Review

An overview of the European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM)

Anne Stavelin*[1], Xavier Albe[2], Piet Meijer[3], Erika Sarkany[4], Finlay MacKenzie[5]

[1]The Norwegian Quality Improvement of Primary Care Laboratories (Noklus), Haraldsplass Deaconess Hospital, Bergen, Norway
[2]Swiss Center for Quality Control (CSCQ), Chêne-Bourg, Switzerland
[3]External quality Control for Assays and Tests with a focus on Thrombosis and Haemostasis (ECAT Foundation), Voorschoten, The Netherlands
[4]In Vitro Diagnostic Quality Control (QualiCont), Szeged, Hungary
[5]United Kingdom National External Quality Assessment Service (UK NEQAS) for Clinical Chemistry, Institute of Research and Development, University Hospitals Birmingham, UK

*Corresponding author: anne.stavelin@noklus.no

Abstract

The European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM) was founded in 1996 and currently has members from 29 European countries and 6 countries from outside Europe. EQALM provides a forum for co-operation and exchange of knowledge on quality-related matters in laboratory medicine, especially with regard to external quality assessment (EQA) programs in Europe. In addition, EQALM represent the EQA providers in laboratory medicine at European level vis-à-vis political, professional, scientific and other bodies, including patients' organisations. To this end EQALM promotes activities such as organizing meetings with scientific and practical themes for members and other interested parties, issuing scientific publications, developing EQA projects and representing laboratory medicine EQA activities within other organisations and networks. EQALM is active in scientific and educational activity in different fields such as survey frequency, haematology, haemostasis, microbiology, nomenclature, virtual microscopy, traceability, accreditation, and quality assurance of the total testing process. The aim of this paper is to give an overview of the EQALM organisation.

Key words: laboratory proficiency testing; quality assessment; laboratory medicine

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Introduction

The medical laboratories play an important role in diagnosis, treatment and follow-up of patients (1). It is important that the laboratories produce high quality test results as they often are basis for clinical decision making (2). Proper quality management is therefore essential. Medical laboratories have internal quality control procedures and participate in national and/or international external quality assessment (EQA) programs. The EQA programs should be fit-for purpose (3) and should include the total testing process; the pre-analytical, analytical and post-analytical phase (4). Many EQA organizers provides programs for all these phases but there is a wide variation in how these programs are organized. It is therefore important for the EQA organizers that there is a forum in which they can share knowledge and co-operate to constantly improve the EQA schemes.

The objective of the European Organisation for External Quality Assurance Providers in Laboratory Medicine (EQALM) is to provide a forum for co-operation and exchange of knowledge on quality-related matters, especially with regard to EQA programs in Europe; to promote the quality of laboratory medicine and the safety of patient care in general and in particular within Europe; and to represent the EQA providers in laboratory medicine at European level vis-à-vis political, profes-

sional, scientific and other bodies, including patients' organisations. To this end EQALM promotes activities such as, but not limited to, organizing meetings with scientific and practical themes for members and other interested parties, issuing scientific publications, developing EQA projects, maintaining the EQALM website, and representing laboratory medicine EQA activities within other organisations and networks. The aim of this paper is to give an overview of the EQALM organisation.

History - the foundation of EQALM

The initial meeting of European EQA organizers was conducted at the 8th European Congress of Clinical Chemistry in June 1989, Milan, Italy. Here a plan for further collaboration was established and in December of the same year, a meeting of 23 European EQA organizers was held in Brussels in conjunction with a meeting on reference methods and reference materials, organized by the European Union agency Community Bureau of Reference (BCR). This was the first meeting between the EQA organizers involved in biochemistry and endocrinology. Later on there were also meetings in haematology and microbiology. With exception of the first group, there were no long-term outcome effects from these meetings. In January 1990, the biochemistry and hormone group had started with a newsletter called "EQAnews" and with informal meetings at international and national congresses.

At the 9th European Congress of Clinical Chemistry in Cracow in 1991, Adam Uldall (Denmark) took the initiative to create three working groups (WG) on EQA related issues: 1) WG A on performance standards in EQA, 2) WG B on target values in EQA, and 3) WG C on control materials in EQA. These WGs published nine scientific papers in the European Journal of Clinical Chemistry and Laboratory Medicine (5-13). These papers are trend-setting publications in the field of clinical chemistry EQA. They were also published as the February issue of EQAnews in 2000.

The informal collaboration between European EQA organizers was formalized in 1996 in Pont à Mousson, France, having the inaugural meeting with the foundation of EQALM.

The EQALM office and executive board

EQALM is managed by an executive board of five to nine members from different EQA organisations and reflects the overall membership of EQALM. The board members are elected by the EQALM full members and are appointed for a term of three years with possibility to be re-elected for one more term. The registered office is in Geneva, Switzerland. The EQALM association is itself a legal entity and is registered with the Register of Commerce in Geneva. The structure of EQALM is shown in Figure 1.

Membership

EQA organisations can apply to be a full member (European) or non-European member if they are an impartial and non-profit EQA provider, which organizes national, regional or international EQA schemes in laboratory medicine. Individuals with an interest in EQA can become an individual member. Commercial providers of EQA in laboratory medicine or other commercial companies with an interest in this field can support EQALM as associate members. Only full European members have the right to vote at the annual General Assembly. EQALM is currently gathering 49 EQA organisations from 29 European countries and 6 countries from outside Europe (Australia, Brazil, Canada, India, Sultanate of Oman and Taiwan).

EQALM aims to represent as most as possible different analytical domains in laboratory medicine. This includes, but is not limited to, clinical chemistry, haematology, haemostasis, microbiology, hormonology, immunology, parasitology, genetics, histopathology, dermatology and urinary analysis.

EQALM Symposium

Exchange of information between EQA organisers is one of the major objectives of EQALM. Therefore, since the start in 1996, EQALM has organized annual meetings that gives members as well as non-members the opportunity to meet and exchange knowledge on EQA topics. In this way, valuable responses to EQA organisation's daily ques-

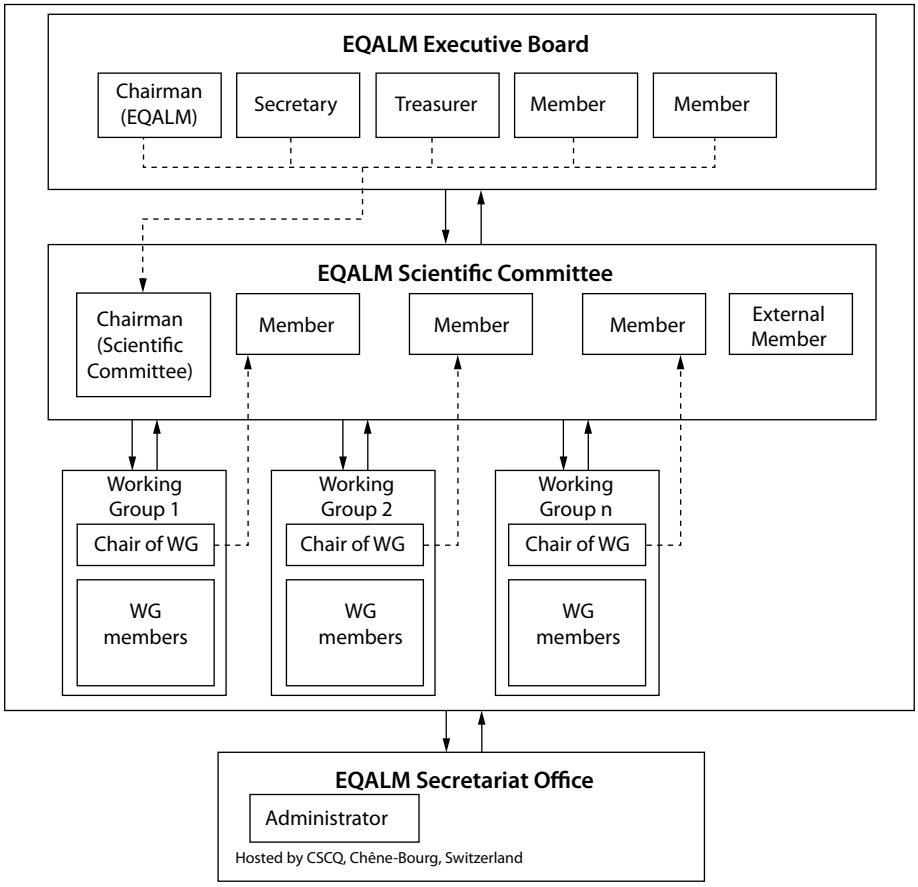

Figure 1. The structure of the EQALM organisation.

tions and practical feedback can be obtained on subjects such as implementation of the ISO 17043 standard "*Conformity assessment — General requirements for proficiency testing*" (14), harmonization of laboratory methods, or statistics. Members are encouraged to share with the other organisations its experience and developments. Most of the presentations of the former symposiums are available on the EQALM website (15). Together with the annual symposium, meetings of the working groups are organised (see below) as well as the EQALM General Assembly.

Adam Uldall Award

In 2009 the Adam Uldall award was established in order to honour the founder of EQALM. The award is given during the annual symposium and goes to a person who has spent much of his/her career pursuing better quality across laboratory medicine and who is a well-known and respected international advocate on quality. The former award winners are Jean-Claude Libeer (2009), Gunnar Nordin (2010), Andre Deom (2011), Carmen Ricos (2012), Dietmar Stockl and Linda Thienpont (2013), David Bullock (2014), Sverre Sandberg (2015) and Per Hyltoft Petersen (2016).

Working groups, scientific activities

Within the framework of EQALM several working groups are established. A working group consist of a number of EQALM members or third parties with a common interest in topics addressing scientific or educational EQA issues. The main objective is to federate the knowledge, experience and development efforts on topics which are of interest for the members. In order to improve the scientific activi-

ty of the working groups and to improve the interaction between the executive board and the working group chairs, a scientific committee was established in 2016 (Figure 1). There are currently 6 active working groups; frequency, haematology, haemostasis, microbiology, nomenclature and virtual microscopy.

Frequency

There is little published evidence of an optimal model for determining frequency of EQA surveys both in terms of distributions per year and number of samples per distribution, or on the relationship between frequency and outcomes. The Frequency working group was created as a result of a questionnaire distributed in 2008, which showed wide variation in practice even within the same speciality. The group had its first meeting in 2009 and the main objective is to review the literature and existing data from EQA providers to provide guidance on the frequency of EQA surveys. The work streams focus on: 1) whether there is evidence to determine whether greater frequency leads to improved performance, 2) gather evidence as to whether multiple samples are more effective than single or few samples and 3) ultimately provide guidance to EQA providers on evidence based models for EQA design.

Haematology

The working group on Haematology was established in 1998 and has focused on several topics over the years. They have published guidelines for setting up EQA schemes for blood smear interpretation, including staining procedure, survey preparation, statistical evaluation and reporting (16,17), and compared evaluation procedures used by EQA providers for haemoglobin and leukocyte concentration (18). Based on the results from the latter study which showed wide variation in evaluation procedures, the Haematology working group decided to propose state-of-the-art performance specifications for automated blood cell counting. In 2013, more than 422,000 data from different EQA providers was collected and after 3 years of statistical analysis and discussions, the working group is now able to proposed concentration-dependent performance specifications for each biological parameter (publication in preparation).

The Haematology working group has also developed a post-analytical EQA scheme where the participating laboratories received a case history with questions about the blood cell counts and graphs obtained with their type of haematology equipment. The objective was to assess the laboratories' ability to adequately analyse pathological rates and alarms, to decide what additional analyses that needs to be performed in different clinical situations, and to make the necessary arrangements to inform the clinician. The scheme showed that the answers were notably depended on the participants' education level, which differs between countries. This post-analytical EQA scheme was organised by Noklus in the period 2010 – 2014 in which more than 10 European countries participated. Current projects in the working group of Haematology are harmonization of evaluation criteria for manual blood cell counting (including commentaries on morphology and diagnosis) used in European EQA schemes, and to investigate the European practice of assessing performance in the haemoglobinopathies.

Haemostasis

The working group of Haemostasis was created in 2004 and focuses on specific matters related to EQA in blood coagulation. As an example, it has been investigated which countries provide EQA for point-of-care (POC) international normalized ratio (INR) and how these schemes are organized (19). This study showed that only 12 EQA organizers from 9 countries provided an EQA for POC INR testing and that there was a wide variation in how these schemes were organized (e.g. survey frequency, acceptability limits and type of control materials used). Another project is the stability of reconstituted quality control samples used in EQA survey for blood coagulation. The report of this project is available at the EQALM website (15). In 2014, the working group of Haemostasis performed a survey of pre-analytical routines for coagulation testing among 28 European countries (662 laboratories). The survey showed that there were different routines both between and within

countries, and that there is a need for harmonisation (publication in preparation). Because EQA organisations from all over Europe participate in this working group it has been able to set up a comparative study on between-laboratory variation and the effect of local calibration for the measurement of INR based on the Quick and Owren test principles. In this study it was shown that the between laboratory variation is significant lower for Owren methods in comparison to Quick methods, but this difference disappear when users of Quick methods perform local calibration of their reagent (publication in preparation). The working group of Haemostasis investigated also the differences in the statistical methods used by different EQA organisations and the effect on the assessment of participant performance (publication in preparation). Currently the working group is focussing on quality assurance for POC devices.

Microbiology

The Microbiology working group has performed several projects and surveys since the start in 2003. An early survey on Microbiology EQA practices found that only a limited number of EQA organisers produced their own EQA samples, but those who did performed some kind of homogeneity and stability testing before distributing the samples, which differed from one organizer to another. Importantly, this survey was done prior to the publication and general adoption of ISO 17043 (14); practices may therefore be different today. Other findings were that the majority of laboratories use antimicrobial susceptibility guidelines produced by either the Clinical and Laboratory Standards Institute (CLSI) (20) or the European Committee on Antimicrobial Susceptibility Testing (EUCAST) (21) with country or regional guideline preferences not based on accreditation requirement. EQA organizers providing samples for blood parasite analysis reported they prepared their blood smear samples manually. Reports and presentations from the different projects are available on the EQALM web site (15). A study from 2008 comparing the results from an EQA concerning *Streptococcus pyogenes* from Canada and Belgium showed that the microbiology laboratories performed well in both countries but there were differences between laboratories in treating EQA samples and reporting results (22). Based on the results of a more current survey performed in 2015 on on-going and future objectives for the EQALM Microbiology working group (15), the EQA organizers (N = 29) identified three major objectives: 1) present new or novel activities or projects that might enhance microbiology EQA, 2) discuss topics, such as changing international regulations, that could potentially impact on the delivery of microbiology EQA products and/or services, and 3) discuss possible shared microbiology EQA projects (e.g. on sample commutability and antimicrobial multi-resistance in bacteria). Plans for new projects in the domain of susceptibility testing and antibiotic resistance are in development.

Nomenclature

This working group was formed in 2003 with the objective of creating a database, which could be used by all EQALM members to assist in uniquely identifying analytical systems that were used across Europe. Though on the surface this might seem to be a straightforward task, the main difficulty was that many products were re-badged by local distributors and that often the same product could have subtly different versions that were on sale in different countries. The rationale for the database was to ensure comparability of coding by EQA Schemes to assist in the vigilance function that the *In Vitro* Diagnostic (IVD) Directive 98/79/EC required. Essentially this was to make sure that when the performance of a product or instrument was highlighted as having potential problems, all EQALM members would be able to assess if that product was causing problems in their jurisdiction irrespective of what name the instrument was sold under. The group has tried to widen its scope from its Haematology starting point into Chemistry where the same issues exist, but the situation is more complex in the way that combinations of instruments, reagents and calibrators are used by laboratories.

Virtual microscopy

The main objectives of this working group is to promote the use of virtual microscopy (VM) in the EQA domain and to establish a framework for the

collaboration and exchanges between EQALM members. The VM working group had its first meeting in 2006. The first action was to identify the EQA domains in laboratory medicine, which could benefit from this new technology, and to identify the EQA providers of VM schemes. The results showed that the EQA domains mainly concerned histopathology and haematology on blood smear and bone marrow but an interest was also identified for urine analysis and parasitology. At that time, EQA VM schemes were proposed by eight organisations using heterogeneous platforms and software making exchanges between organisations very difficult.

The current activities of this group are focused on the creation of an EQALM VM Sharing Platform for sharing VM resources (e.g. scanning, virtual slides, educational contents, surveys, evaluation, and expertise) contributed by EQALM members in a way that is available, beneficial for all, and compatible with the existing VM solutions. It is based on web technologies for an easy and effective use even with limited computing resources. The establishment of standards for resources and exchange protocols is also key point for the success of this project. The progress of the work of the VM working group demonstrates the catalytic and supporting role of EQALM.

Cooperation with other organisations

EQALM is active in different networks and work together with other organisations. In the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), EQALM has two representatives in the working group on pre-analytical phase (WG-PRE) and post-analytical phase (WG-POST). The WG-POST is a joint working group between EQALM and EFLM and has recently published two papers. One of the papers was an international study on how laboratories handle and evaluate patient samples after detecting an unexpected Activated Partial Thromboplastin Time (APTT) prolongation (23). The study showed that many laboratory professionals were not able to support clinicians appropriately in the interpretation of an unexpected prolonged APTT. The second paper investigated if D-dimer is used according to clinical algorithms in the diagnostic work-up of patients with suspicion of venous thromboembolism (24). It showed that adherence to recommendations for the diagnosis of venous thromboembolism needs improvement.

Further, EQALM is an associate member of Eurachem, EuroLab and the European Accreditation (EEE) and has three representatives in the Eurachem Proficiency Testing working group and in the EEE Proficiency Testing Working Group "Proficiency Testing in Accreditation". All EQALM representatives must give a brief annual written activity report to the executive board.

EQALM also co-operate with the Joint Committee for Traceability in Laboratory Medicine (JCTLM) which has one working group on traceability and one on reference materials, procedures and measurement laboratories (the JCTLM Database working group), and has also participated in the harmonization working group of the American Association for Clinical Chemistry (AACC) which resulted in a roadmap of harmonization of clinical laboratory measurement procedures (25).

Conclusion

The EQALM organisation provides an important forum for EQA providers in exchanging knowledge and experience on quality matters in the field of laboratory medicine in Europe. Important scientific and educational activity are performed in different fields such as survey frequency, haematology, haemostasis, microbiology, nomenclature, virtual microscopy, traceability, accreditation, and quality assurance of the total testing process. One important future question is whether EQALM should expand out of Europe and become a worldwide organisation.

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Potential conflict of interest

None declared.

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