

# Is the profession of laboratory medicine uniform across the North Mediterranean countries?

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## ARTICLE INFO

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## ABSTRACT

Harmonization of the postgraduate training of both Clinical Scientists and Physicians, in Laboratory Medicine (LM) has been a goal for many years, for the **European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)** and the **Union Européenne de Médecins Spécialistes (UEMS), Section of Laboratory Medicine/Medical Biopathology**. This was based on the concept of free movement of people within the European Union.

Much has been achieved within the respective European organizations in the development of curricula that will harmonize the postgraduate training at least within the European Union (EU).

Advances in the area of diagnostics and the need for particular expertise in distinct areas have led to the emergence of laboratory scientists and physicians specialized in hematology (including transfusion medicine), clinical biochemistry, immunology, and microbiology.

However, the training and specialization in laboratory medicine is polyvalent in some countries and single specialties in others countries.

Moreover, these advances have led to the involvement of non-medical scientists in the clinical laboratories.

However, the training and the roles of Medical Doctors and Clinical Scientists in a Clinical laboratory, differ from country to country. These differences still remain today throughout Europe and even within the EU.



## INTRODUCTION

The profession of clinical chemistry and laboratory medicine is practiced in all of the North Mediterranean countries. However, it differs among countries in many respects, such as background training, fields of interest, legal status and professional organization.

In Europe, there are two organizations that represent national professional organizations in the field of Laboratory Medicine and Clinical Chemistry: **European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)** and the **Union Européenne de Médecins Spécialistes (UEMS), Section of Laboratory Medicine/Medical Biopathology**.

Both have as objective to promote mutual recognition of laboratory specialists within the European Union (EU). This is closely related to the free movement of people, a major goal of European integration. However, in order this policy to be accomplished in the field of Laboratory Medicine needs equivalence of standards and harmonization of the training curriculum among member states, both the central tasks of the European professional organizations.

Harmonization of the profession has been an important objective, and has a long history. In 1958 – one year after the treaty of Rome was signed – representatives of the professional organizations of medical specialists of the six-member states of the very new European Economic Community (EEC), met in Brussels and created the European Union of Medical Specialists [Union Européenne des Médecins Spécialistes (UEMS)]. The main

objectives of the UEMS are: to promote the highest level of training of the medical specialists, medical practice and health care within the EU and to promote free movement of specialist doctors within the EU. The UEMS represents the medical specialist profession in the member states of the EU, to EU authorities and any other authority dealing with questions concerning the medical profession. Laboratory Medicine as a medical specialty is represented in UEMS.

In 1988 the Federation of European Societies for Clinical Chemistry (FESCC) was founded, joining the different national societies for clinical chemistry and laboratory medicine. The harmonization and recognition of laboratory specialists, particularly of scientific and pharmaceutical background, was the main objective from the start. The EC4 was subsequently founded, with the goal to harmonize the training through the production of a syllabus that will be commonly accepted by all members and establishing a European register for highly trained specialist, whatever their background.

Until the early 90's when European Community started to issue directives to the state members to adopt a system on a uniform basis of graduation and of post-graduation/specialization for all medical graduates, the training of medical doctors in LM was not only variable but in some countries was missing. To be specialized became, over a few years, a pre-requisite for practicing the medical activity in a specific professional field.

However, in most European Hospital Laboratories, are employed not only medical doctors but even pharmacy, biology and chemistry graduates (the so called scientists).

The result was that on the one side we had specialized MDs, on the other side non-specialized, non-MD graduates, creating the potential for serious issues. Each country developed its own solution. Several countries issued by law the training

of non-MD graduates in order to comply with the EU directives while other countries did not. In the latter, professional societies started initiatives of volunteer training programs based on EC4 syllabus. The result is a tremendous diversity not only concerning who is qualified to practice Laboratory Medicine, but also what is the definition of LM and what disciplines should be included in the curriculum. This diversity still exists.

The European Federation of Clinical Chemistry and Laboratory Medicine developed a syllabus for the postgraduate education and training for all Specialists in LM in order to provide a framework for training for all EU countries (now it is in latest version 5 – 2018).

A common syllabus has many useful applications. First, it describes in detail the education and training associated with high-quality, specialist practice but also can help in defining the common set of skills, knowledge and competence for non-medical Specialists in Laboratory Medicine under EU Directive 2013/55/ EU (The recognition of Professional Qualifications).

Second, it helps to give a definition to LM through the training. What disciplines should be included under the umbrella of LM? This is not a static definition and should be evolved as clinical research and technology evolve. and finally, it will provide the specialists with professional qualifications able to work without restrictions throughout EU (complying with EU Directive 2013/55/EU in providing safeguards to professional mobility across European borders).

### THE DEFINITION OF THE PROFESSION ACCORDING TO EFLM AND UEMS

IFCC defines clinical chemistry and laboratory medicine as *“the application of chemical, molecular and cellular concepts and techniques to the understanding and the evaluation of human health and disease”*.

At the core of the discipline is the provision of *“results of measurements and observations, together with interpretation and informed clinical advice relevant to the maintenance of health, the cause of disease, the diagnosis of disease, predicting and monitoring the response to therapy, and follow-up investigations”*. The discipline is committed to deepening the understanding of health and disease through fundamental and applied research.

High technical skills and ability to interpret results and provide consultancy to clinicians are the top requirements for LM scientists

In the latest version of EFLM syllabus the following disciplines are included in the training that could be common for medical and non-medical origin scientists: clinical chemistry, immunology, haematology and blood transfusion (including blood cells, haemostasis, cellular immunology and transfusion serology), microbiology (bacteriology, mycology, virology and parasitology), genetics, genomics and cytogenetics and finally *in vitro* fertilisation. Only anatomic pathology is outside this framework (Figure 1).

While EFLM provides with the present version a uniform framework for all scientists regardless of background, UEMS provides training only for medical doctors and recognizes different specializations for the section of Laboratory medicine.

Under the umbrella of the more recent name of the section, Laboratory Medicine/Medical Biopathology, several subspecialty divisions have been acknowledged.

At present, the section consists of the following divisions (see also Figure 2): the polyvalent General Laboratory Medicine/Polyvalent Medical Biopathology, and the monovalent specialities of Laboratory Medicine-Clinical Chemistry, Clinical and Laboratory Haematology, Clinical and Laboratory Immunology, and Laboratory Genetics (Genetic Pathology/Medical Genomics).

Since 2008 a separate section of Medical Microbiology was created within the UEMS with its own training program. In 1988 Anatomic Pathology was the first specialist section that split off from laboratory medicine section of UEMS, and was recognized as separate section with the main objective to harmonize the practice of pathology in Europe.

It is important to understand that it is not only that the two professional organization have differences when they try to define the profession of laboratory medicine.

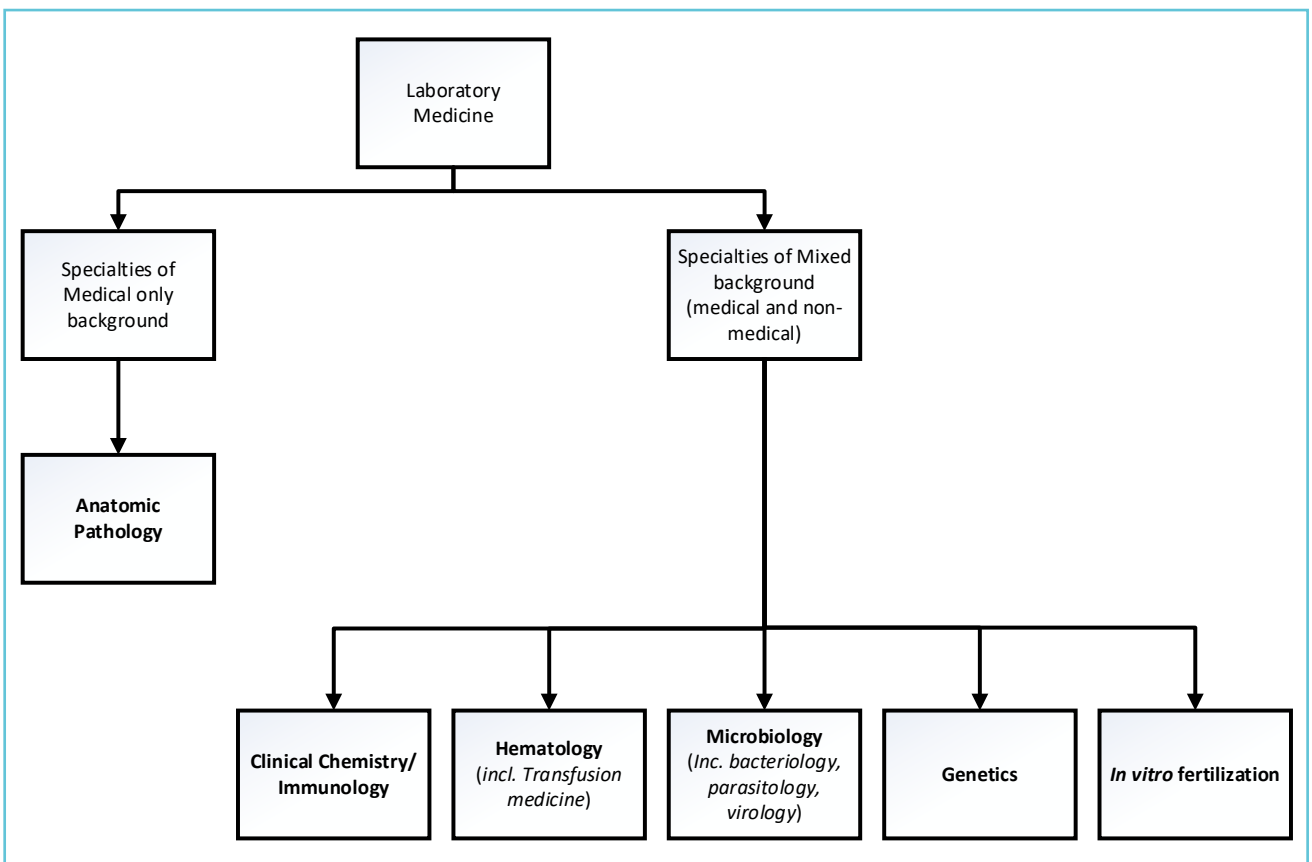
There are huge differences between EU (and of course non-EU) countries. State regulations also allow or not to non-medical scientists to practice the profession of laboratory medicine.

Many specialties are defined differently from country to country within the European Union.

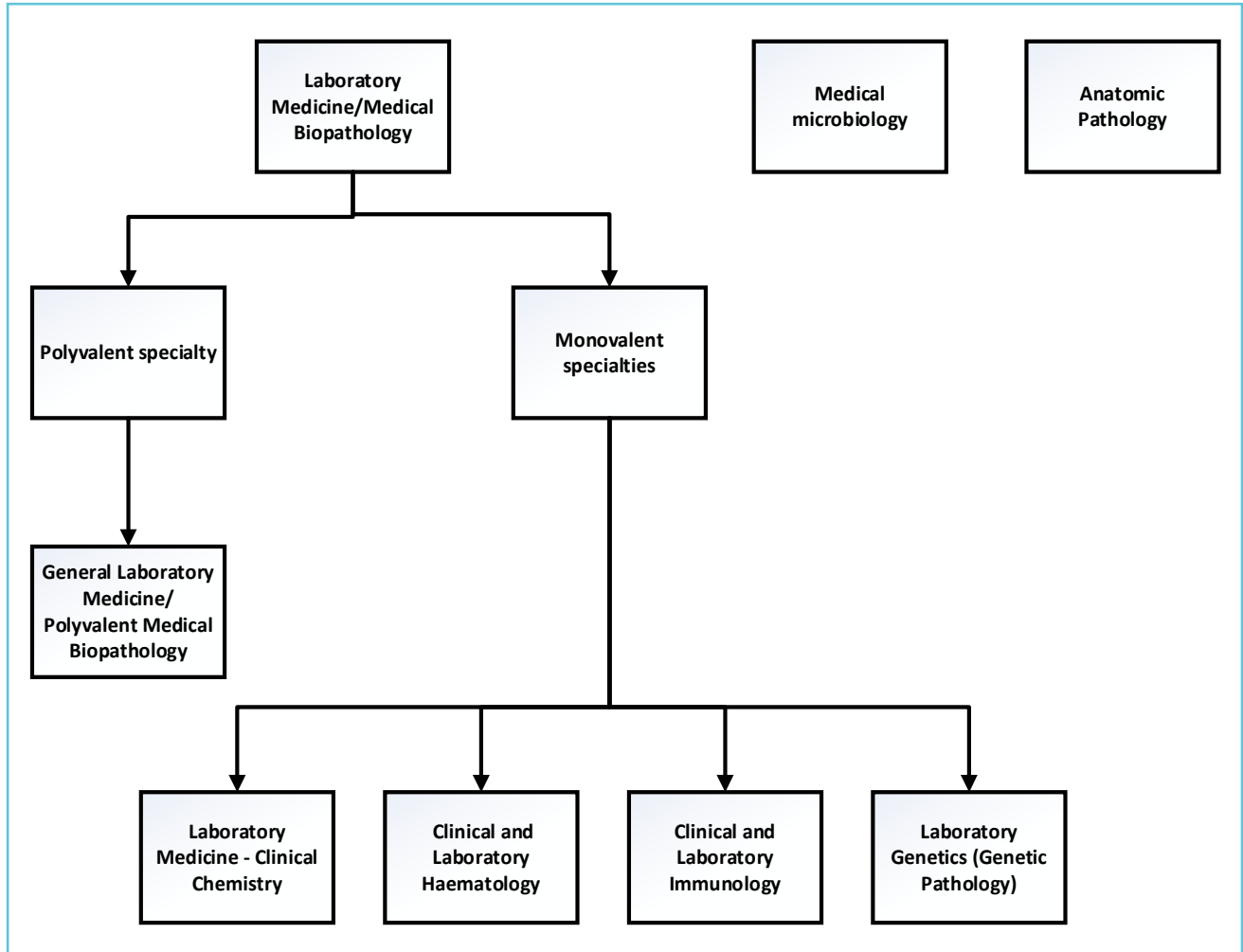
For example, in the Netherlands and Scandinavia, Clinical Chemistry includes biochemistry, immunology, and hematology (most of the subspecialties included in General Laboratory Medicine/Polyvalent Medical Biopathology but excluding Laboratory Microbiology). In other countries (Ireland, UK) LM is named chemical pathology (for the medicine derived scientists) and includes biochemistry and endocrinology or Clinical Biochemistry (for the non-medical clinical scientists).

The clinical component of practice varies among different specialties, with some having a strong clinical emphasis. For example, in the UK, chemical pathologists and immunologists may have independent responsibility for patient care and Clinical Scientists at the consultant level are allowed to provide clinical advice. This is not a common practice in other EU countries.

**Figure 1** Disciplines of LM according to EFLM syllabus



**Figure 2** Polyvalent and monovalent specialties and disciplines of LM according to UEMS syllabus



The name of the discipline also varies between countries and clearly reflects the differences that exist throughout Europe making particularly challenging the task to harmonize specialist training within the EU and Europe in general.

### WHAT IS THE SITUATION NOW IN NORTH MEDITERRANEAN COUNTRIES?

The countries that comprise the North Mediterranean region are (from west to east):

- Spain
- France
- Italy
- Slovenia
- Croatia
- Bosnia and Herzegovina
- Serbia
- Kosovo
- Montenegro
- Albania
- FYROM
- Greece
- Turkey
- Cyprus

All of the above are European countries, with seven of them being EU member states.

In the following paragraphs we try to describe the situation in all north Mediterranean countries. Source of our information was the replies to a questionnaire we sent to all north Mediterranean countries (*see Appendix A - Questionnaire on next page*) and the published documents we found in the internet and scientific journals.

Most of the countries responded to our questionnaire however we did not get responses from Croatia and Montenegro. And while we were able to retrieve information for Croatia from published documents we were unable to have any information from Montenegro. It is not easy to group the practices from these countries since there are huge differences. However, and most interestingly all countries claim that their training is EFLM syllabus compliant.

In Spain there are two specialties which are closer to what EFLM describes as LM are **Bioquímica Clínica** (which is the monovalent specialty), **and Análisis Clínicos** (the polyvalent specialty). Medical Genetics, Transfusion Microbiology-Virology, Immunology, Laboratory Haematology, Medical Microbiology, and Haemostasis constitute separate autonomous monovalent specialties requiring special training. Medical doctors and non-medical scientists (of pharmacy, biology, biochemistry and chemistry background) are eligible for training in LM and are accepted after examination. Training is state regulated the duration is 4 years for everybody and licensed specialists have equal rights in releasing final results and in providing clinical consultancy to clinicians. From the remaining separate specialties only Haematology is strictly a medical specialty and genetics is not yet a medical specialty. The training program is compliant to EFLM syllabus.

In France we discovered that while MD's and Pharmacy graduates can work as LM specialists in all labs and the name of the specialty here is **Biologie médicale**, non-medical scientists can work only in University Hospital labs and when it comes to who has the rights in releasing final results this is not granted to all clinical scientists and they cannot provide any clinical consultancy. Training for medical and pharmacy scientists is state regulated is EFLM syllabus compliant and the total duration of studies is 10 years (including the undergraduate studies).

In Italy the name is **Laboratory Medicine**, the situation is closer to Spain concerning the type of university degrees that are accepted for training. Non-medical trained specialists share the same rights in respect of releasing the final results but are not allowed to provide clinical consultancy. Only medical genetics represent an autonomous specialty. The training program is state regulated and is (at least in part) EFLM syllabus compliant.

Clinical Chemistry and Laboratory Medicine (CCLM) is a scientific discipline within medicine in Slovenia, is the largest sub-discipline of laboratory medicine, and is named **Medical Biochemistry (Medicinska Biokemija)**. The practice of Medical Biochemistry in Slovenia includes clinical biochemistry (including toxicology, therapeutic drug monitoring, endocrinology, molecular diagnostics, immunology), hematology and coagulation. The training is 4 years for all, it is state regulated and open to medicine, pharmacy, chemistry, biochemistry, or other relevant university studies degrees and finally is EFLM syllabus compliant.

**Clinical chemistry** and **Medical biochemistry** is the terms that used in Bosnia and Herzegovina to describe the profession. the specialty is open to scientists from Medical schools, Pharmacy and non-medical (biologists, biochemists, chemists and other graduates from life-sciences). State regulated training is provided for both

**APPENDIX A - Questionnaire**

*What is the term that describes best the specialty (Clinical Chemistry and Laboratory Medicine) in your country? (please check all appropriate replies)*

1. Clinical Chemistry
2. Clinical Biochemistry
3. Laboratory medicine
4. Medical Biochemistry
5. Clinical Biology
6. Chemical Pathology
7. Other (please describe).....

*What is the educational background of the scientific staff working in clinical laboratories in your country (please check all appropriate replies)*

1. Medical (MD)
2. Clinical Scientists (of non-medical, Life Sciences background)
3. Pharmacist
4. Other
5. Mixed (please describe in detail).....

*If the scientific staff is of mixed-background, can the non-medical scientist*

1. final release of results
  - a. YES
  - b. NO
2. provide clinical consultancy
  - a. YES
  - b. NO

*If the scientific staff is only of medical origin, what is the name of the medical specialty that is required from an MD in order to be eligible to work?*

1. Medical Biochemistry
2. Medical Biopathology

3. Chemical Pathology
4. Pathology
5. Clinical Biology
6. Biological Chemistry
7. Other (please specify).....

*Are the following laboratory medicine specialties constitute autonomous medical specialties requiring special and autonomous training?*

1. Medical Genetics
2. Molecular diagnostics
3. Transfusion Microbiology-Virology
4. Immunology
5. Laboratory haematology
6. Medical microbiology
7. Other (please specify).....

*Is the training common in content and duration form medical and non-medical scientists?*

1. Yes
2. No

*What is the total number of years of training required in order to be eligible to work in the clinical lab.*

- A. for medical background
  1. pre-graduate
  2. post-graduate
- B. for non-medical background
  3. pre-graduate
  4. post-graduate

*Is the training program:*

1. State regulated
2. Scientific Society regulated
3. Other.....

*Is your training syllabus EFLM compliant?*

1. Yes
2. No

medical and non-medical background candidates. However non-medical scientists are not allowed to do clinical consultancy. Molecular diagnostics, immunology, laboratory hematology medical microbiology and transfusion medicine are separate monovalent medical specialties in this country. Finally, the training program is not EFLM syllabus compliant.

**Medical biochemistry** and **Medical biochemist (Specijalist Medicinske Biokemije i Laboratorijske Medicine)** are terms commonly used in Croatia, equivalent to Clinical Chemistry and Clinical Chemist, respectively, in most European countries. Medical biochemistry is almost exclusively practiced by medical biochemists. Medical biochemistry in Croatia comprises clinical biochemistry, haematology and coagulation, immunology, toxicology and therapeutic drug monitoring and endocrinology. Blood-banking, microbiology and cytogenetics are separate entities. Medical Biochemistry is studied at the Faculty of Pharmacy and Biochemistry. University degree (Master of Science) is earned after the 5 years of the studies and postgraduate training which is 1 year follows, it is state regulated and is EFLM syllabus compliant. The Faculty of Pharmacy and Biochemistry provides the postgraduate education within the three years of Doctoral studies for: (a) Pharmacy sciences; and (b) Biomedical sciences. PhD degree is requirement for a head of the clinical laboratory at the university hospital. However, PhD degree is not a requirement for medical biochemistry specialists to practice the profession in a laboratory.

In Serbia, the terms used are **Clinical Biochemistry**, **Laboratory Medicine**, and **Medical Biochemistry** and only Medical Doctors and Pharmacists are allowed to enter the profession. The training is 3-4 years depending on background, it is also state regulated compliant to EFLM syllabus but medical genetics transfusion medicine immunology and microbiology are separate medical specialties. And finally all specialists have the right to

both release results and provide clinical consultancy. Kosovo although it is part of Serbia is a recent full member of IFCC. Regulation of the profession in Kosovo is similar to that in Serbia only recently only Medical Doctors can enter the profession.

Small but significant differences we can see in FYROM where the term **Medical Biochemistry** and **Clinical Chemistry** are used. While Medical Doctors, Pharmacists and non-medical scientists are allowed to enter the profession only MD's and Pharmacists have the right to release results and provide consultancy. Moreover, training is state regulated but only for medical and pharmacists it is 4 years and it is EFLM syllabus compliant. No post-graduate training is provided for non-medical scientists.

In Albania, the name is **Clinical Biochemistry** is only open to medical doctors and the training is four years it is state regulated and compliant to EFLM and UEMS syllabus. Clinical biochemistry as a specialty here incorporates Haematology and Immunology but Microbiology is a separate medical specialty.

In Greece and Cyprus, **Medical Biopathology (Iatriki Biopathologia)** is the state regulated multidisciplinary medical specialty that is given only to Medical Doctors. It is 5 years in duration and incorporates microbiology, laboratory haematology, immunology, biochemistry and transfusion medicine. However this training program is partly EFLM syllabus compliant. Medical Genetics is a new state regulated medical specialty which is going to be open to both medical and non-medical scientists, but the training process has not been decided yet. A medical specialty under the name **Clinical Chemistry** (open to both medical and non-medical scientists) is inactive and no regulatory laws are in practice to govern the training of medical and non-medical scientists. The Greek society for clinical chemistry and clinical biochemistry understanding the



gap in non-medical scientists issued a training program that is compliant to EFLM syllabus and it is available for all non-medical scientists.

In Turkey, the situation is a bit more complicated. Training is performed either at hospitals or medical faculties in the universities. Although there is a core curriculum for the training from ministry of health each hospital or medical faculty has its own training program. The graduates from the Medical, Pharmaceutical, Chemistry faculties can participate at an examination in order to start training, but only the medical graduates can be trained at the Medical faculties. Non-medical graduates can be trained only at the state hospitals. They all take exams organised by their organisations in order get the diploma. The graduates with the Medical Biochemistry Diplomas all can work at the Hospital laboratories by law. But the MoH does not allow them for working at the hospital laboratories belonged to the MoH because the MoH and the medical laboratory associations or societies except the Turkish Biochemistry Society are strongly against to the training of non-medical graduates for becoming Medical Biochemist.

### IS THE PROFESSION OF LABORATORY MEDICINE CHANGING?

The definition of Laboratory medicine is not a static one. Changes in technology and in the economic environment drive the changes in the profession. Techniques that a few years ago were available only for research now are ready for everyday clinical use. Moreover, the need for better and individualised care together with these emerging technologies has driven many laboratory tests outside the safe laboratory environment to the clinicians and in certain cases to the patients themselves. Who has the right to perform laboratory tests? This also needs to be re-defined in the next years.

### Changes due to technology

During the last 10-20 years, major scientific and technological advances were the cause of evolutionary changes that happened in the practice of laboratory medicine:

First, the **rise of new technologies** that produce biomedical “big data” (next generation sequencing, multiparameter/multiplex flow cytometry, high-throughput proteomics and metabolomics, systems biology analysis) has caused us to rethink the best approach to diagnostics. Whereas formerly one could easily spend one’s clinical and investigative career developing expertise in just a few analytes, we now have the opportunity to begin to crack the incredible redundant complexity of living organisms. Moreover, the implementation and growth of clinical testing using mass spectrometry and molecular diagnostics. Once only basic research tools, now these technologies provide same-day measurement of proteins, nucleic acids, and therapeutic drugs, improving patient care in complex medical cases.

Second, the advent of the **electronic medical record** (EMR) has added to this potential but, more importantly, has made it much more possible to carry out “cost-efficient” clinical consultation in laboratory diagnostics on specific patients across a wider geographic area. At least theoretically, one pathologist can now consult quickly on multiple patients from a remote location.

Third, **point-of-care** laboratory testing is advancing at a furious pace, resulting in both potential great benefits (imagine each clinical doctor with a handheld device) and potential dangers (the clinician might not be able to tell when the instrument is out of control or not working at all).

Finally, **high-throughput automation**, combined with electronic identification technologies, provides a platform for reduction of laboratory test-related medical errors.

All of these changes work toward progressively greater centralisation. The risk of our profession to become “big business” in its underlying structure is evident, and this makes our second objective (the research) even more difficult.

### **Changes due to increasing economic restrictions**

Governments and private health-care providers try to reduce the cost of healthcare in general and laboratory were easy targets. Laboratory consolidations, outsourcing of services, and hostile takeovers of hospital laboratories by commercial companies were common occurrences in the US in the mid-1990s. These measures led to a reduction not only in the number of positions for clinical laboratory staff, but also to the closing of many medical technology schools, and downsizing of postdoctoral training programs.

These practices crossed the ocean and are now common practices in many European countries. Consolidation and, in some cases, regionalisation of laboratory services with the creation of individual laboratories serving multiple healthcare facilities is now the driving force in many countries. Healthcare in Europe used to be different than in US but is facing the dangers of an increased privatisation. The private–public competition also contributed to the increased perception of health as a commodity (the product of clinical laboratories was no exception). This is a dangerous path often ignoring the importance and the true impact of diagnostic testing in patient’s health.

### **Changes due to regulatory requirements**

Furthermore, the regulatory requirements, quality assessment programs, compliance issues, and general administrative responsibilities of laboratory directors have significantly increased over the past decade. As a result of these clinical service demands, the academic aspects

of the profession and the time to participate in research have seemingly suffered.



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