Section of Laboratory Medicine/Medical Biopathology

Recommended Standards for Training Specialists in Laboratory Medicine/Medical Biopathology

May 2012

Contents

1 Introduction

The European Union of Medical Specialists (UEMS) was founded in1958 and has since taken responsibility as a non-profit organisation aiming to promote the professional interests of medical specialists. The UEMS represents the interests of medical specialists, and is actively working to harmonize training and continuous medical education (CME) of its specialties and to promote the free movement of medical professionals within Europe.
Today delegates from 36 EU states and observers of non-EU countries have been appointed officially by their National Bodies to work within UEMS (currently 30 full members, 4 associate members and 2 observers).
UEMS operates a Secretariat in Brussels, which is governed by a Board, and a Council in which all National Medical Bodies are represented.

The European Union has listed the recognized medical specialties within member states in its Directive 2005/36/EC of the European Parliament and the Council minutes of 7 September 2005 on the recognition of professional qualifications**.**

The Directive lists a diverse list of different specialties in the EU, which require harmonization.

To deal with each specialty UEMS Sections and Boards were founded. These structures provided the framework for the development of specialties under the overarching supervision of UEMS. In each Section two delegates represent their country. Delegates to the Section elect a President of the Section, a President of the Board, a Vice President, a Secretary and Treasurer, and Conveners of Divisions according to specialties represented in the section.

The UEMS Section of Laboratory Medicine/Medical Biopathology was founded in 1962 as the Section of Laboratory Medicine, which was considered an umbrella for all diagnostic- and laboratory-related specialties including Pathology (histopathology).
In 1988, histopathologists decided to form their own section. The Section Laboratory Medicine renamed itself to Medical Biopathology to cover the remaining diverse specialties and interests of doctors practising in either a single specialty (monovalent practice) or across multiple specialties (polyvalent practice).

At present the Section has formed five divisions: General Laboratory Medicine/Polyvalent Medical Biopathology, Laboratory Medicine - Clinical Chemistry, Clinical and Laboratory Haematology and Transfusion Medicine, Clinical and Laboratory Immunology, and Laboratory Genetics (Genetic pathology) (New Division), according to the professional and scientific relations within each field of specialty.

Recently, the name of the Section has been changed to: Section of Laboratory Medicine/Medical Biopathology

The main activities of the Section, Board and Divisions focus on the harmonization of post-graduate education of medical doctors in Laboratory Medicine/Medical Biopathology, specialty training, evaluation of continuing medical education (CME) programmes and conducting visitations of Training Centres.

In 1993 the UEMS published a Charter on the Training of Medical Specialists in the

European Community. Based on this Charter, core curricula for training in polyvalent and monovalent specialty have been laid down by the Divisions describing basic competencies, specialty competencies and clinical competencies in the different Specialties of Laboratory Medicine/Medical Biopathology.

In 1999 the Section Medical Biopathology has published these Curricula in a Blue Book. In 2009 the Section and its Divisions decided to rewrite all Curricula and to publish these in 2012.

Next to its activities to harmonize different curricula, the Board has created a Fellowship in Laboratory Medicine/Medical Biopathology, the role of which is complementary to national examinations where they exist. The European Board Examinations are regarded as a quality mark for safe independent practice at the end of the specialist training. Candidates who pass the UEMS S-LM/MB European Board Examination in Laboratory Medicine/Medical Biopathology and who are certified specialists in an EU/UEMS member state can add "Fellow of the European Board of Laboratory Medicine/Medical Biopathology " (F.E.B.LM/MB**)** to their name either in General Laboratory Medicine - Polyvalent Biopathology or one of the Monovalent Specialties (Laboratory Medicine - Clinical Chemistry, Clinical and Laboratory Haematology and Transfusion Medicine, Clinical and Laboratory Immunology, Laboratory Genetics (Genetic Pathology)). The names of colleagues receiving the “Fellowship” are listed on our website. The Fellowship also acts to enhance the possibility of specialists in Laboratory Medicine/Medical Biopathology to work in various European countries.

A further cornerstone of UEMS is EACCME, the European Accreditation Council for Continuing Medical Education (CME) and Continuing Professional Development (CPD**)**. Organizers of medical congresses can via internet send in an application for approval to EACCME. If approved by the national medical society and by the appropriate section, board and division the congress will be approved by EACCME and participants will receive CME credits accordingly.

The UEMS S-LM/MB Board has developed a Visitation Program through which training facilities can be inspected and recognized using the “Guidelines for the Recognition of Training Centres” and “Standards for training of Specialists in Laboratory Medicine/Medical Biopathology” as background for the visiting specialists.

Lena Norlund
President of the Section

Augusto Machado
President of the Board

Section and Board of Laboratory Medicine/Medical Biopathology

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Division Laboratory Genetics (Genetic Pathology)

Chair Ian Frayling

2 Content of the Training Programmes

In the following pages the European Board of Laboratory Medicine/Medical Biopathology describes the contents of the Training Programme of the various specialties of Medical Biopathology. The curricula will be updated regularly on our section's homepage, http://www.uems-smb.org, since progress in Laboratory Medicine/Medical Biopathology, as in all areas of medicine, is occurring at a very rapid rate. It should be remembered that it is the responsibility of both the Trainee and the Supervisor to ensure that all recent advances are included in the training programme, and that each training programme should be designed around each individual trainee's background knowledge and skills at commencement of training.

Not all hospitals will have all the facilities and expertise required to provide a full training programme, so many trainees will have to rotate between departments to obtain comprehensive training. The European Board of Laboratory Medicine/Medical Biopathology supports the idea of rotations within European countries and also between countries associated with the UEMS.

In the laboratories of the future, more specialised knowledge in many areas will be needed. The importance of physicians in the laboratory increases with the rapid growth of new medical knowledge. Firstly, medical doctors in the laboratory bring with them a specific set of skills that enables effective clinical liaison with other doctors in a hospital or in primary care. Secondly, laboratory physicians, independent of specialty, possess a common set of knowledge and skills, which ensures that laboratories under their direction remain clinically responsive. However, this shared expertise is not enough; more diverse skills are required to be successful in a laboratory. These are exemplified in the following text.

On our homepage e-mail addresses of members of the different specialities in our section are listed if you need more information.

3 General Training Programme

3.1 Definition of Laboratory Medicine/Medical Biopathology

The Specialist in Laboratory Medicine (Laboratory Physician)/Medical Biopathologist is a medical doctor with expertise in several fields of Laboratory Medicine. The trained Laboratory Physician/Medical Biopathologist should be competent to:

1. Give advice to a physician on the diagnosis and monitoring of the treatment of their patients.
2. Select and perform the most appropriate tests to be used.
3. Set protocols and maintain quality standards within the laboratory.
4. Interpret the results of tests for other clinicians.
5. Propose hospital policies on the control of antibiotic usage and antibiotic resistance.
6. Participate in training programs for trainees and be responsible for the assessment of the trainees using the record made in their training logbook.
7. Collaborate with National Surveillance organizations and public health authorities and provide services for the organizations.
8. Undertake research and development in the fields of Laboratory Medicine/Medical Biopathology.
9. Undertake the management responsibilities and communication skills required of the Director of a Laboratory.

3.2 Before specialisation

Throughout the education to become a laboratory physician, basic laboratory skills are acquired and during the specialisation these are deepened.
The intermediate goals referred to below represent a variety of goals of central importance, the attainment of which can be readily assessed. Although they provide no complete description of the content of the specialty, together they allow an assessment of whether competence in the specialty has been achieved.

3.3 Length of training

In accordance with EU Directive 2005/36/EC* the (minimum) duration of training in Laboratory Medicine/Medical Biopathology should be at least 4 years. The Section of Laboratory Medicine/Medical Biopathology decided to recommend 5 years, including one year of clinical practice. This year should be outside the laboratory, and after obtaining licence to practice as a doctor. During this year, the trainee will attend all the activities of the Internal Medicine Department (calls, educational meetings, ward rounds etc). He (she) will also be a liaison between the ward and the laboratory e.g. transfer questions, problems and clinical information from Internists to Laboratory scientists, interpret the diagnostic tests to clinicians, or advise on further testing on patients.
* http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_255/l_25520050930en00220142.pdf

3.4 Areas of competence to be acquired during specialisation

The professional requirements include competence in medicine, in communication, in leadership and management, and in research and development. The intermediate goals referred to below represent a variety of goals of great importance, the attainment of which can

be readily assessed. Although they do not provide a complete description of the content of the specialty, the requirements determined whether competence in the specialty has been achieved.

3.5 Medical competence

Those preparing to be specialists in the laboratory should in the course of their specialized work and training have obtained the knowledge and skills needed to be able to work in a competent and independent manner. This requires them having thorough knowledge in the field as well as theoretical skills in appropriate investigative methods.
Supplemental training in internal medicine or closely allied specialties is required as well, if that is not included in the internship.

3.6 Competence in communication skills

During training, the trainee shall develop the skills required to communicate with both patients and their relatives. It is the patient's right to be informed about their medical results in an open, empathetic way that takes into account his/her background knowledge. Since we have a lot of immigrants in Europe, knowledge about different cultures is also needed.
It is also important to be able to communicate with other physicians, co-workers, and with public authorities in writing. At the same time, the trainee must have the ability to communicate information in a concise and clear manner to colleagues and co-workers. Trainees should from the start familiarise themselves with fundamental aspects of information technology within the laboratory and how IT underpins laboratory practice.

3.7 Leadership competence

During their training, trainees should gain leadership experience and competence. For the laboratory this requires competence in a variety of different areas, such as the planning of work within a unit, management development with the aim of gaining greater effectiveness, and supervisory work. The trainee needs to be able to understand the legal and ethical principles that are integral to the work of a laboratory. A senior trainee should be able to supervise those preparing for the same specialty as oneself. Trainees should be familiar with all health and safety issues including legal aspects.

3.8 Competence in organizational development and medical science

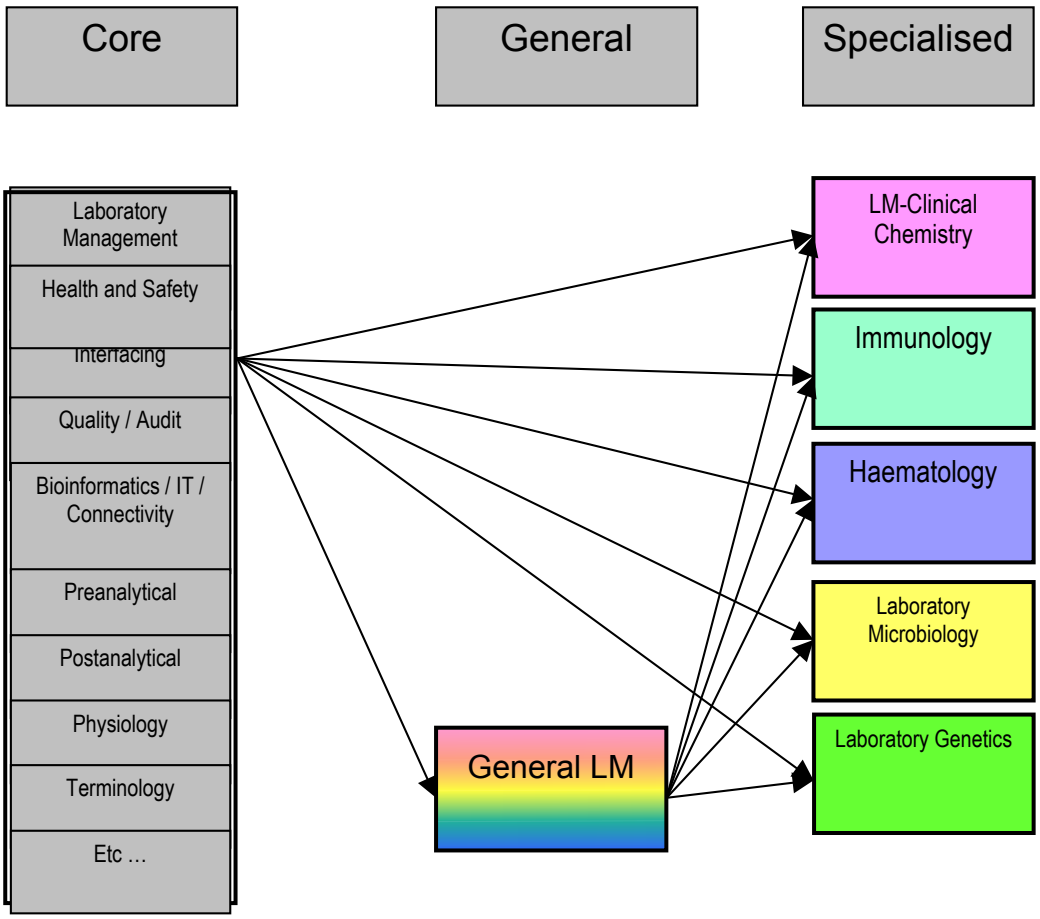
During their training, experience should be gained and competence shown in quality improvement, procedural development and research in medicine. To be able to do this, insight into the logistics of the laboratory is needed. It is also important to be able to organize effectively what one is doing and to contribute to the organization in one's own unit. Also, the trainee needs to be able to critically evaluate scientific articles and other texts as well as newly-acquired knowledge. Keeping abreast of medical research and maintaining a scientific attitude, participating in the planning of scientific studies and of studies on organizational improvement are all key ingredients of success in any specialty. Ideally, the training programme should allow the trainee to undertake a period of original research.

Those preparing to become specialists in Laboratory Medicine/Medical Biopathology - have the responsibility, not only to assimilate knowledge and maintain the competence achieved, but also to improve and refine it as part of the professional scientific community.

4 Overlap between specialties

Many of the specialties are defined differently from country to country within the EU. In some countries such as the Netherlands and Scandinavia for example, Clinical Chemistry includes biochemistry, immunology, and haematology (i.e. all subspecialties included in General Laboratory Medicine/Polyvalent Medical Biopathology but excluding Laboratory Microbiology). In other countries (e.g. Ireland, UK) chemical pathology includes biochemistry and endocrinology. 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. This is a rare practice in other EU countries. The name of the discipline also varies between countries; Clinical Chemistry is called chemical pathology, chemie biologique and clinical chemistry. These differences between EU countries make it a particularly challenging task to harmonise specialist training within the EU.

The figure below depicts schematically the relation between the different specialties within the field of laboratory medicine. There is a basic part in the training, shared by all specialties. A trainee can specialise directly, or after a training in general laboratory medicine. The general specialty is also a separate specialty, practiced a many European countries.



5 Polyvalence versus Monovalence

The EU today, and even more, if the EU is further enlarged in the future will require harmonization of training for mono- and polyvalent specialists in Laboratory Medicine/Medical Biopathology. This will lead to well-trained Laboratory Physicians/Medical Biopathologists who safeguard the high quality and safety of General Laboratory Medicine/Polyvalent Medical Biopathology for outpatients in small and medium sized hospitals as well as the monovalent specialist Laboratory Physician/Medical Biopathologist who does the same in large hospitals, university hospitals and in research.

6 Recommended Regulations and Curricula for Training of Specialists in the different disciplines of Laboratory Medicine/Medical Biopathology in the EU

Preamble

For the purpose of the quality assurance in analytical laboratory medicine and to achieve pan-EU standardization, the UEMS Section of Laboratory Medicine/Medical Biopathology has defined 5-year training curricula in each of the following disciplines:

- General Laboratory Medicine/Polyvalent Medical Biopathology
- Laboratory Medicine - Clinical Chemistry
- Clinical and Laboratory Haematology and Transfusion Medicine
- Clinical and Laboratory Immunology
- Laboratory Genetics (Genetic Pathology)

The national authorities carry out the practical execution and monitoring of the specialist's training, and confer the title of a Medical Specialist - Laboratory Physician

This section on regulations and curricula for specialist training describes the different titles, the necessary conditions for the acquisition of these titles, the training in detail, the arrangements for the conferment of a title and guidance as well as temporary agreements.

A goal of higher training is not only to reach professionalism in analytics and laboratory management, but also to discuss, advice on and recommend laboratory tests and testing strategies, either with fellow pathologists, scientists, physicians of other specialties or patients.

Further, trainees should be capable of interpreting analytical findings in the context of the individual patient, within the limitations of their experience and expertise. Co-operation of the laboratory specialist with the treating physician is the basis for the appropriateness, the effectiveness as well as the economy of laboratory-medical interventions, as required by national laws.

The UEMS Section and Board of Laboratory Medicine/Medical Biopathology approved this specialist-training curriculum.

It was came into force on 12th October, 2010 and replaces the "Training Curriculum of Specialists in Medical Biopathology" as described in "UEMS SMB Blue Book published 1999"

Training Programmes

6.1 Board of Laboratory Medicine/Medical Biopathology

The UEMS Section of Medical Biopathology/Laboratory Medicine has established a "Board of Medical Biopathology/Laboratory Medicine" which has the responsibility for recommending Medical Training in the specialties represented in the section. The responsibility for editing and periodic reviews of the specialist-training curriculum lies with the Board, as is the award of the fellowship title. Furthermore the Board is obliged to consider appeals regarding decisions of the Divisions.

The Board convenes with one representative from each of the following:

General Laboratory Medicine - Polyvalent Medical Biopathology, Clinical and Laboratory Haematology and Transfusion Medicine, Laboratory Medicine - Clinical Chemistry, Clinical and Laboratory Immunology, Laboratory Genetics (Genetic Pathology).

The Board meets periodically as constituted and reports annually to the Section on its activity.

The secretary of the Section acts as secretary of the Board.

6.2 Specialist title categories

There are five different specialist – title categories:

- General Laboratory Medicine/Polyvalent Medical Biopathology

Monovalent specialities:

- Laboratory Medicine - Clinical Chemistry
- Clinical and Laboratory Haematology
- Clinical and Laboratory Immunology
- Laboratory Genetics (Genetic Pathology)

6.3 Duration of training

6.3.1 General Laboratory Medicine/Polyvalent Medical Biopathology

A total training period of 5 years including one year of Internal Medicine or Paediatrics are highly recommended. At least 5 years of training is strongly recommended before taking an examination to receive the title of a Specialist in General Laboratory Medicine - Polyvalent Medical Biopathology. It is mandatory to spend 1 year in Internal Medicine or Paediatrics and 4 years divided for example with 2 years in Laboratory Haematology, Clinical Chemistry and Laboratory Immunology, 18 months in Laboratory Microbiology and Virology, plus 6 months in Laboratory Genetics (with Cytogenetics, and training in DNA/RNA diagnostics)

The title designation for General Laboratory Medicine/Polyvalent Medical Biopathology reads:

- Specialist in General Laboratory Medicine/Polyvalent Medical Biopathology

6.3.2 Monovalent Specialty Titles

A total training period of 5 years including one year in Internal Medicine or Paediatrics is strongly recommended for monovalent specialty training courses.

In the fields of Clinical and Laboratory Haematology, Laboratory Medicine - Clinical Chemistry, Clinical and Laboratory Immunology, and Laboratory Genetics (Genetic Pathology) a single-specialty/specialist training course can each be completed.

Mono-disciplinary training shall be considered complete on the basis of having spent sufficient time in recognized training posts, in accordance with national laws and regulations, that all training aims have been completed and signed off in an appropriate log-book, including the core knowledge syllabus, and having passed an appropriate examination. Equally, some states stipulate the requirement for a qualification in general internal medicine before entering specialist training in Clinical Haematology or Clinical Immunology.

The monovalent specialty titles read:

- Specialist in Laboratory Medicine - Clinical Chemistry
- Specialist in Clinical and Laboratory Haematology and Transfusion Medicine
- Specialist in Clinical and Laboratory Immunology
- Specialist in Laboratory Genetics (Genetic pathology)

6.3.3 Additional specialist titles

The duration of additional training required to acquire the title of specialist in another discipline will depend on the time taken to acquire the competencies detailed in the curriculum for that specialty. This is likely to vary by specialty and will probably require 2 to 3 years.

An additional specialist title can be acquired by those who already hold a title in Polyvalent Medical Biopathology and in certain cases, as specified in the individual specialty curricula, a Single Specialist Title.

6.3.4 Equivalence confirmations

Candidates, who have undergone and completed training in non-EU states, can submit their appropriate documents for validation to the Board of LM/MB, which then examines whether this is equivalent to the UEMS S-LM/MB training programs. All training aims specified in the UEMS program must have been fulfilled.

If this is the case, the Board of LM/MB, will issue to the trainee an equivalence confirmation, if necessary only for certain areas of practice. This route of qualification does not confer an UEMS S-LM/MB title, but does recognise fulfilment of the necessary conditions for specialist training.

In addition, candidates, who wish to practice in gainful employment remunerated by the mandatory health insurance scheme, need such acknowledgment of the equivalence of their training in accordance with the appropriate “Directive of the European Parliament and of the Council on the recognition of professional qualifications” as required by the relevant national Ministry in accordance with national health insurance laws.

6.4 Arrangements for Training in General Laboratory Medicine/Polyvalent Medical Biopathology

6.4.1 Training activity

Training periods in different specialist areas must take place in training posts and according to syllabuses recognized by national authorities and the UEMS S-LM/MB Board on recommendation of the applicable S-LM/MB specialist Divisions.

Trainers must fulfil the following criteria:

- Be holders of the appropriate/respective specialization in Laboratory Medicine/Medical Biopathology or a recognized equivalent (according to article 6.3.4).

- In the former case, they must have been in active clinical laboratory practice at Consultant level for at least three years, responsible for the routine execution of tests on an analysis list of the respective national authorities, and in a department recognized for training.

- Have completed at least one appropriate training course in the teaching of specialist knowledge, laboratory management and laboratory skills.

Training posts are recognized by the UEMS S-LM/MB in laboratories:

- which fulfil the certification requirements of the national law.

- which routinely perform those tests on the analysis list, which are subject of training.

- which preferably already have a number of other training positions, with trainees in post.

- in which a general training plan is present (structured in accordance with the syllabus), which is flexible according to candidates' prior knowledge and progression as monitored by regular assessment.

- which can demonstrate satisfactory internal quality control IQC and successful participation in external quality assessment EQA schemes.

Further the laboratory has to be accredited with a recognized national or international accrediting agency e.g. ISO 15189.

6.4.2 Criteria for recognition and categorization of training posts in the different specialist areas

Specific general points apply to the individual specialist areas as following:

6.4.2.1 Clinical Chemistry

Training

Laboratories or institutes in a university, teaching hospitals or greater private laboratories will be eligible to act as training centres only if they perform a comprehensive repertoire of tests in the discipline on a routine basis and are under the direction of a Specialist in Laboratory Medicine – Clinical Chemistry or General Laboratory Medicine/Polyvalent Medical Biopathology. These individuals will also act as trainers and educational supervisors of trainees.

Time allowance

This may vary according to the category of the training post according to national regulations.

Training in Clinical Chemistry must take place either in a clinical chemistry laboratory (for minimum of 12 months) or in a general laboratory (minimum 24 months).

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan.

6.4.2.2 Laboratory Haematology

Training

Laboratories or institutes in a university, teaching hospitals or greater private laboratories will be eligible to act as training centres only if they perform a comprehensive repertoire of tests in the discipline on a routine basis and are under the direction of a Specialist in Clinical and Laboratory Haematology or General Laboratory Medicine/Polyvalent Medical Biopathology. These individuals will also act as trainers and educational supervisors of trainees.

Time allowance

This may vary according to the category of the training post according to national regulations.

Training in Laboratory Haematology must take place either in a haematology laboratory (for minimum of 6 months) or in a general laboratory (minimum 12 months) and cover the investigation of haematological diseases

The duration of such training will vary with the previous experience of the trainee and whether the trainee wishes to practice predominantly in Clinical or Laboratory Haematology.

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan.

6.4.2.3 Laboratory Immunology

Training

Laboratories or institutes in a university, teaching hospitals or greater private laboratories will be eligible to act as training centres only if they perform a comprehensive repertoire of tests in the discipline on a routine basis and are under the direction of a Specialist in Clinical and Laboratory Immunology or General Laboratory Medicine/Polyvalent Medical Biopathology. These individuals will also act as trainers and educational supervisors of trainees.

Time allowance

This may vary according to the category of the training post according to national regulations.

Training in immunology must take place either in an immunology laboratory (for minimum of 6 months) or in a general laboratory (minimum 12 months) and cover the investigation of suspected immunodeficiency, systemic autoimmune rheumatic disease and the vasculitides and allergy. Individuals wishing to embark on clinical training in immunology will require an additional period of training. The duration of such training will vary with the previous experience of the trainee and whether the trainee wishes to practice predominantly in clinical or laboratory immunology.

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan.

6.4.2.4 Laboratory Microbiology

Training

Laboratories or institutes in a university, teaching hospitals or greater private laboratories will be eligible to act as training centres only if they perform a comprehensive repertoire of tests in the discipline on a routine basis and are under the direction of a Specialist in Medical Microbiology or General Laboratory Medicine/Polyvalent Medical Biopathology. These individuals will also act as trainers and educational supervisors of trainees.

Time allowance

This may vary according to the category of the training post according to national regulations.

Training in Laboratory Microbiology must take place either in a microbiology laboratory (for minimum of 12 months) or in a general laboratory (minimum 24 months).

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan.

6.4.2.5 Laboratory Genetics (Genetic Pathology)

Training

Training in this new emerging specialty is being established. It is important that all those practicing in medicine have some knowledge of genetics.

It is recommended that training in laboratory genetics takes place in a specialist genetics laboratory (as found in Universities, Teaching Hospitals and the private sector). It may be possible to gain some experience in a polyvalent laboratory, but in its very nature, laboratory genetics is a specialist activity, and is unlikely to be performed in a general laboratory.

The trainee should cover the investigation of common genetic disorders (the definition of which may vary between countries, e.g. haemoglobinopathies), and the main analytical techniques. Cytogenetics, molecular cytogenetics and molecular genetics should all be covered, including both constitutional (inherited) disorders and somatic (acquired) disorders (e.g. haematological malignancies and solid tumours). Some time should be spent gaining experience in related laboratory disciplines, such as newborn screening and metabolic medicine/clinical chemistry. Experience of laboratory genetics may also be gained in e.g. haematology, tissue typing, immunology, clinical chemistry and microbiology/virology (including non-human genomes). It is strongly recommended that individuals gain some experience in clinical genetics, by spending time working with a Specialist in Clinical Genetics. A considerable proportion of genetic tests is referred to other laboratories, hence trainees should gain experience in and know how to choose and recommend laboratories to which specialist genetic tests can be referred. Individuals wishing to embark on full training in clinical genetics will require an additional period of training. The duration of such training will vary with the previous experience of the trainee and whether the trainee wishes to practice predominantly in clinical or laboratory genetics.

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan. Laboratories or institutes in a university, larger hospitals or greater private laboratories, in which a majority of the tests are performed as well as in smaller private laboratories and smaller hospital laboratories, in which a considerable portion of the tests are routinely performed, the trainer/s must be Specialists in Laboratory Genetics, either medically or scientifically qualified.

Time allowance

This may vary according to the category of the training post according to national regulations.

Training in genetics must take place in a genetic laboratory for minimum of 6 months.

The institution may guarantee the specialist training curriculum by written agreement with other laboratories, which are specified in the training plan.

6.4.3 Experience in the Laboratory

Whilst working “at the bench” in practical routine diagnostics, trainees will acquire a knowledge of the indications for and interpretation of laboratory tests in the context of clinical care, including diagnostics and therapy, plus laboratory management (including

confidentiality, quality control, and personnel management). This will occupy at least 75% of their activity.

The candidate must be regularly exposed to abnormal results during his/her training with abnormal results in addition to acquiring the expertise required to deal with critical laboratory results that require urgent therapeutic intervention.

Up to one quarter (at the most) of a trainee's time in specialist training will be spent in the acquisition of theory (literature study, attendance of lectures and seminars etc) and experience of research.

6.4.4 Core Knowledge Courses

Higher specialist training will include attending courses and seminars covering what is expected to be known as core knowledge, as well as specialist knowledge.

A Core Knowledge Course has to cover at least 20 course or seminar days. It comprises both mandatory and voluntary modules.

The courses and seminars of the Core Knowledge Course are recorded in a trainee's logbook and certified by the appropriate course leader. Each candidate must prove from the entries in his/her training logbook that he/she has completed the entire Core Knowledge Course.

6.4.5 Training logbook

Each trainee will maintain a logbook of their training, available for inspection as required by officials. These will include the time spent in specialist training, the activities performed, seminars and courses attended, and the results of training assessments signed off by trainers.

6.4.6 Training Assessments

Formal assessments of training, with feedback, will occur at least every 6 months, and at the end of each training period.

Training assessment meetings will involve the head of laboratory and the trainee reviewing the achievements in training that have been accomplished, and specifying training goals to be achieved.

If there is disagreement or conflict additional meetings may be required.

Training assessments and their results must be registered in training logbooks.

6.4.7 Tutor

The tutor should have been practising as a specialist in that specialty for more than 5 years. There should be additional teaching staff. The teacher and the staff should provide training in all aspects of the speciality. When an aspect of training cannot be provided in one centre it will be necessary for the trainee to be taught elsewhere by a teacher approved for that purpose.

The chief of training should work out a training programme for the trainee in accordance with national rules and the recommendations of the Educational Board of S-LM/MB.

The ratio between the number of qualified specialists on the teaching staff and the number of trainees should enable close monitoring of the trainee during their training and complete coverage of the curriculum.

6.5 Training Aims, Syllabus and Logbook

There are two categories of training aims (see logbooks chapter 7):

7.1 Training common to all laboratory specialties including management (common core)

7.2 – 7.6 Training in the different specialties of laboratory medicine

General Laboratory Medicine - Polyvalent Medical Biopathology (7.2)

Monovalent specialities:

Laboratory Medicine - Clinical Chemistry (7.3)

Clinical and Laboratory Haematology and Transfusion Medicine (7.4)

Clinical and Laboratory Immunology (7.5)

Laboratory Genetics (Genetic Pathology) (7.6)

The syllabus specifies the elements of common and specialist training within each discipline. The logbook for each specialty will act as a guide for the trainee and enable appropriate documentation of theoretical and practical aspects of training. The content of individual curricula are designed to comply with the requirements of specialist organisations and national authorities.

6.6 Test regulation

In the context of training for a specialist in Laboratory Medicine/Medical Biopathology there may be two kinds of examinations, which national regulations may require:

- An entrance examination

- A final examination under the auspices of National authorities, Societies or Colleges, which organize the examinations.

6.7 Conferment of a title

6.7.1 Conferment of a title, diploma document

On completion of training, having passed a national final examination and the UEMS S-LM/MB Fellowship examination successfully, the trainee is awarded the appropriate UEMS S-LM/MB Fellowship (in accordance with 2).

Apart from the written confirmation of the conferment of a title each trainee receives a diploma document, which is signed by the President of the Sections, the President of the Board and by the Secretary of the UEMS S-LM/MB.

The document is prepared by the UEMS secretariat in the English language.

6.7.2 Declaration of title and advertisement

The UEMS Fellowship title is conferred for an unrestricted length of time, subject to the fulfilment of CME requirements in accordance with article 9.

The holder of the title may use the appropriate post-nominal description (F.E.B.LM/MB). The wording of the title designations (in accordance with article 2) must be given in English.

6.8 Temporary provisions

6.8.1 "Fellow Specialist in General Laboratory Medicine/Polyvalent Medical Biopathology"

For laboratory specialists already in practice and for those candidates who commenced training in General Laboratory Medicine/Polyvalent Medical Biopathology before 2011, the following regulations determine the award of the title "Fellow specialist of General Laboratory Medicine /Polyvalent Medical Biopathology of UEMS S-LM/MB".

Conditions for the conferment of a title to a specialist already chairing a laboratory.

The applicant must be a responsible laboratory specialist chairing a General Medical Laboratory certified in accordance with national regulations and complying with CME regulations. Two years of practical activity can be taken into account as a 1-year further training.

6.8.2 "Fellow Specialist for Laboratory Medicine - Clinical Chemistry"

The following regulations regulate the modalities of awarding the title "Fellow specialist for Clinical Chemistry UEMS S-LM/MB" to a laboratory specialist acting as head of a clinical chemistry laboratory certified in accordance with national regulations already in practice, and candidates, which began their training in Clinical Chemistry before 2011.

Conditions for the conferment of a title to a specialist already chairing a laboratory.

The applicant must be a responsible laboratory specialist chairing a clinical chemistry laboratory certified in accordance with national regulations and complying with CME regulations. Two years of practical activity can be taken into account as a 1-year further training.

6.8.3 "Fellow Specialist for Clinical and Laboratory Haematology"

The following regulations regulate the modalities of awarding the title "Fellow specialist for Clinical and Laboratory Haematology UEMS S-LM/MB " to a laboratory specialist acting as head of a haematology laboratory certified in accordance with national regulations already in practice, and candidates, which began their training in Clinical Haematology before 2011.

Conditions for the conferment of a title to a specialist already chairing a laboratory.

The applicant must be a responsible laboratory specialist chairing a haematology laboratory certified in accordance with national regulations and complying with CME regulations. Two years of practical activity can be taken into account as a 1-year further training.

6.8.4 ”Fellow Specialist for Clinical and Laboratory Immunology”

The following regulations regulate the modalities of awarding the title “Fellow specialist for Clinical and Laboratory Immunology UEMS S-LM/MB" to a laboratory specialist acting as head of an immunology laboratory certified in accordance with national regulations already in practice, and candidates, who began their training in Clinical Immunology before 2011.

Conditions for the conferment of a title to a specialist already chairing a laboratory.

The applicant must be a responsible laboratory specialist chairing a immunology laboratory certified in accordance with national regulations and complying with CME regulations. Two years of practical activity can be taken into account as a 1-year further training.

6.8.5 “Fellow Specialist in Laboratory Genetics”

The following regulations regulate the modalities of awarding the title “Fellow specialist for Laboratory Genetics UEMS S-LM/MB" to a laboratory specialist acting as head of a genetic laboratory certified in accordance with national regulations already in practice, and candidates, which began their training in Genetics before 2011.

Conditions for the conferment of a title to a specialist already chairing a laboratory.

The applicant must be a responsible laboratory specialist chairing a medical-genetic laboratory certified in accordance with national regulations or a laboratory for the subspecialty cytogenetics or molecular genetics and complying with CME regulations. Two years of practical principal activity can be taken into account as a 1-year further training.

6.9 Promulgation

This regulation comes into force starting from October 12, 2010

7 Logbooks for specialist training in different disciplines of Laboratory Medicine/Medical Biopathology

While the diverse spectrum of disciplines within the umbrella of Laboratory Medicine have specific training aims incorporated into mono-specialty training, an attempt has been made to reconcile the common core with the requirements of the trainee following the General Laboratory Medicine/Polyvalent Biopathology specialist training curriculum.

7.1 Common core

7.1.1 Laboratory management

- Laboratory philosophy (objectives, rules, laboratory statutes)
- Personnel management (employment discussions, product requirement specifications, evaluation and qualification, executive functions)
- Planning (personnel planning, family trees, plans of application, emergency service; Laboratory planning, laboratory equipment, infrastructure; Budgeting, calculation; long-term planning)
- Legal aspects, legal basis, data security
- Documentation

7.1.2 Special laboratory organization

- Internal organization
- Request systems / sample identification
- Result transmission / reporting
- Accounting regulations / systems
- Information systems (contact with cooperating physicians / health insurance companies; Professional secrecy versus third parties)

7.1.3 Laboratory security

- Security concept and laboratory order (including fire-police and radiation security requirements)
- General action in exceptional cases
- Hygiene and other requirements in case of accidents, infections, poisonings.
- Buildings and structural requirements

7.1.4 Sampling and treatment of specimens

- Specimen sampling and collecting techniques; Factors of influence
- Transport of specimens and factors of influence during transport; Organization of specimen transport
- Storage of specimens (pre analytic and long-time storage,)
- Disposal of biological specimens

7.1.5 Quality control and quality assurance

- Internal quality control; Organization; Methods and evaluation of statistics
- External quality control
- Plausibility check

7.1.6 EDP

- Organization of the EDP and work routine
- Analysis of weak points
- Computer operation, data protection, archiving
- Networks and transmission problems
- Error tracing
- Strategic design

7.1.7 Instruments and automatic analytical devices

- Maintenance and repairs
- Procedures of fault tracing
- Application of manual methods on automatic analytical devices
- Evaluation of new analytical devices

7.1.8 Evaluation of methods

Including establishment of working procedures and service instructions

- Diagnostic sensitivity and specificity, plausibility, validity, indication
- Method comparison and evaluation of clinical relevance
- Potentialities of mechanical devices/single test, series, automatic devices including logistic and financial aspects

7.1.9 Reporting obligations / Registration

7.1.10 Data security

7.1.11 Pre-symptomatic diagnostic methods and risk analysis

7.1.12 Scientific co-operation with hospitals and physicians

7.2 Syllabus in General Laboratory Medicine/Polyvalent Medical Biopathology

7.2.1 Laboratory Medicine - Clinical Chemistry

7.2.1.1 Medical knowledge and interpretation of laboratory results

- Guiding laboratory tests in case of uncertain diagnosis
- Important metabolic diseases
- Fundamental knowledge of hereditary diseases
- Molecular biology and organization of genes (including transcription, translation and relevant regulatory regions, mutagenesis and repair mechanisms, mechanisms of the RNA editing)
- Frequent polymorphisms of human genes and post-translation changes of gene products; relation with other analytical results and their clinical correlation
- Recognition of indications for individual genetic consultation
- Important electrolyte disturbances
- Important changes of organ-specific enzymes and proteins
- Important hormone disturbances
- Nutrition (vitamins, trace elements)
- Clinical toxicology (procedure with acute poisonings)
- Therapeutic Drug Monitoring (TDM)
- Drug interferences (in vitro) and drug interaction (in vitro)
- Detection of addictive drugs
- Frequent genetic polymorphisms related to the effect of drugs and foreign products (e.g.: Cytochrom P 450 - variants and neuroleptic drugs)

7.2.1.2 Methodology (theoretical knowledge and skills)

- Physical, optical and electrometric methods (Flame-photometry, ISE, atomic absorption, Osmolality, density, mass spectrometry)
- Separation methods (chromatography, electrophoresis)
- Chemical and enzymatic methods for the analysis of substrates
- Enzymatic methods for the determination of the activity of various enzymes
- Immunological methods (radioimmunoassay, enzyme-immunoassay, fluorescence-immunoassay, fluorescence polarization and luminescence) for analysis of hormones, monitoring of drug concentration or of specific proteins
- Molecular-biological methods (preparation, isolation and quantification of DNA and RNA; Amplification (PCR); DNA-Analysis (Southern blot, restriction-fragment-length-Polymorphism (RFLP), sequencing); Procedures to detect mutations.
- Chemical and morphological urine examinations (urine sediment)

7.2.1.3 Methodology used as well in other specialties

- Work with automatic devices (maintenance, error tracing, repairs)

- Adaptation of manual methods on automatic devices
- Extraction, amplification and verification of DNA and RNA from cells and tissue samples
- Cleavage of DNA by means of restriction enzymes including electrophoresis isolation
- Sequencing of DNA
- Southern blot hybridization
- Bio-mathematical evaluation with Genotype diagnostics
- Electrophoresis and other separation methods

7.2.2 Laboratory Haematology

7.2.2.1 Medical knowledge, evaluation of results

Cellular Haematology

- Reactive changes (including viral infections)
- Different forms of anemia, leucopenia, thrombocytopenia (including analyzed and calculated indices)
- Erythrocytosis / Polycythemia, Leukocytosis, Thrombocytosis
- Myelodysplasias
- Chronic and acute leukemias (including molecular-biological findings, Immuno-phenotyping and Cytochemistry)
- Lymphomas and other lymphoproliferative diseases (including molecular-biological findings, Immunophenotyping and Cytochemistry)
- Parasitosis
- Haemoglobinopathies

Immuno-Haematology

- Blood group identification, clinical relevance
- Allo- and autoantibodies, clinical relevance, relevance for transfusion medicine
- Incompatibility reactions, preventing measures; complications during transfusion

Haemostasis

- Anti-coagulation and control measures
- Haemorrhagic diathesis and classical haemophilia
- Thrombophilia (including molecular-biological findings)
- Thrombocytopenia
- Clinical use of markers of activation and fibrin degradation products
- Consumption coagulopathy, DIC

Molecular biology

- Clinical meaning of frequent molecular-biological findings in haematology

7.2.2.2 Methodology

Cellular Haematology

- Cell counting by means of automatic devices and microscopy with chambers (peripheral blood, marrow, puncture specimens, stem-cell preparations, cell suspensions)
- Differentiation by means of automatic devices and visual findings (peripheral blood, marrow, puncture specimen, master cell preparations, cell suspensions)
- Immune-phenotyping of haematology cells by means of flow cytometry; Phenotyping of haematologic cells by means of cytochemistry
- Determination of normal and abnormal haemoglobins

Immunohaematology

- Blood group testing AB0- and Rhesus-system
- Antibody searching and antibody differentiation (including special methods such as elution-, neutralization- and absorption-methods)
- Direct and indirect Coombs test
- Compatibility tests
- Apheresis of haematology cells

Haemostasis

- “Clotting” assays (including Global test)
- Chromogenic assays
- Antigenic assays
- Platelet function tests

Molecular biology

- DNA /RNA based PCR assays

Methodology used in other specialties as well

- - e.g. electrophoresis, antigen assays (e.g. Laurel, ELISA, EIA, etc.), fluorescence in situ hybridization (FISH), molecular biology assays.

7.2.3 Laboratory Immunology

7.2.3.1 Knowledge in immune physiology

- - Innate immune defences / inflammation
- - Specific immune reactions (antigen recognition, effector mechanisms, etc.)
- - Immune modulation (networks, cytokines, adhesion molecules, etc.)

7.2.3.2 Knowledge in immune pathophysiology

- Allergies, pseudo allergies/ incompatibilities (IgE related / IgE independent)
- Autoimmune diseases (organ-specific/systemic)
- Immunodeficiency syndromes (primary/secondary)
- General immunology of infections (ways of defense, consequences)
- HIV infection, infections with hepatitis viruses A, B, C, D, E
- Immunology of transplantation (organs, stem-cells / marrow-cells, HLA-typing)
- Immunology of tumors (defense and escape mechanisms, tumor antigens)
- Principles of immunological therapies (drug immune modulation, cytokines/anti-cytokines, substitution of Ig- and cells) [laboratory based therapy monitoring]
- Principles of vaccination (active/passive immunization, pre-/post infectious and control of success)

7.2.3.3 Basic principles of immunological methods

- Testing of antibodies/antigens/mediators by means of immunofluorescence
- Immune-precipitation in liquids (nephelometry/turbidimetry)
- Immune precipitation in gels
- Haemagglutination and complement fixation
- Radio- and enzyme-immunological test procedures
- Western blot and similar procedures (e.g. line immune-binding)
- Electrical procedures combined with blotting, precipitation including electrofocusing
- Preparation and enrichment of peripheral cell populations
- Cytofluorometry (cell surface and intracellular structures) diagnostic and preparation
- Lymphocyte function tests
- Immunohistology

7.2.3.4 Special immune diagnostics

- Interpretation of results of individual tests or groups of tests (validity: diagnostic, prognostic, as progress parameter, for therapy monitoring) for the following groups of measured variables:
- Autoantibodies
- Ig classes and - subclasses
- Specific Igs in particular specific IgE s
- Monoclonal and oligoclonal Immunoglobulin changes
- Cytokines and - inhibitors
- Adhesion molecules
- Inflammation parameter including complement factors
- Cryoglobulins
- MHC classes I and II-molecules (HLA typing)
- Serology markers of HIV infection (including viral load) 1)
- Serology markers of infections with hepatitis viruses A, B, C, D, E (including viral load) 1)
- Cell surface structures of leukocytes/lymphocytes (subpopulations)
- Leukocyte/lymphocyte function tests

[1]) Only national and internationally procedures with recognized permission and only in laboratories, which are specially recognized and accredited.

7.2.4 Laboratory microbiology

7.2.4.1 Special laboratory microbiology

7.2.4.1.1 Bacteriology

- Sampling, transport and storage of clinical specimens
- Disposal of samples and laboratory material
- Processing of sample material, as well as direct examination/verification, culture and identification of frequent isolated bacteria including mycobacterium from clinical samples of humans
- Immunologic and serologic tests of bacteria and bacterial infections
- Molecular biological test of bacteria and mycobacterium
- Classification methods of bacteria and mycobacterium
- Antibiotic resistance tests of bacteria and mycobacterium
- Tests for antibiotic concentration in body liquids

7.2.4.1.2 Virology

- Sampling, transport and storage of clinical specimens
- Disposal of specimens and laboratory material
- Processing of specimens, as well as direct examination / tests, culture and identification of frequent viruses
- Immunologic and serologic tests of viral infections
- Molecular-biological tests of viruses and virus infections

- Methods of classification of viruses and of examination of resistance of viruses against antiviral substances

7.2.4.3 Mycology

- Sampling, transport and storage of clinical specimens
- Disposal of specimens and laboratory material
- Processing of specimens, as well as direct examination / tests, culture and identification of frequent yeasts, mold fungi and dermatophytes
- Antigen tests of Cryptococcus
- Serologic methods in mycology
- Antimycotics: - Resistance examination of yeasts and mold fungi

7.2.4.1.4 Parasitology

- Microscopic proof of common Protozoans, larvae, eggs
- Identification of helminths, nematodes, insects, mites
- Serologic methods in parasitology

7.2.4.1.5 Serology

- Sampling, transport and storage of serum
- Disposal of specimens and laboratory material
- Preventive measures for personnel / laboratory worker
- Current methods for antigen and anti-body-tests for frequent microorganisms
- Standardisation and quality control

7.2.4.2 Specific specialty knowledge in:

- Work with automatic devices
- Evaluation of methods
- Automation of manual methods
- Disposal of infectious material
- Preventive measures for the personnel / laboratory worker
- Laws on epidemic diseases, methods of reporting

7.2.4.3 Medical knowledge

- Epidemiology and symptomatology of infections
- Therapy of infections with antibiotics, antiviral substances etc.

- Immunotherapy, immune-prophylaxis
- Control of nosocomial infections
- Zoonosis

7.2.5 Laboratory Genetics

7.2.5.1 Specific specialty knowledge and interpretation of laboratory results

- Genetic diagnostic tests with conventional cytogenetic, molecular cytogenetic and molecular genetics
- Reasons for medical genetic testing
- Effects of genetic defects
- Effects of structural and numeric Chromosome aberrations (including malignant illnesses)
- Possibilities, methods and risks of prenatal diagnosis

7.2.5.2 Cytogenetics

- Sampling and transport.
- Preparing, application and carry through cell cultures.
- Preparations of chromosomes according to standard methods and using synchronization techniques.
- Staining of chromosomes for banding.
- Microscopic analysis of metaphase chromosomes.
- Determination of karyotype and verification of numeric and structural chromosomal aberrations.
- Molecular cytogenetics (FISH).
- ISCN nomenclature (international system for human cytogenetic nomenclature).
- Quality assurance; internal and external quality control.
- Documentation and archiving.
- Compile and draw up descriptions of methods and operating procedures.
- Evaluation, interpretation and written reports of findings.
- Long-term storage of samples and cultures.
- Evaluation of new methods and devices (including comparison of methods).

7.2.5.3 Molecular Genetics

- Sampling, specimen-transport and specimen-treatment
- Preparation and storage of nucleic acids
- Cloning of nucleic acids
- Analysis of nucleic acids (including PCR, DNA Sequencing, restriction cleavage, Southern and Northern Blotting, labeling of probes, verification of mutation)
- Indirect gene diagnostics by means of genetic markers, evaluation and interpretation of the results („linkage „- analysis)

- Direct gene diagnostics for differential diagnosis
- Direct gene diagnostics for determination of carrier status
- Direct gene diagnostics for pre-natal diagnosis
- Pre-symptomatic gene diagnostics
- Quality assurance; internal and external quality control
- Compile and draw up descriptions of methods and operating procedures.
- Documentation and archiving
- Evaluation, interpretation (validity and limits of results) and written report of findings
- Long-term storage of specimens and cultures; Gene banks
- Evaluation of new methods and devices (including method comparison)

Syllabuses in Monovalent Specialities

7.3 Syllabus in Laboratory Medicine/Clinical Chemistry

The trainees will spend more time, compared to the trainee in General Laboratory Medicine/Polyvalent Biopathology, in the specialized laboratory. Although many of the fields of interest will be the same, more time will result in more in depth knowledge of these fields.

7.3.1 Clinical Chemistry

7.3.1.1 Medical knowledge, evaluation of results

- Important metabolic diseases
- Frequent polymorphisms of human genes and post-translation changes of gene products: relation with other analytical results and their clinical correlation
- Important electrolyte disturbances
- Important changes of organ-specific enzymes and proteins
- Important hormone disturbances
- Fertility
- Nutrition (vitamins, trace elements)
- Diabetes monitoring
- pH, blood gas analysis
- Tumor markers
- Clinical toxicology (procedure with acute poisonings): basics
- Therapeutic Drug Monitoring (TDM): basics
- Drug interferences (in vitro) and drug interaction (in vitro)
- Detection of addictive drugs (commercial assays)
- Frequent genetic polymorphisms related to the effect of drugs and foreign products

7.3.1.2 Methodology

- Physical, optical and electrometric methods (Flame-photometry, ISE, atomic absorption, osmolality, density, mass spectrometry)
- Separation methods (different types of electrophoresis techniques including HPLC, capillary)
- Chemical and enzymatic methods for the analysis of substrates
- Enzymatic methods for the determination of the activity of various enzymes
- Immunological methods (enzyme-immunoassay, fluorescence-immunoassay, fluorescence polarization and luminescence) for analysis of hormones, monitoring of drug concentration or of specific proteins
- Chemical and morphological Urine examinations (urine sediment)
- Point of care testing

- Toxicology and therapeutic monitoring: basic principles, screening

7.3.2 Laboratory Immunology

7.3.2.1 Medical knowledge, evaluation of results

- Basic immunology
- Nonspecific and specific immune reactions
- Autoimmune diseases (organ-specific/systemic)
- Immunodeficiency syndromes (primary/secondary)
- General immunology of infections
- Principles of immunological therapies (laboratory based therapy monitoring)
- Principles of vaccination (active/passive immunization, pre-/post infectious and control of success)

7.3.2.2 Methodology

Potential of mechanical devices / single test, series, automatic devices including logistic and financial aspects

- Testing of antibodies/antigens/ mediators by means of immunofluorescence
- Immune-precipitation in liquids (nephelometry/turbidimetry)
- Immune precipitation in gels
- Enzyme-immunological test procedures

7.3.2.3 Special immune diagnostics

- Autoantibodies
- Ig classes and - subclasses
- Specific Ig's in particular specific IgE
- Monoclonal and oligoclonal immunoglobulin changes
- Inflammation parameters including complement factors
- Cryoglobulins

7.4 Syllabus in Clinical and Laboratory Haematology and Transfusion Medicine

Haematology is both a clinical and laboratory speciality. Whilst it is recognised that most Haematologists have responsibilities in both clinical and laboratory areas, the extent of their responsibilities in the different areas will vary. Many Haematologists will work entirely in the laboratory and other Haematologists will work in the field of Transfusion Medicine.

All haematologists should receive training in Laboratory Haematology, Clinical Haematology and Transfusion Medicine. The core curriculum as outlined below includes all these areas. The extent of training in specific areas of the curriculum will depend on whether the trainees intend to pursue a career in Laboratory Haematology, in Clinical and Laboratory Haematology, or Transfusion Medicine.

7.4.1 Medical knowledge, evaluation of results

Trainees will be expected to place particular emphasis on covering the following subject areas of haematology.

- Ethical issues related to clinical and laboratory haematology and transfusion medicine
- Natural history of haematological diseases
- different forms of anaemia
- different forms of leukopenia
- different forms of thrombocytopenia
- Erythrocytosis / Polycythemia, Leukocytosis, Thrombocytosis
- Myelodysplasias
- Chronic and acute leukemias
- Lymphomas and lymphoproliferative diseases
- Haemoglobinopathies
- haemolytic diseases of the newborn
- congenital and acquired haemolytic anaemias and of abnormal haemoglobins and thalassemias
- coagulation disorders
- congenital and acquired bleeding disorders
- monitoring anticoagulant therapy
- thrombophilia and other hyper-coagulable syndromes
- Blood group systems
- MHC and HLA System
- Allo- and autoantibodies against red cells
- Allo- and autoantibodies against leukocytes and platelets
- Incompatibility reactions, preventing measures; complications during transfusion
- clinical indications for the transfusion of blood products including their handling and administration
- safety of blood products
- Transfusion Transmitted Diseases
- blood grouping and cross matching
- use of standards, red cell panels, HLA-typed donor panels

- collection, processing and preservation of stem cells
- apheresis procedure and immunoadsorption
- haemovigilance and look-back procedures

7.4.2 Haematology: Cumulative laboratory/technical experience

- Automated and manual blood counting
- Staining and examination of peripheral blood films
- Cytochemical and immuno-phenotyping examination of bone marrow
- microscopic examination of the blood and the bone marrow
- flow cytometry
- differentiation of haemoglobinopathies
- blood grouping and phenotyping
- allo/autoantibody screening and identification and compatibility testing
- HLA typing
- HNA typing
- HPA typing
- "Clotting" assays (including Global test)
- Chromogenic assays
- Antigen assays
- Platelet function tests
- Whole blood coagulation tests
- preparation of blood products
- Molecular Biology methods

7.4.3 Haematology: Cumulative Clinical Experience

7.4.3.1 Diagnosis and management in Clinical Haematology

Particular emphasis will be placed on trainees gaining experience in the investigation and management of patients

- with non-malignant haematological diseases such as iron deficiency, haemolytic asnaemia, megaloblastic anaemia, bone marrow failure syndromes, haemoglobinopathies and thalassemias and also the myeloproliferative and myelodysplastic disorders
- with malignant disorders including acute and chronic leukaemia, multiple myeloma and the lymphomas
- undergoing haematological stem cell transplantation procedures
- with coagulation disorders including haemophilia, von Willebrands disease, other congenital and acquired coagulation defects and the hypercoagulable syndromes
- congenital and acquired bleeding disorders
- anticoagulant therapy
- thrombophilia and other hyper-coagulable syndromes
- instruction in the haematological aspects of other hospital specialities including intensive care medicine, and obstetrics

- instruction in paediatric haematology including neonatal haematology

7.4.3.2 Management in Transfusion Medicine

- Organisation and management of Blood Transfusion Centres. Knowledge of blood transfusion service at national and international level and, in particular, knowledge of the regulations and standards for transfusion medicine in Europe.
- Management of blood donor sessions including autologous blood donation. The trainee should be aware of the requirement for donor screening.
- Donor management, eligibility and vigilance
- Management of blood supply including quality assurance.
- Management of bleeding patients

7.5 Syllabus in Clinical and Laboratory Immunology

The curriculum in Clinical and Laboratory Immunology incorporating the syllabus and assessment methods have already been published as position statements (*Training programme in immunology of the European Board of UEMS Medical Biopathology.Immunol Letters 2005;96:305-310, Assessment strategy for implementation of the Immunology curriculum of the European Board of UEMS Medical Biopathology. Immunol Letters 2009;125:59-64)*

Key elements of the curriculum are listed here, but the reader is referred to the aforementioned publications for a detailed account.

7.5.1 Fundamental Immunology and its Applications

Trainees will be expected to place particular emphasis on covering the following subject areas of fundamental immunology.

- Cells and organs of the immune system
- Cytokines, chemokines and other inflammatory mediators including lipid mediators
- Phagocytic cells and their function
- Antibody mediated immunity
- Complement system
- Cell mediated immunity
- Natural immunity
- Regulation of the immune system
- Hypersensitivity mechanisms
- Pathogenesis of immunodeficiency
- Pathogenesis of allergic diseases
- Immunological Tolerance and the pathogenesis of autoimmunity
- Immunobiology of transplant rejection and its prevention
- Classification and biology of malignancies of the immune system
- Scientific basis of allergen immunotherapy
- Scientific basis of immunoprophylaxis
- Scientific basis of therapy of primary immunodeficiency
- Scientific basis of immunosuppressive and immunomodulatory therapy
- New developments in therapy of immunodeficiency
- New developments in therapy of allergic disease
- Scientific basis of laboratory immunology

7.5.2 Immunology: Cumulative Laboratory Experience

(See Appendix A, "Laboratory training manual and record in Immunology Letters" 2009;125:59-64)

7.5.3 Immunology: Cumulative Clinical Experience

7.5.3.1 Diagnosis and management of Immunodeficiency disorders in adults and children

Particular emphasis will be placed on trainees gaining experience in the investigation and management of the immunodeficiency disorders listed below.

Clinical assessment of patients with suspected primary and secondary Immunodeficiency

- Antibody deficiencies
- T-Cell /Severe Combined Immunodeficiencies
- Complement deficiencies
- Phagocyte deficiencies
- Asplenia
- Rare conditions
- Clinical features of congenital and acquired immunodeficiency syndromes
- Acquired immune deficiency syndromes: viral (HIV...), drug induced
- Protocols for genetic studies of immunodeficiency syndromes

Selection and interpretation of laboratory investigations for:

- Management of Primary Immunodeficiency
- Management of patients with HIV infection
- Assessment and interpretation of specific antibody and vaccination responses
- Functional analysis of complement components
- Requesting and interpreting specific cellular immunology tests
- Cell surface and cytoplasmic markers in immunodeficiency diagnosis
- Lymphocyte function tests
- Granulocyte function tests

Selection and interpretation of ancilliary investigations (eg. lung function tests, CT scan of chest etc.)

Management of IVIG therapy

Management prophylaxis of infections in the immunosuppressed patient

Diagnosis and follow-up of iatrogenic acquired immune deficiencies secondary to biotherapies and immunotherapies (BMT, organ transplantation, molecular and cell therapies)

7.5.3.2 Autoimmune disorders

Trainees will be able to assess and treat (under supervision of rheumatologist or relevant organ-based specialist) adult patients with systemic autoimmune rheumatic disease and systemic vasculitides with particular emphasis on:

- Diagnosis and management of SLE and lupus-overlap disorders
- Sjogren's syndrome
- Systemic sclerosis
- Systemic vasculitis including cryoglobulinaemia
- Periodic fever syndromes

7.5.3.3 Diagnosis and management of allergic diseases in adults and children

Trainees will be able to assess and treat patients with serious allergic diseases with particular emphasis on those disorders listed below.

- Anaphylaxis
- Urticaria/Angiooedema
- Drug allergy
- Anaesthetic reactions
- Food allergy
- Respiratory allergy
- Venom hypersensitivity

For all of the above areas, a certificate (from a supervisor) assessing through direct observation and critique of technique, attesting to the trainee's acquisition of requisite experience will be required**.** Given that medical education is a life long process, trainees and independent practitioners will be expected to consult as appropriate with relevant specialists or other relevant organ-based specialists regarding patients with complex problems outside their own area of expertise.

7.5.4 Immunology: Cumulative Experience in Practical Procedures

- Administration of. Immunoglobulin (IV)
- Administration of. Immunoglobulin (SC)
- Lung function tests: principles and interpretation
- Imaging
- Skin prick testing
- Patch Tests
- Skin biopsies
- Protocol for systematic investigation of anaphylaxis
- Protocol for emergency management of anaphylaxis in adults and children
- Management of home therapy programmes

7.6 Syllabus in Laboratory Genetics

A detailed syllabus in laboratory genetics is being developed

8 Fellowship

Laboratory Physicians/Medical Biopathologists who have achieved the competencies set out in the respective curricula will be conferred with the Fellowship of the European Board in Laboratory Medicine/Medical Biopathology. Individuals who are already registered medical specialists in one EU country already have an automatic right to practice in another EU country. Acquisition of the fellowship of the European Board of Laboratory Medicine/Medical Biopathology confers no additional rights and is not a mandatory qualification. However, it is hoped that it will facilitate travel and movement within Europe for those individuals from countries who are full or associate members of UEMS. It will also help practising monovalent specialists to move to another country within the EU where a particular specialty may not be officially recognised. Award of the fellowship to such individuals is an acknowledgement of official recognition of the competence of the specialist concerned and thus facilitate practice across Europe. It is also felt that the Fellowship of the European Board of Laboratory Medicine/Medical Biopathology will help in aligning the practice of Laboratory Medicine/Medical Biopathology into various EU countries and in providing a more uniform standard for training in Laboratory Medicine/Medical Biopathology

Conditions for awarding the Fellowship

1. The candidate must be a recognised specialist in Laboratory Medicine/Medical Biopathology for at least three years.
2. It must be demonstrated that the candidate has appropriate expertise in the field of Laboratory Medicine/Medical Biopathology either polyvalent or one of the monovalent specialties.
3. It should be proved that the candidate has shown continuing scientific interest in the specialty and fulfils the requirements for CME/CPD in the specialty.

For the majority of candidates documentary evidence will be sufficient. However, the Examining Board may ask a candidate for further documentary information or may require a candidate to attend for interview.

The application and further information for the fellowship is found on the website of the Section Laboratory Medicine/Medical Biopathology:

http://www.uems-smb.org/board/board.htm

9 Continuing Professional Development (CPD) or Continuing Medical Education (CME)

Continuous Medical Education (CME) refers to education after certification and licensure and is the final part of the Education continuum. It provides a framework for medical practitioners to keep abreast of the continuous pipeline of advances in medical science and treatment. It relied initially on teacher driven training of practicing medical doctors through various traditional or more innovative university or non-university channels. Providers are indeed academic groups, professional associations, pharmaceutical industry and health care institutions committed to producing and delivering educational activities in order to maintain a competent medical and public health workforce and improve the health of both patients and populations.

Continuous Professional Development (CPD) is generally defined as the conscious updating of professional knowledge and the improvement of professional competence throughout a person's working life. In Medicine, it is the process by which health professionals keep updated to meet the needs of patients, the health service, and their own professional development. More learner-driven than CME, it includes the continuous acquisition of new knowledge, skills, and attitudes to enable competent practice. It is a lifelong commitment that builds on formal and informal opportunities to learn emerging science, apply innovations in clinical settings, and expand understandings of caring for patients.

The literature on CME and CPD shows that most passive educational activities are poor at changing physicians' behaviour, the most effective strategies tending to be more active, multiple, based on accurate assessment of need, and aimed at overcoming barriers to change. The new concept of Knowledge Translation offers a more holistic concept, building on CME and CPD. It is defined as the exchange, synthesis and ethically sound application of knowledge (using evidence based clinical knowledge) to accelerate the capture of the benefits of research towards improved health, more effective services and products, and a strengthened health care system.

10 The European Accreditation Council for CME (EACCME)

The European Accreditation Council for CME (EACCME) is run by the European Union of Medical Specialists (UEMS). It delivers European accreditation to organizers of congresses, workshops, symposia that apply for the accreditation of a CME activity. Long distance learning CME activities and enduring materials will also be considered for accreditation in the near future.

In order to obtain EACCME accreditation, the CME activity must be accredited by the national CME authority of the country where the event takes place and approved by the UEMS Section or Accreditation Council. For CME activities taking place in countries where there is no CME authority, the EACCME will rely on the expertise of its Specialist Sections/European Boards.
The criteria for approval by the EACCME are described in the document D 9908 (http://admin.uems.net/uploadedfiles/46.pdf)

Applications should reach the EACCME Secretariat at least 3 months prior to the start of the CME activity in order to allow the EACCME to contact the national CME authority of the host country and the UEMS Section for approval.
Application forms are now available on the EACCME website and will be managed online (http://www.eaccme.eu/)
The provider has to choose the UEMS section, which will evaluate the CME activity. The laboratory medicine - biopathology section is thus competent in evaluating biochemistry, general laboratory medicine - polyvalent biopathology, genetics, haematology, and immunology CME events.
The organisers receive a letter of accreditation with the number of CME credits granted and an invoice for administrative expenses.

The EACCME awards the appropriate number of European credits for each event based on the European CME Credits System (ECMEC's) based on one hour of educational activity equating to one ECMEC with a maximum of 3 ECMECs for a half-day and 6 ECMECs for a whole day.
All CME activities approved by the EACCME are valid for recognition by the American Medical Association (AMA) towards the Physician's Recognition Award (PRA). Conversely, all CME activities approved by the American Medical Association (AMA) are recognized by the EACCME.

The summary details of the event are published on the EACCME website together with the number of CME credits granted.

11 Accreditation of Medical Laboratories

The quality of a laboratory depends on all services provided by the laboratory, starting with the information the laboratory provides to the physician taking samples of patients, conditions of transport of the specimen, quality assurance of the preanalytical and analytical performance by enlisting in proficiency testing (surveys), the reporting of results including interpretation and consulting, up to the management of complaints.

Participating in surveys enables a laboratory to regularly evaluate its performance and improve the accuracy of the patient results it provides. Survey organizers provide individual laboratories with unknown specimens for testing; the participants analyze the specimens and return the results for evaluation. In turn, each participating laboratory receives a report of its performance as well as a report summarizing the results of all participating laboratories.

Participating successfully in surveys for all tests the laboratory performs is a prerequisite for a successful application for accreditation of the laboratory.

Laboratory Accreditation is based on ISO 15189, an internationally accepted accreditation standard. Accreditation meets the needs of a variety of laboratories from complex university medical centres to smaller highly specialized laboratories and should always cover all services the laboratory provides..

Most organizations offering Laboratory Accreditation utilize multi-disciplinary teams of practicing laboratory professionals as inspectors. Because they deal with lab issues on a daily basis, these inspectors are uniquely qualified to provide the inspected laboratory with a thorough inspection that is specific for each section of the laboratory.

The goal of Laboratory Accreditation is to improve patient safety by advancing the quality of laboratory services through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements set by national and state regulatory bodies.

Accreditation helps laboratories to achieve the highest standards of excellence and thus enhances patient care. It is a prerequisite for any laboratory interested in providing training to doctors and scientists.

12 Inspection of Training Centres

The UEMS has produced a Charter on Training of Medical Specialists in the European Community and a Charter on Visitation of Training Centres. These documents state that there is need for a harmonisation in the field of Training, Training Centres and inspection of Training Centres as there is a good deal of variation between national centres.

In order to assure a high quality of training, certain criteria have been laid down concerning the institutions that train Laboratory Physicians-Medical Biopathologists. The inspection of the Training Centres is an important method of ensuring the quality of training and the Training Centres.

Like the UEMS and Sections of the UEMS, the Section of Laboratory Medicine/Medical Biopathology will rely on the national professional authority to undertake the task of visiting Training Centres. However, it does reserve the right to carry out inspections itself should the need arise. One of the tasks of the European Board of Laboratory Medicine/Medical Biopathology (EBLM/MB) is to establish a standard for the training of Medical Biopathologists in Europe.

Requirements for Training Institutions as well as standards for recognition of institutions and teachers in the specialty have been proposed by the Section. These relate to the qualification of the chief of training as well as to the additional staff, the training program for the trainees, the structure of the laboratory and its co-operation with institutions, the number of qualified specialists in the teaching staff, the number of trainees and the diversity of educational training and practical work.

The training program must progressively increase the responsibility given to the trainee. Each trainee must be graded on a regular basis and grades must be officially recorded in a logbook.

Further the laboratory must conduct quality control, quality assurance, participation in user surveys and it has to be accredited according to ISO 15189.

The inspection of training institutions by the UEMS Section Laboratory Medicine/Medical Biopathology will be conducted in a structured manner.

A training centre for specialization in Laboratory Medicine/Medical Biopathology may apply for recognition by the EB-LM/MB. Application material is found on the homepage of the Section.