European Training Requirements for the Specialty of Laboratory Medicine 2025

Contents

Preamble

The UEMS (Union Europe´enne des Médecins Spécialistes, or European Union of Medical Specialists) is a non-governmental organisation representing national associations of medical specialists at the European level. With its current membership of 40 national associations and operating through 43 Specialist Sections and their European Boards, 17 Multidisciplinary Joint Committees and 4 Thematic Federations the UEMS is committed to promote the free movement of medical specialists across Europe while ensuring the professional consensus on the framework for the highest possible level of their training which will pave the way to the improvement of quality of care for the benefit of all European citizens and beyond.

UEMS and its Postgraduate Medical Specialists Training programmes. In 1994, the UEMS adopted its Charter on Postgraduate Training aiming at providing the recommendations at the European level for high quality training. This Charter set the basis for the European approach in the field of harmonisation of Postgraduate Specialist Medical Training, most importantly with the ongoing dissemination of its periodically updated Chapter 6's, specific to each specialty.
After the most recent version of the EU Directive on the recognition of Professional Qualifications was introduced in 2011, the UEMS Specialist Sections and other UEMS Bodies have continued working on developing the documents on European Training Requirement(s) (ETRs). They reflect modern medical practice and current scientific findingsin each of the specialty fields and particular competencies covered and being represented within the UEMS. In 2012 the UEMS Council adopted the document Template Structure for ETR.

The linkage between the quality of medical care and quality of training of medical professionals. It is the UEMS' conviction that the quality of medical care and expertise are directly linked to the quality of training, achieved competencies and their continuous update and development provided to the medical professionals. No matter where doctors are trained, they should have the same core competencies. The UEMS ETRs reflect many years (or even decades) of experience on the ground of the UEMS Sections/ Multidisciplinary Joint Committees (MJCs) and Boards developing in close collaboration with the relevant European Scientific Societies training requirements coupled with European Medical Assessments. It is one among the clear aims of the UEMS ETRs to raise standards of training to make sure that European patients find high quality standards of safe specialist care. While professional activity is regulated by national laws in EU Member States, it is the UEMS understanding that it has basically to comply with international treaties and UN declarations on Human Rights as well as the WMA International Code of Medical Ethics.

UEMS and European legislation facilitating the mobility of medical professionals. The UEMS Council and its Specialist Sections, first created in 1962, have regularly provided advice and expert opinion to the European Commission. This helped create the framework that informed the drawing up of the Doctors Directives in 1975, which provided for the mutual recognition of medical diplomas and the free movement of doctors throughout the EU. The revised EU Directive on the recognition of Professional Qualifications (2013/55/EU) allows member states to decide on a common set of minimum knowledge, skills and competencies that are needed to pursue a given profession through a Common Training Framework (CTF) which represents the third mechanism that could be used to ensure mobility within the EU. This directive states that "professional qualifications obtained under common training frameworks should automatically be recognised by Member States. Professional organisations which are representative at Union level and, under certain circumstances, national professional organisations or competent authorities should be able to submit suggestions for common training principles to the Commission, in order to allow for an assessment with the national coordinators of the possible consequences of such principles for the national education and training

systems, as well as for the national rules governing access to regulated professions". The UEMS supported CTFs since they encompass the key elements developed in modern educational and training models, i.e. knowledge, skills, professionalism. In addition, the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross border healthcare introduced a strong incentive for harmonisation of medical training and achieved competencies among EU/EEA Countries through the requirements to assure good and comparable quality of care to increasingly mobile European citizens.
The UEMS ETR documents aim to provide for each specialty the basic training requirements as well as optional elements, and should be regularly updated by UEMS Specialist Sections and European Boards to reflect scientific and medical progress. The three-part structure of these documents reflects the UEMS approach to have a coherent pragmatic document for each individual specialty, not only for medical specialists but also for decision-makers at the national and European level interested in knowing more about medical specialist training. To foster harmonisation of the ETR by adopting more specific guidelines, the CanMEDS competency framework is recommended which defines the entire set of roles of the professionals which are common across both medicine and surgery. UEMS has an agreement to use an abbreviated version of the competencies within those roles.

Importance of making a distinction between Knowledge and Competency in ETR documents. Competency-based education is not oriented towards the period of clinical rotations, but towards trainee, and trainee's progress in the acquisition of competencies. Having a clear distinction within an ETR's contents between competencies and knowledge helps define both how that training should be delivered and how it should be assessed. The UEMS considers that the appropriate use of different methods of assessment of knowledge and acquired skills, emphasising the workplace based assessment, is an essential component of quality postgraduate training, focused on high standards of specialist medical practice. To improve the methods of assessment it is also recommended to use the so-called Entrustable Professional Activities (EPAs) in all specialties ETRs. In order to recognise common and harmonised standards on the quality assurance in specialist training and specialist practice at a European level some UEMS Specialist Sections and Boards also have, for a long time, organised European examinations (supported and appraised by the UEMS CESMA - Council of European Specialist Medical Assessments).

Overlapping of learning outcomes and competencies. Each of the UEMS ETRs defines a syllabus or knowledge base and describes learning outcomes defined for given competencies. Some of these curricula encompass a whole specialty, other focus on areas within or across specialties and define content of the training requirements for specific areas of expertise. By recognising the potential overlapping it creates the opportunity for those writing ETRs to draft overlapping or common goals for learning outcomes. Similar measurement does not necessarily equate to the same targets. Rather, across different specialties the final goal may differ, i.e. there may be clearly defined individual goals for trainees with different expectations.

UEMS ETRs and national curricula. The UEMS strongly encourages the National Medical Competent Authorities (NMCAs) to adopt such requirements and believes that this is the most efficient way of implementation of good standards in postgraduate training. We clearly respect and support the vital role of the NMCAs in setting high standards of training and care in their respective Countries and checking through robust quality control mechanisms the qualifications of medical specialists moving across Europe. The UEMS ETRs are developed by professionals for professionals and this adds unique value to them. UEMS aim is to indicate the knowledge and competencies that should be achieved by trainees in EU/EEA countries and also competencies and organisation of the training centres. The training environment and results described in UEMS ETRs may be achieved in adapted ways, depending on local traditions, organisation of healthcare system and of medical specialist training.

Adaptation of UEMS ETRs to local conditions assures the highest quality of specialist training and each state may include additional requirements, depending on local needs.

Importance of collaboration with other representative European medical bodies. The UEMS always wishes to work with all Colleagues, NMAs, professional and scientific organisations across Europe. In the process of ETRs development, the UEMS recognises the importance of meaningful collaboration with the other European medical representative bodies, the European Junior Doctors (EJD representing doctors in training), the European Union of General Practitioners (UEMO – Union Europeenne des Medecins Omnipraticiens), the Standing Committee of European Doctors (CPME - Comité Permanent des Médecins Europe´ens), the Federation of European SalariedDoctors (FEMS) and the European Association of Senior Hospital Doctors (AEMH -Association Européenne des Médecins des Hôpitaux). In addition, UEMS continues to develop closer links with the many European Specialist Societies. UEMS, in collaboration with its fellow European representative bodies, has constantly been highlighting the importance of coordinated postgraduate specialist medical training programmes always accepting the differing needs of different specialties. In this way quality medical care is delivered by highly qualified medical specialists - essential to ensuring consumer confidence and protection all over Europe.

Conclusions. UEMS is very proud for all the hard work that has been done until now in developing the UEMS ETRs as well as that they are increasingly implemented as national curricula. However, we also recognise the need for constant improvement, and we are always open to further suggestions. The UEMS insists that the medical profession remains the driver in defining its own specialist training and continuous professional development needs. On this basis, we sincerely look forward to working with the key European Union responsible bodies, as well as the national stakeholders in implementing the basic common strategies and requirements outlined with this initiative. We are confident that the priorities detailed in UEMS ETR documents developed for individual specialties (and/or competencies) will become evident in national strategies and programmes, as well as action plans for postgraduate medical education and training.

References:

1. Charter on Training of Medical Specialists in the European Community, Charter adopted by the Management Council of the UEMS, October 1993
2. Fras Z. The current role, continuing challenges, and future strategy of the UEMS. In: Fras Z, Destrebecq F, eds. Building on solid foundations to improve specialist healthcare for 18th European citizens. UEMS 50th Anniversary Conference, Brussels, April 2008. Book of papers. Brussels: European Union of Medical Specialists, 2008: 37-40.
3. Harvey L. History of the UEMS. In: Fras Z, Destrebecq F, eds. Building on solid foundations to improve specialist healthcare for European citizens. UEMS 50th 18th Anniversary Conference, Brussels, April 2008. Book of papers. Brussels: European Union of Medical Specialists, 2008: 29-32.
4. Twomey C.Postgraduate Training for Medical Specialists – what more can be done for greater harmonisation in Europe? In: Fras Z, Destrebecq F, eds. Building on solid foundations to improve specialist healthcare for European citizens. UEMS 50th 18th Anniversary Conference, Brussels, April 2008. Book of papers. Brussels: European Union of Medical Specialists, 2008: 19-22.
5. Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. http://data.europa.eu/eli/dir/2005/36/oj
6. Directive 2013/55/EU, of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation'). http://data.europa.eu/eli/dir/2013/55/oj
7. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. http://data.europa.eu/eli/dir/2011/24/oj

8. Frank JR, Snell L, Sherbino J, editors. CanMEDS 2015 physician competency framework. Ottawa: Royal College of Physicians and Surgeons of Canada; 2015 Copt©yrigh 2015 The Royal College of Physicians and Surgeons of Canada.https://www.royalcollege.

Specialty of Laboratory Medicine and its Aims

A medical doctor specialist in laboratory medicine provides his/her services in healthcare by appropriate laboratory tests and medical interpretation, quality control and patient safety within the remit of medical laboratory and direct patient care as outcome of laboratory results. Healthcare services between EU member states differ based on culture traditions and healthcare needs so it is not a surprise that the scope of practice of medical doctor specialists in laboratory medicine varies between and within countries (Annex V EU Directive 36/05). Harmonization of competencies in some or all topics covered by laboratory medicine together with EU professional mobility supports equivalence of healthcare standards and safeguards.

The UEMS Section of Laboratory Medicine was established in 1962 with subsequent separation of Section for Pathology and Section for Medical Microbiology. The current name of the Section „Laboratory Medicine / Medical Biopathology“ was accepted by the Council in 1988. The name of the Section and terminology used in this ETR reflects the profession development and healthcare provided by the specialty of modern medicine.

In the Annex V EU Directive 36/05 this medical specialty is represented in two columns (originating in 1974) with generic headings (titles) „Clinical Biology“ and „Biological Chemistry“. EU states have listed for either, and in most cases under both headings their national names, which also display considerable diversity in terminology. Other medical specialties involved in direct laboratory investigations in the Annex V are Pathological Anatomy, Microbiology/Bacteriology and Medical Genetics. Medical specialties practiced in some EU countries, but not in the Annex V are Medical Transfusion and Laboratory Immunology. This ETR takes into account both heterogeneity of practices in the EU states regarding scope and topics of practice, and also supports overlapping and correspondence of competencies and practices between medical specialties mentioned previously. We hope the users of this ETR will accept the pragmatic approach to training standards of medical specialists in laboratory medicine, which at the same time respects subsidiarity of national healthcare practices.

Laboratory Medicine is a specialty requiring a thorough medical knowledge of the function of human body in health and disease, aetiology and pathophysiology of diseases and disorders, including medical presentation, competent use of standard methods of medical investigation and up-to-date laboratory methods. This also includes the management of a medical laboratory and quality policy, competence to introduce and establish new diagnostic methods and the provision of advice on their rational use and interpretation to both other medical specialists, patients and other healthcare professionals. Within the scope of this specialty is patient consultation and treatment according to the laboratory test results through work in „clinics“, within the hospital environment, out-patient clinics or primary care setting with medical laboratory service. This aspect of the specialist of laboratory medicine may include anaemia disorders, anticoagulation therapy, antibiotic therapy, metabolic diseases and their monitoring, and other topics. The scope and specific patient care service is expected to vary between countries not only due to diversity in topics included in laboratory medicine training and specialty, but also depending on the national culture and tradition. Among EU member countries the scope of the specialist of laboratory medicine is diverse and varies depending on the traditions and requirements of the national healthcare system. Nevertheless essential (and other) competencies are consistent across the EU member countries and beyond. It is up to the member States and national healthcare authorities (or governments) to decide on the scope of specialist skills of the laboratory medicine specialist and also with respect to other medical specialiaties. This will also depend on the progress of medical sciences, but needs to take into account ageing population, chronic conditions and consequences of increased travel and mobility and pandemic threats. The aim is to achieve the delivery of high-quality patient care in laboratory

medicine by promoting and harmonizing high standards for medical practice and postgraduate medical specialist education, resulting in medical excellence. The three key aspects of medical specialist training in the EU, i.e. requirements for the trainees, for the trainers and for the training institutions would all benefit from robust criteria for quality assurance and continuous improvement, transparency of governance and equity principles.

Training requirements for trainees

A medical trainee is a doctor who has completed their general professional training as a physician and is in an accredited training programme to become a recognised medical specialist.
Trainees in Laboratory Medicine are medical doctors with a diploma of medical doctor in basic (or undergraduate training). A national authority or other government body can decide on additional entry criteria for candidates for trainees in the medical specialty of Laboratory Medicine. There are differences in organisation of Laboratory Medicine training in each European country, but the broad principles of the curriculum have been developed to allow general applicability and the trainee will have corresponding core competencies with differences in scopes of topics.
The medical trainee must be fit to practice medicine and laboratory medicine. The medical trainee will achieve competency in specialist knowledge, medical and technical skills, ethical and professional attitudes.
Examples of general requirements for the trainee:

- commitment in ethical and professional attitude,
- dedication to patient care,
- follow the highest standard of medical specialists' profession,
- take active part in all recommended activities,
- respect the rules and regulations of the training programme,
- develop communication and social skills, and
- collaboration and teamwork.

Content of training and learning outcomes

The training should be organized to enable the trainee to achieve competency in laboratory medicine specialist knowledge, required medical and technical skills, ethical and professional attitudes under the guidance of the trainer (or mentor).
Rotation periods should enable sufficient experience for all main areas of the specialty or according to the scope of the profession as required nationally. The learning process should be guided and supervised by the mentor, enabling the trainee sufficient opportunities of observing and performing procedures/tasks/evaluations to reach independent expertise for each required competency. This should also include training in hospital departments (specified later in text), outpatient clinics and direct patient care. A recommended number of procedures/tasks can be suggested but should be adapted individually with the aim of achieving the highest level of competency and entrustable professional activities (EPA).
Throughout training an education programme will be followed by the trainee and guided and supervised by the trainer. The training includes attending conferences and scientific meetings, staff meetings, case discussions, working in the medical laboratory environment and hospital deparments, outpatient clinics and direct care of patients. Protected time must be provided to the trainee for study and research. The trainee should be involved in these scientific activities by giving lectures, presentations both locally and at least on the national level. The trainee should also be involved in teaching activities as appropriate to acquired level of competency for a specific topic, to nurses and technicians, younger trainees and colleagues, educating patients and general public.
A certain degree of freedom should be allowed in order to choose an appropriate training concept (path), which enables the trainee to acomplish the required specialist standards as appropriate for the national healthcare requirements.

Transparency - The detailed training programme including the aims of the specialty, competencies and entrustable professional activities, training institutions (or network of institutions), trainers, schedules, portfolio and/or logbook should be available or accessible through national online portal.

It is recommended that the duration of training should be a minimum of 5 years, depending on national requirements. It should be stated that the minimum requirement according to the Annex V Directive 36/05 EU is currently 4 years. The process of education should be guided and controlled by the (regulatory) national authorities. In order to acquire sufficient practice in direct patient care, i.e. competency, the trainee should work at least 12 months (or longer, if required either by the national healthcare plan or for reasons of achieving adequate skills' standards) under trainer's supervision and guidance. The direct patient care setting would preferably be general internal medicine department and outpatient clinic, and also some time spent at the emergency medicine department, general pediatrics department, family medicine (or general practictioner) clinic or other medical services (if required due to trainees interest or future post).
The training should be organized as competency-based medical education, and guided by:

- Focus on competency outcomes
- Regular monitoring of competency level advancement,
- Diverse learning environments adjusted to the trainee for achieving standards,
- Mentoring driven by competencies' levels.

Theoretical knowledge

The educational process in the curriculum includes essentials in medical patient-orentied training and in laboratory-specific knowledge and skills. Due to the different organization and facilities of teaching institutions this process can be modified individually and/or according to national healthcare requirements and traditions. Theoretical knowledge is described in the syllabus part of this document.

Practical and medical skills

The trainee who progresses into medical specialist in laboratory medicine should achieve medical skills as described by the CanMeds framework. This includes good general knowledge on the function of the human body in health and disease, up-to-date knowledge of laboratory methods, rational and appropriate use of laboratory tests, and interpretation of laboratory results in the light of all patient information. Key medical skills include patient evaluation, laboratory (and non-laboratory) investigations, interpration of laboratory tests and integration of all patient information to result in diagnosis, medical advice and treatment. Additionaly this includes communication skills, life-long improvement in self education and engaging in education of others, leadership and organisational skills. The scope of medical skills is expected to vary between EU member states and also to accomodate for national and local healthcare requirements.
Specific skills of medical doctor specialist in laboratory medicine comprise integration of medical knowledge and essential facts of standard and up-to-date laboratory methods to support healthcare by providing competent medical interpretation and advice on laboratory test results to patients and other medical specialists, including direct patient care. These skills are based on previously described roles of the medical doctor, but also include laboratory-related skills (method verification/validation and the associated laboratory processes management, laboratory quality management and accreditation, safety issues, and others). These skills are employed across the entire scope of practice of the laboratory medicine specialist as depending on national requirements, and may be applied to only one topic or a range of topics.

Competencies

In line with the CanMEDS framework (roles of: medical expert, professional, scholar, communicator, collaborator, leader, health advocate) the trainee will strive systematically to master these roles during his/her specialist training aided and under guidance of the trainer and other mentors. The trainee will also, after obtaining the degree of the specialist in laboratory medicine, through continuous professional development further develop the aforementioned roles in his/her professional life.

The levels of competence to be reached accomplished by the trainee and for the trainer to monitor:
Level 1 - to know or know of
Level 2 - to observe and demonstrate/explain
Level 3 - to perform with supervision
Level 4 - to perform without supervision or reach EPA (entrustable professional activity = the specific individual trainee/medical specialist can be entrusted to perform simple and complex tasks within the laboratory medicine scope).

Entrustable Professional Activity (EPA) as a competence-based Unit
In order to apply a competence-based education and assessment to training in Laboratory Medicine the concept *of Entrustable Professional Activity* is being introduced. An EPA is 'a critical part of professional work that can be identified as a unit to be entrusted to the trainee once sufficient competence has been reached'. An EPA goes a level higher than the traditional level 4 of competence which is the 'independence competency'. The key factor is Entrustment**.** The trainee is not only capable of tackling the particular procedures or units independently, but can be trusted to do this competently and safely by his tutors. The level of competency can be verified through e-Portfolio and Logbook (optional national requirements, not yet included in this ETR).

Organization of training

Schedule of training

Depending on national regulations, the training may start immediately after completion/ graduation from medical school and/or full registration by the national regulatory body. It is recommended that at least 12 months of postgraduation training is performed in a hospital ward/deparment, preferably internal medicine, intensive care, emergency admission, pediatric or post-sugery, or two-three departments suggested to obtain direct experience in patient care, use of laboratory test requests and interpretation with regard to a specific patient. The remaining time in training has to be divided and organized to cover and accomplish the required competency in all applicable areas of laboratory medicine, and also include direct patient care initially with the aide of the trainer, initially under supervision and finally independantly. The concept of this ETR comprises specialist training during five years (60 months), although the Directive EU 36/05 Annex V states that 4 years is minimum duration. Having in mind the rapid progress in medical science/technology and consequently the demand on specific and broad competencies of a medical specialist, it is felt that 5 year provides sufficent training time as a general rule . This document does not include a schedule of rotation or time spent to cover some or all areas of laboratory medicine and this has to be decided on national basis as a competency-based specialist medical education. This also includes instances for a specific demand in healthcare with special focus on a special area of laboratory medicine. Sufficient time should be provided for research activities and learning (individual, peer, group discussions, moderated discussions and so forth).

Curriculum of training

During their training the trainee should acquire required knowledge and skills for the practice as a specialist in laboratory medicine. The scope and topics of the speciality of laboratory medicine varies between EU member states (and also other countries wishing to adopt this ETR); however, the general knowledge and skills and most topics are corresponding. This should be acquired during specialist training as competency based training and according to the CanMeds Framework.

Competencies of a specialist in Laboratory Medicine according to CanMeds Framework

1. **Medical Expert** – basic training medical knowledge on the function of human body in health and disease. Rational and appropriate use of laboratory tests within the capacity of current knowledge of medical sciences and according to the national healthcare requirements and scope. The trainee must be capable of summarizing and interpreting the available patient information and laboratory and other investigation results, including the recommendation and interpretation of laboratory tests to both patients and other medical specialists. The trainee should achieve competence in making diagnostic conclusion feeding into the subsequent investigation and treatment. Direct involvement in various and specific aspects of patient care.
2. **Communicator** – communication skills in relationship to healthcare professionals and patients, patient representatives and advocacy groups. Support and enhance collaboration with other medical professionals. Mutual and respectful collaboration at all times.
3. **Collaborator** – skills required for successful teamwork within the various healthcare settings, acknowledge importance of professional overlapping in healthcare.
4. **Leader** – acquire skills of teamwork and leadership necessary to lead the multidisciplinary team. Practices leadership skills in situations where medical qualifications are essential, acquire leadership approach and reasoning in advisory circumstances for other medical specialists. Take an active approach to improvement of patient care incl. establishement and critical approach to new laboratory diagnostics. Organise, prioritise and manage daily work efficiently and effectively.
5. **Health Advocate** – apply state-of-the-art knowledge to promote good health and the highest standards of healthcare in own microenvironment and on the population scale. Promotion of good health, and “quality of life” is an important goal in healthcare. Self-awareness and self-management.
6. **Scholar** – engage in lifelong learning, continuous professional development and medical education within the broadest field of laboratory medicine (and general medicine), take part in teaching and educating of colleagues, collabolators, students and general public (when appropriate). The trainee must learn the critical use of published data and information of relevance for practice, understand and apply principles of ethical research.
7. **Professional** – demonstrate the highest professionalism in everyday work and towards all persons in all working environments, remain a true professional in your life as an ambassador of medical profession and medical specialist. Identifies areas for improvement and initiates improvement projects (incl. audits). Support and participate in the implementation of change.

Entrustable Professional Activity to be achieved during training in laboratory medicine

The EPAs in this ETR for Laboratory Medicine / Medical Biopathology draft update correspond in name to the main topics (chapters in this ETR) of the wide scope of the laboratory medicine specialist practice in the EU. This was chosen as a pragmatic approach to have a reasonable number of EPAs, and to associate competencies (skills, knowledge) to actual practice of the specialist in laboratory medicine (workplace). In some EU countries all these topics will be included, in other EU countries some topics will be included and it is mostly the entire knowledge/skill content of a topic.

For example for the topic of “Laboratory clinical chemistry, medical biochemistry, chemical pathology”, EPAs could be defined according to the body systems (liver, kidney, endocrine) or age group (children, adolescence, elderly), physiological state (puberty, pregnancy, peri-menopause) which would result in too many EPAs. Also within this topic, most of the subjects are practiced simultaneously and thus EPAs would not reflect the practice appropriately.

1. EPA in General Laboratory Medicine Skills
2. EPA in Laboratory Clinical Chemistry / Medical Biochemistry / Chemical Pathology
3. EPA in Laboratory Genetics and Genomics
4. EPA in Laboratory Haematology
5. EPA in Transfusion Medicine
6. EPA in Laboratory Immunology
7. EPA in Medical Microbiology

The CanMeds Framework roles for the specialist in laboratory medicine applies for each of the EPA topics listed. Existing diversity in scope and practice of laboratory medicine as a medical specialty among EU member states may include differences in practice and topics, but general and broad corresponding EPAs are expected. It should be emphasized that the first EPA for the General Laboratory Medicine Skills is included in each of the EPAs or topics.

Documentation of training

Each trainee should keep an official national trainee logbook and/or portfolio. The national authority or regulating body in close collaboration with national medical scientific societies with expertise in medical education (or NMAs or medical chambers or medical schools) should establish logbooks and/or porfolios for recording and monitoring specialist training. It can be expected that these documents will be in electronic format. The national authority should have the logbook/portfolio as record with documents revisited and updated at regular intervals or according to recommendations of appropriate medical educational sciences.

In this logbook/portfolio the trainee demonstrates that he/she has been sufficiently exposed to and performed tasks with levels of competence achieved. The trainee should keep a written record, in the form of a logbook/portfolio, of all relevant activities during training according to the training program. The logbook is also proof of progress or achieved milestones as described by competency level. The recording should include cases, tasks, discussions, education and teaching, problems encountered, conclusions, taking part in various educational activities, hospital meetings, conferences and courses, and do forth.

An independent Training Programme Director, trainer or mentor, is required to monitor and confirm (guarantee) trainee progression i.e. achievement of the required competence (knowledge or skill). The trainer should also work towards good communication with the trainee and support the trainee in the course of training.

The content of a logbook/portfolio depends on the requirements of the particular country and healthcare scope of the specialist in laboratory medicine, and should include:

- information on training posts, dates, duration of training and trainers,
- competence-based list of performed tasks, duties, reports, investigations, tests, analyses, skills for each major topic or area in the training,
- list of (internal and external) courses and audits attended,
- list of publications,
- list of research/medical presentations at a local, regional, national or international meeting,
- list of institutional mandatory training courses completed, including all aspects of safeguarding.

The logbook and portfolio might also be of value for purpose of mobility within the EU and when applying as a candidate for EU UEMS medical specialist exam.

Assessment and evaluation during training

Formative assessment should be part of the training using standard tools for this purpose or its modification(s) at least once a year. The outcomes should be documented and discussed with the trainee. Regular formative appraisal during training can support trainee's progress in acquiring competencies (level 4 and EPA) and help in compensating for delays in individual professional development.

Description of workplace-based assessment tools

- Case-based discussion (CbD)

Trainees present and discuss two cases with a mentor or more experienced colleagues and obtain systematic and structured feedback from the assessor. The CbD is designed to assess decision-making and the application or use of medical knowledge in relation to the patients. It also enables the discussion of the ethical and legal framework of practice and, in all instances, it allows trainees to discuss their decisions. One of the cases is chosen by the assessor and centred on the trainee's documented involvement either in the medical notes or laboratory records and reports.
The purpose of the case-based discussion assessment tool is to:

- indicate that the trainee understands the pathological basis of diseases
- indicate that the trainee can interpret and relate pathological results to the medical findings
- indicate that the trainee can plan an appropriate strategy for the investigation of diseases or medical laboratory problems
- indicate trainees' capability, potential and behaviour
- encourage professional and self-development
- generate candid feedback on trainees' aptitude and progress within the specialty
- enable the trainee to collect evidence for the annual review of competence progression
- provide feedback to trainees about progress and learning needs by highlighting strengths and identifying weaknesses

- Direct observation of practical skills (DOPS)

Assessing trainees for competence in the day-to-day practical procedures as part of their training. The procedure may involve a patient or laboratory technique/test/topic. Strengths and areas for development are identified after each DOPS encounter.
The purpose of the DOPS assessment is to:

- indicate trainees' acquisition of practical skills in the specialty
- indicate trainees' understanding of the use of equipment in the specialty
- show that the trainee can work safely in the medical laboratory and medical areas
- indicate that the trainee interacts appropriately with patients where procedures involve them
- indicate trainees' capability, potential and behaviour
- encourage professional and self-development
- generate candid feedback on trainee's aptitude and progress within the specialty
- enable the trainee to collect evidence for the ARCP
- provide feedback to trainees about progress and learning needs by highlighting strengths and identifying weaknesses

- Evaluation of medical events (ECE)

It provides a method of assessing the trainee in the performance of their duties in complex tasks, often involving teamwork or interacting with other professional staff. Examples include clinicopathological evaluation and reporting of diagnostic procedures and outcomes, presentation of

a case at a multidisciplinary team meeting, or contributing to quality assurance and audit processes in both medical and laboratory settings.
The purpose of the evaluation of medical events assessment tool is to:

- Indicate trainees' accomplishment of medical skills in the specialty
- indicate trainees' accomplishment of professional skills including medical reasoning and the practical application of theoretical knowledge, communication skills, working with colleagues and in teams
- indicate trainees' accomplishment of professional attitudes including maintaining a patient focus, working within a medical governance framework and the appropriate application of professional standards
- indicate trainees' capability, potential and behaviour
- encourage professional and self-development, including personal insight and reflective learning
- generate candid feedback on trainees' aptitude and progress within the specialty
- enable the trainee to collect evidence of achievement/competency for presentation at end of year assessments/ARCP
- provide feedback to trainees about progress and learning needs by highlighting strengths and identifying weaknesses

- Multi-source feedback (MSF)

Comprises observations in a structured form from staff associated with the trainee on his/her practice, including skills and attitudes, etc. The trainee also provides their own assessment of how they think they are doing.
The purpose of the MSF assessment is to:

- indicate trainees' motivation and enthusiasm for the specialty
- indicate trainees' capability, potential, behaviour and attitude
- encourage professional and self-development
- generate candid feedback on trainees' aptitude and progress with the specialty
- enable the trainee to collect evidence for the ESR/ARCP
- provide feedback to trainees about progress and learning needs by highlighting strengths and identifying weaknesses

- Mini clinical evaluation exercise (Mini-CEX)

Mini-CEX is a snapshot of a doctor/patient interaction. It is designed for an assessor to provide trainees with feedback on skills essential to the provision of good medical care by observing an actual medical encounter. The setting for this is usually a clinic or ward, and the assessment is usually only concerned with one aspect of the medical encounter, such as taking a history or one part of the medical examination. This tool can also be modified to include an event in the medical laboratory environment; however, patient safety is always the main outcome of the exercise.
The purpose of the mini clinical evaluation exercise is to:

- indicate trainees' acquisition of medical skills in the specialty
- indicate that the trainee interacts appropriately with patients
- indicate trainees' capability, potential and behaviour
- encourage professional and self-development
- generate candid feedback on trainees' aptitude and progress within the specialty
- enable the trainee to collect evidence for the annual review of competence progression
- provide feedback to trainees about progress and learning needs by highlighting strengths and identifying weaknesses

Assessement or exit exam

Most countries hold validated (exit) assessment at the end of training in the process of certification (awarding of a specialist diploma) by the competent body, national authority or national regulatory body. The actual national competent body depends on the national tradition and requirement, and is usually listed in the Annex V Directive 36/05. The final assessment will confirm overall competence of the specialist in laboratory medicine, relevant to national healthcare requirements, and includes the whole national curriculum for Laboratory Medicine. The final examination might comprise a written test (e.g. MCQ or other format) as a tests of knowledge, and a separate oral examination, which evaluates various medical skills, medical reasoning and related competencies, and some aspects of professional behaviour. The final examination can be provided at a national level following the rules of the National Regulatory Authority in each European country that also stipulates the other parts of the training system before a trainee is recognized/registered as a Specialist as per Annex V Directive 36/05. In some instances, a successful passing of the exit assessment does not necessarily result in specialist status, but will be one of the concluding steps in a training programme where all other steps have been fulfilled successfully.
In future, an EU UEMS specialist examination in Laboratory Medicine may substitute a national exit exam and/or be an additional career progress step of confirmation of European specialist standards. As a part of UEMS work on training standards for medical specialists, most of the Sections are providing EU Board examinations appraised by the Council of European Specialist Medical Assessment. The Section for Laboratory Medicine / Medical Biopathology is in the process of preparation for the EU Board exam which would enable specialists (and trainees in their final training year) in laboratory medicine in the EU to achieve a certificate of the standards in competencies.
An UEMS Assessment is envisaged and information will be included in the appropriate up-date version of the ETR.

Governance

The governance of training for medical specialists in laboratory medicine should be under supervision of appointed/elected director of specialist training for this specialty and responsibility of the appropriate national authority or regulatory body. An official document (or regulation) should be in place with description and definition of all aspects of governance of specialist training for laboratory medicine or for all medical specialties. The document should be available online. A robust process should be in place to ensure good governance of training of medical specialists, criteria and mandates detailed, including quality management or accreditation of the governance. The governance and document on governance should be updated according to the required changes to training of medical specialists and current recommendations on medical educational sciences of national and international scientific societies.

Training requirements for trainers

Process for recognition as trainer

Required qualification and experience

Trainers should be certified specialist in Laboratory Medicine with at least 5 years of specialist experience and must be recognised by the national authority (registered as specialists in Laboratory Medicine). Trainers should provide evidence of academic activities (medical and/or basic research, publications in peer reviewed journals, and participations in scientific meetings) and professional

experience. They should possess the necessary administrative, communicative, teaching and medical skills and commitment to conduct the programme. Trainers and Training Programme Directors must be in active medical practice and engaged in training in the training centre in question. The Training Director organizes and supervises the activities of the educational programme in all institutions that participate in the programme. The trainer should ideally have completed a formal training for the task of mentoring in the course of training of a medical specialists. The trainer skills and educational knowledge should be reviewed or refreshed through courses in a timely fashion, as required by national regulation.

Core competencies for trainers

Include expertise in all aspects of Laboratory Medicine in respective national environment and CPD; experienced in teaching (a lecturer, leadership skills) and in supporting of trainees/students according to individual needs and achievements, should be trained in appropriate medical educational sciences with regular refreshment courses; keep up-to-date their educational and team leader skills. The trainer should be sensitive to trainee problems and identify unsatisfactory professional behaviour, and initiate corrective and supportive measures. Number of trainees per trainer/mentor is usually defined nationally, but reasonable number of trainees should be less or equal to 5.

Quality management for trainers

Trainers and Training Programme Directors will have their job description agreed with their employer which will allow them sufficient time for dedicated time with trainees. Feedback from trainees is necessary for optimal training. Regular evaluation of trainers' performance (annual) and refreshment courses should be in place, or similar quality control processes.

Training requirements for training institutions

Process for recognition as training centre

Requirements for a training institution include recognition by a national statutory authority in a defined and transparent process as a training center, requirements on staff and scope of practice in healthcare services, requirement on equipment and accomodation, quality management of the training institution including nantional accreditation, medical governance, manpower planning, regular reporting and external audits, and structure for coordination of training.
Requirements for training institutions must include:

- departments required for work exposure for the trainee in Laboratory Medicine,
- necessary equipment (in the broadest sense) and healthcare personnel,
- medical or specialty departments and outpatient clinic,
- adequate patient population and diversity of cases,
- enable interaction with other medical specialists and healthcare providers/professionals,
- internal system of medical audit or quality assurance,
- trainers and mentors to provide supervision and guidance,
- secure dedicated time for learning and opportunities for teaching,
- enable and support organized formative assessments with trainers and mentors.

It is essential that the training institution is accredited by a national statutory body (or recognized as such by the regulatory authority) with a national register of approved training institutions, and/or

through UEMS accreditation system. The training institution should be reaccredited in regular intervals.
Training institution or a network of institutions covering for all topic of the specialty in a particular national setting should be recognized as such by a national authority or body for the purpose of training of medical specialists in the optimal healthcare environment. A register for training institutions should be avaialable on national level. Criteria for a training institution should be specified by a reglulation or bylaw and include aspects mentioned previously.

Requirement on staff and medical activities

Training for specialists in laboratory medicine can be organized in one institution or in several institutions (network) to include all the topics of the curriculum and also enable adequate exposure and contact with the working environment, a variety of relevant (medical) situations and medical cases.
The characteristics of training institutions (regardless whether the training is provided in a institution or a network of collaborating institutions) is expected to vary between EU member states. Nevertheless the training institution(s) should enable the trainers and trainees to achieve the highest level of competencies (knowledge and skills) in the scope of laboratory medicine as required by the national heathcare.

Requirement on eqipment, accomodation

For the purpose of specialist training in laboratory medicine training institution(s) should enable to the trainees to obtain sufficient expertise for all topics and areas of Laboratory Medicine specialty as currently included for the national healthcare requirements: hospital departments and wards, outpatient clinics, medical laboratories and other services in medical investigations, might include options of work in primary or family care clinics. Besides clinical and medical work, also areas for teaching and learning should be provided. Director of training, or head trainer and other trainers, medical doctors and medical doctors specialists, nurses, technicians, other healthcare professionals includes training institution(s) staff. Peer support is important for the trainees and thus it would be convenient to have at least another medical trainee present at the same time in the institution.
Equipment for services in laboratory medicine depends on the scope or topics included in medical laboratories, but should also include necessary equipment for and other related healthcare services. A training centre should be equipped with laboratory equipment which will enable the trainee to observe and practice anlytical part of laboratory medicine, validation and verification of methods, get acquainted with laboratory and hospital informatics system. Exposure to laboratory environment also allows to obtain experience in evaluation and purchase of various laboratory equipment and also gain experience of laboratory function and management in the healthcare setting. Training institutions should have a library and internet facilities with access to the current world scientific literature and relevant web sites.
Research is an important part of training and practice of a laboratory medicine specialist as corroborated by the CanMEDS framework. An accredited training institution should provide environment of critical and scientific thinking, design research and scientific projects, critically evaluate and interpret research results. The trainer and teachers/lecturers should actively encourage and stimulate reasearch, and provide guidance for trainees in creating evidence-based project aims and goals, planning methods and processes to achieve project results. Training programmes should provide sufficient flexibility to allow periods of full-time or part-time research with appropriate adjustment of the total training time.

Quality management within training institution

The governance of a training programme is the task of the Programme Director and dependent on the national regulation. A process is in place for chain of responsibilities and duties of the Programme Director and other trainers or mentors involved in the training. Training process includes appointment of a coordinator in charge of organizing and supervising the training programme or its part(s). Manpower planning also depends on national healthcare requirements and population size and the need for specialists and trainess. Reports should be provided for the training programme in line with national regulations. Regular reporting and feedback from trainees and trainers to support quality management and improvements should be instituted.
External audit for training programme and process should be provided for. Feedback from both trainers and trainees is crucial in improvement and development of the training programme.
UEMS strongly encourages training institutions to have the training programmes available on their websites, with information on parts or the entire programme covered by the specific institution for Laboratory Medicine.
Number of trainees per trainer/mentor is usually defined nationally, but reasonable number of trainees should be less or equal to 5. The trainee should be involved in all aspects of training centre work with respect to the curriculum. The independence and responsibility relies on the level of achieved competency, and should be regularily assessed between the trainer/mentor and the trainee. The required activities or skills to be mastered are derived from curriculum and syllabus.
The trainee who has successfully compeleted the training programme (competency-based), fulfilled the criteria for the national or UEMS exit exam and successfully passed becomes a specialist in Laboratory Medicine. Taking into accound diversity and variations of the scope and competencies of a laboratory medicine specialist among the EU member states, in order to facilitate the mobility of specialists in Laboratory Medicine the logbook or portfolio is essential as an official national document of evidence of specialist competencies. In case of differences in training programmes between EU member states, the „candidate“ can additionally compensate for the difference in training and competencies as decided or suggested by the regulatory body of the EU member state of employment.

Syllabus

Chapter 1- General Laboratory Medicine skills

The content of this chapter, including knowledge and skills applies to each and all of subsequent chapters in this syllabus for ETR for Laboratory Medicine.

Topics description:

1.1. Patient care and medical setting

1.2. Use of laboratory tests – appropriate choice and advice for diagnosis, prognosis, monitoring, screening, case finding, etc

1.3. Methodology including near patient testing (point-of-care, POC)

1.4. Laboratory quality management, accreditation and regulations

1.5. Laboratory governance and medical oversight, patient safety

Objective:

- competency in patient care from the perspective of Laboratory Medicine specialist;
- competency in appropriate and rational choice of laboratory tests for purposes of patient care, including interpretation for patients and medical professionals (inludes age and sex, children and adolescents, pregnancy and menopause and geriatric population reference ranges);
- competency in standard laboratory methods and point-of-care (includes method establishment and verification);
- competency in laboratory quality management and accreditation, including relevant regulations;
- competency in laboratory management and patient safety.

Knowledge: required to achieve level 3 and 4 (EPA) of competency for topics 1.1. – 1.5.

Medical skills: appropriate patient care provided by Laboratory Medicine specialist, laboratory management in diverse medical settings; screening strategies applied to specific purposes

Technical skills: basics of standard methods and instruments, method establishment and verification, e.g.

physicochemical methods, ion selective electrodes, biosensors, osmometry
photometric methods including turbidimetry, nephelometry, ultra-violet and infra-red spectrometry, reflectometry, atomic absorption, fluorimetry
particle/cell counting, flow cytometry
radio-isotopes
separation techniques (chromatography – liquid, gas, thin layer, column, high pressure, affinity, electrophoresis – gel, capillary zone, iso-electric focussing), dialysis, centrifugation, ultracentrifugation, tandem/ mass spectrometry
enzymatic methods
immunological methods, immunoassays, immunoelectrophoresis, immunofixation, immunoturbidimetry, immunonephelometry, agglutination techniques,
techniques and methods for allergy testing
signal detection

molecular diagnostics methods
light, fluorescent and microscopy, routine staining techniques including fluorescent dyes and investigation

Chapter 2- Laboratory Clinical Chemistry / Medical Biochemistry / Chemical Pathology

This chapter comprises a range of topics in laboratory diagnostics of disorders and diseases of systems and organs. Objective, medical and technical skills are similar and corresponding, and knowledge for each of the topics covers essential knowledge of function, physiology and pathophysiology, other medical diagnostic modalities, therapy and treatment, monitoring, and specific diseases and disorders. Due to diversity of topics within this chapter the description of the syllabus items is generic. It is up to the national regulatory authority to decide on the scope and breadth of topics included in the national healthcare system within this chapter.

Objective: Competency in laboratory diagnostics, rational and appropriate use of laboratory tests, and competent medical interpretation

Medical skills: indication and choice of appropriate tests, interpretation and other medical diagnostics, essential treatment modalities and patient monitoring, communication with other specialties and healthcare professionals, communication with patients

Knowledge: medical knowledge across all ages (including adolescents and aging population, among others) pertaining to normal function and metabolism, aetiology and pathophysiology of diseases and disorders, medical presentation, other medical investigations, treatment and monitoring.

Technical skills: essentials of methodology and use of instruments, supervision and planning of method validation, also refers to introduction and establishment of new methods and emerging technologies, quality control, interferences and limitations, resolvement of problems, POC when applicable

Topics in Chapter**:**

2.1. Proteins and proteomics (incl. inflammation, benign and malignant M-component assessment)
2.2. Enzymes and metabolomics (amylase and lipase, alkaline phosphatase, aminotransferases, angiotensin converting enzyme, creatine kinase, lactate dehydrogenase, gamma-glutamyl transferase)
2.3. Endocrinology (disorders of hypothalamus, pituitary, thyroid, adrenals, gonads, multiple endocrine neoplasia and polyglandular syndromes, Diabetes Mellitus 1 and 2, monogenic diabetes, diabetes in pregnancy, including advice on glucometers; pregnancy monitoring and fertility investigations)
2.4. Nutrition (incl. obesity and malnutrition, vitamins)
2.5. Cardiac disease (incl. assessment of cardiovascular risks, setting cut-offs for acute myocardial limits)
2.6. Disorders of calcium and mineral metabolism (including vitamin D metabolites, PTH, PTHrP, FGF23, collagen type I metabolism and other bone-related proteins)
2.7. Respiratory system
2.8. Blood gases and acid-base balance (mechanisms of acid-base homeostasis, buffering systems)
2.9. Kidney and urogenital tract, water and electrolytes (glomerular and tubular function/disorder tests, nephro- and urolithiasis, urine sediment evaluation, antidiuretic hormone, renin-angiotensis-aldosterone, natriuretic peptides)
2.10. Hepatobiliary system (hepatitis, cirrhosis, cholestasis, cholelithiasis, NAFLD, malignant diseases, jaundice - neonatal, children and adults, essentials of liver transplantation)

2.11. Gastrointestinal system (pancreas, peptic ulceration, malabsorption, inflammatory bowel disease, intestinal and/or pancreatic failure, neuro-endocrine disorders, malignant diseases),

2.12. Inborn errors of metabolism (affecting amino acid metabolism, e.g. phenylketonuria, maple syrup urine disease; fatty acid oxidation, e.g. medium-chain acyl-CoA dehydrogenase deficiency; urea cycle e.g. X-linked ornithine transcarbamylase deficiency; lysosomal storage disease, e.g. X-linked Fabry disease; mitochondrial metabolism, e.g. mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes MELAS).

2.13. Neonates, childhood and adolescence (physiology in the newborn; specific metabolism in neonates – fluid balance, jaundice, liver disease, glucose metabolism, calcium and phosphate metabolism, magnesium metabolism, lactic acidaemia, cystic fibrosis, nutriton, congenital adrenal hyperplasia, congenital hypothyroidism; specific for children – disorders of growth and development, calcium and phosphate disorders, glucose metabolism, hyperammonaemia, Reye's syndrome, lactic acidosis, renal disorders incl. Fancony syndrome and tubular defects, fluid balance; awareness of need to manage children and adolescents in a child-friendly environment, practices in accordance with child protection guidelines) Cancer and malignant diseases (excluding haematological malignancies; markers for prostate, lung, breast, ovary, gastrointestinal organs, pancreas, thyroid, pituitary, adrenal, neuroblastoma, hepatoblastoma and teratoma) NGS and other molecular diagnostic procedures for detection of mutations leading to tumors (solid, haematology), for therapeutic options, liquid profiling (liquid biopsy, liquid biomarkers) of circulating tumor DNA/RNA and tumor cells.

2.14. Central nervous system and neuromuscular disorders (cerebrospinal fluid, CNS tumour markers, dementia and psychiatric diseases, atypical response to antipsychotic therapy, consequences of other disorders on CNS, rhabdomyolysis, myopathies)

2.15. Toxicology, pharmacogenomics and personalized medicine (intoxication/poisoning, misuse of legal and illegal drugs, acute and chronic poisoning, common poisons - psychotropic, household cleaners, mushroom toxins, toxic plants, organic solvents, paracetamol, cyanide, pesticides, insecticides, animal toxins, heavy metals, primary and secondary poison removal, antidotes, xenobiotics, inhalation poisons, pharmacokinetics and toxicokinetics, legal and regulatory environment)

Chapter 3- Laboratory Genetics and Genomics

Objective: Competency in laboratory genetics and genomics, rational and appropriate use of laboratory tests, and competent medical interpretation

Knowledge: Basic mechanisms of inheritance, including sex chromosomes, autosomes, and mitochondrial DNA; basic molecular biology techniques pertinent to medical testing; Methods of genetic risk assessment; behaviour of genes in a population, including Hardy Weinberg equilibria of alleles; test results interpretation and bioinformatic approaches to interpreting molecular test results, including methods to assign causation to novel findings; the cell cycle and molecular genetics of cancer; DNA, RNA, and protein chemistry, including DNA repair; gene expression and mechanisms of regulation of gene expression and mechanisms of regulation of genes and genomes, including epigenetic regulation; genetic linkage, mapping, and association studies; inheritance of complex traits and genetic variation; mechanisms of chromosomal rearrangement; molecular organization of the genome, including molecular evolution mechanisms; principles of biochemical genetics and metabolism; and, principles of replication, recombination, and segregation of alleles during meiosis. Monogenic disorders (autosomal dominant, autosomal recessive, X-linked recessive, X-linked dominant), oligo- and polygenic disorders, mitochondrial disorders.

Medical skills: Laboratory tests and indications for genetic testing and genomics investigations in peripheral blood, to be performed after clinical examination: constitutional/germline testing, prenatal/carrier testing and non-invasive prenatal testing; postnatal (perinatal, paediatric, and adult non-obstetric) testing, cancer testing. Awareness of limitations of methods, including new and emerging technologies, medical decision-making, and genetic counselling. Interpretation of test results preferably in collaboration with medical specialist medical geneticist, and communication with other medical specialists and patients; relationship of medical aspects (patient & family history and other investigations) with genetic tests including inherited and somatic variants especially likely pathogenic variants or hot variants of unknown significance (does the result fit medically, what does it mean for the patient, their disease, and potentially their relatives).

Technical skills: performance and supervision of tests, supervision and planning of method verification, also refers to introduction and establishment of new methods (analytes) and emerging technologies, nomenclatures and genetic databases, quality control management, gene banks

Chapter 4- Laboratory Haematology

Objective: Competency in laboratory haematology, rational and appropriate use of laboratory tests, and competent medical interpretation

Knowledge: Pathophysiology of anaemias (congenital, acquired) and haemoglobin metabolism (thalassemia), red cell enzyme defects, erythrocytosis, polycythaemia, leukopenia, thrombocytopenia, polycytaemia (erythrocytosis), leucocytosis, thrombocytosis, myelodysplasias, bleeding disorders, thrombophilia and hypercoagulable conditions; acute and chronic leukaemias, lymphomas and lymphoproliferative diseases. Coagulation disorders (acquired and congenital), monitoring of patients using anticoagulant therapy, specific test in investigation of coagulation disorders. Therapeutic options for common disorders in this chapter.

Medical skills: indication and choice of appropriate tests, interpretation and communication with other medical specialists and patients, awareness of limitations of methods, including new and emerging technologies, medical decision making. Relationship of tests with other investigations.

Technical skills: supervision and planning of method validation, also refers to introduction and establishment of new methods (analytes) and emerging technologies

Chapter 5- Transfusion Medicine

Objective: Competency transfusion medicine, rational and appropriate use of laboratory tests and procedures in transfusion medicine (blood bank, tissue bank), competent medical interpretation

Knowledge: Genetics and biochemistry of blood groups; genetic polymorphism of the major histocompatibility complex (MHC); immune profile in transplant candidates and post-transplant monitoring; donor / recipient selection criteria.

Medical skills: Medical practice of transfusion medicine: blood components, derivatives and alternatives, autologous transfusion, blood bank and tissue banks. Prevention, diagnosis and treatment of adverse effects of transfusion. Functional organization of a blood collection sector: promotion of donation, observation and selection of donors, collection of whole blood and collection of components by apheresis.

Technical skills: Techniques for processing blood components, other tissues and their conservation. Supervision and planning of method verification, also refers to introduction and establishment of

new methods and emerging technologies, also includes therapeutic modalities in transfusion medicine (e.g. apheresis, peripheral blood stem cells and umbilical cord cells, haemapheresis, apheresis, bone marrow processing techniques, cryobiology of cells and tissues).

Chapter 6- Laboratory Immunology

Objective: Competency in laboratory immunology, rational and appropriate use of laboratory tests, and competent medical interpretation

Knowledge: immune system's development, structure, and physiology; immune reactions to microorganisms (innate and acquired immunity, and humoral and cellular responses); primary and secondary (e.g., HIV) immunodeficiency syndromes, autoimmune diseases (e.g., lupus, rheumatoid arthritis, Sjögren's syndrome, autoimmune kidney diseases, and endocrine disorders); transplantation immunology (histocompatibility, organ, and stem cell transplantation, immune tolerance, and rejection); immune reactions in transfusion medicine; immunology in cancer therapy; haematological and immune system neoplasms; allergic diseases involving hypersensitivity reactions; reproductive immunology; immunotoxicology; immunoprophylaxis and vaccine safety; immunotherapy, gene therapy and immunomodulation (steroids, monoclonal antibodies, IVIG, cytokines); role of nutrition in immunity. Vaccinology and vaccinations. Tests and techniques: acute phase proteins, cytokines, chemokines, complement components (C3, C4, C1q), complement activity (CH50, AH50), immunoglobulins, paraproteins, cryoglobulins, and specific antibody production in vitro; autoimmunity diagnosis; allergy diagnosis (total and specific IgE levels and delayed hypersensitivity tests); cellular immunity analysis (flow cytometry application in immunophenotyping of leukocytes, haematological diagnostics, drug efficacy assessment, lymphocyte proliferation tests, cytotoxicity, neutrophil and macrophage function tests); HLA typing (serological/DNA); short-term hematopoietic stem cell cultures;

Medical skills: indication and choice of appropriate tests, interpretation and communication with other medical specialists and patients, awareness of limitations of methods, including new and emerging technologies, medical decision making. Relationship of tests with other investigations.

Technical skills: cellular immunology techniques (handling cell lines, isolating immune cells, cell suspensions, in vitro cultivation and activation, immunophenotyping by flow cytometry, and cell isolation by flow cytometry or immunomagnetic methods); cytotoxicity tests; molecular biology techniques (DNA/RNA isolation, PCR, and related methods)

Chapter 7- Medical Microbiology

A comprehensive text on the knowledge and skills for medical microbiology is provided as an addendum to this ETR document.

Objective: Competency in medical microbiology (bacteriology, virology, mycology and parasitology), rational and appropriate use of laboratory tests, and competent medical interpretation

Knowledge: for the subjects of bacteriology, virology, mycology and parasitology includes:

- basic microbial biology (structure, genetics, taxonomy, physiology, epidemiology, classification and typing) of major bacterial, viral, fungal and parasitic agents,
- basis of genetic susceptibility to pathogens and disease,
- basics of the immune response to infection, host defense mechanisms, the immune system and immunity to infection and immunodeficiency,

- different types of host−parasite/pathogen relationships, e.g. symbiosis, viral latency, quasi-species evolution, etc. ,
- isolation, identification of pathogens and further diagnostics including serology, antibiotic and antifungal susceptibility testing, the use of molecular methods
- typing methods (phenotypic and genotypic methods) and their role in incident/outbreak investigations,.
- antimicrobial agents, their mode of action and mechanisms of microbial resistance, antibiotic stewardship,
- the basics of vaccines,
- Public Health and infection control.

Medical skills: Give advice as a physician on the diagnosis, treatment and prevention of microbial diseases. Provide a scientific basis for laboratory diagnosis; to set protocols and to maintain medical and scientific standards within the laboratory. Propose hospital policies on the control of antibiotic usage and on the prevention of hospital acquired infection. Collaborate with national surveillance organisations and public health authorities and to provide services for these organisations. Good medical care skills (history, presentation, examination, investigations, treatment and communication (verbal and written). Currently used (or up-to-date) techniques available to diagnostic laboratories (DNA/RNA preparation, hybridisation, nucleic acid amplification techniques (NAT), MALDI-TOF, etc.) automated and rapid techniques, point of care methods

Technical skills: Technical knowledge and practical laboratory skills. Laboratory safety: standard precautions, hazard groups and containment levels (including national regulations), safety measures for specimen transport, principles and operation of microbiological safety cabinets and the procedures for their decontamination and monitoring, perform an infection−prevention and control-oriented risk assessment. Principles of sterilisation and disinfection. Specimens – handling, collection, storage. Microscopy – use of light, fluorescent and electron microscopy, routine staining techniques including fluorescent dyes and investigation.

Contributions:

The revision process was started in 2020 with online delegate meetings to define the process of updating the syllabus content, harmonizing with the revisions of the ETR requirements and template, aligning with the Annex V EU Directive 36/05, UEMS Statutes and Rules of Procedure and most importantly finding an acceptable solution for an ETR format to provide for the diversity in practice of laboratory medicine in the EU. This process included work of many Section colleagues, experts and a trainee for which contribution we are very grateful, both in electronic communication, online meetings and live Section meetings. During this time, parts of the ETR update document were shared with all delegates, i.e. the "non-syllabus" and the syllabus part separately, and finally the entire document in 2024, which was updated to the current ETR template and ETRs recently approved. One trainee was also included in the review process. We consider this a "living" document with opportunities to adapt to the progress of medical sciences, medical educational sciences and national healthcare practices in the EU.

Aidan Ryan, Ireland
Charlotte Becker, Sweden
Ciara de Buitleir, Ireland – trainee contribution
Eberhard Wieland, Germany
Helena Alves, Portugal
Hrvoje Lalic, Croatia
Ian Freyling, UK
Kari Pulkki, Finland
Luis Nogueira Martins, Portugal
Maria Wieland, Germany
Matthias Orth, Germany
Patrick Twomey, Ireland
Pieter Vermeersch, Belgium
Roberto Verna, Italy
Santiago Prieto, Spain
Stelios Chatzipanagiotou, Greece
Vesna Kusec, Croatia

Appendix- Medical Microbiology (Integral version Syllabus and Curriculum)

Authors: Stelios Chatzipanagiotou, Matthias Orth, Luis Nogueira Martins

This is a comprehensive text on the knowledge and skills for medical microbiology provided as appendix.

1. Objective

Competency in rational use of microbiological procedures and appropriate interpretation for the diagnosis, treatment and management of infectious diseases in the community and in the hospital.

2. Knowledge

a. Theoretical knowledge

The core of Medical Microbiology consists of the subjects bacteriology, virology, mycology and parasitology and includes in these fields the following knowledge: medical advice/counselling: diagnosis, treatment and prevention, isolation, identification of pathogens and further diagnostics including serology, antibiotic and antifungal susceptibility testing, the use of molecular methods within these fields, antibiotic/antimicrobial (antibacterial, antiviral, antimycobacterial, antimycotic and antiparasitic) therapy, and antibiotic stewardship. Laboratory management is an essential part of the abilities of a laboratory physician, and includes quality control and quality assurance, economics/budgeting, and leadership training. Trainees should also learn about Public Health and infection control (such as counselling, auditing and accreditation, by surveillance of pathogens, resistance statistics, statistics of nosocomial infections, epidemiology, bioinformatics and molecular typing). Trainees should have relevant medical practice in his/her training to be able to give informed medical interpretation of test results and be able to give independent medical interpretation of the patient in question. The field of Medical Microbiology covers almost all specialties of medicine and ranges from general practice to specialized hospital programs.

b. Practical and Medical skills

The training should produce specialists able to work independly in their medical discipline and who should have developed the appropriate management skills to lead a laboratory, if required. The trained laboratory physician should be competent to:

1. Give advice as a physician on the diagnosis, treatment and prevention of microbial diseases.
2. Provide a scientific basis for laboratory diagnosis; to set protocols and to maintain medical and scientific standards within the laboratory.
3. Propose hospital policies on the control of antibiotic usage and on the prevention of hospital acquired infection
4. Collaborate with national surveillance organisations and public health authorities and to provide services for these organisations
5. Participate in the training programs for medical trainees, infection control physicians and other experts in the field of microbial diseases.
6. Good medical care skills (history, examination, investigations, treatment and communication (verbal and written).
7. Interpretative skills so that a medically useful opinion can be derived from laboratory data. Emphasis should be made on the importance of medical training and multidisciplinary care.
8.Technical knowledge and practical laboratory skills, gained from familiarity with laboratory technology, so that methodology appropriate to a medical problem can be chosen and so that quality control and quality assurance procedures can be implemented.
9. Data management skills to evaluate information derived from the population served and from the technical procedures applied in the laboratory. These skills should include familiarity with IT and the use of spread sheets, databases and statistical packages etc.
10. Management skills.

3. Syllabus

The proposed duration of training should not be less than 12 months. The following subjects should be covered: Bacteriology, Virology, Mycology and Parasitology. Training should take place in a laboratory that covers all the above fields. In case this is not possible, the trainee should obtain the relevant training from another laboratory with full expertise in Medical Microbiology by a structured and documented exchange program.
Experiences with Public Health and Infection control, as well as science projects (not mandatory) should be obtained in parallel during the whole training period.

The following subjects should be covered:

GENERAL MEDICAL MICROBIOLOGY

Applies to all the sub-disciplines of medical microbiology (bacteriology, virology, mycology and parasitology)

Scientific basis of medical microbiology
At the end of their training trainees should be able to:
a) explain the basic microbial biology (structure, genetics, taxonomy, physiology, epidemiology, classification and typing) of major bacterial, viral, fungal and parasitic agents.
b) use knowledge of basic biology to justify investigations, infection, prevention and control procedures and interpretation of results
c) explain the basis of genetic susceptibility to pathogens and disease.
d) explain the basics of the immune response to infection, host defense mechanisms, the immune system and immunity to infection and immunodeficiency.
e) compare and describe cellular and humoral immunity
f) explain the basis of how the immune response protects against infection, and how it may contribute to the pathogenesis of infectious diseases
g) explain the basis of different types of host−parasite relationships, e.g. symbiosis, viral latency, quasi-species evolution, etc.
h) explain the types of immunodeficiency and how they affect susceptibility to and control of infectious diseases
i) use knowledge of host−pathogen relationships to analyse the clinical presentation of infections and justify investigations and interpretations of results
j) explain microbial pathogenicity and the genetic susceptibility of the host to pathogens and diseases.
k) explain epidemiology of infectious diseases - their surveillance and control.
l) explain typing methods available: the principles, advantages and limitations of various phenotypic and genotypic methods and describe the role of typing in incident/outbreak investigations. As a result, the trainee should be able to recommend appropriate typing methods for medical and infection control situations and interpret the results.
m) understand antimicrobial agents, their mode of action and mechanisms of microbial resistance.
n) explain the basis of how vaccines work

Laboratory safety
Prior to any "hands on" experience of laboratory work, the trainee must be instructed in basic safety requirements. Instruction should also be given on the shipping, the immediate handling, and the disposal of specimens and contaminated articles (e.g. inoculating loops, pipettes), the role of aerosols and the procedure for dealing with spillages.
The objective of the training is to obtain an in-depth understanding of health and safety issues both locally and nationally in order to practice safely in a microbial laboratory and to advice on safe

practice. The candidate should also obtain an understanding of risk assessment for dealing with category 3 and 4 pathogens and be familiar with the requirements for handling of such pathogens.
At the end of formal training, the trainee should be able to:
a) explain the principles of standard precautions, hazard groups and containment levels (including national regulations)
b) explain basic laboratory hazards and the precautions against them
c) work safely in a laboratory at an appropriate containment level
d) describe local procedures for the safe transport of specimens or cultures (including national and international postal and packaging regulations for such materials).
e) work within and explain to others the current requirements and recommendations, including the legislative framework, on safety in microbiological laboratories .
f) explain the principles and operation of microbiological safety cabinets and the procedures for their decontamination and monitoring.
g) perform an infection−prevention and control-oriented risk assessment when required for all procedures undertaken in the the laboratory, for all categories of workers, including the pregnant and immunocompromised
h) act in accordance with the principles of Good Medical Practice

Sterilisation and Disinfection
At the end of formal training, the trainee should understand the principles and uses of sterilisation and disinfection procedures for the preparation of media and instruments and for microbiological waste disposal. Trainees should be familiar with methods of monitoring and be capable of formulating a policy on the use of sterilisation and disinfection in the laboratory, and the role of environmental cleaning and decontamination. They should also be aware of emerging technologies and their applications.
At the end of formal training, the trainee should be able to:
a) describe the process for disinfection and including their indications, advantages, and limitations
b) make an accurate risk assessment
c) demonstrate when urgent action is required if disinfection and sterilisation fails

Handling of specimens
At the end of formal training, the trainee should:
a) be aware and demonstrate that they are able to use this awareness, for each specimen type, of the optimal methods for collection, transport (including transport media) within the hospital and from outpatient offices to the laboratory, storage, reception, identification and documentation, including the requirements and regulations for high-risk specimens. The trainee should develop a sense of the continuity of identification of specimens from collection, through culture and further testing to the issuing of a final report. He or she needs to be aware of critical points in processing where this continuity may fail and be able to minimise the risk of this happening.
b) be able to assess degrees of urgency for the processing of specimens, including the provision for an out of hours service and the communication of preliminary results as applicable
c) be able to decide upon further testing or processing of a specimen, as appropriate.
d) be aware of existing reference laboratories and their appropriate use
e) understand the evidence base behind Standards of Practice (SOPs)
f) be able to describe the indications for referral of specimens to reference facilities/centres/laboratories, both for diagnostic and surveillance purposes
g) be able to refer specimens to reference lab appropriately

Data handling
At the end of formal training, the trainee should:
a) have an understanding of information technology and in particular, computerised data handling.

He or she should have an appreciation of the advantages and disadvantages of such systems and a basic understanding of the need for data protection
b) be aware of available technologies for data broadcasting
c) be aware of the developing issues prompted by computerised management of data in terms of confidentiality, data archiving, electronic health data records, and report validation (electronic signature)

Results reporting
At the end of formal training, the trainee should:
a) be able to report interpreted laboratory results to ensure the patient is appropriately treated
b) be aware of the role of the laboratory report in antibiotic stewardship and infection control initiatives
c) be able to liaise effectively with wards, intensive care units, emergency departments and primary care-based physicians

Microscopy
At the end of formal training, the trainee should:
a) understand the principles of light, fluorescent and electron microscopy and be able to set up a light and a fluorescent microscope
b) be able to perform routine staining techniques including fluorescent dyes
c) be familiar with the appearance of stained preparations and be able to recognise artefacts and their possible origin.

Molecular microbiology and Mass spectrometry
At the end of formal training, the trainee should:
a) be able to describe and have a basic understanding of currently used techniques available to diagnostic laboratories (DNA/RNA preparation, hybridisation, nucleic acid amplification techniques (NAT), MALDI-TOF, etc.).
b) have gained experience with and be able to describe the selection of appropriate diagnostic tests, both molecular and mass spectometry, and their advantages and limitations
c) be able to provide medical advice based on the interpretation of the results of these techniques available to diagnostic laboratories
d) be able to describe automated and rapid techniques available to medical microbiology
e) be able to evaluate critically the need for emerging techniques within the laboratory, including cost effectiveness and effects on staffing levels and working practices
f) be aware of the potential role of point of care testing in microbiology, including quality assurance of these tests

BACTERIOLOGY

At the end of formal training, a trainee should be able to:
a) describe basic diagnostic and screening methods in bacteriology. The methods should include culture methods, microscopy, serology and molecular methods
b) process routine specimens received in the laboratory and carry out further tests necessary for full identification of pathogens.
c) interpret results from diagnostic methods to give medical advice/counselling, for infection control purposes, and for the prevention of bacterial diseases
d) explain about bacteriological policies in relation to health care workers, to pregnant women, to transplantation patients and to immunisation of patients and health care workers
e) refer sample to or request specialist expertise when appropriate
f) perform and interpret antibiotic susceptibility testing

g) recommend appropriate use of anti-bacterial agents
h) differentiate between pathogenic and non-pathogenic mycobacteria; advise on tests for mycobacteria, interpret results and recommend appropriate agents against mycobacteria according to medical context
i) know the definition of microbiome and when it is medically relevant
j) initiate and manage an antibiotic stewardship programme

More specific on culture methods

At the end of formal training, the trainee should be able to:
a) describe the basic principles of the diversity of microbial metabolism
b) choose and use correctly for diagnostic purposes from the wide range of selective, enrichment, inhibitory and chromogenic media available for general and specialised use and be able to choose relevant media in common use in medical laboratories
c) correctly utilise the physical growth requirements of micro-organisms including atmosphere and optimal temperature and have an appreciation of the growth kinetics of both solid phase and broth cultures. It is important in this context to know those microorganisms and medical situations in which detectable growth may require prolonged incubation
d) describe common growth media in use and have an understanding of internal quality control of such preparations. Trainees should at some stage in their training have taken part in the preparation of growth media
e) process all common specimens, recognise potential pathogens from a mixture of colonies on culture plates and separate such colonies in order to achieve the pure growth necessary for further work
f) perform tests leading to the identification of all common pathogens, for instance in house tests, MALDI-TOF, molecular tests and commercially produced kits (e.g. kits for enzyme assays) and rapid diagnostic kits, ELISA, latex agglutination, etc.
g) utilise the principles and methods of molecular identification and epidemiologic typing applied to diagnosis, to outbreak investigation and for epidemiological surveillance
h) be aware of available reference facilities for further identification including serotyping and all other typing schemes, both phenotypic and genotypic

VIROLOGY

At the end of formal training, a trainee should be able to:
a) describe the etiology, risk factors and medical presentation and treatment of viral infections
b) use basic and advanced diagnostic and screening virology methodology, including serology and molecular methods
c) describe methods available for antiviral susceptibility testing and their limitations
d) describe basic antiviral susceptibility testing and interpret antiviral susceptibility testing results
e) recognise when susceptibility testing is required for an individual patient
f) describe the different anti-viral agents and the general principles of their mode of action
g) recommend appropriate anti-viral agents and treatment strategies
h) interpret test results to give medical advice/counselling, for infection control purposes, and for prevention of viral diseases
i) describe in detail the diagnosis and management of viral infections (e.g., rubella, varicella, parvovirus, CMV) in the context of pregnancy
j) describe viral infections causing immunodeficiency (in particular HIV infection): epidemiology, medical features, laboratory diagnosis, prevention strategies
k) describe viral infections associated with severely immunocompromised patients: medical features, laboratory diagnosis
l) explain virology policies in relation to health care workers, for pregnant women, to transplantation patients and the immunisation of patients and health care workers

m) use reference facilities appropriately

MYCOLOGY

At the end of formal training, a trainee should be able to:
a) describe the etiology, risk factors and medical presentation and treatment of both superficial (skin, hair, nails and mucous membranes) and systemic (e.g. candidosis, aspergillosis and cryptococcosis) fungal infections
b) use basic diagnostic mycology methodology, including interpretation of serological tests for fungal antigens and antibodies, and molecular methods (if available)
c) interpret results to give medical advice/counselling, for infection control purposes, and for prevention of fungal diseases.
d) recognise and diagnose superficial and deep-seated fungal infection.
e) recognise special problems associated with the immune-compromised host.
f) examine skin, hair, nails, etc. for presence of fungal elements
g) describe methods available for antifungal susceptibility testing and their limitations
h) recognise patient samples where susceptibility testing is required
i) describe the different anti-fungal agents and the general principles of their mode of action, and recommend anti-fungal treatment strategies.
j) use reference facilities appropriately

PARASITOLOGY

At the end of formal training, a trainee should be able to:
a) describe the epidemiology and medical features of important imported and endemic parasitic diseases likely to present in patients (e.g. malaria, intestinal protozoa, intestinal helminths, leishmaniasis, trypanosomiasis, filariasis, schistosomiasis, toxoplasmosis, toxocariasis, giardiasis and hydatid disease)
b) describe infections associated with severely immunocompromised patients: epidemiology, medical features and laboratory diagnosis (e.g. microsporidiosis, cryptosporidiosis)
c) describe in detail the diagnosis and management of toxoplasmosis in the context of pregnancy
d) use basic diagnostic parasitology methodology: examine blood, stool and other tissues for the presence of protozoa and helminths.
e) identify major parasitic species
f) measure parasite size under the microscope
g) plan and select appropriate diagnostics (microscopy and/or serology and/or molecular methods) for parasite infections
h) interpret diagnostic results to give medical advice/counselling, for infection control purposes, and for prevention of parasitic diseases.
i) explain epidemiology and medical features of important endemic and imported parasitic infections.
j) recommend appropriate anti-parasitic drugs and treatment strategies.
k) use reference facilities appropriately

ANTIMICROBIALS

At the end of formal training, the trainee should:
a. have a thorough understanding and knowledge of the range of therapies available for infectious disease, the medical indications for their use and their side effect profile
b. be able to explain the classification of antimicrobial agents and their modes of action
c. be able to determine the antimicrobial susceptibilities of an isolate using common techniques and

interpret the results using nationally or internationally approved breakpoints, including appropriate quality control
d. be able to perform minimum inhibitory concentrations (MICs) and interpret the results using nationally or internationally approved breakpoints, including appropriate quality control
e. be familiar with the strengths and weaknesses of automated susceptibility test methods
f. have an understanding of the pharmacodynamics, pharmacokinetics and the therapeutic and toxic effects of antimicrobial drugs and be able to advise on appropriate dosage regimens
g. understand the principles of interpretative reading of antibiograms and the use of expert system software for that purpose
h. be familiar with medically relevant natural and acquired resistance phenotypes of common bacterial pathogens, viruses, parasites and yeasts
i. be familiar with the epidemiology of antimicrobial resistance at global and local level and of its medical and financial implications as regards susceptibility testing, choice of therapy and control of hospital infection
j. be able to explain the basic principles of prophylaxis, both with antimicrobials and with immune globulins
k. be able to explain empiric and directed antimicrobial use
l. be able to describe the means of prevention of emergence of antimicrobial resistance.
m. be able to participate in the surveillance of antimicrobial resistance
n. be able to describe existing vaccines and the schedules of immunisation

CLINICAL MEDICINE

At the end of the training the trainee should be able to outline the principles of the epidemiology, presentation, assessment, diagnosis, management and follow-up of the following clinical syndromes:
• urinary tract infection
• respiratory tract infection
• gastrointestinal infection
• skin, soft tissue, bone-and joint infection
• postoperative infection
• encephalitis/meningitis
• hepatitis
• patients with skin rashes and their contacts (pregnant and non-pregnant).
• infections in pregnancy, including methods of diagnosis, and implications of infection for mother and fetus
• Specific requirements for the aging and geriatric population
• congenital infection and infection acquired perinatally
• sexually transmitted infections (STIs)
• infections which constitute medical emergencies
• occupational associated infections
• food- and water-borne infections
• systemic infections including blood stream infections (bacteraemia/septicaemia), vascular graft infections, endocarditis, etc.
• eye infections
• inoculation incident
• brain abscess
• infections in the immunocompromised (both with and without HIV infection) s
• common hospital acquired infection (e.g. device-associated infection)
• infections in travelers (e.g. malaria)