FIRST MEETING

OF

THE EAST AFRICAN REGIONAL QUALITY

ASSURANCE COMMITTEE (EA-RQAC)

Mazsons Hotel, Stone Town,
ZANZIBAR, TANZANIA
26th – 27th APRIL 2006

AMREF 15th May 2006

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ACRONYMS

AFB	Acid Fast Bacilli
AMREF	African Medical and Research Foundation
AKLMSO	Association of Kenya Medical Laboratory Scientific Officers
AKH	Aga Khan Hospital
BMC	Bugando Medical Centre
CDC	Centres for Disease Control and Prevention
CPHL	Central Public Health Laboratory
CPL	Central Pathology Laboratory
EA-REQAS	East African Regional External Quality Assessment Scheme
EA-RQAC	East African Regional Quality Assurance Committee
HIV	Human Immunodeficiency Virus
IDSR	Integrated Disease Surveillance and Response
IATA	International Air Transport Association
KEMRI	Kenya Medical Research Institute
KCMC	Kilimanjaro Christian Medical Centre
LIRI	Livestock Research Institute (Tororo - Uganda)
MOHSW	Ministry of Health and Social Welfare (Mainland and Zanzibar)
MOH	Ministry of Health
MOU	Memorandum of Understanding
MUCHS	Muhimbili University College of Health Sciences
NEQAS	National External Quality Assessment Scheme
NPHLS	National Public Health Laboratory
PHL	Public Health Laboratory
Pf	*Plasmodium falciparum*
Pm	*Plasmodium malarie*
Pv	*Plasmodium vivax*
QA	Quality Assurance
RCC	Regional Coordinating Centre
SOPs	Standard Operating Procedures
TB	Tuberculosis
Tz	Tanzania
TOR	Terms of Reference
WBC	White Blood Cell

BACKGROUND

The first Regional Technical Meeting of the East African Regional Quality External Quality Assessment Scheme (EA-REQAS) was held in Arusha, Tanzania, on 3 - 4 April 2003. At the meeting, participants shared country experiences of National Quality Assessment Schemes (NEQAS) and discussed the operation of a regional scheme and how participation in an EA-REQAS could contribute to strengthening the national schemes.

At the close of the meeting, suggestions and recommendations were made for establishing the EA-REQAS. The Resolutions and Recommendations are given in *Appendix*, page 18. Most of these recommendations have now been carried out including finalizing the Standard Operating Procedures (SOPs) for Essential Laboratory Tests; Laboratory Utilisation for Clinicians: Care and Maintenance of Laboratory Equipment; and the Quality Manual. The other major recommendation was the formation of an East African Regional Quality Assurance Committee (EA-RQAC) tasked with monitoring the operations of the scheme and all related activities.

The first meeting of the East African Regional Quality Assurance Committee (EA-RQAC) took place 3 years after the Arusha meeting following resumption of funding for the project. See invitation letter in *Appendix 2*, page 19.

MEETING PROCEEDINGS

Day 1: 26th April, 2006

- The meeting started at 8:30am. David Ocheng gave welcome remarks and outlined administrative issues and the proposed agenda for the meeting. *See Timetable – Appendix3*, page 20.
- Self introduction of the participants. *See list of Participants Appendix 4*, page 21.
- The Head of Diagnostics Services of the Ministry of Health and Social Welfare (MOHSW), Zanzibar, Mrs. Mwanapenda Mzee, welcomed the participants to Zanzibar.

Election of Chairperson

The participants agreed that the chairperson must be a committee member of the EA-RQAC and the host country takes the chair. The chair would therefore be rotational depending on the location of the meeting. Mrs. Mwanapenda Mzee was elected as the chairperson.

Ms Mwanapenda Mzee (current chairperson) welcoming participants to Zanzibar

Secretariat
AMREF will continue running the Secretariat services.

Terms of Reference (TOR) of the EA-RQAC
Some adjustments were made to the draft document and the Committee included Vision and Mission Statements. *See Document 1*, page 11.

Presentation on current NEQAS
Country committee members gave presentations on the current status of National Quality Assessment Schemes (NEQAS), the composition and activities of the National Quality Assurance Advisory Bodies, and proposed reference laboratories for material production for the EA-REQAS. Committee members also discussed constraints, work plans and the way forward. *See Appendixes 7 to 13*, starting from page 29 to page 48.

SOPs for Preparation of Quality Control Materials
Participants agreed that each country should review the draft SOPs with the hands on users and submit the comments to the Regional Coordinating Centre (RCC) through the AMREF Country Offices by 26th May 2006. The RCC must disseminate the document to the member countries for review and comments. Ethical and packaging issues must be included in the SOPs.

Ethics of sample collection
Each country must obtain clearance to run the scheme from their respective national Ethical Committees. In addition, a consent form is required for patients or individuals providing samples to the Scheme.
Action: Dr Rajab to draft the Consent Form. *See document 3*, page 15.

Transport of infectious material
1. This must follow International Air Transport Association (IATA) regulations
2. Uganda has a body for authorizing transportation of biological materials across borders.
3. The Integrated Disease Surveillance and Response (IDSR) initiative has protocols that can be used by the scheme.
4. Each country to look at packaging and transportation of biological materials within and across the borders.

Action:
1. Mr Onono: to find out from the health desk of East African Community about issues related to transportation of biological materials.
2. Mr Mgaya to avail generic documents for transportation of biological materials and write SOPs on packaging materials for Tanzania, Mr Guma for Uganda and Mr Materu for Kenya.

Selection of Reference Laboratories
- Selected reference laboratories will be assessed using a structured questionnaire.
- The assessment should assist each reference laboratory to upgrade its laboratory standards.
- Sites will be scored during the assessment and gaps identified for strengthening.
- Peripheral laboratories located in areas that facilitate collection of specific samples will be used to provide materials to the reference laboratory.
- No laboratory has adequate staff at any given time; however the capacity of the laboratory to perform these added tasks must be considered.

- The proposed reference laboratories in each country are as follows:

Country	Selected laboratory	Materials
Zanzibar	Pemba Public Health Laboratory	Helminths and *Schistosoma haematobium* ova.
	Mnazi Mmoja National Laboratory	*Wuchereria bancrofti* microfilaria blood films.
Tanzania Mainland	National Reference Laboratory/CPL and MUCHS	- Most of the selected materials - Blood slides for malaria parasites - Syphilis serology
	Southern Highlands Zone Mbeya Referral Laboratory	Blood slides for trypanosomes and *Borrelia*
Kenya	NPHLS, University of Nairobi AMREF	-HIV serology, smears for Gram stain -Peripheral blood films -Preserved lysate -Haemiglobinocyanide standard solution
Uganda	TB Central Laboratory; Wandegeya, Kampala	Sputum smears for AFB
	Livestock Research Institute (LIRI), Tororo	Blood films for trypanosomes

Day 2: 27th April 2006

- The session began at 8:30am with a recap of Day 1 activities
- The Memorandum of Understanding (MOU) between the Reference Laboratories and AMREF was discussed. The Ministries of Health were included as signatories in their respective countries, and their responsibilities were outlined.
- Art 2 was reviewed: Tanzania stands for Mainland and Zanzibar.
- Proper titles were given to each Article.
- Changes were made in the content of the MOU. The following issues were included: -
  - Art 4.1: Disclosure, Inventorship and Ownership
  - Art 4.2: Management
  - Art 4.3: Reservation of rights
  - Art 4.4: Publications
  - Art 4.5: Data
  - Art 6: Validity of the MOU – 2 years

  See document 2 for the final MOU

Selection of Districts

The Ministries of Health have the mandate to select the participating laboratories.
The participants agreed that the initial phase will include a total of 200 laboratories participating in the EA-REQAS.
The distribution of participating laboratories per country is as follows:-

- *Kenya* *60 laboratories*
- *Uganda* *60 laboratories*
- *Tanzania* *60 laboratories*
- Zanzibar *20 laboratories*

Action:
The countries that have not submitted to the EA-RQAC a list of pilot districts to participate in the EA-REQAS should do so within two weeks (by 17th May 2006).

Plans for Material Production
It was agreed that two distributions shall be done per year initially. The distributions for the first 2 years of the scheme will be as follows:-

Year 1:
1st distribution:
- Haemoglobin
- HIV serology
- Blood films for malaria parasites (thick & thin)
- AFB
- Gram stain

2nd distribution:
- Haemoglobin
- HIV serology
- Blood film for Trypanosome
- Stool for parasites
- Thin film for WBC differential count, cell morphology and comments

Year 2:
3rd distribution:
- Haemoglobin
- HIV serology
- Blood film for Borrelia
- Syphilis serology
- Worst performed in previous distributions

4th distribution:
- Haemoglobin
- HIV serology
- Blood films for Microfilaria
- Two worst performed in the previous distributions

Materials to be produced in each country and Reference Laboratories to be visited

Tanzania:
- *Mainland*
  - Borrelia – Mbeya Referral Laboratory
  - Blood slide for malaria parasites – Central Pathology Laboratory - Dar
  - Syphilis serology – Central Pathology Laboratory - Dar
- *Zanzibar*
  - Microfilaria – Mnazi Mmoja
  - Stool – Pemba Public Health Laboratory

Kenya:
- HIV serology - National Public Health Laboratory Services
- Smear for Gram Stain – National Public Health Laboratory Services
- Peripheral blood film – University of Nairobi, Department of Haematology

Uganda:

- Trypanosomes – Livestock Research Institute (LIRI), Tororo
- Sputum smears – Central TB Laboratory, Wandegeya, Kampala

AMREF Laboratory

- Haemoglobin
- Standard Hb lysate

Review of Facility Assessment questionnaire

- The title was changed to read as follows: - "Participating Health Facility Assessment Form"
- Participants agreed to review the form and send comments to the RCC within two weeks (17th May 2006).

Sensitisation workshops

- *Objectives*
  Meeting objectives were reviewed with some changes. An objective was added for the district supervisors on orientation on use of the participating facility assessment form.
- There shall be:-
  - One (1) workshop in each country for district clinical and laboratory supervisors.
  - Two (2) to three (3) workshops for clinical and laboratory staff from participating health facilities, a total of 120-160 participants per country.

Workshop content

The following were included:

- Planning and budgeting for laboratory services in both workshops
- Administrative issues for the participating health facilities
- Demonstration of the REQAS kit for participants

See *Appendixes 5 & 6* (page 23-28) for the Objectives, Content and Timetables for the Sensitisation Workshops for district supervisors & participants.

Review of Scheme Logistics and Reporting

- Prepared materials from the reference laboratories will be sent to the AMREF Country Offices for transportation to AMREF Nairobi for assessment.
- Materials will be repackaged and sent back to the AMREF Country Offices for distribution to the participating health facilities.
  - Uganda: AMREF will deliver the materials to the district for distribution by the District Laboratory Focal Person to the participating health facilities.
  - Tanzania: AMREF will deliver materials to the participating health facilities
  - Kenya: AMREF will arrange delivery of materials to the participating health facilities.
- Modalities of transportation of materials to and results from health facilities will be discussed with supervisors and participants during the sensitisation workshops.
- Regional Coordinating Centre (RCC) will put in place a material tracking mechanism
- Results will be reported within two weeks of receipt of the materials.
- Result sheet copies will be kept by the following: - health facility, district, AMREF Country Office and the RCC.
- The participating health facilities will receive their results plus coded results for other participating health facilities within the districts/regions.
- Ministry of Health, AMREF and Reference Laboratories will get decoded results for all participating health facilities.

EA-RQAC Meeting: Way Forward, Timeline and Responsible persons

1. Debriefing of MOH (due date: May 2nd 2006) (All)
2. Final Report of Proceedings (due date: 2 weeks) (All)
3. Review of Health Facility Assessment Form within 2 weeks (All)
4. Review of SOPs (due date: 26th May 2006) (All)
5. Consent Form prepared within two (2) weeks (12th May 2006, Dr. Rajab)
6. Visits to Reference Laboratories (due date: Mid June – mid July 2006) (AMREF)
7. Identification of participating laboratories (due date: 2 weeks from now) (All)
8. Review transportation/shipment of biohazard material within countries and across country borders (due date: 17th May 2006) (All)
9. Review of MOU with country legal support (due date: 1 month) (All)
10. Letters to the Reference Laboratories (due date: 26th May 2006) (MOH)
11. Signing of MOU (due date: Mid June – mid July 2006) (AMREF)
    a. PS level for signatory
12. Workshops start (due date: August – October 2006) (All)
13. Next EA-REQAC meeting (due date: end of October 2006), venue: Entebbe, Uganda
14. AMREF to establish the electronic database for the scheme

AOB

1. Objectives that appear in the MOU should be reflected in the REQAS Concept Paper. The Concept Paper is not part of the MOU but is available on request
2. Next agenda to include site visits/social evenings

Participants discussing at the meeting

First EA-RQAC meeting

Mr Guma giving a presentation on current status of NEQAS in Uganda

Documents start from page 11
&
Appendices start from page 18

DOCUMENTS

Note: Documents 4 and 5 (Participating Laboratory Assessment Form for Reference Laboratories & SOPs for Materials production to stand on their own)

Document 1:
Terms of reference (TOR) of EA-RQAC
Some adjustments were made in the document and the committee included Vision and Mission the TOR. See Document 1:

1. Vision

Improved health care delivery within the East African region

2. Mission

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

3. Purpose of the East African Regional External Quality Assessment Scheme (EA-REQAS)

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

4. Terms of Reference of the East African Regional Quality Assurance Committee (EA-RQAC)

4.1 To support the development and operation of the EA-REQAS including:
4.2 Selection of tests and techniques addressed by the scheme
4.3 Selection and monitoring of operations of the reference laboratories for quality material production
4.4 Selection and monitoring of the performance of the Regional Coordinating Centre (RCC)
4.5 Monitor scheme activities through quarterly reports from the RCC including number of facilities reached, questions prepared and laboratory performance.
4.6 Review of impact of scheme activities through review of reports from national administrations/regions/districts.
4.7 Create ideas for innovative methodologies and approaches in order to establish best practices for the operation of the EA-REQAS.
4.8 Promote operational and scientific research within the activities of the EA-REQAS.
4.9 Ensure documentation and dissemination of experiences and best practices, including preparation of technical papers and presentations.
4.10 Ensure regular communication between members of the EA-RQAC in partner countries.
4.11 Enhance relationships with the Ministries of Health, World Health Organization, East African Community, other international and regional organisations, development and technical partners to promote awareness and ensure sustainability.
4.12 Establish linkages with international laboratory REQAS.
4.13 Develop plans for expansion of the EA-REQAS within the three East African countries and to other countries, as appropriate.
4.14 Hold meetings at least twice a year to review progress and future plans.

5. Composition of the EA-RQAC reporting to MOH:

Nominating authority is the Ministries of Health and should select two members. The criteria of selection to include the following:-

- Dedicated and actively involved in QA activities
- One member should be a member of the Association of Pathologists and the other a member of the Association of Medical Laboratory Technologists.

5.1 Kenya: Dr. Jamila Rajab, Mr. Laban Onono
5.2 Tanzania: Prof. Ephata Kaaya, Mr. Michael Mwasekaga
5.3 Zanzibar: Mr. Mzee Rajab Khatib, Mrs. Mwanapenda Yahya Mzee

5.4 Uganda: Dr. Y. Mpairwe, Mr. Gaspard Guma
5.5 AMREF: Dr. Jane Carter, Mr. David Ocheng, Mr. Charles Munafu, Mr. Sadiki Materu
Other members co-opted as required:
Mr. Alex Msauka
Mr. Julius Tome
Mr. Sagamo Mattaro
Dr. Rose Mukisa

Document 2:

MEMORANDUM OF UNDERSTANDING BETWEEN
THE MINISTRY OF HEALTH, AFRICAN MEDICAL AND RESEARCH FOUNDATION (AMREF) AND THE REFERENCE LABORATORIES FOR QUALITY MATERIAL PRODUCTION UNDER EA-REQAS PROJECT

The Ministry of Health of PO. Box …….. represented in this MOU by: …….., AMREF of PO Box ……..represented in this MOU by ……and The Reference Laboratory ……..of PO Box …….represented in this MOU by …….. being its legal representative, wishing to carry out together a project to produce quality materials for the East African Regional External Quality Assessment Scheme (EA-REQAS) have agreed to sign the following Memorandum of Understanding.

Art.1: Commitment

1.1 All parties are committed to respect the objectives contained in the project: *"Coordinating an East African Regional External Quality Assessment Scheme for Peripheral Laboratories"* which is appended in Annex 1.

1.2 All commit themselves to the mutual respect of their respective status and philosophy

Art.2: Goal

Goal

The overall goal of the project is to improve the quality of health care services delivery at peripheral level in the countries of East Africa (Kenya, Tanzania and Uganda). AMREF in conjunction with the Ministries of Health of Kenya, Tanzania (Mainland and Zanzibar) and Uganda proposes to address a scheme for establishing standards of laboratory operation and sharing resources and experiences across the three East African countries (Tanzania, Kenya and Uganda) with the aim of improving the quality of medical laboratory services.

Objectives

The objectives of the project are:

a. Establish a EA-RQAC and Regional Coordinating Centre (RCC) to undertake all the activities for the regional operation of the EA-REQAS.
b. Select and provide essential support to reference laboratories in the region to ensure the capability to prepared standardized preserved pathological materials for utilizations in the EA-REQAS.
c. Establish procedures for quality monitoring of prepared materials at the AMREF Laboratories in Kenya, Tanzania and Uganda, and in partnership with other reference laboratories in the region or overseas.
d. Produce questionnaires and educational documents on a regular basis, in conjunction with the East African Regional Quality Assurance Committee (EA-RQAC).
e. Distribute quality materials regularly to the participating laboratories
f. Provide timely reports, comments and recommended remedial measures to the participating laboratories and the Ministries of Health.

g. Provide educational materials for distribution to the participating laboratories.
h. Establish a central data base at RCC with capacity to analyse, store reports and data.
i. Hold regular meetings of the EA-RQAC to review the regional and national scheme activities.

Art.3: Responsibilities.

AMREF will be responsible for:

a. Supplementing essential supplies and materials in sufficient quantity to the reference laboratory for the production of the agreed materials.
b. Providing selected items of equipment that may be required to supplement those already existing at the reference laboratory in order to undertake the production of required materials.
c. Undertaking repairs to essential laboratory equipment in collaboration with respective institutions.
d. Providing Standard Operating Procedures (SOPs) to the reference laboratory for the production, packing and transport of the required pathological materials.
e. Reviewing pathological materials production with the reference laboratory to ensure the procedures are well understood.
f. Providing information to the reference laboratory on the number of samples required, and the expected completion date(s).
g. Appointing its own contact person in each country for all communications relating to the EA-REQAS project.
h. Maintaining good communication with The Reference Laboratory appointed focal QA person in matters related to the EA-REQAS project

The reference laboratory will be responsible for:

a. Producing the agreed number of samples of the agreed type to a high standard of quality according to the Standard Operating Procedures provided **(in a separate document).**
b. Transporting the samples to the AMREF contact person or other agreed institution according to the laid down instructions and agreed time frame.
c. Keeping accurate records of materials and reagents utilized, and informing the MOH and AMREF contact person when supplies need to be replaced.
d. Appointing a contact QA focal person for all communications relating to the EA-REQAS project.
e. Maintaining good communication with the MOH and AMREF contact person

The MOH will be responsible for:

a. Provide essential equipment and supplies to support the EA-REQAS
b. Monitoring and evaluate the quality of diagnostic supplies
c. Deploy adequate qualified laboratory personnel for efficient operation of the EA-REQAS
d. To liaise with AMREF and the reference laboratory in matters related to laboratory quality systems
e. Supervise, monitor and make follow up on the recommended remedial measures in the reference laboratory
f. Ensure an efficient system for Planned Preventive Maintenance (PPM) for equipment
g. Provide a budget to sustain the EA-REQAS activities
h. Ensure participation in the EA-REQAS committee meetings
i. Ensure availability of focal person responsible for laboratory EA-REQAS activities
j. Advocate to the public and other stakeholders support

Art. 4. Intellectual property

4.1 **Disclosure, Inventorship and Ownership:**
The reference laboratories, Ministries of Health and AMREF shall promptly disclose to each other, in the form of a written, confidential invention disclosure, any potentially patentable discoveries or inventions conceived and reduced to practice during and related to the Project. Inventorship shall be determined according to the patent laws of the country in which a patent application is filed. Ownership will follow

Inventorship. Each party shall own its undivided interest in joint inventions; each party shall solely own its sole inventions.

4.2 **Management:**
If The Reference Laboratories, Ministries of Health and AMREF are determined (according to the patent laws of the country in which a patent application is filed) to be joint inventors on a patent application, the parties will then discuss securing intellectual property rights to protect potentially patentable inventions, and determine how expenses and revenue will be shared for the joint invention, and which party will take the lead in patenting and commercializing the joint invention. The parties may choose to memorialize such an arrangement in a written inter-institutional agreement at that time. The lead party will keep the other party informed and involved in decision-making regarding the patenting and commercialization activities of the joint invention. Sole inventions shall be solely managed by the sole owner, with no obligation to share information or revenue.

4.3 **Reservation of Rights:**
The Reference Laboratories, Ministries of Health and AMREF shall reserve the right to use joint inventions (conceived and reduced to practice under the Project by both The Reference Laboratories, Ministries of Health and AMREF inventors) for educational and research purposes, both within the Project and in institutional activities not related to the Project. The royalties so accrued to Ministries of Health, shall be used for improvement of quality systems in the medical laboratory services.

4.4 **Publications:**
Any publications made in the course of execution of this project shall first be reviewed by all parties and EA-REQAC before they are published. EA-REQAC shall develop guidelines to determine authorship.

4.5 **Data:**
All data generated in the course of execution of the project shall be co-owned by the Ministries of Health, AMREF and the EA-REQAC. The EA-REQAS shall be responsible for developing guidelines on accessing the data by other parties. Reference laboratory SHALL NOT disclose the type and expected results to any person(s) outside the EA-REQAS committee members

Art.5. Resolution of dispute

All parties agree that, in the event of any controversy between the MOH, AMREF and The Reference Laboratory, they will accept the mediation of a commission composed of one representative of each party.. All parties will choose a fourth one. Any legal disputes will be resolved according to the laws of the country.

Art.6. Duration

This MOU shall be valid from the date it has been signed by all parties, and shall last for duration of two (2) years subject to renewal.

Art.7. Termination

Each party can terminate this MOU in case of very serious reasons provided a notice of three months is given to the other parties and the mediation process has been employed.

MINISTRY OF HEALTH	**AMREF COUNTRY DIRECTOR**	**HEAD, REFERENCE LABORATORY**
Name: …… Signature: ……..… Date: ……..……..…	Name: …… Signature: ……..…… Date: ……..……	Name: …… Signature: ……..…… Date: ……...……

Document 3:

CONSENT/CLIENT EXPLANATION

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

1. Name of Reference Laboratory……

2. Country ……

3. Consent/client explanation conducted by (Interviewer) ……..

   …….

4. Date of interview …….. _____/_____/_____
   dd mm yy

5. What is your age at last birthday _____/_____/_____ (For patients/clients)
   dd mm yy

   Below 18 years consent from parents or legal appointed guardian must be sought)

6. (To the interviewer) In your assessment, is the patient/client mentally competent

   to give informed consent? Yes [__] No [__]

   If yes, then proceed to the client explanation detailed below:

Q. Why is the scheme/project being undertaken?

A. The scheme is being undertaken to help establish standards of laboratory services with the aim of improving the quality of medical laboratory services. This in turn will help improve the quality of health care services delivered to patients and clients. This scheme is conducted by Ministry of Health appointed staff.

Q. Who will participate?

A. Selected patients and clients whose samples have been preliminarily identified to have certain characteristics that are important for laboratory technicians to be able to recognise. The samples may even be normal. The samples may be blood, stool, urine, pus swabs, sputum or others.

Q. How many people will participate?

A. This is hoped to be an on-going scheme and a large number of people will continuously be identified and requested to give samples for the scheme. So, ultimately many people are likely to participate.

Q. What is involved in the study?

A. If you agree to participate, you will be required to avail a blood, urine, stool, pus swab or sputum sample or any other specimen to the laboratory. The specimens will be processed by a reference laboratory appointed by the Ministry of Health. A number of samples will be prepared from the specimen for distribution as quality control materials nationally and in the East African region to participating laboratories for analysis. There will be no name or personal identification attached to the samples. The participating laboratories will be assessed by the way they analyze and interpret these materials. This will help identify areas that need to be improved in these laboratories.

Q. What are the risks of the study?

A. The laboratory team will do everything to minimize the risks to you as a participant. Some of the samples that will be taken such as blood tests may have some discomfort such as soreness at the site of injection to draw blood. The results may cause some anxiety to you but everything will be explained to you before any test is done and what it means to you and your health.

The collection of these samples will in no way interfere with the subsequent management of your health condition.

Q. What are the benefits of taking part in this study?

A. The benefits to you include a thorough examination of the samples collected from you and all findings will be communicated to your attending physician and will/may contribute to the management of your current health condition. You may not directly benefit from the results of this study, but the samples obtained will help improve the standards of laboratory services in the country and the region and consequently the quality of health care delivered to you and others.

Q. What are my rights as a participant in this study?

A. All information obtained about you will be kept confidential and locked up in a cupboard to which only the laboratory staff will have access. Any information published about this study will not bear your name, and your identity will be protected at all times.

Should you decide to participate in this scheme, participation is entirely voluntary and you will not be penalised for not participating. You may also withdraw from the scheme at any time without losing the health benefits to which you are otherwise entitled.

Q. Whom do I contact if I have any concerns, questions or problems?

A. This scheme has been approved by the Ministry of Health, the Ethics and Research Committee of the relevant body hospital or country.

You may contact:

1. The Head of National Public Health Laboratories (or relevant body)

Mr./Dr……

Ministry of Health
P.O. Box ……..
……..
……..
Tel:…….

2. Mr./Dr……
Ethics and Research Committee
P.O. Box …….
…….
Tel:……..

3. The Country Headquarters
The East African Regional External Quality Assessment Scheme (EA-REQAS)
African Medical and Research Foundation
P. O. Box ……..
……...
Tel:……

4. Mr./Mrs…….
i/c
EA-REQAS, Reference Laboratory
P. O. Box……..
……..
Tel:……

Name of the patient/Client..……

Identification/PPT number……

Registration number…….Telephone number……..

Signature……

Name of the witness/Guardian…….

Signature of the witness…….. Date ……

Appendix -1

FIRST REGIONAL TECHNICAL MEETING OF THE EAST AFRICAN REGIONAL QUALITY ASSESSMENT SCHEME (EA-REQAS) FOR HEALTH LABORATORIES, 3RD – 4TH APRIL, 2003.

RESOLUTIONS

1. In order to realise the EA-REQAS for Health Laboratories, each country will strive to set up a National External Quality Assessment Scheme (NEQAS).
2. 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.
3. 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.
4. AMREF together with one member representing the Ministries of Health of the Region will act as the Interim Secretariat of the EA-RQAC.
5. An East African Regional Quality Assurance Coordinating Centre (RCC) for Health Laboratories will be established. AMREF was appointed to act as the Regional Coordinating Centre in the short term.

RECOMMENDATIONS

1. 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.
2. 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) Secretariat. 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.
3. 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.

Appendix -2

INVITATION LETTER

RE: First Meeting of the East African Regional Quality Assurance Committee (EA-RQAC): 26 – 27 April 2006, Mazson's Hotel, Zanzibar

Dear

AMREF Tanzania has pleasure in inviting you to participate in a two day meeting of the East African Regional Quality Assurance Committee to be held in Zanzibar from 26 – 27 April 2006.

At the Regional External Quality Assessment Meeting held in Arusha in May 2003, it was agreed that each of the four Ministries of Health would nominate two members to the EA-RQAC (one pathologist and one laboratory scientist) to represent the country in taking the activities of the regional quality assurance programme forward. Since that time, various developments have been taking place, including finalisation of the four documents (Standard Operating Procedures and Quality Manual) required for the participants of the scheme. We are pleased to report that these documents are currently at the World Health Organization Headquarters in Geneva where they will be published shortly.

We have now confirmed funding to finalise the other preparations for the scheme and to start its implementation this year. As a nominated member of the EA-RQAC, we request your participation in making this a reality. Please find attached the proposed agenda for the meeting and Terms of Reference to be discussed. All the other documents required for the meeting are being finalised and will be presented to you at least two weeks before the meeting. We request you please to bring with you the following documents and information for sharing with the committee members: Terms of Reference of your national Quality Assurance Committee; selected districts for the pilot project; suggested reference laboratories and materials they could produce.

All expenses relating to your travel, accommodation and meals in Zanzibar will be met by AMREF. We will inform you of the selected venue in due course. For participants from Kenya and Uganda, please organise your air travel with the respective AMREF Country offices. All other claims for transport can be made on production of receipts. We plan to provide half-board accommodation to all participants with a separate daily out of pocket allowance to include dinner.

We look forward to your earliest confirmation, and to a successful meeting.

Yours sincerely

Dr Paul Waibale
Country Director
AMREF Tanzania

Cc
- Dr D K W Lwamafa, Commissioner of Health Services, National Disease Control, Ministry of Health, Uganda
- Dr Jack Nyamongo, Head, Division of Laboratory Services, Ministry of Health, Kenya
- Dr Faustine Ndugulile, Head, Diagnostics Unit, Ministry of Health and Social Welfare, Tanzania
- Mrs. Mwanapenda Yahya Mzee, Head, Diagnostics Unit, Ministry of Health and Social Welfare, Zanzibar
- Dr. T.F. Thani, Director of Curative Services, Ministry of Health, Zanzibar
- Dr Harry Jeene, Head of Programmes, AMREF Headquarters
- Ms Mette Kjaer, Country Director, AMREF Kenya
- Mr Joshua Kyallo, Country Director, AMREF Uganda

Appendix-3

EA-RQAC MEETING, APRIL 26TH – 27TH 2006, MARZONS, HOTEL, STONE TOWN, UNGUJA
PROPOSED TIMETABLE

Date	Tuesday 25th April	Wednesday 26th April	Thursday 27th April	Friday 28th April
0830 – 10.30		Welcome Introductions Election of Chairman Review TORs of EA-RQAC Current status of each national QA Scheme Progress of the EA-REQAS	<u>Project sites & scheme organisation</u> Select/confirm project sites Review facility assessment questionnaire	Departure home
10.30 – 11.00		TEA	TEA	
11.00 – 13.00		<u>Quality Material Production</u> Review materials & SOPs for material production Ethics of sample collection Transport of infectious materials	<u>Project sites & scheme organisation (cont)</u> Review workshop agenda/timetable for sensitisation of regional supervisors Review workshop agenda/timetable for sensitisation of participants	
13.00 – 14.00		LUNCH	LUNCH	
14.00 – 15.30		<u>Quality Material Production (cont)</u> Select reference laboratories Review essential requirements & facility questionnaire Review MOU with reference laboratories Plan country visits to reference laboratories	<u>Project sites & scheme organisation (cont)</u> Review methods of remedial action Review scheme logistics & reporting	
15.30 – 16.00		TEA	TEA	
16.00 – 17.00	Arrival in Zanzibar	Plan material production for the next 2 years	Way Forward & Timeline AOB	

Appendix-4

NAME OF PARTICIPANTS, TITLE, ORGANISATION AND CONTACTS

S/No.	NAME	TITLE	ORGANIZATION	CONTACT	E-MAIL
1.	Vincent Y. Mgaya	Principal Health Laboratory Technologist	MOHSW, Tanzania Mainland	Box 9083, Dar es Salaam Tel: +255 22 2120261-7 +255 744 855600 Fax: 22 2125277	vmgaya@yahoo.com
2.	Prof. Ephata E. Kaaya	Head, Department of Pathology	Muhimbili University College of Health Services	Box 65023 DSM Tel: +255 22 2151117 +255 748 271831 Fax: 255 022 2151350	ekaaya@muchs.ac.tz
3.	Charles Kagoma	National Program Officer – HIV/AIDS	NACP/WHO, Tanzania	Box 9292 DSM Tel: +255 22 2111718 +255 745 788578 Fax: 22 2113180	Kagomac@tz.afro.who.int
4.	Mwanapenda Y. Mzee	HDS	MOHSW, Zanzibar	Box 236 ZNZ, Tel: +255 24 2234720 +255 748 332919 Fax: 0242234720	Mamapenda22@yahoo.co.uk
5.	Shaali M. Ame	Laboratory Scientist	Public Health Laboratory, Pemba	Box 122, ChakeChake, Pemba Tel: 255 24 2452003 +255 777 432094 Fax: +255 24 2452003	info@phlidc.net Shaaliame@yahoo.com
6.	Dr. Jamilla A. Rajab	Pathologist/ Haematologist	University of Nairobi School of Medicine	Box 19304 00202 Nairobi, Tel: +254 2721815, 2726507 +254 722 707421 Fax 2726507	naimjamilla@yahoo.com
7.	Laban Onono	Secretary General	Association of Kenya Medical Laboratory Scientific Offices	Box 55233 Nairobi Tel. 2723162 +254722 709645/0720427971	akmlso@yahoo.com ononolb@yahoo.com
8.	Gaspard Guma	Chief Medical Laboratory Technologist	MOH, Uganda	Box 7272 Kampala Tel: +256772655154 Fax: 254 41 345108	gumagaspard@yahoo.co.uk
9.	Dr. Yusufu Mpairwe	Dr.	NAMELA	Box 4295, Kampala Tel; 256 41 222715 +256 772923989 Fax:256 41 222715	namelaug@yahoo.co.uk

10.	Dr. Jane Y. Carter	Head Clinical Programme	AMREF	Box 30125 Nairobi Tel: 602493 Fax: Nairobi 602191	jcarter@iconnect.co.ke
11.	Dr. Rose Mukisa - Bisoborwa	Project Officer	AMREF	Box 10663, Kampala Tel: +256 41 344579 Tel: +256 772 405736 Fax: +256 41 344565	rosem@amrefug.org
12.	Sadiki Materu	Chief Medical Laboratory Technologist	AMREF	Box 30125, Nairobi Tel: 6994619 +254 722 752975 Fax: +254 602191	sadikim@amrefke.org
13.	David Ocheng	Project Manager	AMREF	Box 2773, Dar es Salaam Tel: +255 22 2116610 +255 748 274355 Fax: +255 22 2115823	DavidO@amreftz.org
14.	Sagamo Mattaro	Project Officer	AMREF	Box 2773, Dar es Salaam Tel: +255 22 2116610 +255 744 290139 Fax: +255 22 2115823	SagamoM@amreftz.org
15.	Martha Pedun	Project Officer	AMREF	Box 10663, Kampala Tel: +256 41250319 0+256 712 804775 Fax: +256 41 344565	PedunM@amrefug.org
16.	Antonio Santoro	Consultant, Ivo de Carneri Foundation of Milan	C/O Resident Research Resident Adviser Research Triangle Institute (RTI)	P O Box 3773 Tel: +255 24 2234970 +255 744 419646	

Appendix-5
PROPOSED CONTENT AND TIMETABLE FOR REGIONAL SENSITISATION WORKSHOP FOR DISTRICT SUPERVISORS

3 DAY WORKSHOP

Meeting objectives
1. Familiarise participants with the REQAS project
2. Introduce the four reference documents
3. Review roles and responsibilities of supervisors
4. Review methods of remedial measures
5. Orient participants on EA-REQAS health facility assessment form
6. Review supervisory checklists for clinical and laboratory staff
7. Discuss administrative issues
8. Share experiences across the region

Participants
Clinical and laboratory supervisors from each selected district in the pilot phase. Total = 30 - 35 people.

1. *Uganda:* One District Laboratory Focal Person (DLFP), one District Clinical Focal Person from each District.
2. *Kenya:* One District Medical Laboratory Technologist (DMLT); one District Clinical Officer (DCO) from each District.
3. *Tanzania:* One District Medical Laboratory Technologist (DMLT); one District Medical Officer (DMO) from each District.
4. *Zanzibar:* One District Medical Laboratory Technologist (DMLT); one District Clinical Officer (DCO) from each District.

Do we need one Regional Laboratory Technologist (RMLT) and one Regional Clinical Officer from each region? What about the Zones?

Facilitators
1. *MOH Staff:*
   - One clinician and one laboratory staff from each Ministry.
2. *AMREF staff:*
   - Clinicians: J Carter, R Mukisa
   - Laboratory staff: D Ocheng, C Munafu, S Materu

Workshop content

Background
- History of REQAS
- Purpose of EQAS
- Advantages of a regional scheme
- Regional components of the scheme
- National components of the scheme
- Role of the regional coordinating centre
- Model of EA-REQAS
- Regional Arusha meeting and major recommendations and resolutions

Tests, techniques and pathology
- Criteria for selection of tests & techniques
- Test, techniques and pathology addressed

Four reference document

- Standard Operating Procedures for Essential Laboratory Tests
- Standard Operating Procedures for Laboratory Utilisation for Clinicians
- Standard Operating Procedures for Care and Maintenance of Laboratory Equipment
- Quality Manual

Organisation of REQAS

- Preparation of materials
- Packaging of materials, questionnaires and answer sheets
- Distribution of materials
- Processing REQAS packages
- Submission of results
- Receiving and acting on feedback

Roles of supervisors

- Roles of District/Regional clinical & laboratory supervisors
- Tasks of supervisors (clinical & laboratory)
- Supervisory checklists (clinical & laboratory)
- Methods of remedial action
- Methods for equipment repair
- Supplies of essential reagents
- Staff supportive supervision
- Orient on EA-REQAS health facility assessment form
- Planning and budgeting for laboratory services

Administrative issues

- Roles of facility boards/councils
- Roles of Medical Officers
- Sources of funds
- Transport
- Way forward

PROPOSED TIMETABLE FOR REGIONAL SENSITISATION WORKSHOP FOR DISTRICT SUPERVISORS

Date	**Day 1**	**Day 2**	**Day 3**	**Day 4**	**Day 5**
08.30 – 10.30		Welcome & Introductions Meeting objectives ***Background*** History of REQAS Purpose of EQAS Advantages of a regional scheme	***Organisation of REQAS*** Preparation of materials Packaging of materials, questionnaires and answer sheets Distribution of materials Processing REQAS packages Submission of results Receiving and acting on feedback Joint session	***Roles of supervisors*** Presentations of practical work Joint sessions	Departure
10.30 – 11.00		**TEA**	**TEA**	**TEA**	
11.30 – 13.00		***Background (cont'd)*** Regional components of the scheme National components of the scheme Role of the regional coordinating centre Model of EA-REQAS Regional Arusha meeting and major recommendations and resolutions Joint session	***Roles of supervisors*** Roles of District/Regional clinical & laboratory supervisors Tasks of supervisors (clinical & laboratory) Supervisory checklists (clinical & laboratory) Methods of remedial action Methods for equipment repair Essential supplies Supportive supervision of staff Orient on EA-REQAS health facility assessment form Joint session	***Roles of supervisors*** Presentations of practical work Joint session	
13.00 – 14.00		**LUNCH**	**LUNCH**	**LUNCH**	
14.00 – 1530		***Tests, techniques and pathology*** Criteria for selection of tests & techniques Test, techniques and pathology addressed Joint session	***Practical sessions*** Review tasks Methods of remedial action Develop clinical and laboratory supervisory checklists Clinical & Laboratory sessions	***Administrative issues*** Roles of facility boards/councils Roles of Medical Officers Sources of funds Transport Joint session	
15.30 – 16.00		**TEA**	**TEA**	**TEA**	
16.00 – 17.00	Arrival	***Introduce four reference documents*** SOPs for Essential Laboratory Tests SOPs for Laboratory Utilisation for Clinicians SOPs for Care and Maintenance of Laboratory Equipment Quality Manual Joint session	***Practical sessions cont*** Review tasks Methods of remedial action Develop clinical and laboratory supervisory checklists Clinical & Laboratory sessions	***Administrative issues (cont)*** Roles of facility boards/councils Roles of Medical Officers Sources of funds Transport Joint session	

Appendix-6

PROPOSED CONTENT AND TIMETABLE FOR COUNTRY SENSITISATION WORKSHOP FOR PARTICIPATING HEALTH FACILITIES

3 DAY WORKSHOP

9. Meeting objectives

- Familiarise participants with the REQAS project
- Introduce the four reference documents
- Review principles of quality management
- Review relevant tasks of clinical and laboratory staff
- Review methods of supervision and remedial action, and roles of supervisors
- Orient participants on EA-REQAS health facility assessment form

10. Participants

- Clinical and laboratory staff (in pairs) from every participating health facility in each selected districts in the pilot phase. Total = 120 - 160 participants per country.

11. Facilitators

- *MOH Staff:*
  - One clinician and one laboratory staff from each Ministry.
- *AMREF staff:*
  - Clinicians: J Carter, R Mukisa
  - Laboratory staff: D Ocheng, C Munafu, S Materu

12. Workshop content

- ***Background***
  - History of REQAS
  - Purpose of EQAS
  - Advantages of a regional scheme
  - Regional components of the scheme
  - National components of the scheme
  - Role of the regional coordinating centre
  - Model of EA-REQAS
  - Regional Arusha meeting and major recommendations and resolutions

13. Tests, techniques and pathology

- Criteria for selection of tests & techniques
- Test, techniques and pathology addressed

14. Four reference documents

- Standard Operating Procedures for Essential Laboratory Tests
- Standard Operating Procedures for Laboratory Utilisation for Clinicians
- Standard Operating Procedures for Care and Maintenance of Laboratory Equipment
- Quality Manual

15. Organisation of REQAS

- Preparation of materials
- Packaging of materials, questionnaires and answer sheets
- Distribution of materials
- Processing REQAS packages
- Practical demonstration of REQAS kit, filling of forms
- Submitting results

- Receiving and acting on feedback

16. Principles of quality management

- Definitions of quality
- Quality policy statement
- Organisational structure
- Setting standards of practice
- Monitoring quality
- Patient/client issues

17. Relevant tasks of clinical and laboratory staff

- **The Diagnostic Cycle:**
  - History taking
  - Physical examination
  - Use of essential clinical equipment
  - Ordering laboratory tests
  - Specimen collection
  - Specimen processing
  - Use of essential laboratory equipment
  - Recording and reporting results
  - Interpreting results
  - Patient management
- Planning and budgeting for laboratory services

18. Roles of supervisors, methods of supervision and remedial action

- Roles of District/Regional clinical & laboratory supervisors
- Tasks of supervisors (clinical & laboratory)
- Methods of remedial action
- Methods for equipment repair
- Supplies of essential reagents

19. Administrative issues

- Roles of facility boards/councils
- Roles of Medical Officers
- Sources of funds
- Transport
- Way forward

PROPOSED TIMETABLE FOR COUNTRY SENSITISATION WORKSHOP FOR PARTICIPANTS

Date/Time	Day 1	Day 2	Day 3	Day 4	Day 5
08.30 – 10.30		o Welcome & Introductions o Meeting objectives	***Organisation of REQAS*** o Preparation of materials o Packaging of materials, questionnaires and answer sheets o Distribution of materials o Processing REQAS packages o Submission of results o Receiving and acting on feedback Joint session	***Practical sessions*** o Present facility outline and major tasks Joint session	Departure
10.30 – 11.00		TEA	TEA	TEA	
11.30 – 13.00		***Background*** o History of REQAS o Purpose of EQAS o Advantages of a regional scheme o Regional components of the scheme o National components of the scheme o Role of the regional coordinating centre o Model of EA-REQAS o Regional Arusha meeting and major recommendations and resolutions Joint session	***Principles of quality management*** o Definitions of quality o Quality policy statement o Organisational structure o Setting standards of practice o Monitoring quality o Patient/client issues Joint session	***Practical sessions (cont)*** o Present facility outline and major tasks Joint session	
13.00 – 14.00		LUNCH	LUNCH	LUNCH	
14.00 – 1530		***Tests, techniques and pathology*** o Criteria for selection of tests & techniques o Test, techniques and pathology addressed Joint session	***Relevant tasks of clinical and laboratory staff*** The Diagnostic Cycle: o History taking o Physical examination o Use of essential clinical equipment o Ordering laboratory tests o Specimen collection o Specimen processing o Use of essential laboratory equipment o Recording and reporting results o Interpreting results o Patient management o Planning and budgeting for laboratory services Joint session	***Roles of supervisors, methods of supervision and remedial action*** o Roles of District/Regional clinical & laboratory supervisors o Tasks of supervisors (clinical & laboratory) o Methods of remedial action o Methods for equipment repair o Supplies of essential reagents Joint session	
15.30 – 16.00		TEA	TEA	TEA	
16.00 – 17.00	Arrival *Participants come with facility assessment form*	***Introduce four reference documents*** o SOPs for Essential Laboratory Tests o SOPs for Laboratory Utilisation for Clinicians o SOPs for Care and Maintenance of Laboratory Equipment o Quality Manual Joint session	***Practical sessions*** o Review tasks in light of facility infrastructure Clinical & Laboratory sessions	***Roles of supervisors, methods of supervision and remedial action (cont)*** o Roles of District/Regional clinical & laboratory supervisors o Tasks of supervisors (clinical & laboratory) o Methods of remedial action o Methods for equipment repair o Supplies of essential reagents Joint session	

Appendix 7.

1

Progress of EA-REQAS – Uganda…

- Meeting to introduce REQAS to MOH (April 2001)
  - Idea accepted; strengthening of national scheme
  - National Health Laboratory Advisory & Coordination Committee (NHLACC) to oversee the project
- Meeting to introduce REQAS to WR-Uganda (April 2001)
  - WHO suggested development of country-specific proposal

3

Progress of EA-REQAS – Uganda

- National proposal presented to and accepted by NHLACC (May 02) and WR (Nov 2002)
  - WHO provided initial start-up funds
- Stakeholders meeting to discuss the Scheme (Oct 2002)
- Workshop to develop SOPs for Essential Laboratory Tests (Dec 2002)
- Districts (3) selected for pilot programme (Jan 2003)
  - Districts visited & evaluated

4

Progress of EA-REQAS – Tanzania

- Meeting to introduce REQAS to MOH (May 2001)
  - National Diagnostic Services Advisory Committee (NDSAC) to oversee the scheme
- Meeting to introduce REQAS to WR-Tanzania (May 2001)
- Meeting to introduce REQAS to MOHSW Zanzibar (Dec 2002)
- Stakeholders meeting to discuss the Scheme (May 2002)
- Draft national proposal drawn up
- Workshop to develop SOPs for Laboratory Use by Clinicians (May 2004)
- Debriefed new HDS, MOHSW (March 2006)

5

Progress of EA-REQAS – Kenya…..

- Meeting to introduce EA-REQAS to NPHLS (April 2001)
  - Idea accepted; sharing of resources foreseen
- Meeting to introduce EA-REQAS to WR-Kenya (April 2001)
  - Pledge to support national component of the Scheme
- Structure to implement REQAS established (June 2001):
  - National Medical Laboratory Quality Assurance Advisory Body (NMLQAA)
  - Technical arm

6

Progress of EA-REQAS – Kenya

- Stakeholders meeting to discuss the Scheme (Dec 2001)
- National proposal presented to WR-Kenya (2002)
- Workshop to develop Quality Manual & SOPs for Equipment Care & Maintenance (Aug 2004)

7

Regional Technical Meeting of EA-REQAS: Arusha, Tanzania April 2003

- Heads of Laboratory Administrations
- National Laboratory Quality Assurance units
- Central Public Health Laboratories
- Pathology/Laboratory Professional bodies
- Medical Laboratory Boards/Councils
- NIMR/PHL Pemba/UVRI/KEMRI
- Private sector
- Faith based organisations
- WHO
- East African Community Headquarters
- Commonwealth Regional Health Community Secretariat

8

Regional Technical Meeting of EA-REQAS…

- Country experiences of National Quality Assurance Schemes
- Update on the Regional External Quality Assessment Scheme
- Regional Issues
- National Issues
- Organisational issues
- Way Forward & Action Plan

9

Regional Technical Meeting of EA-REQAS

Resolutions & recommendations drawn up:

- National Quality Assurance Advisory Body in each country
- East African Regional Quality Assurance Committee (EA-RQAC) established
- East African Regional Quality Assurance Coordinating Centre (EA-RQACC) established
- Quality assurance materials, tools and standards shared
- Report implementation of EA-REQAS to the EAC Health Committee

10

Way forward: Regional activities

- Submit documents to WHO Geneva for publication
- Plan meeting of EA-RQAC in Tanzania to discuss:
  - Terms of reference
  - Sites for material preparation
  - SOPs for material preparation
  - Training strategies
- Visit sites for material preparation:
  - Address supplementary requirements
  - MOU
- Start material production
- Refresher training for District supervisors
- Create a website

11

Way forward: National activities

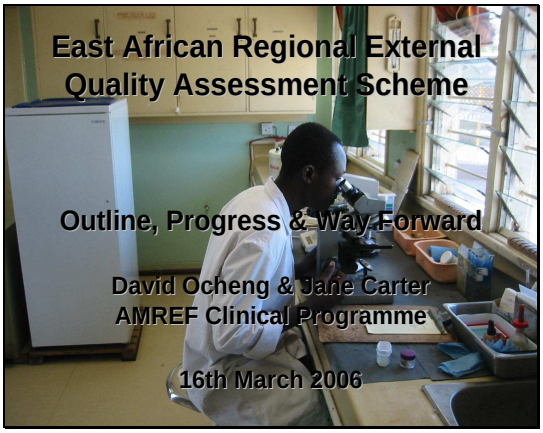
- Confirm pilot Districts
  - Baseline survey
  - Administrative support
- Review reporting systems
- Review remedial action
  - Support supervision
  - Equipment repair/replacement
  - Laboratory supplies
- Refresher training for facility staff
- Submit materials
- Link with other QA programmes
- Discussions

12


Karibuni Unguja
13

Appendix 8.

1



Meeting Objectives

- Introduce EA-REQAS to new MOHSW Laboratory team
- Review of the REQAS Project
- Activities in Tanzania, Kenya & Uganda
- Outcome of the First Regional Technical Meeting
- Way forward

3

History of EA-REQAS

- EQAS for PHC Laboratories in Kenya, Tanzania & Uganda since 1994: AMREF/MOH
- EA-REQAS: idea → concept → proposal (1996 – 1998)
- Initial funding from WHO Geneva (2001)
- In-country development activities: 2001 - 2004

4

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

5

Advantages of a Regional External Quality Assessment Scheme

- Standardise laboratory procedures
- Standardise quality of scheme materials
- Wider range of specimens
- Sharing resources for material preparation
- More national resources spent on remedial action
- Lessons learnt from regional experience
- Increased regional co-operation

6

Regional Components of the Scheme

- Select essential tests
- Standardise test techniques
- Prepare documents (each country):
  - SOPs for Essential Laboratory Tests
  - SOPs for Laboratory Use by Clinicians
  - Quality Manual
  - SOPs for Care & Maintenance of Laboratory Equipment
- Select laboratories for material preparation
  - SOPs for material preparation

7

National Components of the Scheme

- Advocacy at National/District levels
- Select sites & distribute materials
- Sensitise supervisors & participants
- Review tests/questions/educational materials for each distribution
- Review summary reports
- Take remedial action:
  - support supervision
  - supplies/reagents
  - equipment and equipment repair
  - training/workshops
- Develop national proposals

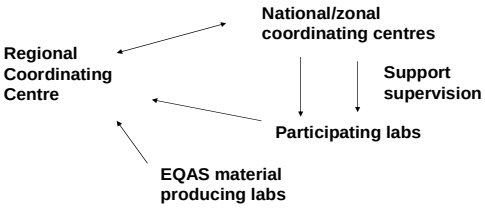
8

Role of the Regional Co-ordinating Centre

- Providing an objective assessment
- Validating quality of prepared materials
- Preparing questionnaires & answer sheets
- Packing and distributing of materials to countries
- Receiving results
- Analysing and submitting results to:
  - national laboratory administrations
  - participating laboratories
- Preparing and distributing educational materials
- Dissemination of lessons learnt
- Advocacy

9

Suggested model of EA-REQAS



10

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 methods of material preparation/preservation are available
- Tests for which standards of measurement/recognition are available

11

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 Giemsa stain Leishman stain**	**Hypochromia/ microcytosis Megaloblastosis Neutrophilis Leucopaenia Parasites**
Stool examination	**Direct microscopy**	**Cysts of protozoa Helminth ova**

12

Tests, Techniques, Pathology

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

13

Progress of EA-REQAS – Uganda…

- Meeting to introduce REQAS to MOH (April 2001)
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  - National Health Laboratory Advisory & Coordination Committee (NHLACC) to oversee the project
- Meeting to introduce REQAS to WR-Uganda (April 2001)
  - WHO suggested development of country-specific proposal

14

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- Workshop to develop SOPs for Essential Laboratory Tests (Dec 2002)
- Districts (3) selected for pilot programme (Jan 2003)
  - Districts visited & evaluated

15

Progress of EA-REQAS – Tanzania

- Meeting to introduce REQAS to MOH (May 2001)
  - National Diagnostic Services Advisory Committee (NDSAC) to oversee the scheme
- Meeting to introduce REQAS to WR-Tanzania (May 2001)
- Meeting to introduce REQAS to MOHSW Zanzibar (Dec 2002)
- Stakeholders meeting to discuss the Scheme (May 2002)
- Draft national proposal drawn up
- Workshop to develop SOPs for Laboratory Use by Clinicians (May 2004)

16

Progress of EA-REQAS – Kenya…..

- Meeting to introduce EA-REQAS to NPHLS (April 2001)
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- Meeting to introduce EA-REQAS to WR-Kenya (April 2001)
  - Pledge to support national component of the Scheme
- Structure to implement REQAS established (June 2001):
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  - Technical arm

17

Progress of EA-REQAS – Kenya

- Stakeholders meeting to discuss the Scheme (Dec 2001)
- National proposal presented to WR-Kenya (2002)
- Workshop to develop Quality Manual & SOPs for Equipment Care & Maintenance (Aug 2004)

18

Regional Technical Meeting of EA-REQAS: Arusha, Tanzania April 2003

- Heads of Laboratory Administrations
- National Laboratory Quality Assurance units
- Central Public Health Laboratories
- Pathology/Laboratory Professional bodies
- Medical Laboratory Boards/Councils
- NIMR/PHL Pemba/UVRI/KEMRI
- Private sector
- Faith based organisations
- WHO
- East African Community Headquarters
- Commonwealth Regional Health Community Secretariat

19

Regional Technical Meeting of EA-REQAS…

- Country experiences of National Quality Assurance Schemes
- Update on the Regional External Quality Assessment Scheme
- Regional Issues
- National Issues
- Organisational issues
- Way Forward & Action Plan

20

Regional Technical Meeting of EA-REQAS

Resolutions & recommendations drawn up:

- National Quality Assurance Advisory Body in each country
- East African Regional Quality Assurance Committee (EA-RQAC) established
- East African Regional Quality Assurance Coordinating Centre (EA-RQACC) established
- Quality assurance materials, tools and standards shared
- Report implementation of EA-REQAS to the EAC Health Committee

21

Way forward: Regional activities

- Submit documents to WHO Geneva for publication
- Plan meeting of EA-RQAC in Tanzania to discuss:
  - Terms of reference
  - Sites for material preparation
  - SOPs for material preparation
  - Training strategies
- Visit sites for material preparation:
  - Address supplementary requirements
  - MOU
- Start material production
- Refresher training for District supervisors
- Create a website

22

Way forward: National activities

- Confirm pilot Districts
  - Baseline survey
  - Administrative support
- Review reporting systems
- Review remedial action
  - Support supervision
  - Equipment repair/replacement
  - Laboratory supplies
- Refresher training for facility staff
- Submit materials
- Link with other QA programmes
- Discussions

23

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Appendix 9.

MAINLAND TANZANIA QUALITY ASSURANCE SCHEME

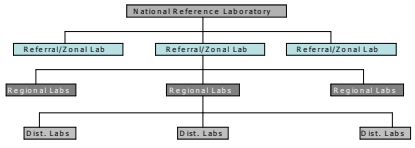
By Prof. E. Kaaya / Mr. V. Mgaya

INTRODUCTION

Organization of the National Laboratory System

- The national laboratory system encompasses both laboratories in *public* and *private hospitals*. Likewise, testing capacity in *autonomous laboratories* is on the rise
- The laboratory system in the country is organized in a four-tier system, according to capacity of the hospital and the laboratory itself. Laboratories in private hospitals are categorized depending on the service capacity of the health facility

ORGANIZATION OF LABORATORY SYSTEMS IN TANZANIA MAINLAND



Background Information on EQAS

- EQA was established in 1994 as NEQAS and REQAS
- Reviewed in 1998 to form ZEQAS with regions assuming the supervising and distribution capacity
- In addition to REQAS and ZEQAS similar EQA schemes operated concurrently such as those under: -
  - National TB and Leprosy Programme
  - AMREF Tanzania
- This scenario led to formulation of Tanzania Mainland QA Framework with an objective of harmonizing the operations under one national scheme

Current Situation and Progress

Human Resource Development

- Diagnostic services at MoHSW has appointed three additional staff responsible for coordinating:
  - Quality Systems (Mr. M Mwasekaga)
  - Laboratory Personnel Training (Dr. F. Mosha)
  - Health Care Technical Services (Mr. Y. Mkwizu)
- Also WHO has provided a Laboratory Technical Support (Mr. C. Kagoma)

Zonal activities

- At the same time, the existing ZEQAS is still operational in the following zones: -
- Eastern Zone: Covering- 160 Laboratories
- Southern Highlands Zone: Covering -31 Laboratories
  - Most of the distributed samples were those performed at level I (Hospital) Laboratories in :
    - Haematology
    - Blood Group Serology
    - Microbiology
    - Clinical Chemistry
    - Parasitology

Tanzania Quality Assurance Framework document (TQAF)

- A meeting was held in Morogoro in 2005 and came out with the TQAF document which is still in a draft form and expected to be finalized and develop implementation plan by May 2006
- Despite being in draft form, implementation has started with CD4 counts under MUCHS department of Microbiology
  - The Programme is supported by Quality Assessment and Standardization for Immunological Measures (QASI), Canada and coordinated by the Diagnostic Services at the MoHSW Mainland Tanzania
  - So far, two CD4 EQA rounds have been conducted to all laboratories performing CD4 counts (42 centres)
  - Results of the first round has been analyzed and feedback given
- SOPs for Haematology and Clinical Chemistry have been revised, while those for CD4 count, Rapid and ELISA HIV tests have been developed

EA RQAS activities

- Tanzania has finalized development of Laboratory Guidelines for Clinicians as part of the tasks under EA-RQAS

COMPONENTS OF MAILAND TANZANIA QUALITY ASSURANCE SCHEME (QAS)

- **Internal Quality Control (IQC)**
  - Standardization of processes and procedures
- **External Quality Assessment (EQA)**
  - Proficiency testing
  - Retesting or rechecking samples
  - On-site evaluation
- **Laboratory Quality Assurance Management**
  - Organization
  - Documentation and Record Keeping
  - Laboratory Network Information Sharing
- **Laboratory QA Monitoring and Evaluation**

NATIONAL LABORATORY QUALITY ASSURANCE ACTIVITIES

- To Strengthen and Coordinate the National Laboratory Quality Assurance Implementation at All Levels
  - Pre-analytic
  - Analytic
  - Post-analytic
- To Establish a Functional Specimen Transportation Network
- To Provide Essential Laboratory Reagents and Other Supplies for all Laboratory Diagnostic tests.
- To Strengthen Zonal Laboratory Equipment Workshops in Order to Provide Planned Equipment Preventive Maintenance
- To Establish a Functional National Laboratory Network
- To Train Laboratory Staff (One National and 4 Zonal Trainings ob QS conducted)
- To Establish the National EQA Operational Matrix

WAY FORWARD ON TESTS TO BE INCLUDED IN EQA

- HIV Diagnosis
  - Rapid testing
  - ELISA
  - PCR (DNA and RNA)
- CD4 testing
- Haematology
- Clinical chemistry
- Infections
  - TB (microscopy)
  - Other bacterial infections
  - STI (microscopy and culture)
  - Malaria (microscopy or rapid test)
  - Stool (microscopy)

Appendix 10

QUALITY ASSURANCE SCHEME, UGANDA

By
Dr Y. Mpairwe
Gaspard B Guma
Martha Pedun
Dr.Rose Mukisa

Country profile

- ❑ Total area: 241,547.6 sq km
- ❑ Population: Approx 26million
- ❑Administration: Decentralized system of governance
- ❑Administrative units: Districts
- ❑Number of districts: 70 (76 by Jul 2006)

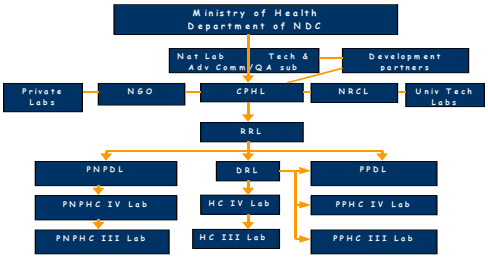
Health delivery system 1

- ❑ Level of delivery: 7
- ❑ Level strata:
  - Health Center I
  - Health Center II
  - Health Center III
  - Health Center IV
  - District Referral

Health delivery system 2

- ❑ Level strata:
  - Regional referral
  - National referral
- ❑ Laboratory services: health center III to national referral

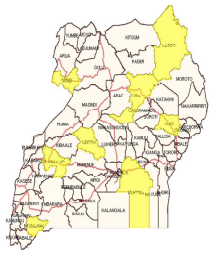
Management of Laboratory services



Proposed districts for pilot

Pilot districts for QA

- **Nebbi**
- **Lira**
- **Kotido**
- **Kumi**
- **Mukono**
- **Kiboga**
- **Ntungamo**
- **Kyenjonjo**



Health Lab Quality Assurance Sub committee 1

- A sub committee of National Lab Technical committee

- Mandate:

To develop, establish and monitor a sustainable national health laboratory quality assurance program

Health Lab Quality Assurance Sub committee 2

- Terms of reference

Coordinate and guide the MoH in designing of the national health laboratory services quality assurance scheme

Guide the MoH through the CPHL in the development and regular review of guidelines for the operationalization of the National Health Lab Quality Assurance Scheme

Health Lab Quality Assurance Sub committee 3

- Terms of reference

Identify and collaborate with reputable institutions in Laboratory Quality Assurance within and without Uganda

Guide the CPHL in the implementation of the National Lab Quality Assurance Scheme

Regularly evaluate the National Lab Quality Assurance Scheme

Provision of feedback to the relevant stakeholder

Suggested Reference Labs 1

Laboratory	QA materials
❑CPHL /AMREF U	- smears for malaria parasites - stool samples for microscopy - smears for Gram staining
CPHL/NAMELA	- serum for HIV and syphilis
❑ CPHL/CDC-Ug	- CD4⁺ whole blood - PCR materials
❑ TB Central Lab	- Sputum smears for AFB
❑ LIRI (Tororo)	- smears for trypanosomes

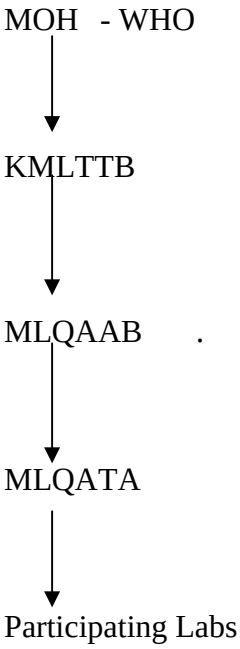
Suggested Reference Labs 2

Laboratory	QA materials
❑ Amudat Hospital Lab	- smears for Leishmania
❑ Arua Plague Lab	- smears for plague
❑ Mulago Haem Lab	- Hb - slides for film comments

Thank you very much

Appendix 11.

The hierarchy for management of NEQAS (Kenya)



INDEX

WHO	World Health Organization
MOH	Ministry of Health
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
MLQAAB	Medical Laboratory Quality Assurance Advisory Board.
MLQATA	Medical Laboratory Quality Assurance Technical Arm

The NEQAS will be owned by the Ministry of Health and regulated by KMLTTB while AMREF will be a member of MLQAAB and also MLQATA.

Appendix 12.

- 1st meeting of the East African Regional Quality Assurance Committee 26 – 27 April 2006

- Presented by;
- Ms. Mwanapenda Yahya Mzee
- Head Diagnostic Services
- Ministry of Health and Social Welfare
- P. O. Box 236
- Email: znzbts@zanlink.com

NATIONAL QUALITY ASSURANCE COMMITTEE

Proposed committee

The committee will comprises of the following members:

- Director of curative services – Chairperson
- Head Diagnostic services – Deputy Chairperson
- Quality Assurance Officer – Secretary
- In charge of Reference laboratory – Member
- Director of Public Health laboratory - Member
- Head Equipment technician – Member
- In charge of Medical Store - Member
- Chairperson of Infection prevention committee - Member
- Member from Private Board - Member

Terms of reference

- To develop policy guidelines and SOPs for Quality Assurance
- To monitor and evaluate implementation of quality management
- To develop training and competence assessment programs
- To develop quality indicators and auditing programs

TOR cont….

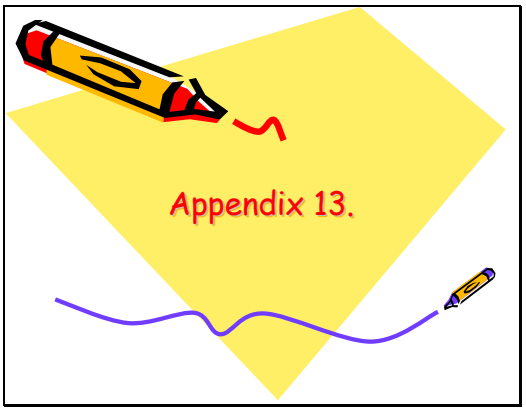
- Seek support and assure commitment from top management
- Mobilize resources
- Monitor and coordinate training plans
- Monitoring and Evaluation

	UNGUJA	PEMBA
Reference laboratories	Mnazi Mmoja hospital laboratory	Pemba Public Health Laboratory - IdC
Pilot Districts	6 districts	4 districts

MATERIALS WHICH CAN BE PREPARED

- Giemsa stained film for malaria parasite
- ZN Stain for AFB
- Gram stain for microorganisms
- Serum for HIV (Rapid method)
- Stool (concentration method)

Thank You Very Much
For Your Attention



PROGRESS OF REQAS IN ZANZIBAR

1st meeting of the East African Regional Quality Assurance Committee 26 – 27 April 2006

Presented by:
Ms. Mwanapenda Yahya Mzee
Head Diagnostic Services
Ministry of Health and Social Welfare
P. O. Box 236
Email. [redacted]

Introduction

- Laboratory Services in Zanzibar are under the Directorate of Curative Services (Hospital Services) of the Ministry of Health and Social Welfare.
- Laboratory Services are a key component of quality health care services.
- The need of quality system is to ensure that tests performed and results generated in the laboratories are reliable, reproducible and as accurate as possible

Organization

Laboratory services in Zanzibar are provided by:

i Hospital based laboratories

ii Public Health laboratory

iii Specialized laboratories that are principally specific diseases

Cont…

Laboratory services structure in Zanzibar is a three tier system consisting of ;

- Reference Laboratory (Mnazi Mmoja)
- District laboratories – Chake Chake, Wete and Mkoani
- Cottage laboratories – Kivunge, Makunduchi (Unguja) and Vitongoji, Micheweni (Pemba)
- Public Health laboratory – (Pemba) – focused mainly on research activities
- Private hospital based laboratories
- Faith based laboratories
- Specialized laboratories for Malaria, Schistomiasis&Helminthiasis,Filariasis etc

Progress

- Diagnostic Services Unit in the MOHSW established.
- Proposal for Quality management system developed, awaiting approval from the Ministry
- Standard Operating Procedures (SOP) developed, awaiting approval

Progress Cont…
EQA Programmes currently available in Zanzibar

- MPEP of CDC on HIV Rapid testing
- ZACP on HIV testing
- MCP on slide microscopy
- TLP on AFB microscopy
- NHLS/ WHO of South Africa on Epidemic prone diseases (Meningitis and Dysentery), and now extended further to Malaria and AFB microscopy
- International EQAS for Clinical Chemistry

Challenges/Constraints

Aged laboratory infrastructure

Budget constrains

Period	*Total Government expenditure in millions*	*Total Government expenditure in the Health sector in millions*	*Per capita public expenditure on Health*	*Government expenditure on Health as a % of total public expenditure*	*Other charges (OC) for the health sector as a % of the total sector government expenditure*
1995/96	*19,717*	*1,769*	*2,172*	*9*	*34*
1996/97	*21,908*	*1,976*	*2,354*	*9*	*27.8*
1997/98	*24,342*	*2,628*	*3,038*	*11*	*27.5*
1998/99	*35,459*	*2,765*	*3,099*	*7.8*	*27*
1999/00	*36,487*	*2,537*	*2,980*	*7*	*15.7*
2000/01	*42,975*	*2,610*	*3,896*	*6.1*	*12.8*
2001/02	*54,936*	*5,064*	*5,282*	*9.2*	*33.4*
2002/03	*69,778*	*4,245*	*4,316*	*6.1*	*14.8*
2003/04	*71,698*	*4,872*	*4,693*	*6.8*	*17.3*

Source: *Ministry of Finance, Zanzibar*

Inadequate Human Resource for quality laboratory services

No trained laboratory manager

Way Forward

- To establish a comprehensive countrywide QA Programme
- To advocate to the MOHSW to allocate more Funds for laboratory services including QA
- To solicit funds for QA from other sources
- To improve/strengthen laboratory networking
- To involve private laboratories in QA Programmes.

Thank You Very Much For Your Attention