

EDUCATION AND TRAINING IN CLINICAL CHEMISTRY IN THE EU: LESSONS FROM THE EXPERIENCES

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Summary: This paper describes the history of FESCC (Forum of the European Societies of Clinical Chemistry and Laboratory Medicine), the actual fields of major activities and the key issues in Europe. The mission of FESCC is to support and promote clinical chemistry in Europe, to aid interactions with IFCC (International Federation of Clinical Chemistry), to develop education and quality in the discipline and to encourage young scientists to take an active role in these activities. The total quality systems in medical and clinical laboratories and accreditation of these laboratories is gaining more and more interest. Laboratory specialists are confronted with a new way of thinking concerning the management and the daily practice of their laboratories. Particularly in the European Union (EU), harmonization of criteria for quality systems is desirable. The freedom of movement and goods within the EU has a large impact for the member states. FESCC launched surveys in Europe on accreditation of medical laboratories and training with special attentions to postgraduate education of the profession. A second survey was launched to gather more information about the managerial situation of the specialists in clinical chemistry in Europe. The harmonization of the profession is one of the challenges for the European specialists in clinical chemistry and for FESCC a major task. Factors defining the future of laboratory medicine are treated.

Key words: IFCC, FESCC, clinical chemistry and laboratory medicine, EU (European Union), Europe, accreditation, education, congresses

FESCC: Serving Clinical Care and Laboratory Medicine in Europe

A discussion is open on the major aspects of education and training in clinical chemistry in Europe reviewing FESCC organisations, activities and future plans and to conclude with lessons from the experiences.

FESCC is the European branch of IFCC and contains 35 countries according to WHO. FESCC is a Forum (Federation) of the national societies, which are concerned with clinical chemistry, and which are members of IFCC. IFCC (International Federation of clinical chemistry and laboratory medicine) is the world organisation of clinical chemistry and is subdivided in 4 regions Asia, Arabia, Europe and Latin America. Between FESCC and IFCC there is a direct link via the different divisions as conference and con-

gress divisions, the scientific and education and management divisions and the communication and publication division. The FESCC vision statement should provide European leadership in clinical chemistry and clinical laboratory medicine to national professional societies, which are full members of IFCC, to the diagnostic industry and to governmental and non-governmental organisations in order to serve the public interest in health care. FESCC mission is to support and promote laboratory medicine in Europe, to aid communication between IFCC and the National Societies, to promote education and quality, and to encourage young European scientist to take an active role and part in the above described activities. The major items of FESCC are described in the strategic plan of 2003–2005 and contain the progress of clinical chemistry and laboratory medicine in science and in the profession, promotion of education and training, and organisation and total quality management of laboratory medicine accreditation. There is a great interest in the profession harmonisation and regulation by law in the European Union and there is also a growing effort in cooperation of the European Societies in Laboratory Medicine.

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Efforts are going on for organizations of international courses and also for exchanges between European subregions. The key strategic issues are: identifying specific European problems, identifying specific sub regional areas of co-operation, improving training and increasing co-operation with other organisations.

FESCC reorganises Europe in different European sub regions. The major group is the European Union (EU) organized in an autonomous FESCC subgroup EC4 (European Communities Confederation of Clinical Chemistry and Laboratory Medicine) who promote harmonization of practice and scientific quality across the EU countries. The political entity of the European Union and the regulations and legislation coming forth from that, makes EC4 a valuable organisation of clinical chemistry in the region. The co-operation is also important in view of the extension of the European Union. A large number of countries are candidate members. Harmonization of the profession via registration will prove to be important. There exists a close co-operation between FESCC and EC4 towards other international bodies. FESCC and EC4 have a joint representative in the European co-operation for accreditation. Accreditation is a very important issue having a major impact on the functioning of laboratories. FESCC represent IFCC by the EC4-FESCC working group on accreditation in the relevant CEN working groups. Also towards the European Diagnostic Manufacturers Association (EDMA) FESCC and EC4 have the same strategy. The co-operation with industry becomes more and more important particularly with respect to the harmonization of laboratory data and the impact of the In Vitro Diagnostics Directive. FESCC recognize the importance of influence on and control from the profession on the developments regarding reference systems. The desired analytical performance of instruments and methods should be able to adapt undesired performance of instruments. FESCC has contacts with the European Commission (EC) and plays an important role with EDMA in order to come to one voice on the European theatre. FESCC continues its efforts to work together with WHO to realize former stated items.

Also the co-operation with the organisation of the biopathologists section of UEMS needs joint attention.

We have further the subgroups from the Balkan, the Baltic, North Europe with the Scandinavian countries, East Europe with Russia, Ukraine and Belarus, and finally the Alps-Adrian group.

FESCC supports activities started by sister societies and extending to an European level. Prof Grünert (Germany) and Prof D. Vonderschmitt (Switzerland) have been working together with China for several years. We had a first congress in Florence (1999) and a second in Shanghai (2001). On the General Assembly a proposal was submitted and accepted to

continue this cooperation under the auspices of FESCC as a »Federation of Chinese and European Societies of Laboratory Medicine«. It is our objective to establish a joint venture for exchange and collaboration. A third meeting in Barcelona (2003) was postponed due to the Sars epidemic and should be replaced in the near future.

The main forum of FESCC

The main act of FESCC for the activities is the *European Congresses of Clinical and Laboratory Medicine*, called *Euromedlab*. It is true, the European congress of clinical chemistry every two years is in fact the FESCC congress. Following a successful discussion with IFCC in Dubrovnik, we dare say that FESCC has become more and more important as to the European activities and organizes with success socially as well as scientifically important *Euromedlab* meetings in Praha (2001) and Barcelona (2003). FESCC is the bond, the cement between all European national societies and the expression of it on an European level. Two other important *Euromedlab* meetings are already fixed in 2005 (Glasgow) and in 2007 (Amsterdam). The aim of FESCC is to activate, to harmonize, to join, to work together for the quality of the profession and to defend the role of laboratory medicine in health care.

Training and education in laboratory medicine is a major task for FESCC. Progress in Laboratory science is largely the result of contributions by scientists with an adequate education and specialisation in the field. Clinical laboratory science has developed on a broad front throughout the European Community, resulting in significant differences in what constitutes a national clinical chemistry service in each state. One of the main tasks of education in laboratory medicine involves bridging the gap between rapidly developing laboratory science and technology and the growing knowledge on characteristics of disease. To ensure freedom of movement in the European Union for employment there is a need for harmonization of training. National diplomas are not automatically recognised, therefore common standards of competence and national diplomas which meet these criteria were developed and accepted by the National Societies of Clinical Chemistry and Laboratory Medicine and described in the EC4 syllabus for post graduate training in clinical chemistry. Registration as »European clinical chemist« is one way for harmonisation of the profession.

FESCC play an important role in **education, exchanges and implementation of new developed diagnostic techniques and diseases**. In collaboration with the Croatian Society of Medical Biochemists we started our annual meetings on continuous post graduate courses in clinical chemistry at the »Interuniversity Centre« of Dubrovnik. Three

important fields of diseases were treated »New trends in classification, monitoring and management of Diabetes Mellitus« (2001), »New trends in classification, monitoring and management of Cardiovascular diseases« (2002) and »Atherosclerosis and Cerebrovascular-Diseases« (2003).

Other very fundamental questions about the essence of our profession, however, need our attention. The »raison d'être« (reason of existence) of Laboratory Medicine is approached and judged on the basis of the impact of the flow of laboratory data on the clinical data. The complexity of the healthcare environment and the ever-expanding array of available laboratory tests will inevitably increase the need for greater integration between clinical information and laboratory data. Our impact on the medical environment of the future will not only to maintain the highest quality of data generated in our labs, but rather to maximize the influence of laboratory results on patient management. It is difficult to predict the future, but that does not mean that we are not in the possibility to prepare for it. Taking all the comments above into account you will feel the need to have a house for Clinical Chemistry in Europe where we can meet and discuss our common interests and differences in order to further develop our basic mission: »Serving Clinical Care and Laboratory Medicine in Europe for the benefit of our patients«. Therefore we started discussions with the Charles University of Prague and signed an agreement on the »**Interuniversity Co-operation The Charles University Prague and FESCC**« Its primary aims are to advance science and medicine in general, to hold scientific and educational events, to co-ordinate activities in the field in Europe and to seek to further European co-operation and harmonisation. In order to encourage and develop the scientific and cultural co-operation of both institutions educational actions and scientific events are organised. Special attention should be given to the organisation of post graduate courses. The house in Prague »Education and training centre for Laboratory Medicine – FESCC – The Carolinum Charles University of Prague« organises a first discussion forum on postgraduate education of clinical chemistry in Europe and the centre is also open for the promotion of the profession.

By each of the subgroups of FESCC regional meetings are organised under the auspices of FESCC and are in functions of the local needs. The activities with the regions are increasing and bring them closer to other National Societies. Special meetings of the Balkan were organised and we succeeded to exchange together with the region of eastern Europe-Russia (2001). The National Days of Laboratory Medicine in Russia together with Bellarius and Ukraine were under the auspices of FESCC. The meeting took place in the light of the association of our sister societies in eastern Europe with Western and Central Europe. With the Slovenian Association for Clinical Chemistry two postgraduate courses were organised

and were entitled »Quality and Accreditation of Medical Laboratories: state of art in Slovenia and harmonization and projects in the European Union«. Similar meetings were organised with the Nordic Scandinavian countries and with the Baltic and Alps-Adria association.

European Regulations as a Basis for Total Quality Management.

Accreditation in the EU: FESCC Survey

During the past 10 years many activities have taken place in the field of quality systems and accreditation in medical laboratories. Each country in Europe has a slightly different approach. FESCC started in 1993 in Nice a working group on accreditation of the EU, and the European Communities Confederation of Clinical Chemistry (EC4) tried to support harmonization of these efforts (1). For this purpose, they edited the Essential Criteria for quality systems of medical laboratories and supported the forthcoming International ISO standard »Quality management for the medical laboratory«. At this moment a model quality manual is ready and can be used as reference standard. The next items are setting up criteria for auditing the quality system and criteria for the accreditation process. The forthcoming international standard ISO 15189, voted and accepted in 2003 by CEN as a European Standard (EN) and officially published in 2004, is a document of great importance for the development of quality systems and accreditation of medical/clinical laboratories (2). For the first time there will be an internationally recognized standard designed especially for the accreditation of medical labs. The document takes into account the special requirements imposed by the medical environment and by the essential contribution of the medical laboratory service to patient care. Very important, it recognizes that medical laboratories must provide not only testing of patient samples, but also advisory, interpretative and educational services. A further document, still in draft form (ISO/DIS 15190) deals with safety management for medical laboratories

Also towards the European Diagnostic Manufacturers Association (EDMA) FESCC and EC4 have a common strategy. The cooperation with the industry becomes more and more important particularly with respect to the harmonization of laboratory data and the impact of the Vitro Diagnostic Directive. FESCC and EC4 recognize the importance of influence on and control from the profession on the developments regarding reference systems. The desired analytical performance of instruments and methods should be defined by the profession. The profession should also be able to adapt undesired performance of instruments.

The freedom of movement of people and goods within the European Union has a large impact for the

member states. Particularly within health care it is important to harmonize the quality of the profession and practice, so that health care is offered at a comparable level. The importance of harmonization also regards clinical chemistry. This was recognized by the IFCC related National Societies of clinical chemistry in EU countries. The common political reality led to the institution of the European Communities Confederation of Clinical Chemistry (EC4). Diagnosis and therapy are now the core business of health care. Medical laboratories play an essential role in this. The broad spectrum of medical laboratory investigations make consultancy of medical laboratory specialists even more important. The quality of both professionals and laboratories, as well as continuity of laboratory data within and between laboratories are of the most importance. The main goal of FESCC is quality through harmonization of our profession in Europe.

The instalment of the EC4 **Register of the European Clinical Chemists** is a large step forward towards the attainment of the first level, harmonization of the profession. In most EU countries National Registers exist and in some others several registers exist, depending on the academic background and education. Colleagues from all relevant academic background, scientific as well as medicine, may and do apply. The EU registration is based on the assignment of equivalence of standards to national register

Accreditation and postgraduate training in European countries

At the present time, there is no detailed knowledge of professional education of specialist in laboratory medicine in the non-EU countries. As harmonization of quality assessment and accreditation procedures are listed among the main goals of FESCC, according to its 1999–2003 strategic plan, it is acceptable that many other countries are willing to adapt their system of professional education to the FESCC EC4 model. By example on this basis, it might be interesting to implement a parallel register for European Clinical Chemist belonging to non EU members.

FESCC launched a survey in July 1998 to gather information on **postgraduate education and on accreditation in clinical chemistry and laboratory medicine**. The major data of the survey are published (3, 4). The questionnaire was sent July 1998 to all presidents of the FESCC related member societies. The most important questions are: which graduate training can lead to a postgraduate training in clinical chemistry and is training in clinical chemistry a post-graduate one. Does training in clinical chemistry (clinical biology) match the European syllabus. The main data considered as a first conclusion provided on accreditation show that the number of accredited laboratories was low in the EU countries and even lower

in the non-EU members. The situation is changing fast and the accredited sites is expected to increase rapidly in the next years. The ISO-Document 15 189 can gather a large consensus from all national European bodies involved in accreditation. There was also a hope that professionals should be vigilant and try to maintain the costs to a reasonable level. The heterogeneity of the data on post-graduate training in clinical chemistry indicates that a great effort will be needed before harmonisation is reached. The data on clinical chemistry training in the non-EU countries show some similarities with the data from the EU countries. The answers on the clinical chemistry curriculum and examinations were quite heterogeneous, a common trend indicated a mixed practical and theoretical training, with similarity in the treated topics, such as general analytical principles and procedures, external and internal quality control, method comparison and laboratory management. Most have no answer whether their training matched the European syllabus. The obtained results provide an interesting basis for further discussion and promotion of post-graduate training in clinical chemistry.

In order to gather information about **the managerial situation of the specialists in clinical chemistry in Europe**, FESCC launched a survey end 2000 (5). The goal of this survey was to provide information to all the FESCC members about the position of the specialist in clinical chemistry in the various medical laboratories and hospitals. It also gives information on the managerial education in the post-graduate training in clinical chemistry. The results of the survey were gathered by a questionnaire to all the FESCC member societies and published in Clin Chem Lab Med 2002; 40 (3): 312–319. Harmonization of the managerial aspects of the profession is one of the challenges for the European specialists in clinical chemistry.

Large differences exist in the disciplines of medical laboratories which are headed, their managerial tasks, the position within the medical staff of hospitals, the advisory task that are practised and the managerial part of the post-graduate curriculum in clinical chemistry. Despite these differences the profession has similar interdisciplinary character in all European countries and ask for harmonization of the profession.

The Future of Clinical Chemistry in Europe

European regulations as a basis for total quality management

I was lucky to be associated to an institution with a history of 900 years, more than 8 centuries. The old St John Hospital is situated at the centre of Bruges and the first ward was built in 1150. Organized laboratory activities started around 1915, a laboratory of micro-

biology and clinical chemistry was established by a chemist-bacteriologist. A new science was born laboratory medicine. This contribution was diagnostically and therapeutically very important. The knowledge of biological parameters has strongly influenced the specialisation in medicine. Over the past 75 years the laboratory analyses have been extremely valuable, especially in the field of preventive medicine. The massive growth of biological possibilities resulted however last years in over consumption, irresponsible requests and finally in a certain devaluation of our profession. The industrial revolution was a first reason for integration. Automatization, robotization, intra and internet systems ask for European standardization, guarantee of quality and accreditation leading to ISO and CEN standards. The cultural exchange between countries and the world economy resulted in unification of Europe. All this raises the actual questions about total quality management in Europe. In view of the new challenges and the implications of them on socio-economical, financial and medical level, the former mentioned questioning towards the European community is quite normal. The application and the integration of the clinical biological parameters go through an enormous development and some examples are obvious and belongs to the strategic plans of FESCC over the period from 2004–2007.

Evidence based medicine (EBM) has been driven by the need to cope with information overload, by cost control and by a public impatience for the best in diagnostics and treatment. Laboratory professionals must direct more effort to demonstration the impact of laboratory tests on a greater variety of clinical outcomes. There is a poverty of good primary studies of

test evaluations. Total quality management is focused on the pre-analytical steps from the patient to the sample. At the present time those are the most important limiting factors of the quality of laboratory results. International standards play an important role in establishing quality systems. A great number has been created by ISO and CEN for medical laboratories. Most standards are suggested by industry or national and international organisations. Individuals rarely influence the contents. The suggested standard (ISO 15 189) on quality specifications in laboratory medicine is an exception. FESCC request special attention to increase efforts for continuous training and education. Molecular diagnostic tools are becoming smaller and the impact on the medical discipline is growing rapidly. Objective evaluation of data in screening of disease and guidelines and algorithms need special attention. One of the major forces in information technology (IT) which provides a new economic and business model for laboratory medicine industry based on an integrated vertical meta-network, summarized in »total laboratory solution (TLS).

Before ending I like to refer to major items of FESCC strategic plan actions for the near future

- Cooperation with and between European FESCC subgroups
- Promotion of a common platform for all disciplines of laboratory medicine
- Harmonization and regulation by law of the profession in Europe based on the principles of free movement of the professionals within Europe (EU-commission).

EDUKACIJA I OBUČAVANJE U KLINIČKOJ HEMIJI U EU: POUKE IZ PRAKSE

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Kratak sadržaj: Ovde se opisuje istorijat razvoja FESCC-a (Forum of the European Societies of Clinical Chemistry and Laboratory Medicine), aktuelne oblasti glavnih aktivnosti i ključne pravci razvoja u Evropi. Misija FESCC-a je da potpomogne i promoviše kliničku hemiju u Evropi, da pomaže u saradnji sa IFCC-om (International Federation of Clinical Chemistry), da razvija edukaciju i kvalitet u disciplini i da ohrabri mlade naučnike da aktivno sudeluju u ovim aktivnostima. Totalni sistem kvaliteta u medicinskim i kliničkim laboratorijama i akreditacija laboratorija postaje sve češća i važnija. Laboratorijski specijalisti se danas suočavaju sa novim načinom razmišljanja u odnosu na rukovođenje i svakodnevnu praksu u laboratorijama. Naročito u Evropskoj Zajednici (EU), harmonizacija kriterijuma kvaliteta je od posebne važnosti. Sloboda kretanja ljudi i dobara unutar EU ima značajan uticaj na svaku članicu posebno. FESCC je obavio istraživanja u Evropi koja se odnose na akreditaciju medicinskih laboratorija i obučavanje sa posebnom pažnjom koja se odnosi na posle diplomsko usavršavanje u okviru profesije. Drugo istraživanje je obuhvatilo više informacija koje se odnose na položaj specijalista kliničke hemije u Evropi. Harmonizacija profesije je jedan od izazova za evropske specijaliste kliničke hemije kao i za sam FESCC. Ovde se opisuju i faktori koji će biti presudni za laboratorijsku medicinu u budućnosti.

Ključne reči: IFCC, FESCC, klinička hemija i laboratorijska medicina, EU (Evropska zajednica), Evropa, akreditacija, edukacija, kongresi

References

1. Jansen RT, Blaton V, Burnett D, Queralto JM, Huisman W. Quality and accreditation systems in clinical biochemistry in the European Union. *Eur J Clin Chem Clin Biochem* 1995; 33: 393–8.
2. International Standard ISO 15189. Medical Laboratories – Particular requirements for quality and competence. ISO, reference number, ISO 15189.2003 (E).
3. Rossier M, Blaton V, Franzini C, Queralto JM, Palicka V. FESCC survey on accreditation and post-graduate training in clinical chemistry in European countries. *Clin Chem Lab Med* 2000; 38: 371–82.
4. Blaton V. Accreditation and postgraduate training in European countries: an FESCC survey. *Clin Chem Acta* 2001; 309: 115–20.
5. de Kieveit W, Blaton V, Kovacs G, Palicka V, Pulkki K. The Management of Clinical Laboratories in Europe: a FESCC Survey. *Clin Chem Lab Med* 2002; 40 (3): 312–9.

Received: April 8, 2004

Accepted: April 23, 2004