S0 - Pre-congress CSMBLM symposium: External Quality Assessment for medical-biochemistry laboratories in Croatia

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Interlaboratory comparisons in laboratory medicine - implementing the requirements of HRN EN ISO/IEC

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The Croatian Society for Medical Biochemistry and Laboratory Medicine has a very long tradition in organizing external quality assessments (EQA) for medical biochemistry laboratories, therefore, in 2012, CROQALM – the Croatian centre for quality assessment in laboratory medicine was established. One of the main tasks of CROQALM is to apply the requirements of the international and European standard for accreditation of proficiency testing providers adopted in the Republic of Croatia as the Croatian Standard HRN EN ISO/IEC 17043 "Conformity assessment – General requirements for proficiency testing". Standard represents internationally harmonised "general requirements" for the accreditation of proficiency testing (PT) providers and requires defining the scope and specifying the requirements concerning the planning, design, testing, distribution, evaluation and reporting of PT/EQA results. In order to support implementation of ISO 17043, Croatian Accreditation Agency, as a national accreditation body, has established the Working Group for Interlaboratory Comparisons which works on PT/EQA regulations and guidelines. CROQALM subcontracts with commercial suppliers providing commutable, stable and homogenous material of high quality for various rounds and conducts schemes for the clinical chemistry, laboratory haematology and coagulation, and in the post-analytical phase, evaluation of laboratory reports. For the purpose of professional supervision, the Croatian Chamber of Medical Biochemists requests to be directly informed on laboratory participation in EQA schemes and achieved results. Therefore, according to the requirement of ISO 17043 regarding the confidentiality of all information supplied by a participant to the PT/EQA provider, CROQALM inform the participants of this action, in advance and in writing.

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Statistical evaluation of proficiency testing scheme results in laboratory medicine

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The primary aim of proficiency testing is to allow laboratories to monitor and improve the quality of their routine measurements. One of the basic elements in every proficiency testing is the evaluation of the performance (score) of each participant. The most common scoring system is the z-score. Two critical steps in performance evaluation are: specifying the assigned value and setting the standard deviation for proficiency assessment. These influence the scores that the participant receives directly and therefore also the way they interpret their performance in the scheme. There are a number of different approaches to obtaining them, each with its advantages and disadvantages. Preferred statistical techniques have been described in the ISO 13528, although other valid approaches can be used (ISO 5725, median and NIQR, fit-for purpose criterion) as long as they are statistically valid and are fully described to participants. Special attention should be paid on data distribution, like presence of outliers and data asymmetry and number of the participants.

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Benefits of the new EQA software for medical laboratories in Croatia

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A significant breakthrough in the acceptance and processing of results of Croatian external quality assessment scheme (EQAS) occurred in 2011 with the introduction of a new software: INlab2*QALM– application for quality assessment in laboratory medicine, developed by Croatian software company, IN2 Ltd. Software was accompanied by illustrative and comprehensive easy-to-use handbooks. Through software module for the implementation of Web access for participants great advantage was achieved in the acceptance of results that was fully implemented through an electronic form, unlike the paper registers used in previous years. Once entered, the settings for the methods, analyzers and reagents will remain available in each subsequent cycle until the participant does not modify them. Fast processing of results is provided through the software module for the administrator and scheme coordinators. Complete data processing can be finished within 2 weeks which is a remarkable improvement over the manual entry of results in previous software. With a very open cooperation among participants and EQAS administrator two cycles of EQAS were completed in 2011 using INlab2*QALM application. The success was very high, 98% of laboratories in cycle 2/2011 and 99% of laboratories in cycle 3/2011 have successfully uploaded their results through a web module and received online certificates of participation. The new functionalities were introduced in the web module in the beginning of 2012 - online application for participation in the EQAS followed by invoices and notifications to users. All laboratories (100%) managed to register for 2012. through web application module.

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Evaluating EQA results in general medical biochemistry - standardization of creatinine measurements

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The standardization of creatinine measurement is critical to promote early detection and management of chronic kidney disease and is mandatory before the routine implementation of the estimated glomerular filtration rate in clinical practice. Actual results for serum creatinine measurement in Croatia were compared with the current recommendations based on creatinine measurements traceable to isotope dilution mass spectrometry (IDMS) reference method within the national External Quality Assessment (EQA) Scheme conducted through Croatian Centre for Quality Assessment in Laboratory Medicine (CROQALM). The results of the cycle 2/2011, 3/2011 and 1/2012 from 187 medical biochemistry laboratories were evaluated. The uncompensated kinetic Jaffe method traceable to National Institute of Standards and Technology (NIST) Standard Reference Material (SRM) 909b level 2 is most widely used in medical biochemistry laboratories (80%, 73% and 68% of participants in the survey 2/2011, 3/2011 and 1/2012, respectively). Only 17%, 24% and 29% laboratories in the survey 2/2011, 3/2011 and 1/2012 used standardized creatinine methods traceable to the IDMS method and SRM 967. The interlaboratory SD for compensated kinetic Jaffe method group, traceable to the IDMS method and SRM 967 was very high: 12.1 µmol/L at a creatinine concentration of 98.8 µmol/L (12%), 19.3 µmol/L at a creatinine concentration of 204 µmol/L (9%) and 28.6 µmol/L at a creatinine concentration of 495.8 µmol/L (6%). One of the main goals of the Croatian EQA program in 2012 is to promote laboratories to implement standardized method and reduce the inter-laboratory variability which affects the total error for creatinine measurement.

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Evaluating participant performance in hormone analysis (TSH)

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Background: TSH measurement has a critical role for detecting thyroid dysfunction. Although the immunoassays for TSH had remarkably improved, their reliability depends on differences in analytical sensibility and performance.

Materials and methods: Croatian EQA results for TSH were analysed for 2008-2011 period. Control samples used for EQA were commercial control materials. Results were evaluated according to analytical methods/instruments except when the number of participants was less than 7 in particular analytical groups. Overall analytical performance was evaluated according to the biological variation.

Results: There is constant increase in number of participants for TSH in Croatian EQA programme from 2008 to 2011 (45, 56, 59 and 62; respectively). Unfortunately, the number of different analytical methods according to manufacturer stayed high (12 in average). The application of defined quality specifications was possible for only 2 analytical methods in 2008-2009 and 3 in 2010-2011. This is equivalent to 25/45 (56%) of laboratories evaluated for TSH according to analytical method in 2008, 29/56 (52%) in 2009, 39/59 (66%) in 2010 and 41/62 (66%) in 2012, respectively. Evaluation for other participants was not method specific due to statistically inadequate number of reported results. EQA results for TSH showed overall variability (all analytical methods/instruments, expressed as coefficient of variation) to be 13.7% in 2008; 14.2% in 2009; 12.3% in 2010 and 14.5% in 2011.

Conclusions: Significant heterogeneity of immunochemical analytical methods and statistically inadequate number of results for most of them resulted in relatively high but still acceptable overall variability in Croatian EQA surveys for TSH.

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The role of EQA in implementation of the HbA1c global harmonization in Croatia

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Harmonization of the HbA1c results has been an ultimate challenge for health-care professionals involved in diabetes care worldwide. Long-term activities in the field resulted into the Global Consensus on the Standardization of HbA1c (2010), with dual reporting units: SI (mmol/mol) and NGSP (%) and IFCC reference system as a standard.

In Croatia, a dedicated module for HbA1c was established within External Quality Assessment Scheme (EQAS) under the auspices of the Croatian Society of Medical Biochemists in 2005, with a primary goal to improve analytical quality and provide data for inter-laboratory comparisons. After a total of 13 EQAS-cycles, HbA1c testing in Croatia considerably improved in both quantity and within-laboratory precision (N = 53 *vs*. N = 27 laboratories, and CV = 5.4% *vs*. CV = 9.52% in 2012 and 2005, respectively).

A pilot-scheme for dual reporting, in accord to the Global Consensus, was organized within regular EQAS-cycle in December 2010. Participating laboratories (N = 48) were provided with a modified result-form, covering both units, and a short explanation of the Global Consensus goals in Croatian language, together with HbA1c conversion table. Results of a pilot-scheme revealed an excellent compliance to the cycle-specific instructions, with 47/48 laboratories returning their results in dual reporting system. Results from the further cycles in 2011-2012 showed an increase in the number of participants and slightly reduced compliance as regards reporting units, indicating necessity for further education on the subject.

Our results reveal a significant improvement in availability and analytical quality and identify EQAS as a valuable tool in harmonization of HbA1c testing in Croatia.

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Postanalytical phase as a modul in EQA – experiences in laboratory haematology

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The Committee for External Quality Assessment of Croatian Society of Medical Biochemists was included in the three projects in the field of laboratory haematology, coordinated by the European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM). One was in the preanalytical phase regarding the stability of the samples for the preparation of blood films for the morphological analysis and two in the postanalytical phase.

The postanalytical phase projects were conducted internationally including 151 laboratories in 2010 and 318 laboratories in 2011. The goal was to examine the synchronization of evaluation of the haematological results on 4 analytical systems (Sysmex, Advia, Cell-Dyn i ABX) in 12 European countries. The original complete blood count (CBC) of the same clinical case from these haematological analyzers was presented. Results from additional analyses, communicating with medical doctors and various laboratory reports were obtained by asking all participants the same questions.

The obtained results are presented statistically according to the type of analyzer and to the country that has participated. These show the CBC results depend on the type and performance characteristics of the analytic system; management of the analytic system and the degree of personnel education.

There are variations between laboratories in the way they operate and perform standard haematological procedures, particularly regarding analysis and interpretation of the obtained results and taking corrective actions. We have noticed differences which depend upon geographical position of the participant laboratory, and differences that depend upon degree of education and organization of health system in each country.