

## THE SCHEMES OF EXTERNAL QUALITY CONTROL IN LABORATORY MEDICINE IN THE BALKANS

### ŠEME SPOLJAŠNJE KONTROLE KVALITETA U LABORATORIJSKOJ MEDICINI BALKANSKIH ZEMALJA

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**Summary:** There are many differences between the national External Quality Control Schemes all around Europe, but the most important ones are certainly those between the countries of the Balkan region. These differences are due to these countries' different political and financial development, as well as to their tradition and the development of clinical chemistry science in each one. Therefore, there are Balkan countries with very developed EQAS and others where there is no such a scheme. Undoubtedly, the scientific community in these countries wants to develop EQAS despite of the financial and other difficulties.

**Key words:** Balkans, Clinical Chemistry, External Quality Assurance, EQAS

### Introduction

The External Quality Control appeared firstly in US a few years after the Second World War. It is a statistical methodology whose purpose is to assure the best reproducibility and accuracy of laboratory results. From the statistical point of view, it is based almost exclusively on the interlaboratory comparisons of the results of a large number of similar laboratories and equipment.

Now it is considered as a mandatory methodology for the quality assurance of the laboratory results all around the world. Although the Schemes of External Quality Control (EQAS) are very common in almost all the developed countries, there are many differences between them. These differences have to do with the countries' legislation about EQAS and how their EQAS works scientifically. The place in Europe where there are largest differences in the national EQAS is certainly the Balkan region.

**Kratak sadržaj:** Nacionalne šeme spoljašnje kontrole kvaliteta razlikuju se širom Evrope, ali najvažnije su svakako razlike koje postoje između balkanskih zemalja. Uzrok tome leži u njihovom različitom političkom i finansijskom razvoju, kao i različitim tradicijama i razvoju kliničke hemije u svakoj od njih. Zbog toga ima balkanskih država sa veoma razvijenim šemama, i onih u kojima takve šeme ne postoje. Naučne zajednice u tim zemljama bez sumnje priželjkuju stvaranje šema uprkos finansijskim ili drugim poteškoćama.

**Ključne reči:** Balkan, klinička hemija, osiguranje kvaliteta, šeme spoljašnje kontrole kvaliteta

In the 14<sup>th</sup> Balkan Meeting of Clinical Chemistry (Sofia 27–30 September 2006) the following six countries participated: Greece, Turkey, Albania, Former Yugoslav Republic of Macedonia (F.Y.R.O.M.), Romania, Serbia. The new members of BCLF, Montenegro and Bosnia&Herzegovina, were not represented in the 14<sup>th</sup> Balkan Meeting.

During the meeting the representatives of the six Balkan countries presented the External Quality Control Schemes (EQAS) of their countries. They spoke exclusively about their national schemes (where they exist) and not about any other private or international EQAS.

Concisely, the representatives of each Balkan Country reported the following:

**Albania.** Albania does not have any national scheme of external quality control. However, some laboratories participate in international programs.

**Bosnia&Herzegovina.** In Bosnia&Herzegovina there exists a national scheme of external quality control since 1996. Organizers are the Society of Medical Biochemistry of Bosnia-Herzegovina and the In-

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stitution of Clinical Chemistry and Biochemistry of the University of Sarajevo. In 2006, 49 public biochemical laboratories from the Croatian-Muslim Federation participated in that scheme. The participation is not mandatory. The organizers send to the participating laboratories lyophilized sera and they determine 24 parameters of clinical chemistry (i.e. glucose, urea). The target values of each parameter come from the company which made the serum. The control limits are based on the biological variations as they have been published by the Spanish Society of Clinical Chemistry.

**Bulgaria.** Bulgaria has the most complete scheme of external quality control in the Balkans. The national program is named BEQAS (Bulgarian External Quality Assessment Scheme in Clinical Laboratory) and is directed by the Bulgarian Society of Clinical Laboratories and the department of Laboratory Medicine of the Medical School of Sofia. The program has been working for 12 years and it is somehow mandatory for all the public and private laboratories. That happens because public and private insurance organizations accept laboratory results, preferably from the laboratories that participate in the national EQAS. BEQAS deals with many fields of laboratory medicine such as clinical chemistry, haematology, coagulation, hormones, tumor markers, urine tests, HbA1c and blood gases. The interval of time between successive postings of control samples varies per field. So the clinical chemistry's control samples are being posted every month, the hormones' samples every four months and the microbiological samples two times per year.

**F.Y.R.O.M.** The Former Yugoslav Republic of Macedonia had its own national EQAS which was regulated and ruled by the Biochemical Laboratory of the University Hospital of F.Y.R.O.M. in Skopje. Due to financial problems, that program ceased its operation in 2001. Nowadays, a lot of laboratories participate in commercial schemes such as RIQAS, EQAS and others.

**Greece.** Greece has its own national EQAS which is administered mainly by the Greek Society of Clinical Chemistry and Medical Biochemistry (GSCC-CB). Its name is »Greek External Quality Assessment Scheme« (GEQAS). 325 biochemical laboratories participate in GEQAS (280 from Greece and 45 from Cyprus). Private and public laboratories participate as well. The Greek representative from GEQAS described its work and gave information about its history and perspectives. GEQAS deals with 23 biochemical analytes (i.e. glucose, urea). Recently, GEQAS introduced, in collaboration with the European Reference Laboratory for glycohemoglobin, a pilot scheme for the external QC of the glycated hemoglobin (HbA1c). Greece is one of the Balkan countries where the participation in EQAS is not mandatory. GEQAS sends

two different sets of control sera to each participating laboratory every two months.

In the field of haematology there is another national EQAS which is run by the Greek Haematology Society. At present, 120 Haematology laboratories participate in it.

**Montenegro.** The laboratories of Montenegro participated in Serbia's EQAS up to May 2006 when Montenegro quit the Federation of Serbia and Montenegro.

**Romania.** Romania has the most ambitious scheme of EQAS. From 1997, Romania has had a national non-profit organization of external quality assurance, the RoEQALM (Romanian Society for External Quality Assurance in Laboratory Medicine). The RoEQALM has been certified with ISO 9001 and carries out educational programs for quality, publishes relative directives (it has translated the EC4 criteria) translated and organizes, in collaboration with the Romanian Society of Laboratory Medicine, the national scheme of external quality control, the EQCP (External Quality Control Program). The participation in the EQCP is not mandatory. In 2006, 270 private and public laboratories participated in EQCP. Romania like Greece uses statistical control limits. The participants receive lyophilized control sera from EQCP every 3 months. Nevertheless, RoEQALM offers services of external quality control in many different laboratory fields such as clinical chemistry, haematology, coagulation, bacteriology and parasitology.

**Serbia.** Serbia has its own national scheme of EQAS that is named SNEQAS—Medical Biochemistry (Serbian National External Quality Assessment Scheme—Medical Biochemistry). The program is directed by the »Committee of Control of Quality and Accreditation«, the members of which belong to the Society of Medical Biochemistry of Serbia and to the government owned »Institute of Medical Biochemistry«. The program functions under the aegis of the Ministry of Health of Serbia and it is mandatory for all the government owned laboratories. Among the participants are also laboratories from the Serbian Republic of the Federation of Bosnia&Herzegovina. In 2006, 295 laboratories participated in the program, were analyzing 29 parameters of classic clinical chemistry every 6 months.

**Turkey.** Turkey does not have a mandatory national EQAS yet. However, the Ministry of Health has recently started to organize such a scheme. For now there are two independent private »national« EQAS which are running in about 100 laboratories. The Ministry of Health encourages the participation of the public laboratories in private EQAS such as CAP, Biorad, Randox etc.

In summary, it is obvious that with the exception of Bulgaria, whose EQAS seems to be equivalent to the corresponding schemes of western European coun-

tries, all the remaining countries have serious problems with the organization of their national EQAS.

The economic problems are the main cause why such programs do not function in some countries (F.Y.R.O.M., Albania), or are financed insufficiently (Serbia). Only in two countries the participation in the national EQAS is more or less mandatory (Serbia and Bulgaria). In Greece and maybe some other countries the reason why EQAS is not mandatory is rather the lack of political will.

The participation of the Balkans in the schemes of external quality control has a mainly scientific and educational role. Indeed, even in countries where the participation is mandatory (Serbia, Bulgaria) there are no penalties in the case of a laboratory giving results out of control limits. In such cases the administrators

give advice and in order the participants to correct their results.

The way of calculating the acceptable limits round the target value is also interesting. While in all programs the target values are calculated statistically (consensus mean of the laboratory values) their acceptable limits of variation elsewhere are calculated statistically (Greece) and elsewhere from tables of biological limits (Serbia, Romania, Bulgaria, Bosnia& Herzegovina, Turkey). Bulgaria's EQAS also uses the American limits of allowable total errors (CLIA).

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