

INFORMATION ABOUT EQAnews 2006**General**

EQAnews provides information on quality assurance in the medical laboratory; Clinical Biochemistry, Clinical Immunology, Clinical Microbiology, Clinical Parasitology, Clinical Virology, Haematology, Coagulation and Haemostasis etc. EQAnews is issued four times per year in February, May, September and December.

SCOPE OF EQAnews

EQAnews regards Quality Assurance (QA) as a professional activity which improves the quality of service provided by the clinical laboratory.

One important aspect of QA is External Quality Assessment (EQA, proficiency testing, inter-laboratory comparison). EQAnews sees External Quality Assessment as a rapidly developing scientific and practical field where world wide understanding and support for further development is essential.

EQAnews is established to facilitate world wide communication of scientific, organizational and practical aspects of EQA.

EQAnews is owned by the European Committee for External Qua-

lity Assurance Programs in Laboratory Medicine, EQALM.

EQALM will ensure contact with the various disciplines of Laboratory Medicine. EQAnews collaborates with IFCC, ECLM and WASP and welcomes co-operation with other scientific organizations.

Subscription

The annual fee is 30 Euro excl. 25% VAT covering one calendar year. Members of EQALM receive EQAnews without additional cost to their membership fee. Readers from developing countries receive EQAnews free of charge.

Contacts regarding enrolment, invoices and payments should be made to Susanne Biron, DEKS, 54 M1, Herlev University Hospital, DK-2730 Herlev, Denmark.

E-mail: susanne.biron@deks.dk

Responsibility for issue:

EQALM board by:

Gunnar Nordin, Chair of EQALM, Box 977, 751 09 Uppsala, Sweden.

E-mail: gunnar.nordin@equalis.se
Web-Site: www.eqalm.org

Editor of EQAnews is:

Gitte M. Henriksen, DEKS, 54M1, Herlev University Hospital, Herlev Ringvej 75, DK-2730 Herlev, Denmark.

E-mail: gitte.m.henriksen@deks.dk

Field specific co-editors are:

Michael Noble (clinical microbiology). Clinical Microbiology Proficiency Testing, University of British Columbia, Room 328A, Heather Pavilion C, Floor 27, Heather Street, Vancouver, BC V5Z, Canada.

E-

mail:mnnoble@interchange.ubc.ca

Joergen Kurtzhals (clinical parasitology). Department of Clinical Microbiology 7602, Rigshospitalet, Blegdamsvej 9, DK-2100 København Ø, Denmark.

E-mail: jkcmp@rh.dk

Igor Bondarenko (clinical virology). Russian Research Institute for Metrology, 19 Moskovsky Pr., St. Petersburg, 198005 Russia.

E-mail: bigor@mail.lanck.net

Nils Joergensen (clinical biochemistry), Afdeling 98, Soenderborg Hospital, DK-6400 Soenderborg, Denmark.

E-mail: njb@mail.dk

Jan Moeller (clinical biochemistry). Department of Clinical Biochemistry, Skejby Sygehus, Aarhus University Hospital, Brendstrupgaardsvej, DK-8200 Aarhus, Denmark.

E-mail: jan@kba.sks.au.dk

Vives Corrons (haematology). Haematology Lab. Dept., Escala 1 B-Planta 3, Hospital Clinic 1 Provincial, C/ Villarroel 170, ES-08036 Barcelona, Spain.

E-mail: jlvives@medicina.ub.es

Timothy AL Woods, UK NEQAS for Blood Coagulation, Rutledge Mews, 3 Southbourne Road, Sheffield, S10 2QN, United Kingdom.

E-mail:

Tim.Woods@coageqa.org.uk

Jonathan Middle (language revision). UK NEQAS, P.O. Box 3909, Birmingham B15 2UE, UK.

E-mail: j.g.middle@bham.ac.uk

Manuscripts

Manuscripts should be received no later than the first working day of the *month prior* to the month of issuing EQAnews, preferably in an electronic medium.

Editorials

Communications in EQAnews which carry no identification of authorship are written by the Editor.

Correspondence to EQAnews

All correspondence to EQAnews should be sent to the Editor.

The Editor takes no legal or financial responsibility for errors or misinformation which may occur in EQAnews.

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Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Contribution of EQA and Expectation from Clinical Practice

Lothar Thomas, Departement Laboratory Medicine, Krankenhaus Nordwest, Frankfurt/Main, Germany. E-mail: th-books@t-online.de

The use of clinical laboratory tests by physicians has a significant effect on the quality of patient care as well as on total health care costs. However, a laboratory test should only be ordered if the result could possibly lead to a change in therapy or other patient management. This change should have a positive effect on the prognosis or quality of life in a wider context. Quality assurance aims at ensuring, for both laboratory staff and clinicians, that the results provided are relevant and reliable. In most elements of the extended concept of quality assurance the laboratory staff and the clinician are involved. Until now EQA is only a small element in the extended concept of quality assurance, but may have a high impact in improving trust in laboratory results. The purpose of EQA is to separate the quality laboratory from the poorly performing one and to improve analytical quality.

Expectations from clinical practice are:

- assessment of more analytes according to the reference value concept
- explanations for failing the EQA program
- information about tests with optimal accuracy
- only analytes with well established reference ranges should be assessed according to the reference value concept
- EQA results should be supplemented with medical decision-making approaches.

In conclusion, the EQA organizers can play numerous roles to improve trust in laboratory results. They are not the stakeholders in patient care, but have an important diagnostic perspective to contribute. For improvement of uncertainty in clinical decisions EQA organizers should educate the laboratory. If the laboratory physician and the clinical chemist are educated in medical decision making approaches they can function as team players with laboratory knowledge in the clinic.

Call for a new EQALM board member

Term: 2007-2010.

Profile:

- Your organisation is a full EQALM member
- You are passionate about EQA
- You are a dynamic person
- You are looking for new challenges

We offer: Small dynamic team with similar passions, friendship and job satisfaction!

Candidatures are open until December 2006.

Please send a mail to the chairman, Gunnar Nordin
E-mail: Gunnar.nordin@equalis.se

New EQALM member

We are pleased to welcome the following new EQALM members:

Full member outside Europe

Programa Nacional de Controle de Qualidade

Contact person:
Dr. José Abol Correia

Full member Europe

European Molecular Genetics Quality Network (EMQN)

Contact person:
Dr. Simon Patton

Standard for the Accreditation of EQA Providers

J.C. Libeer, Scientific Institute of Public Health, Clinical Biology Department, Rue Juliette, Wytsmanstraat 14, B-1050 Brussels, Belgium

The EQALM Vienna resolution 2004 expressed the necessity for a specific EQA/PT standard. Since that time, a whole evolution has taken place. The ILAC general Assembly 2004 in Cape Town decided to review ILAC G13 and to set up a PT consultative WG taken on by Tony Russel (NATA). The WG met for the first time in Auckland (New Zealand) in September 2005 and for the second time in Madrid (12-13 May 2006). The most important work item of this group was the revision of the ILAC guideline G13.

In the revised version most of the complementary items from the IFCC EQAP document will be included. There remain some particular items that could not be taken over in a general PT guideline. (The non-profit status; mandatory advisory committee,....)

The revised ILAC G13 will be used as basic document for the new ISO Guide 43. ISO/ CASCO agree to review ISO guide 43 and to upgrade this guide to a new full

PT standard. This new PT standard of the future (foreseen to be ready at the end of 2008) will be ISO/EIC 17043.

According to the policies of ISO/ CASCO this revision will be done in WG 28 (convened by Dan Tholen) and with members delegated by the national standard bodies of the ISO member state.

For EQALM and the European EQA organizers it is really necessary to be represented in the revision of ISO Guide 43. There will certainly be representation of North America PT providers in the medical sector (US and Canada). The EQALM board is investigating how to be presented as a liaison organization in this revision.

For the follow-up of the development of the standard, an EQALM mirror group will be established. More information on the strategy to follow will be given during the EQALM general assembly in Geneva.

Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Contribution of EQA and Expectation for the Future

Gunnar Nordin, EQUALIS, Box 977, 751 09 Uppsala, Sweden. E-mail: gunnar.nordin@equalis.se

The organisation of External Quality Assurance Programmes has been described in various documents, such as ISO/IEC Guide 43-1, ILAC G13(2000), ISO 13528, IFCC-ECAP, IUPAC Harmonised Protocol. The expectations of EQA from authorities are described in the IVD directive and in EN 14136 (e.g. the vigilance function of EQA). A major future task will be to improve these documents based on hitherto gained experiences.

Whenever possible, reference methods should be used to assign true values with stated uncertainty for materials used in EQA. Reference measurement procedures, however, exist only for a minor part of the perhaps 1000 different properties regularly reported from clinical laboratories, and all of which are used in practice for making clinical decisions. The need for improvement of EQA might even be greater for all the properties, for which we lack reference measurement procedures, than for the minority of properties for which reference methods are available.

Clinicians sometimes ask for 'easy understandable' properties

instead of metrological exactness (such as GFR in stead of creatinine and 'Mean blood glucose' in stead of HbA1c). A challenge for EQA will be to expand EQA from being just a metrological assurance of the laboratory to the assessment of how laboratory test results are used and interpreted in the clinic.

The development of the future EQA ought to be independent from that of manufacturers' development of diagnostic tests. An important challenge will be to finance research and development of the necessary materials and methods. As EQA will be of minor interest for investors, funds must be raised from other sources.

An effective networking among EQA organizers will be the only way to develop and improve independent EQA. EQA organizers should therefore share data and experiences for the purpose of comparison and learning. To improve such comparability a common terminology is needed for properties being investigated - regardless of speciality - and for procedures used by the participants to perform the investigations.

Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Management needs and Data Processing Organization for Proficiency Testing by Interlaboratory Comparisons

Jeanmarc E. Aeschlimann, Nestlé Research Center, Vers-chez-les-Blanc, 1000 Lausanne 26, Switzerland. E-mail: jean.marc.aeschlimann@rdls.nestle.com

In organizing proficiency tests (PT) by interlaboratory comparisons, we have to build a functional system taking into account all required activities in our targeted domain, and to follow good practice rules reported in several national and international standards. Thus, an *ad'hoc* quality system has also to be set up. Starting from actual ideas about automating procedures as far as possible by computer techniques, we review the main points to be carefully checked in building such a PT providing system.

Targets are mainly the skill of analytical laboratories in providing specified determinations (analytes) on biological samples (matrices) in given values ranges

In a PT round, comparable or common PT samples are dispatched among PT participants. Therefore, to correctly detect analytical variations, we have to guarantee the equality of the dispatched samples for these comparisons. From the return of the requested results to the performance of each laboratory, several checks are to be done, as well as to clearly define and to implement a model of performance calculation. The clear communication of reports to each lab and the action to be undertaken afterwards are the main "raison d'être" of this organization system: the maintenance and the improvement of the analytical work.

EQALM Virtual Microscopy Working Group Meeting

The main objectives of the working group on Virtual Microscopy of the EQALM are to promote the use of virtual microscopy in the EQA domain and to establish a framework for the collaboration and exchanges between EQALM members. The activity of the working group will actually begin during the next EQALM meeting in Geneva. An hour discussion is planned on September 11th, 2006 (17:30-18:30).

The objective of this working group meeting is to define a collaboration project and a practice schedule. To that purpose project the following topics will be discussed:

- Virtual microscopy systems and their appropriateness to EQA
- Assessments of needs and existing application
- Common interests and pre-project definition:

- Choice of test samples (haematology, parasitology, ...)
- Scanning of test slides
- Performance evaluation by
- The participants (quality, speed, ...)
- Definition of required associated data and normalization elements (slide databank, application programs, ...)
- Links with existing surveys and interactions with quality centre information systems
- Building of the final project

The group is open to everyone interested in virtual microscopy in the EQA domain. For further information, please contact:

To register, please send an E-mail to:

Xavier.Albe@hcuge.ch.

EQALM Microbiology Working Group Meeting

The working group Microbiology will meet on Monday, September 11 from 17:30-18:30. The results of the questionnaire on post-error contact will be present and can be discussed. The WG can also discuss at which level coope-

ration between organizations, e.g. with regard to sample "sharing", could be possible.

Kris Vernelen.

E-mail:

Kris.vernelen@iph.fgov.be.be

EQALM Nomenclature Working Group Meeting

All EQA organizers face the problem of a suitable and transparent method grouping when presenting results from the surveys. CE registered procedures are sold throughout Europe and results from these procedures appear in any EQA scheme. The purpose of WG Nomenclature is to prepare a common database in which commercial procedures for laboratory medicine can be unequivocally identified by catalogue numbers, trade mark

names etc., and to which EQA organizers can refer for a unique identity of instruments, reagents and calibrators. The database might also contain information and links to manufacturers. On September 11, 2006 at 17:30-18:30 the progress of the work so far will be received.

For further information, please contact: Gunnar Nordin.

E-mail:gunnar.nordin@equalis.se

Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Methodology and Statistics of Performance Evaluation for Proficiency Testing by Interlaboratory Comparisons

Jeanmarc E. Aeschlimann, Nestlé Research Center, Vers-chez-les-Blanc, 1000 Lausanne 26, Switzerland. E-mail: jean.marc.aeschlimann@rdls.nestle.com

As instrument in EQA, proficiency tests (PT) by interlaboratory comparisons are generally included in a programme of several rounds in a year to check the main determinations that a laboratory needs to do routinely with a given requirement. Thus, we assess laboratory performances with the final aim of auto-correction of each outlying lab.

We have first to provide comparable PT samples to dispatch to PT participants, after having checked the samples equivalence, i.e. their homogeneity and stability. From the requested lab's results, we have to set up a model of performance used for

each laboratory. It is generally based on z-scores and repeatability ratios (Mandel's h and k), including known or consensus characteristics and uncertainties of samples. The implementation of adequate tolerances allows us to set up warning and action limits to be communicated to labs in order to take an adequate corrective or preventive action in their analytical work.

We will also show how easier we can use robust estimations instead of outliers tests, as well as the inclusion of several assessments in composite indices of performance.

Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Interest and difficulties of a multinational EQA

*Vivienne James, UK NEQAS for General Microbiology, Colindale, UK,
Jonathan Middle, UK NEQAS for Clinical Chemistry, Birmingham, UK*

Throughout the world, laboratory medicine operates in many different environments, depending on political, economic, technological and infrastructure constraints. These affect the viability and feasibility of EQA services, which require as a minimum, sufficient funding, access to appropriate materials, a reasonably efficient postal service and adequate communications links. EQA services may exist at all size levels from local surveys operated by enthusiasts, through district, national, regional and international services operated by specialised staff at dedicated EQA centres.

As they evolve, EQA programmes may attract participants from outside their main constituency, often because the programme may not exist, or its design and functionality is not attainable at the external location. Growth in participation has benefits of scale (larger method groups; more robust statistics) and income for the Organiser, but there may be disadvantages if material is

scarce, administration is more complex and communication lines are stretched. Furthermore, if participation from other countries increases to the point where it dominates the programme, there may be adverse effects on data integrity, or changes to scheme design to accommodate the needs of foreign users may disadvantage home country participants.

The design *ab initio* of a multinational EQA service, in contrast to one that emerges by evolution, is a major challenge where actual physical specimens are required, mainly because of the volume of material needed and its processing to ensure stability. The production of bland, 'universal' materials may preclude subtle probing of analytical validity. Every other aspect of EQA design, however, including the specimen itself where an image will suffice, is susceptible to the application of internet-based working, which is the ideal technology for truly global EQA provision.

EQALM Working group invitations

EQALM Haemostasis Working Group Meeting

During the EQALM symposium from 11-14 September 2006 in Geneva a meeting of the Working Group on Haemostasis will be held.

The following topics will be discussed:

- International project on INR measurement
- Procedures for the reconstitution of lyophilised plasmas
- Requirements for sample preparation

- Data-evaluation project
- The meeting will be held on Monday 11 September, 2006 from 17.30-18.30.

Every EQA organiser interested in haemostasis is welcome. For further information, please contact the convenor of this working group, Piet Meijer.

E-mail: P.Meijer@ecat.nl

EQALM Haematology Working Group Meeting

Please remember that our WG on Haematology will meet September 11 in Geneva on Monday. The meeting will be held in the Geneva University Hospital, Belle-Idée (Room 11) from 17:30 until 18:30. I kindly invite you to attend this WG activity

The proposed agenda for the meeting is the following:

- Relationships between EQALM WG on Haematology and the renewed International Council for Standardization in Haematology (ICSH)
- Proposals of new guidelines for general haematology laboratory practice
- Unfinished business

As you probably know, our last job on "Guidelines for setting up an External Quality Assessment Scheme for blood smear interpretation. Part II: survey preparation, statistical evaluation and reporting" has been published last month (Clin Chem Lab Med. 2006;44(8):1039-1043). My most sincere congratulations to all who have actively contributed to this success.

With the hope of seeing you in Geneva, I am sending you my best regards, Prof. Joan-LLuis Vives Corrons.

E-mail: Jlvives@clinic.ub.e

- EQA contribution and WHO expectations
Sébastien Cognat
- EQA contribution and Authorities' expectations
Manfred Langenegger

Lunch, poster and industry exhibition

- EQA contribution and legal medicine expectations
Thomas Briellmann
- EQA contribution and industry (EDMA) expectations
Claude Giroud
- EQA contribution and expectations for the future
Gunnar Nordin

Diskussion Forum

- EQA data processing for dummies
Jeanmarc Aeschlimann
- Mathematical and statistical tools
Christian Lovis
- Computer and graphical tools
Gilles Cohen

19.30: EQALM dinner

Wednesday, September 13, 2006

09:00-13:30:

EQALM Symposium

- Auditorium 1
- Should we have a unique EQA in Europe ?
Jack Bierens de Haan
- Are the performances target established in the patient interest?
Claus Heuck
- Interest and difficulties of a multinational EQA
Jonathan Middle, Vivienne James
- Is EQA a business?!
Stéphanie Albaredo
- EQA and emerging countries: Experience of South Africa
Vivian Fensham
- EQA Organisations: role and interactions with International Organisations
Antoine Pierson

General discussion

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Lunch, poster and industry exhibition

13:30-15:30:

EQALM General Assembly

- Reports of the working groups
16:30-17:30:

Visit of the CSCQ facilities

Thursday, September 14, 2006

08:45-13:45:

SCCQ: 35 years of experience

Welcome, coffee, poster and industry exhibition

- Registration
- Introduction
Roberto Della Bruna, president

Communications by Founding

Associations

- SSCC / SGKC
Bendicht Wermuth
- SSM/SGM
Peter Rohner
- SSAI/SGAI
Eric Dayer
- SSH/SGH
- SSGM/SGMG
Morris Michael
- FAMH
Willi Conrad
- SSH/SGH
- Some facts about CSCQ
André Deom

Diskussion

Lunch, poster and industry exhibition

- Closing remarks and opening of the Workshops
Roberto Della Bruna, President
André Deom
- Workshop I (Room 1) :
Swiss legal requirements, EQA, IQA, solving problems
Peter Hagermann
- Workshop II (Room 2 : EQAcom2
Xavier Albe

14:00:16:00:

CSCQ Board meeting (Room 20)

Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

WHO EQA Contribution and Expectations

S. Cognat., WHO Lyon Office for National Epidemic Preparedness and Response, Bureau OMS de Lyon pour la préparation et la réponse des pays aux épidémies, 58 avenue Debourg, 69007, Lyon, France. E-mail: cognats@lyon.who.int

External quality Assessment (EQA) is an essential tool not only to validate the competence of laboratories, but also to document national diagnostic capabilities, and determinate appropriate means by which international public health institution such as WHO could increase the competency of participating laboratories in a sustainable manner and implement corrective actions. WHO coordinate numbers of proficiency testing programs, at regional of global level, for the benefit of the laboratories, the public health managers or the organizations supporting vertical or integrated programs, such as poliomyelitis, tuberculosis, global salmonella surveillance, HIV/AIDS, blood safety, or epidemic-prone diseases

For example, the WHO Lyon office have requested the assistance of the National Institute for Communicable Diseases of the South African National Health Laboratory Service with provision of a Proficiency Testing programme to 72 African National Public Health Laboratories, for enteric pathogens, bacterial meningitis and plague. This programme creates an international channel and network for the laboratory diagnostic issues. It has been recently extended with additional disciplines such as tuberculosis and malaria. A similar programme is planned for the Eastern Mediterranean Region. In addition, national EQA schemes will be supported in 5 African countries.

Poster Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

Performance of the External Quality Assessment Scheme for Clinical Chemistry in Polish. Ten years of experience

*Małgorzata Wróblewska**, *Gabriela Bednarczuk***, *Mirosława Nowacka**, *Jerzy Rogulski***. *Chair of Clinical Biochemistry, Department of Laboratory Medicine, Medical University of Gdańsk, Dębinki 7, 80-211 Gdańsk, Poland. E-mail: wroblew@amg.gda.pl. ** Polish College of Laboratory Medicine, Dębinki 7, 80-211 Gdańsk, Poland

The Polish College of Laboratory Medicine is a non-profit association which was set up in 1993. In 1996 the Council of the college decided to work closely with Labquality (Finland) to promote EQAS in Poland. On the basis of this co-operation, the Common External Quality Assessment Scheme, known as PPZOJMED, was founded in Poland. We started in May 1996 with about 40 participants. Currently up to 400 laboratories participate in our program. PPZOJMED offers not only all the advantages of EQAS organized by Labquality, but also experiences of Polish experts who collaborate with the College. In this manner PPZOJMED, joins the benefits of international and national external quality control. From May 1996 to December 2005, 42.000 surveys were car-

ried out. As the main aim of our activity is to raise the standards of laboratory services, we made an attempt to assess the progress of performance of chosen analysis in clinical chemistry. We analysed more than 40.000 results of sodium, potassium, glucose, cholesterol and creatine kinase obtained in CEQAS by our participants over 10 years. In comparison to 1996, in 2005 the amount of laboratories results which were within the target limits raised significantly in case of potassium (5%), cholesterol (16%), glucose (18%) and creatine kinase (22%). We conclude, that these improvements in performance reflects, at least partly, the impact of participation in EQAS on analytical quality in Polish laboratories.

Programme for the EQALM & CSCQ International Symposium on Quality Assurance and Control in Laboratory Medicine September 11-14, 2006, in Geneva, Switzerland

For more information see www.EQALM.org

Monday, September 11, 2006

08:30-18:30:

1st EQALM course for auditing QA centres

Auditorium 1

Registration

- Introduction
- Information
André Deom / Jean-Claude Libeer
- Accreditation and licensing, a question of definitions
Ian Mann
- Presentation of the various standards and guides : ISO norm 17 020, ISO Guide 43, ILAC G 13, EQAP document
Jean-Claude Libeer

Coffee break, poster and industry exhibition

- How to make people feel at ease with accreditation? - Techniques for audits
Josse Berckmanns

Lunch, poster and industry exhibition

- A practical approach, the METAS check list
Ian Mann
- Statistical calculations
Jeanmarc Aeschlimann
- QC material, validation and storage
Kris Vernelen, Nicole Hamers

Coffee break, poster and industry exhibition

- EA approach and point of view
Ian Mann
- Practical approach for managing documentation
Sylvie Vasey
- Discussion

17:30-18:30:

EQALM Working groups

- Microbiology
Room 10
Kris Vernelen
- Haematology (blood smears)
Room 11
Joan-Luis Vives Corrons
- Haematology (cell counting)
Room 12
Sverre Sandberg
- Haemostasis
Room 13
Piet Meijer
- Nomenclature
Room 14
Gunnar Nordin
- Virtual microscopy
Room 15
Xavier Albe

18:30-19:30:

EQALM Board meeting
Room 20

Tuesday, September 12, 2006

08:30-17:00:

EQALM Symposium

Auditorium 1

Registration

- Introduction
Gunnar Nordin, EQALM President
- Information
André Deom
- EQA contribution and clinical practices expectations
Lothar Thomas
- EQA contribution and medical laboratories expectations
Willi Conrad

Discussion

Coffee break, poster and industry exhibition

Poster Abstract for the EQALM meeting, Geneva, September 11-14, 2006

National External Quality Assurance Scheme in Nepal

Bishnu Rayamajhi*, Marianne Brocqueville**, Dinah-Eva Storm**, Agandhar Sapkota*, Dr Sarala Malla***, Heike Preibe** and Jyoti Acharya*, *Departments of Quality Assurance and Biochemistry, National Public Health Laboratory, Kathmandu, Nepal; **Laboratory Assistance Programme, International Nepal Fellowship; ***Director, National Public Health Laboratory, Kathmandu, Nepal

In Nepal the National Public Health Laboratory (NPHL) in collaboration with the International Nepal Fellowship (INF) started a national external quality assurance scheme (NEQAS) in 1998. The programme began in the Central Region for 22 laboratories with a small number of analytes and gradually expanded to the whole country increasing the number of analytes as well. By February 2006 more than 300 laboratories were participating in the programme and there were 15 different analytes to be checked.

Quality Assurance specimens for Haematology, Biochemistry and Microbiology are locally prepared and dispatched to all the participating laboratories. Stability studies and cross checking by at least two other central level labo-

ratories is performed for each batch of specimens. The participating laboratories send their results back to the NPHL. The Quality Assessors at NPHL record their results and send out feedback forms with appropriate advice.

The main aim of this programme is to encourage the staff at the periphery to improve the quality of laboratory services. A training and supervision programme is complementing the NEQAS, as well as an equipment maintenance programme.

Our experience shows that Quality Assurance specimens can be produced at low cost and with locally available materials. Therefore monitoring of laboratory performance in Nepal has proved to be possible.

Poster Abstract for the EQALM Symposium, Geneva, September 11-14, 2006

National External Quality Control in Romania

Berbecar S, Culea I, Dorobat O, Lazar C, Romania, Bucharest 020125, Sos. Stefan cel Mare 19-21, sector 2, OP10, CP73. E-mail: office@roeqalm.ro

The Romanian Society for External Quality Assessment in Laboratory Medicine - RoEQALM - was founded in 2001 as an independent and non-profit society.

The unique objective of RoEQALM is the quality assurance and external quality control in laboratory medicine. Until the present day it is the only non-profit society with this unique area of expertise in Romania.

Quality assurance has been accomplished through:

- organizing of scientific meetings dedicated to quality assurance: 7 national and 4 international seminars;
- translating and publishing in 2004 of "The Quality Manual in Laboratory Medicine; model according to EC4 essential criteria"
- elaborating and publishing in 2005 of the first volume of

"Recommendations for the Standardizing of the Activity in Laboratory Medicine", which contains the pre-analytic phase.

We made possible external quality control through:

- organizing External Quality Control Programs (EQCP) at a national level in the areas of: Clinical Chemistry, Hematology, Hemostasis, Bacteriology, Parasitology.
- presenting and commenting on the results obtained from the participants at the EQCP (confidentiality is maintained) during some scientific meetings, with the purpose of:
 - Improving the quality of performance;
 - Evaluation of the comparability of the test results at a national level

Poster Abstract for the EQALM meeting, Geneva, September 11-14, 2006

EQUALIS External Quality Assurance of Clinical Physiology/vascular Diagnosis

*Anita Svahn**, *Håkan Lund**, *Reinhard Volkmann***, **EQUALIS AB, Uppsala, **Departments of Clinical Physiology, Sahlgrenska Akademin, Gothenburg, Sweden. E-mail: anita.svahn@equalis.se*

Introduction

Clinical physiology provides functional diagnoses, and its vascular section is first to have External Quality Assurance (EQA) programmes run from a Swedish EQA organisation. An expert group was started in 2003. The first scheme was distributed in 2004.

Material and methods

The distributions consisted of five different cases with anamneses, film sequences and digital pictures of ultrasound examinations of the neck arteries, the lower extremity arteries and veins, as well as peripheral blood pressure measurements. The participants comment on each case and reply via the Internet. Individual answers can be given from several persons at each participating clinic. The expert group provided

the material and evaluated the answers. Scores from 1-3 were given.

Results

Four schemes have been distributed. Answers from 99-134 persons from 21-23 clinics have been registered in each scheme. The individual scores have varied depending on the difficulty of the cases. All participants received their individual scores, comments, and a summary of all results. Results and future activities were discussed at the first Users meeting.

Conclusion

EQA schemes for Clinical Physiology/vascular Diagnosis have now been established. Two schemes will be distributed each year and annual users meetings will be held.

Poster Abstract for the EQALM meeting, Geneva, September 11-14, 2006

MDMA: External Assessment Results from Immunological Tests only detecting Amphetamines and/or Methamphetamine

*Vasey S**, *Deom A***, ***Quality Control Center Switzerland, 1225 Chêne-Bourg, Switzerland. *E-mail: sylvie.vasey@hcuge.ch*

The detection of Methylenedioxy-N-methylamphetamine (MDMA, "Ecstasy") by immunological tests raises many questions about cross reaction between this molecule and Amphetamines (AMP) and Methamphetamine (mAMP). Our objectives are to show that any immunological test result has to be considered as "preliminary" until a chromatographic confirmation has been performed.

We organised a proficiency testing survey for the detection of AMP and mAMP with a sample containing only MDMA. Methods, survey conditions and results are given.

According to both cut-off and cross reactivity peculiar to each reagent used, results

were correct when AMP and mAMP were reported as "detected" or "not detected". Probable causes of error on false results are presented.

It is important to know the cut-off value of the test used at the laboratory as well as the possible cross reactivities. Moreover, a performance evaluation is more specific if compared to cut-off rather than compared to reagent.

Consequently, training of people carrying out analytical tests is critical. In light of the increasing diversity of available tests on the market, external assessment surveys proposed in Switzerland offer an excellent opportunity for this education.