Position statement: Assessment strategy for implementation of the Immunology curriculum of the European Board of UEMS Medical Biopathology

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1. Introduction

In devising an assessment strategy for delivery of the Union of European Medical Specialists’ (UEMS) Immunology curriculum, it is important to recognize the diversity of existing immunology training programmes and variations in the Clinical and Laboratory practice of immunology across Europe. As with the curriculum, the assessment strategy as set out here is by no means meant to be prescriptive but does serve as a useful model for harmonizing assessment programmes in Immunology throughout Europe.

The UEMS recommends that postgraduate training in Immunology should be a minimum of 5 years [1]. The board of the specialist section of Biopathology recommends that a period of clinical training should be an integral part of the training of all Medical Biopathologists. All Immunologists should have at least 1 year of clinical experience as part of their postgraduate training. For trainees who plan to practice predominantly in Clinical Immunology, the period of clinical training in total will last at least 3 years. Trainees in Clinical Immunology will be required to have at least 2 years of laboratory immunology experience. It is strongly recommended that trainees who wish to practise predominantly as Clinical Immunologists have a solid background in general internal medicine validated by a recognized postgraduate qualification in internal medicine. For example, in the United Kingdom, individuals wishing to undertake higher specialist training in Clinical Immunology are required to have passed the examination for Membership of the Royal Colleges of Physicians of the UK (MRCP UK). For trainees wishing to practise predominantly in Laboratory Immunology, 4 years of laboratory practice will be required.

2. Assessment methods

The effectiveness of any assessment strategy is crucially dependent on the extent to which it drives and monitors learning by the trainee. In order to facilitate learning, key learning objectives for each part of the curriculum have been defined.

2.1. Key learning objectives

- The trainee will acquire a sound body of knowledge relating to fundamental immunology required to underpin clinical and laboratory practice in immunology.
- The trainee will acquire and be able to apply a comprehensive body of knowledge relating to the clinical presentation, investigation and management of patients with:
  a. primary and secondary immunodeficiency diseases;
  b. systemic autoimmune rheumatic disease and systemic vasculitides;
  c. allergic diseases of all degrees of severity.
The trainee will acquire and be able to apply a solid foundation of knowledge required to direct a diagnostic immunology laboratory at Consultant level (a specialist capable of independent practice) and effectively interact with medical specialties where patients with immune-mediated disease are managed.

Fulfilment of the above learning objectives will be monitored by a combination of formative and summative assessment methods. The former will comprise assessments in the workplace (workplace-based assessment – WPBA) while the latter will involve a test of knowledge (knowledge-based assessment – KBA).

2.2. Workplace-based assessment

Assessment in the workplace will involve a combination of the following methods:

(i) Directly observed practical skills (DOPS) – for assessing competence in laboratory procedures (see laboratory training manual) and certain clinical skills such as skin testing and training patients in the use of self-injectable epinephrine (adrenaline).
(ii) Assessment of a trainee’s skills in clinical examination.
(iii) Case-based discussions.

It is recommended that trainees undertake a minimum of six workplace-based assessments each year.

2.3. Knowledge-based assessment

It is recommended that individual countries devise an appropriate assessment which would serve as a summative assessment of a trainee’s knowledge. In order to ensure that knowledge-based assessment (KBA) parallels a trainee’s progress through the training programme, it is recommended that any examination is conducted in two parts. Candidates should normally have completed a minimum of 2 years in the training programme before taking the 1st part of KBA. This part of the examination should test:

(i) knowledge of the scientific principles underpinning the practice of clinical and laboratory immunology;
(ii) an assessment of the trainee’s ability to solve diagnostic and management problems in patients with disorders of the immune system.

It is recommended that the 2nd part of KBA be designed as an examination to be taken at the end of the training programme in order to ensure that it functions as a final test of quality assurance that a trainee is competent to practise independently as a specialist in immunology. Part two of KBA should comprise practical, written and oral components.

2.3.1. Practical examination for KBA part 2

The practical examination will test proficiency in standard laboratory procedures and the interpretative use of laboratory data to solve clinical problems. The examination will be structured to include modules in autoimmunity, immunochemistry, ELISA, cellular immunology including flow cytometry, quality control and laboratory safety. Data interpretation will be tested by an assessment of the candidate’s ability to draft succinct, clinically relevant reports based on the interpretation of laboratory data in the context of a clinical vignette.

2.3.2. Written component of KBA part 2

It is recommended that candidates use one of the following options to fulfil the requirements of the written component of the part 2 examination:

(i) a PhD/MD thesis, normally completed during the training period;
(ii) a series of referred, published papers (or in press);
(iii) a casebook consisting of detailed case histories and discussions of a standard deemed to be fit for peer-reviewed publication. The cases selected should cover the major sections of the curriculum—immunodeficiency, autoimmunity and allergy. The general form of case presentation should begin with an introduction, followed by a detailed account of clinical features and investigative work (the major part of which has been carried out by the candidate), management and progress and a critical commentary.

2.3.3. The oral examination for KBA part 2

Candidates will be able to sit the oral examination only after achieving a pass mark in the practical and written components of the part 2 examination. The oral examination will assess in a structured manner clinical liaison and problem-solving skills, in addition to the candidates’ knowledge of laboratory management, budgetary control, audit, health and safety at work and quality assurance. Candidates will also be assessed on their knowledge of recent developments and scientific advances relevant to the practice of clinical and laboratory immunology. The oral examination will last 45–60 min. It will be immediately preceded by a 45–60 min period during which the candidate will be given the structured questions relating to the areas to be examined during the oral examination.

3. Overview of training across objective-based Immunology curriculum

Key elements of the published UEMS Immunology curriculum [1] are reproduced in this section to enable the assessment strategy to be used most effectively when mapped against the curriculum.

(A) Fundamental immunology and its applications

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

1. Pathogenesis of immunodeficiency.
2. Pathogenesis of allergic diseases.
3. Immunological tolerance and the pathogenesis of autoimmunity.
5. Classification and biology of malignancies of the immune system.
7. Scientific basis of immunosuppressive and immunomodulatory therapy.
10. Scientific basis of laboratory immunology.
11. Immunology: Cumulative Laboratory Experience (Please see Appendix A – Laboratory training manual and record)

(B) Immunology: Cumulative Laboratory Experience

1. Diagnosis and management of Immunodeficiency disorders in adults and children.

Particular emphasis will be placed on trainees gaining experience in the investigation and management of the immunodeficiency disorders listed below.
Clinical assessment of patients with suspected primary and secondary Immunodeficiency.

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

Selection and interpretation of laboratory investigations for:

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

Selection and interpretation of ancillary investigations (e.g. lung function tests, CT scan of chest, etc.)

Management of IVIG therapy

Management prophylaxis of infections in the immunosuppressed patient

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

2. Autoimmune disorders

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

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

3. Diagnosis and management of allergic diseases in adults and children.

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

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

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

(D) Immunology: cumulative experience in practical procedures

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

(E) Immunology: record of additional clinics attended

Up to 3 months in each specialty during General Professional Training (GPT)/Higher Specialist Training (HST)

- Rheumatology
- Haematology
- Organ transplantation
- Bone marrow transplantation
- Nephrology
- Infectious Diseases
- Dermatology
- Other

Appendix A. Laboratory training manual and record for trainees in clinical immunology

A.1. Introduction

This manual outlines the Laboratory Training program for trainees in Clinical Immunology.

The Training Programme Director and consultant supervisor will be responsible for the continuous assessment of the trainee. This will be achieved by regular contact between the trainee and their supervisor to assess progress using the record made in their training manual. Sections in the training manual will be signed by the person supervising the training. The log book will be reviewed together with other relevant records like 360 degree assessments (Multi-source feedback) at annual assessments. Satisfactory completion of laboratory training will be assessed and certified at the penultimate year assessment, as a mandatory part of the process.

Differences exist in the type and size of individual training departments and secondments to other units may be necessary to achieve competence in some procedures. Training aims are for the trainee to gain an understanding of immunological mechanisms and apply this knowledge to the investigation and diagnosis of disease processes.

The trainee will develop the expertise needed to advise on the application of laboratory investigations to diseases of the immune system, to interpret the results generated by such investigations, to be aware of the limitations of laboratory assays, to initiate appropriate research and development in diagnostic laboratory immunology.

The Sections highlighted in Bold are regarded as core areas with which the trainee is expected to be fully conversant and demonstrate a level of competence required for independent practice.

A.2. Use of the training manual

This manual covers the areas in which a trainee should gain experience over the duration of the training course. It provides a record of continuous assessment. The supervisor and trainee should indicate the dates on which the trainee has studied a topic and where relevant, the level of competence achieved. It is envisaged that a higher level will be assigned as more experience is gained. A printed certified version should be included in your portfolio for inspection at annual assessments.
The training manual should be augmented with any additional information, which will document the training received and the levels reached. The completed record of training will be used ultimately to assess the successful completion of the training. The Manual is divided into sections

Section 1 Laboratory management
Section 2 Analytical techniques and instrumentation
Section 3 Interpretation of immunology tests
Section 4 Research and development
Section 5 Additional portfolio (meetings attended, presentations given)

A.2.1. Section 1 – laboratory management

This section gives the trainee an insight into the functional organisation and management of a laboratory. The trainee should also understand the importance of quality assurance, clinical governance and Health and Safety aspects of laboratory management. An appreciation of the organisation of the analytical and reporting process should also be obtained. The understanding of theoretical aspects and practical experience should be recorded.

Management and professional structures.
National health system organisation and management.
Hospital management structure.
Laboratory structure.

Handling of information
Initiation of request by clinician
Types of patient records: e.g. paper based, electronic
Patient confidentiality and consent
Laboratory computer system
Use of a personal computer including common programmes
(e.g. word processing, database, statistical analysis, bibliography)
Data protection act
Reporting of results
Telephone enquiries

Sample handling
Specimen collection and transport
Transportation through the post
Sample handling and storage in laboratory
Disposal of clinical waste
High risk samples
Spillage and containment

Quality assurance
The standard operating procedure (SOP)
Document control
Sample requirements
Specimen identity checks
Determining normal ranges
Internal quality control
External quality control
Quality assurance
QC interpretation
Laboratory accreditation
Statutory registration of laboratory staff
Laboratory audit

Health and safety
The laboratory safety policy
Risk management
Health and safety at work act
Fire safety
Dealing with biological hazards in the laboratory
Disinfection and decontamination
Vaccination policy
Chemical hazards
Mechanical hazards (including sharps)
Dealing with needle-stick injuries
Electrical hazards
Ionising radiation
Laser/UV hazards
Genetic manipulation policy
Incident handling
Waste disposal
Safe storage of chemicals

Basic laboratory management
Business planning
Bidding for new services/equipment
Finance control
Staffing and personnel issues
Disciplinary procedures
Organising research and development

A.2.2. Section 2 – analytical techniques and instrumentation/laboratory procedures

The purpose of this section first is to allow the trainee to become familiar with the relevant techniques encountered in the Immunology laboratory and to gain an understanding of the assay principles and their application.

Wide experience rather than in-depth knowledge of a limited number of techniques should be aimed for. Where essential procedures are unavailable, secondment to a laboratory performing those assays should be offered. This should be noted in the secondments section.

Second the trainee should become familiar with specific tests for immunodiagnosis. In this respect knowledge shall be gained regarding the relevance of a particular test for the clinic, the performance of the specific test and the interpretation of particular test results (single as well as in combination with other tests/clinical parameters).

For each entry in this section the competence of the trainee is assessed as follows (evaluation shall include all aspects referring to a particular test (method) (relevance/background, performance, interpretative skills).

• Level 0: Procedure unavailable in laboratory or opportunity for training not available.
• Level 1: Observed a demonstration.
• Level 2: Technique performed under supervision and has a basic understanding of the theory behind the procedure and can rectify any problems that occur.
• Level 3: Technique performed without supervision and has a comprehensive understanding of the theoretical concepts, quality assurance, clinical interpretation and application of the assay.

A.2.2.1. Analytical techniques and instrumentation

A. Basic laboratory techniques

Operation of basic laboratory equipment
Liquid handling using pipettes
Liquid handling using robotics
Balances
Centrifuges
pH meters, concept of buffers
Water purification

Microscopy, types of microscopes
Preparation of sections for microscopy
Fixation and Embedding
Operation of Cryostats

Analysis by immunofluorescence techniques
Principles of immunohistochemistry
Spectrophotometric and related techniques (manual and automated equipment)
Visible and UV spectrophotometry
Nephelometry/turbidimetry
Densiometry
Enzyme linked immunosorbent assay and similar immunoassay techniques

Isotopic techniques
Bet counters
Gamma counters
Radioimmunoassay

Gel phase and electrophoretic techniques
Radial immunodiffusion
Double diffusion
Zonal Electrophoresis
Immunoelectrophoresis
Polyacrylamide gel electrophoresis
Two-dimensional electrophoresis
Isoelectric focusing
Immunofixation
Capillary zone electrophoresis
Gel staining methods
Western blotting
Chromatographic techniques
Column chromatography
Gel filtration
Ion-exchange chromatography
Affinity chromatography

Cellular and tissue immunology
Tissue culture/aseptic technique
Cell and tissue storage
Viability assays
Cellular analysis including cell counting
Light/fluorescence microscopy
Flow cytometry, principles, practise, applications
Leucocyte separation techniques (lymphocytes, monocytes, neutrophils)
Preparation of buffy coats
Cell proliferation assays and their applications
Elispot techniques

Molecular biology
Principles of DNA extraction and DNA analysis
Restriction enzymes
RFLP
DNA probes
Southern blotting
Northern blotting
Polymerase chain reaction (SSP, SSO)
Hybridisation techniques
Ig/T cell receptor gene rearrangement
Others: please specify below

B. Specific laboratory procedures

Protein analysis
Immunoglobulins (G, A, M, D, E)
Immunoglobulin fragments: heavy chains, light chains
Cryoglobulins
Methods for assessing specific antibody responses including limitations
Paraproteins
Beta 2 microglobulin
Immunoglobulin subclasses
Other proteins
Precipitins (avian, fungal)
Specific IgE
Trypsinase
C-Reactive protein
Mannose binding lectin
Complement:
C3, C4
Other components

Functional complement assays:
CH50, CH100
AP50, AP100
C3 nephritic factor
C1 inhibitor: immunochemical and functional

Cytokine detection

Autoantibody analysis:
Rheumatoid factor
Anti-CCP antibodies
Antinuclear antibodies
Anti-dsDNA antibodies
Anti-ssDNA antibodies
Anti-histone-antibodies
Antibodies to extractable nuclear antigens (ENA): Ro, La, Sm, RNP, Jo1, Scl 70
Anti centromere antibodies
Antineutrophil cytoplasmic antibodies: c-ANCA, p-ANCA Anti-MPO, anti-MPO

Smooth muscle antibodies
Anti-actin antibodies
Glomerular basement membrane antibodies
Mitochondrial antibodies (anti-M2)
Antibodies used to diagnose celiac disease: anti-gliadin, anti-transglutaminase, anti-endomysial antibodies
Gastric parietal cell antibodies
Intrinsic factor antibodies
Thyroid autoantibodies (TPO, TG)
Pancreatic islet cell antibodies (GAD-65, IA-2,IAA)
Steroid cell antibodies (adrenal, ovarian, testis)
Anti-phospholipid antibodies: anti-cardiolipin, anti β2GPI antibodies
Liver autoantibodies
LKM antibodies
SLA antibodies
Anti-desmosome antibodies
Anti-epidermal basement membrane antibodies
Anti-ovarian antibodies
Anti-sperm antibodies
Anti-acetylcholin receptor antibodies
Anti-TSH-R antibodies

Neural auto-antibodies
Anti-neuronal antibodies (Yo, Hu)
Ganglioside antibodies
Glutamic acid decarboxylase antibodies (GAD-67)
Myelin associated glycoprotein antibodies

Immunohistology
Renal disease
Skin disease

Phagocyte functions
NBT
Flow cytometry (DHR, DCFA)

Use of Flow cytometry for the diagnosis of immunodeficiency

Principles of diagnosis and classification of lymphoid neoplasms
MHC and tissue typing
HLA typing
Cellular assays
DNA techniques
Alloantibody screening (crossmatch, PRA)
Principles of tissue matching for renal, solid organ and BM transplantation
Other techniques: specify below

A.2.3. Section 3 – interpretation of immunology tests
A Clinical Immunologist must be able to propose the relevant immunological test as well as to interpret laboratory results for communication with/to other clinical colleagues. The trainee is required to develop an understanding of how the immune system responds to different disease processes and how these changes can be used in the laboratory for monitoring and diagnosis. Essential to the interpretive process is an understanding of the assays performed and their limitations. The trainee should have a good knowledge of how patient reports are generated and when additional comments or telephone communication may be required. The role of the immunologist should be to advise clinical colleagues on relevant tests for a given clinical situation. Sections below are provided for recording progress.

A.2.3.1. Interpretation of laboratory data.
Autoantibody tests
Protein tests
Molecular tests
Cellular tests
Allergy tests
Immunohistochemistry

A.2.3.2. Laboratory investigations by disease
Primary and secondary Immunodeficiency:
Antibody deficiency (incl specific autoantibody)
Phagocyte deficiency
Defective cell-mediated immunity
Complement deficiency

Systemic autoimmunity:
Systemic lupus erythematosus
Rheumatoid arthritis
Antiphospholipid syndrome
Scleroderma
Sjögrens syndrome
Systemic vasculitis
Seronegative spondarthropathies
Dermatomyositis
Overlap syndromes

Organ specific autoimmunity
Liver diseases
PBC (primary biliary cirrhosis)
Autoimmune hepatitis
PSC (primary sclerosing cholangitis)

Gastrointestinal disease
Celiac disease
Autoimmune gastritis
Pernicious anemia
IBD (inflammatory bowel disease)

Endocrine disease
Type 1 diabetes
Hashimoto disease
Graves disease
Infertility syndromes

Neuromuscular disorders
Skin diseases
Psoriasis
Bullous disorders

Allergy
Food allergy
Inhalant allergy
Drug allergy
Skin prick testing
Patch testing
Heaf test
Anaphylaxis

Lymphoproliferative disease
Myelomatosis and paraproteinaemias
B-cell malignancies
T-cell malignancies
Myeloid lineage pathologies
Rare disorders

Monitoring of immunotherapies

A.2.3.3. Statistical methods used for interpreting laboratory data
Measures of central tendency
Parametric and non-parametric ways of comparing data
Sensitivity and specificity
Negative and positive predictive value
Receiver operated characteristic curves
Understanding of the impact of prior and posterior probability
Difference between performance of tests to screen for disease versus diagnosis

A.2.4. Section 4 – research and development
The scientific literature
Journals: Multidisciplinary, Immunological Scientific, Immunological Medical
Library facilities, Medline and other Databases: Searching, Clinical databases, Genetic Databases (e.g. OMIM)

Research technique
Ethical issues and approval, Hypothesis, Background, Aims and Objectives, Methods, Recording Results, Handling the data, Statistics, Presentation, Preparing a poster, Preparing a talk, Powerpoint, Routes to publication, Writing a paper, Refereeing.

The funding of research
National Health system research and development, Charities – project grants, Government funding, applying for a Research Grant, Refereeing process.

A.2.5. Section 5 – additional portfolio
Meetings/Seminars/Congresses attended
Presentations given (oral/poster)

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Reference