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VERIFICATION OF IN VITRO MEDICAL DIAGNOSTICS (IVD) METROLOGICAL TRACEABILITY: ROLE AND RESPONSIBILITIES OF LABORATORY MEDICINE SPECIALITS

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To be accurate and equivalent, laboratory results should be traceable to higher-order references. Furthermore, their analytical quality should fulfil acceptable measurement uncertainty defined to fit the intended clinical use. With this aim, IVD manufacturers should define a calibration hierarchy to assign traceable values to their system calibrators and to fulfil during this process uncertainty limits for calibrators, which should represent a proportion of the uncertainty budget allowed for clinical laboratory results. It is therefore important that, from one hand, laboratory profession clearly defines the clinically acceptable uncertainty for relevant tests and, from the other hand, end-users may know and verify how manufacturers have implemented the traceability of their calibrators and estimated the corresponding uncertainty, including, if any, the employed goal. However, full information about traceability and combined uncertainty of calibrators is usually not available as manufacturers only provide the name of higher-order reference material or procedure to which the assay calibration is traceable without any description of steps and their corresponding uncertainty of the implemented traceability chain. In general, it should be possible to establish if the current status of the measurement uncertainty budget associated with the proposed traceability chain is suitable or not for clinical application of the test. Important tools for IVD traceability surveillance are the verification by clinical laboratories of the consistency of declared performance during daily routine operations performed in accordance with the manufacturer's instructions and the organization of appropriately structured External Quality Assessment (EQA) programs. The former activity should be accomplished by analyzing system control materials and confirming that current measurements are in the manufacturer's established control range, with no clinically significant changes in the assumed unbiased results. With regard to EQA, it is mandatory that target values for control materials (including their uncertainty) are assigned with reference procedures by accredited reference laboratories, that materials are commutable and that a clinically allowable inaccuracy for participant's results is defined in order to prove the suitability of laboratory measurements in the clinical setting.

IMPLEMENTATION AND TRANSPOSITION OF THE DIRECTIVE ON PROFESSIONAL QUALIFICATIONS

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The New Directive on Professional Qualifications 2013/55/EU of the European Parlament and the Council, was published in the European Union Official Journal, 17th January 2014. It must be transposed in all EU countries laws, 2 years after publication. We will give a quick overview of the history to enable understanding of where we are now, after active participation in the numerous meetings, questionnaires, and propositions of amendments. We will explain the automatic system for 7 »sectoral professions« and the »general system« for all the other professions including us. European Professional Card (an electronic certificate transmitted via the Internal Market Information System (IMI), alert mechanism, partial access, language skills requirements, Continuous Professional Development (CPD), Common Training Framework (CTF). CTF is a new regime for automatic recognition. It makes possible for EU Member States to decide on a common set of knowledge, skills and competences that are needed to pursue a given profession, stipulating very clearly the need for a serious consultation with the representative organizations of the concerned professions. For each profession 10 countries (governments and professionals) shall propose to the European Commission its CTF and take care of its regulation and protection of the consumer with a general high level of competence of the professionals, public health and patient safety. The Specialists in Laboratory Medicine are ready to make propositions that we will detail. We began the discussions with our governments and coordinators. Through CEPLIS, (European council of Liberal professions) we have contact with the new members of the European Commission who are preparing a document on CTF to facilitate the whole process that will lead to the same system of harmonisation and free movement applicable to the seven sectoral professions.

TOWARDS COMMON TRAINING FRAMEWORKS FOR SPECIALISTS IN LABORATORY MEDICINE

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With the transposition into national law in 2016 of EU Directive 2013/55/EU (The recognition of professional qualifications) the opportunity in 2015 is to establish a Common Training Framework that allows recognition of Specialists in Laboratory Medicine during free professional movement across EU borders. In turn recognition provides a gatekeeper to patients' safety in the care they receive.Through the pioneering work of the European Communities Confederation of Clinical Chemistry and Laboratory Medicine (EC4) a frameworks based on the EC4 syllabus, competencies and code of conduct is near completion. Through the EC4 register over 3000 individuals across the Community have already been acknowledged as meeting the CTF's Equivalence of Standards. This talk will focus on the framework's content, its further development and the need to attract 10 EU member states to act on behalf of all 28 in its presentation to the EU Commission before 2016.

TRAINING OF SPECIALISTS IN LABORATORY MEDICINE IN SERBIA

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Medical biochemistry is the usual name for clinical biochemistry or clinical chemistry in Serbia, and medical biochemist is the official name for the clinical chemist (or clinical biochemist). This is the largest sub-discipline of the laboratory medicine in Serbia. It includes all aspects of clinical chemistry, and also laboratory haematology with coagulation, immunology, etc.Medical biochemistry laboratories in Serbia and medical biochemists as a profession are part of Health Care System and their activities are regulated through: the Health Care Law and rules issued by the Chamber of Medical Biochemists of Serbia. The first continuous and organized education for Medical Biochemists (Clinical Chemists) in Serbia dates from 1945, when the Department of Medical Biochemistry was established at the Pharmaceutical Faculty in Belgrade. Further development in the education of Medical Biochemists was in 1955 with the introduction of a postgraduate specialization in Medical Biochemistry at the Pharmaceutical Faculty of Belgrade University. In 1987 at the same Faculty a five years undergraduate branch was established, educating Medical Biochemists under a special program. In order to get a license to work in clinical chemistry laboratories, students must have one year practical work experiences in hospital laboratories after graduation. The specialists in clinical chemistry up to now are educated in a special 4-year program at the Faculty of Pharmacy or Medical Faculties,covering the organized lectures, practical training in laboratories and examinations. The final examination requires an overall knowledge in medical biochemistry and clinical chemistry. There is also three sub specialisation for clinical medical biochemists: Laboratory Endocrinology, Clinical Enzymology and Clinical Immunochemistry. The program lasts one year. On the completion of the program, a Diploma of Sub specialization in the field is awarded. The Ministry of Education and Ministry of Public Health accredits the programs. Except this possibility up to 2006 we had organized postgraduate studies in medical biochemistry last two year. After passing the examinations, the student is assigned and experimental project by the supervisor. Data obtained from the experiments are presented in a written form and defended before a commission. Candidates for a doctoral degree usually had a Master of Science Degree. All candidates are assigned a project by their supervisor, which they have to work out experimentally. They then write a thesis, which must be defended in front of commission. Since school-year 2006/2007 the new five year undergraduate (according to Bologna declaration) and postgraduate program of four-year specializationaccording to EC4 European Syllabus for Post-Gradate Training in Clinical Chemistry and Laboratory Medicine has been established. Also, in 2006 according to Health Law the new institution – The Chamber of Biochemists of Serbia has been established with aim to do licensing of the medical biochemists. In cooperation with Ministry of Health the Chamber prepared the documents that regulate the program of Continuing Medical Education (CME) and Regulation of Licensing of Medical Biochemists. The program of CME should be accredited by the Republic Health Council, and in program realization the Pharmaceutical and Medical Faculties, The Society of Medical Biochemists and The Chamber of Biochemists of Serbia are participated. The License of medical biochemists will be renewed every 7 years on the basis of successful completion of continuing education requirements during that period. Minimum requirement for renewal of the license is 24 credits per year gathered from different types of the programmes. The Society of Medical Biochemists of Serbia was established in 1955, and since its institutionuntil these days, the Society has accomplished significant activities in the field of education of clinical chemists through the organization of congresses (biennial), innovations in laboratory medicine, seminars etc. The Society has significant publishing activity through Journal and professional-methodological guidebooks for the field of medical biochemistry.

COMMON VALUES IN THE LIBERAL PROFESSIONS IN EUROPE

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The Liberal Professions are those professions where a qualification is required for a practitioner to provide a professional service to a client: this applies to Specialists in Laboratory Medicine. The Liberal Professions are represented by the Conseil European des Professions Liberals (CEPLIS), the liberal professions cover a very wide

range of professions e.g. engineers, lawyers, numbering approximately 600 professions. There is a need for high professional standards; many professions have their own standards of practice and some professions are regulated within their country; there is little commonality across professions and across nations. CEPLIS operates within the EU and have taken the initiative to delineate 'Common Values for the Liberal Professions'. This is important if there is to be freedom of movement and trade within the EU and that common standards are applied to all professions within specialties and given the umbrella nature of the liberal professions to all such professions. There are 17 values and I will explore these, covering confidentiality, conflict of interest, honesty and integrity and standards of practice.

LABORATORY MEDICINE IN THE EU

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The profession of Laboratory Medicine differs between countries within the European Union (EU) in many respects. The objective of professional organizations of the promotion of mutual recognition of specialists within the EU is closely related to the free movement of people. This policy translates to equivalence of standards and harmonization of the training curriculum. In a study that was supported by both the Union Européenne de Médecins Spécialistes (UEMS) and European Federation of Clinical Chemistry and Laboratory Medicine (EFLM), the organization and practice of Laboratory Medicine was evaluated within the countries that constitute the EU. A questionnaire covering many aspects of the profession was sent to delegates of the EFLM and UEMS of the 28 EU countries. Results were sent to the delegates for confirmation. Many differences between countries were identified: predominantly medical or scientific professionals; a broad or limited professional field of interest; inclusion of patient treatment; formal or absent recognition; a regulated or absent formal training program; general or minor application of a quality system based on ISO Norms. The harmonization of the postgraduate training of both clinical chemists and of laboratory physicians has been a goal for many years. Differences in the organization of the laboratory professions still exist in the respective countries which all have a long historical development with their own rationality. It is an important challenge to harmonize our profession, and difficult choices will need to be made. Recent developments with respect to the directive on Recognition of Professional Qualifications call for new initiatives to harmonize Laboratory Medicine both across national borders, and across the borders of scientific and medical professions.

THE IMPLEMENTATION OF CONTINUOUS PROFESSIONAL DEVELOPMENT

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Results of the European Federation of Laboratory Medicine (EFLM) surveys conducted among belonging Societies in 2011 indicated significant differences in the quality, management and evaluation of continuous professional development (CPD) in the profession of laboratory medicine. This observation prompted the EFLM Committee Education and Training and corresponding Working Group Congresses and Postgraduate Education to conduct the additional survey related to the CPD among EFLM members aiming to evaluate educational needs and possibilities for integrative approach to CPD crediting recent and application of innovative educational tools of CPD, respecting national rules. The questionnaire, consisting of 25 questions, was forwarded along with an explanatory letter to representatives of all 39 EFLM member Societies at the end of 2013. Due to poor response

in defined time the survey was re-sent twice in the first half of 2014. By the end of July 2014 complete answers were received from 33 members. Related to continuous postgraduate education (CPE) answers indicated that 30 out of 33 Societies were familiar with CPE activities, but only in 25/33 countries organise CPE events for their members. Replies on questions about preferred type of CPE programme (four belonging to face-to-face education, three to e-learning and two to professional training) indicated the workshops as the most favourable activity, while seminars and symposia were at the second and third place. Moreover, face-to-face education programmes, followed by the training, and had preferences over e-learning on the list of preferred CPE activities among EFLM members. Irrespective which e-learning event was offered (e-seminars, distance learning or teleconferences) the majority of Societies (22/33) indicated that a rather small number of members (<5%) attended e-learning CPE programmes. Survey results revealed that CPD programmes were regularly credited in the majority (26/33) of countries. Differences in categories eligible for crediting and accompanying credit points were not protruding. However, there was a significant variation regarding institutions responsible for recognition and evaluation of CPE activities (professional organization, governmental body or other organizations). In conclusion, the presented data indicate that the CPD and crediting system in EFLM belonging Societies can be consolidated and the new EFLM crediting system may be launched as the EFLM innovative approach to CPD of specialists in laboratory medicine in EFLM member countries.

PRESENT SITUATION OF ACCREDITATION IN EUROPE

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In 2012 the third edition of ISO15189: »Medical laboratories: requirements for quality and competence« was published. It was really revised in comparison with the first edition of 2003. Apart from better clarity and structure of its content, it stressed more the importance of continual improvement. In certain aspects it is less prescriptive, but asks laboratories to make their own judgments. An important factor to do this is risk analysis. Other aspects are the difference between validation and verification and maintenance of measurement uncertainty. Within the EA (European cooperation Accreditation) the WG Health Care has extensively discussed the differences in the new edition. They have stressed the importance of documentation and the presence of risk analysis for the laboratory processes. The EFLM is stakeholder in EA and present in the meetings of the WG HC. Discussion items are POCT, pre-analytical aspects, multi-site laboratories and flexible scope. IFCC has recommended in 2007 medical laboratories to get accreditation for ISO15189 under flexible scope. Part of this recommendation is accreditation for the whole range of tests in a certain area and the presence of consultative function on it. These same items are worded in an EA guideline: EA4/17 »EA position paper on the description of scopes of accreditation of medical laboratories«. During the last ten years several questionnaires were sent around to get information concerning the actual situation of accreditation of medical laboratories in Europe. It shows gradual increase in the number of accredited laboratories, and the recognition of ISO15189 as the standard. But till now only minority of the laboratories is accredited, and extensive differences can be noticed between countries. It is time to consider requirement by law, as in France, or making it reimbursement dependable, as in Romania. For test with a high impact often accreditation is already mandatory. An important discussion factor is accreditation according to ISO22870 of POCT tests. The ISO22870:2006 Point of Care Testing (POCT) – Requirement for quality and competence« is referring to the first edition of ISO15189, but an addendum to correct this is composed by ISOTC212. Unfortunately in many countries POCT is done without a formal link to an accredited laboratory.Accreditation of medical laboratories leads to expenses. This can only be warranted as the assessment process leads to improving the quality of the laboratories. Extensive training of the assessors is essential. Also the national societies should be involved with their Accreditation Bodies. Problems can be discussed on a European level in the EA Health Care WG.

EXPIRIENCE AND SITUATION OF LABORATORY ACCREDITATION IN SERBIA

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Quality medical laboratories are an integral part of health care, medical research and the key partners in patient safety and public health system. Key component of these actions is the enforcement of quality assurance services through accreditation by ISO standards. ISO 15189, based upon ISO 9001 and ISO 17025, requires that medical laboratories comply with requirements for quality management and technical requirements, including pre- and post-analytical phases, as well as the analytical process itself. Laboratory ethics and safety are also included. In Serbia, an ISO standards accreditation system was started in 2000. by the only national accreditation body (ATS). Accreditation is not mandatory, like in France and Latvia. The percentage of accredited laboratories is still small. According to ISO 15189 were accredited 10 laboratories, and according to ISO 17025 another 10 medical laboratories. Nonetheless, according to EFLM/EA questionnaire Serbia enters the group of countries with satisfactory percentage of accredited laboratories.Great importance is in the fact that the percentage of laboratories which are in accreditation process is satisfactory. Large contribution provides accreditation of health care institutions in general, whose are integral part medical laboratories. The criteria and standards for this accreditation are harmonized with the requirements of ISO 15189, so that it can be said that a greater number of medical laboratories its work conducts according by these norms. Accreditation of health care institutions as a whole performs AZUS. Agency for Accreditation of Health Care Institutions of Serbia (AZUS) was founded in October 2008, to perform professional, regulatory and development activities in the process of accreditation of healthcare institutions. The agency aims to fulfil its designated duties that include establishment of health care accreditation standards, evaluation of quality of health care provided to general population, decision making in health care accreditation management issues, awarding accreditation status and issuing public accreditation certificates, and keeping records of accreditation certificates issued. Until now is accredited about 100 medical laboratories, i.e. 100 health care institutions. Accreditation process in Serbia involved all labs types, hospital laboratory, primary care laboratory, clinical trial laboratory and private laboratory. Majority of clinical-medical fields are concerned by accreditation. They are clinical chemistry, microbiology, haematology, blood banking, genetics etc. All phases of the examination, including all medical steps, are covered by accreditation process. These include: the test's selection advice, sample collection and transport to the laboratory, analysis (method and performance), release, reporting and interpretation of results and lab's management system. In most laboratory qquality management system is documented and processed electronically; laboratories have LIS system and also participate in different ILC/PT programs. Accreditation, data management, personnel education, external quality control programs and demonstration of competence to a third party assessor improve laboratory services and business processes, increases the quality of the results, motivates personnel and is beneficial for all interested. Mandatory accreditation seems needed to progress more quickly to complete accreditation.

PREANALYTICAL PHASE QUALITY MANAGEMENT – HOW AND WHY?

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Preanalytical phase is the most vulnerable part of the total testing process and it poses the greatest risk for the occurrence of diagnostic errors. Due to the contribution of laboratory errors to the overall patient safety risk, it is absolutely mandatory to properly manage its quality. Quality management in the pre-analytical phase is challenging and complex and it poses substantial demand in terms of human, financial and organizational resources to the laboratory management. It requires contribution by all involved stakeholders: laboratory professionals, medical doctors, nurses and patients, as well as hospital management and regulatory authorities. Current international standard for medical laboratories (ISO 15189) recognizes laboratory as responsible entity for managing the quality of pre-analytical phase, by carefully monitoring and continuous improvement of all respective processes and steps. According to ISO 15198, pre-examination processes include »all steps starting in chronological order from the clinician's request, including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within the laboratory and ending when the analytical examination starts«. Evidence based approach is crucial to

the proper quality management of the preanalytical phase. It entails collecting the evidence, assessing the reliability of evidence, drawing conclusions from the evidence and implementing the best practice based on the available evidence. This approach should be applied to every step of the preanalytical phase. There is now ample evidence in the literature addressing some key issues in preanalytical phase. Laboratory professionals should take advantage of the existing knowledge and use it to manage their common everyday issues and problems. Once the best practice is in place, there should be a system to consistently enforce compliance to recommended procedure. There should also be an effective error-detection system to continuously assess the system performance as well as to initiate corrective and preventive actions. Last but not the least, there should be continuation in education and training of all members of the staff involved in this processes. The initiatives need to be taken at several levels: by international professional associations in laboratory medicine, by national professional associations and at the level of individual laboratories. International associations should take the lead in defining and providing best-practice recommendations, national professional associations should assist in efficient distribution of those recommendations and individual laboratories should do their best to adhere to the guidance documents.

POST-ANALYTICAL PHASE QUALITY MANAGEMENT: NEW ACHIEVEMENTS

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Managing upstream demand, down-stream interpretation of laboratory results, and subsequent appropriate action through close relationships between laboratories and clinicians remains a crucial issue of the laboratory testing process.These activities are poorly evaluated and monitored, often because the process owner is unidentified and the responsibility falls in the boundaries between laboratory and clinical departments. A body of evidence demonstrates that the risk of errors and patient harm in the »brain-to-brain loop« is significantly decreased within those processes developing within the laboratory, but it is relatively high at the beginning and at the end of the loop, which mostly lie outside the traditional laboratory environment. In particular, data from different clinical settings such as primary care, internal medicine and emergency departments clearly attest that the rates of errors in result interpretation is unacceptably high, and translate in missed, delayed or erroneous diagnoses. Traditionally, laboratory professional focused their efforts to improve the post-analytical phase by avoiding manual transcription of data, improving the validation of results and moving from printed to electronic transmission of data. Evidence is available to demonstrate improvements in quality and turnaround times thanks to the improvements in information technologies. However, recent studies on missed and delayed diagnosis in different clinical settings highlighted mistakes and failure in laboratory data interpretation and utilization. In fact, the post-analytical phase, from the physician (and patient) point of view is complex as it consists of, at least, four steps: 1) Report transmission, 2) Physician acknowledgment and response (results interpretation and utilization), 3) Patient follow-up/monitoring, and 4) Documentation. From the harmonization point-of-view, it should be even more important to find an agreement on the strategies to be used to improve the right interpretation of laboratory results and their optimal utilization in patient care. Fundamental issues that needs an appropriate answer are the following: »how can we define traceable reference intervals and decision limits, how we should inform clinicians on quality of laboratory tests, what is the role of interpretative comments and, finally, what about critical values definition and communication?« In the last few years a body of evidence has been collected to demonstrate the importance and effectiveness of interpretative comments and, even more recently, the link between appropriate and timeliness notification of critical results and clinical interventions.

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APPLICATION OF KEY PROCESSES QUALITY INDICATORS IN SERBIAN MEDICAL LABORATORIES

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Quality indicators (QIs) are tools that allow the quantification of quality in each of the segments of health care in comparison with selected criteria. QIs can be defined as an objective measure used to assess the critical health care segments such as, for instance, patient safety, effectiveness, impartiality, timeliness, efficiency, etc. The criteria for the choice of QIs have been widely accepted by health organizations, and can be grouped into three conceptual areas: 1) significance, 2) scientific base and 3) the possibility of measurement, which are elaborated in detail depending on where they are applied. The total testing process (TTP) in laboratory medicine has traditionally been separated into three phases, the pre-analytical, analytical and post-analytical phase. In laboratory medicine there is a great need to develop QIs or the measure of feasibility for any stage of the TTP. Despite the fact that some countries have been established programs for monitoring QIs, there is no consensus for adoption of universal QIs and common terminology in the TTP. In the year 2008 the IFCC formed within its Education and Management Division (EMD) a task force called Laboratory Errors and Patient Safety (WG-LEPS) with the aim of promoting the investigation of errors in laboratory data, collecting data and developing a strategy to improve patient safety. This task force came up with the Model of Quality Indicators (MQI) for the TTP including the pre-, intra- and post-analytical phases of work. In order to harmonize QIs, a preliminary agreement has been achieved in a Consensus Conference organized in Padua in 2013, after revising MQI. The accepted list of QIs contains a series of QIs, covering all steps of TTP, that have been considered to be applicable to all laboratories despite their organization, complexity, technological level and according to the priority score. The proposed QIs are monitored from all interested clinical laboratories, during the 6 month period, with the aim of giving an opinion on the importance and applicability and with aim to identify further steps in the harmonization project. Eighteen Serbian laboratories from Belgrade, Novi Sad, Nis, Zrenjanin, Jagodina, Vranje and Kraljevo are included in this project with aim to test QIs, collect data and establish preliminary quality specifications for all of them. Periodically collected QIs were sent monthly to the IFCC website (www.ifcc-mqi.com). QIs are monitored by ten laboratories from University Clinical Center of Serbia in Belgrade, one laboratory from University Clinical Center of Nis, five laboratories of General Hospitals and two laboratories from Primary Health Care level. Laboratories are monitored QIs applicable to the health care level: laboratories ofUniversity Clinical centers (tertiary health care level) were followed 15-53 QIs, laboratories of General Hospitals (secondary health care level) were followed 28-40 QIs, laboratories from Primary Health Care level were followed 15-32 QIs. Data on QIs followed in medical laboratories in Serbia will be used for the purpose of harmonization of QIs on international level as well as for definition of national QIs, which will improve the quality of work and avoid potential errors in all the steps of the TTP. According to the international standard for clinical laboratory accreditation (ISO 15189:2012) »the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes«,on which way it hasallowed the control of all the phases of laboratory work with regard to the management of the quality and competence system. In conclusion it may be said that implementing and monitoring the proper QIs may largely improve the TTP of laboratory diagnostics, while reducing the error rate and ensuring patient safety.