UNION EUROPÉENNE DES MÉDECINS SPÉCIALISTES
EUROPEAN UNION OF MEDICAL SPECIALISTS
Association internationale sans but lucratif – International non-profit organisation

Training Requirements for the Specialty of Laboratory Medicine

European Standards of Postgraduate Medical Specialist Training

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7. Education/training/continuous professional development/medical education

8. Data security, Electronic Data Processing(EDP)

9. Instruments and automatic

10. Validation, evaluation and verification of laboratory procedures

11. Reporting obligations / Registration

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Preamble

Introduction

Following the founding of UEMS in 1958 and the formation of medical specialties in 1962, the Section of Medical Biopathology was recognized at a meeting in Brussels in 1992. Gradually, under the umbrella of the more recent name of the section, Laboratory Medicine/Medical Biopathology, and after the founding of a separate section of Microbiology, subspecialty divisions have been acknowledged.

At present the section consists of the following divisions:

- General Laboratory Medicine/Polyvalent Medical Biopathology

Monovalent specialities:

- Laboratory Medicine - Clinical Chemistry

- Clinical and Laboratory Haematology

- Clinical and Laboratory Immunology

- Laboratory Genetics (Genetic Pathology/Medical Genomics)

For the purpose of the quality assurance in Laboratory Medicine and to achieve pan-EU harmonization, the UEMS Section of Laboratory Medicine/Medical Biopathology has defined a 5-year minimum training curriculum for the disciplines represented by the Section.

The national authorities carry out the practical execution and monitoring of the specialist's training, and confer the title of a Medical Specialist - Laboratory Physician. A goal of higher training is not only to reach professionalism in analytics and laboratory management, but also to discuss, advice on and recommend laboratory tests and testing strategies, either with fellow pathologists, scientists, physicians of other specialties or patients.

Further, trainees should be capable of interpreting analytical findings in the context of the individual patient, within the limitations of their experience and expertise. Co-operation of the laboratory specialist with the treating physician is the basis for the appropriateness, the effectiveness as well as the economy of laboratory-medical interventions, as required by national laws. . It should be noted that the following training curricula require continuous updates because of ongoing theoretical and technological developments, and it is the obligation of all stakeholders to integrate them in the professional practices.

Polyvalent Laboratory Medicine versus Monovalent Specialties

In each country the field of Laboratory Medicine is organized in a different manner. National delegates in the Section will often represent different professional domains that are part of - and together constitute - the whole clinical laboratory field. Because the specialties are defined differently from country to country within the EU, it is not possible to describe general training curricula that will apply to all countries. In some countries such as the Netherlands and Scandinavia, the laboratory specialty named 'Clinical Chemistry' includes biochemistry, immunology, and haematology (i.e. all subspecialties included in General Laboratory Medicine/Polyvalent Medical Biopathology but excluding Clinical Microbiology). In other countries (e.g. Ireland, UK) 'Chemical Pathology' includes biochemistry and endocrinology. The clinical component of practice varies among different specialties, with some having a strong clinical emphasis. For example in the UK, chemical pathologists and immunologists – as a registered specialist - may have independent responsibility for patient care. This is a rare practice in other EU countries. One year of clinical work, e.g. in Internal Medicine is obligatory for specialist trainees in many countries. The name of the discipline also varies between countries. These differences between EU countries make it a particularly challenging task to harmonise specialist training within the EU.

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

The present curriculum is divided into a common part and specialized parts for the four different professional domains. There is a basic, common or general part of training, shared by all laboratory specialties both with respect to (theoretical) knowledge as to practical skills. This is described under the heading of "Common Core". It should be noted that the different professional domains do not intend to define the monovalent specialties, and will in most cases not cover or be congruent with the monovalent domains in the EU countries.

Specialist training shall be considered complete on the basis of having spent sufficient time in recognized training posts, in accordance with national laws and regulations, that all training aims have been completed and signed off in an appropriate log-book, including the core knowledge syllabus, and having passed an appropriate examination.

Medical Microbiology including the field of Clinical Microbiology is a medical (monovalent) specialty represented within the UEMS by a separate Section. Clinical Microbiology is however also an essential part of the Polyvalent Specialty of General Laboratory Medicine, and as such included in the present curriculum.

I. Training Requirements for Trainees

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

1. Content of training and learning outcome

Competencies required of the trainee

In order to become a trainee for the speciality of Laboratory Medicine the candidate has to be a qualified medical doctor. Procedures for recruiting medical doctors, who have fulfilled the requirements for basic medical training leading to an EC recognized medical diploma, must be transparent.

The trainees in Monovalent specialties will spend more time, compared to the trainee in General Laboratory Medicine/Polyvalent Biopathology, in the specialized laboratory. Although many of the fields of interest show overlap between the specialties, the more training time will result in more in depth knowledge of these specialized fields.

Training in Laboratory Medicine should be based on the syllabus detailed in the next section. Delivery of a training program in these areas of Laboratory Medicine consists of training in multiple aspects including varying levels of expertise in measurement procedures as well as in diagnosing and in some cases advising on treatment.

Included are common competencies that should be acquired by all physicians during their training starting within their undergraduate career and developed further throughout their postgraduate career. As explained above, almost each country has a different definition and different subspecialties in Laboratory Medicine. The total field of Laboratory Medicine however is equal in all countries and comprises the fields described below.

We refer to the description of the training curricula on a national level for the details in individual countries.

a. Theoretical knowledge

The specialist in Laboratory Medicine should have a thorough understanding of methods used in a clinical laboratory, and will be familiar with and understanding the interpretation of the

analyses commonly employed in investigating the functioning of various organ systems. Below are stated the common knowledge requirements for all specialists disciplines represented within the Section of Laboratory Medicine.

It is assumed that the trainees have, by reason of their completing their initial medical training, sufficient basic (bio)medical knowledge of:

- normal anatomy, physiology and pathology of the body: skeletal-, nervous-, cardiovascular- (including blood, blood vessels and lymphatic system), respiratory-, endocrine-, renal-, gastrointestinal- (including nutrition), urinary- and reproductive systems.

- Embryonic development.

- the chemical, cellular and tissue level of organisation of the body.

- the cellular, tissue and systems responses to disease including cell death, inflammation, neoplasia, hypertrophy, hyperplasia, tissue responses to injury and repair.

- the pathophysiology of disease development in common diseases across the body systems.

- the basic principles of biochemistry, including biochemistry of tissues, cells and body fluids.

- the basic principles of microbiology including infection control, bacteria, recognition of extracellular pathogens, virus types and structures, viral infection and replication.

- the basic principles of immunology, natural defences, B and T cell-mediated immune responses.

- the basic principles of haematology including anaemia, haematological malignancies, blood clotting disorders.

- the basic principles of histology including microscopic and staining techniques.

- the basic principles of genetics, including patterns of inheritance, chromosomes, genes and gene structure, DNA, RNA and protein synthesis and the role of genes and genetics in cancer.

The necessary knowledge (technical and medical) is outlined below under the headings of the specialist domains, but may well apply to more than one laboratory specialties due to extensive overlap between the definitions of (sub)specialties in different countries. It should be understood that the choice to describe skills or techniques under the heading of one specialist domain does not represent the opinion of the Section that these skills or techniques belong solely to one specialty. This will strongly depend on national (or even local) routines and regulations. It is recommended that medical trainees take every opportunity to gain experience in all aspects of laboratory medicine, not merely in one specialty. This breadth of knowledge and experience, for the benefit of the patient, is an important way in which a medical practitioner in laboratory medicine is distinguished from their scientific and technical colleagues. Trainees should also note that this is a living document and inevitably will always

lag behind modern advances, so they are expected as professionals to acquaint and keep themselves informed of recent advances, including by way of Continuing Medical Education throughout their careers. It is also recognised that as individuals develop they may naturally cross existing boundaries and even, perhaps, help to form new and emerging disciplines within laboratory medicine.

A. Haematology: theoretical knowledge

1. General haematologic methods

- General morphology and automated blood counting methods; cell counts and knowledge of haematological parameters;

- Cytochemical and immunophenotyping, examination of peripheral blood and leukocyte sub-grouping; reactive changes (including viral infections); different forms of anaemia, leukopenia, thrombocytopenia; erythrocytosis/polycythemia, leukocytosis, thrombocytosis; myelodysplasias;

- Knowledge of the methods for the identification and the diagnosis of congenital and acquired haemolytic anaemia's and of abnormal haemoglobins and thalassemias;

- Molecular Biology and in particular its role in Haematology;

- Knowledge of the techniques for the diagnosis of coagulation disorders;

- Knowledge of the methods and techniques used for identification of congenital and acquired bleeding disorders. Experience in the monitoring of patients requiring anticoagulant therapy;

- Knowledge of the methods and techniques used for identification and management of thrombophilia and other hypercoagulable states.

2. Cellular Haematology

- Microscopy; light, bright field, phase-contrast, polarising, interference contrast, dark field, fluorescence microscopy; cell staining techniques and preparation of smears, slides or films; (peripheral blood, marrow, puncture specimen, master cell preparations, cell suspensions);

- Flow cytometry; cell counting, cell markers detection and fluorochromes; subsystems: fluidics, optics and electronics;

- Chronic and acute leukaemias, myelodysplasias (including molecular-biological findings, immuno-phenotyping and cytochemistry);

- Lymphomas and lymphoproliferative diseases (including molecular-biological findings, immune-phenotyping and cytochemistry);

- Parasitosis;

- Investigation of anaemias, both congenital and acquired; haemoglobinopathies, detection and measurement of variant and minor (Hb A2 and HbF) haemoglobins; red blood cell enzymes;

3. Immuno-Haematology

- Blood group identification; allo- and auto-anti-bodies; incompatibility reactions, cross matching of blood samples;

- Anti-body searching and anti-body differentiation (including special methods such as elution-, neutralization- and absorption-methods); rhesus- and ABO-antagonism;

- Apheresis of haematology cells;

- Investigation of transfusion reactions;

- Platelet antibodies; typing of leucocytes and tissue antigens.

4. Haemostasis

- Coagulation tests; determination of coagulation factors; control of anticoagulation factors;

- Investigation of fibrinolysis, determination of antithrombin and heparin, heparin induced thrombocytopenia;

- Investigation of platelet function; PFA, thromboelastography; platelet aggregation tests;

- Determination of serotonin; spontaneous aggregation; clot retraction; platelet factor III determination;

- Use of chromogenic substrates for the determination of coagulation factors;

- Detection of circulating inhibitors, diluted curves (e.g. cephalin);

- Protein S, protein C;

- VWD: VWag, VWrico, ADAMTS13;

- Thrombophilia testing (FV Leiden, FII, PAI, MTHFR), lupus anticoagulans testing;

- Thrombin activation: TAT, protrombin fragments F1+ 2, D-dimer;

- DNA /RNA based PCR assays

Clinical Chemistry: theoretical knowledge

- Physicochemical methods. ion selective electrodes (ISE), biosensors, osmometry; titrimetry, nuclear magnetic resonance;

- Photometric methods. flame-photometry, atomic absorption, turbidimetry, nephelometry, fluorimetry, flame emission, reflectometry, infra-red spectrometry;

- Particle counting. impedance (cell counting);

- 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 for the determination of the activity of various enzymes; analytical techniques, reaction rate, end point analyses; enzymes as reagents; enzyme kinetics, inhibitors, allosteric behaviour; chemical and enzymatic methods for the analysis of substrates;

- Immunological methods. Principles of Ag-Ab reactions, avidin-biotin, immunoassay design; competitive immunoassay; non-competitive immunoassay; homogeneous and heterogeneous assays; interference; immuno-precipitation; immuno-electrophoresis, immuno-fixation, immuno-turbidimetry, immuno-nephelometry; agglutination techniques;

- Signal detection systems; use of radioisotopes, colorimetic/fluorimetric/fluorescence polarization/luminescence labels;

- Urinalysis. Chemical and morphological urine examinations (urine sediment).

Immunology: theoretical knowledge

- Testing of anti-bodies / antigens / inflammation-mediators by means of immune-fluorescence; immune-precipitation in liquids (nephelometry / turbidimetry); immune precipitation in gels;

- Haemagglutination and complement fixation; radio- and enzyme-immunological test procedures; Western blot and similar procedures (e.g. line immune-binding); electrical procedures combined with blotting, precipitation including electrical focusing; preparation and enrichment of peripheral cell populations; cyto-fluorography (cell surface and intracellular structures); diagnostic and preparation; lymphocyte function tests; immune-histology;

- Auto-anti-bodies; Ig-classes and –subclasses; specific Ig's in particular specific IgE's;

- Monoclonal and oligoclonal immunoglobulin changes; cytokines and –inhibitors; adhesion molecules; inflammation parameter including complement factors; cryoglobulins;

- MHC classes I and II-molecules (HLA typing);

- Serology markers of viral and bacterial infections(including quantitation of antibodies and pathogen load) ;

- Allergy testing in blood (IgE, RAST, recombinant antigens);

- Bio-mathematical evaluation with Genotype diagnostics; electrophoresis and other separation methods.

Clinical Microbiology: theoretical knowledge

- Specimen selection and sampling (blood, urine, sputum, faeces, others), transport and storage of clinical specimens;

- Specimen processing: smears, staining, cultures including cell cultures, susceptibility testing, antigen detection;

- Culture and sensitivity: microbial culturing, selection of media, incubation conditions, organism identification techniques, antibiotic sensitivity testing;

- Usual techniques for microbe (including parasite and fungus) and virus identification (including principal differential characteristics);

- Microbial cell staining techniques; bacteria, virus, parasite and fungus identification (including principal differential characteristics);

- Molecular biology techniques for characterisation of microbes and viral agents;

- Bacteriological and viral serology, immunological and molecular diagnosis of parasitic and mycological diseases;

- Classification methods of bacteria and mycobacteria; antibiotic resistance tests of bacteria and mycobacteria ~~um~~; tests for antibiotic concentration in body liquids;

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

- Culture and identification of frequent yeasts, molds, fungi and dermatophytes; antigen tests of Cryptococcus; serologic methods in mycology; antimycotics: resistance examination of yeasts, molds and fungi;

- Microscopic proof of common protozoan's, larvae, eggs; identification of helminths, nematodes, insects, mites; serologic methods in parasitology;

- Current methods for antigen and anti-body-tests for frequent microorganisms; standardisation and quality control;

Laboratory Genetics: theoretical knowledge

It should be noted that while Cytogenetics and Molecular Genetics are distinguished here, modern practice is moving towards single genetics laboratories which perform all analyses under one roof, and the distinction between cyto- and molecular genetics is disappearing as technology rapidly advances. In particular, the development of Next Generation Sequencing means that the modern medical practitioner in laboratory genetics is becoming a Genomic Medicine specialist.

Genetics is fundamental to all aspects of medicine, and in particular other laboratory disciplines. Notably, the importance of genetics in metabolic medicine and cancer is not to be underestimated. Hence, trainees should strive to become acquainted with other laboratory disciplines, including cell pathology/histopathology, because multiple strands of evidence are used to interpret genetic findings.

Screening for genetic disease, either e.g. by DNA or biochemical analysis, is a very important aspect of public health medicine. Trainees in laboratory genetics should be knowledgeable about the practical, health economic, and ethical aspects of this.

- Fundamental knowledge of hereditary diseases;

- Molecular biology and organization of genes (including transcription, translation and relevant regulatory regions, mutagenesis and repair mechanisms, mechanisms of the RNA editing); frequent polymorphisms of human genes and post-translation changes of gene products; relation with other analytical results and their clinical correlation;

- Recognition of indications for individual genetic consultation;

- Genetic diagnostic tests with conventional cytogenetic, molecular cytogenetic and molecular genetics;

- Reasons for medical genetic testing; effects of genetic defects; effects of structural and numeric chromosome aberrations (including malignant illnesses); possibilities, methods and risks of prenatal diagnosis;

- The concepts of dominance, recessivity, penetrance, sex limitation, pathogenicity of mutations, phenocopies, and variable expressivity; polygenic disorders;

- mutational mechanisms: somatic, constitutional and germline; gender differences;

- ISCN (international system for human cytogenetic) nomenclature; HGVS (Human Genome Variation Society) nomenclature; genetic database standards; quality assurance; internal and external quality control;

- Direct gene diagnostics for differential diagnosis; direct gene diagnostics for determination of carrier status; direct gene diagnostics for pre-natal diagnosis; pre-symptomatic gene diagnostics; Gene banks;

- Analysis of the following abnormalities and recognition of their diagnostic, prognosis and/or therapeutic interest: chromosome number abnormalities; mosaicism; structure abnormalities in equilibrium and disequilibrium; chromosomal microrearrangement; identification of a chromosomal marker; identification of chromosomal variants; chromosome fragility and chromosome breakage syndromes .

- Analysis of the following pathological types and recognition of their diagnostic, prognosis and/or therapeutic interest: monogenic disorders (autosomal dominant, autosomal recessive, X-linked recessive, X-linked dominant).

- Oligo- and polygenic disorders; mitochondrial disorders.

1. Cytogenetics

- Sampling and transport; preparing, application and carry through cell cultures; preparations of chromosomes according to standard methods and using synchronization techniques; staining of chromosomes for banding; microscopic analysis of metaphase chromosomes; determination of karyotype and verification of numeric and structural chromosomal aberrations;

- Karyotype; knowledge of the different analysable materials and the culture requirements; culture conditions according to the sample and the indications (medium, support, culture time); chromosomal preparations; the acquisition of the principal types of chromosomal bands; high resolution karyotypes (replication bands); microscopic examination, display capture on analyser and karyotype classification; knowledge of the quality of the chromosomal preparations and the resolution level of the chromosomal bands; validity criteria of chromosomal analysis;

- Molecular cytogenetics; in situ hybridisation fluorescent (FISH) technique: centromeric and telomeric probes, specific probe of a locus on metaphase or interphase; comparative genomic hybridisation on microarrays; validity criteria of molecular cytogenetics assays;

2. Molecular Genetics

- Sampling, specimen-transport and specimen-treatment; storage of nucleic acids; procedures of nucleic acid extraction; cloning of nucleic acids; analysis of nucleic acids (including PCR, DNA Sequencing, restriction cleavage, Southern and Northern Blotting, labelling of probes, verification of mutation);

- Indirect gene diagnostics by means of genetic markers, evaluation and interpretation of the results (“linkage”- analysis);

- Nucleic acid analysis; extraction and preparation of DNA and RNA (genomic DNA, RNA, RNApolyA+); polymerase chain reaction (PCR) and reverse PCR; quantitative PCR;

techniques for point mutation detection; techniques for detecting more complex genetic variation; cytogenetic analysis; array technology, DNA sequencing (including "Next Generation Sequencing"), molecular cytogenetics (FISH); DNA-analysis (Southern blot, restriction-fragment-length-Polymorphism (RFLP), sequencing); different methods of study of DNA polymorphisms (SNP, microsatellites);

- Different nucleic acid quantification methods, e.g. MLPA; different methods of gene expression study at RNA level; DNA or cDNA microarrays techniques; validity criteria of molecular genetics analysis.

- The interpretation of mutations as pathogenic or not, including bioinformatics and gene-specific databases, and using adjunctive data from e.g. other fields of pathology and laboratory medicine;

- epigenetics

- pharmacogenetics

- Biochemical genetics and metabolic disease

3. Genomic Medicine

- The practice and use of Next Generation Sequencing (NGS) and associated bioinformatics, including international databases.

- gene dosage techniques based on NGS.

- the advantages and disadvantages of single gene vs. gene panels vs. whole exome vs. whole genome analysis.

- the interpretation of multiple mutations and SNPs in one individual in the diagnosis, assessment of risk and therapeutic options for patients.

- pharmacogenomics

- epigenomics

- the role of genomic testing for somatic mutations in tumours, and how this informs treatment

b. Practical and clinical skills

The specialist training should produce specialists able to provide an independent opinion in their laboratory discipline, including clinical importance, therapeutic relevance, diagnostic

performance, and efficient use of the laboratory tests as a part of relevant epidemiology, clinical diagnostics and monitoring of patients.

The specialists should have developed the appropriate management skills to lead a department, if required. The trained specialist in Laboratory Medicine should be competent in the following fields:

Common Core in Laboratory Medicine: Practical and clinical skills

1.1 Guiding the appropriate use of laboratory tests

The specialist in Laboratory Medicine in a consultative role requires a working knowledge of the subject underlying the choice of tests and interpretation of results.

- Evaluation of individual results (identifying extreme values, recognition of significance of previous results, recognition of combinations of findings typical of diseases);
- Use of reference values: influence of age, genetics, sex, lifestyle, interfering factors, effect of therapeutic agents, biological and analytical variation;
- Longitudinal evaluation of critical differences during disease course, e.g., in long-term conditions, cancer, during therapeutic drug monitoring and as a result of treatment regimen changes;
- Recommended testing strategies in response to clinical demand;
- Diagnostic sensitivity, specificity, positive and negative predictive values, likelihood ratio;
- Independent initiation and/or recommendation of further investigations, reflective testing;
- The laboratory report – provision of evaluation, guidance and interpretive comments, advice regarding therapy can be part of the consultative function;
- Assessment of a new analytical method and introduction of its use clinically;
- The logistics of a laboratory doing routine clinical chemical work'.
- guidance in setting up computerised test requisition panels, testing algorithms and paths for reflective testing;
- guidance of efficient regional laboratory strategies that support regional treatment chains of specific patient populations;

2. Laboratory management

Management and communication skills; personal leadership skills. The trainee should gain experience in all aspects of laboratory planning and management. The trainee should be involved in developing department policies and improve leadership skills.

- Policies on objectives, rules, strategy, setting and establishing policy, laboratory statutes;

- Personnel management. Executive functions related to employment, national laws and local rules of working places, human welfare and qualifications.

- Planning (personnel planning and recruiting, plans of application, emergency service); laboratory planning, specifying requirements, space, laboratory equipment, infrastructure; budgeting, analysing costing (efficiency) and cost-benefits calculation; long-term planning, contracting, performance management, financial controls);

3. Laboratory processes - Internal organization

- Negotiations on clinical need and turn-around times;

- Selection of tests, locations and equipment;

- Centralised, satellite and emergency laboratories, points-of-care;

- Facilities and space utilisation;

- Public tenders and purchasing principles;

- Organising preanalytical processes, sample collection and logistics;

- Analytical processes at different levels of organisation (centralised and satellite laboratories, points-of-care);

- Outsourcing (subcontracting laboratory services);

- Data transfer, pre-analytical, analytical, and post-analytical processes, integration of laboratory information systems with electronic patient records and administrative systems, including national archives of patient results;

- Standard operating procedures, documentation, archiving within the laboratory and at national level;

- Improving laboratory processes

4. Laboratory safety

The trainee should be familiar with all health and safety issues including their legal aspects.

- Security concept and laboratory order, general action in exceptional cases, hygiene and other requirements in case of accidents, infections, poisonings, buildings and structural requirements;

- Handling of potentially infectious samples;

- Handling of noxious chemicals and isotopes;

- Mechanical and electrical safety, fire precautions, radiation security requirements;

- Dealing with an accident, accident prevention and hygiene regulations, occupational diseases, alert systems, incident reporting.

5. Sampling and treatment of specimens

- Specimen sampling and collecting techniques, influence of collection and storage of specimens, place and time of sample collection;

- Patient guidance and preparation to laboratory tests; patient identification, influence of nutrition, drugs, posture, fasting state, etc.;

- Choice and correct use of anticoagulants and transport media, order of draw, tourniquet effects;

- Sample logistics and preservation; transport of specimens and factors of influence during transport, organization of specimen transport;

- Storage of specimens (pre analytic and long-time storage), stability of measurants, influence of temperature, freezing/thawing, disposal of biological specimens, removal of contamination associated with molecular-biological methods.

6. Quality

- ISO15189 and other quality standards, quality management systems;

- Internal quality control; organization, plausibility/delta checks, methods and evaluation of statistics, total error concept, measurement uncertainty concept, multirules;

- External quality assessment;

- Diagnostic quality of tests (clinically needed quality);

- Treatment of non-conformities;

- Quality improvement, process development tools (lean principles).

7. Education/training/continuous professional development/medical education

- Ensuring skills, competencies and motivation of staff meet service requirements;

- Ensuring staff access education and training programmes appropriate for service needs;

- Participation, as appropriate, in staff education, training and appraisal;

- Ensuring staff remain up to date by participation in continuous professional development/continuous medical education (CPD/CME);

- Ensuring own training, education, appraisal and CPD/CME needs are maintained.

8. Data security, Electronic Data Processing(EDP)

- Organization of the EDP and work routine, analysis of weak points, computer operation; data protection, archiving, networks and transmission problems, error tracing, strategic design.

9. Instruments and automation

- Principles of stand-alone and automated instruments;

- Technology of automated sample tracks and sample identification;

- Computerised integration of laboratory and analytical interfaces;

10. Validation and verification of laboratory procedures

- Hierarchy of laboratory procedures and reference materials (starting from primary reference procedures and reference materials to field procedures), traceability;

- Establishment of working procedures and service instructions;

- Evaluation of new analytical devices, adaptation of manual methods on automatic devices;

- Statistical comparison of methods, validation and verification;

- Analytical performance of quantitative and qualitative methods (imprecision, inaccuracy, analytical specificity, analytical sensitivity, dynamic measurement range, limits of detection, limits of quantification, uncertainty of measurements, accuracy, trueness and precision;

- Diagnostic performance. Negative and positive predictive values, likelihood ratios, confidence intervals; critical difference;

- Interference, carry over;

- Definitive methods, reference methods, reference materials, primary and secondary calibrants, traceability;

- Laboratory and population data: sampling, reference values, reference change values, biological variability, genetic influences, environmental influences, age, sex, nutrition, season and time of day, influence of therapeutic agents;

- Diagnostic strategies and analytical goals in the use of clinical chemistry tests; total error and allowable total error concepts;

- Initiation, conduct and evaluation of clinical and laboratory audit to ensure quality, governance and patients' needs continue to be met.

11. Reporting obligations / Registration

- Documentation and archiving; compile and draw up descriptions of methods and operating procedures; evaluation, interpretation and written reports of findings; long-term storage of samples and cultures;

12. Scientific research and scientific co-operation with hospitals and physicians

Throughout their training individuals should be encouraged to critically assesses and evaluate published work. Ideally, the training should allow the individual to undertake a period of original research.

As Laboratory Medicine is continually and rapidly evolving, research and development of both the laboratory aspects and their clinical application are indispensable. The specialist in Laboratory Medicine must maintain up to date knowledge in all relevant diagnostic procedures. Special attention must be paid to the following:

- Development and improvement in technologies, techniques and methodologies; with special emphasis on new developments in areas such as molecular biology, proteomics, mass spectrometry;

- Procedures to test and evaluate the steps of a method and the components of an instrument;

- Initiation, conduct and evaluation of laboratory-based and clinical research and development based on best evidence of practice;

- Generating outcomes of research and development, audit and service improvement programmes using recognised scientific and statistical techniques;

13. Legal environment, national and European legislation

- Ethics, patient rights and protection of privacy on clinical practice and medical research;
- National and European legislation related to health care; laws, regulations, guidelines and recommendations on work in clinical laboratories;
- Regulation of clinical laboratory services, including those on responsible persons;
- Legal and professional management of adverse effects on patients and non-conformity of provided services;
- Legal rules of employment and working conditions; rules and regulations concerning research;
- European directives and national laws related to in vitro devices and purchasing equipment, international tenders;

Laboratory haematology: practical and clinical skills

1. General Objectives in Training

- Specialised knowledge of the natural history of haematological diseases;
- Specialised knowledge of haematological laboratory techniques;
- Interpretative skills so that a useful clinical opinion can be derived from laboratory data and microscopic examination of the blood and the bone marrow;
- Information and communication technology particularly in its application to Haematology and Transfusion Medicine;
- Ethical issues related to clinical and laboratory haematology and transfusion medicine.

2. Laboratory Haematology

- Haematopoiesis and haemostasis physiology;

- Possible causes and background of anaemia's; vitamin B12 and folic acid deficiencies; iron status; haemoglobinopathies;

- Kinetics of blood cells and platelets; enzymology of blood cells and platelets;

- Haemato-oncological abnormalities (leukaemia's, lymphomas, polycythaemia's);

- Immunological determination of coagulation factors and knowledge of coagulation abnormalities (factor deficiency, increased fibrinolytic activity) and regulation and monitoring of thrombosis and disseminated intravascular coagulation; Acute vascular diseases TTP, HUS, HELLP, DIC; the use of anticoagulant drugs; place of plasmapheresis in treatment.

- Blood group antigens and other antigen systems in blood transfusion (including genetics); several types of transfusion reactions, foetal maternal bleeding;

- Selection criteria of donors for blood transfusion;

- Medical applications, clinical relevance and indications for the administration of blood and blood components.

3. Clinical Haematology

- Knowledge of the non malignant haematological diseases such as iron deficiency, haemolytic anaemia, megaloblastic anaemia, bone marrow failure syndromes, haemoglobinopathies and thalassemias and also the myeloproliferative and myelodysplastic disorders;

- The management of patients with malignant disorders including acute and chronic leukaemia, multiple myeloma and the lymphomas;

- The management of patients undergoing haematological stem cell transplantation procedures;

- Knowledge of the diagnosis and the management of patients with coagulation disorders including haemophilia, von Willebrands disease, other coagulation defects both congenital and acquired and the hypercoagulable syndromes; anti-coagulation and control measures; hemorrhagic diathesis and classical haemophilia; thrombophilia (including molecular-biological findings); thrombocytopenia; clinical use of markers of activation and fibrin degradation products; consumption coagulopathy;

- Theoretical background and clinical background and knowledge of the following subjects: prekallikrein, high molecular kininogen determination, plasminogen, antiplasmin, plasminogen activators;

- Knowledge of anticoagulant treatment as well in clinical as in outpatient conditions; haematological aspects of other hospital specialities including intensive care medicine, and obstetrics; paediatric haematology including neonatal haematology.

4. Transfusion Medicine

- Organisation and management of Blood Transfusion Centres; knowledge of blood transfusion service at national and international level and, in particular, knowledge of the regulations and standards for transfusion medicine in Europe;

- Management of blood donor sessions including autologous blood donation; the requirements for donor screening;

- The preparation of blood products including quality assurance;

- Clinical indications for the transfusion of blood products including their handling and administration;

- Safety of blood products; Transfusion Transmitted Diseases;

- Grouping and cross matching and in immuno-haematology; standards for regents and red cell panels; clinical significance of red cell allo-antibodies; prevention and management of haemolytic diseases of the new born and of the immune haemolytic anaemia´s;

- Investigation and management of transfusion reactions; be able to give clinical advice in all areas of Transfusion Medicine;

- White cell and platelet serology; management of HLA-typed donor panels; techniques for the management of HLA sensitisation;

- Techniques for the collection, processing and preservation of stem cells;

- Apheresis procedures both for therapeutic purposes and for the collection of blood products;

- Haemovigilance and the use of look back procedures.

Clinical chemistry: practical and clinical skills

1. Water, electrolyte, acid-base and blood gas disturbances

- Water balance and maintenance of osmolality;

- Intracellular, extracellular and plasma electrolytes;

- Acid-base, blood gases, acid-base balance and disorders, buffer systems, Henderson-Hasselbalch equation, acidosis and alkalosis;

- Renal regulation systems, pulmonary gas exchange, oxygen metabolism.

2. Laboratory markers of organ damage or states due to specific organ systems and conditions

- Cardiovascular tract. Normal and disturbed circulation, myocardial infarction and shock, marker proteins, fluid balance, hypertension, heart failure, blood markers;

- Kidneys and urinary tract. Physiology; normal and disturbed renal function, excretory substances in the plasma and urine, glomerular filtration rate and clearance, activity and effects of diuretics, free water clearance, proteinuria and urinalysis, acute and chronic renal insufficiency, nephritis, nephrotic syndrome;

- Liver and digestive tract. Digestive enzymes in the various sections of the digestive system including the exocrine functions of the liver and pancreas, hydrochloric acid, bicarbonate and bile secretion, fluid and electrolyte secretion, absorption, gastrointestinal hormones, hereditary and acquired disorders of the digestive system, malabsorption including vitamin malabsorption, exocrine functions of the pancreas, acute pancreatitis, chronic pancreatitis; liver and biliary tract. Physiology; normal and disturbed functions of the liver, metabolism, synthesis, biotransformation, excretion; enterohepatic circulation, metabolism of bilirubin and bile acids, hepatitis, cirrhosis, cholestasis, necrosis;

- Skeletal and locomotor system. Function and metabolism of muscles, bones, cartilage, synovial and connective tissues (fasciae, tendons); hereditary and acquired disorders, especially of calcium and phosphate metabolism, vitamin D, collagen and proteopolysaccharide metabolism;

- Nervous system; markers of acute and chronic disease; immunological mediated diseases; cerebrospinal fluid examination;

- Pregnancy, perinatal laboratory analysis. Hormone analyses, in vitro fertilisation, molecular biology of hereditary disorders, inherited metabolic disease, pre-natal screening for foetal abnormalities (first trimester, second trimester); prenatal diagnosis of inborn errors of metabolism.

- Body fluids. Saliva, gastric juice, ascites, chyle etc., composition and appropriate analyses.

3. Metabolic and endocrine diseases

- Endocrine system; physiology biosynthesis and catabolism of hormones, hormonal regulation, hormone transport, receptor systems;

- Diabetes with its complications;

- Thyroid function;
- Other endocrine organs;
- Hyperlipidemia;
- Other inborn or acquired disorders of metabolism of carbohydrates, lipids, nucleic acids and amino acids, as nationally relevant;

4. Plasma proteins

- Albumin and other transport proteins;
- Immunoglobulins, including detection of clonality;
- Proteinuria;
- Specific markers of inflammation and cancer;

5. Vitamins, trace elements, nutrition

- Vitamines (A, B1, B6, B12, folate, C, D, E, K, etc.);
- Iron metabolism;
- Trace elements (Cu, Zn, Se, Co, Pb, Al, I, etc.);
- signs of malnutrition;
- Monitoring of complete parenteral nutrition.

6. Therapeutic drug monitoring (TDM) and toxicology

- Essentials of clinical pharmacology and pharmacogenetics;
- Interference of drugs on each other and on laboratory tests;
- Clinical needs and available laboratory tests for TDM;
- Emergency toxicology;
- Drugs of abuse and adulteration of tests.

7. Point-of-care (POC) testing and self-monitoring

- Assessing clinical need and required quality for POC testing;

- Governance and management of POC services in the laboratory;

- Monitoring and supporting quality of POC tests performed by non-laboratory professionals;

- self-monitoring by patients, such as glucose and thromboplastin time (INR) tests;

- specific telecommunication and information technology related to POC and patient networks.

Laboratory Immunology: practical and clinical skills

1. General Immunology

- Immune system; functions of the humoral and cellular immune systems and their regulation; cytokines; inflammation; acute phase proteins;

- Surface antigens; hereditary and acquired disorders; immunoglobulin deficiency and overproduction, monoclonal and polyclonal immunopathies;

- Major histocompatibility complex;

- Autoimmune diseases; allergy; complement factors;

- Inflammation; cytokines; acute phase proteins.

2. Immune physiology

- Innate immune defences/inflammation; specific immune reactions (antigen recognition, effectors-mechanisms, etc.); immune modulation (networks, cytokines, adhesions molecules, etc.).

3. Immune pathophysiology

- Allergies, pseudo-allergies/incompatibilities (IgE related/IgE independent); autoimmune diseases (organ-specific/systemic); immune deficiency syndromes (primary/secondary); general immunology of infections (ways of defence, consequences);

- HIV infection/infections with hepatitis viruses A, B, C, D, E;

- Immunology of transplantation (organs, stem-cells / marrow-cells, HLA-typing);

- Immunology of tumors (defence and escape mechanisms, tumor antigens);

- Principles of immunological therapies (drug immune modulation, cytokines / anticytokines, substitution of Ig- and cells) [laboratory based therapy monitoring];

- Principles of vaccination (active/passive Immunization, pre-/post infectious and control of success);

4. Immunological laboratory testing

- Allocation of measured variables to physiological and pathophysiological procedures;

- Specific diagnostics (indication, specificity, sensitivity, validity, interpretation); diagnostic pathways, algorithms;

- Correct implementation of tests (individual, serial, with automatic devices); test-related criteria of quality control, sensitivity, specificity of individual parameters;

Clinical Microbiology: practical and clinical skills

1. General Microbiology

- Epidemiology and symptomatology of infections; therapy of infections with antibiotics, antiviral substances etc.; immunotherapy, immune-prophylaxis; control of nosocomial infections; zoonosis;

- The investigation of biological samples in infectious diseases is different from the other specialities in that it requires general knowledge of pathogenic agents (bacteria or viruses) and of host reaction;

- Definition of infection and infectious disease: natural bacteriological ecosystem;

- Pathogenicity of bacteria and viruses; disinfection;

- General epidemiology of infection and infectious diseases (community acquired / hospital acquired).

- Antibiotics and antiviral agents; basic knowledge of antibiotics and antimicrobiological therapy; antibiotic and antiviral sensitivity test; antibiotic and antiviral resistant mechanisms;

- Disposal of infectious material;

- Preventive measures for the personnel / laboratory workers; laws on epidemic diseases, methods of reporting;

- Clinical relevance and interpretation of microbiological findings; secrecy of medical knowledge; forms of communication with clinicians.

2. Bacteria and viruses

- Bacteriological and viral syndromes or diseases; epidemiology, main clinical signs, basis for biological diagnosis, treatment: meningeal syndrome; septicaemic syndrome; urinary and genital infections; bacteriological and viral diarrhoeas; respiratory infections; human acquired immunodeficiency syndrome; sexually transmitted diseases; hepatic virus infections;

Bacteria: *Neisseria gonorrhoeae* and *N. meningitidis, Staphylococcus aureus, Streptococcus pyogenes* , (especially *S. agalactiae* and *S. pneumoniae* , *Escherichia coli* , *Salmonella* , *Shigella* and other enterobacteriaceae, *Vibrio cholerae* , *Pseudomonas aeruginosa, Haemophilus influenzae* , *Clostridium perfringens* , *C.tetani, Bacteroides* spp, *Listeria monocytogenes* , *Legionella* , *Mycobacterium tuberculosis* and others, *Treponema pallidum, Chlamydiae, Mycoplasma* etc.

Viruses: Herpes (herpes simplex, herpes varicellae, cytomegalovirus, Epstein-Barr virus), hepatitis A, B, C, D, E, human immunodeficiency virus, enteroviruses (poliovirus), rubella, mumps, measles, parvovirus B19, RSV, myxovirus, rhinovirus, coronavirus, adenovirus, rotavirus, papillomavirus, rabies etc.

3. Medical parasitology (including mycology)

- Epidemiology, main clinical signs, basis for biological diagnosis (including a succinct description of parasites and fungi), treatment.

- Amoebiasis: *Entamoeba histolytica;*

- Giardiasis, cryptosporidiosis and uro-genital trichomoniases;

- Malaria; Toxoplasmosis;

- Intestinal, hepatic and urinary helminthiasis: strongyloidiasis, ancylostomiasis, enterobiasis, ascariasis, schistosomiasis (*Schistosoma mansoni* et *S. haematobium*) fascioliasis (*Fasciola hepatica*) taeniasis (*Taenia saginata*);

- Fungal infections (*Candida albicans* , *Cryptococcus neoformans* etc);

- Aspergillus infections (*A spergillus fumigatus*);

- Dermatophyte infections (*Microsporum canis* , *Epidermophyton floccosum* , *Trichophyton rubrum* , *Trichophyton mentagrophytes*). Leishmaniosis;

- Echinococcosis; Pneumocystosis; Filariosis;

Laboratory Genetics: practical and clinical skills

- Fundamental knowledge of hereditary diseases;

- knowledge of genetic analysis techniques, including sampling; limitations of the techniques;

- the distinction between diagnostic and predictive testing; screening tests; incidental findings;

- the interpretation of genetic findings in the context of the individual and their relatives, their wishes, their therapeutic options, and the population as a whole;

- the concept that every patient is unique and may reveal a new understanding of genetic disease; to be research aware and constantly look for patterns that might not have otherwise been observed;

(- it is highly recommended that laboratory genetics trainees participate in a research project, and consider a taking a formal degree in research, e.g. MSc, MD or PhD;)

- providing advice to medical, scientific, technical, and counselling colleagues on all aspects of laboratory genetics; liaison; the expertise of writing reports tailored to the recipient's skills and knowledge;

- ability to use clinical judgment and knowledge to deal with unexpected, atypical and complex work, including at short notice in e.g. antenatal or oncological testing;

- awareness of the fundamental place of evidence-based medicine and policy development, and the input to this required of a genetics professional, including research to amass the evidence;

- first hand experience of Clinical Genetics and related practice; genetic counselling; consent and assent;

- participation in multi-disciplinary meetings with Clinical Genetics and/or other medical disciplines, e.g. oncology, immunology, renal medicine etc.;

- Molecular biology and organization of genes (including transcription, translation and relevant regulatory regions, mutagenesis and repair mechanisms, mechanisms of the RNA editing); frequent polymorphisms of human genes and post-translation changes of gene products; relation with other analytical results and their clinical correlation;

- Recognition of indications for individual genetic consultations;

c. Competencies

The Specialty of Laboratory Medicine is the medical discipline that employs biomedical knowledge and measurements to diagnose diseases and monitor the effects of treatment through the investigation of body fluids, cells and excretions from the body and through organ function tests. Laboratory Medicine has its skills in the interface between clinical knowledge and understanding of pathologic mechanisms, biochemistry, analytical chemistry, cytometry, molecular biology and information technology. The Laboratory Specialist is in the position to provide analytical reports with decisive information not only for diagnosis, but also for the prognosis, can make suggestions for treatments and supplies relevant information that will that contribute to the prevention of health disorders as well as to maintain normal health and development, reduce the risk of developing chronic diseases and promote physical and mental health and quality of life.

Consultation of doctors and others working in medical care is one of the core aspects of the profession of the Laboratory Physician.

The abilities that are essential for a specialist in Laboratory Medicine are: being a medical expert, having good communication, academic, cooperative and, organisational/administrative abilities.

It is expected that the finished specialist during his/her education has acquired attitudes that promote a high professional and ethical standard and a positive collaboration with colleagues and other professional groups.

Relevant elements to obtain these qualifications are a recognition that Laboratory Medicine primarily is to serve the patient. This requires a high degree of willingness for fast and good communication with clinical colleagues and patients. A motivation for their own professional development includes, amongst others, participation in continued medical education (CME/CPD). It is expected that specialists in Laboratory Medicine have respect for colleagues and other professional groups working in the medical laboratories. Training in such attitudes comes first and foremost by model learning from supervisor and other senior doctors.

The professional requirements include competence in medicine, in communication, in leadership and management, and in research and development. The intermediate goals referred to below represent a variety of goals of great importance, the attainment of which can be readily assessed. Although they do not provide a complete description of the content of the specialty, the requirements determine whether competence in the specialty has been achieved.

Medical competence

Those preparing to be specialists in the laboratory should in the course of their specialized work and training have obtained the knowledge and skills needed to be able to work in a

competent and independent manner. This requires them having thorough knowledge in the field as well as theoretical skills in appropriate analytical investigative methods.

Supplemental training in internal medicine or closely related specialities such as paediatrics or gynaecology is required as well, if that is not included in the internship.

Competence in communication skills

During training, the trainee shall develop the skills required to communicate with both patients and their relatives. It is the patient's right to be informed about their medical results in an open, empathetic way that takes into account his/her background knowledge. Since we have a lot of immigrants in Europe, knowledge about social and cultural differences is also needed.

It is also important to be able to communicate with other physicians, co-workers, and with public authorities in writing. At the same time, the trainee must have the ability to communicate information in a concise and clear manner to colleagues and co-workers.

Leadership competence

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

Competence in organizational development and medical science

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

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

2. Organisation of training

a. Schedule of training

A trainee in Laboratory Medicine is a medical doctor who has completed the general professional training as a physician and is in an accredited training programme to become a recognised medical specialist. The trainee in Laboratory Medicine must be recognized as a trainee according to the regulations in force for each EU/EEA member state. This stage is variably known in different countries as an intern, fellow or registrar.

In accordance with EU Directive 2005/36/EC* the (minimum) duration of training in Laboratory Medicine should be at least 4 years. The Section of Laboratory Medicine/Medical Biopathology recommends a minimum period of 5 years of training, including one year in clinical practice, after obtaining the national official licence to practice as a medical doctor. This year should be outside the laboratory, and after obtaining licence to practice as a doctor. During this year, the trainee will attend all the activities of the medical department (calls, educational meetings, ward rounds etc). He/she will also be a liaison between the ward and the laboratory e.g. transfer questions, problems and clinical information from Internists to Laboratory scientists, interpret the diagnostic tests to clinicians, or advise on further testing on patients.

Trainees who are unable to work full-time are entitled to opt for less than full time training (LTFT) programmes. The EC Directive 2005/36/EC requires that: LTFT shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities; the competent authorities shall ensure that the competencies achieved during part-time training are not less than those of full-time trainees.

b. Duration of training

A total training period of 5 years including one year of Internal Medicine or Paediatrics are highly recommended. At least 5 years of training is strongly recommended before taking an examination to receive the title of a Specialist in Laboratory Medicine. It is mandatory to spend 1 year in Internal Medicine or Paediatrics.

In General Laboratory Medicine, 4 years will for example be divided between the core curriculum to acquire the general skills and theoretical knowledge that applies to all laboratory (sub) specialties (6 months), 20 months in Laboratory Haematology, Clinical Chemistry and Laboratory Immunology, 16 months in Clinical Microbiology and Virology, plus 6 months in Laboratory Genetics (with Cytogenetics, and training in DNA/RNA diagnostics)

For Monovalent Specialties, time will for example be divided between 8 months for the core curriculum, and the rest of the training period of 4 years devoted to the different fields within the subspecialty. Because the organisation of subspecialties – including the fields of interest – differ considerably between countries within the EU, the lengths of specific training periods are to be adopted nationally. We refer to training schemes on the national level for further details.

Specialisation in Laboratory Medicine requires education within clinical medicine, biochemistry, endocrinology, haematology, immunology, genetics, laboratory management and science. The composition of the training depends on the (sub)specialty. One or more of the subjects that are part of the core curriculum (eg. laboratory management, science) may be integrated within other training periods (e.g. Clinical Chemistry). In this case, documentation for acquired skills is required. Amendments or minor changes that may be necessary in single countries should on a European level comply with a preferred minimum of five years of training.

The training period may be reduced when there is proof of experience in one or more of the major of the subjects that are part of the curriculum.

c. Assessment and evaluation

The training programme should contain sufficient opportunities to check the trainee's proceedings by means of observations during critical practical situations, written proofs of critical assessments by the trainer and examinations of knowledge. The frequency of these tests is laid down in the training programme. Trainers and other staff members involved in the training process should be trained to be able to critically make an assessment of the trainee's knowledge, skills and attitude.

The European Section and Board of Laboratory Medicine support high-quality laboratory services within EU, including documented knowledge in written examinations and demonstration of practical skills relevant for specialist degrees of laboratory physicians. The various European Boards of UEMS organise European examinations to harmonise competencies whenever contents of national medical specialties allow this harmonisation. As long as the European examination for specialties on Laboratory Medicine is lacking, National authorisation shall include detailed documentation of passed written and practical examinations and contents of training is recommended, to allow evaluation of specialists applying for specialist medical positions in another European country than that of education, in addition to the rules of legal acceptance of their specialist degree according to the EU Directive 2005/35/EC and its Annex V.

The section encourages the use of courses, both national and international, to train the candidates.

d. Governance

The National Authorising body is responsible for legalising medical doctors, including lists of specialties and licencing specialists of laboratory medicine, as well as implementation of the European law. The Union of European Medical Specialists together of its Sections and Boards helps National Medical Associations and National associations of Medical specialists to define appropriate contents to be included in these competencies.

Each National Authority should work with the national Laboratory Medicine society and professional union to provide quality assurance of training in Laboratory Medicine. Trainees should have the opportunity to be partly trained in recognized training institutions both in other member states of the EU as well as outside the EU. These training periods have to be approved by the National Authority.

The National Authority should determine each country's process for the selection and appointment of trainees in Laboratory Medicine. The National Authority should implement regulation of access to training in Laboratory Medicine in accordance with national manpower planning projections in the EC member state. There should be close involvement of trainers, training institutions and any other responsible bodies to select and appoint trainees who are suitable for Laboratory Medicine in accordance with the established selection procedure. This selection procedure should be transparent, and application should be open to all persons who have completed basic medical training and have received their medical licensure.

II. Training Requirements for Trainers

1. Process for recognition as trainer

Trainers should be recognized by the relevant national authorities. Each training institution should have a chief of training who should have been practising Laboratory Medicine for at least 5 years after specialist accreditation and should have completed a specific training programme. There should be additional trainers who should be practicing Laboratory Medicine. The ratio between the number of trainers and the number of trainees should allow close personal supervision of the trainee during his/her training. The chief of training shall work out a written training programme for the trainee, including estimated periods used for each topic to be covered and in accordance with the trainee's own requirements, which also complies with national rules, EC Directives and UEMS-Section recommendations.

a. Supervision

All elements of work in training posts must be supervised with the level of supervision varying depending on the experience of the trainee and the exposure to diagnostic problems. Supervision must routinely include the opportunity to personally discuss all cases. As training progresses the trainee should have the opportunity for increasing autonomy, consistent with safe and effective care for the patient. Trainees should have at all times a named supervisor responsible for overseeing their education.

The educational supervisor is a trainer who is selected and appropriately trained to be responsible for the overall supervision and management of a specified trainee's educational progress during a training placement or series of placements.

Opportunities for feedback to trainees about their performance will arise through the use of the workplace-based assessments, regular appraisal meetings with supervisors and other meetings and discussions with supervisors and colleagues.

b. Appraisal with Supervisors and Training Director

The supervisor should provide regular appraisal, at least every 3 months, to discuss progress, activity, individual strengths and weaknesses. Each appraisal meeting should generate a summary agreed by both parties and at the end of the time with a particular supervisor; he/she should issue a formal report on progress, shared with the trainee that will be assessed by the person with end-responsibility for the training (training director). At the end of the period of training in a certain field or subspecialty, each trainee will undergo appraisal with the training director, who will hold ultimate responsibility for "signing off" the training period and the competencies achieved by the trainee. In some countries dedicated software will be available to that end.

2. Quality management for trainers

Evaluation of the training provided should be organized, e.g. evaluation of trainers by trainees.

III. Training Requirements for Training Institutions

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

The general requirements for recognition as a Training centre in Laboratory Medicine are that:

- it is an institution, or group of institutions, which offer the trainee practice across the full range of the specialty including involvement with allied specialties (internal medicine, clinical haematology, paediatric) to provide the trainee the opportunity to develop his/her skills in a team approach to patient care;

- it has all the necessary infrastructure to provide the training in Laboratory Medicine as defined in the curriculum;

- it has adequate teaching staff;

- it provides a good learning environment;

- it provides the trainee with space and opportunities for practical and theoretical study and access to adequate national and international professional literature;

- it has a structured training program, which includes theoretical teaching sessions, training duties for each trainer and adequate numbers of practical procedures per trainee;

- it undergoes monitoring in a structured way by the national authorities including visits and appraisal of their standards as training centres at least every five years;

- it has an internal system of medical audit or quality assurance including features such as clinical case conferences, reporting of accidents in accordance with a structured procedures;

- it has a chief of training recognised by the relevant national authorities who should have been practising the specialty for at least 5 years after specialist accreditation and should have received specific training.

The number of trainees per training centre should be based upon the number of trainees that the centre can train (the number of practical procedures per trainee is the minimum which has to be taken into account) and the manpower planning projection of each EU national state. The national authorities can put into effect additional criteria for training institutions if needed.

A 'good learning environment' includes encouragement for self-directed learning as well as recognising the learning potential in all aspects of day to day work. A supportive open atmosphere should be cultivated and questions welcomed.

The bulk of learning occurs as a result of clinical experience (experiential on-the-job learning) and self-directed study. Lectures and formal educational sessions make up only a small part of the postgraduate training in Laboratory Medicine. Trainees should regularly update their personal portfolio to keep a personal record, and be able to present to others, the evidence of the learning methods used.

Experiential Learning Opportunities: Every patient case will provide a learning opportunity, which will be enhanced by studying the background literature. Joining ward rounds will be a very valuable experience and will help to relate laboratory measurements to clinical problems and outcomes. Trainees should have the opportunity to assess and discuss cases with the supervisor so as to allow feedback on diagnostic skills and gain the ability to advise on investigations. There are many situations where clinical problems are discussed with clinicians in other disciplines. These provide excellent opportunities for observation of clinical reasoning.

Small Group Learning Opportunities: case presentations and small group discussion, particularly of difficult cases, including presentations at clinical and academic meetings; small group sessions of data interpretation, particularly covering problem areas identified by trainees; participation in audit meetings, journal clubs and research presentations.

Audit and Guidelines: trainees should be directly involved in and, after understanding the rationale and methodology, be expected to undertake a minimum of one in-depth audit every two-years of training. Trainees should be involved in guideline generation and review.

Personal Study: personal study including computer-based learning; practice examination questions and subsequent reading; reading journals; writing reviews and other teaching material.

Online Education: e-learning will provide trainees more and more with an educational resource.

1. Process for recognition as training centre

a. Requirement on staff and clinical activities

For each training centre there shall be at least two trained specialists in Laboratory Medicine.

The training centre shall be based in a laboratory of a university hospital, a hospital or a training centre in a private Laboratory.

There must be up to date facilities for: Clinical Haematology, Clinical Chemistry, Clinical Immunology, Clinical Microbiology and Laboratory Genetics. Since it is not expected that every centre will cover all aspects of Laboratory Medicine (or of a Monovalent Specialty), rotation between or secondment to other training centres is recommended.

There must be a regular discussion of indications for laboratory tests; a weekly programme of teaching; regular discussions of morbidity and mortality; ready access to an adequate library with international journals, recent books, electronic journals and data bases; facilities for clinical and experimental research.

The programme of training must give graded and progressive responsibility to the trainee under the supervision of responsible specialist in Laboratory Medicine and must be recorded in a detailed log book.

b. Requirement on equipment, accommodation

The equipment should be of such standard that it meets the current standards of the speciality.

2. Quality Management within Training institutions

The quality of the training institution should be audited by an external team of specialists in Laboratory Medicine, delegated by the national medical association or it's equal. Audit should take place at regular intervals, preferably annually. The training institution and the clinical departments should be subject to auditing procedures according to national requirements for accreditation and certification.

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