot studies.
- Monitoring and Evaluation of the process.
- Modify according to funding.
- Restart the cycle.

Remedial action

Types of remedial action

- SOPS for test procedures
- Selection and standardizing equipment
- Equipment maintenance and repair
- Provision of supplies and reagents
- Training and workshops against specific problem

Remedial action

Bodies responsible for remedial action

- Professional associations and councils
- MOH
- District health services

Means for procuring equipment/supplies

- Central and local governments
- Development partners

Remedial action

Identification of other requirements

- As per findings of technical support supervisors, QA teams and District Laboratory Focal Persons.