



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

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ABSTRACT

The assessment strategy for implementation of the Union of European Medical Specialists' (UEMS) Immunology curriculum is based on a combination of formative and summative assessments. The strategy comprises a combination of workplace-based assessments and knowledge-based assessments designed to ensure acquisition of key learning outcomes as defined in the curriculum. The purpose of this paper is to explicitly link the assessment strategy to the curriculum.

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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 an 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.

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- 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:

- 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).
- Assessment of a trainee's skills in clinical examination.
- 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 examination 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:

- knowledge of the scientific principles underpinning the practice of clinical and laboratory immunology;
- 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:

- a PhD/MD thesis, normally completed during the training period;
- a series of referred, published papers (or in press);
- 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) Cells and organs of the immune system. (2) Cytokines, chemokines and other inflammatory mediators including lipid mediators. (3) Phagocytic cells and their function. (4) Antibody mediated immunity. (5) Complement system. (6) Cell mediated immunity. (7) Natural immunity. (8) Regulation of the immune system. (9) Hypersensitivity mechanisms. (10) Pathogenesis of immunodeficiency. (11) Pathogenesis of allergic diseases. (12) Immunological tolerance and the pathogenesis of autoimmunity. (13) Immunobiology of transplant rejection and its prevention. (14) Classification and biology of malignancies of the immune system. (15) Scientific basis of allergen immunotherapy. (16) Scientific basis of immunoprophylaxis. (17) Scientific basis of therapy of primary immunodeficiency. (18) Scientific basis of immunosuppressive and immunomodulatory therapy. (19) New developments in therapy of immunodeficiency. (20) New developments in therapy of allergic disease. (21) Scientific basis of laboratory immunology.

(B) Immunology: Cumulative Laboratory Experience (Please see Appendix A – Laboratory training manual and record)

(C) Immunology: cumulative clinical 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/angioedema
- 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 regard-

ing 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 speciality 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

Densitometry

Enzyme linked immunosorbent assay and similar immunoassay techniques

Isotopic techniques

Beta counters

Gamma counters

Radioimmunoassay

Gel phase and electrophoretic techniques

Radial immunodiffusion

Double diffusion
Zonal Electrophoresis
Immuno-electrophoresis
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
Tryptase
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-PR3

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 β 2GPI 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

- [1] Choremi-Papadopoulou H, Faure GC, Madden M, Malenica B, Misbah SA, Theodorsson E, et al. Position statement: training programme in immunology of the European Board of UEMS Medical Biopathology. *Immunol Lett* 2005;96:305–10.